

TUBERCULOSIS SCREENING VARIANCE PROPOSAL

In New York City, active tuberculosis cases have declined to an historic low. In 2009, NYC had 760 verified active tuberculosis cases for a case rate of 9.1 cases per 100,000.

Section 3-04(b)(2)(v)(a) of the NYC Board of Correction Health Care Minimum Standards requires, *inter alia*, that a tuberculin skin test (TST) be administered during the intake screening process for inmates who do not have a prior history of a positive reaction to the test.

Given the current epidemiology of tuberculosis in New York City (NYC), the NYC Department of Health and Mental Hygiene (DOHMH) proposes a variance from section 3-04(b)(2)(v)(a) that will allow for:

- 1) The use of either interferon gamma release assays (IGRA) or TST for latent tuberculosis screening; and
- 2) The use of IGRA or TST at intake for all new admissions **unless** the patient has:
 - a history of positive IGRA or TST
 - a history of latent or active tuberculosis (see appended "definitions" page), or
 - a documented negative IGRA or TST in the past 6 months (for the next year after program implementation; thereafter, in the past 12 months, if program evaluation data support the change).

Patients with a positive IGRA or TST will be evaluated further to rule out active tuberculosis disease, as per extant DOHMH policy. The DOHMH will continue our current policy of screening for active tuberculosis disease at every incarceration, using a daily, automated Tuberculosis Registry Crossmatch, screening for signs and symptoms of tuberculosis, and obtaining chest radiographs for persons who are 1) infected with the human immunodeficiency virus; 2) have a history of a positive TST or IGRA; or 3) have a history of latent or active tuberculosis.

This variance is consistent with tuberculosis control guidelines published by the Centers for Disease Control and Prevention (CDC) and with the NYC DOHMH Bureau of Tuberculosis Control (BTBC) Program policies and protocols. Per CDC guidelines, an IGRA may be used in place of (but not in addition to) TST in all circumstances in which CDC recommends tuberculin skin testing as an aid in diagnosing *Mycobacterium tuberculosis* infection. The DOHMH BTBC implemented use of IGRAs in the city tuberculosis clinics in 2006. Expressing his expert opinion on annual screening for TB, Dr. Chrispin Kambili, Assistant Commissioner of BTBC, has stated that, given the current epidemiology of tuberculosis in NYC, it is reasonable to do screening for latent tuberculosis infection (LTBI) once every 12 months for persons entering or residing in the NYC jails who do not report recent exposure to a documented case of active tuberculosis. He pointed out that, in fact, BTBC currently screens its clinic staff for LTBI

only once a year, noting that the current state of local tuberculosis epidemiology makes more frequent screenings unwarranted.

Reason for Request

IGRAs have recently been approved by the U.S. Food and Drug Administration as an aid in diagnosing *M. tuberculosis* infection, including both LTBI and active tuberculosis disease. IGRAs are blood-based tests that measure the amount of interferon-gamma released by a patient's immune cells in response to tuberculosis-specific antigens used in the test; a positive test indicates prior exposure to and infection with tuberculosis. Persons with a positive IGRA must have a work-up to differentiate between LTBI (not contagious) and active tuberculosis (contagious), similar to that done for persons with a positive TST.

Recent studies comparing IGRAs and TST reveal many advantages of IGRAs over the TST. IGRAs are more specific for identifying TB infection than the TST. Unlike the TST, IGRAs use tuberculosis-specific antigens which are absent from most commonly encountered non-tuberculosis mycobacteria and Bacillus Calmette-Guérin (BCG) vaccine strains. Thus IGRAs have a lower rate of false-positives than the TST. Using a more specific test will reduce the unnecessary work-up and treatment of persons who had a false-positive TST and are not infected with tuberculosis. The use of IGRAs also eliminates the need for a second patient visit for TST reading and provides an objective laboratory result which is not subject to the errors of TST placement and reading. In addition, repeated IGRA testing does not result in the "boosting" phenomenon seen with TSTs (false TST "conversion" due to repeated TST placements in persons with remote LTBI infection). Persons with LTBI may have a negative TST if tested years after acquiring their tuberculosis infection. This TST can boost the immune system's response to future TSTs. A subsequent TST may be positive and thus misinterpreted as a TST conversion due to a new infection with tuberculosis, resulting in unnecessary further work-up and treatment. Studies have also shown that the QFT is at least as good as the TST among HIV-infected populations.

The addition of IGRAs for tuberculosis testing at intake is feasible. DOHMH currently conducts serologic testing for other communicable conditions (e.g., syphilis, confirmatory HIV testing) at intake. In addition, all NYC jail intake facilities have the ability to retrieve prior admission records, including an electronic record of the admission history and physical exam, laboratory evaluations, and results of prior intake TSTs and subsequent work-up if a TST was positive (e.g., chest radiograph result). As such, the jail admitting clinician can determine if a newly incarcerated person has a prior history of positive IGRA or TST, a prior history of LTBI or active tuberculosis, or a documented negative IGRA or TST in the past 6 or 12 months.

While we would continue to conduct active tuberculosis screening at every incarceration, we propose to conduct LTBI screening once every 12 months for recidivists. In 2009, NYC tuberculosis case rates reached a historic low with 760 verified active tuberculosis cases for a rate of 9.1 cases per 100,000 persons. Thus, though incarcerated populations are at higher risk of being exposed to tuberculosis than general populations, given the current epidemiology of TB in NYC, screening persons entering NYC jails for LTBI

(using TST or IGRA) more than once every 12 months, in the absence of exposure to a documented case of active TB, is unwarranted. DOHMH data for females incarcerated in NYC jails in 2009 revealed that of 1,177 female recidivists without a prior positive TST or tuberculosis history on their first incarceration, 3% reported a prior positive TST or tuberculosis history and 0.4% additional females tested TST-positive at a subsequent incarceration. A similar analysis among males incarcerated in 2007-2008 revealed that, of 27,334 male recidivists without a prior positive TST or tuberculosis history on their first incarceration, 2.3% reported a prior positive TST or tuberculosis history and 3.6% additional males tested TST-positive at a subsequent incarceration. The median time to these self-reported or documented TSTs was 6 months. However, the current epidemiology of TB in NYC suggests that these data do not necessarily represent true TST "conversions". In addition, there were many inmates who could not have their TST read on the initial incarceration (due to being released from jail within three days of admission); some of these TSTs may have been positive if read. Also, some of the subsequent positive TSTs could have been false-positives due to the non-specific nature of the test or due to boosting. None of the recidivists with a subsequent positive TST had tuberculosis symptoms or were found to have active tuberculosis during the study period. However, as a precaution, we propose to screen all new admissions for LTBI, using IGRA or TST, unless they have a documented negative test in the past 6 months (for the next year after program implementation). We will conduct ongoing assessments of program data. If the data show no significant increases in active TB cases or need for contact investigations, we propose screening all new admissions for LTBI unless they have a documented negative test in the past 12 months and will continue to evaluate program data to assess need for program revisions.

Components of Proposed Active Tuberculosis Screening Program for NYC Jails

The proposed tuberculosis screening program will continue to focus on the identification of potential active tuberculosis cases in NYC jails, while also maintaining a reasonable LTBI screening program consistent with the epidemiology of tuberculosis in NYC. We will remain vigilant to any changes in NYC TB epidemiology and will review and revise our jail-based policies/protocols accordingly.

Admission History and Physical Exam

- All newly admitted patients will be asked their medical history, including history of prior positive TST or IGRA and history of LTBI or active tuberculosis disease.
- All new admissions will be given a physical examination, including vital signs, weight check, a screening for signs and symptoms of active tuberculosis (e.g., prolonged cough, hemoptysis, fever, night sweats, chills, weight loss, and malaise), palpation for enlarged lymph nodes, and auscultation of the lungs.
- Any patient with a history or signs and symptoms of active tuberculosis on admission will be immediately transferred to the Communicable Diseases Unit (CDU) for further work-up and treatment.

Chest Radiography

- All patients presenting with signs or symptoms of active tuberculosis will be transferred to the CDU and will have a chest radiograph as soon as possible.

- Asymptomatic patients with human immunodeficiency virus (HIV) by history or intake testing and persons with a history of positive IGRA or TST will have a chest radiograph within one to three days of admission to screen for active tuberculosis, unless there is documentation of a normal chest radiograph in the last three months.
- Patients with a new positive IGRA or TST will have chest radiography performed within one day of the test result.

NYC DOHMH BTBC Tuberculosis Registry Crossmatch

- A computerized crossmatch between the BTBC Tuberculosis Registry and the NYC Department of Correction Inmate Information System (IIS) is conducted daily on all new intakes.
- The crossmatch enables the rapid identification of any new admissions that are confirmed or suspected active tuberculosis cases needing further evaluation or completion of treatment.
- Admissions identified through the Tuberculosis Registry as having incomplete treatment for active tuberculosis are transferred to the CDU for chest radiography and further evaluation and treatment, in collaboration with BTBC staff.

Ongoing Surveillance

- Clinical staff are trained to be alert for signs and symptoms of active tuberculosis among patients being seen during post-intake clinical encounters such as sick call or chronic care visits. Staff are instructed to have a low threshold for transfer of symptomatic patients to the CDU for further evaluation.
- Any patient remaining in NYC Department of Correction custody for one year or more will have an annual history and physical examination and tuberculosis testing by IGRA or TST if documented negative test at intake.

Contact Investigations

- Contact investigations are conducted to identify and treat secondary cases of active tuberculosis, as well as to identify and treat persons with LTBI, as a result of exposure to a confirmed pulmonary or laryngeal tuberculosis case.

Case-Management by NYC DOHMH BTBC

- All patients with suspected or confirmed active tuberculosis are referred to BTBC staff for case-management during and after incarceration.
- All case-management data are entered into the BTBC Tuberculosis Registry and available for the Tuberculosis Registry crossmatch.

Components of Proposed LTBI Screening Program for NYC Jails

- All new admissions will be screened for LTBI using IGRA or TST **unless** they have a history of positive IGRA or TST, history of LTBI or active tuberculosis, or a documented negative IGRA or TST in the past 6 months prior to admission (for the next year after program implementation), and, if program evaluation data shows no increase in active tuberculosis cases or need for contact investigations, thereafter, in the past 12 months prior to admission.

- If IGRA or TST result documentation is unavailable, the patient will be screened for LTBI using IGRA or TST.
- All patients diagnosed with LTBI will receive a risk assessment for the potential of conversion to active tuberculosis and education allowing them to make an informed decision about treatment options.
- All patients with LTBI who consent to treatment will be offered case-management by BTBC staff during and after incarceration, similar to that done for patients with active TB.

Summary

We request the ability to use IGRAs as an aid in the detection of *M. tuberculosis* infection. We also request that we re-test those with a documented prior negative IGRA or TST only if 6-12 months have elapsed since their last documented negative test. We believe that these changes will lead to improvements and efficiencies in the extant jail tuberculosis screening program. DOHMH will continue to monitor the effectiveness of its tuberculosis screening program, particularly within the context of the epidemiology of TB in NYC. Any subsequent changes would be based on data collected through the program and will occur in conjunction with BTBC and the Board of Correction.

Tuberculosis Screening Minimum Standards Variance Request: Section 3-04(b)(2)(v)(a)

DEFINITIONS

Latent tuberculosis infection (LTBI) means that a patient has been exposed to and infected with the tuberculosis bacteria, but the patient's body has contained the infection and the patient is not symptomatic or contagious. An otherwise healthy person with LTBI has a 10% lifetime risk of progressing to active tuberculosis disease. Persons who are immunocompromised have a 10% annual risk of progressing to active tuberculosis disease.

Active tuberculosis disease means that a person is infected with the tuberculosis bacteria and is symptomatic and potentially contagious (e.g, if the infection is in the lungs or pharynx).

Interferon gamma release assays (IGRA) were approved by the U.S. Food and Drug Administration in 2006 as an aid in diagnosing *M. tuberculosis* infection, including both LTBI and active tuberculosis disease. IGRAs are more specific than and at least as sensitive as the tuberculin skin test (TST). IGRAs are also comparable to the TST in diagnosing tuberculosis infection in human immunodeficiency virus-infected populations. IGRAs (e.g., QuantiFERON and T.SPOT-TB) are blood-based tests that measure the amount of interferon-gamma released by a patient's immune cells in response to tuberculosis-specific antigens used in the test; a positive test indicates prior exposure to and infection with tuberculosis. Persons with a positive IGRA must have a work-up to differentiate between LTBI (not contagious) and active tuberculosis (contagious), similar to that done for persons with a positive TST.