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சுவசிரிபாய
SUWASIRIPAYA

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எனது இல) NPTCCD/HRG/LTBI/2021/90
My No)

ඔබේ අංකය)
உமது இல)
Your No.)

දිනය)
திகதி) 2021/12/05
Date)

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சுகாதார அமைச்சு
Ministry of Health

General Circular Number.....01.-44./2021

All Deputy Director Generals of Health Services,
All Provincial Directors of Health Services,
All Regional Directors of Health Services,
All heads of Decentralized Units/ Special Campaigns,
All the heads of Health Institutions,
Director, National Institute of Health Sciences,
CMOH Colombo Municipal Council,

Guideline on Management of Latent Tuberculosis Infection (LTBI)

Sri Lanka being a country with low Tuberculosis (TB) incidence, less than 100 cases per 100,000 population, is on its way to achieve global end TB targets. The WHO's end TB strategy requires diagnosis and treatment of Latent Tuberculosis Infection (LTBI) at a wider scale. LTBI is defined as a state of persistent immune response to stimulation by Mycobacterium tuberculosis antigens with no evidence of clinically manifested active TB. Nearly one-third of the world's population is infected with TB, and the prevalence rate of LTBI in low- or middle-income countries is estimated to be as high as 51.5% of the population. Proper treatment of LTBI can reduce the risk of developing active TB by 60-90%. Considering the local epidemiology and feasibility, LTBI screening and treatment will be carried out in a phased-out manner. First phase of implementation will be from 2022 to 2024 and in this phase following risk groups will be considered after excluding active TB.

	Risk Group	Time line
1	People Living with HIV (PLHIV)	Already in practice. To be continued as per LTBI guideline (Management of LTBI NPTCCD 2021) from 2022 Refer Annex 1 A and 1 B
2	HIV-negative close contacts of a person with pulmonary TB who is either bacteriologically confirmed or clinically diagnosed. <ul style="list-style-type: none"> • Contacts below 5 years • Contacts 5 - < 15 years • Contacts ≥50 years. • Contacts (15 to 50 years) of a person with pulmonary TB 	<p>Already in practice for contacts of bacteriologically confirmed PTB patients. To be continued as per LTBI guideline (Management of LTBI NPTCCD 2021) from 2022 Refer Annex 1 D</p> <p>To be implemented as per LTBI guideline (Management of LTBI NPTCCD 2021) from 2022 Refer Annex 1 C</p> <p>To be implemented as per LTBI guideline (Management of LTBI NPTCCD 2021) from 2023 Refer Annex 1 C</p>
3	HIV-negative clinical at-risk groups <ul style="list-style-type: none"> • Patients receiving dialysis • Patients preparing for solid organ or hematopoietic stem cell transplantation • Patients receiving anti- TNF alpha therapy • Patients with silicosis 	<p>Screening and management should be done as per LTBI guideline (Management of LTBI NPTCCD 2021) Refer Annex 1 E</p> <p>To be considered depending on the resource availability and treating Consultant's opinion</p>

A thorough risk assessment is recommended before initiating LTBI management. The parameters to be assessed are **status of the infectiousness of the index case, type of the contacts - household/non-household/duration of the contact, age of the patient, co – morbidities, drug history and history of allergies.** The opinion of consultant respiratory physician or relevant specialist should be obtained before initiating LTBI treatment for clinical risk groups and for contacts with co morbidities as per LTBI guideline. Please refer Annex 2.

Kindly advocate all clinicians and other relevant officers in your institutions to identify the patients who belong to above mentioned categories in order to carry out following actions;

People Living with HIV (PLHIV) will be screened at the District Chest Clinic (DCC) or relevant STD clinic (if facilities available). Existing TB HIV 2 format should be used for reporting to the chest clinic. LTBI management will be initiated at DCC and follow up will be carried out either in DCC/branch clinic or relevant STD clinic depending on the feasibility.

HIV-negative close contacts of a person with pulmonary TB will be screened and treatment for LTBI will be initiated at DCC/branch clinic. They will be followed up at same DCC/branch clinic.

HIV negative other clinical risk groups. During this phase clinical risk groups will be screened based on treating clinician's judgement. Screening of patients will be done at DCC or relevant specialized clinic once trained staff are available. LTBI management will be initiated at DCC and follow up will be carried out either in DCC/ branch clinic or the relevant specialized clinic depending on the feasibility.

Following investigations are recommended to diagnose LTBI and both tests are recommended as equivalent options.

- **Tuberculin Skin Test (TST).**
- **Interferon Gamma – release assay (IGRA)** This test is currently not available in the government sector. NPTCCD is planning to establish this facility at National Tuberculosis Reference laboratory (NTRL) – Welisara in near future.

Proper record keeping should be maintained at all DCCs for persons who are screened, persons who are found to have LTBI and persons who are started treatment. Status of LTBI screening and outcomes should be reported to the NPTCCD on a quarterly basis. Following are the records and reports that should be maintained at DCCs.

LTBI 01: LTBI Screening Record LTBI (**Annexure 3**)

LTBI 02: Treatment Card (**Annexure 4**)

LTBI 03: LTBI DOTS Card (**Annexure 5**)

LTBI 04: LTBI Treatment Record (**Annexure 6**)

LTBI 05: District LTBI Screening Register (**Annexure 7**)

LTBI 06: District LTBI Treatment Register (**Annexure 8**)

LTBI 07: Quarterly Return on LTBI Screening and Case Finding (**Annexure 9**)

LTBI 08: Quarterly Return on treatment outcome of persons started on LTBI treatment of patients registered 12-15 months earlier (**Annexure 10**)

Your kind cooperation to implement LTBI management will be highly appreciated.
For further details, please refer the LTBI guideline (<https://www.nptccd.health.gov.lk/>) or contact NPTCCD
(Tel:0112368386) /DCC.



Dr. Asefa Gunawardana
Director General of Health Services

Dr. ASELA GUNAWARDENA
Director General of Health Services
Ministry of Health
"Suwasiripaya"
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Colombo 10.

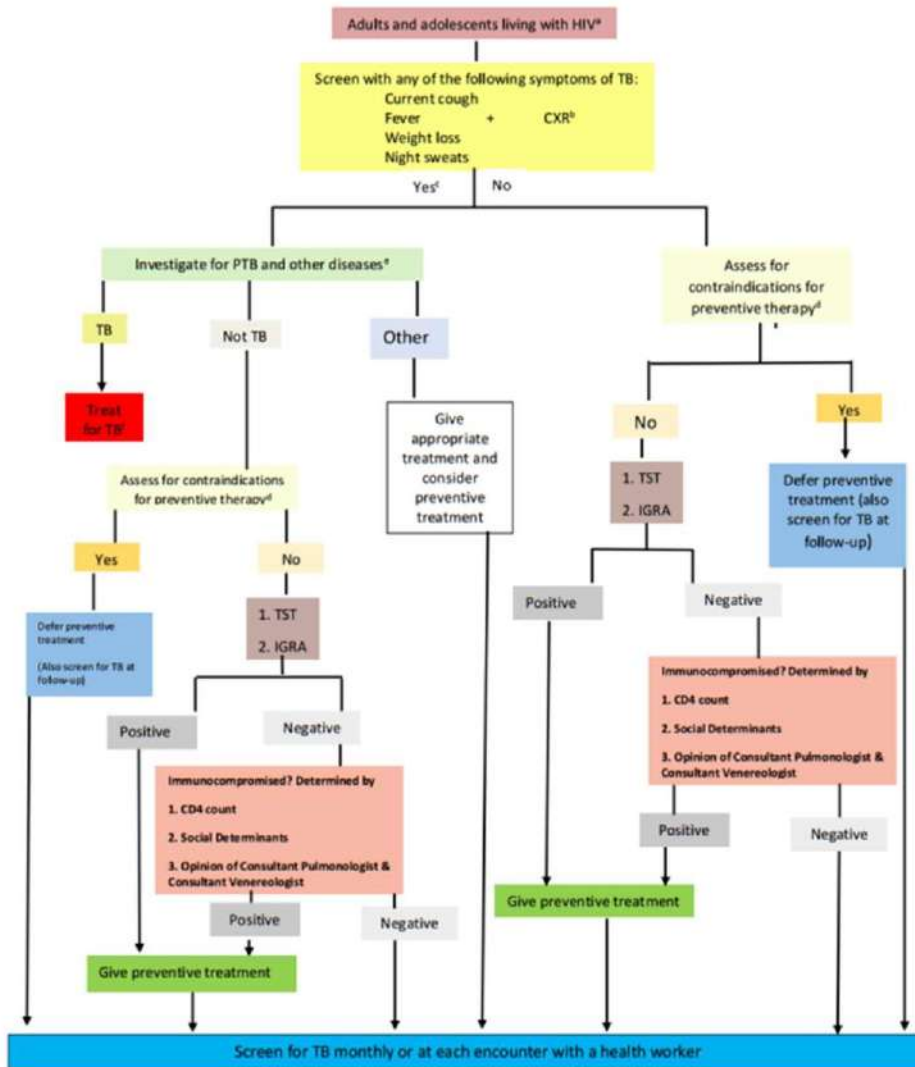
Copies:

President, Sri Lanka College of Pulmonologists
President, Sri Lanka College of Physicians
President, Sri Lanka College of Sexual Health and HIV Medicine
President, Sri Lanka College of Nephrologists
President, Sri Lanka College of Microbiologists
President, Sri Lanka College of Rheumatologists
President, Sri Lanka College of Surgeons
President, Sri Lanka College of Paediatricians
President, Sri Lanka College of Haematologists
President, Sri Lanka College of Oncologists
District Tuberculosis Control Officers

Annexure 1 -Algorithms for management of LTBI

Annexure 1 A. People Living with HIV (PLHIV) - All adults and adolescents including those who have previously been treated for TB and pregnant women living with HIV

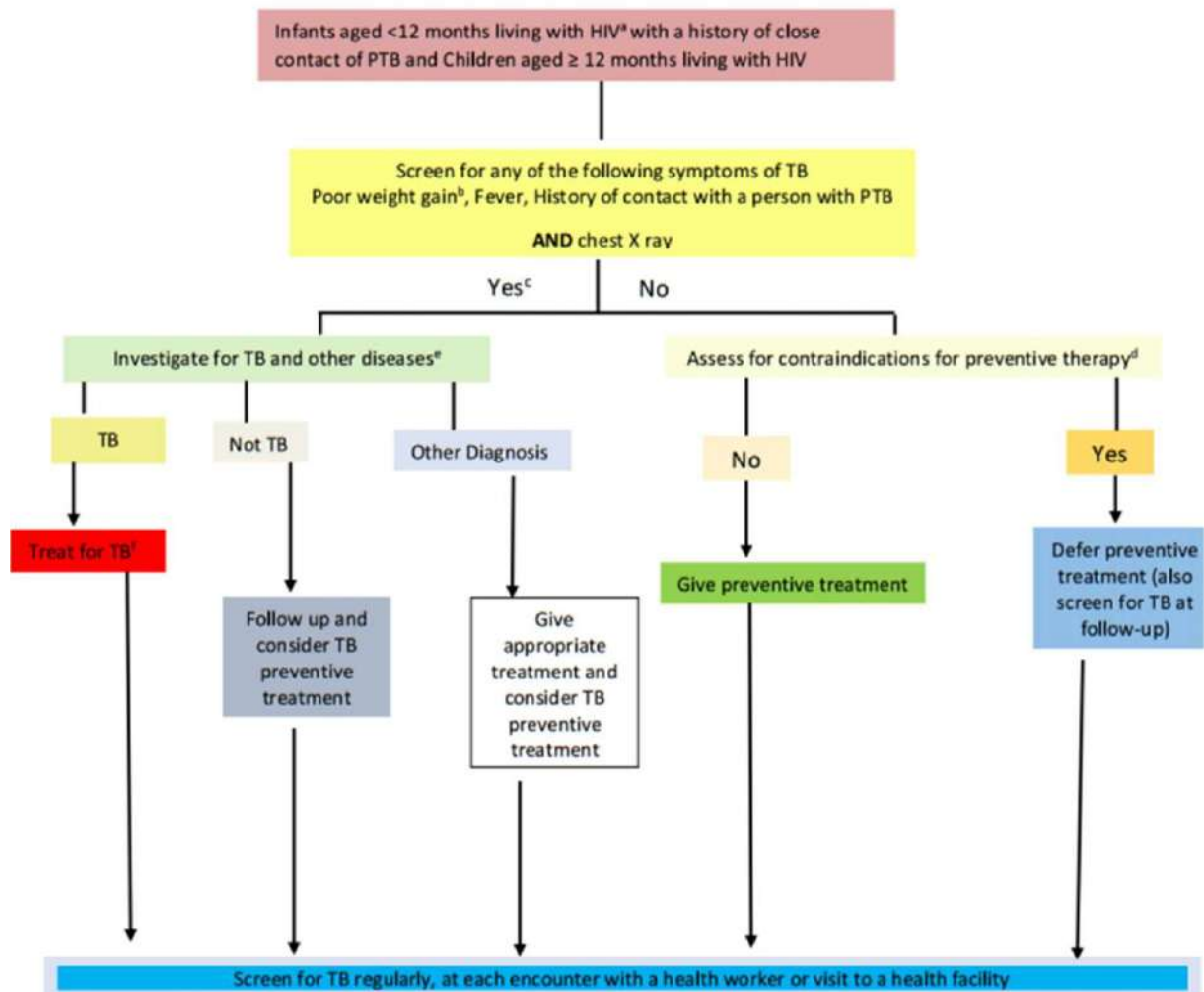
Algorithm for screening Adults and adolescents living with HIV for LTBI



- Every adult and adolescent should be evaluated for eligibility to receive ART. Infection control measures should be prioritized to reduce *M. tuberculosis* transmission in all settings in which care is provided.
- Chest radiography is included in the initial screening tool / can be done if available, particularly for people living with HIV on ART, but is not required to classify patients into TB and non-TB groups.
- Either symptoms or Xray or both are suggestive of TB or other diseases
- Contraindications include: active hepatitis (acute or chronic), regular and heavy alcohol consumption and symptoms of peripheral neuropathy. History of TB and current pregnancy should not be contraindications for starting preventive treatment.
- Xpert MTB/RIF should be used as the initial diagnostic test for TB.
- Resume regular screening for TB reactivation after completion of treatment for active TB disease.

Annexure 1 B. People Living with HIV (PLHIV) - Infants aged < 12 months, and are in contact with a case of PTB and Children aged ≥12 months, even when there is no contact with a case of TB

Algorithm for screening Infants and children living with HIV for LTBI



a. All infants < 1 year of age should be given preventive treatment if they have a history of household contact with a TB case.

b. Poor weight gain is defined as reported weight loss, very low weight-for-age (< -3 z-score), underweight (weight-for-age < -2 z-score), confirmed weight loss (> 5%) since the last visit or growth curve flattening.

c. Either symptoms or CXR abnormality or both are suggestive of TB or other diseases

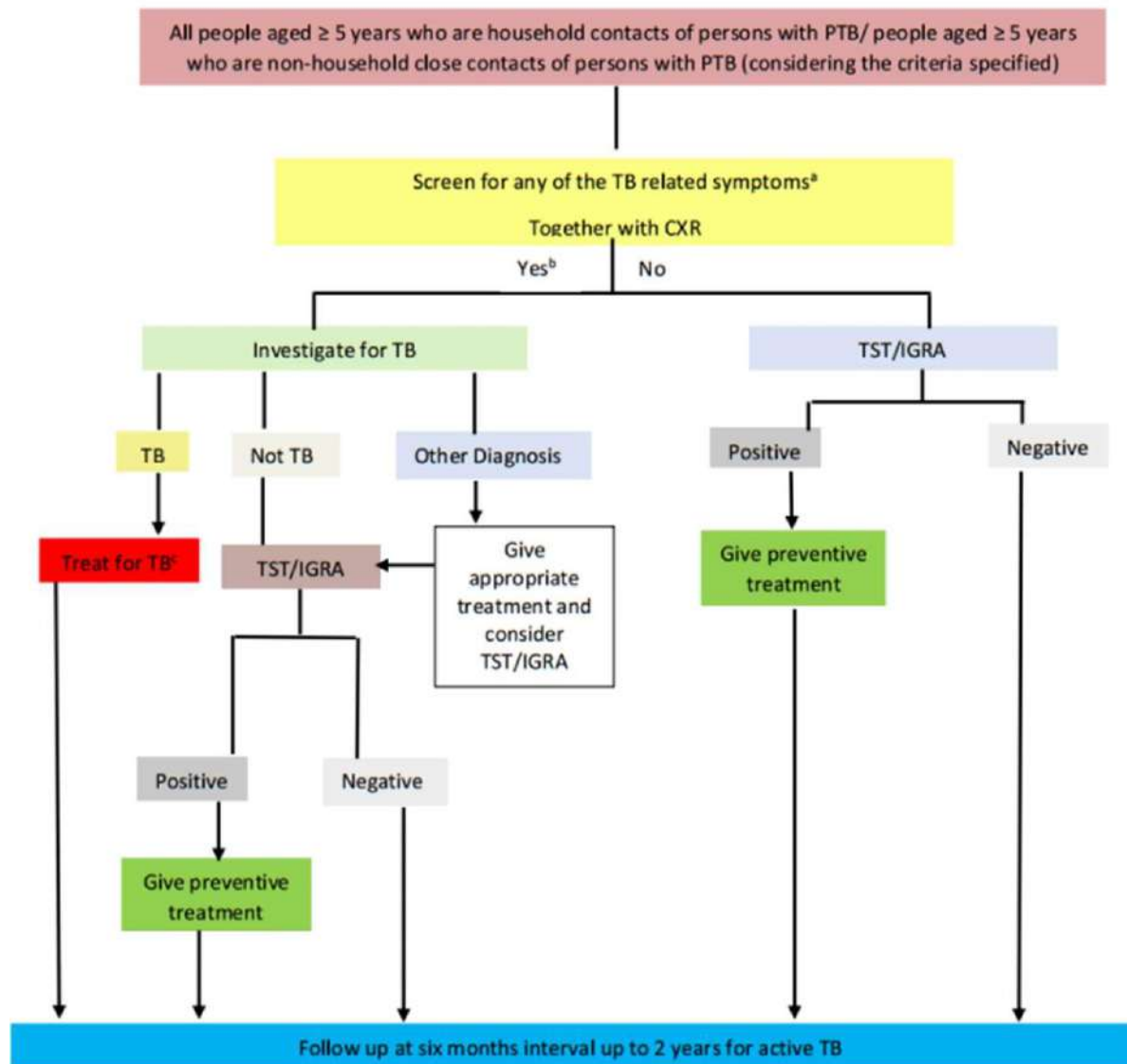
d. Contraindications include active hepatitis (acute or chronic) and symptoms of peripheral neuropathy. A past history of TB should not be a contraindication for starting preventive treatment

e. Xpert MTB/RIF should be used as the initial diagnostic test for TB

f. Resume regular screening for TB reactivation after completion of treatment for active TB disease..

Annexure 1 C. HIV-negative close contacts of a person with pulmonary TB who is either bacteriologically confirmed or clinically diagnosed – all people aged ≥ 5 years who are household contacts of persons with PTB/ people aged ≥ 5 years who are non-household close contacts of persons with PTB

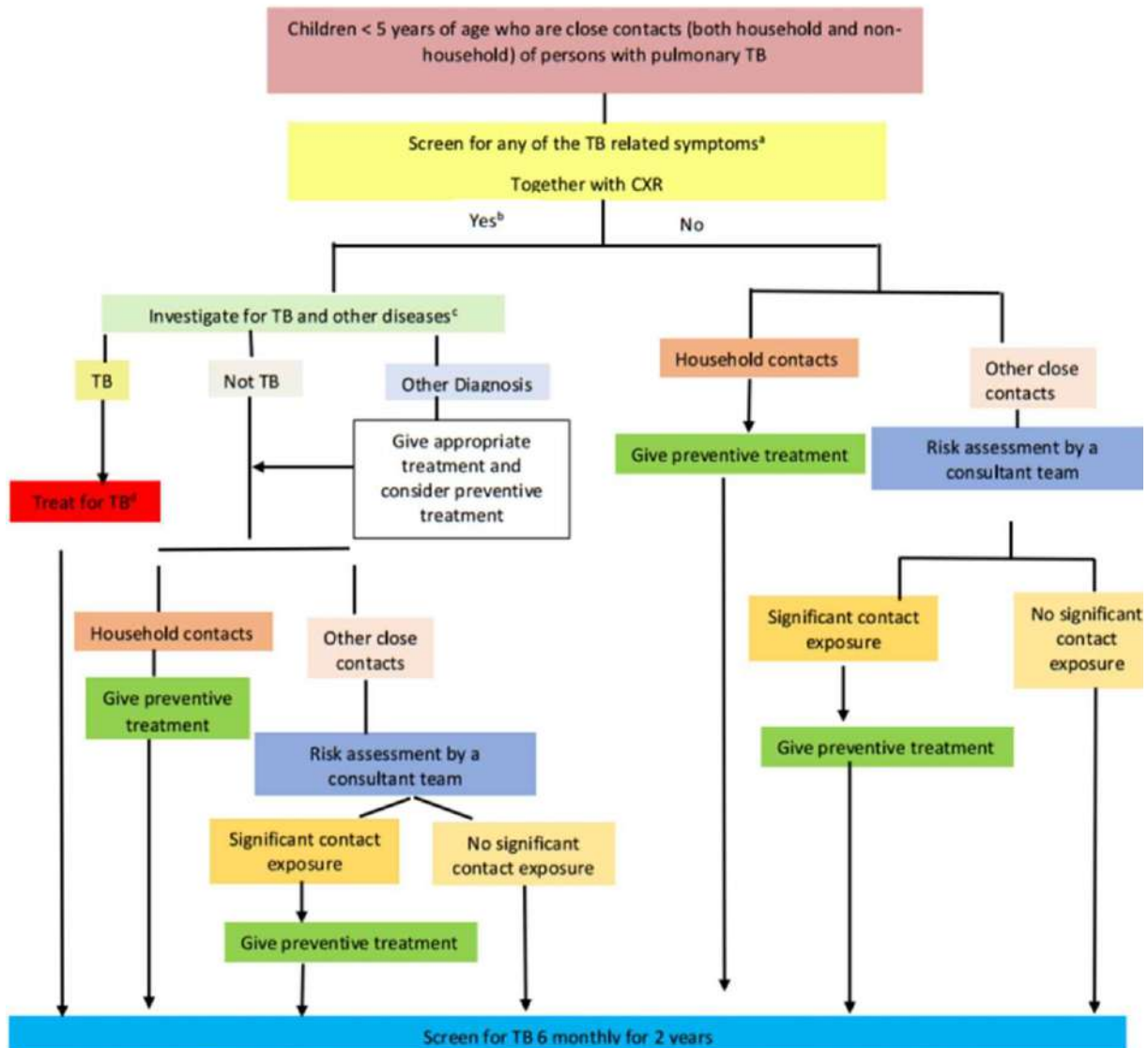
Algorithm for screening HIV-negative aged ≥ 5 years who are household contacts of PTB cases for LTBI



- a. Any symptom of TB: cough, hemoptysis, fever, night sweats, weight loss, chest pain, shortness of breath, fatigue.
- b. Either symptoms or CXR or both are suggestive of TB or other diseases.
- c. Resume regular screening for TB reactivation after completion of treatment for active TB disease..

Annexure 1 D. HIV-negative close contacts of a person with pulmonary TB who is either bacteriologically confirmed or clinically diagnosed – Children < 5 years of age who are close contacts (both household and non-household) persons with pulmonary TB

Algorithm for screening HIV-negative infants and children < 5 years of age who are close contacts of PTB cases for LTBI



a. The commonest TB-related symptoms are persistence of: cough, fever, not eating well/anorexia, weight loss/poor weight gain, reduced playfulness and decreased activity. Poor weight gain is defined as reported weight loss, very low weight-for-age (< -3 z-score), underweight (weight-for-age < -2 z-score), confirmed weight loss (> 5%) since the last visit or growth curve flattening.

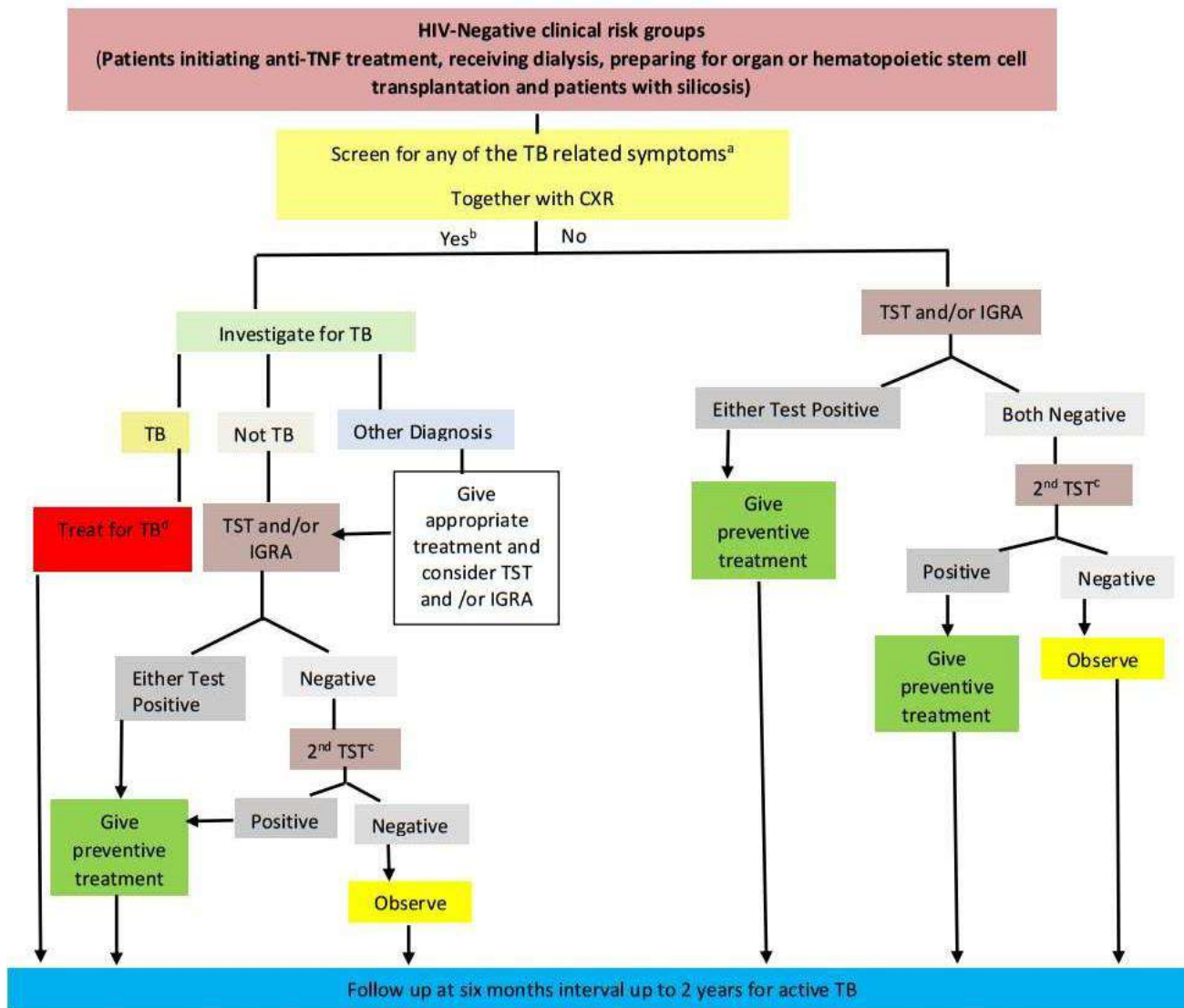
b. Either symptoms or Xray or both are suggestive of TB or other diseases

c. Xpert MTB/RIF should be used as the initial diagnostic test for TB.

d. Resume regular screening for TB reactivation after completion of treatment for active TB disease..

1.E. HIV-negative other at-risk groups - Patients on anti TNF alpha therapy, patients receiving dialysis, patients preparing for organ or haematopoietic stem cell transplantation and patients with silicosis

Algorithm for screening HIV Negative Clinical Risk Groups for LTBI



- Any symptom of TB: cough, hemoptysis, fever, night sweats, weight loss, chest pain, shortness of breath, fatigue
- Either symptoms or chest Xray or both are suggestive of TB or other diseases.
- If unable to perform IGRA or both initial TST and IGRA are negative perform 2nd TST. (As part of two step TST Refer page 44)
- Resume regular screening for TB reactivation after completion of treatment for active TB disease..

Annexure 2 - Recommendations of treatment options for identified LTBI patients in Sri Lanka, by risk category

Risk category	Treatment options			Remarks
	6H	3HR	3HP	
				Despite lack of strong evidence to recommend a single regimen, shorter regimen is preferred whenever possible
Adults and adolescents living with HIV	X	X	X	To be decided by an expert on the use of rifampicin containing regimen depending on the ART regimen
Children living with HIV	X	X	X	To be decided by an expert on the use of rifampicin containing regimen depending on the ART regimen
Adults and adolescents with LTBI who are contacts of PTB	X	X	X	
Children <5 who are contacts of PTB	X	X	X	
Non- Household close contacts			X	
Patients initiating anti-TNF treatment diagnosed with LTBI	X	X	X	To be decided by an expert
Patients receiving dialysis diagnosed with LTBI	X	X	X	To be decided by an expert
Patients undergoing organ or hematological transplantation diagnosed with LTBI	X	X	X	To be decided by an expert
Patients with silicosis diagnosed with LTBI	X	X	X	To be decided by an expert

“X”- Preferred regime

Annexure 3 – LTBI 01: LTBI screening record



National Programme for Tuberculosis Control and Chest Diseases

LTBI Screening Record	Chest Clinic		Date of Screening	
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GENERAL INFORMATION			
District LTBI screening no/Standard card no:			
Name of patient:			
Date of birth:		Age:	
Sex:	Male <input type="checkbox"/> Female <input type="checkbox"/>	Contact number:	
Complete address			
Past TB history:			

Presumptive LTBI category			
HIV positive	PLHIV		<input type="checkbox"/>
HIV negative	Close contacts	Close contact of TB patient – (Age <5 years)	<input type="checkbox"/>
		Close contact of TB patient – (Age >5 years)	<input type="checkbox"/>
		If close contact, DTB no of index TB patient	
	Clinical risk groups	Patient on treatment with anti-TNF alpha	<input type="checkbox"/>
		Patient on treatment with non-anti-TNF alpha biologics	<input type="checkbox"/>
		Patient receiving dialysis	<input type="checkbox"/>
		Patient preparing for solid organ transplantation	<input type="checkbox"/>
		Patient preparing for Hematopoietic stem cell transplantation	<input type="checkbox"/>
	Other vulnerable groups	Patients with silicosis	<input type="checkbox"/>
		Healthcare workers	<input type="checkbox"/>
	Prisoners	<input type="checkbox"/>	

CLINICAL FEATURES	
Symptoms (If any)	
Signs (If any)	

INVESTIGATIONS				
Investigation	Report number	Results	Date test done (dd/mm/yyyy)	Date of results (dd/mm/yyyy)
TST				
IGRA		Positive/Negative/Indeterminate		
CXR				
Sputum AFB				
GeneXpert				
Any other (specify)				

SCREENING OUTCOME		
Active TB	Positive	<input type="checkbox"/>
	Negative	<input type="checkbox"/>
LTBI	Positive	<input type="checkbox"/>
	Negative	<input type="checkbox"/>

MANAGEMENT			
Action	Date	DTB/LTBI No	
Registered for TB Treatment	<input type="checkbox"/>		
Registered for LTBI Treatment	<input type="checkbox"/>		
Other (Specify)	<input type="checkbox"/>		

Annexure 4 – LTBI 02: LTBI Treatment Card



National Programme for Tuberculosis Control and Chest Diseases

LTBI Treatment Card

Chest Clinic		DTCO Contact No	
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Full Name			
District LTBI No			
Age		Sex	
Complete Address			
Mobile No			

Date	Investigation	Results
	TST	
	IGRA	
	Other (specify)	

Treatment regimen		Date started
3HP	<input type="checkbox"/>	
3HR	<input type="checkbox"/>	
6H	<input type="checkbox"/>	
Other	<input type="checkbox"/>	



Date of appointment	Date attended	Signature of clinician	Comments

Outcome		Date
Treatment completed	<input type="checkbox"/>	
Treatment failed	<input type="checkbox"/>	
Died	<input type="checkbox"/>	
Lost to follow up	<input type="checkbox"/>	
TPT discontinuation due to toxicity	<input type="checkbox"/>	
Not Evaluated	<input type="checkbox"/>	

Annexure 5 – LTBI 03: LTBI DOTS Card



National Programme for Tuberculosis Control and Chest Diseases

LTBI DOTS Card			District LTBI Number	Chest Clinic																											
Name			Age																												
Complete Address			Sex		M <input type="checkbox"/> F <input type="checkbox"/>																										
LTBI Regimen			Contact Number																												
3HP <input type="checkbox"/>			3HR <input type="checkbox"/>		DOT Center																										
6H <input type="checkbox"/>			Other																												
DRUG ADMINISTRATION CHART																															
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month																															

Mark '✓' for supervised administration, 'S' for supply for self-administration & '0' for treatment interruption

Annexure 6 – LTBI 04: LTBI Treatment Record



National Programme for Tuberculosis Control and Chest Diseases

LTBI Treatment Record

Chest Clinic	
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GENERAL INFORMATION						
District LTBI no:						
Name of patient:						
Date of birth:		Age:				
Sex:	Male <input type="checkbox"/>	Female <input type="checkbox"/>	Contact number:			
Complete address						
HISTORY						
Symptoms:						
Past TB history:						
Past medical history:						
Past surgical history:						
Drug allergies:						
Food allergies:						
Smoking	Present	<input type="checkbox"/>	Past	<input type="checkbox"/>	Never	<input type="checkbox"/>
Alcohol	Present	<input type="checkbox"/>	Past	<input type="checkbox"/>	Never	<input type="checkbox"/>
Illicit drugs	Present	<input type="checkbox"/>	Past	<input type="checkbox"/>	Never	<input type="checkbox"/>
EXAMINATION						
Weight		Height				
General examination:						
Cardiovascular system:	BP:					
Respiratory system:						
Any other significant finding:						

INVESTIGATIONS				
Investigation	Results		Date test done (dd/mm/yyyy)	
TST	In mm 1. 2. 3.			
IGRA (IFN gamma)	Positive	<input type="checkbox"/>		
	Negative	<input type="checkbox"/>		
	Indeterminate	<input type="checkbox"/>		
CXR				
Sputum AFB				
GeneXpert				
Any other (specify)				
Any other (specify)				
DIAGNOSIS OF LTBI				
Date of diagnosis (dd/mm/yyyy):		Date of registration (dd/mm/yyyy):		
LTBI category				
HIV positive	PLHIV		<input type="checkbox"/>	
HIV negative	Close contacts	Close contact of TB patient – (Age <5 years)	<input type="checkbox"/>	
		Close contact of TB patient – (Age >5 years)	<input type="checkbox"/>	
		If contact, DTB number of index TB patient		
	Clinical risk groups	Patient on treatment with anti-TNF alpha		<input type="checkbox"/>
		Patient on treatment with non-anti-TNF alpha biologics		<input type="checkbox"/>
		Patient receiving dialysis		<input type="checkbox"/>
		Patient preparing for solid organ transplantation		<input type="checkbox"/>
		Patient preparing for Hematopoietic stem cell transplantation		<input type="checkbox"/>
		Patients with silicosis		<input type="checkbox"/>
	Other vulnerable groups	Healthcare workers		<input type="checkbox"/>
Prisoners		<input type="checkbox"/>		

MANAGEMENT					
Date treatment started (dd/mm/yyyy):					
Drug Treatment					
Regimen	Frequency	Duration	Dose		
			Isoniazid	Rifapentine	Rifampicin
3HP					
3HR					
6H					
Other: 1HP/9H/36H/3-4HR					
Other drugs					
Drug	Dose	Frequency	Duration		
DOTS					
DOT center:					
Name of the DOT provider:					
Designation of the DOT provider:					
Contact Number of DOT provider:					
Health Education					
Area				Date given	
Disease process					
Rationale for medication in the absence of symptoms and normal CXR					
Treatment duration					
Importance of continuing treatment for LTBI					
Possible side effects and steps to follow in a case of a side effect					

DRUG ADMINISTRATION CHART

Day Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31			

Mark '✓' for supervised administration, 'S' for supply for self-administration & '0' for treatment interruption

FOLLOW UP VISITS			
Due Date:		Date attended:	
Complaints if any:			
Symptoms suggestive of TB disease		Duration	
Cough	<input type="checkbox"/>		
Low grade fever	<input type="checkbox"/>		
Loss of appetite	<input type="checkbox"/>		
Malaise	<input type="checkbox"/>		
Any other (specify)	<input type="checkbox"/>		
Signs suggestive of TB disease			
General examination:			
Respiratory system examination:			
Investigation Results			
Investigation	Date	Result	
Adverse Effects			
Effect	Possible Drug	Action	
Investigation Requests		Prescriptions	
Remarks:			

TREATMENT OUTCOME			
Outcome		Date	Comments
Treatment completed (Completed the treatment within due period)	<input type="checkbox"/>		
Treatment failed (Development of active TB while on TPT)	<input type="checkbox"/>		
Died (Death due to any reason while on LTBI treatment)	<input type="checkbox"/>		
Lost to follow up (2 consecutive months for H, one month for HP and HR)	<input type="checkbox"/>		
TPT discontinuation due to toxicity	<input type="checkbox"/>		
Not Evaluated (Please mention reason)	<input type="checkbox"/>		

Remarks:	
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Annexure 7 – LTBI 05: District LTBI Screening Register

District LTBI Screening Register																		
Date of screening	LTBI Screening No ¹ /Standard Card No	Full name	Complete address	Age	Sex	Latent TB screening category				Investigations for active TB				Active TB screening outcome ²	Investigations for latent TB		Latent TB screening outcome ²	Remarks ⁴
						PLHIV	Close contact ³	If close contact, DTB no of index patient	Clinical risk group ²	Other vulnerable group ³	Sputum	CXR	Xpert MTB-RIF		Other (specify)	TST		

1: Enter "H" for household close contacts and "NH" for non-household close contacts

2: Enter "TNF" for patients on treatment with anti-TNF alpha, "NTNF" for patients on treatment with non-anti-TNF alpha, "HD" for patients receiving dialysis, "SOT" for patients preparing for solid organ transplantation, "HSC" for patient preparing for hematopoietic stem cell transplantation, "SIL" for patients with silicosis

3: Enter "H" for health care workers and "P" for prisoners

4: Enter "Y" for positive and "N" for negative

5: Enter "P" for positive and "N" for negative

6: Enter DTB no where TB treatment started and DCTBI no where LTBI treatment started

Annexure 8 – LTBI 06: District LTBI Treatment Register

District LTBI Treatment Register

Date of registration	District LTBI No	Full name	Complete address	Age	Sex	Latent TB category				Treatment Regimen ⁴				Outcome of LTBI treatment ⁵					Remarks ⁶		
						PLHIV	Close contact ¹	If close contact, DTB no of index patient	Clinical risk group ²	Other vulnerable group ³	3HP	3HR	6H	Other (specify)	Treatment completed	Treatment failed	Died	Lost to follow up		Discontinued due to toxicity	Not Evaluated

1: Enter "H" for household close contacts and "NH" for non-household close contacts

2: Enter "TN" for patients on treatment with anti-TNF alpha, "NTN" for patients on treatment with non-anti-TNF alpha, "HD" for patients receiving dialysis, "SOT" for patients preparing for solid organ transplantation, "HSCT" for patient preparing for hematopoietic stem cell transplantation, "SB" for patients with silicosis

3: Enter "C" for health care workers and "P" for prisoners

4: Enter Date treatment started in the relevant regime column

5: Enter Date of outcome in the relevant outcome column

6: Enter Reasons for not evaluated

Annexure 9 – LTBI 07: Quarterly Return on LTBI screening and Case Finding

Quarterly return on LTBI screening and case finding

		Number of persons screened for LTBI							Number of persons started on LTBI treatment								
		0-4		5-14		≥15		Total	0-4		5-14		≥15		Total		
		M	F	M	F	M	F		M	F	M	F	M	F			
HIV positive	PLHIV ¹																
HIV negative	Close contacts	Close contact of TB patient ²															
	Clinical risk groups	On treatment with anti-TNF alpha															
		On treatment with non-anti-TNF alpha biologics															
		Receiving dialysis															
		Preparing for solid organ transplantation															
		Preparing for Hematopoietic stem cell transplantation															
		With silicosis															
	Other vulnerable groups	Healthcare workers															
		Prisoners															

1- Mention the number of PLHIV screened for active TB as they are not entitled for LTBI screening

2- For age <5years, mention the number of children screened for active TB as they are not entitled for LTBI screening

