DEPARTMENT OF MINERAL RESOURCES AND ENERGY

NO. 5404 **11 October 2024**

MINE HEALTH AND SAFETY ACT, 1996 (ACT NO. 29 OF 1996)

GUIDANCE NOTE FOR THE MANAGEMENT OF LATENT TUBERCULOSIS INFECTION IN THE SOUTH AFRICAN MIING INDUSTRY

I **DAVID MSIZA**, the Chief Inspector of Mines, in terms of Section 49 (6) read together with Sections 9 (2) and 9 (3) of the Mine Health and Safety Act, 1996 (Act No. 29 of 1996), hereby issue the Guidance Note for the Management of Latent Tuberculosis Infection in the South African Mining Industry, as set out in the schedule below.

DAVID MSIZA
CHIEF INSPECTOR OF MINES
DEPARTMENT OF MINERAL RESOURCES AND ENERGY

SCHEDULE

REFERENCE NUMBER:	DMRE 16/3/2/3-B5
DATE FIRST ISSUED:	First edition
LAST REVISION DATE:	First edition
EFFECTIVE DATE:	2025-01-01

DEPARTMENT OF MINERAL RESOURCES AND ENERGY

MINE HEALTH AND SAFETY INSPECTORATE

GUIDANCE NOTE FOR

THE MANAGEMENT OF LATENT TUBERCULOSIS INFECTIONS IN THE SOUTH AFRICAN MINING INDUSTRY

CHIEF INSPECTOR OF MINES

mineral resources & energy
Department:
Mineral Resources and Energy
REPUBLIC OF SOUTH AFRICA

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PART A: THE GUIDANCE NOTE

1. FOREWORD

1.1. The Mining Industry Tuberculosis, Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome Advisory Committee (MITHAC) established a task team to facilitate the development of a guidance note for the management of **LTBIs** for the South African mining industry.

1.2. This guidance note has been developed to provide a framework to the mining industry for the management of **LTBIs**.

1.3. This guidance note has been developed based on the standards and procedures of global as well as the national departments of health.

1.4. The guidance note will be reviewed based on regulated time frames or emerging developments pertaining to **LTB** management.

2. SCOPE

2.1. This guidance note applies to the South African mining industry, the mining communities and **peri-mining communities**.

3. STATUS OF THE GUIDANCE NOTE

3.1. The guidance note has been compiled specifically with the view to provide guidance to all stakeholders regarding their respective roles and responsibilities with regard to the management of **LTBI** in the South African mining industry.

3.2. This guidance note sets out good practice for the management of **LTBI**.

4. THE OBJECTIVES OF THE GUIDANCE NOTE

4.1. The objective of this guidance note is to assist employers to reduce the incidence of **TB** in the mines by preventing progression from **LTB** to **TB disease**.

4.2. Furthermore, this guidance note is meant to upscale and further enhance **TB** preventive programmes in the South African mining industry, which have been affected by the COVID-19 pandemic through a focused approach on the management of **LTBI**.

5. DEFINITIONS AND ACRONYMS

5.1. In this guideline for a **COP** or any amendment thereof, unless the context otherwise indicates, the acronyms are:

5.1.1. **3HP** means three months of once-weekly **INH** plus Rifapentine.

5.1.2. **4R** means four months of daily rifampicin.

5.1.3. **Adherence** means the extent to which the behaviour of a person corresponds with agreed recommendations from a healthcare worker for taking medication, following a diet and/or making lifestyle changes.

5.1.4. **Clinician** means a health professional, such as a doctor or nurse, who is directly involved in patient care.

5.1.5. **DMRE** means the Department of Mineral Resources and Energy.

5.1.6. **DR-TB** means drug-resistant **TB**.

5.1.7. **GXP** means GeneXpert.

5.1.8. **HIV** means Human Immunodeficiency Virus.

5.1.9. **INH** means isoniazid.

5.1.10. **LTB** means latent **TB**.

5.1.11. **LTBI(s)** means latent **TB** infection(s) which is a state of persistent immune response to stimulation by the Mycobacterium **TB** antigens without evidence of clinically manifested active **TB**.

5.1.12. **Monitoring** means the tracking of key elements of programme performance (inputs, activities and results) on a regular basis to provide continuous information on the progress towards achieving goals, and alert staff and managers to problems, providing an opportunity for these to be resolved early.

5.1.13. **NDOH** means the National Department of Health of South Africa.

5.1.14. **Peri-mining communities** means the people who live in the vicinity of mining operations and who have been, or could be directly affected by mining-exploration, construction, operational or divestment activities.

5.1.15. **PLHIV** means people living with **HIV**.

5.1.16. **PPD** means purified protein derivative standard; **TB** skin test; **TST**; Mantoux **TST**.

5.1.17. **PTB** means pulmonary **TB**.

5.1.18. **Significant TB exposure** means a known exposure to a person with **PTB** who shared the same enclosed space for one or more nights, or for frequent or extended daytime periods during the three months before the index patient starting their **TB** treatment.

5.1.19. **Silicosis** means a lung fibrosis caused by the inhaling of silica-containing dust.

5.1.20. **TB** means tuberculosis.

5.1.21. **TB contact** means all people (family members, colleagues and other individuals, regardless of age and/or **HIV**-status) who have had a **significant TB exposure**.

5.1.22. **TB disease** means a disease caused by the Mycobacterium tuberculosis bacterium, either bacteriologically confirmed or clinically diagnosed.

5.1.23. **TPT** means **TB** preventive treatment.

5.1.24. **TST(s)** means tuberculin skin test(s).

5.1.25. **WHO** means the World Health Organization.

6. MEMBERS OF THE GUIDELINE REVIEW TASK GROUP

6.1. This guidance note was prepared by members of the Task Team, which comprised of:

CHAIRPERSON		
	Dr D Mokoboto	
STATE	**EMPLOYERS**	**ORGANISED LABOUR**
Ms. B Senabe	Dr K Baloyi	Mr. J Benade
Ms. M Hlapane	Dr B Ramantsi	Mr. J Kok
CONSULTED EXPERTS		
	Dr R Matji (Aquity Innovators)	
	Dr S Nyathi (Aquity Innovators)	

6.2. To align with prevailing **NDOH** guidelines on managing **LTBIs**, the following members were part of the review of the guidance note:

STATE	EMPLOYERS	ORGANISED LABOUR
Dr L Ndelu	Dr P Mothapo	Mr. J Benade
Dr D Mokoboto	Dr N Moyo	Mr. C Mkhumane
Ms. M Hlapane	Mr. L Gaseemeloe	
Ms. B Senabe		
Mr. N Korie		
Dr L Mvusi (**NDOH**)		

7. BACKGROUND

7.1. The **WHO** define **LTB** infection as "*a state of persistent immune response to stimulation by Mycobacterium tuberculosis antigens without evidence of clinically manifested active **TB***".

7.2. A third of the world population is estimated to be infected with **TB** according to the **WHO**, a significant majority without signs or symptoms thereof, yet at risk of developing active **TB** and becoming infectious. The lifetime risk of progression to active disease, is noted to be dependent on the immunological status of the host and occurs within the first five years after initial infection.

7.3. Those at highest risk of progressing to active **TB disease** are people who are immuno-compromised (e.g. **HIV** infection), on dialysis, preparing for organ or hematologic transplant, **PTB** household contacts (particularly children younger than five years of age) and those who have **silicosis** from exposure to silica dust.

7.4. South Africa is noted to have one of the highest burdens of **LTBIs** in high-risk groups such as young children, adolescents, household **TB contacts**, **PLHIV**, gold mine workers and healthcare workers.

7.5. South African mines have elevated levels of **TB**, **HIV** and **silicosis**, and **silicosis** is an independent risk factor for **TB**. Gold mine workers with **silicosis** have a three-fold higher incidence of **TB** compared to non-silicotic workers, and in some instances patients with **silicosis** and a positive **TST** have an estimated 30-fold higher odds of developing **TB** than the general population.

7.6. A dose-response has been demonstrated between cumulative silica dust exposure and the risk of **TB**, even in the absence of **silicosis**. It has also been shown that **HIV** and **silicosis** increase the risk of **TB** multiplicatively.

7.7. Prevention of **TB disease** by treatment of latent infections is incorporated in the National Strategic Plan for **HIV**, **TB** and sexually transmitted infections (STIs) 2023-2028 of South Africa and a critical component of the **WHO** End **TB** Strategy.

7.8. To address the scourge of **TB disease** in the South African mining industry, the **DMRE** issues guidance notes to guide implementation by the mines. As a minimum this guidance note should be read in conjunction with, but is not limited to, the following documents:

7.8.1. Guidance Note for a Management and Control Programme for Tuberculosis in the South African Mining Industry (DMR 16/3/2/3-A8).

7.8.2. Guidance Note for Implementation of **TB** Preventative Therapy among People Living with **HIV** and **silicosis**.

7.8.3. Prevailing guidelines or guidance notes from the **NDOH** on managing **LTBI**.

8. ASPECTS TO BE ADDRESSED IN THE MANDATORY COP

8.1. Target population

8.1.1. The main target population for this guidance note is the employees in the South African mining industry, mining communities and **peri-mining communities** who are exposed to **TB** and may require **TPT** once the disease has been excluded through testing and the exclusion criteria has been considered.

8.1.2. Eligibility for **TPT** should be guided by the risk assessment of the mine, considering the risk populations.

See Annexure B: Algorithm for managing the population at risk of developing **LTBIs** in the South African mining industry.

8.1.3. The following are identified as risk populations for developing **LTBIs**:

8.1.3.1. Mine employees exposed to silica dust and those with **silicosis**.

8.1.3.2. Mine employees with compromised immune systems e.g. **HIV** disease, cancer, diabetes, etc.

8.1.3.3. Pregnant women with **significant TB exposure** irrespective of age, **HIV** status or **TB** exposure.

8.1.3.4. Healthcare workers exposed to employees with **TB disease** and those at the highest risk with compromised immune systems e.g. **HIV** disease, on cancer therapy, diabetes, etc.

8.1.3.5. Families of mine employees, mining communities and **peri-mining communities** where the contacts of mine employees with **TB disease** should be assessed for eligibility for **LTB** treatment. The high-risk groups include children under the age of five years, those living with **HIV** and the elderly.

8.2. Identifying **LTB** cases (case finding)

8.2.1. Screening for active **TB** should be done on all high-risk populations before **LTB** testing and assessing for **TPT** eligibility.

8.2.1.1. **TB** screening

See Annexure C: **TB** symptom screening tool for adults and children (adopted from the **NDOH TB** screening and testing standard operating procedure 2022)

8.2.1.1.1. All mine employees should be screened for **TB** symptoms at each clinic visit and all the points of care, and those that are symptomatic, should be tested and treated for active **TB**.

8.2.1.1.2. Employees who have been previously treated for **TB** should be screened and tested after each exposure to a person with **TB**.

8.2.1.1.3. Employees newly diagnosed with **HIV** should be screened and tested for **TB** at the **HIV** diagnosis.

8.2.1.1.4. **PLHIV** in care should be tested annually for **TB** and this should be linked to the viral load follow up visit. In between the testing, **PLHIV** should be screened, tested and offered **TPT** where **TB disease** has been ruled out.

See Annexure C: **TB** symptom screening tool for adults and children (adopted from the **NDOH TB** screening and testing standard operating procedure 2022)

8.2.1.1.5. All contacts of people with **TB disease** should be screened, tested - irrespective of symptoms - and treated for **TB**.

8.2.1.1.6. The identified risk populations for **LTB** should be screened for **TB** symptoms, **TB** radiological changes (chest X-ray) and **TB** sputum to exclude active **TB disease**.

See Annexure C: **TB** symptom screening tool for adults and children (adopted from the **NDOH TB** screening and testing standard operating procedure 2022)

8.2.1.1.7. Risk populations who have completed **TB** treatment and have bacteriological proof of cure should be screened for **TB** symptoms and assessed for **TPT** eligibility. If a bacteriological cure is not demonstrated after the completion of treatment, reassess the patient for **TPT** eligibility three months after completion of the **TB** treatment.

8.2.1.1.8. People with a history of silica dust exposure and those living with **silicosis**, may present with similar symptoms and signs of **TB**. Therefore, it is imperative to exclude active **TB disease** and offer **TPT**.

8.2.1.2. Diagnosis and confirmation of **LTBI**

8.2.1.2.1. **TST** may be used to identify those infected with **LTB**.

See Annexure D: Tuberculin Skin Test

8.2.1.2.2. The unavailability of **TST** should not be a barrier to the provision of **TPT** (once active **TB disease** has been adequately excluded).

8.3. Management

8.3.1. It is essential that **TPT** is scaled up to reduce the burden of **TB** in South Africa. Previously, **TPT** was offered only to people who were at the highest risk of progressing to **TB disease** after exposure (i.e. children younger than five years of age and all **PLHIV**, regardless of age). However, to achieve **TB** elimination, it is crucial to implement **TPT** more comprehensively for everyone with **significant TB exposure** and all other individuals at high risk of **TB disease**.

8.3.1.1. Those that are eligible for **TPT**:

See Annexure B: Algorithm for managing the population at risk of developing **LTBIs** in the South African mining industry.

8.3.1.1.1. All people, regardless of age and **HIV-**status, after **significant TB exposure**.

8.3.1.1.2. Those who are immune-compromised, regardless of known exposure, after **TB disease** has been ruled out.

8.3.1.1.3. People living with **silicosis** regardless of whether they have a known significant exposure, regardless of prior **TB** treatment or **TPT** unrelated to **silicosis**.

8.3.1.1.4. Pregnant women living with **HIV** should be provided with **TPT** irrespective of the clusters of differentiation (CD4) cell count.

8.3.1.2. Other risk groups that may be considered for **TPT** based on risk assessment and selection criteria:

See Annexure B: Algorithm for managing the population at risk of developing **LTBIs** in the South African mining industry.

8.3.1.2.1. Healthcare workers to be considered during a routine occupational **TB** screening programme.

8.3.1.2.2. People who have previously had **TB** and those who previously completed **TB** treatment since they are at higher risk of getting **TB** again. Some may experience multiple significant exposures or, acquire or develop immune-compromising conditions over the course of their lives. **TPT** is indicated at each new **TB** exposure to a **TB contact** or each period of immuno-compromise.

8.3.1.3. Those that are not eligible for **TPT**:

8.3.1.3.1. Individuals diagnosed with **TB disease**.

8.3.1.3.2. Individuals that have active liver disease (acute or chronic).

8.3.1.3.3. Individuals that have signs or symptoms of severe peripheral neuropathy (could consider **4R**).

8.3.1.3.4. Individuals that have a history of adverse reactions to any of the medication used for **TPT**.

8.3.1.3.5. Individuals that drink alcohol excessively and are unwilling, or unable, to scale down. Use the following measures:

a) For men: more than five standard drinks on any day or 15 drinks per week.

b) For women: more than four standard drinks on any day or eight drinks per week.

8.3.1.4. For individuals with abnormal baseline liver function test results, sound clinical judgement is required to ensure that the benefit of **TPT** outweighs the risks, and these individuals should be tested routinely at subsequent visits.

8.3.1.5. **Treatment**

8.3.1.5.1. Initiation

a) If **TB** symptoms appear, the employee needs to be tested for **TB** to exclude **TB disease**.

b) People offered **TPT** should be offered appropriate education (including information on adverse events), counselling prior to **TPT** initiation and support throughout the **TPT** journey. This is also for **adherence** purposes.

c) Education on **TPT** should consider the following:

i) Adverse drug reactions.

ii) Duration of the treatment.

iii) Distance from a health facility.

iv) Absence of the perception of the risk.

v) Presence of stigma.

vi) Alcohol and drug use.

vii) Socio-economic factors.

viii) Time lag between diagnosis and treatment.

NOTE:
All healthcare providers need to be trained and updated on **TPT** guidelines.
Education should address that subsequent **TPT** will be required following completion of the treatment.
If another **significant TB exposure** occurs, they should access care for **TB** evaluation.

8.3.1.5.2. Treatment options

a) As per the guideline for **TPT** of the **NDOH**, the treatment regimen chosen will depend on:

i) The weight (for children)

ii) The **HIV**-status.

iii) The type of patient.

iv) The circumstances.

v) Household or family considerations.

vi) Other medications including anti-retroviral therapy (ART).

vii) The availability of formulations.

viii) Current evidence.

NOTE:
Refer to the prevailing National Guidelines on the Treatment of **LTBIs** of the **NDOH**.

b) It is recommended that where possible, individuals in one household or a group receive the same treatment regimen to lessen the burden and complexity of **TPT** on the individuals.

c) Treatment options in South Africa as recommended by the **NDOH** include:

i) Six months **INH**.

ii) 12 months **INH**.

iii) **3HP**; or

iv) **4R**; or

v) 3 - 4 months of daily **INH** plus Rifampicin (3HR).

d) A short course treatment regimen such as **3HP** and **4R** are considered safer and effective since it has higher completion rates and lower risks of adverse effects than the longer regimens. Therefore, where feasible, shorter treatment options should be offered.

e) Options for **TPT** regimens may be revised as new evidence regarding safety, efficacy, appropriate dosing and the required patient friendly formulations become available.

f) Prevailing approved regimens may be undertaken by mines as per the prevailing **NDOH** recommendations.

g) The employer is to familiarise themselves with the health benefits and possible adverse health effects of each regimen.

8.3.1.5.3. Treatment under special conditions

a) Pregnant and breastfeeding women should be treated as per the national guidelines on the treatment of **LTBIs** of the **NDOH**.

b) Contacts of people with **DR-TB** to be treated as per the national **DR-TB** guidelines.

8.3.1.5.4. Clinical **monitoring** and outcomes

a) For the duration of the treatment, employees must be monitored for the emergence of **TB** symptoms and any adverse health effects for safety, support and adjusting the dose as needed.

b) In the event that the employee who is on treatment for **LTBI**, is diagnosed with active **TB**, they must be treated for **TB** as per existing South African mining industry **TB** management guidelines and prevailing **NDOH** guidelines.

8.3.1.5.5. Management of individuals who decline treatment

a) Contacts who are eligible for **TPT** but decline treatment despite counselling, should be counselled further regarding **TB** symptoms and should be offered **TPT** again at the next opportunity.

b) If individuals develop symptoms suggestive of **TB**, they should be evaluated for **TB disease** again and be offered **TB** treatment if they test positive for **TB**. Alternatively they should be offered **TPT** once more if **TB disease** has been excluded.

8.3.1.5.6. Management of individuals who miss doses of **TPT**

a) **Adherence** and completion of **TPT** treatment are important for ensuring the successful prevention of **TB**. It is important to be incorporated into the education and counselling provided to employees. Table 1 below provides guidance on how to manage individuals who interrupt **TPT**.

*Table 1: Management of individuals who miss doses of treatment, **NDOH** guidelines **TB** Preventive Therapy-2021*

DURATION OF INTERRUPTION	MANAGEMENT
If an individual misses one dose	· The individual should take the missed dose(s) as soon as they remember within the same day. If the day's dose is missed, take the next scheduled dose and continue with the regular schedule. Do not take two doses on the same day. · For the weekly doses, take the missed dose as soon as they remember. If this is on the following day, continue with the next dose on the new day.
If an individual interrupts treatment for: Less than one month for a short regimen or Three consecutive months for a longer **TPT** regimen	 · Enquire about the reasons for the treatment interruption. · Address the concerns of the individual. · Counsel the individual on the importance of **adherence**. · Screen clinically for **TB** symptoms. · Conduct investigations to exclude **TB**, if signs and symptoms of **TB** are present.

DURATION OF INTERRUPTION	MANAGEMENT
	· If asymptomatic and there are no signs of **TB disease**, continue **TPT** to complete the remaining treatment.
If an individual interrupts treatment for more than one month for a short regimen or Three consecutive months for a longer **TPT** regimen.	· If this is the first interruption, the individual returns at any point and commits to taking treatment. · The individual may be reassessed for eligibility, counselled and restarted on treatment and referred to relevant health workers (psychologist, dietitian, social worker, pharmacist, etc.).
If an individual interrupts treatment for a second time regardless of the duration of interruption, despite **adherence** counselling.	· Do not consider for treatment.

b) Should there be situations where treatment is not adhered to, the prevailing **NDOH adherence** guidelines for **TB** should be followed.

8.3.1.5.7. Completion of treatment

a) It is important to ensure that individuals who start **TPT**, complete it. **Monitoring** and support are important throughout the course of the treatment. The **clinician** is to determine the outcomes at the completion.

8.3.1.6. **Management of adverse health effects**

8.3.1.6.1. While most adverse drug reactions are minor and occur rarely, it must be noted that maximum attention should be paid to the prevention of drug-induced hepatotoxicity.

8.3.1.6.2. Drug-specific adverse reactions can occur with:

a) Isoniazid (asymptomatic elevation of serum liver enzyme concentrations, peripheral neuropathy and hepatotoxicity).

b) Rifampicin and Rifapentine (cutaneous reactions, hypersensitivity reactions, gastrointestinal intolerance and hepatotoxicity).

8.3.1.6.3. Early identification and management of an adverse reaction is critical to ensure retention on treatment.

8.3.1.6.4. It is crucial that employees are furnished with information to identify and report signs and symptoms of adverse health effects to the **clinician**.

8.3.1.6.5. The **clinician** must carefully assess the employee and report all the adverse health effects using the standard reporting form as per the National Pharmacovigilance Centre guidelines.

PART B: IMPLEMENTATION

1. IMPLEMENTATION PLAN

1.1. The employer must prepare an implementation plan for a guidance note that makes provision for issues such as organisational structures, responsibilities of functionaries and programmes and schedules for the guidance note, which will enable proper implementation of the guidance note (a summary of and a reference to, a comprehensive implementation plan may be included).

1.2. Information may be graphically represented to facilitate easy interpretation of the data and to highlight trends for the purposes of risk assessment.

2. COMPLIANCE WITH THE GUIDANCE NOTE

2.1. The employer must institute measures for **monitoring** and ensuring compliance with the guidance note.

3. ACCESS TO THE GUIDANCE NOTE AND RELATED DOCUMENTS

3.1. The employer must ensure that a complete guidance note and related documents are kept readily available at the mine for examination by any affected person.

3.2. A registered trade union with members at the mine, or where there is no such union, a health and safety representative on the mine, or if there is no health and safety representative, an employee representing the employees on the mine, must be provided with a copy. A register must be kept of such persons or institutions with copies to facilitate the updating of such copies.

3.3. The employer must ensure that all employees are fully conversant with those sections of the guidance note relevant to their respective areas of responsibilities.

PART C: MONITORING AND EVALUATION

1. Employers must ensure that:

1.1. Internal **monitoring** and evaluation of the **TB** management and control programme is conducted and recorded.

1.2. Annual **monitoring** of the **TB** management and control programme is conducted.

ANNEXURE A: REFERENCES

1. Department of Health, 2016. Adherence Guidelines for HIV,TB and NCDs: Policy and service delivery guidelines for linkage to care, adherence to treatment and retention in care. Available at: https://www.knowledgehub.org.za/system/files/elibdownloads/2020-08/15%202%2016%20AGL%20policy%20and%20service%20delivery%20guidelines_0.pdf

2. Department of Health, 2023. National Guidelines on the treatment of Tuberculosis infection. Available at: https://knowledgehub.health.gov.za

3. Department of Mineral Resources and Energy, 2018. Guidance Note for the Management and Control Programme for Tuberculosis in the South African Mining Industry. Available at: https://www.gov.za/sites/default/files/gcis_document/201808/41839gon851.pdf

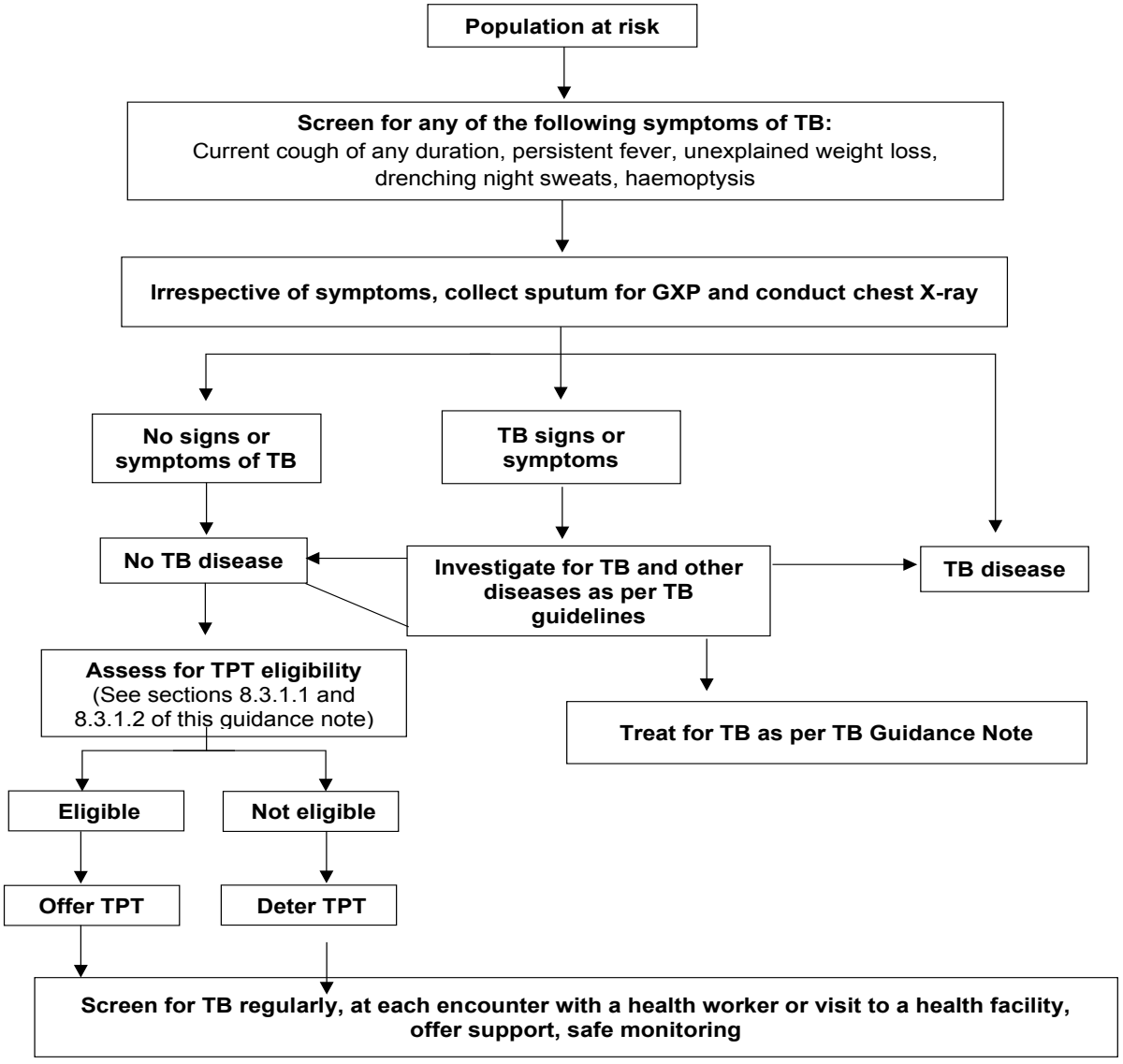
4. South African Health Products Regulatory Authority (SAHPRA), 2020. Guideline for Adverse Drug Reactions (ADRs) reporting for Healthcare Professionals. Available at: https://www.sahpra.org.za/wp-content/uploads/2020/04/ADR-Reporting-Guideline_HCPs_v1_for-commenting_March-2020.pdf

5. Southern African Development Community (SADC). Declaration on Tuberculosis in the Mining Sector. Available at: https://stoptb.org/assets/documents/news/Declaration%20on%20Tuberculosis%20in%20the%20Mining%20Sector2012English.pdf

6. World Bank, 2014. A Framework for the Harmonised Management of Tuberculosis in the Mining Sector. Available at: https://thedocs.worldbank.org/en/doc/815231483123459059-0010022016/original/FrameworkfortheHarmonizedManagementofTuberculosisintheMiningSector.pdf

7. World Health Organization, 2018. Latent tuberculosis infection: Updated and consolidated guidelines for programmatic management. Available at: https://www.who.int/publications/i/item/9789241550239

ANNEXURE B: ALGORITHM FOR MANAGING THE POPULATION AT RISK OF DEVELOPING LTBIS IN THE SOUTH AFRICAN MINING INDUSTRY



ANNEXURE C: TB SYMPTOM SCREENING TOOL FOR ADULTS AND CHILDREN (ADOPTED FROM THE NDOH TB SCREENING AND TESTING STANDARD OPERATING PROCEDURE 2022)

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

TB SYMPTOM SCREENING TOOL FOR ADULTS AND CHILDREN

PATIENT DETAILS **000001**

Surname: _____ First name: _____

Physical address: _____ Age: _____

_____ Gender: _____

Telephone number: _____ Patient folder number: _____

MEDICAL HISTORY (Tick ✓ where applicable)

Close contact of a person with infectious TB:	Yes	No	Unknown
Type of index patient:	DS-TB	Rif Resistant TB	MDR-TB or XDR-TB
Diabetic:	Yes	No	Unknown
HIV status:	Positive	Negative	Unknown

Other (specify): _____

TB SYMPTOM SCREEN (Tick ✓ where applicable)

1. ADULTS:

Symptoms (Tick ✓ where applicable)	**Yes**	**No**
Cough of two weeks or more OR of any duration if HIV-positive		
Persistent fever of more than two weeks		
Unexpected weight loss > 1.5 kg in a month		
Drenching night sweats		

2. CHILDREN:

Symptoms (Tick ✓ where applicable)	**Yes**	**No**
Cough of two weeks of more which is not improving on treatment		
Persistent fever of more than two weeks		
Documented weight loss / failure to thrive (check Road to Health Card)		
Fatigue (less playful / always tired)		

If "yes" was ticked to one or more of these questions, consider TB.
If the patient is coughing, collect a sputum specimen and send it for GXP testing.
If the patient is not coughing but has other symptoms, clinically assess the patient or refer the patient for further investigation.

Date of last TB test: _____

Patient referred for assessment and investigation:	Yes	No

Date of referral: _____ Facility name: _____

ANNEXURE D: TUBERCULIN SKIN TEST

1. Performing a Mantoux **TST**

1.1. The Mantoux **TST** is the most reliable test available and the test requires:

1.1.1. Two units of tuberculin **PPD**-RT23 2TU, or

1.1.2. Five units of **PPD**-S 5TU.

1.2. Use a single-dose tuberculin syringe and a short 27-gauge needle with a short bevel to do the test.

1.3. Draw up 0.1ml of **PPD** of the correct strength into the syringe.

1.4. Clean an area of skin in the mid-anterior section of the forearm.

1.5. The **PPD** is injected between layers of skin (intradermally) by keeping the needle almost parallel to the skin, with the bevel pointing upwards during insertion. It is important to ensure that the injection goes into and not under the skin.

1.6. A small papule should form at the injection site and if it does not form, the **PPD** has been injected too deeply and the test should be repeated at a different site.

1.7. The reaction to the test at the site of the injection is measured 48 to 72 hours later by noting the widest transverse point across the edges of the raised, thickened area. This area of induration, and not redness, is measured.

1.8. To help measure accurately, mark the edges of the induration at the widest point with a pen and measure the exact distance between the two points in millimetres.

2. Interpreting a positive **TST**

2.1. The **TST** measures the hypersensitivity to tuberculin **PPD**.

2.2. A positive **TST** does not indicate the presence or extent of **TB disease**. It only indicates **TB** infection since it takes between 6 to 12 weeks after exposure for a positive **TB** to develop. A negative **TST** soon after exposure does not exclude **TB** infection.

2.3. In a child under five years or an **HIV**-infected child of any age, a positive skin test indicates recent infection and is a risk factor for progression to disease. In the presence of other features such as a history of a **TB contact**, signs and symptoms of **TB** and chest x-ray changes, a positive **TST** is suggestive of **TB disease** in children.

2.4. There are different types of **TSTs** but the Mantoux **TST** is the recommended test.

2.5. The test is read after 48 to72 hours and it is positive when the transverse diameter of skin induration is 10 mm or greater (refer to Table 2 below).

2.6. In **HIV**-infected children, the **TST** is less likely to be positive and an induration of 5 mm or greater is regarded as positive.

2.7. A negative **TST** does not exclude **TB** infection and also does not rule out diagnosis of **TB disease**, as various conditions may suppress the reaction.

2.8. The **TST** can be negative in a person with **TB** infection due to severe malnutrition, **HIV**-infection, disseminated **TB** such as military **TB** or **TB** meningitis, and immunosuppressive drugs e.g. a high dose steroids.

*Table 2: Reading the **TST***

READING THE TST		
Immune status	**HIV** positive; malnourished; severe illness.	Others (including previous Bacillus Calmette-Guérin [BCG])
Diameter of induration in a positive test	≥ 5 mm	≥ 10 mm

2.9. A positive test of infection indicates a higher risk of future **TB disease** progression and may therefore influence the decision to offer preventive therapy. However, a negative test of infection does not rule out **TB** infection.

3. Interpreting a negative **TST**

3.1. A negative **TST** does not exclude **TB** and various conditions may cause a false negative reaction including:

a) **HIV** infection.

b) Malnutrition.

c) Severe viral infections (e.g. measles, chicken pox, etc.).

d) Cancer.

e) Immuno-suppressive drugs (e.g. steroids).

f) Severe disseminated **TB**.

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ISBN: 978-0-621-51962-4

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