UNMC TUBERCULOSIS EXPOSURE CONTROL PLAN

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ENVIRONMENTAL HEALTH & SAFETY

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Tuberculosis Exposure Control Plan Updated 10-19-2021

I. Purpose

a. The purpose of the Tuberculosis (TB) Exposure Control Plan is to protect patients, visitors, staff, students, and volunteers from transmission of TB and to comply with recommendations for control of TB.

II. Introduction

In accordance with recommendations from the Centers for Disease Control and Prevention (CDC) and the <u>UNMC Tuberculosis Exposure Policy</u>, the Tuberculosis Exposure Control Plan at UNMC is based on a hierarchy of the following control measures:

a. Administrative controls to reduce the risk of TB exposure

- i. Assigning responsibility for TB infection control
- ii. Conducting an annual TB risk assessment
- iii. Developing and instituting a written TB infection control plan to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease
- iv. Ensuring timely lab testing and reporting of results
- v. Implementing effective work practices
- vi. Ensuring proper cleaning, disinfection, and sterilization of potentially contaminated equipment (e.g., endoscopes)
- vii. Training and educating health care workers (HCWs¹), staff and students regarding TB, with specific focus on prevention,transmission, and symptoms
- viii. Screening and evaluating HCWs staff and students who are at risk for TB disease or who might be exposed to *M.tuberculosis (MTB)* complex (i.e., TB screening program)
- ix. Applying epidemiologic-based prevention principles
- x. Using appropriate signage advising respiratory hygiene and cough etiquette, and
- xi. Coordinating efforts with the local or state health department.

b. Environmental controls to prevent the spread and reduce the concentration of infectious droplet nuclei in the air.

- i. Primary controls:
 - 1. Direct source control using local exhaust ventilation to dilute and remove contaminated air by using general ventilation.
- ii. Secondary controls:
 - 1. Control direction of airflow and clean the air via filtration and/or ultraviolet irradiation.

c. Respiratory-Protection controls to reduce HCW, student, and researcher² exposure to TB.

- i. An appropriate respiratory protection program,
- ii. HCW, student, and researcher education,
- **iii.** Educating patients, family, and visitors about respiratory hygiene and cough etiquette practices.

The goal of this hierarchy is to detect, isolate, and treat those with active infectious TB and to decrease the risk of TB transmission. In this control plan, HCW refers to persons who provide healthcare to patients or that work in the institution, which provides patient care. The risk of exposure varies within NM based on the patient population, the job category of the HCW, and effectiveness of the control interventions. Risk is increased in areas where patients are cared for before diagnosis and initiation of TB precautions or where diagnostic or aerosol generating procedures are performed.

III. Assignment of Responsibility

a. Responsibility for carrying out the TB Control Plan is a joint effort of administration, medical staff, departmentmanagers, patient care employees, Pulmonary Medicine, Respiratory Care, Facilities Management, Radiology Pathology, Employee Health (EH), Environmental Services, Environmental Health and Safety Operations, and Infection Control and Healthcare Epidemiology.

IV. Risk Assessment

a. The UNMC TB Control Plan is based on an assessment of the risk of TB transmission within the system (see Appendix 1). The risk assessment evaluates the incidence of TB, management of patients with TB, screening protocols for HCWs, implementation and effectiveness of the TB Infection Control Program, Laboratory practices for TB patients and research, and the facility respiratory protection program. According to the risk assessment, UNMC is in a low-medium risk group for TB transmission.

V. Detection of Patients who may have TB

- a. Preventing TB transmission relies on early detection of patients who may have active pulmonary TB, promptinstitution of TB precautions, and prompt initiation of effective treatment. A diagnosis of active pulmonary TB should be considered in any patients with:
 - i. A persistent cough (greater than 3 week's duration)
 - ii. Bloody sputum
 - iii. Night sweats
 - iv. Weight loss
 - v. Anorexia
 - vi. Fever
 - vii. Fatigue, or
 - viii. Chest pain
- b. A history, physical examination, diagnostic test (PPD³ or IGRA⁴), chest radiograph, and sputum cultures (AFB⁵ or PCR⁶ assay) may help in the diagnosis of TB. It is the responsibility of the physician to notify HCWs if active pulmonary TB is suspected in a patient, particularly when an invasive procedure is scheduled, such as bronchoscopy. HCWs are to assess patients for the possibility of TB and take the appropriate precautions to protect themselves and others.

Pathology immediately reports positive AFB smear test results to the patient's physician and Infection Control. The Radiology department is to promptly report suspicious radiographs to clinicians or Infection Control.

Infection Control will notify the patient care providers. Positive culture results for *(MTB)* complex are also reported to the health department by Pathology or Infection Control.

¹ HCW refers to all paid and unpaid persons who provide healthcare services or healthcare support services in the institution who have the potential for exposure to TB.

- ² Researcher refers to all paid and unpaid persons working in laboratories and other research areas
- ³ PPD = Purified Protein Derivative Tuberculin Skin Testing
- ⁴ IGRA = Interferon Gamma-Release Assay
- ⁵ AFB = Acid Fast Bacilli
- ⁶ PCR = Polymerase Chain Reaction test

Isolation requirements for Mycobacterium tuberculosis (MTB)

Type of MTB	Precautions/Isolation	Explanation
Confirmed or suspected Active pulmonary or laryngealdisease,	Airborne	 Signs and symptoms of active pulmonary disease mayinclude – persistent cough, hemoptysis, chest pain, night sweats, unexplained weight loss, anorexia, fever/chills, Weakness or fatigue. Chest radiograph is used to aid in the diagnosis of TB through the detection of abnormalities (cavitary lesions,etc.). Immunocompromised patients (e.g., HIV) may have very subtle pulmonary symptoms and X-ray findings ofTB, and should be placed in airborne isolation until TBis ruled out Protocol to rule out TB: Three negative sputum smears for AFB (collected at least eight hours apart), or Two negative direct probe tests Discontinue airborne isolation only when TB has been ruled out (must meet protocol above) or TB is diagnosed and patient has been on effective therapy for 2 weeks and shows clinical improvement.
Extra pulmonary – draining lesions, Or urinary system, with noevidence of pulmonary involvement	Airborne/contact	 Extrapulmonary <i>MTB</i> is isolated from other body system, other thanlungs. Discontinue precautions only when Patient is improving clinically, Drainage has ceased, or Three consecutive negative cultures of continue drainage.
Extrapulmonary – non-draining lesions Meningitis, spinal disease, etc. with no evidence of pulmonary involvement	Standard **Airborne for Infants and Children**	 **For infants and children, use airborne precautions untilactive pulmonary TB in visiting family members is ruled out. **
Latent	Standard	 Latent TB is when <i>MTB</i> bacteria live in the body not causing active illness. Patient does not have signs or symptoms of active pulmonary disease, but patient has positive skin test or bloodtest Patients with latent TB are NOT infectious and CANNOT spread TB bacteria to others. Patients with latent TB can potentially progress to active tuberculosis and therapy may be considered.

VI. Isolation for Infectious TB Patients

- a. Evaluation
 - i. Those suspected of having *MTB* should be aggressively evaluated if they have signs and symptoms suggestive of TB.
- b. Treatment
 - i. Patients who have confirmed active disease or who are likely to have active TB should receive prompt and appropriate treatment (see Appendix 2). Care is coordinated with the Public Health Department when planning for patient discharge or contact tracing.
- c. Isolation
 - i. Airborne infection isolation should be initiated when:
 - 1. Signs and symptoms of TB are present,
 - 2. The history and physical examination reveal possible TB,
 - 3. When tests for AFB are ordered and the patient has clinical symptoms,
 - 4. Or when laboratory or radiology tests indicate possible TB (see Appendix 2).
 - ii. Patients suspected or known to have infectious TB are placed into Airborne Infection Isolation(AII). This requires of the following:
 - 1. Patients are placed in a private negative airflow room with the door(s) closed.
 - 2. Airborne Isolation Cart is ordered, or appropriate supplies (N95) are ordered to the nurse server,
 - 3. An Airborne Isolation Stop Sign is placed on the door frame,
 - 4. An Airborne Isolation Flag will be added to the patient chart,
 - iii. If this is not possible, patients should wear procedure masks when outside their room and be scheduled for activities or procedures during lulls in the workload to reduce their contact with others. Patients should only leave their room when medically necessary.
 - iv. Registered nurses, physicians, and Infection Control personnel may place patients in precautions. Infection Control will be notified when a patient is placed in Airborne Precautions.
 - v. Airborne isolation may be initiated and discontinued at the direction of the patient's physician orInfection Control. Infection Control must be notified prior to Airborne Isolation Removal for TB.
 - vi. Patient care staff must call Facilities Management or enter a Project Work Request (PWR) online, to set up the negative pressure room. Setup is available 24 hours a day.
 - vii. Facilities Management must perform a quality test (i.e., flutter-strip test or digital read out), on negative rooms prior to patient admittance to ensure functionality of the negative air system. Staffconducting the test must have completed the learning module on Flutter-strip testing via the Apollo System. Flutter-strip or digital meter testing must be conducted daily as long as the room is in use for airborne precautions.
 - viii. All rooms are single patient rooms with appropriate ventilation (at least six air changes per hourin existing units, and twelve air changes per hour in newly constructed areas). The rooms are atnegative pressure to the halls and surrounding areas, and are monitored when used for TB patients
 - ix. Patient care staff at Nebraska Medicine will follow the protocol outlined in Appendix 5 if the room air monitor alarms. Facilities Management is notified if the room is not at negative pressure. Facilities Management will correct deficiencies or ask to have the patient moved to a room meeting the special ventilationrequirements. Facilities Management will review airflow of selected rooms at appropriate intervals. All doors to the rooms are kept closed to maintain negative airflow. Air is not re- circulated into the general ventilation unless filtered through a HEPA filter
 - x. Patient care providers will educate patients, families, and visitors on transmission of TB and importance of wearing a mask. Patients are taught to cover their mouths and noses with a tissuewhen coughing or sneezing and discard the tissue directly into a waste receptacle.
 - All ventilation in treatment/procedure rooms should be appropriate for airborne isolation. If All isunavailable the patient should remain masked during the procedure, if possible. Bronchoscopiesperformed on patients suspected or known to have TB will be done in the patient room or in the endoscopy room, if possible.
 - xii. The number of people entering All rooms is restricted. All HCWs who enter the room must wear appropriate respiratory protection (Fit Tested N95 respirators or other approved devices). Respirators are removed **outside** of the patient's room when exiting. Close family of patients in All rooms are encouraged to wear aprocedure mask, and other visitors should be discouraged from visiting.

- xiii. All may be discontinued when:
 - a. The patient is on effective therapy (2 weeks),
 - b. Is improving clinically, and
 - c. Has a sputum smear that is negative for AFB on three consecutive days, or two PCRassays (nucleic acid amplification-based (NAA) test) negative for acid-fast bacilli, collected at least 8 hours apart,
 - d. Or is determined by the Infection Control to be non-infectious.
- xiv. Patients with Multi-Drug Resistant TB (MDR-TB) are to be isolated for the duration of their hospitalization.
- xv. When isolation is discontinued, or the patient transfers to a new room, patient care staff are to allow the HEPA air filtering unit to run with the doors closed until 99.9% of particles are removed from the air. In most patient rooms with six air changes per hour, this will be 60 minutes. Those needing to enter the room during that time are to wear N95 respirators or other approved devices.
- xvi. In rooms with portable HEPA units, Environmental Services (EVS) staff will disinfect the outside of the unit and the flexible duct hose. Patient care staff will notify Facilities Management to pick up the unit after the appropriate period of time has elapsed. If dividers are used to decrease noisefrom the unit. EVS staff will disinfect the dividers as well. Facilities Management will turn off the unit and the room air monitor. Facilities Management will remove the portable unit for storage.
- xvii. If the patient is in isolation for suspected TB and is found not to have TB equipment may simplybe removed from the room without further action.
- xviii. Upon readmission to the hospital or clinic, patients with TB who have not had documented negative sputum smears should be placed in AII precautions until they are determined to be non-infectious.
- xix. Any issues with patient noncompliance will be dealt with according to Policy IC 7- ICE Authority

VII. Engineering Controls

- a. Fixed and portable ventilation systems, air pressure gradient monitoring devices, and ventilation system checks will be used to decrease exposure of HCWs to TB. Room pressure is to be monitored when the room is used for a suspected or known TB patient. HEPA filters will be checked and replaced by Facilities Management. Staff will wear appropriate respirators when checking/repairing HEPA units or replacing filters used for TB.
- b. Ventilation
 - i. Airflow and the number of air changes per hour are monitored in selected areas of UNMC/NM by Facilities Management at appropriate intervals. The ventilation system and direction of airflow is verified when construction has been completed in an area or when work is performed on an air handler. Air exchanges in current TB patient rooms should be at least six per hour. Areas of newconstruction should have twelve air changes per hour.
- c. HEPA filtering unit
 - A HEPA filtration system is used in all designated rooms. Preferably, air is exhausted outdoors, away from air intakes and people. If air is re-circulated into the general ventilation, it will pass through the HEPA filter first. The system helps establish negative airflow. Maintenance of the filters and ultraviolet lights contained in the HEPA unit will be performed by Facilities Management in accordance with manufacturers' guidelines.
- d. Ultraviolet (UV) Irradiation
 - i. UV light may be used to supplement the HEPA air purification system, it does not substitute forproper ventilation.

VIII. Respiratory Protection

a. Disposable N95 respirators or other approved devices are worn by HCWs (including students) when caring for patients with known or suspected TB. HCWs are fit-tested to achieve a face-seal leakage of <10% and are instructed how to wear the respirator. When there are shortages of N95 respirators, procedures for re-use of the N95 respirators are outlined in Infectious Disease Protocols- COVID-19. HCWs using respiratory protection are included in the respiratory protection program. The selection of respirators used by the organization is based on current data regarding safety, cost, regulations, PPE</p>

availability, and the hospital's TB risk assessment.

b. Based on each employee's job description and physical job analysis, those with risk of exposure to respiratorycommunicable diseases should be fit tested, annually and as needed. Managers or designees of patient careareas will determine members of their staff who will be fit tested so that patient care needs are accommodated. Managers/designees will also assume responsibility for ensuring completion of staff fit testing, for obtaining the appropriate respirators for their employees, for personnel training, and maintaining staff documentation of fit testing. (See Respiratory Protection Program)

IX. High-Risk Procedures

- a. High Risk Procedures should be performed only when necessary on a patient who is suspected to have TB. A room meeting the ventilation requirements should be used, and patients should be kept in the room away from other patients until coughing subsides or until recovered from sedatives or anesthesia. HCWs should wear designated N95 respirators or other approved devices during procedures where TB is suspected. Required air exchanges must occur so 99.9% of airborne particles are removed prior to the room be opened for another patient.
- b. Pulmonary Function Testing and Bronchoscopy
 - i. Pulmonary Function Tests and Bronchoscopies performed on those who are suspected to have TB should be delayed if possible until the patient is noninfectious. If these tests must be performed while the patient is infectious, staff conducting the test should wear appropriate respirators, and the testing should take place in the patient's All room or negative air endoscopyroom.
- c. High Risk Procedures that increase the probability of droplet nuclei being expelled into the air include:
 - i. Endotracheal intubation and suctioning
 - ii. Sputum induction
 - iii. Bronchoscopy
 - iv. Aerosol treatments (including Pentamidine)
 - v. Pulmonary function testing
 - vi. Autopsy
 - vii. Wound irrigation
 - viii. Centrifuging/vortexing of specimens containing MTB
 - ix. Frozen section of tissue potentially containing M. Tuberculosis complex or other potential infectious airborne agent.

X. Education and Training of HCWs

a. It is the responsibility of management and administration to provide HCWs education regarding TB that is applicable to their job category. Training is to occur before their initial assignment (e.g., orientation) and at the annual mandatory education program or competency assessment.

XI. HCW Counseling, Screening and Evaluation

- a. A TB screening and prevention program is in place to identify, evaluate, and rule out TB in HCWs and volunteers. Those with positive testing results, or conversions should be evaluated for preventive therapy. Effectiveness of current control practices are evaluated usingthis data.
- b. Counseling
 - i. HCWs may seek counseling by Employee Health regarding risks of caring for patients with communicable diseases, including TB, especially if HCWs are immune compromised. The importance of following existing recommendations to reduce risk of exposure will be emphasized.
- c. Screening HCWs and Researchers
 - i. Pre-Hire:
 - Baseline TB screening of all HCWs and research personnel with identified need will be performed upon hire to NM or UNMC, including a symptom evaluation and test (TST or IGRA) for those without documented prior TB orLatent Tuberculosis Infection (LTBI).
 - ii. Post-Hire Screening:
 - 1. Annually
 - Patient Care Personnel: All colleagues who work in clinical environments (patient facing) and/ or those who are involved in TB research are expected to fill out their TB online questionnaire within the health tracking system (HTS) between October

5th and December 28th. As of May 2019, the Centers for Disease Control and Prevention (CDC) no longer requires annual testing for all health care personnel.

- Research personnel: Those who require Category III clearance will be screened through the RSS process although they can still complete through the HTC. Other research personnel should complete screening in HTC. Testing may be required for HCW's and research personnel as dictated by annual risk assessments.
- Laboratorians: Those who handle specimens or MTB cultures should undergo an annual assessment along with testing.
- Individuals who were hired between October and January DO NOT need to complete this questionnaire, as they have already done so during their post offer appointment.
- 2. Serial screening for HCWs without LTBI is not routinely recommended, however, it maybe considered in high-risk areas as deemed by Employee Health
- iii. Post-exposure Screening:
 - 1. Postexposure screening and testing will be performed when an exposure is recognized. Follow-up testing and treatment will be managed and directed by Employee Health.
- d. Screening Students:
 - i. New Students must meet the screen requirements prescribed by student health. More information can be found here <u>https://www.unmc.edu/familymed/studenthealth/required-immunizations/immunizations-new-students.html</u>
 - ii. Annually Students must complete the Tuberculosis (TB) Symptom Review Form
 - iii. Postexposure screening and testing will be performed when an exposure is recognized. Follow-up testing and treatment will be managed and directed by Student Health.
- e. PPD or IGRA tests are administered, read, and interpreted by Employee Health or their designee according to currentguidelines (see Appendix 2). Results of PPD/IGRA tests are recorded in the Employee Health Department database. Employees who have documented unprotected exposure to patients with TB and terminate their employment are to have TB screening within 30 days of termination of employment.
- f. All costs for employee screening, diagnosis, and therapy for TB due to job-related exposure will be borne by UNMC or third parties as appropriate.
- g. Evaluation and Management
 - i. Employees with newly recognized positive IGRA tests are promptly evaluated for active TB including chest radiography. Volunteers and those not employed by the organization are referred to their primary care physician for evaluation for preventative therapy if recommended. Students are referred to Student Health or evaluation for preventative therapy if recommended
 - ii. HCWs with pulmonary or laryngeal TB are a risk to others while they are infectious and will be excluded from work until no longer infectious. The HCW infected with active TB will be referred to his/her physician or referred to a specialist and provide a note to EH from their treating physicianonce cleared to return to work. Before returning to work, HCWs with contagious TB should have started adequate therapy, have resolution of cough, and be considered noninfectious. Once cleared by the treating provider, EH will perform a Fit for Duty exam prior to return to work (See NM Employee Health Policy EH011 Fit for Duty/ Return to Work Exam.) HCWs that stop treatment without medical permission before the recommended course of therapy is completed will be excluded from work until treatment is resumed, adequate response to therapy is documented, and AFB smears remain negative. HCWs receiving preventative treatment for TB are allowed to continue working as usual.

XII. Problem Evaluation

- a. TB Conversions and Active TB in HCWs, Laboratorians and Researchers
 - i. If a skin test conversion is confirmed with a positive IGRA or IGRA conversion occurs in a HCW:
 - 1. The HCW/Researcher is promptly evaluated to rule out active TB
 - 2. If the HCW/Researcher converts, EH will refer
 - 3. the HCW/Researcher to an appropriate medical provider
 - 4. If a HCW/Researcher develops active TB, the above steps will be taken, the employee with be promptly referred to his/her primary care physician and the public health department willbe notified.
- b. Transmission of TB

Hospital-acquired cases of TB will be investigated according to hospital's surveillance plan and Infection Control Committee policies and procedures. This will include contact investigation, problem evaluation and coordination with patient's physician. HCWs are identified and evaluated according to Employee Health policies and procedures

- c. Laboratory acquired infections will be investigated by the Employee Health and the UNMC/UNO Environmental Safety and Health. This will include contact investigation, problem evaluation and coordination with patient's physician. HCWs are identified and evaluated according to Employee Health policies and procedures
- d. Decontamination of Equipment
 - i. Cleaning, disinfection and sterilization of reusable equipment is done according to policies and procedures

XIII. Selected Areas of the Facility

- a. Operating Rooms
 - i. Elective procedures on patients with TB are delayed until the patient is no longer infectious. If procedures must be performed, they are done when a minimum number of people are present and at the end of the day. Doors to the operating room are kept closed and traffic is kept to a minimum. When general anesthesia is required, a bacterial filter will be placed on the endotracheal tube or expiratory side of the breathing circuit of the anesthesia machine. Patients will be recovered in an area with appropriate air handling. Portable HEPA units are not required inthe operating room. Surgery patients whose procedure cannot be delayed should have it performed in an operating room with recommended ventilation controls.

b. Autopsy

i. Those performing or assisting with autopsies will wear respirators (or equivalent) for all autopsies. The room will have at least 12 air changes per hour and be at negative pressure to the surrounding area. After an autopsy is performed on suspected or confirmed TB disease case, allow adequate time to elapse to ensure removal of *MTB*- contaminated air before performing another procedure in the same room. If time delay is not feasible, the autopsy staff should continue to wear respirators while they are in the room.

- c. Emergency Department
 - i. If patients must be in common areas where there is no special ventilation, they should wear procedure masks. The attending HCWs should wear designated respirators with suspected TBpatients. Place patient in recommended All room as soon as possible. Patients should observestrict respiratory hygiene and cough etiquette procedures.
- d. Clinics and Ambulatory Care
 - i. HCWs are responsible for wearing designated respirators when caring for those with possible TBuntil they are no longer infectious. Patients should be greeted at the door with masks and placedin exam rooms as quickly as possible. HCWs should instruct patients to use tissues for coughingor sneezing and discard the used tissue into a waste receptacle. The protocol for scheduling active TB patient appointments, and instructions on the protocol for their care while in our facility/clinics can be found in Appendix 4.
- e. Pathology/Laboratory/Research
 - i. Areas processing specimens for mycobacterial studies (AFB smears, PCR, and cultures) require the use of BSL-3 practices, containment equipment, and facilities. Laboratory activities involving thepropagation and manipulation of cultures of any of the subspecies of the *MTB* complex are performed in a BL3 facility (<u>Biosafety in Microbiological and Biomedical</u>)

Laboratories, 6th Addition, 2020) See Appendix 5. In the frozen section lab (FSL), the tubercle bacilli may be aerosolized in the preparation of frozen sections. Capture devices on the cryostats do not use HEPA filter technology and cannot be relied on to prevent aerosolization of tubercle bacilli into the FSL. Thepresence of a potentially infectious aerosol hazard requires the use of appropriate respiratory protection by all personnel in the room during frozen section processing of known or suspected TB cases, and afterward until sufficient air changes have occurred to remove potentially contaminated air.

ii. Annual air balance testing is performed to verify negative pressure of room.

References:

<u>Biosafety in Microbiological and Biomedical Laboratories, 6th Edition, 2020</u> Employee Health Policy, TB Screening Program <u>https://www.cdc.gov/tb/default.htm</u> <u>https://emergency.cdc.gov/bioterrorism/</u> <u>http://www.idsociety.org/Other_Biodefense_Resources/</u>

Appendix C. Risk classifications for health-care settings that serve communities with high incidence of tuberculosis (TB) and recommended frequency of screening for *Mycobacterium tuberculosis* infection among health-care workers (HCWs)*

	Risk classification [†]			
Setting	Low risk	Medium risk	Potential ongoing transmission [§]	
Inpatient <200 beds	<3 TB patients/year	≥3 TB patients/year	Evidence of ongoing <i>M. tuberculosis</i> transmission, regardless of setting	
Inpatient ≥200 beds	<6 TB patients/year	≥6 TB patients/year		
Outpatient; and nontraditional facility-based	<3 TB patients/year	≥3 TB patients/year		
TB treatment facilities	 Settings in which persons who will be treated have been demonstrated to have latent TB infection (LTBI) and not TB disease a system is in place to promptly detect and triage persons who have signs or symptoms of TB disease to a setting in which persons with TB disease are treated no cough-inducing or aerosol-generating procedures are performed 	Settings in which • persons with TB disease are encountered • criteria for low risk is not otherwise met		
Laboratories	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> are not manipulated	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> are manipulated		

TABLE. Comparison of 2005* and 2019[†] recommendations for tuberculosis (TB) screening and testing of U.S. health care personnel (HCP)

Return

Category	2005 Recommendation	2019 Recommendation
Baseline (preplacement) screening and testing	TB screening of all HCP, including a symptom evaluation and test (IGRA or TST) for those without documented prior TB disease or LTBI.	TB screening of all HCP, including a symptom evaluation and test (IGRA or TST) for those without documented prior TB disease or LTBI (unchanged) ; individual TB risk assessment (new) .
Postexposure screening and testing	Symptom evaluation for all HCP when an exposure is recognized. For HCP with a baseline negative TB test and no prior TB disease or LTBI, perform a test (IGRA or TST) when the exposure is identified. If that test is negative, do another test 8–10 weeks after the last exposure.	Symptom evaluation for all HCP when an exposure is recognized. For HCP with a baseline negative TB test and no prior TB disease or LTBI, perform a test (IGRA or TST) when the exposure is identified. If that test is negative, do another test 8–10 weeks after the last exposure (unchanged) .
Serial screening and testing for HCP without LTBI	According to health care facility and setting risk assessment. Not recommended for HCP working in low-risk health care settings. Recommended for HCP working in medium-risk health care settings and settings with potential ongoing transmission.	Not routinely recommended (new) ; can consider for selected HCP groups (unchanged) ; recommend annual TB education for all HCP (unchanged) , including information about TB exposure risks for all HCP (new emphasis) .
Evaluation and treatment of positive test results	Referral to determine whether LTBI treatment is indicated.	Treatment is encouraged for all HCP with untreated LTBI, unless medically contraindicated (new) .

Source: Federal Register. Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005.

BOX 5. Factors affecting treatment decisions during the medical and diagnostic evaluation, by tuberculin skin test (TST) result

TST result ≥5 mm _is positive	TST result ≥10 mm is positive	TST result <u>></u> 15 mm is positive*	
 Persons infected with HIV[†] 	 Recent immigrants (i.e., within the previous 5 years) from countries with a high incidence of TB disease 	• Persons with no known risk factors for TB disease	
 Recent contacts of a person with tuberculosis (TB) disease Persons with fibrotic changes on chest radiograph consistent with previous TB disease Organ transplant recipients and other immunosuppressed persons (e.g., persons receiving ≥15 mg/day of prednisone for ≥1 month)^{\$} TB suspects^{\$} 	 Persons who inject illicit drugs Residents and employees (including health-care workers [HCWs])** of the following congregate settings hospitals and other health-care facilities long-term-care facilities (e.g., hospices and skilled nursing facilities) residential facilities for patients with AIDS^{††} or other immunocompromising conditions correctional facilities homeless shelters 	 HCWs who are otherwise at low risk for TB disease and who received baseline testing at the beginning of employment as part of a TB screening program** 	
	 Mycobacteriology laboratory personnel Persons with any of the following clinical conditions or immunocompromising conditions that place them at high risk for TB disease diabetes mellitus silicosis chronic renal failure certain hematologic disorders (e.g., leukemias and lymphomas) other specific malignancies (e.g., carcinoma of the head, neck, or lung) unexplained weight loss of ≥10% of ideal body weight gastrectomy jejunoileal bypass 		
	 Persons living in areas with high incidence of TB disease 	gh incidence of TB	
	 Children aged <4 years Infants, children, and adolescents exposed to adults at high risk for developing TB disease 		
	 Locally identified groups at high risk 		
 TST results ≥15 mm is positive in disease, and if disease is excluded, † Human immunodeficiency virus. ⁵ The risk for TB disease in persons ⁵ Persons with suspected TB disease * For HCWs who are otherwise at lo as part of a TB infection-control sc on baseline or follow-up testing is 	anyone. These persons should receive a symptom screen and do not need be tested they should be offered treatment for latent TB infection (LTBI) if they have no c treated with corticosteroids increases with higher doses and longer duration of cc can be treated based on the medical and diagnostic evaluation, regardless of the w risk for LTBI and progression to TB disease if infected and who received baseline reening program, a TST result of ≥ 15 mm (instead of ≥ 10 mm) is considered to b considered a positive result for HCWs for the purposes of referral for medical and	again. They should be evaluated for TB ontraindication to treatment. TST results. e testing at the beginning of employment be positive. Although a result of ≥10 mm d diagnostic evaluation, if the TST result	

is 10–14 mm on baseline or follow-up testing, the referring clinician might not recommend treatment of LTBL SOURCE: Marsh BJ, SanVicente J, vonReyn F. Utility of dual skin tests to evaluate tuberculin skin test reactions of 10 to 14 mm in health-care workers. Infect Control Hosp Epidemiol 2003;24:821–4.

Source: Federal Register. Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-CareSettings, 2005.



Appendix 5 Monitor Alarms for Patient Care Negative Air Rooms at Nebraska Medicine



Management of Outpatients in Ambulatory Areas with Suspected or Documented TB Protocol

Outpatients with suspected or documented TB should be scheduled and cared for in areas that have Airborne Infection Isolation (AII) rooms. These patients will generally be seen in the Infectious Disease or Pulmonary Clinic at Internal Medicine DOC.

- 1. If a patient arrives at a clinic <u>without</u> an All room, follow TB precautions including:
 - a. Greet the patient at the door
 - b. Provide the patient with a surgical mask
 - c. Place the patient in a private room separated from other patients
 - d. Staff will wear N95 respirators
 - e. If clinic is located in DOC, attempt to contact Internal Medicine at 402-559-4015 to see if patient can be transferred to their AII room. If the patient cannot be accommodated there, continue with assessment ofpatient, following this protocol as situation allows.
- 2. When scheduling a patient with suspected TB:
 - a. Contact the Internal Medicine Clinic at 402-559-4015 to determine availability of the AII room (exam room#13, DOC 5692)
 - b. The staff member that schedules the patient will enter "mask and room 13" in the appointment notes.
 - c. Patient will be instructed to come to DOC 1st floor circle drive drop off and should be met at the door to receive a mask, facial tissues, amd instruction on respiratory cough etiquette.
 - d. The patient, wearing a surgical mask, will be escorted by clinic personnel directly to exam room #13 via theback hallway (patient greeting and escort duties will be coordinated by Infection Control and/or Internal Medicine Clinic.)
 - e. If possible, the patient should call the Internal Medicine Clinic at 402-559-4015 just as they reach the parking structure or circle drive.
- 3. When caring for a patient with suspected TB in an ambulatory clinic:
 - a. Patient must keep their surgical mask on during their entire stay at the clinic.
 - b. Limit activity outside of the patients room.
 - c. An Airborne Isolation sign will be placed on door to exam room and the door will remain closed at all times.
 - d. A sufficient supply of each size of N95 respirator required by staff must be readily available at the entranceto the exam room.
 - e. All staff entering the All room are required to have been N95 fit tested and are to use the appropriate sized N95 respirator.
 - f. The patient exam, and all other services, i.e. phlebotomy, chest x-ray, or procurement of sputum specimens, will be performed, if possible, in the room. Contact 402-559-1002 or pager #402-888-5609 forchest x-ray. If sputum induction is needed, contact the Pulmonary Function Lab at 402-559-4430.
 - g. The patient is to remain in the All room during the performance of all activities.
- 4. If an induced sputum specimen is required:
 - a. The Internal Medicine clinic staff will call the Pulmonary Function Lab at 559-4430 to coordinate dates foravailability of the AII room.
 - b. In order to maximize AFB (acid fast bacilli) sampling, the appointments will be scheduled for early morning(8:00 or 8:30) on consecutive days.
 - C. Pulmonary Function Lab will ensure that the patient is given a mask for their return the next day and thatthey are given a sputum cup to collect a sample at home if they are able to provide sputum on their own.
- 5. The patient check-out process may include:
 - a. Filling prescription in outpatient pharmacy
 - i. The physician or nurse phones the prescription to the Outpatient pharmacy 9-5215

- ii. If pharmacist needs to obtain demographic information or counsel the patient, then the call is made to outpatient pharmacy from the room and patient and pharmacist communicate via telephone.
- iii. Clinic staff pick up medication at outpatient pharmacy, where they will be required to sign for themedications.
- b. If another appointment or sputum induction needs to be scheduled, the Internal Medicine clinic staff willcoordinate available dates for future appointments based on AII room availability.
- c. Upon completion of the visit, the patient leaves All room wearing a surgical mask via back hallway escortedby staff with an N-95 respirator to the exit.
- d. The door to the room must remain closed with airborne isolation sign in place and room is not used for 1hour to allow for exchange of air.

Mycobacterium tuberculosis complex information from <u>Biosafety in Microbiological and Biomedical Laboratories</u>, <u>6th Edition</u>, 2020

The Mycobacterium tuberculosis complex includes the species M. tuberculosis, M. bovis, M. africanum, M. caprae, M. microti, M. canettii, M. pinnipedii, and the recently described species M. mungi and M. orygis. ^{163,164} M. tuberculosis grows slowly, typically requiring several weeks for formation of colonies on solid media. Incubation in broth culture can at times reduce the incubation time to less than one week if the inoculum is sufficient.¹⁶³ The organism has a thick, lipid-rich cell wall that renders bacilli resistant to harsh treatments including alkali and detergents. Mycolic acid in the cell wall results in a positive acid-fast stain.

Occupational Infections

M. tuberculosis and M. bovis infections are a proven hazard to laboratory personnel and others who may be exposed to infectious aerosols in the laboratory, autopsy rooms, and other healthcare facilities.^{36,84,165–169} The incidence of tuberculosis in health care personnel working with M. tuberculosis-infected patients has been reported to be significantly higher than that of those not working with the agent.¹⁷⁰ Multidrug-resistant (MDR) and extensively drug resistant (XDR) strains are of particular concern.^{109,171} Naturally or experimentally infected NHPs are a proven source of human infection.¹⁷² Experimentally-infected guinea pigs and mice do not pose the same hazard because droplet nuclei are not produced by coughing in these species; however, litter from infected animal cages may become contaminated and serve as a source of infectious aerosols.

Natural Modes of Infection

M. tuberculosis is the etiologic agent of tuberculosis, a leading cause of morbidity and mortality worldwide. Infectious aerosols produced by coughing spread disease from person to person. Some individuals will develop active disease 174 Biosafety in Microbiological and Biomedical Laboratories within months of infection, and some of those will clear the infection completely. Others will achieve immunological control with latent (but viable) organisms, with potential for reactivation later upon immunosuppression. Approximately 5–10% of latent infections progress to active infections. The primary focus of infection is the lungs, but extra-pulmonary disease does occur, primarily in immunocompromised individuals. Miliary (disseminated) tuberculosis has the most serious consequences with meningitis developing in 50% of cases, along with a high fatality rate if not treated effectively. HIV infection is a serious risk factor for the development of active disease. M. bovis is primarily found in animals but can also infect humans. It is spread to humans, primarily children, by consumption of non-pasteurized milk and dairy products, by handling of infected carcasses, or by inhalation. Human-to-human transmission of M. bovis via aerosols is possible.

Laboratory Safety and Containment Recommendations

Tubercle bacilli may be present in sputum, gastric lavage fluids, CSF, urine, and in a variety of tissues. Exposure to laboratory-generated aerosols is the most important laboratory hazard encountered. Tubercle bacilli may survive in heat-fixed smears and, if present, may be aerosolized in the preparation of frozen tissue sections.¹⁷¹ Because of the low infective dose of M. tuberculosis (<10 bacilli), it is recommended that sputa and other clinical specimens from suspected or known cases of tuberculosis be considered potentially infectious and handled with appropriate precautions. Mycobacteria can be resistant to disinfection and may survive on inanimate surfaces for long periods. Needlesticks are also a recognized hazard. Selection of an appropriate disinfectant is an important consideration for laboratories working with mycobacteria. See Appendix B for additional information.

BSL-3 practices, containment equipment, and facilities are recommended for laboratory activities in the propagation and manipulation of cultures of any of the subspecies of the M. tuberculosis complex. Use of a slide-warming tray, rather than a flame, is recommended for fixation of slides. ABSL-3 practices are recommended for animal studies using experimentally or naturally infected NHPs or immunocompromised mice, as high titers may be found in organs from immunocompromised animals. Animal studies using rodents (e.g., guinea pigs, rats, rabbits, mice) can be conducted at ABSL-2 with ABSL-3 practices.¹⁷⁴ All airborne infections of rodents using M. tuberculosis must be performed in an appropriate ABSL-3 laboratory.

BSL-2 practices and procedures, containment equipment, and facilities are recommended for non-aerosolproducing manipulations of clinical specimens. Manipulation of small quantities of the attenuated vaccine strain M. bovis Bacillus Calmette-Guérin (BCG) can be performed at BSL-2 in laboratories that do not culture M. tuberculosis and do not have BSL-3 facilities. However, considerable care is suggested to verify the identity of the strain and to ensure that cultures are not contaminated with virulent M. tuberculosis or other M. bovis strains.

Special Issues

Be advised of possible misidentification using automated systems. For identification using MALDI-TOF MS, it is recommended to use alternative tube extraction that kills viable organisms in the BSC, and not direct spotting of plates in the open laboratory.

Surveillance Annual or semi-annual skin testing with purified protein derivative (PPD) or FDA-approved Interferon-Gamma Release Assay (IGRA) of previously skin-test-negative personnel can be used as a surveillance procedure.¹⁷⁵

Vaccines The attenuated live BCG is available and used in other countries but is not generally recommended for use in the United States.

Transfer of Agent Importation of this agent requires CDC and/or USDA importation permits. Domestic transport of this agent may require a permit from USDA APHIS VS. Consult with the <u>UNMC Export Control Office</u> prior to transporting this agent.

References noted in this appendix can be found starting on page 191 of the <u>Biosafety in Microbiological and</u> <u>Biomedical Laboratories, 6th Edition, 2020</u>.