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CIRCULAR H84/2023

CIRCULAR H64 IS REPEALED AND REPLACED BY THIS CIRCULAR DUE TO THE UPDATED DEFINITION OF 'CLOSE CONTACT'

SYSTEMATIC SCREENING FOR TUBERCULOSIS (TB) USING TARGETTED UNIVERSAL TB TESTING (TUTT)

Background

South Africa is one of 8 countries collectively accounting for two thirds of the global Tuberculosis (TB) burden. The annual TB prevalence according to the 2018 South African National TB Prevalence Study was 737 cases per 100 000 population. The TB cascade analysis based on 2018 data showed that only 86% of people were reached with TB testing services, 93% of those tested were diagnosed with TB and 76% of those diagnosed with TB were started on treatment. Based on this prevalence and the number of patients notified, it was estimated that there were just over 150 000 missing patients. The "Finding the missing TB patients" strategy, developed to strengthen TB screening and testing of patients, has not resulted in increased TB notifications. The World Health Organisation (WHO) states that people with untreated TB disease, contribute to increased transmission as well as increased morbidity and mortality. It now recommends systematic active case finding directed at those with highest risk of contracting the disease.

Standard Operating Procedure (SOP) for Implementation of Systematic Screening for TB

The National Department of Health has published the "TB Screening and Testing Standard Operating Procedure, June 2022" (Annexure 1). The SOP provides guidelines for quality TB screening and early linkage to care, using a Targeted Universal TB Testing (TUTT) approach.

A study conducted in South Africa (Martinson et al., 2022)[1] showed that universal testing for people classified as high risk for TB using Xpert MTB/RIF Ultra and culture irrespective of the presence of symptoms resulted in an overall yield of 6% of laboratory- confirmed TB. TUTT has been included in the National and Provincial TB Recovery Plans, which are aimed at mitigating the negative impacts of the COVID-19 pandemic on delivery and uptake of TB screening, diagnosis and treatment services.

TUTT Implementation in the Western Cape

On 28 March 2023 OPEXCO endorsed the implementation of TUTT as part of the Provincial TB recovery plan.

TUTT services will be offered at hospital, primary care, and community level. Implementation of TUTT at healthcare facilities will be scaled up according to facility readiness over the next 3-6 months.

Implementation at community level will be initiated in selected high-burden areas pending availability of resources. This will include targeting of "hotspot" areas, key populations and congregate settings such as workplaces and schools.

Included find TUTT implementation guidance inclusive of the following areas:

1. Eligible groups for TB testing regardless of TB symptoms
2. Clinical Considerations
3. Operational Considerations and risks
4. Funding
5. GXP targets
6. Training
7. Supply Chain Management
8. Information, Education and Communication
9. Recording and Reporting
10. Monitoring and Evaluation

1. **Eligible groups for TB testing regardless of TB symptoms**:

- HIV positive clients on Antiretroviral Therapy (ART) (annual TB testing)
- Newly diagnosed HIV positive clients (include those returning to care after LTFU)
- HIV positive clients that are pregnant (at first antenatal booking)
- People who received TB treatment in the previous two years (annual testing)
- People who were close contacts of a person with TB within the previous 12 months **All people (family members and other individuals; regardless of age and HIV status) who have had significant TB exposure- that is shared the same enclosed space or shared living arrangement with a TB index patient for one or more nights or for frequent or extended daytime periods during the three months before the start of current treatment in the TB index patient with Pulmonary TB**

2. Clinical Considerations

- TB symptom screening using the WHO 4 symptom screening questionnaire must be conducted at every visit for all clients presenting to healthcare facilities as per current standard of care.
- **Symptomatic clients and TUTT- eligible clients** (symptomatic and asymptomatic) should be tested for TB using Xpert MTB/RIF Ultra. Send two sputum specimens for adults & adolescents >13 years old and one specimen for children & adolescents ≤ 13 years old.
- **Symptomatic clients who are unable to expectorate** should be referred for clinical assessment, sputum induction and a chest X-ray.
- **Asymptomatic clients who are unable to expectorate** should continue routine care and be offered specimen collection at their next visit.
- Clinicians must **record the client's HIV status (if known) and history of TB in previous 2 years on the lab form** when requesting Xpert MTB/RIF Ultra test.
- In addition, clinicians must request culture & LPA (line probe assay) for:
    - all clients who received TB treatment in the previous 2 years
    - healthcare workers and prisoners
    - close contacts of Rifampicin Resistant (RR)-TB clients.
- **"Reflex" culture** (culture done automatically without request from clinician) will be conducted for the following Xpert MTB/RIF Ultra results:
    - HIV pos clients only: MTB complex not detected
    - All clients: MTB Trace detected/ RIF unsuccessful
- Clients who have received **treatment for TB in the previous 2 years** may receive a positive Xpert result due to the presence of dead TB bacilli in the sputum.
    - Asymptomatic clients with a positive Xpert result should only be initiated on TB treatment if the smear or culture result is positive.
    - Symptomatic clients with smear negative results should referred for chest X-ray and assessment by a medical officer (MO).
    - Symptomatic clients with previous severe TB disease or multiple previous episodes of TB may have concomitant features of post-TB lung disease- refer for chest X-ray and assessment by a MO.
- In a recent TUTT study, Berhanu et al (2023)[2] found that only 10% of **Trace positive results** were associated with a positive culture result.
    - All clients with a Trace positive result should be assessed for TB symptoms.
    - If symptomatic, refer for chest X-ray and clinical assessment by a MO.
    - If asymptomatic, treatment should only be initiated if the culture result is positive.
- **Management of children:**
    - Sputum specimens should be collected from all children who are eligible for TUTT if they are able to expectorate.
    - Children who are not able to expectorate should be referred to a medical officer for assessment and chest X-ray if clinically indicated.

- **Refer to Circular H58/2022:** Rapid guidance for referral of children for collection of respiratory specimens for diagnosis of uncomplicated pulmonary tuberculosis (TB) (Annexure 3) for management of children with presumptive TB.

- For further guidance on management of Xpert results, refer to the revised Western Cape Xpert MTB/RIF Ultra Diagnostic Algorithm for Pulmonary TB (Annexure 2).
- Clients who are tested for TB under TUTT eligibility in-facility and out of facility should be managed as per current NDOH guidelines (National Tuberculosis Management Guidelines -2014 and Management of Rifampicin Resistant Tuberculosis: A Clinical Reference Guide- 2019) with regard to provision of results, linkage to care and initiation of treatment.
- Ensure that TB culture & LPA results are followed up timeously.
- All HIV positive clients and close contacts of TB clients in whom TB disease has been excluded (clinically and/or microbiologically) should be assessed for eligibility of TB Prevention Treatment (TPT) according to current guidelines.

3. Operational Considerations & Risks

- **Laboratory readiness:** the National Health Laboratory Service (NHLS) will scale up capacity to meet the requirements for increasing TB testing (GXP & culture).
- Potential risk of GXP test kit shortage in the future due to increased demand. NHLS will be closely monitoring supply and demand of GXP tests.
- **Infrastructure constraints:** TUTT implementation will require additional space and sputum booths at some facilities, as well as review of Infection Prevention Control (IPC) practices. Services will review needs and explore alternative procurement streams.
- **Impact on human resources** due to increased volume of clients requiring TB testing and adjunct services such as TB linkage to care & treatment, HIV testing and HIV treatment. Services are encouraged to review the human and physical resource requirements with additional human resources having been allocated as part of the funding allocation from Global Fund for TUTT implementation.
- **Increased referrals for chest x-rays** will be a challenge for current radiology services therefore booking systems for chest x-rays need to be strengthened.

4. Funding for TUTT

TUTT will be funded through the various streams, with the funding envelope tied to specific testing targets, which cumulatively make up the provincial TUTT target for 2023/24.

5. GXP targets

Districts targets for Number of GXP tests to be conducted are presented below (source: NDOH National TB Recovery Plan April 2022 – March 2023)

Note :

- Targets include **routine TB testing with Xpert MTB/RIF Ultra** for symptomatic clients and eligilbe TUTT clients
- NDOH targets are based on achieving a reduction of GXP positivity rate to <8%, but actual testing volumes vary, and will be dependent on number of people eligible for TUTT in each category per district.

District	Total GXP target
Cape Winelands	94 414
Central Karoo	8592
Cape Metro	325 251
Garden Route	68 325
Overberg	25 521
West Coast	54 424
Western Cape Total	**576 527**

6. Training

- CIR training:
  - Information Management Directorate conducted training on Case Identification Register(CIR) recording and reporting on 25 and 26 April 2023.
- PDC training package:
  - TUTT will be incorporated into the current TB training package offered by PDC.
  - The training sessions scheduled for MDHS **12 July 2023** and **RDHS 26 July** will focus on recent policy changes in HAST including TUTT.
  - The monthly webinar sessions "Working Better Together", a collaborative initiative between SPC and PDC will commence **30 June 2023**. These sessions will be focussed on updating services regarding Circulars and Policy changes.
  - The policy changes will be integrated across current training programmes including the new **CHW curriculum.**

7. Supply Chain Management

Gene Xpert Tests

Gene Xpert tests will be provided according to current supply chain management (SCM) prescripts and testing done by NHLS. Supply of GXP test kits will be monitored by NHLS

Case Identification Registers

The Provincial Office has undertaken to provide Case Identification Registers for all districts. Districts will be required to provide registers to NPO partners. While awaiting the SCM processes districts are printing copies of the CIR from the electronic version provided to them by SPC Directorate (Annexure 4)

8. Information, Education and Communication (IEC) Material

IEC material will be developed by the Communications and Wellness units.

9. Recording and Reporting

Clients who present with symptoms or are screened positive for TB symptoms will be recorded in the case identification register (CIR, Annexure 4).

CIR will be used both at facility level as well as at community levels. **Facilities** will use the CIR as the **source document for reporting to NDOH** while **community based NPOs** will use the CIR to **track performance of TUTT against targets**. Quarterly reporting will continue to be done as per conditional grant Division of Revenue Act (DoRA) framework for reporting of TB performance.

Indicators linked to TUTT	
Data recorded in CIR in Facility and captured into Sinjani	• Child under 5yrs eligible for TB test • Client 5yrs and older eligible for TB test • DS-TB Bacteriologically confirmed under 5 years • DS-TB Bacteriologically Confirmed 5 years and older • DS-TB clinically diagnosed under 5 years • DS-TB clinically diagnosed 5 years and older • RR-TB bacteriologically confirmed • TB test under 5 years using GeneXpert • TB test 5 years and older using GeneXpert • DS-TB treatment start under 5 years • DS-TB treatment start 5 years and older • TB contact under 5 years start on TPT • TB contact 5 years and older start on TPT
Indicators recorded in service point tally sheet then transferred to CIR in clients in Community who screen positive	• Screen for TB symptoms under 5 years – Outreach • Screen for TB symptoms 5 years and older - Outreach (outreach activities will be recorded by NPO partners separate from the data reported by facility)
Indicators required for monthly NIDS reporting	• Screen for TB under 5 years *(in facility)* • TB contact under 5 years • TB contact under 5 years on TPT lost to follow up • TB contact under 5 years successfully completed TPT • Screen for TB 5 years and older *(in facility)* • TB contact 5 years and older • TB contact 5 years and older on TPT lost to follow up • TB contact 5 years and older successfully completed TPT

Indicators required for quarterly DORA reporting	• Number of patients tested for TB using Xpert • Number of eligible HIV positive patients tested for TB using urine lipoarabinomannan assay • Drug sensitive TB treatment start rate (under five years and five years and older) • Number of rifampicin resistant/ multi drug resistant TB patients started on treatment

10. Monitoring and Evaluation

TUTT progress will be discussed and monitored at the following platforms:

- Provincial CSS forum
- NDOH TB Programme Managers monthly meeting
- Metro Health Services HAST forum, and
- Rural Health Services Integrated Health Services Meeting

Annexures

1) National Department of Health TB Screening and Testing Standard Operating Procedures, 2022
2) Xpert MTB/RIF Ultra Diagnostic Algorithm for Pulmonary TB (Western Cape TB Algorithm Version 2.1, May 2023)
3) Circular H58/2022: Rapid guidance for referral of children for collection of respiratory specimens for diagnosis of uncomplicated pulmonary tuberculosis
4) Case Identification Register (CIR)- data collection fields

References

[1] Martinson NA et al. A Cluster Randomized Trial of Systematic Targeted Universal Testing for Tuberculosis in Primary Care Clinics of South Africa (The TUTT Study). 2022. http://dx.doi.org/10.2139/ssrn.4092970

[2] Berhanu RH et al. Yield of Facility-based Targeted Universal Testing for Tuberculosis With Xpert and Mycobacterial Culture in High-Risk Groups Attending Primary Care Facilities in South Africa, Clinical Infectious Diseases, Volume 76, Issue 9, 1 May 2023, Pages 1594–1603, https://doi.org/10.1093/cid/ciac965

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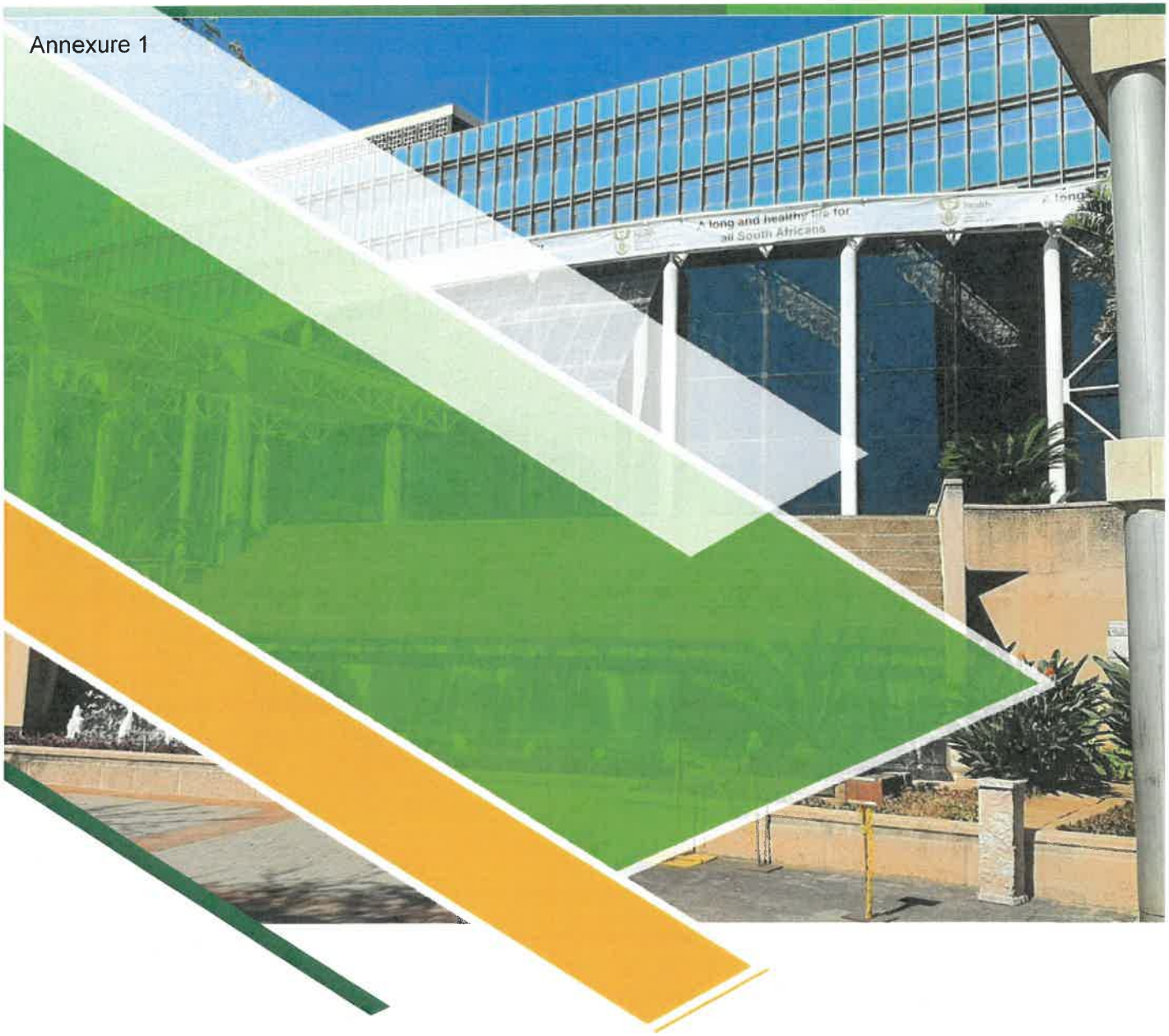
Ms. J.O Arendse

Chief Director: Emergency and Clinical Services Support (ECSS)

Date: 07/07/2023

Annexure 1



TB SCREENING AND TESTING

STANDARD OPERATING PROCEDURE

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030
NDP

Document Name	TB Screening and Testing Standard Operating Procedure
Date of this Version	June 2022
Date of review	May 2023
Contact details for enquiries	Dr L Mvusi *Lindiwe.Mvusi@health.gov.za*
Signature	

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Abbreviations

ANC	Ante Natal Care
ART	Anti-Retroviral Treatment
CHW	Community Health Worker
CXR	Chest X-ray
DS-TB	Drug Susceptible Tuberculosis
DST	Drug Susceptibility Testing
DR-TB	Drug Resistant Tuberculosis
EN	Enrolled nurse
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IPC	Infection Prevention and Control
LPA	Line Probe Assay
NHLS	National Health Laboratory Services
OTL	Outreach Team Leader
PHC	Primary Health Care
PHLIV	People Living with HIV/AIDS
PN	Professional nurse
PPE	Personal Protective Equipment
QI	Quality Improvement
TB	Tuberculosis
TPT	Tuberculosis Preventive Treatment
WBOT	Ward-Based Outreach Teams
WHO	World Health Organisation

Definitions

Systematic screening: Screening for TB disease in a systematic way to identify people with active TB disease, using a standardised questionnaire, procedures, or tests such as Xpert MTB RIF Ultra assay, chest x-rays etc.

Household contact: A person who shared the same enclosed living space for one or more nights or for frequent or extended periods of up to 8 hours during the day with the index patient, during the 3 months before the start of current treatment episode.

Close contact: A person who shared an enclosed space, such as a social gathering place, workplace or congregate setting, more than 15 minutes over a period of 24 hours with the index patient, during the 3 months before commencement of the current treatment episode.

Outreach team leader: A person (Nurse) appointed to lead the ward-based outreach team. This person is responsible for ensuring that the work of the WBOT is linked to service delivery targets and that team members are adequately supported and supervised to meet these.

Ward-based Outreach Teams: are teams comprising community health workers and a team leader. They are linked to PHC facilities and provide integrated primary health care services to households and individuals within its catchment area.

Community health worker: Refers to any worker who is selected, trained, and works in the community. They are the first line of support between the community and various health and social development services. Their role is to empower community members to make informed choices about their health and psychosocial wellbeing and to provide ongoing care and support to individuals and families.

Background

South Africa is one of eight countries that collectively account for two thirds of the world TB disease burden. The annual TB incidence in 2019 was estimated to be 615/100 000. The TB prevalence in the country was estimated to be 737 per 100 000 and that 58% of people who had confirmed TB had abnormal chest x-rays. Based on the TB prevalence estimate, the notification gap was 154 348 (missing persons with TB) which could be attributed to underreporting and underdiagnosis.

The TB cascade analysis based on 2018 data showed that only 86% of people were reached with TB testing services, 93% of those tested were diagnosed with TB and 76% of those diagnosed with TB were started on treatment[1].The "Finding the missing TB patients" strategy, developed to find additional people with TB by strengthening TB screening and testing of patients in PHC facilities has not resulted in increased TB notifications.

A Targeted Universal TB Testing (TUTT) study[2] conducted in the country showed that universal TB testing for patients at high risk for TB using Xpert and culture irrespective of the presence of TB symptoms resulted in a 6% overall yield in laboratory confirmed TB. The Table 1 below summarises the findings of this study.

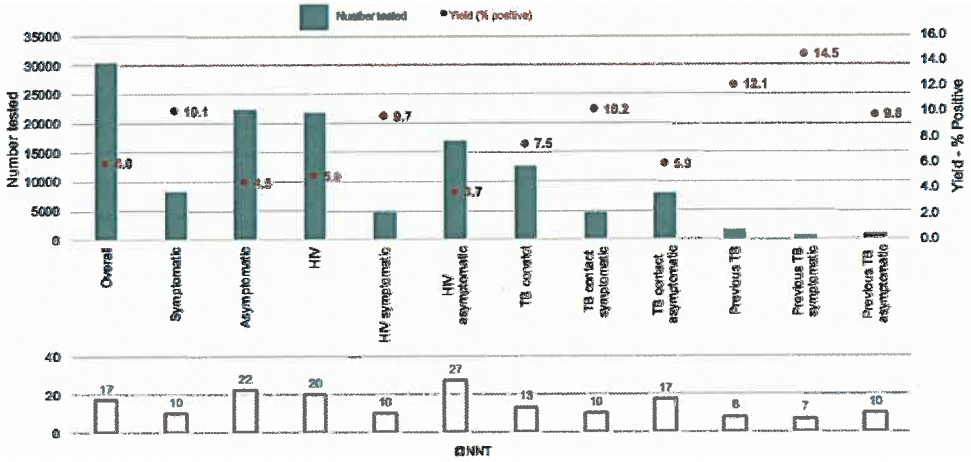


Table 1: TB yield by risk factor and symptoms & NNT

Targeted universal testing for TB in clinics in South Africa: A cluster randomized trial, N Martinson, L Lebina et al

This SOP aims to simplify the implementation of the administrative controls of TB infection prevention and control[3] using the FAST approach. FAST which stands for **F**inding people with TB **A**ctively, **S**eparate safely, and **T**reating effectively, is a quality improvement intervention aimed at preventing the spread of TB in congregate settings.

[1] 2018 TB Cascade Analysis, P Naidoo et al

[2] Targeted universal testing for TB in clinics in South Africa: A cluster randomized trial, N Martinson, L Lebina et al

[3] National Infection Prevention and Control Guidelines for TB, MDR AND XDR-TB, NDOH.2015

The key activities addressed under the administrative controls of TB-IPC include:

- screening for TB,
- cough hygiene/etiquette,
- separation and isolation,
- fast tracking of patients with symptoms of TB
- investigating patients with symptoms of TB,
- prompt treatment
- clear discharge plan (in hospitals)

The WHO recommendations on systematic TB screening[4] are summarised below:

- Systematic screening for TB disease in the general population and among people with risk factors, household and close contacts, inmates, PLHIV, people exposed to silica in workplaces in areas with a high TB prevalence.
- Use of symptom screen, chest X-ray or molecular WHO-recommended rapid diagnostic tests, alone or in combination to screen for TB disease in people 15 years and older
  - Use of the four-symptom screen and chest x-ray as a screening tool in adults and adolescents living with HIV. With those who report any one of the symptoms of current cough, fever, weight loss or night sweats evaluated for TB.
  - Use of TB symptom screen including any one of current cough, fever, poor weight gain or close contact with a TB patient in children <10 years living with HIV
  - Use of symptom screen including any one of cough, fever or poor weight gain; or chest radiography; or both in children < 15 years who are close contacts of a person with TB
  - Use of molecular WHO-recommended rapid diagnostic tests to screen for TB disease in adults and adolescents living with HIV
  - Use of digital chest x-rays with computer-aided detection software programmes as a screening tool in people aged 15 years and older

Purpose

The purpose of this document is to outline the process and procedure for quality TB screening and early identification of patients who require TB testing to minimize avoidable delays in diagnosis and treatment thus reducing TB transmission.

[4] WHO Consolidated Guidelines on Systematic Screening for TB disease, 2021

Scope

This SOP details screening and testing processes for TB, describes the procedures for triaging patients to testing and linking them to treatment in health facilities and at community levels.

Objectives

The objectives of this document are to:

- To improve the quality of TB symptom screening services
- To provide guidance on the universal TB testing of high-risk groups
- To provide health care workers with operational information on delivery of TB screening and testing services.

Applicable Legislation, Policies and Guidelines

- National Health Act 61 of 2003 as amended, and regulations issued in terms of the Act
- The National TB Management Guidelines, 2014
- Guidelines for the Management of TB in Children, 2013
- Management of Rifampicin-Resistant TB Booklet, 2019 V6
- Policy Framework and Strategy for Ward based Outreach Teams 2018/19 - 2023/24
- Ideal Clinic Framework and Manual, April 2020
- Integrated Clinical Services Management, 2016
- National Infection Prevention and Control Strategic Framework, 2020
- Policy framework on decentralized management of MDR-TB, May 2019
- National Prevention and Control Guidelines for TB, MDR-TB and XDR-TB, 2015
- National Health Laboratory Service Act (37 of 2000)
- National Health Laboratory Service Amendment Bill (1093 of 2015)

Target Population

The intended audience for this SOP includes the management and operational staff of clinical and community outreach settings who will be conducting the screening, testing. These include the following:

- Doctors
- Nurses
- Community Health Workers
- Outreach Team Leaders
- TB and HIV Managers
- District support/ implementing partners
- Civil society partners
- Community representatives

Settings for implementation

This SOP is for implementation in health facilities and at community level, the settings include:

- Hospitals
- Community Health Centers
- Clinics (including mobile clinics)
- Community sites (including households)

Values and safety precautions

The following values must be upheld when providing TB screening and testing services:

- Courtesy and with consideration of patients' rights
- Privacy
- Confidentiality
- Respect
- Dignity

Infection control practices must be always adhered to.

Appropriate PPE should be used

A dedicated safe and private sputum collection area must be identified in all settings.

Roles and responsibilities

The table below outlines the roles and responsibilities of key personnel in providing TB screening and testing services.

Table 1: Roles and Responsibilities of staff, managers and partners

Staff category	Roles and responsibilities
Medical Officer/ Nurse	• Conduct TB screening of patients. • Clinical assessment of patients • Collect specimens from all eligible patients for TB testing. • Ensure all specimens collected are correctly labelled. • Complete the laboratory request forms. • Ensure the patient is given the next appointment date for follow up • Follow up patient results. • Ensure follow up of patients who miss appointments. • Complete patient clinical records, PHC Tick and TB Identification registers
HTS Counsellors	• Conduct TB screening of patients. • Collect specimens from all patients for testing. • Refer and actively link patients to services • Complete the HTS register

Staff category	Roles and responsibilities
CHW	• Conduct TB screening of patients. • Collect specimens from all eligible patients for TB testing. • Ensure all specimens collected are correctly labelled • Follow up patient results. • Trace and refer patients for results. • Complete the community outreach forms and registers
Data Capturer	• Capture data on the electronic TB information system and other related systems • Ensure completeness of data. • Print out patient appointment list daily • Print out outstanding laboratory results line list daily • Print out facility reports weekly for analysis and actioning.
Sub/ District TB Manager	• Plan and conduct social mobilisation and awareness campaigns, health promotion and educational campaigns on TB screening and testing. • Develop and distribute relevant IEC (information, education and communication) materials on TB screening and testing in local language. • Coordinate training and mentoring for facility staff. • Coordinate laboratory services and communication with laboratories • Conduct support visits to health facilities to monitor implementation. • Ensure reporting by all facilities. • Collate and validate health facility data
Civil society partners and community leaders	• Demand creation through community education • Educating communities on rights and addressing TB stigma and myths.
Facility Managers	• Ensure TB screening is conducted effectively in the facility. • Review patient flow processes to allow for TB screening and specimen collection. • Ensure training of all facility staff on TB clinical management. • Ensure training of all facility staff on TB Infection Control • Ensure completeness of data • Conduct monthly data reviews • Ensure that remedial interventions are implemented to improve service delivery where the data shows inadequate performance

TB symptom screening

TB symptom screening must be conducted for all patients seen in health facilities and in targeted community settings.

1. Facility level screening

This applies to screening conducted in health facilities – clinics (fixed, mobile), and community health centers.

Preparation

1. Introduce yourself to the client.
2. Explain the purpose and the actual screening process to the patients.
3. Explain that the screening will take approximately five minutes to conduct.
4. Patients should be offered the option to self-screen by completing the screening form or use the TBCheck platform.
   4.1 For patients who opt for self-screening:
   - The screening tool should be made available in local languages for patients who prefer self-screening
   - The self-screening form must be provided to the health care provider,
   - The health care provider must go through the responses, ask clarity seeking questions where required, communicate the results based on the patient's responses and advise on the follow up action.

   4.2 For patients who opt for screening by the health care provider:
   - The health care provider should administer the questionnaire in patient's preferred language and complete the form
   - The health care provider must communicate the results based on the patient's responses and advise on the follow up action.

Facility Level Tools for data collection

- Integrated TB and Covid-19 Screening form
- Patient Clinic Record
- TB Identification Register
- PHC Tick Register
- TIER.Net

2. Community Level Screening

This applies to screening conducted at community level as part of outreach programmes. This includes household contact tracing, door to door campaigns and wellness campaigns – Checka Impilo.

Preparation

1. Introduce yourself to the person undergoing screening
2. Explain the purpose and the actual screening process.
3. Explain that the screening will take approximately five minutes to conduct.
4. The community health worker should administer the questionnaire in the patient's preferred language and complete the screening form.

5. The community health worker must communicate the results based on the patient's responses and advise on the follow up action.

Community level tools for data collection

- Integrated TB and Covid-19 Screening form
- WBOT Register
- WBOT Referral forms

3. Hospital level screening

This applies to screening in hospital outpatient departments and wards (including mental health facilities, excluding TB hospitals). Routinely asking patients about TB symptoms and triaging them to urgent testing by laboratory whilst patients are waiting in the OPD clinics will result in early TB detection and reduce risk of transmission in these settings. Emergency and casualty patients who end up in the wards must be screened for TB once their condition has stabilized.

Patients with TB symptoms must be educated on cough hygiene which should include the importance of using masks and separation. They must be provided with surgical masks and take their position in the waiting area or where feasible they can wait in a separate adequately ventilated waiting area.

In the wards patients with TB symptoms must be isolated in a side ward or provided with a surgical mask where separation is not feasible.

Preparation

1. Introduce yourself to the client.
2. Explain the purpose and the actual screening process to the patients.
3. Explain that the screening will take approximately five minutes to conduct.
4. Patients should be offered the option to self-screen by completing the screening form or use the TBCheck platform.

   4.1 For patients who opt for self-screening:

   - The screening tool should be made available in local languages for patients who prefer self-screening
   - The self-screening form must be provided to the health care provider,
   - The health care provider must go through the responses, ask clarity seeking questions where required, communicate the results based on the patient's responses and advise on the follow up action.

4.2 For patients who opt for screening by the health care provider:

- The health care provider should administer the questionnaire in patient's preferred language and complete the form
- The health care provider must communicate the results based on the patient's responses and advise on the follow up action.

Facility Level Tools for data collection

- Integrated TB and Covid-19 Screening form
- Patient Clinic Record
- TB Identification Register
- TIER.Net

TB and Covid-19 Symptoms

The Table 2, below demonstrates the overlap of symptoms between the two diseases hence the need for integrating for integrating screening and testing services. Examples of screening tools that can be used are in Annexure A.

Table 2: Symptoms of TB and Covid-19

TB symptoms in Adolescents and Adults	TB Symptoms in Children
– Cough of any duration – Fever more than 2 weeks – Loss of weight (>1.5kg in a month) – Drenching night sweats	– Cough of any duration – Fever – Documented weight loss/ failure to thrive – Fatigue
Covid-19 symptoms	
– Cough – Fever – Fatigue – Shortness of breath – Sore throat – Headache – Chills – Loss of smell/ taste – Arthralgia/ myalgia	

Chest x-ray screening

Digital chest x-rays with computer aided diagnosis are recommended for screening purposes. The following groups of people should be considered for chest x-ray screening, irrespective of HIV status:

- People who do not present with TB symptoms especially in high TB settings.
- People with TB symptoms other than cough.
- Symptomatic clients with a dry cough and cannot produce a sputum specimen.
- Current and former mineworkers with silica exposures.
- Symptomatic clients with a history of chronic lung disease

Refer to the chest x-ray screening guide for further information.

Note: Chest x-rays are NOT recommended for screening in children below the age of 15 years

Note: Chest x-ray screening should not act as a barrier to testing. Patients should not be referred to the next level of care for chest x-ray screening.

All people presenting with any TB symptom must be tested for TB

All people presenting with an abnormal chest x-ray suggestive of TB must be tested for TB

Screening Algorithms

Figure 1: Health Facility TB Screening Algorithm

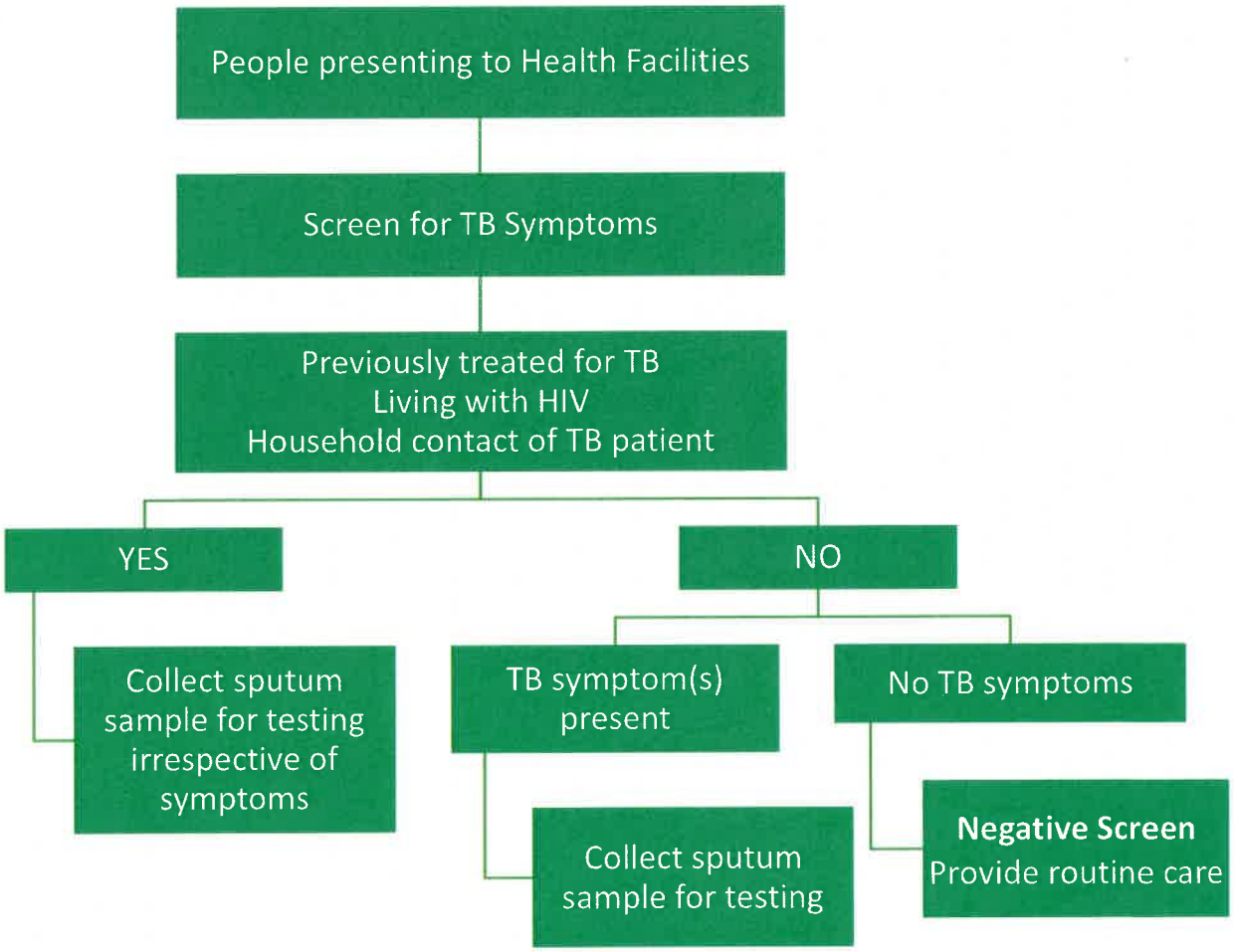


Figure 2: Community TB Screening Algorithm

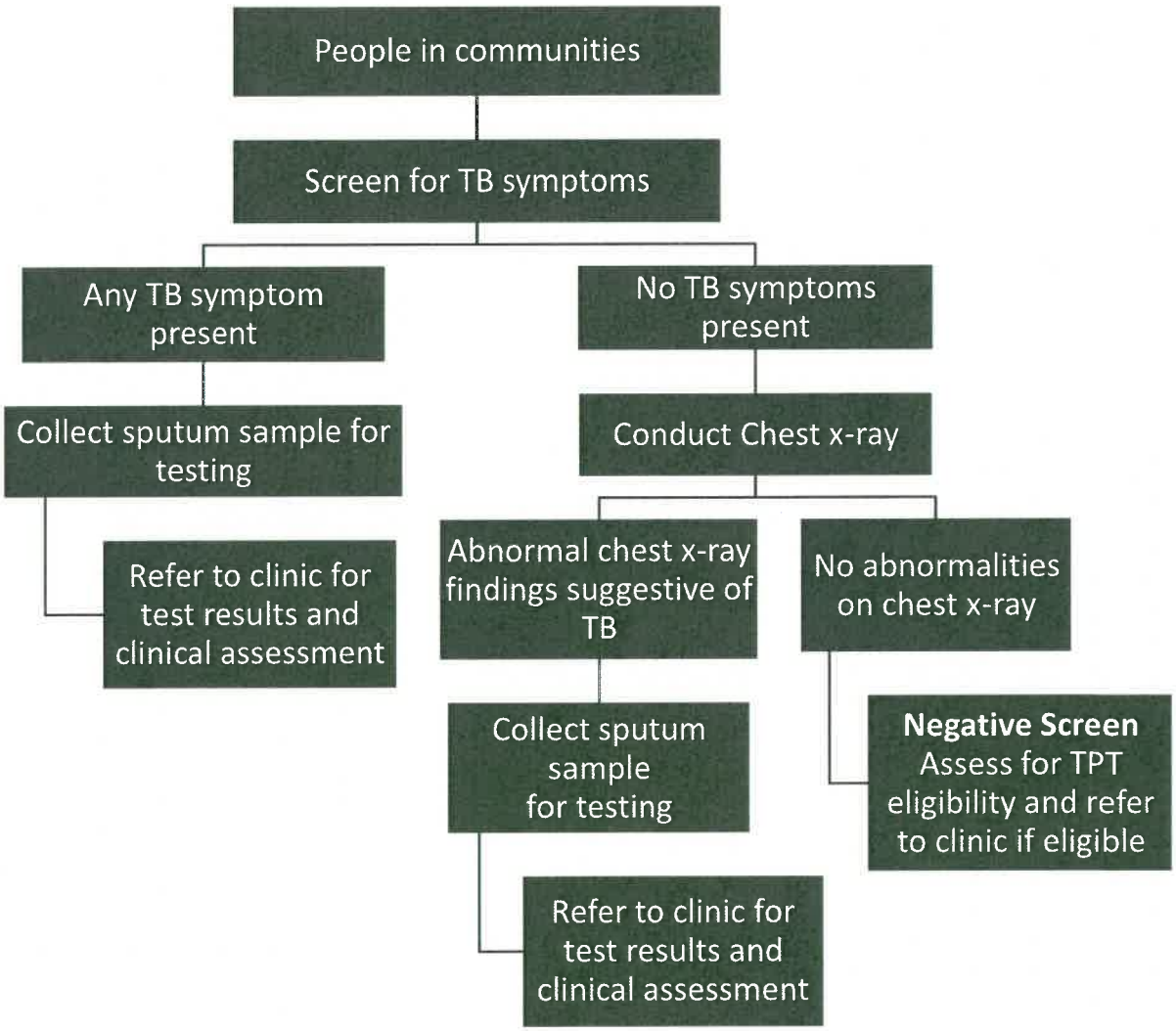
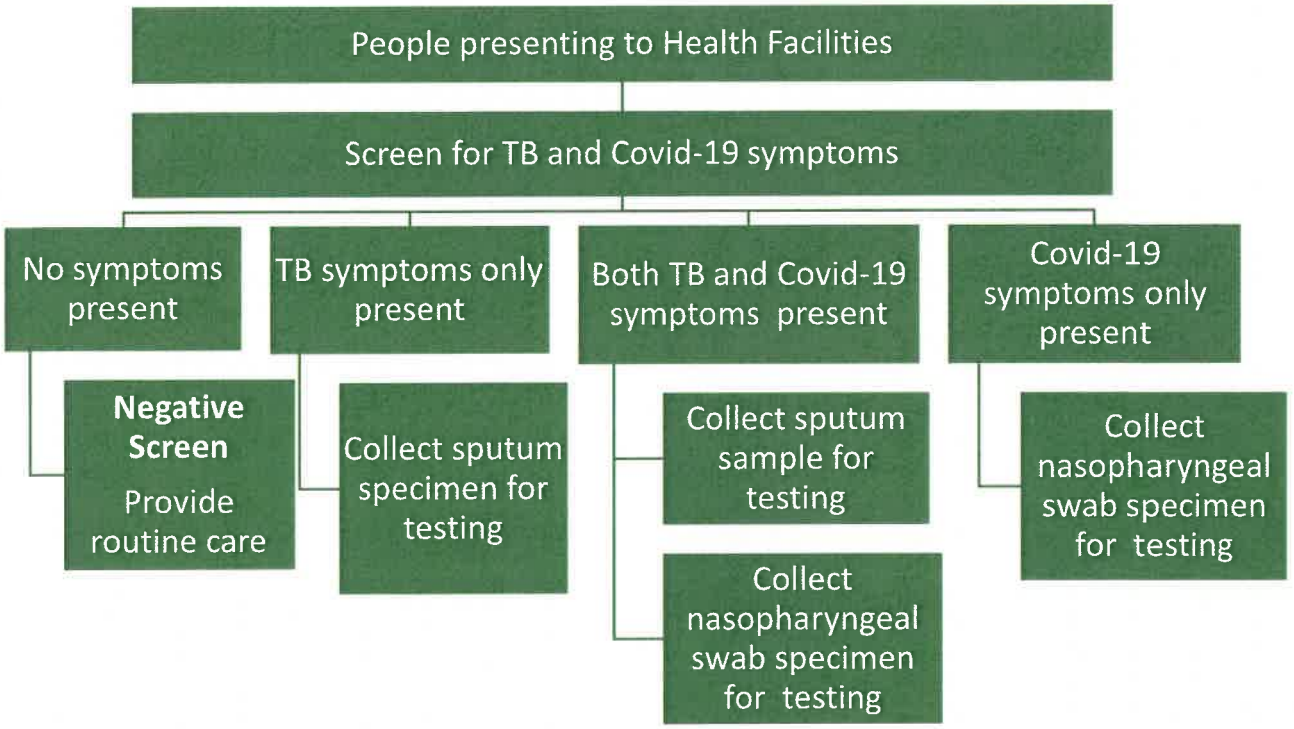


Figure 3: Integrated TB and Covid-19 Screening Algorithm



Risk Assessment

To assess the patient's risk of developing TB, medical history must be obtained from the patient or guardian (in children), this should include the following:

1. Chronic medical conditions
   - HIV status
   - Diabetes
   - Chronic lung disease including Silicosis
2. History of previous TB disease
   - Has patient had TB (DS or DR) disease in the past 2 years?
3. History of close contact with a person who was diagnosed with TB disease/ on TB treatment in the past
4. Smoking and alcohol use
   - people with alcohol use disorder are at high risk of TB
5. Assessment for under nutrition
   - people with a body mass index (BMI) ≤ 18 are at high risk of TB

Testing for TB

Who must be tested for TB?

A specimen must be collected for TB testing in the following groups:

- People (children, adolescents, and adults) with any one of the TB symptoms
- People who have been in close contact with a person diagnosed with TB or TB treatment in the past year irrespective of TB symptoms
- People who have been treated and completed TB treatment in the past two years irrespective of TB symptoms.
- Newly diagnosed PLHIV irrespective of symptoms

Frequency of testing

1. General population
   - Only when they present with any TB symptom or chest x-ray changes suggestive of TB
2. People living with HIV
   - At the time of HIV diagnosis
   - On enrolment in Antenatal care for pregnant women
   - Annually for PLHIV on treatment linked to VL monitoring follow up visits
3. Household contacts of people diagnosed with TB
   - After each exposure to a person with a confirmed TB diagnosis
4. People previously treated for TB
   - Annually for a period of two years

In-between the annual testing, PLHIV and people previously treated for TB must be screened for TB symptoms and tested only if symptomatic.

Procedure for collecting quality sputum sample

1. Equipment and Materials Instruments and supplies required

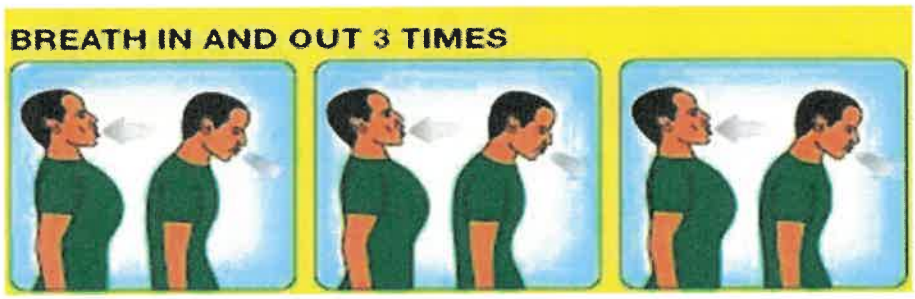
- Sterile specimen jars
- Laboratory Request Form
- Specimen Bags
- Laboratory Bar code stickers
- Disposable plastic gloves
- Respirator masks
- Sterile, filtered water or normal saline (150-250 mL)

- Box of tissues/ wiping paper
- A hand-held nebulizer with mouthpiece
- 15 mL vial of 3% saline
- Pen
- Cooler box and ice packs for specimen storage

2. Pre sputum sample collection procedure

2.1 Expectoration

- Explain the procedure for sputum sample collection to the patient
- Give the patient the container and explain how to open and close the lid
- Rinse your mouth with water
- Open the container without touching the inside of the lid and container
- Take a deep breath and exhale two times
- On the third time, cough deeply from your chest



- Place the open sterile specimen jar close to your mouth and spit into the container without contaminating the outside
- Spit into the container without contaminating the outside
- Repeat steps 2 and 3 times until at least 5 - 10ml (1 – 2 Tablespoons) of specimen is obtained
- Advise patient to make sure the container is tightly closed and to wipe the outside of the container to clean any spillages
- Direct the patient to the designated sputum collection area. This should be an area that is well ventilated and offers the patient some privacy
- Advise the patient on what to do with the specimen after collection based on facility process flow
- Advise patient to wash or sanitise hands after sample collection.

2.2 Nebulized sputum induction and collection

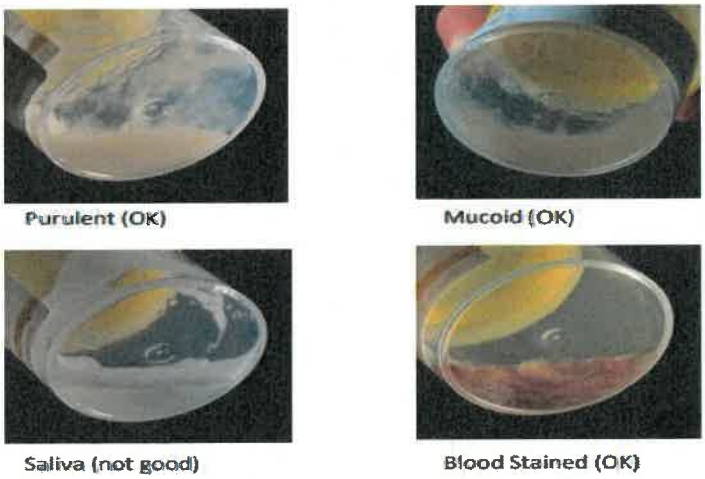
Nebulisation is recommended for patients who have dry, non-productive cough.

- A N95/ FFP2 respirator masks must worn by healthcare personnel for cough-producing procedures.
- Place approximately 5 mL of 3% saline into the hand-held nebulizer.
- Set the flow at 6-8 L/min and nebulize saline for 7-10 minutes or until sputum is expectorated.
- The maximum nebulization time is 20 minutes. Note: More saline may be added to the nebulizer if more than 10 minutes is needed to produce an adequate cough.
- Ask the patient to inhale the nebulized 3% saline deeply 2-3 times followed by a vigorous cough. This will assist in expectorating quality sputum.
- Collect the sputum into a sterile specimen container. Repeat until a minimum of 5ml of sputum is collected.
- Document the procedure in the patient's medical record.

3. Post sputum collection

- Put on gloves.
- Check if the sample is adequate and that the container is tightly closed. At least 5ml of sputum must be collected if less request the patient to produce more.

Figure 4: Illustration of acceptable sputum quality



- Peel-off one of the pre-printed barcoded labels from the Laboratory request form and place horizontally on the specimen container
- Complete the laboratory request form. Ensure all information is completed, if there is any missing information in patient folder verify with patient.
- Place the specimen container and request form in the appropriate compartment of the specimen plastic bag.

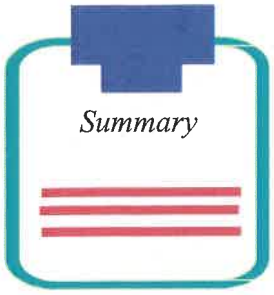
- If more than one specimen is collected from a patient, all the specimens should be placed in one bag with the relevant request form/s.
- Inform the patient on estimated date of results and how these will be communicated.
- Provide a follow up appointment date for TB results.

TB tests conducted.

The following laboratory tests are available:

1. Nucleic Acid Amplification tests (NAATs)
   - Xpert MTB/RIF Ultra
   - Line Probe Assays (LPAs) such as First-line LPAs (FL-LPAs) e.g., GenoType MTBDR*plus* and Second-line Line Probe Assays (SL-LPAs) e.g., GenoTypeDR*sl*
2. Culture
   - Using liquid media e.g., automated BACTEC™ MGIT™ 960 TB System
3. Smear Microscopy

All people must be tested using the Xpert MTB RIF Ultra as a first line test. People diagnosed with RR-TB must be tested for first and second-line DST. Previously treated patients must be tested using TB Culture and DST/1st Line LPA. Smear microscopy is used as a baseline test following a positive RS-TB test result and as a monitoring test at 7 and 23 weeks. The TB Culture test is used if the RIF testing on Xpert MTB RIF Ultra is unsuccessful, in PLHIV with a negative Xpert MTB RIF Ultra test result, and when DST is required.



- All clients entering the health facility must be screened for symptoms of TB and Covid-19
- Where available, a chest x-ray may be conducted for people without TB symptoms to screen for TB
- People who present with any of the TB symptoms or who have an abnormal chest x-ray suggestive of TB must have a sputum sample collected for Xpert MTB RIF testing
- People living with HIV must have a sputum sample collected for Xpert MTB RIF Ultra testing, irrespective of TB symptoms
- People who are close contacts of TB patients must have a sputum sample collected for Xpert MTB RIF Ultra testing, irrespective of TB symptoms
- People who have been previously treated for TB must have a sputum sample collected for Xpert MTB RIF Ultra testing irrespective of TB symptoms
- Patients must be requested to return for test results in two days
- Always offer an HIV test to people who do not know their HIV status and those who tested negative more than 3 months ago

Table 3: Interpretation of Xpert MTB RIF Ultra test results

Result	Meaning	Comment
Mycobacterium tuberculosis (MTB) complex detected. RIF resistance NOT detected	MTB DNA was detected in the specimen; therefore, the patient has bacteriologically confirmed TB. Rifampicin resistance was not detected; therefore, patient has RS-TB.	**This patient has Rifampicin susceptible TB** A second specimen for baseline microscopy should be submitted if this has not been done already.
Mycobacterium tuberculosis (MTB) complex detected. RIF resistance detected	MTB DNA was detected in the specimen therefore the patient has bacteriologically confirmed TB. Rifampicin resistance was detected, therefore patient has RR-TB	**This patient has Rifampicin Resistant TB.** Refer URGENTLY to an appropriate treatment facility and refer to the Drug Resistant TB management guidelines.
Mycobacterium tuberculosis (MTB) complex detected. RIF unsuccessful	MTB DNA was detected in the specimen therefore the patient has bacteriologically confirmed TB, however testing for rifampicin was unsuccessful.	**This patient has TB.** The rifampicin testing was unsuccessful. Another specimen should be submitted for culture and LPA (if not done already). Start first line TB therapy and monitor response to treatment. Follow up result of culture and LPA
Mycobacterium tuberculosis (MTB) complex NOT detected.	MTB DNA was not detected in the specimen.	A negative MTB result by Xpert Ultra does not always exclude TB in patients with paucibacillary disease i.e. children, HIV-positive patients with PTB and patients with EPTB. The sensitivity of Xpert may be low in smear negative, culture positive patients. This result therefore means that TB disease could not be confirmed bacteriologically. Further investigations are required to confirm TB in these patients if TB remains to be a possible diagnosis.
MTB Trace detected. RIF unsuccessful	A very low amount of MTB DNA was detected in the specimen.	*Mycobacterium tuberculosis* DNA detected at the lowest limit (trace). The rifampicin testing was unsuccessful. Refer to the TB management guidelines and the "trace" flow diagram
Unsuccessful	The test was unsuccessful. This may be due to poor quality specimen or technical causes. The test should be repeated on a newly collected specimen	The GeneXpert MTB/RIF Ultra assay was unsuccessful. Please submit a second specimen for repeat GeneXpert testing.

NOTE:

- PLHIV present with pauci-bacillary PTB or EPTB therefore a negative Xpert MTB RIF result must be followed by clinical assessment, chest x-ray and culture and DST to confirm the diagnosis of TB.
- People who are asymptomatic but test positive on Xpert MTB RIF must be clinically assessed for TB (including proper history taking), chest x-rays, culture and DST or other tests must be conducted to confirm TB.
- In people who completed TB treatment in the past two years, a "Positive" or "Trace" Xpert MTB RIF test result may indicate presence of live (active TB disease) or dead (left over from previous TB episode) bacilli or DNA. Therefore, the test result must be considered along with the clinical findings before treatment initiation and a TB culture conducted to confirm active TB disease.

Figure 5: Diagnostic algorithm for Xpert MTB RIF Ultra Positive result

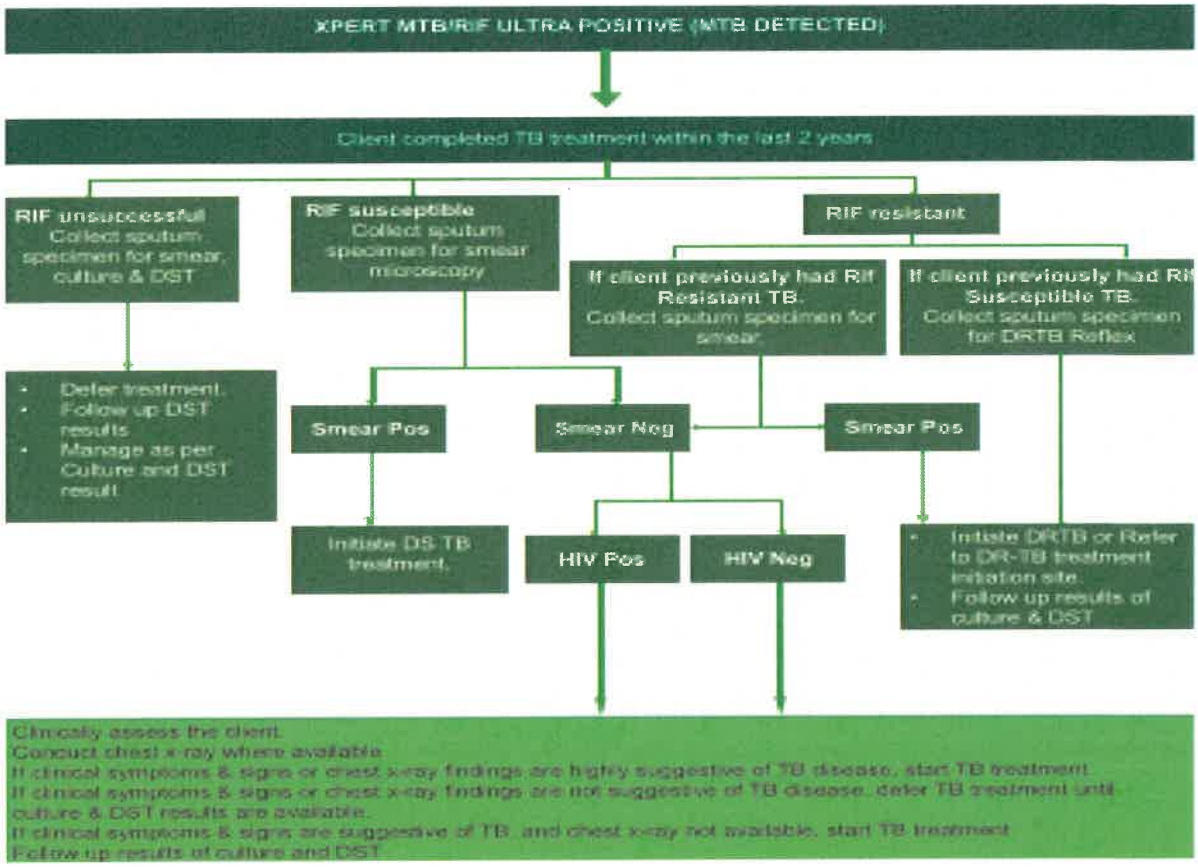


Figure 6: Diagnostic Algorithm for Xpert MTB Ultra Positive Result

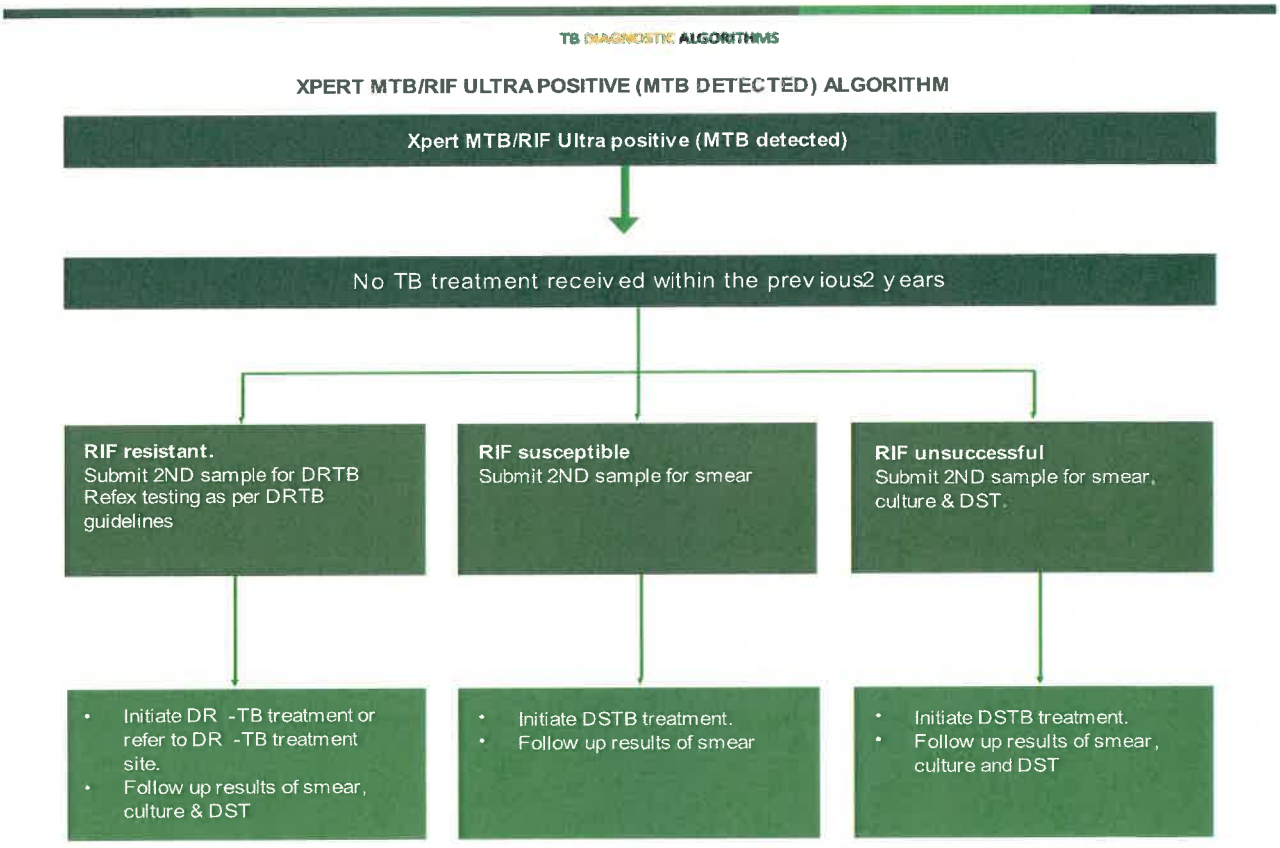


Figure 7: Diagnostic Algorithm for Xpert MTB RIF Ultra Trace result

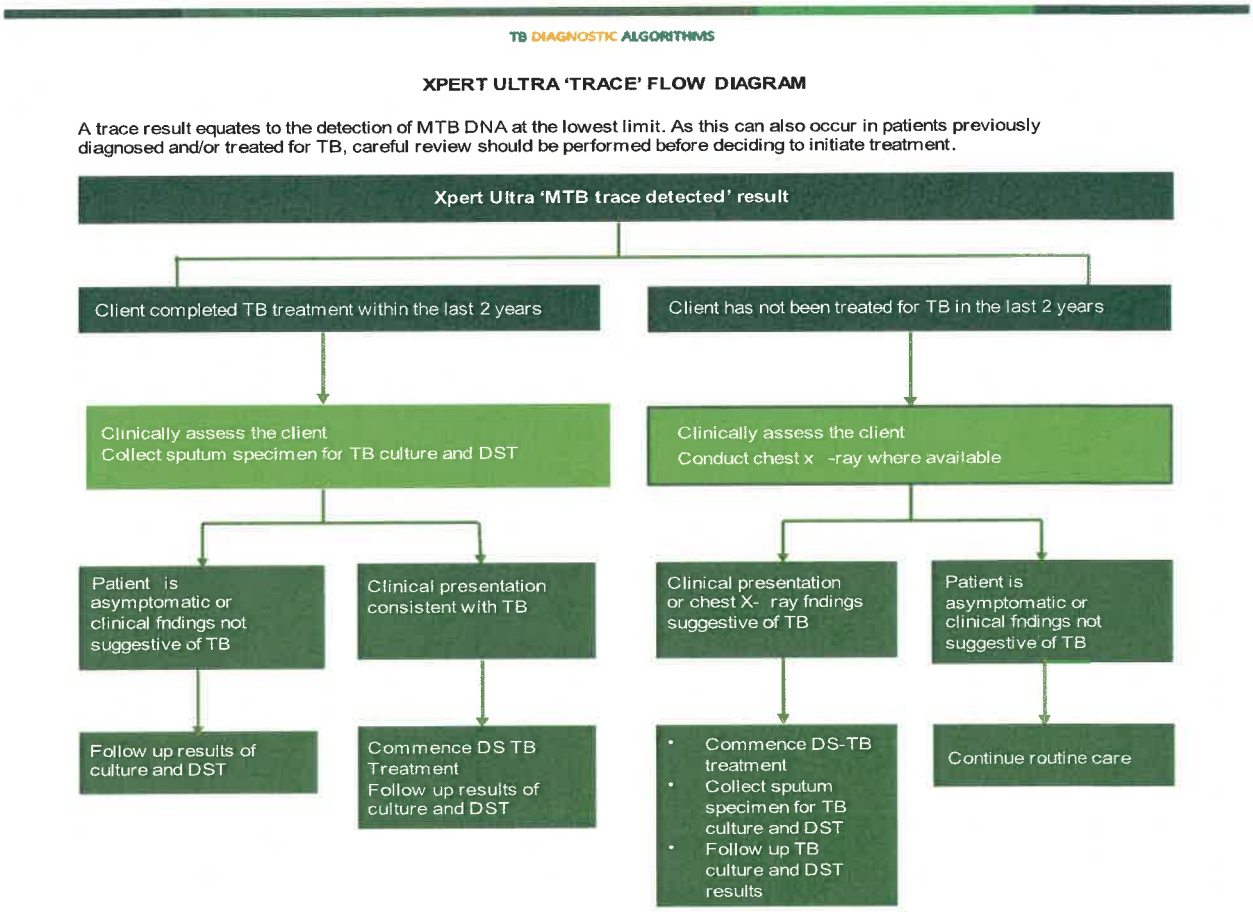


Figure 8: Diagnostic Algorithm for Xpert MTB RIF Ultra Negative result

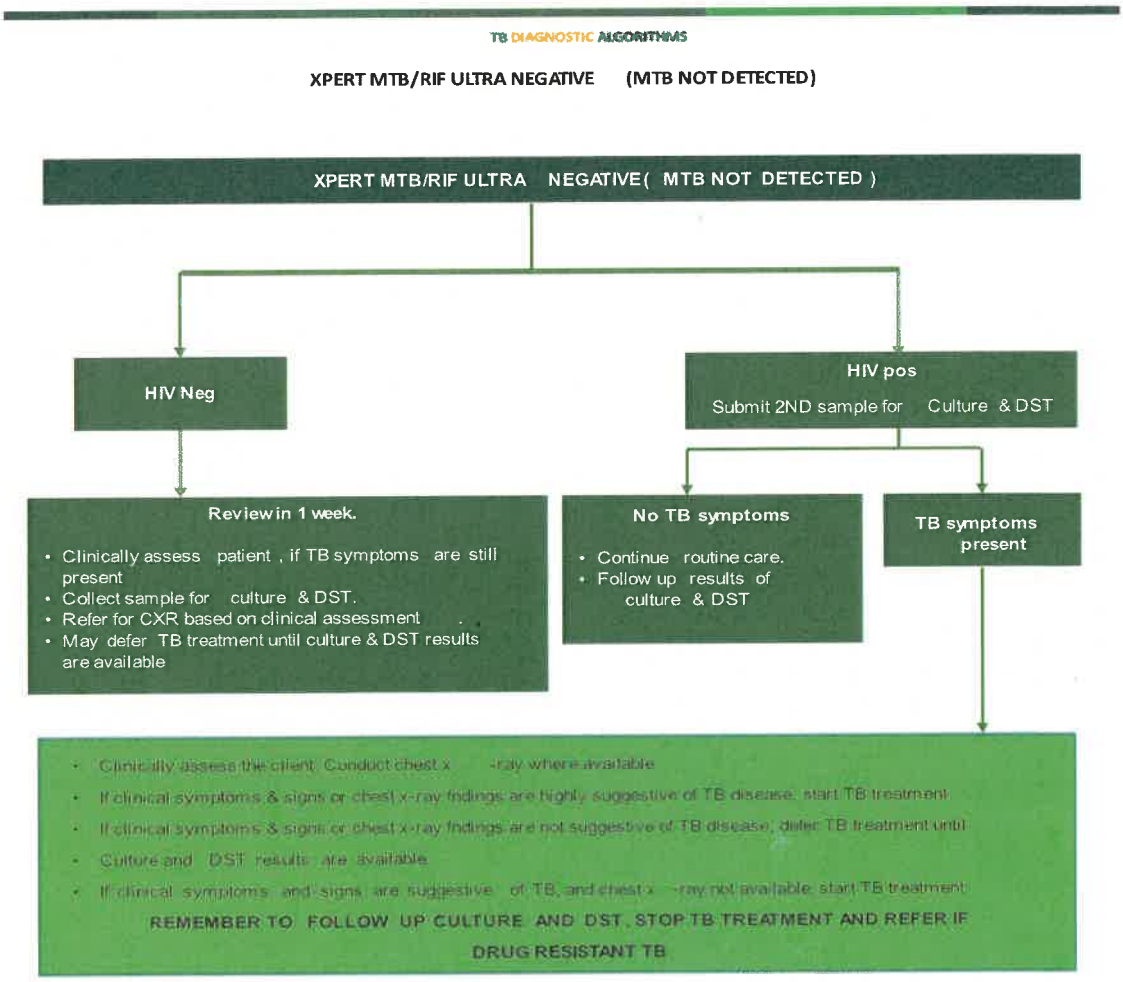


Figure 9: TB and Covid-19 Symptom Screening Tool for self- screening

health

TB SYMPTOM SCREENING TOOL

PATIENT DETAILS

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
What type of TB does the person have?	DS TB	MDR TB/ XDR TB	Unknown
Do you have diabetes?	Yes	No	Unknown
Do you know your HIV Status? (specify status if known)	Positive	Negative	Unknown
Do you have a lung disease?	Yes	No	Unknown
Do you smoke cigarettes or tobacco?	Yes	No	Not Applicable
Do you drink alcohol?	Yes	No	Not Applicable
Have you had TB/ taken TB treatment in the past year?	Yes	No	

TB SYMPTOM SCREEN

1. SYMPTOMS

(Tick √ where applicable)	Yes	No
Do you have a cough?		
When did the cough start?		
Do you/ have you had a fever (high temperature) in the past two weeks		
Additional questions for Adolescents and Adults	**Yes**	**No**
Have you been losing weight without trying in the past month?		
Are you sweating a lot at night?		
Additional questions for Children	**Yes**	**No**
Is the child less playful or always tired?		
Has the child lost weight?		
Is the child growing well?		

If "Yes" to one or more of these questions, consider TB.

Collect sputum specimen and send it for Xpert testing.

Additional Covid-19 questions	Yes	No
Do you have a sore throat or pain when swallowing		
Shortness of breath or difficulty breathing noticed recently		
Have you noticed any changes in your ability to taste or smell things recently?		
Do you have muscle or joint pains?		
Are you always tired?		
Do you have a headache?		

If "Yes" to one or more of these questions, consider Covid-19.
Collect sputum specimen and send it for SARS Cov-2 testing.

Date of last TB test: _____

Patient referred for assessment and investigation:	Yes	No
Sputum specimen collected:		

Date of referral: _____ **Facility name:** _____

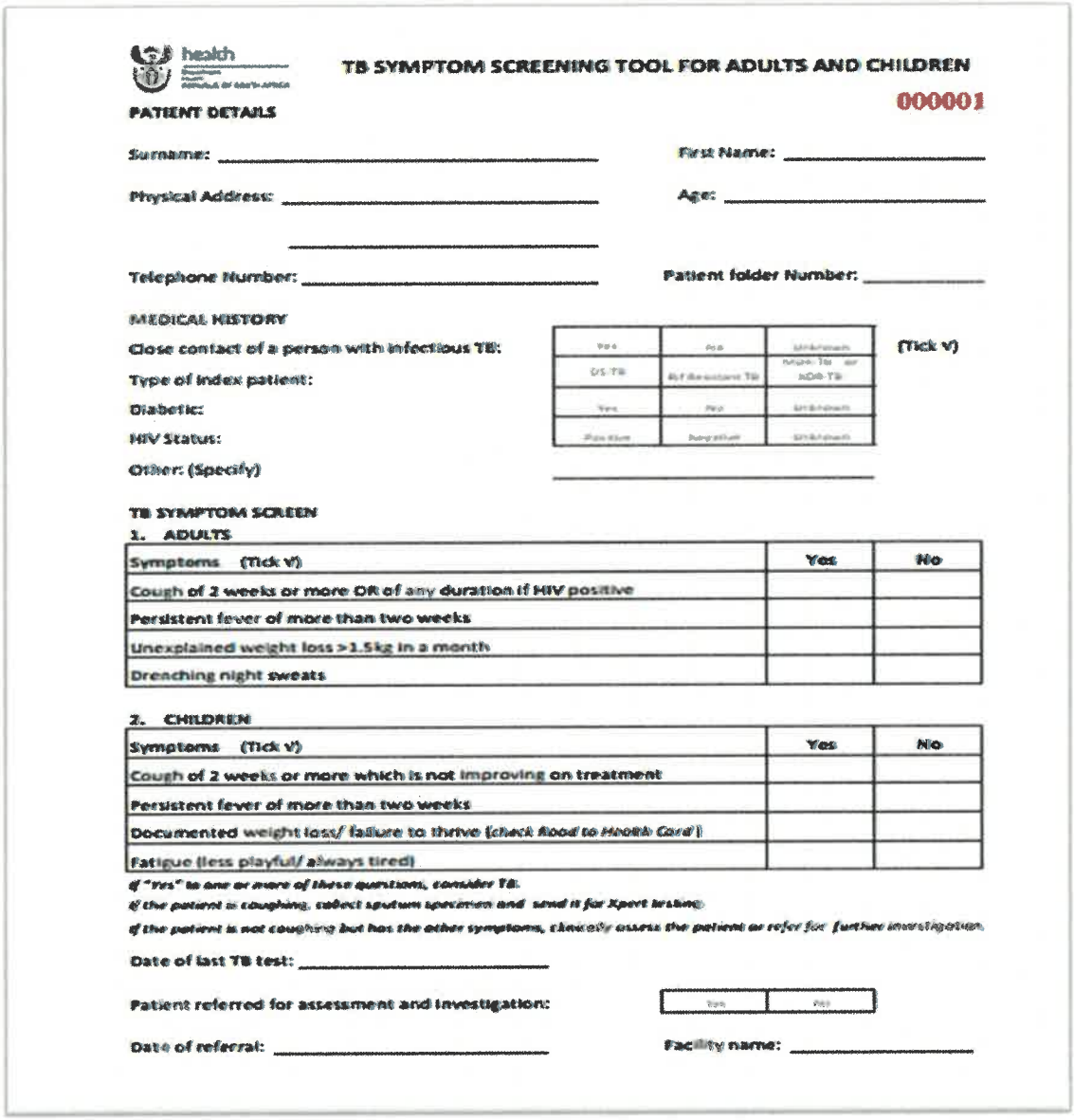
Name: _____ **Date:** _____/_____/_____

Figure 10: TB Check for self-screening

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

TB Check

Figure 11: TB symptom screening tool for use in households and community



health

TB SYMPTOM SCREENING TOOL FOR ADULTS AND CHILDREN

000001

PATIENT DETAILS

Surname: _____ **First Name:** _____

Physical Address: _____ **Age:** _____

_____

Telephone Number: _____ **Patient folder Number:** _____

MEDICAL HISTORY

Close contact of a person with infectious TB:	Yes	No	Unknown	**(Tick √)**
Type of index patient:	DS-TB	Rif Resistant TB	Mono-TB or ADR-TB	
Diabetic:	Yes	No	Unknown	
HIV Status:	Positive	Negative	Unknown	

Other: (Specify) _____

TB SYMPTOM SCREEN

1. ADULTS

Symptoms (Tick √)	**Yes**	**No**
Cough of 2 weeks or more OR of any duration if HIV positive		
Persistent fever of more than two weeks		
Unexplained weight loss >1.5kg in a month		
Drenching night sweats		

2. CHILDREN

Symptoms (Tick √)	**Yes**	**No**
Cough of 2 weeks or 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" to one or more of these questions, consider TB.

If the patient is coughing, collect sputum specimen and send it for Xpert testing.

If the patient is not coughing but has the other symptoms, clinically assess the patient or refer for further investigation.

Date of last TB test: _____

Patient referred for assessment and investigation:	Yes	No

Date of referral: _____ **Facility name:** _____

Annexure 2

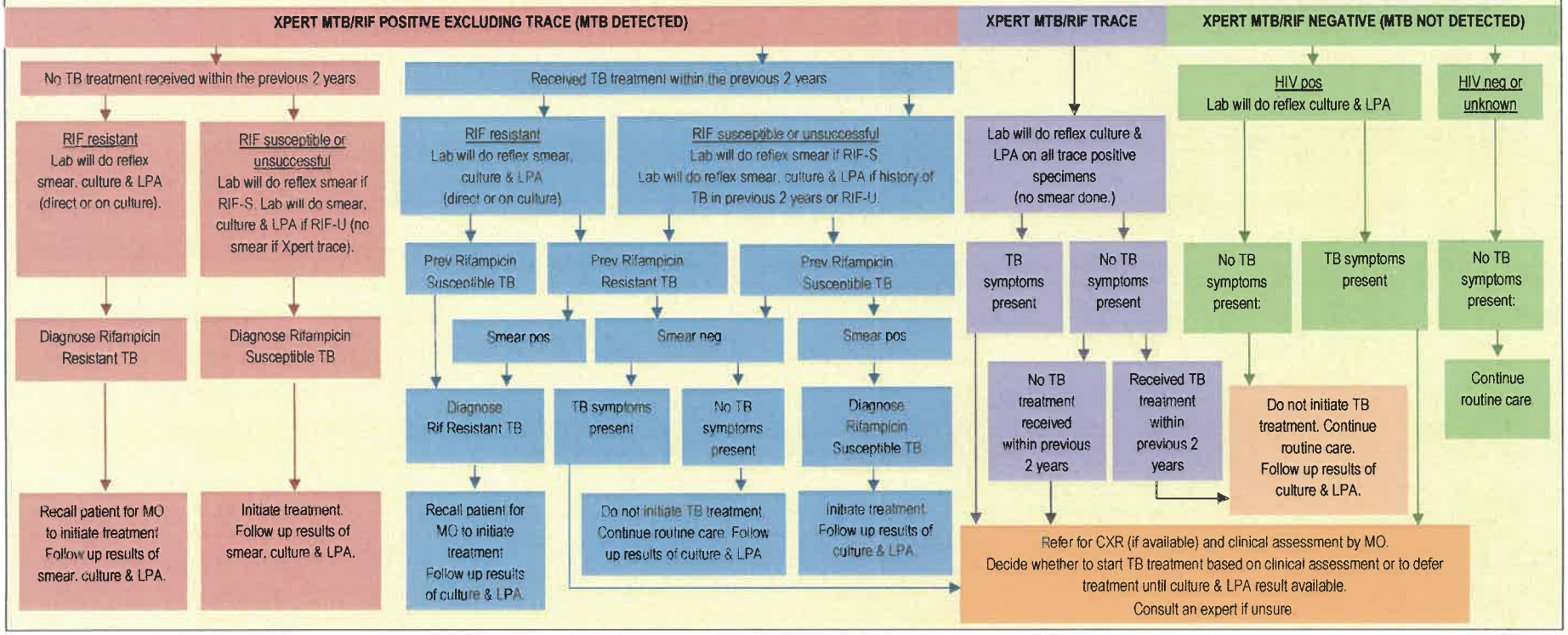
XPERT MTB/RIF ULTRA DIAGNOSTIC ALGORITHM FOR PULMONARY TB

Version 2: May 2023

- All clients attending a PHC facility must be screened for symptoms of TB [cough (≥2 weeks if HIV neg or any duration if HIV pos), recent loss of weight, fever, night sweats].
- If client screens **positive for 1 or more TB symptoms of pulmonary TB** send **sputum** to lab for testing using **Xpert MTB/RIF Ultra**. Send two specimens if >13 years old or one specimen if ≤13 years old. If unable to expectorate or extrapulmonary TB suspected, refer for CXR and assessment by medical officer (MO).
- If TB symptoms present + HIV pos with CD4<200 cells/uL, do urine LAM on same day. If positive result, initiate TB treatment and follow up result of XpertMTB/RIF Ultra.
- **Eligible for TUTT regardless of whether or not TB symptoms are present**: HIV pos pregnant clients (at first BANC visit), newly diagnosed HIV pos clients & those returning to care after LTFU, clients on ART (annually) and those who received TB treatment in previous two years (annually), close contacts of TB clients.
- **Always do HIV test** if status unknown and **repeat HIV test** if previously tested HIV-ve >3 months ago.
- If client received TB treatment in past 2 years, a positive or trace Xpert MTB/RIF Ultra result may indicate live TB bacilli (active disease) or dead TB bacilli/DNA left over from the previous disease. The result of Xpert MTB/RIF Ultra must be considered along with all clinical information & TB culture result. Advice may be sought from a TB expert.
- **If client is a healthcare worker, prisoner or close contact of DR-TB patient, or has received TB treatment in previous 2 years request Xpert, smear, culture & LPA.**
- Ask clients to return **within 2 days** for results of Xpert MTB/RIF Ultra and smear done on sputum specimen.

Refer to Medical Officer urgently (same day) if:

- Breathlessness at rest or while talking
- Respiratory rate ≥ 30 breaths/minute, temp>38°C, heart rate >120 beats per minute, BP < 90/60
- Coughing up blood
- BMI (<18.5) or severely underweight or wasted
- Confusion, agitation or unable to stand/walk unaided
- HIV positive with TB symptoms, CD4<350 & Xpert neg



Western Cape Government
FOR YOU
Health and Wellness

CITY OF CAPE TOWN
ISIXEKO SASEKAPA
STAD KAAPSTAD

Annexure 3

Western Cape Government

Department of Health and Wellness
Chief Directorate: Emergency & Clinical Services Support
Directorate: Service Priorities Coordination
Enquiries: Dr Vanessa Mudaly & Dr Hilary Goelman
Vanessa.Mudaly@westerncape.gov.za | Tel: 021 8158741

CHIEF DIRECTORS: **METRO HEALTH SERVICES, RURAL HEALTH SERVICES, STRATEGY AND SUPPORT**

EXECUTIVE DIRECTOR **CITY OF CAPE TOWN**
DIRECTORS: **DISTRICTS AND SUB STRUCTURES, PHARMACY SERVICES**
CEOs: **HOSPITALS**
FOR ATTENTION: **FACILITY MANAGERS, PHARMACISTS, PHARMACY ASSISTANTS, MEDICAL OFFICERS, CLINICAL NURSE PRACTITIONERS, NIMART NURSES**

CIRCULAR H 58/2022

RAPID GUIDANCE FOR REFERRAL OF CHILDREN FOR COLLECTION OF RESPIRATORY SPECIMENS FOR DIAGNOSIS OF UNCOMPLICATED PULMONARY TUBERCULOSIS (TB)

Background

Only 10% of childhood TB diagnosed in the community and 25-40% of TB diagnosed in hospital are confirmed despite extensive investigation. Where children are unable to expectorate, we accept that not all children should be required to have microbiological testing on a respiratory sample (gastric washing/induced sputum) in order to make a treatment decision BUT that for some children this will add value. Timeous initiation of treatment in children infected with TB can improve clinical outcomes significantly. Conversely, delaying treatment initiation results in poor outcomes.

Purpose of this circular

- Provides advice on the appropriate referral of children with presumptive TB to obtain respiratory specimens in the community.
- Facilitates community-based management of uncomplicated pulmonary tuberculosis in children
- Remove barriers to initiating TB treatment by deferring tests that rarely add value and which may cause delay in the treatment of uncomplicated drug sensitive pulmonary TB
- Does not replace referral and diagnostic approaches for complicated/severe tuberculosis or disseminated and extrapulmonary tuberculosis or uncomplicated nodes in the neck.

Which children should NOT be managed with this rapid advice?

The following children should not be managed by this rapid guide, and may require referral:

- Difficulty breathing with chest indrawing, nasal flare, grunting, unable to feed properly, struggling to speak, blue lips and tongue or saturation of <93% in air
- Persistent vomiting, headache, neck stiffness, seizures, focal neurological features
- Severe backache with or without abnormal spine curvature
- Abdominal distention

In which children SHOULD a respiratory specimen be taken?

Respiratory specimens should be taken in the following cases:

- ALL children with SYMPTOMS of TB OR suspected pulmonary TB who can expectorate sputum should have it collected at their local clinic.
- The following children with suspected pulmonary TB who CANNOT expectorate should be referred for a respiratory sample to the closest site that has the capacity to perform them:
  - Children living with HIV who have symptoms of TB
  - Children living with HIV who have no symptoms of TB but have a known exposure to TB AND an abnormal CXR
  - Children with TB symptoms who have known exposure to a drug-resistant TB case
  - Children without TB symptoms who have been exposed to a drug-resistant TB case AND have an abnormal CXR
  - Children with symptoms of TB and severe disease on the CXR regardless of whether there is a known exposure to a TB case and irrespective of the drug susceptibility of the source case. This include children with cavitation or significant alveolar opacification
  - Where the diagnosis of TB is not clear

When should the specimen be done?

- The sample should be taken as soon as possible.
- The time taken for sample collection and for the results to be returned should not interfere with the appropriate initiation of therapy.
- **NOTE: Children with suspected uncomplicated drug sensitive pulmonary TB who do not have one of the mentioned indications for specimen collection can initiate therapy without referral for collection or delay.**

Which sample should be taken?

The preferred respiratory specimen is determined by local expertise and includes both gastric aspiration OR induced sputum. Induced sputum requires appropriate technology and hypertonic saline, but no overnight fast and can be performed throughout the day. Gastric aspiration requires overnight fast and access to sodium bicarbonate. Although more specimens may have a higher yield the collection of one specimen is the minimum requirement.

How to use the result?

- In children who expectorated sputum
  - If the Xpert MTB/RIF result is positive, this assists in making the decision to start treatment if the child is not already on treatment and to utilize the rifampicin susceptibility to guide appropriate therapy.
    - If Xpert MTB/RIF result is positive and rifampicin is resistant or indeterminate, a further sample should be collected for culture prior to starting therapy if therapy has not yet been initiated. The referral path for drug-resistant TB should be followed.
  - If the Xpert MTB/RIF result is negative
    - Already on therapy: Do not alter therapy if already on treatment, follow the clinical course and consider referral to MO if not previously done.
    - Not on therapy: Manage according to the history of contact, clinical features and CXR

Summary Algorithms

The recommendations are summarized in algorithms attached as annexures (see below). It is acknowledged that clinical diagnosis of TB and exclusion of TB in children who are close contacts of people with TB can be very challenging. The intention is not to delay initiation of TB treatment or TPT unnecessarily. Therefore, if unsure of how to proceed, discuss with an expert.

Local Referral pathways

Currently, respiratory specimen collection by gastric aspiration or induced sputum is offered at all district and regional hospitals and a few primary health care facilities. Referral pathways differ within districts and sub-districts and may be confirmed with the relevant managers.

Upscaling of access to community-based specimen collection

Where capacity and expertise are available, primary health care facilities are encouraged to offer on-site respiratory collection for eligible children. The People Development Centre (PDC) is developing an on-line training package on respiratory specimen collection for children via induced sputum and/or gastric aspiration methods. Contact Ceridwyn.klopper@westerncape.gov.za for further information.

Implementation

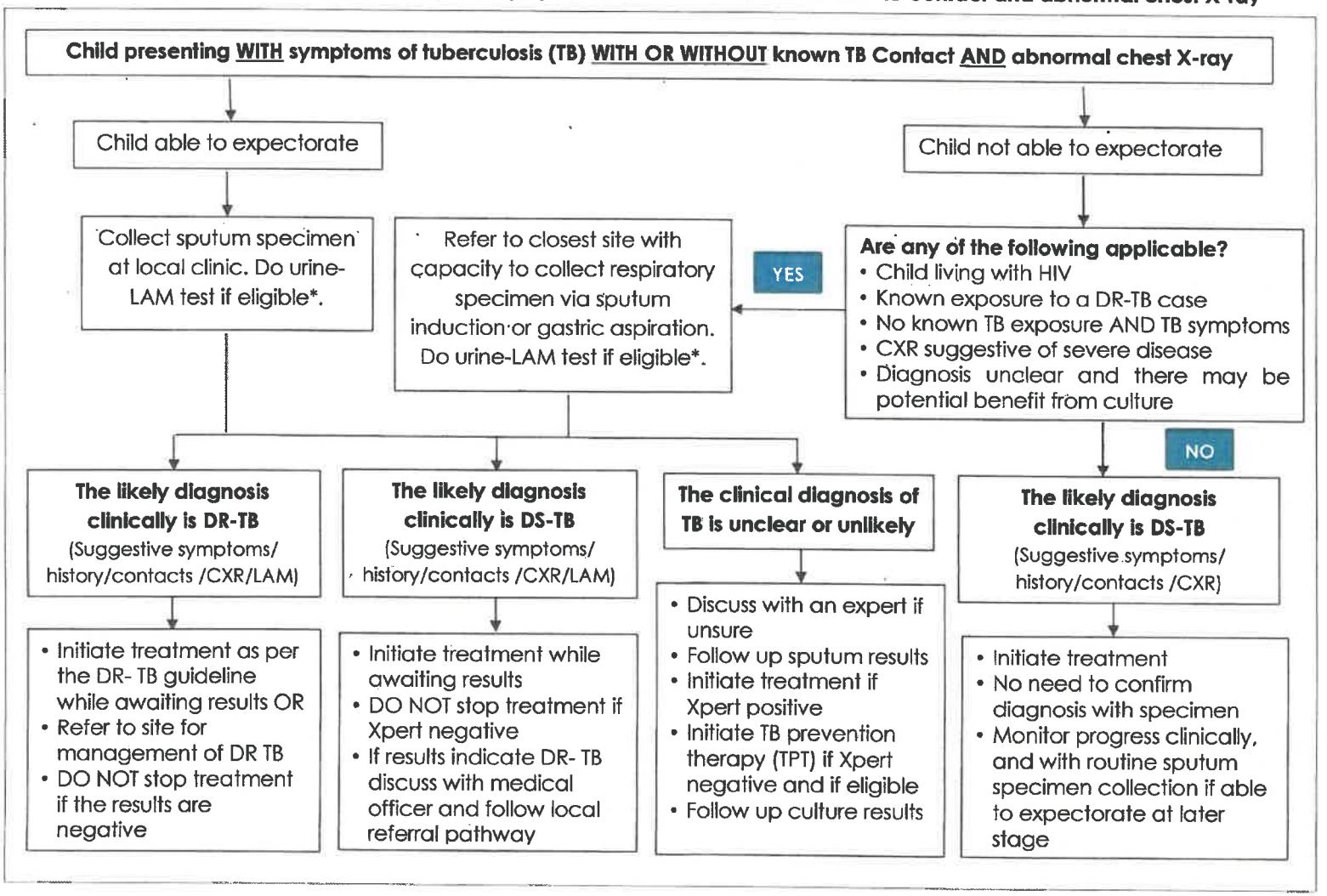
The recommendations of the rapid guide can be implemented with immediate effect.

Ms KB Lowenherz

Acting Chief Director: ECSS

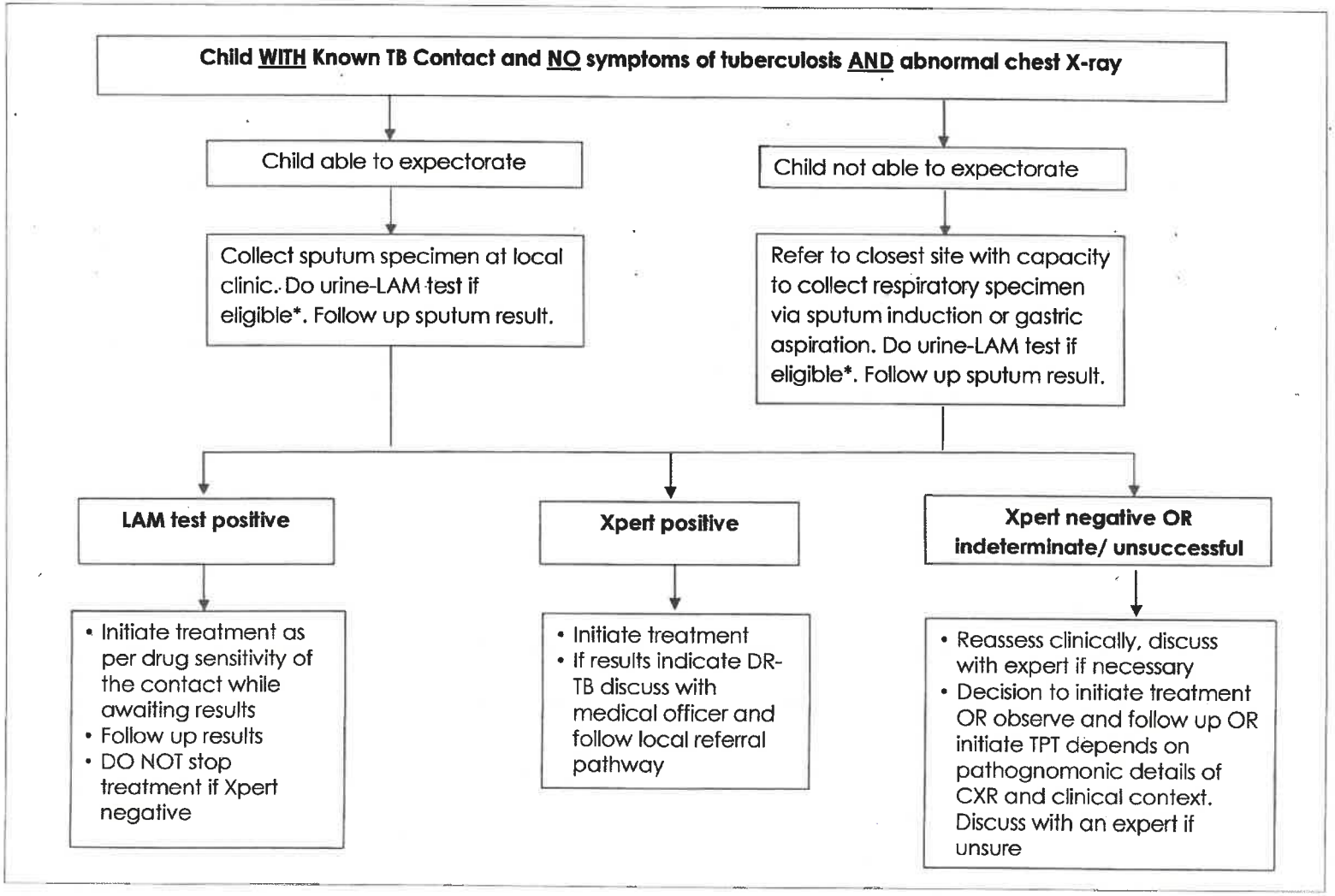
Date: 22/04/22

Annexure 1: Algorithm for child presenting with symptoms of TB with or without known TB contact and abnormal chest X-ray



*Refer to Guidance Document: Guidance on the use of urine LF-LAM for the diagnosis of people living with HIV. NDOH. April 2021

Annexure 2: Algorithm for child WITH known TB contact and NO symptoms of TB AND abnormal chest X-ray



*Refer to Guidance Document: Guidance on the use of urine LF-LAM for the diagnosis of people living with HIV. NDOH. April 2021

Annexure 4

Clinical Location/Area: ----------

Book: ----------of ----------

National Tuberculosis Control Programme

TB IDENTIFICATION REGISTER

2023 Version
GW20/13

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

END TB

FACILITY NAME :.....

YEAR: .....

START DATE: .....

END DATE: .....

AIM

The aim of this Register is to collect all the necessary information on clients who are **eligible** for TB test, to assist with the following:

1. Early identification and follow up of people diagnosed with TB who do not come back for their results.
2. Identification and follow-up of patients referred to hospital for further investigations
3. Monitoring the turnaround time for the laboratory results
4. Monitoring reporting of results and follow up of outstanding results with the laboratory
5. Estimating the laboratory supplies needed by the facility.

WHO SHOULD BE CAPTURED IN THIS REGISTER

1. All clients who report one or more TB symptoms as indicated in the TB screening tool
2. Clients who do not have TB symptoms but who screen positive for TB using other TB screening test e.g. abnormal chest X-ray suggestive of TB using DCXR, reactive TST in children using Mantoux test, etc.
3. All contacts of clients diagnosed with TB, clients living with HIV (including pregnant women on enrolment in ANC), people previously treated for TB in the past two (2) years, irrespective of the TB screening outcome.

COMPLETION OF THE TUBERCULOSIS IDENTIFICATION REGISTER

Ensure that all the relevant fields are completed

1. The 'Specimen Barcode Sticker' is the small barcode label on the laboratory request form. The label can be peeled off from the form and affixed in the appropriate row under this column.
2. Under Column "Physical home address/ landmark" write the full address of the client's home or that of an easily noticed building/ shop/ house/ landscape etc. which is nearest to the client's home.
3. A telephone or cellphone number of a client must be requested and documented, where is not available a cellphone number of a close (sibling, parent or a child) relative or a family friend must be recorded.
4. The Column "Positive TB screen" refers to results of positive TB screening tool recorded when the client screen positive from a screening tool, digital chest X-Ray suggestive of TB and Mantoux test reactive. write "Yes" (yes) in the top row, if the client reported any of the TB symptoms. Write "No" (no) if the client did not report any TB symptoms. In the bottom row record the code/s based on the symptoms reported by the individual as shown below:

   1 = Cough of any duration
   2 = Fever of more than 2 weeks
   3 = Unexplained loss of Weight/ Failure to thrive for children
   4 = Drenching night sweats
   5 = Fatigues or less playful for children
   6 = Positive TB Screening outcome from any TB screening tests (e.g. suggestive of TB, or reactive TST)

   If a client reports more than one symptom, use a semi colon (;) to separate the numbers.
5. Under the Column "TB Contact, write "Y" (yes) in the top row if the client has been in close contact with a person diagnosed with TB. Write "N" (no) if the client has no history of being in close contact with a person diagnosed with TB. In the bottom row of the same column indicate whether the index patient had drug susceptible TB (DS-TB) or drug resistant TB (DR-TB) or UNK if client

does not know the type of TB the index patient has (this is only for people who are contacts).

6. Under Column "HIV Status" write "Pos" if patient is a known HIV positive person, "Neg" if patient tested negative in the past six (06) months, "Unk" if the client does not know their HIV status, has never tested before, or tested more than 6 months ago and refuses to test for HIV.
7. Under Column "Previously treated for TB" write "Y" (YES) if client has been treated for TB within the past two years. Write "N" (no) if the client has not been treated for TB in the past two years.
8. Under Columns "Diabetes", "Pregnant", "Silicosis", only tick (√) for the client based on reported or known medical history or medical assessment.
9. Under Column "Xpert Test" use the top row to record the **first** specimen taken for testing. The date the specimen was collected must be entered in the "Date specimen collected" column and the date the results were received at the facility entered in the "Date Results received" column. The format for the date must be day, month and year as indicated in the register.
10. Under column "Xpert Test results" in the top row record the results of the first test conducted. Write "Pos" if the result is "MTB Detected", "Neg" If the result is "MTB Not Detected" and "Trace" if the result is "MTB Trace Detected". If the result of the first Xpert test is "Unsuccessful" write "Unsc", collect another specimen and record in the bottom row under "Xpert Test" column.
11. Where the first specimen sent for the Xpert test is unsuccessful (e.g. rejected by the laboratory due to leaked or insufficient specimen or contaminated), a second specimen must be collected and recorded in the bottom row under the column "Xpert Test".
12. Record the Xpert Rif susceptibility result under Column "Rif Resistance profile". Write "RS" if the Xpert result is Rifampicin susceptible, "RR" if the result is Rifampicin Resistant. If the rifampicin susceptibility testing is "Unsuccessful", write "RU" and collect a second specimen for Culture and DST, this must be recorded under the Column "Culture"
12 If a TB Culture Test is required with or without a drug susceptibility test, The date the specimen was collected must be entered under the column the "Date specimen collected" in the top row and record the date results received in the bottom row. Culture result must be recorded under the "Result" column. Write "Pos" if MTB was isolated on culture, "Neg" if MTB was not isolated on culture, "**Cont**" if the result is contaminated.
13 If the Line Probe Assay (LPA) or other Drug Susceptibility Testing (DST) are conducted following a positive culture, the results must be recorded under the "LPA/DST Results" Column. Write "RS" if the result is Rifampicin Susceptible, "RR" if Rifampicin Resistant under "RS/RR" Column. Similarly for Isoniazid, write "HS" if the result is Isoniazid susceptible and "HR" if Isoniazid resistant
14 If non-bacteriological tests are conducted, these must be recorded under the column "Non-Bacteriological Test". The date when the test was conducted must be recorded in the bottom row, the test result must be recorded in top row.
15 For Chest x-ray results write "Pos" (positive) if the result is abnormal chest x-ray suggestive of TB, "Neg" (negative) if normal Chest x-ray findings, under the "X-Ray result" Column.
16 For urine LF-LAM assay results, write "Pos" if the test is positive, "Neg" if the test is negative, under the "urine LF-LAM result" Column. Use the Remarks column to record the U-Lam Lot number & expiry date
17 If "Other tests" were conducted write the result of the test as positive "Pos" or Negative "Neg" in the top row and the date the test was requested/ specimen collected in the bottom row. Use the remarks column to record the name of the "other test conducted.
18 For all patients diagnosed with TB (DS-TB/DR-TB) the treatment start

date must be entered in the "TB Treatment Start Date" column in the correct format i.e. day, month, year. The treatment start date for patients referred to an MDR-TB Treatment site must be obtained from the site and recorded. The name of the treatment site must be recorded under the "Remarks" Column.

19 If the patient is reported or confirmed to have died before treatment start, place a tick (√) under the column "Died before treatment start" and record the date of death in the remarks column if known

20 If a patient cannot be found after failed attempts to trace him/ her, place a tick (√) under the column "Lost to follow up" and write the outcomes of the tracing under the "Remarks" column. The definition of loss to follow up in this case is a patient who missed an appointment for the results, traced but not found within a period of two weeks.

21 All clients eligible for TPT and started on TPT, the treatment start date must be recorded under the Column "TPT start date" in the correct format' i.e. day, month, year.

22 At the bottom of each page the totals must be calculated and entered in the last row labelled "Totals" for each of the relevant rows and indicated the register.

23 The person completing the register totals must write his/her name and sign at the bottom of each page.

24 The person who checks the data for correctness and completeness must write his/her name and sign at the bottom of each page as the verifier.

COMPLETION OF THE DATA SUMMARY SHEET

1. At the end of each register there is a data summary sheet. This must be completed at the end of each month.
2. The monthly summary sheet has been aligned with the reporting needs of the programme.
3. At the end of each quarter the data must be collated and submitted to the district as part of the quarterly reports.
4. The data summary sheets must be retained in the facility for audit/ data verification purposes.

HOW TO COMPLETE THE DATA SUMMARY SHEET

1. All clients recorded in the TB ID register are eligible for TB Test. Clients must be recorded longitudinally in the register irrespective of number of investigation conducted. Count each client once in the register.

2. Clients who screen positive for TB, has "Yes" in the column Positive TB Screen.

3. Under the column 'Clients tested using GXP", count each client once who has a Xpert test done. A client with two GXP tests, only the successful test must be counted. Clients who do not have Xpert test results must be excluded when reporting.

4. Count ALL clients tested using LF Lam. These clients may be reported also in tested using GXP as per the guidelines.

5. Under column DS TB Clients Bacteriologically confirmed, count all clients who has a positive GXP ,Culture or DST result for the reporting month. If a client has both positive bacteriological test and non-bacteriological, the client must be reported under bacteriologically confirmed. Bacteriological takes precedence over non bacteriological6. For DS TB Clinically diagnosed. Count each client who has been clinically diagnosed. These will be clients diagnosed with TB based on a positive non- bacteriological test, i.e. with no proof the presence of the TB bacteria by any laboratory test done in the lab, clinical presentation of the client and history of the client.

7. DS TB Confirmed Clients Total is the sum of all the DS TB Bacteriologically confirmed and DS TB Clinically diagnosed.

8. For DS-TB treatment started count all clients initiated on DS-TB treatment regardless of the diagnostic method (either bacteriological or clinically diagnosed).

9. RR-TB Started on treatment clients- count all clients who were initiated on RR-TB treatment.

10. Count all clients with a tick under died before treatment start and those with a tick under loss to follow up.

11. All TB contacts MUST be obtained from the contact line list monthly summary and be recorded under column TB contacts.

12. Count ALL contacts in the TB ID register, and record the total under column TB Contacts Traced

13 Count all contacts who have been initiated on TPT and the TPT initiation start date has been recorded in the TB ID register.

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TUBERCULOSIS IDENTIFICATION REGISTER

GW20/13

Version 2023

Sub District: _____

Quarter: _____

Specimen Barcode Sticker	Patient Folder Number/HPRN	Surname (Top row) / Name(s) (Bottom Row)	Date of birth (Top row) DD/MM/YYYY / Age (bottom row)	Gender M/F	Physical Home Address/ Land Mark	Nearest	Telephone / Celphone	Positive TB Screen Y/N (Top Row) / if Yes (Code) (bottom row)	Risk Groups: TB Contact Y/N (Top Row) / DS-TB/DR-TB/Unk (Bottom Row)	HIV Status (Pos/Neg/Unk)	Previously treated for TB (Y/N)	Diabetes Mellitus (Y/N)	Pregnant (Y/N)	Silicosis (Y/N)	TB Tests – Bacteriological Tests: Xpert test: Date Specimen collected DD/MM/YYYY	Xpert test: Date Result Received DD/MM/YYYY	Xpert Test Result (Pos/Neg/Trace/ Unsc)	Rif Resistance profile RR/RS/RU	Culture: Date specimen collected / Date result received	Culture: Result (Neg/Pos/ Cont)	LPA/DST Results: RR/RS	LPA/DST Results: HR/HS	Non-Bacteriological tests: X-Ray Result (top row) / Date DD/MM/YYYY (bottom row)	Urine LF-LAM Result (Pos/Neg) (top row) / Date DD/MM/YYYY (bottom row)	Other Tests Results (top row) / Date DD/MM/YYYY (bottom row)	TB Diagnosed (DS-TB and DR-TB): TB treatment Start Date DD/MM/YYYY	Died before Treatment Start (Yes)	Lost to follow-up (Yes)	TPT Start Date DD/MM/YYYY	Remarks Urine LF- LAM assay Lot Number (if conducted)
TOTALS:																															

1 Place /Stick/Barcode from laboratory specimen form, eg. AAGX3450

2. HPRN is system generated number from HPRS

3 Full detailed adress of where the patient can be traced during the day/s landmark (where the client do not have a formal adress, easily recognizable building, shop or house nearest to the patient's place of residence can be used) next to where the patient resides.

4. Use the coding below for TB symptoms 1
= Cough; 2 =
Fever of more than 2 weeks, 3=
Unexplained weight loss/Failure to thrive in children; 4 =
Drenching night sweat, 5.
Positive Screening test outcome

5. Write down the date on when the patient produced a specimen

6. Date when the sputum results were received by the facility i.e. either hard copy, lab track or telephonic

7. Date treatment started - TB treatment card was opened

8. Write the date when TPT was started

9. Write urine LF-LAM test Lot number (where this was conducted), this is found on the left side of the test strip card. Can also write patient referral details, date of death (if available), name of additional test requested to make a diagnosis or other relevant comments

Compiled by: _____ Signature: _____ Date: _____

Verified by: _____ Signature: _____

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SUMMARY FOR TB DETECTION

GW20/13
Version 2023

Year: _____		Number of client eligible for TB test			Number of Clients with Positive TB Screen		Number of client tested for TB using Xpert		Number of Clients tested for TB using LF-Lam		DS-TB Confirmed Clients						RR-TB Bacteriologically confirmed	TB Treatment Initiation				Number of clients died before treatment start		Number of clients lost to follow up before Treatment Start		TB Contacts Identified		TB Contacts Traced		Number of Contacts started on TPT	
											Bacteriologically Confirmed		Clinically Confirmed		Total			DS-TB Treatment Start		RR-TB Tratment Start											
		Total	< 5yrs	≥ 5yrs	<5 yrs	≥5 yrs	<5yrs	≥5yrs	< 5 yrs	≥5yrs	<5yrs	≥5yrs	<5yrs	≥5yrs	<5yrs	≥5yrs		<5yrs	≥5yrs	<5yrs	≥5yrs	< 5 yrs	≥ 5yrs	< 5 yrs	≥ 5yrs	< 5 yrs	≥ 5yrs	< 5 yrs	≥ 5yrs	< 5 yrs	≥ 5yrs
Quarter 1	January																													
	February																													
	March																													
Total																														
Quarter 2	April																													
	May																													
	June																													
Total																														
Quarter 3	July																													
	August																													
	September																													
Total																														
Quarter 4	October																													
	November																													
	December																													
Total																														

Compiled by: Name & Surname: _____ Date: _____

Verified by: Name & Surname: _____ Date: _____

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