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Attachment #13 Preparedness Plan for Emerging Infectious Diseases

ABBREVIATIONS

All: Aerosol Infection Isolation

AFB: Acid-fast bacilli

ACH: Air exchanges per hour

ATD Aerosol Transmissible Disease Standards

AICC Associate Infection Control Coordinator

BCG: Bacillus of Calmette and Guerin: A TB vaccine used in many parts of the world

CDC: Centers for Disease Control

COEM: Center for Occupational and Environmental Medicine

DOT: Directly observed therapy

EH&S: Environmental Health & Safety

F&E: Facilities and Engineering

HEPA: High-efficiency particulate air filter

HIV: Human immunodeficiency virus infection

IGRA: Interferon Gamma Release Assays (IGRAs). QuantiFERON®- TB Gold test (QFTG) and T Spot are two blood tests that are called Interferon Gamma Release Assays (IGRA). They are approved by the FDA.

IPCE: Infection Prevention and Clinical Epidemiology

ICP: Infection Control Practitioner

LTBI: Latent TB infection

LEV: Local exhaust ventilation

MDR-TB: Multidrug-resistant tuberculosis

N95: A disposable respirator mask which is capable of 95% minimum efficiency

NTM: Non-tuberculous mycobacteria

PAPR: Positive Air Pressure Respirator

PPD: Purified protein derivative-tuberculin

QFTG: QuantiFERON

TB Check: TB testing required by the COEM EMS Plan. TB Check may be TST, QFT, chest X ray, Questionnaire and or fit testing.

COEM EMS Program of SD County: The Health and Human Services Agency Public Health Services, COEM EMS Branch, San Diego County

TST: Tuberculin Skin Test or Purified protein derivative (PPD)-tuberculin test

1.0. Policy and Purpose

This document is intended to be a comprehensive description of all aspects of the COEM EMS Plan at UC San Diego Health System. ^ All prior policy statements regarding COEM EMS are superseded by this document. It is the policy of the UC San Diego Health System to provide care to patients with tuberculosis (TB) in a manner that minimizes the risk of transmission of TB to others. Early diagnosis, timely and effective treatment of individuals with active pulmonary TB; effective use of administrative, work practice and engineering controls; the use of respiratory protection; and a comprehensive health care worker (HCW) surveillance program are key components of this policy.

The Tuberculosis Exposure Control Plan is intended to serve as the guidance document for preventing health-care associated transmission of tuberculosis. The policies and procedures in the document are consistent with the current recommendations from the Centers for Disease Control and Prevention and Cal-OSHA compliance guidelines. The COEM EMS Plan is a section of the Aerosol Transmissible Disease Exposure Control Plan that deals specifically with tuberculosis. Regulatory Reference: Title 22, California Administrative Code, Article 70723 (http://www.calregs.com/)

Occupational Safety and Health Administration (OSHA) standard, 29 CFR, 1910.139 CDC MMWR Recommendations and Reports December 2005

2.0. **Scope**

The policies and procedures in the ATD/ Tuberculosis Control Plan are applicable to all individuals who work at the UC San Diego Health System and have face to face contact with patients regardless of funding source, including volunteers, physicians, and rotating staff such as travelers, registry staff, licensed independent practitioners (LIP's), first-, second-, third-, and fourth-year medical students, residents, respiratory therapists, etc. This policy also applies to any Medical Center-funded HCW whose work-site location may be away from the Medical Center. Casual, part-time, and temporary HCWs are also governed by the ATD/ COEM EMS Plan and may include, lab workers who work with specimen or tissues that may be infected with M. tuberculosis -or other potentially - aerosolized transmissible disease are included. All these groups of workers will be referred to collectively as health care workers (HCW). Personnel who do not have face to face direct patient care and contact with patients will follow the Bypass Process.

2.1. HCW Employed by non UCSD Contractors

These HCW are required to comply with all elements of this plan. Administration, monitoring and testing will be performed by the contractor. Contract negotiated with UCSD Med Center will contain appropriate language.

3.0. Responsibility

3.1. Individual HCW, Employees and Physicians

Each individual who works at the medical center has responsibility to know, understand and follow the ATD/COEM EMS Plan. Specifically, they must wear respiratory protection as described in this plan, complete TB screening at time of hire (baseline) and if an unprotected exposure to active tuberculosis occurs and -respirator fit testing (every 12 months) and report all incidents of exposure to tuberculosis to COEM EMS. Individuals should provide COEM with documentation or proof of immunity with regard to ATD immunity upon request. ATD immunity requirements include: pertussis (TDAP); measles, mumps, rubella (MMR); varicella (history of disease not acceptable)

Any HCW who has concerns about ventilation of a room used for respiratory isolation must communicate with Facilities Services/Engineering regarding those concerns to ensure proper HEPA filtration and monitoring of TB isolation rooms. ^

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3.3. Department Managers/Physician Chiefs

- 3.3.1. Ensure that annual department-specific TB prevention-related in-service is provided and documented.
- 3.3.2. Assist with HCW exposure follow-up process.
- 3.3.3. Monitor compliance of HCWs and physicians with exposure follow-up; document non-compliance, counsel, re-educate and apply progressive discipline to non-compliant HCWs and physicians.
- 3.3.4 .Ensure that identified HCWs and physicians who may work with suspected or confirmed TB patients are fit tested and wearing their correct respirator when caring for a patient in airborne precautions.
- 3.3.5. Order, stock, and make readily available all sizes and types of N-95 respirators outside the negative pressure rooms from Materials Management

3.4 Senior Management Team (SMT)

- 3.4.1. Enforce, facilitate and supervise the overall COEM EMS program management.
- 3.4.2. Ensure that the entire management team carries out supervisory activities to ensure that HCW's are informed about the importance of following the COEM EMS Plan and that the persons they supervise are in full compliance with all aspects of the COEM EMS Plan.

3.5. IPCE and COEM Employee Medical Surveillance

- 3.5.1. Perform annual risk assessment to determine the risk for transmission of M. tuberculosis and ensure this is reported to the Infection Control Committee.
- 3.5.2. Review this plan annually and revise as necessary.
- 3.5.3. Act as a resource for COEM Employee Medical Surveillance and Center for Occupational and Environmental Medicine (COEM) staff.
- 3.5.4 .Act as a resource for department managers for training, clarification and review of TB related departmental policies and procedures and/or concerns.
- 3.5.5. Report any observed deficiencies in compliance with this plan to the appropriate department manager and to the EH&S Department.
- 3.5.6. Work to identify incidents of unprotected exposure to M. tuberculosis and work with the ICP, and EH&S to ensure appropriate follow up procedures are undertaken.
- 3.5.7. Assists EH&S to evaluate hazards, whether respiratory protection is needed, and (if so) what type
- 3.5.8. Report surveillance trends and post-exposure conversion data to the Infection Control Committee (ICC) guarterly

3.6. Infection Prevention and Clinical Epidemiology Unit Director IPCE)

- 3.6.1. Assist with annual risk assessment to determine the risk for transmission of M. tuberculosis and ensure this is reported to the ICC.
- 3.6.2. Assist with the review of this plan annually and revise as necessary
- 3.6.3. Implement the COEM EMS Plan
- 3.6.6. Provide consultation on all aspects of plan
- 3.6.7. Coordinate TB suspect case reporting and exposure follow up
- 3.6.8. Communicate observed problems with environmental controls and isolation practices.
- 3.6.9. Communicate with COEM, EMS, SD County TB control when appropriate
- 3.6.10 IPCE to review and update the LMS TB Education required annually of HCWs.

3.7. Environmental Health and Safety Department (Director EH&S)

3.7.1. Monitor engineering controls such as ventilation, negative pressure and performance of HEPA filters.

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- 3.7.2 Report deficiencies in engineering performance to appropriate department managers and to Infection Prevention and Clinical Epidemiology Unit.
- 3.7.3. Act as a resource for training and to department managers for clarification and review of departmental policies and procedures and/or concerns.
- 3.7.4. Act as the administrative liaison during a Cal/OSHA inspection and coordinate follow-up activities.
- 3.7.5. Ensure that the Facility Injury and Illness Prevention Program staff addresses TB transmission as a potential hazard and whether respiratory protection is needed, and the type of protection needed.

3.8. Center for Occupational and Environmental Medicine (Administrative Director COEM EMS)

- 3.8.1 Supervise the COEM Employee Medical Surveillance services, which include TB screening and N95 respirator fit testing for all HCW's.
- 3.8.2 Assist with review of this plan annually at the request of the Infection Control Committee (ICC).
- 3.8.3 Evaluate all QFTG-positive HCWs and QFTG –indeterminate identified by the COEM EMS Plan. COEM will coordinate the identification and referral process. Evaluation by COEM will follow guidelines and COEM protocol (Attachment 13)
- 3.8.4. TST or QFTG conversions resulting from occupational exposures will be recorded on the OSHA 300 Log and coded as a "respiratory condition" by Medical Center Worker's Compensation Office or UCSD Campus Workers Compensation Office.
- 3.8.5. Provide pre-placement Tuberculosis Screening as described below in 4.1
- 3.8.6. Diagnose and treat LTBI as described below in 4.0
- 3.8.6.1. Review the chest X ray reports of HCWs who have had at pre-placement, post exposure or other x rays requested under this plan. COEM provider will examine patients who need further evaluation. COEM will have mechanisms in place that are needed to coordinate the ordering and receiving of CXR reports of HCWs
- 3.8.6.2. Refer HCWs who need further evaluation for consideration of active TB for consultations to ID or Pulmonary physicians as is clinically appropriate.
- 3.8.6.3. Perform history and physical examination as indicated of HCWs who are TST or QFTG reactors and evaluate them for treatment of LTBI
- 3.8.6.4. Follow those who are eligible for and elect to receive treatment by COEM
- 3.8.7 Periodically review annual and post exposure related HCW TB testing performed to ensure compliance with post exposure HCW testing, including baseline and 10 week follow up and present at the Infection Control Committee Meeting.

3.9. Facilities and Engineering Services (Director of FE)

- 3.9.1. Ventilation system filters: FE staff will change filters as required. When changing ventilation system filters, personnel will wear an N 95 respirator or PAPR.
- 3.9.2. When HEPA filters in negative pressure rooms are replaced, the used filter will be disposed of as bio-hazardous waste.
- 3.9.3. Negative pressure checks will be performed on all rooms occupied by TB patients for greater than 24 hours.
- 3.9.4. Air changes per hour will be calculated monthly in all rooms by actual measurement of air flow. Cubic feet per minute (CFM) will be calculated and differential negative pressure for each room determined.
- 3.9.5. Maintain all necessary records/documentation regarding assessments of negative pressure rooms for 5 years. Ensure annual certification of the negative pressure rooms.
- 3.9.6 Report the negative pressure room readings to Infection Control Committee (ICC) on a quarterly basis

3.10. COEM Employee Medical Surveillance (Administrative Director COEM EMS)

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- 3.10.1 Perform QFT blood draw on all HCW's as indicated in this plan and with the advice of the COEM Employee Medical Surveillance.
- 3.10.2 Manage+ the QFTG (QuantiFERON TB Gold test) program.
- 3.10.3 Perform fit testing on all HCW as indicated in this plan annually and as needed and with the advice of the COEM Employee Medical Surveillance and COEM provider.
- 3.10.4 Work with computer services to send out notices to HCWs of the need for TB Screening and fit testing
- 3.10.5 Review list of HCW who are non-compliant and communicate with PCIS/EPIC to bar use by noncompliant HCW.

3.11. Infection Control Practitioner (ICP) Associate Infection Control Coordinator (AICC)

- 3.11.1 Role: The ICP is responsible for coordination of all aspect of the COEM EMS Plan as it relates to patients.
- 3.11.2 Implement and manage a system for identifying active TB cases at UC San Diego Health System.
- 3.11.3 Monitor patients for appropriate isolation precautions and placement into All rooms when necessary
- 3.11.4. Liaison between direct patient care providers, case managers and COEM EMS Program of SD County and ensure correct reporting to the COEM EMS Program of SD County of active TB cases in order to establish an effective liaison with personnel at COEM EMS Program of SD County.
- 3.11.7. Assist COEM EMS staff in updating and revising the COEM EMS plan
- 3.11.8. Educate nurses and ancillary staff about TB by providing training on a regular basis.

3.12. Respiratory Therapy (RT)

3.12.1. Aerosol Sputum Induction: RT Technicians who have been trained will perform aerosol induced sputum collections for all inpatients and outpatients. To call for an appointment for outpatients dial 619-543-5740. Inpatient induced sputum's are ordered through EPIC.

3.13. Case Management

- 3.13.1. In coordination with IPCE ICP, the case manager will identify patients with active or suspected pulmonary TB upon notification from IPCE ICP, interdisciplinary rounds, consult in EMR or initial review. Because patients on anti-TB medications may be admitted over the weekend or on holidays when IPCE is not available, case management is ultimately responsible for reviewing their patients for any conditions that would require a TB discharge plan.
- 3.13.2 The case manager will collaborate with IPCE ICP to ensure appropriate and timely notification (within 24 hours) to the San Diego Health Department COEM EMS branch.
- 3.13.3 The case manager will complete the County of San Diego Public Health COEM EMS Branch Discharge Plan for all patients with active pulmonary TB. http://www2.sdcounty.ca.gov/hhsa/documents/TB-273DischargeOfSuspect.pdf
- 3.13.4 The case manager will fax the completed Discharge Plan to (619) 692-5516 SDPH COEM EMS Branch and or call (619) 692 8610- at least three (3) days prior to discharge. If a home visit is needed, SDPH COEM EMS Branch will need notification four (4) days prior to discharge. For discharges on the weekends or holidays please page (877) 401-5701.
- 3.13.5 SDPH COEM EMS Branch will contact the Case Manager within 24 hours of receipt of Discharge Plan to approve or request additional information for the discharge plan.

4.0. TB Surveillance of Health Care Workers (HCWs)

The following test is offered by UC San Diego Health System at no cost to the HCW: QFT Blood Draw. TB tests performed at other health facilities may be accepted at UCSD however will not be paid for. Written documentation of testing performed by another facility must be provided and must include the date, the test performed including antigen and technique and the result of the test. TST results must be reported as mm of reaction and will be accepted only from facilities that are approved by TJC

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or those who use skin test technicians who are specifically trained to perform TST as described in the California Health Code.

- 4.0.1. History and physical examination may be provided by COEM as needed to clarify the risk of TB, latent or active. This examination will include a history of BCG vaccination, active TB or exposure to active TB as well as physical examinations and studies needed to clarify the TB status of the HCW.
- 4.0.2. TB screening tests; There are now 3 tests approved by the FDA for TB infection: TST, QuantiFERON Gold and T Spot. The QFTG are provided by UC San Diego Health System.

4.1. Post Offer Screening

4.1.1 HCW as defined in 2.0 will participate in the "Post offer" (pre-employment and post offer) tuberculosis screening program as described in this plan. Post Offer examination will be performed by COEM. Regarding visiting or temporary HCW such as medical student, residents, faculty, traveling nurses, respiratory therapy workers not directly employed by UCSD, these individuals are required to provide documentation of TB screening equivalent to that required in this plan for HCW. This responsibility will be borne by the individual or their parent institution. These HCW must provide documentation to the COEM Employee Medical Surveillance when it is requested.

Acceptable: pre hire post offer baseline TB screening includes a symptoms review questionnaire plus one of the 3 acceptable testing's listed below:

- 2 step TST/PPD testing done up to 360 days apart and last TST done within up to 3 months before the work start date.
- IGRA lab testing (QFT, TSPOT) done within 3 months from the start date
- Chest Xray done within 3 months from start date.

It is a condition of employment for UCSD-HS HCW to demonstrate immunity to listed infections below. If the HCW is unable to demonstrate immunity, the HCW will be referred to Human Resources for review of essential job functions and possible accommodations.

1. Documented vaccination or immunity records following CDC and ACIP recommendations of HCW vaccinations:

Vaccine	Schedule
Influenza	One dose annually
Measles	Two doses
Mumps	Two doses
Rubella	One dose
Tetanus, Diptheria, and Acellular Pertussis (Tdap)	One dose, booster as recommended
Varicella-zoster (VZV)	Two doses

Newly hired personnel are evaluated at the time their pre-placement examination. (Refer to MCP 611.3, Employee Physical Examination Program).

4.1.2. The examination will include history and physical examination test for TB infection and chest X-ray when appropriate as described above.

4.1.3 Evaluation of Post Offer examinations: Please refer to Attachment 13.

4.2. Assessment of TB testing interval

The testing of TB healthcare workers shall be conducted on hire and in cases of a defined exposure. However, the CDC guidance suggests that an institution may reconsider this guidance if TB transmission appears to be elevated in the facility. IPCE in collaboration with COEM and EH&S will reevaluate the testing schedule annually, upon new guidance from the CDC or local (state or county) TB control officer and if baseline testing from exposures demonstrates a rate of TB conversion significantly above that seen prior to the introduction of less frequent testing.

4.3. TB Screening

In August 2012, UC San Diego switched from (TST) skin testing to QFT blood draw for HCW TB Screening. Interferon Gamma Release Assays (IGRAs). QuantiFERON - TB Gold test (QFTG) and T Spot are two blood tests that are called Interferon Gamma Release Assays (IGRA). They are approved by the FDA. Guidelines for using QuantiFERON – TB Gold are available from the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a4.htm. New Guidelines for both IGRA are expected shortly and when available will guide the use of the T Spot test. The IGRA are far more specific that the TST.

- 4.3.1Target Population: COEM EMS will offer all UC San Diego System HCW's and Providers with direct patient care
 QFTG as a means for screening for TB. .
- 4.3.2 Blood Draw. Blood drawing may be performed by a Certified Phlebotomist (CPT) or trained licensed professional and must be performed with a special heparinized vacutainer tube, and delivered to the microbiology laboratory. (MCP 615.1: Blood Specimen Collection, Purposes of Clinical Laboratory Testing)
- 4.3.3 Interpretation: If the QFTG test is POSITIVE (>0.35 >10) the HCW will be referred to COEM for further evaluation and rule out active TB has been ruled out. A letter will be sent to them with the information for follow up with COEM. (Attachment 3). If the QFTG test is negative (0.0 <0.35) it is likely that the patient was not infected with Mycobacterium tuberculosis. For all POSITIVE and INDETERMINANT results, please see COEM algorithm (attach. 3) Note that the QFTG is not completely effective to rule out TB infection or disease. The COEM EMS Medical Director will determine whether or not each patient who has a QFTG is infected with TB by evaluating the entire situation and determining the appropriate follow up on an individual basis. Options include: 1) treatment for LTBI, 2) Follow up with QFTG, chest X-ray, and questionnaire (Attachment 13)</p>
- 4.3.4. Communication of non negative results to HCW tested with QFTG: HCWs offered QFT will be notified in writing of the results, recommendations and limitations of QFTG Testing using the QFTG Results and Recommendation Form, Attachment 3.

4.4. Chest X rays.

4.4. Chest X ray as deemed necessary by COEM (see Attachment #13)

4.5. TB Screening for Follow-Up Questionnaire for Positive Reactors See attachment # 13.

4.6. Alternative Screening Procedures.

HCW who are immunocompromised by co-morbid conditions or medications that may make testing for TB infection less reliable may request alternative screening procedures. The request should be made to COEM. Once approved the HCW will be screened as indicated by the risk discussed below by having four tests per provider's discretion; TST, QFTG, chest x ray and questionnaire. If any there is any abnormality reported on any of these tests, the HCW will be examined by COEM.

4.7. Exposure Work Up

An exposure is defined as an unprotected exposure to a patient or HCW suspected to have contagious TB as determined by IPCE.

4.7.1 Identification of HCW exposed. When TB is diagnosed on a patient who has been in a clinical area that is not on respiratory precautions, HCW who have spent 1 or more hours cumulatively

- within 3 feet of the patient without the use of an N95 respirator are said to be exposed. The department supervisor must notify IPCE when it is suspected that an unprotected exposure to contagious TB has occurred to a patient/s or staff.. The department supervisor will review the source patient's chart to identify and list all HCW's and patients who were exposed to the suspected contagious case. The department manager will send a list of employees potentially exposed to COEM, and a list of patients potentially exposed to IPCE. In addition the Department manager on the floor will notify HCWs that an exposure has occurred and that they should contact the Department Manager for further information.
- 4.7.2 Review of Exposed HCW. The department manager will give the list to COEM. COEM will review the TB record of each HCW.COEM will notify the employee of the exposure, and provide education on the plan for testing, symptoms of infection, and treatment plan, if needed. Employees who have not had TB screening within the past 3 months will require baseline screening. All exposed employees will be required to have TB screening ten to twelve weeks after the exposure. TB screening will include a TB questionnaire, and may include Quantiferon gold test, and or chest xray. Screening tests are determined by the the COEM licensed provider and based on the employee's TB medical history.
- 4.7.3. HCW who are not directly employed by UCSD. COEM staff will notify the agencies to inform their employers that the HCW has been exposed to a patient suspected of active TB and the HCW must receive follow up as recommended in this Plan for UCSD HCWs. A Workers comp case will be opened for these employees and they must be seen in person at the COEM clinic.
- 4.7.4. Conversions. A HCW whose QFTG test from negative to positive is at risk for progressing to active TB and should be evaluated for treatment of LTBI. The patient will be contacted by COEM for evaluation of and treatment for LTBI if appropriate. COEM will inform the HCW of the result and the need for evaluation (see attachment 3). QFTG conversion or development of active TB related to an work exposure in a HCW will be referred to Worker's Compensation and be reported as such. Compliance with the provisions of MCP-611.8, "Employee Worker's Compensation" is mandatory. COEM shall report to the Workers' Compensation Reporting System at (619) 543-7877.
- 4.7.5.1 Exposure incident: Any RATD case, or suspected case, or an exposure incident involving an ATP-L shall do all of the following:
 - 1. Within a timeframe that is reasonable for the specific disease, but in no case later than 96 hours following, as applicable, conduct an analysis of the exposure scenario to determine which employees had significant exposures. This analysis shall be conducted by an individual knowledgeable in the mechanisms of exposure to ATPs or ATPs-L, and shall record the names and any other employee identifier used in the workplace of persons who were included in the analysis. The analysis shall also record the basis for any determination that an employee need not be included in post-exposure follow-up because the employee did not have a significant exposure or because COEM determined that the employee is immune to the infection in accordance with applicable public health guidelines. The exposure analysis shall be made available to the local health officer upon request. The name of the person making the determination, and the identity of COEM or local health officer consulted in making the determination shall be recorded.
 - Within a timeframe that is reasonable for the specific disease, but in no case later than 96 hours of becoming aware of the potential exposure, attempt to notify employees who had significant exposures of the date, time, and nature of the exposure.
 - 4.7.6 Review of Exposure Work Up. Within 3 months of the opening of an exposure workup the COEM will assemble the results of the testing of HCW performed as a result of the exposure and make every effort to ensure that each HCW has been fully informed about the exposure and had every effort to be tested. The Compliance Enhancement Program

described below will be engaged to the maximal extent. A final report will be made to the COEM/COEM Employee Medical Surveillance at 6 months. COEM will report to Infection Control Committee (ICC) all HCW exposures and follow up.

4.8. Compliance Enhancement Program

- 4.8.1 HCWs are responsible for understanding the COEM EMS Plan, the risks of TB in the workplace and to act to reduce that risk. HCWs will be notified 1 month prior to their annual due date when annual N95 fit test is dud. The HCW will be notified of the need to complete fit testing
- 4.8.2. Department Directors or Supervisors have the responsibility for ensuring that the personnel for whom they are responsible comply with the COEM EMS Plan. In addition, they must implement disciplinary measures required by this plan for HCW who are past due for TB screening. Appropriate Medical Center administrative support will be called upon when necessary.
- 4.8.3. Non-compliant HCW. HCW who are employees of the Medical Center who past the date that testing is due will be suspended and denied access to PCIS/EPIC. The manager will be responsible for placing those HCWs who fail to complete the testing on <u>LEAVE</u> <u>WITHOUT PAY</u> until completion is verified. The manager will notify those individuals of their change in status by way of verbal and written memorandum. The Chief Medical Officer will enforce managers taking the appropriate action.
- 4.8.4 Personnel who are not HCWs but who have duties in the medical center will be restricted as follows:
- 4.8.4.1. Medical Staff: The Department Chair or Division Chief will be notified of the noncompliant physician. Non-compliant physicians will be denied access to PCIS/EPIC and will not be permitted to renew hospital privileges.
- 4.8.4.2. Interns and Residents: The Medical Director and appropriate Residency Program Director will be notified of noncompliant personnel. Noncompliant personnel will be denied access to PCIS/ EPIC
- 4.8.4.3. Medical Students: The Medical Student Affairs Office will be notified, and the student will be denied access to t UC San Diego Health System.
- 4.8.4.4. Volunteers: Volunteers will be sent home until they are in compliance.
- 4.8.4.5. Pool Personnel: Will be issued a warning through their supervisor that they will not be allowed to work beyond a given date until they are in compliance.

5.0. Patient Care Issues

Because TB is transmitted by the respiratory route, COEM EMS must emphasize decreasing droplet nuclei at the patient source and minimizing inhalation of droplet nuclei by those individuals who share the air space with the infectious patient.

5.1. Patient Screening

- 5.1.1. Chest x rays or other methods (example CT or MRI): The chest x-ray is an appropriate screening tool for TB in patients admitted to UC San Diego Health System. This is particularly so in patients who have symptoms of a pulmonary infection, are in one of the high risk groups (e.g. foreign born from a high TB incidence country or have significant immunosuppression due to comorbidity or medications).
- 5.1.2. Acid-Fast Bacilli (AFB) examination of specimen: Sputum should be examined by AFB smear and culture when patients are suspected of having active TB. At UCSD the sensitivity of this test is approximately 80% and the specificity is approximately 90%. All precautions need NOT always be instituted when sputum for AFB is ordered if TB is low on the list of differential diagnoses. Should smear be positive for AFB, precautions will be

- instituted immediately. IPCE staff in collaboration with the TB control medical director may wave this in cases with known non- tuberculosis acid fast bacilli.
- 5.1.3 Nucleic Acid Amplification (NAA). The UCSD Micro lab performs the Mycobacterium direct tuberculosis test (MTB). This test should be performed if there is a high suspicion for active TB, but the AFB is negative. In addition, whenever the AFB is positive, the MTB should be performed to confirm if it is M. tuberculosis. The attending physician must order and evaluate NAA results on the first positive AFB smear from a respiratory secretion. The sensitivity of this test at UCSD is approximately 90% and the specificity is approximately 98%
- 5.1.4. Tests for TB infections CDC recommends the use of TST or IGRA tests to detect TB infection. The IGRA tests are new blood tests that use measure the release of interferon gamma following stimulation by highly specific TB antigens. There are two such tests approved by the FDA. At UCSD the QuantiFERON TB Gold test is available. CDC guidelines suggest that it is as sensitive at the TST or the detection of TB infection but because of the specificity of the antigens has a much greater specificity than the TST. CDC recommends that these tests are effective to identify persons who are infected with TB but should never be used to exclude the possibility of active TB as none of the tests for TB infection is 100% sensitive. Routine tests for TB infection, TST or QFT is recommended for individuals having a greater likelihood of exposure to TB than the general population.
- 5.1.4.1. TST (for Inpatients and Outpatients)
- 5.1.4.2. Training of TST technicians shall include didactic information on the pathogenesis, diagnosis, treatment and public health aspects of TB in addition to technical information about the antigen, placement and reading of TST. This shall include at least 2 hours of instruction, as well as placement of 20 intra-dermal skin tests and reading of 10 TST reactions of 3 mm or more. Also, UC San Diego Ambulatory/ COEM EMS 4 hour training is acceptable.
- 5.1.4.3. Quality Assurance. Any nurse, respiratory technician or Medical assistant (MAs) who has completed training as described above must read 10 TST reactions (more than zero) each year in tandem with a certified TST reader and demonstrate that 80% of the readings are within +/-2 mm from the certified reader.
- 5.1.4.4. Definition of TST reactions.
- 5.1.4.5. A significant TST, as defined by the Centers for Disease Control & Prevention (CDC), MMWR, December 30, 2005/54 (RR17), is as follows:
- 5.1.4.6. TST \geq 5mm is positive in:
 - a. Persons infected with HIV
 - b. Recent contacts with a person with TB disease
 - c. Persons with fibrotic changes on chest radiograph consistent with previous TB disease
 - d. Organ transplant recipients and other immunosuppressed persons (e.g. persons receiving ≥15 mg/day of prednisone for ≥ 1 month)
 - e. TB suspects
- 5.1.4.7. TST \geq 10 mm is positive in:
 - a. Recent immigrants (i.e. within the previous 5 years) from countries with a high incidence of TB disease
 - b. Persons who inject illicit drugs
 - c. Residents and HCWs (including HCW) of the following congregate settings:
 - i. Hospitals and other health care facilities
 - ii. Long-term care facilities (e.g. hospices and skilled nursing facilities
 - iii. Residential facilities for patients with AIDS or other immunocompromising conditions
 - iv. Correctional facilities
 - v. Homeless shelters.
 - d. Mycobacteriology laboratory personnel

- e. Persons with the following clinical conditions or immunocompromising conditions that place them at high risk for TB disease
 - i. diabetes mellitus
 - ii. silicosis
 - iii. chronic renal failure
 - iv. certain hematologic disorders (e.g. leukemias and lymphomas)
 - v. other specific malignancies (e.g., carcinoma of the head, neck or lung)
 - vi. unexplained weight loss ≥10% of ideal body weight.
 - vii. gastrectomy
 - viii. jejunoileal bypass
- f. Persons living in areas with high incidence of TB disease.
- g. Children < 4 years of age.
- h. Infants, children and adolescents exposed to adults at high risk for developing TB.
 - i. Locally identified groups at high risk.
- $5.1.4.8. \text{ TST} \ge 15 \text{ mm}$ is positive in:
 - a. Persons with no known risk for TB
 - b. Persons who are otherwise at low risk for TB and who received baseline testing at the beginning of employment as part of a TB screening.
- 5.1.4.9. TST skin test conversion will be defined according to the Centers for Disease Control & Prevention, MMWR, December 30, 2005/54 (RR17) and is as follows:
 - a. For HCW with no known TB exposure:
 - i. TST increases >10mm and a change of 6 mm or more within 2 years
 - b. For HCW with close contact to TB
 - i. TST increase > 5mm in HCW whose prior TST was 0 mm
 - ii. If prior TST was >0mm and <10 mm and subsequent TST is >10 and a change of 6 mm or more
- 5.1.5.The Clinical Laboratories, Microbiology Section, will notify the attending physician and COEM EMS staff of all specimens found to be smear positive for acid fast bacilli (AFB), of specimens found to be culture positive for Mycobacterium tuberculosis (MTB), and of drug susceptibility results for MTB isolates. Results will be reported for inpatients and outpatients.

5.2. Initial Evaluation of TB suspects

Patients suspected of having active TB are placed into All until TB has been ruled out by appropriate evaluation. Examinations shall include: (a) a history and physical examination; (b) a chest imaging including X-ray or CT; (c) examination of three sputum samples by acid-fast bacilli (AFB) smear microscopy and culture (obtained every 8 hours on the first day or 2 negative sputa with 2 negative MTB PCRs (if not induced, preferably 1 morning specimen and the 2nd specimen obtained 8 hours after the 1st). If extra-pulmonary TB has been ruled out in a patient without pulmonary symptoms, it is not necessary to complete the pulmonary rule-out. Aerosolized induction services are available to assist in collecting sputum from patients who cannot bring up a good sputum specimen when asked to do so. Aerosol induction services can be obtained by appointment from Respiratory Therapy; (d) a MTB test to confirm smear-positive cases prior to availability of culture results.

The recommendation for evaluation of patients in AII is the following:

- 1) The attending should assess and document the clinical suspicion of TB (CSTB) by answering the question "What is your estimate of the likelihood that, at the end of the patient workup, the patient will be proven to have active TB? Estimate the likelihood on a scale from 1% (lowest suspicion) to 99% (highest suspicion)." The result should be clearly noted in the patient chart
- 2) Collect three (3) sputum samples at any time during the first day in isolation. Order AFB smears microscopy and culture. Use aerosol induction only if the patient cannot expectorate sputum.

- 3) If the CSTB is between 25% and 75%, or any AFB smear is positive, order one MTB.
- 4) Collect two (2) additional sputums sample on Day 2.
- 5) If the CSTB is high (>75%), consider consulting a pulmonary or infectious disease physician for appropriate patient management from the onset of care.

This plan will allow for most patients who have active TB to be diagnosed within 24 hours of admission and placed in All rooms, with cultures to confirm all presumptive decisions.

5.3. Clinical Management of Perinatal/ OB Patients

- 5.3.1. Prenatal Outpatients
- The Prenatal Algorithm (Attachment 5) should be followed. In areas where patients with undiagnosed TB may be present, an individual with symptoms of TB should be managed in a manner that minimizes risk of transmission.
- 5.3.1.1 Patient reception, admitting, and waiting areas should have ventilation that provides a minimum of 6 air changes per hour (ACH). Facilities Engineering will be responsible for monitoring ACH every 6-12 months.
- 5.3.1.2. Any coughing patient should be instructed to effectively cover their coughs with a handkerchief, tissue, or surgical mask. Signs with this request (non-verbal/pictograph and/or in several languages) should be prominently posted. Tissues, alcohol hand gels and masks should be readily available in waiting areas.
- 5.3.1.3 If a patient is a suspect of TB or has a confirmed diagnosis, communication by phone shall occur to other departments prior to transport of the patient to those departments.
- 5.3.1.4 High risk medical procedures will be managed according to Section 5.4

5.4. Pregnancy, Delivery and Lactation

(Appendix 6: Algorithm for TST in Inpatient Setting for Women and Infant Services)

- 5.4.1. Mothers with known or suspected TB, untreated, or apparently inactive TB, will be handled as follows:
- a. A patient with positive TST as defined by CDC Guidelines (5 mm is + if HIV infected or household contact or 10 mm for foreign borne patients and no evidence of a current disease (patient asymptomatic and CXR shows no evidence of TB) is considered to have latent TB infection (LTBI).
- b. Mothers with no symptoms or extenuating circumstances should be considered for treatment of LTBI three months after conclusion of pregnancy. If the mother is thought to be at high risk for developing active disease before that point and exception should be considered with consultation from ID or Pulmonary.
- c. Mother-infant contact permitted
- d. Breast feeding permitted
- e. Education regarding TB and the risk of TB to the baby along with education around the effects of INH to the baby in breast milk
- 5.4.2. Mother with untreated (newly diagnosed) TB disease, sputum smear-negative, or has been treated for a minimum of 2 weeks and is judged to be noncontiguous at delivery.
- a. Careful investigation of household members and extended family is <u>mandatory</u>. Public Health referral to county of residence is required as soon as possible.
- b. Mother-infant contact permitted if compliance with treatment by mother is assured. If the mother's compliance is in question, the issue MUST be reviewed by the TB Liaison Nurse
- c. Breast feeding permitted. INH is secreted in breast milk but safe for the baby.
- d. Infant should receive INH. BCG vaccine may be considered if mother is non-compliant.
- e. Consultation with Pulmonary Services, Infectious Disease or Infection Control is recommended.
- 5.4.3. Mother has current TB disease and is suspected of being contagious at time of delivery (abnormal CXR consider TB or AFB smear positive).
- a. "STOP"/Airborne sign precautions on the door of mother's room, until discharge.

- b. The mother must wear surgical mask when she has contact with the infant within UC San Diego Health System
- c. Visitors must wear surgical mask when they have contact with the Patient.
- d. COEM EMS, San Diego County must be contacted by the Case Manager or discharge planning team within 24 hours of TB diagnosis when patient has been diagnosed with TB. A suspect report will be completed.
- e. The Case Manager is to be notified of COEM EMS SD County's approval of the discharge.
- 5.4.4. Mother with extrapulmonary TB is not usually a concern unless a tuberculosis abscess with copious drainage is forcefully irrigated resulting in aerosolization of that drainage. In that situation, consult with the COEM Employee Medical Surveillance and the patient should be placed on all precautions.

5.5. Clinical Management of Inpatients Suspected of Having Active TB

- 5.5.1. Direct Admissions: The COEM EMS SD County may ask for a direct admit to the UC San Diego Health System Hospital. The Hospitalist on duty will make decisions regarding the appropriateness of direct admission to the Medical Service. If the patient is to be admitted, then the patient will be masked (surgical mask) prior to entering the Medical Center.
- 5.5.2. All AFB Precautions shall be initiated by physicians and nurses when active pulmonary/laryngeal TB is diagnosed or when there is high clinical suspicion for TB. This includes patients readmitted with persistent or recurrent symptoms and those whose duration of drug therapy has been inadequate to render the individual noninfectious.
- 5.5.3. AFB testing while in AII. It is recommended that AFB sputums be repeated every four days when the initial sputum AFB smears are 3+ to 4+ until the AFB sputums are 1+ to 2+. Once the patient has 3 consecutive negative AFB smears and the patient has received 2 weeks of a TB regimen, AII precautions may be removed when no cultures are found to be positive.
- 5.5.4. TB Suspects: Persons with suspected or confirmed active TB should be considered infectious and placed in All Precautions. The protocol described in 5.4.2 should be followed to rule TB in or out. The patient may be taken out of isolation when TB is judged to be unlikely as described in 5.2. If the diagnosis of active TB is established then the patient must be kept in All until the infection is judged to be nil. Medical staff will determine when the patient is medically stable and ready for discharge. The patient cannot be discharged until COEM EMS; SD County has approved the discharge plan.
- 5.5.5. Patient mobility: A patient with TB, suspected TB or rule-out TB should not leave his/her room, except under the circumstances or conditions described below.
 - 1. If the patient must leave his/her room for diagnostic purposes, a mask (regular surgical mask) will be put on the patient.
 - 2. The patient may leave his/her room to shower provided he/she is the last patient to use the shower that day. The patient will wear a mask when moving between his/her room and the shower room. A sign will be affixed outside the shower door stating "Not ready for use until _____ (date) _____ (time)", with a date/time noted that is 6 hours after the patient's shower has ended.

A patient with TB, suspected TB or rule-out TB who is on an extended hospital stay may leave the building for 30 minutes twice a day, with the approval of the charge nurse, and provided that the patient is accompanied by a nursing staff member. Approval will depend on staff availability and unit activity. When a patient is outside the building, he or she may remove his/her mask. The patient must put his/her mask back on when re-entering the hospital and wear it until once again his/her room.

If a patient with TB, suspected TB or rule-out TB states intent to elope (leave the hospital), UC San Diego Health System Patient Care and Security Services staff should:

1. attempt to calm the patient down

2. not attempt to restrain or physically prevent the patient from leaving

If the patient successfully elopes and Security is unable to locate the patient, the House Supervisor staff should contact the San Diego County Health Department COEM EMS at (619) 692-8610 and leave a message with the Patient's Name, MRN and date of elopement.

5.6. Discontinuation of All Precautions

At physician discretion, precautions may be continued for longer than the Plan requires. A patient may be considered for removal from All in the following circumstances:

- 5.6.1. TB ruled out: The diagnosis of a pulmonary process in which TB risk assessment and clinical course indicate TB is not highly suspected.
- 5.6.2. Patients known to have a diagnosis of active TB can be released from Airborne Precautions after 3 negative cultures NOT smears have been recorded.

5.7. Discharge from Hospital

Discharge should be considered when the patient no longer requires acute care. Negative AFB smears are not always required by San Diego TB control. Patients with confirmed pulmonary or laryngeal TB may be discharged on a case by case basis with careful consultation with the COEM EMS SD County, the care coordination manager and the attending physician.

5.8. Reporting to COEM EMS SD County

- 5.8.1 Reporting a New Diagnosis of active TB: The COEM EMS SD County must be notified within 24 hours of the diagnosis of TB or the initiation of multiple drug therapy for TB.
- 5.8.2 Discharge of a patient with active TB or taking multiple anti TB drugs must be approved by the COEM EMS SD County prior to discharge. This is also the case if a patient was known to have TB prior to admission.
- 5.8.3. The COEM EMS SD County does NOT need to be notified of the diagnosis of latent TB infection.
- 5.8.4. The COEM EMS SD County does NOT need to be notified of putting a TB suspect into isolation or removal from isolation.
- 5.8.5 The COEM EMS SD County does NOT need to be notified of an exposure to active TB in the hospital of a HCW, a patient or visitor.

5.9. Mandatory Direct Observation Treatment (DOT)

Patients on TB medications must have DOT by the nurse observing ingestion of the TB medications and ensure that the patient swallowed the medications. It is not an acceptable practice for the health care worker to leave TB medications at the bedside for later ingestion by the patient.

5.9.1. Required Consultations. Pulmonary TB cases with co-morbidities such as HIV infection or pregnancy should have pulmonary and/or ID consults performed as early as possible for discharge planning. When a diagnosis of extra-pulmonary TB is made, an ID consult should be requested.

5.10. Monitoring Levels of Anti TB Drugs

Consideration should be given to obtaining drug levels in clinical situations when conversion of AFB smear is delayed or when there is a question regarding malabsorption or the patient appears not to be responding to treatment in the time course expected. This decision is best made in consultation with ID or Pulmonary. The attending physician shall always coordinate with TB Liaison nurse, Pharmacy and the lab prior to blood level draws. No weekend or holiday draws are available. On the day drug levels are to be drawn, the dosage and time of drug administration must be carefully noted on the lab requisition. Follow up blood levels can be drawn in red top or green top tubes. Peak levels usually occur at about 2 hours, however, delayed absorption maybe monitored at 6 hour intervals; therefore optimal times for blood level monitoring are 2-6 hours

post ingestion; in some cases 1-4 hours maybe useful. It is critical that the blood be separated and frozen within 45 minutes. The serum is sent to a reference laboratory for measurement of drug level.

5.11. Discharge Planning

The COEM EMS Plan at the UC San Diego Health System requires that all hospitalized cases of suspected or confirmed pulmonary tuberculosis are required to have a consultation by either the pulmonary or infectious diseases services prior to discharge. Planning for discharge should begin when TB treatment is started. California law requires that the local health department approve discharge plans for all patients with active TB. The coordination manager is responsible for communications with the SD TB Health Department.

5.12. Latent TB Infection

A patient may be worked up for active TB and found not to have active TB. However if the TST or QFT is reactive the patient may likely have LTBI and if they don't have TB now may be at significant risk of developing active TB in the near future. Such a patient should be considered for treatment of LTBI

- 5.12.1. Targeted Testing for LTBI. CDC has identified certain categories of high risk TB populations who should be tested for LTBI. The largest groups are those who are foreign born, those who are immunosuppressed and most important those who were/or may have been exposed to active TB such as residents of congregate living situations such as prisons, jails and health care facilities. Patients in high risk categories should be tested for TB infection by use of the TST or QFT. Testing for LTBI carries the responsibility to treat LTBI if the patient does not have active TB. Patients who should be tested include immunosuppressed or foreign born individuals. TST is the time honored test for LTBI however the IGRA are more specific and may overcome some inflammatory lesions making the TST inaccurate in certain situations.
- 5.12.2. Treatment of LTBI. CDC recommends treatment with INH 300 mg/day for 9 months or rifampin 600 mg/ day for 4 months. Prescriptions should be written for 30 days and not refilled without follow up examination. Patients may be seen monthly by any prescribing physician. Initial and follow up transaminase testing is performed as indicated by clinical findings.

6.0. Engineering Controls of Airborne Transmission of TB

6.1. General Ventilation

Dilution reduces the concentration of contaminants by supplying clean air that mixes with and displaces the contaminated room air. Air removal occurs when the diluted contaminated air is exhausted. General ventilation will be managed in a manner that contains and reduces the concentration of contaminants in the air by the following methods. A minimum of 12 ACH for every patient room is required. Higher ventilation rates result in greater reduction in the concentration of contaminants.

6.2. All Room

☐ The patient will be housed in a private room or enclosure.
☐ All precautions signage will be posted on or directly adjacent to the door of the All room.
☐ Air pressure within the All room will be negative to surrounding rooms and hallways.
☐ A minimum of 6 air changes per hour (ACH) will be provided. Exhausted air or ambient air
will not be recirculated without HEPA filtration. Local exhaust ventilation (LEV) devices
may be utilized as an adjunct to, or instead of general ventilation.
☐ Windows must remain closed and doors are to be opened for entry/exit only.
☐ No special procedures are required for the handling of trash, linen, and soiled equipment
and will be handled according to Standard Precautions.

- ☐ Housekeeping duties will occur as for any occupied patient room. Worker will wear respiratory protection as per Section 5.3.2.5
- 6.2.1. Directional air flow/"Negative Pressure" should
 - Provide optimal air flow patterns by preventing stagnation or "short circuiting" of air
 - Contain contaminated air in designated areas and prevent its spread to uncontaminated
 - areas (Anteroom may be used to reduce escape of droplet nuclei). Enclosures (booths or
 - tents) with HEPA filtered exhaust may be used.)
 - Provide air flow from less contaminated areas (hallways and adjacent rooms) to more contaminated areas (All room)
 - Create a "negative" pressure environment (exhaust > supply) [Pressure differential
 is based on a closed space and will be altered by opening doors and windows.
 Doors must remain closed except for room access. Surrounding air spaces may
 be pressurized (supply > exhaust).]
- 6.2.2. Monitoring: Airflow and velocity (ACH) in rooms used for All or for cough-inducing treatments or procedures will be assessed on a regular basis by Facilities Engineering. Facilities Engineering Department measures air exchanges and flow in patient rooms every 30 days if unoccupied. If occupied, monitoring it is daily and is posted on the FE website daily. A copy of the report is posted on the FE website and any discrepancies are reported to TB and Infection Control immediately. Summary reports are provided quarterly at the Infection Control Committee (ICC) meeting.
- 6.2.3. Room Clearance: When a patient who is on AII in a negative pressure room vacates a room, it must be left vacant for 30 min. When a patient undergoes aerosol induction for sputum collection the room must be closed for 1 hour. HCW who must enter a "closed room" must wear an N95 respirator. If a patient is in a non-negative pressure room and is moved to an AII room, the non-negative pressure room needs to be closed to all persons for 1 hour. HCW's, EVS etc. can go into the room after the patient has been out of the room BUT must wear the NIOSH approved N-95 respirator if it has been less than 30 minutes for a negative pressure room and 1 hour for a non-negative pressure room.

6.3. Respiratory Protective Equipment (Refer to Attachment 311 ATD Standards)

- 6.3.1. General: The most effective way to control respiratory hazards is to follow correct work practices and prescribed (mask/respirator) will be used to further ensure that individuals are not exposed to airborne biohazardous contaminants
- 6.3.2. Types of Air-Purifying Mask/Respirators
- 6.3.2.1. Negative pressure respirators (N95- NIOSH Approved) filters contaminants when inhalation creates negative pressure within the device and air flows through the filter material.
- 6.3.2.1.1 Respirator maintenance and storage. N95 respirators are disposable but can be used repeatedly throughout a work shift with the same patient and or left in the anteroom, if there is one unless they become wet or damaged. Respirators must be discarded at the end of the shift. The respirator must be inspected before and after each use to ensure that it is clean and intact. The respirator should be discarded and/or replaced if soiled, distorted, or in disrepair or if outside of the respirator is wet.
- 6.3.2.1.2. Disposable respirators may be discarded as regular waste.
- 6.3.2.1.3. Fit testing Respirator fit testing of all HCWs at risk for possible exposure to patients with infectious tuberculosis or other ATD's is required by OSHA standard for respiratory protection (29 CFR 1910.139). A baseline fit test will be done with follow-up testing as needed for possible changes in facial structure due to weight loss or gain of 10 lbs. or more, extensive cosmetic surgery, or anything else which may alter the size or shape of the face

- 6.3.2.1.4. The COEM EMS Unit will perform fit testing using Saccharin or Bitrex or with the fit testing machines.
- 6.3.2.1.5. Fit Test Report: After the correct respirator is determined, the HCW's manager/supervisor has access to an online report (HCW's name, size and type of the HCW's respirator. Report is designed to assist the supervisor in her/his record keeping responsibilities. COEM EMS Unit will submit monthly fit testing summaries.
- 6.3.2.1.6. Education. By the end of the fitting session, the HCW will know how and when to
 - · Don and adjust the respirator;
 - Store the respirator, when appropriate;
 - Return for training, fit testing, and medical surveillance;
 - Discard and replace the respirator
- 6.3.2.1.7. Beards and Facial Hair: The COEM EMS Unit may not perform a fit test on individuals who have hair where the respirator touches the face.
- 6.3.2.1.8. A non-compliance letter will be sent to HCWs and their Managers who are not on record for having their annual fit testing.
- If the HCW's job responsibilities do not include a requirement for them to wear an N-95 respirator in the next 12 months, the HCW will follow the Bypass Procedure. (See Attachment 11)
- 6.3.2.1.9. Individuals who need fit testing for a mask/respirator must undergo medical screening by the COEM Employee Medical Surveillance. The screening form will be reviewed by the COEM EMS technician. If a medical problem is identified, COEM EMS Department will determine the HCW's ability to wear a respirator form D2304 (Attachment 12).
- 6.3.2.1.10. Respirator Training Individuals who receive respirator medical clearance must complete respirator training and be fit tested by the COEM EMS Unit. Respirator training must include the following elements:
 - · Reasons why a respirator is worn
 - Types of respirators available
 - Purpose of the medical screening/examination
 - Conditions that prevent a good face seal
 - Necessity of wearing the respirator as instructed, without modification
 - When to change respirator
 - · Sanitary care of respirators
 - Proper way to don and fit check a respirator
 - · Individual responsibility
- 6.3.2.1.11. A baseline fit test is done during new employee orientation with follow-up testing for anyone needing to wear a respirator.
- 6.3.2.1.12. N95 Respirator must be approved by NIOSH. Other higher protection respirators such as PAPR with HEPA filtration can also be used. The HCW must remember if they were fitted with one size fits all respirator or a particular size (large, medium or small)
- 6.3.2.1.13. All employees who have direct patient contact or laboratory contact with Mtb are required to be fit tested by OSHA standard for respiratory protection for M. tuberculosis
- 6.3.2.1.14. The Department Head or Supervisor must insure that all HCWs who require fit testing and tuberculosis screening comply with this policy:
- 6.3.2.1.15. Physicians who work in the Medical Center, regardless of their source of income are responsible for demonstrating that they have complied with the TB Control Policies of UC San Diego Health System in general and fit testing In particular. The Compliance Enhancement processes will be utilized to insure compliance by medical staff.

6.3.2.1.16. N 95 respirators shall be worn by HCWs in the following situations:
☐ When entering a room/enclosure where a patient with known or suspected TB
is in All Precautions.
□ When entering an All room or other air space that has been occupied by an
unmasked source case in the last hour.

- □ When sharing other air space with an unmasked infectious TB patient (e.g., ED or clinic exam room)
 □ When performing any high-risk medical procedure (HRMP) or when in a room in which a HRMP is being performed.
 □ In settings where administrative and engineering controls are not likely to protect individuals from inhaling droplet nuclei (e.g., transporting an unmasked patient in a vehicle)
 □ When changing filters from air filtration devices or ventilation ducts when those filters were used to remove TB bacteria
- 6.3.2.2. Positive air pressure respirators (PAPR) are available for individuals with facial hair who perform high-risk procedures. (refer to section 7.6).
- 6.3.2.2.1. Annual PAPR maintenance shall be performed by clinical engineering according to manufacturer's specifications.
- 6.3.2.2.2. Positive pressure respirators (PAPR) are <u>powered</u> by a portable battery pack which pumps air through a filter unit and then distributes the filtered air into the hood of the respirator.
- 6.3.2.2.3. HCWs will be informed and are responsible for obtaining a PAPR as follows:
- 6.3.2.2.4. PAPR's need to be ordered by the HCWs home department and training, storage and care coordinated with EH&S. 6.3.2.2.3.2. PAPR's should only be used in high-risk areas when fit testing has failed and the HCW's are caring for TB or other ATD patients or suspect TB or ATD patients.

6.4. Patient Issues

- Patient must wear snugly fitted, well-secured surgical mask (NON N95 respirators) when outside the isolation room. The mask provides a physical barrier to capture droplets produced during coughing, sneezing or talking.
- Patient transport/transfer within the facility will proceed with minimal elapsed time in which the patient is out of an AII room.
- Notification of receiving department or unit concerning TB diagnosis and required precautions must occur prior to patient transport and is nursing responsibility.
- The patient will receive education concerning TB transmission and the need for All room from the primary nurse.
- A report of each TB case to COEM EMS SD County must be done by the IPCE ICP, Case managers or the patient's physician.
 Negotiation needs to take place if public health authority does not agree with medical team's discharge plan. The COEM Employee Medical Surveillancer will be responsible for developing a successful plan in problematic cases.
- A COEM EMS SD County Authorized Discharge and Treatment Plan is required prior to discharge. The case managers shall be responsible for completing the required forms. Additional time for interaction may be needed if public health authority is not in agreement with medical team's discharge plan. Must consult with the COEM Employee Medical Surveillancer regarding conflicts between physicians at UC San Diego Health System or between UC San Diego Health System physicians and COEM EMS SD County.
- Patients who are non-compliant with AII precautions should be reported to the COEM EMS SD County
- Exposure of other patients to a non-isolated or unmasked TB patient will be managed as described in sections 4.8
- Facilities without AII Isolation capabilities (negative pressure rooms) must transfer TB suspect cases out to a facility with AII capabilities

6.5. Family/Visitors Issues

- Visitation to these patients should be limited to patients close contacts.
- Family/visitors will wear a surgical mask that is well secured and snugly fit.

 Non-compliant visitors will be instructed of their risk of exposure by not wearing a mask, and to seek medical care with their PCP or TB control at SDPH if symptoms of TB (cough > 2 weeks, fever, night sweats, fatigue, productive cough that may be blood tinged or bloody.

6.6. High-Risk Medical Procedures (HRMP)

These procedures should be evaluated by the primary physician caring for the patient to determine if they can be delayed until the patient is not contagious

- 6.6.1. A procedure performed on a suspected or confirmed infectious TB case which can aerosolize body fluids likely to be contaminated with TB bacteria including, but not limited to:
 - Sputum induction [a procedure in which the patient inhales an irritant aerosol (e.g. water, saline, or hypertonic saline) to induce a productive cough]
 - Operative procedures such as tracheotomy, thoracotomy, or open lung biopsy
 - Respiratory care procedures such as tracheostomy or endotracheal tube care
 - Diagnostic procedures such as bronchoscopy and pulmonary function testing
 - Resuscitative procedures performed by emergency personnel
 - I & D or abscess known or suspected to be caused by Mtb
 - Aerosolized pentamidine administration
 - Autopsy, laboratory, research, or production procedures performed on tissues or body fluids known or suspected to be infected with TB which can aerosolize TBcontaminated fluids.
- 6.6.2. The following cough-producing procedures require local exhaust ventilation if performed on a suspect or confirmed infectious TB case when performed outside of a AII Precautions room.
 - coughing (voluntary, assisted, or induced) for therapeutic mobilization of secretions or diagnostic sputum induction
 - suctioning (pharyngeal or endotracheal)
 - aerosol therapy (bronchodilator, antibiotics or hypertonic saline)
 - artificial airway placement, repositioning or removal (e.g., bronchoscope, intubation's, extubation, repositioning of oropharyngeal or nasopharyngeal airways, endotracheal, or tracheostomy tubes)
 - pulmonary function testing (bedside or laboratory) in which a forced expiratory effort is required
 - Intermittent positive pressure breathing (IPPB) or positive expiratory pressure (PEP) therapy
 - Chest physical therapy (postural drainage & percussion).
- 6.6.3 To the extent possible and consistent with sound medical practice HRMP will be performed in a manner which minimizes the risk of transmission of TB. HRMP shall be performed with:
 - Effective local exhaust ventilation (LEV) in conjunction with dilution ventilation OR HEPA filtration to effect a minimum of 6 ACH.
 - If LEV is not present, HRMP are to be conducted in conjunction with dilution ventilation to effect a rate of at least 15 ACH.
 - HCWs and other individuals in the shared air space must wear N 95 respirator.
- 6.6.4. The LEV device should be turned on prior to beginning the procedure and left on for 30 minutes after coughing has subsided.

6.7. Local Exhaust Ventilation

(LEV) LEV is a source control method that prevents or reduces the spread of infectious droplet nuclei into general air circulation. LEVs include partial or complete patient enclosure such as a hood, booth, or tent with a high volume exhaust fan and a HEPA filter (e.g., biosafety cabinet (BSC), Emerson Booth and Biosafety Aerostar Aerosol Protection).

- 6.7.1. Purpose of LEV is to capture airborne contaminants at or near their source (source control method) and to remove them without exposing persons in the area.
- 6.7.2. Policies
- 6.7.2.1. LEV shall be used for the performance of high-risk medical procedures (HRMP), unless the patient is in an AII Precautions isolation room.
- 6.7.2.2. LEV must be positioned close enough to the patient's breathing zone to maximize the capture of contaminated air. If the LEV system is not a complete patient enclosure, the air intake must be positioned sufficiently close to the patient's airway to capture all exhaled air and cough generated particles. The LEV device should be positioned so as to direct air from the patient and away from personnel and other occupants in the room.
- 6.7.2.3. Facility Clinical Engineering will service local exhaust ventilation (LEV) devices and will have written policies and procedures governing their use and maintenance including the following:
 - Pre-filter and HEPA filter changes
 - Maintenance log shall be kept
 - Specially trained personnel, who are capable of recertifying the machine at the time of HEPA filter

change, shall be utilized for that process

- Spent filters will be placed into red bags and disposed of as a biohazardous waste
- HEPA filters will be certified annually
- 6.7.2.4. Before using LEV equipment, personnel must be trained in the proper use and cleaning/disinfection of the equipment.
- 6.7.2.5 Specific personnel will be assigned responsibility for assuring LEV equipment is properly maintained. Filter replacement is to be performed by qualified personnel according to policy and procedures.
- 6.7.2.6. Air exhausted from source control devices shall be:
 - Discharged directly to the outside of the building, away from air intakes, open windows, and people; OR
 - · If recirculated, HEPA filtered

7.0. Laboratory Issues

To prevent laboratory personnel from incurring unprotected exposure to cultures and specimens known or suspected to contain Mycobacterium tuberculosis

7.1. Collection

- Specimens will be collected in rigid plastic containers labeled with patient's name and unit number.
- Containers will be securely closed to prevent leakage.
- Containers will be placed in clear plastic bag with a red hazard label
- Appropriate Microbiology request form must accompany specimen. DO NOT place form inside specimen portion of bag.

7.2. Transport

Once the specimen is in a sealed plastic bag, it will be transported to the laboratory using Standard Precautions.

7.3. Laboratory Handling/Processing

Lab personnel will handle specimens and cultures in a safe manner that prevents exposure to M. tuberculosis.

7.4. Laboratory Workers

Laboratory workers who work in the TB lab or rotate through the TB laboratory will participate in the TB screening and fit testing programs

8.0. Education and Training

TB education and training is provided to Medical Center personnel who have potential contact with patients or specimens that may transmit TB. Pulmonary and ID divisions provide educational offerings on TB for their members; such offerings are also available to all medical units for continuing medical education.

8.1. Annual Safety Fair

Education and training on issues involving TB is incorporated as part of the annual safety training online thru LMS for all medical center personnel. Participation in the online Annual Safety Fair is mandatory. The Safety Control Office will maintain records for attendance.

8.2. Teaching Methods

Teaching methods will be varied to allow for diverse audiences (lecture, video tape or computer modules) as deemed appropriate by the COEM EMS Unit.

GLOSSARY

This glossary contains many of the terms used in the plan, as well as others that are encountered frequently by persons who implement TB infection-control programs. The definitions given are not dictionary definitions but are those most applicable to usage relating to TB.

All: Aerosol Infection Isolation refers to a negative pressure room from which exhaust air is not recirculated.

AFB: Acid-fast bacilli

Bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria. When AFB are seen on a stained smear of sputum or other clinical specimen, a diagnosis of TB should be suspected; however, the diagnosis of TB is not confirmed until a culture is grown and identified as M. tuberculosis.

ACH: Air exchanges per hour

Aerosol: The droplet nuclei that are expelled by an infectious person (e.g., by coughing or sneezing); these droplet nuclei can remain suspended in the air and can transmit M. tuberculosis to other persons.

Air changes: The ratio of the volume of air flowing through a space in a certain period of time (i.e., the airflow rate) to the volume of that space (i.e., the room volume); this ratio is usually expressed as the number of air changes per hour (ACH).

Air mixing: The degree to which air supplied to a room mixes with the air already in the room, usually expressed as a mixing factor. This factor varies from 1 (for perfect mixing) to 10 (for poor mixing), and it is used as a multiplier to determine the actual airflow required (i.e., the recommended ACH multiplied by the mixing factor equals the actual ACH required).

Anergy: The inability of a person to react to skin-test antigens (even if the person is infected with the organisms tested) because of immunosuppression.

ATD: Aerosolized Transmissible Disease Standards required by law from Cal OSHA

BCG: Bacillus of Calmette and Guerin: A TB vaccine used in many parts of the world.

Booster phenomenon: A phenomenon in which some persons (especially older adults) who are skin tested many years after infection with M. tuberculosis have a negative reaction to an initial skin test, followed by a positive reaction to a subsequent skin test. The second (i.e., positive) reaction is caused by a boosted immune response. Two-step testing is used to distinguish new infections from boosted reactions (see Two-step testing).

Bronchoscopy: A procedure for examining the respiratory tract that requires inserting an instrument (a bronchoscope through the mouth or nose and into the trachea). The procedure can be used to obtain diagnostic specimens.

CDC: Centers for Disease Control

COEM: Center for Occupational and Environmental Health

Contact: A person who has shared the same air with a person who has infectious TB for a sufficient amount of time to allow possible transmission of M. tuberculosis.

Conversion, TST: See TST conversion.

Culture: The process of growing bacteria in the laboratory so that organisms can be identified.

DOT: Directly observed therapy: An adherence-enhancing strategy in which a HCW or other designated person watches the patient swallows each dose of medication.

Droplet nuclei: Microscopic particles (i.e.1-5µm in diameter) produced when a person coughs, sneezes, shouts, or sings. The droplets produced by an infectious TB patient can carry tubercle bacilli and can remain suspended in the air for prolonged periods of time and be carried on normal air currents in the room.

Drug resistance, **acquired**: A resistance to one or more anti-TB drugs that develops while a patient is receiving therapy and which usually results from the patient's non-adherence to therapy or the prescription of an inadequate regimen by a health-care provider.

Drug resistance, primary: A resistance to one or more anti-TB drugs that exists before a patient is treated with the drug(s). Primary resistance occurs in persons exposed to and infected with a drug-resistant strain of M. tuberculosis.

Drug-susceptibility tests: Laboratory tests that determine whether the tubercle bacilli cultured from a patient are susceptible or resistant to various anti-TB drugs.

EH&S: Environmental Health & Safety

Exposure: The condition of being subjected to something (e.g., infectious agents) that could have a harmful effect. A person exposed to M. tuberculosis does not necessarily become infected (see Transmission).

F&E: Facilities and Engineering

HEPA: High-efficiency particulate air filter: A specialized filter that is capable of removing 99.97% of particles ≥0.3 μm in diameter and that may assist in controlling the transmission of M. tuberculosis. Filters may be used in ventilation systems to remove particles from the air or in personal respirators to filter air before it is inhaled by the person wearing the respirator. The use of HEPA filters in ventilation systems requires expertise in installation and maintenance.

HIV: Human immunodeficiency virus infection: Infection with the virus that causes acquired immunodeficiency syndrome (AIDS). HIV infection is the most important risk factor for the progression of latent TB infection to active TB.

IGRA

Immunosuppressed: A condition in which the immune system is not functioning normally (e.g., severe cellular immunosuppression resulting from HIV infection or immunosuppressive therapy). Immunosuppressed persons are at greatly increased risk for developing active TB after they have been infected with M. tuberculosis. No data are available regarding whether these persons are also at increased risk for infection with M. tuberculosis after they have been exposed to the organism.

Induration: An area of swelling produced by an immune response to an antigen. In tuberculin skin testing or anergy testing, the diameter of the indurated area is measured 48-72 hours after the injection, and the result is recorded in millimeters.

Infection: The condition in which organisms capable of causing disease (e.g., M. tuberculosis) enter the body and elicit a response from the host's immune defenses. TB infection may or may not lead to clinical disease.

Infectious: Capable of transmitting infection. When persons who have clinically active pulmonary or laryngeal TB disease cough or sneeze, they can expel droplets containing M. tuberculosis into the air. Persons whose sputum smears are positive for AFB are probably infectious.

Intradermal: Within the layers of the skin.

INH: Isoniazid. A first-line, oral drug used either alone as preventive therapy or in combination with several other drugs to treat TB disease.

LTBI: Latent TB infection: Infection with M. tuberculosis, usually detected by a positive PPD skintest result, in a person who has no symptoms of active TB and who is not infectious.

LEV: Local Ventilation Exhaust Local exhaust ventilation (Portable room-air HEPA) units: Free-standing portable devices that remove airborne contaminants by circulating air through a HEPA filter.

MDR-TB: Multidrug-resistant tuberculosis: Active TB caused by M. tuberculosis organisms that are resistant to more than one anti-TB drug; in practice, often refers to organisms that are resistant to both INH and rifampin with or without resistance to other drugs (see Drug resistance, acquired and Drug resistance, primary).

M. tuberculosis complex: A group of closely related mycobacterial species that can cause active TB (e.g., M. tuberculosis, M. bovis, and M. africanum); most TB in the United States is caused by M. tuberculosis. References to TB or M. Tb in this document refer to any of the organisms in the M. TB complex group.

N95: A disposable respirator mask which is capable of 95% minimum efficiency when tested according to the criteria described in NIOSH 42 CFR, Part 84.

Negative pressure: The relative air pressure difference between two areas in a health-care facility. A room that is at negative pressure has a lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas. The room is shut down for 30 minutes after discharge of the patient and prior to another patient getting admitted to it if it is a negative pressure room. For regular patient rooms without negative pressure, you must wait 1 hour after the patient is discharged before putting another patient in the room.

Nosocomial: An occurrence, usually an infection that is acquired in a hospital or as a result of medical care.

NTM: Non-tuberculous mycobacteria. These organisms are closely related to M. tuberculosis but are not contagious.

PAPR: Positive Air Pressure Respirator. Has an air supply and blower. This respiratory protection is used for staff who are not fit tested for N95 or staff with beards/facial hair.

PCP: Primary care physician

Positive TST reaction: A reaction to the purified protein derivative (PPD)-tuberculin skin test that suggests the person tested is infected with M. tuberculosis. The person interpreting the skin-test

reaction determines whether it is positive on the basis of the size of the induration and the medical history and risk factors of the person being tested.

Preventive therapy: Treatment of latent TB infection used to prevent the progression of latent infection to clinically active disease.

PPD: Purified protein derivative-tuberculin. A purified tuberculin preparation was developed in the 1930s, and was derived from old tuberculin. The standard Mantoux test uses 0.1mL of PPD standardized to 5 tuberculin units.

QuantiFeron Gold (QFT): A blood test for T cell reactivity to an increase in specific antigens from MTB

Recirculation: Ventilation in which all or most of the air that is exhausted from an area is returned to the same area or other areas of the facility.

Resistance: The ability of some strains of bacteria, including M. tuberculosis, to grow and multiply in the presence of certain drugs that ordinarily kill them; such strains are referred to as drug-resistant strains.

Room-air HEPA recirculation systems and units: Devices (either fixed or portable) that remove airborne contaminants by re-circulating air through a HEPA filter.

Single-pass ventilation: Ventilation in which 100% of the air supplied to an area is exhausted to the outside.

Smear (AFB smear): A laboratory technique for visualizing mycobacteria. The specimen is smeared onto a slide and stained, then examined using a microscope. Smear results should be available within 24 hours. In TB, a large number of mycobacteria seen on an AFB smear usually indicate infectiousness. However, a positive result is not diagnostic of TB because organisms other than M. tuberculosis may be seen on an AFB smear (e.g., non-tuberculous mycobacteria).

Source case: A case of TB in an infectious person who has transmitted M. tuberculosis to another person or persons.

Source control: Controlling a contaminant at the source of its generation, this prevents the spread of the contaminant to the general work space.

Specimen: Any body fluid, secretion, or tissue sent to a laboratory where smears and/or cultures for M. tuberculosis will be performed.

Sputum: Phlegm coughed up from deep within the lungs. If a patient has pulmonary disease, an examination of the sputum by smear and culture can be helpful in evaluating the organism responsible for the infection. Sputum should not be confused with saliva or nasal secretions. Sputum induction: A method used to obtain sputum from a patient who is unable to cough up a specimen spontaneously. The patient inhales a saline mist, which stimulates a cough from deep within the lungs.

Symptomatic: Having symptoms that may indicate the presence of TB or another disease.

TB case: A particular episode of clinically-active TB. This term should be used only to refer to the disease itself, not the patient with the disease. By law, cases of TB must be reported to the local health department.

COEM EMS SD County: The Health and Human Services Agency Public Health Services, COEM EMS Branch, San Diego County.

TB infection: A condition in which living tubercle bacilli are present in the body but the disease is not clinically active. Infected persons usually have positive tuberculin reactions, but they have no symptoms related to the infection and are not infectious. However, infected persons remain at lifelong risk for developing disease unless preventive therapy is given.

Transmission: The spread of an infectious agent from one person to another. The likelihood of transmission is directly related to the duration and intensity of exposure to M. tuberculosis (see Exposure).

TST: Tuberculin Skin Test or Purified protein derivative (PPD)-tuberculin test. A method used to evaluate the likelihood that a person is infected with M. tuberculosis. A small dose of tuberculin (PPD) is injected just beneath the surface of the skin, and the area is examined 48-72 hours after the injection. A reaction is measured according to the size of the induration. The classification of a reaction as positive or negative depends on the patient's medical history and various risk factors.

TST conversion: A change in PPD test results from negative to positive. A conversion within a 2-year period is usually interpreted as new M. tuberculosis infection, which carries an increased risk for progression to active disease. A booster reaction may be misinterpreted as a new infection (see Booster phenomenon and Two-step testing).

Tuberculosis (TB): A clinically active, symptomatic disease caused by an organism in the M. tuberculosis complex (usually M. tuberculosis or, rarely, M. bovis or M. africanum).

Two-step testing: A procedure used for the baseline testing of persons who will periodically receive tuberculin skin tests (e.g., HCWs) to reduce the likelihood of mistaking a boosted reaction for a new infection. If the initial tuberculin-test result is classified as negative, a second test is repeated 6 weeks later. If the reaction to the second test is positive, it probably represents a boosted reaction. If the second test result is also negative, the person is classified as not infected. A positive reaction to a subsequent test would indicate new infection (i.e., a skin-test conversion) in such a person.

Ultraviolet germicidal irradiation (UVGI): The use of ultraviolet radiation to kill or inactivate microorganisms.

Unprotected Exposure: The sharing of air space with a patient who has not been treated, is AFB smear-positive, and has pulmonary laryngeal TB.

Ventilation, dilution: An engineering control technique to dilute and remove airborne contaminants by the flow of air into and out of an area. Air that contains droplet nuclei is removed and replaced by contaminant-free air. If the flow is sufficient, droplet nuclei become dispersed, and their concentration in the air is diminished.

Ventilation, **local exhaust**: Ventilation used to capture and remove airborne contaminants by enclosing the contaminant source (i.e., the patient) or by placing an exhaust hood close to the contaminant source.

ATTACHMENT 1: COEM EMS Blood Drawing Policy

COEM EMS Policy UC San Diego Health System

ABSTRACT:

The quality of laboratory test results is critically dependent on the quality of the specimen presented for analysis. Proper specimen acquisition performed by COEM EMS staff authorized to do lab draws within their scope of practice by law, starts at the time an order is placed, and ends with specimen delivery to the appropriate clinical laboratory. The policy defines the method of blood specimen collection of Quantiferon tests and each sequential step to be followed to ensure proper patient identification and specimen collection.

RELATED POLICIES:

Aerosol Transmissible Disease (ATD) Standards/Tuberculosis (TB) Control Plan Clinical Laboratories Specimen Processing- SPECIMEN TRANSPORT USING MANUAL TRANSPORT LOGS

MCP 615.1, Blood Specimen Collection, Purpose of Clinical Laboratory Testing MCP 300.2, Patient Identification

REGULATORY REFERENCE:

The Joint Commission (TJC)

California Business and Professions Code: Sections 1240-1246.5

California Code of Regulations- Title 17: Section 1034

California State Department of Public Health, http://www.cdph.ca.gov/programs/lfs/Pages/Phlebotomist.aspx

Health and Safety Code: Sections 120580

I. DEFINITIONS

- A. ATD: Aerosol Transmissible Disease Standards
- B. COEM: Center for Occupational and Environmental Medicine
- C. IGR: Interferon Gamma Release Assays (IGRAs). QuantiFERON®- TB Gold test (QFTG) and T Spot are two blood tests that are called Interferon Gamma Release Assays (IGRA). They are approved by the FDA.
- D. IPCE: Infection Prevention and Clinical Epidemiology
- E. QFTG: QuantiFERON

- F. Venipuncture is the process of obtaining a blood sample through the vein in either an upper or lower extremity.
- G. Evacuated system is the use of Vacutainer tubes to draw a predetermined amount of blood specimen.
- H. Winged infusion set with leur adapters (butterfly) is used to obtain a blood specimen from a very difficult vein.
- I. A quality specimen is one that has been collected from a properly prepared patient, all specimen/requisition identifiers are correct, drug interference is avoided, the right tubes are used and have the required volume of specimen, and timed specimen draws are correctly timed and documented. Specimens are placed in biohazard bags and transported to the clinical laboratory in a timely fashion to ensure specimen viability.
- J. Vacutainer needle is a double pointed needle that is designed for use with an evacuated tube system. The longer end is used for penetrating the vein and the shorter end is used to pierce the rubber stopper of the evacuated tube. The shorter end is covered by a rubber sheath that prevents leakage when multiple tubes are drawn.

II. POLICY

Following UCSD's ATD Standard and COEM EMS plan, HCW's are to be TB screened at hire and fit tested annually and as needed for TB exposure workups. The COEM EMS Office will be conducting TB screening using the lab test QFT, questionnaire without QFT as appropriate, determined by HC treatment, Hx. BCG vaccination, or prior positive QFTg results with history of INH treatment. The COEM EMS Office will be performing annual fit testing.

The Hours of Operation and Location of each clinic can be found on the IPCE website and is updated regularly. Please check the website at http://www.ucsdhealthcare.ucsd.edu/ic/TB_Hours.htm

- A. Registration: Upon arrival to the COEM Employee Medical Surveillance you will be asked for identification for the purposes of creating a Patient ID for this visit. You will not be charged for this test and screening. You will also be asked to complete a fit test screening/questionnaire.
- B. Ordering QFT lab draw: Under the a standing order from the COEM EMS Medical Director, QFT blood tests for TB Screening, COEM EMS staff will follow the standing order for QFT blood testing of all UCSD HCW's (staff, physicians, volunteers, etc).
- C. All persons performing phlebotomy who are not California licensed physicians, nurses, clinical lab scientists or other licensed professionals where phlebotomy is not in their scope of practice, must be certified as a phlebotomist before they can draw blood, in accordance with State of California Department of Public Health. This applies to blood draws for clinical as well as research purposes.
- D. Upon written/electronic order for clinical laboratory testing, a specific process is followed to ensure that the best quality specimen is obtained. The person collecting the blood specimen will complete all steps, up to the point of transportation to the Lab. No hand offs of specimens are to be permitted, during the identification, drawing, and labeling process.

- E. Blood Specimen Collection: QFT's will be drawn using the methods and procedures for blood specimen collection in MCP 615.1 (Attachment A).
- F. Notification of results: Notification of QFT results ordered by the COEM Employee Medical Surveillance will be sent to the HCW. The letter of notification will list the results of the QFT test and will direct the HCW for any further follow up as needed. (Attachments B -3 letters of notification)

III. PROCEDURES AND RESPONSIBILITIES

- A. General Phlebotomy Protocol:
 - 1. Work Station:
 - a. Obtain labels and laboratory requisition
 - b. Specimen tubes
 - c. Disposable gloves
 - d. Tourniquet
 - e. Alcohol pads
 - f. Gauze
 - g. Adhesive or paper tape
 - h. QFT lab tubes
 - i. Alcohol wipes for lab tubes
 - j. Biohazard labeled specimen transport bag
 - 2. Blood Draw area:
 - a. Greet HCW and explain procedure
 - b. Identify the patient by performing the Triad Check of the requisition, HCW's ID and the label(s), ensuring patient name and DOB match.
 - c. Wash hands and don gloves
 - d. Obtaining specimen:
 - (1) Collect specimen
 - (2) Label specimen with a printed patient label at the bedside
 - (3) Reconfirm the Triad Check of the requisition, patient's ID band and specimen label
 - e. Place specimen and requisition in biohazard bag
 - f. Remove gloves and wash hands
 - g. Follow any special specimen handling requirements for QFT specimens within the Manufacturer's guidelines (Attachment C)

For detailed instructions, please refer to "Detailed Instructions to Perform Venipuncture, Line Draw, Microcollection, and Timed Draw" (see Attachment A).

For additional information, refer to the "Laboratory Guide" on UC San Diego computer systems or via the Internet

3. Specimen Delivery:

Follow procedure for SPECIMEN TRANSPORT USING MANUAL TRANSPORT LOGS (see Attachments D and E)

- a. All specimens transported from one clinic location to a laboratory or from one laboratory to another must have a list of the patient names and MRN's matching specimens drawn, completed by the staff prior to transport. The Transport Log must accompany the specimens with any printed or written test requests.
- b. At the top of the manual transport log write the name of the clinic in the "From: Other" field. In the "To" field Check the box where the specimens are being sent.
 - 1) Microbiology Transport Log (non-blood)
 - a) Hand write the patients name and medical record number in the specimen identification field or apply a patient demographic label.
 - b) Check the box that describes the sample type being sent or write a description of the sample type in the Other" field.
 - c) Record the initials of the person filling out the log in the "Tech Code/Initials" field.
 - d) At the bottom of the form have the courier fill in the date and time when the specimens were picked up. A copy should be kept with the sending clinic.
 - e) Place manual transport log(s) inside of specimen bag and send to performing laboratory.
- c. Place bagged specimen and requisition in designated location for transport to Clinical Laboratories.

IV. ATTACHMENTS

Attachment A: Detailed Instructions to Perform Venipuncture, Line Draw, Microcollection, and Timed Draw.

Attachment B: QFT Manufacturer's Guidelines

Attachment C: Procedure for Specimen Transport Using Manual Transport Log

Attachment D: Manual Transport Log

V. RESOURCES

UC San Diego Health System IPCE Website UC San Diego Health System Laboratory Guide

VI. APPROVALS

Attachment A

Detailed Instructions to Perform Venipuncture

A. General specimen collection steps:

- 1. Generate laboratory requisition manually or by order entry.
- 2. Print patient label
- 3. Assemble needed supplies
- 4. Greet the patient, introduce yourself
- 5. Wash hands and put on gloves
- 6. Identify patient by performing the Triad Check of matching the laboratory requisition and label(s) with the patient identification band.
- 7. Select the venipuncture site
- 8. Apply tourniquet (2 to 3 inches above the puncture site) and ask patient to make a fist. Use your index finger to palpate and trace the path of vein.
- 9. Clean the venipuncture site with alcohol pad and allow to dry.
- 10. Perform specimen collection procedure. (See specific specimen collection instructions below.)
- 11. Release the tourniquet once the specified number of tubes has been collected and prior to removing the needle. (The tourniquet should not be left on the arm for more than 2 minutes)
- 12. After completing the procedure, fold and place 2x2 gauze over the puncture site and gently withdraw the needle from the vein and activate appropriate needle safety protection device. Discard the needle properly in a Sharps container.
- 13. Apply direct pressure at the puncture site (2 to 3 minutes) and place a piece of tape/bandaid to hold the gauze in place. Instruct the patient to maintain pressure (if able) on the site for an additional 2 minutes.
- 14. Label each tube with the correct patient's pre-printed labels.
- 15. Write the actual collection time and your initial on each labeled specimen and requisition.
- 16. Place the specimen and requisition in a biohazard bag.
- 17. Remove gloves and wash hands.
- 18. Follow any special handling requirements for special tests (refer to Online Guide to Laboratory Services).
- 19. Follow your unit protocol by placing the bagged specimen in the designated location for transport to the Clinical Laboratories.
- B. Specific specimen collection instructions:

Select the appropriate venipuncture protocol (for Blood Cultures refer to MCP policy 616.1)

- 1. Peripheral venipuncture:
 - a. Evacuated System
 - (1) Follow steps 1 through 9 in Section A "General Specimen Collection Steps"
 - (2) Open the Vacutainer needle by twisting off the protective paper seal and secure the needle onto the standard-size Vacutainer holder by screwing the needle firmly onto the holder.
 - (3) Grasp the patient's arm. Use thumb to draw the skin taut and insert the needle (bevel up) at a 15 to 30 degree angle through the skin into the vein.
 - (4) Push the Vacutainer tube into the back end of the holder. Blood should flow into the tube. If not, check the position of the needle in the vein and adjust if necessary.

- (5) Follow correct order of draw. Tubes without preservatives or anticoagulants first to avoid backflow, followed by tubes with additives. The correct order of draw is Blood Culture bottles (aerobic then anaerobic), blue citrate tube, red plain tube, serum separator tube, green heparin tube, lavender EDTA tube, grey sodium fluoride and potassium oxalate tube, yellow ACD tube.
- *Note: Under no circumstances should blood from one tube be transferred into another. If the proper tube is not collected you must re-draw the patient.
- (6) Continue by following steps 11 through 18 of Section A, "General Specimen Collection Steps".
- b. Winged infusion/Butterfly without Luer Adapter.
 - (Syringe is attached to the end of the infusion set to draw specimen.)
 - (1) Follow the same order of specimen collection listed in Section A, Evacuated Systems.
- c. Winged Infusion/Butterfly with Luer Adapter

A Vacutainer holder is attached to the Luer adaptor and blood is drawn by inserting Vacutainer tubes

(1) Follow the same order of specimen collection listed in Section B.1.a. *Note: When using a Butterfly a blue citrate tube must be used as a "clearing tube" prior to collecting any samples requiring a blue citrate tube. (i.e. when drawing a PT/INR a blue "clearing tube" must be used to clear the air in the butterfly tubing first, the "clearing tube" is discarded after collection).

Attachment B

QFT Manufacturer's Guidelines

Attachment C

SPECIMEN TRANSPORT USING MANUAL TRANSPORT LOGS

I. Purpose

In order to document and ensure all specimens are tracked to their proper destination in a timely manner the following protocol will be followed.

SCOPE

The guidelines and responsibilities outlined in this policy are to be strictly adhered to by all Clinical Laboratories Staff, Residents, and Attending Pathologists.

II. POLICY

All specimens transported from one clinic location to a laboratory or from one laboratory to another must have a list of the patient names and MRN's matching specimens drawn, completed by the staff prior to transport. The Transport Log must accompany the specimens with any printed or written test requests. The delivery time of the specimens to the Laboratory will be recorded via time stamp by laboratory staff upon arrival. Specimens will be matched up with Transport Log listing to ensure all specimens sent are received. Should a problem occur in the

transport process that renders the specimen unusable for analysis (i.e. too long in transport, not kept cold etc.), a suboptimal specimen report form will be filled out by receiving laboratory staff members and kept on record for quality assurance purposes and supervisor review.

III. PROCEDURE

When an electronic transport log cannot be generated from the Laboratory Information System, a manual transport log will be used to accompany all Specimens.

- A. Determine the appropriate manual transport log to use by identifying the performing laboratory for the testing and sample type being sent. At the top of the manual transport log write the name of the clinic in the "From: Other" field. In the "To" field Check the box where the specimens are being sent.
 - 1) Microbiology Transport Log (non-blood)
 - a) Hand write the patients name and medical record number in the specimen identification field or apply a patient demographic label.
 - b) Check the box that describes the sample type being sent or write a description of the sample type in the Other" field.
 - c) Record the initials of the person filling out the log in the "Tech Code/Initials" field.
 - d) At the bottom of the form have the courier fill in the date and time when the specimens were picked up. A copy should be kept with the sending clinic.
 - e) Place manual transport log(s) inside of specimen bag and send to performing laboratory.
 - 2) Automated Lab Transport Log (HLA, Cytogenetics, Serology, Flow, Chemistry, Hematology, Coagulation, Urinalysis)
 - a) Hand write the patients name and medical record number in the specimen identification field or apply a patient demographic label.
 - b) Check the box that describes the tube or sample type being sent or write a description of the sample type in the Other" field.
 - c) Record the initials of the person filling out the log in the "Tech Code/Initials" field.
 - d) At the bottom of the form have the courier fill in the date and time when the specimens were picked up. A copy should be kept with the sending clinic
 - e) Place manual transport log(s) inside of specimen bag and send to performing laboratory.
 - 3) Surgical Pathology/ Cytology Transport Log
 - a) Hand write the patients name and medical record number in the

- specimen identification field or apply a patient demographic label.
- b) Check the box that describes the sample type being sent or write a description of the sample type in the Other" field.
- c) Record the initials of the person filling out the log in the "Tech Code/Initials" field.
- d) At the bottom of the form have the courier fill in the date and time when the specimens were picked up. A copy should be kept with the sending clinic
- e) Place manual transport log(s) inside of specimen bag and send to performing laboratory.

4) Packaging

- a) Specimens should be placed inside a plastic Ziploc biohazard bag.
 Multiple blood tube specimens may be put into a specimen rack and then placed in a large Ziploc biohazard bag.
- b) The requisitions and manual transport list should be folded in half and placed in the outside pocket of the biohazard bag with a routing slip.
- c) Routing slips are color coded for each performing laboratory department. Routing slips having designated handling temperature boxes that need to be checked to denote temperature handling for the specimens, ie. Frozen, Refrigerated and Room Temperature. Specimens will bagged according to the performing department and handling temperature, and a manual transport list and routing slip should always accompany the specimens and match the performing department.

Attachment D

UCSD Clinical Laboratory

Microbiology Transport Log (non-blood)

Froi	m: Hillcrest CALM	Thornto	on 🗀] _K	ncc [(Other _			
To:	Hillcrest CALN	Thornto									
	PATIENT DEMOGRAPHIC or BAR- CODE LABEL	Bld. Cult. Bottle	Swab	Bronch Wash	Sputum	Urine	Fluid / CSF	Stool	Bone Marrow	Other	
	Patient Name: Med. Record #: Tech Code/Initials :										
	Patient Name: Med. Record #:										
	Tech Code/Initials : Patient Name: Med. Record #:										
	Tech Code/Initials :										
	Patient Name: Med. Record #:										
	Tech Code/Initials :										

Aerosol Transmissible Disease (ATD) Stan- Approval: 9/03/2008 Revision date: 1/6/201 2/27/17, 06/2017, 12/2017, 01/2018, 10/20	0,7/20/2					÷е

Patient Name:					
Med. Record #:					

Instructions: Use this log to track all specimens transported to UCSD laboratories. Also use as "downtime" manual transport log when an electronic transport list cannot be generated. Place patient demographic label in far left column or write in patient name/medical record number; indicate number of specimens sent by tube type. Send the original copy with the specimens and maintain a copy for your records.

Courier Initials Date: Time:	
------------------------------	--

ATTACHMENT 2: TB Screening of Obstetrical Patients (p. 1 of 3)

POLICY/PROCEDURE TITLE: TB SCREENING & MANAGEMENT OF OB AND NEWBORN PATIENT			
PAGE 40 OF <u>2</u>			
8/98, 7/99, 4/01, 0, 4/11,5/12			
Unit/Department of Origin: L&D			
95, 7/99, 4/11			
ATTACHMENTS: ALGORITHMS:			
PRENATAL TESTING & MANAGEMENT INPATIENT TESTING & MANAGEMENT			
С			

POLICY STATEMENT:

- 1. Because of the potential risk to the fetus/newborn, all women delivering babies at UCSD need to have tuberculosis screening during pregnancy,
 - A. First, the "OB TB Screening Questionnaire" (in EPIC) will be initiated during prenatal care in the ambulatory care setting.
 - B. Second, a **quantiferon blood test** (QFT-GIT) or a skin test (TST) will be performed; a follow-up chest X-ray (CXR), sputum tests and/or medication may be necessary depending on the findings.
 - C. QFT-GIT tests are run 4-5 times/week and results are available within 48 hours except on the weekend.
 - D. A TST is interpreted (read) within 48-72 hours after placement by qualified staff/provider.

<u>RESPONSIBLE PARTY</u>: All MD's, CNM's & RN's caring for OB patients in the ambulatory care and inpatient settings

EQUIPMENT:

QFT: none-send to lab for blood draw

Skin test: TB syringe, tuberculin purified protein derivative

PROCEDURE:

I. Prenatal Care

A. Complete "Obstetric Tuberculosis Screening Questionnaire" in EPIC

Page 40 of 88

- B. Follow prenatal care algorithm (see attached).
- C. Obtain QFT-GIT first; however if TST is chosen,
 - 1. In Family Medicine clinics, TST is placed in the office during the visit.
 - 2. In Perlman, ACC and other clinics, the TST is read by the placing clinic.
- D. If the QFT-GIT (or TST) result is Negative and patient is asymptomatic with no recent contact with an active TB case then no CXR is needed.
- E. If TST is positive and patient is asymptomatic with no recent contact with an active TB case, get QFT-GIT; if QFT-GIT result is Positive, follow-up CXR is needed.
- F. If QFT-GIT is equivocal, repeat QFT-GIT.
- G. If the patient refuses all testing, the provider will document counseling and patient refusal in the prenatal record.

II. Inpatient Care

- A. Review prenatal record for TB screening test results.
- B. If no records or no prenatal care:
 - 1. Complete "Obstetric Tuberculosis Screening Questionnaire" in EPIC
 - 2. Follow inpatient algorithm (see attached).
 - 3. Obtain QFT-GIT first only if results will be available prior to discharge.
 - 4. If TST is chosen
 - a. Charge tuberculin 0.1ml in PYXIS and remove from refrigerator.
 - b. Place tuberculin purified protein (0.1 ml) intradermally on forearm with site marked and documented for later "read".
 - d. Document on tuberculosis screening questionnaire Section IV #1 site, date, time and initials.
 - e. Place "Read skin test date ____" sticker on front of patient's chart and indicate proper date to be 48-72 hours from date given.
 - f. Enter skin test order in computer, with comment "L&D, date placed, time" (see attached).
 - 5. Interpretation of QFT-GIT and TST
 - a. If the QFT-GIT or TST result is Negative and patient is asymptomatic with no recent contact with an active TB case then no CXR is needed.
 - b. If QFT-GIT is equivocal, repeat QFT-GIT.
 - c. Stat Chest X-ray to be obtained prior to transfer of patient from L&D to maternity unit if:
 - QFT-GIT or TST is positive
 - Positive response to questions 4-8 on "Obstetric Tuberculosis Screening Ouestionnaire "and/or
 - Respiratory findings on exam, that is suspicious of tuberculosis.
- C. Post-partum patients who have a positive TST or positive QuantiFeron (and no follow-up CXR result available) must remain in L&D until the results of the STAT CXR are ready.
 - 1. If CXR is normal, transfer to postpartum

- 2. If the CXR is abnormal, initiate respiratory isolation per hospital protocol (get provider order) and follow management guidelines depending on if the patient is Symptomatic or Asymptomatic (see Inpatient Algorithm attached).
- 3. If the Q QFT-GIT or TST is pending and patient is asymptomatic with no recent contact—with an active TB case, mom and baby can be transferred to postpartum awaiting results.
- 4. If patient refuses CXR, maintain respiratory isolation until discharge and request Pulmonary consult.

D. Prior to discharge

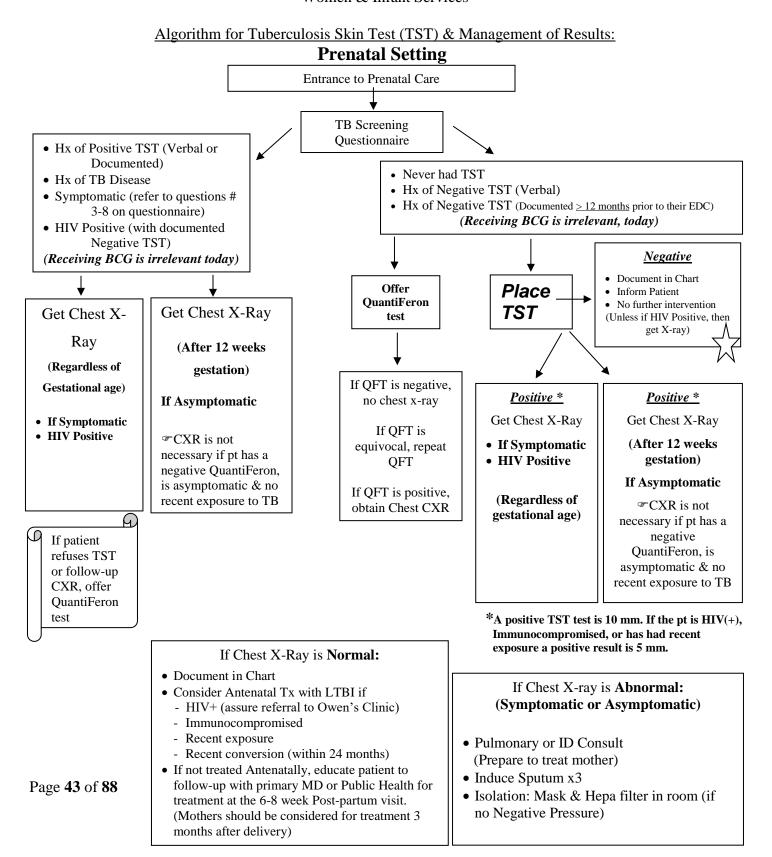
- 1. Skin tests can be read as "preliminary" at 24 by qualified staff/ provider.
- 2. Document results in EMR on "Obstetric Tuberculosis Screening Questionnaire"
 - a. If result is negative, no follow up is needed.
 - b. If TST is positive (10mm induration) a CXR is required before discharge.
 - If <u>CXR is normal</u>, the Skin Test Technician/OB staff will contact the OB Provider and Case Manager for follow-up plan of care (see inpatient Algorithm).
 - If <u>CXR</u> is abnormal, the Skin Test Technician/OB staff will contact the OB Provider and Case Manager for follow-up plan of care which will include pulmonary or ID consult and multiple interventions depending on if the patient is Symptomatic or Asymptomatic (see inpatient Algorithm attached).
 - c. If patient refuses CXR, offer QFT-GIT test if not previously obtained this pregnancy
- 3. If TB test results are unavailable at discharge, Pediatrics and OB will collaboratively determine management on an individual basis.

REFERENCES

- 1. Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings. MMWR, 2005; 54: RR-17.
- 2. Center for Disease Control and Prevention. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection. MMWR, 2010; 59:RR-5.Nhan-Chang, C and Jones, T. Tuberculosis in Pregnancy. Clinical Obstetrics and Gynecology. 2010; 53:2 311-321.
- 3. American Academy of Pediatrics Redbook: 2009 Report of the Committee on Infectious Diseases. 27th Edition. Pgs 680-701...

ATTACHMENT 3: OB Algorithm – Prenatal Setting

UCSD MEDICAL CENTER Women & Infant Services

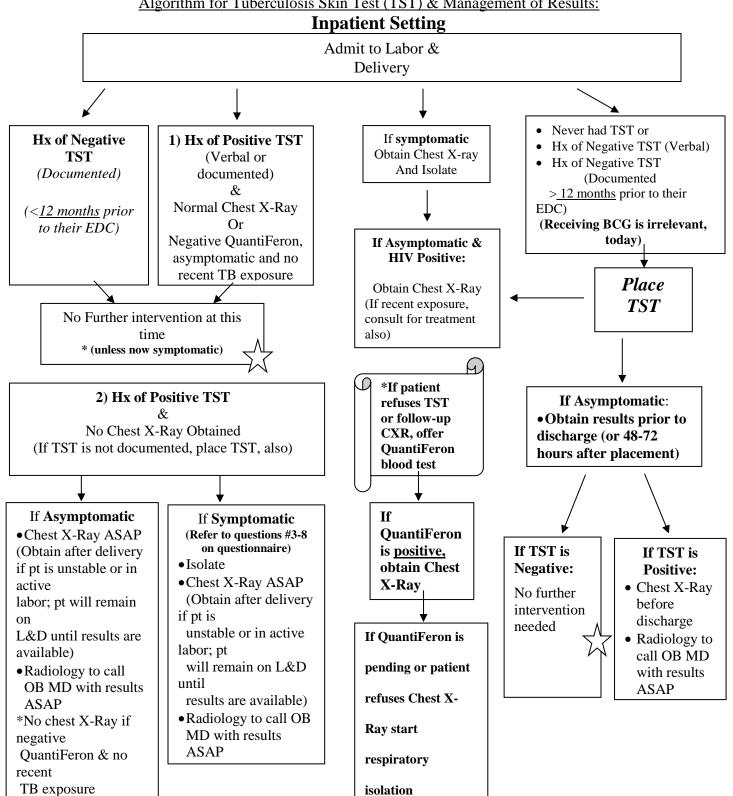


ATTACHMENT 4: OB Algorithm - Inpatient Setting

UCSD MEDICAL CENTER

Women & Infant Services

Algorithm for Tuberculosis Skin Test (TST) & Management of Results:



Attachment 4: OB Algorithm - Inpatient Setting

UCSD MEDICAL CENTER Women & Infant Services

Algorithm for Tuberculosis Skin Test (TST) & Management of Results:

Inpatient Setting

If Chest X-ray is *Normal*

- •Document in Chart
- •Consider Antenatal treatment with LTBI
 - HIV+ (assure referral to Owen's Clinic)
 - Immunocompromised
 - Recent exposure
 - Recent conversion (within 24 months)
- •If not treated Antenatally, educate patient to follow-up with primary MD or Public Health for treatment at the 6-8 week Post-partum visit.

(Mothers should be considered for treatment 3 months after delivery)

If Chest X-ray is **Abnormal**

Asymptomatic

(And Chest X-ray not suspicious for TB)

- Pulmonary Consult
- Isolation: Negative Pressure room & Mask (Request a Hepa Filter if no Negative Pressure room available)
- Mom is restricted to her room
- Newborn may "room in"; mom must comply with wearing mask "24/7"; Breastfeeding is permitted
- Induce sputum x3 (3 separate days)
- * If any **sputum specimen is** *positive*: Newborn to ISCC; Peds to call ID; newborn may receive pumped

breast milk

- Prior to discharge, contact Case Manager to notify Public Health
- •OB MD to notify OB Clinic for patient follow-up

Symptomatic

(Or Asymptomatic & suspicious X-Ray)

- Pulmonary or ID Consult
- Isolation (see Asymptomatic)
- Mom is restricted to her room
- Newborn to ISCC; may get pumped breast milk
- Induce Sputum
- If **3** negative sputum: Newborn may "room in"; No mask needed
- Prior to discharge, contact Case Manager to notify SD Public Health TB Control.
- OB MD to notify OB Clinic for patient follow-up

ATTACHMENT 5: Obstetric TB Screening & Plan of Care Form

Obstetric Tuberculosis Screening

In the interest of safety to you and your baby, all pregnant patients receiving care and/or intending to deliver at UC San Diego Health System need to have tuberculosis screening in the antepartum period. Follow up may include a skin test (TST), a chest X-ray with abdominal shielding, sputum tests and/or medication depending on the findings.

2. 3.							
In the p	ast three (3) mont	hs have you ex	perienced any of	the following sy	mptoms?		
4. 5. 6. 7. 8.	Chronic cough (Bringing up spu Coughing up blo Night sweats (sw	more than 3 we turn everyday food? No veats occurring	g <u>only</u> at night)?	□ No □Yes ore? □ No □Yes □ No □Yes			
**]	f any of the question	s 4-8 are "yes", co	onsider the patient <u>sy</u>	<u>mptomatic</u> and foll	ow the Prenatal Algorithm	**	
 Interviev	ver		Ι	Date & Time			
				Plan of Car	e^		
□ соғ	EM EMS to place	and read Skin	Test (TST) (resul	ts posted in the c	computer)		
_	•		l (fax this form to	•			
	Antigen	Lot#	Exp.	Site	Name	Date/Time	
	Read:	mm x	mm		Name	 Date/Time	
	TST results a	are posted in th	e computer.			2	
☐ PA	& Lateral Chest X	-ray with abdo	ominal shield.				
		•	sease for follow-u	ıp.			
Provider			PID#		Date & Time	;	

ATTACHMENT 6: TB Discharge Care Plan

University of California, San Diego medical center		
TUBERCULO	SIS DISCHARGE CARE PLA	AN
Patient Name:	Submitted By:	
D.O.B:/ _/ MR#:	Phone:	Pager:
Payor Source:	Facility:	
Pulmonary TB Dates of three consecutive negative smear	rs <u>/ / _ / /</u>	
Date Patient to be Discharged:/		
Discharge to: [] Home [] Shelter [] SNF/BC [] Jail/Prison [[] Other
Discharge Address:		
Discharge Phone#: SN	IF Contact:	Phone:
Physician Assuming TB Care:		Phone:
Follow-up appointment date:/_/		
TB Medication at Discharge Wt: INH mg Rifampin mg Ethambutol mg	Number of Days Medicatio (3-5 days pills not script)	on Supply
Pyrazinamide mg B6 mg Other	All SD County patients to be Directly Observed Therapy	
Contact Information/Household Compose People in Household # Children < 4 years old # Any Immunocompromised individuals?	sition	
FOR TB CONTROL USE ONLY		
DHS Review - Problems noted		Discharge Approved
Action taken before discharge	10	Yes No

(SEE REVERSE SIDE FOR INSTRUCTIONS FOR USE)

D1543 (10-6)

Reviewed by ____ Date of Review

ATTACHMENT 7: Environmental Controls Record & Evaluation

Appendix D. Environmental controls record and evaluation*

Type of environmental control [†]	No.§	Location in the health-care setting1	How often maintained⁺*	How often evaluated**	Last evaluation date	Next evaluation due date
		<i>**</i>			100	
					1	

^{*} Some settings will not be able to complete all parts of the table. List environmental controls in order of effectiveness.

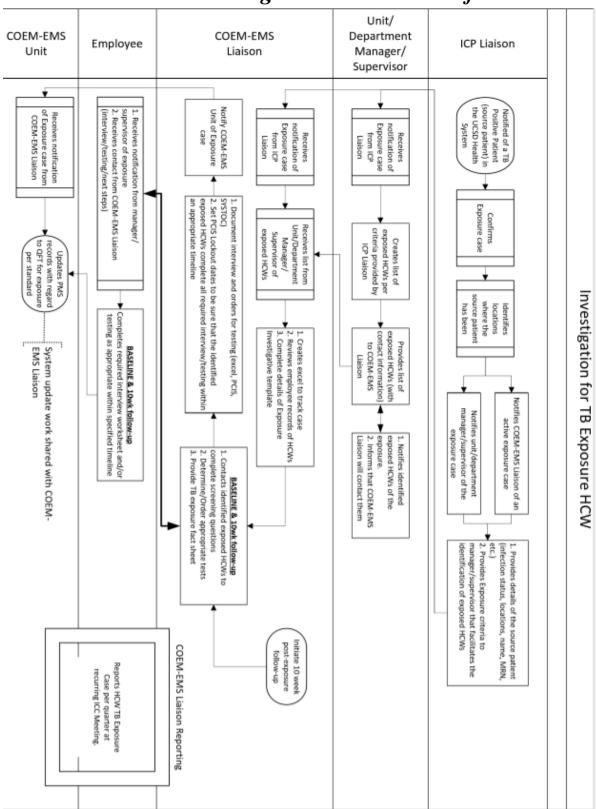
[†] For example, ultraviolet germicidal inadiation (UVGI), high-efficiency particulate air (HEPA) fitters, or airborne infection isolation (AII) room.

[§] Number of UVGI units, HEPA filters, and All rooms in each location of the health-care setting.

¹ For example, inpatient rooms, emergency departments, bronchoscopy suites, sputum induction rooms, curpatient areas, and waiting areas.

^{**} Daily, weekly, morthly, annually, or other frequency (describe).

ATTACHMENT 8: TB Algorithm: Work Plan for Possible TB Exposure



ATTACHMENT 9: Aerosol Transmissible Disease (ATD) Standards Protocol

I. PURPOSE

This section outlines the identification of safe work practices to minimize the incidence of occupationally acquired diseases that are transmissible through aerosols in the healthcare setting. This policy is mandated by the State of California Title 8, Section 5199, Aerosol Transmissible Diseases Standard.

II. SETTING

Medical Center – Note: Airborne pathogen control in the research setting is governed by University of California, San Diego Medical Center Refer to UC San Diego Bio Safety Plan thru the Lab.

III. DEFINITIONS

- A. Diseases/Pathogens Requiring Airborne Infection Isolation:
 - 1. Aerosolizable spore-containing powder or other substance
 - 2. Avian Influenza (transmissible to humans)
 - 3. Herpes Zoster (varicella zoster) (shingles), disseminated disease in any patient. Localized disease in immunocompromised patient until disseminated infection is ruled out
 - 4. Measles (rubeola)
 - 5. Monkeypox
 - 6. Novel or unknown pathogens
 - 7. Severe acute respiratory syndrome (SARS)
 - 8. Smallpox (variola; see vaccinia for management of vaccinated persons)
 - 9. Tuberculosis (M.Tuberculosis), extrapulmonary draining lesion, pulmonary or laryngeal disease-confirmed, pulmonary or laryngeal disease-suspected
 - 10. Varicella and any emerging disease determined by public health to have airborne transmission
- B. Diseases/Pathogens requiring Droplet Precautions:
 - 1. Diphtheria/Corynebacterium diphtheriae pharyngeal
 - 2. Epiglottitis, due to Haemophilus influenzae type b
 - 3. Group A Streptococcal (GAS) disease (strep throat, necrotizing fasciitis, impetigo)/Group A streptococcus
 - 4. Haemophilus influenzae Serotype b (Hib) disease/Haemophilus influenzae serotype b -- Infants and children
 - 5. Influenza, human (typical seasonal variations)/influenza viruses
 - 6. Meningitis
 - a. Haemophilus influenzae, type b known or suspected
 - b. Neisseria meningitidis (meningococcal) known or suspected
 - 7. Meningococcal disease/*Neisseria meningitidis*: sepsis, pneumonia (see also meningitis)
 - 8. Mumps (infectious parotitis)/Mumps virus
 - 9. Mycoplasmal pneumonia/Mycoplasma pneumoniae
 - 10. Parvovirus B19 infection (erythema infectiosum, fifth disease)/Parvovirus B19
 - 11. Pertussis (whooping cough)/Bordetella pertussis

- 12. Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr virus, Herpes simplex virus,
- 13. Pneumonia
- 14. Adenovirus
- 15. Chlamydia pneumoniae
- 16. Mycoplasma pneumoniae
- 17. Neisseria meningitidis Streptococcus pneumoniae
- 18. Pneumonic plague/ Yersinia pestis
- 19. Rubella virus infection (German measles) (Also see congenital rubella)/Rubella virus
- C. **Aerosol Transmissible Disease (ATD) or aerosol transmissible pathogen (ATP)-**-A disease or pathogen for which droplet or airborne precautions are recommended
- D. **Airborne Infection Isolation (AII)**--Infection control procedures as described in Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. These procedures are designed to reduce the risk of transmission of airborne infectious pathogens, and apply to patients known or suspected to be infected with epidemiologically important pathogens that can be transmitted by the airborne route
- E. **Airborne Infection Isolation Room or Area (AIIR)**--A room, area, booth, tent, or other enclosure that is maintained at negative pressure to adjacent areas in order to control the spread of aerosolized **M. tuberculosis** and other airborne infectious pathogens
- F. **Airborne Infectious Disease (AirID)**--Either: (1) an aerosol transmissible disease transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the disease agent for which AII is recommended by the CDC or CDPH, as listed in Appendix A, or (2) the disease process caused by a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that the pathogen is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.
- G. Case--(A) A person who has been diagnosed by a health care provider who is lawfully authorized to diagnose, using clinical judgment or laboratory evidence, to have a particular disease or condition; or (B) A person who is considered a case of a disease or condition that satisfies the most recent communicable disease surveillance case definitions established by the CDC
- H. Droplet Precautions. Infection control procedures as described in Guideline for Isolation Precautions designed to reduce the risk of transmission of infectious agents through contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than 5 μm in size) containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism
- I. Exposure Incident--An event in which an EMPLOYEE has been exposed to an individual who is a case or suspected case of a reportable ATD, the exposure occurred without the benefit of applicable exposure controls required by this section, and it reasonably appears from the circumstances of the exposure that transmission of disease is sufficiently likely to require medical evaluation.

- J. **High Hazard Procedures-**-Procedures performed on a person who is a case or suspected case of an aerosol transmissible disease or on a specimen suspected of containing an ATP-L, in which the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens. Such procedures include, but are not limited to, suctioning (except closed circuit suctioning), sputum induction, bronchoscopy, aerosolized administration of pentamidine or other medications, and pulmonary function testing. High Hazard Procedures also include, but are not limited to, autopsy, clinical, surgical and laboratory procedures that may aerosolize pathogens.
- K. IGRA Interferon Gamma Release Assays (IGRAs). QuantiFERON® TB Gold test (QFTG) and T Spot are two blood tests that are called Interferon Gamma Release Assays (IGRA). They are approved by the FDA.

Latent TB Infection (LTBI)--Infection with *M. tuberculosis* in which bacteria are present in the body, but are inactive. Persons who have LTBI but who do not have TB disease are asymptomatic, do not feel sick and cannot spread TB to other persons. They typically react positively to TB tests.

M. Tuberculosis--Mycobacterium Tuberculosis - The scientific name of the bacterium that causes tuberculosis.

Negative Pressure--The relative air pressure difference between two areas. The pressure in a containment room or area that is under negative pressure is lower than adjacent areas, which keeps air from flowing out of the containment facility and into adjacent rooms or areas.

Novel or Unknown ATP--A pathogen capable of causing serious human disease meeting the following criteria:

- 1. There is credible evidence that the pathogen is transmissible to humans by aerosols;
- 2. The disease agent is:
 - a. A newly recognized pathogen, or
 - b. A newly recognized variant of a known pathogen and there is reason to believe that the variant differs significantly from the known pathogen in virulence or transmissibility, or
 - c. A recognized pathogen that has been recently introduced into the human population, or
 - d. A not yet identified pathogen.

NOTE: Variants of the human influenza virus that typically occur from season to season are not considered novel or unknown ATPs if they do not differ significantly in virulence or transmissibility from existing.

Occupational Exposure--Exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting any disease caused by ATPs or ATP-Ls if protective measures are not in place.

Reportable Aerosol Transmissible Disease (RATD)--An aerosol transmissible disease or condition which a health care provider is required to report to the local health officer, in accordance with Title 17 CCR, Chapter 4, and for which the CDC or the CDPH recommend droplet precautions or All.

and

Respirator--A device which has met the requirements of 42 CFR Part 84, has been designed to protect the wearer from inhalation of harmful atmospheres, and has been approved by NIOSH for the purpose for which it is used.

Respiratory Hygiene/Cough Etiquette in Health Care Settings--Respiratory Hygiene/Cough Etiquette in Health Care Settings, CDC, November 4, 2004, which is hereby incorporated by reference for the sole purpose of establishing requirements for source control procedures

. **Source Control** Measures--The use of procedures, engineering controls, and other devices or materials to minimize the spread of airborne particles and droplets from an individual who has or exhibits signs or symptoms of having an ATD, such as persistent coughing.

Surge--A rapid expansion beyond normal services to meet the increased demand for qualified personnel, medical care, equipment, and public health services in the event of an epidemic,

Susceptible Person--A person who is at risk of acquiring an infection due to a lack of immunity.

Suspected Case--Either of the following:

- 1. A person whom a health care provider believes, after weighing signs, symptoms, and/or laboratory evidence, to probably have a particular disease or condition listed in section III.A and B.
- A person who is considered a probable case, or an epidemiologically-linked case, or who has supportive laboratory findings under the most recent communicable disease surveillance case definition established by CDC
- **TB Conversion**-- A change of QFT result from negative to positive.
- . **Tuberculosis** (**TB**)--A disease caused by *M. tuberculosis*

IV. POLICY

- A. This plan is administered by the University of California, San Diego Medical Center (UCSDMC) Infection Prevention is available on call 24/7, through the paging operator.
- B. The plan is evaluated and updated to include methods for controlling/preventing respiratory pathogen transmission i.e., new engineering and work practice controls, new cleaning and decontamination procedures, changes in isolation procedures, use of PPE, determining EMPLOYEE exposures, and surge procedures.
- C. The following methods are used to prevent exposures to aerosol transmissible diseases/pathogens:
 - 1. Promptly identify suspect patients.
 - a. Transfer to an appropriate room (AII) within the institution for airborne infectious disease patients
 - b. When it is not feasible to provide airborne isolation rooms for a novel disease, provide other effective control measures, i.e. PPE, cohort patients, hand hygiene,

social distancing, keep 6 feet apart.

- D. Apply appropriate isolation precautions.
- E. Maintain Appropriate Engineering Controls. To prevent transmission i.e. ventilation systems and fresh air exchanges in AIIRs are used to manage the environment of patients with ATD:
 - 1. Ventilation rate is 12 or more air exchanges
 - 2. Maintain ventilation systems by inspection and monitoring for exhaust and recirculation filter loading and leakage at least annually.
 - 3. Air from airborne isolation rooms and areas connected via plenums or other shared air spaces are exhausted directly outside, away from intake vents and people.
 - 4. Air that cannot be exhausted in this manner must pass through HEPA filters before discharge or recirculation.
 - 5. Negative pressure rooms are used for airborne transmissible disease.
 - a. Negative pressure is visually demonstrated by smoke trails or other devices that show air is moving into the room instead of out of the room.
 - b. Doors and windows of airborne isolation rooms are kept closed while in use for AII, except when doors are opened for entering or exiting
 - c. Portable HEPA filter units may be used to increase the number of rooms, diagnostic areas available to treat ATD patients and/or ATP.
 - d. Proper pressurization is checked daily by PO&M when a room is occupied by a patient requiring airborne infection isolation.
- F. Implement Appropriate Work Practices to Prevent Transmission:
 - 1. Dietary/Nursing staff deliver food trays to patients in airborne isolation rooms.

4. ^

- 4. Healthcare workers with a documented history of a positive tuberculosis skin test (PPD) who received adequate treatment or adequate preventative therapy for infection will need a baseline OFT blood draw.
- 5. All healthcare workers, including those with a positive QFT blood test are responsible for reporting to Employee Health Services for any symptoms suggestive of pulmonary tuberculosis.
- 6. Routine chest radiographs are not required for asymptomatic QFT negative healthcare workers.
- 7. Healthcare workers with a positive QFT test should have a chest radiograph as part of the initial clinical evaluation. Those with active tuberculosis are excluded from work until non-infectious. Those who do not have TB are evaluated for preventative therapy.
- 8. New EMPLOYEEs with a positive QFT blood draw will have a chest radiograph as part of the new employee health screening. If the chest radiograph is negative, repeat x-rays are not required unless symptoms develop that may be due to TB. These EMPLOYEEs have a responsibility to report any symptoms suggestive of TB to Employee Health Services.

- 9. Healthcare workers with pulmonary or laryngeal TB are considered communicable and are excluded from work until they are no longer Ainfectious.@ Employee Health Services will provide a work clearance for these EMPLOYEEs before they return to work. Three sputa collected on three different days should be negative before the EMPLOYEE can return to work. An adequate response to therapy is also required.
- 10. When a case or suspected case vacates the AII room, the room or area is ventilated for one hour to allow removal efficiency of 99.9% of the air before EMPLOYEEs are permitted to return to the room.
- 11. Respiratory etiquette is practiced by EMPLOYEEs.
 - 12. Using personal protective equipment to protect EMPLOYEEs from other pathogens spread by the airborne/droplet route of transmission, i.e., influenza.
- 13. Wash hands before and after patient contact.
- 14. Anterooms are used when feasible for negative pressure rooms.
- 15. Identify and review annually, (in conjunction with Patient Care Services, Infection Prevention and Employee Health Services), the work locations at higher risk for exposure to ATD and/or ATP.
 - a. All inpatient areas;
 - b. Main OR and Recovery, Emergency Department;
 - c. Radiology, Respiratory Therapy, Patient Escort, Housekeeping, Phlebotomy, Family Practice, ,ER Registration/Admitting, Cardiac Cath Lab, Interventional Radiology, and Ambulatory Clinics.
- G. Source Controls Are Established:
 - 1. Conduct high hazard procedures in airborne isolation rooms, booths or tents. When this is not feasible, use appropriate PPE.
 - 2. Respiratory etiquette is taught to patients; patients wear a surgical mask, cover cough/sneeze.
 - 3. Patients with the same respiratory illness diagnosis may be placed in a cohort on a designated unit during times of high census, such as a pandemic.
 - 4. Inform persons entering the facility about our source control practices; visitors are to wash hands, use respiratory etiquette and wear mask when indicated.
 - 5. Controls are implemented to protect EMPLOYEEs who operate/maintain vehicles that transport persons with aerosol transmissible disease (ATD); provide barriers and air handling systems where feasible; if this is not feasible, EMPLOYEEs wear an N 95 respirator while transporting persons with suspected ATD.

- 6. Respirators are not used when an EMPLOYEE is operating a vehicle and the respirator may interfere with the safe operation of the vehicle. The employer shall provide barriers or source control measures.
- 7. Law enforcement personnel transporting an airborne infectious case do not use respiratory protection if a solid partition separates the passenger area from the EMPLOYEE area.
- 8. Document how protection is provided for person transporting ATD patients.
- 9. Document how vehicles are cleaned/disinfected.
- 10. All referring employers (agencies employing emergency medical technicians (EMTs), police, fire) who transport patients are required to follow the same the procedures CAL-OSHA requires for hospitals to follow in order to assure their EMPLOYEEs are protected.
- 11. Hospitals do not provide names of patients suspected/confirmed of having an ATD to referring employers.

H. Respiratory Protection

- 1. Respirators are NIOSH approved.
- 2. Fit testing occurs in accordance with UCSDMC. A fit test program with a wider scope will be established in an emergency incident, i.e. an influenza pandemic (See COEM EMS Plan respiratory protection section 6).
- 3. N95 respirators will be reused when there is a lack of available inventory, i.e. pandemic or epidemic. The N95 can be worn for one shift of work or more often depending on the need. The N95 is not to be worn if it is damaged in any way. As an alternative, elastomeric masks may be used when there is an N95 shortage.
- 4. Beginning September 1, 2010, provide a PAPR with HEPA filters or a respirator providing equivalent protection for EMPLOYEEs performing high hazard procedures on airborne infectious diseases cases, and for EMPLOYEEs performing high hazard procedures on cadavers potentially infected with ATP, unless the patient is placed in a booth, hood or other ventilated enclosure (See COEM EMS Plan Section 6).

V. PROCEDURE

- A. Confirmed or suspected ATD patients are placed in designated negative pressure rooms on AII. Patients will be placed in a designated isolation room until medically determined to be non-infectious. (Refer to COEM EMS Plan Section 5)
- B. Patients suspected or confirmed as infectious due to an airborne pathogen will wear a surgical mask until an appropriate room is available.
- C. Visitors going into Negative Pressure rooms housing ATD patients will wear a surgical mask or equivalent during the visit.

- D. Engineering Controls
 - 1. These controls are monitored by Facilities Engineering (FE) .AIIRs are checked daily for proper pressurization when rooms are occupied by a patient requiring airborne infection isolation.
 - 2. Environmental Health and Safety collaborates with FE for monitoring some systems.
- E. Work Practice Controls Department managers are responsible for enforcing EMPLOYEE work practice controls. The following work practice controls are implemented to prevent exposure to airborne pathogens:
 - 1. EMPLOYEEs taking care of patients with suspected or confirmed airborne diseases must wear respiratory protection.
 - 2. Patients with communicable airborne diseases must wear a surgical mask during transport and other times when patients are out of designated isolation rooms (unless the patient is intubated).
 - 3. Patients in airborne isolation rooms must have the doors closed at all times.
 - 4. EMPLOYEEs must wash hands after removal of gloves.
 - 5. Occupational exposures are to be reported to supervisor immediately.
 - a. Exposures are investigated promptly, and everyone who may have been exposed is informed
 - b. Do not provide the name of the source patient to other employers, i.e. EMTs, fire, police.
 - 6. Visitors will wear surgical masks when entering negative pressure rooms when an airborne precautions patient is in the same room.
- F. EMPLOYEE Surveillance and Post-exposure Follow-up. Employee Health Services is responsible for new EMPLOYEE and EMPLOYEE surveillance for post-exposure follow-up for airborne pathogens.
 - 1. Related Policies: refer to UCSDMC Policies and Procedures for the following conditions:
 - a. MCP 558.1 Fitness for Duty, b. MCP 611.5 Employee Exposure to Communicable
- G. Medical Services for EMPLOYEEs with Occupational Exposure to ATD
 - 1. Assess exposures; QFT blood draws are provided at time of hire & more frequently if a TB exposure occurs.
 - 2. EMPLOYEEs with baseline positive QFT test shall have an annual symptom interview.

- 3. EMPLOYEEs with TB test conversions are referred to a professional knowledgeable about TB.
- 4. Diagnostic tests and treatment options are provided to the EMPLOYEE.
- 5. Record TB conversions as required by the State of California.
- 6. Investigate the circumstances of occupational exposures to any ATD. Document the investigation.
- 7. Vaccinations shall be made available to all EMPLOYEEs with occupational exposures unless the employee has already received the vaccine or it is determined the EMPLOYEE has immunity, or the vaccine is contraindicated for medical reasons.
- 8. Individual providing vaccine or determining immunity provides information to the employer (name, date, dose, immunity, any restrictions on the EMPLOYEE's exposure, if additional vaccine is required, and date/dose it should be provided).
- 9. If vaccine is not available, employer documents unavailability of the vaccine and checks on availability every 60 days.

H. Training

- 1. New employee orientation and annual education of EMPLOYEEs.
- 2. Written module about ATD is provided to EMPLOYEEs during the orientation classes. The topics include transmission, symptoms, incidence, risk group vaccines, and exposure prevention strategies.

I Recordkeeping

- 1. Employees and Medical Staff/Faculty Physicians ATD Immunity status (measles, mumps, rubella, varicella, pertussis is recorded in the PCIS/PMS System.
- 2. Employee's QFT blood test are ordered by Employee Health Services and results recorded in Epic.
 - 3. New employee and annual education of EMPLOYEEs is recorded by the Center for Continuing Nursing and Medical Education. These records are maintained for three years.
 - 4. EMPLOYEE information is kept confidential. Records are maintained throughout the EMPLOYEE career and for 30 years thereafter.

REFERENCES

Refer to UCSD MC Lab Biological Safety Plan

Title 24, California Code of Regulations 5199, Aerosol Transmissible Disease Standard CDC Guidelines For Preventing the Transmission of Mycobacterium Tuberculosis in Health care Facilities, December 2005/54/(RR17);1-141.

Title 24, California Code of Regulations, Mechanical Code.

Sent to the following for review:

Francesca Torriani, MD Kim Delahanty, RN Karl Burns Leslie Caskey/Patrick Daniel/Mike Dayton William Hughson, MD/Tricia Foster Infection Control Committee Environment of Care Committee

UC San Diego Health

STANDARDS PRESENTATION TO CALIFORNIA OCCUPATIONAL SAFETY AND HEALTH STANDARDS ROARD

Name:	
DOB://	
MR#/Emp#:	

AND HEALTH STANDARDS BOARD MR#/Emp#:						
PROPOSED STATE STANDARD, TITLE 8, DIVISION 1, CHAPTER 4						
Aerosol Transmissible Diseases Appendix B – Alternate Respirator Medical Evaluation Questionnaire (This Appendix is Mandatory if the Employer chooses to use a Respirator Medical Evaluation Questionnaire other than the Questionnaire in Section 5144 Appendix C)						
To the employer: Answers to questions in Section 1, and to question 6 in Section 2 do not require a medical examination. Employees must be provided with a confidential means of contacting the health care professional who will review this questionnaire. To the employee: Can you read and understand this questionnaire (check one): Yes No Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.						
Section 1. The following information must be provided by every employee who has been selected to use any type of respirator (please print).						
Today's date:						
Name: Job Title: Your age (to nearest year): Sex (check one): Male Female						
Your age (to nearest year): Sex (check one): Male Female Height: ft. in. Weight: Ibs.						
Phone number where you can be reached (include the Area Code):						
The best time to phone you at this number:						
Has your employer told you how to contact the health care professional who will review this questionnaire (check one):						
Section 2. Questions 1 through 6 below must be answered by every employee who has been selected to use any type of respirator (please check "yes" or "no").						
Have you ever had any of the following conditions? Allergic reactions that interfere with your breathing: Yes No						
Claustrophobia (fear of closed-in places) Yes No What did you react to?						
2. Do you currently have any of the following symptoms of pulmonary or lung illness? Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Have to stop for breath when walking at your own pace on level ground: Shortness of breath that interferes with your job: Yes No Coughing that produces phlegm (thick sputum): Yes No Wheezing that interferes with your job: Yes No Chest pain when you breathe deeply: Yes No No No Chest pain when you breathe deeply: Yes No No Chest pain when you breathe deeply:						
D2304 (12-15) FRONT ~ OSHSB-98(2/98) PLEASE CONTINUE TO NEXT PAGE						

UC San Diego Health

STANDARDS PRESENTATION TO CALIFORNIA OCCUPATIONAL SAFETY AND HEALTH STANDARD BOARD

Name:			
DOB:		_/_	
MR#/E	mp#:		

AND	HEALTH STANDARD BOARD	MR#/Emp#:
	ED STATE STANDARD, DIVISION 1, CHAPTER 4	
Any other symptoms that you think may be related to lung problems:	No	
3. Do you currently have any of the following cardi: Frequent pain or tightness in your chest: Yes Pain or tightness in your chest during physical activity: Yes	No Pain or tightness in your chest that interferes with your job:	Yes No
4. Do you currently take medication for any of the Breathing or lung problems: Heart trouble: Nose, throat or sinuses Are your problems under control with these medications? Yes	following problems? No No No No No	
(If you've never used a respirator, check the fo <u>llowing</u>	No General weakness or fatigue: Yes No	
questionnaire: Yes No Employee Acknowledgement:	onal who will review this questionnaire about your as	
Employee Signature	Date HCP Signature	Date
	FOR COEM STAFF USE ONLY	
Type of mask used: 1870+ 1860S 1860R Agent Used: Saccharin Bitrex	Gerson 2130 Other:	
Respirator fit testing is to be performed annually 1. A change in the condition of the workplac 2. A change in the employer's respirator prof 3. A change in the employee's facial features.	pliance with OSHA 29CFR 1910.134 – Appendix A or or if one of the following conditions apply: e that may substantially increase the physiological burde gram.	
EmployeeSignature D2304 (12-15) BACK ~ OSHSB-98(2/98)	Date Tester	Date

ATTACHMENT 10: COEM-UCSD Tuberculosis Surveillance for Health Care Workers

Standardized Procedures

Protocol Name	COEM-UCSD Tuberculosis Surveillance for Health Care Workers Standardized Procedures
	Standardized Procedures
Effective Date:	
Original	
Approval Date:	
Revised Date(s):	

ABSTRACT:

This protocol governs the actions of the COEM-EMS nurse, provider, or support staff as appropriate, with regard to the following objectives as described within this document:

- A. EMR and employee database documentation management of diagnostic test order(s) and result(s)
 - a. EPIC
 - b. PCIS/PMS
 - c. SYSTOC
- B. Summary understanding of the UCSD medical center *ATD Standards and TB Control Plan*, with regard to TB Screening and n95 respirator fit testing of Health Care Worker (HCW) both new employees entering into the UCSD Health System (UCSD HS) and those existing employees required to complete annual n95 respirator fit testing.
 - a. Indication of diagnostic test orders per HCW/employee needs and organization directive
 - b. Diagnostic test results and guidelines
 - i. Quantiferon
 - ii. Chest X-ray
 - iii. TB screening questionnaire
 - c. Diagnostic test result management by COEM-EMS nurse, provider, and support staff
 - d. Employee education, with regard to Tuberculosis (TB)
- C. Tuberculosis Post-Exposure process steps and employee education
- D. To define operational workflow and responsibilities of Aerosol Transmissible Diseases (ATD) related respirator medical clearance questionnaire for fit testing clearance of an n95 mask or Powered Air Purifying Respirator (PAPR) in association with OSHA Respiratory Protection Regulations.
 - a. Guidelines to address some of the common unexpected responses to the OSHA Aerosol Transmissible Diseases (ATD) alternate Respirator Medical Evaluation Questionnaire by the employee

RELATED POLICIES:

- ➤ **UCSDH MCP 18.1**: Guidelines for E-Mail or Electronic Mail Communications Containing Personally Identifiable Information
- ➤ UCSDH Procedure ISP3.13: TB Control Suspension for EPIC EMR
- > UCSDH: Aerosol Transmissible Disease (ATD) Standards and Tuberculosis (TB) Control Plan

RESOURCES:

- ➤ The Centers for Disease Control and Prevention (CDC):
 - o http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6253a1.htm .
 - http://wwwn.cdc.gov/nndss/conditions/tuberculosis/case-definition/2009/.
 - o http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm
 - http://www.cdc.gov/tb/publications/guidelines/infectioncontrol.htm
 - http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e
 - http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5202a2.htm
 - o http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a4.htm

REGULATORY REFERENCES:

- ➤ Title 8, California Code of Regulations:
 - o http://www.dir.ca.gov/title8/5199.html
- Occupational Safety and Health Administration (OSHA):
 - o http://www.cdph.ca.gov/programs/ohb/Pages/ATDStd.aspx
 - o CPL 02-02-078 EFFECTIVE DATE: 06/30/2015

DEFINITIONS:

- ➤ ATD: Aerosol Transmissible Diseases infectious diseases that can be transmitted by inhaling air that contains viruses, bacteria or other disease organisms
- **COEM**: Center for Occupational and Environmental Medicine
- **EMR**: Electronic Medical Record
- **EMS**: Employee Medical Surveillance (previously known as TB Control), extension of COEM
- **EPIC**: Medical record system
- > HCW: Health Care Worker, individual working directly or indirectly with patients of the health care system
- ➤ IPCE: Infection Prevention Control and Epidemiology, department within UCSD HS specialized and content experts, with regard to infection prevention, control, and pathogen epidemiology
- ➤ **NEO**: New Employee Orientation
- > OSHA: Occupational Safety and Health Administration
- > PCIS/PMS: Patient Care Information System, system database used at UCSD to manage employee health records
- > PCP: Primary Care Provider
- > PHI: Protected Health Information
- **PLHCP**: Physician or other Licensed Health Care Professional
- > SYSTOC: Medical record systems used specifically by COEM

- > Tuberculosis (TB): a highly contagious ATD that attacks the lungs and can spread throughout the body. Infected individuals can harbor *mycobacterium tuberculosis* for years without developing the disease. An individual with TB disease is contagious, while an individual with TB infection is not contagious.
- ➤ LTBI: Latent TB Infection, infection with *mycobacterium tuberculosis* pathogen without active tuberculosis disease
- > UCSD HS: University of California San Diego Health System
- **X-ray**: a photographic or digital image of the internal composition of something, especially part of the body
- ➤ QFT: Quantiferon, diagnostic laboratory (blood) test used to determine if an individual has been sensitized to tuberculosis infection

PROTOCOL:

All internal communications with regard to PHI, will be completed with regard to UCSD privacy guidelines. Surveillance applies to UCSDH staff, physicians, advanced practice providers (NPs, PAs, etc.), volunteers, pharmacy students, and medical students

EXCEPTION

COEM does not maintain records with regard to ATD immunities or TB surveillance of contracted individuals, rotators, or visiting scholars unless otherwise specified in contract between UCSDH and the agency. All records not maintained by COEM are maintained by the contracting agency or UCSDH sponsor/sponsor division. The contracting agency or UCSDH sponsor/sponsor division must provide any records associated with ATD immunity status and/or TB surveillance status upon demand.

EMR and HCW/employee database documentation management of diagnostic test order(s) and associated result(s)

- a. All diagnostic orders are placed and resulted in EPIC
- b. QFT and Chest X-ray results are filed to EPIC in-baskets/pools per EPIC routing scheme. Final database tracking is completed in PCIS/PMS
 - i. EPIC In-Basket/pool routine scheme
 - All QFT results ordered by EMS staff are routed to the EMS EPIC in-basket result pool "EMP HLTH SCRN RSLTS TB". EMS staff ONLY follow-up with regard to negative or low mitogen/indeterminate QFT results
 - a. All positive results ordered by EMS staff simultaneously route to the COEM inbasket result pool "EMP HLTH SCRN RESULTS COEM" and are designated with Dr. John Kim (COEM provider) as the authorizing provider for the order. Positive QFT results ordered from EMS staff are managed by a designated COEM NP.
 - 2. All QFT results ordered by COEM providers are routed to the COEM EPIC in-basket result pool "EMP HLTH SCRN RESULTS COEM" and are managed by each ordering provider.
- B. Summary understanding of the UCSD medical center ATD Standards and TB Control Plan.
 - a. Indication of diagnostic test order(s) per HCW/employee needs and organization directive.
 - i. New HCWs/Prospective Employees: (evaluation performed only within COEM) all new HCWs/prospective employees, or Campus HCWs entering UCSD HS are required to have a baseline QFT regardless of a historical positive TST/PPD result, unless they have a documented QFT result within the past 3 months. **NOTE** Employees who have a history of a positive past TB test and have completed LTBI treatment, will need a baseline QFT and chest X-ray, followed by annual questionnaires.
 - 1. Negative QFT results = No additional screening unless exposed to TB.
 - 2. Positive QFT results (with regard to QFT component value TB Antigen Nil) =
 - a. Result greater than or equal to 1.0 IU/mL
 - i. Order Chest X-ray PA 1 view
 - 1. Negative TB questionnaire and Negative Chest X-ray for active TB disease
 - a. Refer to PCP for LTBI treatment (notify HCW/prospective employee via MyChart) and update

record to indicate the use of TB Screening Questionnaire for annual TB surveillance

- 2. Positive Chest X-ray for active TB disease
 - a. NOT cleared to work. Refer to PCP for treatment and active TB disease clearance
 - b. HCW/prospective employee must have a new evaluation in COEM with clearance letter from PCP documenting [no active TB disease and treatment compliance]
 - c. Further consultation with Infection Prevention Control and Epidemiology (IPCE) as needed

3. ****NOTE****

- a. Short deadline for hiring (within 3 days of NEO), provider may order a Chest X-ray PA 1 view or accept a Chest X-ray (CXR) from an outside record, if the CXR results are within 3 months of hire date at the time of COEM physical exam
 - i. **Provider's decision** is based on risk factors that include, but not limited to, prior history of LTBI treatment.
- ii. Existing HCWs/employees, Volunteers, Contracted specific HCWs/employees: (evaluations performed in EMS extension of COEM) **NOTE** If LTBI treatment was completed as per a past positive TST/PPD or QFT, then future annual TB surveillance is managed with a TB Screening Questionnaire NOT a QFT. **Update PMS record from "F" for QFT to "Q" for questionnaire**
 - Negative QFT results = Result range less than 0.35 IU/mL with no prior history of completed LTBI treatment
 - a. Notify HCW/employee via MyChart result letter template
 - 2. Low Mitogen/Indeterminate QFT results =
 - a. Notify HCW/employee via MyChart result letter template
 - Repeat QFT immediately [Document in PCIS/PMS repeat QFT "Return date" two weeks from date of 2nd QFT collection – to be sure of HCW/employee compliance with a resulting EPIC lockout, if HCW/employee does not comply]
 - i. If repeat QFT result is again Low Mitogen/ Indeterminate
 - Notify HCW/employee via MyChart result letter template that he/she will need to schedule a follow-up appointment with a COEM NP for evaluation and further testing [Document in PCIS/PMS repeat QFT "Return date" two weeks from date of 2nd QFT collection – to be sure of HCW/employee compliance with a resulting EPIC lockout, if HCW/employee does not comply]
 - Need evaluation that includes consideration of TST/PPD, CXR, or repeat QFT
 - 3. <u>Positive QFT results</u> = Result range greater than 0.35 IU/mL, will be managed by COEM-EMS nurse or provider **NOT** by EMS staff or support staff
 - a. Result range 0.35 0.99 IU/mL
 - i. Notify HCW/employee via MyChart result letter template

- ii. Repeat QFT immediately [Document in PCIS/PMS repeat QFT "Return date" two weeks from date of 2nd QFT collection to be sure of HCW/employee compliance with a resulting EPIC lockout, if HCW/employee does not comply]
 - 1. If 2nd QFT result is less than 0.35 IU/mL, no further diagnostic action needed.
 - a. Notify HCW/employee via MyChart result letter
 - i. **NOTE** If LTBI treatment was completed as per a past positive TST/PPD or QFT, then future annual TB surveillance is managed with a TB Screening Questionnaire NOT a QFT. **Update PMS record from "F" for QFT to "Q" for questionnaire**
 - 2. If 2nd QFT result range is again within 0.35 -0.99 IU/mL
 - a. Notify HCW/employee via MyChart result letter and telephone that he/she will need further testing
 - b. Order Chest X-ray PA 1 view
 - c. Enter "Return date" in PMS two weeks from the date of the 2nd QFT collection
 - d. Consider result a possible conversion, if past results were less than 0.35 IU/mL.
 - e. Discuss case with COEM Medical Director or other COEM provider
 - f. Be sure that HCW/employee is scheduled with a COEM provider
 - i. Offer treatment for latent TB infection, if indicated*
 - ii. Document in SYSTOC that counsel and treatment were offered and the HCW/employee's response
 - iii. Complete iReport, if work related conversion is suspected
 - iv. Initiate Worker's Compensation claim
 - g. Add HCW/employee to the "convertor" tracking excel spreadsheet found on the "G-drive"
 - h. Update PMS record from "F" for QFT to "Q" for questionnaire
- b. Result range greater than 0.99 IU/mL
 - i. Notify HCW/employee via MyChart result letter and telephone that he/she will need further testing
 - ii. Order Chest X-ray PA 1 view
 - iii. Enter "Return date" in PMS two weeks from the date of the 2nd QFT collection

- iv. Consider result a possible conversion, if past results were less than 0.35 IU/mL.
- v. Discuss case with COEM Medical Director or other COEM provider
- vi. Be sure that HCW/employee is scheduled with a COEM provider
 - 1. Offer treatment for latent TB infection, if indicated*
 - 2. Document in SYSTOC that counsel and treatment were offered and the HCW/employee's response
 - 3. Complete iReport, if work related conversion is suspected
 - 4. Initiate Worker's Compensation claim
 - a. **NOTE** not all converters will be treated as worker's comp, consider the following and consult with the COEM Medical Director as needed:
 - i. Job duties
 - ii. Amount of patient contact
 - b. HCW/employees NOT determined to be a converter, will be referred to their PCP or the health department for treatment as appropriate.
- vii. Add HCW/employee to the "convertor" tracking excel spreadsheet found on the "G-drive"
- viii. Update PMS record from "F" for QFT to "Q" for questionnaire
- C. In order to be sure that UCSD HCW/employees are in compliance with TB surveillance and N95 fit testing requirements, an EPIC lockout control method is in place as most UCSD HCW/employees are required to use EPIC as part of their work. **NOTE** Some employees do not have need to use EPIC, compliance enforcement, with regard to TB surveillance requirements, is the responsibility of each employees' supervisor/manager.
 - a. PCIS-INFOPAC (data archival system) reports that managers may run ad lib:
 - i. EHSS211 monthly report that lists the date of an employee's last TB surveillance
 - 1. Reflects archived data per the 1st of each month
 - a. Report can be run ad lib, however, the data on the report will remain the same, as per the data on the 1st of each month
 - ii. EHSS215 daily report that lists the date of an employee's last TB surveillance
 - 1. Reflects archived data per the day prior
 - a. Report can be run ad lib, however, the data on the report will reflect changes from the day prior. For example, if a record was updated on 12/21, then the changes will not be noted on the report until 12/22.
 - b. PCIS and associated PMS HCW/employee database records are interfaced with EPIC HCW/employee User access profile.
 - i. TB surveillance reminder notifications are sent to HCW/employee UCSD email addresses from the PCIS mainframe per date of last TB screening entry 364 days plus the date of last test. Notices are produced between 30 and 45 days prior to date of non-compliance and again at between 7 and 10 days prior to date of non-compliance. A final non-compliance notice is sent once the HCW/employee is non-compliant.

- ii. A TB surveillance suspension report is produced daily in the EMS extension of COEM. EMS staff review the list for non-compliant HCW/employees then begin the process of locking the PCIS records.
- iii. Every odd hour beginning at 0600 ending at 1500 Monday through Friday, a one way interface communication occurs between PCIS and EPIC. If a PCIS record is locked, then the associated EPIC access record will be locked. The non-compliant HCW/employee will not have the ability to log into EPIC to work. Please refer to policy/protocol [ISP3.14 TB Control Suspension for EPIC EMR].
- c. In order to avoid an inadvertent EPIC lockout of a compliant HCW/employee, while waiting for a QFT result, the following process steps will be followed by EMS staff or COEM support staff (MAs). Steps occur in the PMS record of the HCW/employee.
 - i. PCIS/PMS documentation process steps to complete at time of QFT draw
 - 1. REPLY field enter: ehsaft
 - 2. Description field enter: screening
 - 3. Approve Manager field enter: (the name of the ordering provider)
 - 4. Place of Test field enter: (location of the ordering provider, e.g. COEM HC, COEM LJ, TB HC, TB LJ)
 - 5. Return Date field enter: (a date that is two weeks from the date of the QFT draw)
 - 6. QFT Comments field enter: Drawn
 - 7. Press keyboard function key 'F1' to "post" the documentation
 - 8. Ask yourself the following questions: If yes, the chances are that the HCW/employee is already locked out of EPIC and will need to be unlocked in PCIS before EPIC access is restored. Please follow-up with the COEM-EMS RN or an EMS staff member to have the HCW/employee unlocked in PCIS.
 - a. Is the HCW/employee due for TB Screening today?
 - b. Is the HCW/employee past due for his/her TB Screening?
 - ii. PCIS/PMS documentation process steps to complete at time of QFT result entry (EMS and COEM support staff do not enter Positive results)
 - 1. REPLY field enter: record | DATA field enter: (the correlating line for the QFT draw)
 - 2. Delete the Return Date
 - 3. Note the Result Date
 - 4. Put an 'x' in the correlating *result type* line: Negative, Positive, or Indeterminate) depending upon the result
 - 5. Add comments if appropriate
 - 6. Press keyboard function key 'F1' to "post" the documentation
- D. Those HCW/employees who meet the criteria listed on the *TB Surveillance Bypass form*, may have his/her supervisor/manager complete the *TB Surveillance Bypass Form* on his/her behalf. The supervisor/manager completing the form will be required to attach the completed form to an email message and send to coemtbbypass@ucsd.edu in order to initiate the TB surveillance bypass request process. A COEM-EMS nurse will review the form then update the HCW/employee record as appropriate. An email response from the COEM-EMS nurse to the requesting supervisor/manager will dictate if the request was approved or denied.
 - a. Rotators are placed on TB Surveillance Bypass, per the office of GME with completed TB Surveillance Bypass form.

b. Visiting Scholars may be placed on TB Surveillance Bypass, per the sponsoring department with a completed TB Surveillance Bypass form.

Annual fit testing by pass form:

TB Surveillance and nN95 Respirator Fit Test Consent for Minors (Volunteer Services):

Minors associated with Volunteer Services may complete the requisite TB Surveillance and n N95 Respirator Fit Testing without the presence of a legal guardian with the below completed consent form. This form is provided to the minor by Volunteer Services and approved by Legal.

CONSENT FOR TB SCREENING FOR MINOR

As the parent/guardian of consent for a TB screening, which will consist of a bloomask fit test, and the mask fit test, provided by UC San Environmental Medicine. These services are provided a	d draw, medical evaluation questionnaire relating to a Diego Health, Center for Occupational &
CONSENTIMIENTO DE LA PRUEBA DE T	UBERCULOSIS PARA MENORES DE EDAD
Como padre / tutor de consentimiento para un examen de tuberculosis que con evaluación médica sobre la prueba de ajuste de respira proporcionado por UC San Diego Health, Centro de M proporcionados sin costo alguno al voluntario.	asistirá en una extracción de sangre, un cuestionario de dores, y la prueba y ajuste del respirador,
	Parent/Guardian Signature/(firma del padre/tutor)
Print Par	rent/Guardian Name/(nombre imprimido del padre/tutor)
	Date/(fecha)

E. TB Post-Exposure Workflow.

- a. An IPCE department representative will notify COEM department by sending a **high priority** message to the following email address: coemexposure@ucsd.edu alerting COEM of a TB Exposure. The email address is a distribution list (DL) that contains specific members from COEM.
- b. An ICP nurse/authorized IPCE representative will inform the COEM nurse/provider of the following details:
 - i. Details of the index patient
 - 1. Name
 - 2. MRN
 - 3. Degree of infection (e.g. AFB smear 4+, etc.)
 - ii. The period of infectiousness of the index patient
 - iii. The location(s) of the index patient during time before precautions instituted
 - iv. When the index patient was placed on precautions
 - v. The names and contact information of the managers of the affected areas
- c. The ICP nurse/authorized IPCE representative will have provided the terms of what will define an employee exposure to the managers of the locations where the index patient was before the patient was placed on precautions.
- d. The manager(s) of the clinical area(s) identified by ICPE department, will provide a list of all staff who were identified as exposed to COEM via the following email address: coemexposure@ucsd.edu
- e. The COEM nurse/provider will contact the manager(s) of the clinical area(s) where the patient was located while infectious and not on respiratory precautions. (Managers of ancillary services (phlebotomy, PT, radiology, etc.) should also be contacted to determine if there were additional employees exposed.)
 - i. Managers will provide the COEM nurse/provider with a listing of all staff that meet the exposure criteria defined by the ICP nurse/authorized IPCE representative
 - 1. An employee is considered to be exposed if he/she had one or more hours of continuous face-to-face contact or four or more cumulative hours during a single shift without the use of n95 respirator mask
 - a. **The following information is PHI and is to not be shared with any managers**
 Additional considerations with regard to determining if an employee is
 "exposed", is the health of the employee. If the employee is immune
 compromised (by condition or medication), the employee will be considered
 "exposed" regardless of the amount of time spent face-to-face with the index
 patient without the use of n95 respirator mask. **Dr. Torriani will determine
 the exposure standards for each case**
- f. After compiling the list of exposed employees, the COEM nurse/provider will give this list to the COEM clinic manager. The clinic staff will be directed to:
 - i. print out each employee's PMS record
 - ii. Put a phone consult in Systoc for each employee on the nurse or provider's schedule.
- g. A spreadsheet will be created and put in the 'G'-drive. The spreadsheet will include:
 - i. The employee's name, contact info, location of work, manager
 - ii. Baseline test date and result, post exposure test and result
 - iii. Baseline TB screening questionnaire result and date
 - iv. The follow-up TB screening questionnaire result and date.

- v. Comments that specify length of unprotected face-to-face contact
- h. The COEM nurse/provider will notify each employee of the exposure
 - i. Will send educational information (TB Post-Exposure fact sheet)
 - 1. about TB transmission
 - 2. disease progression
 - 3. how and when the HCW/employee will be tested
 - 4. symptoms and what to do if symptoms should develop
 - 5. treatment
 - 6. who to contact when there are questions
 - ii. A baseline TB test is required which could be (one or any combination of):
 - 1. QFT
 - 2. CXR
 - 3. TB Screening Questionnaire
 - iii. The COEM nurse/ provider will order the necessary tests in EPIC.
 - 1. If laboratory or x-rays are needed, the nurse/provider will notify the COEM clinic manager and the staff will register the employee with the med center exposure bulk account.
 - 2. If the employee's new hireTB testing was done within 3 months of the exposure, it can be used as the baseline test.
 - 3. If the employee has a complicated history (e.g. prior LTBI treatment, immunosuppression) then a physician should be consulted.
 - 4. The COEM nurse/provider will document what was done in the Systoc phone consult note.
 - a. Also, an entry will be put in each employee's PMS record, and if a baseline TB test is needed, a return date will be put in PMS to assist with compliance.
 - iv. 10 to 12 weeks after the last day of possible exposure. The employee will need to be tested.
 - 1. The COEM nurse/provider will notify the COEM clinic manager, who will direct staff to:
 - a. Put each employee on the Systoc schedule for a phone consult
 - b. Register employees in EPIC who need lab or CXR.
- i. The COEM nurse/provider will:
 - i. Contact each employee
 - 1. Obtain a symptom questionnaire from the employee
 - 2. Order the appropriate tests in EPIC
 - 3. Document the testing in PMS
 - 4. Enter the test results on the tracking spreadsheet found on the 'G'-drive
 - ii. If any employees convert to positive, or become symptomatic
 - iii. The employee, COEM physician and IPCE need to be notified.
 - 1. The employee will be instructed to fill out an iReport to start a Work Comp claim
 - 2. The employee will be offered LTBI treatment.

Post-Exposure PMS Documentation Standard:

Standard PMS Exposure X-Ray Documentation & Display (immune compromised is added to the standard comment if an individual is immune compromised):

```
TEST DATA: TEST DATE ( 01 - 07 - 16 )
DESCRIPTION ( SCREENING )* FIT FREQ ( )
TEST TYPE ( CHEST XRAY )*
LOT|EXPOSURE NO ( ) ( )
RETURN DATE ( - - )

RESULT DATA: RESULT DATE ( 01 - 07 - 16 )
SKIN TEST RESULT ( X ) OR ( )*
ASSESS|PASS FAIL ( ) ( )
XRAY-QUES RESULT ( NAD )*
IF TEST RESULT ( NAD )*
IF TEST RESULT ( - ) ( - )
MED MONTH ( )
COMMENT ( TB EXP2015#4 BASELINE IMMUNECOMPROMISED )
```

Standard PMS Exposure QFT Documentation:

Standard I MIS Ex	posure Qr i Documentation	u.
TEST DATA:	TEST DATE	(01 - 07 - 16)
	DESCRIPTION	(SCREENING)
	TEST TYPE	< QFT >
	APPROV. MANAGER	(H.HERRING, RN)
	PLACE OF TEST	(UCSD LAB)
	RETURN DATE	(00 - 00 - 00)
RESULT DATA:	RESULT DATE	(– –)
	RESULTS	NEGATIVE (X) IU/ML
		POSITIVE () IU/ML
		INDETERMINATE ()
	QFT COMMENTS	(0.012
	EXP COMMENTS	(2015#4 BASELINE
	EXPOSURE NO	(4)

PMS Exposure OFT Documentation Display:

```
LIN TEST DT DESCRIPTION TEST TYPE TEST RESULT DATE START STOP

1 01-07-16 SCREENING QFT NEGATIVE
QFT-COMMENT 0.012
COMMENT 2015#4 BASELINE
```

TB Post-Exposure email Script:

Dear USCD Employee,

While at work on _______, you were exposed to a patient with active tuberculosis

(TB). Although it is difficult to become infected from working with a patient, we need to screen you to be sure that there was no transmission of infection. Two conditions will increase the probability of exposure: Prolonged unprotected contact with an infected individual or presence during a high risk procedure, such as, induced sputum or bronchoscopy. Prolonged contact is defined as your face-to-face presence with an infected individual for one or more hours or a cumulative of four or more hours. Since your last TB test was greater than 3 months ago, we need to establish a baseline result now. Please proceed to any UCSD outpatient lab for a quantiferon gold test. I have ordered the test in EPIC. Please complete this testing by _______ to avoid being locked out in EPIC. In 10 weeks, (approx. ______) you will be notified to again have a quantiferon test, which will be the post exposure result. Please review the attached information about tuberculosis infection and please complete the attached contact investigation form and return by fax. Feel free to contact me if you have any questions.

TB Post-Exposure Investigative Questionnaire:



Employee Tuberculosis Exposure Evaluation

Today's Date:							
TB Case MRN:							
TB Exposure # & Year:							
Date(s) of Exposure:							
Location of Exposure:							
Last Name, First Name:	st Name, First Name: Phone Number: Work email address:						
	()						
Supervisor:	Department:	Job Title:					
DOB:	Gender:	MRN:					
Charlebana							
Check box:		at it is a site of					
	e or more hours of continuous time	e with the patient without the use					
of an N95 respirator? YES NO: Did you spend fou	ur or more hours of sumulative tim	e with the patient, during the same					
shift without the use of an N95 res		e with the patient, during the same					
	in the room during aerosolizing pr	ocedure (e.g. sputum induction					
bronchoscopy, etc.) performed on							
Did you perform any aerosolizing p							
Yes No Please explain:	roccoures on any patient. E.g. spo	real made tion, pronenoscopy					
Were you wearing an N95 mask wh	nen you were with the patient?	Yes No					
, ,	<u> </u>						
Have you had any of the following	symptoms since your exposure?						
None							
Fever							
Cough							
Excessive sweating at night							
Excessive fatigue (tiredness) Coughing up blood							
Excessive/unplanned weight lo							
	/es No Not sure						
Is your immune system weakened either by a condition or by medications? Yes No							
e.g. autoimmune disorder, HIV/AIDS, steroids, chemotherapy, cancer, chronic kidney disease							
Please explain:							
FOR INTERNAL USE ONLY							
Meets the exposure time Baseline TB test/date/result: Follow-up TB test due date:							
threshold? Yes No	baseline 1b test/date/result.	rollow-up 15 test due date.					
Follow-up TB test/date/result:	Final outcome:	LTBI treatment:					
	No Infection LTBI offered scheduled						
		declined; counseled					
Date employee notified of	Date employee notified of Employee sent TB information COEM Contact Dates:						
Exposure:	fact sheet: Yes No						

TB Exposure Fact Sheet (attached to post-exposure email):

EXPOSURE TO TUBERCULOSIS

What is tuberculosis and how is it spread?

Tuberculosis (TB) is a disease caused by a bacterium called mycobacterium tuberculosis that is spread through the air. TB usually affects the lungs, but can also affect other parts of the body. An exposure to TB does not always result in an infection.

What is an exposure to TB?

A person is considered to be exposed if there is shared breathing space with someone with infectious pulmonary or laryngeal tuberculosis at a time when the infectious person is not wearing a mask and the other person is not wearing an N95 respirator. Usually a person has to be in close contact with someone with infectious tuberculosis for a long period of time to become infected; however, some people do become infected after short periods, especially if the contact is in a closed or poorly ventilated space.

What should I do if I am exposed?

You should be evaluated for TB at baseline immediately after the exposure, and again at 10 to 12 weeks after the exposure. Evaluation may require a symptom questionnaire, Quantiferon-gold blood test, and/or a chest x ray. If your TB screening was done within 3 months prior to the exposure, this would count as your baseline, and you will not need another baseline test. You will be contacted by the staff of COEM to arrange for your testing.

What is latent TB infection?

Persons with latent TB infection (LTBI) are infected with the TB bacteria. They usually have a positive reaction to the TB skin test or to the Quantiferon-gold blood test, but do not feel sick and do not have any symptoms. They are not infectious and cannot spread the TB infection to others.

What is TB disease?

In some people, the TB bacteria overcome the defenses of the immune system, resulting in the progression from latent TB to TB disease. Some people develop TB disease soon after infection, while others never develop TB disease or develop it later in life when their immune system becomes weak. Persons with TB disease usually have symptoms and can spread the infection to others.

When will I know for certain whether I've been infected?

The time from infection to development of a positive TB test is approximately 2 to 12 weeks. This is the reason a 2nd TB test is done 10-12 weeks after exposure.

What are the symptoms of active TB?

Feeling sick or weak, weight loss, fever, night sweats, cough, chest pain, coughing up blood. If you develop these symptoms, contact COEM immediately.

ecti	<u> </u>								
Personal TB Risk factors (immuno-	₩ Have you ever had Tuberculosis?	Were you vaccinated with BCG?	History of past positive results?	What screening tests were done?	Date last screened	Previous TB Screening done?	₩ Test reason	Symptoms experienced for more than 3 weeks at a time.	¬ TB Screening
L) Yes No	L Yes No	Yes No NA	L Yes No	TST/PPO QFT CXR Questionaire		Yes No	Step 1 Step 2 Ann Exp 1 Exp 2		-
								Coughing up blood Persi	
								Persistent cough Persistent fever	
								None	

EPIC Indeterminate/Low Mitogen Result Letter:

Dear UC San Diego Health System Employee:

Your QuantiFERON TB test was INDETERMINATE. You will need to repeat this test.

An indeterminate result can be related to either a biological or specimen processing issue.

We have placed another order for Quantiferon TB Gold. You may go to any UC San Diego Health laboratory or TB Control office to have your blood drawn.

We have provided a two week timeframe to allow you to return for your blood draw.

Failure to comply within the timeframe allotted will result in EPIC lock-out or other disciplinary action.

In addition you received a Mask Fit Test with the following results:

Fit testing	1/15/2016	3/11/2015	2/7/2014	2/15/2013
Gerson 2130	-	-	-	Pass
(N95 One Size				
Fits All)	:	• • • • • • • • • • • • • • • • • • •	· •	<u> </u>
3M 1870 (N95		Fail	Pass	Pass
One Size Fits				
All) Retired				
Read only		•	•	-
3M 1870+ Aura	Pass	-	<u> </u>	

Please keep this letter for your records.

Quantiferon TB Gold is a new test used to detect TB infection. Quantiferon TB Gold is approved by the FDA and recommended by CDC as an alternate to the TB skin test. It has the advantage of using highly specific TB antigens that do not cross react with BCG, the TB vaccine.

Your QuantiFERON TB Gold test was performed by the UC San Diego Health SystemLaboratory per the UCSD ATD Standards & TB Control Plan and approved by the Department of Health Services.

EPIC Negative Result Letter:

Dear UC San Diego Health System Employee:

Your Quantiferon TB Test was NEGATIVE.

In addition, you received a N95 Respirator mask fit test with the following results:

1/15/2016	3/11/2015	2/7/2014	2/15/2013
-	-	-	Pass
	:	:	
-	Fail	Pass	Pass
<u> </u>	<u>:</u>	<u>:</u>	
Pass			
	-	Fail	Fail Pass

You will need to return in one year for your annual TB Screening and N95 Respirator mask fit test.

Please keep this letter for your records.

Quantiferon TB Gold is a new test used to detect TB infection. Quantiferon TB Gold is approved by the FDA and recommended by the CDC as an alternate to the TB skin test. It has the advantage of using highly specific TB antigens that do not cross react with BCG (a TB vaccine).

Your Quantiferon TB Gold test was performed by the UC San Diego Health SystemIaboratory per the UCSD ATD Standards & TB Control Plan and approved by the Department of Health Services.

EPIC Positive Result Letter:

Dear UC San Diego Health System Employee:

Your QuantiFERON TB test was POSITIVE. This means that you have been infected with the TB germ. Infection with the TB germ does not always cause active disease. You must contact COEM as soon as possible to schedule follow-up care. Please call (619) 471-9210 to schedule an appointment, Monday-Friday 8am-4pm. Failure to comply may result in EPIC lock-out or other disciplinary action.

QuantiFERON TB Gold is a new test for TB infection that is approved by the FDA and recommended by CDC as an alternate to the TB skin test. It has the advantage of using highly specific TB antigens that do not cross react with BCG, the TB vaccine.

Your QuantiFERON TB Gold test was performed by the UC San Diego Health System Laboratory under the UCSD TB Control & ATD Standards plan approved by the Department of Health Services.

In addition you received a Mask Fit Test with the following results:

Fit testing	1/15/2016	3/11/2015	2/7/2014	2/15/2013
Gerson 2130 (N95	-	-	-	Pass
One Size Fits All)				
3M 1870 (N95 One		Fail	Pass	Pass
Size Fits All) Retired				
Read only				
3M 1870+ Aura	Pass	-	-	-

Please keep for your records.

ATTACHMENT 11: Biosafety Plan

Biosafety Plan http://ucsdhealthcare.ucsd.edu/safetyoffice/

ATTACHMENT 12: CAL-OSHA Appendix C-1 and Appendix C-2) Vaccination Declination Statement

http://www.dir.ca.gov/title8/5199c1.html

§5199. Appendix C1.
Appendix C1 – Vaccination Declination Statement (Mandatory)
The employer shall ensure that employees who decline to accept a recommended vaccination offered by the employer sign and date the following statement as required by subsection (h)(5) (E):
I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring infection with
Employee Signature Date
http://www.dir.ca.gov/title8/5199c2.html
§5199. Appendix C2.
Appendix C2 – Seasonal Influenza Vaccination Declination Statement (Mandatory)
The employer shall ensure that employees who decline to accept the seasonal influenza vaccination offered by the employer sign and date the following statement as required by subsection (h)(10):
I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring seasonal influenza. I have been given the opportunity to be vaccinated against this infection at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at increased risk of acquiring influenza If, during the season for which the CDC recommends administration of the influenza vaccine, I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.
Employee Signature Date

ATTACHMENT 13: Preparedness Plan for Emerging Infectious Diseases

Preparedness Plan for Emerging Infectious Diseases

1. Exposure Control Plans

UC San Diego Health System (UCSDHS) has established protocols for Bloodborne Pathogen (BBP) Exposure Control Plan, and Aerosolized Transmissible Diseases/Tuberculosis Control Plan. The purpose of these control plans is to minimize or eliminate employees' exposure by implementing a range of exposure control measures, including engineering and work practice controls, administrative controls, and use of personal protective equipment (PPE).

These exposure control plans are updated to include emerging infectious disease management to ensure healthcare workers providing care to suspected or confirmed emerging infectious disease patients are protected during the course of treatment.

A. Active Employee Involvement

All employees are encouraged to inform their supervisor or manager about workplace safety to reduce potential risk of disease, injuries, and illnesses. Thus, healthcare workers (HCWs) who are at risk of exposure to an emerging infectious disease or involved in the care of suspected or confirmed infectious disease patients must address their occupational safety concern to their department supervisor or manager.

In reference to UC San Diego Health System's (UCSDHS) Injury and Illness Prevention Plan (IIPP), employees are encouraged to report any potential health or safety hazard to the Safety Office. They should realize there are no reprisals for expressing a concern, comment, or suggestion or complaint about a safety matter. If desired, employees can anonymously report safety issues through our Safety Plus Website. Such reports are given a priority with documented follow up activities. Adherence to safe work practices and proper use or personal protective equipment is integral parts of workplace safety.

Active involvement of employees on safety matters within the UC San Diego Health System is stipulated in the Health System's Injury and Illness Prevention Plan and in the Environment of Care Program (MCP 811.1).

B. Exposure Determination

The following UCSDH medical personnel are determined to be at the higher risk of exposure to an emerging infectious disease because they are directly involved with providing care to suspected or confirmed infectious disease. These medical providers the following:

• Emergency Medicine medical doctors and nurses

- All medical providers assigned to Infectious Disease Care Unit (IDCU)
- Medical doctors and nurses from Medical staff assigned to other departments where suspected infectious patients are likely to be admitted
- Medical doctors and nurses from Critical Care, Ambulatory, and OB
- Respiratory Therapists
- Infection Prevention and Clinical Epidemiology (IPCE) staff

Allied HCWs who are providing operational support to this core group of medical providers are also at risk of exposure to an infectious disease. These allied healthcare workers are the following:

- Respiratory therapists
- ED technicians
- Support medical staff assigned to IDCU but not directly in contact with suspected or confirmed Ebola patients
- Environmental Services staff

A complete list of all UC San Diego healthcare worker job classifications determined to be at risk for occupational exposure is listed in the Health System's Bloodborne Pathogen Exposure Control Plan. Further, the Health System's Aerosolized Transmissible Diseases Standard/Tuberculosis Control Plan provides a comprehensive procedure in minimizing the risk for transmission of aerosol transmissible disease (ATD) infection.

C. Engineering Control

The Infectious Disease Care Unit (IDCU) is the official Ebola treatment area at UCSDHS. This is an isolated area away from the general patient population. The IDCU is constructed in different isolation rooms and designated for a specified functionality. These rooms are:

- Treatment room
- Observation room
- Donning room
- Doffing room
- Soiled utility room
- Doffing observer room
- Clean changing room
- Staff waiting area

In addition, this unit has negative air pressure, which means the air pressure inside the isolation room is slightly lower than that outside so particles from inside the room cannot float out. IDCU runs its own air circulation system and the air is passed through a high-efficiency particulate air (HEPA) filter before it is vented outside of the building.

More comprehensive IDCU information can be found in the document, *UC San Diego Infectious Disease Care Unit (IDCU), and Staffing Plan.*

D. Work Practice Control

Only IPCE team can activate IDCU and the Hospital Command Center (HCC). When the HCC is activated, the Nursing Supervisor is the incident commander until the administrator-on-call (AOC) arrives.

The Isolation and transfer procedures and protocols, along with work practice controls, are delineated in IDCU's Patient Flow Protocols consisting of the following:

- a. Path of Travel
 - Admission to Hillcrest Pathway
 - Admission to Thornton Pathway
 - Admission Request to Transfer Center
- b. Patient Flow
 - Direct Admission Ebola Viral Disease Screening
 - Patient Transport for Suspected/Known emerging infectious disease
 - Suspect infectious disease Patient Contact Tracer
- c. Clinical Laboratory Emerging infectious disease Handling Procedure

The procedure for collection, transport, and testing performed on any clinical specimen in the clinical laboratories is clearly defined in the UC San Diego Health System's documents, *Enhanced Precautions for Collection, Transport, and Testing of Clinical Specimens from patients with suspected infectious disease* and *IDCU protocol for Testing, Malaria testing, and Blood cultures*.

E. Personnel Protective Equipment

Healthcare providers caring for suspected or confirmed infectious disease patients should have no skin exposed. Therefore, all healthcare workers directly involved with caring for such patients must wear the proper personal protective equipment (PPE) provided by UCSDHS.

There are two different PPE configurations that must be worn by healthcare providers in providing care for infectious patients.

- a. Level 1: involves donning and doffing of lower level protective equipment which is used for patients that do not have uncontrolled infectious fluids.
- b. Level 2: involves donning and doffing a higher level of protective equipment which is used for patients that excrete infectious body fluids.

The following lists are the authorized PPE for each degree level.

- a. Level 1 PPE
 - Boots cover
 - Nitrile ambidextrous gloves
 - Surgical gloves
 - Fog-free surgical mask with lining

- AAMI 4 Breathable High Performance Gown
- Washable boots
- Surgical hood
- Scrubs

b. Level 2 PPE

- Powered Air Purifying Respirator (PAPR) and Hood
- AAMI 4 Breathable High Performance Gown
- Washable boots
- Boots cover
- Nitrile ambidextrous gloves
- Surgical gloves
- Cap (if needed)
- Impermeable apron
- Tyvek Coverall Tychem
- Scrubs

Proper PPE is required for all healthcare workers entering the room of a patient hospitalized with an infectious disease. Each step of every PPE donning/doffing procedure must be supervised by a trained observer to ensure proper completion of established PPE protocols.

Procedures for donning and doffing of Level 1 and Level 2 required PPE are found in the following documents:

- a. Donning PPE, Level 1
- b. Doffing PPE, Level 1
- c. Donning PPE, Level 2
- d. Doffing PPE, Level 2

F. Medical services

The IDCU is a free standing unit designed to provide care to suspected or confirmed infectious patients. The level of staffing and medical services is covered in the document, *UC San Diego Infectious Diseases Care Unit (IDCU) and Staffing Plan*.

Under the Bloodborne Pathogens (BBP), Aerosolized Transmissible Diseases (ATD), IIPP, and Respiratory Protection standards, UCSDHS provides medical services to employees, such as vaccinations, medical evaluation for the use of respirators, and post-exposure follow-up. In addition, all employees who will use respirators must be given a medical evaluation to determine whether the employee can safely use a specific type of respirator under the conditions at the worksite.

All employees involved in direct or indirect patient care or waste management are required to measure their temperature and complete a symptom questionnaire twice daily from the first shift on the Unit until 21days from the last shift worked on the Unit. COEM will review the data on a daily basis and follow up with employees as indicated.

G. Training

As part of the comprehensive and coordinated response to treating infectious disease patients, UCSDHS IPCE team provides continuous training for licensed clinicians (e.g. physicians, nurses, and allied healthcare providers). All medical providers engaged with providing care to patients with infectious diseases, and all allied healthcare workers providing support to these medical providers must undergo intensive training and drills on all aspects of care, including the proper and safe use of PPE.

The training must be geared towards the methodology of preventing employees' exposure to any recognized hazards while providing care to suspected or confirmed infectious disease patients. The following training for protecting healthcare workers whose work activities are conducted in an environment that is known or reasonably suspected to be contaminated with an infectious disease must include but not limited to:

- a. Application of good infection control practices, complying with applicable requirements in the Bloodborne Pathogens Exposure Control Plan, Personal Protective Equipment, Respiratory Protection Program, and Aerosolized Transmissible Diseases Standards.
- b. Knowledge on the following standards:
 - Bloodborne Pathogen
 - Respiratory Protection
 - Aerosolized Transmissible Diseases Prevention
 - Injury and Illness Prevention Plan
- c. Employees' participation in reviewing and updating the exposure control plans.
- d. Use of proper personal protective equipment (e.g. hands-on training on the donning and doffing of PPE).
- e. Practice good hand hygiene protocols to avoid exposure to infected blood and body fluids, contaminated objects, or other contaminated environmental surfaces.
- f. Cleaning and decontamination of infectious disease on surfaces.
- g. Safe handling, transport, treatment, and disposal of infectious disease contaminated waste.
- h. Sources of infectious disease exposure and appropriate precautions.
- i. Control measures used to prevent employee exposure
- j. Access to medical care or services

2. Personal Protective Equipment (PPE)

Healthcare providers wearing PPE ensemble are subjected to additional workload on their body. Under the Injury and Illness Prevention Program (IIPP) standard and UCSDHS Respiratory Protection Program, hospital employers must establish work regimens allowing employees sufficient

time and opportunity to recover, and they must monitor the health status of employees using the PPE ensemble.

UCSDHS Center for Occupational and Environmental Medicine (COEM) provides medical evaluation, assessment, and medical monitoring of healthcare workers during the course of providing care on Ebola patients.

IDCU provides onsite management and oversight on the safe use of PPE and implement administrative and environmental controls with continuous safety checks through direct observation of healthcare workers during the PPE donning and doffing processes.

3. Respiratory Protection

Basic principles of respiratory protection dictate that employers select respirators based on the respiratory hazard to which the employees are exposed, as well as workplace and user factors that affect respirator performance and reliability.

UCSDHS Respiratory Protection Program is in place to protect employees by establishing accepted practices for respirator use, providing guidelines for training and respirator selection, and explaining proper storage, use and care of respirators.

All healthcare workers engaged with the care of infectious patients are issued the correct configuration of respirators (e.g. PAPR and N-95 respirators), depending on the provision of the level of care (e.g. Level 1 or Level 2).

Cleaning of the PAPR after its use is found in the document, *PAPR Reprocessing: New Clean Nurse Duties.*

4. Environmental Services:

Waste generated in the care of patients with known or suspected infection is subject to procedures set forth by local, state and Federal regulations. Basic principles for spills of blood and other potentially infectious materials are outlined in the Bloodborne Pathogen Exposure Control Plan.

All waste generated from suspected/confirmed patient should be treated as special Category A infectious substance regulated as hazardous waste under the Department of Transportation (DOT) Hazardous Material Regulation.

IDCU has established protocols for safe handling, transport, and disposal of infectious contaminated waste stipulated in the following documents:

- a. Environmental Services Module
- b. Waste Management for Patients with infectious disease
- c. Cleaning of the Clinical Care Environments
- d. Donning of Environmental Services PPE
- e. Doffing of Environmental Services PPE