

**A description of Patients with Recurrence of Pulmonary Tuberculosis
in TB Hospital, Ermelo**

BY

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**A Research Project submitted in partial fulfillment of the Requirement
for MMed Family Medicine Degree of the University of Stellenbosch.**

DECLARATION

I hereby declare that this is an original work undertaken by Dr. Ubon S. Akpabio. All information and data relating to previous studies have been duly referenced.

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SUMMARY

South Africa is one of the high burden countries for TB in Sub Sahara in Africa with Mpumalanga as one of the provinces with a high burden of disease. Data available on tuberculosis in Msukaligwa indicate the following: Cure Rate 40%; Smear conversion at the end of intensive phase 35% and Defaulter Rate 27.5%.

The problem of TB is made worse by the twin epidemic of HIV, with a prevalence of 38.9% in our district -the highest among the 3 districts in the province. Retreatment TB carries the risk of developing TB drug resistance with severe consequences for the patient and the population. Understanding the characteristics of these patients will help in designing interventions to prevent the problem, promote a high cure rate for patients with TB in our health care system and reduce to minimum the burden of re-treatment pulmonary TB on our health care facilities and community. One critical precondition for Retreatment TB is non adherence to TB treatment. Factors responsible for non adherence could be classified as individual patient factors; Co-morbid conditions; Health system; treatment related and Community factors. The outcomes of Retreatment TB could be, cure, and death and failure of treatment leading to drug resistance.

The **Setting** of this study is the 58-bedded TB hospital in Ermelo. **The Aim** of the study was to describe the occurrence, characteristics and management outcome of Retreatment Pulmonary Tuberculosis in patients in the Ermelo TB hospital. The specific **Objectives** were to describe the socio-demographic, behavioural and clinical factors related to recurrence of the TB in patients; to determine the contribution of non adherence to treatment on recurrence of TB in the study population; to identify the prevalence of resistance to TB medication among patients with Retreatment TB ; to identify treatment outcomes in patients who have been followed up for the duration of Retreatment TB and finally to make recommendations to the Department of Health, Mpumalanga towards minimizing Retreatment TB and improving the overall TB programme.

The Study design is cross sectional and descriptive; the study population comprised of patients admitted with TB at Ermelo TB hospital aged 15 years and older between 1 January 2005 and 31 December 2007.No specific probability sampling was applied in the selection of the patients.

Data Collection involved visits to the TB hospital during the period and extracting the relevant information from the patient medical records and the TB register using a predesigned data collection form. **Data analysis** was done by the statistician from the Centre for Statistical Consultation, University of Stellenbosch. Being a descriptive study, the data analysis expresses the prevalence of various factors associated with retreatment TB. This study met the Ethical

approval of the University of Stellenbosch as well as the Research Ethics Committee of the Department of Health & Social Services, Mpumalanga.

Findings

All the three hundred and eighty eight patient records with retreatment TB forming 19.6% of TB patients admitted between 2005 and 2007 were reviewed. The distributions of the patients were: males 66%; mean age of 41.4 years; females 34%; mean age 35.3 years. They were mostly unemployed; primary education 93%; unmarried 43% and married 34%.Retreatment TB was diagnosed with sputum smear microscopy in 71% with bacilli load of 3+ in 45%.The sources of referral to TB hospital were: public hospital 71 %; private doctors 2%. 74% of the patients have had TB 1-3 years before the episode under study. Retreatment TB categories were: after treatment completed 69%; default 19%; after cure 8% and treatment failure 4%. 98% of patients tested had +ve HIV status; the median CD4 cell count was 106 cells/µl at the time of retreatment; very few (5%) were on ART. Drug resistance to primary TB drugs was as follows: Rifampicin 16%; Isoniazid 29%; Ethambutol 19% and Streptomycin 23%. The treatment outcomes for those whom data were available were: successful 49.1%, death 23.8%; treatment default 22.9%. MDR-TB complicated 3.3% of the patients.

Conclusion: Majority of the retreatment TB patients were males with an average age of 41years and unemployed. More than two thirds of the patient had completed TB treatment previously and default on treatment accounted for less than one quarter of retreatment categories. The process of care was better in terms of diagnosis of TB with sputum smear. Improvement in the documentation of key factors like smoking, alcohol, drug use among patients and co-morbidity as well as counselling and testing for HIV and provision of ARTs is required. Treatment outcomes with regards to successful outcome need to be monitored and improved upon.

INTRODUCTION and BACKGROUND

Tuberculosis (TB) is a major public health problem worldwide and since 1993 the WHO¹ has proclaimed it as a public health emergency. South Africa is one of the high burden countries for TB with a very high annual estimated incidence². In the Mpumalanga province of South Africa, the burden of tuberculosis reflects the national trend. The incidence of TB in our municipal area is estimated as second highest in the district at about 450/100,000³. Other health indicators available for tuberculosis in Msukaligwa municipal area indicate a serious problem with the

following for 2006: Cure Rate 40%; Smear conversion at the end of intensive phase 35% and Defaulter Rate 27.5%³

The TB problem is worsened by the twin epidemic of HIV disease with the prevalence of HIV (38.9%) in our district being the highest (National Dept of Health, 2006 survey). Improper treatment and default on treatment could result in TB bacilli developing resistance to treatment with dire consequences for the patient and the population. Patients who present with re-treatment Pulmonary TB represent a group that could eventually lead to development of drug resistance. Understanding the characteristics of these patients will help in designing interventions that will prevent non adherence to treatment, enhance adherence and high cure rate for patients with TB in our health care system as well as reduce to minimum the burden of re-treatment pulmonary TB on our health care facilities and community.

The setting of this study is the TB hospital located in Ermelo, Msukaligwa municipality in Gert Sibande district of Mpumalanga. This is one of the 2 TB hospitals in the district with a bed capacity for 58 beds; it is a dedicated institution for the admission of adult TB patients. Patients are referred from the one regional, 5 district hospitals, primary health care clinics and private doctors in the Gert Sibande district for admission at the hospital.

All Retreatment TB patients who are ill and live far away from the hospital are usually admitted for an initial period of 6-8 weeks. During this admission sputa are collected at intervals specified in the National TB treatment guidelines and Retreatment regimen commenced. Decisions on the continuation of treatment, sputum culture, drug sensitivity and treatment failure are made depending on the sputum smear results at these periods. On discharge, patients can be reviewed monthly as outpatients in the hospital or followed up at the nearest primary healthcare clinics in their area. All patients who choose to be followed up at the clinics are given letters of referral to the clinic sister. Once they are at the clinic they are referred for supervision of treatment under DOTS programme and will visit the clinic monthly to collect their medication until the treatment is completed.

LITERATURE REVIEW

Retreatment TB occurs within the context of related issues of non- adherence to TB treatment in the first instance. The conceptual framework therefore is that non adherence to TB treatment leads to continuing illness which is diagnosed by the clinical process, sputum smear and chest X-ray as Retreatment TB and then commenced on treatment.

According to WHO² (2007), it is estimated that there were 8.8 million people diagnosed with new TB cases in 2004 (136 per 100000), including 3.9 million (60 per100000) new smear positive cases. The 2005 estimate puts the incidence of TB in South Africa at 245 cases (200-302) per 100000 population per year and prevalence at between 344-718 cases/100000 population. It is also estimated that mortality due to TB varies between 47-107deaths /100000 populations (71/100000); proportion of new adult TB cases 15-49 years that are HIV+ 58% (49-65%); New TB cases multidrug resistant 1.8% (1.4-2.3%) and previously treated TB cases that were multidrug resistant in 2002 as 6.7% (5.5-8.1%)².

Retreatment Tuberculosis occurs after a person may or may not have completed the scheduled treatment course for TB. It can occur due to endogenous reactivation or exogenous re-infection^{4,5}. In the South African National TB Control Program⁶ various categories of Retreatment TB have been identified.

A recent systematic review⁷ found the rates of recurrence of TB after successful treatment to vary from 0% to 14 % due to a number of factors that included treatment regimen, presence of concomitant diseases. However, they submitted that the observed differences in recurrence rates could be explained by the key factors of whether the treatment is taken daily compared with intermittently (three times weekly), the characteristics of patients included in the studies, and poor treatment adherence as a result of the difficulties of direct observation of doses. In a study among South African mine workers⁸,it was found that the recurrence rate for TB was 10.3 episodes per 100 person years at risk during a follow up of the patients for the median period of 25.1months with most of the recurrence occurring within the first 6 months of follow up. Another study⁹ found that the rate of recurrence TB was 18 % in the study population with recurrence occurring after successful treatment and after default. In those in which DNA finger printing was available most recurrences after successful treatment were due to re-infection. The re-infection rate after successful treatment was estimated at 2.2 per 100 person years. People with previous TB have a four times higher risk of TB compared to TB naïve patients.

The determination of whether an episode of TB infection is a relapse or reinfection with a new TB strain is one of the issues in Retreatment TB. This differentiation can be done using DNA finger printing techniques with Mycobacterium TB^{8, 9,10,11,12, 13, 14} . Whether re-treatment TB in a patient is due to re-infection or re-activation is not clinically distinguishable. The mechanisms that have been postulated as leading to the development re-treatment TB in patients are either

endogenous and true treatment failure or exogenous re-infection. Two separate studies in Rwanda^{10,11} using molecular techniques and DNA finger printing respectively found that recurrent TB and treatment failure was not due to re-infection and that most MDR-TB patients were found to be related to reactivation and treatment failure. In an area of low TB incidence and low HIV prevalence, studies have revealed that re-infection with new M. tuberculosis strain is considered a rare cause of recurrent TB¹⁴. This contradicted the findings in a population-based retrospective case-control study¹⁵ in Houston, USA, where re-infection with new strain of M. Tuberculosis was the cause of recurrent TB.

In a setting of high TB and HIV prevalence respectively, as in South Africa the relative contribution of re-infection or relapse to recurrent TB is different. A study¹⁰ among South African mine workers, found that most recurrent TB was due to relapse within 6 months with re-infection common in patients with HIV infection. An earlier study in South Africa¹² using DNA finger printing had shown that re-infection was the cause of recurrence of tuberculosis. Using DNA finger printing in a population-based retrospective longitudinal study¹⁶ in Spain; researchers also found Mycobacterium strains from some patients with episodes of recurrent TB indicating relapse in most while the rest suggested re-infection. They concluded that re-infection is possible among people in developed countries but at lower rates than those in high risk areas of tuberculosis. In an earlier study¹³ in the same environment, investigators argued that re-infection plays an important part in recurrent TB in a population without the usual clinical and epidemiological characteristics that are assumed to favour it.

One of the underlying issues predisposing to Retreatment TB is non-adherence which can be considered under personal, health system; co-morbid and community related factors.

A number of individual factors have been known to affect adherence to TB treatment. Several studies in Africa and elsewhere^{17,18,19,20} have shown that males are more likely to default on TB treatment than females who are more likely to have excellent adherence to TB treatment^{21,22}. However, in a community-based study in Zambia²³, a slightly more females were found to have stopped taking their TB medication after they started feeling better. Among other things, the study also found that age, marital status were not associated with compliance. While age is linked to default on TB treatment, no particular age is singled out. One study found that a younger age is associated with increased adherence²⁴. A study from Turkey²⁵ that reported on a default rate of 5.1% among patients in one TB center, also stated that a risk factor for non successful treatment were patients older than 46 years. Other studies from Nigeria¹⁸ found that

44.2% who defaulted treatment were older than 65yrs while a study in India²⁰, found that not completing the process of diagnosis of TB was higher in >50yrs age.

Social, economic and behavioural factors play important role in adherence to TB treatment. These have been found in studies in Nepal²⁶ and Russia²⁷. The factors identified were unemployment, low status occupation, low income, cost of transport to facility and homelessness. In yet another study in Brazil ²⁸, it was found that the rate of default on TB treatment was 10 times (11.7%) higher in the poorest patients in a study than among the wealthiest members of the study population (1.6%).

Behavioural factors related to smoking, use of alcohol and drug use are known to affect outcome of TB treatment. Smoking has been found to be independent predictors of relapse and poor adherence to TB treatment and contributed to default on treatment of MDR-TB^{18,19, 29,30,31,32}.

The associations of Retreatment TB with other diseases like COPD, chronic bronchitis, peptic ulcer, chronic hepatitis and occupational hazards been described by various workers^{33, 34}. In most developing countries, particularly in Africa an important co-morbid condition in TB is the HIV infection. Many studies in South Africa, Zambia and other parts of Africa ^{8, 35, 36,37,39,38}, have highlighted the importance of HIV as a risk factor not only for the re-treatment TB, but also in terms of outcomes. In a setting of high risk of TB infection, HIV-1 infection increases the risk of recurrent tuberculosis because of the risk of re-infection. Retreatment TB in these patients was associated with severe immunosuppression as shown by low CD4 counts³⁸.

The behaviour of healthcare professionals is important for adherence to TB treatment under DOTS. An aspect of this behaviour is the quality of communication between the patient and the provider about aspects of the disease and treatment expectations. A study has shown that poor grade communication between patients and health care professionals were significantly associated with non adherence³⁹. A review of patient defaulters by in-depth interviews and participant observation⁴⁰ identified a number of pertinent health system factors that affected adherence as inconvenient timing of the clinics, non provision for treatment in event of family emergency and inability to deal with complicated cases like alcoholics. In a South African study³¹ on MDR- TB, it was shown that defaulters reported more dissatisfaction with healthcare workers attitudes and therefore missed treatment due to this. Disrespectful treatment from the health care worker and not being told the reason for receiving treatment for one year by health care worker led to their default from treatment³¹.

Medication related factors have been found to be associated with tendency towards recurrent TB in patients as well as defaulting on treatment among MDR-TB patients³¹. A study in Uganda⁴¹, found that patients treated with Thiacetazone containing regimen were more likely to relapse after treatment than those treated with Rifampicin containing regimen because of the serious side effects associated with Thiacetazone.

The possible outcomes in TB treatment are cure, treatment failure and death. According to WHO², the targets that TB programs should achieve are: a smear positive detection rate of 70%; a cure rate of 85% and no default on treatment. There have been no specific targets set for re-treatment TB. However, considering the seriousness of this problem on public health, the target for cure for Retreatment TB should be the same for all new TB naïve cases. Treatment outcomes for TB in South Africa are still below the target of 85% set by WHO and many patients are lost to follow up: more than 10% of patients had no recorded outcome. According to WHO², the success rate for re-treatment TB by 2005 was 73%. In comparing Retreatment TB with new TB patients, three patterns appear. These are: treatment success rate in Retreatment TB lower than for new cases; patients who default from their first treatment tended to default when treated again; patients retreated after relapse or failure fared better in completing treatment and finally the high death rates for Retreatment patients in Africa region.

One of the key consequences of non- adherence to TB treatment is drug resistance to TB medication. This could be mono, multidrug or extreme drug resistance. While previous TB treatment has been indicated as risk factor associated with drug resistant TB⁴², an earlier study in a South African rural health district⁴³, found that previous treatment history for TB was not associated with drug resistance. Other factors shown not to be associated with drug resistance in that study were age, sex and known HIV status. Reasons for the previous treatment history probably not being a risk factor were use of multiple drug regimen, DOTS and high completion rates in the treated patients.

Other studies in the South Africa gold mines^{44, 45} found that patients with Retreatment TB were more likely to have resistance to any TB drug or MDR-TB. The prevalence of HIV infection or the level of CD4 cell count has been found not to a significant factor with the primary or acquired resistance to TB medication^{44,45,46}.The only predictor for MDR-TB in HIV +ve patients with recurrent TB patient is the history of TB and not their HIV status^{47,48}.

Appropriate interventions to prevent and minimize the occurrence of Retreatment TB needs to be considered in Africa. Initiatives to promote adherence to TB treatment has been designed and included in some TB treatment and preventative programmes in various parts of the world. A study⁴⁹ from some regions in Russia identified lack of social support among the reasons for default on treatment and proposed collaboration between the TB programmes and social organizations as modalities for improving adherence. Similar studies in other places^{28, 30, 49, 50} had also raised the issue of social incentives to promote adherence to treatment and classified them into economic, health service support, administrative and habits. They concluded that financial incentives for food and transportation subsidies may be required to improve treatment compliance among the poorest TB patients, the homeless and drug users in the community. This fact was reaffirmed in a randomized clinical trial on incentives to the poor⁵¹. While this was concerned with adherence to treatment for latent TB infection, it serves to emphasize the role of simple, low cost incentives in getting the poor patients to adhere to treatment interventions.

The **AIM** of the study is to describe the occurrence, associated factors and management outcome of Retreatment Pulmonary Tuberculosis in patients in the Ermelo TB hospital.

The **OBJECTIVES are:** **1** To describe the socio-demographic and behavioural characteristics of retreatment TB patients in Ermelo TB Hospital. **2.** To determine the contribution of non adherence to treatment to retreatment TB in the study population. **3.** To identify the prevalence of resistance to anti TB medication among patients with Retreatment TB in Ermelo. **4** To identify treatment outcomes in patients who have been followed up for the duration of Retreatment TB.

5. To make recommendations to the Department of Health, Mpumalanga towards minimizing Retreatment TB and improving the overall TB programme.

METHODOLOGY

The Study Design is Descriptive. The **Study Population** comprised of *all* patients admitted with TB at the TB hospital in Ermelo the 3 year study period. The sample for actual study population was all patients aged 15 years and older who have been diagnosed with Retreatment TB and commenced on TB treatment between 1 January 2005 and 31 December 2007. These are patients who have been entered in the hospital-based TB register with medical records available in the hospital. Patients excluded were: those with extra pulmonary TB, patients with Retreatment TB started on treatment in 2004 and completing in 2005.

The required information was extracted from the TB register and patients medical records. All the information extracted was entered into the **data collection form** that was used for each identified patient. The data collection form had three digit serial numbers with no patient identifiers on it, but could be cross referenced to the medical record should it be necessary. Information for analysis was derived from the data collection form and entered into the spreadsheet designed for the analysis.

The reliability of the data collected was assured by clear definition of the terms and concepts relevant to the study. For this, the case definitions as contained in the South African National TB control programme guidelines was used. This applied to definitions such as “Retreatment TB”; “Retreatment categories”; “treatment outcomes” and “drug resistance”. To ensure the validity of the data collected, reference was made to each of the patient’s records to ensure that what is reflected in the TB register is as it appeared in the patient’s medical record.

The Pilot Study consisted of using the data collection form with a few selected patient files and TB register. Necessary modification was made to reflect comments and to refine the form as a better data collection tool. **The Procedure for data collection** involved visits to the Ermelo TB hospital during the period of the data collection. The total number of patients treated over the study period was ascertained from TB register and patients with Retreatment TB identified. From the patients identified in the TB register, the medical records were requested in order to extract detailed information about the patient based on the data collection tool developed for this purpose.

The Data analysis was done by Prof M. Kidd from the Centre for Statistical Consultation; University of Stellenbosch. The statistician was contacted from the early stage of the study and during the data collection. The data collection form was sent to the statistician who designed the spreadsheet on which data on each of the variables contained in the questionnaire was entered and subsequently analyzed. Being a descriptive study, the data analysis expresses the prevalence of various factors associated with retreatment TB using summary statistics. The data is presented mainly in the form of histogram chart reflecting the variables of interest to the study.

DEFINITIONS

The focus of the study is mainly on Pulmonary Tuberculosis. The diagnosis of tuberculosis was considered to be based on any of the following: microscopy- sputum smear and standard

reporting of the bacilli load; clinical evaluation of the patient (history: symptoms and signs of illness; examination) and chest radiography interpretation. In addition any patient with TB on treatment with Regimen 2 was considered to have Retreatment TB and in the absence of any documentation this was taken as Pulmonary TB.

In order to facilitate the collection of the required data all the definitions applied to the study were those defined in the South African TB Control Programme Practical Guidelines 2000⁶.

ETHICAL CONSIDERATIONS

Relevant guidelines and laws of South Africa pertaining to health research were adhered to. Adequate ethical considerations were made with regards to the following: Protecting the interests of the research participants; confidentiality of personal information and freedom to draw own conclusions and publish the research findings. The interest of the patients was protected by ensuring that the information obtained was not linked to the patients. As a retrospective study with data collection by record review, there was no direct patient interaction, hence no informed consent was necessary from the patients to use their records.

The confidentiality of the patient information was safeguarded and respected by keeping the medical records safe and inaccessible to others who were not directly involved with the study. All the activities of the study did not bring any harm to the patients whose records was reviewed or disadvantaged them in any way with regards to future timely access to care in the TB hospital.

It is an expectation that the findings of this study will be published through presentation at relevant conferences and publication in medical journals in order to share the research findings with others and enrich our understanding of issues associated with Retreatment TB.

This research was submitted to the Committee for Human Research at the University of Stellenbosch for approval which was granted. It was also approved by the Research Ethics Committee of the Department of Health, Mpumalanga.

RESULTS

A total of 388 patients with Retreatment TB were seen at the TB Hospital between 2005 and December 2007. These constituted 19.6% of the total 1980 patients treated for TB during the period. Males were 66 % while the females were 34%; male: female ratio of 1.9: 1. The mean age for the males was 41.4 years while for the female it was 35.3 years. For each of gender the most affected age group was 35–44 years for male and 25-234 years for females. The men

were older than the females. Ninety three percent (93%) had primary education; 2% high school and 6% no formal education and 92.7% were unemployed /blue collar workers. Information on social habits: smoking, alcohol and drug use was not known for 98% of the patients. With regards to marital status, (43%) were unmarried; in 23 % the marital status was not known;34 % were reported as married. On the number of people in the same household excluding the patient at the time of the episode of retreatment TB treatment, majority (72%) of the patients lived in households with least 2 persons. Majority (97%) of the patients has had TB once in the past years and for these 74% had TB in the past 1-3yrs before the episode under study. Information on co- morbid conditions were very limited to make logical interpretation as it was both 1% for Diabetes and Epilepsy and 0% for COPD and hypertension. Drug resistance to primary TB drugs was as follows: Rifampicin 16%; Isoniazid 29%; Ethambutol 19% and Streptomycin 23%. In terms of treatment outcome, successful outcome was 49.1% (cured and completed treatment) failure 4.2%; default 22.9% and death 23.8% among those who were followed up at the TB hospital. MDR-TB resulted from 3.3% (7/214) of the patients followed up in the hospital.

Figure 1 shows the combined age distribution of the patients in the study.

Figure 2 shows the distribution of the retreatment TB patients by gender.

Figure 3 shows the bacilli load in patients diagnosed with sputum microscopy.

Figure 4 shows how the patient was referred to TB hospital.

Table 1 shows the distribution of the patients by two broad occupational groups

Table 2 shows the **main** diagnostic tool for the TB, in the retreatment TB patients. "Other means" - included the use of Pleural fluid ADA.

Table 3 shows the Retreatment TB categories based on the previous TB episode.

Table 4 shows the information on drug sensitivity testing pattern for the primary TB drugs. On the whole, records were available for analysis for about 25.9% (100/386) of the patients. Slightly more patients were resistant to Isoniazid compared to Rifampicin.

Table 5 shows the "Treatment Outcomes" for the retreatment TB. MDR-TB is included in the Failures. It is a serious complication of retreatment TB and not a treatment outcome.

Fig. 1 Age distribution of the Retreatment TB Patients

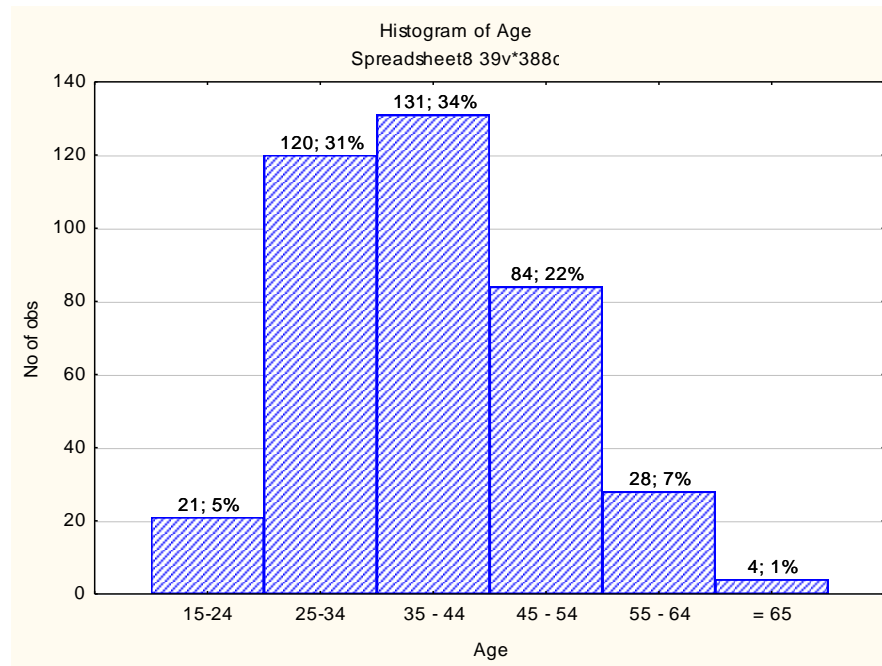


Fig 2 Age distribution by Sex of Retreatment TB patients

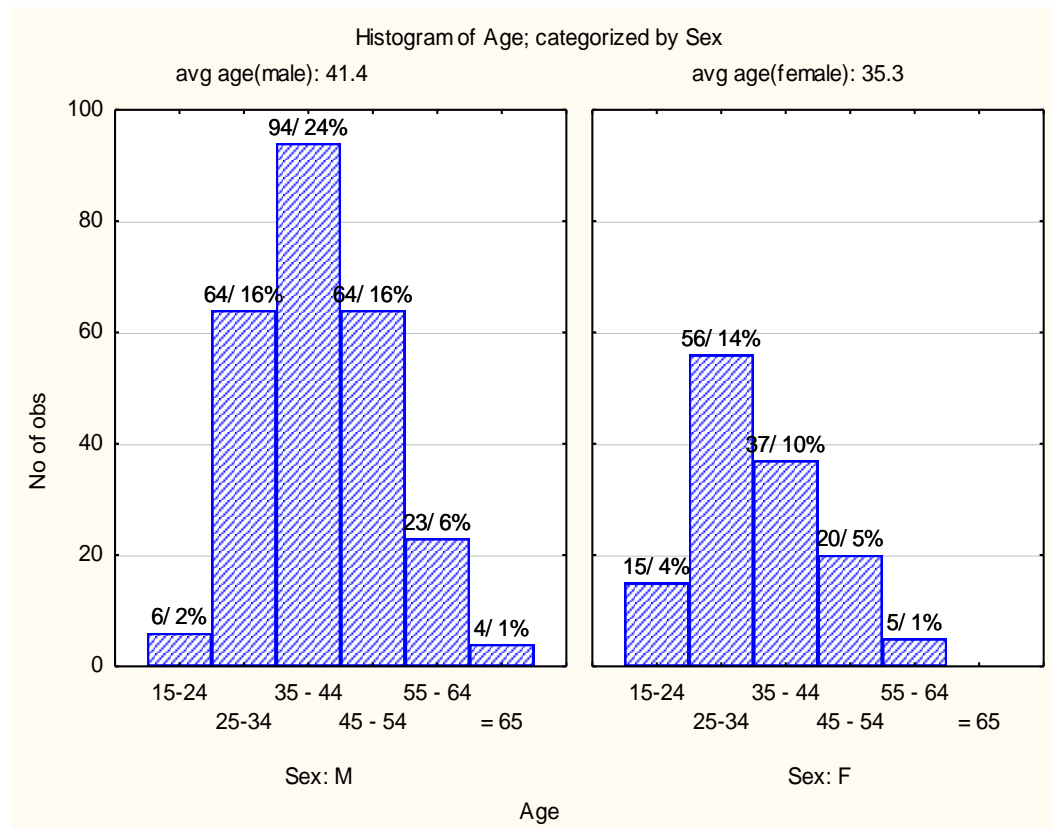


Table 1. Distribution by Occupation of Retreatment TB Patients

OCCUPATIONAL GROUP	NUMBER OF PATIENTS (%)
Unemployed /Blue- collar (laborer , unskilled)	360 (92.7)
Employed / White-collar (salaried professional educated workers	28 (7.2)

Table 2. Distribution of Retreatment TB patients by How TB was first Diagnosed

Main Diagnostic tool	Number of Patients (%)
Sputum AFB	276 (71.1)
Chest X-Ray	93 (23.9)
Others	19 (4.9)

Fig.3 Distribution of Retreatment TB patients by Bacilli load

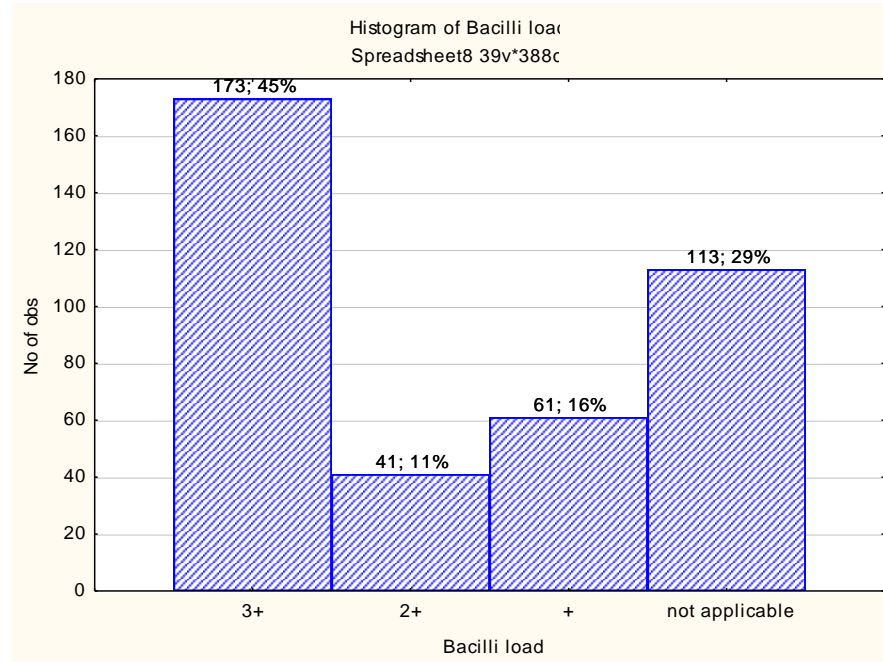


Fig. 4 Referral Source of Retreatment TB Patients

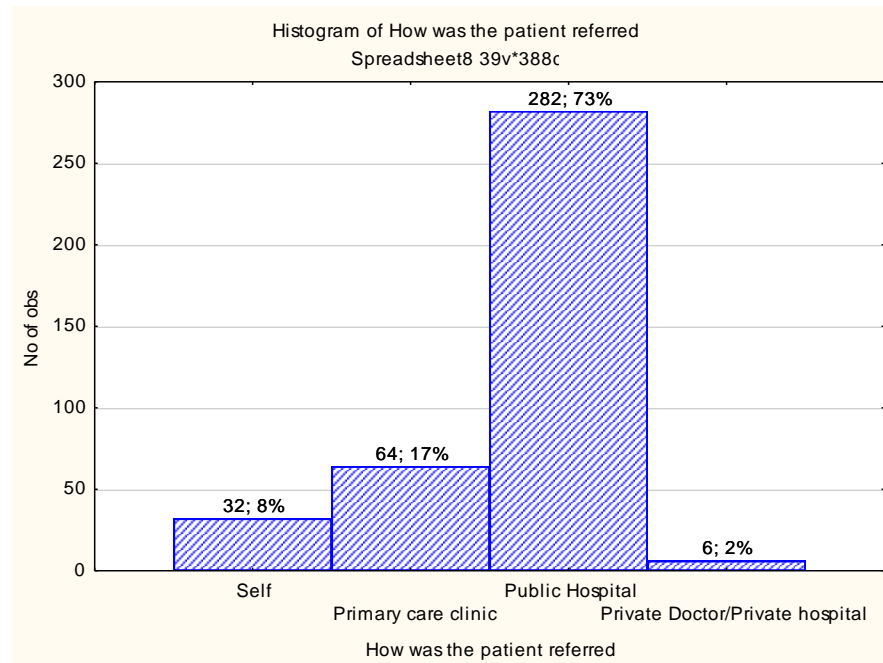


Table 3. Distribution of Retreatment TB patients by Re-treatment TB category

(Based on previous TB episode)

Re-treatment TB Category	No of Patients (%)
After treatment completed	266 (69)
After cure	31 (8)
After default	75 (19)
After failure	16 (4)

Fig. 5, 6 and 7 show HIV-related factors. In Fig 5, 98 % (169/172) patients who were tested and results known had +ve results while 3 (1.7%) were -ve.

Figure 6 shows the distribution of the CD4 count. The median CD4 count is 106 cells/ μ l.

Figure 7 shows the distribution of patients on ART. Within the period of this study, the roll out of ART within the public sector was just beginning within the district.

Fig. 5 Distribution of Retreatment TB Patients by HIV status

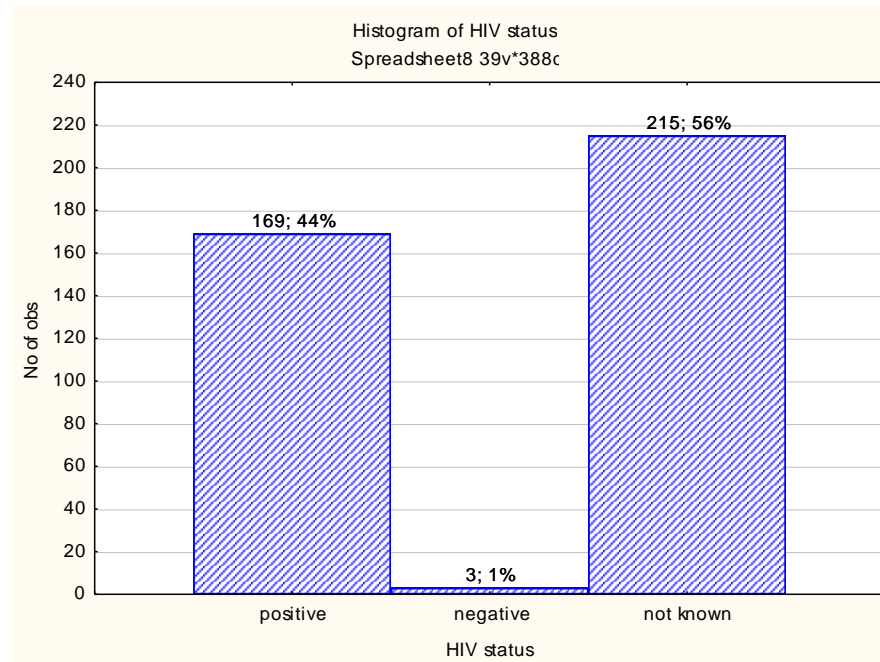


Fig. 6 Distribution of Retreatment TB Patients by CD4 count

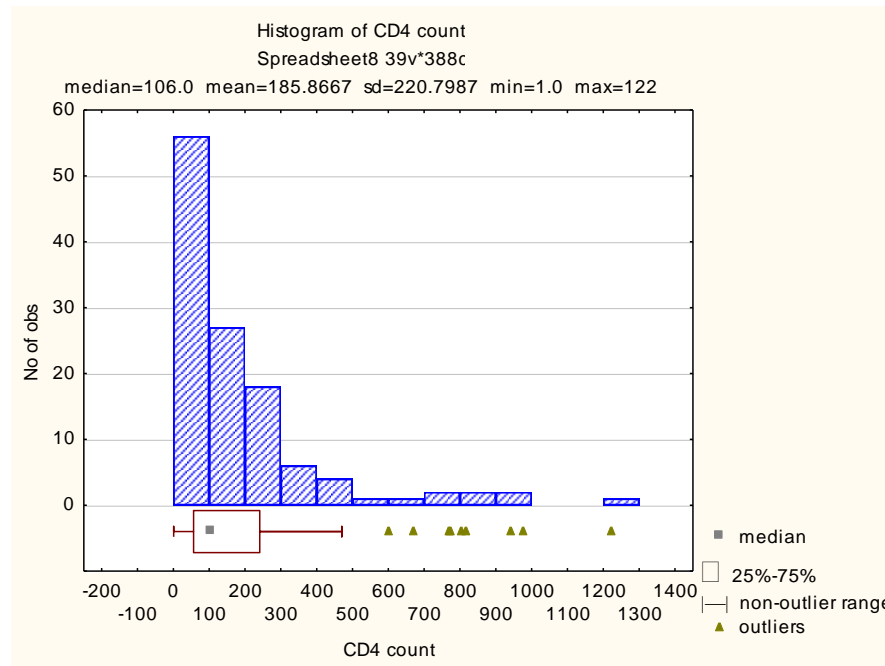


Fig. 7 Distribution of Retreatment TB Patients by ART

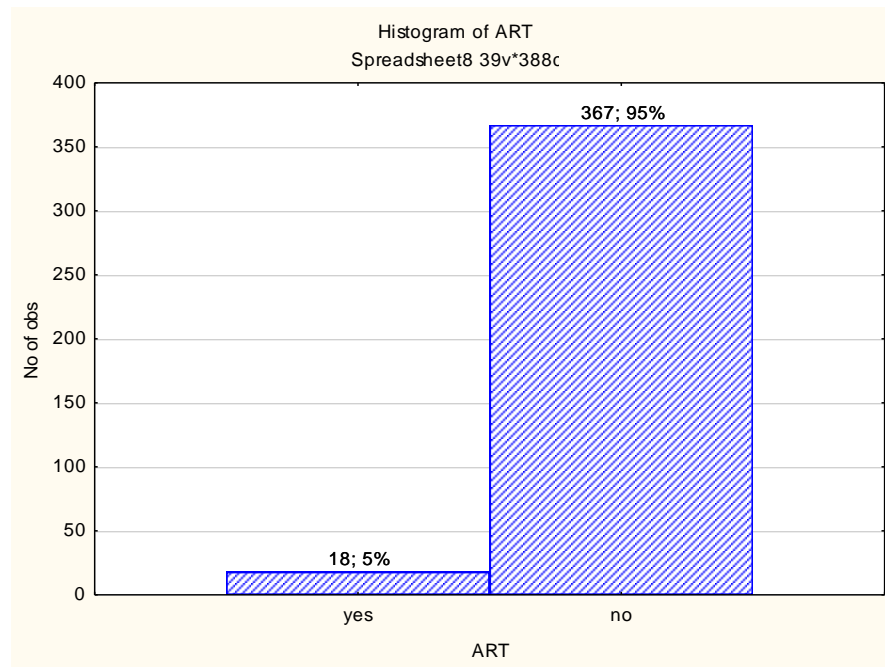


Table 4. Distribution of Retreatment TB patients by Drug Sensitivity Testing profile

Drug	Total no. of patients	No. of patients not tested	No. of patients tested	Sensitive (%)	Resistant (%)
Rifampicin	386	286	100	84 (84.0)	16 (16.0)
Isoniazid	387	287	100	71 (71.0)	29 (29.0)
Ethambutol	387	288	99	80 (80.8)	19 (19.1)
Streptomycin	387	288	99	76 (76.7)	23 (23.2)

Table 5. Distribution of Retreatment TB Patients by Treatment Outcome for patients followed up at the hospital (n= 214)

TREATMENT OUTCOME	NUMBER OF PATIENTS (%)
CURED	19 (8.9)
COMPLETED TREATMENT	86 (40.2)
FAILURE*	9 (4.2)
DEFAULTED	49 (22.9)
DEATH	51 (23.8)

* Includes patients with MDR- TB (n=7) MDR-TB rate of 3.3%.

One hundred and seventy one patients 44% (171/388) were transferred to the clinics and records were not available for review.

DISCUSSION

Summary of the main Findings

All the three hundred and eighty eight patient records with retreatment TB were reviewed. This was 19.6% of TB patients admitted between 2005 and 2007. The distributions of the patients were: males 66%; mean age of 41.4 years; females 34%; mean age 35.3 years. 92.7% were unemployed/blue-collar workers; primary education 93%; unmarried 43% and married 34%. Retreatment TB was diagnosed with sputum smear microscopy in 71% with bacilli load of 3+ in 45%. The sources of referral to TB hospital were: public hospital 71 %; private doctors 2%. 74% of the patients have had TB 1-3 years before the episode under study. Retreatment TB categories were: after treatment completed 69%; default 19%; after cure 8% and treatment failure 4%. 98 % (169/172) of patients tested had +ve HIV status; the median CD4 cell count was 106 cells/ μ l at the time of retreatment; very few (5%) were on ART. Drug resistance to primary TB drugs was as follows: Rifampicin 4%; Isoniazid 7%; Ethambutol 5%% and Streptomycin 6%. The treatment outcomes for those whom data were available were: successful 49.1%(107/214) (cured + completed treatment); death 23.8%; treatment default 22.9% and failure 4.2%. MDR-TB resulted from 3.3% (7/214) of the patients followed up in the hospital.

Comparison to the Literature

Although the proportion may not directly estimate the extent of retreatment TB in the population, it, however, gives some indication of the burden of this problem on the health system within the context of already high prevalence of TB and HIV diseases in the community. It reflects a fair measure of the load of TB patients that the health care workers and the institution have to cope with. The extent of retreatment TB have been estimated to vary from 0 to 14 % after successful treatment while a study among South African miners found a rate of 10.3 episodes per 100 person years at risk during a follow up of patients for the median period of 25.1 months^{7,8,9} with most recurrence occurring within the first 6 months of follow up of patients. This study found that 74% of patients had TB 1- 3 years before the current episode which compares with the Malawi⁵² study that found 60% having another episode of TB within the first 2 years of completing treatment.

The study also revealed some personal factors associated with retreatment TB among the patients studied. Most of the patients with retreatment TB were men with a mean age of 41.4 years compared to women who were relatively younger at an average age of 35.3 years. The mean age of females was at least 6.1years less than that of males. While there have not been

consistent finding on the effect of gender and default from TB treatment, most studies had shown that males are more likely to default TB treatment than females. This may partly explain the relative large proportion of males with retreatment TB in this study. The finding of this study with regards to males is similar to others that have been reported from studies in Turkey, Nigeria and India. In the Turkey study²⁵, the risk factors for non successful treatment were determined to be re-treatment patients older than 46 years of age while in the Nigerian study¹⁸, the 44.2% who defaulted treatment were older than 65 years and in India²⁰, not completing the process of diagnosis of TB was higher in >50 years age.

The prevalence of behavioural and social factors like unemployment, smoking, alcohol and drug use in patients with retreatment TB has also emerged from the study. Seventy five per cent of the study population indicated being unemployed at the time of treatment. This is the only factor that the study was able to pick up and compares well with what has been reported in studies in other parts of the world like Nepal, Russia and Brazil ^{26,27,28}. There was little data on smoking, alcohol and drugs use as it was not documented in the records. This is an important omission in the process of care of these patients which should be remedied realizing that there is some linkage between these social habits and retreatment TB.

There was some limited information on the HIV status of the patients with retreatment TB. Information on the HIV status was only available for only 44% of the patients. In this study, among those who were tested data indicate that 98% were HIV +ve. Previous study³⁴ among miners in South Africa has shown that HIV infection was associated with significantly increased rates of recurrent TB with an incidence of 8.2 per 100 person-years in HIV positive compared to 2.2 per 100 person-years in HIV negative men. The need to test patients is recognized in the hospital; however, patients can decline after voluntary counseling.

Another HIV-related factor to the recurrence of TB is the level of immunocompromise as reflected by the CD4 counts. Information on this was available on a very small number of patients. Other studies^{53,54} have showed that the risk of developing recurrent TB is increased as the immunity worsens with declining CD4 counts. In this study, the median CD4 count for those that were available was low at 106cells/ μ l. The use of ART has been very low in the study patient population. This is not unexpected as the roll out of ART in public sector was only initiated within the period of the study hence most of those HIV positive patients at that time did not have access to such services.

The study also shows some information on drug sensitivity patterns amongst patients. There is large proportion of non documentation relating to drug resistance and sensitivity to TB drugs used as data was only available for 25.9%(100/386) of the patients studied. The low proportion of sensitivity testing reflects the non rigorous attention to this aspect of care process for the TB patients with regards to documentation in the patient files. The drug resistance to primary TB drugs varied from 16% for Rifampicin to 23% for Isoniazid. Some bacteria isolates in the patients showed some dual resistance to Rifampicin and Isoniazid -a criterion for diagnosis MDR-TB. Previous TB treatment is an obvious risk factor for drug resistance. The significance of this resistance is in the emergence of Multi-drug resistance TB which is an important and serious unsuccessful outcome of retreatment TB.

The outcomes of retreatment TB in this study is only for those who were seen at the TB hospital and followed up on discharge. Those who defaulted treatment were those who were followed up as out patient in the Hospital after the initial phase of treatment. According to WHO², the targets of TB programs for new PTB patients are smear positive detection rate of 70% and a cure rate of 85%. While no specific targets for the outcomes have been set for retreatment TB, all indications are that they should not be less than for new TB cases. In terms of the smear positive detection rate, the management of TB programme at the hospital has performed well as it achieved 71% comparing with the WHO set target of 70%, as the TB patients were mostly diagnosed with sputum smear microscopy. The treatment outcomes (cured and completed treatment) together were found to be 49.1%. This is much less than the 73 % reported by WHO in its 2005 global review of TB programmes. Of great significance is the 3.3% MDR-TB found in this study. The MDR–TB is very expensive to treat and longer treatment duration which makes it difficult for patients to adhere to treatment. This proportion does not, however, derive from the estimated proportion of TB cases that were treated during the period which will make the overall proportion low. Among new TB cases in South Africa, previous studies had shown the MDR-TB rate to be relatively low at 1.6%, while that for retreatment TB was 6.6 %(4.0-13.9%)³¹ . When compared with this, our figure of 3.3% for the retreatment TB cases is relatively small. However, this should be seen against the setting that about 44% of the retreatment TB patients were transferred out to other facilities for which information on outcome was not available.

Limitations of the study

The study is limited by its design which is mainly descriptive and retrospective in nature. The study relies on the previously collected data and information on the patient file for analysis.

Some of the information was incomplete thus making it difficult to have a complete perspective of the problem under study. In situations where the diagnosis of TB was based on the chest radiograph, this information was accepted as it was recorded and the study did not seek to look at the chest radiograph in question. The treatment outcomes of patient discharged from the TB hospital and followed up at the clinics were not ascertained due to limited resources to visit the clinics.

The study is further limited by the fact that there is no control or comparison group on which to make in-depth analytical appraisal of the identified related factors of retreatment TB. Time and resources had made this not possible. This aspect should be explored in future study on this problem.

RECOMMENDATIONS

1. All TB patients (new or retreatment TB) should be consistently offered voluntary counseling and testing for HIV. Those who are HIV positive should be enrolled into ART programme and monitored regularly to detect any deterioration in immune status by regular CD4 measurement and necessary intervention started.
2. Improve process of care by appropriate and complete documentation in the patient file of all potential factors impacting on retreatment TB at the time of admission into the treatment programme and any new developments reviewed and updated as situations develop in the patients over the period of care. This will provide sufficient data on which the burden of the problem could be understood and allow dominant factors identified to be addressed with relevant interventions. Strengthening the institutional capacity to do this will be required in terms of personnel and other resources for monitoring and reporting on outcomes for retreatment TB patients.
3. Further researches that involve data collection from the patients directly using quantitative and qualitative approaches to allow for quantitative analysis of factors and test associations with retreatment TB.

CONCLUSION

This study has confirmed some factors related to retreatment TB to be similar to what obtains elsewhere. Specifically in our situation majority of patients had completed TB treatment previously and default occurred in less than one quarter of the patients. For those tested for HIV they were overwhelmingly positive. There is need to improve the quality of care for these

patients by paying attention and documenting these factors. This study opens up areas of further research in our setting to test associations and prominence of some of the identified factors.

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Appendix 1 : DATA COLLECTION SHEET

TOPIC: A description of patients with Recurrence of Pulmonary TB in TB Hospital, Ermelo.

STUDY NUMBER

1. Age (years)

15-24

25-34

35 - 44

45 - 54

55 - 64

≥ 65

2. Sex

M F

3. Occupation

Unemployed

Self employed

General Worker/Farm Labourer

Teaching/Scholar

Administrative/Clerical/Sales

Professional/Technical/Mine worker

4. Habits

Smoking

Alcohol

Other drug use (dagga, etc)

Not Known

5. Education

- No formal education
- Primary school
- High School
- Tertiary
- Other (specify) _____

6. Marital status

- Married
- Unmarried
- Divorced
- Separated
- Not Known

7. Number of people in the same Household

- 1- 2
- 3- 6
- Above 6
- Not Available

8. How was TB first diagnosed?

- Sputum AFB microscopy
- Chest X-ray
- Clinical features
- Others (specify) **TB Culture, Pleural Biopsy, ADA, CSF**

9. Sputum smear result

- Positive
- Negative
- Not Applicable

10. Bacilli load

- + + +
- ++
- + /scanty
- Not Applicable

11. How was the patient referred with Retreatment TB to the TB HOSPITAL?

- Self
- Primary care clinic
- Public Hospital
- Private Doctor/Private hospital
- Others _____(Specify)

12. How many times has the patient had TB in the past?

Specify years _____

13. Interval since last TB treatment

- < 1yr
- 1-3yrs
- 4-6yrs
- 7- 9yrs
- ≥ 10yrs

14. Re-treatment TB category

- Re-treatment **after failure** of previous treatment (Sputum smear +ve).
- Re-treatment **after default (interruption of treatment for > 2 months)**.
- Re-treatment **after cure or** (smear result negative at end of treatment).
- Re-treatment **after treatment** completed (no sputum smear result).
- Chronic case – sputum is positive at end of re-treatment.

15. HIV status

- + ve
- ve
- Not Known

16. If Positive, what was the CD4 count _____

17. Is the patient on ART?

Yes

No

18. Indicate the TB Drug sensitivity Testing pattern.

Item	DRUG				
	Rifampicin	Isoniazid	Ethambutol	Streptomycin	Pyrazinamide
Sensitive/Susceptible					
Resistant					
Not done					

19. Treatment Outcome

Cured (Finished treatment with negative sputum smear)

Completed treatment (no sputum result)

Failure (sputum still positive at 6 months despite adherence to treatment)

Defaulted/Interrupted treatment for 2 months or more

Death

Transfer /Moved out

MDR - TB

20. Other associated conditions

Diabetes mellitus

Hypertension

Epilepsy

COPD

Other _____ (specify)

21. COMMENTS