DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF
DASG-PPM-SA

27 MAY 2003

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Army Latent Tuberculosis Infection (LTBI) Surveillance and Control Program

1. Purpose. The enclosed document prescribes policy and procedures for testing, evaluation, treatment, monitoring, referral, documentation and tracking of Army personnel and beneficiaries requiring tuberculin skin testing (TST). The goal is to identify and treat those infected with tuberculosis as soon as possible after exposure and while still in the latent stage.

2. Scope. This policy applies to all medical activities in the U.S. Army, who will develop implementing standard operating procedures.

3. Policy Summary.

a. Program management responsibilities are delineated and include advanced practice Community Health Nurses among those who can initiate LTBI treatment.

b. TSTs are required for new accessions, beneficiaries with risk-enhancing clinical conditions, personnel undergoing separation, employees in high-risk occupations, and inmates of detention facilities. Travel-related TSTs are only required when Army soldiers, family members, civilians or contractors travel (PCS or deploy) to areas where the endemic incidence rate of active tuberculosis (TB) disease is high (ie, equal to or greater than 25 new cases per 100,000 persons annually). Country-specific incidence rates of tuberculosis are provided in the World Health Organization's annual report on Global Tuberculosis Control (http://www.who.int/health-topics/tb.htm). Use of this threshold eliminates the requirement for TSTs for personnel traveling to most of Western Europe, for example. TSTs should be performed both prior to and after completion of travel according to guidance in the enclosure.

c. Health care workers and those with increased occupational risk should have initial two-step TSTs.

d. Routine baseline laboratory testing is no longer needed for those with positive TSTs in the absence of other risk factors.

e. Occupation and TB disease risk will be considered in selecting a treatment regimen or temporary deferment of treatment. The introduction of short-term therapies plus the increase in op tempo and associated medication costs add an extra dimension to selecting a treatment regimen (paragraph 6b, Enclosure).

f. Electronic entry of the test and manufacturer/lot number into the Military Occupational Database System/Medical Protection System is required for soldiers as will be future use of Composite Health Care System II as an electronic registry. Use of other local electronic databases is approved in conjunction with the Military Occupational Database System/Medical Protection System.

4. Point of contact is LTC Lois Borsay, Proponency Office for Preventive Medicine – San Antonio, DSN 471-7998 or Commercial (210) 221-6612.

Encl
as

JAMES B. PEAKE, M.D.
Lieutenant General
The Surgeon General

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Commander, U.S. Army Special Operations Command, ATTN: Surgeon, Fort Bragg, NC 28307-5200

THE ARMY LATENT TUBERCULOSIS INFECTION SURVEILLANCE AND CONTROL PROGRAM

1. Purpose. The purpose of the Army Latent Tuberculosis Infection Surveillance and Control Program is to prevent active tuberculosis cases through the identification and treatment of persons with latent tuberculosis infection (LTBI).

2. References.

a. Army Regulation (AR) 40-5, Preventive Medicine, 15 Oct 90.

b. AR 40-66, Medical Records Administration and Health Care Documentation, 3 May 99.

c. American Thoracic Society: Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children, 1993.

d Armed Forces Epidemiology Board (AFEB) Recommendations Regarding "Risk-based Tuberculosis Screening Policies and New Technologies," 12 May 2000, at http://www.ha.osd.mil/afeb/2000/2000-04.pdf

e. World Health Organization Report 2002-Global Tuberculosis Control: Surveillance, Planning, Financing, at http://www.who.int/gtb/publications/globrep02/index.html

f. American Thoracic Society: Diagnostic Standards and Classification of Tuberculosis, 1999.

g. Core Curriculum on Tuberculosis, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of Tuberculosis Elimination, Fourth Edition, 2000, at www.cdc.gov/nchstp/tb/pubs/corecurr/CoreCurronTB.pdf

h. Morbidity and Mortality Weekly Report: Centers for Disease Control and Prevention. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis. MMWR 2000,49:RR-6.

i. Memorandum, Office of The Surgeon General, DASG-PPM-NC, 9 July 2002, subject: Post-deployment Screening for Latent Tuberculosis Infection (LTBI).

3. Program Management.

a. The Chief, Preventive Medicine, is responsible for implementing local TB surveillance and control activities. The Chief, Community Health Nursing, or designee, manages local TB surveillance and control activities.

b. A preventive medicine physician, or other privileged provider, initially evaluates individual patients with LTBI and prescribes appropriate chemoprophylaxis.

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c. Staff Community Health Nurses are authorized to refill isoniazid and pyridoxine via specific medical protocols approved by a preventive medicine physician or other designated physician. Management of pediatric LTBI patients will be determined by the individual military treatment facility (MTF) based on coordination among Chiefs of Preventive Medicine, Community Health Nursing, Pediatrics and Primary Care.

4. Testing.

a. Groups to be tested.

(1) For personnel not previously known to have a positive Tuberculin Skin Test (TST), skin tests will be administered to:

(a) Health care beneficiaries based on risk in accordance with current Centers for Disease Control and Prevention (CDC) guidelines. (Pregnancy and prior Bacille Calmette-Guerin (BCG) vaccination are not contraindications to TST.)

(b) Personnel on initial entry for active duty of 30 days or more as part of reception processing. ROTC cadets participating in Advanced Camp training do not require TST testing.

(c) Military personnel, civilian employees, contractors, or family members who travel (PCS or deploy) to and reside in a geographic area of the world where the endemic incidence rate of active tuberculosis disease is high (ie, equal to or greater than 25 new cases per 100,000 persons annually). TSTs should be performed both prior to and after completion of travel. Deploying personnel should have a TST performed prior to travel, at the time of redeployment, and again at 3 to 6 months after redeployment. The following areas are considered low threat areas for tuberculosis. Personnel who travel only to these locations do <u>not</u> require skin testing:

(1) Canada, Greenland, Iceland
(2) Cuba
(3) Chile, Costa Rica, French Guiana
(4) British Isles
(5) Norway, Sweden, Finland, Denmark, France, Belgium, Netherlands, Luxembourg, Monaco, Switzerland, Austria, Germany, Czech Republic, Italy, Greece, Cyprus
(6) Australia, New Zealand
(7) Lebanon, Libya, Jordan, United Arab Emirates, Oman, Qatar
(8) Libya

(d) Military personnel undergoing separation, or retirement physical examinations, unless one has been administered within the past 12 months.

(e) Prospective employees (military and civilian), students, and volunteers as a condition for employment in health care facilities, schools, or in other facilities where

tuberculosis transmission is of substantial concern, as defined by the CDC, state law or local ordinance. Additional periodic screening will be based on occupational risk.

(f) Contracting officers and their representatives will include requirements in all contracts to ensure that contractors and their employees undergo tuberculin skin testing whenever said employees are working in an environment in which DoD employees would normally be required to undergo this testing. Tuberculin skin testing will be paid for by the contractor.

(g) Inmates of detention and confinement facilities IAW CDC guidelines.

(2) For individuals known to have a positive TST previously, as per CDC guidelines based on risk, no further TSTs will be applied. Exceptions to this rule to be considered include: clinically valid doubt about previously recorded result (e.g. talking with the patient reveals that prior reading ignored induration), borderline result categorized as 'positive' at prior test time (e.g., 9mm reaction in a patient with questionable risk factors, not previously treated); and those cases for whom a 10mm increase in reaction size or other factors might warrant treatment.

b. Tuberculin Skin Testing.

(1) The standard tuberculin skin test to be used by the US Army Medical Department is the Mantoux test (as described below). While other tests for tuberculosis are available (eg, multi-puncture devices/tine tests), these are not reproducible and are less sensitive and should not be used.

(2) The Mantoux test is the intradermal injection of 0.1 milliliter of purified protein derivative (PPD) tuberculin containing 5 tuberculin units. Administration, classification and interpretation of reactions to the Mantoux test will be according to guidelines published by the CDC. The area of induration (palpable raised hardened area) around the site of injection is the reaction to tuberculin. The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis). Erythema (redness) should not be measured. All reactions should be recorded in millimeters, even those classified as negative. If no induration is found, "0 mm" should be recorded. Reactions as small as 5 mm may be classified as "positive," depending on the presence of various risk factors. If the reading is indeterminate or the patient fails to return within 72 hours, the tuberculosis test should be very carefully repeated in the opposite arm, unless one of the following factors is present:

(a) Readable induration may persist up to one week after test placement. If the result is clearly positive after 96 hours, the patient should be referred to a qualified physician for evaluation.

(b) There is suspicion of hypersensitivity to a component of PPD based on history or residual clinical findings.

(3) TST sensitivity and immunity to tuberculosis after receiving BCG vaccine is highly variable. As well, there is no reliable method for distinguishing tuberculin reactions caused by BCG from those caused by natural infection. Since the incidence of TB is high in countries with BCG vaccination programs, a positive TST should be evaluated independently of BCG history. See CDC guidelines.

(4) Administration and reading of TSTs requires special training. Local policies should define who qualifies to administer and read TSTs and should require written certification of such individuals. Qualified personnel will receive annual retraining in the administration and reading of TSTs.

(5) TST may be placed concurrently with live-virus vaccines or delayed until at least 4 weeks after live-virus vaccine administration.

(6) Any medical condition or medication that suppresses cellular immunity may interfere with the reliability of TST results and should be considered in the screening process for the test and test interpretation. Although not usually necessary or recommended, an anergy panel (delayed type hypersensitivity skin testing) may be helpful in evaluating the degree of cellular immunosuppression. Individuals who are partially or completely anergic are at increased risk of being unable to respond normally to TST. Referral to allergy-immunology for questions regarding immunodeficiency may be indicated.

(7) To reduce the likelihood that a boosted reaction will be misinterpreted as recent infection, two-step testing should be conducted as the initial testing for person who will be tested periodically, i.e., health care workers. In two-step testing, if an initial placement is negative, a second test is placed 1-3 weeks later on the other arm. A positive result indicates the second test is probably a boosted reaction (past infection or previous BCG immunization). The individual should be managed based on the results of the second test. If a boosted reaction is observed, it is not considered a skin test conversion. If the second test is negative, consider the person uninfected.

(8) Classification of the TST reactions will follow current CDC/American Thoracic Society (ATS) guidelines. A TST "reactor" is defined as an individual who has a positive skin test per CDC guidelines. A TST "converter" is defined as an individual who has an increase of 10mm or greater in the size of induration within a 2-year period, regardless of age.

5. Evaluation and Referral.

a. Medical Evaluation. For individuals identified for the first time as TST-positive, a medical evaluation (as defined in the CDC guidelines) will be performed to determine if active disease is present and to determine if there are risks or contraindications to chemoprophylaxis. The evaluation will include a careful medical history eliciting signs or symptoms suggestive of infection and a chest x-ray. A posterior-anterior radiograph of the chest is the standard view used for the detection and description of chest abnormalities. In some instances other views

(e.g., lateral, lordotic) or additional studies (e.g., CT scans) may be necessary. Information on medical history and results of diagnostic tests (e.g., chest radiographs) will be entered in the medical record.

b. All individuals with a positive TST will be referred to Army Community Health Nursing and will receive a medical evaluation by a physician or other appropriately privileged provider for consideration of preventive treatment for LTBI.

6. Treatment and Monitoring of LTBI.

a. Treatment Regimens. Treatment regimens have been published by the CDC and provide guidance on drugs, intervals and duration for LTBI treatment. Selection of the appropriate regimen is based on clinical evaluation and consultation with a physician. Preferred specialists for prescribing initial treatment are physicians certified in a preventive medicine specialty (including public health and occupational medicine), internal medicine, credentialed community health nurses with prescriptive authority, or any primary care physician with special training or experience in LTBI (i.e.: allergy-immunology, infectious or pulmonary disease specialists). If there is any doubt about the possibility of active disease, the preferred consultant is a pulmonary or infectious diseases specialist.

b. Treatment of individuals with LTBI who are deploying may be deferred. Recommendation for deferral is made by the evaluating provider on a case-by-case basis (see para 3b, above). Relevant factors to consider in this decision include how recently the infection occurred, operational duties of the individual, and the capabilities of medical support during deployment.

c. For pregnant women with LTBI, decisions to initiate prophylactic treatment will be made in consultation with the practitioner managing her pregnancy.

d. Patients on chemoprophylaxis for LTBI will be provided appropriate education on the disease process, medication and their individual treatment plan. The treatment plan and education provided will be documented on a locally produced DA 4700 overprint, SF 600 nursing note or equivalent printable electronic medical record.

e. All treatment decisions will be made as a consultation with the patient's primary care manager. For children under the age of 13, the decision to initiate treatment will be made in consultation with a pediatrician, or with a family practitioner who manages pediatric patients. The responsibility for follow-up visits and monitoring of pediatric patients will be made by the local MTF commander in consultation with the Chief, Pediatrics; Chief, Preventive Medicine; and Chief, Community Health Nursing.

f. Baseline laboratory testing is not indicated routinely at any age. Baseline hepatic enzymes are checked in patients with viral hepatitis or HIV who are pregnant or have delivered within the last 3 months, who use alcohol regularly, or who have other history or risk of liver

disease. Laboratory monitoring during treatment is indicated for patients with abnormal baseline evaluation, high risk for hepatic disease, HIV, pregnancy or other symptoms of hepatotoxicity. If transaminase levels exceed three times the upper limit of the normal range of the laboratory, a physician or other appropriately privileged provider makes a recommendation on the continuation of treatment with consideration of tuberculosis disease risk and the need for close clinical monitoring.

7. Documentation and Tracking.

a. The date of testing for all TSTs on active duty, USAR and National Guard soldiers will be entered into the database of the Military Occupational Database System/Medical Protection System (MODS/MEDPROS). Individuals with positive test results, as per CDC guidelines, will have the medical exemption code, Medical Permanent (MP) entered into MODS/MEDPROS, to document no further testing. The test results, manufacturer and lot numbers for all TSTs will be documented in the medical record and shot records. Upon redeployment, deployment-related fields will be updated in MODS/MEDPROS including: dates of departure and return, deployment location and the name of the operation.

b. In addition, a local tuberculosis registry will be maintained by Army Community Health Nursing of all persons under treatment for active disease and LTBI. This registry will also include contacts of active disease cases requiring medical follow-up. DA Form 3897-R (Tuberculosis Registry) will be used for this purpose and will be locally reproduced. DA Form 3897-R is located at the back of this regulation. Use of electronic databases is authorized when associated with IM/IT protections and IAW Health Insurance Portability and Accountability (HIPAA) requirements but still must be annotated in MODS.

c. For personnel being treated for LTBI who are undergoing a change of station, DA Forms 3897-R and 3763 will be mailed or sent electronically to the supporting Preventive Medicine Service of the gaining organization to ensure continuity of care. If there is no MTF available, the person will be referred to the local public health department or designated health care provider. The individual will be counseled prior to his or her departure.

d. For personnel under treatment departing military service, the Preventive Medicine Service of the supporting MTF will notify the appropriate health department where the individual will be living. For Reserve and National Guard soldiers leaving active duty, a referral will be made to the soldier's home unit where follow-up will be conducted under the Feds Heal program. The Veterans Administration ordinarily assumes responsibility for military separatees who are under active surveillance for LTBI.

e. Medical records will be annotated to reflect TST test results, to include a specific record of the size of induration. Lot number and manufacturer of PPD material used must be recorded, along with the date and name of the test interpreter Personnel are not authorized to read their own skin tests. For individuals with a documented history of a prior positive TST, an annotation will be made in the medical record to reflect when that evaluation was performed. If anti-TB

therapy had been instituted, this information, along with details of duration of therapy and recommendations for follow-up, will be recorded in the record. TST results will be documented on the DD 2766 PPIP flowsheet, on HHS Form PHS 731 (International Certificates of Vaccination) and in the appropriate electronic format as available.

f. The Composite Health Care System (CHCS II) as an electronic health record will meet the functional requirements of a centralized electronic registry in order to track and store data while ensuring patient privacy. It is Army policy to use this system when it is on-line.

8. Coding. The following International Classification of Diseases, 9th edition, Clinical Modification (ICD-9-CM) codes are to be used for entering visits related to tuberculosis surveillance and control:

a. V74.1 Screening examination for pulmonary tuberculosis.

b. V01.89 Contact with or exposure to other communicable diseases.

c. V01.1 Contact with or exposure to tuberculosis.

d. V68.1 Issue of repeat prescriptions.

e. V72.7 Diagnostic skin and sensitization tests.

9. Program Management Forms.

a. DA Form 4700/MCEUL OP 525: Preliminary Evaluation of Tuberculin Skin Test Reactor.

b. DA Form 5569-R: Isoniazid (INH) Clinic Flow Sheet.

c. DA Form 3897-R: TB Registry Card.

d. DA Form 3763 - AEM OP 40-71B-R: Community Health Nursing - Case Referral.

e. DD 2766 PPIP flow sheet.

f. PHS 731: International Certificate of Vaccination.

g. DA Form 600/MCEUL OP 108. Annual Tuberculosis Screening for Health Care Workers.