DETAINEE HOSPITAL GUANTANAMO BAY, CUBA Title: LATENT TUBERCULOSIS MANAGEMENT	SOP NO: 031 Page 1 of 10 Effective Date: 16 Jul 03
SCOPE: Detention Hospital	

Encl: (1) Latent Tuberculosis Infection Management Algorithm
(2) Initial/Annual Tuberculosis Patient Questionnaire
(3) Guidelines for Liver Function Test monitoring While on INH Therapy
(4) INH Therapy Monthly Patient Questionnaire
(5) INH Therapy Medical Provider Review

I. BACKGROUND:
Identification and treatment of latent tuberculosis infection (LTBI) in detainees offers improved Force Health Protection for Joint Task Force personnel in close contact with the detainee population by decreasing the probability of tuberculosis disease among detainees, and protects other detainees from the potential spread of disease between detainees. The policies and procedures stated in this SOP have been coordinated with the Centers for Disease Control (CDC) and the United States Public Health Service.

II. POLICY:
This is a revision of the Latent Tuberculosis Infection Management in Detainees SOP dated 21 Mar 03 and supercedes that document. This SOP should be used in concert with the SOP for Active Tuberculosis Management. Exceptions to this policy must be based on compelling clinical evidence and will be discussed with the Infectious Disease staff physician prior to implementation.

III. PROCEDURES:

- As per the Active Tuberculosis Management SOP, all detainees will be screened for clinical and radiological evidence of active tuberculosis; this includes placing a Tuberculin Skin Test (TST). The plan for identification, evaluation, treatment, and monitoring of LTBI in detainees is demonstrated in enclosure (1). Detainees that have been ruled out for active tuberculosis disease will enter the LTBI flowchart at the point were previous evaluations ended.

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- The following sections deal with the description, definitions, and amplification of the Latent Tuberculosis Infection Management flowchart. The areas involved in current operations and many of the potential areas considered as possibilities for future operations have high incidences of tuberculosis. Foreign-born persons that migrate to the U.S. continue to demonstrate incidences of tuberculosis that reflect the level of the country of origin for as long as five years after migration. This would result in a number of cases of tuberculosis disease in the detainee population with subsequent potential exposure of JTF personnel. Identification and treatment of LTBI in detainees will decrease this potential.

- All detainees will receive a TST in conjunction with inprocessing upon arrival. TST screening will use 5TU of Purified Protein Derivative (PPD) in the standard Mantoux method. The medical staff responsible for detainee healthcare should insure that all personnel placing and reading the PPD are trained adequately and understand the importance and limitations of this test.

- The classification of the PPD reaction depends on the clinical situation of the detainee. Most detainees are recent arrivals from high-prevalence countries and will be considered abnormal with a reaction of 10mm or more. Detainees considered positive at 5mm of induration should have the reason for this deviation from standard documented in the health record. For example, detainees with chest x-ray findings of fibrotic changes consistent with old healed tuberculosis, those with recent active TB contacts, and those with HIV infection or other immunocompromising conditions should be considered PPD abnormal with induration of 5 mm or more.

- Detainees with a negative PPD on initial testing will have the PPD repeated at the next monthly weigh-in. Implementation of the 'two-step PPD' will identify detainees with prior tuberculosis infection and is standard for persons enrolled in a periodic PPD screening program. Two-step testing is used to reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection. If the reaction to the first test is classified as negative, a second test should be done. An abnormal reaction to the second test probably represents a boosted reaction (past infection or prior BCG vaccination). On the basis of this second test result, the person should be classified as previous infected and cared for accordingly. This would not be considered a skin test conversion. If the second test result is also negative, the person should be classified as uninfected. In these persons, an abnormal reaction to any subsequent test is likely to represent new infection with *M. tuberculosis* (skin test conversion). Two-step testing should be used for the initial skin testing of adults who will be retested periodically.

- Detainees with the second PPD classified as negative will be enrolled in an annual PPD program. This does not preclude the routine clinical use of the PPD as an adjunct to appropriate clinical evaluations.

- Detainees classified as having a positive PPD on initial or second testing.

normally ≥ 10mm induration will be evaluated for signs and symptoms suggestive of tuberculosis disease [enclosure (2)].

- If there is suggestion of tuberculosis disease, the detainee will undergo an appropriate clinical evaluation as outlined in the Active Tuberculosis Management SOP. If evaluation is not suggestive of tuberculosis disease or if the clinical evaluation for active tuberculosis disease is negative, the detainee is evaluated for treatment of LTBI.

- Evaluation for LTBI treatment should include an attempt to document any history of treatment for LTBI or disease. This history may be difficult to obtain and unreliable. Determine if there are any preexisting medical conditions that are a contraindication to treatment or are associated with an increased risk of adverse effects of treatment. Review current and previous drug therapy for potential adverse reactions or interactions. Baseline laboratory testing is not routinely indicated for all patients at the start of treatment for LTBI. Baseline hepatic measurements of serum AST (SGOT) or ALT (SGPT) and bilirubin are indicated for patients whose initial evaluation suggests a liver disorder. Baseline testing is also indicated for persons with a history of chronic liver disease (e.g., hepatitis B or C, and others who are at risk of chronic liver disease). Testing should be considered on an individual basis, particularly for patients who are taking other medications for chronic medical conditions [see enclosure (3)]. Active hepatitis and end-stage liver diseases are relative contraindications to the use of isoniazid or pyrazinamide for treatment of LTBI. Use of these drugs in such patients must be undertaken with caution.

- If there are no contraindications for LTBI treatment, the standard course for detainees will be isoniazid, INH, 900mg, twice weekly for nine months. Peripheral neuropathy, caused by INH's interference with metabolism of pyridoxine, is uncommon at a dose of 5 mg/kg. However, in this detainee population, where some may be malnourished, treatment with pyridoxine could be considered (i.e. Pyridoxine 100 mg twice a week given with INH). In persons with conditions in which neuropathy is common (e.g., diabetes, uremia, alcoholism, malnutrition, and HIV infection), pyridoxine should be given with INH.

- All detainees on LTBI treatment will be monitored at least monthly [see encl. (4 and 5)]. This evaluation will include screening for signs and symptoms of active TB disease, and signs or symptoms of hepatitis. Routine laboratory monitoring during treatment of LTBI is indicated for persons whose baseline liver functions test are abnormal and for other persons with a risk of hepatic disease [see enclosure (3) for further details]. There should be laboratory testing, such as liver function studies for detainees with symptoms compatible with hepatotoxicity or a uric acid measurement to evaluate detainees who develop acute arthritis, to evaluate possible adverse reactions that occur during the treatment regimen.

- Discontinuation of INH should be considered for detainees with liver functions three times normal levels with symptoms, liver functions five times normal levels without symptoms, or when otherwise clinically indicated.

- Please refer to encl. (5) concerning detainee refusals of medication. After completion of LTBI treatment detainees will be screened annually [encl. (2)].

- Detainees with contraindications for LTBI treatment should be re-evaluated. The risk-benefit of LTBI treatment must be considered. Alternate regimens, per reference (b) should be considered. If clinically appropriate, treatment should proceed. These cases may require more frequent or more robust monitoring. If LTBI treatment is contraindicated, these contraindications will be documented in the detainee health record. The detainee will be followed with annual screenings. A sample questionnaire for these annual screenings can be found in enclosure (2).

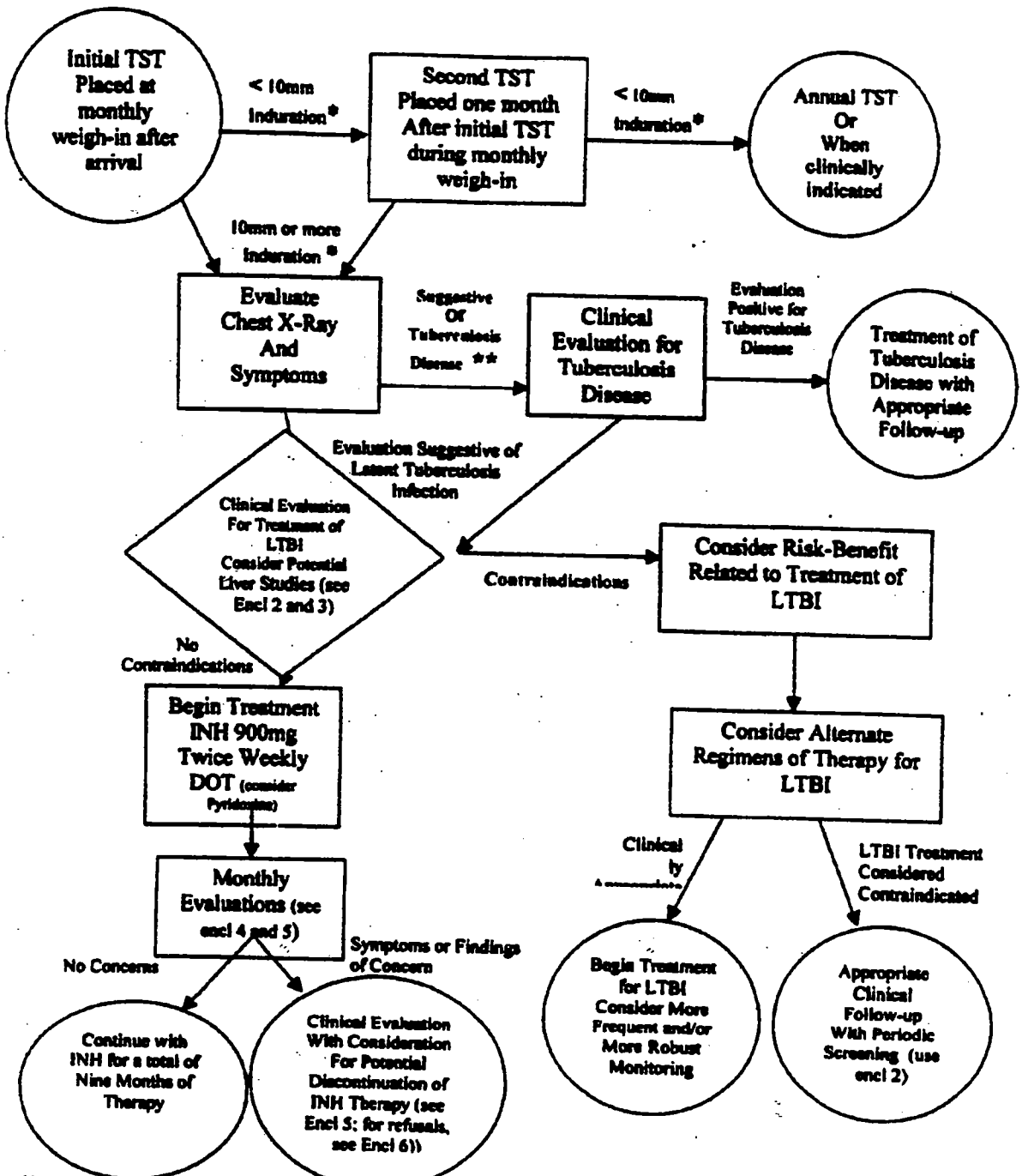
- Application of the Latent Tuberculosis Infection Management program will require tracking of PPDs, medications, and monitoring in a database/spreadsheet that will provide reports to the JTF Surgeon periodically on the status of the program.

- For detainees who refuse medication for LTBI, the following considerations will be used in determining the appropriate course of action:

  - There is no risk of inducing INH resistance in detainees who periodically refuse INH. The goal of therapy is to have the detainee take at least a total of 52 doses in 9 months or 76 doses in 12 months. If the total number of doses meets these guidelines, therapy is considered to be complete.

- Detainees continually refusing medications will not be required to take INH per SOUTHCOM policy. They will be screened annually with a medical screening questionnaire on the yearly anniversary of their negative chest x-ray, generally obtained at their in-processing date.

[redacted]



(*)Varied clinical situations recommend LTBI Treatment a different parameters of induration. Ten millimeters is the level for most of the detainees received.

(**)In cases where signs and symptoms are highly suggestive of tuberculosis disease, begin treatment concurrent with laboratory evaluation and confirmation.

27 May [redacted] (Encl 1)

NOV00230

Detainee Number: _____ Age of Detainee: _____ Date: _____

Initial/Annual Tuberculosis Patient Questionnaire

Are you experiencing any of the following problems:

Fever for more than 7 days	Yes	or	No
Cough for more than 2 weeks in a row	Yes	or	No
Sweating at night for more than 7 days	Yes	or	No
Coughing up bloody phlegm	Yes	or	No

Medical Provider Review:

History of TB, previous treatment for TB, or BCG vaccine in past? _____

History of liver disease/hepatitis/jaundice? _____

Date and Result of Last PPD (no need to repeat once positive)_____

Results of hepatitis/HIV screening at inprocessing _____

Current Medications: _____ Allergies:_____

Medical officer evaluation (if indicated from above symptoms): _____

_____

_____

Are repeat/new LFT monitoring recommended? _____

Date drawn _____ Results _____

Is a repeat CXR needed (if annual screening, repeat is recommended)? _____

Ordered? _____ Result of CXR? _____

Have AFB smears/cultures been or are being collected? _____Results: _____

_____

Further actions required/Medications Prescribed?_____

Enclosure (2)

005073

NOV00231

Guidelines for Liver Function Test Monitoring While on INH Therapy

Baseline LFTs for:

- History of liver disease
- Hepatitis B surface Antigen positive or Hepatitis C Antibody positive
- Concurrent therapy with other possible hepatotoxic medications
- Signs or symptoms of liver disease
- HIV Infection
- Pregnancy/Less than 3 months post-partum

Monthly LFTs indicated for:

- History of elevated LFTs at baseline (discontinue monitoring if asymptomatic and LFTs normalize)
- Persons at risk for hepatic disease (i.e. persons with Hep B/C with elevated LFTs at baseline, h/o chronic liver disease, etc.)

All persons should be screened monthly for signs of hepatotoxicity [see INH Therapy Monthly Patient Questionnaire enclosure (2)]. The medical officer in charge of the LTBI program will complete or review the INH Therapy Medical Provider Review [enclosure (3)]. Persons identified as having signs or symptoms of possible hepatotoxicity will be evaluated further by a medical officer to decide whether further testing and/or discontinuance of the medication is indicated.

Enclosure (3)

005074

Detainee Number: _____ Age of Detainee: _____ Date: _____

INH Therapy Monthly Patient Questionnaire

Are you experiencing any of the following problems:

Fever for more than 7 days	Yes	or	No
Cough for more than 2 weeks in a row	Yes	or	No
Sweating at night for more than 7 days	Yes	or	No
Coughing up bloody phlegm	Yes	or	No
Nausea or vomiting for more than 7 days in a row	Yes	or	No
Abdominal pain for more than 7 days in a row	Yes	or	No
Yellow discoloration of skin	Yes	or	No

Enclosure (4)

005075

Detainee Number: _____ Age of Detainee: _____ Date: _____

INH Therapy Medical Provider Review:

MAR Review: Number of doses refused in last month? _____

Does their course of medication need to be extended? _____

Signature of staff modifying the MAR _____

Medical officer evaluation (if indicated from above symptoms): _____

_____

_____

Are repeat/new LFT monitoring recommended? _____

Date drawn _____

Results _____

Is a repeat CXR needed? _____ Ordered? _____

Result of CXR? _____

Further actions required? _____

Enclosure (5)

005076

NOV00234

STANDARD OPERATING PROCEDURES
Detention Hospital
Guantanamo Bay, Cuba

REVIEWED AND APPROVED BY:

_____ _____
Officer In Charge Date

IMPLEMENTED BY:

_____ _____
Director for Administration Date

_____ _____
Senior Enlisted Advisor Date

ANNUAL REVIEW LOG:

By:_____ Date:_____
By:_____ Date:_____
By:_____ Date:_____
By:_____ Date:_____
By:_____ Date:_____
By:_____ Date:_____

SOP REVISION LOG:

Revision to Page:_____ Date:_____
Revision to Page:_____ Date:_____
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ENTIRE SOP SUPERSEDED BY:

Title:_____
SOP NO:_____ Date:_____

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