

499. TUBERCULOSIS SURVEILLANCE PROGRAM

- I. Purpose: The purpose of the Tuberculosis Surveillance Program (TBSP) is to minimize the risk of occupational or nosocomial transmission of *Mycobacterium tuberculosis* (*Mtb*) to workers, patients or nonhuman primates (NHP) used in research studies, and to provide medical support services to eligible employees who are diagnosed with work-related tuberculosis (TB). To this end, the program is intended to provide:
 - A. Early detection of latent TB infection (LTBI) or infectious TB among workers.
 - B. Education, counseling, medical evaluation, and treatment or referral for clinical care as indicated.
- II. Relevant Occupational Medical Service (OMS) Procedure Manual Sections
 - A. Contact Study Guidelines. SOP 300.306
 - B. International Travel. SOP 300.327
 - C. Occupational Injury and Illness. SOP 300.354
 - D. Preplacement Medical Evaluation. SOP 300.363
 - E. Animal Exposure Program. SOP 400.404
 - F. Biological Surety Program. SOP 400.412
 - G. Medical Services for *M. tuberculosis* Researchers. SOP 400.468
- III. Attachments
 - A. Questionnaire for Tuberculin Skin Testing. Attachment I
 - B. Outside Placement of Tuberculin Skin Test. Attachment II
 - C. Certificate of Tuberculosis Screening Test Results. Attachment III
 - D. TB Symptoms Questionnaire and Quiz. Attachment IV
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 - J. Periodic Tuberculosis Reminder. Attachment X
 - K. Report of Employee TB Exposure Form. Attachment XI
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 - M. TB Contact Investigation Summary. Attachment XIII
- IV. Appendices
 - A. Tuberculosis Screening. Appendix I
 - B. TB Risk Factors. Appendix II
 - C. TB Screening Recall. Appendix III
- V. Eligibility – NIH position applicants and current federal employees are screened for TB infection, if they:

- A. Work in close proximity to patients;
- B. Have access to NHPs or their living quarters;
- C. Have an increased risk of an occupational exposure to *Mtb*; examples include:
 1. Work in the Mycobacteriology Laboratory or with *Mtb* cultures;
 2. Conducting bronchoscopies or cough-inducing procedures;
 3. Work in Respiratory Therapy;
 4. Work in the Pulmonary Lab; or
 5. Work in a research setting with strains of viable *Mtb* strains or experimentally *Mtb* -infected animals (see OMS procedure *Medical Services for M. tuberculosis Researchers*).
- D. Experience a recognized potential exposure to *Mtb* such as:
 1. Being in close contact with a person with infectious TB or their clinical specimens without adequate protection.
 2. A breach in personal protective equipment in the presence of *Mtb* in a clinical or research laboratory setting.
 3. All NIH workers involved in such work-related incidents, including contract staff and volunteers who are presumed to have acquired a work-related TB infection, are eligible for TB screening and may be considered to receive treatment as indicated through OMS.

VI. Identification of Eligible Workers

- A. Supervisors are responsible for identifying workers who are expected to have contact with patients or NHPs, and workers at increased risk for occupational exposure to *Mtb*, at the time of the preplacement evaluation and when a worker changes to a new position with such risks.
- B. The Hospital Epidemiology Service (HES) is responsible for:
 1. Ensuring that Clinical Center (CC) supervisors identify workers at increased risk of *Mtb* exposure based on their work responsibilities;
 2. Identifying workers potentially exposed to *Mtb* during a contact investigation in CC areas under HES purview; and
 3. Referring workers to OMS who are identified to be at increased *Mtb* exposure risk, e.g., during periodic HES risk assessments in the CC.
- C. Safety specialists of the Safety Operations and Support Branch (SOSB) and the Biorisk Management Branch, or their counterparts at the CC are responsible for identifying and referring to OMS all workers at increased *Mtb* exposure risk:
 1. Related to their work responsibilities in all NIH non-clinical areas and occupational groups; and
 2. During a TB contact investigation in NIH work areas and non-clinical areas in Building 10.
- D. Principal Investigators working with *Mtb* are responsible for identifying workers who enter their facilities where research with *Mtb* conducted (see OMS procedure *Medical Services for M. tuberculosis Researchers*).
- E. OMS clinicians may identify workers at risk for *Mtb* exposure and enroll them into the TBSP during preventive services designed to capture this need, or when

the need for required TB screening is discovered incidentally during an unrelated OMS service.

- F. Workers are responsible for reporting to OMS immediately in case of a potential occupational exposure to MTB (see OMS procedures *Occupational Injury and Illness and Medical Services for M. tuberculosis Researchers*).

VII. Definitions

- A. BCG – Bacillus Calmette-Guérin, an attenuated *M. bovis* strain, a live TB vaccine strain.
- B. Conversion – denotes that the same type of screening test for TB has changed from negative to positive in the preceding 24 months.
1. TST conversion – an increase in induration of ≥ 10 mm within 24 months indicating recent infection with MTB.
 2. IGRA conversion – positive IGRA at least twice on successive testing, preferably of the same type, and a negative IGRA within the previous 24 months.
 3. TST conversion after known exposure to MTB – induration ≥ 5 mm after previously nonreactive TST.
- C. IFN- γ – interferon-gamma, a glycoprotein secreted by T cells to fight certain infections; important for innate and adaptive immunity.
- D. IGRA – interferon-gamma release assay, an *in vitro* blood test to detect TB infection that quantifies the IFN- γ released by sensitized T-lymphocytes. As with TST, IGRA results must be interpreted within the context of each case.
1. QuantiFERON®-TB Gold In-Tube (QFT-G) and T-SPOT.TB® (T-SPOT) are two currently licensed tests that rely on IFN- γ release. They measure this response in different ways and thus they may not be fully interchangeable. e
 2. A positive IGRA is more specific for TB infection than a positive TST because it measures the immune response to MTB peptides not present in BCG or most atypical mycobacteria.
 3. IGRAs are resulted as positive, indeterminate, or negative based on generally accepted cut-off values determined by community TB indices.
- E. MTB – *Mycobacterium tuberculosis*, or *M. tuberculosis*, cause of TB (see OMS procedure *Medical Services for M. tuberculosis Researchers* for more details).
- F. NTM – Nontuberculous mycobacteria; not typically communicable but some may be pathogenic in humans, especially those with a depressed immune system. Prior exposure may affect the interpretation of TB screening test results (false positives), more likely with TST than with IGRAs.
- G. Position applicant – a person not yet hired or who is being considered for a new position.
- H. TB – tuberculosis; infection caused by MTB and closely related species; the clinical spectrum ranges from asymptomatic to rapidly progressive forms (see OMS procedure *Medical Services for M. tuberculosis Researchers*).
1. Active TB – the disease phase of TB infection when those with active pulmonary or laryngeal forms of TB are infectious and can transmit

- MTB to others (infectious TB).
2. Latent TB Infection (LTBI) – the dormant phase after infection with MTB when the infected person cannot pass MTB to others because the bacilli are contained by the host’s immune system.
 3. Extrapulmonary TB – non-communicable forms of active TB disease confined to organs other than the respiratory tract. However, affected tissues, e.g., in clinical specimens or on instruments contaminated with such tissues, may serve as potential sources of MTB infection.
- I. TB Contact Investigation Coordinator – OMS clinician responsible for overseeing the OMS portion of a TB contact investigation; serves as point of contact for non
- J. TB contact investigation – an epidemiological study of persons at risk for MTB exposure (contacts) during a specified period of infectivity (see OMS procedure *Contact Investigation Guidelines*).
1. Requires risk stratification and prioritization of contacts based on:
 - a. The index patient’s or source material’s infectiousness;
 - b. Circumstances of the potential exposure (timing, location, protective measures); and
 - c. The contact’s risk factors.
 - d. Resources available to evaluate each potential contact.
 2. Close contact – a person at risk for TB infection due to prolonged exposure and close proximity to the index case in high-risk settings (small, enclosed spaces with poor ventilation); contact case criteria are defined by investigators for each contact investigation.
 3. High priority contact – any
 - a. Close contact,
 - b. Contact with an intense exposure of any duration (e.g., a bronchoscopist without adequate protection performing high-risk procedures), and
 - c. Contact at increased risk for poor outcome if infected with MTB (e.g., HIV infection, immune system suppression, or cancer).
 4. Low priority contact – a person with minimal risk for TB infection and no conditions associated with progression to active TB; may rise in priority as investigation evolves, e.g., if TB test conversions are found among close contacts.
- K. TB exposure – an incident or time period associated with potential transmission of MTB by inhalation or percutaneous inoculation such as sharing breathing space with an individual with infectious TB, or a sharps injury or splash involving viable MTB, absent adequate personal protection (see OMS procedure *Occupational Injury or Illness*).
1. There is no safe exposure for MTB due to its low infectious dose (possibly fewer than ten bacilli); however, typically new infections do not occur without prolonged or intense exposure to the index patient.
 2. Risk of exposure increases with:
 - a. Highly infectious index cases,
 - b. Prolonged and frequent contact (cohabitation, confined shared

- workspace, common ventilation),
 - c. Close proximity to the index case,
 - d. Exposure in small, poorly ventilated spaces, and
 - e. High concentration or large quantity of inoculum.
3. Casual contact of a healthy person to the index patient for a few minutes or longer periods while in open, well ventilated areas does not constitute a significant exposure risk.
- L. TBSP Coordinator – the OMS clinician who oversees the TBSP.
- M. TB risk stratification (institution-based) – estimated exposure risk to healthcare workers (HCW) based on unrecognized active TB cases in a facility per year:
- 1. An inpatient hospital with at least 200 beds and fewer than six TB patients per year, or fewer than three TB patients per year in a less than 200-bed facility, is considered at low risk for TB exposure. The NIH CC is generally considered a low-risk setting.
 - 2. Certain clinical occupations or areas carry an increased risk of MTB exposure such as respiratory therapy, bronchoscopy, or mycobacteriology regardless of facility risk level.
- N. TBSP Work Category – the group a worker being screened for TB is assigned to in the OMS Clinical Access Manager (CAM) TBSP module; based on risk of exposure to MTB during routine duties; drives recall periodicity for TB screening.
- O. TST – tuberculin skin test; the intradermal injection of 0.1 ml of purified protein derivative (PPD) to detect infection with Mtb.
- 1. Positive TST – a reaction to a TST, which suggests infection with MTB. The determination is based on the transverse diameter of the induration at the test site measured 48 to 72 hours after injection in combination with the individual’s relevant medical history (TB risk factors).
 - a. ≥ 15 mm, regardless of TB risk factors.
 - b. ≥ 10 mm and
 - i. A TST conversion (see VII.B. above);
 - ii. Immigration from or prolonged stay in a country with a high TB prevalence in the past five years (www.stoptb.org/countries/tbdata.asp);
 - iii. Mycobacteriology lab personnel;
 - iv. Prior work or residence with a high risk population without adequate personal protective equipment; or
 - v. Medical conditions with increased risk for progression to active TB, e.g. diabetes mellitus, chronic renal failure, silicosis, gastrectomy or intestinal bypass surgery, or injection drug use.
 - c. ≥ 5 mm and
 - i. Recent contact with a person with infectious TB;
 - ii. Infection with HIV;
 - iii. Radiographic evidence of prior TB (fibrotic changes);
 - iv. Immunosuppression (e.g., after organ transplant, receiving more than 15 mg of prednisone per day for a

- month or longer, TNF- α antagonists); or
 - v. Malignancies such as hematologic neoplasms, solid tumors of the head and neck.
- 2. Negative TST – any reaction to a TST that does not meet the criteria for a positive TST.
- 3. Two-step testing – the administration of a second TST one to three weeks after the initial negative TST.
 - a. A positive response to the second test suggests remote TB infection (booster phenomenon).
 - b. Recommended for all with risk factors for prior TB infection who anticipate repeat TST to avoid impression of new infection.

VIII. Skin Testing

- A. Prior to administering the TST, the worker is asked to provide a targeted personal medical history (Attachment I, Appendix I) to help determine which test, if any, should be administered, and if the worker has any TB risk factors that may affect the test performance, its interpretation or subsequent recommendations (Appendix II). The worker is asked for a history of:
 - 1. A prior reactive (positive) TB screening test (TST or IGRA),
 - 2. Prior vaccination with BCG,
 - 3. Receipt of a live virus vaccine in the prior six weeks,
 - 4. A viral infection in the preceding month,
 - 5. Non-occupational risk factors for infection with MTB, and
 - 6. Medical conditions and treatments that may affect TST interpretation.
- B. TST may be used in most cases where TB screening is required, including for serial testing.
- C. An initial TST is not performed if the worker:
 - 1. Has a history of a positive TB test (TST or IGRA) or clinical TB;
 - 2. Can document negative TST results on two-step testing with the second test within in the previous 24 months and has no new TB risk factors; or
 - 3. Declines to receive a tuberculin skin test. The employee is then instructed to negotiate relief from the requirement with the party requiring the testing.
- D. The second-step TST is not performed, if the employee can document a negative TST (first step) in the prior 24 months.
- E. Immunization with BCG vaccine is not a contraindication to skin testing as TST reactivity diminishes over time. However, prior receipt of BCG may cause a positive TST due to sensitization when the individual is not infected with MTB (false conversion). A BCG vaccine recipient with:
 - 1. Unknown or no history of TST is preferably screened by IGRA.
 - 2. Negative serial TSTs subsequent to receipt of BCG may continue screening by TST. However, if frequent TB screening is expected, the worker may be tested by IGRA.
- F. Neither pregnancy nor breastfeeding is a contraindication to administering a TST.

- G. Administering a TST:
 - 1. 0.1 ml of PPD is injected into the intradermal space on the volar surface of the forearm. A 27 gauge needle is used with the bevel side of the needle up and parallel to the skin surface. Done correctly, this produces a visible and palpable wheal that is 6 to 10 mm in diameter.
 - 2. If the entire amount is not injected into the skin, or if the wheal is not produced, the test is repeated on the opposite arm and the occurrence is noted in the record. The test is repeated only once. If the second test also is unsuccessful, the occurrence is noted in the employee's medical file and the employee is instructed to return to the clinic in one week for another attempt.
 - H. Measuring a TST response:
 - 1. Reactions to TSTs are read 48 to 72 hours after injection to be valid.
 - 2. The transverse diameter of the response (induration) is determined using a ballpoint pen.
 - a. The pen is held perpendicular to the skin surface and, while applying mild pressure, a line is drawn from normal skin toward the center of induration, stopping when resistance from the "edge" of induration is encountered. The patient will typically report increased sensitivity when the true edge of induration is felt. The distance between opposing interrupted lines is measured in millimeters.
 - b. Erythema in the absence of induration is not significant but is reported in the progress note.
 - c. Employees are not permitted to "self-read" nor have a co-worker read their TST for OMS.
 - I. An employee who works a part-time schedule and cannot have the test placed and read in OMS may have a TST placed and documented by their personal healthcare provider (Attachment II), and an OMS clinician will read the TST.
- IX. IGRA testing
- A. TB screening by IGRA is preferred when its greater specificity for detecting TB infection provides an advantage (e.g., serial testing and prior BCG vaccination, or likely to be infected and low risk of progression to active TB), or when a second visit to read a TST is impossible in cases when TB screening is immediately indicated.
 - 1. IGRA results may fluctuate spontaneously from negative to "conversions" with subsequent reversion back to negative results have been observed on periodic TB screening.
 - 2. A worker who has received the BCG vaccine, whose TSTs have been negative on infrequent screening, should consider IGRAs for more frequent, closely spaced screening, e.g., a low priority contact in a TB contact investigation.
 - B. An initial IGRA is not performed if the employee:
 - 1. Had positive IGRA confirmed on repeat testing in the past;

2. Can document a negative IGRA within the past twelve months;
 3. Has a credible history of TB screening test conversion (TST or IGRA), e.g., after exposure to MTB; or
 4. Declines to receive a tuberculin skin test. The employee is then instructed to negotiate relief from the requirement with the party requiring the testing.
- C. An IGRA is interpreted as negative, indeterminate, or positive based on the relative IFN- γ release in response to specific MTB antigens (TB response) and mitogen, a ubiquitous antigen (positive control) compared to the antigen-free nil tube (negative control). Cut-off values are set by expert consensus.
- D. A newly positive IGRA must be repeated to be considered a true conversion. Although there is no minimum waiting period, it is reasonable to wait at a week or more before repeating an IGRA depending on the clinical context.
- E. An indeterminate IGRA is repeated on a different blood sample; no waiting period is necessary.
- F. Fluctuations, i.e. spontaneous conversions and reversions, are known to occur without clear change in a worker's risk of TB exposure. Their clinical significance is not well understood such as the likelihood of an actual MTB transmission or development of TB subsequently.
- G. T-SPOT is acceptable for all purposes of TB screening.
1. An applicant's negative T-Spot within the past 24 months is acceptable for baseline data.
 2. It may be used cautiously when comparing directly to QFT-G results when the two IGRAs differ.
 3. It is accepted as a prevalent positive TB test if there is a history of at least two positive IGRAs.
- H. TST and IGRA results may be concordant or discordant and must be interpreted in the context of all clinically relevant information.
- I. Dual testing for Mtb infection with IGRA and TST is generally not recommended. However, it may be helpful in certain situations (see Appendix II) such as:
1. A false-positive TST is suspected in someone without TB risk factors and both tests are required to be positive to diagnose LTBI (i.e., if one test is negative a person not likely infected and at low risk for progression is considered to have negative TB screening.
 2. A false-negative test may have serious consequences (i.e. someone likely infected with high of progression tests negative on initial screening).
- X. Initial TB Screening - Test Negative – the applicant is medically cleared for duty.
- A. The applicant is medically cleared for duty. If the individual is newly hired, the OMS clinician issues the applicant a Request for Medical Determination and Report of Findings form (see OMS procedure *Preplacement Medical Evaluation*) clearing the individual for work
 - B. If the applicant was screened by:
 1. TST, the applicant is scheduled for an appointment to receive a second

TST within one to three weeks unless the TST performed satisfies criteria for the second step a two-step test. The second test is placed on the opposite forearm.

2. IGRA, a single negative test is sufficient except when a falsely negative result is suspected.
- C. False-negative TB screening results – Repeat screening may be indicated.
1. Negative TB screening in a person with a suppressed immune system must be interpreted with caution. They may respond to antigens due to anergy, i.e., lack of immune memory, e.g., with chronic steroid therapy, hematologic malignancies, HIV infection.
 2. False-negative TST or IGRA results are also thought possible after a recent viral infection or immunization with live virus vaccine. Testing should be delayed by four to six weeks after receipt of a live virus vaccine.
- D. The OMS clinician advises the applicant of:
1. The expected recall periodicity and notification procedures as long as TB screening remains negative;
 2. The worker’s specific requirements to remain compliant with the TBSP and the employee’s responsibilities for meeting those requirements; and that
 3. Failure to maintain full compliance for those with access to NHP areas or A/BSL-3 laboratories may result in an administrative adverse action (see OMS procedures *Animal Exposure Program* and *Biological Surety Program*).
- E. A Certificate of Tuberculosis Screening Test Results (Attachment III) is provided to the worker on request.
- F. Record keeping – All IGRAs and related TBSP entries are recorded in CAM and the worker’s OMS chart (See section XV., below).
- XI. Initial TB Screening Test Other Than Negative (Positive or Indeterminate)
- A. Applicant with a “prevalent positive” TB screening test – provides a history of reactive TB screening discovered elsewhere.
1. The OMS clinician administers the TB Symptoms Questionnaire and Quiz (Attachment IV). The Questionnaire is intended to detect symptoms of active tuberculosis and to enhance the employee’s understanding of the illness.
 2. The OMS clinician questions the worker regarding:
 - a. The findings on a chest radiograph (CXR) following that TB test,
 - b. The type and duration of related treatment, if any, and
 - c. His or her compliance with treatment recommendations.
 3. If the applicant has no symptoms of infectious TB, and either had a normal CXR following the positive TB test or completed adequate TB treatment, the OMS clinician issues the applicant a *Request for Medical Determination and Report of Findings* form with clearance for work.

4. If the applicant cannot provide a history consistent with a normal CXR or adequate TB treatment following the prior positive TB test, the OMS clinician orders a posterior-anterior (PA) chest radiograph.
 5. If the responses to the TB Symptoms Questionnaire and the radiographic findings are not suggestive of active pulmonary disease, the OMS clinician:
 - a. Provides the applicant with detailed counseling on the significance of the findings, TB risk factors and related CDC handouts (see section XVI, *Resources*).
 - b. Issues the completed *Request for Medical Determination and Report of Findings* form clearing the applicant for work. This form is held for applicants with access to NHPs or their living quarters, pending the receipt of a radiology report that does not have findings suggestive of infectious TB.
 - c. Instructs the applicant to report to OMS if he or she develops signs or symptoms suggestive of active TB disease at any time during their employment at the NIH (see Attachment IV).
 - d. Refers the applicant to his or her personal physician or local Health Department, if LTBI treatment may be beneficial (Appendix II), with a *Referral for Evaluation of Latent TB Infection* (Attachment V), and a copy of the CXR and radiology report.
 6. If the applicant provides a history of consistent with TB test conversion within the preceding 24 months, the OMS Clinician administers the TB Risk Factor Survey (Attachment VI), and follows the steps outlined in the following section, XI.B.3. (recent converter).
- B. Applicant with a positive initial TB screening test discovered by OMS
1. The OMS clinician:
 - a. Administers the TB Symptoms Questionnaire and Quiz (Attachment IV) and the TB Risk Factor Survey (Attachment VI). The Survey is intended to discover TB risk factors for infection, and for progression to active TB, or poor outcome, if infected.
 - b. Orders a PA chest radiograph.
 2. If the applicant has no history of exposure to Mtb within the past 24 months (prevalent positive), and no clinical or radiographic evidence of infectious TB, he or she is processed as outlined in section XI.A.5., above.
 3. If the positive TB test represents a recent conversion (“converter”) because either the same type of TB test was negative within the past 24 months or a significant TB exposure occurred within the past 24 months, and the applicant is free of clinical nor radiographic findings suggestive of infectious TB, and he or she is expected to have:
 - a. No access to NHPs or their living quarters, the OMS clinician follows the steps outlined in XI.A.5, and strongly encourages the applicant to receive treatment for LTBI if he or she is likely to be

- infected and has risk factors for progression to active TB.
- b. Access to NHPs or their living quarters, the OMS clinician:
 - i. Clears the applicant for work but restricts the applicant's access to live NHPs and their quarters.
 - ii. Notifies the Human Resources specialist identified on the Request for Medical Determination and Report of Findings form by email.
 - iii. Holds clearance until the applicant either accepts treatment for LTBI, or until 24 months after the newly positive TB test or recognized Mtb exposure.
 - c. If already hired, and the worker declines LTBI treatment, he or she is asked periodically to return to OMS for reevaluation until 24 months after conversion or known Mtb exposure. The TBSP coordinator may periodically send recent converters with risk factors for progression to active TB the memo *Tuberculosis Reminder after Recent TB Test Conversion* (Attachment VII) to invite them for reevaluation and follow-up counseling.
4. False positive TB screening
- a. TST may yield false-positive results, i.e., the applicant is not infected with Mtb, especially in populations with low risk of TB infection (low specificity). Prior exposure to the same antigens found in PPD preparations, for example, BCG or numerous NTM species, may sensitize a person to TST even though not infected with Mtb. The OMS clinician may offer re-testing by either TST or IGRA depending on the relevant history and TST reactivity.
 - b. False-positive IGRAs may result from spontaneous fluctuations of the relative TB response around the lower limit, errors in technique and processing, past exposure to three atypical mycobacteria that are antigenically closely related to MTB, and theoretically during a short window after TST administration. False-positive IGRAs on repeat testing are rare.
 - c. If a false-positive TB test result is suspected using one type of test, the OMS clinicians offers retesting by the other type unless repeating IGRA is clearly indicated (e.g., weakly positive IGRA and prior negative IGRA).
- C. Applicant with a positive TB screening test and clinical or radiographic evidence of infectious TB:
1. If the individual has not already been hired, the OMS clinician:
 - a. Follows the steps outlined in section XIV.B.1. to 5., below).
 - b. Immediately notifies the Human Resources specialist identified on the Request for Medical Determination and Report of Findings form by telephone that the applicant is not medically cleared for duty.
 - c. Refers the applicant to a personal physician or the Health Department of the county of residence for further evaluation and

- treatment.
 - d. Confers with HES or DOHS, if needed, to determine the need for a contact investigation.
 - 2. If the individual is already employed, the OMS clinician follows the relevant steps outlined in XIV.B., below.
 - D. Applicant with repeatedly indeterminate IGRA testing:
 - 1. The OMS clinician:
 - a. Administers the TB Symptoms Questionnaire and Quiz (Attachment IV) and the TB Risk Factor Survey (Attachment VI).
 - b. Orders a PA chest radiograph.
 - c. May consider the use of TST to elucidate the test results in some cases where TST is not contraindicated.
 - 2. If the applicant has no history of exposure to Mtb within the past 24 months, and no clinical or radiographic evidence of infectious TB, he or she is processed as outlined in section XI.A.5.a. and b., above except:
 - a. The worker with access to NHPs and their living quarters is given an appointment within ten weeks for repeat IGRA.
 - 3. If the applicant provides a history of a significant recent TB exposure, and the applicant is free of clinical and radiographic findings suggestive of infectious TB, and he or she is expected to have:
 - a. No access to NHPs or their living quarters, the OMS clinician follows the steps outlines in XI.A.5.a. and b., and schedules an appointment in ten weeks for retesting by IGRA.
 - b. Access to NHPs or their living quarters, the OMS clinician:
 - i. Clears the applicant for work but restricts the applicant's access to live NHPs and their quarters.
 - ii. Notifies the Human Resources specialist identified on the Request for Medical Determination and Report of Findings form by email.
 - iii. Holds clearance until the applicant returns for repeat IGRA testing within ten weeks.
 - E. Record keeping – All IGRAs and related TBSP entries are recorded in CAM and the worker's OMS chart (see section XV. below).

XII. Recall for Periodic and Incidental TB Screening

- A. OMS recalls TBSP participants, whose TB screening tests are negative, and who require repeat TB testing.
- B. Periodic TB screening is performed very twelve months and is:
 - 1. Mandatory for anyone with access to live NHP and their living quarters.
 - 2. Required for employees in work areas and occupational groups with an increased risk for occupational MTB exposure (see V.C. above).
 - 3. Not required for most HCW after initial TB screening; however, any HCW is eligible for voluntary annual TB screening.
 - 4. TB researchers working in areas where high-consequence Mtb strains are

handled or stored are screened every six months (see OMS procedure *Medical Services for M. tuberculosis Researchers*).

- C. Incidental TB screening consists of a clinical evaluation and a baseline TB test as soon as a potential exposure to Mtb is recognized, followed by another evaluation and test (same type) ten to twelve weeks after the last possible exposure. Only those whose baseline test is negative are retested. It is:
1. Mandatory for Mtb researchers, veterinary or animal care staff with a potential exposure to Mtb in a BSL-3/ABSL-3 (see OMS procedure *Medical Services for M. tuberculosis Researchers*).
 2. Required for all workers who sustained a potential Mtb exposure involving clinical specimens, including in non-research laboratory settings, and all who are enrolled in a TB contact investigation (see XIII., below).
 3. Offered to workers who expect to be at increased risk for Mtb exposure, e.g., work-related travel to a country with a high TB prevalence or a work-related attendance at a facility with increased risk for unrecognized contact with active TB patients.
 4. Offered to workers in an area or occupational group where a significant increase in the rate of TB screening conversions is observed without a discernable reason. Repeat testing may be offered every ten to twelve weeks for employees until the TB test conversion rate reverts to baseline.
- D. Implementation:
1. A worker subject to periodic recall, receives one of two recall email notices, based on the type of TB test previously used, at the beginning of the month the employee due to return for retesting (Attachment VIII). For workers who are recalled to maintain access to:
 - a. Live NHPs and their quarters, the steps are as outlined in the OMS procedure *Animal Exposure Program* using the recall notices in that procedure.
 - b. A BSL-3 or ABSL-3 research facility where Mtb is stored or handled, the steps are as outlined in the OMS procedure *Medical Services for M. tuberculosis Researchers*. TB screening of BSP participants is coordinated with other requirements for medical clearance of the BSP (see OMS procedure *Biological Surety Program*). If needed, the notices in this procedure apply.
 2. If the worker does not return for testing within a month of being recalled, OMS sends a second and final recall notice to the employee (Attachment IX). As with the first notice, the text of the notice is based on the type of TB test last used. The second notice alerts the employee that he or she is no longer in compliance with indicated screening for TB infection (see CC policy).
 - a. Supervisors of non-compliant NHP workers and BSP participants are notified if a second notice is issued.
 3. Workers with a prior positive TB screening test (prevalent positive), who would be subject to periodic recall, may receive the memo *Periodic Tuberculosis Reminder* (Attachment X) asking them to report any signs

or symptoms of active disease to OMS immediately.

- E. Periodic testing is performed as described in VIII. and IX., above.
- F. If the periodic TB screen is negative, the employee is returned to duty; their records are updated as compliant with required screening (see section XV., below).
- G. If repeat TB screening is newly positive (converter):
 - 1. The OMS clinician:
 - a. Obtains a detailed clinical, epidemiological and occupational history from the worker.
 - b. Completes a TB Symptoms Questionnaire and Quiz (Attachment IV) and TB Risk Factor Survey (Attachment VI).
 - c. Orders additional testing as indicated, e.g., radiographic imaging.
 - d. Repeats TB screening as indicated, e.g., if a TST was used, considers repeating the TST with a different manufacturer's product or orders an IGRA to clarify the significance of the findings.
 - e. A newly positive IGRA must be repeated.
 - f. Consults with HES or DOHS safety specialists to assess the risk of an occupational Mtb exposure.
 - 2. Restricts access to live NHPs and their quarters for AEP participants enrolled in the NHP portion of that program, notifies the worker's supervisor, and follows the steps outlined in XI.B.3.b. and c., above.
 - 3. A determination of work-relatedness must be made. It relies on findings of a joint investigation by OMS and HES or DOHS.
 - a. A work-related transmission of MTB is presumed in cases of documented conversion after a recognized MTB exposure at work such as a laboratory incident with an elevated risk of exposure, close, unprotected contact with a person with infectious TB at work (contact investigation), or significant exposure to a clinical specimen from such a person, even when there non-occupational risk factors for TB infection exist.
 - b. TB infection is presumed to be not occupationally acquired if the risk assessment results in consensus that there is no discernable risk of exposure to MTB at work during the period under investigation.
 - c. If the worker's duties entail a risk of an unrecognized exposure to MTB, and there are no risk factors for non-occupational MTB or NTM exposure to account for the change in TB test reactivity, it may be considered an occupationally acquired TB infection.
 - 4. When the TB test conversion is presumed to be work-related, the OMS clinician:
 - a. Counsels the worker about the significance of the findings and options for TB treatment.
 - b. Consults with an infectious disease specialist versed in the management of TB.
 - c. Offers treatment for LTBI, once active TB is ruled out.

- d. Immediately reports to HES or DOHS, depending on whether or not CC patients are at risk due to the finding, to determine how the worker may have been infected at work, and to what extent others may be at risk of Mtb exposure. Overriding the individual's privacy concerns with those for public health, the report includes the worker's:
 - i. Name,
 - ii. Occupation and
 - iii. Work location(s) during the time period of concern, i.e., when the conversion may have occurred.
- e. Baseline and repeat TB testing ten weeks later is provided for coworkers with a potential common exposure (see XIII.C.3.).
- 5. New converters without occupational risk for Mtb exposure are referred to their personal physician or public health for evaluation (see XI.A.5.d.).
- 6. If the employee has either clinical or radiographic evidence of active TB, the course of action is as outlined in Section XIV.C., below.

XIII. TB Contact Investigation

- A. Investigations of contacts of persons with infectious TB and treatment of those infected with MTB are integral to an effective TB control program. OMS is responsible for conducting TB contact investigations in the workplace in accordance with established guidelines (see Appendix XX). An OMS nurse is designated to coordinate each contact investigation working closely with co-investigators such as HES epidemiologists, DOHS safety specialists, public health officers or treating physicians of index patients (see OMS procedure *Contact Investigation Guidelines*).
- B. Identification of index case:
 - 1. HES identifies index patients who put HCW at risk for MTB exposure to the OMS clinician. Most index patients are CC patients; NIH workers with infectious TB who may come into contact with CC patients also fall under HES purview.
 - 2. Supervisors, co-workers, safety specialists, OMS clinicians, public health officers, and treating healthcare providers may make a report a person with infectious TB in the workplace directly to OMS. OMS investigates all potential MTB exposures in the workplace in non-clinical areas in collaboration with safety specialists, public TB control officers of the worker's county of residence, and, if indicated, the index patient and his or her treating physician. In such cases OMS may play a dual role conducting the contact investigation in the workplace and performing the worker's return-to-work evaluation.
 - 3. The OMS contact study coordinator obtains the following index case information from co-investigators (HES, DOHS or outside epidemiologist):
 - a. Patient's name and medical record number (CC patients) or contact information (NIH employees). The index case initials

and date of first report to OMS serve as unique identifier for each contact investigation while maintaining confidentiality (see Attachment XI).

- b. Name and contact information of the attending physician (CC or outside provider), and, for CC patients, their principle diagnoses, including factors that may affect infectiousness of the source.
 - c. Period of infectivity, i.e., from the first to last possible exposure (e.g., from admission until airborne isolation measures are taken).
 - d. Areas and work groups where workers may have had contact with the index patient sufficient for possible MTB exposure.
- C. Identification of contacts – Criteria for inclusion into a TB contact investigation typically include close proximity to the index patient without adequate personal protection in a small, enclosed room for a period of time presumably sufficient to inhale TB bacteria.
1. HES identifies contacts of index cases who put CC HCW at risk using contact case criteria established by the HES medical staff.
 2. DOHS safety specialists investigate the workplace of index cases without contact to CC HCW and refer potential contacts to OMS using criteria established by the OMS physician in consultation with public health officers.
 3. Potential contacts may refer themselves for evaluation to OMS and are subject to the same criteria as contacts referred by HES or DOHS.
 4. Occasionally the TBSP Coordinator observes a significant increase in the rate of TB screening conversions in an area or occupational group, and may identify workers from such groups as potential contacts to an unidentified source. Depending on the area HES or DOHS conducts a site investigation in coordination with OMS.
- D. Initial visit:
1. All potential contacts are asked to complete the Employee Portion of the Report of Employee TB Exposure (Attachment XI, sections I.-III.) and the TB Quiz (Attachment IV).
 2. An OMS clinician interviews each potential contact regarding his or her exposure, current symptoms and relevant past medical history, and determines if the worker meets criteria for:
 - a. Enrollment into the contact investigation, and
 - b. High-priority or low priority contact case applying parameters specific to each contact investigation.
 - c. Those who do not meet contact case criteria receive counseling as appropriate but are not enrolled as contacts of the index case.
 3. All contacts with previously negative TB screening receive detailed counseling on the significance of their exposure and receive a baseline TB test unless their most recent documented negative TB test was performed with the past ten weeks.
 - a. The OMS contact study coordinator may call for high-priority contact screening before expanding testing of low-priority contacts depending on available resources.

- b. If more than ten weeks have passed since the last possible exposure to the MTB source, the TB test at enrollment may be compared to the most recent TB test available, regardless of type, taking into account any intervening TB risk factors.
 - c. If a different type of TB test is indicated for purposes of the contact investigation, a baseline test should be performed regardless of date of most recent TB screening.
4. Choosing type of TB test for screening contacts:
- a. The test of choice is a TST for most contacts.
 - b. IGRA may be preferable for contacts with an increased chance of an apparent new conversion due to prior sensitization (history of BCG, remote exposure to MTB).
 - c. If a contact subject to recall did not complete two-step testing at preplacement, and the last documented TST occurred more than two years prior to this test, two-step testing should be performed at baseline contact screening.
5. Prior positive TB test contacts (prevalent positive) receive detailed counseling on the significance of their exposure and a follow-up appointment in ten to twelve weeks; a TB test is not performed. If the estimated risk of exposure to MTB is elevated the OMS clinician may advise the contact to consider a course of LTBI treatment.
6. Contacts, whose baseline TB test is negative, are notified with the results and recalled by ten weeks after last possible exposure (see XII.C. and D., above). (
7. Contacts whose baseline TB test is positive (discovered by OMS), receive detailed counseling on the significance of their exposure and a follow-up appointment in ten to twelve weeks. In addition, the OMS clinician follows the relevant steps in Section X.B.1.b.-3., above, and may consider offering LTBI treatment for occupational MTB exposure(s).
8. The OMS clinician completes the section relevant to the initial evaluation in the OMS Clinician Portion of the Report of Employee TB Exposure (Attachment XI, section IV.).
9. All high-priority contacts, regardless of initial TB screening status, receive detailed counseling on the significance of their exposure and are strongly encouraged to return for a follow-up evaluation ten to twelve weeks after enrollment into the contact investigation, and anytime they develop signs or symptoms suspicious for active TB. The OMS contact investigation coordinator may recall those with risk factors for rapid progression or poor outcome if infected individually if they do not respond to the second and final recall notice.
- E. Follow-up visit:
- 1. The OMS clinician interviews the contact regarding relevant symptoms and any relevant interim medical history Report of TB Exposure form (Attachment XI, section V.) is completed ten weeks from the date of the last contact with the index case.
 - 2. The same type of TB test as for baseline screening is performed for

- contacts with a negative baseline test.
3. If a repeat TB screen is positive and deemed a work-related TB infection, the course of action is as outlined in sections XII.G.3. and XIV.B., after active TB has been ruled out.
 4. Converters during a contact investigation and prevalent-positive contacts with and elevated-risk exposure to MTB who decline LTBI treatment, may be reminded if the elevated risk-period for developing active TB for the first two years after the presumed TB infection at the discretion of the OMS contact investigation coordinator (Attachment VII).
- F. If any signs or symptoms of active TB emerge in a contact during the CI the course of actions is as outlined in XI.C and XIV.C.

XIV. Management of TB Infection

- A. LTBI – Treatment options include pharmacologic treatment or watchful waiting. Current first-line regimens consist of a nine-month course of daily isoniazid (INH) or a weekly two-drug regimen (INH and rifapentine) for twelve weeks
1. The worker with occupationally acquired LTBI is fully evaluated and counseled prior to starting LTBI treatment regarding:
 - a. Expected treatment plan and follow-up at OMS;
 - b. Potential adverse effects of medication;
 - c. Alternatives to treatment with antitubercular medications, including passive symptoms watch for at least two years after exposure or test conversion; and
 - d. Risk factors for progression to active TB disease,
 - e. Signs and symptoms suggestive of early infectious TB and notification procedures of OMS with complications of TB infection or its treatment.
 2. The employee is advised that he or she may transfer care to a medical provider of his or her choice at any time prior to or during treatment.
- B. Active TB as an occupational illness is expected to occur only rarely at the NIH given the relatively low-risk in most clinical settings and state-of-the-art biocontainment measures. It requires a significant, likely recognized exposure to MTB such as prolonged contact with a TB patient or laboratory exposure. At presentation of a person suspected of infectious TB to OMS, the OMS clinician:
1. Gives the worker a surgical mask and instructs him or her to wear it;
 2. Escorts the worker to an unoccupied room;
 3. Dons appropriate respiratory protection (e.g., an N-95 respirator);
 4. If not already done, obtains a detailed clinical, epidemiological and occupational history from the worker, and completes a TB Symptoms Questionnaire and Quiz (Attachment IV) and TB Risk Factor Survey (Attachment VI);
 5. Provides the worker with detailed verbal counseling and written information appropriate to the employee's level of education;
 6. Notifies the supervisor that the employee is not permitted to return to the

- worksite until the medical evaluation is completed and the individual is medically cleared by OMS;
7. If this is the worker's first report of a potential occupational exposure to Mtb, and he or she has a prior negative TST performed by OMS, the relevant steps in XII.G.2. and 3. are followed;
 8. Immediately notifies HES as soon as the diagnosis is suspected and, if the clinical impression of active TB is confirmed, a TB contact investigation is initiated.
 9. Notifies DOHS to collaborate in a TB contact investigation once it is determined that CC HCW or CC patients are not at risk for MTB exposure.
 10. Assuming that an occupational exposure to Mtb is suspected, the following clinical evaluation is performed by the OMS physician in consultation with a CC infectious disease expert or public health officer and under the appropriate respiratory isolation measures:
 - a. A sputum sample is obtained and sent to the CC Microbiology Laboratory for:
 - i. A smear for acid-fast bacilli (AFB) stain,
 - ii. Rapid diagnostic testing such as nucleic acid amplification tests (NAAT), and
 - iii. AFB culture with speciation and sensitivity testing.
 - b. If AFB and NAAT are negative on initial evaluation two more sputum samples are sent for the same test on two successive mornings.
 - c. If all three sputum smears are negative for AFB and the clinical or radiographic findings can reasonably be attributed to a condition other than infectious TB, the OMS clinician returns the worker to work.
 - d. If any of the three sputum smears are positive for AFB or the clinical or radiographic findings cannot rule out infectious TB:
 - i. Medical clearance to return to work is provided only after the individual completes at least two weeks of an appropriate TB treatment regimen and has three consecutive negative sputum smears.
 - ii. If the individual works in any capacity with, or in close proximity to NHPs, the appropriate IC Animal Program Director (APD) is notified.
 11. The responsible OMS clinician may refer a worker with suspected or confirmed active TB to an outside physician at the employee's request or the clinician's discretion at any time.
 12. An applicant with suspected infectious TB at initial evaluation or worker who opts to be evaluated and treated by his or her physician must provide detailed medical documentation from the treating physician equivalent to the steps outlined in this section before a *Request for Medical Determination and Report of Findings* form with clearance for full duty is issued.

13. The TBSP Coordinator closely monitors the subsequent clinical course and compliance with treatment.

XV. Recordkeeping and Reports

A. Recordkeeping

1. At enrollment into the TBSP the OMS adds a single record to the worker's electronic medical record in CAM's Tuberculosis module (Surveillance Programs folder).
2. The OMS clinician opens the Tuberculosis module in the worker's CAM record and selects the applicable TBSP Work Category.
 - a. None (No Agents) – applies to individuals who receive initial screening but are not expected to require periodic retesting (examples include workers with patient contact and workers previously enrolled who no longer require recall).
 - i. This option excludes all other Work Categories and must be cleared if another TBSP Work Category applies.
 - ii. It must be reselected if recall is not required.
 - b. Nonhuman Primates (NHP) – applies to anyone who “shares airspace” with NHPs.
 - c. Respiratory Therapy, Performs Bronchoscopy – applies to two specific clinical positions associated with high-risk procedures.
 - d. Other Group Requiring Recall – applies to any worker who has an increased risk for MTB exposure due to duties that do not fit in any other TBSP Work Category.
 - e. TB Bacteria-Low Risk – applies to workers who handle Mtb or Mtb-infected animals in a clinical and most research laboratory settings such as those working exclusively with drug-sensitive Mtb strains.
 - f. TB Bacteria-High Risk – applies to laboratorians and support staff who are expected to work with drug-resistant Mtb strains performing high-risk activities such as handling large Mtb quantities or high concentrations, aerosolizing Mtb during inoculation, or directly handling Mtb-infected animals (see OMS procedure *Medical Services for M. tuberculosis Researchers*).
 - g. Contact Study – applies to workers who require one-time recall after potential exposure to Mtb at work.
3. Every TB screening test is recorded in the Labs and Procedures module of a worker's CAM record. A new record is added for each test identified by date on which it was performed.
 - a. All TSTs read by OMS staff are recorded by the OMS clinician in the CAM in the Labs and Procedures module as a new entry, including those placed by a personal healthcare provider. The OMS clinician reading the TST records the number of mm of induration and the interpretation of the significance of the findings in the TBSP module.

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- b. All documented QFT-GIT results, including those from outside facilities, are recorded as IGRAs in the CAM Labs and Procedure module. Quantitative data is entered manually in the Results window in International Units per milliliter (IU/ml).
 - c. OMS laboratory staff enters IGRA results on all in-house tests and alerts the clinician who ordered the test except for Mtb researcher whose results are reported to the TBSP Coordinator.
 - d. The TB Screen Status that best fits the worker's history and test results is selected; it determines if there is a "Compliance End Date."
 - e. In order to activate the recall date ("Compliance End Date") for those with negative TB screening and in a TBSP category requiring recall, the TBSP module must be opened once after entering a new TB screening test result.
 - f. The TB Screen Type (TST or IGRA) determines which test will be offered for further screening.
 - g. The Referred pick list permits the OMS clinician to document whether or not s/he referred a worker with a positive TB screening test for further evaluation and possibly treatment.
4. Recall and periodic testing:
- a. Recall is facilitated by selecting all applicable TBSP Work Categories at the time of enrollment and subsequently updating the employee's Laboratory and Procedures and TBSP modules in CAM with each periodic TB screening.
 - b. Updates to the TBSP occurs when new test results are entered and the TBSP module is opened (negative results only).
 - c. A TBSP Work Category may be added or deleted as needed. For example, the "Contact Case" may be used to facilitate recall of contact after enrollment during a contact investigation and then is dropped to revert to the prior category once follow-up is complete.
5. The periodicity for recall of an employee is determined by the TBSP Work Category with the shortest maximum interval between TB screenings. The CAM TBSP module allows for three fixed intervals:
- a. Twelve months for NHP workers and employees at increased risk of occupational exposure to MTB, including MTB researchers in a low-risk research environment.
 - b. Six months for workers in certain TB research settings.
 - c. Ten weeks for follow-up testing for incidental TB screening; kept in place until frequent screening is no longer indicated. Limitations arise when potential exposure occurs over a period of time requiring manual adjustment of follow-up TB screening.
- Positive on recall and work-related: The occurrence is recorded as an occupational illness and the worker is provided with guidance on filing a Federal Workers' Compensation claim, if she or he is a federal employee (reference the Occupational Injury and Illness procedure).

6. Once an employee is enrolled in TBSP and has no current retesting requirements, the CAM record is retained.
 7. If a TBSP participant fails to return for retesting despite two email notices, and neither has contact with NHPs nor works in a BSL-3 laboratory with MTB, the TBSP module remains unchanged to reflect the employee's noncompliance with indicated TB screening. It will be updated at the earliest opportunity to complete repeat testing if the need to screen for TB infection persists.
 8. A worker's TBSP record is deleted from CAM but maintained in the OMS chart once OMS is notified that he or she no longer is required to be enrolled in the TBSP.
- B. Contact investigations:
1. To maintain confidentiality the contact investigation is only identified by index case initials and date of first report (see Attachment XI).
 2. The TB Contact Investigation Coordinator maintains a running log of TB contacts during an investigation (Attachment XII) and a manifest for manual recall of high-priority contacts with risk factors for rapid progression or poor outcome if infected.
- C. External Reports
1. The Contact Investigation Coordinator is responsible for summarizing the contact data (Attachment XIII) at the conclusion of an investigation, and, for CC TB contact investigations, sending this report to HES as soon as completed.
 2. DOHS and HES each receive quarterly summaries of any TB CI completed during the interval (Attachment XIII). Personal identifiers are excluded from CI summaries to maintain the medical confidentiality of both the index case and participating employees.
 3. HES and DOHS may receive interim summaries of ongoing investigations on request.
 4. If a public health officer was involved in a TB contact investigation, the OMS Contact Investigation Coordinator sends the assigned TB control officer a completed summary upon request at the conclusion of the investigation.
 5. The OMS physician notifies:
 - a. The Director of DOHS with any cases of confirmed occupationally acquired TB disease or TB test conversions stemming from exposure to MTB at work as soon as they occur.
 - b. The CC Hospital Safety Officer with all such cases arising in patient care areas.
 - c. The public health TB control officer of the applicant's county of residence with any case of active TB case according to reporting requirements for notifiable diseases.

XVI. Resources and References

- A. Resources:
1. CDC Fact Sheet. TB Elimination: Targeted Tuberculosis Testing and Interpreting Tuberculin Skin Test Results. (PDF). November 2011; accessed May 2014.
<http://www.cdc.gov/tb/publications/factsheets/testing/skintestresults.pdf>
 2. TB – What you Need to Know about the Tuberculosis Skin Test (2008; reprint 2015). CDC educational pamphlet:
https://www.cdc.gov/tb/publications/pamphlets/tb_skin_test.pdf
 3. CDC Fact Sheet. TB Elimination: Interferon-Gamma Release Assays (IGRAs) – Blood tests for TB Infection. (PDF). December 2011; accessed May 2014.
<http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.pdf>
 4. CDC Fact Sheet. Tuberculosis – Testing and Diagnosis. Updated April 10, 2014. Accessed May 2014.
<http://www.cdc.gov/TB/TOPIc/testing/default.htm>
 5. BCG Atlas: <http://www.bcgatlas.org/>
 6. CDC Latent TB Infection and TB Disease (2016):
<https://www.cdc.gov/tb/topic/basics/tbinfectiondisease.htm>
 7. CDC TB Risk Factors (2017):
<https://www.cdc.gov/tb/topic/basics/risk.htm>
- B. References:
1. Official American Thoracic Society/Infectious Diseases Society of America/ Centers for Disease Control and Prevention Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children. Lewinsohn DM, et al. *Clin Infect Dis* (2017) 64(2):21-e33. DOI: <https://doi.org/10.1093/cid/ciw694>
 2. Centers for Disease Control and Prevention. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection, United States. (PDF) *MMWR* 2010; 59 (No.RR-5). http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e
 3. IFN- γ Release Assay Conversions and Reversion. Joshi M, et al. *Ann Am Thorac Soc* (2014). 11(3):296-302. DOI: 10.1513/AnnalsATS.201310-378OC
 4. Guidelines for Preventing the Transmission *M. tuberculosis* in Health-Care Settings, 2005. *MMWR* 2005, 54 (RR17).
 5. Targeted Tuberculin Testing and Treatment for Latent Tuberculosis Infections. *MMWR* 2000, 49 (RR06).
 6. Tuberculin Skin Testing Fact Sheet, CDC. online:
<http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm>.
 7. CDC pages: Basic TB Facts:
<http://www.cdc.gov/tb/topic/basics/default.htm>;
 8. The BCG World Atlas: A Database of Global BCG Vaccination Policies and Practices. Zwerling A, et al. *PLoS Medicine* (2011) 8(3): e1001012.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3062527/pdf/pmed.100>

- [1012.pdf](#)
9. TB Exposure Assessment:
<http://www.cdc.gov/tb/topic/basics/exposed.htm>
 10. Tuberculin Skin Testing Fact Sheet, CDC. online:
<http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm>.
 11. http://www.emedicinehealth.com/tuberculosis_tb-health/page3_em.htm
 12. Sokal JE: Editorial, Measurement of Delayed Skin-Test Responses. *N Eng J Med* 293:501502, 1975.
 13. Villarino et. al.: Skin Testing with Two Commercial Tuberculin Reagents: Indistinguishable Specificity in Persons at Low Risk for Tuberculosis Infection. *JAMA* 1999, Jan 13; 281 (2): 169-71.
 14. <http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm>
 15. <http://www2c.cdc.gov/podcasts/player.asp?f=3739#>
 16. <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.pdf>
 17. <http://www.cdc.gov/tb/education/ssmodules/module6/ss6contents.htm>
 18. Guidelines for the Investigation of Contacts of persons with Infectious Tuberculosis (2005). *MMWR* 54(RR):1-37
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm>
 19. <http://www.cdc.gov/tb/education/ssmodules/module6/ss6contactinvestigations.htm>
 20. TB in NHPs – The Disease.
http://www.dpz.eu/fileadmin/content/Infektionspathologie/Bilder/Dokumente/MAETZ-RENSING%20TB-the%20disease%20FORMAT%20COP_Korr.pdf
 21. Extrapulmonary tuberculosis: an overview. Golden PM, Holenarasipur RV (2005). *Am Fam Physician* 72(9):1761-8.
<http://www.aafp.org/afp/2005/1101/p1761.pdf>

Questionnaire for Tuberculin Skin Testing

Please answer the following questions. Your responses will help determine which test, if any, you should receive to screen for prior infection with *Mycobacterium tuberculosis* and how your test should be interpreted.

- | Have you: | Yes | No |
|---|--------------------------|--------------------------|
| 1. Had a reactive TB screening test (skin or blood test)?
If yes, please describe the test, date performed, and result or reaction to it:

_____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Been vaccinated with BCG?
If yes, when and where did you receive the vaccine?

_____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Received an immunization for measles, mumps, rubella, yellow fever, or varicella (chickenpox) within the past six weeks? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Had a viral infection (for example, influenza, mononucleosis, hepatitis, chicken pox, or herpes simplex) within the past month? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Had close contact with anyone with active TB disease during the past two years? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Had close contact with people who have a higher risk of TB infection in the past (for example, people from countries with high rates of TB, people living with HIV, residents or employees in certain institutions or facilities such as inner-city hospitals, nursing homes, homeless shelters, correctional facilities, injection drug users)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Do you currently have a medical condition or received medical treatment that may affect your immune system (e.g., steroid or chemotherapy, organ transplant, HIV infection, diabetes, chronic renal disease, injection drug use, leukemia or lymphoma)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Have you ever had an abnormal chest X-ray or been treated for TB infection? | <input type="checkbox"/> | <input type="checkbox"/> |

The OMS nurse will discuss your tuberculosis screening options with you.

Reviewed by: _____ Date: _____

Date:

To: Tuberculosis Surveillance Program (TBSP) Participant

From: TBSP Coordinator
Occupational Medical Service, DOHS

Subject: Outside Placement of a Tuberculin Skin Test

If you are unable to have your tuberculin skin test (TST) placed and read by the Occupational Medical Service (OMS), you may have your personal health care provider place the skin test. Please have your health care provider complete the form at the bottom of this memorandum.

An OMS clinician must read the test no earlier than 48 hours and no later than 72 hours after it is placed. Bring this memorandum with you when you visit OMS. You may schedule an appointment by calling your local OMS clinic.

This is to certify that we placed a tuberculin skin test for:

_____ on: _____ .

TST 0.1 ml ID: _____ L, _____ R forearm

Manufacturer: _____, Lot #: _____

Signature: _____

Address: _____

OMS Contact Numbers:

Bethesda, MD: 301-496-4411

Frederick, MD: 301-631-7233

Baltimore, MD: 443-740-2309

Hamilton, MT: 406-375-9755

**NIH Occupational Medical Service
Certificate of Tuberculosis Screening/Test Results**

This is to certify that _____ has been screened for tuberculosis.

Placement:

TST 5 TU (0.1 ml) ID L R forearm

Mfg/Lot Number/Expiration: _____

Date Placed: _____

Results:

TST Read on: _____

Negative: _____ mm induration

Positive: _____ mm induration *

Conversion: Yes No

IGRA (Quantiferon) done on: _____

Results: Negative Indeterminate Positive

Quantitative: _____

(Nil/ Mitogen / TB response)

Chest x-ray done on: _____

Results: _____

Referred to personal physician to discuss TB prophylaxis

Comments:

Read/verified by: _____

OMS Clinician's Signature

OMS Contact Numbers :

Bethesda, MD: 301-496-4411

Frederick, MD: 301-631-7233

Baltimore, MD: 443-740-2309

Hamilton, MT: 406-375-9755

Research Triangle Park, NC: 919-541-4689

***Do not receive another TB skin test. Keep this form for your records.**

TB Symptoms Questionnaire and Quiz

Name: _____ ID No.: _____
 Date: _____ Institute/Center: _____ Bldg: _____ Room: _____
 Phone: (W): _____ (C): _____ (H): _____
 Current residence (City, State): _____

Have you had any of the following within the past 12 months?

	<u>Yes</u>	<u>No</u>	<u>Comments</u>
1. Fatigue or general loss of energy lasting two weeks or longer.	<input type="checkbox"/>	<input type="checkbox"/>	
2. New, unexplained cough lasting three weeks or longer.	<input type="checkbox"/>	<input type="checkbox"/>	_____
3. Loss of appetite for more than two weeks.	<input type="checkbox"/>	<input type="checkbox"/>	_____
4. Fever greater than 100°F that lasted for at least two weeks.	<input type="checkbox"/>	<input type="checkbox"/>	_____
5. Night sweats (drenching bed clothes) that lasted for at least one week.	<input type="checkbox"/>	<input type="checkbox"/>	_____
6. Unexplained weight loss of 10 lbs. or more than 10% of your usual body weight.	<input type="checkbox"/>	<input type="checkbox"/>	_____
7. Any significant change in your health. If yes, please explain:	<input type="checkbox"/>	<input type="checkbox"/>	_____

OVER

Please mark the following questions as True or False.	True	False
1. Tuberculosis is a disease caused by bacteria which grows best in the small sacs of the lungs, but may also infect other parts of the body.	<input type="checkbox"/>	<input type="checkbox"/>
2. TB bacteria are usually spread when you inhale respiratory (lung) droplets which become airborne by coughing, sneezing, and talking.	<input type="checkbox"/>	<input type="checkbox"/>
3. A person who has TB infection cannot transmit TB until he or she has active TB disease of the lungs or airways.	<input type="checkbox"/>	<input type="checkbox"/>
4. A person with active TB typically experiences low grade fever, night sweats, fatigue, weight loss and a persistent cough.	<input type="checkbox"/>	<input type="checkbox"/>
5. The risk of becoming infected with TB bacteria from a person with TB disease increases if the room is poorly ventilated, if the number of TB bacteria in the air increases or if the exposure takes place over a long period of time.	<input type="checkbox"/>	<input type="checkbox"/>
6. If your tuberculin skin test is positive and you do not have any symptoms of the active disease, your risk of developing clinical (active) tuberculosis is greatest in the first two years following your infection with TB.	<input type="checkbox"/>	<input type="checkbox"/>
7. A positive TB skin test, even with a negative chest x-ray, can suggest infection with <i>M. tuberculosis</i> .	<input type="checkbox"/>	<input type="checkbox"/>
8. Taking treatment for latent TB infection (LTBI) decreases the chances of developing active TB later.	<input type="checkbox"/>	<input type="checkbox"/>
9. Active TB can be successfully treated by seeking appropriate medical attention and taking multiple medications prescribed by your physician for at least of six months.	<input type="checkbox"/>	<input type="checkbox"/>
10. A person who was infected with TB bacteria in the past can become infected again with a new exposure.	<input type="checkbox"/>	<input type="checkbox"/>
11. One of the newer blood tests (IGRA) will not turn positive with repeated use when a person was vaccinated with BCG and has not been infected with <i>M. tuberculosis</i> .	<input type="checkbox"/>	<input type="checkbox"/>
12. A negative IGRA result does not exclude the possibility of TB infection.	<input type="checkbox"/>	<input type="checkbox"/>
13. The test results of a TB skin test and an IGRA don't always agree.	<input type="checkbox"/>	<input type="checkbox"/>
14. Both screening methods (TST and IGRA) rely on an intact immune system, especially cellular immunity (as opposed humoral immunity).	<input type="checkbox"/>	<input type="checkbox"/>
15. There is no single test that can determine with certainty whether or not someone was infected with TB bacteria during the dormant phase (LTBI).	<input type="checkbox"/>	<input type="checkbox"/>

Date:

To:

From: (OMS clinician)
Occupational Medical Service, DOHS

Subject: Referral for Evaluation of Latent Tuberculosis Infection

_____ is referred to you for evaluation and consideration of treatment options of LTBI. His/her intermediate strength (5 TU) tuberculin skin test read today measures ____ mm (millimeters) of induration. His/her interferon- γ release assay (QuantiFERON[®]-TB Gold In-tube) report showed the following: Positive with a quantitative TB response of _____ IU/mL. The PA chest radiograph does not reveal any pulmonary abnormalities. The patient has a copy of the radiograph.

Please call OMS, if you have any questions.

(OMS clinician's signature)

OMS Locations and Numbers:

Bethesda, Building 10, Room 6C306
301-496-4411

IRF Fort Detrick, Room 1B116
301-631-7233

Baltimore Bayview, Room 01B210
443-740-2309

Rocky Mountain Laboratories, Room 5202
406-375-9755

TB Risk Factor Survey

Name: _____ ID No.: _____

Date: _____ Institute/Center: _____ Bldg: _____ Room: _____

Phone: (W): _____ (C): _____ (H): _____

Current residence (City, State): _____

1. Have you been in close contact with a person with infectious tuberculosis (active TB) or enrolled in a TB contact investigation in the past 24 months?

If yes, give details: _____

2. Did you immigrate or repatriate to the U.S. from another country within the past 5 years?

If yes, give details: _____

3. Over the past 2 years, have you resided in U.S. Territories, States or counties known to have TB rates above the national average such as Hawaii, Alaska, Washington, D.C., California or Texas?

<https://www.cdc.gov/tb/statistics/default.htm><https://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm>

If yes, give details: _____

4. Over the past 2 years, have you traveled outside the U.S. to any foreign countries
 Yes No

http://gamapservr.who.int/mapLibrary/Files/Maps/Global_TBincidence_2015.png<http://www.who.int/tb/country/data/profiles/en/><http://www.who.int/tb/publications/2009/airborne/background/info/en/>

If yes, give details: _____

5. Over the past 2 years, have you worked or volunteered in settings where you had close contact with (check all that apply):
- Patient populations with elevated TB prevalence rates (e.g., healthcare facilities seeing high number of underserved patients)
 - Recent immigrants
 - Homeless persons
 - Persons using illicit drugs, especially by intravenous injection
 - Residents or employees of nursing homes
 - Residents or employees of correctional facilities or orphanages
 - Immunosuppressed persons, people with HIV
 - Patients in healthcare facilities with an increased risk for TB transmission
 - Mycobacteria*, especially *M. tuberculosis*, in any work setting, e.g., in a clinical or research laboratory?

If any selected, give details: _____

6. Over the past 2 years, have any close friends or family members had symptoms of active pulmonary tuberculosis (Please circle all that apply: persistent cough over 2 weeks, unexplained weight loss, fever, night sweats, malaise)?

If any selected, give details: _____

7. Have you been diagnosed or treated with any of the following (circle all that apply)?

- | | |
|-----------------------|--|
| Diabetes mellitus | Substance or alcohol use disorder |
| Severe kidney disease | Low body weight (10% or less normal body weight) |
| Head or neck tumor | Weight reduction surgery |
| Rheumatoid arthritis | Intestinal disorders, e.g., Crohn's disease |
| Organ transplant | Corticosteroid or TNF- α antagonist therapy |
| Abnormal chest X-ray | Tuberculosis |
| HIV infection | Silicosis |

If any selected, give details: _____

Tuberculosis Reminder after Recent TB Test Conversion

Your Occupational Medical Service (OMS) record indicates that you converted on tuberculosis (TB) screening, i.e., you have a positive TB test after a previously negative test. A positive TB screening test suggests that you may have been infected with the TB bacterium. Most people who have been infected with the TB bacterium remain healthy and cannot infect others. However, approximately one of ten infected people will develop active tuberculosis sometime during their life; most of those will do so sometime within the first two years after becoming infected. People who complete recommended treatment for dormant TB infection greatly reduce their chances of developing active disease, but even they are not completely protected. In addition, prior TB infection does not protect against re-infection. If you develop infectious TB (pulmonary TB or active TB in the upper respiratory tract) you can transmit the TB bacterium to others, including nonhuman primates. Because this may devastate people whose immune system may be suppressed or nonhuman primates who are extremely susceptible to severe TB disease, you must not have any contact with them or their living quarters.

I am writing to invite you for a follow-up evaluation at OMS recommended for two years following a new TB infection. I also want to remind you of the earliest symptoms of active tuberculosis. These symptoms include: unusual, unexplained fatigue or weakness; persistent loss of appetite; a fever of unknown origin of 100° F (38° C) or greater that lasts more than two weeks; a new, unexplained cough lasting three weeks or longer; profuse sweating at night and weight loss without another reason. This may progress to a more productive cough possibly with blood-tinged sputum, chest pain, worsening fatigue and pronounced loss of weight.

Please bear in mind that you must not have any contact with patients or nonhuman primates until cleared by OMS when you can document that you are either taking appropriate treatment for presumed TB infection or are no longer at increased risk for developing active TB disease.

Please call OMS if you develop any of the symptoms listed above and for your semiannual follow-up appointment. If you have any related questions or concerns, please give me a call (301-496-4411).

(TBSP Coordinator's signature)

OMS Locations and Numbers:

Bethesda, Building 10, Room 6C306; Tel: 301-496-4411

IRF Fort Detrick, Room 1B116; Tel: 301-631-7233

Baltimore Bayview, Room 01B210; Tel: 443-740-2309

Rocky Mountain Laboratories, Room 5202; Tel: 406-375-9755

Recall Notice for TB Testing

Dear _____,

OMS records indicate that you are enrolled in the Tuberculosis Surveillance Program (TBSP) and that you are due for repeat screening for tuberculosis (TB) infection. Compliance with periodic testing is required for employees in areas or occupations with an increased chance to become infected with the bacteria that cause TB. Employees who have had contact with a person with active TB or a recognized work-related exposure to TB bacteria must also comply with retesting requirements.

You may call 301-496-4411 within two weeks of the date of this memorandum to schedule an appointment to receive a skin test for tuberculosis or attend one of the following walk-in clinics in the OMS Bethesda clinic.

(Six dates and times offered for tuberculin skin test placement and reading)

If you work in Baltimore, you may schedule an appointment by calling 443-740-2309.

If you work in Frederick, you may schedule an appointment by calling 301-631-7233.

If you work at RML, you may schedule an appointment by calling 406-375-9755.

Thank you.

OR

Dear _____,

OMS records indicate that you are enrolled in the Tuberculosis Surveillance Program (TBSP) and that you are due for repeat screening for tuberculosis (TB) infection. Compliance with periodic testing is required for employees in areas or occupations with an increased chance to become infected with the bacteria that cause TB. Employees who have had contact with a person with active TB or a recognized work-related exposure to TB bacteria must also comply with retesting requirements.

Please call OMS at 301-496-4411 within two weeks of the date of this memorandum to schedule an appointment for an IGRA blood test. Please note this test must be done before 11AM to allow for same day processing.

If you work in Baltimore, you may schedule an appointment by calling 443-740-2309.

If you work in Frederick, you may schedule an appointment by calling 301-631-7233.

If you work at RML, you may schedule an appointment by calling 406-375-9755.

Thank you.

Occupational Medical Service
Division of Occupational Health and Safety, ORS

Reviewed March 2017
SOP 400.499

Recall for TB Testing - Second and Final Notice

Dear _____,

OMS records indicate that you did not respond to a prior request to return to the clinic for repeat screening for tuberculosis (TB) infection as part of your participation in the Tuberculosis Surveillance Program (TBSP). Compliance with periodic testing is required for employees in areas or occupations with an increased chance to become infected with the bacteria that cause TB. Employees who have had contact with a person with active TB or a recognized work-related exposure to TB bacteria must also comply with retesting requirements.

You must call 301-496-4411 within two weeks of the date of this memorandum to schedule an appointment to receive a skin test or attend one of the walk-in clinics below. Failure to comply with TB screening as may result in adverse health outcomes for you and others or administrative actions.

(Six dates and times offered for tuberculin skin test placement and reading)

If you work in Baltimore, you may schedule an appointment by calling 443-740-2309.

If you work in Frederick, you may schedule an appointment by calling 301-631-7233.

If you work at RML, you may schedule an appointment by calling 406-375-9755.

Thank you.

OR

Dear _____,

OMS records indicate that you did not respond to a prior request to return to the clinic for repeat screening for tuberculosis (TB) infection as part of your participation in the Tuberculosis Surveillance Program (TBSP). Compliance with periodic testing is required for employees in areas or occupations with an increased chance to become infected with the bacteria that cause TB. Employees who have had contact with a person with active TB or a recognized work-related exposure to TB bacteria must also comply with retesting requirements.

You must call 301-496-4411 within two weeks of the date of this memorandum to schedule an appointment to schedule an appointment for an IGRA blood test. Please note this test must be done before 11AM to allow for same day processing. Failure to comply with TB screening as may result in adverse health outcomes for you and others or administrative actions.

If you work in Baltimore, you may schedule an appointment by calling 443-740-2309.

If you work in Frederick, you may schedule an appointment by calling 301-631-7233.

If you work at RML, you may schedule an appointment by calling 406-375-9755.

Thank you.

Occupational Medical Service
Division of Occupational Health and Safety, ORS

Reviewed March 2017
SOP 400.499

Periodic Tuberculosis Reminder

Dear _____,

Your Occupational Medical Service (OMS) record indicates that your tuberculosis (TB) screening test was positive (reactive) in the past. A positive TB test suggests that you may have been infected with the TB bacterium. Most people who have been infected with the TB bacterium remain healthy and cannot infect others. However, approximately one of ten infected people may develop active tuberculosis sometime during their life. Most of those who will progress to active TB will do so sometime within the first two years after becoming infected. People who complete recommended treatment for latent tuberculosis infection greatly reduce their chances of developing active disease, but even they are not completely protected.

As someone who is enrolled in the NIH TB Surveillance Program, you are eligible for periodic screening for TB infection. I am writing to remind you of the earliest symptoms of active tuberculosis. These symptoms may include: unusual fatigue or weakness; persistent loss of appetite; a fever of unknown origin of 100° F (38° C) or greater that lasts more than two weeks; a new, unexplained cough lasting three weeks or longer; profuse sweating at night and weight loss without another reason. This may progress to a more productive cough possibly with blood-tinged sputum, chest pain, worsening fatigue and pronounced loss of weight. A significant change in the health of your immune system may increase the risk of developing infectious TB increasing your own health risks and those of others, including nonhuman primates. If you have active TB you must not work with patients or nonhuman primates which could devastate them.

If you are no longer required to participate in the TB Surveillance Program please let your local OMS clinician know that your status should be updated.

Please call OMS if you develop any of the signs or symptoms listed above. If you have any related questions or concerns, please give me a call (301-496-4411).

Thank you.

OMS Locations and Numbers:

Bethesda, Building 10, Room 6C306; Tel: 301-496-4411

IRF Fort Detrick, Room 1B116; Tel: 301-631-7233

Baltimore Bayview, Room 01B210; Tel: 443-740-2309

Rocky Mountain Laboratories, Room 5202; Tel: 406-375-9755 Job Title

Contact Info (W ph) _____ (C) _____ (H) _____ (email) _____

For Office Use Only: Report Date: _____ CI ID: _____

Usually the index case initials and date TB contact investigation initiated. Leave blank only if employee is evaluated for silent conversion on TB screening.

Report of Employee TB Exposure (Employee Portion)

I. Employee Information: SSN (last 4) _____
 Employee Name _____ Date of Birth _____
 Work Address _____

Please indicate preferred method for OMS clinicians to contact you.

II. Exposure to Index Patient/Source

Skip to Employee Health History, if your TB test converted (reactive) recently without recognized exposure to *M. tuberculosis*.

Date(s) of exposure _____ Date of last exposure _____
 Frequency weekly daily hourly # of times with index case _____
 Duration _____ hours/minutes (total time spent); _____ hours/min (longest time spent)
 Purpose Patient Care Physical Examination Housekeeping
 Dietary Phlebotomy Social Work
 Other, explain _____

Was the index patient coughing? Yes No
 What, if any, personal protection were you using? _____

III. Employee Health History:

Do you have any chronic illnesses? Yes No
 If yes, please list _____

Has there been any change in your health during the past year? Yes No
 Describe briefly _____

Do you have any medical conditions affecting your immune system? Yes No
 If yes, please list (e.g. malignancy, HIV, autoimmune disorders) _____

Have you been prescribed medications that alter immune function? Yes No
 If yes, please list (e.g. corticosteroids, anti-cancer medications, TNF inhibitors) _____

Have you ever been told that you had a positive tuberculin skin test? Yes No
 Size of test _____ mm When? _____

Have you ever had a blood test to screen for tuberculosis? Yes No
 Type (QFT, T-SPOT) _____ Result _____ When? _____

Last CXR _____ Result _____
 Were you immunized with BCG? Yes No

Where were you born? City: _____ State: _____ Country: _____

Have you ever resided in areas or countries where TB is likely prevalent, e.g., Yes No
 some U.S. regions (Hawaii, Alaska), certain parts of Europe, Australia, S. America, Africa or Asia?
 If yes, please list location and duration _____

Report of Employee TB Exposure (Employee Portion) - continued

Prior to this TB contact investigation have you had close contact with a person with active TB or been enrolled in a TB contact investigation? Yes No

If yes, please describe briefly _____

Have you ever received medical treatment for tuberculosis? Yes No

If so, what did you receive and for how long?

Medication	Duration/Dates	Comments/Adverse Effects
Isoniazid (INH)		
Rifampin		
Pyrazinamide		
Ethambutol		
Streptomycin		
(Other)		

Since your last negative TB screening, have you volunteered, worked or lived in settings that may have exposed you to persons at increased risk for TB (nursing home, correctional facility, IV drug users, HIV-infected persons, recent immigrants, healthcare facility with increased risk of undiagnosed TB**)? Yes No

If yes, please describe briefly _____

Since your last negative TB screening, have you traveled outside the U.S. to any foreign countries or resided in areas within the U.S. with a high TB incidence rate (e.g. HI, DC, CA)? Yes No

If yes, please list location and duration _____

Since your last negative TB screening, have any close friends or family members had signs or symptoms of active tuberculosis (persistent cough over 3 weeks, unexplained weight loss, fever, night sweats, worsening fatigue or weakness)? Yes No

If yes, please describe briefly _____

Since your last negative TB screening, have you had signs or symptoms of active tuberculosis (loss of appetite, unexplained weight loss, fever, night sweats, worsening fatigue or weakness, persistent cough over 3 weeks, productive cough, bloody sputum, chest pain)? Yes No

If yes, please describe briefly _____

* Usually the index case patient's initials and the date TB contact investigation is initiated. Leave blank only if employee is evaluated for implicit exposure to M. tuberculosis with documented "silent conversion" of TB screening test.

** 6 TB patients per preceding year for 200+ bed facility; 3 TB patients per year for less than 200 beds or outpatient settings.

Additional comments _____

Employee Name: _____ SSN (last 4): _____

Report of Employee TB Exposure (OMS Clinician Portion)

Report Date _____

CI ID* _____

IV. Baseline OMS Assessment:

Meets contact case criteria? Yes No High-priority contact? Yes No

Contact case parameters (HES): _____

Close contact parameters (OMS) _____

TB risk factors for progression or poor outcome? Yes No If yes, please specify: _____

V. Baseline exposure TB screening:

Initial 2 step test required Yes No

Step One:

TST date/time _____ Read TST date/time _____

0.1ml PPD (5TU), ID:R/L arm _____ mm negative/positive

Manufacturer/lot# _____ Read by _____

Placed by _____

Step Two:

TST date/time _____ Read TST date/time _____

0.1ml PPD (5TU), ID:R/L arm _____ mm negative/positive

Manufacturer/lot# _____ Read by _____

Placed by _____

IGRA indicated Yes No

Please give reason: _____

Type _____ Date _____ Result (units) _____

CXR date _____ Results _____

Ordered by _____

Ordered on the basis of:

- Positive TB screening test(s) at baseline testing
- History of symptoms suggestive of TB
- No CXR within 2 years post positive TB test

Follow up in 10 weeks Yes No

Employee prefers e-mail notification inter-office mail

Employee Name: _____ SSN (last 4): _____

Report of Employee TB Exposure (OMS Clinician Portion) - continued

Report Date _____
CI ID* _____

10 Week Post Exposure follow up:

Number of weeks following the last possible significant exposure to the index patient: _____

In the past month, have you had:

Table with 3 columns: Symptom, Yes, No. Symptoms include Persistent cough, Productive cough, Persistent loss of appetite, Unexplained weight loss, Night sweats, Unexplained fever/chills, Unexplained fever/chills. Includes 'Describe' and 'Estimate' fields.

If yes, please give details, incl. any testing or treatment, if any. _____

Follow up testing:

TST date/time _____ Read TST date/time _____
0.1ml PPD (5TU), ID:R/L forearm (circle) _____ mm negative/positive (circle)
Manufacturer/lot# _____ Read by _____
Placed by _____

IGRA Type: [] QFT-G [] Other _____ Date _____

Result: Qualitative: [] Negative [] Indeterminate [] Positive; Quant.: _____
(Nil / Mitogen / TB)

CXR date _____ Results _____

Ordered by _____

Ordered on the basis of:

- [] Positive TB Screening test at baseline testing
[] History of symptoms suggestive of TB

OMS recommendations:

- [] HES notification
[] No further recall
[] Recall per OMS TB surveillance (NHP only)
[] Treatment as follows per _____ M.D.

Employee Name: _____ SSN (last 4): _____

TB Contact Investigation SummaryContact with: CC Patients

CI ID*: _____

 Non-human primatesPathogen: *M. tuberculosis*

Index Patient's Initials*	Period of Infectivity (at NIH)	Index Patient's Location(s)		
Index Patient's Attending	Index Patient's Diagnosis/es	HES/DOHS Consultant		
Date OMS Notified*	Responsible OMS Staff	OMS Contact Phone		
DESCRIPTION	DATE(S)	#	%	
Employees potentially exposed			NA	
Employees reporting for baseline evaluation				
TST prevalent positive				
TST positive, discovered at baseline				
IGRA prevalent positive				
IGRA positive, discovered at baseline				
Converter				
Not a converter				
TST negative				
IGRA negative				
Follow up evaluation				
TST prevalent positive – IGRA negative				
TST positive, converter				
TST negative				
Comments:				

Tuberculosis Screening

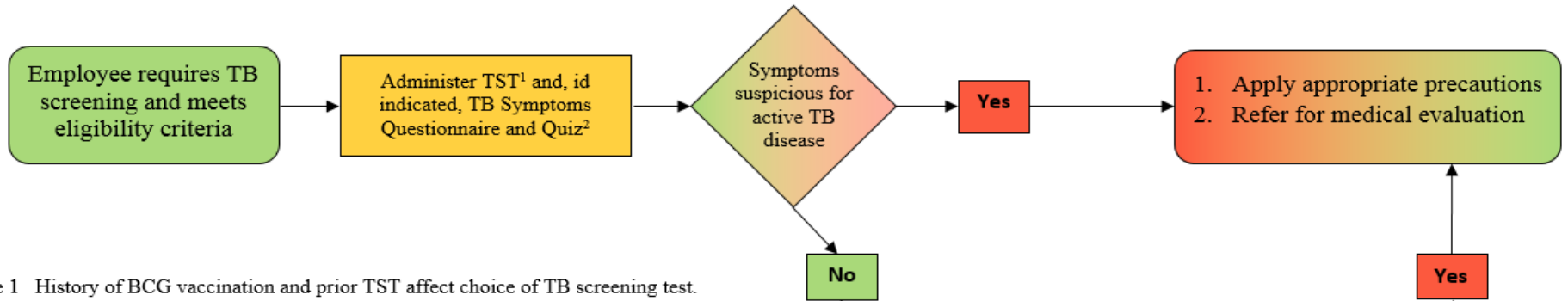
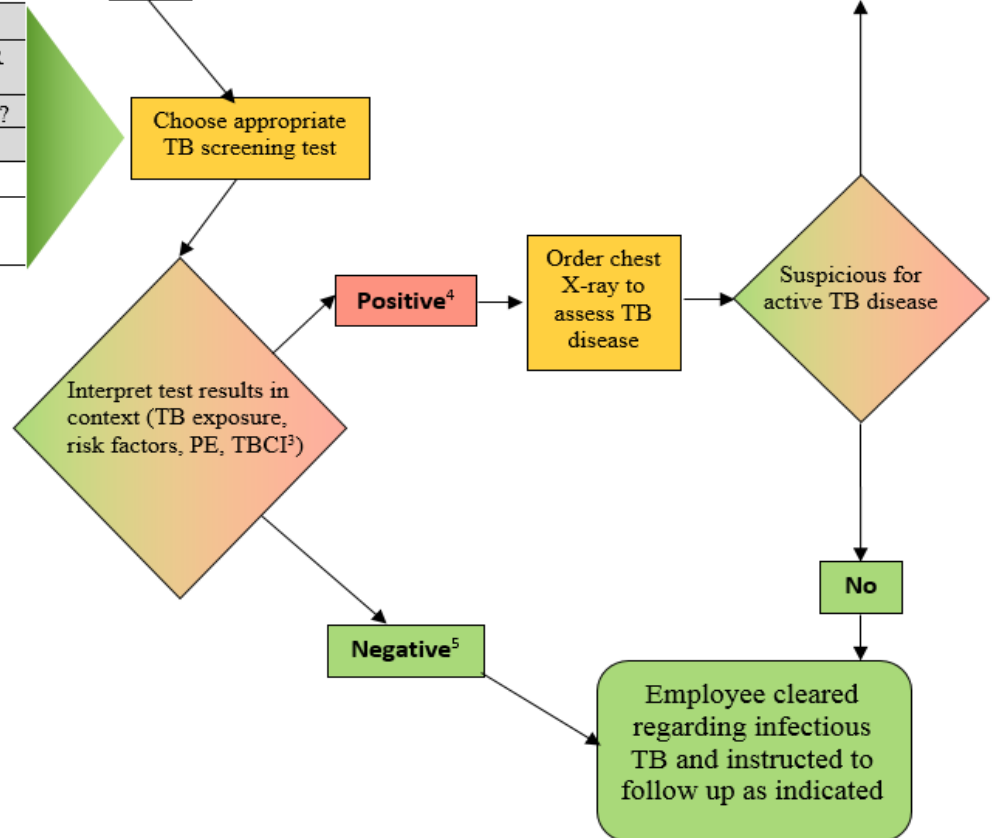


Table 1 History of BCG vaccination and prior TST affect choice of TB screening test.

Hx of BCG?	No Prior TST or Results Unknown	Negative TST*		Positive* TST	
				And has Hx of Normal CXR after pos. TST	And NO Hx of Normal CXR after pos. TST
				Mtb Exposure past 24 mo?	
No	TST	TST		Yes	No
Yes	IGRA	Recall ≥ q6 months? °		SSx Quiz	CXR
		Yes	No	SSx	IGRA
		IGRA	TST		

* If no documentation available history should be at minimum corroborated by plausible details such as size of induration (in mm), clinical details.
 ° An IGRA is preferred when more frequent TB screening is anticipated. A positive TST cannot distinguish between sensitization due to BCG or true conversion from exposure (new LTBI).



Footnotes:

- ¹ Questionnaire for Tuberculin Skin Testing (Att. I) elicits answers that affect choice of test and its interpretation (TB risk factors).
- ² TB Symptoms Questionnaire and Quiz screens for active TB and elicits worker's understanding of TB and his or her TB status.
- ³ PE – preplacement evaluation; TBCI – TB contact investigation.
- ⁴ Interpretation of the test results depends on the context of the screening and TB risk factors.
- ⁵ It may involve more than one step to be considered “negative” for TB infection such as a 2-step TST, or a repeated IGRA.

TB Risk Factors

Retrospective TB Risk Factors: What is risk that the person to be screened for TB has been infected? If so, how long ago?

Prospective TB Risk Factors: Is the person at high risk for developing TB disease either due to recent infection or a weakened immune system? Is the person at risk for progressing quickly to infectious TB if newly infected (rapid progression)? Is there a risk that a person may be more likely to develop active TB disease, if infected in the past (reactivation disease)?

Risk of Infection ↑	Groups with Increased Likelihood of Infection with Mtb	Benefit of Therapy	LTBI Testing Strategy	
		Household contact or recent exposure of an active case	Yes	Likely to be Infected Low to Intermediate Risk of Progression (TST ≥ 10mM)
	Mycobacteriology laboratory personnel	Not demonstrated		
	Immigrants from high burden countries (>20 / 100,000)	Not demonstrated		
	Residents and employees of high risk congregate settings	Yes		
	None	Not demonstrated	Unlikely to be Infected (TST > 15mM)	
	Risk of Developing Tuberculosis if Infected →			
	Low		Intermediate (RR 1.3 -3)	High (RR 3-10)
	No risk factors		Clinical predisposition Diabetes Chronic renal failure Intravenous drug use	Children age less than 5 HIV infection Immunosuppressive therapy Abnormal CXR consistent with prior TB Silicosis
	Benefit of Therapy			
	Not demonstrated		Yes	

In developing a diagnostic approach for the evaluation of those with suspected LTBI, we recommend the clinician weigh the likelihood of infection, the likelihood of progression to TB if infected, and the benefit of therapy (Horsburgh, C.R., Jr, and E.J. Rubin. 2011. Clinical practice. Latent tuberculosis infection in the United States. The New England journal of medicine 364:1441-1448). Recommendations were formulated for each of the three groups illustrated above. These groups are concordant with current recommendations for the interpretation of the TST (2000. Targeted tuberculin testing and treatment of latent tuberculosis infection. American Thoracic Society. MMWR Recomm Rep 49:1-51).

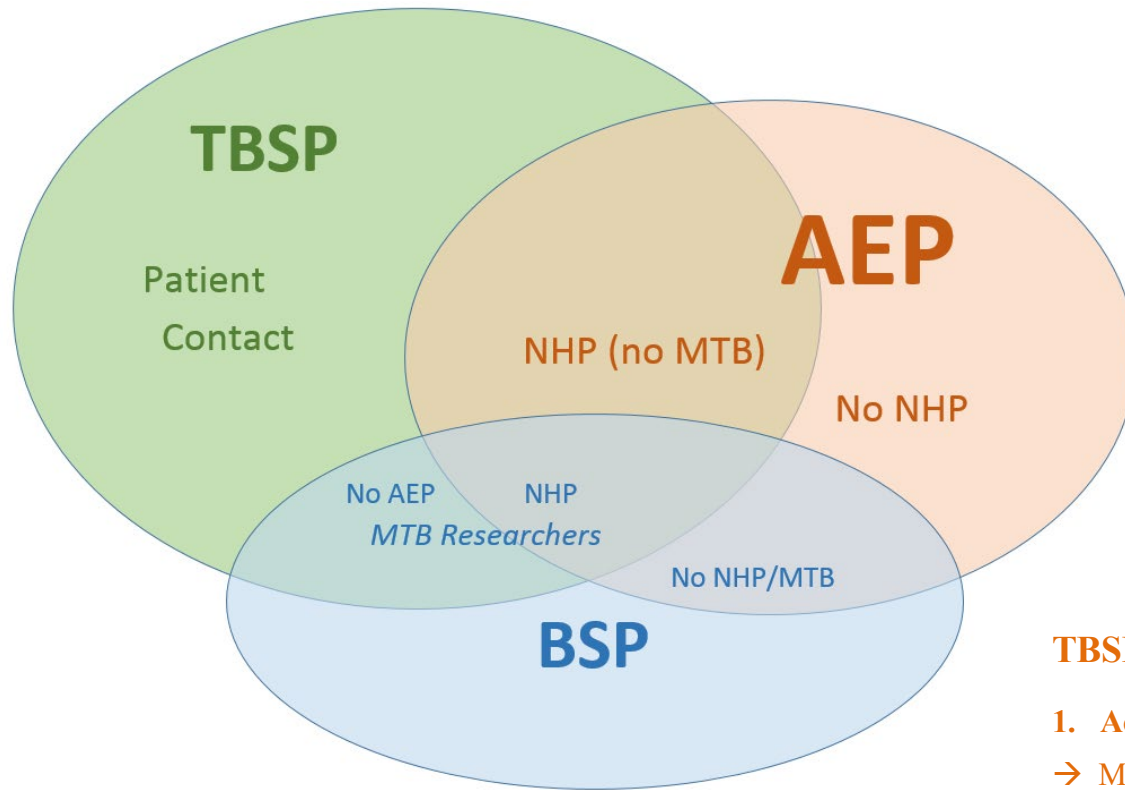
Group	Testing Strategy	Considerations
Likely to be Infected High Risk of Progression (TST ≥ 5mM)	Adults Acceptable: IGRA OR TST Consider dual testing where a positive result from either result would be considered positive	Prevalence of BCG vaccination Expertise of staff and/or laboratory Test availability Patient perceptions Staff perceptions Programmatic concerns
	Children ≤ 5 years of age Preferred: TST Acceptable: IGRA OR TST Consider dual testing where a positive result from either would be considered positive ¹	
Likely to be Infected Low to Intermediate Risk of Progression (TST ≥ 10mM)	Preferred: IGRA where available Acceptable: IGRA or TST	
Unlikely to be Infected (TST > 15mM)	Testing for LTBI is not recommended If necessary: Preferred: IGRA where available. Acceptable: Either IGRA OR TST For serial testing: Acceptable: Either IGRA OR TST Consider repeat or dual testing where a negative result from either would be considered negative ²	

1. Performing a second diagnostic test when the initial test is negative is a strategy to increase sensitivity. This may reduce specificity, but the panel decided that this is an acceptable tradeoff in situations in which the consequences of missing LTBI (i.e., not treating individuals who may benefit from therapy) exceed the consequences of inappropriate therapy (i.e., hepatotoxicity).
2. Performing a confirmatory test following an initial positive result is based upon both the evidence that false-positive results are common among individuals who are unlikely to be infected with Mtb and the committee's presumption that performing a second test on those whose initial test was positive will help identify initial false-positive results.

References:

1. CDC – Tuberculosis (TB): TB Risk Factors (last reviewed March 18, 2016)
2. Official American Thoracic Society/Infectious Diseases Society of America/ Centers for Disease Control and Prevention Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children (2017)

TB Screening Recall



TBSP – BSP

1. **Works with Mtb or in areas where Mtb is stored**
 - Mandatory screening at enrollment and every 12 months (annual)
 - Required exposure reporting (contact investigation and OIs)
 - Must report any febrile illnesses, including suspected TB
2. **Works with or has access to MDR/XDR Mtb**
 - Required additional recall every 6 months

TBSP – Patient Contact Only

1. **No increased-risk activities or areas**
 - No recall required after (TB screening required at PE only)
 - Required exposure reporting (contact investigation and occupational injury)
 - Eligible for annual TB screening on request
2. **Increased-risk clinical work group or area**
 - Required recall every 12 months (annual)
 - Required exposure reporting (contact investigation and occupational injury)

TBSP – AEP, NHP portion

1. **Access to live NHPs or shared airspace with NHPs**
 - Mandatory recall every 12 months (annual)
 - Required exposure reporting (contact investigation and occupational injuries)
 - Must report any signs or symptoms of active TB
2. **No access to live NHPs or shared airspace**
 - TB screening at enrollment only; no recall