



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
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REPLY TO
ATTENTION OF

AFEB (15-1a) 00-4

12 May 2000

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiology Board (AFEB) Recommendations
Regarding "Risk-based Tuberculosis Screening Policies and New
Technologies"

1. At the 28-29 February meeting of the AFEB, the Board was asked by the Air Force Medical Operations Agency (AFMOA) to review current Armed Forces tuberculosis screening policies and make recommendations for modifications to the current policies (enclosed). Specifically, the Board was asked to assess three issues.

- Recommend tuberculosis screening approaches (including optimal frequency, cut-offs, role of two-step testing, and quality assurance) based on potential risks of deployment, overseas assignment, or other factors;
- Provide priorities for further research; and
- Define desirable capabilities or characteristics of new diagnostic tests.

2. A series of presentations were made to the Board on the subject of tuberculosis. These included:

- An overview of tuberculosis in the military.
- An outbreak of tuberculosis on a Navy ship.
- A pseudo-outbreak of tuberculosis on a Coast Guard cutter.
- An analysis of risk factors for tuberculosis skin test (TST) conversions in Air Force personnel.
- A series of presentations on a recently developed whole blood assay for tuberculosis infection and its evaluation in military personnel.

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a. Studies of incoming Navy recruits demonstrated that approximately 3-4% have positive TSTs upon entry, and that foreign born recruits have consistently higher rates of TST-positivity than recruits born in the United States. TST skin test conversions (from negative to positive) do occur during military service, and risk factors can be identified which are associated with conversion, such as deployment or overseas tours of duty in the Pacific-rim countries. Despite the prevalence of positive skin tests on enrollment and skin test conversions, the number of cases of active tuberculosis in military personnel is low and has consistently declined in recent years.

b. As demonstrated by a recent outbreak of tuberculosis on the USS WASP, tuberculosis remains a concern in military settings. In this outbreak, a number of administrative problems were seen. This included delayed diagnosis of illness in the source crew member, delays in the reporting of the diagnosis once the source crew member was removed from the ship, inadequate screening of shipboard personnel once the diagnosis was reported, and failure to complete preventive therapy. These factors perpetuated the outbreak.

c. A pseudo-outbreak of tuberculosis infections on a Coast Guard cutter illustrates issues related to tuberculosis screening which have also occurred in other military settings. The current tuberculin skin test has a number of problems. It requires experience to administer and read, is subject to inter-observer bias, and can easily be misinterpreted. The test is affected by factors such as infection with non-tuberculous mycobacteria, immune status, and previous administration of BCG vaccine; test results can vary from lot-to-lot and when preparations from different manufacturers are used. Different interpretation schemes have been employed. The Advisory Committee on the Elimination of Tuberculosis of the Centers for Disease Control and Prevention recommends the use of different cutoff values based on the presence or absence of specific risk factors for tuberculosis infection. The military services have employed these recommendations with varying success. A final problem with the current skin test is that it requires two health care interactions: One to administer and the second to read the test

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result 48 hours later. In some military situations, particularly with reservists, this poses logistical challenges.

d. The military services have established different policies for tuberculosis screening. To some degree, these differences are justified based on circumstances specific to each service branch. However, all require baseline screening at entry with repeat testing during periodic routine physicals (if previous tests are negative), and all require testing in association with deployments and overseas tours-of-duty. Compliance with these requirements poses logistical challenges and varies among the services. Even more problematic is the delivery of preventive therapy when positive skin tests are found on service entry or when skin test conversions occur. Little information is available about completion rates for preventive therapy, and there is anecdotal evidence to suggest it is not optimal. None of the services have the resources to deliver directly observed preventive therapy. However, based on the low number of cases of active tuberculosis observed in military populations, it would appear that preventive therapy success is high or the currently available data overestimate the prevalence of infection.

e. Because of the low rates of active tuberculosis and problems administering the tuberculin skin test, there is a desire to review and simplify current policies related to tuberculosis screening. Such simplification can take several forms, including changing the frequency of, and criteria for, tuberculosis screening. Another is to change to a different test method for evidence of infection.

1) There has long been a desire to develop a test for tuberculosis infection which is more reliable than the skin test method. Recently, a whole blood cell assay has been developed which detects the presence of t-lymphocytes activated against *M. tuberculosis* due to prior exposure. The assay comes as a kit which also determines immune responsiveness and prior infection with non-tuberculous *Mycobacterium avium* complex. These additional assays improve test performance by eliminating two of the common causes of false-positive and false-negative

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assays with the skin test. The Australian developers of the assay have already successfully marketed a similar test for bovine tuberculosis.

2) To date, the whole blood cell assay has only been tested in research settings and is not licensed for use by the Food and Drug Administration. CDC is currently funding a series of studies to address its performance against the TST in the United States. The U.S. Navy has done a head-to-head comparison of the two tests at the Great Lakes Training Center. Although these studies have not been published, data were presented to the Board which showed generally similar results. Recognizing that there is no "gold standard" for tuberculosis infection, there is significant correlation between the two tests. However, there are also significant numbers of discrepancies, with TST-positive individuals who are whole blood cell assay-negative, and vice-versa. In the Great Lakes study, the whole blood cell assay appeared to be more "sensitive," in that the percent of recruits who were positive with this assay 8% was significantly higher than the percent who were positive with the TST 2.7%, even when different cutoff values for the TST were applied. Because the whole blood cell assay is unlicensed, individuals who were positive in this test but negative by TST were not given preventive therapy. Unfortunately, due to the nature of the study, it is not possible to follow these individuals in longitudinal fashion with the two tests or to determine whether they are at higher risk of developing tuberculosis.

3) Cost comparisons suggest that there may not be significant differences in cost between the two tests. While the whole blood cell assay is more expensive than the TST, there are significant cost offsets because only one patient encounter is required. One problem with the whole blood cell assay is that the test must be performed within 12 hours of blood draw, a significant issue in many military settings. There is little information about performance of the test outside of rigorous research settings. Given the variety of clinical testing sites in the military, this could significantly affect the reliability of the assay.

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3. In light of these findings, the Board recommends the following in response to the questions posed to it.

a. WHAT IS THE OPTIMAL FREQUENCY OF SCREENING FOR TUBERCULOSIS IN MILITARY PERSONNEL?

- 1) ALL RECRUITS SHOULD UNDERGO TUBERCULOSIS SCREENING AND RECEIVE PREVENTIVE THERAPY WHEN INDICATED. ALL PERSONNEL WHO ARE NOT POSITIVE ON ENTRY SHOULD UNDERGO TUBERCULOSIS SCREENING AT THE TIME OF PERIODIC ROUTINE PHYSICAL EXAMINATIONS (EVERY 1-5 YEARS DEPENDING ON AGE AND SERVICE). CURRENT POLICIES REGARDING TUBERCULOSIS SCREENING AFTER A KNOWN EXPOSURE TO AN INDIVIDUAL WITH ACTIVE TUBERCULOSIS SHOULD BE FOLLOWED.
- 2) SCREENING IS CURRENTLY RECOMMENDED PRE- AND POST-OVERSEAS DEPLOYMENT OR TOUR-OF-DUTY. THE INTERVALS FOR SUCH SCREENING TO BE DONE (PRE AND POST) VARY WITH THE SERVICE. THE NECESSITY FOR SUCH SCREENING IS QUESTIONABLE, PARTICULARLY FROM THE COST-BENEFIT POINT OF VIEW IN LIGHT OF THE OVERALL LOW RATES OF TUBERCULOSIS. WE BELIEVE THAT CONSIDERATION SHOULD BE GIVEN TO EPIDEMIOLOGIC INFORMATION REGARDING THE SITE, LENGTH, AND NATURE OF THE DEPLOYMENT OR TOUR-OF-DUTY IN MAKING DECISIONS ABOUT WHETHER SCREENING IS NEEDED. SOME OVERSEAS LOCATIONS HAVE RATES OF INDIGENOUS TUBERCULOSIS WHICH ARE LOWER THAN THE RATE IN THE UNITED STATES. EXAMPLES INCLUDE MANY COUNTRIES OF WESTERN EUROPE. A TOUR OF DUTY IN SUCH A LOCATION SHOULD NOT SIGNIFICANTLY INCREASE THE RISK OF TUBERCULOSIS INFECTION ABOVE WHAT IT WOULD BE IN THE UNITED STATES. THE AFEB DOES NOT RECOMMEND TUBERCULOSIS SCREENING POST-DEPLOYMENT OR TOUR OF DUTY IN LOCATIONS WITH RATES OF TUBERCULOSIS EQUAL TO, OR LOWER THAN, THE UNITED STATES. SIMILARLY,

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DEPLOYMENTS TO AREAS WITH A HIGHER INCIDENCE OF INDIGENOUS TUBERCULOSIS MAY ALSO NOT CARRY A SIGNIFICANTLY INCREASED RISK IF THERE IS LITTLE CONTACT WITH THE LOCAL POPULATION. NONETHELESS, THE AFEB WOULD RECOMMEND POST-DEPLOYMENT OR TOUR-OF-DUTY TESTING.

- 3) WE RECOGNIZE THAT IT MAY BE DIFFICULT TO DEVISE A POLICY WHICH CALLS FOR AN EPIDEMIOLOGIC EVALUATION OF THE RISK OF TUBERCULOSIS EXPOSURE AS THE BASIS FOR SCREENING RECOMMENDATIONS. HOWEVER, HOST COUNTRY INDICES AND OTHER RISK FACTORS WHICH CAN BE QUANTIFIED COULD BE DEVELOPED TO FORM THE BASIS FOR AN EASY TO USE SCORING SYSTEM. IF WIDELY APPLIED, THE LIKELY RESULT WOULD BE TO DECREASE THE TOTAL NUMBER OF SCREENINGS CONDUCTED, WHICH SEEMS APPROPRIATE IN LIGHT OF THE LOW RATES OF ACTIVE DISEASE.
 - 4) SCREENING POLICIES SHOULD BE HARMONIZED AMONG THE MILITARY BRANCHES. HOWEVER, THERE ARE CERTAIN UNIQUE CIRCUMSTANCES WHICH SHOULD REQUIRE MORE FREQUENT SCREENING. THE CLOSE CONFINEMENT OF SHIPBOARD OR SUBMARINE SERVICE HAS CONSISTENTLY BEEN ASSOCIATED WITH TUBERCULOSIS TRANSMISSION WHEN SOMEONE WITH ACTIVE DISEASE HAS BEEN ONBOARD. WE BELIEVE THAT ANNUAL SCREENING OF PERSONS IN THESE SETTINGS SHOULD BE CONTINUED. SIMILARLY, CDC SCREENING RECOMMENDATIONS FOR HEALTH CARE WORKERS AND OTHER HIGH RISK PERSONNEL SHOULD BE FOLLOWED.
- b. WHAT CUTOFFS SHOULD BE EMPLOYED FOR TUBERCULOSIS SKIN TEST SCREENING?

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THE CUTOFFS CURRENTLY RECOMMENDED BY CDC SHOULD BE USED FOR MILITARY SCREENING PROGRAMS (SEE ENCLOSED TABLE). ALTHOUGH THE CDC CUTOFFS ARE MORE COMPLICATED THAN USE OF A SINGLE VALUE TO GUIDE PREVENTIVE THERAPY RECOMMENDATIONS, THE BOARD SAW NO REASON TO DEVIATE FROM THESE STANDARDS.

c. WHEN SHOULD TWO-STEP TESTING BE EMPLOYED?

TUBERCULOSIS SCREENING DONE IN THE MILITARY, PARTICULARLY IN RECRUIT SETTINGS, DOES NOT WARRANT TWO-STEP TESTING.

d. WHAT QUALITY ASSURANCE MEASURES SHOULD BE IN PLACE?

THE PRESENTATIONS GIVEN TO THE BOARD SUGGESTED A NUMBER OF ISSUES WHICH SHOULD BE ADDRESSED. THESE INCLUDE:

- TRAINING AND MONITORING OF PERSONNEL PERFORMING SKIN TESTS.
- MINIMIZE THE NUMBER OF PERSONNEL AND SITES IN WHICH SKIN TESTS ARE PERFORMED TO INCREASE RELIABILITY OF RESULTS.
- PERIODIC REVIEWS OF MEDICAL RECORDS TO ASSURE COMPLIANCE WITH SKIN TESTING POLICIES AND APPROPRIATE RECORDING OF RESULTS.
- EXAMINING WAYS TO ASSURE COMPLIANCE WITH PREVENTIVE THERAPY. CONSIDERATION SHOULD BE GIVEN TO DIRECTLY OBSERVED PREVENTIVE THERAPY, POSSIBLY EMPLOYING TWICE-WEEKLY REGIMENS AS AN ALTERNATIVE TO DAILY MEDICATION.

e. WHAT ARE THE PRIORITIES FOR RESEARCH?

- 1) THE WHOLE BLOOD CELL TUBERCULOSIS ASSAY HOLDS GREAT PROMISE AS AN ALTERNATIVE METHOD FOR TUBERCULOSIS SCREENING OF MILITARY PERSONNEL. WHILE THE INCIDENCE OF ACTIVE TUBERCULOSIS IS

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LOW, IT HAS THE POTENTIAL TO RISE IN THE FUTURE DUE TO PEACETIME OPERATIONS IN HIGH RISK SETTINGS, AND THE INCREASING NUMBER OF FOREIGN-BORNE PERSONS WHO WILL BE ENTERING MILITARY SERVICE.

2) AT PRESENT, THIS ASSAY IS NOT LICENSED FOR USE IN THE UNITED STATES, AND THESE ARE A NUMBER OF QUESTIONS WHICH SHOULD BE ADDRESSED BEFORE IT COULD BE CONSIDERED FOR GENERAL USE IN MILITARY POPULATIONS. OBSERVATIONS AT GREAT LAKES SUGGEST THAT THIS TEST COULD SIGNIFICANTLY INCREASE THE NUMBER OF RECRUITS FOUND TO BE INFECTED, GREATLY INCREASING THE NEED FOR EFFECTIVE PREVENTIVE THERAPY.

- STUDIES SHOULD BE DONE TO DETERMINE COMPLIANCE WITH PREVENTIVE THERAPY AMONG RECRUITS AND SKIN TEST CONVERTERS. THIS SHOULD INCLUDE ADDRESSING RISK FACTORS FOR NONCOMPLIANCE.
- A COST EFFECTIVENESS STUDY OF DIRECTLY OBSERVED PREVENTIVE THERAPY SHOULD BE UNDERTAKEN, INCLUDING ALTERNATIVE DOSING REGIMENS.
- ADDITIONAL HEAD-TO-HEAD COMPARISONS OF TST VERSUS THE WHOLE CELL BLOOD ASSAY SHOULD BE DONE.
- COHORT STUDIES OF PERSONNEL SHOULD BE UNDERTAKEN TO DETERMINE SEQUENTIAL BEHAVIOR OF THE WHOLE BLOOD ASSAY, INCLUDING REPRODUCIBILITY OF RESULTS.
- THE COHORT OF PERSONNEL WHO ARE SKIN TEST NEGATIVE, BUT WHOLE CELL ASSAY-POSITIVE SHOULD BE FOLLOWED TO DETERMINE THEIR RISK FOR ACTIVE TUBERCULOSIS.
- TEST REPRODUCIBILITY SHOULD BE STUDIED BY SPLITTING SAMPLES BETWEEN LABORATORIES TO GAUGE CONSISTENCY OF RESULTS. SUCH STUDIES SHOULD BE DONE IN THE TYPES OF SETTINGS WHERE
- SCREENING WILL LIKELY OCCUR IN THE MILITARY.

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- STUDIES SHOULD BE DONE TO DETERMINE THE FEASIBILITY OF USING WHOLE BLOOD ASSAYS GIVEN THE 12-HOUR TIME CONSTRAINT FOR THE TEST TO BE RUN.
 - COST ANALYSIS IS NEEDED TO DETERMINE THE COST IMPACT OF SWITCHING TO A WHOLE BLOOD CELL ASSAY AND CHANGING SCREENING POLICIES.
- f. WHAT ARE THE DESIRED CAPABILITIES AND CHARACTERISTICS OF ANY NEW TUBERCULOSIS INFECTION SCREENING TEST?
- 1) AS WITH ANY SCREENING TEST, PREFERRED CHARACTERISTICS INCLUDE SENSITIVITY, REPRODUCIBILITY, EASE OF USE, AND REASONABLE COST. IN THE CASE OF TUBERCULOSIS, SENSITIVITY IS PROBABLY A HIGHER ATTRIBUTE THAN SPECIFICITY, AS ONE WOULD LIKE A TEST WHICH CAPTURES ALL PERSONS WHO ARE TRULY INFECTED IN ORDER TO ASSURE PREVENTIVE THERAPY CAN BE ADMINISTERED. HOWEVER, A TEST WITH A HIGH FALSE-POSITIVE RATE HAS RAMIFICATIONS IN UNNECESSARY COURSES OF PREVENTIVE THERAPY. THE TEST MUST PERFORM WELL IN THE VARIETY OF SETTINGS IN WHICH MILITARY PERSONNEL UNDERGO SCREENING, AND BE REPRODUCIBLE FROM ONE LABORATORY TO ANOTHER. A MAJOR LIMITATION OF TUBERCULIN SKIN TESTING IS THE REQUIREMENT FOR TWO VISITS, AND THE INTER-OBSERVER VARIATION IN INTERPRETING TEST RESULTS. ANY TEST WHICH REPLACES TST SCREENING SHOULD REQUIRE ONLY ONE VISIT, AND HAVE CLEAR CUTOFFS FOR INTERPRETATION.
 - 2) THE WHOLE BLOOD CELL ASSAY HAS MANY OF THE DESIRABLE FEATURES, BUT THE BOARD BELIEVES ADDITIONAL STUDIES ARE REQUIRED BEFORE THIS TEST COULD BE USED AS A SUBSTITUTE FOR CURRENT SKIN TESTING POLICIES. IN ADDITION, THE ASSAY SHOULD BE LICENSED BY THE FOOD AND DRUG ADMINISTRATION FOR GENERAL USE. HOWEVER, IF THESE STUDIES DEMONSTRATE ACCEPTABLE PERFORMANCE

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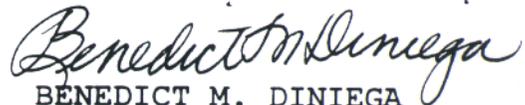
IN MILITARY SETTINGS, THIS ASSAY HOLDS THE PROMISE TO SIMPLIFY TUBERCULOSIS SCREENING AND TO REPLACE THE CURRENT SKIN TESTING PROGRAM.

4. The Board unanimously approved the above statements of support and recommendation.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:



F. MARC LAFORCE, M.D.
AFEB President



BENEDICT M. DINIEGA
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Encl
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TABLE SUMMARIZATION OF INTERPRETATION
OF TUBERCULIN SKIN-TEST RESULTS

- 1) An induration of ≥ 5 mm is classified as positive in the following:
 - Persons who have had recent close contact with persons who have active TB.
 - Persons who have human immunodeficiency virus (HIV) infection or risk factors for HIV infection but unknown HIV status.
 - Persons who have fibrotic chest radiographs consistent with healed TB.

- 2) An induration of ≥ 10 mm is classified as positive in all persons who do not meet any of the above criteria, but who belong to one or more of the following groups having high risk for TB:
 - Injecting-drug users known to be HIV seronegative;
 - Persons who have other medical conditions that have been reported to increase the risk for progressing from latent TB infection to active TB. These medical conditions include diabetes mellitus, conditions requiring prolonged high-dose corticosteroid therapy and other immunosuppressive therapy (including bone marrow and organ transplantation), chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck), weight loss of $\geq 10\%$ below ideal body weight, silicosis, gastrectomy, jejunioileal bypass;
 - Residents and employees of high-risk congregate settings: prisons and jails, nursing homes and other long-term facilities for the elderly, health-care facilities (including some residential mental health facilities, and homeless shelters;

- Foreign-born persons recently arrived (i.e., within the last 5 years) from countries having a high prevalence or incidence of TB.
 - Some medically underserved, low-income populations, including migrant farm workers and homeless persons;
 - High-risk racial or ethnic minority populations, as defined locally
 - Children <4 years of age or infants, children, and adolescents exposed to adults in high-risk categories.
- 3) An induration of ≥ 15 mm is classified as positive in persons who do not meet any of the above criteria.
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Enclosure



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

FEB 25 2000

MEMORANDUM FOR ARMED FORCES EPIDEMIOLOGY BOARD

FROM: AFMOA/CC

SUBJECT: Risk-based Tuberculosis Screening Policies and New Technologies

Tuberculosis (TB) is endemic in many countries, but is currently low in prevalence in the United States. The CDC does not recommend universal screening in the United States, but instead advocates risk-based screening, based on several criteria. In addition, the current test used for screening, tuberculin skin testing with purified protein derivative (PPD), requires interpretation 48 hours after placement which necessitates a return visit. The current test is logistically problematic for Reserve components and is prone to false positive readings depending on provider training, experience, and measurement cut-offs used.

Joint Staff policy on deployment screening currently requires PPD placement within two years of deployment and another within one year after return from deployment. Some facilities are confused on whether to use a 10mm or 15mm cut-off based on deployment risk. Service, and even intra-Service, policies vary and may require annual or biannual PPD testing. This may potentially result in thousands of false positive tests given a low risk population, resulting in unnecessary chest X-rays and possibly INH prophylaxis.

Unfortunately, there have been no good studies on actual deployment risk of TB since the Vietnam War, although some studies have been published on conversion within the Services. Some preliminary data suggest risk is more prominent for assignment to a country on the Pacific Rim, or other areas where TB is endemic. In addition, certain populations, such as special operational forces or shipboard personnel may have unique circumstances potentially placing them at greater risk.

New diagnostic and screening technologies for TB are in development, including whole blood assays which may afford some advantages, including: (1) no requirement for follow-up visits, (2) results within 24 hours, (3) better inter-rater reliability, and (4) perhaps better specificity.

Given these issues, we ask the following questions of the Board:

a. Based on current knowledge, what are the recommended TB screening approaches (including optimal frequencies, cut-offs, role of two-step testing, and quality assurance) for the various Services based on potential risks of deployment and assignment overseas, or other identified risks?

b. If current knowledge is inadequate, what are the priorities for further research?

c. What desirable capabilities or characteristics should any new TB screening or diagnostic tests have, and what role, if any, might they play in the military?

We appreciate the AFEB's consideration of the above questions and look forward to the Board's recommendations. If further information is required in regard to this memorandum, my POC is Col. Dana Bradshaw, AFMOA/SGOP, phone 202-767-4268, e-mail dana.bradshaw@usafsg.bolling.af.mil.

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