Recommendations for Implementation of the Indiana State Department of Health's Tuberculin Shortage Guidelines for Acute and Long Term Care Facilities in the State of Indiana -- September 20, 2013

The following recommendations are based on earlier health advisories from the Centers for Disease Control and Prevention[i,ii] and the Indiana State Department of Health (ISDH) TB/Refugee Health Division concerning the shortage of tuberculin and the prioritization of its use. (See attachment A)

I. Recommendations for health care facilities regulated ISDH Long Term Care Division.

A. Pre-employment of Staff

1. Pre-employment screening is required for all hires and must include one of the following tuberculosis (TB) screening tests no more than one month prior to employment:

2. Tuberculin Skin Test (TST). A two step screening is required unless the applicant had a TST within the past 12 months and can provide documentation of date given and read, results in millimeters and interpretation (positive or negative), then only a single (one step) follow-up TST is needed.[iii] If the TST is positive the applicant must be evaluated for TB infection/disease.

3. Interferon Gamma Release Assay (IGRA) TB blood test. T-Spot® and QFT-IT® are both **acceptable IGRA screening tests for TB and can be used in lieu of a TST. If the IGRA is positive, applicant must be evaluated for Tuberculosis infection/disease. Since IGRAs do not cause boosting like the TST, only one test is needed to fulfill pre-employment requirements.[iv]**

B. Pre-admission of Residents

1. Pre-admission screening is required for all new residents and must include one of the following no more than three (3) months prior to admission:

a) A two-step TST must be given, unless a resident is being transferred from another health facility and has a documented TST within the past 12 months which includes date TST given and read, results in millimeters and interpretation , then a single (one step) TST is acceptable.

b) An IGRA blood test. Both T-Spot® and QFT-IT® are acceptable IGRA screening tests for TB and can be used in lieu of TST. Since IGRAs

do not cause boosting, only one test is needed to fulfill pre-admission requirements.

C. Surveillance and Infection Control Plan for Current Staff and Residents

1. The Indiana Administrative Code requires annual/yearly TB screening of current employees and residents. Since tuberculin is not available, the following will be accepted in the interim of the shortage for employees with a prior negative TB screening test result: an IGRA blood test or a TB Risk Assessment Questionnaire. (See above for information on the use of IGRA screening tests.) For employees with a prior positive TB screening result, follow the facilities current policy.

2. Both T-Spot® and QFT-IT® are acceptable IGRA screening tests for TB and can be used in lieu of TST.

3. For facility employees the TB Risk Assessment Questionnaire may be self-reported. For facility residents the questionnaire may be either self-reported or completed by facility staff. The Questionnaire should include but not be limited to the following:

a) Name of employee or resident

b) Date, millimeters and interpretation of last TST, date and results of last IGRA or date and results of last chest x-ray.

c) Date annual/yearly TB screening test was/is due.

d) Do you live with or have close contact with someone who has been diagnosed with TB in the past 12 months?

e) Have you had a cough that lasted longer than 3 weeks during the past 12 months?

f) Have you coughed up blood in the past 12 months?

g) Have you lost your appetite for food in the past 12 months?

h) Have you lost more than 10 pounds in a two 2 month period without trying during the past 12 months?

i) Do you have night sweats (need to change your clothes or sheets due to sweating) which cannot be explained by other medical conditions (menopause or the change of life for women)?

j) Signature of the employee, the resident or employee completing the questionnaire for a resident and date completed.

k) Signature of reviewing infection control staff and date reviewed.

l) The next TB screening with tuberculin or IGRA will be due at the employee's next scheduled annual/yearly screening date.

4. These questionnaires should be filed in the employee's medical record file.

II. Recommendations for health facilities regulated by ISDH Acute Care Division.

A. Pre-employment of Staff

1. Pre-employment screening requirements are based on the facilities infection control plan and the Indiana Administrative Code. If tuberculosis (TB) screening is required for new hires, one of the following screening methods should be used.

a) Tuberculin Skin Test (TST). A two step screening is required unless the applicant had a TST within the past 12 months and can provide documentation of date given and read, results in millimeters and interpretation (positive or negative), then only a single (one step) follow-up TST is needed.[iii] If the TST is positive the applicant must be evaluated for TB infection/disease.

b) Interferon Gamma Release Assay (IGRA) blood test for TB. Both T-Spot® and QFT-IT® are acceptable IGRA screening tests for TB and can be used in lieu of TST. If the IGRA is positive, applicant must be evaluated for Tuberculosis infection/disease. Since IGRAs do not cause boosting like the TSTs, only one test is needed to meet pre-employment requirements.[iv]

B. Surveillance and Infection Control Plan for Current Employees

1. If the facility's current infection control policy/plan or Indiana Administrative Code requires annual or yearly TB screening of employees and tuberculin is not available, the following will be accepted in the interim of the shortage for employees with prior negative TB screening tests: an IGRA blood test or a TB Risk Assessment Questionnaire. (See above for information on the use of IGRA screening tests.) Both T-Spot® and QFT-IT® are acceptable IGRA screening tests for TB and can be used in lieu of TST. For employees with a prior positive TB screening test result, follow the facility's current policy for prior positive employees.

2. The TB Risk Assessment Questionnaire may be self-reported for facility employees with prior negative TST results. The Questionnaire

should include but not be limited to the following information and questions:

a) Name of employee.

b) Date, millimeters and interpretation of last TST or date and results of last IGRA or date and results of last chest x-ray.

c) Date annual/yearly TB screening test was/is due.

d) Have you lived with or have close contact with someone who has been diagnosed with TB in the past 12 months?

e) Have you had a cough that lasted longer than 3 weeks during the past 12 months?

f) Have you coughed up blood in the past 12 months?

g) Have you lost your appetite for food in the past 12 months?

h) Have you lost more than 10 pounds in a two 2 month period without trying during the past 12 months?

i) Do you have night sweats (need to change your clothes or sheets due to sweating) which cannot be explained by other medical conditions (menopause or the change of life for women)?

j) Signature of the employee, the resident or employee completing the questionnaire for a resident and date completed.

k) Signature of reviewing infection control staff and date reviewed.

l) If infection control plans or Indiana Administrative Code, requires annual/yearly screenings, the next TB screening with tuberculin or IGRA will be due next year at the employee's scheduled annual/yearly screening date.

3. These questionnaires should be filed in employee's medical file in lieu of a TST or IGRA TB result for 2013.

C. Patients Discharged from Acute to Long Term Care facilities

Both TSTs and IGRAs are acceptable TB screening tests for admission to long term care facilities during the interim period of the tuberculin shortage.

If you should have questions about these interim recommendations please contact the appropriate individual listed below:

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[i] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6216a5.htm?s_cid=mm6216a5_w
[ii] http://emergency.cdc.gov/HAN/han00355.asp
[iii] Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005; 54 (No.RR-17)
[iv] Centers for Disease Control and Prevention. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection – United States, 2010. MMWR 2010: 59 (No. RR-5)

Approved by ISDH TB Medical Advisory Board via email 9/20/2013

August 14, 2013
Indiana State Department of Health

Isoniazid (INH) Shortage Guidelines Rescinded
Tuberculin Shortage Guidelines Remain in Effect

ISONIAZID

The INH shortage appears to be resolved and the shortage designation has been removed from the FDAs website. Please return to pre-shortage guidelines when initiating treatment for new TB and LTBI patients. See below for patients currently being treated using the interim shortage guidelines.

LTBI patients currently on six months of daily Isoniazid (INH) treatment due to interim guidelines: Continue INH for full six months. It is at the clinician's discretion if he/she wishes to prescribe an additional three (3) months of INH treatment for a total of 9 months (the pre-shortage accepted optimal duration of INH treatment).

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LTBI patients currently on four months of daily Rifampin (RIF) due to interim guidelines:
Continue the RIF for the full four months.

LTBI patients currently on the twelve week once weekly doses of Rifapentine and INH:
Continue treatment for full 12 weeks using directly observed therapy for each weekly dose.

Public Health Nurses will need a physician's script to change from 6 months to 9 months of INH treatment if the original treatment script was for 6 months of INH.

New LTBI patients: Recommendations for treatment prior to shortage should be followed. These include 9 months of daily INH or 12 weeks of once weekly Rifapentine and INH (the accepted optimal treatments), as well as the alternative treatments of 4 months of daily RIF or 6 months of daily INH.

TUBERCULIN

Tuberculin shortage continues, interim guidelines remain in effect until further notice.

Indiana State Department of Health's TB Program recommends the following measures until the shortage is resolved.

Recommendations for Responding to Tuberculin Shortages

• If available and appropriate, screen for LTBI with an Interferon Gamma Release Assay (IGRA) (T-SPOT®.TB and QuantiFERON® Gold in-tube) instead of a tuberculin skin test (TST).
• Prioritize TSTs if necessary. High priority groups include:
  ○ Contacts to a person with pulmonary or laryngeal TB
  ○ Persons who are immunoccompromised
  ○ Evaluation of persons with symptoms suggestive of TB disease
• If necessary, defer annual screening of employees, residents, and/or inmates as part of an infection control plan until sufficient tuberculin becomes available.

Thank you for your patience and understanding during this time of shortage.

If you have questions or encounter problems obtaining INH and/or Tuberculin, please notified the Director of TB/Refugee Health at the Indiana State Department of Health, Sarah Burkholder (317) 233-7545 or email her at sburkholder@isdh.in.gov .