25. POINTS OF VARIATION FROM THE NATIONAL GUIDELINES

1. Annual education is formalised
2. Annual chest x-rays are specifically examined for tuberculosis
3. Those adults sharing the same house or sleeping room are screened
4. Up to 3 sputum specimens are examined for AFBs
5. Culture and identification of sputum is requested for all suspects
6. Only quality-assured laboratories may be used
7. The category "smear status unknown" is introduced
8. The definition of a "retreatment" case is simplified
9. Industry-wide drug susceptibility surveillance to take place triennially
10. Sputum smear positive patients to be treated, where possible, as in-patients, until smear conversion has been established
11. DOTS provided by a trained treatment supporter in the workplace
12. Cultures to be requested, 1 month before treatment ends, on all patients
13. Treatment outcome categories are extended to sub-categories
14. Chest x-rays are required on the completion of treatment
15. Patients to be reviewed 18 months after the start of treatment
16. Special provisions are made to prevent nosocomial spread
17. The national registers should be adapted to allow for the additional information required concerning case definitions and treatment outcomes
18. The cause of death while on treatment to be established by autopsy
19. Annual internal reviews are to be held
20. External reviews are required once every 5 years
21. Reporting of cases to the Medical Bureau for Occupational Diseases required.

26. A LIST OF RESOURCES FOR FURTHER READING

23. PROGRAMME REVIEWS

As indicated earlier, there should be an annual industry-wide review of TB control activities. In addition, the following is recommended:

23.1 TB control activities should be subject to external review once every five years. Such an external review should be done on the TB control activities of both the mines as well as the public sector as the two are part of a unified attempt to control the spread in the country once every five years.

23.2 Internal review should be conducted on all mines annually, in the light of the industry-wide review.

23.3 Autopsy findings should be incorporated into the annual review of the programme, so that the extent of under-diagnosis and the cause of death may be ascertained. Cases where TB was not diagnosed in life should be investigated to discover possible missed opportunities and possible remediable reasons why the diagnosis was not made.

23.4 The best time for these reviews is during September. The purpose of the reviews is to examine outcome and performance indicators against these practice standards, and to determine the extent to which these practice standards are being met.

23.5 The review should also examine the suitability of policies, structures, managerial processes and commitment, and training of staff, as well as the effectiveness and adequacy of health education and promotion activities, health and safety and workers chronic diseases committees and community liaison.

24. MULTI DRUG RESISTANT TUBERCULOSIS

Patients with MDR-TB should be treated according to the guidelines issued by the Department of Health, and under the guidance of provincial MDR-TB referral clinics, where these exist. The standardised regimen is recommended, except that clinicians may wish to use streptomycin rather than kanamycin during the intensive phase, provided that the organism is still susceptible.

If, for logistic reasons, clinicians on mines wish to manage patients with MDR-TB without referral, then they should first make sure that they are fully conversant with the national guidelines for the treatment of such patients, and should have a copy of those guidelines available for easy reference at all times. They should be particularly careful to adhere to the recommended regimens contained therein. Copies of these guidelines (for the management of MDR-TB) may be obtained from the Department of Health.

It is recommended that patients with MDR-TB should be treated as in-patients until such time as 3 consecutive monthly sputum specimens are culture negative. If, for any reason, separation of the worker is contemplated, before sputum conversion has been obtained, and the recommended full treatment course completed, then adequate arrangements should be made for the effective referral of the worker for further treatment. The rate of MDR disease should be scientifically assessed from the industry-wide surveillance for drug susceptibility, referred to earlier on.
22.1. Outcome targets:

Unless otherwise stated, the denominators below refer to those with drug susceptible disease and who are still in the programme at the end of treatment.

1.1 Percentage of smear positive patients cured or complete treatment: ≥ 85%

For example, if 250 smear positive patients were diagnosed during 1998, and, by September 1999, 200 of these are cured and 20 are classified as "treatment completed", then the calculation is 100 x (200 + 20)/250 = 88%, and the target has been met.

1.2 Case fatality rate (the percentage of patients who die from TB): ≤ 10%

For example, if 320 patients were diagnosed with TB during 1998, and, by September 1999, 16 have died as a result of TB, then the calculation would be 100 x (16/320) = 5%, and the target has been met.

1.3 Recurrence of disease in new smear +ve patients within 2 years of completing treatment: ≤ 5%

For example, if 180 new smear positive patients were diagnosed during 1997, and were either cured or classified as "treatment completed", and were still employed by the mine within 24 months of their recorded treatment outcome, and, of these, 12 had a microbiologically proven recurrence of disease during their initial 24 months following cure or treatment completion, then the calculation would be 100 x (12/180) = 6.67% and the target would have been met.

1.4 Percentage of patients for whom the treatment outcome is known: ≥ 90%

For example, if 350 patients were diagnosed during 1998 and, at September 1999, outcomes are known and documented for only 300, then the calculation would be 100 x (300/350) = 85.7%, and the target will not have been met.

22.2. Process targets:

The following indicators have been selected as critical process measures.

2.1 Percentage of pTB cases bacteriologically proven: 80%.

2.2 Percentage of proven pulmonary cases classifiable by smear status, and with culture and organism identification requested: 100%.

2.3 Percentage of new smear positive cases, still smear positive at the end of the intensive phase for which culture and susceptibility for rifampicin is requested: 100%.

2.4 Percentage of retreatment cases for which culture and susceptibility for rifampicin is requested at the start of treatment: 100%.

2.5 Percentage of new smear positive pTB patients receiving at least 90% of intensive phase doses, as well as at least 90% of continuation phase doses: 100%.

2.6 Percentage of pTB patients with 2 sputum smears requested at the end of the intensive phase and at the end of the continuation phase: 100%.
5. THE OBJECTIVES OF TUBERCULOSIS CONTROL ON THE MINES:

- To cure 85% of patients detected with smear positive, drug susceptible, TB.
- To implement DOTS ("Directly Observed Treatment, Short Course") for 100% of cases of pTB (intensive and continuation treatment phases)
- To notify 100% of all cases to the local authority
- To record case details in a register such as the NTBCP register, and to analyse and act (if indicated) on the results of this analysis, on a quarterly basis for all TB patients.

6. PASSIVE CASE FINDING

Passive case finding should be promoted through the following practices:

6.1 There should be a TB education initiative, which may be through peer educators or formal presentations, and which will reach all employees at least once a year. The symptoms of TB should be made known. Employees should be told about the importance of early diagnosis.

6.2 Employees should be encouraged to present early as early detection and treatment would prevent loss in performance bonuses etc.

6.3 A high index of suspicion for TB should be inculcated in all healthcare workers, and should be maintained through training as well as regular awareness campaigns.

6.4 All mines should provide easy access to a good quality, client-orientated, diagnostic and treatment service for tuberculosis.

7. ACTIVE CASE FINDING

7.1 Where risk assessment indicates that workers should be screened by means of annual chest x-rays, a competent person should perform these x-rays.

7.2 Consideration should be given to the screening of all mine hostel contacts that share the same sleeping room as someone diagnosed with TB. Screening should be by means of an interview for relevant symptoms, or, if they have a productive cough, by means of a (single) sputum smear examination.

8. CASE DEFINITIONS AND DIAGNOSIS

This document focuses on cases of adult respiratory disease caused by infection with organisms of the Mycobacterium tuberculosis complex. A case is one in which infection with Mycobacterium tuberculosis, M. bovis or M. africanum has been shown, or is strongly suspected, as being the cause of pulmonary disease. The case definition includes any patient with the following:

Compatible clinical or radiological features AND

- a positive sputum smear OR
- a positive sputum culture OR
- smear -ve, culture contaminated/lost in a patient who has not responded to a course of broad spectrum antibiotics.

Provided, in all cases, that disease due to NTM has not been established. In all suspected cases, the following investigations should be requested:

- up to three sputum smear examinations
- sputum for culture and organism identification
- chest x-ray

18. TRAINING AND SUPPORT

18.1 Treatment supervisors should receive specific training to ensure that they not only observe and record the treatment being given, but also encourage and support the patient. They should also be trained to ask the patient for possible symptoms of side effects or non-improvement, and to refer such patients to the mine health centre without delay.

18.2 Medical and nursing staff involved with the TB treatment process should be specifically trained in the contents of this document as well as the current NTBCP guidelines.

18.3 All mine health and safety staff should be trained about the signs and symptoms of pTB, and should be trained to actively seek new cases at all suitable opportunities.

18.4 Where nurse clinicians are responsible for the day-to-day management of patients with TB there should be a tuberculosis-trained medical officer appointed for support and assistance.

19. PERFORMANCE REVIEW

19.1 There should be an annual industry-wide tuberculosis review, during which this document may be revised.

19.2 Health staff should analyse their performance on an annual basis, during September for the previous calendar year's newly registered cases.

19.3 Groups of mines (i.e. corporations, or mines of a certain type and in a certain area) may also gain insight through pooling their data for analysis, especially if the numbers of cases on individual mines are low.

20. LIAISON WITH THE PUBLIC SECTOR

It is recommended that health workers who are involved with the management of patients with tuberculosis should interact with district health staff, on a regular basis, in order to discuss how collaboration may improve TB epidemic control.

21. POLICIES

21.1 Copies of the current NTBCP guidelines, as well as these practice standards, should be available in all clinics and centres where TB is treated.

21.2 There should be written policies for the management of TB on mines.

22. TARGET SETTING

Targets should be set during September for the next year's performance. The process of target setting should start on individual mines, and targets should always be negotiated with those responsible for service delivery. The targets are informed by the analysis of the previous year's performance.

The financial implications of the targets should be spelled out so that they can be incorporated into the mine's budget and risk management strategy. Where a target has not been met an analysis of the possible reasons should be carried out, and a suitable plan of action devised. The following targets are suggested as representing good practice:
15. THE PREVENTION OF NOSOCOMIAL SPREAD
Nosocomial spread may affect either health care workers or other patients, and is usually airborne.

Health workers should maintain a high index of suspicion for TB, and ensure an early diagnosis and rapid introduction of effective treatment.

Wherever possible, investigation for TB should be carried out on an out-patient basis.

Once TB has been diagnosed, smear positive patients should be isolated from non-infected persons if at all possible. Sputum specimens should be obtained in a well-ventilated area or else out of doors.

Staff working in high risk areas (for example TB wards, microbiology laboratories, radiography departments, bronchoscopy suites, physiotherapy departments and intensive care units) should be advised of the dangers to them if they should be HIV infected. They should be offered free, voluntary, informed and confidential testing for HIV infection. If found to be positive, they should be offered alternative employment, should such work be available. The decision whether to continue working with TB patients, however, should be for the worker to make, once all the risks and options have been explained. If they elect to work in a high risk area they should be offered chemoprophylaxis. This should also be offered to them if they are PPD positive and elect to move to low risk areas of work.

16. CHEMOPROPHYLAXIS
Chemoprophylaxis against TB should be offered to any worker known, or suspected, to be infected with the HIV, or known to have silicosis. Isoniazid, taken daily, 3 times a week, for 6-9 months, is recommended at present. Patients who choose to take chemoprophylaxis need not be directly supervised. However, they should never be given more than a month's supply of tablets at any one time. On a monthly basis, patients should be questioned, and, if they are symptomatic, should be examined by a medical practitioner in order to exclude active TB. Single drug prophylaxis should only be continued if the clinician responsible is confident that the patient does not have active tuberculosis.

17. MONITORING AND REPORTING
1. All patients with TB should be entered in a national TBCP register, or an industry- and government-approved adaptation, supplemented with the outcomes listed earlier on. Outcomes should be documented for patients who are transferred out, since the register data is to be used to monitor the epidemic situation on the mine.

2. All patients started on anti-TB treatment should be notified to the district health authorities, except for patients who are changed to another regimen without a "cure" or "treatment completed" status intervening.

3. All deaths presumed to be due to TB should be notified to the Department of Health on the usual notification form, even though the patient would have had his disease notified when the diagnosis was first made. This is a legal requirement and it helps the Department to monitor the case fatality rate. This is required in addition to the completion of a death certificate.

4. Quarterly returns should be made to the district health authorities.

5. All cases should be reported in the prescribed manner to the Director, Medical Bureau for Occupational Diseases at the time of diagnosis and if considered to have permanent cardio-thoracic disability following reassessment 12 months after cessation of treatment.
12. FITNESS TO RETURN TO WORK

Evaluation of fitness to return to work should be individualised. As a general guide individuals should be feeling well and be smear negative. Clinical evaluation of fitness should find the individual to be apyrexial, with a normal pulse rate and gaining weight. Significant anaemia or other co-morbid illness should be excluded or treated if present. Consideration should be given to the occupation that the individual is returning to. Temporary options for surface work should be explored or considered before returning individuals to underground work. If there is concern about the ultimate fitness of individuals to return to work in silica dust environments they should be referred for vocational assessments and possible retraining. Reference should be made to the Guideline for minimum standards to perform work at a mine. If there is exposure to heat stress environments the individual should be fit enough for heat tolerance testing before there is consideration of returning to work. Employees are entitled to receive 75% of their salary during temporary permanent disablement. Some Chamber members have an agreement to provide 100% sick pay for 84 days and 50% for the balance of six months.

13. CASE MONITORING

- All sputum smear positive patients should be treated as in-patients, until smear conversion has taken place, or until they are separated for any reason.
- Treatment should be taken under direct observation. A trained lay treatment supporter may supervise treatment away from the clinic.
- Sputum smear examination should be performed on 2 specimens at the end of the intensive phase of treatment, and the recommended course of action, as laid down in the national guidelines, should be taken depending on the results.
- One sputum specimen should be sent for smear examination and culture, at the end of the 5th month of treatment (7th month for retreatment regimens). If either test is positive, then susceptibility testing should be requested.
- If, in spite of adequate attempts, it is not possible to obtain a sputum specimen, then, if the patient is clinically well, a single saliva specimen should be submitted for smear examination only, and treatment should be stopped at the end of the continuation phase (this recommendation is made in order to encourage attempts to obtain an end-of-treatment sputum specimen).
- A chest x-ray should be performed at treatment's end.
- A spirometric test of lung function should be performed six months to twelve months after completion of therapy.

14. TREATMENT OUTCOMES AND FOLLOW-UP

Outcomes should be recorded as follows:

- **CURED** - treatment completed with a negative smear and culture in the last month of treatment.
- **TREATMENT COMPLETED** - treatment completed but cure not documented bacteriologically.
- **DIED** - Died from TB
- **DIED** - Died from other causes
- **DIED** - Cause of death not determined
- **TREATMENT FAILURE** - Positive smear or culture in the last month of treatment
- **TREATMENT INTERRUPTED** - Not recorded in the first month of therapy. Thereafter interruption of treatment for 10 days in the intensive phase of treatment and more than one month during the continuation phase of treatment.
- **TRANSFERRED OUT** - For treatment elsewhere (still an employee)
- **TRANSFERRED OUT** - Due to separation
- **TRANSFERRED OUT** - For treatment elsewhere (no longer an employee)
- **TRANSFERRED OUT** - Due to separation

In general, the definitions of these outcomes is identical to those in the NTBCP guidelines. However, patients with a negative sputum culture at the end of treatment are also to be classified as cured. In addition, deaths while on treatment should be sub-classified as those due to TB, those due to other causes, and those in which the cause of death could not be determined. Autopsy results should be requested from the NCOH in order to assist with this classification where compensation is indicated. Where autopsies are requested, these should only be performed with appropriate consent of the relatives.

Note that as far as possible, the dismissal of employees whilst on TB therapy must comply with statutory requirements for a lawful and fair dismissal. Guidelines are set out in the Labour Relations Act and Schedule 8 of the Act, for a fair procedure relating to a dismissal for incapacity due to ill health.

Where a worker is separated while on treatment the mine should make all reasonable efforts to determine the final outcome.

The patient should be provided with a letter detailing the diagnosis, results (including dates) of smear, culture and susceptibility tests, and treatment received to date. The letter should also indicate the expected date for follow up (at the end of treatment) at the mine health centre.

Finally, the letter should request the referral treatment centre to provide documentation of the patient's progress for the follow up visit. If for some reason the patient is unable to return (i.e. due to death intervening) the referral centre should be asked to post the final details to the mine health centre. The patient must be told where to go with this letter in order to complete treatment.

The mine should, as reasonable practice, try to arrange for the patient to return for assessment (at the end of treatment). If this is not possible, alternative arrangements must be put in place to determine the outcome. All patients should be seen again 12 months after completion of treatment in order to complete their ODMWA compensation assessments. A repeat chest x-ray and lung function test are indicated at this assessment.