Instructions for use of the Registry

Objectives:
The registry is to be used for:

1. Day to day management - recording index cases and their contacts, summarizing key information and actions taken at each step of the cascade.
2. Teaching tool – for initial training of the strengthened LTBI management and expanded contact investigation.
3. In-service training – the registry will be used during regular visits by research staff for in-service training of the clinical staff to reinforce the steps in the cascade the procedures for contact investigation and LTBI diagnosis and treatment.
4. Program evaluation – The information from the registry will be used for interim periodic analysis to monitor progress, detect new problems, and develop new solutions.

Target:
These instructions are for the ACT4 investigators and research staff.

Instructions - how to complete the Contact Management Registry – Step by Step

(these instruction should be printed on pages 1 and 2 of the new registry)

Reminder for study PI:
In this registry there are three "special" columns (called the grey columns, because they are shaded in grey). These grey columns require interpretation of local guidelines and of all data collected in the registry up to that column to make a decision, case by case , if contact has 1) completed the initial assessment; 2) needed a medical evaluation and 3) completed a medical evaluation.
While all other columns can be filled in by health care workers with information available in the patient and contacts cards, filling in the grey columns, requires a specific training and supervision by the PI.

Index case
Name: Mark the full name of the index case.
Mark only one index case per household. If a second active TB case is diagnosed **within 3 months** do not enter this as a new index case, simply count this as an active secondary case diagnosed as part of the contact investigation.
If a new active case is diagnosed in the same household **more than 3 months** after the first then this person is entered as a new index case. All contacts in the household should be re-listed. Presumably some or many or all will be already TST positive and on LTBI or active TB treatment which will simplify the contact investigation but this should all be recorded.

Registry number

Mark the national TB program number (if applicable). Mark any other TB program case identifying number used for TB reporting, to track that individual.

Date of diagnosis
Mark the date (day/month/year) of TB diagnosis for index case. This is the date in which exposure for households contacts ended, usually, as treatment is started.

Type of TB
Usually contact investigations are performed only for microbiologically confirmed pulmonary TB. Mark whether smear or GeneXpert positive and/or culture positive, or both (for example S+C+; S-C+).
If smear and culture are not done, write CLIN for "TB only clinically diagnosed".

< note for study PI: the letters used above (C, S, CLIN, etc) are only examples. Please use the abbreviations that are more appropriate for your site >

Step 1. Identification of Contacts
Name (and registry number if any):
Mark the name or any registry number (if available) of all identified household contacts. These should be marked on sequential lines beside the index case. Do not repeat the name and other information for the index case - if the household contacts are listed one below the other, simply mark "Same" for the index case.
If an additional household contacts is identified later on for the same index case, when other index cases and their contacts have been already added to the registry, then re-write the index case before the newly identified contact (so it is possible to link the new contact to the index case).

Type of contact
If this is a traditional or typical house – mark household (HH). If a place such as a boarding house, or other communal living - mark OTHER.

Age
Mark the age in years in the corresponding column. A high priority should be given to getting contacts <5yreas old evaluated and started on treatment as soon as possible. Once a child <5 years old is identified as a contact, the child should be immediately referred for medical evaluation (and start LTBI treatment).

Initial assessment
Have symptoms? :
Write "Yes" if the contact, of any age, has symptoms of TB (chough, fever, weight loss, failure to thrive, ect). "No" if contact was checked for symptoms and had none (i.e. contact was asymptomatic).

Contraindications to TST/IGRA?:

Contacts with previous treatment for latent or active TB, or documented previously positive TST should not have a TST placed. Also contacts who previously had a blistering reaction to TST should not have a TST. They should all be referred directly for medical evaluation. If this is the case for a contact, please write in this column ("Contraindications for TST?") the reason for it, for example "prior TB" or "prior LTBI". If there is not contraindication to TST write "No".

How many TST done?
Write how many TST that contact has done during the current investigation: usually it is either none (ND=not done) or 1 (if contact did one TST). The possibility of having 2 tests done is for sites in which young children with negative TST have a second TST repeated after 8 weeks from end of exposure.

<Note to site PI: if in your site only one TST is done, you could rename this column: TST done? And the possibility would be just Yes, No. Please decide what is more appropriate for your site>

Date of last TST:
If the test is administered, write the date (day/month/year) in which the test was done (i.e. ppd injected). In cases in which 2 TST were done, write only the date of the last TST.

Result of last TST:
If the TST is read, mark the transverse diameter of induration in millimetres. Mark 'zero' if no reaction, otherwise write the exact reading. If no reading had been done, leave the space empty.
If the contact had a second TST done 8 weeks after the first, write only the result of the second TST.

Household contacts with TST of ≥5mm should be referred for medical evaluation.
Contacts with symptoms of TB (cough, fever, sweats, weight loss, etc.) should also be referred, even if TST negative. All children <5 years old, should be referred for medical evaluation (regardless of their TST).

Step 2. Completed Initial assessment (GREY COLUMN)

<note for site PI: please note that Instructions for GREY COLUMNS vary from site to site. What written here may not apply completely to your site. You need to modify this section below so that it is correct for your site>

Initial assessment is conducted by asking the contacts about TB symptoms and by doing a TST.

- For a contact ≥5 years old: if contact has been asked about symptoms and has done a TST write "Yes" in this column (i.e. initial assessment is considered completed for this contact).
  If TST is not available, then initial assessment is considered as completed if at least symptoms screening is done.

- For a contact <5 years old:
    - All children under five should be referred for medical evaluation and treatment initiation-if active TB is ruled out. Therefore once a contact <5 years old has been indentified, write "Yes" in this column, even if TST is not done.

Need medical evaluation (GREY COLUMN)

<note for site PI: please note that Instructions for GREY COLUMNS vary from site to site. What written here may not apply completely to your site. You need to modify this section below so that it is correct for your site>

The following contacts need further medical evaluation (once they have competed the initial assessment):

1. All children <5yrs old
2. All symptomatic contacts (of any age)
3. All contacts with positive TST
4. All contacts for whom TST is not indicated (because of previous TB/LTBI)
5. Contacts with HIV

A contact would be considered as "needing medical evaluation" if any of the above 5 conditions is true (for example: a 2 years old child with no symptoms; a 44 yrs old man with positive TST, a 35 yrs old woman with symptoms; etc)

For contacts who has "No" in this column (i.e. medical evaluation not needed), you can strike through all the next cells after this, as they will not need further evaluation or LTBI treatment (i.e. they cascade of care ends here).

Medical evaluation

Contact seen by nurse or doctor

If the contact is seen for medical evaluation (symptom assessment, risk assessment & physical exam by nurse or doctor) – mark "Yes". If contact has not been seen, write "No".

Chest X-ray done:

Mark Yes if a chest-x ray has been done as part of the medical evaluation and No if it has not been done.

Chest X-ray is recommended as part of medical evaluation, for all contacts age ≥5 with positive TST or with symptoms. For <5 years old child contacts, chest-x ray is required only in some cases, to exclude active TB (estimated about 20% of contacts <5yrs old; see SOP 14 "**LTBI management"** for more details).

Chest-x ray date:

Mark the date (day/month/year) the chest x-ray is performed.

Chest X-ray result: Mark one of 3 choices: "Normal" or "Abnormal, possible TB" or "Abnormal not TB".

If chest-x ray should have been done but was not available, write “Not done” or “Not available”.

Sputum for TB (or GeneXpert) result:
Mark result for each sample sent. Mark result as negative or positive – for AFB smear or GenXpert or culture. If active TB is diagnosed – mark this also in Comments. If smear or GeneXpert are postive WRITE IT IN RED INK.

Sputum samples should be collected and sent for AFB smear (and culture, or GenXpert - if available) for contacts with symptoms suggestive of active disease and/or whose chest X-ray is abnormal (See SOP 14 “**LTBI management**” for more details).

Step 3. Completed medical evaluation (GREY COLUMN)

<note for site PI: please note that Instructions for GREY COLUMNS vary from site to site. What written here may not apply completely to your site. You need to modify this section below so that it is correct for your site>

In contact ≥5years old with TST positive or symptoms, medical evaluation consists on a physical examination by health care worker (doctor/nurse) plus a chest-x ray.
In contacts <5years old a physical examination by health care worker is the essential component of the medical evaluation and chest-x ray is not always necessary.
Further testing (i.e. sputum (AFB, culture) or geneXpert, in contacts of all ages can be required by doctor (or nurse) depending on the results of physical evaluation and chest-x ray.

Write “Yes” in this column, if :

- For contacts <5yrs:
  - Examination by doctor/nurse alone has been done (because the chest x-ray is not always necessary)

- For contacts >=5yrs old:
  - Chest-x ray & examination by doctor/nurse (with/without sputum or geneXpert) is done. Note: if contact has done a chest-x ray and the result is reported, we assume a doctor/nurse has seen the contact, even if this is not specifically reported.
  - If chext-x ray is not available: examination done by doctor plus additional test as per doctor advice (for example sputum).

Latent TB treatment recommended:

Write Yes if latent TB treatment has been recommended. If latent TB treatment was not recommended mark reason in the "Comments" column. Example of reasons would be: old age, liver disease, active TB diagnosed, etc.

Step 4. Latent TB Treatment Started

Yes/No

Indicate 'Yes' if patient accepts to start LTBI treatment that has been recommended and a prescription or medications are given to the patient.
If the patient does not start mark "No", and give the reason in comments (patient refuses, patient "wants to think about it", stock-out of medication, etc).

Date latent TB treatment started:

Write the date (day/month/year) the treatment had started (i.e. the date the pills were given to the contact).

STEP 5: LTBI treatment completed

Yes/No

If LTBI treatment is completed as planned write "Yes" in the Yes/No column.
If treatment is stopped early by provider, such as for an adverse event, write "No" in the Yes/No column and write reason in the "Comments" column. If LTBI treatment not completed for any other reason, mark "No" and provide reason (patient's decision, lost to follow-up, etc.) in comments column.

Date of LTBI treatment completed/stopped

Write the date in which LTBI treatment has been completed (if treatment is completed) or the date in which was stopped (day/month/year).

Comments

You can write here any comment you think useful for interpretation of results, for example: Active TB diagnosed, or, Referred for medical evaluation because HIV positive; the reasons for not recommending or Not starting LTBI treatment; the reason why patients stop LTBI treatment early (patient decision, lost to follow-up, adverse event), etc

How to complete the bottom row : "TOTALS"

At the bottom of each page is a row to calculate the total number for most of the columns. Every 3 months, the number of index cases and contacts in different categories, and at each STEP in the cascade of care should be summed up. This means the total number of contacts who complete each step 1-4. The number who complete LTBI treatment (STEP 5) will have to be estimated at least 6 months later. This could be part of an annual total.

NOTE: Totals that appears in Grey boxes in the Registry, are essential to calculate the proportion of contacts retained in each STEP using the Registry Analysis Tool.

Total for each column:
Total clinically diagnosed cases: if there were index cases who were diagnosed only clinically (without microbiological confirmation), please write the total here.

Total Index Cases (in GREY): add up all the index cases reported in that registry page.
Note: If an index case has been already mentioned in earlier pages (because contact investigation was not completed before and a new contact has been identified, or because there was enough space on previous page for writing down all contacts of that index case), do not count that Index case again.

Contacts identified <5yrs old; ≥5yrs old (in GREY): total up the contacts indentified that are <5 years and the contacts that are ≥5 years old.

Symptoms: Total up the number of contacts who HAVE symptoms.

Contraindication to TST: Total up the number of contacts who have contraindications to TST

TST result: Consider positive all results of induration of 5 mm or more. Total up the number of contacts with ≥5 mm induration and write them as total positive. Total up the contacts with induration 0-4mm and write them as total negative.

STEP 2 COMPLETED INITIAL ASSESSMENT (in GREY): Sum the Yes in the column " STEP 2: Completed initial assessment" for contacts <5yrs and the Yes for contacts ≥5years.

NEED MEDICAL EVALUATION (in GREY): Sum the Yes in the column " Need medical evaluation" for contacts <5yrs and the Yes for contacts ≥5years.

Chest X-ray result: Sum the total of contacts who had a result reported for a chest-x ray (i.e. sum the "Normal", "Abnormal possible TB" , "Abnormal not-possible TB").

Sputum for TB (or GeneXpert):Sum the positive smear (or GeneXpert) results. This total will be the total of active TB cases detected during the contact investigations. This could be up to about 3-6% of the total contacts.

STEP 3: COMPLETED MEDICAL EVALUATION (in GREY):
Sum the "Yes" for "STEP 3: COMPLETED MEDICAL EVALUATION" for contacts <5yrs and the Yes for contacts ≥5years.

Latent TB treatment recommended:
Sum the total with LTBI treatment recommended (Yes).

STEP 4: LATENT TB TREATMENT STARTED (in GREY):

Sum the “Yes” for “STEP 4: Latent TB treatment started” for contacts <5yrs and the Yes for contacts ≥5years.

Total contacts of clinically diagnosed TB cases started

In case also contacts of cases with clinical diagnosis only (without microbiological confirmation) have been put on LTBI treatment, sum here their total.

STEP 5: Latent TB treatment completed.

Sum the “Yes” for “STEP 5: Latent TB treatment completed” for contacts <5yrs and the Yes for contacts ≥5years.