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சுகாதார அமைச்சு
Ministry of Health

Circular Letter No. 02-102/2013

To
All Provincial Directors of Health Services,
All Regional Directors of Health Services,
Hospital Directors/ Medical Superintendents,
Heads of Medical Institutions,
Directors of Special Campaigns/Units,
Director / Private Health Sector Development,
Presidents of Colleges/Associations in Medical Profession.

Guidelines for Mantoux Testing

Tuberculosis is considered as one of the priority health problems in Sri Lanka. In 2012, there were 9343 cases of all forms of TB and out of that 4269 are new smear positive pulmonary TB, 1889 are new smear negative pulmonary TB and 2349 are EPTB. Early Diagnosis of TB plays a major role in preventing further spread of TB in the community and complications due to TB.

There are several methods for diagnosis of TB.

Sputum smear microscopy is considered as the most reliable and cost effective method in diagnosis of infectious cases of pulmonary tuberculosis. Other methods used for diagnosis of TB are TB culture, chest X Ray, rapid molecular diagnostics and tuberculin skin test, and they have varying levels of validity and usefulness. Procedural errors and errors in interpreting results of tuberculin skin testing have been reported. Everybody should be adhered to the following guidelines in order to prevent such errors in future.

Tuberculin

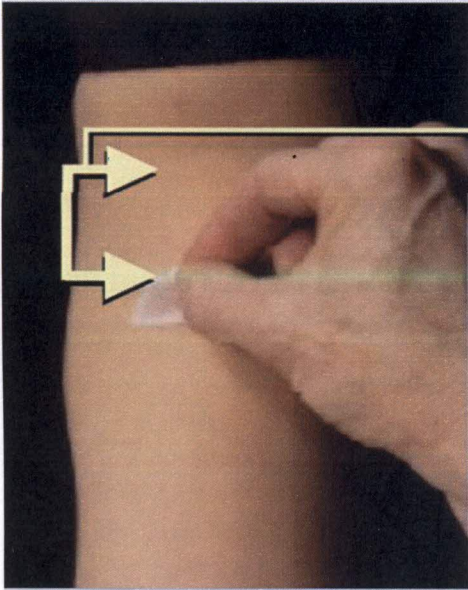
Tuberculin is a purified protein derived from tubercle bacilli. Infection with *Mycobacteria*, causes the development of hypersensitivity to tuberculin. This is useful in identification of tuberculous infection. However, the Tuberculin skin test is of limited value in clinical work, especially in countries with a high prevalence of TB. A positive test only indicates the infection but not the presence or the extent of tuberculous disease. At the same time, a negative test does not necessarily exclude active TB. It also does not have a value in the diagnosis of re-activation of tuberculosis. Mantoux should not be repeated in the clinical diagnosis of tuberculosis.

There are several methods of performing the Tuberculin Test. In Sri Lanka, Mantoux is used as the tuberculin skin test. Out of the several preparations of Tuberculin available, the National TB Control Programme at present, uses PPD 5 TU which is bioequivalent to the previously used PPD-RT-23 (2 TU/0.1 ml) solution.

Technique of Mantoux test

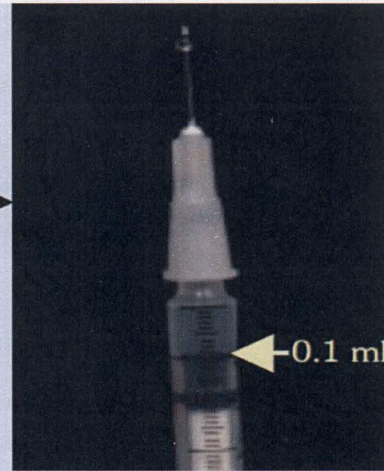
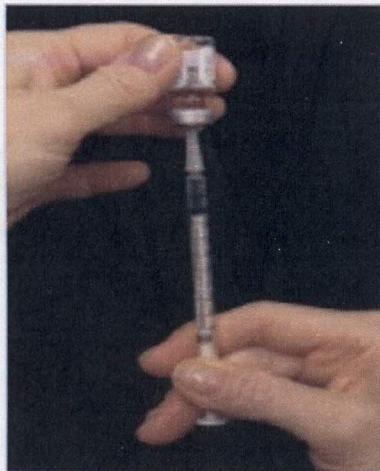
Mantoux test is done by intradermal injection of 0.1 ml of tuberculin to the anterior aspect of the left forearm. The transverse diameter of the induration is measured after 72 hours.

- Administration and reading



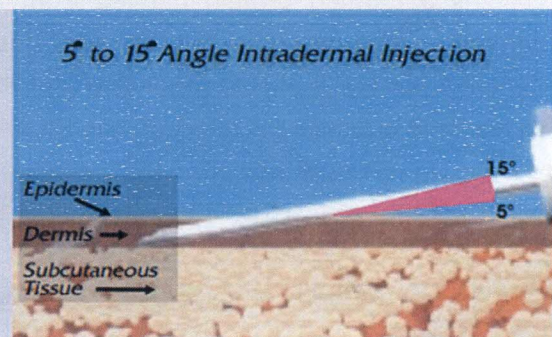
Location of a clean injection site

- Select an area in the middle one third (2-4 inches below the elbow joint) of the anterior aspect (palm side) of the left forearm.
- Place the palm side of the left forearm up on a firm well lit surface.
- Select an area free of barriers (eg. Scars, Sores) to placing and reading.
- Clean the area with an alcohol swab.



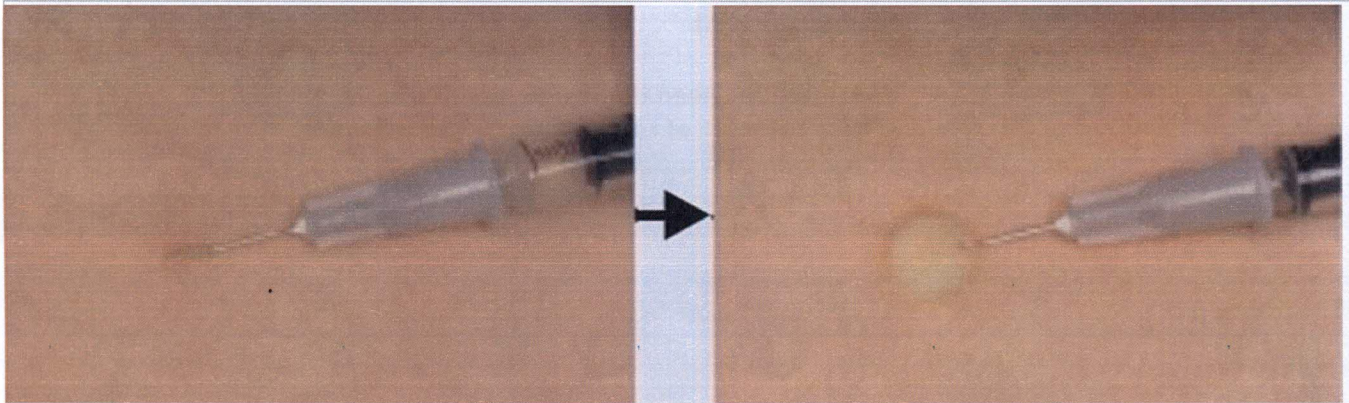
Prepare Syringe

- Check the expiry date of the vial and ensure vial contains tuberculin.
- Use a single dose tuberculin syringe (1ml syringe) with a short bevel needle (27 gauge).
- Fill the syringe 0.1ml of tuberculin.



Inject Tuberculin

- Insert slowly bevel up intradermally at a 5-15° angle.

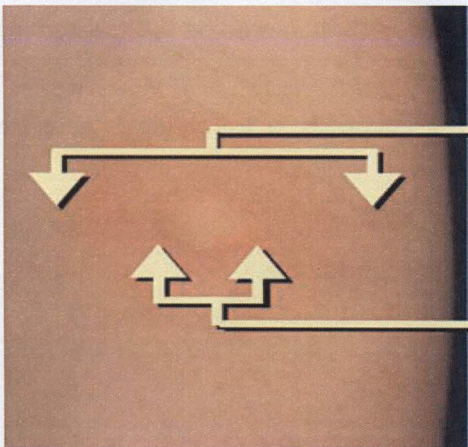


- Needle bevel can be seen just below the skin surface.
- After injection, flat pale intradermal weal of 8-10 mm should appear over the needle and will remain for about 10 minutes.
- If a papule does not appear test can be repeated on the other arm; or if the same arm is used the injection site should be separated at least 4cm from the first injection site.

Reading

The reading should be taken after 72 hours.

Induration should be measured with elbow extended using a flexible transparent ruler.



Visually Inspect the site under good light.

You can see an induration as well as erythema around it.

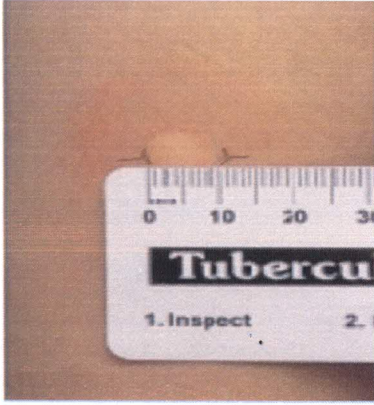
Erythema (reddening of the skin) – Do not measure

Induration (Hard , dense, raised formation)



Mark induration

- Run a ball point pen from the outer forearm to the weal until the resistance is felt . Draw a line perpendicular to the weal.
- Repeat same in the inner aspect of the forearm.
- May use finger tips as a guide for marking widest edges of the induration across the forearm.



Measurement

- Measure between the two perpendicular lines
- Place "0" mark of ruler line inside the left mark
- Read ruler line inside right mark
(use lower measurement if between two gradients on mm scale)
- Document measurement in mm

2. Interpretation of Tuberculin Skin Test

In HIV negative individuals,

0-9 mm	- negative
10-14 mm	- Positive
15mm or more	- Strongly positive

In HIV positive patients, a Mantoux test of 5 mm or more is considered as positive.

In BCG vaccinated individuals, Mantoux can be positive due to the vaccination itself.

A Positive Tuberculin Test- Tuberculin test per se is not a diagnostic test for TB. It should be interpreted in the context of clinical picture and results of other investigations.

A positive tuberculin test is only one piece of evidence in favour of a diagnosis of tuberculosis more so in children and in EPTB.

Tuberculin test can be positive in the absence of active TB in the following conditions:

- Past TB disease
- BCG vaccination
- Latent TB infection
- Exposure to environmental *Mycobacteria*

A Negative Tuberculin Test- A diameter of skin induration less than 10 mm is considered as negative.

However this does not exclude the diagnosis of tuberculosis.

Mantoux can be negative in the presence of active tuberculosis in following conditions:

- In HIV infection and in other immunocompromised situations
- Malnutrition
- Disseminated TB and millary TB
- Severe bacterial infections
- Recent infections such as whooping cough, measles, chickenpox etc.
- Wrongly applied tuberculin test

Management

If Mantoux is positive but patient is clinically well,

- Take detailed clinical history to exclude active disease.
- Get chest X ray to look for radiological evidence of active or latent TB.
- If no evidence of active disease, probably latently infected. These individuals are not of infective risk. Follow them up and advice as appropriate. Current NPTCCD guidelines do not advocate treatment for latent TB.

In Children below 10 years of Age

- Take detailed clinical history to exclude active disease, if active disease is excluded refer them to chest clinic for INAH prophylaxis.

The following precautions should be taken to ensure the quality and potency of the mantoux solution.

- Should not be frozen but to be kept refrigerated.
- Optimal temperature for storage is 2-8°C.
- Once opened should be used within 24 hours.
- Skin test should be performed soon after the syringe is filled.

Since the Mantoux solution come in multi-dose vials, usage of Mantoux should be done cost effectively. A vial should not be used for a single patient other than in an emergency to avoid wastage. The days for Mantoux testing can be arranged considering the number of patients and storage precautions, once or several days a week. Single vial can be used on two consecutive days, for example if the vial is opened at 10.00 am on the first day, testing can be done until the 10.00 am on the following day.

In future, all healthcare professional should be adhered to the above guidelines. If there are any doubts with regards to the Mantoux testing, it should be conveyed to the Director, National Programme for Tuberculosis Control and Chest Diseases, Public Health Complex, 555/5, Elvitigala Mawatha, Colombo 05 (Telephone: 0112368276, 0112368386, Fax: 0112368386, email: dnptccd@gmail.com)



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