RESEARCH PROPOSAL

An Evaluation to asses the holistic care of Tuberculosis patients with palliative care needs in the Western Cape, South Africa.

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Declaration of own work

I, Stephanie Rene Krause, hereby declare all the following work is my own work. The biostatistical analysis was done by a biostatician, Maryn Viljoen.

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CHAPTER 1

Orientation to the study

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1. Title:

This is an evaluation of the holistic care of Tuberculosis patients with palliative care needs in the Western Cape, South Africa.

1.1. Introduction:

Tuberculosis (TB) is a curable disease but has caused significant mortality and morbidity for centuries. The developed world claims to have a well managed TB control program with an incidence rate of 4.2/ 100 000 in 2001 in the USA[1]. It is estimated that a third of the world's populations is exposed to Tuberculosis and therefore at risk of developing TB disease[2]. Currently the main burden of TB in South Africa and other Sub-Saharan countries is seen among patients with compromised immunity due to the Human Immunodefiency Virus (HIV). The result is that countries in Sub-Saharan Africa, with a high prevalence of HIV, are now facing a crippling pandemic causing significant illness and death. According to the World Health Organisation (WHO), South Africa is ranked 9th of the 22 countries listed as the hardest hit with TB. The incidence rate in 2005 in South Africa was 600/ 100 000 population per year[3]. In 2007 the incidence rate had increased to 948/100 000[4] .

The incidence rate was 460.3 per 100 000 population per year in the Western Cape in 2008 for new smear positive TB patients. According to statistics in 1996 there were 39258 new smear positive patients and the cure rate was 53.9%[3]. In 2005 the number of patients had increased to 141667 with a cure rate of 57.7%[3]. The mortality rate for all forms of TB was 230 deaths per

100 000 population per year[4]. The Multi Drug Resistant (MDR) TB rate among previously treated TB cases was 6.7% in 2005[4].

From these statistics, the question arises as to why an apparently curable disease such as TB is on the increase in Africa and especially in a well-resourced area such as the Western Cape Province of South Africa? The Sub-Saharan Africa region is currently facing an epidemic of HIV creating a pool of immune-compromised patients susceptible to TB. Against this background, it is also recognised that Africa’s resources are being depleted by poverty, war and the exodus of educated people, including health professionals, from the continent.

TB is traditionally a disease of the poor and very little research has been done on the development of new drugs by big pharmaceutical companies. The most recent new TB drug, namely Rifampicin, was developed in 1966[1].

These factors contribute to the devastating increase in the statistics of morbidity and mortality of people infected with TB in the Western Cape.

1.2 Tuberculosis management

The focus of TB management has always been on curing the disease. However, we cannot always cure the patient’s illness. Various negative factors impact on the TB control program making it difficult to achieve the desired 80% cure rate as recommended by the WHO.

These factors include patients who interrupt their treatment due to lack of insight into the disease, drug reactions or difficulty to obtain the treatment. There is an increase in the incidence of MDR cases due to lack of compliance or primary MDR TB. The TB control programme is negatively affected by insufficient human and technical resources. Some patients have co-morbid diseases that are incurable, such as cancer, HIV and COPD, which contribute to the poor cure rate. It is this patient population that needs comprehensive care, including palliative care.

An incurable disease such as cancer predisposes patients to being more vulnerable to developing TB disease and unfortunately sometimes dying with or from TB. Many terminally ill patients have weakened immune systems and are more vulnerable for developing TB disease. Factors that contribute to developing active TB disease are malnutrition, toxins and drugs (e.g. alcohol, tobacco, corticosteroids and other immunosuppressants); concomitant disease (e.g. HIV, diabetes, leukaemia) and patient's age (the very young and the very old)[5] . Against this background, healthcare providers now face the dilemma of managing a contagious disease and caring for a dying patient. These palliative care patients with concomitant TB need special assessment and care. These needs are not always considered in a TB management programme with a strong focus on cure. In the light of resource constraints, patients whose foreseeable outcome is death have very low priority in the current healthcare system.

1.3. Signs and Symptoms of TB.

TB is a disease with significant morbidity and mortality. This dissertation will demonstrate that most patients with TB experience pain and other distressing symptoms. TB patients commonly suffer with chronic coughing, anorexia, haemoptysis, night sweats and lethargy[6]. All of these symptoms need active palliative care to improve the patient's and caregiver's quality of life.

TB is a disease which affects the whole family, not only because the disease is spread by droplet infection - putting the whole family at risk of developing TB - but also because of the psychosocial affect it has on the family. Just as HIV carries a stigma, TB also carries the stigma of poverty, unclean living and in South Africa, of being HIV positive. Healthcare providers communicate through masks with the patients and patients enter at different clinic entrances. This leads to isolation and a lack of support for the patients and their families. In most cases the TB clinic nurse has to deal with a range of co-morbid conditions affecting the TB patients. Nurses are not always skilled at providing this care, especially palliative care, to these patients. The lack of palliative care knowledge and skills and the pressure of health care needs often result in patients dying in distressing circumstances, in pain and abandoned by the formal health care system. This reality leaves lasting sad memories which contribute to the morbidity of this pandemic.

1.4. Diagnosis of TB

It is notoriously difficult to diagnose TB in immune-compromised patients because their smear microscopy is often negative, they have atypical chest x-rays and they have atypical symptoms. This diagnostic dilemma and the fact that the clinicians focus on the primary disease (e.g. HIV or the cancer) results in fragmented care and these patients seldom receive the holistic care they need. TB is also commonly wrongly diagnosed in patients with another severe co-morbid disease.

1.5. Treatment of patients with TB

TB treatment extends over a minimum period of six months. Retreatment patients receive treatment for 8 months and Multi Drug Resistant (MDR) TB patients receive treatment for 24 months6. Most TB programmes insist on the DOTS system where the clinic can directly observe the patient drinking his/her treatment for the first few weeks. This means that the patient must walk to the clinic, wait to be seen and then take the tablets. Patients with palliative care needs are weak and find it difficult to attend the clinics. This sometimes means family members have to collect tablets which can lead to loss of their employment. Complying with the above has a negative impact on the patient's and the family's daily tasks. The home-based care system has been developed to encourage caregivers to assist sick patients at home, but is not adequately funded to ensure directly observed treatment daily.

The treatment protocols which are mainly prescribed are Pyrazinamide, Ethambutol, Rifampicin and Isoniazid and if the patient is a retreatment patient, intramuscular streptomycin is added to the regime for the first 2 months[6]. The above-mentioned medication comes in a combined form called

Rifafour. This is a big tablet which is very difficult to swallow. These tablets have severe side effects of which peripheral neuropathy, skin reactions, joint pains, loss of vision, nausea and vomiting and hepatotoxicity commonly occur[6]. The hepatotoxicity can lead to liver failure and death.

These side effects are more common in immune compromised patients due to immune dysregulation. Hepatic steatosis is common in HIV patients and predisposes them to drug-induced liver injury[7]. Side effects lead to many patients not completing their treatment resulting in worsening TB symptoms and a growing infectious pool. The main aim of palliative care is to achieve the best quality of life for patients and their families by treating distressing symptoms and by giving treatment support. Palliative care should be used as an essential tool to improve TB compliance in the terminally ill patient.

1.5. The role of the carers

The World Health Organisation defines Palliative Care as an approach that improves the quality of life of patients and their families facing problems associated with life threatening illness, through the prevention and relief of suffering, the early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual[46]. Palliative Care aims to improve the quality of life of the patient and their families. These families have the daunting task of caring for a loved one with a contagious disease. Family carers often have to provide close physical care in small shacks without the luxury of masks or good ventilation. Very few family members have themselves tested for TB and INH prophylaxis is not widely available in the Western Cape. Very often these family members also have compromised immune systems, resulting in the infectious pool growing. According to Rev. Fox, compassion for the sick and dying is easy; responding with insight, skill and love is a challenge[8]. Many of the family carers do not have the insight into TB transmission, and hence lack the skills to ensure that they and their families are adequately protected.

TB clinics are overcrowded and the health care professionals do not always have the time to spend with families in meaningful counselling. TB services, frequently needed for palliative care patients, are often limited to TB hospitals. These hospitals are not always skilled in the practice of palliative care. Patients are transferred to TB hospitals far away from their families, leaving them isolated and emotionally unsupported. The loss of a loved one leads to a wide range of emotional issues, change in family dynamics, socio-economic losses and role overload. Many patients die alone, isolated from their families in poorly resourced TB hospitals, because of the fear of spreading TB and poor nursing resources in the community.

1.7. The role of Hospice

Home care skills in caring for the dying TB patient are best provided by personnel trained in palliative care such as found in hospices. Previously hospices were not involved in care of TB patients, as TB was seen as a curable infection. Hospices are now developing TB policies and procedures to improve their management of TB patients who have been referred to them. Hospices are not equipped to deal with contagious diseases, especially in sub-Saharan Africa. It is only recently that the Lizo Nobanda MDR TB Hospice has been opened in Cape Town to provide for the palliative care needs of these patients.

Hospices are playing an increasingly bigger role in caring for the terminal HIV patients who have a high incidence of TB co-infection. In some cases TB is diagnosed only at the hospice when the patient presents with spiking temperatures. The reluctance of hospitals to readmit palliative care patients puts the responsibility of the TB management on the hospice. In order to fulfil this responsibility, it is essential for hospices to develop skills in caring for TB patients and to source funding to care for them.

The palliative care team aims to integrate the psychological and spiritual aspects of patient care. It also helps the family cope during the patient’s illness. This holistic core care needs to be incorporated into the TB management of the palliative care patient. Family involvement may be the most important element of successful rehabilitation and long-term home care[9]. The family need information about TB and the other co-morbid disease and need counselling on the impact this condition may have on their psychosocial and physical lives. The stigma of TB may extend to the whole family resulting in social isolation. This puts a further burden on the family and in some cases this makes denying the presence of TB easier. This denial, lack of information and stigmatisation lead to non-compliance and the growth of the TB epidemic.

1.8. Ethical Issues

An ethical dilemma has developed for health care providers when considering the withdrawal of TB treatment from a patient, and in particular from the palliative care patient who is not tolerating TB medication or is not responding to treatment due to drug resistance. Is it socially or ethically acceptable to discontinue these drugs exposing more people to TB? On the other hand, is it inhumane to expose a dying patient to drugs which they are not tolerating or from which they will not benefit? These are the ethical issues facing doctors on a daily basis.

1.9. Presentation of the Study

The chapters in this study will be presented in the following order:

Chapter 1

An orientation to the study in which the necessity for this research is shown to be essential for palliative care and comprehensive TB management.

Chapter 2

An extensive literature survey focuses on the current management of TB patients and the effect that palliative care has on the quality of life of all concerned parties.

Chapter 3

In this chapter the detailed aims and objects of this study are stated.

Chapter 4

The method and study design, with special reference to the validation of the study, are described in this chapter.

Chapter 5

The processed results in both table and chart form are presented in this chapter. This presentation is offered in three main themes that correspond to the research instrument, namely the file review, the interview with the patient and the assessment of the caregiver's quality of life

Chapter 6

The results of this study are integrated with the background information and then reviewed to explore the issues identified during the study.

Chapter 7

Conclusions and recommendations, based on observations discussed in chapter 6, are presented here. In addition recommendations for future studies are offered.

1.10. Conclusion

This orientation demonstrates the pressing need for an evaluation of this nature. The following chapter will demonstrate the increasing problems in providing holistic, appropriate palliative care for TB patients.

CHAPTER 2

Literature Review

2.1. Introduction

The literature search, using Medline, Science Direct, Google Scholar, EBSCO Host and PubMED, did not yield any research that has been previously done on TB management of palliative care patients. Keywords used were: TB (Tuberculosis) management in/of/and palliative care, palliative medicine, palliative need*.

There are 8 million cases with TB reported worldwide and 2 million deaths each year are attributed to TB as the main cause of death.[10] However, from this literature review it is clear that the main aim of TB research has been to cure the disease, and very little research has been done on providing quality of life to affected patients and their relatives. Most of the research that has been done on TB concerns drug therapy and laboratory findings. These findings reflect the emphasis on curative care and the lack of holistic care. The concern of this study is the lack of research that has been done on the management of TB in the palliative care setting.

International research done by the Union against Tuberculosis and lung disease found that a third of the 40 million people who are HIV-positive are also infected by TB[10]. In Sub-Saharan Africa this incidence of co-infection has increased to 75%. Tuberculosis remains one of the main causes of death when patients are infected with HIV. In Myanmar, 56% of the co-infected patients were enrolled in the HIV care programme[10]. This left a considerable proportion of the patients with no comprehensive care. No articles could be found to evaluate the number of patients diagnosed with TB and immune-compromising diseases other than HIV. In a study done by Kim in South

Korea, where the incidence of active TB is 70/100 000 persons-year, it showed that patients with solid-organ malignancy have a 4.69 times higher risk of developing active TB than patients without malignancy[11]. This study continued to state that advanced HIV, old healed TB, chronic renal failure, infliximab therapy, poorly controlled diabetes, underweight, silicosis and gastrectomy are widely accepted risk factors for reactivation of TB[11]. The shortcomings of this study were the wide confidence interval and the heterogeneity of the population group. From the researcher's clinical experience, a considerable number of diabetic patients, cancer patients and patients on immune-compromising drugs are being seen at the TB clinics.

2.2. Symptoms of Tuberculosis

The symptoms of TB include a cough which continues for longer than 2 weeks, weight loss, fatigue, pain, haemoptysis, fever and night sweats[6]. These are all aggravated by co-morbid conditions such as AIDS, cancer, COPD (Chronic Obstructive Pulmonary Disease) and other terminal illnesses. Palliative care focuses on pain and symptom control alongside the active management of the disease. No articles could be found on pain and symptom control of the TB patient. Hitchcock states that there is a need for improved pain control in AIDS patients to improve their quality of life and assist them in remaining economically active[12] The TB co-infected patient deteriorates more rapidly than the HIV-infected patients[13]. Terminal patients co-infected with TB are burdened with severe symptoms of which pain is the most understated.

2.3. The Diagnosis of TB

The diagnosis of TB is based on the collection of sputum to identify acid fast bacilli in the sputum[6]. In 2003 Siddiqi published in the Lancet Infectious Disease Journal that HIV modifies the clinical presentation of TB, especially in patients with advanced immunosuppression[14]. Saranchuk has discovered that the compromised immune response causes less cavity formation and therefore fewer sputum positive smears[15]. However, this study was only done on HIV positive patients. The diagnostic delay leads to further deterioration of the disease and the patient[15]. No articles could be found to describe the problematic diagnoses in other immunocompromised patients. Due to this difficulty and delay in diagnoses rapid diagnoses methods have recently been developed namely, the GenoTypeMTBDRplus. This assay allows the detection of Mycobacterium Tuberculosis and its resistance to INH or Rifampicin within 5 hours.

2.4. Clinical Picture

The World Health Organisation defines health as '….a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'[16]. In a qualitative study done by Hansel at John Hopkins University, she explored the quality of life of patients with TB in Baltimore City by conducting four focus groups. She concluded that TB carries the extra burden of social stigmatization, isolation, pill burden, long duration of treatment, sexual dysfunction, loss of income and fear[17] . However, spiritual well being and a positive perspective on life were found to be positive influences. This study also emphasises that, despite the improvements in treatment and mortality outcomes of TB patients in the USA, TB and its treatment continue to have a broad impact on the lives of affected individuals. It was concluded that TB affected all domains of quality of life of patients; for example, general health perception, somatic sensation, psychological health, spiritual well being, and physical, social and role functioning[17]. The limitation of this study is that only 10 patients where interviewed from the same cultural and demographic background. This was a small self-selected population group that may not be representative of the entire US TB population. The health care providers and patients were from one medical centre and possibly knew each other, which could have introduced an element of bias in the study.

Kelly-Rossini state that patients feel lonely and abandoned and they suffer from depression and anxiety because of confinement and uncertainty about the future[18] In the palliative care patient these factors are amplified with the burden of a terminal diagnosis.

2.5. Treatment Approach

Marra found that there are extreme negative feelings associated with the diagnosis of TB. Marra did a qualitative multi-site study in Canada on 39 patients from different ethnic backgrounds to assess the factors which influence the QOL of patients with active TB. This study included hospitalized and ambulatory patients. Open-ended questions where asked and patients where asked to discuss their experience of being diagnosed with TB.

This study focuses on 4 main themes, namely;

- The diagnosis: The difficulty in making a correct diagnosis and the problems with a delayed diagnosis. The feeling of isolation associated with hospitalization. This study states that the patient feels scared, shocked and depressed on receiving TB as a diagnosis.
- The medication: In this study patients complain of the gastrointestinal side effects and itchiness caused by the medication. They find the size of the medication and the amount of medication troublesome.
- The social support: In this study most patients had disclosed to their family members and friends that they had TB, but one patient did not disclose because he was afraid of mass hysteria. Most patients felt supported by their friends in this study.
- Health behaviour: Most patients in this study had done nothing else besides taking their medication to improve their TB outcome.

Marra also found that the treating doctors lack knowledge about TB. . Patients where frustrated with their primary physicians for the lack of prompt diagnoses and inappropriate management. There were extreme negative feelings associated with hospitalization. Unfortunately, this study did not explore the spiritual aspects of QOL. There was possible bias in this study because it examined a self-selected group of TB patients who may not be representative of the entire TB population in Canada. In conclusion this study stated that the impact of TB on quality of life is either underestimated or not considered[19].

2.6. Medical Treatment and Side effects

According to Spilker the treatment of active TB requires prolonged therapy of at least 6 months with multiple toxic drugs, which can lead to side effects in a significant number of patients[20]. There are many articles addressing the side effects of anti-TB drugs. Gastro-intestinal side-effects such as nausea and vomiting, and itchiness were the main complaints from patients on TB treatment in a study in Canada[19]. According to Durand, the physician's education should include the hepatotoxic effect of antitubercular treatment, especially in patients with predisposing conditions[7]. These predisposing conditions are seen in patients with viral hepatitis, patients on concomitant paracetamol, known alcohol abuse and pregnant women[21]. According to the CDC (Centre for Disease Control and prevention) TB commonly occurs in association with other diseases and conditions[22]. Other associated diseases are: HIV infection, haematological or reticuloendothelial malignancies, immunosuppressive therapy, chronic renal failure, poorly controlled insulin-dependant diabetics, and malnutrition[8]. Therapeutic decisions about these patients should be individualized, taking into account the severity of the TB and the response to treatment[22]. The CDC also concluded that the TB treatment of patients with liver disease is problematic and can lead to fatal liver failure. These patients should be treated with fewer hepatotoxic drugs in consultation with an expert[22.] Laughon states that there is a need to modify the treatment modalities, especially in the choice of drugs and duration of therapy when TB occurs in special situations such as pregnancy, liver disease, renal failure or co-infection with HIV[1].

Bateman states that although doctors and nurses know that cancer causes pain, they do not understand that AIDS causes pain. This leads to poor assessment of pain and under-prescribing of morphine[44]. This statement is further supported by Norval, who states that barriers to pain management in South Africa include the lack of knowledge of HIV/AIDS, palliative care and pain control as well as access to essential analgesic drugs and pain management specialists[23]. This is supported internationally by Selwyn from the USA who states that studies have consistently documented the under-recognition and under treatment of pain and other symptoms in patients with AIDS[24]

2.7. World Health Organization; Quality of Life

From the above-mentioned studies, it is clear that TB and its treatment impacts poorly on the quality of life of terminally ill patients. Quality of life measures are tools which describe the personal and social context of patients[25]. There is no substitute for measuring outcomes associated with disease but there is an adjunct to them which is a highly individual concept[25]. Mount and Scott said the assessment of quality of life is like assessing the beauty of a rose: no matter how many measurements are made, the full beauty of the rose is never captured[26]. There are many QOL measures and in a recent review in Palliative Medicine 29 such tools were compared[27].This study concluded that they cannot provide an explicit recommendation for the use of one specific instrument.

The WHO first designed the WHOQOL-100 scoring system which used 6 domains to calculate quality of life. This has been adjusted to the WHOQOL-BREF which only uses 4 domains of measurement.

In this study the World Health Organisation Quality of Life Questionnaire (WHOQOL BREF) was used.

The questionnaire uses the following 4 domains to assess the quality of life;

Domain 1: Physical health:

- Activities of daily living
- Dependence on medicinal substances and medical aids
- Energy and fatigue
- Mobility
- Pain and discomfort
- Sleep and rest
- Work capacity

Domain 2: Psychological:

- Body image and appearance
- Negative feelings
- Positive feelings
- Self-esteem
- Spirituality/ Religion/ Personal beliefs
- Thinking, learning, memory and concentration

Domain 3: Social relationships:

- Personal relationships
- Social support
- Sexual activity

Domain 4: Environment:

- Financial resources
- Freedom, physical safety and security
- Health and social care: accessibility and quality
- Home environment
- Opportunities for acquiring new information and skills
- Participation in, and opportunities for recreation/ leisure activities
- Physical environnent (pollution/noise/trafic/climate)
- Transport[28]

The mean score of items within each domain is used to calculate the domain score. Explicit instructions are used to calculate each domain score. Domain scores are scaled in a positive direction (higher score donates higher quality of life)[28]. There are two items which are examined separately:

- Question 1: asks about an individual's overall perception of quality of life.
- Question 2: asks about an individual's overall perception of their health[28].

In a study done on traumatic head injuries it stated that the WHOQOL-BREF is an appropriate health-related quality of life instrument, because of its very good internal consistency and test-retest reliabilities; good convergent validity and responsiveness and therefore a valid tool to use[29]. This study was not done in a palliative care setting. It also found that the WHOQOL tool does not differentiate between sex and intimacy. The validity of this tool is not fully documented according to the Oxford Textbook of Palliative Medicine. The rationale for developing the WHOQOL tool arises out of the need for a genuinely international measure of QOL and was therefore constructed within 15 culturally diverse field centres[28]. It was for this reason that this tool was used in the South African multicultural society.

2.8. Caregivers' Quality of Life

Quality of life is as important for the family as it is for the dying patient and for those around them[8]. No studies could be found on the effect of the treatment of TB patients on caregivers. However, we know that any illness puts an immense burden on caregivers. According to Holicky predictable areas of concern for caregivers are emotional issues, role overload, and poor health and changed family dynamics[30]. He also concluded that family caregivers may be the most important element in successful rehabilitation and long term home care. Caregivers are very often the intermediary between a health facility and the patient. The entire family experiences and shares the illness. Caring for caregivers can be seen as a preventative measure for preventing a downward spiral[30] . Doyle strengthens this statement by stating that the relatives are the principal providers of care[47].These areas of concern and prevention are very important to facilitate effective TB control and holistic palliative care. In a large study of 142 patients done by Bond over 2 months in Lusaka, exploring the widening role of home-based carers in the management of TB, the need for a parallel system involving Home Base Care, Hospices and TB control was emphasised[31]. According to Lidell, support in emotional communication relieves the burden of care-giving on the caregiver[32]. This type of support is often forgotten when dealing with TB, especially in the terminally ill patient. Interventions to relieve the burden of care-giving have been identified as: counselling; addressing active problem solving and knowledge about the disease; professional care for high risk cases; encouraging the carer to join support groups as well as keeping in contact with the carer at predetermined times[33]. Ferrel states that a consistent finding in research on caregivers' experience is that the fear, inappropriate knowledge and beliefs of caregivers are often worse than those of the patient themselves[34]. Ferrel continues by stating that in a literature review in 1992, the most neglected area in publications was that which covered the needs and role of the caregiver[34].

2.9. Precautions for the Caregivers

Caring for TB patients in any setting presents the risk of the caregiver contracting TB. Preventative measures such as masks, chemoprophylaxis and proper ventilation are not always possible for caregivers. INH prophylaxis is recommended for patients with suspected infection and for caregivers who are in contact with high risk patients and could develop active TB[35]. This is however, not the regime in South Africa.

2.10 Research Question

This study intends to explore whether patients with palliative care needs are receiving appropriate TB management.

This is an evaluation addressing the holistic management and approach to the palliative care patient suffering from TB and the impact this condition has on the family carer.

TB treatment is one aspect of the care of TB patients, but the management includes infection control, pain and symptom control, prophylaxis and counselling about the disease.

Palliative care is not only the care of the terminal patient, as some clinicians believe. It includes the improvement of the QOL of the patient and the families of patients with life threatening illness. The acceptance by society that TB can be cured is not reflected by South Africa's TB mortality rate, whether TB is the main cause of death or not. It is therefore essential to evaluate the management and QOL of these patients and their families during this difficult time so that we can improve their care. This study was designed to assess the level of improvement in symptoms and quality of life that patients experience who are suffering from TB, are on TB treatment, but also have palliative care needs, and what impact TB has on the patient and family's quality of life.

2.11 Conclusion

From the literature review it is clear that there is a pressing need for research on TB management of patients with palliative care needs, as well as research into associated subjects such as the patient's quality of life and the burden on the caregiver. This need prompted this research project.
The following chapter will address the aims and objects on which this research was based.

CHAPTER 3

Aims and Objectives

3.1. Introduction

This is an evaluation to assess whether the level of care of patients with TB, who have an additional life-limiting illness, is appropriate. Through personal experience and the literature survey (Chapter2), it has become clear that there are many different factors impacting on this issue.

Problems that patients suffering from TB face are fragmented care, hospices denying patients admission due to infectivity, co-morbid conditions and the burden carried by the caregiver/family member. All of these factors require attention in order to deliver a holistic, appropriate palliative care service. Aspects such as the side effects and complication of medical intervention are very often neglected. No documented research could be found addressing the TB management of palliative care patients.

3.2. Research question

Are the palliative care needs of palliative patients, infected with TB, being appropriately managed?

3.3 The Aim

The main aim of this study is to assess the holistic care of TB patients with palliative care needs.

3.4. Objectives

- To describe the management of TB in palliative care patients.
- To determine the symptom management and quality of life in the above-mentioned patients.
- To assess the effect of the TB diagnosis on the family/caregiver.

3.5 Conclusion

The method that was used to capture the aims and objective for this study will be outlined in chapter 4

CHAPTER 4

Research design, Method and Techniques

4.1. Introduction:

In planning a research project, it is of extreme importance that the researcher establishes beforehand what kind of data will be required to solve the research problem, that is, the researcher must decide which methods and techniques would serve the purpose of the research most effectively[38]. Leedy states that all data will reach the researcher either as words or as figures.

A descriptive study design was therefore used for this research and a questionnaire was used as measuring instrument. Elements of quantitative and qualitative research were built into the measuring instrument by coding the responses which also facilitated the bio-statistical processing.

In planning this study it was decided to use the survey method with a qualitative design, the aim being to explore, describe and develop[38].

Three data collection tools were used: a literature survey, semi-structured interviews and a questionnaire. This constituted the technique of triangulation which was used to compare the data collected from the various research techniques in order to ensure the credibility and dependability of this study[41].

4.2. Study Design

The descriptive study design that was employed for this research used both qualitative and quantitative methods to explore and describe the holistic care of patients who are terminally ill.

4.3. Study site

This study was performed at two hospices and three TB hospitals across the Western Cape. Permission was obtained from the Department of Health and the Chief Executive Officers of the relevant sites listed below.
The Hospices used were;

- St Luke's Hospice (Kenilworth and Lentegeur) in Cape Town
- Bethesda Hospice in George

The TB Hospitals used were;

- Harry Comay TB hospital in George
- Brewelskloof Hospital in Worcester
- DP Marais Hospital in Cape Town

A letter of information, describing the study, was sent to the various managers of the institutions to obtain consent to perform this research and to obtain access to the selected patients' clinical notes (Appendix E). This was necessary in order to screen appropriate patients, to determine their TB treatment and what symptom control they were receiving and to ensure that the study sample was suitable to answer the research question.

4.4. Study Population

The study population was constituted from TB patients with life-threatening illness in the George, Cape Town and Worcester areas of the Western Cape, South Africa. The sample size was determined by the researcher's current working situation in 2008 which was then in the Harry Comay TB hospital in George. In 2008, 413 patients were admitted to the hospital with 95 patients dying with/ from TB in the hospital in that year.

In conducting research in palliative care, the researcher should consider that this is a frail population whose physical and cognitive abilities may be compromised. Is it ethical to be using some of the valuable time of patients whose time is short? The awareness of the vulnerability of the population was considered when dealing with all of these patients, particularly in the recruitment of participants, taking informed consent and being sensitive to participants who wished to withdraw from the interview in accordance with the distress protocol. Another challenge in this area of research is attrition in that patients may die in the course of the research.

4.5. Sampling (Selection of study population).

A study population is any group that is the subject of research interest. It is often not practical or possible to study an entire population. In cases like this it is necessary to make general findings based on a study of a sub-group of the population only. Such sub-groups are called samples[37]**.** Samples must be representative of the population concerned, otherwise no general observation about the population can be made from studying the sample.

Sample bias

A sample is said to be biased if it represents only a specific sub-group of the population or if certain sub-groups are over- or under-represented[40] This study has an element of being biased because it does not represent TB patients who are not in hospitals or hospices.

Twenty patients and 16 caregivers were chosen by means of purposive sampling. Purposive sampling is a deliberate non-random method of sampling, which aims to sample a group of people, or setting, with a particular characteristic, usually in qualitative research design[36]. In purposive sampling, the researcher might choose subjects who are judged to be typical of the population in question, or particularly knowledgeable about the issues under study. Researchers often use purposive sampling when they want a sample of experts, as in this case, an evaluation of the patients' experience of TB care in the context of palliative care [36] .

Sample size:

In a cross-sectional survey where the outcome is a percentage in order to assess the holistic management of the palliative care TB patient, 96 patients would have been the ideal sample size. This estimate is based on QOL of 50% and that 50% has poor QOL. Due to financial and time constraints, a joint decision was made to interview 20 TB patients with life-threatening illnesses. This is a pilot survey and this study recommends that further patients be interviewed.

4.6. Selection Criteria

The following criteria were used to include patients in the study:
Inclusion criteria of a patient:

- Has a diagnosis of TB
- Been diagnosed with a co-existing life-limiting illness.
- Over 18 years of age
- Has been on TB treatment for at least one month.
- Has a caregiver involved in his/her care.
- Is able to understand English or Afrikaans to facilitate the interview process.

The following criteria were used to exclude patients from the study:
Exclusion criteria of patients:

- Patients who were not cognitively able to participate in the research
- Were younger than 18 years of age
- Living alone with no caregiver involved in their treatment

4.7. Data collection

Descriptive research gives an accurate account of the characteristics of a particular individual, situation or group, and is a means of discovering new meaning, describing that which exists and categorising it[37]. According to

Leedy[38] the descriptive survey method in research is based on looking into a phenomenon. Such a phenomenon may be viewed in different ways, for example by means of questionnaires, interviews, observations and inventories.

The problem addressed in this study did not lend itself to precise analytical research techniques, but could benefit from subjective judgements on a collective base.[39]

4.7.1. Data collection tools

The compilation of the data collection tools was based on a network literature survey that addressed palliative health care with particular reference to TB patients with co-morbidities. The search included looking at QOL tools, caregivers' experiences and problems associated with TB treatment. The researcher's personal experience with TB patients was also employed.

Three data collection tools were used, namely;

1. Data extraction sheet: information from the patient's file (appendix A):

   The section of the data extraction sheet that documented the information, obtained from the patient's file, was developed to access the use of TB drugs and common TB side effects of each patient as discussed in the literature survey. The patient's terminal illness was also assessed by applying the knowledge and experience commonly acquired by the researcher in palliative care diseases.

2. A structured interview with the patient (Appendix B).

   This interview guide was developed to elicit data on the patient's quality of life by using a standardised questionnaire (The World Health Organisation Quality of Life Score). This was a structured interview with set questions and open-ended questions. The patient was also asked to describe his/her current symptoms and whether these symptoms had improved since being on TB drug treatment. Here open-ended questions were used. The symptom list and treatment was based on the literature survey and the researcher's personal experience confirmed by discussion with colleagues. The list specifically addressed TB symptoms and the management thereof.

3. A Semi-structured interview with the caregiver with open-ended questions.

(Appendix C)

The interview was conducted to assess the effect of the patient's TB condition on the caregiver's quality of life (QOL). This was a semi-structured interview with set questions and open-ended questions to describe in detail their experience. This questionnaire was developed on "broad questions" to assess QOL of the caregiver and included establishing whether the caregiver, who could be a member of the family, was using any preventative measures to protect themselves from infection. These questions were based on the researcher's personal experience and endorsed in a focus group discussion with colleagues experienced in TB care.

4.7.2. Validation of the research instrument

The validation of the research instrument refers to the ability of the instrument to measure what it is supposed to measure.[40]. Based on the researcher's and supervisors' experience in both TB and palliative care, as well as the literature survey, the file review, patient interview and caregiver interview were designed to measure aspects necessary to answer the research question. The World Health Organisation Quality of Life Questionnaire is a valid and reliable instrument as discussed in the literature review. Against this background, validity of the research instrument was assured. Three instruments were used:

- The data extraction sheet: information from the file.

  Validation was assured in this section by working with experts in the field in its development and by using the literature review.
- Patient Interview.

Here validation was assured by using an already valid instrument, namely, the WHO BREF questionnaire. The semi-structured interview included additional questions which were designed by consulting expert advice on open-ended questions gathered during focus group discussion and further validated by piloting.

- Caregiver Interview.

  Validation was assured by personal and expert opinion. The literature helped in making this a valid instrument.

4.7.4. Piloting

The research instrument was developed over a period of three months. The instrument was tested in patient interviews of 3 patients by a practicing medical doctor who worked at the Harry Comay TB hospital. Where questions and responses were unclear or misinterpreted, alterations were made to the interview guide. These alterations clarified the questions and enhanced content validity. In addition more options on the treatment of the side effects and the caregiver's quality of life were added to improve face validity.

4.7.5. The reliability of the research instrument

Reliability refers to the accuracy and consistency of a research instrument[41]. Albeit that absolute reliability can never be attained, instruments used should produce a high level of consistency when used by different people. If the use of a valid instrument leads to the same observations when used by different test subjects under different circumstances, it is a reliable instrument. Therefore, reliability is achieved when the same method (the research instrument), is used at different times, by different people (domain experts) and produces the same results.

Reliability is influenced by four variables, namely the researched, the subject, the research instrument and the research content[37]. Reliability was therefore assured in this study by an extensive literature survey, the use of astute, experienced interviewers and the stringent selection of the study population.

Reliability is further insured by determining the Cronbach's Coefficient Alpha. Analyzing latent constructs (such as job satisfaction, motor ability, sensory recognition, or customer satisfaction) requires instruments to accurately measure the constructs. Interrelated items may be collated to obtain an overall score for each participant. Cronbach's coefficient alpha estimates the reliability of this type of scale by determining the internal consistency of the test or the average correlation of items within the test (Cronbach 1951).

When a value is recorded, the observed value contains some degree of measurement error. Two sets of measurements on the same variable for the same individual may not have identical values. However, repeated measurements for a series of individuals will show some consistency. Reliability measures internal consistency from one set of measurements to another.

The larger the overall alpha coefficient, the more likely it is that the items contribute to a reliable scale. It is generally accepted that 0.70 is an acceptable reliable coefficient; smaller reliability coefficients are seen as inadequate. However, this varies from discipline to discipline.

To determine how each item reflects the reliability of the scale, a coefficient alpha is calculated after deleting each variable independently from the scale.

4.7.7. Data collection method

Interviews took place between the patient and predetermined selected medical doctors, who were research assistants. Doctors with experience in TB were approached to participate by acting as interviewers. A training session was held to familiarise the doctors with the research methods for this study and to revise ethical research conduct. Five medical doctors were approached and requested to complete a written contract in which they agreed to perform the interviews (appendix F).

The following criteria were used for the selection of the domain experts who interviewed the patients for this study;
They had to:

- Be qualified medical doctors in possession of a MBCHB
- Be involved, or have a special knowledge of the treatment of TB patients
- Be prepared to complete the contract form (appendix F)
- Attend the research workshop

Written consent was obtained from the patient in the language in which he/ she was fluent. (appendix D). The interview also took place in the language in which the patient and the interviewer were fluent, where necessary an interpreter was used. A distress protocol was used with vulnerable patients (see 4.8).

The doctor was assigned the responsibility of contacting the appropriate family member/ caregiver to assess their burden of care. This was done either by direct interview or telephonically. Consent was obtained from the family member (Appendix D). Four of the caregivers could not be contacted for the interview because they did not have telephones.

4.7.8. Application of triangulation

In this study triangulation was applied to ensure the comprehensiveness of the data. This involved the comparison of the results of two or more different methods of data collection.[41] This study used 3 methods of data collection to evaluate the patient's experience, namely a file review, patient interview, a quality of life evaluation. This allowed for an in-depth review of the patient's

TB management and the patient's experience. All the information was analytically processed by a bio-statistician.

Triangulation relies on the assumption that any weakness in one method will be compensated for by strengths in the other. In the key findings of this study the researcher looked for patterns of convergence to develop and corroborate an overall interpretation[42].

4.8. Data analysis

The questionnaires were collected by the researcher and presented to the bio-statistician. Frequencies and percentages were calculated for categorical data. Means and standard deviations or medians and percentiles were calculated for continuous data. Analysis of the data was done by a bio-statistician using SAS software package 9.1.3.

The WHOQOL-BREF consists of 4 domains as stated in the literature study. Domain scores are scaled in a positive direction, the higher the score the better the quality of life. The mean score of items within each domain was used to calculate the domain score. Mean scores are multiplied by 4 in order to make domain scores comparable with scores in the WHOQOL-100. Explicit instructions for computing scores are given in appendix G. Where more than 20% of data is missing from the assessment, the assessment should be discarded[28]. In this study all assessments were fully completed.

Correlation of data was determined by determining the Pearson Correlation Coefficients. The Pearson correlation is a parametric measure of association for two variables. It measures both the strength and direction of a linear relationship. If one variable X is an exact linear function of another variable Y, a positive relationship exists if the correlation is 1 and a negative relationship exists if the correlation is -1. If there is no linear predictability between the two variables, the correlation is 0. If the two variables are normal with a correlation 0, the two variables are independent. However, correlation does not imply causality because, in some cases, an underlying causal relationship may not exist. It has the range between -1 and 1.

4.9. Qualitative analysis

Qualitative analysis was done on the open-ended questions asked in the interview. The qualitative research was limited to these open-ended questions. It was important to include these to further explore patient experience. Only open-ended questions concerning the symptoms were asked from patients because psycho-social issues were dealt with in the WHOQOL interview. Comments about the WHOQOL are included in the results.

The researcher firstly read and reread the comments to familiarize herself with the content. The researcher then identified the main issues by highlighting phrases which related to the same issues. Comments of the effect of TB and TB treatment and care on patients and caregivers were highlighted. This allowed the researcher to categorise the main issues and to develop themes and subthemes. Data was then further analysed to identify data most relevant to each theme. Hospitalization was mentioned repeatedly and formed a subtheme in the study. In this process the influence of the researcher is acknowledged, but this qualitative data is supported by the structured interview data.

4.9. Ethical considerations

The advancement of knowledge through research must not be at the cost or detriment of those who are the subjects of the research. Polit and Hungler state that "when humans are used as subjects in scientific investigations great care must be exercised in ensuring that the rights of those humans are protected."[42] As the interviewers were only required to complete the questionnaire, and the confidentiality of the information was ensured by not using the patient's name or the name of the treating facility or treating doctor, the rights of the patients were protected. There was also no medical intervention and no alteration was made to the patient's treatment.

Informed consent was obtained from all of the participants, the patients and the caregivers. An information document about the study was given out and explained to all of the patients. The caregivers who could only be reached telephonically were telephonically informed about the study and permission was telephonically obtained.

A distress protocol was used to ensure the safety of the patient and the family members. All participants were fully informed as to the nature of the issues to be raised in both qualitative and quantitative data collection. Any respondent who appeared to become distressed was offered the opportunity to cease the interview, and to either abandon or restart it when they were more comfortable. The interviewer was asked to pass on any information or request from the patient's family to the nurse, with permission from the patient. All information was treated as confidential except where the patient's family's safety was at risk, in which case due action could be taken.

Palliative care patients or any sick patients are considered a vulnerable population. This group of people may often feel obliged to answer to please the researcher in order to obtain maximum care. They can be considered a „captive audience' who may feel coerced into giving the right answer[43]. Central to research in palliative care is autonomy and that is why participation was voluntary and informed consent was obtained. Patients where informed that participation in this study would not affect their care at all. In order to make sure that the patients understood this aspect of the study, the study and the contents of their letter of consent were explained to them in their language of preference.

Ethical approval was obtained from the Research Ethics Committee of the University of Cape Town. Permission was also obtained from the various managers of the institutions, the doctors involved in the study, consent from the patients and their caregivers.

4.10. Conclusion

It is believed that the research design and research process, as described in the above chapter, sufficed in addressing the research question and associated issues.

CHAPTER 5

Results of the study

5.1. Introduction

Chapter 5 presents the processed results of this study. Twenty patients were interviewed and in addition relevant information from their clinical files was captured and documented using the questionnaire as measuring instrument. All the patients met the inclusion criteria. Appropriate patients were selected in the Western Cape. Only 16 caregivers/family members were used for the caregiver/family section of the questionnaire because 4 could not be telephonically reached. The information was processed by a bio-statistician.

The results are presented in the same order in which the questionnaire was compiled. In most cases the frequencies and percentages captured and processed from each question are presented with an explanatory chart to follow. Graphs and charts were used in this study to give a better overview of the results.

5.2 File review of Patients

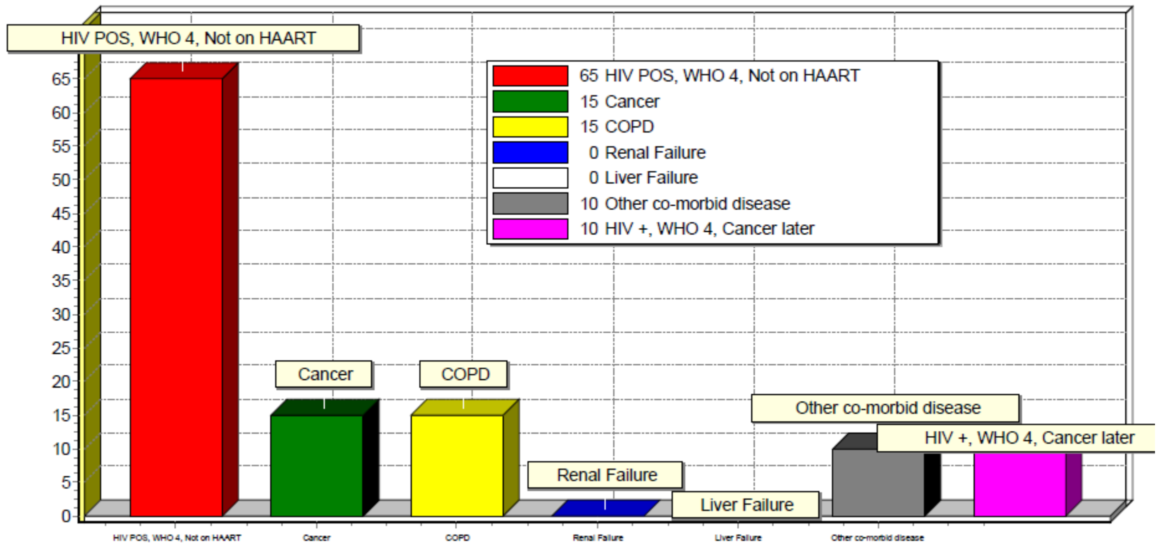
The responses to the following questions were captured from the study population's files.

Question 1: Determine what the patient's terminal illness is. (Diagnoses)

Table 1: Patient's terminal illness

	Question	Number	Percentage
1	HIV positive, WHO stage 4, not on HAART	13	65
2	Cancer	3	15
3	COPD (Chronic Obstructive Pulmonary Disease)	3	15
4	Renal failure	0	0
5	Liver failure	0	0
6	Other co-morbid disease (later specified as TB)	1	10
7	HIV, WHO stage 4, later diagnosed with cancer	1	10

Chart 1: Percentage of patients with a terminal illness



Question 2: Does the patient have complications from the above mentioned illness?

Table 2: Complications from the above-mentioned illness

	Question	Number	Percentage
	Yes	13	65
	No	7	35

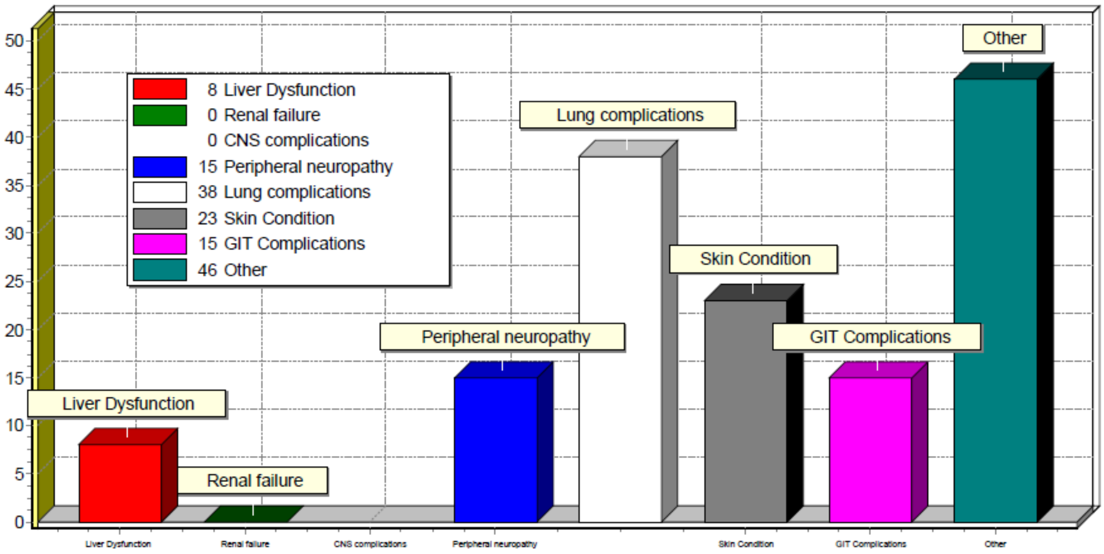
Question 2:1. If yes, name the complication(s):

This question was asked to specify the complication(s) that patients (13) responded positively to in question 2. It was not necessary to offer any further information to negative responses.

Table 2.1: Complications

	Question	Number	Percentage
1	Liver problems	1	8
2	Renal failure	0	0
3	Central nervous system complications	0	0
4	Peripheral nervous system complications	2	15
5	Lung complications	5	38
6	Skin involvement	3	23
7	Gastrointestinal complications	2	15
8	Other complications	6	46

Chart 2.1: Percentage of patients with complications



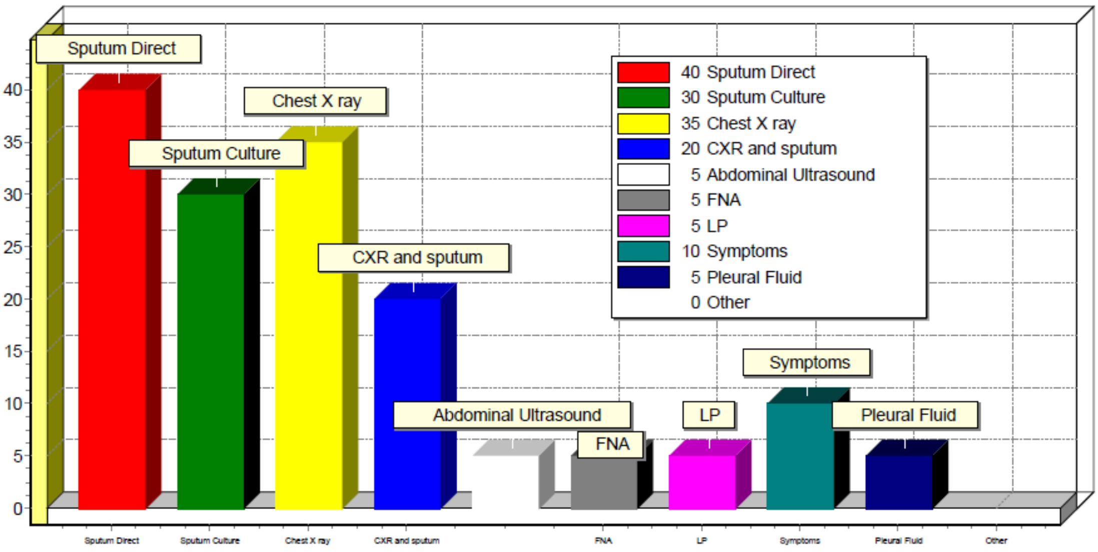
Question 3: How was the patient positively diagnosed with TB?

This question was asked in order to ascertain what tests were performed to make a positive diagnosis.

Table 3: Tests performed to positively diagnose for TB

	Question	Number	Percentage
1	Sputum samples	13	65
	Direct microscopy (AFB)	8	40
	Culture tests	6	30
2	X-rays	7	35
3	Abdominal sonar	1	5
4	Fine needle aspiration	1	5
5	Lumbar puncture	1	5
6	Symptoms alone	2	10
7	Pleural fluid	1	5
8	Other	0	0

Chart 3: Percentage of patients who had the following tests done

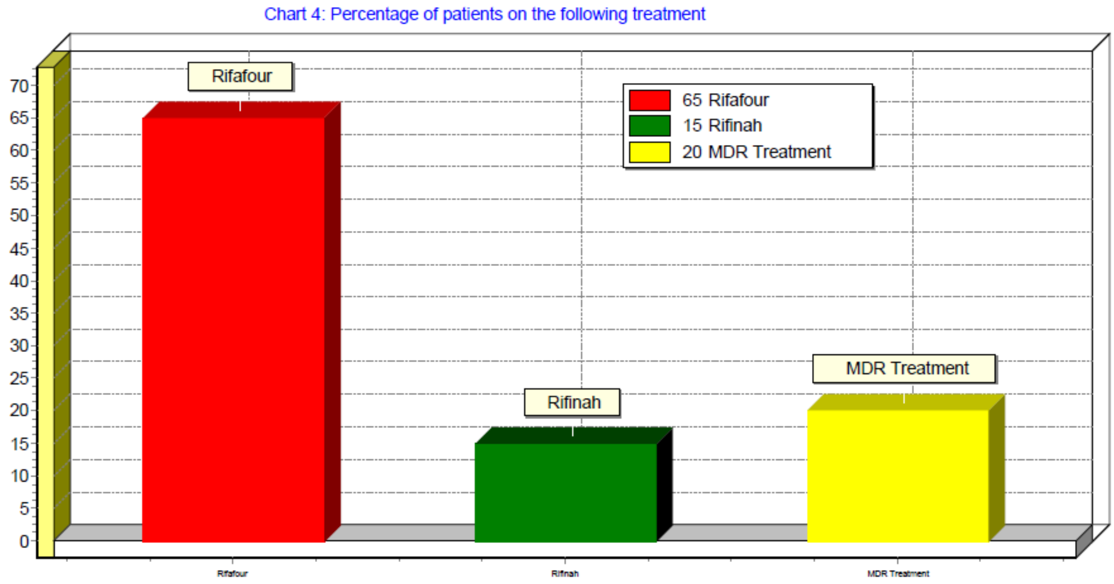


Question 4: List the patient's TB medication.

With this question the researcher was able to assess whether the patient is receiving appropriate medication.

Table 4: List of patient's TB medication

	Medication	Number	Percentage
1	Rifafour	13	65
2	Rifinah	3	15
3	Standard MDR Regime	4	20



Question 5: List the dosage.

This question was asked to ascertain whether the correct dosage of the appropriate TB treatment was being administered. Unfortunately due to an oversight in the study design, the patient's weight was not determined. The weight of the patient determines the correct medication dosage. The results of this question could therefore not be used for the study.

Question 6: Outline the intended duration of treatment

Table 6: Intended duration of treatment

	Duration	Number	Percentage
1	6 months	6	30
2	8 months	9	45
3	9 months	1.	5
4	Longer	4	20

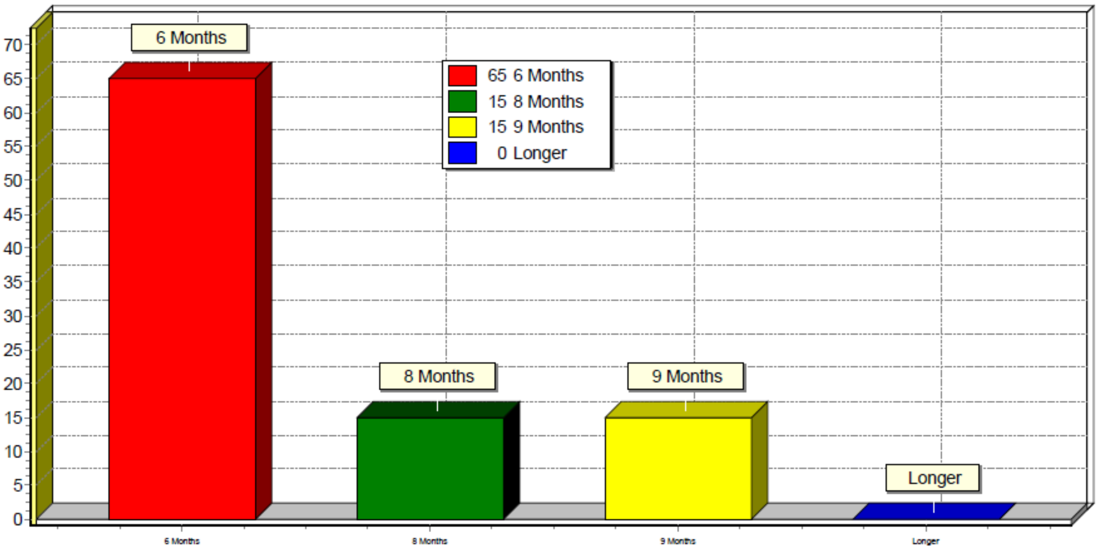


Chart 6: Percentage of patients and duration of treatment

Question 7: Has the patient developed side effects from the TB treatment according to the clinical notes?

The aim of this question was to select the patients in the study population who had developed side effects from the TB treatment regime that they were on.

Table 7.1: Side effects from TB treatment

	Response	Number	Percentage
1	Yes	9	45
2	No	11	55

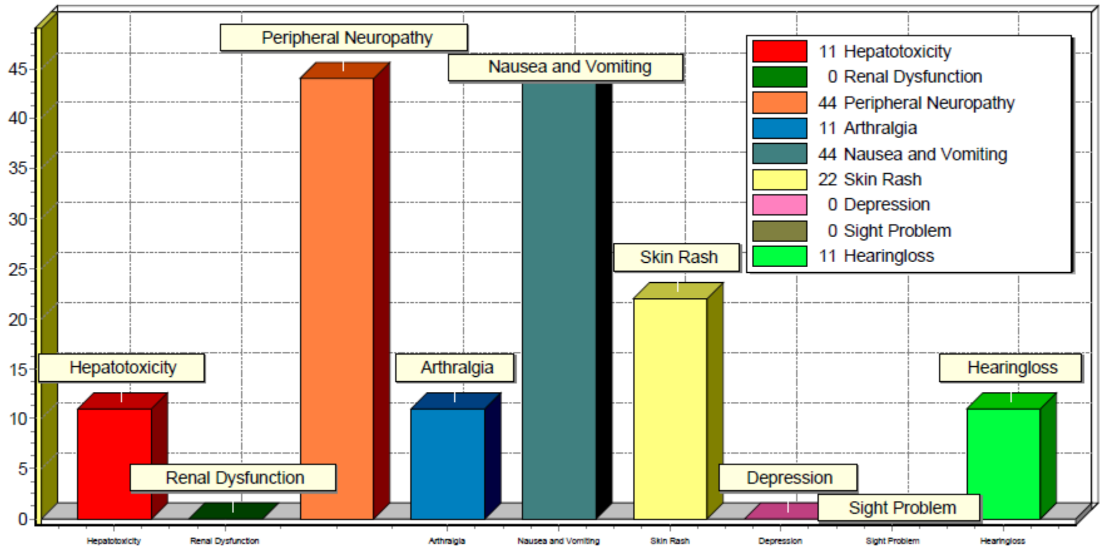
Question 7.1: If yes, what are they?

From this question the 9 positive responses from question 7 could be expanded..

Table 7.2: Side effects

	Side effects	Number	Percentage
1	Hepatotoxicity	1	11
2	Kidney failure	0	0
3	Peripheral neuropathy	4	44
4	Athralgia	1	11
5	Nausea and vomiting	4	44
6	Skin rash	2	22
7	Depression	o	0
8	Sight problems	o	0
9	Other, please specify	1	11

Chart 7.1: Percentage of patients with complications from the above mentioned illness



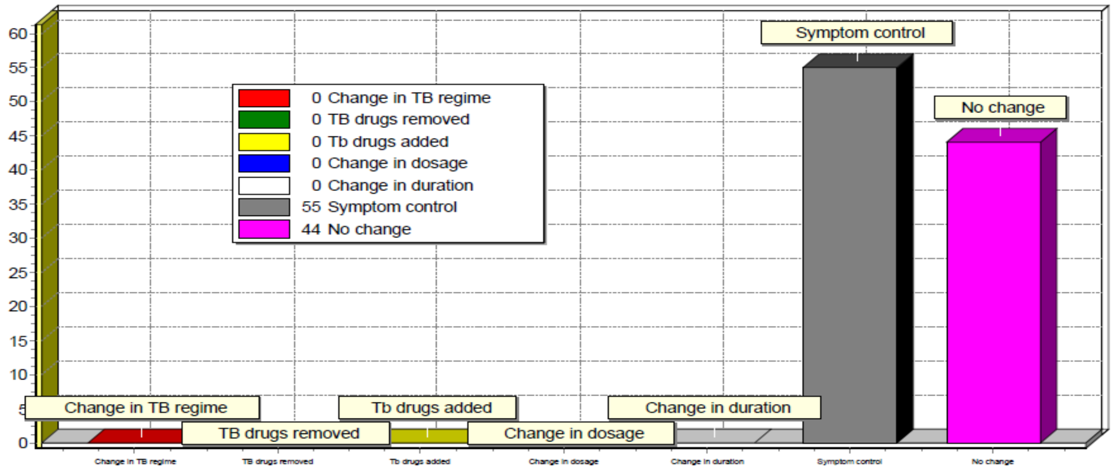
Question 8: How have these side effects been managed?

This question was designed to determine if the side effects are being actively and effectively managed.

Table 8: Management of side effects

	Side effects management	Number	Percentage
1	Change in TB regime	0	0
2	TB drugs removed	0	0
3	TB drugs added	0	0
4	Change in dosage	0	0
5	Change in duration	0	0
6	Symptom control	5	55
7	No change	4	44

Chart 8: Management of side effects



Question 9: Have any changes been made to the TB treatment to avoid complications?

From the responses to this question it could be determined if any active management had been implemented to prevent complications.

Table 9: Changes to treatment to avoid complications

	Responses	Number	Percentage
1	Yes	3	15
2	No	17	84

Question 10: If yes, specify.

This question was asked to ascertain the exact nature of the changes that had been implemented to the TB treatment. However, because this is an open-ended question it is difficult to quantify exactly.

Table 10: Specific changes to treatment

	Specific responses	Number	Percentage
1	Stopped treatment for 10 days	1	33
2	Stopped streptomycin	1	33
3	Added terizodone and INH	1	33

5.3 Interview with patient.

Question 11.1: What were your symptoms before you started TB treatment?

The responses to the following questions were captured by selected medical doctors who performed interviews with the study population.

Table 11.1: Symptoms before start of TB treatment

	Symptoms before TB treatment	Number Yes	Percentage Yes	Number No	Percentage No
1	Cough	14	70	6	30
2	Lethargy	15	75	5	25
3	Weight loss	17	85	3	15
4	Night sweats	11	55	9	45
5	Pain	14	70	6	30
6	Shortness of breath	14	70	6	30
7	None of the above	0	0	0	0
8	Other (fever, vomiting)	2	10	18	90

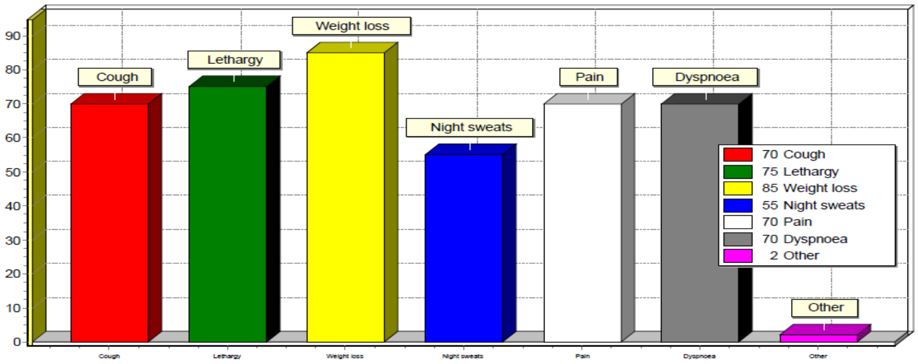


Chart 11.1: Percentage of patients with the following symptoms

Question 11.2: Describe your symptoms.

In this question the patient was asked to expand on question 11.1. The results will be offered in a cumulative table. The headings of the columns refer to the numbers in table 11.1

Table 11.2: Description of symptoms

Cough	Lethargy	Weight loss	Night Sweats	Pain	Dyspnoea	None of the above	Other	Frequency of symptom complex	Percentage
		●	●	●	●			1	5
	●	●						1	5
	●	●			●			1	5
	● ● ●	● ● ●	● ● ●	● ● ●				3	15
●		●			●		●	1	5
●		●		●				1	5
●		●		●	●			1	5
●		●	●	●	●			1	5
●	●				●			1	5
●	●		●					1	5
●	●		●	●	●			1	5
●	●	●			●			1	5
● ●	● ●	● ●		● ●	● ●			2	10
● ● ●	● ● ●	● ● ●	● ● ●	● ● ●	● ● ●			3	15
●	●	●	●	●	●		●	1	5

Explanation: Each ● represents a patient. One patient can have more than one symptom or be part of more than one symptom complex

Question 12: Have these symptoms improved since you started with the TB treatment?

This question formed the foundation on which this study was designed. The responses determined whether palliative care patients, co-infected with TB, experienced an improvement to their symptoms when TB drugs were administered.

Table 12: Improvement in symptoms since the start of treatment

	Responses	Number	Percentage
1	Yes	16	80
2	No	4	20

Once again the patients were asked to expand on the above responses which constituted an open-ended question and responses. The qualitative responses will be offered in 5.6.2.

Question 13.1: What are your current symptoms?

This question was designed to determine the patient's symptoms.

Table 13.1: Current symptoms

	Current symptoms	Number Yes	Percentage Yes	Number No	Percentage No
1	Cough	8	40	12	60
2	Lethargy	10	50	10	50
3	Weight loss	7	35	13	65
4	Night sweats	2	10	18	90
5	Pain	9	45	11	55
6	Shortness of breath	7	35	13	65
7	Nausea and vomiting	5	25	15	75
8	Itching	5	25	15	75
9	Swelling	4	20	16	75
10	Feeling sad	0	0	0	0
11	Anxiety	7	35	13	65
12	Diarrhoea	4	20	16	80
13	Other, please specify	0	0	0	0

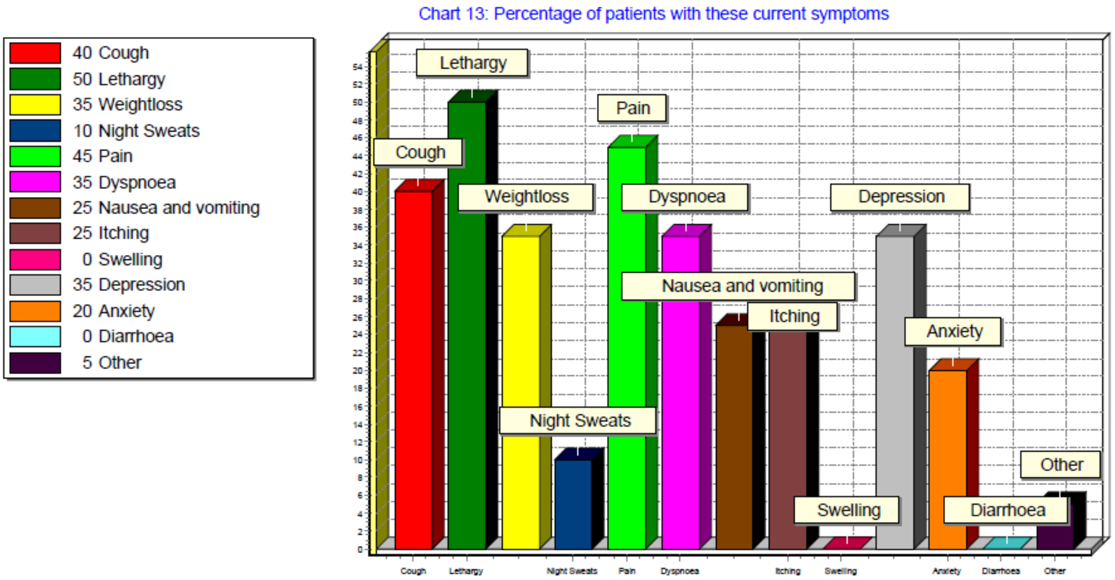


Table 13.2: The cumulative responses to this question

1	2	3	4	5	6	7	8	9	10	11	12	13	14	Frequency of symptom complex	Percentage
								●						1	5
				●						●	●			1	5
				●		●							●	1	5
			●		●									1	5
		●												1	5
	●									●	●			1	5
	●					●		●		●				1	5
	●			●	●					●				1	5
	●●	●●						●●						2	10
	●	●			●		●							1	5
	●	●	●	●		●	●			●	●			1	5
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●	●	●		●	●									1	5

1	Cough	8	Itching
2	Lethargy	9	Swelling
3	Weight loss	10	Feeling sad
4	Night sweats	11	Anxiety
5	Pain	12	Diarrhoea
6	Shortness of breath	13	Other
7	Nausea and vomiting		

Explanation: Each ● represents a patient. One patient can have more than one symptom or be part of more than one symptom complex

Question 14: Are you receiving treatment for the above-mentioned symptoms?

Once again, this question shed more light on whether the patient’s symptoms were being actively managed.

Table 14: Patients receiving treatment for the above-mentioned symptoms

	Responses	Number	Percentage
1	Yes	13	65
2	No	6	35
3	Only some symptoms were treated	1	5

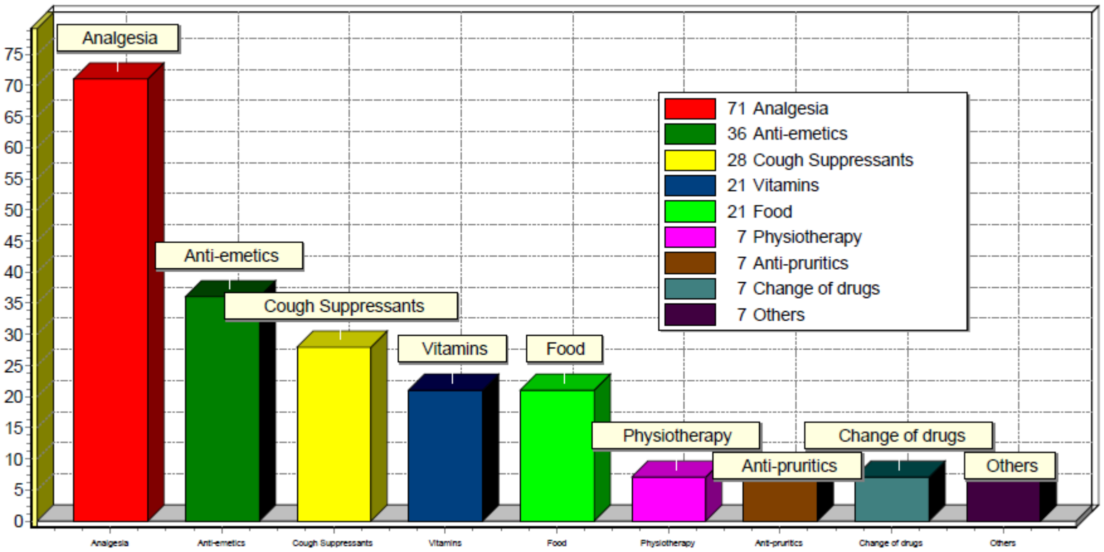
Question 14.1: Please name the treatment.

There were 13 positive responses to question 14 and one response which indicated that all the symptoms were being treated. The study population therefore used in question 14.1 is 14.

Table 14.1: Treatment received

	The treatment	Number	Percentage
1	Analgesia	10	71
2	Anti-emetics	5	36
3	Cough suppressants	4	29
4	Vitamins	3	21
5	Food	3	21
6	Physiotherapy	1	7
7	Anti-pruritics	1	7
8	Change of drugs causing adverse effects	1	7
9	Other (including traditional healers)	1	7
10	No treatment	7	40

Chart 14.1: Percentage of patients receiving current intervention



5.4. The World Health Organization Quality Of Life (WHOQOL) The patient's perception

The questions used in this section of the measuring instrument came directly from the WHOQO document and the responses are divided into the four domains as discussed in the literature survey. The collective responses are offered as positive, neutral and negative responses.

The responses were captured from the medical doctor's interview with the members of the study population.

There were no data missing from the assessment of these forms.

Quality of life is defined as an individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns [23]

Question 1 asks about an individual's overall perception of quality of life[23].

Table 5.4.1: Overall perception of quality of life

Response	Frequency	Percentage
Positive (good / very good)	6	30
Neutral	5	25
Negative (poor / very poor)	9	45

Question 2 asks about an individual's overall perception of their health[23]

Table 5.4.2: Overall perception of life

Responses	Frequency	Percentage
Positive (satisfied / very satisfied)	7	35
Neutral	3	15
Negative (dissatisfied / vey dissatisfied)	10	50

Domain 1 refers to a patient's **physical health** in the previous four weeks. The following questions and responses were asked under this domain [23]

DOMAIN 1: Physical Health

Question 3: Pain and discomfort

To what extent do you feel that physical pain prevents you from doing what you need to do?

Table 5.4.3: Extent to which physical pain prevents patient from doing what they want to do.

Responses	Frequency	Percentage
Not at all / a little	8	40
Moderate amount	4	20
Very much/ extreme amount	8	40

Question 4: Dependence on medical substances and medical aids

How much medical treatment do you need to function in your daily life?

Table 5.4.4: Medical treatment needed to function daily.

Responses	Frequency	Percentage
Not at all / a little	7	35
Moderate amount	5	25
Very much / extreme amount	8	40

Question 10: Energy and Fatigue

Do you have enough energy for everyday life?

Table 5.4.5: Energy for everyday life.

Responses	Frequency	Percentages
Not at all / a little	13	45
Moderate amount	1	5
Mostly / completely	6	30

Question 15: Mobility

How easily are you able to move around?

Table 5.4.6: Ease with which to move around.

Responses	Frequency	Percentages
Good / very good	5	25
Neutral	2	10
Very poor / poor	13	65

Question 16: Sleep and Rest

How satisfied are you with your amount and level of sleep?

Table 5.4.7: Amount and level of sleep

Responses	Frequency	Percentage
Satisfied / vey satisfied	9	45
Neutral	0	00
Dissatisfied / very dissatisfied	11	55

Question 17: Activities of daily living

How satisfied are you with your ability to perform your daily living activities?

Table 5.4.8: Ability to perform daily living activities

Responses	Frequency	Percentage
Satisfied / very satisfied	7	35
Neutral	2	10
Dissatisfied / very dissatisfied	11	55

Question 18: Work Capacity

How satisfied are you with your capacity to work?

Table 5.4.9: Capacity to work

Responses	Frequency	Percentage
Satisfied / very satisfied	16	80
Neutral	1	5
Dissatisfied /very dissatisfied	3	15

SUMMARY DOMAIN 1: Physical Health

	Positive		**Neutral**		**Negative**	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Pain and discomfort To what extent do you feel that physical pain prevents you from doing what you need to do?	8	40	4	20	8	40
Dependence on medical substances and medical aids How much medical treatment do you need to function in your daily life?	8	40	5	25	7	35
Energy and Fatigue Do you have enough energy for everyday life?	6	30	1	5	13	45
Mobility How easily are you able to move around?	5	25	2	10	13	65
Sleep and Rest How satisfied are you with your amount and level of sleep?	9	45	0	0	11	55
Activities of daily living How satisfied are you with your ability to perform your daily living activities?	7	35	2	10	11	55
Work Capacity How satisfied are you with your capacity to work?	16	80	1	5	3	15

Domain 2 refers to a patient's **psychological wellbeing**. The following questions and responses will be offered under this domain.[23]

DOMAIN 2: Psychological wellbeing

Question 5: Positive feelings

How much do you enjoy life?

Table 5.4.10: Enjoyment of life

Responses	Frequency	Percentage
Extreme amount / very much	12	60
Some	3	15
Not at all / a little	5	25

Question 6: **Spirituality/ religion/ personal beliefs**

To what extend do you feel your life to be meaningful?

Table 5.4.11: Extent to which life is meaningful

Responses	Frequency	Percentage
Extreme amount / very much	14	70
Some	3	15
Not at all / a little	3	15

Question 7: Thinking, learning, memory and concentration

How well are you able to concentrate?

Table 5.4.11: Level of concentration

Responses	Frequency	Percentage
Extreme amount /very much	9	45
Moderately	7	35
Not at all / a little	4	20

Question 11: Bodily image and appearance

Are you able to accept your bodily appearance?

Table 5.4.12: Acceptance of bodily appearance

Responses	Frequency	Percentage
Mostly / completely	6	30
Moderately	2	10
Not at all / a little	12	60

Question 19: Self-esteem

How satisfied are you with yourself?

Table 5.4.13: Satisfaction with yourself

Responses	Frequency	Percentage
Satisfied / very satisfied	10	50
Neutral	4	20
Dissatisfied / very dissatisfied	6	30

Question 26: Negative feelings

How often do you have negative feelings such as blue moods, despair, anxiety, depression?

Table 5.4.14: Negative feelings

Responses	Frequency	Percentage
Seldom / never	7	35
Quite often	3	15
Very often /always	10	50

SUMMARY DOMAIN 2: Psychological wellbeing

	Positive		Neutral		Negative	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Bodily image and appearance Are you able to accept your bodily appearance?	6	30	2	10	12	60
Negative feelings How often do you have negative feelings such as blue moods, despair, anxiety, depression?	10	50	3	15	7	35
Positive feelings How much do you enjoy life?	12	60	3	15	5	25
Self-esteem How satisfied are you with yourself?	10	50	4	20.00	6	30
Thinking, learning, memory and concentration How well are you able to concentrate?	9	45	7	35	4	20

Domain 3 refers to a patient's **social relationships**. The following questions and responses will be offered under this domain:

DOMAIN 3: Social relationships

Question 20: Personal relationships

How satisfied are you with your personal relationships?

Table 5.4.15: Satisfaction with personal relationships

Responses	Frequency	Percentage
Satisfied / very satisfied	14	70
Neutral	1	5
Dissatisfied / very dissatisfied	5	25

Question 21: Sexual Activity

How satisfied are you with your sex life?

Table 5.4.16: Satisfaction with sex life

Responses	Frequency	Percentage
Satisfied / very satisfied	7	37
Neutral	3	16
Dissatisfied / very dissatisfied	9	47

Question 22: Social support

How satisfied are you with the support you get from your friends?

Table 5.4.17: Satisfaction with support from friends

Responses	Frequency	Percentage
Satisfied / very satisfied	10	50
Neutral	0	00
Dissatisfied / very dissatisfied	10	50

SUMMARY DOMAIN 3: Social relationships

	Satisfied		Neutral		Dissatisfied	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Personal relationships How satisfied are you with your personal relationships?	14	70	1	5	5	25
Social support How satisfied are you with the support you get from your friends?	10	50	0	0	10	50
Sexual Activity How satisfied are you with your sex life?	7	37	3	16	9	47

Domain 4 covers the way a patient experiences the **environment.**
The following questions and responses will be offered under this domain:

DOMAIN 4: Environment

Question 8

How safe do you feel in your daily life?

Table 5.4.18: Safety in daily life

Responses	Frequency	Percentage
Extreme amount / very much	13	65
Moderate	4	20
Not at all / a little	3	15

Question 9: Freedom, physical safety and security

How healthy is your physical environment?

Table 5.4.19: Health of physical environment

Responses	Frequency	Percentage
Extreme / very much	9	45
Moderate	4	20
Not at all / a little	7	35

Question 12: Financial Resources

Have you enough money to meet your needs?

Table 5.4.20: Enough money to meet daily needs

Responses	Frequency	Percentage
Completely / mostly	0	0
moderate	1	5
Not at all / a little	19	95

Question 13: Opportunities for acquiring new information and skills

How available to you is the information that you need in your day-to-day life?

Table 5.4.21: Availability of necessary information for day-to-day living

Responses	Frequency	Percentage
Completely / mostly	7	35
Moderately	3	15
Not at all / a little	10	50

Question 14: Participation in and opportunities for recreation / leisure activities

To what extent do you have the opportunity for leisure activities?

Table 5.4.22: Extent of leisure activities

Responses	Frequency	Percentage
Completely / mostly	4	20
Moderately	2	10
Not at all / a little	14	60

Question 23: Home environment

How satisfied are you with the conditions of your living space?

Table5.4.23: Satisfaction with conditions of living space

Responses	Frequency	Percentage
Satisfied / very satisfied	9	45
Neutral	4	20
Dissatisfied / very dissatisfied	7	35

Question 24: Health and social care: accessibility and quality

How satisfied are you with your access to health services?

Table 5.4.24: Access to health services

Responses	Frequency	Percentage
Satisfied / very satisfied	10	50
Neutral	3	15
Dissatisfied / very dissatisfied	7	35

Question 25: Transport

How satisfied are you with your transport?

Table 5.4.25: Satisfaction with transport

Responses	Frequency	Percentage
Satisfied / very satisfied	7	35
Neutral	4	20
Dissatisfied / very dissatisfied	9	45

SUMMARY DOMAIN 4: Environment

	Positive		Neutral		Negative	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Financial Resources Have you enough money to meet your needs?	0	0	1	5	19	95
Freedom, physical safety and security How healthy is your physical environment?	9	45	4	20	7	35
Health and social care: accessibility and quality How satisfied are you with your access to health services?	10	50	3	15	7	35
Home environment How satisfied are you with the conditions of your living space?	9	45	4	20	7	35
Opportunities for acquiring new information and skills How available to you is the information that you need in your day-to-day life?	7	35	3	15	10	50
Participation in and opportunities for recreation / leisure activities To what extent do you have the opportunity for leisure activities?	4	20	2	10	14	60
Transport How satisfied are you with your transport?	7	35	4	20	9	45
Safety in daily life How safe do you feel in your daily life?	13	65	4	20	3	15

The following table refers to the cumulative responses from the WHOQOL interviews with the caregivers. This is a scale of 1-100. Therefore, for domain 1 the median score is 38.

Table 5.4.26 Cumulative responses from WHOQOL interviews with caregivers

Variable	Median	Mean	Std. Dev.
Domain 1	17	17.15	4.84
Trans1-0-100	38	36.35	17.55
Domain 2	19.5	19.15	3.42
Trans2-0-100	56	55.05	13.99
Domain 3	10	9.45	3.17
Trans3-0-100	56	53.05	26.92
Domain 4	22	21.40	5.85
Trans4-0-100	44	42.95	18.02

Cronbach's Alpha Coefficient:

The Cronbach Alpha Coefficient shows how consistent patient answers are on questions and therefore their insight into the questions. An alpha value above 0.7 is considered consistent. The Cronbach Coefficient Alpha was 0.927 showing that these answers are consistent and that patient's answers are reliable.

Cronbach Coefficient Alpha

Variables	Alpha
Raw	0.927095

Cronbach Coefficient Alpha with Deleted Variable

Deleted Variable	Raw Variables	
	Correlation with Total	Alpha
WHOQOL_1	0.27	0.93
WHOQOL_2	0.60	0.92
WHOQOL_3	0.70	0.92
WHOQOL_4	0.44	0.93
WHOQOL_5	0.47	0.93
WHOQOL_6	0.53	0.92
WHOQOL_7	0.38	0.93
WHOQOL_8	0.10	0.93
WHOQOL_9	0.16	0.93
WHOQOL_10	0.64	0.92
WHOQOL_11	0.58	0.92
WHOQOL_12	0.10	0.93
WHOQOL_13	0.64	0.92
WHOQOL_14	0.57	0.92
WHOQOL_15	0.66	0.92
WHOQOL_16	0.65	0.92
WHOQOL_17	0.84	0.92
WHOQOL_18	0.70	0.92
WHOQOL_19	0.74	0.92
WHOQOL_20	0.60	0.92
WHOQOL_21	0.78	0.92
WHOQOL_22	0.64	0.92
WHOQOL_23	0.58	0.92
WHOQOL_24	0.53	0.92
WHOQOL_25	0.51	0.92
WHOQOL_26	0.58	0.92

Pearson Correlation: The Pearson correlation is a parametric measure of association for two variables. This table shows the correlation between question 1 (overall perception of QOL), question 2 (overall perception of health) and the 4 domains. There is a strong correlation if the r value is closer to 1 and a poor correlation if the r value is closer to 0. Therefore, there is a strong correlation between domain 1 and WHOQOL-2.

Pearson Correlation Coefficients, N = 20
Prob > |r| under H0: Rho=0

	Domain 1	Domain 2	Domain 3	Domain 4
WHOQOL_1	r = 0.09820 p= 0.6804	r = 0.19216 p=0.4170	r = 0.12247 p = 0.6070	r = -0.03693 p = 0.8771
WHOQOL_2	r = 0.64004 p = 0.0024	r = 0.41229 p = 0.0709	r = 0.49750 p = 0.0256	r = 0.21065 p = 0.3727

5.5. Interview with the caregiver/family member

In many cases the caregiver is a member of the family.

Where the responses captured from the caregiver interviews were graded on a 1 to 5 Likert scale, the results will be offered as a graph or chart. The Yes/No responses will also be offered in a chart.

Only 16 caregivers met the interview criteria. Four family members could not be contacted and therefore not be included in the study.

The caregivers were individually interviewed by a medical doctor

Chart 1: Caregiver's quality of life since the patient's onset of illness.

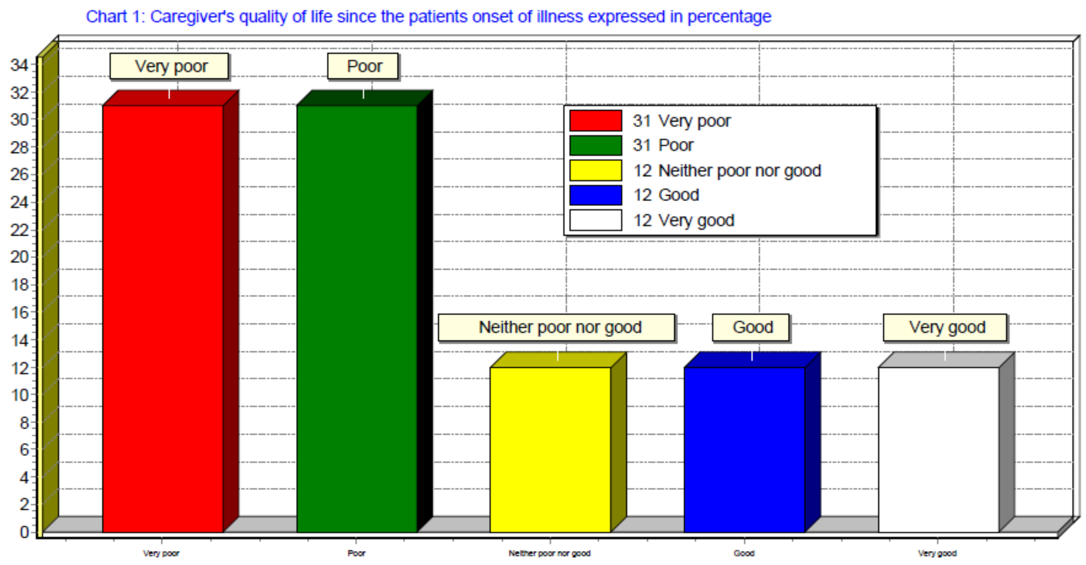
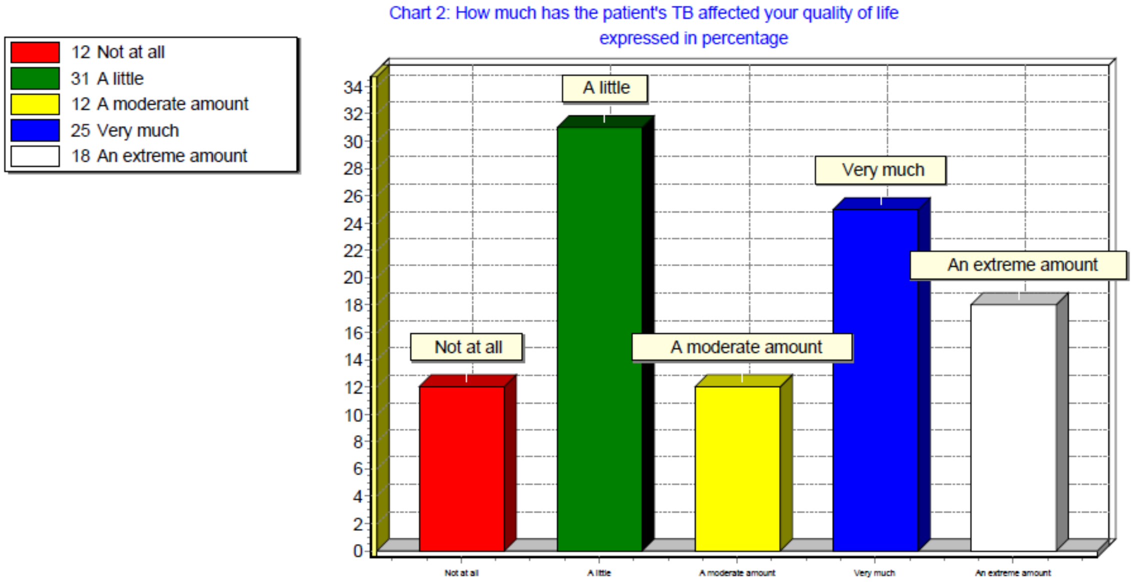


Chart 2: Effect of the patient’s TB on the caregiver’s quality of life



Where the caregivers responded positively to the above question they were asked to elaborate on their response. This information will be discussed in Chapter 6.

Table 5.5.1: Caregivers who were tested for TB

	Responses	Percentage
1	Yes	25
2	No	75

Table 5.5.2: Persons at home on TB treatment besides the patient

	Responses	Percentage
1	Yes	19
2	No	81

Table 5.5.3: Caregivers worried about contracting TB.

	Responses	Percentage
1	Yes	50
2	No	50

Table 5.5.4: Caregiver’s response to having close contact with the patient

	Responses	Percentage
1	Yes	44
2	No	56

Table 5.5.5: Caregiver's response to question concerning close contact with the patient

	Responses	Percentage
1	Yes	82
2	No	18

Chart 8: Caregiver's possible symptoms

During the implementation of this study it was realized that no space was allowed for the caregiver with no symptoms. The chart therefore has one extra response.

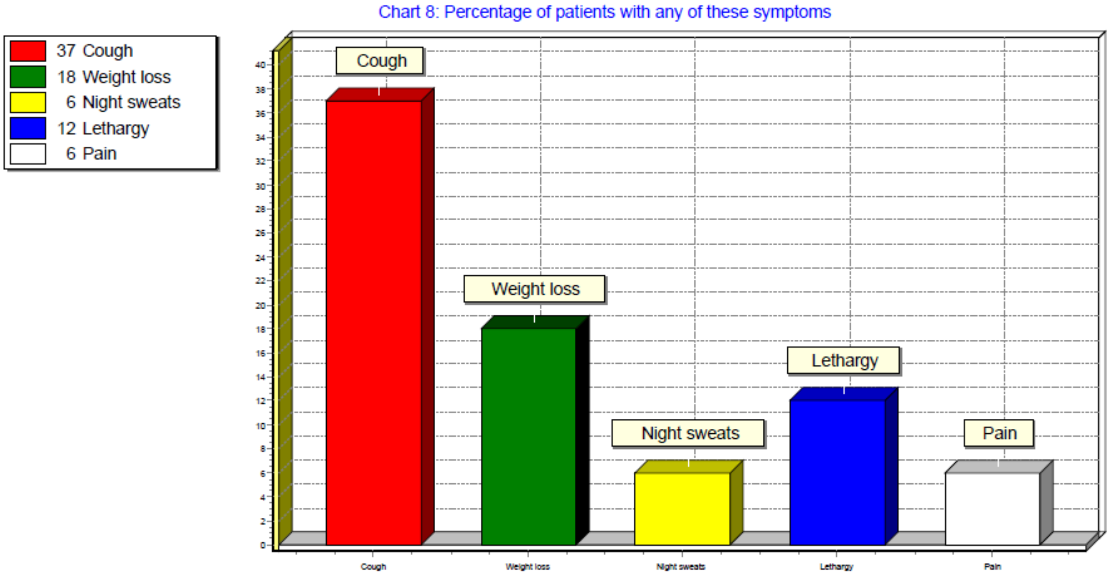


Chart 8: Percentage of patients with any of these symptoms

Table 5.5.6: Positive changes in relationship between Caregivers and patients due to TB

	Responses	Percentage
1	Yes	34
2	No	56

Expansion to this question will be offered in Chapter 6

Table 15.5.7: Financial burden on caregiver

	Responses	Percentage
1	Yes	56
2	No	44

Table 5.5.8: Counselling about TB from a healthcare Professional

	Responses	Percentage
1	Yes	50
2	No	50

Table 5.5.9: Caregiver's attitude (happy) about the way the healthcare team is treating the patient's TB.

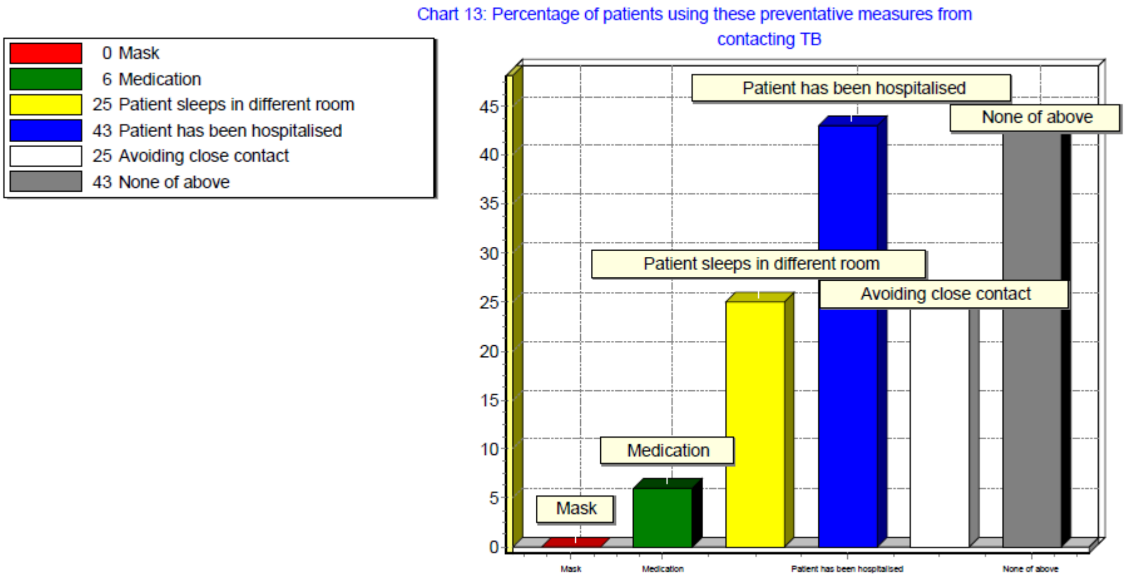
	Responses	Percentage
1	Yes	94
2	No	6

Further explanation to this question was asked for and will be offered under the qualitative responses

Question 13: Are you using preventative measures against contracting TB?

Table 5.5.10: Preventative measures against contracting TB.

	Preventative measures	Number of caregivers
1	Mask	0
2	Medication	6
3	Patient sleeps in different room	25
4	Patient has been hospitalised	43
5	Avoiding close contact	25
6	None of above	43



5.6. Qualitative responses to the questionnaire

The qualitative responses offered in this section were captured from the open-ended questions used in the semi-structured interviews and documented in the measuring instrument.
Once again this reporting will follow the same sequence as the questionnaire.

5.6.1 File Review

This section of the questionnaire had no open-ended questions and therefore no qualitative responses.

5.6.2 Interview with patient

The following open-ended questions were asked and the following themes were identified within the responses. Two themes were identified namely: the effect of TB on the patients' and caregivers' lives; and the effect of the current TB treatment and care on the patients; and caregivers' lives.

The influence of TB on the:	**The Influence of TB treatment and care on the:**
1.1 Patient ○ Physically	**2.1 Patient** ○ Physically Positive Negative
1.2 Caregiver ○ Physically ○ Emotionally ○ Socially ○ Financially	**2.2 Caregiver** ○ Home Care Positive Negative ○ Hospitalization Negative Positive

Theme 1

1.1 The influence of TB on the patient:

The patients were asked open-ended questions on their physical symptoms only, because the emotional and social aspects of care were addressed in the QOL questionnaire.

From the 9 patients who specified their symptoms, two main symptoms emerged predominantly, namely lethargy and pain.

Their exact responses follow;

"I felt very tired"

"Ek het net gelé" (I just lay down)

"Ek het lam gevoel" (I felt lame)

"I had general body weakness"

"Whole body pain"

„Vomiting and abdominal pain"

"Sweaty at night, pain in whole body"

1.2. The influence of the patient's TB on the caregiver

The patients' TB had affected their caregivers in various ways which included physically and emotionally, socially and financially.

Physically and emotionally:

"I was warned about my husband. My high blood pressure and diabetes has got worse."

"Disappointed and worried, very depressed about this."

Fear of contracting TB was expressed by two caregivers:

„We are scared of getting TB."

„Always worried about also getting sick"

Four caregivers indicated that the condition had brought them closer together but one caregiver remarked:

„no more sex'

Four caregivers remarked that it made no difference to their lives:

“Makes no difference”

“Life goes on”

“Generally the condition did not affect my quality of life other than the patient is chronically ill.”

Socially

Ten caregivers said that their friends already knew about the condition, were sorry for the patient but they had no secrets from one another. They also said that they visited the patient in the hospital.

Four patients said that they hid the diagnosis from their friends because;

“*We are afraid of what they might say, they might avoid us”*

“Only the patient’s sister knows”

“I do not have to give information about my patients to my friends”

“I have only discussed it with my colleagues who understand”

Financial

Financial implications were also mentioned by one caregiver,,saying:

“Lack of finance as well as support for her children.”

2.1. The influence of TB treatment and care on the patient’s life

From the quantitative responses we can see that 80% of patients reported improvement of symptoms on TB treatment and this is how 13 patients expanded positively on their treatment:

Lethargy: 6 patients commented on their improvement by saying;

“*Minder moeg” (Less tied)*

“mobilizing more”

“ Ek kan nou loop”(I can walk now)

Pain: 3 patients had no more pain.

Coughing: 4 patients said they were coughing less frequently

Shortness of breath: 2 patients had fewer incidences of shortness of breath

Five people said that their specific symptoms were not being treated because they were on TB treatment.

Five patients reported that they were feeling worse on TB treatment with the following responses:

"I am coughing more"
"I am still short of breath"

Two patients remarked on increasing pain with;.
"*Still severe abdominal pain"*
"Pain all over body"

2.2. The influence of TB treatment and care on the caregivers' lives.

<u>The effect of home care:</u>
There were 3 negative responses to home care:

" My wife suffered and I felt helpless"
"Very stressed looking after the patient, as he is stubborn and does not help at home"
"With work it is difficult to give medicine at the correct time"

There was one positive response to home care:
"I have to adapt a lot. I had to learn new skills."

Three respondents were positive about their patient's treatment at the clinics with remarks such as;
"Good service from the clinic"
"Patient does not have to fetch her own pills, the clinic gives them to her"

“They are concerned about her, look after her and treat her well”

The effect of hospitalization:

Six caregivers said that hospitalization of the patient disrupted their home life, the remarks were:
“Children have not got a mother at home”;
„Missed patient when she was admitted to hospital, but home care goes on at home”
“With prolonged hospitalization we experienced emotional difficulty with adjusting to the illness’
“It leads to disruption of the situation at home as there is a three year old child.’;
“Would like the patient to come home for a day or two to look after her child’
“Do not talk about TB”
Very upset, late diagnoses that was missed by GSH (Groote Schuur Hospital).’

Positive comments were:
“*Good management”*
“„She is getting better”
’„Difficult to explain, care is oraait”
“Doing well, the condition has changed”

5.6.3. Responses to WHOQOL interview

There were 10 comments offered in this section.

The general attitude obtained from this interview was that the patients need to talk about their condition.

Six patients said they felt good about expressing their feelings with remarks such as;

"It makes me feel good to express my feelings and how I feel now that I am sick"
"Goed om oor myself te praat" (It is good to talk about myself)
"Feels allright – First time I can say this thing"

4 patients felt good about talking about TB
"Nobody has ever discussed the TB with my family. Very uninformed"
"Good to talk about the disease"

5.7. Conclusion

The results of this study have been extensively reported in this chapter. Tables, charts and verbal responses have been given. These responses will be discussed in chapter 6.

CHAPTER 6

Discussion

6.1. Introduction

South Africa is currently ranked 9th among the 22 countries listed as having the highest incidence of TB[3]. This pandemic has a negative impact on South Africa's human, medical and economic resources and therefore an emphasis is being placed on curing TB. The South African Department of Health's STOP TB campaign emphasises the fact that TB can be cured. TB is a curable disease, but many of the concomitant conditions lead to the death of patients before the infection can be cured. However, one must bear in mind that the mortality rate of all forms of TB was 230 per 100 000 population in 2005[4]. The fact that patients are dying of, or with TB can, therefore, not be ignored. Palliative Care has an important role to play in improving the QOL of these patients and their families. This can be done by means of symptom control, spiritual and psycho-social care and of course by improving infection control. Many of these patients need hospice care and hospices need to be empowered to care for these patients both at home and in inpatient units. The discussion in this chapter will reflect on the care of 20 palliative care patients and their families and how the condition has affected their quality of life. This research and discussion will be presented in the same sequence in which the literature survey and results were presented.

6.2. Management of TB in palliative care patients

The patients used for this study were recruited from 3 TB hospitals and 2 hospices in the Western Cape. Recruitment of patients who met the inclusion and exclusion criteria was relatively easy, indicating how many palliative care patients are infected with TB. Sixty-five percent of the patients, who were HIV WHO stage 4, were not on HAART, which also reflects on the prevalence of HIV in the Western Cape and that a high percentage of HIV patients still are not on HAART. Terminally ill patients very often have weakened immune systems, either due to the disease itself or the treatment, which increases their risk of developing TB as shown in the study done by Kim in South Korea. The researcher's study included 3 cancer patients, 3 COPD patients and 1 patient with both HIV and cancer; emphasising how susceptible palliative care patients are to contracting TB. COPD patients were included in this study due to the progressive nature of this illness and their need for palliative care, especially when infected with TB. This study therefore indicates that screening for TB in the palliative care setting, regardless of diagnosis, is essential, especially in Africa.

Sixty-five percent of the patients had additional complications over and above their terminal illness. These additional complications can complicate both the TB management and symptom control. Only one patient had liver complications. TB drugs can cause hepatotoxicity[6] and for this reason these patients need skilled TB care and monitoring. Only one patient may seem a very low incidence, but from previous experience it has been noted that hepatotoxicity is a major problem among very ill TB patients. Although, the results of this study did not show a high incidence of liver problems, clinicians should be vigilant in monitoring hepatotoxicity in the HIV population.

Five of the selected patients were suffering from lung complications, impacting on their poor performance status. There is a need for specialised palliative care skills to manage conditions like dyspnoea in patients suffering from TB. The palliative care management of dyspnoea can improve the quality of life of TB patients. However, as indicated in the literature survey, there is still opioid phobia and the lack of knowledge regarding the benefit of morphine in the management of dyspnoea which leads to unnecessary suffering.

Peripheral nervous system complications identified in the study population were mainly peripheral neuropathy which can be either due to the disease itself (HIV) or the TB treatment (INH). Two patients had peripheral nervous system complications. Peripheral neuropathy can be managed following the WHO guideline for pain control.

Two patients had GIT side effects which can be due to either the treatment or an opportunistic infection, of which TB is one of the most important GIT infections in the immune compromised patient. GIT side effects are a common reason for defaulting treatment because TB drugs can cause severe nausea and vomiting.

Six patients had other complications such as Moderate XDR, heart failure, inability to swallow, cardiac effusion and sepsis. These are all patients who require specialised care which complicates the TB management to prevent iatrogenic side effects. The one patient with the inability to swallow complicates the care because TB drugs can only be given orally. This poses the question of when TB drugs should be stopped in the palliative care patient.

From the above-mentioned we can conclude that these patients need holistic professional care in their TB management to improve their quality of life. These patients do not only need specialised medical care, but also impeccable infection control and a dedicated team to care for their psycho-social needs.

6.3 The diagnosis of TB

Diagnosis of TB in the palliative care population is of vital importance because of the susceptibility of this population to developing TB in the South African setting and the relatively high mortality rate from TB co-infection.

However, the diagnosis of TB in the immune compromised patient is notoriously difficult because of the inability to attribute the symptoms to TB or to the progressive nature of the concomitant disease. Negative smear microscopy and atypical X-rays complicate the diagnosis even further. In this study 13 patients were diagnosed from positive sputum tests. Eight patients had positive direct microscopy and 6 patients had positive culture tests. In an ideal situation all immune compromised patients should have culture tests done.

Seven patients were X-rayed as the method of diagnosis. Four of the seven patients were X-rayed and had sputum tests done. One patient's X-ray was abnormal and the patient was symptomatic and 2 patients were only X-rayed as a method of diagnosis. The inability to obtain a positive result from sputum from these patients led to clinicians relying on CXR as the method of diagnosis. However, in the immune compromised patients these X-rays can be atypical and the diagnosis relies heavily on the clinician's radiological skills. Misdiagnosis of TB as cancer or visa versa leads to treatment delay and anguish of patients and relatives. Palliative care patients need to have microscopic confirmation of their TB because this is the only method their TB progress can be monitored.

It is notoriously difficult to obtain positive results from sputum tests in immune compromised patients; however it must be remembered that it is detrimental to prescribe TB drugs incorrectly for patients suffering from AIDS or cancer when the side effects of the treatment can increase their morbidity. The problem of misdiagnosis is compounded when the palliative care patients are incorrectly diagnosed with TB and admitted to a TB hospital where they will surely be exposed to TB.

One patient had abdominal sonar to diagnose TB. Abdominal sonar is a non-invasive, reasonably inexpensive method to diagnose TB in immune compromised patients. However, it is operator dependent and a false positive diagnosis can easily be made.

A fine needle aspiration was performed on one patient, and procedures such as a lumbar puncture and a pleural fluid tap were each performed on one patient. These patients, it was ascertained, had TB outside the lungs and thus had extra pulmonary TB. These findings confirm the high incidence of extra pulmonary TB in this study population.The compromised immune response causes less cavity formation and further spread of the TB.

The diagnosis of TB in 2 patients was solely based on their symptoms. As described, this raises doubt as to the accuracy of the diagnosis. Palliative care patients are known to have a lot of symptoms because of the progressive nature of the illness. They are frequently bed bound and malnourished due to anorexia. To initiate TB treatment in these patients on symptoms alone needs a team assessment and continuous reassessment. If treatment is initiated in palliative care patients on symptoms alone, the risk/benefit of treatment must be considered for all patients. Not only must the drug side effects be considered but the psycho-social implications.

6.4. TB Treatment

Thirteen patients were receiving Rifafour (a combination of Rifampicin, INH, PZA and Ethambutol) which is the standard TB treatment. Seven of these patients were also receiving Streptomycin which is routine for retreatment patients. Three patients were receiving Rifinah (a combination of Rifampicin and INH) which is the standard treatment for the continuation phase. Four patients were receiving MDR treatment. Three patients were receiving standard MDR treatment of Kanamycin, ofloxacin, ethionamide, ethambutol and PZA. One patient, who was a moderate XDR, received kanamycin, ethionamide, ofloxacin, double dose INH, ethambutol, PZA and Terizidone. All these patients were in a MDR unit. This demonstrates how frequently palliative care patients are admitted to these units and how many drugs they have to take. The futility of this expensive treatment must be considered in palliative care patients. Healthcare professionals find it challenging to declare treatment futile because of the infectious risk to society and the perception that they are “giving up” on the patient. However, these drugs carry a high morbidity risk and can have a negative impact on the QOL of these patients. In the palliative care patient, where cure is not viable,only drugs which can improve QOL of the patient or the family should be used. MDR drugs do improve the QOL of most MDR patients but for a small minority these drugs are futile, providing no benefit to the patient, especially in the palliative care setting. Therefore, the initiation or discontinuation of all TB drugs should be assessed on an individual patient basis, and the patient clearly informed about the benefits and side effects of the treatment.

The question concerning the patient’s dosage of TB drugs was asked to ascertain whether the patient was receiving appropriate TB treatment.

Unfortunately, in this study design a question to ascertain the patients' body weight was not included. The weight of the patient determines the patient's medication dosage.

The duration of treatment was used to determine whether the patient was receiving appropriate TB treatment, as determined by the South African National TB Guidelines. A discrepancy was identified in that 4 patients were diagnosed as having extra-pulmonary TB, but only 1 patient was scheduled to receive treatment for 9 months. This demonstrates that the scheduled duration of treatment for 3 patients is incorrect. The lack of TB knowledge and the lack of adherence to TB protocols are two of the reasons for the development of MDR TB. This can be attributed to the fact that the mainstay of TB treatment, prior to HIV, was administered by professional nurses and many doctors' knowledge of TB had not been updated. There is a great need to develop TB skills in doctors in South Africa so that TB protocols can be followed, but also adjusted in special circumstances such as in the palliative care patient.

We can also conclude that 70 percent of these palliative care patients were to be on TB treatment for 8 months or longer. This is a long time for a palliative care patient to be on treatment. However, this study also concludes that 80% patients do have improved symptom control on TB treatment.

Palliative care patients commonly develop side effects from TB drugs due to immune disregulation and poly-pharmacy. According to the clinical notes, forty-five percent of the patients had developed side effects from the TB treatment and fifty-five percent had no side effects. These results reflect that TB drugs must be used appropriately and with care because of their potential for morbidity. Once again this demonstrates that skilled TB care is essential in the palliative care setting so that the quality of life of these patients can be improved.

6.5. Management of side effects

The most common side effects that were identified were nausea and vomiting (4 patients) and peripheral neuropathy (4 patients). Nausea and vomiting is a common side effect from TB drugs and a main reason for non-compliance to TB medication. This can be easily managed by careful liver function monitoring and the commencement of central-acting anti-emetics. This is unfortunately not routinely done at TB clinics where symptom control is not a priority. Fifty-five percent of patients received medication for symptom control. This was mainly for the nausea and vomiting for which metaclopramide was prescribed. Metaclopramide increases the gastric emptying time and is therefore not the most appropriate drug to be prescribed when TB drug absorption is needed.

Peripheral neuropathy causes severe pain and immobility which needs to be managed with pyridoxine and the WHO guideline for pain control. One patient developed severe athralgia while receiving TB drugs. This is a common side effect of PZA which needs careful monitoring and analgesia prescribed. Two patients developed skin rashes on the TB drugs. Any of the TB drugs can cause this and skilled care is needed to adjust the TB drugs to stop the rash.

Hepatotoxicity is a common side-effect of TB drugs, especially in patients with pre-existing liver disease. In this study only one patient developed jaundice from TB drugs, which is a very low incidence. One MDR TB patient developed hearing loss which is a common side-effect from the aminoglycosides. This again raises the ethical question of the futility and beneficence-maleficence of unnecessary treatment in palliative care MDR patients.

TB treatment can be adjusted to avoid complications in high risk patients. Fifteen percent (three patients) received measures to prevent complications and the remainder of the patients received no preventative measures. Simple changes in dosage or regime can decrease the incidence of side effects. Laughon states that there is a need to modify the treatment modalities, especially with choice of drugs and duration of therapy, when TB occurs in special situations such as pregnancy, liver disease, renal failure or co-infection with HIV[1]. Palliative care patients should be included in these „special situation' patients. One patient„s treatment was stopped for 10 days because of the nausea and vomiting. Another patient did not receive streptomycin because of increased urea. In one interview, the interviewer response did indicate change in treatment, and stated that terizodone and INH had been added because the patient was a moderate XDR. This was done to prevent further resistance.

At the forefront of palliative care is symptom management, which does not imply prescribing medication only, but also withdrawal of treatment when necessary so that the patient has optimum quality of life. Careful clinical monitoring of patients is essential to prevent serious complications such as liver failure, deafness and kidney failure.

The withdrawal of treatment should not take place simply because of the side effects of the treatment. When treatment is prescribed or withdrawn, the beneficence and the maleficence of this treatment should always be considered so that the patient and society can have optimum quality of life. In this study it was ascertained that no patient's TB treatment had been changed. This is a worrying statistic, because the patient who was jaundiced was still on Rifafour and streptomycin and no change had been made to the patients' medication. The patient who was suffering from hearing loss was still on a full dose of kanamycin.

Four patients received no treatment to manage their side effects. This is one of the most important reasons why patients are non-compliant with their TB drugs. The drugs make them feel unwell and healthcare professionals are not addressing the necessary and appropriate symptom control. These are palliative care patients and pain and symptom control must be the most important approach to their care. The TB Clinics are mainly focusing on cure and are not always skilled in caring for palliative care patients.

6.6. Symptom management

The first question asked was to ascertain what the patient's symptoms were before they started TB treatment. In this question, where patients were asked to describe their symptoms, weight loss was the main complaint and secondly lethargy. This general body weakness and weight loss are common in all palliative care patients which makes a diagnosis so very difficult. A senior palliative care sister expressed it this way: *"Most of my patients cough, they all lose weight, many have night sweats; many suffer from lassitude and fatigue. All of the above is part of the cancer package that our patients are living with on a daily basis."* This is an indication that the diagnosis of TB in the palliative care patient cannot be made on symptoms alone and the need for laboratory diagnosis is essential. Identifying the cause of the symptom is often difficult. However, the symptom itself must still be managed alongside disease-specific treatment when appropriate The monitoring of progress in the unconfirmed cases must be done by a team so that the patient does not receive fragmented care.

Seventy percent of patients indicated that they had pain before starting TB treatment. Two patients talked about their entire body being in pain which correlates well with the nonspecific type of pain patients with TB experience. In investigating the efficacy of pain control, it was found that 45% of patients still had pain. Relief of pain has been identified as a human right and is included in South Africa's Patient's Rights Charter. However, healthcare professionals are so busy treating the TB and co-morbid conditions, that pain control is not emphasised. Palliative care plays an essential role in promoting pain control as a basic human right. Sixty-five percent of patients in this study were receiving treatment for their symptoms and thirty-five percent had not received symptom control. Seventy-one percent of patients were receiving analgesia for their symptom control. It would seem that pain treatment was sub-optimal because 45% of patients still had pain. This study would have been more effective if it could have determined which analgesia these patients were receiving. According to Bateman in the South African Medical

Journal in 2007, there is ignorance concerning the efficacy and the correct use of opioids among doctors and nurses and there is continuing resistance to the prescription of these drugs, which contributes to unnecessary suffering[44].

The main comment captured during the patient interviews was the improvement of the lethargy. Lethargy was a frequently reported symptom and although it had improved with TB treatment, it was not completely cured. This picture fits in with the fact that these patients have a terminal illness as well as TB. The acknowledgment of lethargy and simple life changes can decrease the demands on the patient and therefore improve their QOL.

The other interesting conclusion is that 40% of patients were still coughing after being on treatment for a month. Terminally ill patients have weakened immune systems and this result raises the question of whether these patients were still infective? Coughing is a distressing symptom which causes pain and lack of sleep. Unfortunately, only 4 patients were receiving cough suppressants. From the above conclusions, it seems that patients were receiving symptom control, but what they where receiving was not adequate to manage the symptoms.

From the file review we know that 4 of the patients had nausea and vomiting as a complication from the treatment and 5 patients still had nausea and vomiting after being on treatment for a month. Nausea and vomiting have a wide range of causes especially in the palliative care situation. It is very important to determine the cause and to then prescribe the correct anti-emetic for that specific cause. TB drugs cause nausea because of their toxic effect. Haloperidol is the drug of choice but is unfortunately not widely prescribed. Haloperidol is not licensed as an antiemetic, but has antiemetic properties for causes of nausea through the Chemo emetic trigger zone[46].

It is interesting to note that 30% (six) of the patients had no coughing history. One patient had no symptoms. Seven patients complained of lethargy and weight loss and seven patients of lethargy and shortness of breath as symptoms. This makes the diagnosis of TB in palliative care patients so difficult, because these are symptoms of most terminally ill patients and the symptoms vary between patients. Palliative care health professionals must therefore always be alert to diagnose TB in their patients and ensure that a laboratory diagnosis is used to confirm TB.

The main aim of this study was to determine whether the symptoms of the participating patients in the study population had improved from the time the TB treatment was commenced. Eighty percent of the patients had improved on TB treatment. These results indicate that although TB treatment seems futile in the palliative care patient, it definitely plays a role in the improvement of the QOL for these patients. MDR and XDR drugs are very expensive drugs and the justification for treatment becomes more difficult in a country with limited resources. This study shows that most patients do feel better on their TB drugs and that the TB drugs play an important role in symptom management. However, TB drugs should rather be stopped in palliative care patients if they cannot tolerate an effective regime. An effective regime cannot be given if a patient cannot swallow tablets or constantly vomits. The continuation of an ineffective regime leads to the development of further resistance and the spread of XDR TB. It is therefore essential that TB treatment should be individualised by an experienced TB doctor, according to the patient’s side effect profile, so that TB treatment regimes can be given in the right dosages and for the right period of time to prevent further resistance. Palliative care and TB care should be integrated so that optimal TB and palliative care can be given.

Four patients said that they did not feel better on TB treatment. One patient’s pain had worsened. This particular patient had no bacteriological TB diagnosis and was started on TB treatment on a CXR alone. One patient complained that the vomiting had increased. One patient had worsening of his respiratory symptoms. It is therefore important to review the impact of the drugs on each patient and to combine the drugs with symptom control drugs. In these patients the futility of treatment should be considered and the QOL of the patient should be the main factor in the decision-making process.

Doctors treating these patients could easily identify them as patients with progressive illness who could not be cured, which was demonstrated by the ease with which the patients were recruited for this study. These patients need basic palliative care symptom control to improve their quality of life.

6.7 Quality of Life

Modern medicine is moving towards evidence-based medicine to determine the best possible outcome for a patient. However, the holistic approach for patients receiving care is seldom determined. Quality of life is subjective and quality of life measures will never capture all aspects of living that are important to a patient's life. Quality of life measures are an adjunct to measuring outcomes associated with disease[25]. It is not ideal to give an ordinal value to QOL, but it helps in clinical practice to ensure that treatment and evaluations focus on the patient rather than on the disease.

In the first question that was asked about an individual's overall perception of their QOL, 45% indicated that they have poor QOL and 25% gave neutral answers. This correlates with the fact that these patients are facing a terminal diagnosis. Fox states that when we die we are losing our life in the world[8]. We are losing all the links and bonds that give our life texture, colour, dimension, value, meaning and some people believe we are losing ourselves. This is a profound shock and nothing prepares us for this. Our response is to mourn for ourselves and there can be a feeling of being cheated or stolen from, leading to anger and confusion[8]. But within this process of illness, 30% of patients still indicated that they were experiencing good QOL. QOL is subjective and we can adapt to changing circumstances. Therefore, these patients still subjectively experienced good QOL.

Question 2 asked about the patients' overall perception of their heath. Fifty percent had poor overall QOL and poor perception of their health which correlates with their physical wellness as proven by the Pearson correlation.

Physical health is therefore the factor which plays the most important part in their poor QOL.

Physical Health:

Domain 1 evaluates the patient’s physical health which includes 7 facets of health as discussed in the literature review. This domain score had the lowest domain score of 38, which is an indication of how poor these patients’ physical health is. Sixty percent of patients felt that physical pain is hampering their daily activities and this correlates with the symptoms patients reported in the patient interview. Pain relief is one of the cornerstones of palliative care and these results indicate that the terminal TB patient’s palliative care needs are not being met. This also correlates with the reported lack of knowledge healthcare professionals have about opioid usage in the management of the HIV, TB population.

Sixty-five percent of patients also needed medical treatment (this includes medication, aids and medical supplies) to function daily, which indicate a high level of care needs. The majority of patients did not have energy for daily living; they were immobile and could not perform their daily activities, indicating their poor performance status. Studies done by Marra and Hansel also found that patients indentified that fatigue was one of their main complaints. These patients therefore need a higher level of care than that which is being offered at mainstream clinics. These results also indicate the high burden of care that the family of dying, contagious patients have to carry. These patients need full nursing care at home, as well as having their drugs collected from overcrowded clinics. Family members do not have the knowledge or the means to protect themselves from TB, as substantiated in the carer interview and by Ferrel[34].

The effect of TB on QOL is poorly described in the literature studies. Hansel states that TB patients are often classified as “chronically ill” patients because it is difficult to distinguish between their other medical and social needs[2]. This statement is especially true of the palliative care patient co-infected with TB because no literature could be found covering this topic.

Psychological:

Domain 2 evaluates the patient's psychological wellbeing and the median score was 56. Spirituality, or that which gives meaning to us, is at the forefront of our minds when we are facing our mortality. In the case of people who are dying, their inner resources become the cornerstone of their coping mechanisms[8]. This study reflects this resilience, because 60% of patients still enjoyed life, fifty percent still had good self-esteem and 70% of patients felt that their lives had meaning. The importance of spiritual care cannot be over-emphasised especially when dealing with a terminal disease which isolates and stigmatises patients.

In the context of this picture of resilience, fifty percent of patients felt despair, depression and anxiety. These feeling are normal when facing a terminal illness. Elisabeth Kubler-Ross states that that the dying patient is in the process of losing everything and everybody he loves. "If he is allowed to express his sorrow he will find a final acceptance much easier, and he will be grateful to those who can sit with him during this stage of depression without constantly telling him not to be sad"[45]. Currently, there is very little psycho-social support in clinics and in TB hospitals for patients and in addition the inability of healthcare professionals to deal with these issues leads to further isolation of patients.

The profound weight loss and cachexia of TB patients leads to huge changes in body image and this correlates with the fact that 70% of patients had negative feelings towards their body image. These negative feelings lead to further desperation and isolation of patients. Counselling at this stage of the illness can have a huge impact on the patient's wellbeing and the way he interacts with his carers.

Social Relationships:

Domain 3 looks at the patient's social relationships and the median score was 56. Seventy percent of patients were satisfied with their personal relationships. Terminal illness can bring families closer and strengthen bonds. These results correlate with Marra who concluded that most patients felt supported during their illness. However, more than 50% were not satisfied or had a neutral response to their sexual relationships. Sexuality suffers in palliative care patients due to poor self esteem, social anxiety, self consciousness and depression[46]. The change in family dynamics, physical exhaustion and also the fear of contracting TB contribute to partners physically withdrawing from patients, resulting in isolation. Palliative care plays a huge role in opening communication within families by offering holistic care by an interdisciplinary team.

Environment:

Domain 4 explores how patients experience their environment and the median score was 44. From these results it can be concluded that patients feel safe in their physical environment (65%), in their home environment (65%) and in their daily life (85 %). In a country with a high crime rate, poverty and a large proportion of the population living in informal housing, patients still feel secure in their environment.

Most of the patients interviewed did not have enough money for their daily needs. The loss of the patient's job, the fact that the caregiver often has to stop working to care for the patient, the increasing number of hospital appointments and the impact of the current financial crisis, that the world is facing, places a huge burden on families. This again emphasises how important the team approach is in managing these patients, with the involvement of the social worker. Nobody can manage TB treatment on an empty stomach. Malnourishment increases the risk of contracting TB and families burdened with full time care have decreased incomes. The whole family is subsequently impoverished.

The team approach also improves patients' QOL by offering leisure activities (60% of patients had no opportunity for leisure activities) and solutions to practical matters such as transport for the very ill patients. Forty-five percent of patients were dissatisfied with their transport which can also correlate with lack of finances.

Summary of QOL results:

The QOL scores showed that the patients' physical health and especially their pain were not optimally managed. They have highlighted the great financial burden these patients carry and the poor body image and sexual isolation patients experience. It is postulated that a palliative care approach can impact positively on these issues. Cure of TB is essential but not always attainable. Changing the focus from TB cure to TB care, and working within a team where patients receive holistic care that includes TB treatment, will not only improve compliance but will also help to support the families during this difficult period.

These results have also shown how important spiritual wellbeing is in end-of life-care because 70% of the patients felt that their life still had meaning even though they were sick and away from their families. Patients also felt supported by their families. This is contrary to the perception that people avoid TB patients. These results should help TB hospitals and hospices to strengthen their spiritual care and family support when dealing with a terminal TB patient. The most important aspect about these interviews was that patients had an opportunity to talk about themselves and to affirm their value as a person. This affirms the need patients have for emotional and spiritual care.

6.8. Caregiver/ family experience

Doyle states that the principal providers of care are actually the relatives. Doyle further states that we are still not doing enough to empower, strengthen, educate and support carers and to use imaginative means to help and support them through this difficult time[47]. TB is not the disease of one person in the home; the infection is spread to the most vulnerable in the home, the young and the old. Caring for a terminal patient places the extra emotional pressure, change in family dynamics, role overload and change in family dynamics on the carers. If these carers are not supported, a downward emotional spiral occurs which leads to bigger health problems.

Carers were asked how they would rate their QOL since the patient had been diagnosed. Sixty-two percent indicated that they were not satisfied with their QOL. They indicated that it was due to being worried about the patient and the rest of the family's future, and the stress and the helplessness of the situation. These stresses could be reduced with good counselling and a social worker's input.

QOL in every family is different and the social dynamics were far more important to these family members than the fear of contracting TB. Health care professionals should have a dual focus on counselling families about infection control and the impact on care giving. Holicky concluded that family caregivers may be the most important element in successful rehabilitation and long term home care and therefore it is essential to include them in decision making[9].

Two family caregivers indicated that their QOL had improved because of the improvement of their skills. These carers had been empowered and felt that what they were doing was being acknowledged and affirmed.

Eighty-six percent of patients said that that the TB itself had affected their QOL. However, only 2 patients were scared of contracting TB.

This could be attributed to denial or to the ignorance of our society concerning TB and the need for positive informative press in our communities and for family support and counselling.

The most significant reported effect which TB has had on the caregiver's life was when the patient was hospitalised. This reinforces what Marra found, namely that there are extreme negative feelings associated with long term hospitalization[19].

Palliative care in the South African setting provides care at home, where the patient can receive appropriate emotional and spiritual support, which is not available in the clinic and hospital setting. Hospices therefore need to equip themselves to care for the dying TB patient at home, although TB patients have not traditionally been part of hospice care. Hospices are very reluctant to take up this task due to increasing patient numbers, staff health, inadequate knowledge about TB and environmental control. However, in a country with such a high incidence of TB, hospices can not turn a blind eye to these patients but confine their care to the TB patients who need palliative care and not general TB care. Public/private partnerships are essential to empower hospices to care for these patients. Hospices need to develop criteria for deciding which patients they can manage. Symptom control in palliative care TB patients needs to be reviewed with the Department of Health so that it is accessible in the state sector, and so that it can be rolled out to a wider patient population. Infection control, in hospices and in the home setting, needs to be reviewed and taught to all personnel. The most important task is to develop clear guidelines on how, and when, treatment with TB drugs can be terminated. This ethical dilemma is more apparent when XDR treatment is futile and these patients want to die at home. Hospices and the Department of Health will have to develop partnerships with clear guidelines for the management of these patients. This cannot be done without additional resources being made available to Hospices so that the patient, the family and the healthcare provider are safe and cared for.

This study also reflects Marra's study that there was a lack of prompt diagnoses and inappropriate management[19]:

South Africa is facing an epidemic of TB, but there are still very few health care providers who are skilled TB care providers. South Africa's public health sector is also losing doctors and nurses to overseas and the private sector, leaving a huge gap in health care for the most vulnerable communities.

This study reflects the huge lack of insight and knowledge about TB among the caregivers. When asked whether they had had themselves tested for TB, only 25% reported that they had been tested, in spite of having symptoms of TB. Caregivers were not adequately counselled regarding infection control measures and were therefore not worried about contracting TB. This lack of knowledge leads to delayed diagnosis of TB in relatives and an increase in the infectious pool. Forty-three percent of the caregivers had no preventative measures in place and the other 43% percent saw hospitalisation as a preventative measure. No masks where offered to caregivers. N95 respirator masks are the only masks that can protect carers but are relatively cheap in comparison to treating a new patient. Only 1 caregiver received preventative medication. This study has therefore shown the enormous need to counsel family members and the community at large about TB.

The last part of the interview was to ascertain the social interaction of the caregiver with the patient and the community. Fifty-six percent indicted that that the condition had brought no positive changes to their relationship with the patient. One caregiver indicated: "*no more sex*" which again highlights how important it is to talk about sexuality with patients and partners and how important touch is in end-of-life care. As Stanley Kunitz said:

"*Darling, do you remember*
The man you married? Touch me,
Remind me who I am"[8]

Those who reported positive changes in their relationship, resulting from the illness, said that it had brought them closer together. Dying often teaches us how to live and open communication, forgiveness and acceptance are highlighted when confronting a terminal illness[8].

6.9. Limitations of the study

A bigger sample size would have ensured further validity to this study.

On reflection, this study needed to include the patients' weights to adequately determine whether the correct treatment was offered. Giving a too high or too low dose of TB drugs can lead to increased side effects or increased resistance.

This study also needed to include the specific analgesia patients were receiving so that detailed recommendations could be made to improve pain control in TB patients.

The open-ended questions asked in the patient interview should have included more psychosocial questions. However, the QOL score was a valuable tool to explore the psychosocial issues.
This study has an element of being biased in that it does not represent TB patients who are not in hospitals or hospices. The researcher was aware of her previous experience in caring for TB patients and her perception of the possible benefit of palliative care, which may have affected objectivity in the research. Research reflection and objectivity are needed to lessen bias.

6.10. Conclusion

This discussion has not only highlighted how common TB is in terminally ill patients, but also how difficult it is to diagnose and treat these patients. These patients need a team approach to individualised TB care, which includes decision making about treatment regimes and the initiation and termination of the treatment. Pain and symptom control should be at the forefront of care to improve QOL. Most patients feel more supported at home and hospitalisation appears to have a negative impact on the wellbeing of the patient and the family. However, caregivers are not adequately prepared for caring for the dying TB patient at home.

CHAPTER 7

Conclusion

7.1. Introduction

The aim of this study was to assess the holistic care of TB patients with palliative care needs. „Holistic' implies that patients are cared for physically, socially, psychologically and spiritually. The mortality rate of TB patients in South Africa in 2005 was 230 deaths per 100 000 population per year[4]. At the end of life, holistic care becomes paramount for the comfort of the patient and the wellbeing of the patient's family. Palliative care is an approach that improves the quality of life of patients and their families facing problems associated with life-threatening illness, through the prevention and relief of suffering, the early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual[46].

This study addressed holistic palliative care by evaluating the overall management of TB patients. This included reviewing the patient's clinical file, interviewing the patient to determine the symptom management and the patient's QOL. In addition the family members involved in caring for the patient were interviewed to assess the impact of the TB diagnosis on the family.

7.2. The management of TB in palliative care patients

TB is a curable disease but patients are dying of, or with, TB as illustrated by the fact that it was easy to select suitable patients for this study who complied with the inclusion and exclusion criteria. Doctors found it easy to select patients with very poor prognoses, including MDR TB patients, but had not referred all the patients for palliative care. However, TB patients are now being cared for in hospices, not only in TB hospitals. It is essential for medical professionals to screen for TB in the terminally ill patient. This study recommends that hospices, especially in Africa, need to be equipped to manage TB and have appropriate infection control measures in place to protect staff. TB hospitals, on the other hand, need to gain palliative care skills in order to care for these patients in TB hospitals.

The complexity of these patients' conditions and the fact that the diagnosis of TB was difficult, makes it essential that these patients be treated by a skilled team so that a holistic approach can be applied which includes the impeccable assessment of all the medication and the need for it. Impeccable assessment should include symptom management. The most common reported side effects of TB treatment were nausea and vomiting and peripheral neuropathy. These are easily managed by good palliative care, but only 5 patients received symptom control and 85% of the patients had no preventative measures in place to avoid complications.

Seventy percent of the patients were to be on treatment for 8 months or more which is a long time for a terminally ill patient to be on toxic drugs. However, this study has found that most patients felt better while being administered with TB drugs, and therefore it appears that TB drugs do improve the physical wellbeing of the patients. This wellbeing can only continue if these patients' symptoms are constantly monitored and symptom control is applied.

TB drugs are toxic, difficult to swallow and interact with a large number of other drugs. It is therefore essential that the patients, who have been correctly screened, are placed on the correct treatment, as well as the correct dosage for the correct period of time. The patient's treatment must be adjusted if and when there is any change in the condition of the patient. Although we recognise resource constraints in South Africa, patients such as these need regular review.

This study concludes that it is essential to review the patient in total before initiating TB medication, and in particular the symptoms, and which drugs should be avoided or included in order to obtain the best outcome from the treatment. This study therefore describes the management of TB in patients with palliative care needs as problematic, because the diagnosis and the treatment are difficult. The most important element of treatment is not to do further harm, especially in the terminally ill patient. This study recommends that the TB treatment in these patients should be individualised and managed within a team, which includes a trained palliative care professional.

7.3. The symptom management and quality of life in the palliative care patient infected with TB

Eighty percent of patients felt better while being administered with TB treatment. When initiating a terminally ill patient on toxic, curative treatment, the question all clinicians have to answer is whether we are prolonging life or prolonging suffering. This study therefore concludes that, although it seems futile to start a palliative care patient on TB treatment, the treatment does improve the QOL of the patients. However, 20% of patients did not feel better on TB treatment and here the futility of the treatment should be evaluated. It is essential in the treatment of the MDR patient, where very toxic, expensive treatment is administered, to assess how beneficial the treatment will be. For these reasons TB treatment in these patients should be individualised and constantly reviewed. Patient autonomy is a cornerstone of good palliative care and the informed patient and family should be part of this decision making process.

Pain control is a basic human right. It was found that 45% of these patients still had pain in spite of 71% of patients receiving analgesia. Unfortunately, due to an oversight in the study design, a detailed list of pain medication was not required; this information would have added validity to the study. There is a huge lack of knowledge concerning the use of opioids which results in tremendous suffering in these patients. Low dosage of morphine helps tremendously for dyspnoea and as a cough suppressant. This study recommends that pain control training, and especially training concerning morphine, should be initiated in the health care setting were patients with TB are treated.

This study, therefore, concludes that TB treatment has a role in symptom management but that pain and other distressing symptoms were not well managed. Palliative care principles should be taught and implemented in all facilities facing the dilemma of the dying TB patient.

The World Health Organisation Quality of Life BREF score has proved to be a valuable document to prioritise problems, facilitate communication, screen for potential problems and identify preferences. Forty-five percent stated that they have poor health of which their physical health was the worst.

Fox's book states that dying can become the deepest spiritual experience of a lifetime[8]. This is reflected in this study which showed that 70% of patients found meaning in their lives. Spiritual support should be part of essential care and especially where patients are hospitalised for long periods of time. The deep despair and anxiety patients feel when facing a terminal diagnosis are worsened when they are removed from their secure homes. The loss of body image, sexual wellbeing and self-esteem are factors that contribute hugely to poor QOL and should be managed within an interdisciplinary team. The loss of a job, the significant costs incurred by going to a clinic daily or by relatives visiting hospitalized family members place stress on the patient and the family. The involvement of a social worker and active participation of the patient and family should be encouraged to determine the best place of care for the patient.

The statement in which the patient said: “It makes me feel good to express my feelings and how I feel now that I am sick” summarises the need and value of holistic care and the value of the WHO BREF QOL score.

7.4. The impact of the TB diagnosis on the family

Family members indicated that most of them did not have good QOL, and the main reasons the impact was largely psychosocial was because the patients were hospitalised, they felt helpless and there was the financial burden associated with hospital visits. Only half of the family members were afraid of contracting TB. Patients can be cared for at home, provided good infection control procedures are in place. Health professionals are not necessarily improving care by hospitalising the patient.

These family members had already been exposed to the TB before the patient was hospitalised, indicating that it is now most important to test the family members. This study also shows the ignorance concerning the transmission of TB and the lack of preventative measures to protect the caregivers. This study recommends that much more time and money should be spent on empowering and protecting the family members when caring for the dying TB patient. Family members need emotional support as well as financial support when caring for a dying loved one. Social workers need to be actively involved from the beginning, when the diagnosis is made.

Most family members had told their friends about the patient’s diagnosis because they felt supported by them and only 4 family members were afraid of stigmatization. This shows the good support that is available in the communities. However this will only be maintained if positive counselling takes place concerning TB, instead of only doomsday news paper reports.

Hospices play an important role in affirming life and regard dying as a normal process. In a country burdened by a high incidence of TB, we must accept that patients are going to die with or because of TB. Hospices should therefore concentrate on incorporating these patients into their care and not excluding them from their admission criteria. However, there should be financial support to hospices to provide adequate infection control measures.

7.5. Further Studies

This is a broad evaluation of the current care that patients with TB, who have palliative care needs, are receiving. This study recommends that further research should be done in the following areas:

- An in-depth qualitative study of patients' and families' experiences concerning end-of-life issues in TB patients
- A comparison of the care received in TB hospitals with community based care.
- Financial implications for Hospices caring for TB patients
- The practical and ethical implications of stopping TB treatment in palliative care patients

7.6. Conclusion

With the growing prevalence of XDR and MDR TB in the world, palliative services are challenged to deliver safe and compassionate care to these patients and their families. Palliative care should be included in all TB services to provide holistic care to these patients. Society can only be protected if it is informed; informed about the advantages and disadvantages of TB treatment, informed about palliative care and knowing that they still have a choice.

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APPENDICES

A Qualitative study to asses the holistic care of Tuberculosis patients with palliative care needs in the Western Cape, South Africa.

S.R. KRAUSE

INDEX OF APPENDICES

Appendix A

Extract from clinical records

Patient ….................   DATE…......................................

File Review

Tick the appropriate box

1. Determine what the patient's terminal illness is

☐ HIV, WHO 4, not on HAART

☐ Cancer

☐ COPD

☐ Renal failure

☐ Liver failure

☐ Other

2. Does the patient have complications from the above mentioned illness?

☐ Yes

☐ No

2.1 If YES, name the complication(s):

☐ Liver

☐ Renal

☐ Central nervous system

☐ Peripheral nervous system

☐ Lung

☐ Skin

☐ Gastro-intestinal

☐ Other, please specify

3. How this patient was positively diagnosed with TB?

- ☐ Sputum
  - ☐ AFB
  - ☐ Culture
- ☐ Chest X-ray
- ☐ Abdominal Sonar
- ☐ Fine needle aspiration
- ☐ Lumber Puncture
- ☐ Symptoms alone
- ☐ Pleural Fluid
- ☐ Other, please specify

4. List the patient's TB medication

Medication 1…………………………………………………………………………………………………

Medication 2…………………………………………………………………………………………………

Medication 3…………………………………………………………………………………………………

Medication 4…………………………………………………………………………………………………

Medication 5…………………………………………………………………………………………………

Medication 6…………………………………………………………………………………………………

5. List the dosage

Dosage of Medication 1……………………………………………(milligram per DAY)

Dosage of Medication 2……………………………………………(milligram per DAY)

Dosage of Medication 3……………………………………………(milligram per DAY)

Dosage of Medication 4……………………………………………(milligram per DAY)

Dosage of Medication 5……………………………………………(milligram per DAY)

Dosage of Medication 6……………………………………………(milligram per DAY)

6. List the intended duration of treatment

- ☐ 6 months
- ☐ 8 months
- 9 months

☐ Longer

7. **Has the patient developed side-effects from the TB Treatment according to the clinical notes?**

☐ Yes

☐ No

7.1 If YES, what are they?

☐ Hepatotoxicity

☐ Kidney failure

☐ Peripheral neuropathy

☐ Athralgia

☐ Nausea and vomiting

☐ Skin rash

☐ Depression

☐ Sight problems

☐ Other, please specify

8. **How has these side-effects being managed?**

☐ Change in TB regime

TB Drugs removed

Name

TB drugs added

Name

Change in dosage

Name

Change in duration

Name

☐ Symptom control.

No change

9. Has any changes been made to the TB treatment to avoid complications?

☐ Yes

☐ No

10. If YES, specify

………

………

………

………

………

Appendix B

Interview with patient

11. What where your symptoms before you started TB treatment?

☐ Cough

☐ Lethargy

☐ Weight loss

☐ Night sweats

☐ Pain

☐ Shortness of breath

☐ None of the above

☐ Other, please specify

Describe your symptoms:_______________________________________
____
____

12. Have these symptoms improved since you have started TB treatment?

☐ Yes

☐ No

Explain how your symptoms have changed:______________________________
____
____

13. What are your current symptoms?

☐ Cough

☐ Lethargy

☐ Weight loss

☐ Night sweats

☐ Pain

☐ Shortness of breath

☐ Nausea and vomiting

Itching

☐ Pain

☐ Swelling

☐ Feeling sad

☐ Anxiety

☐ Diarrhoea

☐ Other, please specify

14. Are you receiving treatment for the above mentioned symptoms?

☐ Yes

☐ No

26.1 **If YES, please name the treatment**:

☐ Analgesia

☐ Anti-emetics

☐ Cough suppressants

☐ Vitamins

☐ Food

☐ Physiotherapy

☐ Anti-pruritcs

☐ Change of drugs causing adverse effects

☐ Other, (including traditional healers)……………………………………………………………………

a. If NO, Why not:____

WHOQOL

THE WORLD HEALTH ORGANIZATION
QUALITY OF LIFE (WHOQOL)-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How would you rate your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical	1	2	3	4	5

	environment?					

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5
20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite Often	Very Often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

....

Appendix C

Interview with the caregiver/ family

1. How would you rate your quality of life since the patient has been ill?

   ☐ Very poor

   ☐ Poor

   ☐ Neither poor nor good

   ☐ Good

   ☐ Very good

   Explain why:

2. **How much has the patient's TB affected your quality of life?**

   ☐ Not at all

   ☐ A little

   ☐ A moderate amount

   ☐ Very much

   ☐ An extreme amount

   Explain why:

3. **Have you had yourself tested for TB?**

   ☐ Yes

   ☐ No

4. **Is any person in the home on TB treatment besides the patient?**

   ☐ Yes

   ☐ No

5. **Are you worried about developing TB?**

   ☐ Yes

   ☐ No

6. **Has the TB prevented you from having close contact with the patient?**

   ☐ Yes

   ☐ No

7. **Have you told your close friends that the patient has TB?**

   ☐ Yes

   ☐ No

   Explain your answer:

8. **Do you have any of these symptoms?**

   ☐ Cough

   ☐ Weight loss

   ☐ Night sweats

   ☐ Lethargy

   ☐ Pain

9. **Has the TB brought any positive changes in your Relationship with the patient?**

   ☐ Yes

   ☐ No

   If yes, what changes ________________________________

10. **Has the patients Illness put a financial burden on you?**

    ☐ Yes

    ☐ No

11. **Have you had any counselling about TB from a health? care professional?**

    ☐ Yes

    ☐ No

12. **Are you happy with the way the health care team is treating the patient's TB?**

☐ Yes

☐ No

Why? ....

....

....

....

....

13. Are you using preventative measures from contracting TB?

☐ Mask

☐ Medication

☐ Patient sleeps in a different room.

☐ Patient has been hospitalised

☐ Avoiding close contact

☐ None of the above.

○ Appendix D

CONSENT TO PARTICIPATE IN RESEARCH

- You have been asked to participate in a research study.
- You have been informed about the study by ……………………………………… .
- *(Where applicable):* You have been informed about any available compensation or medical treatment if injury occurs as a result of study-related procedures;
- You may contact …………….. at ……………. any time if you have questions about the research or if you are injured as a result of the research.
- You may contact the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS at telephone number (051) 4052812 if you have questions about your rights as a research subject.
- Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to terminate participation.
- If you agree to participate, you will be given a signed copy of this document as well as the participant information sheet, which is a written summary of the research.

- The research study, including the above information has been verbally described to me. I have had the opportunity to ask questions about the research and I understand what my involvement in the study means. I understand that I can withdraw from the study at any time and my treatment will not be affected. I voluntarily agree to participate.

________________________	____________________
Signature of Participant	Date
________________________	____________________
Signature of Witness	Date
(Where applicable)	
________________________	____________________
Signature of Translator	Date
(Where applicable)	

Appendix D

TOESTEMMINGS BRIEF

U is gevra om aan ‘n navorsingsstudie deel te neem

U is oor die studie ingelig deur---

U mag enige tyd vir Dr. Krause by 083 445 2304 kontak ondien u ‘n problem met die studie het.

U mag die sekretariaat van die Etiese Komitee van Kaap Stad Universiteit by telefoon nommer 021 4066492 kontak indien u enige vrae oor u regte as navorsings persoon het.
U deelname in hierdie studie is vrywillig, en u sal nie gepenaliseer of enige voordele geweier word sou u deelname weier of beëindig.
Sou u instem om deel te neem sal ‘n getekende kopie van hierdie document sowel as die deelnemers se inligtingstuk, wat ‘n skriftelike opsomming van hierdie studie is , gegee word.

Die navorsings studie, met die bogenoemde inligtingstuk is mondelings aan my verduidelik .Ek is die geleentheid gegee om vrae oor die navorsing te vra en ek verstaan wat my deelname in die studie is. Ek verstaan dat ek enige tyd van die studie mag onttrek en dat dit nie my behandeling sal beinvloed nie.
Ek stem vrywillig in om deel te neem.

----------------------------------	------------------------
Handtekening van deelnemer	Datum
---------------------------------------	--------------------------
Handtekening van getuie	Datum
-------------------------------	--------------------------
Handtekening van tolk	Datum

Appendix E

INFORMATION DOCUMENT

Study title:Tuberculosis management in Palliative Care patients

Greeting:

Introduction:

Dr S.R. Krause, an MPhil Palliative Care student, is doing research on the Tuberculosis management in palliative care patients . Research is just the process to learn the answer to a question. In this study we want to learn whether palliative care patients on TB treatment are receiving appropriate TB management and how TB is affecting their quality of life. We also want to determine whether their TB symptoms are being managed and whether they developed any complications from their TB management. We also want to assess how TB affected the quality of life of the patient's family or caregivers.

Invitation to participate: We are asking/inviting you to participate in a research study

What is involved in the study : This study will be done by means of reviewing the files of palliative care patients on TB treatment to determine: how the patient was diagnosed with TB, their co-morbid disease, to review whether the patient is receiving appropriate TB management, whether the patients has developed side effects from the treatment and how it is being managed. An interview will take place between the patient and a doctor to determine the patient's current symptoms and how TB is affecting the patient's quality of life. An interview will also take place between the patient's caregiver and the doctor to determine the affect of TB on the caregiver's quality of life. The doctor reviewing the files and interviewing the patient and caregiver will have a TB background. All information will be held confidential and the protocol will be approved by the Ethics Committee of UCT. Twenty patients will take part in this study in the Western Cape.

Risks: There will be no change in the current management of the patient. A distress protocol will be followed if the patient or caregiver becomes distressed during the interview and the interview will be either abandoned or restarted when the patient/caregiver is more comfortable. All information will be treated as confidential.

Benefits: The patient/caregiver will receive no incentives to be in this study. TB is a massive burden in the South Africa and kills 2 million people yearly worldwide. This research is essential for palliative care in South Africa.

The subject will be given pertinent information on the study while involved in the project and after the results are available.

Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Confidentiality: Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.
Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Ethics Committee..

If results are published, this may lead to individual/cohort identification.

Contact details of researcher(s): Dr S.R Krause
Address: P.O. Box 4494, George East, 6539
E-mail: marvel @doctors.org.uk
Tel : 0834452304

Contact details of REC Secretariat and Chair: Mr Xolile Fula
Old main Building E 53-44.1
Groote Schuur
Faculty of Health Sciences
Observatory
7925
Tel: 021 4066492
Fax: 021 4066411

INLIGTINGS DOKUMENT

Titel van Studie:

A qualitative study to asses whether the level of care of patients, with life limiting illnesses, who are co-infected with TB, are receiving appropriate TB management.

Inleiding:

Dr S.R.Krause, ‘n MPhil student in Palliatiewesorg, is tans besig om navorsing in Turberkulosis (TB) versorging van palliatiewe pasiente te doen. Navorsing is net die process om ‘n vraag te beantwoord. In hierdie studie wil ons vasstel of palliatiewesorg pasiente op TB behandeling geskikte TB behandeling ontvang en hoe TB hulle lewens kwaliteit beinvloed. Ons wil ook vasstel of hulle TB simptome behandel en versorg word en of hulle enige komplikasies van hierdie versorging het. Ons wil ook bepaal of TB die familie of versorger se lewens kwaliteit beinvloed.

Uitnodiging aan deelnemer:

Ons vrae/nooi u uit om deel te neem aan ‘n navorsings studie.

Wat behels die studie:

Hierdie studie sal uitgevoer word deur palliatiewe pasiënts se leêrs deur te gaan om hulle TB behandeling vas te stel; hoe die pasient met TB gediagnoseer was; hulle **co-morbiede** siekte en om te bepaal of die pasënt geskikte TB versorging ontvang en enige newe effekte van die versorging ontwikkel het. ‘n Onderhoud sal tussen die pasiënt en die doctor plaas vind om vas te stel of die pasiënt tans enige simptome ervaar en hoe TB die pasiënt se lewens kwaliteit beinvloed. ‘n Onderhoud sal ook tussen die pasiënt se versorger en die dokter plaas vind om vas te stel wat die invloed van TB op die versorger se lewens kwaliteit is. Die doctor wat die leërs nagaan en die onderhoud met die pasiënt en die versorger voer sal ‘n agtergrond oor TB hê. Alle inligting sal konfidensieel wees en die protocol sal deur die Etiese Komitee van Kaap Stad Universiteit goedgekeur word. Twintig studente van Wes Kaap sal aan hierdie studie deel neem.

Gevare:

Die huidige versorging sal nie verander word nie. ‘n **Distress** protocol sal gevolg word sou die pasiënt of versorger tydens die onderhoud stress ervaar. In so ‘n geval sal die onderhoud, of afgelas word, of op ‘n later stadium, wanneer die pasiënt/versorger meer op hulle gemak is hervat word. Alle inligting sal as konfidensieel beskou word.

Voordele:

Die pasiënt/versorger sal geen insentiewe ontvang om aan hierdie studied deel te neem . TB is ‘n groot las op Suid Afrika en 2 million mense wêreld wyd sterf jaarliks daar van. Hierdie studie is noodsaaklik vir palliatiewe sorg in Sui Afrika.

Tydens hierdie studie sal die deelnemer pertinent inligting word aangaande die studie en na afloop van die studies al die resultate beskikbaar gestel word.

Deelname is vrywillig, en weiring om deel te neem sal geen straf of verlies van voordele wat die deelnemer andersins sou ontvang inhou nie. Die pasiënt mag enige tyd deelname staak sonder enige straf of verlies van voordele wat die pasiënt andersins sou ontvang het.

Vertroulikheid :

Alle pogings sal gemaak word on persoonlike inligting vertroulik te hou.

Totale vertroulikheid kan nie gewaarborg word nie. Persoonlike inligting mag onthul word sou die Wet dit vereis.

Organisasies soos b.v. die Etiese Komitee mag u navorsings resultate inspekteer of herhaal vir kwaliteitsversekering.

Sou resultate gepubliseer word mag dit tot individuele/kohort identifikasie lei.

Kontak besonderhede van navorser(s); Dr. S.R.Krause
Adress; Posbus4494, George Oos,6539
E-pos: marvel@doctors.org.uk
Tel: 0834452304

Kontak besonderhede van NEK Sekretariaat en Stoel: Mr. Xolile Fula
Old Main Building
Groote Skuur
Fakulteit van Gesondheiswetenskappe
Observatory
7925 APPENDIX?

CONTRACT BETWEEN RESEARCHER AND INTERVIEWER

Dear Doctor,

I am currently doing research for a M. PHIL. Degree at Cape Town University.

The aim of my study is to assess whether the level of care of patients, with life limiting illnesses, who are co-infected with TB, are receiving appropriate TB management.

I am using the qualitative descriptive method with a questionnaire as measuring instrument. An element of quantitative research will be build into the measuring instrument by coding the responses to facilitate the biostatistic processing.

Appropriate patients will be selected by myself. However, I do require assistance with the completion of the questionnaires.

Would you be prepared to interview four patients and complete the questionnaire.

You will be required to complete some of the questions from the clinical notes, some of the questions from the interview with the patient and some of the questions from an interview with the primary care giver.

If you agree to this request will you kindly complete the following;

- What is your basic qualification --
- Have you any additional qualifications --
- Pleases give them ---
- Have you any experience with the management of TB patients -------------
- If so, please state ---

I thank you for your assistance.

Interviewer------------------------------ S. R. Krause--

Signed at------------------ On -------- of ----------------- 200--

Tel: 021 4066492

Faks: 021 4066411

Appendix F

Scoring the WHOQOL-BREF

The WHOQOL-BREF (Field Trial Version) produces a quality of life profile. It is possible to derive four domain scores. There are also two items that are examined separately: question 1 asks about an individual's overall perception of quality of life and question 2 asks about an individual's overall perception of their health. The four domain scores denote an individual's perception of quality of life in each particular domain. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100. Explicit instructions for checking and cleaning data, and for computing domain scores, are given in Table 3. A method for the manual calculation of individual scores is given on page 1 of the WHOQOL-BREF assessment form. The method for converting raw scores to transformed scores when using this method is given in Table 4, on page 11 of these instructions. The first transformation method converts scores to range between 4-20, comparable with the WHOQOL-100. The second transformation method converts domain scores to a 0-100 scale.

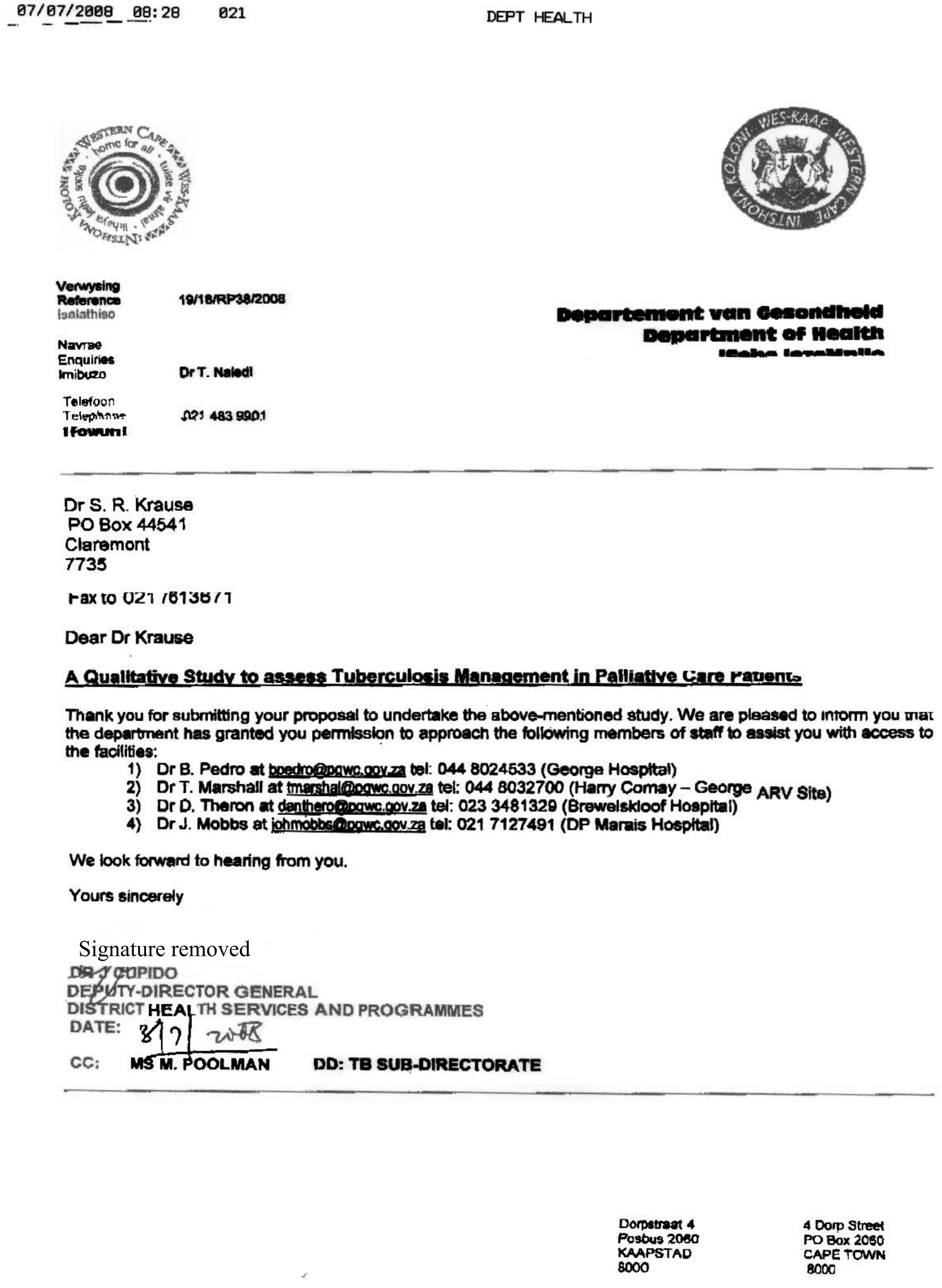
Where more than 20% of data is missing from a assessment, the assessment should be discarded (see Step 4 in Table 3). Where an item is missing, the mean of other items in the domain is substituted. Where more than two items are missing from the domain, the domain score should not be calculated (with the exception of domain 3, where the domain should only be calculated if $\leq$ 1 item is missing).

Any national items should be scored separately from the core 26 item of the BREF. During the analysis the performance of any national items will be examined for possible use in alter national studies. At this stage of field testing national and core items must not be mixed in administration or scoring of the BREF.

Table 3 - Steps for checking and cleaning data and computing domain scores

	Steps	SPSS syntax for carrying out data checking, cleaning and computing total scores
1.	Check all 26 items from assessment have a range of 1-5	RECODE Q1 Q2 Q3 Q4 Q5 Q6 Q7 Q8 Q9 Q10 Q11 Q12 Q13 Q14 Q15 Q16 Q17 Q18 Q19 Q20 Q21 Q22 Q23 Q24 Q25 Q26 (1=1) (2=2) (3=3) (4=4) (5=5) (ELSE=SYSMIS). (This recodes all data outwith the range 1-5 to system missing).
2.	Reverse 3 negatively phrased items	RECODE Q3 Q4 Q26 (1=5) (2=4) (3=3) (4=2) (5=1). (This transforms negatively framed questions to positively framed questions)
3.	Compute domain scores	COMPUTE DOM1=MEAN.6(Q3,Q4,Q10,Q15,Q16,Q17,Q18)*4. COMPUTE DOM2=MEAN.5(Q5,Q6,Q7,Q11,Q19,Q26)*4. COMPUTE DOM3=MEAN.2(Q20,Q21,Q22)*4. COMPUTE DOM4=MEAN.6(Q8,Q9,Q12,Q13,Q14,Q23,Q24,Q25)*4. (These equations calculate the domain scores. All scores are multiplied by 4 so as to be directly comparable with scores derived from the WHOQOL-100. The '.6' in 'mean.6' specifies that 6 items must be endorsed for the domain score to be calculated).
4.	Delete cases with >20% missing data	COUNT TOTAL=Q1 TO Q26 (1 THRU 5). (This command creates a new column 'total'. 'Total' contains a count of the WHOQOL-100 items with the values 1-5 that have been endorsed by each subject. The 'Q1 TO Q26' means that consecutive columns from 'Q1', the first item, to 'Q26', the last item, are included in the count. It therefore assumes that data is entered in the order given in the assessment). FILTER OFF. USE ALL. SELECT IF (TOTAL>=21). EXECUTE. (This second command selects only those cases where 'total', the total number of items completed, is greater or equal to 80%. It deletes the remaining cases from the data set).
5.	Check domain scores	DESCRIPTIVES VARIABLES=DOM1 DOM2 DOM3 DOM4 /STATISTICS=MEAN STDDEV MIN MAX. (Running descriptives should display values of all domain scores within the range 4-20).
6.	Save data set	Save data set with a new file name so that the original remains intact.

Appendix G



07/07/2008 08:28 021 DEPT HEALTH

Departement van Gesondheid
Department of Health

Verwysing
Reference
Isalathiso 19/18/RP38/2008

Navrae
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Imibuzo Dr T. Naledi

Telefoon
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IFowuni 021 483 9901

Dr S. R. Krause
PO Box 44541
Claremont
7735

Fax to 021 7613871

Dear Dr Krause

A Qualitative Study to assess Tuberculosis Management in Palliative Care Patients

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you permission to approach the following members of staff to assist you with access to the facilities:

1) Dr B. Pedro at bpedro@pgwc.gov.za tel: 044 8024533 (George Hospital)
2) Dr T. Marshall at tmarshal@pgwc.gov.za tel: 044 8032700 (Harry Comay – George ARV Site)
3) Dr D. Theron at danthero@pgwc.gov.za tel: 023 3481329 (Brewelskloof Hospital)
4) Dr J. Mobbs at johmobbs@pgwc.gov.za tel: 021 7127491 (DP Marais Hospital)

We look forward to hearing from you.

Yours sincerely

Signature removed

DR J CUPIDO
DEPUTY-DIRECTOR GENERAL
DISTRICT HEALTH SERVICES AND PROGRAMMES
DATE: 8/7/2008

CC: MS M. POOLMAN DD: TB SUB-DIRECTORATE

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CAPE TOWN
8000

St Luke's Hospice*
Accredited to the Hospice & Palliative Care Association of SA

3 June 2008

To Whom it May Concern

We herewith officially give permission to Dr Rene Krause to conduct her research called

> " A Qualitative Study to explore Tuberculosis Management in Palliative Care Patients in the Western Cape"

at our St Luke's Hospice Lentegeur Ward situated on the grounds of Lentegeur Hospital.

We wish her well with the research and are convinced that St Luke's Hospice will be able to benefit from the findings and recommendations of the research.

Signature removed

PRISCILLA NELSON
HOSPICE MANAGER

Branches at:
Athlone
City Bowl/Atlantic
Constantiaberg/Hout Bay
False Bay
Grassy Park
Guguletu
Khayelitsha
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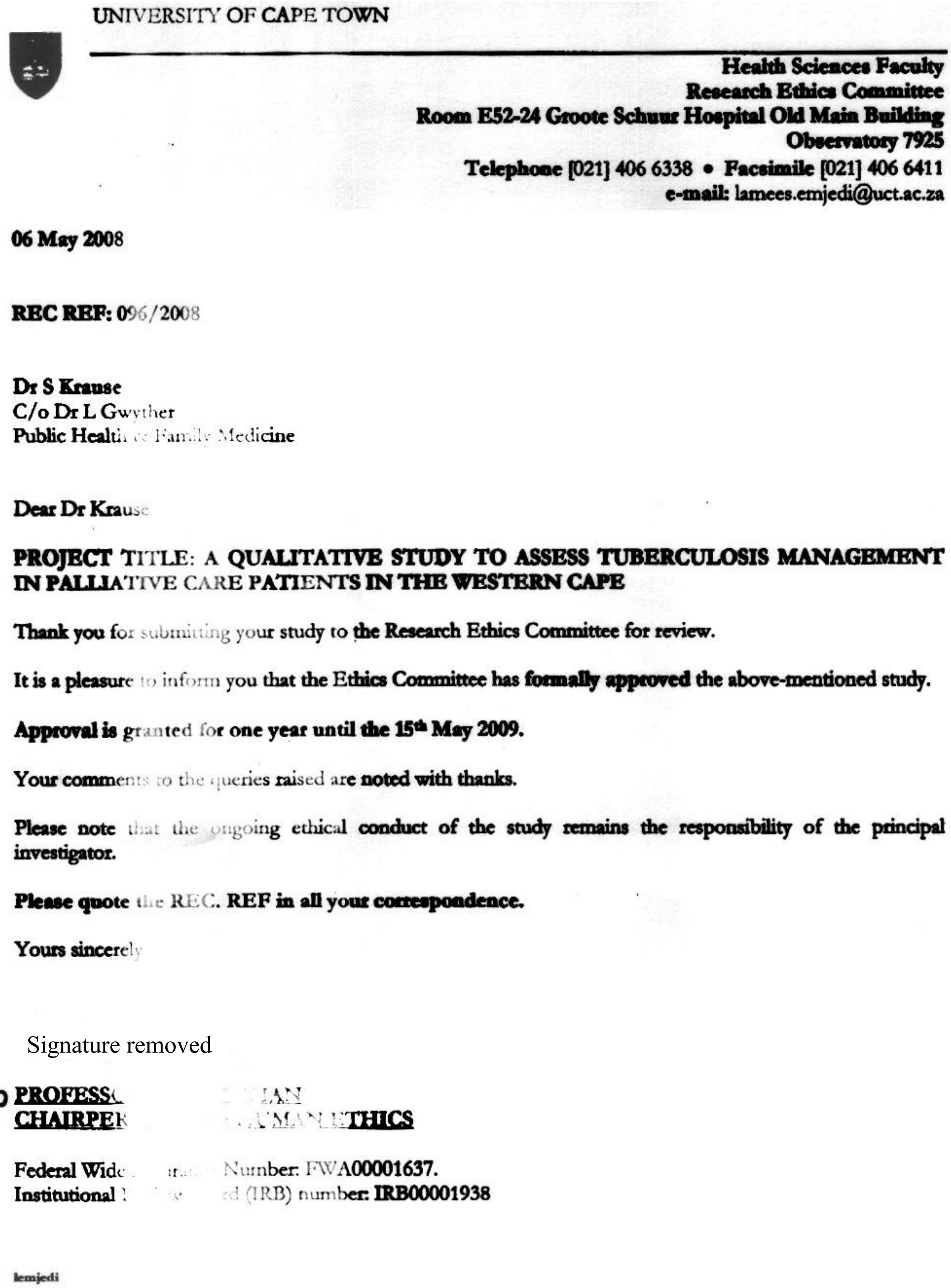
Association incorporated under Section 21
NPO 007-350/9399

Appendix H



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06 May 2008

REC REF: 096/2008

Dr S Krause
C/o Dr L Gwyther
Public Health & Family Medicine

Dear Dr Krause

PROJECT TITLE: **A QUALITATIVE STUDY TO ASSESS TUBERCULOSIS MANAGEMENT IN PALLIATIVE CARE PATIENTS IN THE WESTERN CAPE**

Thank you for submitting your study to the Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for **one year until the 15th May 2009.**

Your comments to the queries raised are **noted with thanks.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. **REF in all your correspondence.**

Yours sincerely

Signature removed

pp **PROFESS** [illegible] **IAN**
CHAIRPER [illegible] **UMAN ETHICS**

Federal Wide [illegible] Number: FWA00001637.
Institutional [illegible] (IRB) number: **IRB00001938**

lemjedi