

AN EVALUATION OF THE PALLIATIVE CARE-RELATED

OUTCOMES OF A COHORT OF TB PATIENTS IN A

DISTRICT HOSPITAL SETTING: A MULTIPLE METHODS

QUALITY IMPROVEMENT STUDY

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Kathleen Mary Defilippi

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ABSTRACT

Background

Although curable, tuberculosis (TB) remains a serious health care problem. During 2011 there were almost 9 million new cases and 1.4 million TB deaths worldwide. The World Health Organisation (WHO) lists South Africa as a country with a high TB, HIV and MDR-TB burden. In this country the dual TB/HIV epidemic which has reached critical proportions is fuelled by the high TB/HIV co-infection rate.

By definition the focus of palliative care is on the alleviation of suffering associated with life-limiting illnesses. TB clearly falls into this category. The palliative care-related outcomes of a cohort of hospitalized TB patients were determined during this prospective longitudinal study and a quality improvement strategy was then generated from the audit data.

Methods

The APCA POS, a validated outcome measurement tool was used to conduct weekly interviews. The audit sample comprised 57 patients with MDR-TB and 57 with drug responsive TB (n=114). The intensity of the multi-dimensional palliative care-related problems experienced by TB and MDR-TB patients on admission as well as the differences that occurred over time were measured over four consecutive weeks.

In order to get staff perspectives on using the audit data to develop a quality improvement strategy, a report on the analyzed audit data formed the basis of a focus group discussion (FGD). The purposive sample of FGD participants included key members of staff from the TB and MDR TB wards.

Results

Audit findings indicated that on admission to hospital the predominant problems were pain, symptoms and worry. On a Lickert scale of 0-5 with 0 indicating best and 5 worst, the median score for both pain and other symptoms was 3.0, with an inter-quartile range of 2.00-4.25. Participants' worry about their illness attained the worst median baseline score of 4.0. Neither pain nor symptoms showed any sustained improvement over the four weeks of data collection. A statistically significant improvement in worry which moved from 4.0 to 2.0 occurred after week 1 but then remained static. An unexpected crucial finding was that the collective score for participants with drug responsive TB was worse than for those with MDR-TB for both the physical and psycho-social components, and at each time point. Using the APCA POS audit data as the basis of a FGD with key staff members resulted in the development of an appropriate palliative care-focused quality improvement strategy which they considered to be realistic and achievable within their busy hospital setting.

Conclusion

Findings from this study support the recent WHO Declaration on the provision of palliative care for people with drug-resistant TB. Furthermore they clearly show that patients with drug responsive TB should not be excluded from a comprehensive palliative care person-centred approach. Palliative care within the context of TB is still an emerging concept. This study makes a meaningful contribution to the scarce information currently available. The topic is important in that the suffering experienced by vast numbers of TB patients and their families could and should be substantially relieved. It is suggested that it would be valuable to explore the impact of a palliative care approach on TB treatment outcomes.

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LIST OF ACRONYMS AND ABBREVIATIONS

APCA – African Palliative Care Association

APCA POS – African Palliative Care Association African Palliative Outcome Scale

ARVS – Anti Retro Virals

CEO – Chief Operating Officer

COHSASA – Council for Health Care Accreditation of Southern Africa

Dr – Medical Doctor

FBO – Faith Based Organisation

FGD – Focus Group Discussion

HAART – Highly Active Anti Retro-Viral Treatment

HIV – Human Immuno Virus

HIV+ - Human Immuno Virus positive

HPCA – Hospice Palliative Care Association

IQR – Inter Quartile Range

KZN – KwaZulu-Natal

MDG – Millenium Development Goals

MDR-TB – Multi Drug Resistant Tuberculosis

NGO – Non-Governmental Organisation

PC – Palliative Care

POS – Palliative Outcome Scale

QI – Quality Improvement

STAS – Support Team Assessment Schedule

TB – Tuberculosis

WHO – World Health Organisation

WPCA – Worldwide Palliative Care Alliance

XDR-TB – Extensively drug resistant tuberculosis

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INTRODUCTION

This study was prompted by the magnitude of the tuberculosis (TB) epidemic in South Africa and around the world, in terms of the following:

- Sheer size of the problem
- HIV/TB co-infection rate
- Increase in drug-resistant TB
- High burden of symptoms experienced by TB patients
- Poor cure rate
- Substantial mortality rate associated with drug-resistant TB
- Need for palliative care within the context of TB ¹⁻⁵

Background

In order to halt and reverse the TB epidemic, in 1993, the World Health Organisation (WHO) declared TB to be a global public health emergency and in 2000, the United Nations Millennium Development Goals (MDGs) adopted by all nations included global TB health care targets aimed at halving the incidence, prevalence and deaths from this disease by 2015.¹ The latest WHO report states that the global MDG TB health targets have already been achieved but warns that “global progress also conceals regional variations” and the African and Eastern

European Regions are not on track to halve 1990 mortality levels by 2015.² The HIV/TB co-infection rate is largely responsible for this unfortunate scenario, almost 80% of the HIV infected people with TB in the world live in Africa.^{3,6} TB remains a serious health problem. During 2011 there were almost 9 million new cases reported and 1.4 million TB deaths worldwide.²

Progress in responding to drug-resistant TB remains slow and the number of MDR-TB cases in the 27 WHO high-burden countries is increasing and reached almost 60 000 in 2011.^{2,7} Extensively drug resistant tuberculosis (XDR-TB) has been reported by 84 countries and accounts for an average of 9% of people with MDR-TB.^{2,4,8} Every year tuberculosis still takes a huge toll in terms of unnecessary deaths, especially for poor and vulnerable people who are most at risk and have the least access to quality health care.⁹

WHO lists South Africa as a country with a High TB Burden, High HIV Burden and High MDR-TB Burden, the 27 high-burden countries currently account for over 80% of the world's TB cases. The 2012 WHO Global Tuberculosis report states that India, China, the Russian Federation and South Africa have almost 60% of the world's cases of MDR-TB. Overall, the African Region carries 24% of the global TB burden and has the highest rates of cases and deaths per capita. In 2011 the population in South Africa was estimated at 50 million with a TB incidence of 993 per 100 000. This figure includes 5000 new and 3100 retreatment MDR-TB cases with 65% of the TB patients in whom HIV status was known co-infected with HIV.²

Study summary

This study was divided into two phases. A measurement of the palliative care –related problems experienced by hospitalized TB patients admitted to a rural District Hospital formed the focus of the first phase. A validated outcome measurement tool, the APCA (African Palliative Care Association) African POS (Palliative Outcome Scale) was used for this purpose. The APCA POS was rigorously validated and found to be suitable for use within the resource-constrained African context. This brief multi-dimensional outcome measure uses patient and family-level indicators that could be used in the routine clinical practice of palliative care. The tool is simple and easy to use and was developed so that it could be applied so that the quality of care provided could form part of a continuous improvement strategy that could be used to inform daily practice. Because of varying levels of literacy in Africa, the APCA POS is administered by a health care worker.^{10, 11}

The prevalence and intensity of the multi-dimensional physical, social, emotional and spiritual problems of hospitalized TB patients in a rural District Hospital in KwaZulu-Natal were identified and measured on a weekly basis for four consecutive weeks. Data was collected on a weekly basis. The first interview took place on a Tuesday and included participants admitted to the hospital on that day or during the previous 7 days. The following three interviews were conducted on consecutive Tuesdays for the following three weeks. The vast majority of the audit interviews were conducted in isiZulu by the research assistant, an experienced Zulu-speaking palliative care trained professional nurse.

Phase 1 findings

Audit findings indicated that the predominant problems experienced by participants on admission to hospital were pain, symptoms and worry. For both pain and symptoms, on a Lickert scale of 0-5 with 0 indicating best and 5 worst, the median score was 3.0, with an inter-quartile range of 2.00-4.25. The question regarding worry about their illness attained the worst median baseline score of 4.0. Neither pain nor symptoms showed any sustained improvement over the four weeks of data collection. Worry did show a statistically significant improvement after week 1 but then no further change.

An unexpected finding was that the scores for participants with drug responsive TB were worse than for those with MDR-TB with regard to both the physical and psycho-social components at each time point. Almost three times as many deaths occurred in this patient population. This finding does, however, need to be considered within the context of drug responsive TB being predominantly managed in the community. As a result only patients with advanced illness or severe problems are admitted to hospital.

Phase 2 findings

During the second phase of the study, data obtained from this audit of 114 TB patients, half of whom (57) were diagnosed with MDR-TB and half with drug responsive TB, were reviewed by key staff members in a focus group discussion (FGD). The FGD participants used the audit findings, particularly the predominant problems of pain, symptoms and worry to generate an appropriate palliative care-focused quality improvement strategy.

Importance of this study

Palliative care within the context of TB is still an emerging concept. It is hoped that this study will make a meaningful contribution to the scarce information currently available on a topic of great importance that could substantially relieve the suffering experienced by vast numbers of TB and MDR-TB patients and their families.⁵ It is the first study to demonstrate the palliative care-related needs and outcomes of this patient population. As such it has responded to the urgent call in the literature.^{10, 12, 17, 52, 64} By including the development of a quality improvement strategy within the context of TB, it will support the existing Guidelines for Providing Palliative Care to Patients with Tuberculosis. These guidelines have recently been translated into Portuguese and French.⁵

LITERATURE REVIEW

Perceptions about palliative care for people with tuberculosis

Because the provision of palliative care for people with TB is still in an early developmental phase, no studies on the specific subject of this research were located. Several publications that mention the term palliative care in relation to TB were reviewed.¹²⁻¹⁵

Palliative care at the end of life

Authors of these articles mentioned in the paragraph above all acknowledge the value of palliative care at the end of life when curative treatment has been shown to be futile. Harding et al focus on the life-threatening nature of MDR and XDR-TB and describe the 'burden of disease management in terms of symptoms, adverse treatment effects, adherence, stigma and subsequent discrimination and social isolation' to demonstrate the need for holistic care. They assert that to date the relief of suffering has, for the most part, been restricted to physical aspects. The existing WHO definition of palliative care is appropriate for patients with drug-resistant TB in that it aims to improve the quality of life for individuals as well as their families, and advocates for palliative care alongside treatment.²¹

It is proposed that the WHO definition allows for the provision of palliative care to patients with drug-resistant TB from the point of diagnosis to eventual cure or death.¹² After drawing attention to the fact that the prognosis of XDR-TB patients can range from several weeks to years, Dheda and Migliori suggest that because of the lack of palliative care facilities patients are unable to die with dignity, in particular those for whom there are no further therapeutic options. They suggest that priority should be given to building 'palliative care treatment facilities' that would prioritize infection control and function like the sanatoria that existed prior to the availability of effective TB treatment.¹³ The terminology 'embracing palliative care' is used by Upshar et al as an endorsement of the palliative care mantra that withdrawing futile treatment does not mean withdrawing care and actually indicates the need for care to increase and include meticulous attention to the control of pain and other symptoms. They advocate for palliative care to be offered to all XDR-TB patients who no longer qualify for active treatment so that they are permitted to live their lives out with minimal suffering and loss of dignity.¹⁴

Palliative care throughout the disease trajectory

The apparent focus of the literature on end-of-life care may be attributed to the fact that modern palliative care was introduced fairly recently and initially focused on the provision of end-of-life care¹⁶, and that perceptions about palliative care being limited to care of the dying have not yet substantially changed. In welcoming the WHO declaration regarding the systematic inclusion of competent palliative care services in TB treatment programmes, Connor et al suggest that current TB policy and strategy should make a more explicit reference to palliative care.¹⁷ Palliative care has always been comprehensive in the approach to patients.

It was initially focused on dying cancer patients but has gradually broadened its scope to include other life threatening diseases including AIDS.^{17, 18} Co-infection of TB and HIV as well as the rise in drug-resistant TB and its high mortality has highlighted the need for palliative care for this patient population.^{6,12,13} Abiding by the principle of impeccable management of holistic patient and family needs is as applicable to end-of life care as to palliative care which is provided early in the disease process. Furthermore, palliative care may continue to be provided throughout an extended course of a chronic life-threatening disease, regardless of the prognosis.^{13, 16, 18} The control of pain and other distressing symptoms along with an accompanying emphasis on the quality of life, the value of life and the meaning of life are the hallmark of palliative care throughout the disease trajectory.^{19,20} This is in alignment with definitions of palliative care by the WHO and the Worldwide Palliative Care Alliance which both state that it is applicable from the time of diagnosis and throughout the course of any life threatening illness.^{21, 18}

Palliative care improving survival outcomes

Although the focus of palliative care is about adding life to the remaining days rather than days to the remaining life, practitioners have long held the anecdotal opinion that this holistic approach to care contributes to improved outcomes in terms of survival. A recent study conducted by Temel et al in the United States which demonstrated that in addition to better quality of life, the median survival was longer among patients with metastatic non-small-cell lung cancer who received early palliative care than those receiving standard care, supports this notion.²²

Comparable aspects of palliative care for HIV/AIDS and TB

A systematic review by Harding et al²³ to appraise the effect of models of palliative care on patient outcomes utilised data from published papers involving 34 services. Their study demonstrated that patients with HIV infection require palliative care throughout the disease trajectory in order to control pain and symptoms, promote treatment adherence and manage the side effects of treatment. They reached this conclusion because of the following five key factors:

1. The mortality rate of HIV infected patients including those on highly active antiretroviral treatment (HAART) continues to be higher than in the uninfected.
2. HAART is associated serious side effects such as peripheral neuropathy.
3. New co-morbidities such as end stage liver disease secondary to hepatitis, myocardial infarction and various neurological disorders have come about due to a longer prognosis.
4. Some HIV-related carcinomas including cancer of the cervix have not declined in incidence with HAART.
5. Many HIV infected people do not know their status and only present with advanced disease.²³

The need for holistic care

In another review the same authors made the pivotal point that “optimal care for those with HIV disease continues to be a priority alongside prevention and treatment, and the provision of HIV/AIDS medical care focusing on the purely technical elements of HAART would be detrimental to both patients and carers”.²⁴ In their protocol for a study currently underway in

Kenya and South Africa, Lowther et al reiterate this concept by suggesting that effective treatment for the virus might not be enough to alleviate the suffering experienced by HIV infected people.²⁵ They based this statement on findings of studies conducted in Brazil,²⁶ the United States,²⁷ South Africa²⁸ and Malawi.²⁹

There is a strong case for assuming that these findings related to HIV infection would be mirrored in respect of TB. This assumption is strengthened by the high HIV/TB co-infection rate and the fact that TB remains the leading cause of death in HIV infected patients in South Africa and at 53%, the highest number of TB deaths, are attributable to HIV.³ In addition to the pain and symptoms associated with the disease process of tuberculosis which is often exacerbated by HIV co-infection, distressing side effects of treatment have been documented.

Side effects of TB treatment

In a retrospective record review of a substantial sample of 350 outpatients at the MDR-TB clinic King George V Hospital in Durban, Jacobs and Ross reported adverse events in 80.6% of the patients. These included hearing loss (28.7%); peripheral neuropathy (23.2%); diarrhoea, nausea and vomiting (20.5%); rashes and dermatological effects (other than Stevens-Johnson syndrome, (no reason was given for the exclusion of Stevens-Johnson syndrome) (14%); abdominal pain and dyspepsia (10.3%); and psychoses and confusion (8.3%).³⁰ An HIV/TB co-infection rate of 74.5% was reported in this study in KwaZulu-Natal where the estimated provincial HIV prevalence in the general population was 24.9% in 2010. In keeping with Harding's finding, there was no statistically significant difference in the

development of adverse events in HIV+ patients who were on HAART and those who were not.^{24, 25}

Although treatment of the side effects was not included in the record review, it can be extrapolated from the findings that effective symptom control related to the side effects of treatment would be beneficial to MDR-TB patients. Additionally, if these patients were offered palliative care they would be likely to benefit from an overall improved quality of life.^{5,18}

Focus of TB literature

The bulk of the current TB literature focuses on treatment outcomes and how these can best be attained. This is in line with what Harding et al referred to as the 'purely technical aspects of HAART' in relation to the treatment of HIV infection.²⁴ In general, scant attention has been given to the person with tuberculosis and how the disease and treatment is affecting his/her quality of life and that of the person's family.^{31,32} There are, however, a number of exceptions, Yew et al acknowledge that psychosocial support is an important element in the management of adverse events and that education, counseling and encouragement can all contribute towards achieving successful patient outcomes in terms of treatment adherence.³³ In a US study published in 2009 Miller et al made the point that people who are cured of TB are 'left with lifetime sequelae that substantially reduce their quality of life'.³⁴ These consequences of TB are likely to be exacerbated in the resource-constrained African setting where large numbers of vulnerable people do not have access to affordable services of sufficient quality.⁹ This view is echoed by Hanson et al who refer to the enormous direct and indirect costs associated with tuberculosis in terms of the social consequences for the individual patient,

family and community.^{35,36} An Indonesian study which investigated the social aspects of patients with pulmonary tuberculosis found that socio-economic constraints and social problems were serious and common. They recommended that priority should be given to developing programmes aimed at providing family support.³⁷

All the psycho-social aspects mentioned by the authors cited in the previous paragraph resonate with the practice of palliative care, in concert with the resolution of pain and other distressing physical symptoms.^{38, 39}

Value of care in terms of TB treatment outcomes

It is important to note that these 'soft' issues are important both in terms of patient care and disease outcomes within the context of TB. This was demonstrated by an MDR-TB programme run by Medecins Sans Frontiers in Khayelitsha in which a patient-centred decentralized model of care increased case finding and improved treatment outcomes thereby reducing further MDR-TB transmission.⁴⁰

Using audit results to improve the quality of palliative care

In keeping with Crombie et al's definition of audit as *the process of reviewing the delivery of care to identify deficiencies so that they may be remedied*⁴¹ the second phase of this study is focused on using audit results to develop a strategy to improve the quality of palliative care. According to Selman and Harding clinical audit is a cyclical activity. The first phase involves the identification of areas that need improvement by analyzing data obtained from the administration of an appropriate and validated questionnaire. This should be followed by

setting measurable quality of care targets in specific areas, designing and implementing quality improvement strategies and then re-evaluating the quality of care using the same questionnaire to assess progress in meeting the targets.⁴² Generically, quality of health care has been described as the extent to which health services provided to patients improve desired health outcomes.⁴³

Outcomes

Outcomes can be understood as any end result that can be attributed to a targeted health intervention.^{42, 43} Making use of a patient outcome scale is relevant because it measures the results of care directly, as experienced by patients.⁴² Measures of quality of care and patient or family satisfaction have increased in use over the last two decades. According to Heyland et al in the field of palliative care, however, lack of valid and reliable measures makes their use uncommon.⁴⁴ The goals of palliative care include improving health-related quality of life as well as spirituality, coping with loss and grief and family involvement, it follows that palliative care outcome measures need to reflect this.⁴⁵

Palliative care outcome measures

In 1986 Higginson and her colleagues from Kings College in London headed up the development of the Support Team Assessment Schedule (STAS) which was constructed to evaluate the palliative care provided by support teams. This was the precursor to the Palliative Outcome Scale (POS) which was developed in 1999.⁴⁶ In a systematic review undertaken by

Bausewein et al the point that STAS was developed for exclusive use by health care professionals is made. The POS, however, has a staff and patient version. A further development of the POS is the addition of a symptom list (POS-S). Adapted versions of POS-S have been used in patients with multiple sclerosis and renal failure. Both of these palliative care outcome measures were originally validated in patients with advanced cancer and most studies using STAS reflect this. The POS, however, has recently been increasingly used in non-cancer patients and there are plans to develop a modular system with different symptom lists adapted for different conditions.⁴⁷ In a study examining the internal factor structure of the POS, Siegert et al concluded that the POS appears to capture emotional status and quality of care as well as three items that function independently namely family anxiety, symptoms and pain control.⁴⁸ Together with colleagues from Columbia University, Krug conducted a study to compare the self-assessments of late-stage HIV/AIDS patients regarding their symptomatology and sense of self-worth, to assessments completed by their informal caregivers. They found that there was substantial to moderate agreement to four items assessing physical and emotional status and only fair to slight agreement to the remainder, including those assessing the patient's sense of self-worth, family/friends' anxiety, interactions with family/friends and practical matters. These findings underscore the importance of assessing patient care outcomes directly and suggest that more effective communication about relevant health issues among seriously ill patients and their informal caregivers and health care providers is needed.⁴⁹ This was echoed by Stevens et al in an earlier study which found that at the initial assessment, staff underestimated patients' pain and overestimated problems related to information giving and patients' ability to share their feelings.⁵⁰ In a challenging article in which Baldwin et al describe the impact of the social media on patient empowerment, they argue for

the inclusion of a separate definition for patient reported information and describe how this differs from patient reported outcomes. They suggest that these new emergent data from the social web have important implications for decision making as well as for changing the relationships between health care providers and patients.⁵¹ Social media is already having an impact on health in the developed world and is probably poised to do the same in Africa.

Measuring palliative care outcomes in sub-Saharan Africa

In an appraisal of the status of palliative care in Africa conducted on behalf of the Diana Princess of Wales Memorial Fund in 2004, Harding and Higginson stated that for the overwhelming majority of Africans who currently endured cancer, HIV/AIDS and other life-limiting diseases, access to culturally appropriate holistic palliative care that included effective pain management was 'at best limited and at worst nonexistent.'⁵² Not surprisingly the need for increasing the access and coverage of palliative care without comprising on quality was identified as a primary concern among palliative care practitioners in the region.¹¹ However, measuring the actual quality of care provided was problematic without having rigorously validated outcome measures that reflected the disease profile on the continent and were suitable for use within the resource-constrained and culturally different African context. The focus of the POS which was widely used in the first world was on measuring the patients physical symptoms, psychological, emotional and spiritual needs, and the provision of information and support at the end of life.^{53,54} The APCA POS, a brief multi-dimensional outcome measure using patient and family-level indicators that could be used in the routine clinical practice of palliative care was developed specifically for use in the African context.^{10,}

This tool was developed under the auspices of APCA by a multi-professional expert group that included appropriately experienced local and international palliative care practitioners including two from South Africa. It was informed by but significantly adapted from the original POS.⁴⁶ The group deemed it important for a palliative care measurement tool for use in Africa to be locally validated, appropriate for both cancer and HIV infected patients and to be relevant across the disease trajectory.⁴² While scientific principles underpinning palliative care outcome measurement are transferable it is essential that outcome measures reflect the prevailing illnesses and culture.⁵⁵

Validation of the APCA POS

The study which subsequently validated the APCA POS and had it translated into 8 different languages, including isiZulu, concluded that it had sound psychometric properties, was well comprehended, and brief and easy to use. Owing to the varying levels of patient and family literacy in Africa, the APCA POS is completed by a member of staff.^{10,11} All answers are scored using Likert scales from 0-5, with numerical and descriptive labels. The items address physical and psychological symptoms, spiritual and emotional concerns as well as psychosocial needs. The APCA POS measures the key domains of palliative care which include pain and symptom relief, emotional/spiritual support and grief counseling, support for family caregivers and advanced care planning.^{10, 11} It was necessary for the tool to be simple and easy to use so that progress achieved in the quality of care provided could form part of a continuous improvement strategy that could be used to inform daily practice.⁵⁶

Linking audit findings to quality improvement

According to Scally and Donaldson, a commitment to deliver high quality care should be at the heart of everyday clinical practice.⁵⁷ In terms of the clinical audit cycle described above setting targets for quality improvement is the step which follows the gathering of patient outcome data.⁴² Dunckley et al endorse the value of clinical audit in providing an evidence base for service development and emphasise its importance in resource-limited settings where it is essential that limited health care resources are used in an effective and efficient way. Their study identified a top-down approach, time constraints, limited access to resources for data analysis, perception of irrelevance to practice and lack of knowledge about the importance of outcome measures, as barriers to their routine implementation. Participative management, use of a brief outcome measure at an appropriate (not too often) frequency, linkage to a research resource and staff training were identified as facilitators.⁵⁸ In similar vein Johnston et al suggest that whilst clinical audit could provide valuable assistance to programmes aiming to improve the quality of health care delivery, it is necessary to address the concerns of the professionals involved.⁵⁹

Organisational factors that affect quality improvement initiatives

The Council for Health Service Accreditation of Southern Africa (Cohsasa) decrees that the quality improvement process should be consistent with the organisations' mission and plans; meet the needs of patients, families, staff and others; and make use of current clinical practice guidelines and other relevant evidence-based information. The use of a validated audit tool to improve the quality of care has been included as a criterion in the Quality Management and

Improvement service element in the second edition of the Hospice Palliative Care Standards.⁶⁰ According to Walshe and Freeman the organisational context is a crucial determinant of the effectiveness of quality improvement initiatives. Some organizational cultures seem to provide fertile ground for quality improvement because of a fit with their organizational values whilst others simply do not.⁶¹⁻⁶³ One of the reasons for selecting Murchison Hospital as the site for this research is that the facility is committed to the provision of quality care and actually lists commitment to performance and quality improvement as one of its core values. In 2002, this 260-bed hospital was the first KwaZulu-Natal hospital to achieve Cohsasa accreditation at its first attempt. It is therefore anticipated that the organisational culture will be conducive to quality improvement.

Importance of this study

This is the first study to report the needs and outcomes of this patient population in response to the urgent call in the literature.^{12, 17, 52, 64} By including the development of a quality improvement strategy within the context of TB it will support the existing Guidelines for Providing Palliative Care to Patients with Tuberculosis. These guidelines have recently been translated into Portuguese and French.⁵

AIM

The aim of this study is to determine the palliative care outcomes of a cohort of hospitalized TB patients, and to generate a quality improvement strategy from the data.

OBJECTIVES:

1. To measure the prevalence and intensity of multi-dimensional problems among TB patients on admission to the hospital TB and MDR-TB wards
2. To conduct an audit of palliative care outcomes for study participants to determine whether there is a difference in the prevalence and intensity in the problems experienced between TB and MDR-TB patients on entry to the hospital
3. To measure change in problem intensity over time (4 x weekly interviews)
4. To convene a quality improvement focus group discussion with key members of staff selected from the TB care sites in order to use the data from objectives 1-3 to generate a quality improvement strategy
5. To report on the development of a palliative care-related quality improvement strategy.

METHODOLOGY

STUDY DESIGN

This is a multiple methods prospective longitudinal study. The quantitative data obtained from auditing the palliative care-related needs and problems of a cohort of hospitalised TB patients was used to develop a quality improvement strategy.

The study was divided into two phases. The first phase of the study dealt with the determination of the palliative care-related outcomes in a cohort of TB patients. This was linked to the second phase during which qualitative data was collected via a focus group discussion with key staff members from the TB care sites. The aim of phase two was the generation of a palliative care-related quality improvement strategy based upon the audit findings.

In this chapter the methods related to each phase will be reported separately.

PHASE 1:

AUDIT OF THE PALLIATIVE CARE-RELATED PROBLEMS EXPERIENCED BY A COHORT OF HOSPITALISED TB PATIENTS

OBJECTIVES:

1. *To measure the prevalence and intensity of multi-dimensional problems among TB patients on admission to the hospital TB and MDR-TB wards*
2. *To conduct an audit of palliative care-related outcomes for study participants to determine whether there is a difference in the prevalence and intensity in the problems experienced between TB and MDR-TB patients on entry to the hospital*
3. *To measure change in problem intensity over time (4 x weekly interviews)*

Protocol amendments

The following two amendments to the original protocol were approved during the sixth week of data collection:

1. During weekly visits to Murchison Hospital to conduct an audit interview with participants who have given informed consent - *collect additional data by asking the professional nurse in charge of each of the TB wards whether any TB patients died in the ward during the preceding week.*
2. *Add “considered to be too ill to approach with study information” by either the professional nurse in charge of the ward or the researcher to the exclusion criteria for participation in the study.*

The rationale for making these changes and collecting the additional data was that patients who had been admitted and died during the week or had been considered too ill to approach with study information could have benefited from palliative care.

Description of study site/s

Audit interviews were conducted at the TB and MDR-TB Wards of Murchison Hospital and two satellite facilities the Dunstan Farrel TB Hospital in Hibberdene and Genesis Care Centre in Port Shepstone, and in a few instances in the homes of participants who had been discharged.

On average 45 TB patients are admitted and treated in the hospital each month, 30 of these patients are admitted to the TB ward and 15 to the MDR-TB wards. Some of the patients from both sections may go back and forth to one of the two satellite facilities during the intensive phase of treatment. Patients are also sometimes sent straight home. The average length of stay in the TB ward is 22 days and in the MDR-TB ward it is 66 days. Criteria for admission to the TB ward include that a patient must have a confirmed diagnosis of pulmonary TB and have been started on first line TB treatment either in Casualty or the Outpatient Department. For admission to the MDR-TB ward patients have to be culture positive with a resistance to Isoniazid (INH) and Rifampicin. When bed availability is problematic preference is given to patients with social problems in both sections.

All the wards are well ventilated. The TB ward at the hospital is rather crowded with limited space between beds and little opportunity for sitting outside. The male and female MDR-TB wards are much more spacious. There is also a roofed outdoor sitting area attached to the MDR-TB section with a lovely view. This was, however, hardly used by patients during the time

that the researchers were present as almost all the mobile MDR-TB patients gathered at the fence which overlooks the road in the hope of seeing a relative or friend coming to visit them. A number of the audit interviews were consequently conducted on this verandah which the researchers preferred to the wooden and not nearly as well ventilated Wendy House office which they were offered. The remaining MDR-TB patient interviews and all the interviews in the TB ward were conducted at the bedside of consenting participants.

The Murchison and Dunstan Farrel Hospitals are state health facilities. The Genesis Care Centre is a faith based organization (FBO) which provides in-patient care and a Step Down service to Murchison and Port Shepstone Hospital, the two provincial hospitals serving the area. The patients who were visited at home were on the South Coast Hospice home care programme, the hospice is a non-Governmental organisation (NGO),

Infection control

There was consistent evidence of the implementation of effective infection control during the 32 weeks of data collection. Researchers were given a N95 respirator on arrival and told to put it on before entering the patient care section of the ward. Hand washing facilities were adequate and meticulous attention was paid to hygiene, particularly in the MDR-TB wards.

Ethical considerations

Permission to conduct the study

The UCT Faculty of Health Sciences Human Research Ethics Committee granted approval for the study on 14 May, 2012. (Appendix 1) This, together with the research proposal was given to the UGU District Health Manager who wrote a letter of support and forwarded the study proposal to the KwaZulu-Natal Research Committee. By the end of May permission to conduct research at the two state health care facilities, the Murchison and Dunstan Farrel Hospitals had been received. (Appendix 2) A letter from the CEO of the Genesis Care Centre indicated that the organization was willing to be included as a study site (Appendix 3).

Process

Once the required permission had been obtained to proceed with the study the following occurred:

- An experienced palliative care qualified Zulu-speaking professional nurse from the local hospice was appointed as research assistant for this phase of the study.
- The hospice was advised about submitting invoices so that the organisation could be reimbursed for her time from the study budget
- The research assistant was given a copy of the research proposal and training which focused on:
 - orientation to the study design
 - sharing information via the participant information leaflet

- obtaining informed consent and giving participants the option to withdraw consent at any stage
 - completion of the data collection tool (APCA POS) using the English or isiZulu translation that had been done during the validation process
 - confidentiality and the allocation of study numbers in place of names on the data collection forms
 - the need to be continuously mindful of the need to protect and show respect to vulnerable participants so as to lessen the “power imbalance” that exists between a health care professional as the researcher and TB patient as the participant ⁶⁵
 - implementation of the distress protocol.
- In liaison with the CEO, a senior psycho-social professional at South Coast Hospice was approached, told about the study and agreed to her name and contact details being included in the distress protocol.

Preparatory visits were then made to all the sites by the researcher and her assistant. Study information was shared verbally with key staff members who were also given a written copy of the protocol. It was agreed that Tuesday mornings would be a mutually convenient time for the audits to take place. Data collection duly commenced on 26 June, 2012 at Murchison Hospital.

Privacy/confidentiality

Participant confidentiality was safeguarded by having no personal identification information documented on the for

m. Only blank questionnaires containing demographic data and the study number were in the possession of the research assistant.

Obtaining informed consent

On arrival, a professional nurse on duty in each of the wards gave the researchers the names and bed numbers of new patients who had been admitted during the preceding week whom he/she considered well enough to approach with the study information. She/he was asked how many deaths had occurred during the week and the number of new patients who were considered to be too ill to approach and these figures were noted by the researcher. In a few instances the researchers decided that a patient whose name they had been given was too ill to be disturbed and that person was not given the study information. All potential participants who met the inclusion criteria were assured that learning about the study was voluntary and that choosing to learn about the study and then deciding not to participate would also have no impact on their care. Those who were interested were given information about the study in the language of their choice (isiZulu or English) by the research assistant (Appendix 4). It was made clear that there was no direct personal reward for participating in the project but that it was hoped that their participation would lead to better care for all TB patients in the future. Those wishing to participate then signed consent (Appendix 5) all the participants accepted the offer of being given a written copy of the information leaflet, in some instances saying that they would keep it for a family member who could read. Participants were reminded that they could withdraw at any time during the study and the distress protocol was explained. At each consecutive interview consent was verbally verified prior to the administration of the APCA POS questionnaire (Appendix 6). After completing the fourth consecutive weekly interview the research assistant thanked the participant and informed them that she would not be interviewing them again the following week.

Family members

Participants were asked to consent to the interview of a family member whom they had identified to participate in the study, the family member would then be informed about the study and asked to sign consent. . However, because so few family members were available in the hospital setting, with only 7 interviews conducted with a family member this data was not included in the study.

DATA COLLECTION

Table 1 on the next page indicates the data that is required for each of the objectives for the first phase of the study and the methods for collecting, analyzing and presenting this.

University of Cape Town

TABLE 1: DATA COLLECTION PLAN FOR PHASE 1

OBJECTIVE	METHOD	DATA
To measure the prevalence of multi-dimensional problems on admission	Administer APCA POS questionnaire within the week of admission to hospital. Compile table of combined baseline scores for each question.	1. Intensity of pain 2. Intensity of other symptoms 3. Level of worry 4. Ability to share feelings 5. Feeling of life being worthwhile 6. Feeling at peace 7. Enough help and advice for family to plan for future
To conduct an audit of palliative care-related outcomes to determine whether there is a difference in the prevalence and intensity in the problems experienced between TB and MDR-TB patients on entry to the hospital	Document TB status so as to be able to differentiate between TB and MDR-TB participants. Compile table showing multi-variate analysis for total POS score	As above (all 7 patient-related items listed on APCA POS)
To measure change in problem intensity over time	Conduct APCA POS interviews on a weekly basis over four consecutive weeks. Indicate the data collected at each time period in a box plot for each APCA POS item.	As above (all 7 patient-related items listed on APCA POS)

Table 1 above shows how the data for the first phase of the study would be collected and how it would be analysed and presented.

Data collection procedure

Consenting participants were issued with a study number which reflected the week in which they were recruited, whether they had TB or MDR-TB and where they fitted into the sequence in terms of the required 57 participants for each type of TB. For example study number W4T4 would indicate that the fourth participant with drug responsive TB had been recruited in week 4 and W7M3 would show that the third participant with MDR-TB had been recruited in week 7. The study number, together with the required demographic information which was obtained from the patient record was then entered onto the data collection sheet (Appendix 6). This form

was devoid of any personal identification details. A separate form was used for each consecutive interview.

Information regarding Partner/Spouse, Total number of children and Children under 5 years old, was self-reported by participants. The remainder of the demographic and medical information that was documented was accessed from the participants' patient records.

Storage of data

Once the consecutive APCA POS audits had been completed or the participant had withdrawn consent or died the forms were collated per participant and kept in a locked container in the researcher's office. The signed consent forms together with the completed APCA POS questionnaires are stored in a locked cabinet in the researcher's office. Data was entered into an Excel spreadsheet on a weekly basis.

Sample

The sample size of 114 participants was based on 135 TB admissions to Murchison Hospital over a three month period. This size sample allowed the prevalence of a single audit indicator e.g. pain with a 50% response distribution and comparison of the problems experienced by TB and MDR-TB participants at baseline to be detected. It also allowed for the change in intensity of symptoms over time to be measured via four weekly interviews. The latter is with reference to the Encompass audit baseline POS data of HIV patients (n=413)¹¹ using the physical and

psycho-social POS problems, to detect a difference of 2.5 with a standard deviation of 4.13, 90% power and 5% significance, n = 114.

Inclusion criteria: Adult patients, eighteen years and older, with a confirmed diagnosis of TB who had been admitted to the hospital during the preceding week.

Exclusion Criteria:

1. Children under the age of 18 years
2. TB patients reported by the professional nurse in charge of the ward, as not being cognitively able to respond to the study questions
3. Patients whom either the professional nurse in the ward or the researchers had considered to be too ill to approach with study information.

No data was collected with regard to the numbers of consecutive patients who fitted these exclusion data.

Prospective primary data was collected from individual participants by conducting a weekly audit over a period of four consecutive weeks to determine the palliative care-related outcomes in respect of the patient outcome indicators listed on the APCA POS.

Process of data collection

A separate APCA POS questionnaire containing standardized participant demographic and diagnostic variables was used for each interview.

Once a participant had given informed consent, the first of four consecutive weekly individual interviews was conducted. The first interview always took place in the hospital setting in either

the TB or MDR-TB ward. The setting for subsequent weekly interviews was dependent upon whether the participant was still in hospital, had been transferred to a satellite facility or discharged home. With the exception of the first interview which took a little longer, each interview took less than 10 minutes.

DATA COLLECTION TOOL

The African Palliative Care Association African Palliative Outcome Scale (APCA POS), a brief multi-dimensional outcome measure using patient and family-level indicators was used to collect quantitative audit data. The APCA POS was developed under the auspices of the African Palliative Care Association by a multi-professional expert group that included palliative care practitioners from South Africa. All answers are scored using Likert scales from 0-5, with numerical and descriptive labels. The items address physical and psychological symptoms, spiritual and emotional concerns as well as psychosocial needs. The APCA POS form was completed by the research assistant who asked each participant the questions listed in Figure 1 which follows on the next page.

Figure 1: APCA POS Patient Questionnaire

ASK THE PATIENT	POSSIBLE RESPONSES
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	0 (no pain)- 5 (worst/overwhelming pain) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	0 (not at all)- 5 (overwhelmingly) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q3. Have you been feeling worried about your illness in the past 3 days?	0 (not at all)- 5 (overwhelming worry) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	0 (not at all)- 5 (yes, I've talked freely) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q5. Over the past 3 days have you felt that life was worthwhile?	0 (no, not at all)- 5 (yes, all the time) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q6. Over the past 3 days, have you felt at peace?	0 (no, not at all)- 5 (Yes, all the time) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q7. Have you had enough help and advice for your family to plan for the future?	0 (not at all)- 5 (as much as wanted) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>

Only the questions for the patient are included in Figure 1. To view the complete APCA POS which includes questions for the family please refer to Appendix 6.

Validity and Reliability

In a paper reporting on the full, international multi-centre clinical validation of the APCA POS Harding et al noted that an analysis of in-depth qualitative interviews with patients and family members had confirmed that the tool had face validity in terms of being appropriate and acceptable to the target population. Internal consistency was established with test/re-test

reliability indicating the stability of the measure in terms of it being appropriately sensitive to change. The validation study concluded that the APCA POS had sound psychometric properties and high levels of acceptability in the African clinical setting.¹¹

During this study the isiZulu and English translations were used according to participant preference. Additional demographic and diagnostic data were added to the questionnaire as reflected in Appendix 6.

Distress Protocol

As is routine during the implementation of the APCA POS a distress protocol was put into place. Any participant who had appeared to become distressed would have been offered the opportunity to cease the interview and either abandon or restart when they were comfortable to do so. The interviewer would have passed on any information to the nurse responsible for their care at the patient's/family's request and the participant offered counselling from a psycho-social professional from the local hospice programme. Please refer to the Participant Information Leaflet for details. (Appendix 4)

QUANTITATIVE DATA ANALYSIS

All data was entered into Excel and then imported into SPSSV21 for analysis.

All data were cleaned and checked, and POS items reversed as necessary so that 0=best and 5=worst score. Baseline data were presented in full with all responses tabulated.

First the sample characteristics were analysed using descriptive methods. The response rate and completeness of data by time point were also calculated.

The baseline scores were then presented for each item and response level together with the median and inter-quartile range.

Association with baseline scores was determined using linear regression, with the POS total score and factor 1 (physical and psychological problems) as dependent variable for each model. Univariate analyses were conducted first followed by multivariable analyses, with independent variables significant at 25% level in univariate analyses entered into the multivariable model.

As can be seen in the chapter which follows, the B unstandardised coefficient and its 95% confidence interval are presented. For those who participated in every data collection point, box plots are presented for several items showing the median and interquartile range.

The change over time for matched pairs on the entire sample was conducted for each item using Wilcoxon signed rank.

PHASE 2:

GENERATING A PALLIATIVE CARE FOCUSED QUALITY IMPROVEMENT STRATEGY FROM THE AUDIT FINDINGS.

OBJECTIVES:

- 1. To convene a quality improvement focus group discussion with key members of staff selected from the TB care sites in order to use the data from phase 1 to generate a quality improvement strategy.*
- 2. To report on the development of a palliative care-related quality improvement strategy.*

1. FOCUS GROUP DISCUSSION (FGD)

This qualitative method of data collection was selected because of the need to create new ways of thinking about palliative care-related quality improvement in a hospital setting. It was felt that data collection would be enriched by both the individual contributions members made and how these contributions would mix together in a focus group and spark further discussion.⁶⁷ The FGD which was taped, was conducted in English and moderated by the researcher who was assisted by an observer skilled in note taking.

Study population

The study population for phase 2 was the professional health care staff at the Hospital MDR-TB and TB wards and two satellite facilities.

Recruitment

A purposive sample of 12 participants was invited to attend the FGD at Murchison Hospital on 28 February, 2013. The persons respectively in charge of the male and female MDR-TB units and TB ward at Murchison Hospital were asked to collectively select 10 health care professionals with a key role in quality improvement and interest in palliative care, to participate in the 90 minute FGD. The senior managers at the two satellite facilities (Genesis Care Centre and the Dunstan Farrel TB Hospital) were each invited to select 1 health care professional to represent their organisation at the FGD.

Selection Criteria

Inclusion Criteria: Members of the health care team from the district hospital and/or satellite facility who have freely consented to participate in the focus group after reading the detailed information sheet which stipulates that internal confidentiality cannot be guaranteed. (Appendix 7 – FGD Information Leaflet.)

Exclusion Criteria: None

Preparation for the FGD

Selected participants were issued with invitations which doubled as the FGD participant information leaflet three weeks before the event (Appendix 7) together with a copy of the semi-

structured questionnaire which would be used to guide the FGD (Appendix 8) and a copy of the consent form that they would be required to sign (Appendix 9). Because all the potential invited participants have hectic schedules, they were reminded of the time and venue of the FGD the day before it took place

Observer training

The FGD Observer was given training on the study design as well as the role of an FGD Observer and the ethical considerations that pertain to FGDs. A pilot FGD was then conducted at South Coast Hospice during which participants discussed compliance with the criteria stipulated in the Quality Improvement Service Element of the Hospice Palliative Care Standards.⁶⁰ The pilot FGD served as practical training for the observer and although it was tape recorded, the data is not included in the study.

Ethical considerations

Informed consent

To ensure that consent was informed, participants were given an information sheet which detailed the ground rules and latent risks associated with participation in a focus group (Appendix 9) three weeks before the FGD. While the researcher can give potential participants in a focus group the ethical assurance that he/she will safeguard their privacy and keep their verbal contributions confidential, this amounts to what Tolich refers to as external

confidentiality. It is not possible to offer internal confidentiality because once the FGD has been completed the behavior of other participants is out of the researcher's control.⁶⁹

Participants were assured that they would be free to withdraw at any time despite having given signed consent.

Privacy and confidentiality

Participants would be acknowledged by participant numbers on the tape and their names do not appear in the FGD report.

Distress protocol

The name and contact details of a psycho-social professional from the local hospice who was available to provide FGD participants with debriefing/counselling was included in the information leaflet. **(Appendix 7)**

Procedure used for the FGD

Seating was arranged in a round table format. On arrival FGD participants were asked to sign the attendance register and hand in their signed consent form. (Appendix 9) They were then issued with a participant number which they placed on the table in front of their chair. Each participant was given a handout **(Appendix 10)** which explained that the purpose of the meeting was to review the summarised audit findings and explore ideas in terms of using these

to develop a palliative care-related quality improvement strategy. Two of the invitees sent apologies as they were required to attend other meetings and one failed to attend without offering any explanation. 75% of the purposive sample of health care professionals invited to the FGD (n=9) participated.

The FGD was conducted in English and moderated by the researcher. FGD participants were reminded that an experienced psycho-social professional from the local hospice was available in the unlikely event that any participant became distressed and required counselling.

After introducing herself, the research assistant and FGD observer, the moderator established the ground rules which are reflected on the information sheet.(Appendix 7) Members were reminded that their input would be taped and asked to state their participant number prior to making any verbal contribution.

The moderator alerted group members when the tape recorder was switched on and recording commenced.

Data collection tools and process

The semi-structured questionnaire (Appendix 8) together with the FGD participant handout (Appendix 10) which included a summary of the audit findings were used to guide the discussion. In addition to asking the pre-determined questions, the moderator followed up on comments by participants. The observer made notes on the group dynamics and body language of the group members , these were used to inform the final FGD report.

Before concluding the FGD at the scheduled time the moderator gave participants an opportunity to make any final contribution to the discussion. Informal discussion regarding the way forward continued for the next 20 minutes over a light lunch.

2. REPORT ON THE DEVELOPMENT OF A QUALITY IMPROVEMENT STRATEGY

Analysis of qualitative data

The researcher typed up the taped FGD verbatim within hours of the event and immersed herself in the data. The transcripts were then enhanced by the notes taken by the observer with regard to the mood, attitudes and feelings displayed by participants as well as dynamics within the group. This formed the basis of the report on the development of a quality improvement strategy which is included in Chapter 7. Data analysis was done manually by compiling a taxonomy that incorporated the recurrent comments and concepts iterated by FGD participants (Table 24). This allowed the data to be focused by topic and organized into categories that identified the trends and general themes. Ultimately, relational action codes linked to quality improvement activities were created.^{67, 68} The entire process was independently checked and validated by an academic colleague experienced in qualitative research and palliative care.

Storage and dissemination of the FGD data

The digital recording was transcribed verbatim by the researcher who will retain one hard copy for five years in a locked cabinet. FGD participants will be sent a summary of the report on the development of a quality improvement strategy.

RESULTS FOR PHASE 1: AN AUDIT OF THE PALLIATIVE CARE-RELATED PROBLEMS OF A COHORT OF HOSPITALISED TB PATIENTS

OBJECTIVES:

1. *To measure the prevalence and intensity of multi-dimensional problems among TB patients on admission to the hospital TB and MDR-TB wards*
2. *To conduct an audit of palliative care-related outcomes for study participants to determine whether there is a difference in the prevalence and intensity in the problems experienced between TB and MDR-TB patients on entry to the hospital*
3. *To measure change in problem intensity over time (4 x weekly interviews)*

A summary of the quantitative findings of the audit of palliative care-related outcomes using a validated outcome measure, the APCA POS are presented in this chapter. A discussion of the results and the research limitations for the first phase of the study follow in the next chapter.

Sample characteristics

The majority (n=76, 66.7%) were female (missing n=1, 0.9%). The mean age was 33.2 (SD=10.4, minimum=18 maximum=65). The proportion of respondents who reported having a partner was 53.5% (n=61, missing n=5). The vast majority (n=91, 79.8%) had children (with a range of 1-7 children). With respect to their TB, 50% (n=57) had a diagnosis of MDRTB. The

vast majority had HIV co-infection (n=97, 85.1%). Of those with HIV, n=82 (84.5%) were currently on ART, n=13 not (13.4%) (missing n=2). All participants (100%, n=114) were currently on TB treatment. Previous TB treatment was reported by 65 respondents (57%), and of these n=33 (28.9%) were cured, n=15 (13.2%) completed, n=8 (7.0%) defaulted, and n=8 (7.0%) failed. Weight in Kg was a mean 51.7)

Only 58/97 HIV pts had their CD4 recorded.

Other chronic conditions noted on patients file were:

Diabetis Mellitus – 2

Chronic Obstructive Airways Disease – 2

Hypertension – 1

Epilepsy - 1

Differences between the participants with drug responsive and drug resistant TB are illustrated in Table 2 on the following page. Some of the interesting facts that can be seen are that more than half of the participants with drug responsive TB and a third of those with MDR-TB had not previously been treated for TB. Of those who had previously been treated the cure rate was better for the MDR-TB participants even though treatment failure was reported in 5 of these participants compared to 3 with drug responsive TB. The overall rate for defaulting on previous treatment is relatively low. There is a very high HIV/TB co-infection rate for both groups at 80% and 91% respectively. All (100%) of the MDR-TB patients with HIV co-infection were on HAART compared to 68% of those with drug responsive TB. More males than females had

MDR-TB. Participants with drug resistant TB collectively had more children overall as well as more children under the age of 5 years.

Table 2: Information regarding participants with TB and MDR-TB

Information	TB	MDR-TB
First TB treatment	30 (53%)	19 (33%)
Previously treated for TB	27 (47%)	38 (67%)
Cured with previous treatment	8 (14%)	25 (44%)
Completed previous treatment	9 (16%)	6 (11%)
Defaulted previous treatment	2 (4%)	6 (11%)
Previous treatment failed	3 (5%)	5 (9%)
Co-infected with HIV	45 (80%)	52 (91%)
On HAART	34 (60%)	50 (88%)
HIV negative	9 (16%)	5 (9%)
HIV status unknown	3 (5%)	0 (0%)
Males	17 (30%)	21 (37%)
Females	40 (70%)	36 (63%)
Average age	35.6	32.7
Average weight in Kg	48.7	54.5
Partners	26 (46%)	35 (61%)
Total number of children	92	108
Children younger than 5 years	15	22
Died	5 (9%)	3 (5%)

Recruitment

The full sample n=114 was recruited into the study.

Table 3: Summary of participant recruitment

Number of potential participants who were given study information	132
Number who consented to participate in the study	114
Number of new patients who were too ill to approach	46
Number who withdrew consent during the course of the study	9

As we can calculate from the table above, the response rate was 86.3%.

Half the participants (57) had been diagnosed with MDR-TB and the other half with drug responsive TB. It took 24 weeks to recruit the 57 participants with drug responsive TB and 32 weeks to recruit the same number of MDR-TB participants due to a slower rate of admission of patients with drug resistant TB. (See Table 4 on the next page)

MDR-TB had been excluded in the 3 participants with drug responsive TB in whom previous TB treatment had failed. All the participants were on TB treatment. Of the 13 who were HIV positive and were not currently receiving HAART:

- 9 had been admitted to fast-track ARVs
- 2 had been on ARVs but defaulted and were to be given counseling and education before being re-started
- 1 was very recently diagnosed HIV+

- 1 was considered to be too ill with TB to be started on HAART although able to answer APCA POS questions

The weight in Kilograms was a mean 51.7. The 10 participants who were not weighed were unable to stand on the scale.

Deaths during the data collection period

As illustrated in the Table 4 below proportionately many more deaths occurred in the TB ward than in the MDR-TB section of the hospital. In calculating the percentages 24 weeks was considered as 6 months and 32 weeks as 8 months.

Table 4: Number of deaths

TB WARD		MDR-TB WARDS	
Average monthly admissions	30	Average monthly admissions	15
No of deaths during 24 weeks of data collection	40	No of deaths during 32 weeks of data collection	15
Deaths as a % of admissions	22.22%	Deaths as a % of admissions	12.5%

As we can see in Table 4 the number of deaths as a % of admissions is almost double in the ward catering for people with drug responsive TB compared to the MDR-TB wards. The figures reflected in this table include study participants as well as patients who were admitted and died during the week between the data collection day and those who were considered to be too ill to approach with study information. Table 5 below gives a breakdown with regard to the deaths of study participants.

Table 5: Deaths of study participants

Number	Age	Gender	Diagnosis	ART	CD4	Weight	Baseline Pain	Children
W9T17	35	F	TB/HIV	YES	29	-	1	1
W13T29	46	F	TB/HIV	YES	-	50Kg	1	0
W16T35	25	F	TB/HIV	YES	9	56Kg	4	2
W16T36	38	F	TB/HIV	YES	-	42Kg	3	2
W18T45	32	M	TB/HIV	NO	33	51Kg	4	2
W20T51	34	F	TB not HIV+ve	N/A	N/A	52Kg	3	1
W20T52	22	F	TB/HIV	YES	-	48Kg	5	1
W22M32	35	M	MDR-TB/HIV	YES	49	54Kg	1	0
W24M37	33	M	MDR-TB/HIV	YES	480	49Kg	5	2

Table 5 shows that 7 of the 9 participants who died during the study (78%) had been diagnosed with drug responsive TB and 6 (67%) were female. Collectively the study participants who died had 11 children. 89% or 8 of 9 were co-infected with HIV. The only HIV+ participant who was not on ART had been admitted to fast track the commencement of anti-retroviral treatment. There does not seem to be any correlation between the pain rating on admission to the likelihood of death.

Audit interviews

As illustrated in Table 6 below all 114 participants had one interview, 94 were available for the second interview, 79 for the third and 64 had four consecutive weekly interviews.

Table 6 : APCA POS Interviews

Participant diagnosis	1st	2nd interview	3rd interview	4th interview	TOTAL
TB	57	43	33	26	159
MDR-TB	57	51	46	38	192
	114	94	79	64	351

The attrition rates for each time point calculated from Table 4 above are indicated in Table 7 below.

Table 7 : Attrition rate for each consecutive time point

Participant diagnosis	After 1st interview	After 2nd interview	After 3rd interview
TB	24.5%	23.2%	21.2%
MDR-TB	10.5%	9.8%	17.3%
	35%	33%	38.5%

As we can see from Table 7 that the attrition rate was considerably higher in the group with drug responsive TB.

Place of interview

A total of 351 interviews were conducted. The majority n= 313, (89%) and all of the first interviews were conducted at Murchison Hospital, 8 at the Genesis Care Centre and 5 at the

Dunstan Farrel TB Hospital. The remaining 25 interviews took place after a participant was discharged home. In 2 instances it was possible to visit the home for a face to face interview, in the remaining 23 instances the interview was conducted telephonically. 19 participants who had been sent home could not be reached and were lost to follow up. More than half of these participants (n=10 or 53%) had three interviews, 5 or 26% had two interviews and the remaining 21% were lost to follow up after the first interview.

Withdrawal of consent

During the course of the study, consent was withdrawn by 9 participants, 9 died and in 3 instances an enrolled participant was not approached for the next interview because the researchers considered the person to be too ill to be disturbed. Five of the participants who withdrew consent had MDR-TB and 4 drug responsive TB. Of the participants who died 6 had drug responsive TB and 3 MDR-TB. Of those considered to be too ill to approach for the next interview by the researchers 2 had drug responsive TB and 1 MDR-TB.

Distress protocol

Although they were made aware of the distress protocol, this was not required by any of the participants during the course of the first phase of the study.

Interview questions

The APCA POS audit form showing the questions which participants were asked for four consecutive weeks is replicated below as a reminder to the reader, as each of the items will be reported on later in this chapter.

Replica of Figure 1: APCA POS Patient Questionnaire

ASK THE PATIENT	POSSIBLE RESPONSES
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	0 (no pain)- 5 (worst/overwhelming pain) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	0 (not at all)- 5 (overwhelmingly) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q3. Have you been feeling worried about your illness in the past 3 days?	0 (not at all)- 5 (overwhelming worry) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	0 (not at all)- 5 (yes, I've talked freely) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q5. Over the past 3 days have you felt that life was worthwhile?	0 (no, not at all)- 5 (yes, all the time) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q6. Over the past 3 days, have you felt at peace?	0 (no, not at all)- 5 (Yes, all the time) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
Q7. Have you had enough help and advice for your family to plan for the future?	0 (not at all)- 5 (as much as wanted) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>

Only the APCA POS questions for the patient are shown in Figure 1. To see the questions for family members please refer to Appendix 6.

Measurement of the prevalence of multi-dimensional problems experienced by TB patients on admission to hospital:

Table 8 below shows the baseline data for the full sample of participants on admission to the hospital. Baseline data are presented in full with all responses tabulated together with the median and interquartile range scores. All data were cleaned and checked, and POS items reversed as necessary so that 0=best and 5=worst score.

Table 8: Baseline APCA African POS scores for full sample of patients with drug responsive and drug resistant TB

	0 (Best status) n (%)	1 n (%)	2 n (%)	3 n (%)	4 n (%)	5 (worst status) n (%)	Median (IQR)
Pain	11(9.6)	14 (12.3)	20 (17.5)	21 (18.4)	20 (17.5)	28 (24.6)	3.0 (2.00-4.25)
Symptoms	7 (6.1)	7 (6.1)	14 (12.3)	51 (44.7)	23 (20.2)	10 (8.8)	3.0 (2.25-4.0)
Worry	7 (6.1)	5 (4.4)	9 (7.9)	24 (21.1)	33 (28.9)	36 (31.6)	4.0 (3-5)
Life worthwhile	32 (28.1)	33 (28.9)	22 (19.3)	7 (6.1)	3(2.6)	17 (14.9)	1.0 (0-2)
Share feelings	12 (10.50)	22 (19.3)	29 (25.4)	11 (9.6)	15 (3.2)	25 (21.9)	2.0 (1-4)
At peace	10 (8.8)	30 (26.3)	57 (50.0)	12 (10.5)	4 (3.5)	1 (0.9)	2.0 (1-2)
Help/advice*	24 (21.1)	24 (21.1)	19 (16.7)	4 (3.5)	5 (4.4)	35 (30.7)	2.0 (1-5)

Note re missing data: n=3 with regard to help/advice in planning for the future and symptom rating n=2

It is clear from Table 8 that the predominant problems experienced by participants on admission to hospital related to pain, symptoms and worry. The majority of the participants had severe pain on admission with a quarter rating their pain as 5 which equates to the worst imaginable or overwhelming pain. Over 80% of participants rated their symptoms at 3,

indicating that it was moderate to severe, or higher. The table also shows that the worst score was in relation to how worried participants felt about their illness.

Fifteen participants rated both their pain and worry as overwhelming with a score of 5 for both these items at baseline. As shown in Table 9 on the next page two thirds of these participants had MDR-TB, the majority were female and co-infected with HIV and ten had children under 5 years old. This will be elaborated on in the discussion which follows.

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TABLE 9: PARTICIPANTS WITH OVERWHELMING PAIN AND WORRY ON ADMISSION

Type of TB	Gender	Age	Children (under 5yrs)	HIV status	TB Rx history
MDR-TB	Female	33	3 (1)	HIV+ on ART	Completed Rx
MDR-TB	Female	38	3 (1)	HIV+ on ART	Previous TB cured
MDR-TB	Male	21	1 (1)	HIV negative	1 st TB Rx
MDR-TB	Female	39	3 (1)	HIV+ on ART	1 st TB Rx
TB	Female	38	4 (1)	HIV+ on ART	Defaulted
TB	Female	48	-	HIV negative	1 st TB Rx
TB	Female	28	2 (1)	HIV negative	1 st TB Rx
e 85.MDR-TB	Female	65	5	HIV+ on ART	Defaulted
MDR-TB	Male	23	(1)	HIV+ on ART	Previous TB cured
TB	Female	24	0	HIV+ on ART	Previous TB cured
TB	Male	19	0	HIV negative	1 st TB Rx
MDR-TB	Female	31	(1)	HIV+ on ART	Previous TB cured
MDR-TB	F	62	1	HIV+ on ART	Completed TB Rx
MDR-TB	F	30	(1)	HIV on ART	Completed TB Rx
MDR-TB	F	25	3 (2)	HIV+ on ART	Defaulted

The characteristics of the participants reflected in Table 9 are discussed on page 85.

The last four APCA POS questions concerning feeling that life is worthwhile, ability to share feelings, having a sense of peace and sufficient help and advice to plan for the future, scored well compared to the first three.

Differentiation of TB and MDR-TB problems on admission

Audit to differentiate the prevalence and intensity of palliative care-related problems experienced between TB and MDR-TB patients on entry to hospital.

Table 10 on the next page shows univariate associations with the POS total score, and POS factors at baseline. Association with baseline scores was determined using linear regression, with the POS total score and factor 1 (physical and psychological problems) as the dependent variable for each model.. This is followed by Table 10 which shows the multivariate analyses, for total POS score with age and gender entered into the model.

It can be seen from Tables 8 and 10 that older patients and patients whose TB is NOT drug resistant have the worst total POS score for Factor 1 (physical and psychological problems) worse problems are associated with TB that is NOT drug resistant.

Table 10: Univariate association with the POS total score, and POS factors at baseline

Independent variables		Outcomes (dependent)			
		POS total B (95% CI) p	Factor 1 Physical & psychological		
Age		B=0.112 (0.032, 0.191) p=0.006	B=0.046 (-0.011, 0.104) p=0.115		
Gender		B=-0.308 (-2.136, 1.519) p=0.739	B=-0.840 (-2.127, 0.446) p=0.198		
Drug resistance		B=1.764 (0.100, 3.428) p=0.038	B=1.697 (0.535, 2.859) P=0.005		
Partner or not		B=-0.291 (-2.040, 1.458) p=0.742	B=-0.320 (-1.562, 0.922) p=0.611		
Prior treatment		B=-0.057 (-0.851, 0.462) p=0.558	B=-0.040 (-0.510, 0.429) p=0.865		
Weight		B=0.020 (-0.062, 0.102) p=0.635	B=0.054 (-0.003, 0.110) p=0.063		

Table 11: Multivariate analyses for total POS score

Independent variables		Outcomes (dependent)			
		POS total B (95% CI) p	Factor 1 Physical & psychological		
Age		B=0.113 (0.035, 0.191) p=0.005	B=0.041 (-0.024, 0.106) p=0.214		
Gender		-	B=-0.502 (-1.801, 0.797) p=0.445		
Drug resistance		B=1.797 (0.187, 3.408) P=0.029	B=1.997 (0.761, 3.234) p=0.002		

Measurement of change in problem intensity experienced over time.

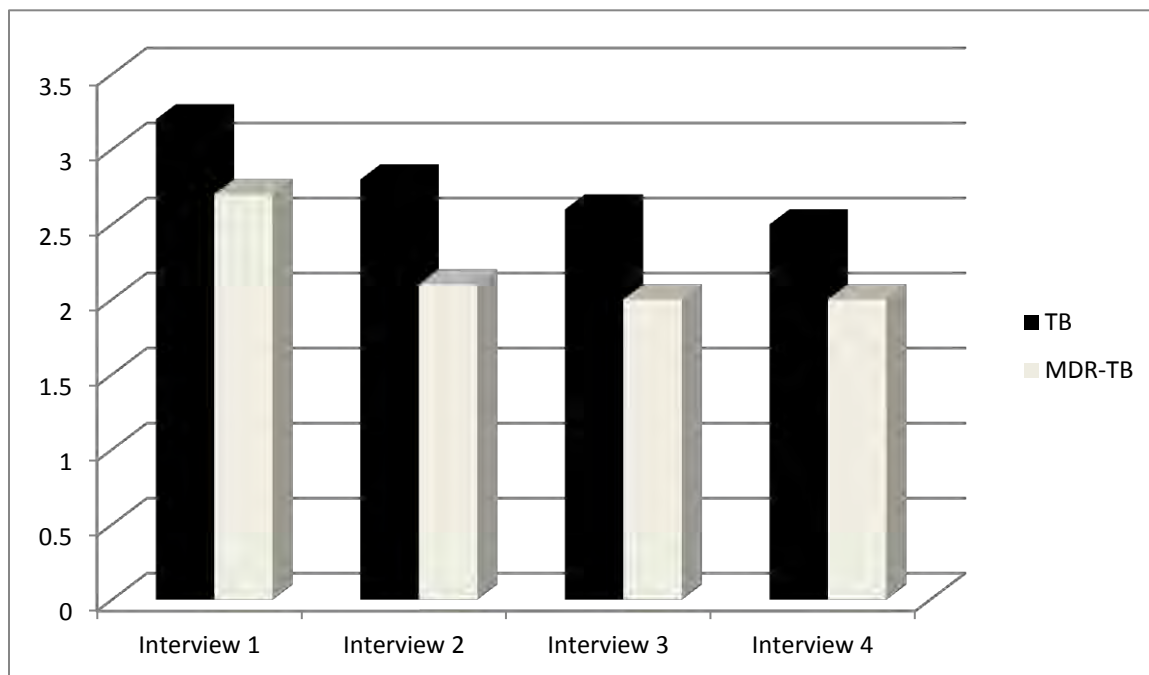
The graphs that follow show the mean score attained for each of the APCA POS criteria disaggregated by participant diagnosis of drug responsive or drug resistant TB (TB or MDR-TB). It should be noted that in these graphs the POS items are represented in their original format and have not been reversed. The lowest score is therefore best for the first three questions e.g. 0=no pain and 5 = worst possible pain. Whereas for questions 4, 5, 6 and 7 the best score is the highest in that for example 0= never at peace and 5 = always at peace. In each of these graphs the first interview shows the rating for the specific problem participants experienced on admission to the hospital. The next three interviews indicate change in the problem intensity over the following three weeks.

As will be seen, the predominant problems experienced by both groups of participants were worry, pain and symptoms.

It is also evident that the burden of pain, symptoms and worry was highest in the participants diagnosed with drug responsive TB.

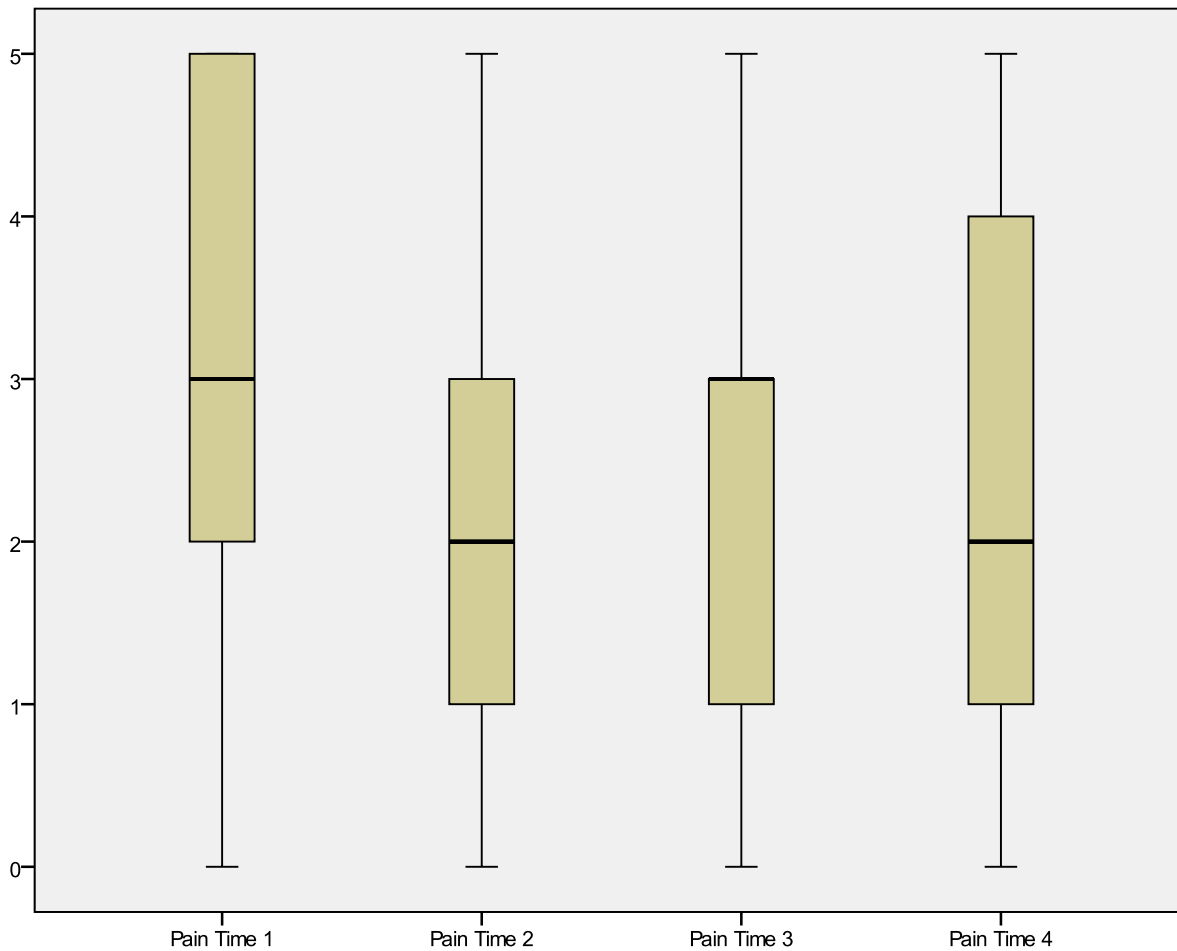
Box plots and a table showing an analysis of the pain, symptoms and worry experienced by participants are included here.

Figure 2: Mean scores for pain



It is clear from Figure2 above that the mean score for pain was higher (worse) for the participants with drug responsive TB.

Figure 3: Pain over time



The Figure 3 box plot shows us that for the 62 patients who completed every time point, pain did not seem to show any sustained change, with the median changing between 3 and 2 then back to three and returning to 2. The IQR ends up between 1 and 4.

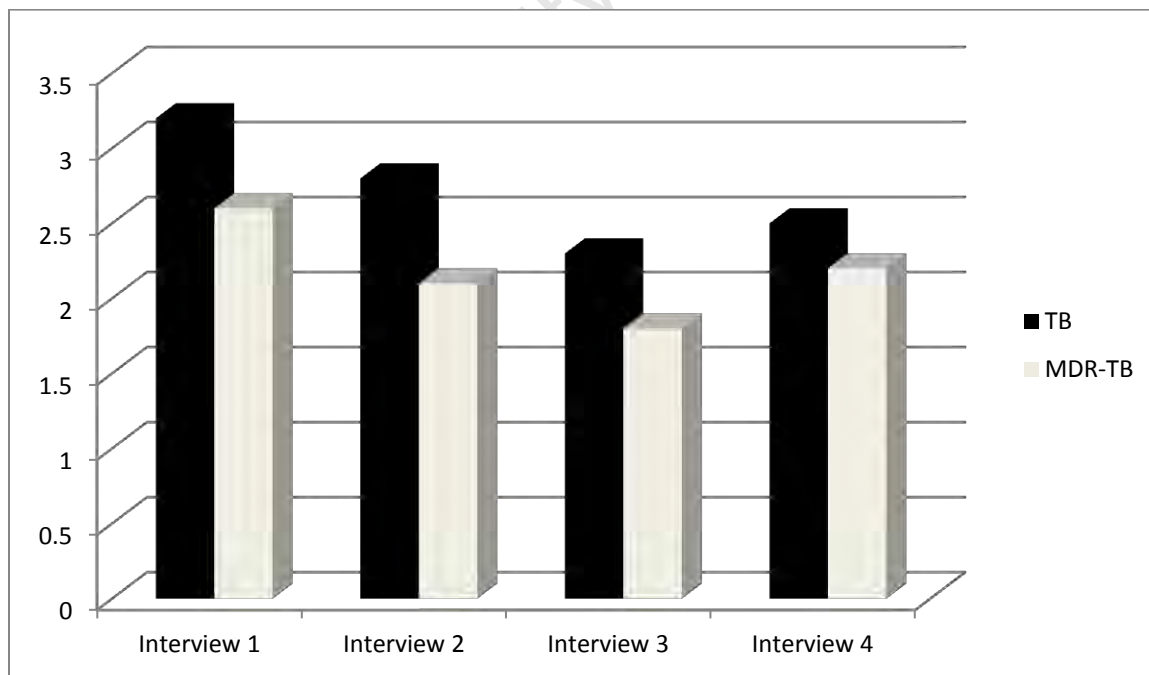
The non-parametric analysis of change for the full sample is shown in Table 12 below.

Table 12: Non-parametric analysis of change with regard to pain

Pain	Median	Wilcoxon signed rank comparing to previous time point Z score	P value
T1 n=114	3		
T2 n=92	3	-1.917	0.06
T3 n=77	3	-0.055	0.96
T4 n=63	2	-1.410	0.159

Table 12 shows that while between T1 and T2 there was a borderline statistically significant change between T1 and T2, there was no significant change in pain during the data collection period. It should be noted that, on a pain scale of 0-5, the median remains in the top half of the scale.

Figure 4: Mean scores for symptoms

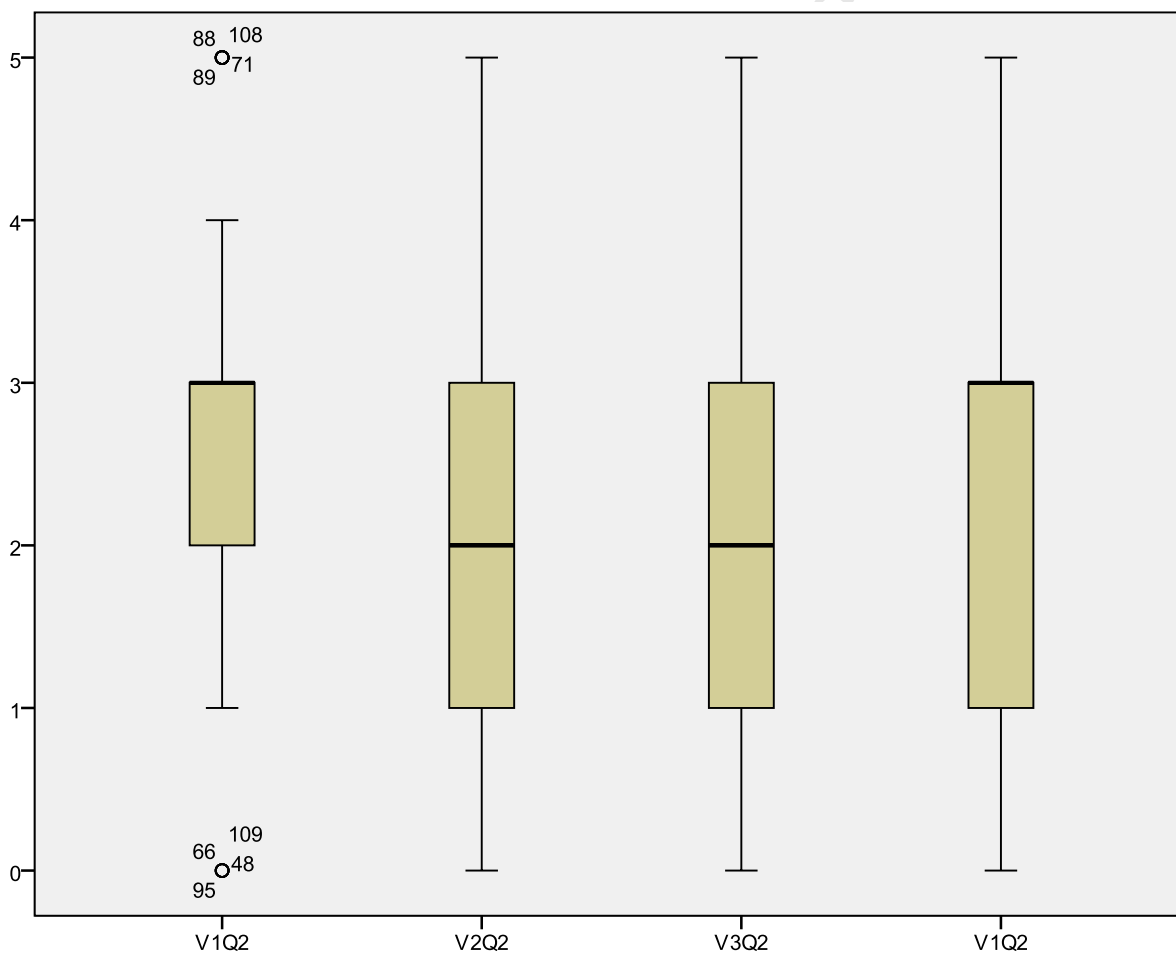


We can see from Figure 4 that the symptoms experienced by participants with drug responsive TB in this cohort of hospitalised patients were more severe than those experienced by participants with MDR-TB.

Symptoms over time

From Figure 5 we can see that for the 62 patients who completed symptoms at all the time points the median score remains around 3.

Figure 5: Symptoms over time



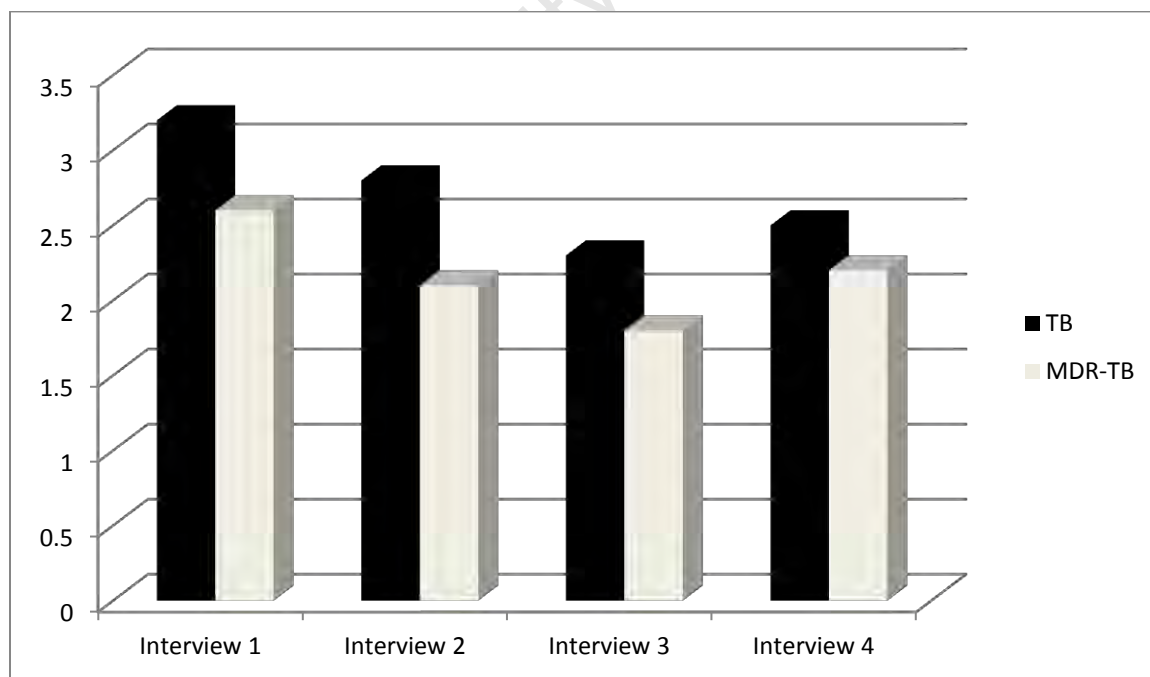
The non-parametric analysis of change regarding symptoms is shown in Table 13 below.

Table 13: Non-parametric analysis of change in symptoms

Symptoms	Median	Wilcoxon signed rank comparing to previous time point Z score	P value
T1 n=112	3		
T2 n=90	3	-1.590	0.112
T3 n=76	2	-1.814	0.070
T4 n=62	3	-1.176	0.240

Table 13 above shows that while there was a borderline significant change between T2 and T3 at no point was the change significant at the 5% level.

Figure 6: Mean scores for worry



We can see from Figure 6 that the participants with drug responsive TB experienced more worry than those with MDR-TB at each time point.

Figure 7: Worry over time

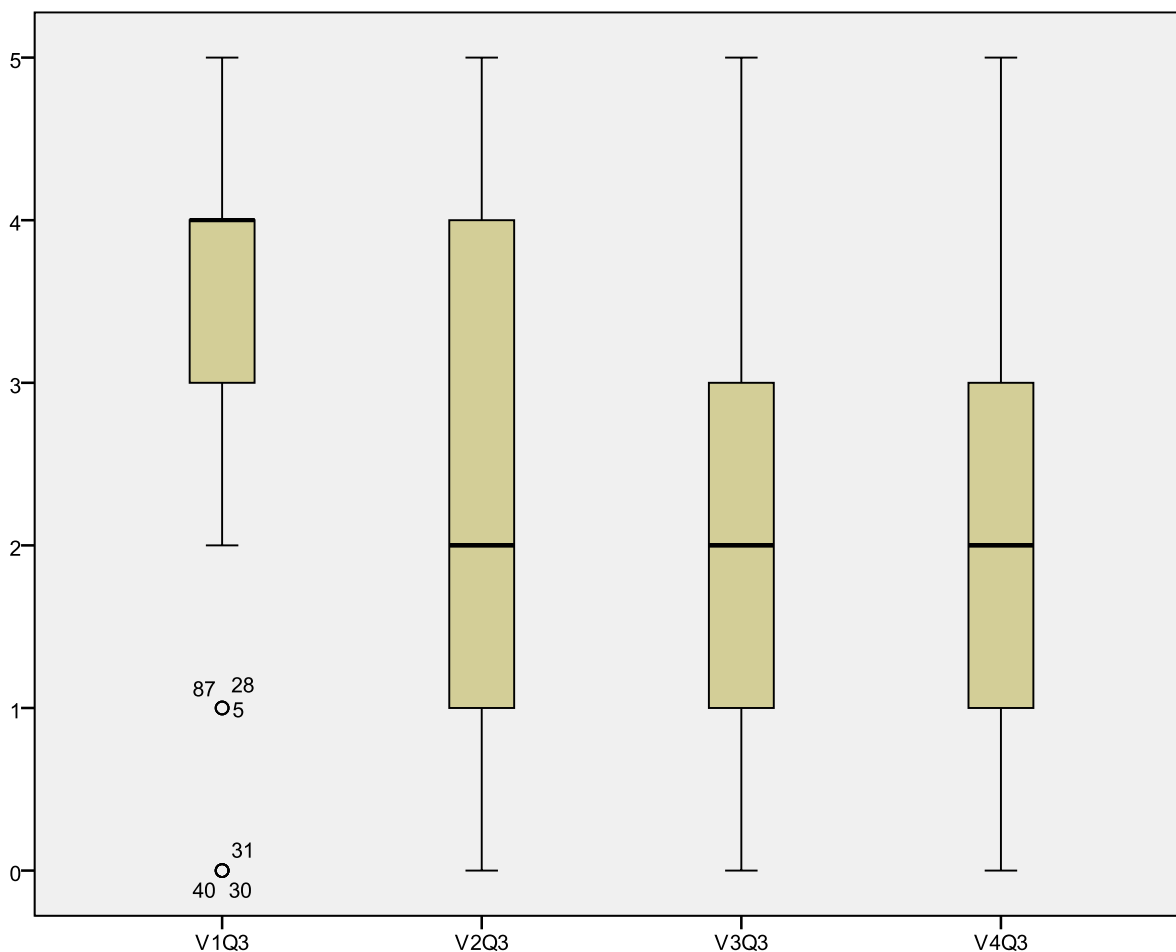


Figure 7 shows us the high level of worry experienced by participants on admission and how this improved by week 2.

For the entire sample, the non-parametric analysis of change with regard to worry is shown in Table 14 on the next page.

Table 14: Non-parametric analysis of change in worry

Worry	Median	Wilcoxon signed rank comparing to previous time point Z score	P value
T1 n=114	4		
T2 n=93	2	-4.144	0.001
T3 n=76	2	-0.186	0.853
T4 n=63	2	-0.535	0.593

Table 14 shows us that, while a statistically significant reduction in worry happens by T2, this does not change any further.

Figure 8: Mean scores for ability to share feelings

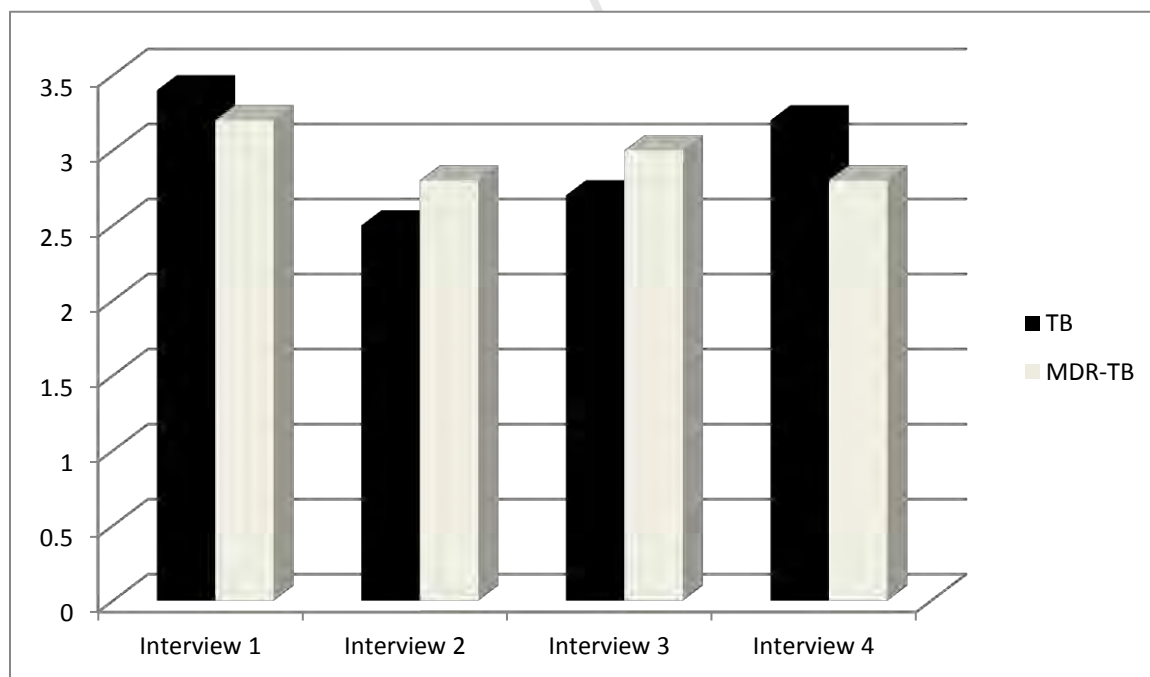
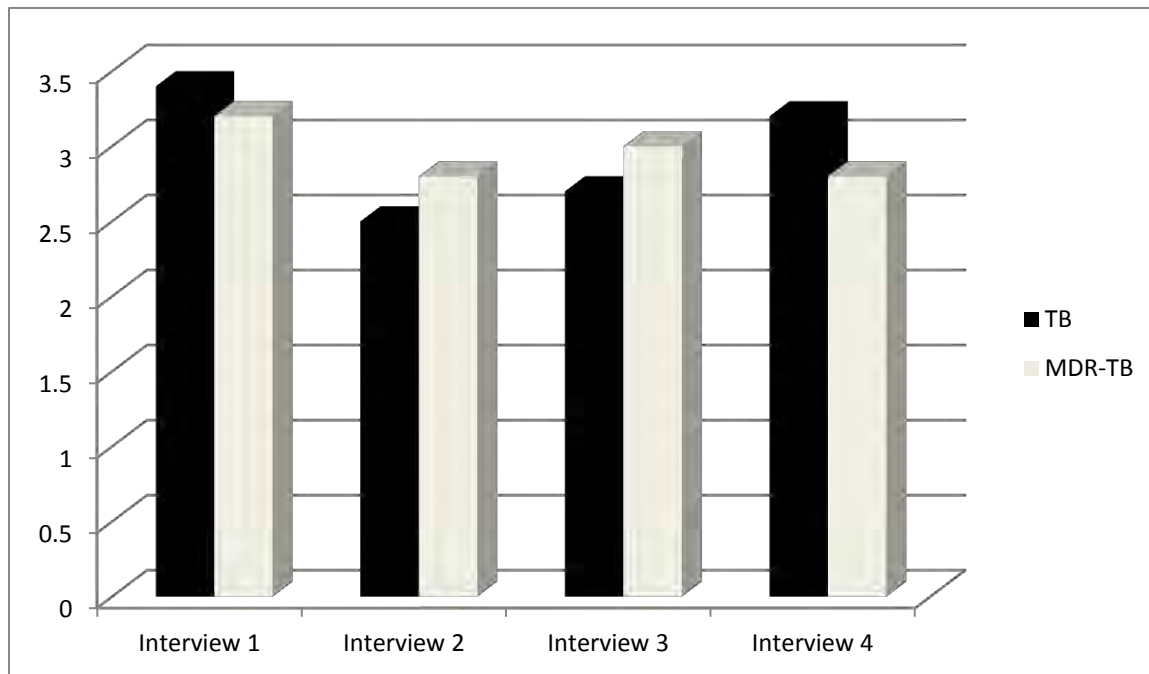


Figure 8 on the previous page tells us that there was no real difference in the ability that participants from both groups had to share how they were feeling with family or friends.

Figure 9: Mean scores for feeling that life is worthwhile



We can see from Figure 9 that participants with MDR-TB felt that life was more worthwhile than those with drug responsive TB. Although the scores relating to feeling that life was worthwhile were not as serious as those for pain, symptoms and worry the matched analysis is depicted in Table 15 because this item worsened after the first time point.

Table 15: Matched analysis of life worthwhile

Feeling life worthwhile	Median	Wilcoxon signed rank comparing to previous time point Z score	P value
T1 n=114	1		
T2 n=93	2	-3.785	0.001
T3 n=77	2	-1.047	0.295
T4 n=63	2	-0.455	0.649

We can see in Table 15 above that over time feeling that life was worthwhile actually worsened by a statistically significant margin by the second visit then did not change significantly.

Figure 10: Mean scores for feeling at peace

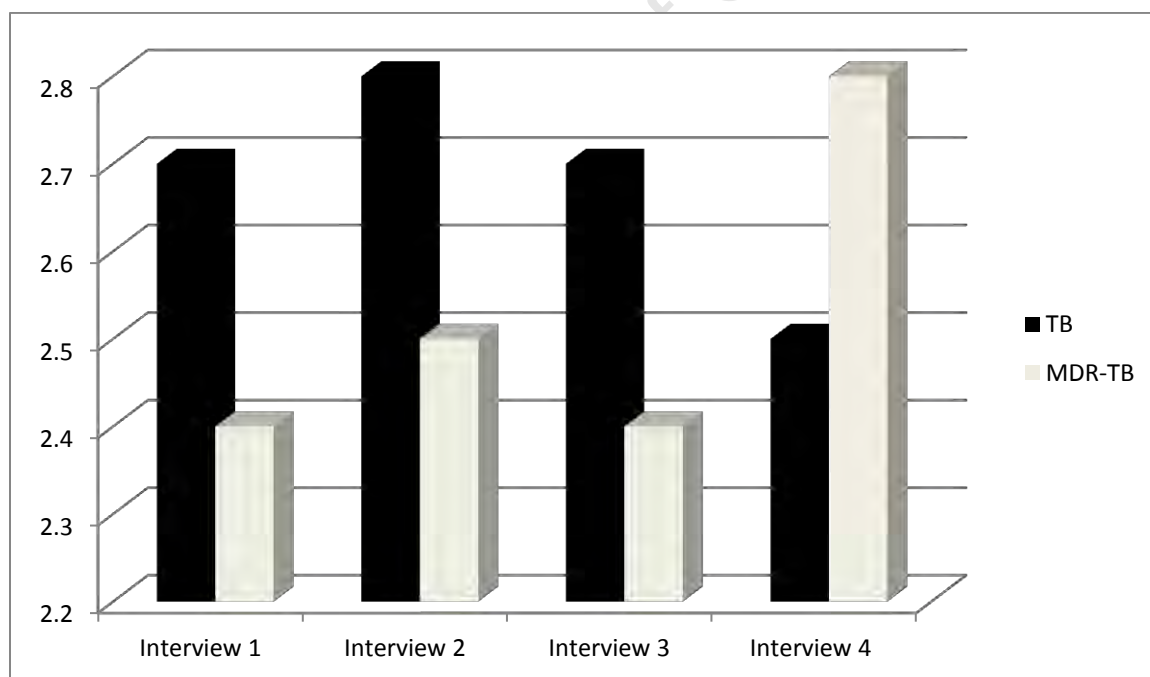


Figure 10 above shows us that the score for feeling at peace went up and down for both groups of participants. At the fourth week after the initial interview the participants with MDR-TB scored best for this item.

Figure11: Mean scores for help and advice in planning for the future

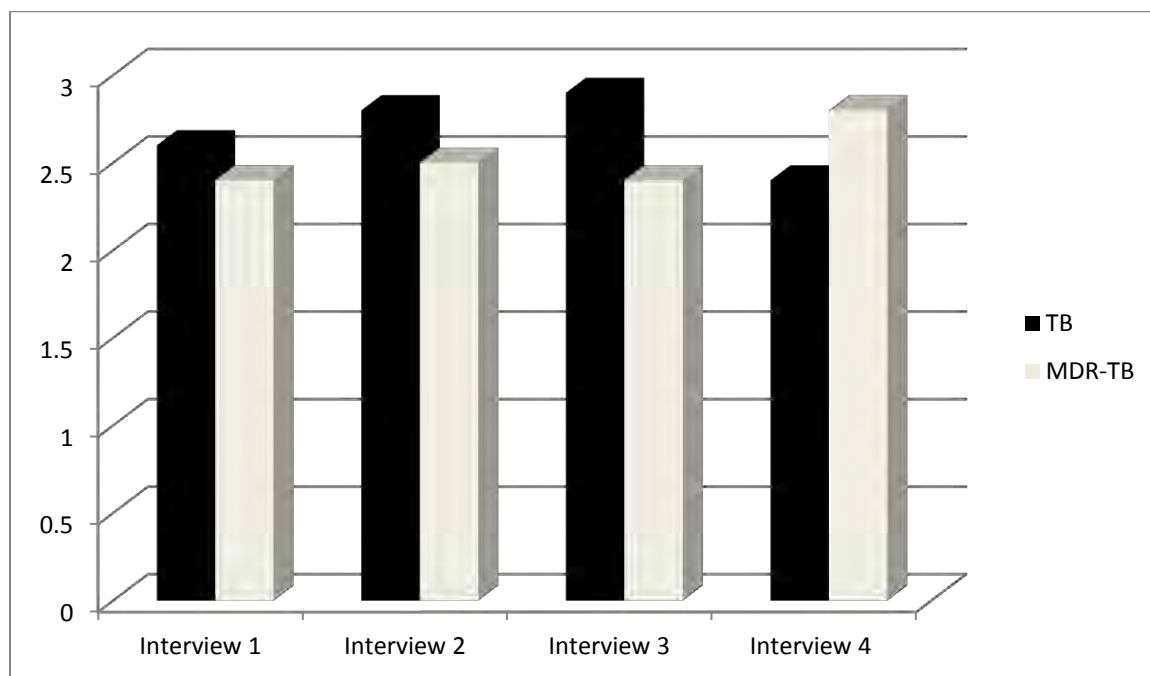


Figure 11 above shows that there is very little difference between the two groups of participants regarding the question 'Have you had enough help and advice for your family to plan for the future.' There is an improvement by the 4th week but this is not statistically significant.

Predictors of attrition

In order to determine whether those lost to follow-up had different problem intensity compared to those who remained in the study, the total POS score and POS items for those who had interviews at all 4 time points and those who did not was compared. No statistically significant difference was found in the two groups.

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DISCUSSION OF PHASE 1 RESULTS**AN AUDIT OF THE PALLIATIVE CARE-RELATED PROBLEMS EXPERIENCED BY A COHORT OF HOSPITALISED TB PATIENTS**

In this section the results presented in Chapter 4 are discussed and expanded upon in relation to the available literature and the study objectives for the first phase of the study.

OBJECTIVES OF PHASE 1

- 1. To measure the prevalence and intensity of multi-dimensional problems among TB patients on admission to the hospital TB and MDR-TB wards.*
- 2. To conduct an audit of palliative care-related outcomes for study participants to determine whether there is a difference in the prevalence and intensity in the problems experienced between TB and MDR-TB patients on entry to the hospital.*
- 3. To measure change in problem intensity over time (4 x weekly interviews).*

Study participants

An additional 5 weeks (29) was required to recruit the same number of MDR-TB participants (57) compared to participants with drug responsive TB (24 weeks). This is linked to the longer length of stay in hospital by patients with MDR-TB that results in fewer admissions. On

average the time spent in hospital in the MDR-TB wards is 66 days, compared to 22 days in the TB Ward.

The greater proportion of females with MDR-TB (61.4%) is in keeping with findings of a retrospective record review of patients with MDR-TB in Durban in 2011.³⁰ This may well be linked to the high TB/HIV co-infection rate in the sample as, in this country, the incidence of HIV is higher in women than in men.⁶ In Africa, HIV is the single most important contributing factor to the escalating TB epidemic³ and according to the WHO Global Tuberculosis Report for 2012, 'TB is one of the top killers of women.'²

In this study 79.8% of the participants were parents who collectively had 200 children, 42 of whom were younger than 5 years old. These children become extremely vulnerable when orphaned. Traditional African models of surrogate care can no longer accommodate the sheer numbers of orphaned children brought about by the AIDS pandemic.⁷⁰ The APCA POS baseline score showed that 84% of participants with children younger than 5 years (n=25) rated their worry between 3 and 5. Table 12 shows that of the 15 participants who rated both their pain and worry as 5 i.e. overwhelming, 12 (80%) had children and 10 (67%) had children under the age of 5 years. It is therefore probable that concern about their children contributed significantly to the worry experienced by participants

MDR-TB

Stigma, together with a legitimate fear of contracting TB⁷¹ is prevalent among health care workers who may be inclined to lay the blame of the MDR-TB crisis on defaulting patients.^{13, 14}

It is therefore worth emphasizing that only 6 participants or 10.5% of the sample of MDR-TB participants in this study had defaulted on their previous TB treatment.

A third of the sample of participants with MDR-TB (19/57) in this study had never been treated for TB before. This is consistent with findings from a postmortem study conducted at a public hospital in KZN, where 16% of patients who died from MDR-TB did so during their first ever course of TB therapy⁷². It is likely that these patients were primarily infected with MDR-TB.

The high level of poverty in the rural area served by the hospital, together with a TB/HIV co-infection rate of 82.5% would seem to indicate that there was an impressive commitment to a difficult treatment protocol by the majority of the MDR-TB participants. Many of these people live in a challenging environment.

Deaths

An unexpected finding was that almost three times as many deaths occurred in the TB ward (40) compared to the MDR-TB wards (15) as indicated in Table 4 in the previous chapter. This does, however, need to be considered within the context of drug responsive TB being predominantly managed in the community. As a result, only patients with severe problems and/or advanced illness are admitted to the limited number of beds in the 'ordinary' TB ward. Therefore the fact that this study was limited to participants admitted to hospital does to a degree, account for this finding. It is, however, alarmingly similar to findings from the postmortem study mentioned above, in which 70% of the patients who died from TB while receiving treatment, had drug responsive TB.⁷² The expectation is that patients with drug responsive TB who are on treatment will be cured.

Prevalence and intensity of problems on admission to hospital

Measurement of the prevalence and intensity of multi-dimensional problems among TB patients on admission to the hospital TB and MDR-TB wards.

Table 8 in the previous section indicated a high score with regard to patients experiencing worry, pain and symptoms on admission to the hospital. The least problems were associated with the sharing of feelings, being at peace and feeling that life was worthwhile. The latter may seem strange given the findings regarding the high burden of pain/ symptoms and worry. There could be a connection between this apparent anomaly and the fact that the vast majority of the sample population comprised rural Africans. The research assistant who grew up in the area suggested that rural communities have the ability to retain a sense of peace even in the face of severe suffering. In any event the way people perceive quality of life is affected by culture⁷³ and can be influenced by both experience and expectations.⁷⁴

Differentiation of problems of TB and MDR-TB patients on admission

An audit of palliative care outcomes for study participants to determine whether there is a difference in the prevalence and intensity in the problems experienced between TB and MDR-TB patients on entry to the hospital.

The graphs depicted in Figures 2, 4 and 6 in the previous chapter, indicate that patients with both TB and MDR-TB experienced significant physical and psychological problems on

admission to hospital. This finding confirms what current literature asserts regarding the need for palliative care in drug-resistant TB.^{12, 17}

Significant problems associated with drug responsive TB

The fact that the overall POS scores were higher for participants who did not have MDR-TB, however, provides substantial new information regarding the extensive palliative care-related needs of patients with drug responsive TB. This could be linked to the higher death rate for this group as well as the finding that participants with MDR-TB found life to be more worthwhile than those with drug responsive TB.

In their report entitled *Groundbreaking meeting on MDR and XDR TB and palliative care*, the World Wide Palliative Care Alliance mentions that palliative care is rarely included in guidelines and policies relating to the treatment and care of MDR and XDR patients.⁷⁵ No mention is made of drug responsive TB which was not on the agenda of the consultative meeting regarding palliative care and TB held in Geneva in November, 2010. The challenge now, is for 'ordinary' drug responsive TB to be included in this type of communication within both palliative care and TB circles.

Change in problem intensity over time

Measurement of change in problem intensity over time (4 x weekly interviews)

Pain

It is clear from Figure 2 that the pain experienced by participants did not show any significant change over time. The median level of pain changed between 3 and 2 and then went back

to 3. This suggests that the hospital staff have not considered pain to be a priority within the context of TB disease or the side effects of treatment.^{29, 30} It therefore follows that hospital doctors and nurses would benefit from the pain control aspects of palliative care training.¹⁸

Symptoms

The same applies to the management of symptoms as can be seen in Figure 5. The median score for symptoms also moves from 3 to 2 and then back to 3. The predominant symptoms were cough, nausea and constipation. Although no specific prompt was given with regard to dyspnoea this was not generally apparent to the researchers.

The APCA POS is administered by a health care professional. Participants volunteer the symptoms, but as can be seen from Figure 1, cough, nausea, vomiting and constipation are listed as potential prompts for the interviewer. Consideration could be given to adding dyspnoea to this list of potential symptoms when using it with a population of TB patient. Adapted symptom versions of the POS have been used in other specific patient groups.⁴⁷

Palliative care-related audit findings

The audit findings regarding pain and symptoms resonate with a statement made within the context of MDR-TB which asserts that the alleviation of suffering associated with disease and its management has been restricted mostly, but not adequately to physical aspects.¹² The participant's patient records/clinical notes perused during this study focused on demographics,

medical history, nutritional and treatment issues. The management of pain and symptoms were seldom prominent in the participants' patient records.

Psychological problems

As shown in Table 8 and Figures 6 & 7, on admission to hospital the entire sample experienced a substantial amount of worry. The median rating for worry was 4. Some of this may have been associated with fears about hospitalization in that the median score was statistically significantly reduced by the second week to 2, after which there was no further change. The vast majority of the 15 participants who had overwhelming pain and worry on admission were females with MDR-TB who had young children at home, this is likely to have significantly contributed to their worry. (Table 9, pg 69) .

No mention of worry was found in any of the patient records perused during the study. The fact that patients and families affected by life threatening illness face difficulties which span physical, emotional, social and physical aspects is well documented in the literature.^{5,15,19}

Palliative care training includes a focus on communication regarding the honest sharing of sensitive and frightening information.^{15, 12} The best outcome scores were attained with regard to the questions regarding the ability to share feelings, being at peace and having sufficient help and advice to plan for the future. This finding contrasts with an in depth qualitative study conducted in palliative care programmes in South Africa and Uganda that found that 'individuals in Africa with progressive incurable disease need better information and communication about their disease and its management'.⁷⁶

Promoting cure via care

A focus on the provision of more holistic care could be a key issue in improving TB treatment outcomes. The latter notion is supported by an MDR-TB programme run by Medecins Sans Frontiers in Khayelitsha in which a patient-centred decentralized model of care increased case finding and improved treatment outcomes thereby reducing further MDR-TB transmission.⁴⁰

Psychosocial support has been acknowledged as an important element in the management of adverse events related to TB treatment. Education, counseling and encouragement can all contribute towards achieving successful patient outcomes in terms of treatment adherence.³³

Optimal care for those with HIV disease continues to be a priority alongside prevention and treatment. The provision of HIV/AIDS medical care that focused solely on the technical elements of HAART would be detrimental to both patients and carers.^{24, 25} It is strongly suggested that this point of view is as applicable within the context of TB.

Attrition

The overall rate of attrition was 21% (24/114). Nine participants withdrew consent (7.8%) during the course of the study. Five did so because they felt too ill to be interviewed. Three decided they no longer wished to participate in the study for no apparent reason, and one who was a traditional healer, because she had embarked upon a spiritual ritual during which she was not permitted to speak about herself. A further 9 participants died and in 3 instances an enrolled participant was not approached for the next interview because the researchers

considered the person to be too ill to be disturbed. It can be projected that the participants who died or were too ill to continue with the study would have benefitted from palliative care-related interventions.⁴⁴ A comparison of the total POS scores between participants who had all four weekly interview and those who did not showed no statistically significant difference. It can therefore be presumed that the same symptom intensity was experienced by the group that was lost to follow up.

Summary of key findings The key findings with regard to the data gathered during phase 1 are summarized in Figure 12.

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Figure 12: Summary of key findings of phase 1 (APCA POS audit)

The predominant palliative care-related problems experienced by all participants on admission to hospital were worry, pain and symptoms

The burden of pain, physical symptoms and worry was highest in participants with drug responsive TB

Nearly three times as many deaths occurred in the ward for drug responsive TB (40) as in the MDR-TB wards (15) during the data collection period

One third of the MDR-TB participants (19/57) had not previously been treated for TB and probably contracted MDR-TB as their primary infection

Only 10.5% (6/57) of MDR-TB participants had defaulted on previous treatment

There was no significant sustained change in the level of pain and symptoms experienced by participants over four consecutive weekly audit interviews

RESEARCH LIMITATIONS REGARDING PHASE 1

1. .Because the vast majority of the audit interviews took place in the hospital setting for the most part family members were not available to participate. The 7 family member interviews that were conducted were not included in the data analysis.
2. Due to the logistical problems associated with following up participants discharged from hospital it was often not possible to conduct face to face interviews, 19 interviews were therefore conducted telephonically. This could introduce bias in that privacy could not be guaranteed.
3. The APCA POS was used in its original form and did not include a prompt in respect of dyspnoea. It is therefore possible that this important TB symptom was not fully captured during the audit process.
4. Data collected on the number of new patients too ill to approach was regrettably not disaggregated by diagnosis of TB or MDR-TB or gender and this information is therefore unavailable.
5. This study was limited to auditing the palliative care-related problems experienced by hospitalised patients with drug responsive TB, whilst the vast majority of these patients are managed in the community. The study sample can therefore not be considered to be representative of the broader TB patient population.
6. Although data was collected on the number of children under 5 years, no information was obtained with regard to what was done for this high risk group.

PHASE 2 RESULTS

GENERATING A PALLIATIVE CARE FOCUSED QUALITY IMPROVEMENT STRATEGY FROM THE AUDIT FINDINGS.

OBJECTIVES:

- 1. To convene a quality improvement focus group discussion with key members of staff selected from the TB care sites in order to use the data from phase 1 to generate a quality improvement strategy.*
- 2. To report on the development of a palliative care-related quality improvement strategy.*

The qualitative findings from the focus group discussion (FGD) during which the audit results were reviewed with the aim of generating a palliative care-related quality improvement strategy, are presented in this section. These are followed by a report on the quality improvement strategy agreed to by the FGD participants.

Recruitment

A purposive sample of 12 health care professionals was invited to attend the FGD in the Board Room of Murchison Hospital. N=9, (75%) of the sample participated.

Description of participants

The 9 participants comprised:

- the 3 professional nurse managers in charge of the respective male and female MDR-TB units and the TB ward
- the clinical manager from the Genesis Care Centre one of two satellite sites where some of the audit interviews were conducted
- the hospital CEO
- the TB matron
- the medical doctor from the TB ward
- the person responsible for overseeing quality improvement in the hospital
- one professional nurse from the TB ward

Themes and codes emerging from FGD

The researcher and an independent academic colleague agreed that the following four themes captured the essence of the FGD:

1. Understanding of palliative care
2. Pain within the context of TB
3. Worry experienced by hospitalised TB patients
4. Building on existing quality improvement (QI) initiatives and additional opportunities identified for enhancing palliative care-related patient outcomes.

The numbered codes* below indicate the actions identified as being required to match the specified participant input.

Palliative care training *¹

Collaboration with the local hospice and other NGOs*²

Specific QI initiatives*³

Table 16 below illustrates the above by capturing participant comments and suggestions under a selected theme together with the relevant action oriented code. Participant comments are reflected under a specific theme although they may fit with more than one.

Table 16: Summary of FGD aimed at generating palliative care-related QI

Theme	Input from FGD participants	Identified action code
Understanding of palliative care (pc)	‘Giving up on a patient as a Dr, or stepping back’	1*; 2*
	‘pc should not be considered as the point of giving up but rather the starting point of giving total care and promoting hope in TB patients and their families’	1*; 2*
	‘I thought pc was applied when cure was no longer an option and the patient was kept comfortable and given holistic care so that they could die in peace and with dignity’	1*
Pain within the context of TB	‘TB is not considered to be a painful condition, why do patients have pain?’	1*
	‘MDR-TB patients often have severe chest pain when large cavities are present. There are often also side effects of TB medication like peripheral neuropathy. The MDR section started a garden project which did not work because the patients’ feet were too painful for them to be able to participate’	1*; 3*
	African patients don’t complain of pain unless specifically asked and nurses should probe and be proactive regarding this’	1* 3*

Pain within the context of TB (continued)	<p>‘could anything be done to improve pain experienced by emaciated TB patients related to daily intramuscular injections?’</p> <p>‘important to reflect pain in care plan and use a measuring tool or pain scale’</p> <p>‘important to re-assess pain after analgesia is prescribed’</p> <p>‘we should include a discussion on pain in the recently introduced weekly ward round’</p>	<p>2*</p> <p>3*</p> <p>3*</p> <p>3*</p>
Worry experienced by hospitalised TB patients	<p>‘patients in the TB ward usually have advanced illness and dire social circumstances, the TB ward should screen all admissions with a view to facilitating grants as is done in the MDR section’</p> <p>‘we should consider the high level of worry as a wake-up call and have the social worker see all the patients’</p> <p>‘it is important for the team to have their communication skills improved, it is difficult to get alongside a patient to enable them to talk about what is really worrying them’</p> <p>‘whole team needs pc training including communication skills’</p> <p>‘Patients in hospital worry about their families at home’</p>	<p>3*</p> <p>3*</p> <p>1*</p> <p>1*</p> <p>2* 3*</p>
Building on existing QI initiatives and additional opportunities identified for enhancing pc-related patient outcomes	<p>‘start with pc training for Drs so that they prescribe medication in line with WHO analgesic ladder. As a pc trained nurse I am not comfortable telling Drs what to prescribe’</p> <p>‘all team members need pc training, not only Drs they all need to focus on pain management and holistic care’</p> <p>‘it would be good to increase liaison with the local hospice especially Dr to Dr as it would be more acceptable for our Drs to take advice from another medical Dr’</p> <p>‘Consider pain as a vital sign’</p> <p>‘Appoint a pain nurse in each of the TB wards and consider pain as important as infection control’</p> <p>‘get into the habit of assessing pain regularly and add a pain scale to the patient records’</p> <p>‘Explore ways of facilitating contact between hospitalised MDR-TB patients and their families at home with a view to reducing their worry, ensure that this thought is pursued with the upcoming MDR-TB partnership with South Coast Hospice’</p>	<p>1*</p> <p>1* 3*</p> <p>2*</p> <p>3*</p> <p>3*</p> <p>3*</p> <p>2* 3*</p> <p>2* 3*</p>

Building on existing QI initiatives and additional opportunities identified for enhancing pc-related patient outcomes (continued)	'in relation to the MDR-TB partnership, perhaps a staff exchange programme could be arranged with the hospice so that staff from the MDR-TB wards work in their in-patient unit for a few days to learn pc while hospice staff work in the MDR-TB wards to learn more about MDR-TB	3*
	' we can reflect pain in the care plan and put a pain scale in the records straight away'	3*
	'Appointing one nurse in the ward as the person responsible for reminding the whole team of pain'	1*, 2*
	'Arrange pc training for Drs and the rest of the team'	1*

The key contributions made by the participants in the FGD are reproduced in the taxonomy (Table 16) above.

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DISCUSSION OF PHASE 2 RESULTS

GENERATING A PALLIATIVE CARE - FOCUSED QUALITY IMPROVEMENT STRATEGY FROM THE AUDIT FINDINGS.

The following two objectives will be respectively reported on in the first and second section of this chapter.

OBJECTIVES:

- 1. To convene a quality improvement focus group discussion with key members of staff selected from the TB care sites in order to use the data from phase 1 to generate a quality improvement strategy.*
- 2. To report on the development of a palliative care-related quality improvement strategy.*

SECTION 1

FGD aimed at generating a quality improvement strategy.

It is worth noting that the participating professionals who comprised 75% of the purposive sample who had been invited to the FGD were representative and included senior people who have the authority to make decisions. They were all already involved in quality improvement (QI) and had demonstrated an interest in palliative care-related issues. This is in keeping with a simple FGD Interview definition 'An interview with a group of individuals assembled to discuss a given topic'.⁷⁷ The group were given the opportunity to focus their discussion on a topic in which they were interested.⁷⁸

The FGD summary portrayed in Table 14 in the section above gives an indication of the frank and open discussion that took place. All the participants made valuable contributions and seemed to be at ease with one another.

The purpose of data analysis is to organize, provide structure to, and elicit meaning from research data. In qualitative data analysis this involves the identification of themes and concepts.^{79, 80}

The first 3 themes that emerged from the FGD transcript were:

understanding of palliative care;

pain within the context of TB;

worry experienced by hospitalised TB patients.

These together with each of the linked action codes of **palliative care training; collaboration with the local hospice and other NGOs** and **specific QI initiatives** informed the quality improvement strategy. They are summed up in the fourth theme that equates with the QI strategy developed by the FGD participants viz. ***Building on existing QI initiatives and additional opportunities identified for enhancing palliative care –related patient outcomes.***

SECTION 2

The development of a palliative-care related quality improvement strategy.

As well as a number of specific QI initiatives the palliative care-related QI strategy developed during the FGD at Murchison Hospital prioritized the identified actions related to palliative care training and enhanced collaboration with HPCA, South Coast Hospice and other NGOs in the area, as cross cutting issues.

CROSS CUTTING ISSUES

Palliative care training

Arranging for initial palliative care training for the entire team was considered to be an important foundational step which would be followed up with in-service training on the topic. The latter would be ensured by including a palliative care slot on the In-service Training Register. Besides the need for training related to pain and symptom management, teaching on communication skills was considered to be a prerequisite in terms of addressing the main QI

indications arising from the APCA POS audit. As one participant said 'it is difficult to get alongside a patient to enable them to talk about what is really worrying them'. This is made more difficult by the perception that the need to wear a N95 respirator whenever there is direct contact with a potentially infectious patient presents a barrier to sensitive communication.

The poignant comment by another participant regarding the inability of MDR-TB patients to participate in a garden project 'because their feet were too painful' highlights the need for training to include the management of pain and symptoms related to the side effects of treatment. The question/comment 'why do TB patients have pain, it is not considered to be a painful condition' underscores a widely held misconception as well as the need for a training focus on pain within the context of TB.

Provision of holistic care

FGD participants recognized the need for a more holistic approach to care. To quote a participant from the ordinary TB ward 'we should consider the high level of worry in our patients as a wake-up call and have the social worker screen all patients on admission.' A professional nurse in charge of one of the MDR-TB wards mentioned how 'patients in hospital worry about their families at home' and went on to say how this would be exacerbated by the extended time period currently spent in hospital by MDR-TB patients. This is of particular significance when one considers that 66% of the sample who participated in the first phase of the study was female and that there were more females $n=35$ than males $n=22$ in the MDR-TB sample. In general, African women are probably more inclined to worry about home than their male counterparts. In addition only 53.5% of the sample reported having a partner although

they collectively described having 200 children, 42 of whom were younger than 5 years old. The latter statement raises real concerns about the apparent disconnect between hospital and home given that this group of children with immature immune systems are at particular risk of contracting TB.⁶⁶

Enhanced collaboration

A person from the FGD was nominated to approach South Coast Hospice to request palliative care training for the Drs, nurses and social workers working in the TB and MDR-TB section of the hospital. In the words of one participant, 'it should start with palliative care training for the Drs so that they prescribe medication in line with the WHO analgesic ladder. As a palliative care trained nurse I am not used to or comfortable about telling Drs what to prescribe.' This concept was endorsed by another participant who said 'it would be good to increase liaison with the local hospice especially Dr to Dr as it would be more acceptable for our Drs to take advice from another medical Dr.'

Potential future plans

By the time the FGD took place the effect of the faster and more accurate diagnosis of MDR-TB brought about by the introduction of GeneXpert⁸¹ was already having a serious impact on bed availability for these patients. A Dr at the hospital informed the researcher that there had been as many new cases of MDR-TB diagnosed within the first three months of 2013 as there had been for the whole of 2012. This crisis had prompted preliminary negotiations with HPCA and South Coast Hospice with regard to the establishment of a specific formal networking

arrangement that would allow selected MDR-TB patients who would normally be hospitalised to receive home based care.

During the FGD several suggestions were made with regard to this pending arrangement. These included 'explore including the possibility of facilitating contact between hospitalised MDR-TB patients with their families at home' and 'perhaps a staff exchange programme could be arranged so that staff from the MDR-TB wards work in the hospice in-patient unit for a few days to learn more about palliative care while hospice staff work in the MDR-TB wards to learn more about caring for people with drug resistant TB'.

Track record

The excellent track record that exists between these organisations bodes well for the implementation of both of these valuable and innovative ideas.⁸² The former would be likely to reduce the high level of worry experienced by hospitalised TB patients and the latter could prove to be a mutually beneficial practice-based learning opportunity. It is not inconceivable that in the process networking would be further enhanced and potentially lead to further benefits for TB patients and their families.

Specific QI initiatives aimed at improving palliative care-related patient outcomes

In this section bullet points that represent the way forward are presented under the three themes that comprise the palliative care-related QI strategy.

Understanding of palliative care

- Introductory palliative care training for Drs, nurses and social workers
- Six-monthly in-service training on a relevant palliative care-related topic
- Explore the possibility of more professionals including at least one medical Dr getting a recognised qualification in palliative care

Managing pain within the context of TB

- Appoint a 'pain nurse' in each of the TB wards and make him/her responsible for reminding the whole team of pain and ensure that it is included in the weekly ward round discussion
- Consider pain as a vital sign and ensure that it is reflected in the care plan
- Include a pain scale in the patient records
- Document the regular re-assessment of pain after the prescription of analgesia.

Worry experienced by hospitalised TB patients

- Social worker to screen all admissions to the TB ward with a view to facilitating grants as is already done in the MDR-TB section
- Improve communication skills through palliative care training to enhance sensitive communication that will allow hospitalised patients to talk about their fears and worries
- Pursue the exploration of facilitating communication between hospitalised TB patients and their families, particularly young children, at home

Limitations of the study with regard to Phase 2 (Using the audit data to generate palliative care-related quality improvement)

Despite the high number of deaths that occurred during the study period, end of life care which remains an important part of palliative care, was not deliberated during the FGD.

This study was limited to the identification of a QI strategy and did not assess its implementation or the impact it had on improving palliative care related patient outcomes.

Due to the fact that there was no audit data available for children and adolescents under 18 years, the palliative care-related needs of this group were not included in the FGD.

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CONCLUSION AND RECOMMENDATIONS

Overview

This multiple methods longitudinal study was divided into two phases. During the first phase, the prevalence and intensity of the multi-dimensional physical, social, emotional and spiritual problems of a cohort of hospitalized TB patients in a rural District Hospital in KwaZulu-Natal were identified and measured. A validated outcome measurement tool, the APCA POS (Appendix 6) was used for this purpose. The audits took place on a weekly basis over four consecutive weeks. The study sample comprised 114 participants half of whom had been diagnosed with drug responsive TB and half with MDR-TB.

During the second phase of the study, the data obtained from this audit were reviewed by key staff members in a focus group discussion (FGD) meeting. The aim of the FGD was to use the audit findings to generate a palliative care-focused quality improvement strategy.

Phase 1 findings

The baseline APCA POS scores showed that both groups of TB patients, those with drug responsive TB and those with drug resistant TB had significant physical symptoms including pain, cough and nausea. Over 80% were co-infected with HIV. Many of the 55 patients who

died during the data collection period were bread winners and had left small children behind. The worst audit scores were attained with regard to pain, symptoms and worry.

An important and unanticipated finding was that patients with drug responsive TB who were admitted to hospital experienced more severe physical and emotional palliative care-related problems than those with drug resistant TB.

There was no sustained statistically significant change in the intensity of problems experienced by the participants over four consecutive weekly interviews.

It is evident that a comprehensive approach of good palliative care with a focus on the whole person is needed for all TB patients.

Personal reflection

On a personal level I have grappled with the ethical dilemma of relinquishing the role of palliative care nurse in order to fulfill the role of researcher. Identifying serious palliative care-related problems in TB patients and then not trying to influence any intervention to address their suffering because they were participants in my study does not feel right. This pertains particularly to pain, is it ethical to measure pain and then do nothing about controlling it? Can this passive acceptance of unnecessary suffering in 114 research participants be justifiable if it leads to better care for many more people with TB?

This dilemma highlights the issue that palliative care and the relief of pain ought to be universally recognised as a human right.⁸³

Value of the APCA POS

The full intrinsic value of the APCA POS as a validated outcome measure can only be achieved when it is linked to improving clinical care. It is therefore imperative that audit findings are linked to quality improvement. As mentioned in the literature review, audit should be seen as the process of reviewing the delivery of care to identify deficiencies so that they may be remedied ^{41, 42}

Phase 2 findings

The themes which emerged from the FGD as issues that needed to be addressed were:

- Understanding of palliative care;
- Pain within the context of TB;
- Worry experienced by hospitalised TB patients
- Building on the existing quality improvement (QI) infrastructure.

A palliative care-related QI strategy was developed with the aim of improving pain and symptom control and addressing the fears of TB patients. This comprised palliative care training, a focus on the identification and management of pain and plans to ameliorate the level of worry experienced by hospitalised TB patients.

Recommendations for further research

1. Assess the impact of the QI strategy developed during this study on patient care by a repeat APCA POS audit within the next 6-12 months
2. Conduct similar studies of linking APCA POS audits to quality improvement in additional hospital settings
3. Conduct a community-based assessment of the palliative care-related problems experienced by people with drug responsive TB and their primary caregivers/family members
4. Conduct a study to investigate how much support and prophylactic TB intervention is provided to the families of hospitalised TB patients, particularly children under 5 years old
5. Evaluate the impact of palliative care training given to all cadres of hospital staff caring for patients with drug responsive and MDR-TB
6. Conduct a similar study to assess the problems experienced by children with TB by using the paediatric version of the APCA POS, as soon as the validation process for this outcome measurement tool has been completed
7. Consider adding dyspnoea to the list of symptoms mentioned on the APCA POS form when it is used in the TB context.
8. Evaluate the impact of partnerships between palliative care programmes and hospitals providing care to patients with drug responsive and MDR-TB
9. Assess the impact of a comprehensive palliative care approach on TB treatment outcomes.

Policy related recommendations

- The provision of palliative care should be explicitly included in policies and guidelines relating to the care of people with both drug responsive and drug resistant TB
- Conduct audits of the palliative care-related needs of hospitalised TB patients linked to quality improvement initiatives at least once a year
- Stimulate partnerships between palliative care programmes and hospitals providing care to patients with drug responsive and MDR-TB
- Facilitate palliative care training for all cadres of hospital staff providing care to patients with drug responsive and MDR-TB

CONCLUSION

Palliative care within the context of TB is still an emerging concept. This study makes a meaningful contribution to the scarce information currently available. The topic is of great importance in that the suffering experienced by vast numbers of TB patients and their families could and should be substantially relieved.⁵ This study has identified the need for a comprehensive palliative care person-centred approach in this patient population. As such it has responded to the request for the evidence called for in the literature.^{10, 12, 17, 52, 64} It is hoped that the linking of audit findings to quality improvement within the context of TB will stimulate similar research and ultimately lead to consistent improved patient care. As such it will support the existing Guidelines for Providing Palliative Care to Patients with Tuberculosis.⁵

It is hoped that national and international policy makers will take cognizance of these findings and give due consideration to the explicit inclusion of palliative care in all TB related policies and guidelines.

Funding that is made available to stimulate the provision of palliative care training and delivery in the context of TB could have considerable impact in terms of relieving unnecessary suffering and promoting better treatment outcomes.

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APPENDICES

University of Cape Town



UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Faculty of Health Sciences Research Ethics Committee
Room E52-24 Grootte Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

14 May 2012

HREC REF: 220/2012

Mrs Kathleen Defilippi
c/o Dr L Gwyther
Family Medicine
Falmouth Bldg
FHs

Dear Mrs Defilippi

PROJECT TITLE: AN EVALUATION OF THE PALLIATIVE CARE OUTCOMES OF TB PATIENTS IN A DISTRICT HOSPITAL SETTING: A MULTIPLE METHODS QUALITY IMPROVEMENT STUDY

Thank you for submitting your study to the Faculty of Health Sciences Human 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 till the 28 May 2013.

Please submit a progress form, using the standardised Annual Report Form (FHS016), if the study continues beyond the approval period. Please submit a Standard Closure form (FHS010) if the study is completed within the approval period.

Please note the reviewer's comments:

The protocol is very well written, the researcher certainly seem to have the relevant experience both clinically and research related, the setting is in a District Hospital which has pioneered palliative care and the overall risk to participants is minimal and well explained in the information sheet. Our recommendation is that someone other than the research assistant should be available to communicate in a language other than English about questions related to the project (see Appendix 1). Participants in the focus group discussion (Appendix 4) should similarly have access to the researchers, and this information should be contained on the information leaflet. The details of the Human Research Ethics Committee should be added to both information leaflets.

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.

sAriefdien

hrec/ref;220/2012

Yours sincerely



M
PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.



health

Department:
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Health Research & Knowledge Management sub-component
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Reference : HRKM69 /12
Enquiries: Mrs G Khumalo
Telephone : 033 – 395 2805

28 May 2012

Dear Ms K Defilippi

Subject: Approval of a Research Proposal

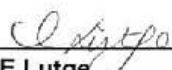
1. The research proposal titled '**An evaluation of the palliative care outcomes of a cohort of TB patients in a district hospital setting: A multiple methods quality improvements study**' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at Murchison and Dunstan Farrell TB Hospitals.

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mrs G Khumalo on 033-395 3189.

Yours Sincerely



Dr E Lutge

Chairperson, Health Research Committee
KwaZulu-Natal Department of Health

Date: 21/05/2012

uMnyango Wezempilo . Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope

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Website: www.genesishope.co.za

THE NORWEGIAN SETTLERS CHURCH
COMMUNITY OUTREACH PROGRAMME

Trust Number: IT 1550/ 02 Public Benefit Organisation Number: 930000242

Monday 30 April 2012

Attention: To Whom It May Concern
University of Cape Town
Cape Town

Dear Sir/Madam

RE: AN EVALUATION OF THE PALLIATIVE CARE OUTCOMES OF A COHORT OF TB PATIENTS IN A DISTRICT HOSPITAL SETTING : A MULTIPLE METHODS QUALITY IMPROVEMENT STUDY

We herewith grant permission for a research survey to be conducted by Ms Kath Defilippi at the Genesis Care Centre.

This study will take the form of a weekly audit over a period of four consecutive weeks to explore the development of a quality improvement strategy.

Yours sincerely

Sharon Jones

SHARON JONES
Operations Manager
Genesis Care Centre



APPENDIX 4

INFORMATION LEAFLET FOR PEOPLE PARTICIPATING IN THE PALLIATIVE CARE AUDIT

AN EVALUATION OF THE PALLIATIVE CARE OUTCOMES OF TB PATIENTS IN A HOSPITAL SETTING:

You are invited to participate in this research project which is being conducted by Kath Defilippi, she has many years of experience in palliative care and is now studying for a MPhil palliative medicine degree at the University of Cape Town. The study aim is to evaluate how the care received by hospitalised TB patients affects their quality of life. Hospitalised TB patients will be asked the same set of questions once a week for four consecutive weeks by this research assistant, a palliative care trained person from South Coast Hospice who is fluent in isiZulu. If you leave the hospital before the four weeks have been completed, if it is possible you will be visited at your new address to get your answers to the questions for the full four weeks. The researcher may, however, decide to withdraw you from the study for this or any other unforeseen circumstance that would make your continued participation problematic. With the exception of the first interview which make take a little longer, each session will take less than 10 minutes. There are 10 questions, the first 7 are for the person with TB to answer and the last 3 for a family member if they are available. You are welcome to ask the research assistant any further questions about this project, or if you wish to SMS Kath Defilippi directly on 0784564606 she will phone you back but will, unfortunately, only be able to answer questions in English.

There is no direct personal benefit to you for participating in this study. However, once all the answers to the questions from all the participants have been analysed, a meeting will be held with the relevant people at the hospital to discuss how best to use the information gained from all the completed questionnaires to produce a palliative care quality improvement strategy that could benefit many people with TB in the future.

You are welcome to think about this and/or discuss it with your friends or family before freely making a decision about accepting the invitation to participate or not. If you do decide to be part of this study you will be asked to sign a consent form. You will, however, still be free to withdraw at any time without this in any way influencing your care. No personal details will appear on any of the research forms and nobody will know what your answers to the questions were except the research assistant who is explaining the study to you.. The Hospice Palliative Care Association of South Africa (HPCA) will be reimbursing South Coast Hospice for her time and travel costs.

In the unlikely event of you finding the questions upsetting, you can stop the interview at any time. The research assistant would also be able to arrange for you to receive counselling, from a qualified person from South Coast Hospice, if you so wish.

Thank you for taking the time to read this or listening while it was explained to you by the research

APPENDIX 5

CONSENT FORM FOR PARTICIPATION IN PALLIATIVE CARE AUDIT

STUDY TITLE: AN EVALUATION OF THE PALLIATIVE CARE OUTCOMES OF TB PATIENTS IN A DISTRICT HOSPITAL
SETTING: A MULTIPLE METHODS QUALITY IMPROVEMENT STUDY

DATE:

I confirm that I have been informed about the above study being conducted by Kath Defilippi.

I have also received, read (or had explained to me), and understood the study as explained in the Participant Information Leaflet.

I understand that my personal details (any identifying information) will be kept strictly confidential.

I understand that I may, at any stage, withdraw my consent and participation in the study without any questions being asked and that I will continue to receive appropriate standard care.

I have had sufficient opportunity to ask questions and am prepared to participate in the study.

SIGNATURE OF PARTICIPANT:

DATE:

SIGNATURE OF INDEPENDENT WITNESS:

DATE:

THIS SECTION IS TO BE COMPLETED BY RESEARCH ASSISTANT

I have explained the above research protocol and am confident that this consent is informed and has been given freely.

Name of participant:

SIGNATURE:

DATE:

APPENDIX 6: APCA AFRICAN POS TB PATIENT AUDIT FORM

DATE:	CONFIRMED DIAGNOSIS: tick one	INTERVIEW SETTING: tick
STUDY NUMBER:	PTB	M HOSPITAL
PARTICIPANT AGE:	MDR-TB	SATELLITE DF
PARTNER/SPOUSE: YES / NO tick	ON TB Rx: YES / NO tick one	SATELLITE G
TOTAL NUMBER CHILDREN:	1 ST LINE Rx	HOME
CHILDREN UNDER 5 YEARS:	2 ND LINE Rx	HIV +: YES / NO tick one
GENDER: MALE / FEMALE tick one	REPEAT TB Rx: YES / NO	ART: YES / NO tick one
ADDITIONAL COMMENTS:	RESULT OF PREVIOUS TB Rx: tick	CD 4 Count:
	CURED	WEIGHT:
	COMPLETED	
	FAILED	
POS no 1 st <input type="checkbox"/> 2 nd <input type="checkbox"/> 3 rd <input type="checkbox"/> 4 th <input type="checkbox"/>		
ASK THE PATIENT	POSSIBLE RESPONSES	
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	0 (no pain)- 5 (worst/overwhelming pain) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	0 (not at all)- 5 (overwhelmingly) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
Q3. Have you been feeling worried about your illness in the past 3 days?	0 (not at all)- 5 (overwhelming worry) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	0 (not at all)- 5 (yes, I've talked freely) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
Q5. Over the past 3 days have you felt that life was worthwhile?	0 (no, not at all)- 5 (yes, all the time) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
Q6. Over the past 3 days, have you felt at peace?	0 (no, not at all)- 5 (Yes, all the time) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
Q7. Have you had enough help and advice for your family to plan for the future?	0 (not at all)- 5 (as much as wanted) 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	

ASK THE FAMILY CARER

Q8. How much information have you and your family been given?

0 (none)- 5 (as much as wanted)

N/A

0 1 2 3 4 5

Q9. How confident does the family feel caring for ___?

0 (not at all)- 5 (very confident)

N/A

0 1 2 3 4 5

Q10. Has the family been feeling worried about the client over the last 3 days?

0 (not at all)- 5 (severe worry)

N/A

0 1 2 3 4 5

University of Cape Town

APPENDIX 7

INFORMATION LEAFLET FOR FOCUS GROUP DISCUSSION PARTICIPANTS

You are invited to participate in a focus group discussion which forms part of a research project which is being conducted by Kath Defilippi, she has many years of experience in palliative care and is now studying for a MPhil palliative medicine degree at the University of Cape Town. The aim of the study is to use the data from an audit of the palliative care outcomes in hospitalised TB patients to generate a quality improvement strategy. A representative sample of hospitalised TB patients will be asked the questions as set out on the APCA POS (African Palliative Care Association Palliative Outcome Scale) which has been validated as an audit tool suitable for use in Africa, and translated into isiZulu. The APCA POS will be administered to participants who have freely consented to participate in the study, once a week for four consecutive weeks by the research assistant, a palliative care trained person from South Coast Hospice who is fluent in isiZulu. As you will see from the attached APCA POS questionnaire there are 10 questions, the first 7 are for the person with TB to answer and the last 3 for a family member if they are available.

A maximum of 12 consenting members of the health care team will participate in a focus group interview which will be conducted in English and moderated by the researcher. During the allotted 90 minutes the group will review the analysis of the APCA POS audit findings and share ideas about how this data could be used to generate a strategy to improve the quality of palliative care given to hospitalised TB patients. The attached semi-structured questionnaire will be used to guide the focus group discussion.

Focus group members will be asked to commit to ground rules that emphasise listening with respect to the opinions of others; keeping the discussion relevant in terms of the intended outcome; allowing all participants to contribute to the discussion and to keeping these individual discussions confidential. The researcher can give you the ethical assurance that she will safeguard your privacy and keep your audio-taped verbal contributions confidential she cannot, however, control the behaviour of other group members once the focus group discussion has been concluded. By giving your consent you agree to accept this risk inherent to focus groups.

There is no direct personal benefit to you for participating in this study. However, by generating and implementing a palliative care quality improvement strategy based upon the audit data you have the potential of contributing to improving the quality of palliative care given to many people with TB in the future.

You are welcome to think about this before freely making a decision about accepting the invitation to participate in the focus group or not. If you do decide to be part of this study you will be asked to sign a consent form. You will, however, still be free to withdraw from the focus group discussion at any time. The moderator could also ask you to leave the focus group if she deems your participation to be problematic. If you have any questions you would like to discuss please feel free to phone or send a text message to Kath Defilippi on 0784564606.

In the unlikely event of you finding the questions upsetting, you may request debriefing from a psychosocial professional from South Coast Hospice by phoning 039-692301 and asking for Dominique Burton or by e-mailing dominique@schospice.co.za

Thank you for taking the time to read this information leaflet.

APPENDIX 8

FOCUS GROUP DISCUSSION MEETING

Semi- structured Questionnaire

What does the term palliative care mean to you?

How have you been involved with Quality Improvement activities?

Based upon the audit findings, how you would prioritize palliative care quality improvement opportunities for TB patients?

What are the most important things that would need to be considered in the formulation of a QI strategy to enhance the delivery of palliative care-related activities in your setting?

How could this concept of a palliative care-related QI strategy be taken forward?

Do you have any further comments pertaining to the topic?

APPENDIX 9

CONSENT FORM FOR PARTICIPATION IN A TAPE RECORDED FOCUS GROUP DISCUSSION

STUDY TITLE: AN EVALUATION OF THE PALLIATIVE CARE OUTCOMES OF TB PATIENTS IN A DISTRICT HOSPITAL
SETTING: A MULTIPLE METHODS QUALITY IMPROVEMENT STUDY

DATE:

I confirm that I have been informed about the above study being conducted by Kath Defilippi.

I have also received, and understood the Participant Information Leaflet and realise that the focus group discussion will be recorded on a tape recorder.

I understand that my personal details will be kept strictly confidential by the researcher but that confidentiality cannot be absolutely guaranteed in a focus group setting, as indicated in the participant information leaflet.

I understand that I may, at any stage, withdraw my consent and participation without any questions being asked.

I have had sufficient opportunity to ask questions and am prepared to participate in the focus group discussion with the intended outcome of generating a palliative care quality improvement strategy for TB patients. I am available to attend this focus group discussion in the Board Room at Murchison Hospital on Thursday 28 February from 11.30-13.00 after which light refreshments will be served.

SIGNATURE OF PARTICIPANT:

DATE:

SIGNATURE OF INDEPENDENT WITNESS:

DATE

APPENDIX 10

FGD HANDOUT

AN EVALUATION OF THE PALLIATIVE CARE-RELATED OUTCOMES OF A COHORT OF TB PATIENTS IN A DISTRICT HOSPITAL SETTING: A MULTIPLE METHODS QUALITY IMPROVEMENT STUDY

This study was divided into two phases. A measurement of the palliative care –related problems experienced by hospitalized TB patients admitted to the Hospital formed the focus of the first phase. A validated outcome tool, the APCA (African Palliative Care Association) African POS (Palliative Outcome Scale) was used for this purpose. This brief multi-dimensional outcome measure uses patient and family-level indicators that could be used in the routine clinical practice, is based upon the WHO definition of palliative care. Prevalence and intensity of the multi-dimensional physical, social, emotional and spiritual problems of hospitalized TB patients in the TB and MDR-TB wards were identified and measured on a weekly basis for four consecutive weeks. The vast majority of the audit interviews were conducted in isiZulu by Sr Francisca Dladla who is an experienced palliative care trained professional nurse.

The full sample of 114 participants was recruited into the study, 57 from the MDR-TB wards and 57 from the TB ward. We would like to thank all concerned particularly Sr Singh, Mr Ngobese and Sr Memela for the hospitality and co-operation extended to us during the 32 weeks of data collection.

Study information was given to 132 participants, 24 declined to participate and the remainder signed consent. During the 32 weeks of data collection 46 patients were considered to be too ill and were not approached and 9 withdrew consent following at least one interview. A total of 351 interviews were conducted, 313 or 89% at Murchison Hospital, 8 at Genesis Care Centre

and 5 at Dunstan Farrel TB Hospital, the remainder took place in the patient's home after discharge. In 19 instances we were unable to reach patients who had been discharged home. An unexpected finding was that pain and symptoms were marginally worse in patients who did not have MDR-TB and that fewer deaths (15) were reported in the MDR-TB wards than the TB ward (40).

The purpose of today's meeting is to review the audit findings and explore your ideas regarding the potential of linking these findings to the development of a palliative care-related quality improvement strategy. This forms the second phase of the study.

University of Cape Town

APPENDIX 11 - FGD INTERVIEW GUIDE

Objectives

1. To identify quality improvement activities to improve the quality of care for TB patients based upon the audit findings.
2. To explore the generation of a quality improvement strategy with hospital and satellite staff.

Introduction

Thank everyone for coming and check that they have all given signed consent

Remind the group of the purpose of the FGD as per the objectives and mention that there are extra copies of a summary of the audit findings available in case anyone forgot to bring their copy.

Introduce Moderator and Observer

Review ground rules and remind everyone to mention their participant number before answering questions

State that taping will now commence.

Please tell me about your individual roles and responsibilities? 10 mins

Semi- structured Questionnaire

What does the term palliative care mean to you? 10 mins

How have you been involved with Quality Improvement activities?
10 mins

Based upon the audit findings, how you would prioritize palliative care quality improvement opportunities for TB patients? 15 mins

What are the most important things that would need to be considered in the formulation of a QI strategy to enhance the delivery of palliative care in your setting? 15 mins

How could this concept of a palliative care QI strategy be taken forward? 15 mins

Closure

Do you have any further comments pertaining to the topic? 15 mins

Thank you for your participation, the FGD is now closed. Please help yourselves to refreshments.