The tuberculosis control programme in the

industry in Swaziland:

a critical evaluation

Dissertation to fulfil the requirements for completion of

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I declare that the dissertation, which I hereby submit for the degree MMed (Community Health) at the University of Pretoria, is my own work and has not previously been submitted by me for a degree at another university.

H R Lemmer

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Thanks to my parents for their continuous support and prayers. A special sincere thanks to my wife, best friend, colleague and most ardent supporter, Moira, without whom this would have been a bridge too far, and my daughters Lara and Nicola, for their belief in me.

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LIST OF ACRONYMS

AFB   - Acid-fast Bacilli

ANC   - Ante-natal Care

AIDS   - Acquired Immunodeficiency Syndrome

ART   - Anti-retroviral Therapy

BCG   - Bacillus Calmette-Guerin

CDR   - Case Detection Rate

CI   - Confidence Interval

DOT   - Directly Observed Treatment

DOTS   - Directly Observed Treatment Short Course

HIV   - Human Immunodeficiency Virus

IUATLD   - International Union Against Tuberculosis and Lung Disease

MDR   - Multi-drug Resistance

PTB   - Pulmonary Tuberculosis

SAMRC   - South African Medical Research Council

SD   - Swaziland

SMO   - Senior Medical Officer

STI   - Sexually Transmitted Infection

TB   - Tuberculosis

TBCP   - Tuberculosis Control Programme

VCT   - Voluntary Counselling and Testing

WHO   - World Health Organization

SUMMARY

<u>Keywords:</u>   Tuberculosis, treatment outcome, smear conversion, radiology, patient awareness, DOTS, industry, Swaziland.

<u>Background:</u> Tuberculosis (TB) is a major public health problem in Swaziland aggravated by the escalating HIV epidemic. Health services in five of the major industries in Swaziland represent the potential for the highest quality of TB care in the country, arising from increased supervision and better case holding. The guidelines of the national TB control programme (TBCP) are mostly adhered to, but there is a tendency to rely on clinical and radiological parameters for diagnosis due to problems with sputum microscopy.

<u>Aim and Objectives:</u> The aim of this study was to evaluate current TB management protocols by describing case management and treatment outcomes in these five industries. Specific objectives included the determination of quantitative outcomes (cure and treatment completion, smear conversion, treatment interruption and failure, and mortality). Patient knowledge of TB and its treatment as well as health worker practices were also assessed.

<u>Methods:</u> Descriptive questionnaire survey.

<u>Results:</u> The majority of TB patients (79%) were young (mean age 38 yrs) males. 81% of patients were treated for TB for the first time. The HIV status of a third of patients was known, and 82.7% of these were positive. There were significant differences between the perceptions of health workers and patients on the delivery of TB care and the time lapse between diagnosis and treatment. Chest X-ray was the main diagnostic tool used. In more than 97% of cases the TBCP prescribed treatment regimen was used. Directly observed treatment was provided to 77.4% of patients. The majority of patients had some knowledge of TB and its spread. 73.4% of patients knew about available TB treatment, and 75% about treatment duration. Coughing was identified as an important

symptom by 84.5% of patients. There was a significant difference between calculated and estimated adherence to treatment. In 55.6% of patients no sputum smear was done at two months. Treatment outcome was favourable in 83.7 % of patients, compared to only 62.1% of TBCP patients in 2001. Outcome analysis showed that the participating industries had a highly successful TB control programme compared to the national TBCP, with outcome indicators meeting international standards. A serious deficiency detected was the lack of smear microscopy for diagnosis and treatment monitoring.

Limitations: The possibility exists that patients presenting to the Health Centres were not registered sequentially. The usual limitations relating to questionnaires are applicable.

Recommendations: Directly observed treatment coverage and supervision can be improved in industry as the patient group is well-defined and captive. Sputum microscopy should become the mainstay of diagnosis and monitoring. Health care providers should be primed to detect co-existing lung disease and HIV, and TB drug side effects. Accurate recording and reporting systems should be introduced without delay. Communication between the TBCP and the non-governmental health institutions in Swaziland needs improvement.

OPSOMMING

<u>Agtergrond</u>: Tuberkulose (TB) is 'n ernstige publieke gesondheidsprobleem in Swaziland en word vererger deur die toenemende menslike immuungebrekvirus (MIV)-epidemie. Gesondheidsdienste in vyf van die grootste industrieë in Swaziland verteenwoordig die potensiaal vir die lewering van beste-kwaliteit TB diens in die land, voortspruitend uit toenemende toesighouding en verbeterde gevalshantering. Die riglyne van die Nasionale TB Beheerprogram word grootliks gevolg, maar daar is 'n geneigdheid om staat te maak op kliniese en radiologiese parameters vir diagnose as gevolg van probleme rondom sputum-mikroskopie.

<u>Doelwit en Doelstellings</u>: Die doelwit van die studie was die evaluering van huidige TB beheermaatreëls in die vyf industrieë, deur middel van 'n beskrywing van gevalshantering en behandelingsuitkoms. Spesifieke doelstellings het ingesluit die bepaling van kwantitatiewe uitkomste (genesing en volledige behandeling, sputumkonversie, onderbreking en faal van behandeling, en sterfte). Pasiëntkennis van TB en die behandeling, sowel as gesondheidswerkerpraktyke is ook ondersoek.

<u>Metodes</u>: Beskrywende vraelys-opname.

<u>Resultate</u>: Die meerderheid TB-pasiënte (79%) was jong mans (gemiddelde ouderdom 38 jr). 81% van pasiënte is vir die eerste keer vir TB behandel. Die MIV-status van 'n derde van pasiënte was bekend, waarvan 82.7% positief was. Beduidende verskille is gevind tussen die persepsies van gesondheidswerkers en pasiënte rakende TB-dienslewering en die tysduur tussen diagnose en behandeling. Behandeling onder direkte toesig is gelewer aan 77.4% van pasiënte. Borskasradiografie was die hoof-diagnostiese opsie. Die meerderheid van pasiënte het beperkte kennis van TB en siekte-oordraging gehad. Hoes is geïdentifiseer as 'n belangrike simptoom deur 84.5% van pasiënte. 73.4% van pasiënte het kennis omtrent TB-behandeling gehad, en 75% omtrent die tydsduur van behandeling. 'n Beduidende verskil is gevind tussen

berekende en geskatte volhouding van behandeling. Vir 55.6% van pasiënte is geen

sputumsmeer gedoen teen twee maande nie. Behandelingsuitkoms was positief in

83.7% van pasiënte, vergeleke met slegs 62.1% van Nasionale TB

Beheerprogrampasiënte. Uitkomsanalise het getoon dat die deelnemende industrieë 'n

hoogs-suksesvolle TB beheerprogram het wanneer dit vergelyk is met die Nasionale

Beheerprogram, met uitkomsindikatore binne internasionale standaarde. 'n Ernstige

leemte was egter die gebrek aan smeer-mikroskopie vir diagnose en monitering van

behandeling.

Gevolgtrekkings: Dekking van die TB program en direkte toesighouding van

behandeling kan verbeter word, aangesien die pasiëntbevolking goedgedefineer en

geslote is. Sputum-mikroskopie behoort die kem van diagnose en monitering te word.

Gesondheidswerkers behoort gesensitiseer te word om ander longsiektes en MIV, asook

newe-effekte van TB geneesmiddels te identifiseer. Akkurate rekordhouding en

verslaggewende stelsels moet sonder verwyl in werking gestel word. Kommunikasie

tussen die Nasionale TB Beheerprogram en nie-regerings gesondheidsinstellings in

Swaziland moet verbeter word. Toenemende klem op pasiëntopvoeding aangaande die

prosesse van diagnose en behandeling word aanbeveel.

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1. INTRODUCTION

In this dissertation the author has attempted to evaluate the adequacy of tuberculosis (TB) control measures taken in five industries in Swaziland over the period 1998 to 2001. In the first section the relevant literature is reviewed and the importance of adequate TB control measures in the era of the human immunodeficiency virus (HIV) epidemic is explained, as well as the reasons why very good TB control practices are required. The purpose of this study is thus justified and the research question is formulated. In the second part of this dissertation the methodology used to carry out the study is described in detail. Thereafter the results are presented. Finally, the results are discussed, bearing in mind the limitations of the study. The results of other, similar, published research are compared to the results from the study; conclusions are drawn and recommendations made.

2. BACKGROUND AND LITERATURE REVIEW

While tuberculosis (TB) will virtually be eliminated in developed countries in a few decades, it continues to be a major problem in developing countries. This observation by Styblo in 1986 (1) was accurate. Estimates suggest that approximately one third of the world population is currently infected with *Mycobacterium tuberculosis* (2). Tuberculosis is a major problem in most low-income countries and it is the single most frequent cause of death in individuals aged fifteen to forty nine years (3). In 1999 there were an estimated 8.4 million new cases of TB in the world (4) (5). Sub-Saharan Africa is the region most severely affected by the disease (4) (6). HIV fuels the TB epidemic: nearly three-quarters of people infected with both HIV and *M. tuberculosis* live in sub-Saharan Africa (4) (6). The World Health Organization (WHO) predicts that by 2005 there will be 3.4 million TB cases in Africa (4) (5).

The forty-fourth World Health Assembly in 1991 recognised the growing importance of TB as a public health problem and the potential for cost-effective control using currently available tools (7) (8). In 1993 the WHO declared a state of global emergency for tuberculosis, due to the steady increase in the disease worldwide (9). Delays in TB case finding and poor adherence to TB therapy are the greatest problems facing tuberculosis programmes today (10) (11) (12) (13).

Swaziland, as part of sub-Saharan Africa, is not spared this problem. The larger industrial settings in Swaziland provide comprehensive health care to a captive population, and are in a position to deliver a higher quality service than the public sector. Five of these large industries which provide extensive healthcare were identified to participate in this study (Figure 1). A questionnaire-based evaluation of all aspects of TB care provided to employees in these industries was undertaken. Treatment outcome featured prominently as the priority indicator of TB control programme effectiveness. Data collection started in 1998 and continued until a predetermined number of TB cases were registered.

The importance of TB as a public health problem in Swaziland was previously demonstrated in two prevalence studies, one conducted by the WHO in late 1956 (14) and the other more recently by the SA Medical Research Council (MRC) in 1990 (15).

In the prevalence study carried out by the WHO between October 1956 and February 1957 the investigations included tuberculin testing, Ziehl-Neelsen microscopy and culture of all sputum specimens found to be positive on direct smear, as well as culture of a randomly selected sample of the remaining smear-negative specimens. A total of 3051 persons from six local traditional authority areas were included in the investigation. Estimates of

Figure 1: Distribution of participating industries, Swaziland, 2000

(Source: Adapted from 1997 MAGELLAN Geographix (805) 685-3100

www.maps.com)

prevalence of infection were based on persons with tuberculin reactions of 10 mm or more and it was shown that the frequency of large reactions increased with age, up to the age of 30 or 40 years, when the large majority of people fell into the category "presumably infected" (14).

1% of the persons aged 13 years and older were found to have acid-fast bacilli on direct smear microscopy. However, because of the small sizes of the samples examined, this estimate was considered to be imprecise and the actual smear positive prevalence was estimated at between 0.6% and 1.6% (14). Under the conditions prevailing during the survey, culture was found to be no more sensitive than direct microscopy. Definite trends in the prevalence by age or sex could not be established because of the small number of cases (16 in total) found, but both the sex and age distribution seemed to be more or less equal (14).

In the more recent South African MRC prevalence survey, conducted in September 1990, similar epidemiological indices to those of the earlier WHO study were used (15). Tuberculin testing, bacteriological investigations and chest radiography were used independently to evaluate the magnitude and trends in the prevalence of tuberculosis in the community. BCG coverage was reasonably high as indicated by 71% scar prevalence in the childhood population 0 - 14 years (15).

Prevalence of infection in the 5 - 9 year age group was established at 9%, with a subsequent annual risk of infection calculated at 1%. Children between the ages of 10 and 14 showed a prevalence of infection of 12%, with a corresponding annual risk of infection of 1.5%. An annual downward trend in the risk of infection of 3-4% was observed (15).

Bacteriological evidence of disease in adults was indicated by a prevalence of 0.1% on sputum smear microscopy and 0.4% on culture (*Mycobacterium tuberculosis*). Radiology indicated 2.3% parenchymal changes in adults, of which 0.2% seemed to be of recent origin (15).

These results indicated that at the time approximately 600 - 800 new cases of tuberculosis were expected in Swaziland annually. Both infection and disease prevalence rates in Swaziland were on par with inland regions of Southern Africa and were significantly lower than in coastal regions. BCG coverage was satisfactory, being well over 90%, and it was recommended that the major emphasis of the control programme should be on improved screening of populations, on case finding and on case-holding (15).

The situation appears to have significantly worsened since 1990, with increasing numbers of TB admissions at all hospitals in Swaziland. Up to 25% of general hospital patients currently are TB cases (Personal communication, Dr J Kunene, Mbabane Government Hospital, June 1997). The national TBCP quotes a 24.6% escalation in new TB cases between 1994 and 1996 (16), while surveillance data from the National AIDS Programme revealed an escalating HIV prevalence rate of 31.13% amongst TB patients in 1994 (17), 58.1% in 1998 (18) and 78.6% in 2000 (19). HIV prevalence amongst TB patients was not determined in the 1996 HIV Sentinel Surveillance survey (20). The increases in HIV prevalence demonstrated in 1994 (21.42%) (17) and 1996 (31.8%) (20) lead to the general assumption that the escalation in TB prevalence in Swaziland is substantially related to the worsening HIV epidemic, illustrated in Figure 2. Similar trends of increasing numbers of HIV positive cases were observed amongst ante-natal care (ANC) and sexually transmitted infection (STI) patients (16) (17) (18) (19) (20).

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HIV infection has a dramatic impact on the trend in tuberculosis rates; where the two infections coincide in a population it is important to determine the level and trend of HIV infection in tuberculosis cases (3). Access to specific interventions targeted at HIV related diseases requires knowledge of the individual's HIV serostatus, best achieved through voluntary counselling and testing (4). HIV has already caused a dramatic rise in the numbers of tuberculosis patients in several countries, and has resulted in tremendous constraints on health services (2). Accurate planning and budgeting can only be carried out when there is knowledge of how the two infections coincide in the community (3).

The introduction of HIV into the community has upset the balance between TB micro-organisms and the human host (3). HIV infection tends to induce increasing immunosuppression with increasing duration of infection (2). The immune system, which normally halts the progress from tuberculosis infection to tuberculosis disease, becomes relatively inefficient (3). An individual who is infected becomes much more likely to develop disease and to become infectious. The number of infectious cases in the community increases, thereby increasing the risk of transmission (3).

TB patients infected with HIV are more likely to experience toxic reactions to anti-tuberculosis drugs (3), leading to interruptions of treatment and occasional fatalities (4). They are also more likely to die during the course of their TB treatment, usually from other causes. Health workers and patients who are HIV seropositive should be carefully protected from exposure to patients with TB. The risk of infection is high where HIV positive patients come together in groups, e.g. in hospices or support groups. Every effort should be made to quickly diagnose and treat TB in these settings. Once a TB

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Figure 2: HIV prevalence data from sentinel serosurveillance

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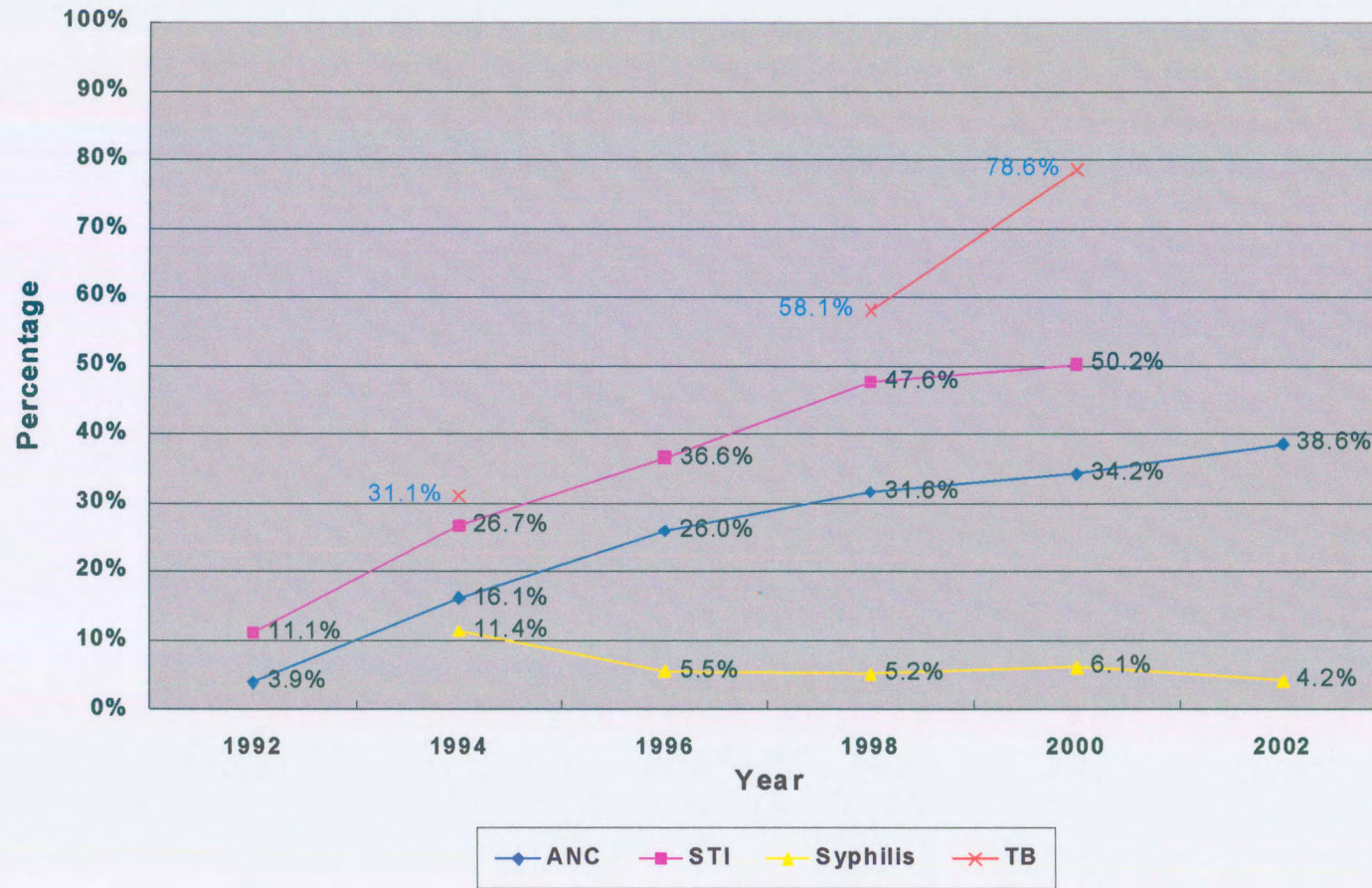
patient is on treatment, no special precautions need to be taken to prevent the spread of infection (with the exception of multi-drug resistant TB) (3).

HIV infection remains the single most important factor that increases the risk of developing TB. HIV infection, and particularly the degree of immunosuppression in HIV positive individuals with pulmonary TB, has been reported as a major determinant of mortality (21). Revised estimates of global TB-HIV epidemiology (7) indicate that 11% of all new TB cases in adults (15 – 49 years) in 2000 were attributable to HIV infection. The fraction was greater in Africa (31%). Of 1.9 million deaths from TB, 18% were attributable to HIV. TB was the immediate cause of 15% of all adult AIDS deaths (7). 20% - 30% of HIV-positive smear-positive pulmonary TB patients die before the end of treatment. Even higher mortality rates are observed in HIV-patients with smear-negative TB (6). Recurrence rates of TB have increased (4). African countries with good DOTS programmes continue to have escalating notifications of TB cases in the face of high HIV infection rates (7). Therefore, TB control programmes should be linked closely with HIV/AIDS prevention and control strategies (7). TB AIDS programmes can promote voluntary counselling and testing for HIV as an entry point for access to the whole range of measures that are potentially available for people infected with HIV (7).

The five elements of the DOTS strategy are political commitment, case detection using sputum microscopy among persons seeking care for prolonged cough, standardised short course chemotherapy including directly observed treatment, regular drug supply, and a standardised recording and reporting system to assess the outcome of individual patients and programme performance (7). This strategy acknowledges access to TB care as a human right, and as an important tool in the alleviation of poverty (7). The DOTS programme should be made an integral health system activity with nation-wide

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coverage that anchors TB activities throughout the health system at all levels, including peripheral health facilities and the community. All DOTS programmes should aim at achieving total geographical and total patient coverage in due course (7).

Research was done to study the results of the DOTS strategy in China after 10 years of implementation (22). Treatment outcomes were excellent, with a cure rate of more than 90% reported. The case detection rate (number of notified cases divided by the estimated number of cases in the population), however, was 54%, falling short of the 70% global target (22). China was the first large country to successfully expand DOTS coverage rapidly (22). The DOTS strategy was also successfully implemented in India, with cure rates exceeding 80% and case detection rates of 55% - 60% (23). In both countries the conclusions were that both government and the private sector need to be involved in DOTS implementation. In the Indian study it was found that certain parts of the public sector, specifically industries, did not partake fully. In China, the recommendation was made that someone from outside the family of the patient should directly observe treatment, as treatment observed by family members was often ineffective (22). The experience in India demonstrated that effectively managed DOTS programmes can achieve high case-detection and cure rates even with limited technology and a sub-optimal public health infrastructure (23). It is, however, already evident that the DOTS strategy needs to widen its scope to provide comprehensive support to patients and providers. It has been suggested that expansion of the DOTS programme to include active case detection should be explored as a means of reducing TB prevalence and mortality, especially in high prevalence settings (21).

Smear microscopy for diagnosis is essential as it efficiently identifies the cases that are most infectious, and therefore have the highest priority for care. In most low-income

countries it is the only means by which the diagnosis of TB can be confirmed (3) (23). In ideal circumstances the diagnosis of TB may be established and treatment commenced on the same day, eliminating long delays (24). The results are to be recorded prior to the commencement of treatment. Priority is given to treatment of smear-positive patients, who are the most potent sources of infection in the community. Sputum smear examination is used not only for diagnosis, but also to monitor progress during treatment. After two months of intensive phase treatment the sputum of smear-positive patients should be re-examined. Patients who are at this stage smear-negative should start the continuation phase of treatment. If the smear is still positive, the intensive phase is prolonged to three months (3). In all initially smear-positive patients, microscopy is repeated at five months. If the result is negative, treatment is continued. A positive result should be confirmed by another positive result, before the patient is declared a treatment failure, and given the re-treatment regimen (3). Quality-assured sputum microscopy should be accessible to monitor the treatment progress, assess treatment outcomes and certify cure among pulmonary TB patients (7). Sputum microscopy makes it possible to identify patients, who, if untreated, would have a most unfavourable prognosis, and would be the most dangerous sources of infection in the community (25).

The DOTS strategy includes the establishment and maintenance of a recording and reporting system, based on standardised recording of each patient (including information on treatment outcomes) in registers maintained at an appropriate peripheral level, and on analysis and reporting in a prescribed format (7). This system provides, through sputum smear examination, clear information on type of disease and case category, and through cohort analysis, information on treatment results (7).

In view of the escalating HIV epidemic, the WHO has stressed the necessity for communities and for all categories of the medical profession to have an increased awareness of symptoms suggestive of TB. Patients with a cough for several weeks in particular should have their sputum examined by microscopy as the first priority. The emphasis is on case-finding and treatment of symptomatic patients (25). The structure used to deliver and monitor anti-TB treatment to TB patients throughout the developing world could be an excellent model for delivering anti-retroviral therapy (ART) for HIV-infection. Building on an established TB control infrastructure would be most cost-effective for delivery of ART (4).

The Tanzanian study on the knowledge of disease and treatment among TB patients emphasised important patient-related issues. The level of knowledge of TB was significantly higher amongst more educated patients, and among patients who had received information before diagnosis. The vast majority of patients (82%) believed that the disease was curable, but only half of the patients knew the correct duration of treatment (11). Only 29% knew at least one correct side effect of anti-tuberculosis medication. This fact was ascribed to possible deficits in the health system, indicating the need to improve the education of TB patients (11). The fact that patients performed poorly when questioned about the duration of treatment and drug side effects was reported as a surprising finding, as one would expect patients already receiving treatment to be informed about different aspects of TB (11). It is therefore important to teach patients to take their medication, but also to help them to gain sufficient understanding of the need to complete treatment and of medication side effects (11).

Untreated smear-positive patients are the most important sources of infection, and the situation is aggravated where there is poverty and overcrowding. Poverty may also

reduce access to health care services, thus prolonging the period of infectiousness of TB patients (2). The likelihood that a susceptible person will be exposed to an infectious tuberculosis patient increases with population density (2). These patients would have had close or prolonged contact with possibly infectious cases, leading to increased exposure to TB (3). The risk of becoming exposed is greatly enhanced if infectiousness is prolonged, i.e. when diagnosis and treatment are delayed (2). Preventive care of household contacts of TB patients cannot, therefore, be over-emphasised. The most important group requiring preventive care is children under the age of five. Children of this age who are symptomatic should receive full TB treatment. Asymptomatic household contacts under the age of five should receive isoniazid 5mg/kg daily for six months (3).

Delays in diagnosis and start of effective treatment increase morbidity and mortality from TB as well as the risk of transmission in the community. Starting TB patients on treatment as early as possible plays a major role in reducing disease transmission in the community. Key to this is increasing awareness of the signs and symptoms of TB and ensuring easy access to diagnostic facilities and treatment (26).

Swaziland recently participated in a regional multicentre survey on multi-drug resistant (MDR) TB, conducted by the SA MRC. The results of this study indicated a relatively low multi-drug resistance rate of 0.9% among new patients, similar to the rate observed in South Africa at the time, but a considerably higher MDR rate of 12% among retreatment patients, a rate three times that of South Africa (27). One in four retreatment cases had strains resistant to isoniazid and one in five cases harboured strains resistant to streptomycin. For this reason a change in the treatment protocol was recommended, substituting streptomycin with ethambutol, and the importance of establishing cure-rates of

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85% in new smear positive patients was stressed. Close monitoring of cure rates and improved case-holding were also recommended (27).

It is unfortunate that the TB control programme of Swaziland was not consolidated and the recommendations of the 1990 and 1995 surveys implemented before the current situation, generated by the escalating HIV epidemic and its synergism with TB, arose.

An evaluation of the TBCP in Swaziland conducted by the WHO in 1994 (28) highlighted serious limitations. The evaluation concluded that the management structure was too vertical and that the limited staff was unable to maintain adequate supervision. Very limited case holding beyond the initial period of hospitalisation was compounded by poor record keeping and by the virtual absence of case registers. Two key findings of the evaluation were that treatment outcome could be determined in only 50% of cases and that documentation of completed treatment could be determined for only 45% of cases (28). These figures fell far short of the WHO goal of 85% cure in-patients initiating TB treatment (3). The evaluation further highlighted the weakness in the diagnostic capacity generated by the centralisation of microscopy services and the availability of only one microscopist for the entire programme. Overall the epidemiological database was found to be inadequate and evaluation demonstrated the limited capacity of the TB control programme to handle the current TB-HIV co-epidemics.

TB drugs used in Swaziland were from an older schedule despite evidence concerning drug susceptibility patterns and the prevalence of drug resistance in Swaziland suggesting that the drug regimen used needed modification (27) (28). Diagnostic centralisation and the use of streptomycin as a core drug lead to prolonged hospitalisation being a feature of the management of TB in Swaziland, since case holding was predominantly through

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hospitalisation. There was strong suspicion of non-compliance with treatment after discharge from hospital (28) and no evaluation of the outcome of treatment was performed prior to 2001.

3. RATIONALE

Initially, the aim of this study was to evaluate TB control in Swaziland as a whole; however, permission from the Ministry of Health TBCP could not be obtained. The industrial setting was therefore chosen as an alternative. TB patients in the industry make a significant contribution to the total number of TB cases in the country. Furthermore, these patients, being mostly young adults from the economically active sector of the population, are in the age group most at risk of HIV infection, and therefore also of opportunistic infections, of which TB is the most prevalent.

The health services of each of the five major industries in Swaziland collectively represent the potential for the highest quality of TB care currently practised in the country. Given that the health services in industry are dedicated to a captive and well-defined population with resulting higher levels of supervision and better case holding, the same level of TB care would be difficult in other settings. Logistically, the accrual of information would be simplified in this controlled setting.

Although compliance with treatment and the quality of supervision were thought to be significantly better in the industrial setting, there was widespread concern among health service managers about the outcome of TB treatment in the services at the time. The industrial health services by and large adhered to the national TBCP Treatment Guidelines.

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Patients were put on the six-month short course regimen, i.e. two months of streptomycin, isoniazid, pyrazinamide and rifampicin, followed by four months of rifampicin and isoniazid (28). Lack of written guidelines was a major drawback in the attainment of good treatment results (28). There was an increasing tendency to deviate from these guidelines because of various problems around diagnosis and treatment. Among the principal points of deviation were (i) the reliance on clinical and radiological parameters for diagnosis because of problems with sputum microscopy and the absence of any capacity for sputum culture, (ii) the use of ethambutol as a substitute for streptomycin as recommended internationally and (iii) an increasing tendency towards empirical treatment because of the changing clinical picture of TB in association with HIV. The rising incidence of TB related to the HIV epidemic has also led to the practice, especially in industry, to routinely determine the HIV status of TB patients.

The principal investigator of this study was intimately involved with both of the SA MRC studies (1990 & 1995) and is currently a Health Services Manager in the industrial sector in Swaziland (Usutu Pulp). For these reasons it was felt appropriate to base this MMed dissertation on the problems associated with TB control in the industrial sector in Swaziland, with particular emphasis on the outcome of treatment and the delivery of TB care within current national TBCP guidelines.

4.   AIM AND OBJECTIVES

The overall aim of this study was to evaluate current TB management protocols by describing case management and treatment outcomes in the five major industries in Swaziland, viz. Havelock Asbestos Mines (SD) Ltd (Bulembu), Mhlume Sugar Company (SD) Ltd (Mananga), Simunye Sugar Estate, Ubombo Ranches Ltd (Big Bend), and Usutu

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Pulp Company Ltd {Sappi} (Bhunya) (Figure 1). This was done within the framework of the Swaziland TBCP guidelines.

Specific objectives of the study included the following:

1. To describe the effectiveness of TB case management in these five industries in terms of quantitative primary and secondary treatment outcome indicators, i.e.:

    Primary outcomes:

    1.1.   Smear conversion after two months of TB chemotherapy;

    1.2.   Treatment success (cure and treatment completed) after six months of TB chemotherapy;

    Secondary outcomes:

    1.3. Treatment failure, treatment interruption, death, and patient loss to follow-up or transfer.

2. To describe the current practices in TB case management in these industries under the current national treatment protocols.

3. To describe the application of the TBCP at the industrial clinic level. The following aspects were studied:-

    - Screening methodology

    - Diagnostic methodology

    - Referral patterns

    - Treatment prescription and counselling

    - Case holding and follow-up

    - Patient awareness of TB signs and symptoms, and treatment

    - Patient adherence to treatment

5.   METHODS

5.1.   Definitions

Standardised international definitions (29) were used to define the following:

- A case of tuberculosis:

A patient in whom tuberculosis has been bacteriologically confirmed, or has been diagnosed by a clinician. (Note: Any patient given treatment for tuberculosis should be recorded.)

- A definite tuberculosis case:

A patient with culture positive for the *Mycobacterium tuberculosis* complex (in countries where culture is not routinely available, a patient with two sputum smears positive for acid-fast bacilli (AFB) is also considered a "definite" case.)

- Pulmonary tuberculosis - sputum smear-positive (PTB+):

1. Two or more initial sputum smear examinations positive for AFB, or

2. One sputum smear examination positive for AFB plus radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician, or

3. One sputum smear positive for AFB plus sputum culture positive for *M. tuberculosis*.

- Pulmonary tuberculosis - sputum smear-negative (PTB-):

A case of pulmonary tuberculosis that does not meet the above definition for *smear-positive* tuberculosis. Note: In keeping with good clinical and public health practices, diagnostic criteria should include:

1. At least three sputum specimens negative for AFB, *and*

2. Radiographic abnormalities consistent with active pulmonary tuberculosis, *and*

3. No response to a course of broad-spectrum antibiotics, *and*

4. Decision by a clinician to treat the patient with a full course of anti-tuberculosis chemotherapy.

- <u>Extra-pulmonary tuberculosis:</u>

Tuberculosis of organs other than the lungs e.g., pleura, lymph nodes, abdomen, genito-urinary tract, skin, joints, bones, and meninges, etc. Diagnosis should be based on one culture-positive specimen, or histological or strong clinical evidence consistent with active extra-pulmonary tuberculosis, followed by a decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy. (A patient diagnosed with both pulmonary *and* extra-pulmonary tuberculosis should be classified as a case of pulmonary tuberculosis.)

- <u>New case of tuberculosis</u>:

A patient who has never had treatment for tuberculosis, or who has taken anti-tuberculosis drugs for less than one month.

- <u>Relapse case of tuberculosis:</u>

A patient previously treated for tuberculosis who has been declared cured or treatment completed, and is diagnosed with bacteriologically positive (sputum smear or culture) tuberculosis.

- <u>Failure:</u>

A patient who, while on treatment, is sputum smear positive at five months or later during the course of treatment.

- <u>Return after default:</u>

Patient previously treated for tuberculosis whose treatment failed, who defaulted (treatment interrupted), or who relapsed.

- <u>Transfer in:</u>

A patient who has been transferred from another tuberculosis register to continue treatment.

- <u>Other:</u>

All cases which do not fit the above definitions, including,

- <u>Chronic cases:</u>

A patient who is sputum positive at the end of a re-treatment regimen.

- <u>Cured:</u>

A patient who is sputum smear negative in the last month of treatment, and on at least one previous occasion.

- <u>Treatment completed:</u>

A patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure.

- <u>Treatment failure</u>:

A patient who is sputum smear positive at five months or later during treatment.

- <u>Died</u>:

A patient who dies for any reason during the course of treatment.

- <u>Defaulter</u>:

A patient whose treatment was interrupted for two consecutive months or more.

- <u>Transfer out</u>:

A patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known.

- <u>Treatment success</u>:

The sum of patients who are cured and those who have completed treatment.

- <u>Cohort</u>:

A group of patients diagnosed and registered for treatment during a specific time period (usually one quarter of the year).

- <u>Directly observed treatment</u>:

A trained and supervised person observes the patient swallowing the tablets.

5.2. Exclusion and inclusion criteria

All full-time employees in the particular industry who were diagnosed with TB and started on TB treatment were included over the study period, starting

simultaneously on a pre-determined date (January 1998), until the relevant numbers were obtained.

No children were included in the study.

5.3. Study design, population and sampling

This was a descriptive study on the conduct and outcome of TB case management at five major industries in Swaziland. The study population involved a cohort of newly diagnosed TB patients (all patients started on TB treatment) amongst full-time employees at each of the five industries.

The sample size was calculated on the assumption that 80% of all patients started on TB treatment would be cured or the treatment would be completed (primary outcome). Using the number of permanent employees in each workforce (denominator) which totalled 11 280, calculated within a 5% test precision range (75% - 85%) and with a 95% confidence interval (CI) using Epi Info 6.04d, a total sample size of 241 was required. It was also assumed that no patients would be lost to follow up.

According to existing information at the time, it seemed as if there was a significant difference in the caseload between the health centres in the west (Bulembu and Usutu Pulp), and the health centres in the east (Simunye, Mananga and Ubombo Ranches) of the country. Each Health Centre therefore was to register the number of study patients proportional to their caseload of the previous year.

The numbers needed per health centre were as follows:

- Bulembu Mine   -   10 (4.1%)

- Mananga Health Services   -   47 (19.3%)

- Simunye Health Services   -   101 (41.4%)

- Ubombo Ranches Health Services -   57 (23.4%)

- Usutu Pulp Health Services   -   29 (11.9%)

                    TOTAL   -   244 (100%)

5.4.   Measurement tool

Three questionnaires were designed to be completed at different stages and by different persons during the process of diagnosis and treatment. These are presented in Annexures 1 to 3. A TB Questionnaire Guideline (Annexure 4) was provided to the Health Centres to ensure uniformity of data collection.

The questions were put to the patients by a person other than the person who provided the patient with information on tuberculosis (counselling). This was done to determine the patient's knowledge regarding TB and its treatment as independently as possible.

Each questionnaire was covered by a removable page, which contained the name, reference number and the dates on which the questionnaire was completed. This page was retained at the different Health Centres to maintain confidentiality. Only the sequential reference number allocated by the Health Centres appeared on the actual questionnaires. All three questionnaires contained both structured and open-ended questions. Structured questions were

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used to facilitate standardisation and ensure uniformity in data collection. Open-ended questions were used to elucidate patient knowledge in particular.

Questionnaire 1 and 2 were completed within two weeks of diagnosis, preferably at the same time. Questionnaire 1 was completed by the relevant health worker and Questionnaire 2 by the patient with the help of a health worker. The health worker at the completion of the treatment cycle completed Questionnaire 3.

The questions were aimed at determining the current practices in diagnosis and treatment of patients at the different Health Centres, the knowledge of the patient regarding TB in general, its treatment, side effects of the drugs, and the patient's experience regarding directly-observed treatment (DOT).

Questionnaire 3 focused on the provision of DOT, patient adherence, smear status at two months, treatment outcome, side effects experienced and the HIV status of the patient, if known.

5.5. Logistics

Sputum smear examination was to be done at point of entry, after two months to determine smear conversion (proxy for eventual cure) and after six months to determine treatment outcome.

Sputum samples were collected from patients during the initial visit, and on two subsequent days (early morning specimens). The health care provider instructed the patient on the technique of producing sputum, and provided the patient with

specimen containers. Microscopy was done on direct smears using Ziehl-Neelsen staining.

Visits were made to each facility and the principal investigator maintained regular telephone contact with the health workers involved. The principal investigator collated information at monthly intervals over the duration of the study. The data was entered on a laptop computer by a data clerk, verified by the health service manager at the respective centres and checked at the respective Centres by the principal investigator.

5.6. HIV testing

HIV status of TB patients was not specifically determined for the purpose of the study; however, where this was known it was recorded.

5.7. Verification

Data verification and quality assurance were performed by comparing the information on the questionnaires with the patient's record, on a random sample of 25% of patients. To protect patient confidentiality, this was done by the health services managers of the individual industries, who had regular access to patient files.

All questionnaires were manually checked for missing information by the principal investigator. Every effort was made to retrieve the missing information from the relevant Health Centres. In selected cases the incomplete questionnaires were returned to the Health Centres for completion.

5.8. Analysis

The data was originally captured in a Microsoft Access database, and converted to Epi Info 6.04d (2001) for analysis purposes. P-values were calculated to indicate categorical differences and mid-level confidence intervals around proportions were determined using Epi Info 6.04d (2001). The manuscript was prepared using Microsoft Word 2000, and tables and figures prepared using Microsoft Excel 2000.

6. ETHICAL CONSIDERATIONS

Permission was obtained from the industries participating in the study through authorisation letters, provided in Annexure 5. Approval by the University of Pretoria (UP) Ethical Committee was also obtained (Annexure 6).

Patients were assured that all information would be treated confidentially.

All procedures conformed to the prescribed protocols of the Swaziland TBCP. Individual counselling, health education and contact tracing were prominent features in all instances. Any local variations or deviations from these protocols were described and the potential impact assessed. The study itself did not introduce any unusual or additional element of care that would have had ethical implications.

HIV status is commonly but not universally established in TB patients in Swaziland. In the course of this study HIV status was included in Questionnaire 3 only if it was known. It was not established as a requirement of the study. Confidentiality of all information collected for the purpose of the study was ensured by coding of the questionnaires. The detachable portion of the questionnaire which contained personal details of the patient was secured and retained by the medical officer in charge or the TB supervisor (or the HIV/AIDS

counsellor where relevant) of the particular health service where an individual patient was treated. These details were not at any stage made known to the principal investigator or to any other person associated with the study. In this way HIV status, like any other information collected for the purpose of the study, was anonymous.

The Informed Consent Form (Annexure 7) described the different aspects of the study i.e. the Purpose, Description of Procedures, Risks and Discomforts, Benefits, Voluntary Participation, and Confidentiality. A health worker explained the content of the form to the patient. The patient, health worker and two witnesses signed the form. The form was retained at the different health centres to ensure patient confidentiality.

7.   STUDY LIMITATIONS

The majority of cases (>95%) were registered between 1998 and 2001. The collection of data took about twice as long as originally anticipated, largely due to the following problems:

-   It proved to be very difficult to motivate the health personnel involved to start registering patients for the study. There is a tendency in Swaziland whereby researchers, especially from international agencies, reward personnel financially for gathering data, even though this is done during their usual working time. In this study there was no financial incentive and it therefore prolonged the process.
-   Personnel changes at the different study sites required re-establishment of arrangements.
-   Havelock Asbestos mine (Bulembu) ceased operations during the latter part of 2001; however, the required number of questionnaires was obtained before this time.

Due to the problems described above, it is possible that TB patients presenting to the Health Centres during the study period were not registered sequentially. However, patient registration was continued until the required number per Health Centre was reached.

The collection of data was done through questionnaires and the usual limitations relating to this type of study methodology would apply, e.g. health worker bias in interpretation, patient bias (giving answers that they thought the health workers might expect), and both health worker and patient recall bias. To avoid this as much as possible structured questionnaires were used, preceded by training of the health workers and guided by the TB Questionnaire Guideline. The study evaluated TB control in the industry as an entity; therefore inter- and intra-variation (health workers and Health Centres) was not assessed.

The HIV problem was of critical importance, but during the planning of the study the HIV component was not that significant.

8. RESULTS

8.1. Response rate

Health Centres were requested to continue registering patients until the required numbers were reached. Table I indicates the response rate of each centre. All centres except Simunye reached the required number. Three centres exceeded the required number by a few patients, while Simunye registered only 90% of the required target. All results were used for analysis.

8.2. Demographic profile

There were no differences between the health centres with regard to age and gender distribution and results were therefore combined.

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Table I shows the demographic profile of the study population. As expected within the industrial setting the majority of patients (> 85%) were in the 25 – 54 year age group. The mean age was 37.8 yrs, range 17 – 63 years.

Also, as expected in this environment, the vast majority of patients (79%) were male.

Table I. Demographic characteristics
(TB control in SD industries 1998 - 2001)

Response rate	Expected	Actual	%
Bulembu	10	12	120.0
Mananga	47	47	100.0
Simunye	101	91	90.1
Ubombo	57	72	126.3
Usutu	29	30	103.4
Total	244	252	103.3
Age Group	**n**	**%**	**95% CI**
15 - 24	20	7.9	5.1 - 11.8
25 - 34	82	32.5	27.0 - 38.5
35 - 44	79	31.4	25.9 - 37.3
45 - 54	54	21.4	16.7 - 26.8
55 - 64	17	6.8	4.1 - 10.4
Total	252	100.0	
Gender	**n**	**%**	**95% CI**
Female	53	21.0	16.3 - 26.4
Male	199	79.0	73.6 - 83.7
Total	252	100.0	

8.3. Smear conversion

Table II shows the smear conversion at two months. Only 36.1% of patients (91/252) had a negative smear result, while in 55.6% of patients (140/252) no smear was done and in 8.3% of patients (21/252) no information was available.

Inter-centre differences were evident, in that 97.9% of patients at Mananga, 80.2% of patients at Simunye, 58.3% at Bulembu, 40% at Usutu, and 2.8% at Ubombo had no smear examination done. A high smear-conversion rate of 90.2% was recorded at Ubombo, while for the rest of the Centres the smear conversion was below 55% (53.3% at Usutu, 33.3% at Bulembu, 6.6% at Simunye, and 0% at Mananga).

Table II. Smear conversion (all centres combined)
(TB control in SD industries 1998 - 2001)

Smear conversion	n	%	95% CI
Negative	91	36.1	30.4 - 42.2
Not done	140	55.6	49.4 - 61.6
No information	21	8.3	5.4 - 12.3
Total	252	100.0	

8.4. Treatment outcome

Table III presents the treatment outcome by individual Health Centre and for all five Centres combined. Because of low numbers, caution should be applied in the interpretation of Centre-specific outcomes.

Table III.   Treatment outcome by Health Centre
(TB control in SD industries 1998 - 2001)

Treatment outcome	Bulembu		Mananga		Simunye		Ubombo		Usutu		Total		
	n	%	n	%	n	%	n	%	n	%	n	%	95% CI
Successful treatment	8	66.7	42	89.4	74	81.3	61	84.7	26	86.7	211	83.7	78.8 - 87.9
Died	3	25.0	3	6.4	10	11.0	3	4.2	1	3.3	20	7.9	5.1 - 11.8
Transferred out	0	0.0	2	4.3	1	1.1	1	1.4	1	3.3	5	2.0	0.7 - 4.3
Treatment interrupted	1	8.3	0	0.0	6	6.6	4	5.6	1	3.3	12	4.8	2.6 - 8.0
Treatment failed	0	0.0	0	0.0	0	0.0	3	4.2	1	3.3	4	1.6	0.5 - 3.8
Total	12	100.0	47	100.0	91	100.0	72	100.0	30	100.0	252	100.0	
Favourable outcome	8	66.7	42	89.4	74	81.3	61	84.7	26	86.7	211	83.7	78.8 - 87.9
Unfavourable outcome	4	33.3	5	10.6	17	18.7	11	15.3	4	13.3	41	16.3	12.1 - 21.2
Total	12	100.0	47	100.0	91	100.0	72	100.0	30	100.0	252	100.0	

Successful treatment was defined as the sum of patients cured and those where treatment was completed but no bacteriological evidence of cure was provided. This was necessary due to low numbers in the 'cured' category, largely because the smear investigations had not been done.

- Successful treatment

83.7% (211/252) of the patients in the study population were successfully treated. However, differences between the Health Centres were evident as illustrated in Figure 3, with the highest treatment success calculated for Mananga (89.4%), followed by Usutu (86.7%), Ubombo (84.7%), Simunye (81.3%), and Bulembu (66.7%).

- Death

A total of 20 (7.9%) deaths were recorded. Considerable differences were observed between the Health Centres, albeit at low numbers: At Bulembu 25.0% (3/12) of patients died, at Simunye 11.0% (10/91), at Mananga 6.4% (3/47), at Ubombo 4.2% (3/72) and at Usutu 3.3% (1/30).

- Treatment interrupted

Of the total study population 4.8% (12/252) fell into this category. Centre-differences were again evident: At Simunye 6/91 (6.6%) interrupted, at Ubombo 4/72 (5.6%), at Bulembu 1/12 (8.3%) at Usutu 1/30 (3.3%) and none at Mananga.

- Treatment failed

1.6% (4/252) of the study population fell into this category. Only Ubombo and Usutu recorded patients who had failed treatment (3/72 and 1/30 respectively).

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Figure 3: Treatment outcome by Health Centre
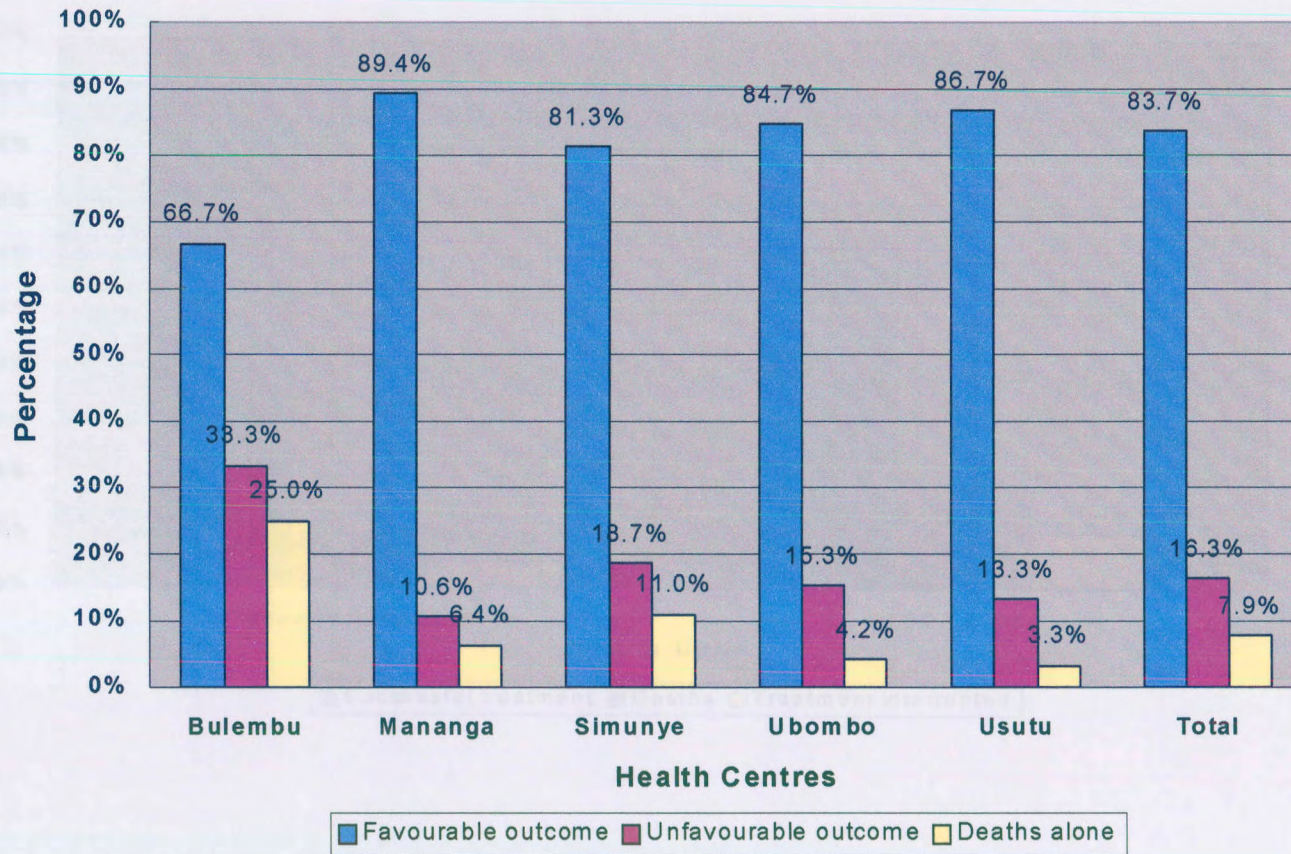
- Transferred

Only 2% (5/252) of the study population fell in this group. Bulembu had no transferred patients, Simunye, Ubombo and Usutu each had one (1.1%, 1.4% and 3.3% respectively), and at Mananga two patients (4.3%) were transferred.

Outcomes were grouped into Favourable (cured, treatment completed) and Unfavourable (died, failed, interrupted, transferred) and the results are presented in Table III. In total, a favourable outcome was obtained in 83.7% of study patients, while 16.3% had an unfavourable outcome. Centre differences were evident, with an unfavourable outcome recorded in 33.3% of patients at Bulembu (4/12), 18.75% (17/91) at Simunye, 15.3% (11/72) at Ubombo, 13.3% (4/30) at Usutu, and 10.6% (5/47) at Mananga, as illustrated in Figure 3.

Table IV and Figure 4 show the comparison in treatment outcome between industry (as determined in this study) and available data for 2001 from the national TBCP. Successful treatment (cure plus treatment completed) was achieved in 62.1% of TBCP patients, compared to 83.8% in industry patients (p<0.0001). In the TBCP group 18.8% of the cohort died, compared to 7.8% in industry. Treatment interruption was 10% in the TBCP and 4.8% in industry. These differences were not statistically significant (p>0.05), in all probability due to low numbers in the respective categories.

Univariate analysis of the association between favourable or unfavourable outcomes and demographic variables is presented in Table V.

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**Table IV. Comparison of treatment outcome between industry and TBCP Swaziland
(TB control in SD industries 1998 - 2001)**

Treatment outcome	Industries total			TBCP 2001			
	n	%	95% CI	n	%	95% CI	p
Successful treatment	211	83.8	78.8 - 87.9	429	62.1	58.4 - 65.7	<0.0001
Died	20	7.8	5.1 - 11.8	130	18.8	16.0 - 21.9	0.5396
Transferred out	5	2.0	0.7 - 4.3	62	9.0	7.0 - 11.3	#
Treatment interrupted	12	4.8	2.6 - 8.0	69	10.0	7.9 - 12.4	0.7414
Treatment failed	4	1.6	0.5 - 3.8	1	0.1	#	#
Total	252	100.0		691	100.0		

Figure 4: Comparison of treatment outcome between Industry and TBCP Swaziland
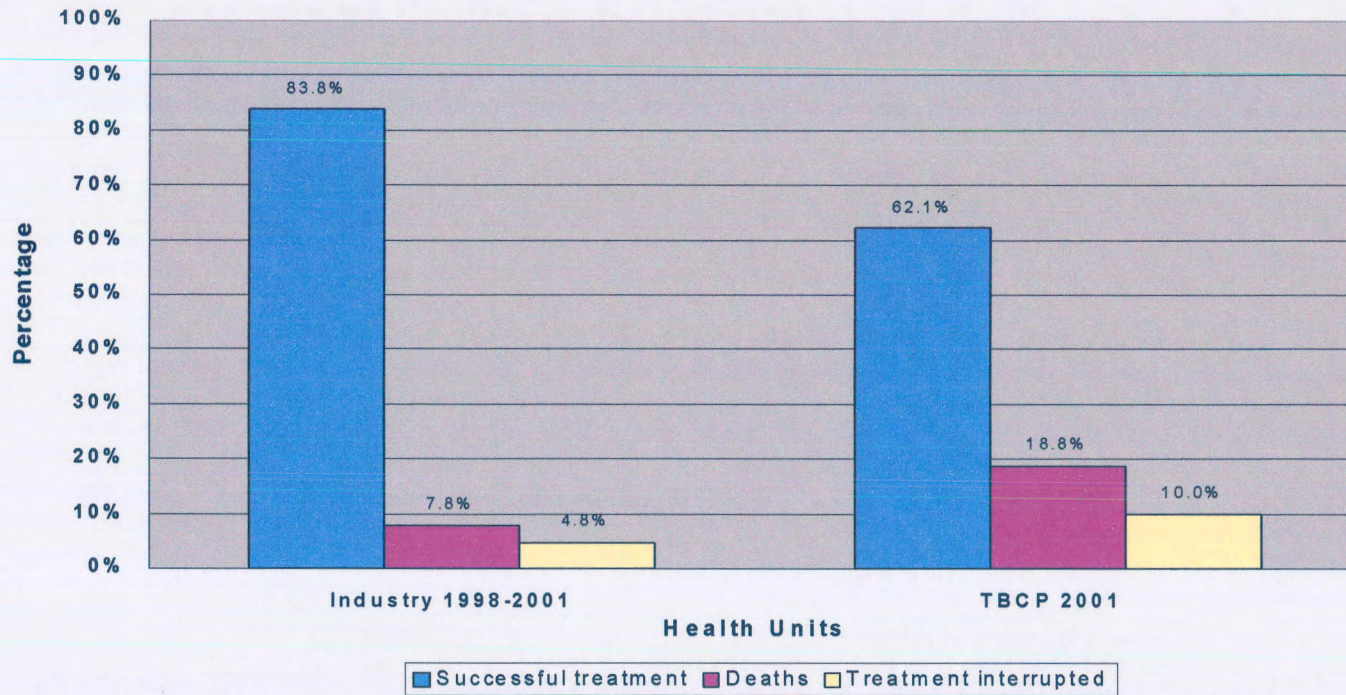
Table V. Treatment outcome - univariate analysis
(TB control in SD industries 1998 - 2001)

Variable		Outcome			
		Favourable	Unfavourable	Total	
		n (%)	n (%)	n (%)	p
Gender	Female	46 (86.8%)	7 (13.2%)	53 (100%)	
	Male	165 (82.9%)	34 (17.1%)	199 (100%)	
	Total	211	41	252	
					p=0.4967
Age	15 - 24	16 (80.0%)	4 (20.0%)	20 (100%)	
	25 - 34	73 (89.0%)	9 (11.0%)	82 (100%)	
	35 - 44	68 (86.1%)	11 (13.9%)	79 (100%)	
	45 - 54	42 (77.8%)	12 (22.2%)	54 (100%)	
	55 - 64	12 (70.6%)	5 (29.4%)	17 (100%)	
	Total	211	41	252	
					p=0.2170
HIV status	No	150 (84.7%)	27 (15.3%)	177 (100%)	
Known	Yes	61 (81.3%)	14 (18.7%)	75 (100%)	
	Total	211	41	252	
					p=0.5022
HIV status [Yes]	Negative	13 (100.0%)	0 (0%)	13 (100%)	
	Positive	48 (77.4%)	14 (22.6%)	62 (100%)	
	Total	61	14	75	
					p=0.1315
DOT	No	44 (77.2%)	13 (22.8%)	57 (100%)	
	Yes	167 (85.6%)	28 (14.4%)	195 (100%)	
	Total	211	41	252	
					p=0.1285

Gender did not show any association with outcome. Females tended to have slightly better outcomes (86.8% vs. 82.9%), however, this was not statistically significant (p = 0.4967). Similarly, age had no effect on treatment outcome (p = 0.2170). Whether a patient's HIV status was known did not influence treatment outcome (p = 0.5022), although patients for whom HIV status was known (positive or negative) had a slightly higher proportion of unfavourable outcomes (18.7% vs.15.3%). Patients who were HIV-positive tended to have worse outcomes (22.6% unfavourable vs. 0%); however, this association was not statistically significant (p = 0.1315). Similarly, patients who did not receive DOT tended to have worse outcomes (22.8% unfavourable vs. 14.4%), but again this did not approach statistical significance (p = 0.1285).

8.5. Related health data

Table VI represents TB and related health data. The majority of patients (81%) were treated for the first time for TB, while 13.9% indicated a history of previous treatment and for 5.1% no information was available.

The majority of patients (87.7%) had no co-existing lung disease.
The HIV status of 29.7% of patients was known. Of these patients 82.7% were positive. One exception was Simunye where no patient's HIV status was recorded on the questionnaires.

8.6. Tuberculosis care delivery

The delivery of TB care is presented in Table VII. Answers given by the health worker and those by the patient regarding the time-lapse between presentation at the Health Centre and confirmation of the diagnosis are compared in Table VIIa.

Table VI. Related health data
(TB control in SD industries 1998 - 2001)

Previous treatment	n	%	95% CI
Yes	35	13.9	10.0 - 18.6
No	204	81.0	75.8 - 85.5
Unknown	13	5.1	2.9 - 8.5
Total	*252*	*100.0*	
Co-existing lung disease	n	%	95% CI
Yes	10	4.0	2.0 - 7.0
No	221	87.7	83.2 - 91.3
Unknown	21	8.3	5.4 - 12.3
Total	*252*	*100.0*	
HIV status known	n	%	95% CI
Yes	75	29.7	24.4 - 35.6
No	177	70.3	64.4 - 75.6
Total	*252*	*100.0*	
HIV positivity	n	%	95% CI
Negative	13	17.3%	10.0 - 27.2
Positive	62	82.7%	72.9 - 90.0
Total	*75*	*100.0%*	

Significant differences between the answers of health workers and patients are evident: More than 73% of patients indicated that it took less than two days to obtain a diagnosis, compared to less than 26% of health workers. Of particular relevance was the observation that 45.6% of patients reported this time-lapse to be less than one day, while only 14.7% of health workers reported the same (p = 0.0005). Similarly, only 8.3% of patients reported a time-lapse of more than 10 days, compared to 36.5% of health workers (p = 0.0149).

Table VII. TB care delivery
(TB control in SD industries 1998 - 2001

Table VIIa. Time between presentation and diagnosis

Time	Patient			Health worker			p
	n	%	95% CI	n	%	95% CI	
< 01 day	115	45.6	39.6 - 51.8	37	14.7	10.7 – 19.5	0.0005
1 - 2 days	71	28.2	22.9 - 34.0	28	11.1	7.7 - 15.5	0.0640
3 - 5 days	35	13.9	10.0 - 18.6	38	15.1	11.1 – 19.9	0.8576
5 - 10 days	9	3.6	1.8 - 6.5	57	22.6	17.8 -28.1	0.2510
> 10 days	21	8.3	5.4 - 12.3	92	36.5	30.7 – 42.6	0.0149
No info	1	0.4	#	0	0.0	#	#
Total	252	100.0		252	100.0		

Table VIIb. Time between diagnosis and treatment

Time	Patient			Health worker			p
	n	%	95% CI	n	%	95% CI	
< 01 day	25	9.9	6.7 - 14.1	136	54.0	47.8 – 60.1	<0.0001
1 - 2 days	22	8.7	5.7 - 12.7	69	27.3	22.1 – 33.1	0.0738
3 - 5 days	32	12.7	9.0 - 17.3	29	11.5	8.0 - 15.9	0.8899
5 - 10 days	53	21.0	16.3 - 26.4	7	2.8	1.2 - 5.4	0.4156
> 10 days	119	47.3	41.1 - 53.4	11	4.4	2.3 - 7.5	0.0070
No info	1	0.4	#	0	0.0	#	#
Total	252	100.0		252	100.0		

Table VIIc. DOT provided

Table VIIc. DOT provided				n	%	95% CI	
Yes				195	77.4	71.9 -82.2	
No				57	22.6	17.8 – 28.1	
Total				252	100.0		

Table VIIb compares the time-lapse between diagnosis and the onset of treatment. Again a significant difference was observed between health workers and patients: While more than 81% of health workers stated that it took less than two days, more than 68% of patients indicated that it took more than five days. Again, the difference was most striking in the categories 'less than one day' and 'more than 10 days': 54% of health workers indicated that less than one day lapsed between diagnosis and treatment initiation, while only 9.9% of patients gave the same response (p<0.0001). 47.3% of patients indicated that the delay was more than 10 days, compared to only 4.4% of health workers (p=0.0070).

77.4% of patients received medication under conditions of Direct Observed Treatment (DOT), as indicated in Table VIIc. Inter-centre differences were significant: At Mananga all patients were provided with DOT, at Simunye 95%, at Bulembu and Usutu 75%, and at Ubombo only 40% received DOT (data not shown).

8.7. Tuberculosis diagnosis

Table VIII presents the different diagnostic options that were utilised. Chest radiographs were taken in 86.5% of patients. Sputum evaluation was only done in 56.3% of patients, while clinical signs and symptoms were used in 42.1% to determine the diagnosis.

In only 36% of patients was the diagnosis by sputum evaluation confirmed at a referral laboratory (data not shown). Significant inter-centre differences occurred.

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While more than 70% of diagnoses at Bulembu and Usutu were confirmed at a referral laboratory, the corresponding figures were only 15% and 4% for Mananga and Ubombo respectively. At Simunye approximately 50% of diagnoses were confirmed at a referral laboratory.

Table VIII. Tuberculosis diagnosis (n=252)
(TB control in SD industries 1998 - 2001)

Diagnostic options*	n	%	95% CI
Clinical	106	42.1%	36.1 - 48.2
X-rays	218	86.5%	81.9 - 90.3
Sputum	142	56.3%	50.2 - 62.4
Other	11	4.4%	2.3 - 7.5

* Multiple response question, sum not equal to 100%

8.8. Tuberculosis treatment

More than 97% of cases received the prescribed treatment regimen of the Swaziland TBCP. In six patients (five at Simunye) streptomycin was replaced with ethambutol.

Patients were seldom referred. Only 5 (2%) patients were transferred out for treatment (data not shown). Most cases were treated and followed-up at the Health Centres where the initial diagnosis had been made.

8.9. Patient knowledge and awareness

Patient knowledge and awareness of TB are given in Table IX. The majority (194/252, 77.0%) of patients had some knowledge of their disease.

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**Table IX. Patients' knowledge & awareness re. TB (n=252)
(TB control in SD industries 1998 - 2001)**

Symptoms*	n	%	95% CI
Cough	164	84.5	59.0 - 70.8
Weight loss	107	55.2	36.5 - 48.6
Chest pain	69	35.6	22.1 - 33.1
Night sweats	74	38.1	24.0 - 35.2
Appetite loss	36	18.6	10.4 - 19.0
Unknown	58	23.0	18.1 -28.5
Diagnosis*	**n**	**%**	**95% CI**
Clinical	15	8.8	3.5 - 9.4
X-ray	132	77.6	46.2 - 58.5
Sputum	91	53.5	30.4 - 42.2
Unknown	82	32.5	27.0 - 38.5
Treatment*	**n**	**%**	**95% CI**
Medication	182	98.4	66.4 - 77.5
Traditional healing	4	2.2	0.5 - 3.8
Isolation	2	1.1	0.1 - 2.6
Unknown	67	26.6	21.4 - 32.3
Treatment duration	**n**	**%**	**95% CI**
Known	189	75.0	69.4 - 80.1
Unknown	63	25.0	20.0 - 30.6
Total	*252*	*100.0*	
Period of treatment	**n**	**%**	**95% CI**
< 6 months	37	19.6	14.4 - 25.7
6 months	141	74.6	68.0 - 80.4
> 6 months	4	2.1	0.7 - 5.0
No info/other	7	3.7	1.6 - 7.2
Total	*189*	*100.0*	
Known TB Contacts*	**n**	**%**	**95% CI**
Family	76	45.0	24.7 - 36.0
Friends	100	59.2	33.8 - 45.8
Not known	83	32.9	27.3 - 38.9
Transmission*	**n**	**%**	**95% CI**
Air	126	79.7	43.8 - 56.2
Blood	6	3.8	1.0 - 4.9
Touching	2	1.3	0.2 - 2.6
Cultural practices	3	1.9	0.3 - 3.2
Unknown	94	37.3	31.5 - 43.4

* Multiple response question, sum not equal to 100%

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Regarding symptoms, 84.5% were aware of the importance of coughing, 55.2% of weight loss, 38.1% knew of night sweats, 35.6% knew about chest pain, and 18.6% of appetite loss. For 23.0% of patients no information on symptom recognition was given.

Concerning diagnosis, 67.5% (170/252) of patients reported that they knew how TB could be diagnosed. 77.6% knew about X-rays, 53.5% about sputum evaluation, and 8.8% about clinical diagnosis. Almost a third (32.5%) of patients did not know anything about the way that TB was diagnosed.

74.4% (185/252) of patients had knowledge about TB treatment. The majority of these patients (98.4%) knew about medication as treatment option. Very few patients (2.2%) indicated traditional healing as an option, while two patients (1.1%) felt that TB patients should be isolated to achieve cure. 26.6% of patients gave no indication of knowledge about treatment.

The majority of patients (189/252, 75.0%) had some knowledge about the duration of treatment. Of these, 74.6% were aware that the treatment duration would be six months. Nearly 19.6% thought that it would be less than six months and 2.1% thought that treatment would extend beyond 6 months.

169/252 (67.1%) of patients knew somebody who had had TB. Of these contacts, 45.0% were family, and 59.2% were friends.

158/252 (62.6%) of patients had knowledge about the transmission of the disease. Nearly 80% of these were aware of air-borne transmission.

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8.10. Supervision of treatment and patient adherence

Table X presents the results on supervision of treatment.

84.1% (212/252) of the patients received their medication daily, 13.9% (35/252) monthly, and 1.6% (4/252) weekly.

20.6% (52/252) of patients saw the same health worker at every visit, 35.7% (90/252) saw the same health worker at most visits and 43.3% (109/252) seldom saw the same health worker. Inter-centre differences were observed: 94.4% of patients seldom had the same health worker at Ubombo, 29.8% at Mananga, 20.9% at Simunye, 20% at Usutu, and 16.7% at Bulembu. In contrast, 83.3% of patients at Bulembu, 80% at Usutu, 78% at Simunye, 70.2% at Mananga, and only 5.6% at Ubombo had the same health worker at most or every visit (data not shown).

Patient adherence was estimated by the health worker and calculated from the patient cards. Health workers estimated that 75.4% of patients had taken more than 75% of the prescribed doses. However, the actual calculation showed that only 47.2% had been adherent, a difference that was highly significant (p<0.0001). Differences in the other categories of adherence were also evident, as indicated in Table X. However, because of low numbers, statistical significance could not be shown. Of interest was also the observation that adherence was estimated for all but one patient by the health workers; however, when actual adherence was calculated 104 (41.3%) of the patients did not have adherence records in their treatment cards.

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Drug side effects were recorded in 4.4% of patients (11/252) only (data not shown).

Side effects mentioned were itching, skin rashes, impotence and jaundice.

Table X. Supervision of treatment and patient adherence
  (TB control in SD industries 1998 - 2001)

Treatment given	n	%	95% CI					
Daily	212	84.1	79.2 - 88.3					
Weekly	4	1.6	0.5 - 3.8					
Monthly	35	13.9	10.0 - 18.6					
No info	1	0.4	#					
Total	252	100.0						
Same health worker at:-	n	%	95% CI					
Every visit	52	20.6	16.0 - 26.0					
At most visits	90	35.7	30.0 - 41.8					
Seldom	109	43.3	37.2 - 49.4					
No info	1	0.4	#					
Total	252	100.0						
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Patient adherence							
	Estimated			Actual			
	n	%	95% CI	n	%	95% CI	p
< 50%	9	3.6	1.8 - 6.5	5	2.0	0.7 - 4.3	#
50% - 75%	52	20.6	16.0 - 26.0	24	9.5	6.3 - 13.6	0.2928
> 75%	190	75.4	69.8 - 80.4	119	47.2	41.1 - 53.4	<0.0001
No info	1	0.4	#	104	41.3	35.3 - 47.4	#
Total	252	100.0		252	100.0		

9. DISCUSSION

Although problems were experienced with health staff reluctance to participate in the study without additional payment, the targets were eventually reached in all but one centre while two centres registered more patients than required. The practice of additional financial compensation for health care workers involved in operational research should be evaluated by the TBCP and policy guidelines developed, as it is doubtful whether public sector-funded research activities will be able to sustain this practice.

It was difficult to assess the quality of the information gathered. To a large extent, subjective views of health workers and patients had to be relied upon and much of the objective information provided could not be verified. Findings were based entirely on information supplied by the Health Centre personnel and subject to human bias.

Incidence rates for the industries were not established. There is a constant workforce turnover and subsequently, persons included in the denominator are not always included in the numerator. Also, the denominator for new TB cases would have to be studied for one year as there may be seasonal differences in incidence rates. One problem was that all cases of TB might not have been included during the study period. Breaks in enrolment due to the problems described before mean that the number of cases recorded was not necessarily the total number of cases for the study period. Also, the actual study duration differed at the different Health Centres because of the pre-determined numbers required at each centre. The numbers of patients recorded at each Health Centre over different periods do not, therefore, reflect incidence rates at these centres.

All recorded cases had not been definitively proven to be TB cases, since sputum examination was not used to confirm all diagnoses. The age and gender profiles of the study population were also different from those usually observed in the general population (2) (24); however, they were expected for the setting of the study and similar to the demographic distribution of the denominator population (industrial work force with a preponderance of young adult males).

The proportion of patients achieving a successful treatment outcome (84%) was very encouraging, almost reaching the international WHO target of 85% cure of detected new smear-positive cases (4) (29). If deaths are omitted from the cohort analysis, 91% of patients were successfully treated. However, using the strict definition of cure, only 28% of patients met this criterion due to the low percentage of sputum investigations done at the end of treatment. This is of serious concern and needs to be addressed through increased focus on smear microscopy (also for diagnosis). These outcomes are significantly superior to those currently obtained by the TBCP, confirming the assumption that TB control in industry in Swaziland is considerably more successful. This observation is also evident from the lower interruption rate (4.8% compared to 10% in the TBCP) and lower death rate (8% compared to 19% in the TBCP).

Also of serious concern was the fact that smear conversion could be determined for only about a third of patients, due to smears not having been done. The organisation of microscopy services was problematic, given that only two centres had resident laboratory technicians and that the others had to rely on microscopy diagnosis being done in remote laboratories within the governmental or private sector. Problems around the centralisation of microscopy services and the lack of quality assurance within the TBCP were also highlighted in the WHO review (28). Examination of sputum smears is

still highly centralised, with one microscopist at the Central Laboratory in Manzini, and another at Good Shepherd Hospital near Siteki. The ideal would be to have a network of decentralised laboratory centres carrying out sputum smear microscopy at a highly technical level (24). Studies have found that non-specialised staff of general health institutions are capable of carrying out satisfactory smear microscopy. The performance of such microscopists can be maintained at a satisfactory level after a short period of training, by continuous supervision and by corrective retraining (25). It is generally recommended that one microscopy centre be developed for each unit of population containing between 50 000 and 150 000 inhabitants, and that the microscopy centre be located at the same site as the treatment centre (3). Ideally, a reference laboratory should be available for quality control (1) (7).

Nearly 14% of the study population had been treated for TB before. This proportion was higher than that recorded in the MRC drug resistance survey (10.8%) (27) and reported by the Swaziland TBCP (6.3%). This may indicate a greater willingness of industry patients to divulge previous treatment (probably as a result of better counselling and questioning) and shows that TB control in the industry in Swaziland is moving closer to the target of 10% retreatment evident from good TB control programmes elsewhere (2) (22) (23) (30).

Given the nature of the industrial settings where the study participants were employed (asbestos mining, forestry/pulp, sugar industry) a higher number of patients with co-existing lung disease was expected. Occupational asthma, fibrogenic lung disease (e.g. asbestosis), occupational bronchitis, and allergic alveolitis were some of the expected conditions (31), yet co-existing lung disease was only recorded in 4% of the study population (conditions were not listed). The low prevalence of other lung diseases found in this study may indicate under-detection or under-reporting of these conditions. Under-

reporting of morbidity is a known phenomenon in the mining industry, where productivity of mining shifts is determined collectively and where patients are known to hide their diseased status for as long as possible in order not to jeopardise their shift's productivity. More diligent screening of co-existing lung diseases among TB patients will allow a clearer picture of this problem in other types of industry workers. A study amongst South African gold-miners showed that HIV infection and silicosis were both powerful risk factors for TB and were associated with an increased risk of death (21). The precise occupation of the patient in the industry is also of importance in the determination of risk of TB (2).

The incidence of drug side effects recorded was low. Possible reasons for this could be a lack of knowledge by both patients and health care providers and lack of observation by the latter. Clinical signs and symptoms might not be recognised as possible drug side effects. Increased awareness of possible clinical presentations of side effects and their management is therefore indicated.

Given the magnitude of the HIV epidemic in Swaziland, the close relationship of HIV with TB and existing policies for active voluntary counselling and testing (VCT), a much higher proportion of study patients was expected to have an existing HIV result. All participating Health Centres have active VCT programmes for HIV and there is a general tendency to test all HIV-positive individuals for TB and vice versa. (Personal communication, SMOs Participating Health Centres, May 2001). The principal investigator has had personal experience with this approach at Usutu, where all patients diagnosed with TB are tested for HIV, and all HIV-positive individuals are tested for TB (with informed consent as outlined in policy guidelines). The fact that only about a third of study patients had an HIV result points to an urgent need for more aggressive implementation of VCT and screening for TB as an integral component of these

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strategies, particularly as the provision of ante-retroviral therapy is currently being considered for selected industries in Swaziland (Personal communication, confidential, July 2002).

The high prevalence of HIV infection (>80%) among the relatively small number of TB patients with known HIV status in this study was not surprising and was similar to rates found among miners in SA (21) and even to rates found in TBCP's in other countries in the Southern Africa region (9) (30). TB is one of the most prevalent opportunistic diseases in HIV-infected individuals and is curable (2). Several studies have shown a dramatic increase in TB case notifications, linked to the HIV epidemic; even more alarming from an epidemiological point of view is the fact that the age-distribution of sputum smear-positive cases has shifted very clearly to a younger age-group (2).

The escalation in TB incidence in Swaziland, which has been ascribed to the worsening HIV epidemic (18) (19) (20), further demonstrates the need for expanded VCT and a comprehensive package of care. This is particularly relevant to the industry in Swaziland, which relies almost exclusively on recruitment of their workforce from the Swaziland population.

In essence all Health Centres used the same procedures for TB case detection and management. These usually consisted of passive case finding (symptomatic patients presenting at the Health Centres), diagnosis based mostly on chest radiography and to a lesser extent on bacteriology and clinical grounds, treatment according to Swaziland TBCP policy and patient follow-up through regular visits to the Health Centres. Patient contact with the health services was very regular (daily in more than 80% of cases); however, continuity of care in terms of contact with the same health worker was less

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consistent (only one in five patients reported seeing the same health worker at every visit). This largely reflects the high turnover of staff in these Health Centres, a problem also experienced by the Swaziland TBCP (Personal communication, Mr T Dlamini, TBCP, September 2002).

According to the existing management guidelines, TB patients are supposed to receive counselling about their disease and the treatment process. Successful treatment requires that the patient understands the nature of the disease and its management. The relationship developed between the patient and the caregiver requires investment of time and energy, but is the key to achieving success. If the patient understands the disease and its treatment, this information will be passed on to the community. As a result, other individuals with TB will be encouraged to come forward to seek diagnosis and treatment (3).

It has long been recognised that case-finding and chemotherapy are the most important measures of control of the TB epidemic (1). Early diagnosis and prompt institution of effective treatment are two of the key components of a good TB control programme. This is especially important in smear-positive pulmonary TB patients, to try and reduce the transmission of the disease in the community (30). If the majority of smear-positive cases of pulmonary tuberculosis could be rendered non-infectious, the risk of tuberculosis infection would immediately start to fall (1).

Results from this study indicated varying levels of success and differences between the Health Centres, substantiated by the responses from patients regarding their perception of the disease and its treatment. The wide difference between patients' perception of the time between presentation and diagnosis and that reported by health workers may

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be related to an impression by patients that the diagnosis is made as soon as they present to the health service. The delay reported by health workers (longer than five days reported by almost two-thirds of workers) is probably more realistic. Although this delay is much shorter than that routinely reported from TBCP's in the Southern Africa region (9) (30), it indicates a problem area that should be improved, particularly given the captive nature of the population concerned. Together with the limited use of smear microscopy as diagnostic option found in this study, it is clear that the diagnosis of TB in industry needs improvement, with turn-around times for smear microscopy to be shortened to a maximum of 48 hours.

The discrepancy between patients' and health workers' perspectives of the time delay between diagnosis and commencement of treatment was also significant and probably linked to the observation above - patients may have felt that it took a long time before treatment was started due to their belief that the diagnosis was made almost as soon as they presented to the Health Centre. Interviewee bias could also have played a role. Again, the health workers' perspective may be more realistic and indeed reassuring, given that treatment was started within two days following the diagnosis in more than 80% of patients. This finding compares favourably to studies done in other Sub-Saharan countries (26) (30). A study in Tanzania found that the mean period from first reporting to a health facility to diagnosis was 21 days. Close to 90% of this delay was due to the patient, and was linked to factors such as the distance from home to clinic, education level, and the patient's knowledge about TB. It was suggested that the most important determining factors for patient action were availability and accessibility of medical services, and knowledge about the disease (9). The point was highlighted that patients who had information on TB prior to diagnosis had shorter delays in reporting to health services (9).

Studies carried out in other African countries illustrated delays of three to four months between onset of symptoms and diagnosis in patients with pulmonary TB. The main reasons for the delay were patients seeking alternate ways of treating their cough, and health services failing to perform sputum examination, even after repeated visits (30). It was found that up to 40% of patients reported an improvement in their symptoms after treatment with antibiotics, leading to a further delay in diagnosis (30).

Study patients seemed to be well educated about TB symptoms and transmission, and the fact that treatment relies on medication (rather than other options such as traditional healing). This finding was different to that of the study done in Tanzania, where only 30% of patients had satisfactory knowledge of disease and treatment (11). Other studies have found that most patients who were smear positive were aware of one or more symptoms suggestive of TB, the most common being that of coughing (11) (26).

A very high proportion of patients either had a family member or knew someone in their circle of friends with TB, indicative of the severity of the TB epidemic in Swaziland. This finding corresponds with studies done in other African countries, where it was found that knowing another person with TB was especially common in urban areas, relating the disease to overcrowding and urban poverty (30). It has been shown that one untreated smear-positive tuberculosis patient can infect up to 15 other people in the course of one year (9). The integrated services rendered at the Health Centres require that patients are requested to have their contacts screened for TB, either at the same Health Centre or at one of the government TB centres. This could also partly explain the high level of patient knowledge about their own disease.

Of particular interest was the observation that almost 80% of patients knew that TB was transmitted through the air-borne route, compared to the study done in Tanzania, where 37% of patients knew how TB was caused and how it was spread (11). Together with their extensive knowledge about TB symptoms and its treatment, this indicates that patient education in the industrial setting in Swaziland is effective and that current campaigns can benefit from an increased focus on the processes around diagnosis and treatment.

Studies conducted among health workers in India and TB patients in South Africa showed relatively low levels of information among these groups (11). The community's knowledge, attitude and perception of TB are important in influencing health-seeking behaviour. Knowledge within the community is essential to encourage individuals with symptoms to present themselves to the health services for diagnostic examination, and to ensure that TB patients continue to take their treatment until they are cured (3).

Health education campaigns remain an important aspect of TB control (9). Experience in rural Nigeria with patent medicine vendors demonstrated that training in primary care medicine could significantly improve the health care knowledge and behaviour of non-medically trained personnel (30). In Malawi, information was given to the general population through educational talks on the radio, posters, TB messages painted on buses, and TB sponsored football matches. Health centre meetings were held in different areas to brief traditional healers about TB (30). It was strongly recommended that there should be more dialogue between the TB programme and individuals within the community, such as patients who are responding well to TB, traditional healers, village headmen and school teachers, to try and improve case detection rates and reduce delays in diagnosis (30).

The industries covered by this study largely serve a captive and stable population and DOTS coverage should therefore be close to 100%. However, only around 77% of patients were found to receive directly observed treatment and only around 50% had smear microscopy done – two of the cornerstones of the DOTS strategy (3) (7) (25) (29).

Diagnosis was primarily based on chest radiography, and in line with this practice 78% of patients listed chest X-rays as the diagnostic option. This is of serious concern, as diagnosis by means of radiographic examination is known to be unreliable. Radiographic appearance of TB is non-specific; the lesions of pulmonary TB can take almost any form on a chest X-ray (24). Abnormalities on a chest radiograph may be due to a variety of other conditions (3) (25); many diseases of the lung show a similar radiographic appearance and can easily imitate TB (25). Also the efficacy of chest radiography is determined largely by the reader's ability to detect abnormal opacities and to interpret them correctly (25). Over-diagnosis is common, and conversely, pulmonary TB is often not diagnosed when chest X-ray is relied upon. Radiography is expensive, requiring complicated machines prone to breakdowns, and specialised technicians (25). Indiscriminate mass miniature radiography (MMR) therefore has no place in any TB control programme (1).

The reliance upon clinical and radiological evidence at the cost of sputum investigations in the diagnosis of TB in this study might have led to the diagnosis and treatment of patients who were not true TB cases. An inflated successful treatment outcome might therefore have been achieved.

Only one in two patients knew about sputum microscopy, a finding similar to the utilisation of this option in this study. The recommended method of case detection

remains sputum smear microscopy among symptomatic persons seeking health care (7) (24), especially in developing countries (25).

As resources increase, additional diagnostic tools such as chest X-ray, mycobacterial culture and drug susceptibility testing may be added to supplement sputum smear microscopy (7). Sputum culture is superior to both microscopy and chest X-ray in case-finding. This is not at present an option in developing countries, as a rather intricate infrastructure is required, and there is a period of four to six weeks before results become available, after which period many patients do not return (25).

The official TBCP treatment protocol was changed in May 2000 to accommodate the use of ethambutol rather than streptomycin for the intensive phase treatment of new TB cases, following the implementation of IUATLD/WHO-recommended treatment guidelines (3). Unfortunately, this extremely important policy change took place without any announcement or dissemination of information to most units outside the government sector (Personal communication, Mr T Dlamini, TBCP, September 2002). The majority of treatment units outside the government sector therefore were still using the old regimen, although it was realised that a policy change might have occurred when streptomycin availability from the Government Medical stores was reduced (Personal communication, Dr CA Hearn, Usutu, September 2002).

Another most important policy change that was not communicated outside the government sector was the introduction of the WHO system for TB recording and reporting, and the implementation of an electronic TB register in government clinics in 2001. Improved and ongoing interaction between government programmes for TB and HIV/AIDS control and the private sector (including industry) in Swaziland is of the utmost importance if both

epidemics are to be addressed effectively. As a first step, the introduction of the TB recording and reporting system in industry Health Centres is recommended. This will allow for standardisation of control programme activities and will ensure comparability of outcome findings. As treatment monitoring is an essential component of this system, implementation will also address the problem around accurate calculation of patient adherence pointed out in this study. Periodic reviews performed to compare the names of smear positive patients with the list of patients on treatment would ensure that no patients identified in the laboratory go without treatment (3). Non-governmental organisations providing tuberculosis services often work under difficult conditions. They should, however, be able to undertake their activities in co-ordination with government services and follow national TB guidelines (3). Improved communication between the TBCP and the industry Health Centres is essential. The DOTS strategy requires the establishment of treatment services within the primary health infrastructure, where directly observed short-course chemotherapy is given priority and patient education is provided (7). The Tanzanian study stressed the importance of the increasing role of private health facilities in the fight against TB, and the need for national TB programmes to utilise the private sector, complementary to public services (11).

An effective national TB programme should be integrated within the general health services of the community, as symptomatic patients present at every level of the health service (3). The study in China found that the rapid expansion of DOTS was critically dependant upon a decentralised system of TB institutions, from central to peripheral level, which permitted the rapid dissemination and implementation of a single set of guidelines for TB control, and a flow of information and resources between the different levels (22). The use of locally appropriate and acceptable ways of community-based or workplace-based direct observation of treatment should be explored (7). The Tanzanian study found that

former TB patients were an important source of TB information. This may indicate the potential for including former TB patients in community-based TB treatment (11) and has relevance to the industrial setting in Swaziland.

Collaboration and synergy among the public, private and voluntary sectors are essential to ensure accessible and quality-assured TB diagnosis and treatment. The increasing impact of HIV on the incidence of TB, especially in Sub-Saharan Africa, calls for new partnerships and approaches (7). Effective involvement of private health care providers is imperative in order to achieve total geographical and patient coverage for DOTS implementation. Involvement of the private sector in DOTS programmes can enhance patient access and acceptance, increase case detection and improve treatment outcomes (7).

10. CONCLUSIONS AND RECOMMENDATIONS

The study of TB management and treatment outcome in the industry in Swaziland showed that the participating industries had a more successful TB control programme when compared to the government TBCP. (However, it is debatable whether the government TBCP is a desirable benchmark for industry). Outcome indicators from industry were within the international standards for effective TB control. Aside from the under-utilisation of microscopy as diagnostic and monitoring tool no major deficiencies were detected. The patient education programme seems to be adequate to address the basic elements of disease knowledge but could benefit from increased focus on the processes of diagnosis and treatment. Both DOTS coverage and supervision of treatment by health workers could be improved to expectations for a well-defined captive patient group. The under-detection of co-existing lung disease and the low HIV detection rate are of concern.

Finally, lack of communication between the TBCP and non-governmental health centres led to the continued use of an outdated treatment regimen and to the non-utilisation of the WHO recommended TB recording and reporting system. This should be rectified at the earliest opportunity.

The following recommendations are made:

1. DOTS coverage should reach 100% in all Health Centres in industry by 2003;

2. Sputum evaluation by microscopy should become the mainstay of diagnosis and treatment monitoring. This will require decentralisation of the service to achieve a turn-around time of less than 48 hours and both internal and external quality assurance. Physicians in industry will require training and education on the need for microscopy diagnosis and the algorithm for identifying TB suspects;

3. The WHO treatment regimens for new and re-treatment cases need to be introduced immediately;

4. Clinicians should be sensitised through continuous education to identify co-morbidity, especially industry-related diseases;

5. The close relationship between TB and HIV necessitates the implementation of an active VCT programme for TB patients. It is recommended that all HIV positive patients be screened for TB;

6. Health care providers should be more aware of TB drug side effects, and should actively enquire and look for signs and symptoms;

7. Patient information, education and counselling programmes on all aspects of TB need to be improved, particularly with regard to the interaction with HIV and the diagnostic and treatment processes;

8. Active case finding among contacts of TB patients should be encouraged;

9. The WHO TB recording and reporting system should be introduced in industry without delay. The TBCP is willing to install the electronic TB register and to provide training to health staff in all Health Centres. Meticulous recording of results and routine quarterly analysis of data is recommended;

10. Communication and cooperation between the industrial Health Centres and the TBCP should be enhanced, and formal mechanisms established to discuss and share resources, results and problems.

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ANNEXURES

Annexure 1: Questionnaire 1

Annexure 2: Questionnaire 2

Annexure 3: Questionnaire 3

Annexure 4: TB Questionnaire Guideline

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Annexure 6: UP Ethics Committee approval

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Annexure 1:   Questionnaire 1

CONFIDENTIAL

THE TUBERCULOSIS CONTROL PROGRAMME IN THE INDUSTRY IN SWAZILAND:

A CRITICAL EVALUATION

QUESTIONNAIRE ONE [01] - *HEALTH WORKER*

[FILL IN WITHIN *TWO WEEKS* OF *DIAGNOSIS*]

{Please complete all spaces and /or circle appropriate information.}

REFERENCE NUMBER: .... SEX: M / F   AGE: ....

DATE COMPLETED: ....

EDUCATIONAL STATUS OF PATIENT : ....

OCCUPATION: ....

HEALTH CENTRE : BULEMBU / MANANGA / SIMUNYE / UBOMBO / USUTU

SIGNATURE OF HEALTH WORKER [HW]: ....

PLEASE PRINT NAME: ....

1. HW: Time elapsed between the first presentation of the patient and the diagnosis:

      < 01 day / 1 - 2 days / 3 - 5 days / 5 - 10 days / > 10 days

2. <u>HW</u>: Time elapsed between the diagnosis and the onset of treatment:

< 01 day / 1 - 2 days / 3 - 5 days / 5 - 10 days / > 10 days

3. <u>HW</u>: Which of the following were used to make the diagnosis?

3.1. Clinical signs and symptoms: YES / NO

3.2. X - rays   : YES / NO

3.3. Sputum microscopy   : YES / NO

3.4. Other   : YES / NO   If <u>YES</u>, specify: ....

....

4. <u>HW</u>: Were any extra-pulmonary sites of TB identified? YES / NO

If <u>YES</u>, specify:...

....

5. <u>HW</u>: Was the diagnosis confirmed at an outside laboratory [e.g. Central Laboratory]: YES / NO

If <u>YES</u>, at which one: ....

6. <u>HW</u>: Will the Government protocol for tuberculosis treatment be used: YES / NO

If <u>NO</u>, what will the modifications be: ....

....

....

7. <u>HW</u>: Has this patient previously been treated for TB? YES / NO / UNKNOWN

If <u>YES,</u> was treatment completed? YES / NO / UNKNOWN

8. <u>HW</u>: Is there any history of co-existing lung disease? YES / NO / UNKNOWN

Annexure 2: Questionnaire 2

CONFIDENTIAL

THE TUBERCULOSIS CONTROL PROGRAMME IN THE INDUSTRY IN SWAZILAND:

A CRITICAL EVALUATION

QUESTIONNAIRE TWO [02] - *PATIENT*

[FILL IN WITHIN *TWO WEEKS* OF *DIAGNOSIS*]

REFERENCE NUMBER: ....   DATE COMPLETED: ....

IMPORTANT NOTE: Do not lead the patient in answering the questions. Patient to answer and HW to circle the appropiate answer on the questionnaire, or note any alternative answers in space provided.

1. Pt: Time elapsed between your first presentation and the diagnosis:

    < 01 day / 1 - 2 days / 3 - 5 days / 5 - 10 days / > 10 days

2. Pt: Time elapsed between the diagnosis and the onset of treatment:

    < 01 day / 1 - 2 days / 3 - 5 days / 5 - 10 days / > 10 days

3. Pt: Do you know anything about the signs and symptoms of TB?   YES / NO

    If YES, which ones: COUGH / WEIGHT LOSS / CHEST PAIN / NIGHT SWEATS /

    APPETITE LOSS / OTHER, describe: ....

4. Pt: Do you know anybody who has been treated for TB? YES / NO

    If YES, are they: FAMILY / FRIENDS

    If YES, do you know the outcome of their treatment: WELL / STILL ON TREATMENT / DIED

5. Pt: Did anybody tell you how TB is spread? YES / NO

      If YES, which ones: AIR / BLOOD / TOUCHING / CULTURAL PRACTICES / OTHER,

      describe: ....

6. Pt: Did anybody tell you how TB is diagnosed? YES / NO

      If YES, which ones: SPUTUM / X-RAY /CLINICAL / OTHER, describe: ....

7. Pt: Did anyone tell you how TB is treated? YES / NO

      If YES, which ones: MEDICATION / BLOOD LETTING / TRADITIONAL HEALING /

            ISOLATION / OTHER, describe:..

8. Pt: Did anyone tell you how long you will be on treatment? YES / NO

      If YES, how long: < 01 MONTH / 1 - 2 MONTHS / 2 - 4 MONTHS / 6 MONTHS /

            > 6 MONTHS / OTHER, describe: ....

9. Pt: Were you given your TB medicines [tablets]: DAILY / WEEKLY / MONTHLY

10. Pt: Did you have the same supervisor at: EVERY VISIT / AT MOST VISITS / SELDOM

11. Pt: Did anybody inform you about the side effects of the TB treatment [medicines]? YES/NO

      If YES, what were you told: ....

      ....

      ....

      ....

Annexure 3: **Questionnaire 3**

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THE TUBERCULOSIS CONTROL PROGRAMME IN THE INDUSTRY IN SWAZILAND:

A CRITICAL EVALUATION

QUESTIONNAIRE THREE [03] - _HEALTH WORKER_

[HW TO FILL IN AT THE _END_ OF THE _TREATMENT CYCLE - SIX MONTHS_.]

REFERENCE NUMBER [Same as on Questionnaires 01 & 02]:..

HEALTH CENTRE: BULEMBU / MANANGA / SIMUNYE / UBOMBO / USUTU

DATE COMPLETED:..

1. Was Direct Observed Treatment [DOT] provided to the patient? YES / NO

   If <u>YES</u>, how was it done: ....

   ....

   ....

**2. Calculate the patient's compliance with the treatment, as per formula provided:

   < 50% / 50% - 75% / > 75%   [Actual value:..........................%]

3. Smear status at two months: POSITIVE / NEGATIVE / NOT DONE / NO INFORMATION

4. Treatment outcome:

      4.1. CURED [= Treatment completed and negative smear at end of cycle, or negative smear at

          02 months + documented proof of adherence]

      4.2. TREATMENT COMPLETED [= Clinically healthy, but no smear result]

      4.3. TREATMENT INTERRUPTED [= A total of more than 02 months of 06 month cycle on no

          treatment]

      4.4. TREATMENT FAILED [= Positive smear after completed treatment]

      4.5. DIED [TB or other cause]

      4.6. TRANSFERRED OUT [= Sent to another treatment centre]

      4.7. NOT TB [= While on TB treatment, diagnosed as another disease]

5. Did the patient experience any side effects of the treatment? YES/NO

      If YES; [5.1] Describe the side effects:...

          ....

          ....

      [5.2] Name the drugs involved: ....

          ....

          ....

      [5.3] How was it managed: ....

          ....

          ....

6. Is the HIV status of the patient known? YES/NO

      If YES; is it POSITIVE / NEGATIVE

SIGNATURE OF HEALTH WORKER : ....

PLEASE PRINT NAME: ....

Annexure 4:   TB Questionnaire Guideline

THE TUBERCULOSIS CONTROL PROGRAMME IN THE INDUSTRY IN SWAZILAND:

A CRITICAL EVALUATION

TB QUESTIONNAIRE GUIDELINES

METHOD

1. Questions should be put to a patient by someone different than the person who provided the patient with information on TB.

2.Questionnaire one [01]and two [02] should be completed within two weeks of diagnosis, preferably at the same time; questionnaire one [01] to be completed by the Health Worker [HW], and questionnaire two [02] by the patient [Pt] with the help of a Health Worker.

3. Questionnaire three [03] should be completed by a Health Worker, at the completion of treatment.

4. The study will be conducted simultaneously at the five major industries, Bulembu Mine Health Services, Mananga Medical Services, Simunye Sugar Health Services, Ubombo Ranches Health Services and Usutu Pulp Health Services.

5. All patients [permanent employees] with diagnosed TB and on TB treatment to be included in the study over a period of a number of pre-determined months, starting simultaneously on a predetermined date. [01 November '97]

   {The sample size will depend on the annual TB case load and the total number of permanent employees in the workforce per Health Service, and is specified per industry in the protocol.}

6. Reference numbers in each Company will be allocated as follows. Each Company will be assigned an alphabetical number corresponding to the company's initials. Each patient registerd will be numbered sequentially from one [1] onwards, e.g. UR 01, UR 02 etc.and BM 01, BM 02 etc.

- UR = Ubombo Ranches

- BM = Bulembu Mine

- MM = Mananga Medical Services

- SS = Simunya Sugar

- UP = Usutu Pulp

7. The HIV status of patients will have a significant influence on the results of the study. To maintain confidentiality, the names of the patients will only be known to the relevant Health Workers as decided by each individual Health Service, and the information on the questionnaire will be anonymous to the investigator.

8. The tear off portion at the top of Questionnaire one [01] contains the personal detail referred to above. This should be removed once the reference number of that particular patient is assigned, and retained by a designated Health Worker at each health service.

9. On Questionnaire two [02], no. 2: Compliance must be calculated using the following formula;

$$\% \text{ Compliance} = \frac{\text{Number of days drugs taken}}{\text{Total number of days treated}}$$

Thank you.

CONFIDENTIAL

THE TUBERCULOSIS CONTROL PROGRAMME IN THE INDUSTRY IN SWAZILAND:

A CRITICAL EVALUATION

NAME OF PATIENT: ....

REFERENCE NUMBER: ....

DATE COMPLETED   - QUESTIONNAIRE ONE [01]: ....

                                  - QUESTIONNAIRE TWO [02]: ....

                                  - QUESTIONNAIRE THREE [03]: ....

[Tear off and file securely]

Annexure 5: Letters of participation of Swaziland Industries

MANANGA MEDICAL SERVICE

Serving
Mhlume (Swaziland) Sugar Co. Ltd.
Swaziland Irrigated Farms
Vuvulane Irrigated Farms
Mananga Management Centre

P.O. Box 1, Mhlume Swaziland
Phone (09268) 31418/31211
Fax (09268) 31418/31309

TO WHOM IT MAY CONCERN

We have been requested by Dr Richard Lemmer to take part in a study in order for him to complete his thesis and meet the requirements of his MMED (Civ) degree being done through the Faculty of Medicine, University of Pretoria. We are prepared to participate in this study, titled "The Tuberculosis Control Programme in Industry in Swaziland : A critical evaluation", and believe the outcome of the study will benefit our community.

IAN GILBERTSON
SENIOR MEDICAL OFFICER

4.9.97

CONSMINING

HVL Asbestos (Swaziland) Limited
Bulembu Mine
(Incorporated in the Kingdom of Swaziland)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

4 September 1997

Re. Participation: Tuberculosis Study

We have been requested by Dr. Richard Lemmer to partake in a study in order to complete his thesis to comply with the requirements of his MMED (Civ) degree through the Faculty of Medicine, University of Pretoria. We are prepared to participate in this study titled "The Tuberculosis Control Programme in the Industry in Swaziland: A critical evaluation". We believe the outcome of this study will benefit our community.

Chief Medical Officer
Bulembu Mine

SIMUNYE
HEALTH SERVICES

3 September, 1997

To Whom It May Concern

Re: STUDY TO EVALUATE TB CONTROL PROGRAMMES IN SWAZILAND INDUSTRIES

We have been requested by Dr Richard Lemmer to partake in a study needed to complete his M Med (CIV) thesis through the Faculty of Medicine, University of Pretoria.

Presently, we are prepared to assist in this study, titled "The Tuberculosis Control Programme in the Industry in Swaziland: A Critical Evaluation".

We believe the outcome of the study will possibly benefit our community in various ways.

Sincerely

Dr T. Lapidos

UBOMBO F ☒ HOSPITAL

29th August 1997

TO WHOM IT MAY CONCERN

re : "TUBERCULOSIS CONTROL PROGRAMME"
BY DR RICHARD LEMMER

This is to certify that we have been requested by Dr Richard Lemmer and agree to take part in a study in order to complete his thesis as part of requirements for his MMED (CIV) degree through the Medical Faculty of the University of Pretoria. We will participate in this study titled "The Tuberculosis Control Programme" in the Industry of Swaziland. A critical evaluation. We believe the outcome of this study will benefit our community.

Yours sincerely,

DR BJ KAVUMBURA
MBChB(Zim) M.GenMed(Zim) DTM&H(Wits)

Annexure 6: UP Ethics Committee approval

PROVINSIALE ADMINISTRASIE

= = = = = = = = = = = = = = =

GAUTENG

= = = = = = = = = = = = = = = =

Enquires: Dr R Sommers

Reference:

Address: Ethics Committee
Ward 4 Room 19
Pretoria Academic
Hospital
Private Bag x 169
PRETORIA
0001

Tel: (012) 354 1560

Fax: (012) 354 1702

Date: 13/02/98

~~~~~~

Nommer : 224/97

TITEL : The Tuberculosos Control Programme in the Industry in Swaziland: A Critical Evaluation.

AANSOEKER : Dr HR Lemmer;(MMed)Dept. Gemeenskapsgesondheid; (Dr P G D Rautenbach - Hoof van Departement) Pretoria Academic Hospitals;PRETORIA.

This study and the Informed Consent has been considered by the Ethics Committee,Faculty of Medicine,Univ.of Pretoria and Pretoria Academic Hospitals on 28/01/98 and found to be acceptable.

Prof A.L. Coetzee	MA (Clin Psych); DSocSc (Leiden); MPA (Pret): Psychologist
Dr J.E.Davel (female)	MBChB: Hospital Superintendent
Prof A.P.du Toit	BA; Dipl Theo (Pret) BA (Hons) (Rhodes);MA;DPhil(Pret):Philosopher
Prof C.I. Falkson (female)	MBChB;M.Med(Int);MD;Med.Oncologist
Prof G. Falkson	MBChB;M.Med(Int);MD;OSG:Medical Oncologist
Prof S.V. Grey (female)	BSc (Hons)(Stell); MSc (PU vir CHO) DSc (Pret): Deputy Dean
Dr S.W. Johnson	MBChB: Hospital Superintendent
Dr V.O.L. Karusseit	MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
Ms B.C.F. Magardie(female)	B Cur: Matron/ Senior Nursing Sister
Senior Sr J. Moerane(female)	BCur (E et Al)Senior Nursing Sister
Prof T.R. Mokoena	MBChB; FRCS (Glasgow); DPhil (Oxford): Surgeon
Prof H.W. Pretorius	MBChB;M.Med (Psych)MD: Psychiatrist
Dr P. Rheeder	MBChB; MMed (Int); LKI (SA); MSc (KLIN.EPI): Specialist Physician
Prof J.R. Snyman	MBChB, MPharm Med: Pharmacologist
Prof De K Sommers	BChB; HDD; MBChB; MD: Pharmacologist
Prof S.K. Spies	MBChB; M.Med (Int) MD: Specialist Physician
Advokaat L.G.Thomas (female)	B.Iuris (University of the North); LLB (University of the Western Cape)
Prof F.W. van Oosten	BA; LLB; LLD (Pret); LLD (Unisa): Prof in Criminal and Medical Law

PROF G FALKSON; MBChB; M.Med (Int);MD;OSG; VOORSITTER

Annexure 7: Informed consent form

INFORMED CONSENT FORM

THE TUBERCULOSIS CONTROL PROGRAMME IN THE INDUSTRY IN SWAZILAND:

A CRITICAL EVALUATION

Research Study

I, ... willingly agree to participate in this study which

has been explained to me by .... This research is being conducted

by Dr Richard Lemmer of the Department of Community Health, University of Pretoria.

Purpose of the study

It has been explained to you that you have **tuberculosis**. You have been invited to participate in this

research study. This study will not interfere with your treatment process. The purpose of this study is to

evaluate the outcome of treatment of TB using the current standard management protocols of the National

Tuberculosis Control Programme [TBCP] in Swaziland.

Description of Procedures

This study involves research on the outcome of treatment of TB using existing protocols. The study will

not in any way influence your treatment, it will merely evaluate the outcome of this treatment. After you

have been diagnosed with TB, you will be asked to participate in the completion of a number of

questionnaires which are designed to establish the efficiency and completeness of your treatment.

Risks and Discomforts

The study will not pose any additional risks or discomforts beyond those associated with standard TB

treatment.

Benefits

The expected benefit of this study is better knowledge about TB and its management in the Industries in Swaziland which may help improve the quality of TB treatment and the outcome for patients throughout the country.

Voluntary Participation

Your participation in this study is voluntary. No compensation for participation will be given. It is planned to request the participation of every employee diagnosed with TB and undergoing treatment in the participating companies, within the anticipated study period of approximately 18 months. Your refusal to participate or subsequent withdrawal of your participation will in no way influence the treatment of your illness.

Confidentiality

The information that you will be asked to provide will be confined to your illness and the information about it that you will receive during your treatment. No personal details will be asked. All the information in the questionnaires, as well as information obtained from your file, will be kept confidential and will be anonymous to the research investigator. No information by which you can be identified will be included in any reports or publications.

****

All of the above has been fully explained to me, and my questions have been satisfactorily answered. I hereby consent willingly to participate in this study.

....
[Patient Signature or Sign]   [Date]

....
[Witness I Signature]   [Witness II Signature]   [Date]

....
[Health Worker Signature]   [Date]