Western Cape Government

DEPARTMENT OF HEALTH
Chief Directorate: Emergency & Clinical Services Support
Directorate: Service Priorities Coordination
Enquiries: A Van Zyl/ N Firfirey/ V Mudaly
Enquiries: Vanessa.mudaly@westerncape.gov.za
or Nousheena.firfirey@westerncape.gov.za or
Alice.vanZyl@westerncape.gov.za
Tel: 021 815 8741

CHIEF DIRECTORS:	**METRO HEALTH SERVICES, RURAL HEALTH SERVICES, STRATEGY**
DIRECTOR:	**CITY HEALTH**
DIRECTORS:	**DISTRICTS AND SUB-STRUCTURES, MEDICINE MANAGEMENT**
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CIRCULAR H.64/2023

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 3 months **(Close contact** is a person who shared an enclosed space, such as a social gathering place, workplace, congregate setting or household, **for more than 15 minutes over a period of 24 hours with a person diagnosed with TB** (index patient), during the 3 months before the index patient commenced TB treatment.)

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

JO Arendse
Chief Director: Emergency and Clinical Services Support (ECSS)
Date: 24 May 2023

Western Cape Government

Annexure 1: TB screening and Testing Standard Operating Procedure attached

Annexure 2

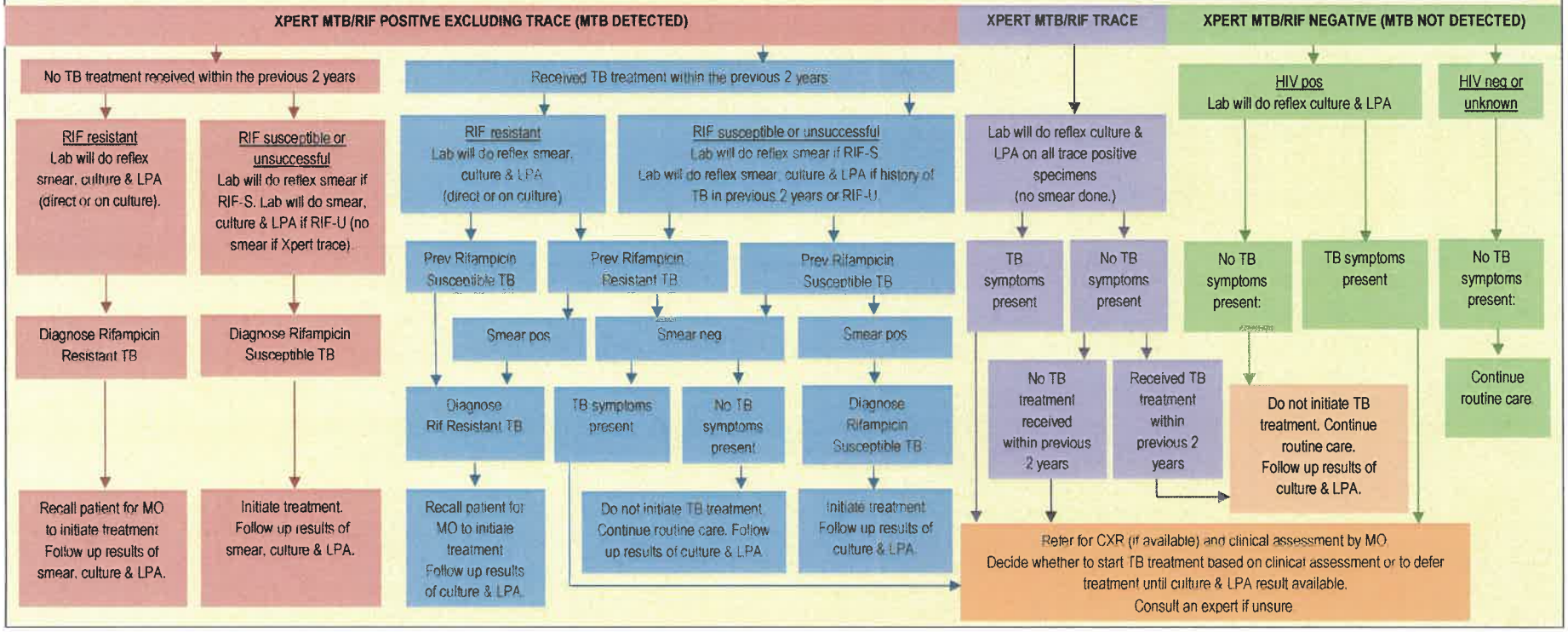
XPERT MTB/RIF ULTRA DIAGNOSTIC ALGORITHM FOR PULMONARY TB

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

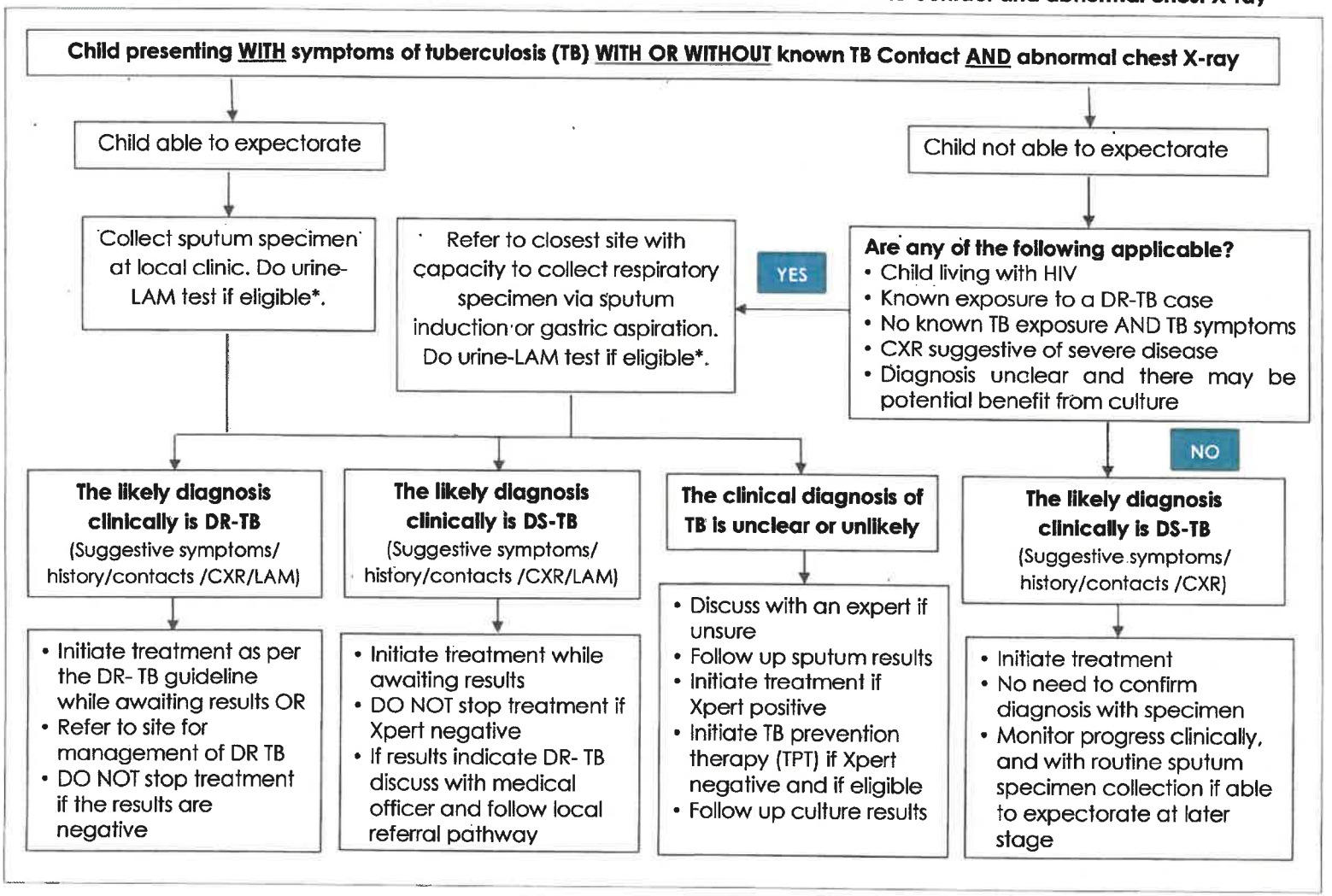
The recommendations of the rapid guide can be implemented with immediate effect.

Ms KB Lowenherz

Acting Chief Director: ECSS

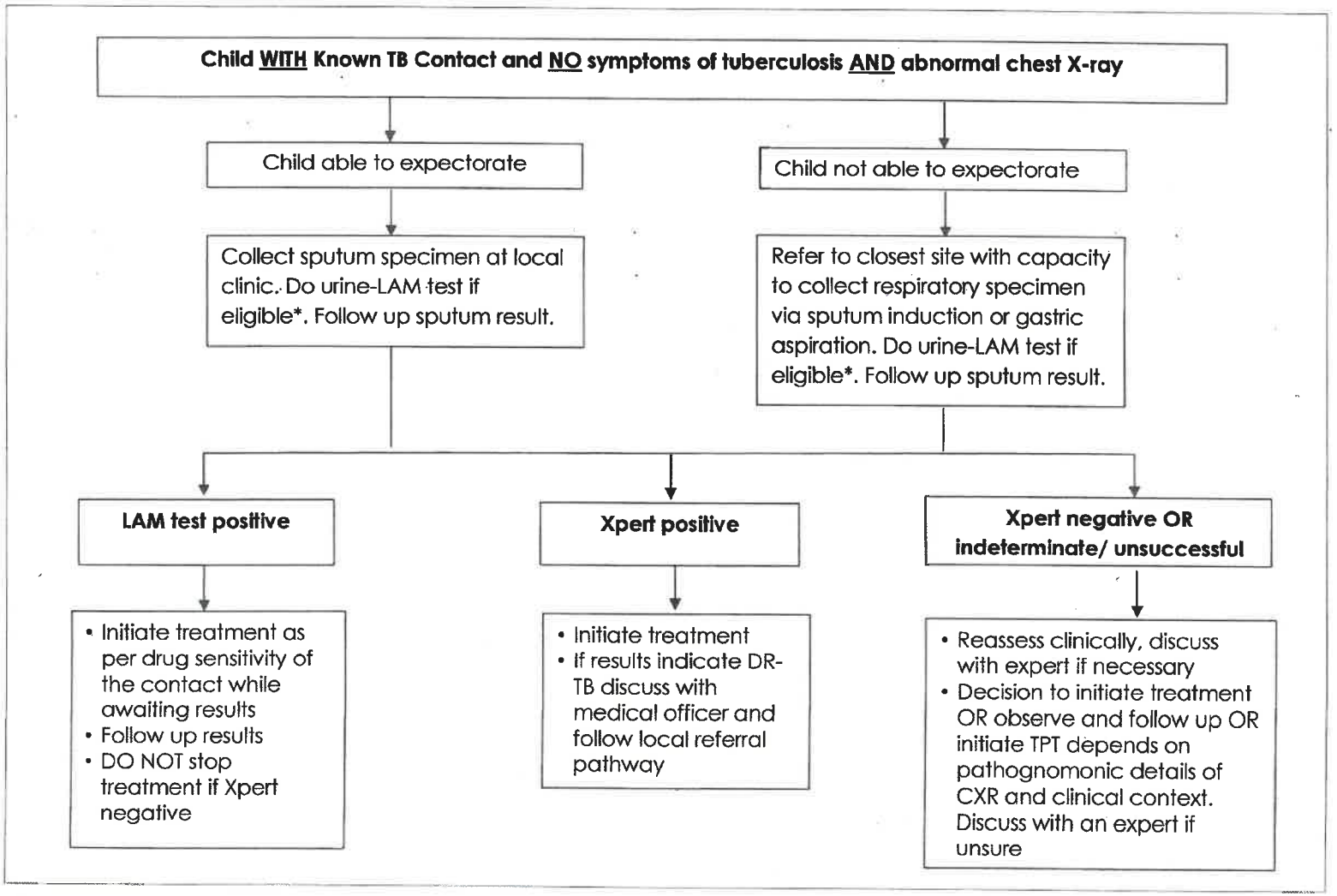
Date: 22/04/22

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(#) (Bottom Row)	Date of birth (Top row) DD/MM/YYYY Age (bottom row)	Gender M/F	Physical Home Address/ Nearest Land Mark	Telephone / Cellphone	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 Tested 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: R/RRS	LPA/DST Results: H/RHS	TB Tests: 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 Article/Barcode from laboratory specimen form, eg. AAQ18459

2. HPRN is system generated number from HPRS

3. Put detailed address of where the patient can be traced during the days (landmark (where the client do not have a formal address , easily recognizable building, shop or house nearest to the patient's place of residence can be used) near 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 = Sweanding: night sweat.
5. Positive Screening test outcome

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

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

7. Date treatment started - TB treatment card was started

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	
											Bacteriologicall y 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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