Mine Health and Safety Council

Development of a TB Programme Review tool for the South African mining industry

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1. Executive summary

1.1 Introduction

TB has been recognised as one of the challenges facing the mining industry. In 2004, Girdler-Brown undertook a MHSC project to develop sensitive tools for active case finding of TB[1]. One of the conclusions of this project was that, before mass screening methods are researched further, mines should work to improve the standard of delivery of the tried and proven methods for TB case detection and management. The project described below, phase 2, arose from this recommendation.

1.2 Literature review

The MHSC has been involved in a number of initiatives involving TB programmes in the South African (SA) mining industry. In 2001 Corbett demonstrated the role of preventative therapy in reducing the burden of TB infection and disease in SA gold miners.[2] The “Thibela” study, currently underway in gold mines is comparing community-wide and targeted isoniazid prophylaxis.

With regard to case finding of TB, in 2003 Churchyard demonstrated that performing 6 monthly x-rays compared to annual x-rays did not significantly improve case finding but did demonstrate a decrease in the mortality rate during the first 2 months of treatment.[3] In another study, on analysis of 2000 miners at annual fitness examination, Churchyard showed that the presence of a new radiological abnormality or any of the 3 symptoms of TB deserves investigation and that this investigation should include at least 2 sputum smears.[4]

In 2000 Murray reviewed the autopsy findings and medical records of miners who died during 1999. It was found that clinicians failed to diagnose PTB in 44%, incorrectly ascribed PTB as the cause of death in 29%, and correctly ascribed PTB as the cause of death in 27% of cases who either had TB on autopsy or were diagnosed as having TB during life.[5]

The Process- Based Performance Review (PBPR) arose as a result of the findings of the above- mentioned studies and essentially aims to identify “missed opportunities” for TB diagnosis and improve clinician performance. Process based performance review, undertaken by clinicians themselves, has been identified to be one of the most effective ways of developing successful practice habits.[6] On evaluation of this tool, although the doctors disappointingly did not independently participate in the review process; they were supportive of the programme and stated that it has changed their clinical practices with regard to diagnosing PTB.[7]

A literature review of national and international guidelines and standards of practice relating to TB programmes were undertaken. A search for national and international TB programme review tools revealed information which mainly applied to national TB programme reviews. During the project, stakeholders were requested to make their TB programme review tools available.

The TB programme review tool was developed in close alignment with the NTBCP guidelines and the DME TB guidance note.

1.3 Methodology

Recommendations and learning from the literature review and guidelines were considered when ***drafting the TB programme review tool*** and supporting notes. It was recognised that assessing both process of care and outcomes are important in improving health care systems.

There are many processes and indicators which can be measured in a TB programme. The most valid and measurable factors were chosen in the health and occupational health services as outlined below:

1. Documentation
    - Policy
    - Staff training
    - Employee and patient education
        - Reporting
        - TB clinic processes
2. TB Case finding at Occupational Health Centres
3. TB Case finding at Primary Health Care
4. Directly Observed Treatment
5. TB clinic
    - Diagnosis of TB
    - Monitoring of TB
    - Referral
    - TB and HIV
6. Laboratory
    - Quality control
    - Result turnaround time/tracking
7. Radiology
8. Pharmacy
9. In -depth review of clinical care and processes: Process Based Performance Review.

The “targets” included in this tool were taken directly from the DME guidance note, the project team suggests strongly that these targets needed to be reviewed but that reviewing these targets was beyond the scope of this project.

The rationale for inclusion of the abovementioned areas in the TB review tool is outlined in ***supporting notes*** which will accompany this tool.

Industry medical advisors, TB programme managers and other stakeholders were identified to participate in this project in the form of making company review tools available, reviewing drafts of the tool and participating in a workshop. Sectors included the Department of Health, National and Provincial, the Department of Minerals and Energy, Academic and Research Institutions, Organised labour and mining.

The review tool was piloted after being approved by the MHSC. The ***pilot*** was undertaken in 3 mining companies covering 3 different commodities in Gauteng, Mpumalanga and North West Province. The tool was refined after each pilot to make it more generic and user-friendly but still able to achieve its objective. Please refer to a separate “excel document” for a reporting format which may be used with this tool.

1.4 Conclusion

The pilots showed the review tool to be appropriate and comprehensive. It is estimated that the review will take 2 staff members about 2 days to perform, depending on the size of the site and the format of documentation at the site.

1.5 Recommendations

- This tool was designed to be used internally. It is recommended that the review process be undertaken by the doctor responsible for the TB programme, in collaboration with TB clinic staff. The review should be undertaken annually.

- Technology transfer to promote this tool would be extremely beneficial. This could take the form of workshops which may be more time-efficient. However, undertaking the review on-site with the staff responsible for the TB programme was found to be very beneficial during the pilot; consideration may be given to doing site visits as an element of technology transfer. This technology transfer should be undertaken by personnel with experience in TB programme implementation.

- The DME guidance note was released in 2003. Given the latest developments in the TB arena, especially with regard to MDR TB, updating this guidance note is a matter of priority. The targets set out in this guidance note should be reviewed. Once updated, technology transfer should include distribution of hard and electronic copies to all mining health services.

- To encourage the use of this tool to improve performance, it is suggested that the tool does not become a regulatory document but rather a “guidance note”, promoting and delineating best practice as stipulated in the NTBCP guidelines and the DME guidance note. However, mines should be strongly encouraged to keep accurate company TB statistics, which are updated with new information on a quarterly basis. Outcomes and results of sputum sensitivity testing should be retrospectively entered to update statistics.

2 Acknowledgements

The researchers would like to thank the MHSC for funding this project and the members of OHTAC for its support. Special thanks to Dr Banyini and Ms Woods respectively for valuable technical support and administrative support.

The researchers are grateful to the Department of Health, the Department of Minerals and Energy, Academic and Research Institutions and organised labour who provided input at the workshop. This project would not have been possible without the support of the mining community who provided expertise and sites for the pilots.

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Please refer to a separate "excel document" for a reporting template for the review tool

4 Glossary

TB	Tuberculosis
MHSC	Mine Health and Safety Council
MMOA	Mine Medical Officer/s' Association
OHTAC	Occupational Health Technical Advisory Committee
NTBCP	South African National TB Control programme
DME	Department of Minerals and Energy
Sputum smear	Microscopic test performed on a sample to detect AFB
DOT(S)	Directly observed therapy, short course
New TB	First episode of TB
Reactivation	TB disease which occurs as a result of flare-up of latent TB infection
Reinfection	TB disease that results from infection with a new strain rather than reactivation of latent infection
Recurrent TB	Refers to both "reactivation" and "reinfection" and is the preferred term if the patient has had a previous episode of TB
AFB	Acid Fast Bacilli-the bacilli generally causing TB which are seen under the microscope
Sputum smear	Examination of sputum under the microscope for TB bacilli
Smear positive	AFB are seen under the microscope, these patients are generally more infectious than those with "smear negative" TB
Smear negative	AFB not seen under the microscope but TB may be diagnosed by another method e.g. TB culture
Culture	Test of sputum or other tissue in the laboratory for growth of TB bacilli
Organism identification	Laboratory test to distinguish *Mycobacterium tuberculosis* from non-tuberculous mycobacteria
Sensitivity testing	Performed on cultured TB specimen to detect whether organism sensitive to INH and Rifampicin (and other drugs if required)
INH	Isoniazid- one of the main drugs used to treat TB
Rifampicin	The most important first line drug used in TB treatment
MDR TB	Multi- drug resistant TB. TB caused by bacteria resistant to at least INH and Rifampicin (and possibly other drugs)
EPTB	Extra pulmonary TB: TB which occurs outside of the lungs
HIV	Human immunodeficiency virus
ART	Antiretroviral therapy

5 Introduction

TB has been recognised as one of the challenges facing the mining industry. In 2004, Girdler-Brown undertook a MHSC project to develop sensitive tools for active case finding of TB[1]. One of the conclusions of this project was that, before mass screening methods are researched further, mines should work to improve the standard of delivery of the tried and proven methods for TB case detection and management. The project described below, phase 2, arose from this recommendation.

6 Literature Review

The MHSC has been involved in a number of initiatives involving TB programmes in the South African (SA) mining industry. In 2001 Corbett demonstrated the role of preventative therapy in reducing the burden of TB infection and disease in SA gold miners.[2] The “Thibela” study, currently underway in gold mines is comparing community-wide and targeted isoniazid prophylaxis.

With regard to case finding of TB, in 2003 Churchyard demonstrated that performing 6 monthly x-rays compared to annual x-rays did not significantly improve case finding but did demonstrate a decrease in the mortality rate during the first 2 months of treatment.[3] In another study, on analysis of 2000 miners at annual fitness examination, Churchyard showed that the presence of a new radiological abnormality or any of the 3 symptoms of TB deserves investigation and that this investigation should include at least 2 sputum smears.[4]

In 2000 Murray reviewed the autopsy findings and medical records of miners who died during 1999. It was found that clinicians failed to diagnose PTB in 44%, incorrectly ascribed PTB as the cause of death in 29%, and correctly ascribed PTB as the cause of death in 27% of cases who either had TB on autopsy or were diagnosed as having TB during life.[5]

The Process- Based Performance Review (PBPR) arose as a result of the findings of the above mentioned studies and essentially aims to identify “missed opportunities” for TB diagnosis and improve clinician performance. Process based performance review, undertaken by clinicians themselves, has been identified to be one of the most effective ways of developing successful practice habits.[6] On evaluation of this tool, although the doctors disappointingly did not independently participate in the review process; they were supportive of the programme and stated that it has changed their clinical practices with regard to diagnosing PTB.[7]

A literature review of national and international guidelines and standards of practice relating to TB programmes were undertaken.[8-22] Notably, the recently released International Standards for Tuberculosis Care served as a valuable reference document.[23]

A literature search for national and international TB programme review tools revealed information which mainly applied to national TB programme reviews. Key websites were searched including the WHO, IUATLD and CDC and a general literature search was performed. [24-28]

The tool was developed in close alignment with the South African National TB Control programme (NTBCP) guidelines [29-31] and the Department of Minerals and Energy (DME) TB guidance note.[32]

7 Methodology

Recommendations and learning from the literature review and abovementioned guidelines were considered when ***drafting the TB programme review tool and supporting notes.*** It was recognised that assessing both process of care and outcomes are important in improving health care systems.

There are many processes and indicators which can be measured in a TB programme. In order to complete the review within 2 days, the most valid and measurable factors were chosen in the health and occupational health services as outlined below:

1. Documentation
   1.1. Policy
   1.2. Staff training
   1.3. Employee and patient education
   1.4. Reporting
   1.5. TB clinic processes
2. TB Case finding at Occupational Health Centres
3. TB Case finding at Primary Health Care
4. Directly Observed Treatment
5. TB clinic
   5.1. Diagnosis of TB
   5.2. Monitoring of TB
   5.3. Referral
   5.4. TB and HIV
6. Laboratory
   6.1. Quality control
   6.2. Result turnaround time/tracking
7. Radiology
8. Pharmacy
9. In-depth review of clinical care and processes: Process Based Performance Review.

The “targets” included in this tool were taken directly from the DME guidance note, the project team suggests strongly that these targets needed to be reviewed but that reviewing these targets was beyond the scope of this project.

The rationale for inclusion of the abovementioned areas in the TB review tool is outlined in ***supporting notes*** which will accompany the tool.

Industry medical advisors, TB programme managers and other stakeholders were identified to participate in this project. Sectors included the Department of Health, National and Provincial, the Department of Minerals and Energy, Academic and Research Institutions, Organised labour and mining (Chamber of mines, gold, coal, diamond, platinum, small mining sector. Companies were requested to make their specific TB programme review tools available to the project.

The information obtained in the literature review described was collated to inform the ***drafting of a review tool***. Several drafts of the review tool were prepared, altered and discussed among the project team.

A formal workshop invitation and draft agenda was distributed to the above-mentioned stakeholders by the project leader and via the MHSC to other MHSC stakeholders, some of whom expressed interest in joining the workshop.

A document containing the elements of the review tool was circulated to workshop attendees. They were asked to consider the most ***important indicators*** and the most ***valid method*** to measure these indicators for the following areas:

1. Documents
   1.1. Policy
   1.2. Staff training
   1.3. Employee and patient education
   1.4. Infection control
   1.5. Reporting
      1.5.1. Department of Health
      1.5.2. MBOD
2. Primary Health Care
   2.1. Case finding
   2.2. DOT
3. TB clinic-Patient monitoring
4. Medical ward-Case finding
5. Laboratory
6. Radiology
7. Pharmacy
8. Other

The review tool was piloted after being approved by the MHSC. The ***pilot*** was undertaken in 3 mining companies covering 3 different commodities in Gauteng, Mpumalanga and North West Province. The tool was refined after each pilot to make it more generic and user-friendly but still able to achieve its objective.

Brief summary of findings from site evaluations:

- No sites were aware of the existence of the DME TB guidance note. All were aware of the NTBCP guidelines and reported that their programme were in line with this guideline.
- A lack of integrated company statistics with updated outcomes and sputum sensitivity results was found. Companies relied on the statistic submitted to the DOH, usually on a monthly basis. These statistics, which usually include only incidence and outdated outcomes, did not give an accurate indication of the overall TB programme.
- There were no written policies regarding TB in contract workers and generally the staff felt that this area was unclear; often differing among contracting companies. This resulted in a gap in TB control, with contract workers with undiagnosed and incorrectly treated TB working, and sometimes living, alongside permanent employees.
- Some sites reported good relationships with the local DOH, with consistent regular visits by the same staff; others reported that it varied over time. Some sites sent their staff to the training provided by the DOH; however only one site was sending staff other than TB clinic staff.
- Although there were notable exceptions, generally the opportunity for TB case finding at occupational health and the primary health care centres were not being optimally used.
- Compliance and adherence to DOT varied widely across sites.
- Generally the TB register was fairly well kept. Most patients received adequate documentation when transferred out but none were called back to the mining health service for review post TB treatment.
- HIV testing and ART information was difficult to obtain from the TB notes, usually reported as being captured elsewhere.

- 2 out of the three sites reported an AFB turn-around time of more than 48 hours, as they were using external laboratories. TB cultures for diagnosis and monitoring and sensitivity testing were being sent erratically and there was generally no system to follow up results. External laboratories were accredited for TB testing.
- Radiology services generally had quality control measures in place.
- Pharmacy stock control of TB drugs was good.
- Data from autopsies was not being used routinely to evaluate the process of care.

The three sites differed in size, structure and nature of documentation but ***most components of the tool were measurable at all sites***. Aside from the NTBCP register and TB clinic forms, which are compulsory for mines to use, the nature of the records kept differed significantly. To maximize the mutual benefit gained from the review process, it was found to be very helpful when the doctor running the TB programme accompanied the reviewers and actively participated in the review.

The tool was refined after each pilot to make it more generic and user-friendly and superfluous data fields were removed. Comments from collaborators and other stakeholders were collated and incorporated into the review tool. The initial intention was to question staff and patients regarding a few aspects of TB control. This was not found to be practical and, given its subjectivity, was not considered to be useful for an internal review tool.

During the development of the tool, it became apparent that this review would need to be overseen by a doctor, preferable the TB programme manager. This was borne out during the pilots; the nature of a TB programme is such that insight is required to interpret information gathered.

Reports were provided to the companies outlining the findings of the review. Recommendations for improvement were made, based on the reviewer's experience. Due to the confidential nature of the review, findings could not be included in this document. The outline demonstrates how the elements of the tool can be reported and measured. Calculations can be performed using a Microsoft"excel" spreadsheet which has been designed for this purpose. This spreadsheet will be made available to health services with the review tool. Please refer to a separate "excel document" for this reporting format.

The reporting process was helpful in refining the tool and reporting format. Recipients were asked to complete a questionnaire regarding the report.

8 Conclusion

The pilots showed the review tool to be appropriate and comprehensive. It is estimated that the review will take 2 staff members about 2 days to perform, depending on the size of the site and the format of documentation at the site.

9 Recommendations

- This tool was designed to be used internally. It is recommended that the review process be undertaken by the doctor responsible for the TB programme, in collaboration with TB clinic staff. The review should be undertaken annually.

- Technology transfer to promote this tool would be extremely beneficial. This could take the form of workshops which may be more time-efficient. However, undertaking the review on-site with the staff responsible for the TB programme was found to be very beneficial during the pilot; consideration may be given to doing site visits as an element of technology transfer. This technology transfer should be undertaken by personnel with experience in TB programme implementation.
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- The DME guidance note was released in 2003. Given the latest developments in the TB arena, especially with regard to MDR TB, updating this guidance note is a matter of priority. The targets set out in this guidance note should be reviewed. Once updated, technology transfer should include distribution of hard and electronic copies to all mining health services.

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11 TB programme review tool and supporting notes

11.1 TB programme review tool

Checklist	
1. Documents	
a. General policy	
b. Staff training	
c. Employee and patient education	
d. Reporting	
e. TB clinic processes	
2. Occupational Health Clinic	
a. Convenient sample	
b. Patients sent for chest investigation	
3. Primary Health Care Clinic	
a. Last visit	
b. Previous year	
4. Directly Observed Treatment	
a. General adherence	
b. Individual adherence	
5. TB Clinic	
a. No outcome	
b. Transfer out	
c. Cured	
d. Treatment interrupted	
e. Smear positive at 2/3 months	
f. Culture Results	
g. EPTB	
h. HIV	
6. Laboratory	
a. Accreditation/ Quality Control	
b. Turnaround time AFB	
b. Turnaround time Culture	
7. Radiology	
8. Pharmacy	
9. Deceased Patients	

Ideally these policies should be documented in hard or electronic copy. If no written policy exists, the current practice should be described.

1. Documents		
Table A: Policy	**Y/N**	**Comments**
1. Is there a copy of the company TB policy available?		
1.1 Does the policy endorse the DME and NTBCP guidelines?		
1.2 Does the policy stipulate responsibility for the TB control programme?		
1.3 Does the policy include contractors?		
1.4 Does the policy include reporting requirements?		
2. Is there a hard copy of the DME guidelines available?		
3. Is there a hard copy of the NTBCP guidelines available?		
4. Is there an infection control policy?		
5. Is there a policy on sputum collection?		
6. Is there a policy on Health Care workers and TB?		
7. Is there evidence that employee representatives are involved in the TB programme?		
8. Are there written guidelines on fitness during/after TB treatment?		
9. Is there an MOU with the Department of Health? Described the relationship with the Department of Health. Do staff attend meetings regularly?		
10. Are AFB positive TB patients admitted in a separate ward until smear-negative?		
11. Is there a contact tracing policy?		
12. Is there a policy on INH prophylaxis?		
13. Is there a policy on MDR Rx and referral?		
14. Is provision made for TB programme reviews-internal and external?		
15. Is there a policy on HIV testing for all TB patients?		
16. Is there a referral system for TB patients for ART?		

Table B: Staff training	Y/N/P	Comments
1. How many staff members have received formal training in TB (DOH or other) in the last year?		
2. When was the last training session?		
3. Which area were staff who attended training from (circle): TB clinic/ TB ward/ Medical ward/Outpatients/Periphery		
4. Do TB doctors receive training on TB control programmes?		

Table C: Employee and patient education	Y/N/P	Comments
1. Does TB education form part of annual induction for ***all*** employees?		
2. Is there a hard copy of a TB-specific "patient's rights" document?		
3. Is there an education plan for ***TB patients***?		

Table D: Reporting: 1. Department of Health	Y/N/P	Comments
1. Are "notification of medical condition" forms available? (GW 17/5)		
2. Is the DOH register kept?		
3. Are summary reports submitted to the DOH?		
4. Is the "Tuberculosis Suspect register" (GW 20/13) maintained?		
5. Are "Patient transfer" forms available? (GW20/14)		
6. Are DOH "notification of death" forms available?		

Table D: Reporting: 2. Medical Bureau of Occupational Disease (if applicable)	Y/N/P	Comments
1. Recording system for submissions to MBOD and responses from MBOD?		
2. Are MBOD forms filled in correctly with the applicable results?		

Table D: Reporting: 3. Rand Mutual submissions: Staff with TB	Y/N/P	Comments
1. Are Rand Mutual forms (RMD) available for submission of staff with TB?(WCL 1)		

Table E: TB clinic processes	Y/N/P	Comments
1. Is there a clinic booking diary?		
2. Is there a recording / tracing system for patients who don't return for review?		
3. Is there a formal process for referral from the wards to TB clinic?		
4. Is there a formal process for referral from the central clinic to the peripheral or local DOH clinic?		
5. Is there a leave policy?		
6. Is there a policy for those who leave employment whilst on TB treatment (including return to health service for review on treatment completion)?		

2. TB Case finding at Occupational Health							
Table 2 a: Occupational Health: Take a convenient sample of 20 records of *periodical* reviews-cough							
No.	**a. Patient number**	**b. Date of examination**	**c. Was patient *questioned r*egarding a cough at last episode?**	**d. If yes to "c" *was patient coughing for more than 2 weeks*?**	**e. If yes to "d" was patient investigated for TB?**	**f. If yes to "e" what were the results of the investigations (AFB/TB culture?)**	**g. If AFB or TB culture positive, was patient started on TB treatment?**
1							
2							
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20							

Table 2 b: Occupational Health: Take a convenient sample of 20 records of *periodical* reviews- CXR							
No.	**a. Patient number**	**b. Date examination**	**c. Was the CXR reported?**	**d. If yes to "c" was an abnormality noted?**	**e. If yes to "d" was patient investigated for TB?**	**f. If yes to "e" what were the results of the investigations (AFB/TB culture?)**	**g. If AFB or TB culture positive, was patient started on TB treatment?**
1							
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Table 2 c: Occupational Health - Employees sent from OHC for TB investigation one year previously					
No.	**a. Patient number**	**b. Date sent**	**c. Outcome recorded at OHC**	**d. What were the results of the investigations**	**e. If AFB or TB culture positive, was patient started on TB treatment?**
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

3. TB Case finding at Primary Health Care

Table 3a. Take a convenient sample of 20 records. Review the entries for the previous year and answer the questions below

No.	a. Patient number	b. Dates of examination	c. Diagnosis	d. Was the patient coughing productively for more than 2 weeks? Y/N	If the patient was coughing		
					e. Was patient investigated for TB?	f. What were the results of the investigations (AFB/TB culture?)	g. If AFB or TB culture positive, was patient started on TB treatment?
1							
2							
3							
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5							
6							
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8							
9							
10							
11							

12							
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15							

General: General Primary Health Care		
Table 3b: PHC	**Y/N**	**Comment**
1. Patients for investigation who are coughing are separated in the waiting area		
2. Sputum collection takes place in a well-ventilated area		
3. Is there a documented protocol for TB investigation which is displayed at PHC?		

4. Directly Observed Treatment (DOT)

Table 4a: *Programmatic* compliance on DOT. This assesses *all* the patients who should be receiving DOT at one centre. Take all cards at the treatment point and tick off in either column- whether they received treatment the day before (column 1) or did not receive Rx (column2)(NB ask if cards of those who didn't receive treatment on previous day have been put elsewhere)

1. Received treatment yesterday	2. Missed treatment yesterday	**Total**

Table 4b*: Individual* adherence to DOT. Take a convenient sample of 20 records tick off in either column- whether they received treatment the day before (column 3) or did not receive Rx (column 4) (NB ask if cards of those who didn't receive treatment on previous day have been put elsewhere)		
3. Received all doses	4. Missed any doses (indicate number of doses missed out of all possible doses)	**Total**

Table 4c: Observing DOT	**Y/N**	**Comments**
1. Is there water for the patient to drink their tablets with in the same room as the nurse administering DOT?		
2. Are there clean cups for each patient?		
3. Is the position of the water such that the nurse sees the patient swallowing the medication?		
4. Does the nurse check that the patient has swallowed treatment?		

5. TB clinic		
Step 1: Go to the TB register on the same date one year previously and find 5 records each:		
		Element to be reviewed:
a	Extra Pulmonary TB	How was the diagnosis made?
b	Convenient 5 retreatment patients with PTB	Were initial culture and sensitivity results obtained?*
c	5 patients who were smear positive at end of intensive phase	Was intensive phase continued for another month? Was a TB culture taken?
d	5 patients on whom no outcome was entered	Why was outcome not entered?
e	5 patients who outcome was entered as "cured"	Were AFB s and TB culture done at the end of treatment? Did the patient return for reassessment 6-12 months after completing treatment?
f	5 patients who had "treatment interrupted" entered as an outcome	Was an attempt made to find patients?
g	5 patients who were "transferred out"	Was the correct referral procedure followed?
h	Convenient 10 patients	Was patient counseled and tested for HIV and treated appropriately?
Step 2: Find the abovementioned patient TB clinic records		
Step 3: Where applicable, enter how many records were searched to find the relevant records e.g. if no outcomes were entered for 5 consecutive records, there is a problem with data capture		

*Cross- reference to table 6d – review the turnaround time of the TB culture results in the patient's file

TB clinic										
Table 5a: Case finding of Extra Pulmonary TB										
No.	**a. Register number**	**b. Patient clinic number**	**c. Rx start date**	**d. Patient category (new/ retreatment)**	**e. Site of disease**	**f. AFB result**	**g. Culture result**	**h. Histopathology result**	**i. Other results**	**j. Comments**
1										
2										
3										
4										
5										

TB clinic								
Table 5b: Monitoring on TB treatment-Culture and sensitivity results at start of TB treatment- Retreatment PTB								
No.	**a. Register number**	**b. Patient clinic number**	**c. Rx start date**	**d. Date TB culture**	**e. Result of culture (positive/negative/ contaminated)**	**f. Organism identification (MTB/ NTM)**	**g. Result sensitivity**	**h. Comments**
1								
2								
3								
4								
5								

TB clinic										
Table 5c: Monitoring on TB treatment-smear pos at end of intensive phase (new pt-after 2 months/ retreatment pt –after 3 months)										
No.	**a. Register number**	**b. Patient clinic number**	**c. Rx start date**	**d. Patient category (new/ retreatment)**	**e. Site of disease**	**f. AFB result end intensive phase (in clinic file not register)**	**g. If AFB positive at end intensive phase in file**			
							h. Was intensive phase Rx continued	**j. Result and date sensitivity**	**k. Describe ongoing management**	**l. Comments**
1										
2										
3										
4										
5										

TB clinic										
Table 5d: Monitoring whilst on TB treatment: No outcome entered										
No.	**a. Register number**	**b. Patient clinic number**	**c. Rx start date**	**d. Patient category (new/ retreatment)**	**e. Site of disease**	**f. AFB result end treatment**	**g. Culture result end treatment**	**h. Treatment stop date**	**i. Outcome**	**j. Comments**
1										
2										
3										
4										
5										

Estimate of completeness of records:	
No. of records reviewed to find 5 records with no outcome entered	

TB clinic										
Table 5e: Monitoring on TB treatment- Outcome entered as "cured" for PTB patients										
No.	**a. Register number**	**b. Patient clinic number**	**c. Rx start date**	**d. Patient category (new or retreatment)**	**e. Site of disease**	**f. AFB result end treatment (from register or file)**	**g. Culture result end treatment**	**h. Treatment stop date**	**i. Did pt come back for spirometry (6-12 months after completing Rx)**	**j. Comments**
1										
2										
3										
4										
5										

Estimate of completeness of records:	
No. of records reviewed to find 5 records with outcome entered as “cured”	

TB clinic									
Table 5f: Monitoring on TB treatment- Treatment defaulters									
No.	**a. Register number**	**b. Patient clinic number**	**c. Rx start date**	**d. Patient category (new or retreatment)**	**e. Date last seen**	**f. Evidence that attempts were made to follow up patient**	**g. Restarted on retreatment regimen**	**h. Incorrect register entry(i.e. not "interrupted")**	**h. Comments**
1									
2									
3									
4									
5									

TB clinic									
Table 5g: Monitoring on TB treatment: Transferred out									
No.	**a. Register number**	**b. Patient clinic number**	**c. Rx start date**	**d. Date T/F out**	**e. Was a DOH "transfer" form completed?**	**f. Is there evidence of communication with the referral clinic (note of telephone calls/receipt of referral letter)?**	**g. Was at least 2 weeks worth of TB treatment given to patient?**	**h. Was provision made for the patient to return for assessment post TB treatment?**	**i. Comments**
1									
2									
3									
4									
5									

TB clinic											
Table 5i: HIV (complete using the same records as above table B.1)											
No.	**a. Register number**	**b. Patient clinic number**	**n. HIV counseling & testing**				**o. HIV positive Y/N**	**If HIV positive**			
			HIV status already known	**Tested**	**Refused testing**	**No record of counseling**		**p. Cotrimoxazole prescribed**	**q. CD4 done**	**r. Already on ART**	**s. Considered for ART- comment when started**
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											

6. Laboratory Quality Control		
Table 6a: Accreditation-in house lab	**Y/N**	**Comment**
Is there an internal Quality Control programme?		
Is there an external Quality Control programme?		

Table 6b: Accreditation-Referral lab	**Y/N**	**Comment**
Is the lab accredited for TB by SANAS?		

6. Laboratory Continued							
Table 6c: Turnaround time AFB (take sample of finalised AFB reports)							
	Date sent(check not weekend)		**Pt number**	**Date reported**	**Time taken to report (days)**	**AFB result**	**If positive, when was patient started on TB treatment?**
Today's date	**24/07/2007**						
1 week ago	17/07/2007	1					
		2					
		3					
		4					
		5					
		6					
		7					
		8					
2 weeks ago	10/07/2007	9					
		10					
		11					
		12					
		13					
		14					
		15					

Table 6d: Turnaround time Culture (take sample of finalised culture reports)							
	Date sent(check not weekend)		**Pt number**	**Date reported**	**Time taken to report (weeks)**	**Culture result**	**If positive, when was patient started on TB treatment?**
Today's date	**24/07/2007**						
6 weeks ago	12/06/2007	1					
		2					
		3					
		4					
		5					
		6					
		7					
		8					
8 weeks ago	29/05/2007	9					
		10					
		11					
		12					
		13					
		14					
		15					

Table 6e: Results to ward: Do all AFB positive results get to the ward/TB clinic and do patients start treatment timeously						
All positive AFB results from 2 months ago (up to 10 positive AFB results)	**No.**	**Date**	**Patient lab number**	**Pt number**	**Date TB treatment started**	**Location (inpatient/outpatient)**
	1					
	2					
	3					
	4					
	5					
	6					
	7					
	8					
	9					
	10					

7. Radiology		
	Y/N	**Describe**
1. Is there a programme in place for Quality Assurance?		
2. Are records available for daily processor QC?		
2. Do the doctors have access to a radiologist for referral?		

8. Pharmacy		
	Y/N	**Describe**
1. Is there a stock control policy?		
2. Of a sample of 20 boxes, how many had an expiry date less than 6 weeks away?		
3. Are standardised Department of Health treatment regimens used		

9. Deceased patients			
Are post-mortem specimens sent to the NIOH? Y/N			
5 most recent post-mortem reports or patients who died: Process-Based Performance Review. Please note, this process can also be performed for patients discharged from any wards (medical/surgical/TB)			
No.	**a. Patient no.**	**Missed opportunities(out of 15)**	**Corrective action/unanswered questions**
1			
2			
3			
4			
5			

Process-based performance review (clinical / pathological tuberculosis) : Current contact

1 Demographics and diagnosis

Requirements: ☐ Autopsy report ☐ Notes on last admission ☐ All previous medical records ☐ X-rays ☐ Complete CPD attendance list

Pathology number
Cause of death on death certificate
Autopsy report

Date of admission
Date of death
Duration of hospital stay

Start date of TB treatment
Duration of TB therapy
Previous TB therapy

Circle category

Clinically Neg - Pathology TB
Clinically TB - Pathology TB (early death <30 days)
Clinically TB - Pathology TB (late death 30 + days)
Clinically TB - Pathology Neg

2 Important clinical actions

	Y / N / O
Surveillance (link 1)	
X-ray	
History (link 2)	
Chest complaint (cough / haemoptysis/ pain)	
Loss of weight	
Night sweats / fever	
Examination (link 3)	
Abnormal chest auscultation	
Evidence of weight loss	
Pleural effusion (link 4)	
Lymphadenopathy, 1cm or more (link 5)	
Hepatosplenomegaly	
Neck stiffness / confusion	
Investigations	Y / O / NA
Chest x-ray (link 6)	
Sputum TB smears, include number (links 7,8,9)	
Sputum TB culture	
Lymph node FNA / biopsy (link 10)	
Pleural biopsy / pleural fluid aspiration (link 11)	
CSF (link 12)	
Other (bone marrow, blood (link 13), liver biopsy (link 14))	

3 Evaluating the process of care

	Y / O / NA	Missed opportunities	Corrective action and unanswered questions
Was the film done within the last year?			
Did the presence of **ANY** of these prompt investigations for TB? (Guidelines include sputum TB culture)			
If these signs were found, were they investigated?			
Were these results obtained and acted upon?			
Were these results obtained and acted upon? (These may be NA for sputum positive patients.)			

Total
Missed opportunities out of 15

4 Response to therapy (link 15)

	Y / N		
TB therapy		Improvement in 3 weeks? (link 16, 17)	
		Was the patient at risk for drug resistant TB? (link 18)	
		Smear and culture at 2 / 5 months treatment?	
Pneumonia / PCP therapy		Improvement in 7 to 10 days?	
		Could this have been pneumonia in a patient with TB?	
		Follow up X-ray at about 6 weeks?	

Distinguishing TB from pneumonia (links 19, 20, 21)

Additional aspects

Was there contact with the medical services within 3 months of this admission? (link 22)		If YES, complete a previous contact form
Could a sputum sent for TB culture during a previous encounter with the medical services have changed management on this occasion?		
Could a more aggressive search for extrapulmonary TB have helped?		
Was miliary TB considered and looked for? (links 23, 24)		
Would empirical TB treatment have been appropriate? (link 25)		

10. Programme targets						
Table A: Outcome targets						
	a. No. of smear positive patients diagnosed in year	**b. No. "cured" or "treatment completed"**	**c. Percentage**	Gold standard	Bench mark	Target
1. Percentage of smear positive patients cured or completed treatment				100%	> 85%	
	d. No. of patients diagnosed in year	**e. No. died**	**f. Percentage**	Gold standard	Bench mark	Target
2. Case fatality rate (the percentage of patients who die from TB)				0%	<10%	
	g. No. of smear positive patients diagnosed 2 yrs previously	**h. No. of pts with another episode of TB**	**i. Percentage**	Gold standard	Bench mark	Target
3. Recurrence of disease in new smear positive patients within 2 years of completing treatment				0	<5%	
	j. No. of patients diagnosed in year	**k. No. for whom outcome is known**	**l. Percentage**	Gold standard	Bench mark	Target
4. Percentage of patients for whom the treatment outcome is known				100%	>90%	

Table B: Process targets						
	a. No. of PTB cases diagnosed in one year	**b. No. on whom AFB/Cultures were sent**	**c. Percentage**	Gold standard	Bench mark	Target
1. Percentage of PTB cases bacteriologically proven				100%	> 80%	
	d. No. of proven PTB cases diagnosed in one year	**e. No. with culture and organism ID**	**f. Percentage**	Gold standard	Bench mark	Target
2. Percentage of proven pulmonary cases classifiable by smear status, and with culture and organism identification requested				100%	100%	
	g. No. of smear positive patients still smear pos at end intensive phase	**h. No. on whom cult and sensitivity performed**	**i. Percentage**	Gold standard	Bench mark	Target
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%	100%	
	j. No. of retreatment cases diagnosed in year	**k. No. on whom cult and sensitivity requested**	**l. Percentage**	Gold standard	Bench mark	Target

4. Percentage of retreatment cases for which culture and susceptibility for rifampicin is requested at the start of treatment: 100%.				100%	100%	
	m. No. of new smear positive patients	**n. No. who received 90% of doses**	**o. Percentage**	Gold standard	Bench mark	Target
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%	100%	
	p. No. of PTB patients	**q. No. for whom smears requested**	**r. Percentage**	Gold standard	Bench mark	Target
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%	100%	

11.2 Supporting notes

There is a large body of evidence supporting the South African National TB Control programme (NTBCP)[1] guidelines and the Department of Minerals and Energy (DME) TB guidance note[2]. The recently released International Standards for TB Care (ISTC) [3] confirm and expand on the recommendations in the abovementioned guidelines and the reader is encouraged to familiarize themselves with these documents, which have been used to develop the TB programme review tool. The notes below outline the rationale for the structure of the draft TB programme review tool.

1. Documents

1.1 Policy

Although having a policy does not necessarily mean that procedures are implemented, it is a necessary starting point; thus the tool begins with the review of essential TB programme policies.

The company should have a written policy which covers all aspects of TB management. This policy should be in line with the current NTBCP and DME guidelines. The DME guidance note stipulates that practice standards should apply equally to contract workers. Copies of this company policy and the guidelines should be available at all TB treatment points.

A hospital TB infection control policy should include work practice, administrative and environmental control measures to eliminate nosocomial spread of TB. HIV and TB in health care workers and multi drug resistant TB should also be addressed.

A collaborative relationship with the local Department of Health (DOH) is essential for an effective TB programme; this relationship should ideally be defined in writing.

Due to the unique environment and risks on the mines the DME guidelines differ from those of the NTBCP in recommending, where possible, that sputum smear positive patients are to be treated as in-patients until smear conversion. The guidance note also suggests that consideration should be given to screening room contacts of a TB patient.

1.2 Staff training

The tool covers documentation of TB training in health care staff; all of whom should receive some training in TB; inculcating a high index of suspicion for TB when treating all patients, especially those living with HIV. The WHO Stop TB strategy[4] emphasizes training of staff involved in all aspects of the TB programme. Doctor's and nursing staff involved with TB treatment should receive specific training provided by the DOH to ensure adherence to the NTBCP guidelines.

1.3 Employee and patient education

Employees should be informed about the symptoms of TB and the importance of early diagnosis through an education initiative reaching all employees at least once a year. The Patient's Charter for Tuberculosis Care[5] outlines the specific rights and responsibilities of people with tuberculosis, empowering people with the disease and their communities through this knowledge.

1.4 Reporting

Accurate reporting is essential to monitor a TB programme; documentation is reviewed in this section of the tool. All TB patients, TB deaths and outcomes on TB treatment should be reported to the local DOH. Where the mine falls under the ODMWA, all patients 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.

1.5 TB clinic

As the hub of the TB Programme, the TB clinic should have written procedures for referral between health care points, patient follow up and record keeping which should be strictly adhered to.

2. Case finding at Occupational Health

The Occupational Health Centre (OHC) which provides an ideal opportunity for early diagnosis of TB and is thus included in the TB programme review. The mining environment is unique in that the annual fitness examination, which may include x-ray screening, provides an opportunity for early TB detection. In particular, patients should be questioned regarding persistent, productive coughing; the most common symptom of pulmonary tuberculosis. Analysis of all available literature has resulted in the ISTC concluding that focusing on patients presenting with chronic cough maximizes the chances of identifying patients with pulmonary tuberculosis. Systems should be in place at the OHC to ensure that patients who are referred for TB investigation are followed up.

3. Primary Health Care

Similarly, the Primary Health Care Clinic (PHC) is reviewed because all visits to the PHC provide an opportunity to question patients regarding cough. Systems should be in place at the PHC to ensure that patients who are referred for TB investigation are followed up.

4. Directly observed treatment (DOT)

The practices around DOT are reviewed as, by treating TB, a mining heath service is assuming an important public health responsibility. To fulfill this responsibility they must be capable of assessing the adherence of the patient to the standardised TB treatment regimen and addressing poor adherence when it occurs. It has been shown that observing a patient taking treatment results in a high cure rate and a reduction in the risk of drug resistance. One of the objectives set out in the DME guidance note is DOT for 100% of cases of PTB. Correct DOT includes watching the patient swallowing treatment and checking the patient’s mouth thereafter to ensure that medication was indeed swallowed.

5. TB clinic

In order to understand the processes around diagnosis of TB, monitoring on treatment and transferring patients out of health care services, the tool uses the TB register to select a sample of TB clinic records to review:

5.1 Diagnosis of TB

In spite of the difficulties, the basic principle that bacteriological confirmation of TB should be sought still holds and every effort should be made to this end. Sputum culture is a useful tool to diagnose paucibacillary TB, more common in HIV positive patients.

5.2 Monitoring on TB treatment

Drug susceptibility testing should be requested in all retreatment and, ideally, all new TB patients at the start of treatment. All patients should be monitored for response to therapy, best judged in patients with pulmonary tuberculosis by follow-up sputum smear microscopy at the time of completion of the initial phase of treatment and at five or seven months(retreatment). Patients with positive smears at any of these timelines should be treated according to the national guidelines; which include repeat sputum sensitivity testing.

5.3 Outcomes of patients on TB treatment

An outcome should be entered in the TB register for all patients. 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 these are negative the patient can be regarded as “cured”. A CXR should also be done at treatment end. The DME guidance note stipulates that all patients should be have a repeat CXR and spirometric assessment 12 months after completion of treatment in order to complete their ODMWA compensation assessments.

5.3.1 Transferring patients out of the mining health care services

The dismissal of employees whilst on TB therapy must comply with statutory requirements for a lawful and fair dismissal; according to the Labour Relations Act ; especially relating to dismissal for incapacity due to ill health.

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. The mine should arrange for the patient to return for assessment at the end of treatment.

5.4 Integration of TB and HIV programmes

Coordination and communication between HIV and AIDS and TB programmes must be prioritised; information on HIV testing and ART should be included in the TB clinic notes. HIV counseling and testing is indicated for all tuberculosis patients as part of their routine management; co-infected

patients may benefit by access to antiretroviral therapy and/or through administration of co-trimoxazole for prevention of opportunistic infections.

6. Laboratory Quality Control

Monitoring of accurate and timeous laboratory testing is central to the smooth functioning of a TB programme. Only laboratories with internal quality assurance measures in place and undergoing external quality control checks with a recognised TB reference laboratory should be used. Smear results should be available within 48 hours and culture and first line sensitivity results within 6 weeks. There should be a procedure in place to ensure that the results reach the appropriate clinic timeously; receipt of these results should be documented.

7. Radiology

Diagnosis and follow up of TB on chest and other X-rays is an important component of the TB programme. Quality control in the radiology department is important in terms of quality of the films produced as well as competency of the medical staff that read and interpret the X-rays. Access to a consultant radiologist may be beneficial to this service.

8. Pharmacy

An uninterrupted supply of the correct TB drugs is essential and requires continuous monitoring.

9. Deceased patients

According to ODMWA, the cardiothoracic organs of deceased miners must be sent to the NHLS/NIOH for autopsy for assessment for appropriate compensation. Where autopsies are requested, these should only be performed with appropriate consent of the relatives.

These autopsy results are also useful to determine the cause of death and possibly undiagnosed TB which previous research has shown may be a problem.[7] The Process- Based Performance Review (PBPR) [8] arose as a result of the findings of the above mentioned study and essentially aimed to identify “missed opportunities” for TB diagnosis and improve clinician performance. Process based performance review, undertaken by clinicians themselves, has been identified to be one of the most effective ways of developing successful practice habits. Use of the PBPR was reported by doctors to have changes their clinical practices regarding diagnosis of TB and it is thus included as part of this review tool. [9] PBPR is regarded as an essential component to improve clinical practice as well as identify challenges within the programme and is thus included in the TB programme review tool.

10. Targets

Measuring programme outcome and process targets should form part of the quarterly review of the TB programme undertaken by management; submitting TB statistics to the DOH should not be seen as a substitute for the company measuring their own TB programme outcomes. Based on these outcomes, the DME guidance note recommends that targets should be set during September for the next year's performance.

References (to supporting notes)

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5. The Patients Charter for Tuberculosis Care. The Tuberculosis Coalition for Technical Assistance (TBCTA) 2006. http://www.thoracic.org/sections/about-ats/assemblies/mtpi/istc.html
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