

**COMPLIANCE WITH DRUG TREATMENT AMONG PATIENTS
WITH TUBERCULOSIS IN THE SHILUVANE LOCAL AREA,
MOPANI DISTRICT, LIMPOPO PROVINCE, SOUTH AFRICA**

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MOPANI DISTRICT, LIMPOPO PROVINCE, SOUTH AFRICA**

by

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DEDICATION

This dissertation is dedicated to my family, especially my father Phutiane William Letsoalo, husband Seriri Jack Mabitsela, children Ngoako Abram, Mabati Sylvester, Mosibudi Elizabeth, Ledile Anita, grand children Nadine, Lesego and Tshegofatso for their understanding, support and encouragement.

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God for giving me strength to continue even though sometimes it looked impossible, I really witness that nothing is impossible with God.

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ABSTRACT

INTRODUCTION

Tuberculosis (TB) is the cause of 1, 8 million deaths annually, 99% of the deaths occurs in the developing countries and among the poorest people of these countries. Studies between high and low income countries demonstrate that rates of TB are significantly higher in poorer populations. World Health Organization introduced DOTS as global strategy for providing TB services which was expected to be delivered primarily by government run public health services (Malmborg, Mann, Thomson, & Squire, 2006).

AIM

Investigate factors that influence compliance and non-compliance to treatment among patients on tuberculosis drug treatment.

STUDY SITE

This study was conducted in Shiluvane local area in Greater Tzaneen Municipality under Mopani District in Limpopo Province, South Africa. One district hospital, one health centre and five clinics were selected for this study: Dr CN Phatudi hospital, Shiluvane Health Centre, Moime, Lenyenyene, Mogoboya, Maake and Lephepane Clinics.

STUDY DESIGN

This is a quantitative and qualitative study as mixed methods were used to get a comprehensive research report.

SAMPLING

The sample size used 150 of a given population using Morgan and Krejcie table (1994). The case register was used to select respondents. The respondents were selected according to particular interval; each second name on the list was selected. Questionnaire and structured interview was selected for data collection. Questionnaires were distributed among clients who are able to read and write for them to complete, the researcher and the assistant helped to fill questionnaires for those who cannot read or write. The study was conducted at identified hospital, health center and clinics.

RESULTS

Education Level, the findings of this study displays that only 3,7% of participants hold tertiary qualifications, and 50% secondary education and 37,3% of primary education.

Occupation, 76.4% of participants are unemployed.

Income, 52,6% of participants earn between R1000-R2999 and 17,5% does not have income.

CONCLUSION

In conclusion based on the results and objectives of this study compliance with drug treatment among patients with tuberculosis in Shiluvane local Area, Mopani District, Limpopo province is 90.9%.

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DEFINITION OF CONCEPTS

Tuberculosis

Tuberculosis is an infection with the with bacterium *Mycobacterium tuberculosis*, which commonly affect the lungs to become Pulmonary Tuberculosis or can affect other systems like the central nervous system, circulatory and skeletal system.(Dept of health, 2000)

Self-Administration Therapy

Self Administered Therapy is defined as unsupervised administration on anti-tuberculosis medications by patients as prescribed by the provider (Dept of health, 2000).

Compliance

Compliance is an adherence of patient to the prescribed treatment. Patients have treatment supervisor who monitors patients swallowing her treatment on daily basis for the first two months of the treatment. (Dept of health, 2000)

Epidemic

Epidemic is the occurrence in a community or region of cases of illnesses or outbreak with a frequency clearly in excess of normal expectancy. (APHA)

Multi Drug Resistant tuberculosis

Multi drug resistant tuberculosis is the tuberculosis which is resistant to at least isoniazid and rifampicin drugs (Dept of health, 2000)

New case

A patient who never had treatment for tuberculosis or patient who has taken anti tuberculosis drugs for less than four weeks (Dept of health, 2000).

Treatment after interruption

A Patient who returns for treatment after interrupting treatment for two or more months and returned to health services with sputum smear positive results. (Dept of health, 2000).

Cure

Patient who is smear negative at one month prior to, the completion of treatment and on at least one previous occasion (Dept of health, 2000).

Treatment Failure

A patient who while on treatment, remained or became again smear positive five months or later after commencing treatment. It is also a patient who was initially smear negative before starting treatment and became smear positive after the second month of treatment (Dept of health, 2000).

Relapse

A patient who has been declared cured of any form of TB in the past , after one full course of treatment , and has become sputum smear-positive (Dept of health, 2000).

Treatment interrupted

A patient whose treatment was interrupted for two or more months

AIDS

Acquired Immune Deficiency Syndrome is a disease of the human immune system caused by the human immunodeficiency virus.

Airborne

A mechanism of transmission of an infectious agent by particles, dust, or droplet nuclei suspended in the air. Medical dictionary (2000)

Bacteria

Single –cell organisms which can exist either as independent organisms or as parasites.

Sputum

The mucous and other matter brought up from the lungs, bronchi and trachea that one may cough up and spit out or swallow.

ABBREVIATIONS

TB = Tuberculosis

PTB= Pulmonary tuberculosis

SAT = Self Administered Therapy

DOT = Directly Observed Treatment

DOTS = Directly Observed Treatment Short- course

MDR TB = Multi Drug Resistant tuberculosis

NTCP = National Tuberculosis Control Programme

WHO = World Health Organisation

SPSS = Statistical Package for Social Sciences

HIV= Human Immunodeficiency VIRUS

AIDS = Acquired Immune Deficiency Syndrome

APHA= American Public Health Association

CHAPTER 1

1. INTRODUCTION

Tuberculosis (TB) is one of the serious health problems in South Africa. It has the highest morbidity and mortality rate compared to any other single pathogen, it is estimated that one third of the world's population is infected with *Mycobacterium tuberculosis* as confirmed by Volmink, Garner, (2006). The report further states that about eight million people contact TB annually, mostly (95%) from developing countries. It is indicated in annual report of the Department of Health in South Africa (1998) that 1 16 000 people were treated for TB and 65 700 were infected, meaning that they were able to spread the infection to people around them.

South Africa has the largest per capita TB burden in the world and its notification is highest in crowded urban areas. Kironde(2000) Although directly observed therapy has reduced TB prevalence and death rate in regions of the world according to Kironde(2000)Adult TB disease is a combination of recent infections and reactivation of latent TB. Anti tuberculosis treatment should be administered to greatest possible number of patients in order to cure them, and interrupt transmission of TB within population. The most serious problem hindering TB treatment is non compliance of patients. It is believed to delay sputum conversion to smear negative, increases the relapse rate 5-6 times, and help the emergence of resistant mutant strains. Kironde(2000)

Tuberculosis is the most major infectious disease, infecting two billion people or one- third of the population and two million deaths in developing countries. TB is one of the top three infectious killing diseases in the world: HIV/AIDS kills three millions. It kills two millions and Malaria kills one million. The World Health Organization declared TB a global emergency in 1993 as stated by Volmink and Garner, (2006).

Adherence to treatment requires active participation of the patient in self management of treatment and cooperation between the patient and the health care provider. The reason for poor adherence are multifaceted and complex, including characteristics of the individual patient and social and economic factors such as the availability of drugs, communication between the patient and the health care providers, duration and number of medications needed, side effects, cost of treatment, demanding time, contradictory norms or expectations of families and cultural groups and poor quality of the TB control infrastructure as stated by The present study was conducted to determine compliance with drug treatment among patients with TB in Shiluvane Local area, and to study factors associated with it.

1.1MOTIVATION OF THE STUDY

The researcher observed that some of TB patients do not comply with treatment after few months of starting treatment. The treatment course takes six months.

The patients starts treatment at health facilities and take treatment on out patient basis, unless in cases where patients are in a critical condition which warrant admission to the hospital. This motivated the researcher to investigate causes of compliance and non-compliance. The results of this study will help in getting correct intervention within the team. According to the researcher, programmes are effective and important when well implemented.

1.2 PROBLEM STATEMENT

Health workers are faced with challenges that some patients on anti-tuberculosis drug do not complete treatment.

1.3 RESEARCH QUESTION

The study answered the following question:

- Which factors encourage compliance and non-compliance among patients who are on tuberculosis drug treatment?

1.4 AIM OF THE STUDY

The aim of the study was to investigate factors that influence compliance and non-compliance to treatment among patients on tuberculosis drug treatment.

1.5 OBJECTIVES OF THE STUDY

The objectives of this study are to:

- Identify factors that influence compliance and non-compliance to treatment among patients on tuberculosis drug treatment.
- Recommend to policy makers strategies to improve compliance to TB treatment.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter discusses the literature review on the research. The purpose of reviewing literature was to gain broad background of the available and related information. This background enabled the researcher to build on the work of others which is essential discoveries in a field related to previous work. The literature review also promotes the identification of feasible research purposes and sub –problems, which direct the development of methodological sound studies Burns and Grove, (2001). The purpose of literature review in a qualitative study is to place the findings in the correct context of what is already known. It tells the researcher how the findings fit into what is already known about the topic.

Findings from previous studies assist researchers in refining parts of their studies, especially with regard to the problem statement, conceptual framework, and study design and data analysis process. It also assists in forming a basis for comparison when interpreting findings of the current study.

The review of literature in current study of compliance with drug treatment among patients with tuberculosis will assist the researcher to have a broader picture on how research studies are conducted. The researcher will be able to gain knowledge from other studies conducted on compliance with drug. The other completed research projects will also serve as a guide for the researcher to be able to develop the relevant data analysis tool for questionnaire development and to gain knowledge on the research topic. This chapter focuses on the international and national perspective to review focuses on studies conducted national and internationally.

2.2 INTERNATIONAL PERSPECTIVE

A study conducted in prisons in Azerbaijan on drug resistant tuberculosis, it was found that drug resistant *Mycobacterium tuberculosis* strains are common. The selection criteria focused on prisoners who were serving long sentences. The study showed that prison cells were overcrowded with poor general health and this was one of the risk factors for the infection. Prisoners with short sentences were excluded from the study and allowed only prisoners who could complete full course of treatment. The study further showed that the problem tend to worsen as short sentenced prisoners without treatment are released into communities and become common vehicles of direct transmission of tuberculosis(Cornix , Pfyffer , Mathieu,1998).

A study which was conducted in San Francisco revealed that tuberculosis patients treated by Directly Observed Treatment (DOT) strategy had higher cure and lower rates mortality than patients who were treated with Self-Administered Therapy (SAT). There were following gaps in the study:

The first gap was that patients with extra-pulmonary tuberculosis were excluded. The second gap was that patients with tuberculosis and who was culture negative were excluded from the study , the exclusion left patients with other types of TB not supervised when taking treatment , as only patients with active pulmonary TB were included in the study . Jasmer , Seaman , Conzales, Kawamura , Osmond and Daley,(2004).

In other parts of Israel a study to monitor compliance with Isoniazid (INH) treatment of latent tuberculosis infection (LTBI) was conducted using the Arkansas color method in order to evaluate drug compliance and factors that can predict treatment adherence in patients being treated for LTBI with single dose of INH. Urine sample were tested for INH metabolites with Arkansas color method. The results revealed non compliance to treatment by patients, no factor was found to predict compliance Eidlitz-Markus, Zeharia, Baum and Ami (2003).

A study conducted in Portugal on the role of compliance in TB HIV-positive patients treated with an ambulatory regime. Results revealed that TB presents particular features, like development of extra-pulmonary disease and the presence of atypical features in chest radiograph which supports non-compliance as the strongest determinants for poor outcome of TB in HIV-infected patients Rocha, Pereira, Ferreira and Barros, (2003).

2.3 SOUTH AFRICAN PERSPECTIVE

A study conducted in the Western Cape, South Africa, to establish reasons why tuberculosis patients at clinics stop their treatment and the conclusion was that patients should not carry primary responsibility for their adherence to treatment but to become part of the team. The team comprises of health workers, family, friends and community. For tuberculosis treatment to be adhered to patient cooperation and information need to be addressed and the existing services to be more accessible and acceptable according to Portwig and Couper (2006).

The presentation which was conducted for Multi Drug Resistant (MDR) tuberculosis treatment in five districts of South Africa, Eastern Cape, Western Cape, Northern Cape, Kwazulu Natal and Mpumalanga.

The results revealed that there is poor patient-provider relationship as clients are not satisfied with health workers attitudes, lack of support during treatment from families and friends and socio economic factors like homelessness and alcoholics can contribute to of non compliance to tuberculosis treatment Holtz, Lancaster, Laserson, Wells and Weyer, (2001).

A study conducted in Kwazulu Natal, in South Africa between 1991 and 1994 on DOT for tuberculosis it was observed that community based directly observed therapy that uses intermittent drug regime and supervisors like volunteers, storekeepers and health workers can achieve high treatment rate even if resources are poor Wilkinson, (1996).

A study conducted in Cape Town, South Africa on systematic review of randomized controlled trials of strategies to promote adherence to TB treatment. Some strategies used aimed at changing staff behaviors in order to train and supervise the patients; other strategies are at patients including education, and incentives. The study showed that half of all patients with tuberculosis do not complete treatment lasting for 24 months which prolong infection, drug resistance and avoidable death, the study showed that reliable evidence is available to show that some specific strategies improve adherence to TB treatment Volmink and Garner, (1997)

In conclusion, the literature reviewed did not clearly address factors that influence compliance to drugs among patients with TB in South Africa, especially in Limpopo Province. However, the literature review has revealed that according to global strategy on compliance to drug treatment among patients with Tuberculosis, DOT is the recommended strategy.

2.4. CONSEQUENCES OF TB & HIV VIRUS IN SOUTH AFRICA

The increase in TB incidence is attached to the spread of HIV in Africa; about 13% of new TB adults were infected with HIV in 2004, of which 34% were in the African region, 1, 4% in Western pacific region. The growing HIV problem feeds into the spread of tuberculosis, because of their low immunity; people with HIV are 30 times more likely than general to acquire TB. According to South African Health Review (2000) Kironde States that up to 40% of South African TB patients are co-infected with HIV African life expectancy of HIV-infected person with TB is measured in weeks if the patient is not on treatment Kironde (2000).

2.5 PSYCHOLOGICAL IMPACT OF TB

In some setting TB is considered to be inherited and associated with unclean habits. This kind of information is shared among the poor, could be a result of impaired access to information. The associated stigma of TB leads to fear of loss of employment and income, and social exclusion.

The fear can promote denial, undermine self esteem and ultimately prevent early diagnosis and effective treatment of TB. The perceptions can results in resistance to help people with TB. Health education on stigma can be reinforced by stressing the importance of safe disposal of sputum. Nhlema, et.al (2003)

2.6 ECONOMICAL FACTORS

2.6.1 LINK BETWEEN TB AND POVERTY

Tuberculosis is influenced by poor socio-economic conditions. The researcher has observed this, as most of the patients suffering from TB are living in poor socio-economic conditions Rocha et al, (2003).

Poverty is the greatest impediment to human and socioeconomic development .In health poverty represents a principal barrier to health and health care, WHO is committed to integrate the promotion of equity and pro –poor policies throughout its work. Addressing poverty in TB control encompasses the needs of those facing not only economic impoverishment but also all relatively vulnerable, disadvantage, marginalized, stigmatized, and other excluded sections of the population, who are poor, vulnerable and what is inequity Nhlema, Kemp, Steenbergen, Theobald,Tang and Squire , (2003) agrees that there is Economic Poverty which measures absolute and relative poverty.

The first step to reach all poor individuals is to give special attention in improving health and health care to places where relative poverty of assets and living conditions is concentrated. Vulnerability to disease and ill health results from underlying biological factors, socio economic factors affecting individuals, households and communities. Vulnerability can emerge from massive fronts including exclusion from access to services as results of race gender, residence, or because of underlying lack of education to enable more secure employment, help seeking behaviors by people in their own homes. Vulnerability to disease can also emerge in special situation, as massive population movement caused by living or working condition. Nhlema et.al. (2003)

2.6.2 HEALTH INEQUITY

Reduction of TB prevalence among the poor has been identified as a contributor to reduce overall inequity in health and advancing welfare of the poor. Inequities can be measured across income groups, gender and social group. 80 percent of avoidable mortality has been caused by communicable disease in low income countries. The poor nations carry a burden of avoidable mortality Nhlema, et. al (2003).

TB thrives in poverty and can worsen poverty. It is acknowledge that TB is not the disease of the poor but the association between poverty and TB is well established and widespread. In the process of income poverty, the poor lack food security, income stability and access to health care. TB may lead to loss to 20-30% of annual wages among the poor and global economic costs. Predisposing factors of tuberculosis are: poor housing the researcher stays and work within the community which is rural, many houses are poorly built due to lack of funds, caused by high rate of unemployment and overcrowding. The problem of poor housing contributes towards poor control of the spread of infection as stated in the study conducted by Cornix, Pfyffer, Mathieu (1998).

There are different factors that cause malnutrition which results from an imbalance between the required amount of nutrient in the body and the actual amount of nutrients introduced or absorbed by the body. Food quantity and quality which relates to quantity of food consumed quality of overall diet, energy density and frequency of consuming. Health and sanitation, safe water supplies, adequate sanitation and good housing are preconditions for adequate nutrition. Inadequate sanitation and hygiene are major contributing factor for anemia. Social and care environment contributes to malnutrition due type of feeding, cultural factors such as income, time, knowledge about nutrients contributes to malnutrition Hanson, (2002).

2.7 CAUSES OF TUBERCULOSIS

There are different causes of tuberculosis although two types are mentioned being *mycobacterium tuberculosis* and *bovis mycobacterium*. Several sources agree that tuberculosis is a chronic disease caused by specific bacillus of mycobacterium which varies from patient to patient, depending on variety of factors Glatthaar (1991)

2.8 PREDISPOSING FACTORS FOR TUBERCULOSIS

TB is aggravated by poor socio economic conditions: poor housing, malnutrition , ill health and overcrowding which result in cross infection between members of the family This is supported by Cornix (1998) who pointed out that prisoners serving long sentence, who are in close contact with an infected person were at risk. The problem of poor housing and overcrowding contributes towards poor control of the spread of TB Cornix (1998). In the community where the research was conducted most people are unemployed: as a result some depend on grant for living and some of the patients does not get grant and there was no income for the family.

Some people's immune system are weakened and become subject to TB as they live in a prevalent area. Tuberculosis is prevalent in areas where there is poor nutrition, illiteracy and high incidence of disease.

Ill health can be caused by diseases like AIDS and renal failure which lowers person's immune system and T.B takes advantage of the person. It is of great importance for the health team to educate people in order to take necessary precaution as there are different predisposing factors.

2.9 MODE OF TRANSMISSION

Tuberculosis is spread through water droplets which are expelled when people with infectious TB diseases coughs, speaks or sing. People with prolonged contacts are at the highest risk of becoming infected. This includes residents and employees of high congregate setting, health care workers nursing high risk clients and medically underserved with low income. Transmission can occur from persons with active disease not latent TB infection. Cornix, et.al(1998). It is spread by person who has active pulmonary disease to susceptible persons who inhale the droplet nuclei generated from the bronchial secretions of persons while maintains that transmission of infection involves the transfer of bacillus from a source to a new host. Transmission is mostly through inhalation rarely through digestion of contaminated food or drink. Overcrowding is often a risk factor

The probability of transmission depends upon infection of the person with TB, the environment of exposure, duration of exposure, and virulence of the organism. The factors increasing transmission include cavitary disease and sputum positivity as well as the number of small particles formed portal of entry by the organism to the body is usually through the nostrils to the lower respiratory area. The targeted organs are the lungs. Glatthaar, (1991).

2.10 SIGNS AND SYMPTOMS OF TUBERCULOSIS

Majority of patients with pulmonary tuberculosis is asymptomatic or have minor symptoms. At the time of developing cell-mediated immunity some patients may develop mild fever and x-ray abnormalities including hilar lymphadenopathy, mid and lower lung zone infiltrates. Hypersensitivity phenomena like erythema nodosum, phlyctenular conjunctivitis and arthritis may also occur. Few patients may develop pleurisy which resolves spontaneously. Raviglione, Uplekar ,(2006)

The risk of progressing to active disease is relatively high in infancy and lower in older children; it increases rapidly during adolescence and then more slowly through out adulthood. In the absence of the other predisposing factors, only about 5% of infected people will develop progressive primary disease within five years of infection.

Post primary tuberculosis may occur either as a result of reactivation of latent tuberculosis or due to re-infection with *Mycobacterium tuberculosis*. Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome (HIV/AIDS) is the greatest risk factor for post primary tuberculosis. About 85 percent of post primary tuberculosis in HIV negative patients is pulmonary tuberculosis and the symptoms varied depending on the individual patient and range from slow insidious symptoms to rapid progression and critical illness. Perkins, Rodriguez, Mwamba, (2006)

The respiratory symptoms include cough which is initially dry and later productive, pleuritic or non-specific chest pain, sparse to massive haemoptysis and dyspnoea which is usually associated with advanced disease or superimposed infection. The constitutional symptoms of post primary tuberculosis are weakness, loss of weight, drenching night sweats and fever.(ref) Physical examination is usually unremarkable with the exception of wasting. Localised or post tussive crackles may be present on auscultation but the lung fields are usually clear until the disease is advanced.

Direct lymphatic spread of the Mycobacterium bacilli results in extra pulmonary tuberculosis which accounts for about 10 to 30 percent of the disease, which is more common in women, children and people infected with HIV. The extra pulmonary disease includes Pott's disease, meningitis, pericarditis, uro-genital and disseminated tuberculosis.

2.11 TREATMENT OF TUBERCULOSIS

The huge public health importance of tuberculosis is attributable not so much to the high incidence of the disease, particularly in developing countries, but so much to the high case fatality rate and disability among untreated or improperly treated patients. Some patients have cultural and traditional value about health that leads to seeking traditional, ancestral or spiritual healing first and modern medicine when others failed, which delays diagnosis and may cost time and transport. The patient should be evaluated for adherence to the prescribed treatment, signs and symptoms monthly until culture convert negative. If culture remain positive despite treatment for three months initiate DOTS. Study reveals that about two-thirds of untreated smear positive patients will die within five to eight years, the majority within the first 18 months of development of the disease.

Majority of the patients that survive beyond eight years will have quiescent tuberculosis with high susceptibility to relapse, while a few become chronic carriers. That said even for untreated smear-negative patients the case fatality is about 10-15 percent

The control of tuberculosis is one of the United Nations Millennium Development Goals (MDGs) and the targets are to achieve 70% diagnosis of sputum-smear-positive cases and 85 percent treatment cure rate of such cases by 2005. The overall expectation is to reduce tuberculosis prevalence and case –fatality rates by 2015; however the realization of these targets will require a set of interventions that are not only cost-effective but also affordable and capable of having far reaching effect.

The cornerstone of the control and management of tuberculosis is the Directly Observed Treatment Short Course (DOTS) strategy which is centered on early diagnosis and treatment of the most severe and infectious (smear-positive) forms of tuberculosis but also including treatment for smear-negative and extra-pulmonary cases World Health Organization, (2002). The five elements of DOTS strategy are:

- Political commitment with increased and sustained financing.
- Case detection through quality-assured bacteriology.
- Standardized treatment with supervision and patient support.
- An effective drug supply and management.
- Monitoring and evaluation system, and impact measurement.

The SCC for active tuberculosis has been found to be a comparatively cost-effective intervention and one of the most cost-effective of all health interventions. The patients can be treated more effectively and conveniently outside the health care facilities by health staff or with the assistance of family and community members without compromising treatment success rate. The monetary savings derivable from a reduction in incidence of 26% between 2000 and 2015, which could be sufficient to achieve the MDG targets, can be influenced by adjustments to the DOTS strategy Nhlema, et.al (2003).

The introduction of resistance testing, second-line drugs, longer treatment regimens(12-18 months), microbiological and clinical monitoring all increase the cost tuberculosis treatment programme without necessarily ensuring high cure rates.

2.12 ADHERENCE TO TREATMENT

Adherence to treatment needs active participation of the patient in self-management of treatment and cooperation between the patient and the health care provider, It has been pointed out that reasons for poor adherence are multifaceted and complex but include the characteristics of the individual patient and health care providers, duration and number of medication needed, side effect, and cost of treatment, contradictory norms or expectations of families and cultural groups and poor quality of the TB control infrastructure.

World Health Organization (WHO) DOTS strategy helped in improving outcomes in many ways as resources have been channeled towards TB control programmes, drug supplies, information systems and targets have been set and governments put more efforts in TB control programmes .Nhlema ,et.al(2003)

Policy makers and providers are to deliver the intervention that is highly effective against the debilitating and life-threatening disease. If the large proportions of people do not complete treatment, the health system failed, by failing to deliver according to promises. The viewpoint emphasize that the health system operate according to the client's needs, rather than to control patient's behaviour WHO (2007).

CHAPTER 3

3 RESEARCH METHODOLOGY

3.1 INTRODUCTION

Methodology is the process of following the steps, procedures and strategies for gathering and analyzing the data in a research investigation. These methods describe in detail how the study was conducted. According to Burns and Grove (2001), methodology includes the design, setting, sample, methodological limitations and data collection and analysis techniques employed to obtain valid knowledge.

A qualitative and quantitative approach was used for this study. A qualitative approach that is systematic, exploratory, descriptive and inductive not generalisable which words were used with the aim of determining factors that influence compliance and non-compliance among patients on tuberculosis drug treatment in Shiluvane Local area, Mopani District of Limpopo Province.

From the findings of this study the researcher will be able to increase the knowledge of the community and policy makers on strategies that will improve compliance.

Quantitative research was used to measure attitude, commitment of patients and satisfaction rate that can be tracked over time and used as part of planning and strategy process.

The basis of quantitative research comes from the sample and survey type that is statistical in case of this research, the design of the questionnaire which is fixed as it was administered the same way, for each respondent to obtain a reliable measure of the compliance and non-compliance to TB treatment. The approach is systematic, objective, deductive and use numbers (Burns and Grove, 2001)

3.2 STUDY SITE

The research was conducted in Shiluvane local area which is located in greater Tzaneen Municipality under Mopani District in Limpopo Province, South Africa. Shiluvane local area is has 27 villages, one district hospital DR CN Phatudi, one health centre Shiluvane and five clinics Maake, Mogoboya, Moime, Lenyenyene and Lephepane.

3.3 STUDY DESIGN

The study design direct the researcher in planning and implementing the studying away that is most likely to achieve the intended goal. It is a blue print for conducting the study (Burns and Grove, 2001).

3.4 ETHICAL CONSIDERATIONS

Ethical measures are important in qualitative, quantitative research including conduct towards informants' information as well as honest reporting of the results. The ethical measures in this study include consent, confidentiality, privacy, dissemination of results and the right to withdraw from the study.

Ethical approval

The researcher's request for permission to conduct the study was forwarded to Head of Department of health and social development, Limpopo Province, following the provincial ethical guidelines in conducting a research study. Written permission was sought from participants. Before the study was conducted, an informed consent that describes the purpose of the study, potential benefits, right to confidentiality, and right to withdrawal, were distributed and explained to all informants (Burns and Grove, 2001)

Confidentiality

Confidentiality is the researcher's management of private information shared by an informant that must not be shared with others without the authorization of the informant. Polit and Hungler (1999) stated that confidentiality means that no information that the participants divulge is made public or available to others. The anonymity of a person or an institution is protected by making it impossible to link aspects of data to a specific person or institution. Confidentiality and anonymity are guaranteed by ensuring that the data obtained are used in such a way that no one other than the researcher knows the source

Dissemination of results

The participants were informed that a copy of the findings would be handed to the health facilities where the study was conducted and the Limpopo Department of Health. The information would be published in relevant journals. The participants informed of the findings if they so desire.

Withdrawal from the study. Informants may discontinue participation at any time without loss of benefits (Burns and Grove, 2001). The participants were informed that they could withdraw from the study at any time if they wished to. This right was explained to them prior to engagement in the study.

This right is part of the informed consent. Limitations are restriction that may decrease transferability of findings. There are two types of limitations: conceptual and methodological:

Conceptual limitations restrict the abstract transferability of findings. Methodological limitations restrict population to which findings can be transferred to Burns and Grove, (2001). With this study methodological limitation was that only adult TB patients were selected, as such this only applies to TB patients in Shiluvani Local Area in particular.

3.5 SAMPLING

Burns and Grove (2001) pointed out that during the process of selecting or sampling, the aim is to get a sample that is as representative as possible of the target population. The researcher has chosen probability sampling for this study. There are different types of probability sampling and the type that was found suitable for this study was systematic sampling. The population for this study consisted of 300 males and females patients with TB, collecting treatment from DR C N Phatudi hospital, Shiluvane health centre, and Maake, Mogoboya, Moime, Lenyenye and Lephepane clinics.

The sample size was 150 of a given population using Morgan and Krejcie (1994). The case register was used to select respondents. The respondents were selected according to particular interval; each second name on the list was selected.

3.6 DATA COLLECTION

A questionnaire and structured interview were selected for data collection, the response were limited with few open ended questions. Questionnaires were distributed among clients who were able to read and write for them to complete, the researcher and the assistant helped to fill questionnaires for those who could not read or write. The study was conducted at the identified hospital, health center and clinics.

3.7 DATA ANALYSIS

Data analysis is done to preserve the uniqueness of each participant's information while permitting an understanding of the phenomenon under investigation. Data analysis engages the researcher in a search for patterns in data, through the process of examining, sorting, categorizing, evaluating, comparing and synthesizing the coded data as well as reviewing the raw and recorded data. Burns and Grove, (2001)

The following statistical analysis was employed:

Descriptive statistics such as frequencies, percentages, tables, graphs and Analysis of Variance (ANOVA) were utilized to analyze the data. All statistical analysis was performed using computer software called Statistical Product for Service Solutions (SPSS).

3.8 CONCLUSION

This chapter dealt with qualitative research methodology, study design, population, sampling, data collection, data analysis and ethical considerations.

CHAPTER 4

4. RESULTS

4.1 INTRODUCTION

The chapter contains the results of variables

The research team visited patients at clinics, health centre and the hospital during December 2009 and January 2010. A predesigned questionnaire was completed using self –report method. The questionnaire was composed of the following variables: a) demographic characteristic of patient, e.g. age, sex, education, work and income : b) knowledge about tuberculosis, its complications and treatment: c) compliance, where the patient was asked about the drugs taken, where taken, means of transport used, regularity, how taken, reminder, reasons for non compliant. The patients were considered non compliant if they did not take the medication as prescribed.

4.2 Education level and Age

Education seems to be a contributing factor towards TB compliance, findings shows 5(3.7%) has tertiary education,67(50%) has secondary education, 50(37%) has primary education and 12(9%) has no qualification out of 134 participants, this stress that people with better education are less infected by TB.

People with no or lower education are more vulnerable to TB as confirmed by Nhlemo , et al. (2003) as they stated that marginalized groups and the poor have limited access to information and where female literacy and education is low the stigma may be particularly marked for women. Results reflected that 96.3 percent of respondents either did not have education or have education until secondary level.

Education level plays an important parting the ability of patients to understand the treatment of TB. The patient may fail to follow treatment because of lack of understanding or inability to read the information provided. A comprehensive TB health promotion plan should be developed to raise awareness and knowledge about TB. Messages should be clear, focused, short, culturally sensitive and appropriate. This is shown in the table below (table 4.1)

Table 4.1: Educational level and Age

Education	Age								Total	
	Age group									
	16-29		30-49		50-69		70+			
None	2	5%	7	10%	1	4%	2	50%	12	9%
Primary	7	7%	20	30%	21	96%	2	50%	50	37%
Secondary	31	76%	36	54%	0	.0%	0	0%	67	50%
Tertiary	1	2%	4	6%	0	.0%	0	0%	5	4%
Total	41	100%	67	100%	22	100%	4	100%	134	100%

EDUCATION AND AGE

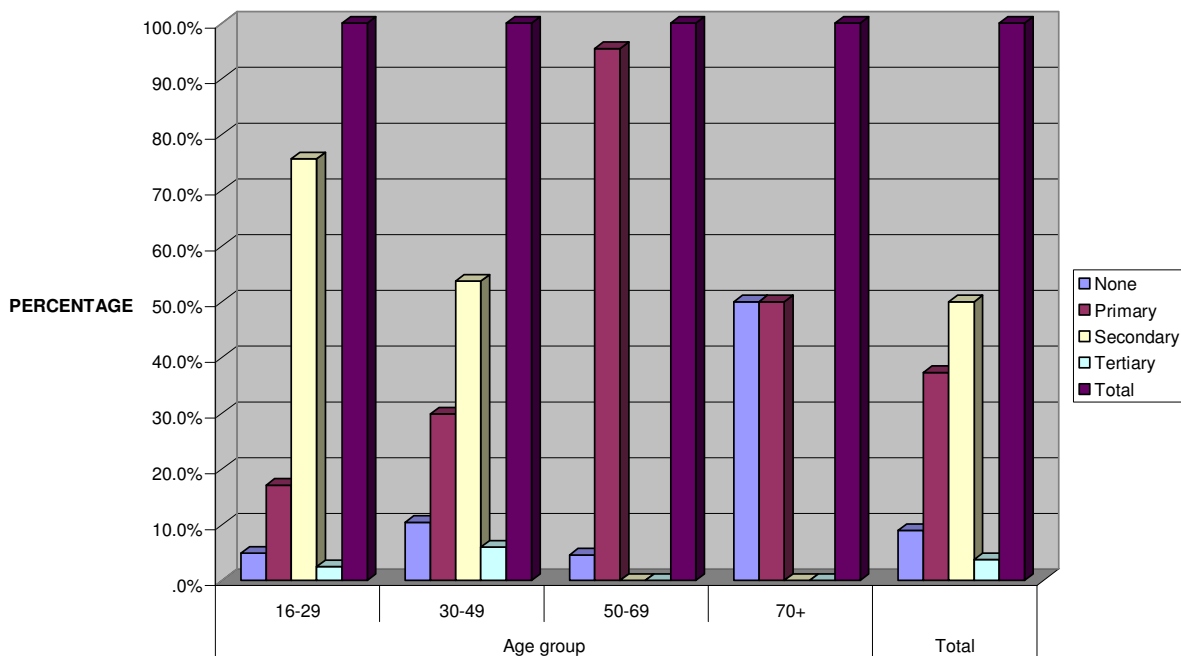


Figure 4.1 Education level and Age. Education was not found statistically associated with compliance

4.3 Occupation and Age

South Africa still has high rate of unemployment. The most affected age group is between 30-49yrs, as it is shown that 45 participants of 94 (74%) falling within that age group are unemployed. Unemployment was found to be statistically associated with predisposing causes of Tuberculosis as confirmed by Nhlemo. et al. (2003). 76 %(94 of 123) respondents are unemployed, 2% (2) government worker, 2% self employed, 12% (15) were on contract which confirms that poverty and unemployment predispose to Tuberculosis as only 5 respondents are employed.

This is shown in the table below (Table 4.2)

Table 4.2 Occupation and Age

Occupation	Age								Total	
	Age group									
	16-29		30-49		50-69		70+			
Unemployed	27	75%	45	74%	19	83%	3	100%	94	76%
Government	0	0%	2	3%	0	0%	0	0%	2	2%
Self employed	0	0%	2	3%	1	4%	0	0%	3	2%
Contract	4	11%	10	16%	1	4%	0	0%	15	12%
Other	5	14%	2	3%	2	9%	0	0%	9	7%
Total	36	100%	61	100%	100.0%	100%	3	100%	123	100%

OCCUPATION AND AGE

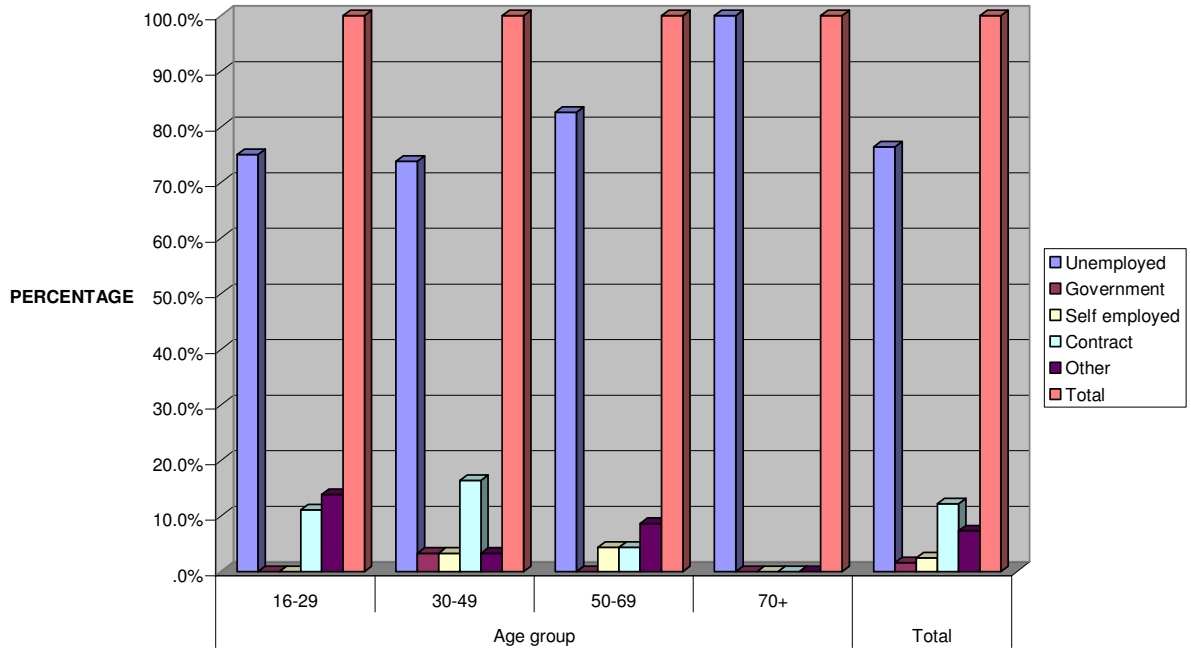


Figure 4.2 Occupation and Age .The figure shows that unemployment is high and was found to be statistically associated with non – compliance to treatment.

4.4 Income and Age

Poverty can be associated with predisposing causes of TB as 51 participants (52.6%) of sample size earned between R1000-R3000 more especially age group between 30-49yrs. Income was found to be statistically associated with compliance with drug treatment amongst patients with TB. This age group is still active but is unemployed and relies on grants to feed the family. Most patients use transport to and from health facilities for treatment which requires frequent travel and the transport may accumulate costs even with small distance Nhlema et al. (2003) this is shown in the table below (Table 4.3)

Table 4.3 Income and Age

Income		Age								Total	
		Age Group									
		16-29		30-49		50-69		70+			
Income	R100-499	1	38%	3	6%	1	5% 5.3%	0	0%	5	5.2%
	R500-999	4	15%	15	31%	3	16%	1	25%	23	23%
	R1000-2999	10	38%	24	50%	14	74%	3	75%	51	53%
	R4000+	0	0%	1	2%	0	0%	0	0%	1	1%
	No income	11	42%	5	10%	1	5%	0	0%	17	18%
Total		26	100%	48	100%	19	100%	4	100%	97	100%

INCOME AND AGE

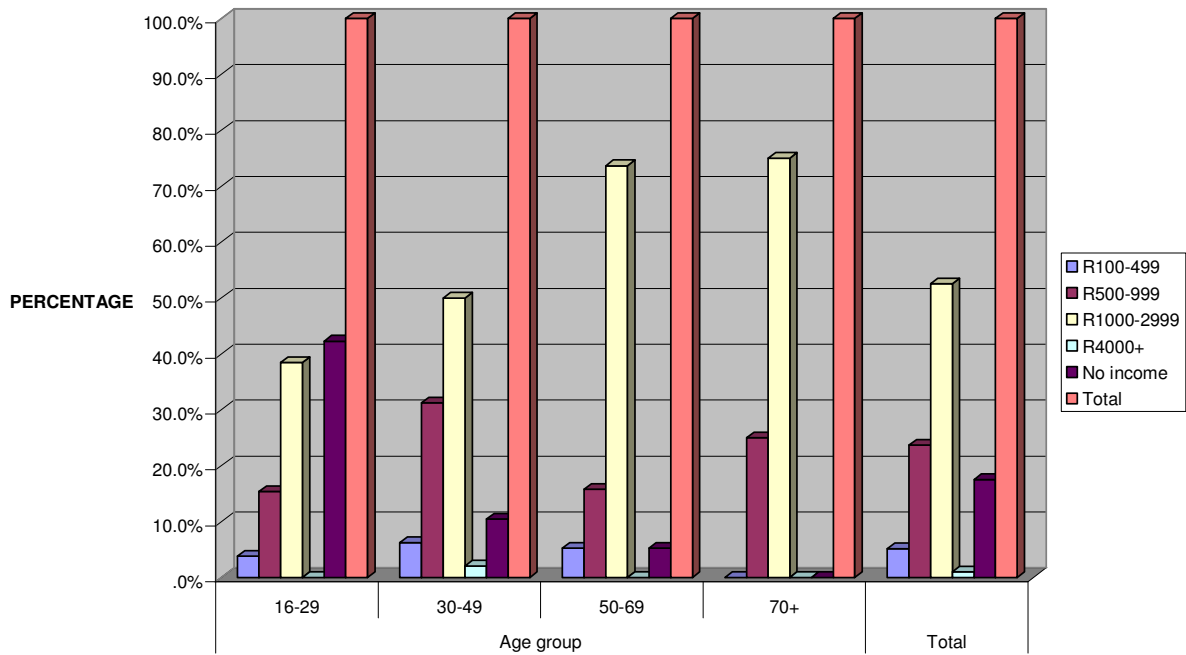


Figure 4.3 Income and Age. The figure shows that 51(53%) participants earned between R1000 –R2999, 23 (24%) earned between R500-R999, 5(5%) earned between R100-R499 and no income for 17(16%) participants which confirms that income was found statistically associated with compliance with treatment.

4.5 Compliance , non compliance and Age

Non compliance is 9.1 % (7 of 12) ranges between 30-49yrs and followed by 16-29yrs (3 of 12), and (1 of 12) from 50-70+ years.

The survey showed that compliance is 90.9% (120 of 132), 95.8% ranges between 50-69yrs followed by 92.7% ranging between 16-29 yrs.

The support from family members and health workers played the most important part in compliance to TB treatment as observed in this study, support the study conducted in Kwa Zulu Natal through 1991-1994.

Most patients indicated that they were worried about the duration of the treatment, as they completed the course of treatment but within short period they contacted Tuberculosis again. The results revealed that there was poor patient relationship as clients were not satisfied with the attitude of health workers. Age was not found to be statistically associated with compliance with drug treatment amongst patients with Tuberculosis Wilkinson,(1996) , this is shown in table (4.4) below.

Table 4.4 Levels of compliance, non-compliance and Age

Compliance and non-compliance		Age								Total	
		16-29		30-49		50-69		70+			
Non-compliance	3	7%	7	11%	1	4%	1	25%	12	9%	
Compliance	38	93%	56	89%	23	96%	3	75%	12	91%	
Total	41	100%	63	100%	24	100%	4	100%	132	100%	

COMPLIANCE AND NON-COMPLIANCE

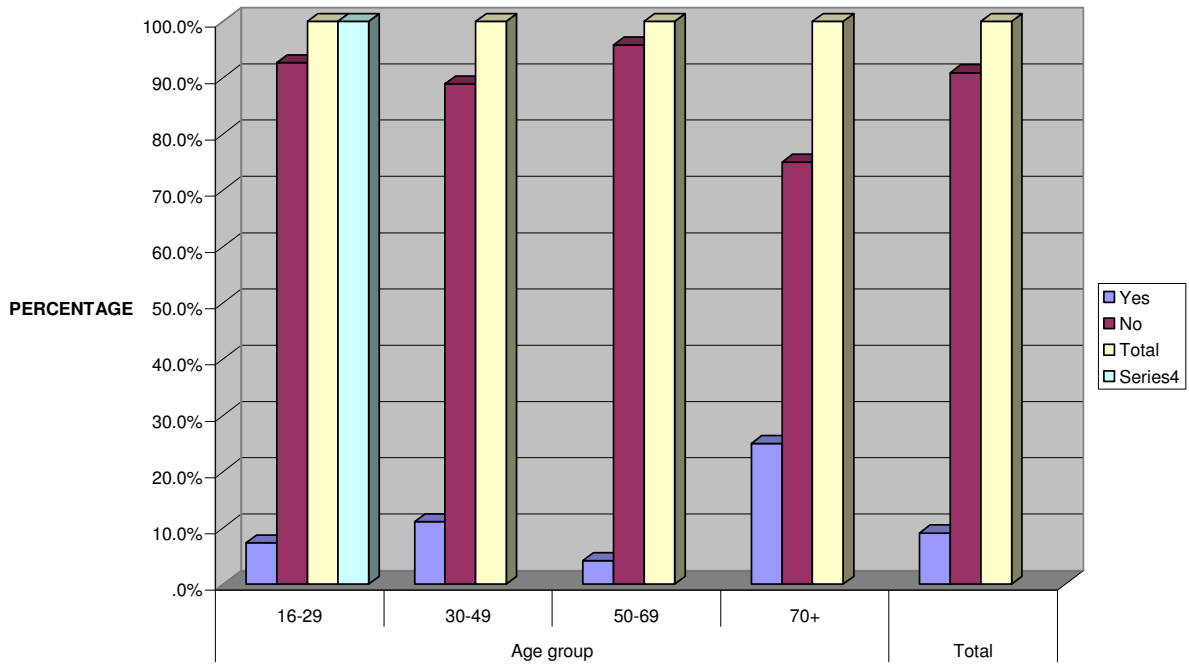


Figure 4.4 Compliance, Non-Compliance and Age .The present study shows that 90.9% of the participants studied were compliant with the prescribed regime. About 9% of the patients were noncompliant, which may results in treatment failure.

4.6 Conclusion

To increase the compliance rate among TB patients, more information about Tuberculosis must be given to them at the time of diagnosis through health education sessions, should be appropriate to educational standard and cultural beliefs. Give more details on instructions, effectiveness and the importance of the TB treatment. Encourage admission of all patients once diagnosed and treatment is started.

CHAPTER 5

5.1 DISCUSSION, CONCLUSION AND RECOMMENDATIONS

The aim of the study was to explore compliance and non-compliance amongst TB patients on tuberculosis drug treatment. The objectives of this study are met thorough the literature. Results from analysis answers the research question with following variables: Education level and age in this study conducted shows that education plays an important part as it guides in showing on the ability of patients to understand the importance of TB treatment. The study further showed that 50% of the researched community reached secondary education and 76% were unemployed. The findings of this study shows similarities as confirmed by Nhlemo et al, (2003) where he clearly suggested that people with no or lower education are more vulnerable to Tuberculosis. South Africa still has high rate of unemployment. Poverty and unemployment predispose to Tuberculosis, only 4% were employed and 12% were on contract basis which confirms Nhlemo, et, al (2003) that poverty and employment predispose to Tuberculosis

Income and age poverty can also be associated with predisposing causes of TB as most patients use transport to health facilities to collect treatment which may accumulate costs even with small distance .Tuberculosis is influenced by poor socio-economic conditions as confirmed by Rocha et al, (2003).where he confirmed that about 52.2% respondent depends on grants for living.

Age is not associated with compliance, there was no similarity between compliance and age as only 9.1% of respondent did not comply with treatment and 90.1% complied with treatment. According to Portwig and Couper, (2006) cooperation from the patient, knowledge and information on TB are factors needed in compliance to TB treatment.

5.2 CONCLUSION

This study has enabled the researcher to investigate factors that lead to compliance and non-compliance with drug treatment among patients with tuberculosis. This study will be of assistance for future studies to be conducted on factors contributing to patients who do not comply with TB treatment, as well as to future investigate on traditional believe concerning on the cause of TB as patients had strong beliefs that TB carries social stigma.

The findings of this study assisted the researcher to suggest some recommendations and strategies to insure compliance and encourage interdisciplinary collaborations with other health workers involved in care of TB patients such as dieticians, social worker, pharmacists, and laboratory technicians.

5.3 RECOMMENDATIONS

- Health education to communities about TB through awareness campaigns, road shows, door-to-door campaigns, educating people about TB to reduce the myths surrounding TB and HIV, as well as educating people about the importance of compliance with TB treatment and the dangers of interrupting treatment.

- Disability grant should be granted to TB patients with chronic conditions as they are unable to be employed again.
- Carers should implement DOTS strategy
- Traditional healers should be incorporated in the as DOT supporters.
- Volunteers should be trained on patient supervision. E.g. Supervise taking of medication, Volunteers could form part of a valuable support system.
- Attention should be given to psychology and social implications of TB and treatment to patients and their families as it carries a social stigma.
- Integrate services as much as possible within primary health setting, if possible the patient should go for treatment, review at the nearest health facility to avoid costs.
- Develop an appropriate community-based TB care model, e.g. form support groups in communities to share their experiences about the disease, to make TB sufferers feel belonging to others, thus reducing the impact if stigma of TB. Invite former TB patients and support groups to advocate for TB services and help with community mobilization.

- Ensure that health staff attitude and behavior does not reinforce stigma
- Reinforce for legal framework to protect employees from loss of employment as a results of TB.

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APPENDICES

7.1 Questionnaire

7.2 Consent Form

7.3 Approval Letters:

7.3.1 University Ethics Committee

7.3.2 HOD Health and Social Development

7.3.3 Mopani District Manager

APPENDIX 1

COMPLIANCE TO DRUG TREATMENT QUESTIONNAIRE

Name of Hospital / Health Centre / Clinic

Date:.....

1. DEMOGRAPHIC DATA

1.1 Name of the patient.....

1.2 Age

1.3 Gender

Male	
Female	

1.4 Marital Status

Single	
Married	
Divorced	
Widowed	

1.5 Education

None	
Primary	
secondary	
Tertiary	

1.6 Religious Denomination

Traditional	
Christian	
NO religion	
Other specify	

1.7 Occupation

None	Labourer	Nurse	Teacher

Other specify -----

1.8 Monthly income

None	
R500 – R1000	
R1 000 - R3000	
R3000 - R4000	
R4500 and above	

2. Knowledge and Understanding of TB

2.1 What is TB?

2.2 What are dangers of untreated TB?

2.3 Were you informed about the period of taking treatment? _____

2.4 Were you made aware that there is TB treatment available?

- (a) Yes
- (b) No

3. Factors Associated with Compliance to Treatment

3.1 Where do you collect your medication?

- (a) Clinic
- (b) Health Centre
- (c) Hospital

3.2 Mode of transport used to collect treatment

- (a) Walking
- (b) Own transport
- (c) Public transport

3.3 When do you take your medication?

- (a) Morning
- (b) Afternoon

- (c) Evening
- (d) At bed time

3.4 How do you take your medication?

- (a) Before food
- (b) With food
- (c) After food
- (d) Other, specify _____

3.5 What reminds you to take your medication?

- (a) Family member reminds you
- (b) Keep medicine visible
- (c) DOT supporter reminds you
- (d) Other, specify _____

3.6 In the last 7 days, did you miss taking your TB medication?

- (a) Yes
- (b) No

3.7 If yes how many doses did you miss? _____

3.8 Why did you miss taking your medication? _____

3.9 When was the last time you missed your TB treatment?

- (a) Within past week
- (b) 1-2 weeks ago
- (c) 2-4 weeks ago
- (d) More than one month ago
- (e) Never missed medication

3.10 Why would you stop taking TB treatment? _____

3.11 Is there anything that you would want to add?

Thank you for your time!!!!

UNIVERSITY OF LIMPOPO

PROJECT TITLE; COMPLIANCE WITH DRUG TREATMENT
AMONG PATIENTS WITH TUBERCULOSIS IN THE
SHILUVANE LOCAL AREA, MOPANI DISTRICT, LIMPOPO
PROVINCE, SOUTH AFRICA.

PROJECT LEADER; DR M.B.L. MPOLOKENG

CONSENT FORM

I,hereby voluntarily consent to
participate in the following project; compliance with drug treatment among patients with
tuberculosis.

I realize that;

1. The ethics committee has approved that individuals may be approached to participate in the study;
2. I will be informed of any new information that may become available during the research that may influence my willingness to continue with research;
3. Access to the records that pertain to my participation in the study will be restricted to persons directly involved with the research;
4. Any questions that I may have regarding the research, or, related ,matters, will be answered by the researchers;
5. Participation in this research is voluntary and I can withdraw my participation at any stage;
6. IF any medical problem is identified at any stage during the research, or when I am vetted for participation, such condition will be discussed with me in confidence by a qualified person or I will be referred to the doctor
7. I indemnify the University of Limpopo and all persons involved with the above projector that may be related to it for whatever reasons, including negligence on the part of the mentioned persons.

SIGNATURE OF RESEARCHED PERSON.....

SIGNATURE OF THE WITNESS.....

SIGNATURE OF THE RESEARCHER

Signed aton the... 2009

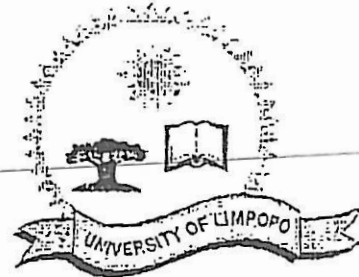


LIMPOPO

PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH AND SOCIAL DEVELOPMENT

ETHICS COMMITTEE
CLEARANCE CERTIFICATE
UNIVERSITY OF LIMPOPO
Polokwane/Mankweng Hospital Complex



PROJECT NUMBER: 106/2009

TITLE: Compliance with Drug Treatment Among Patients with Tuberculosis in the Shiluvane Local Area, Mopani District, Limpopo Province, South Africa

RESEARCHER: M.S. MABITSELA

ALL PARTICIPANTS:

Department: PUBLIC HEALTH

Supervisor: DR M.B.L. MPOLOKENG

Co-Supervisor:

Date Considered: 19/03/2009

Decision of Committee: Recommended for Approval

Date: 24/08/2009


Prof A.J. Mbokazi

Chairman of Pietersburg Mankweng
Hospital Complex Ethics Committee

Note: The budget for research has to be considered separately. Ethics Committee is not providing any funds for projects.



DEPARTMENT OF HEALTH AND SOCIAL DEVELOPMENT

Enquiries: Ramalivhana NJ/Malomane EL

Ref: 4/2/2

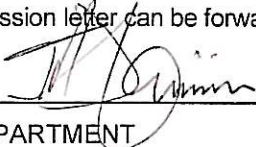
03 August 2009
Mabitsela M.S
P.O.BOX 283
LENYENYE
0857

Dear Mabitsela M.S

“Compliance with drug treatment among patients with tuberculosis in the shiluvane local area, Mopani District, Limpopo Province, South Africa”

Permission is hereby granted to Mabitsela M.S to conduct a study as mentioned above in **the shiluvane local area, Mopani District, Limpopo Province, South Africa”**

- The Department of Health and Social Development will expect a copy of the completed research for its own resource centre after completion of the study.
- The researcher is expected to avoid disrupting services in the course of his study
- The Researcher/s should be prepared to assist in interpretation and implementation of the recommendations where possible
- The Institution management where the study is being conducted should be made aware of this,
- A copy of the permission letter can be forwarded to Management of the Institutions concerned



HEAD OF DEPARTMENT
HEALTH AND SOCIAL DEVELOPMENT
LIMPOPO PROVINCE



LIMPOPO

PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF
HEALTH AND SOCIAL DEVELOPMENT
MOPANI DISTRICT

Ref: S5/4/1
Enq: Maluleke B.H
Tel: 015 811 6542
Date: 13/11/2009

TO WHOM IT MAY CONCERN

Re: PERMISSION TO CONDUCT RESEARCH ON COMPLIANCE WITH DRUG TREATMENT AMONG PATIENTS WITH TUBERCULOSIS IN THE SHILUVANE LOCAL AREA, MOPANI DISTRICT, LIMPOPO PROVINCE, SOUTH AFRICA

1. The above matter refers.
2. Permission to conduct research at Shiluvane Local area is granted to Mabitsela MS .
3. Please note that participation in practicals does not involve salary or remuneration by the Department.
4. The candidate shall not willfully disclose any information which may prejudicially affect the institution and the department
5. We hope that you will find this in order.


DISTRICT EXECUTIVE MANAGER


DATE