Standardized Procedures for Tuberculosis-ERNs

February 2006

LOS ANGELES COUNTY
TUBERCULOSIS CONTROL PROGRAM
STANDARDIZED PROCEDURES FOR TUBERCULOSIS EXTENDED ROLE NURSES

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TUBERCULOSIS CONTROL PROGRAM
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In accordance with the Department of Health Services/Policy for utilizing nurses in an expanded role, this document contains policies, and protocols governing the practice of the Extended Role Nurse in the management of tuberculosis.

General Policy Component:

The Tuberculosis Extended Role Nurse (ERN) is a registered nurse who has had additional training in tuberculosis (TB) control practices and the management of patients who have latent tuberculosis infection (LTBI) or TB disease. The ERN is specifically prepared to implement and supervise patients for whom Isoniazid (INH) therapy for LTBI is indicated. As determined, tested and monitored by the Los Angeles County Tuberculosis Control Program, the ERN may also supervise the care of patients who have other LTBI treatment regimens and who have uncomplicated pulmonary tuberculosis (PTB) disease (Class III) which is stable on a medical regimen prescribed by a physician. The ERN may perform these functions under the following conditions:

1. ERNs will acquire their caseload as follows:

   A. The following categories of patients may be started on a daily INH treatment regimen for LTBI by the ERN and followed without first being seen by the physician per Protocol #1:

      Converters and reactors (TB Class II) who are ages 4 through 34 years. (Exceptions: See "B" below and "C" next page).

      The physician must review the charts of these patients, sign the prescription, and sign the order referring the patient to the ERN, within one week of starting LTBI therapy.

   B. The following categories of patients may either be examined by the physician before referral to the ERN, or after a review of the medical record, the physician may refer the patient directly to the ERN to initiate LTBI therapy. The order for LTBI therapy and the order referring the patient to the ERN must be signed by the physician prior to the patient being seen by the ERN:

      (1) All contacts: TB Class I or II. If the drug sensitivities of the index case are not known when the contact is assigned to the ERN, the ERN must obtain the drug sensitivities as soon as they are available. Should any drug resistance be found, the ERN must refer the contact to the physician (per Policy - ERN Caseload: C-3, p. 2) for possible re-evaluation of LTBI therapy.
      (2) Reactors with certain high risk medical conditions that have been associated with an increased risk of TB disease such as diabetes, injection drug use, chronic immunosuppression, and end-stage renal disease.
      (3) Reactors with other medical conditions such as seizure disorders, any type of cancer treatment, complex medical treatment regimens for other health problems, etc.
      (4) Class I contacts or TB Class II patients who are pregnant or less than 6 months postpartum for whom LTBI therapy is indicated.

(5) For patients who have had a break in therapy of greater than one month, the physician must decide if LTBI therapy is to be restarted and for how long, and order another chest x-ray if indicated.

C. The following categories of patients must be seen by the physician at least for the initial exam before referral to the ERN:

(1) Stable PTB, Class III.
(2) HIV-positive patients or those at high risk of acquiring HIV infection.
(3) All contacts to drug-resistant TB.
(4) All patients diagnosed with TB (Class IV). This includes all Class B Aliens.
(5) Patients at increased risk of liver disease, including ≥ 35 years old, a history of hepatitis, liver disease, or chronic liver disease including carriers of hepatitis, the daily use of alcohol, current or past injection drug use.
(6) Patients with a history of allergy or adverse reaction to anti-TB medications.
(7) All children under age 4.
(8) Any patient on LTBI treatment regimens other than INH daily.

D. The following categories of patients should NOT be referred to the ERN and must be followed by the physician:

A. Unstable PTB, Class III
B. Extra-Pulmonary TB, Class III
C. Drug-Resistant TB, Class III
D. PTB, Class III/HIV-positive
E. TB, Class V

E. ERNs may administer Directly Observed Therapy (DOT) or Directly Observed Preventive Therapy (DOPT) to any patient for whom it is ordered per the physician.

2. The TB credentialed physician(s) will provide medical consultation and supervision for the ERNs, and will meet with the ERN on a regular basis. Protocols 1, 2 and 3 describe situations necessitating referral to or consultation with a TB physician. It is not essential that a credentialed physician be on the premises for ERNs to perform their role; however, a credentialed physician must be readily available by phone for consultation. ERNs may also book the patient's medical record to chart review for consultation, or return the patient to the physician's care by giving the patient an appointment to the doctor's clinic, and recording the reason for the action in the progress notes. A Public Health Nursing Supervisor or Supervising Clinic Nurse will provide supervision for the ERN's independent nursing functions.

3. ERNs will provide care primarily in the clinic setting, however, broken appointment follow-up and/or monitoring for adverse reactions to medication may be done via phone or coordinated with the District Public Health Nurse (DPHN).

4. ERNs may label and dispense medications that have been prescribed by the physician as outlined in Appendix 1.

5. Each ERN shall have possession of a copy of the signed Standardized Procedures for TB-ERNs.

6. Patients are to be informed that they are being seen by an ERN who has had additional training to provide the required care and that they may see a physician upon request.

7. ERNs shall wear name tags clearly identifying them by name and classification.

8. ERNs may do tuberculin skin testing (TST), pregnancy testing as per CHS Policy #320, or draw blood for liver function tests (LFTs) related to their caseload and other tests as ordered by the physician.

9. These procedures will be reviewed annually and revised as necessary.

EXTENDED ROLE NURSE REQUIREMENTS:

1. Training Course Eligibility (to be determined by TB Control Program)
   Current Requirements Are:
   a. current valid California registered nurse license
   b. completion of a half-, and one- or two- day General TB In-service or an equivalent course presented by the TB Control Program within the previous 5 years
   c. one year of experience in tuberculosis nursing
   d. an agreement by the nurse and supervision that the nurse will practice on a regular basis as an ERN for at least one year after completion of the course.
2. Training Course and Certification
   The ERN will be certified when the nurse has:
   a. completed the Extended Role Nurse Education Course designed and administered by TB Control Program
   b. scored 80% or better in the course written examinations
   c. assumed a caseload within 3 months following successful completion of the course
   d. satisfactorily demonstrated competency and quality of care as determined by TB Control Program staff using the TB-ERN Clinic Observation and Chart Review during on-site evaluations conducted at 3 months and 6 months after the ERN has assumed a caseload.
3. The certification process must be completed within one year of taking the course. Certification will continue for a period of 3 years after which time the ERN must be recertified.
4. Recertification will be done for each ERN every 3 years or at the discretion of the district health center supervision or TB Control using the following criteria:
   a. continues to practice as an ERN (MINIMUM – 1 ERN clinic monthly) under a credentialed TB physician
   b. satisfactory completion of a one-day recertification course offered by TB Control Program or, on-site evaluation at discretion of district health center staff or TB Control Program
   c. attendance at 50% or more of the ERN Continuing Education classes which are offered by TB Control Program 4 times per year
   d. continued competency on the annual performance evaluation.
5. The TB Control Program must recertify an ERN who becomes inactive by failing to meet the requirements stated in #4 above, before resuming active practice as an ERN. An ERN may resume active status as follows:
   a. If the period of inactivity has been less than 2 years, the ERN must complete a recertification course offered by TB Control

b. If the period of inactivity has exceeded 2 years, the ERN must repeat the 5 day ERN course. Exceptions may be considered on an individual basis if the ERN has remained active in TB services.

APPROVAL

The Standardized Procedures for tuberculosis extended role nurses have been approved by:

Authorized Persons	Date of Approval
Annette T. Nitta, M.D. Director, Tuberculosis Control Program	_____
Robert Kim-Farley, M.D., MPH Director, Communicable Disease Control Programs	_____
A. Belinda Towns, M.D., MPH Medical Director, Public Health	_____
Nancie S. Bendaña, RN, MS Interim Nursing Director, Public Health	_____
April King-Todd, R.N., BSN, MPH Nurse Manager, Tuberculosis Control Program	_____

DISTRICT APPROVAL **HEALTH CENTER**: _____

The physicians and ERNs listed below agree to function under the ERN Standardized Procedures. These Standardized Procedures for TB-ERNs have been approved by:

Date of Approval:_____

_____ _____

Area Health Officer Area Medical Director

_____

Nurse Manager

CERTIFIED TUBERCULOSIS EXTENDED ROLE NURSE(S) AUTHORIZED TO FUNCTION UNDER THESE STANDARDIZED PROCEDURES

Name/Title	**Date**

The TB credentialed physician(s) listed below has/have agreed to be medical consultants for the above Tuberculosis Extended Role Nurse(s), who are authorized to function under these Standardized Procedures.

No names may be added after the date signed by the physician(s) below without their prior approval and dated initials.

PHYSICIAN(S)

Name/Title	**Date**

These Standardized Procedures shall be reviewed annually. A new signature page will be requested by TB Control Program.

SIGNATURE PAGE CONTINUED HEALTH CENTER:

This page is to be used in the event that additional TB credentialed physicians (e.g., "AS NEEDED", new or transfer physicians) or ERNs (e.g., newly trained or transfer ERNs) are utilized in the chest clinic.

EXTENDED ROLE NURSE(S)

Name/Title	**Date**

PHYSICIAN (S)

Name/Title	**Date**

PROTOCOL #1
MANAGING HIGH RISK CONTACTS (TB CLASS I), CONVERTERS AND REACTORS WITH LATENT TB INFECTION (TB CLASS II)

POLICY: Extended Role Nurses (ERN) may implement Isoniazid (INH) for the treatment of LTBI infection and supervise the treatment of high risk contacts, converters and reactors. Please see General Policy Component (A. p.1) -ERN Caseload regarding which patients may be started on LTBI therapy by the ERN before the prescription is signed (General Policy Component), and which patients must have the prescription signed before the ERN can initiate or continue LTBI therapy (General Policy Component). The medical record must have a completed TB EPI (screening) Report (H-304), results of baseline liver function tests (LFTs) when the history reveals potential for liver damage - see Protocol #1: D-12 (p.11), an order referring the patient to the ERN, and a prescription for LTBI therapy signed by the physician. The prescription is to be written on form H-261. The ERN may also supervise patients for whom Rifampin preventive therapy is ordered by the physician (e.g., contacts to an INH-resistant index case).

PROTOCOL:

A. DEFINITIONS:

1. High-Risk Contact: a person exposed to someone with infectious TB disease (either close or other-than-close). The (TST) given by the Mantoux method may be positive (5mm or greater) or negative. The chest x-ray is normal.*
2. Converter: a person with a TST given by the Mantoux method that has increased at least 10mm of induration from <10mm to ≥ 10mm within two years. The chest x-ray is normal.*
3. Reactor: a person that has a positive TST and no clinical, bacteriological or radiographic evidence of current disease. The TST reaction must be documented in "mm." If no documentation can be obtained, the TST should be repeated, unless contraindicated per the physician's evaluation, before the initiation of LTBI therapy. The chest x-ray is normal.*
4. Positive TST: a reaction of measurable induration in the skin after intradermal injection of 5 tuberculin units (5TUs) by the Mantoux method. Patients with the following reaction have a positive TST at:

   ≥5mm:
   1) High-Risk Contacts
   2) Chest x-ray and clinical findings consistent with TB: follow per Protocols #2 & #3
   3) Immunosuppressed individuals
   4) Infected with HIV or those at high risk of acquiring HIV infection.

   ≥10mm: All others regardless of age

   *If the chest x-ray is less than 3 months old and the patient is asymptomatic, there is no need for a repeat chest x-ray. If the chest x-ray is over 3 months old the patient must have a repeat chest x-ray before INH is started. A repeat chest x-ray on a patient who restarts LTBI therapy is at the discretion of the physician. Consideration should be given to the length of time the patient has been off medication, the amount of medication already taken, the risk level of the patient, and the development of any TB symptoms.

PROTOCOL #1
MANAGING HIGH RISK CONTACTS (TB CLASS I), CONVERTERS AND REACTORS WITH LATENT TB INFECTION (TB CLASS II)

B. DATABASE:

1. Subjective: Asymptomatic. May have history of contact to an infectious case of TB.
2. Objective: TST and chest x-ray reading. The TB physician may do a chest x-ray reading. The TB physician must review a chest x-ray report by a radiologist if the report is other than normal or within normal limits.

C. ASSESSMENT/DIAGNOSIS:

1. High-risk contact with negative TST reaction – TB Class 1.
2. Positive TST reaction – TB Class II (latent TB infection).

D. TREATMENT PLAN AND FOLLOW-UP:

1. Patients with a positive TST at the time of the skin test reading must be assessed for conditions that increase the likelihood of the patient developing TB disease. The priority status must then be recorded in box #4 of the H-304 and H-261. (See chart in Appendix 6 – "Priorities for Targeted Skin Testing"). For all patients with Priority I risk factors, these conditions should be documented on the "Master Problem List."

2. Patients with a positive TST will also be assessed for the presence of high risk factors for HIV infection. All patients with risk factors for HIV will be strongly encouraged to have HIV counseling and testing. HIV-positive patients and those at high risk of acquiring HIV infection may be at significant risk for developing TB disease and should be evaluated by the physician before referral to the ERN.

3. Implement/continue LTBI therapy per protocol. Medication may be dispensed as per Appendix 1. The risks and benefits and the need for compliance must be explained to the patient at each visit before dispensing medication. The patient must give verbal consent before proceeding.

4. The patients will be seen monthly to monitor compliance, to determine how medication is being tolerated, to assess or monitor for signs and symptoms of toxicity, and to obtain prescription refill if indicated. Note: The patient should be seen in person. A rare exception may be made for "return" patients who come in for a refill if extenuating circumstances do not permit the patient to be present and the patient has been compliant. If the patient is absent, a refill may only be given to a close relative (e.g., parent, legal guardian, spouse). This person must be able to provide an accurate history about the patient's compliance, problems, etc. If the nursing assessment indicates any possible area of concern, or if the nurse is not comfortable giving the refill, the medication

should not be given. The physician must approve any refill given when the patient is absent.

5. The usual length of LTBI therapy is 6 months or as otherwise ordered by the physician. EXCEPTIONS: HIV-positive reactors or individuals at high risk for HIV infection and children and adolescents less than 18 years of age should receive 9 months of INH. The physician must authorize any other time interval.

6. Discontinue medication if it is not tolerated due to side effects. After evaluating the patient and consulting with the physician, medication may be restarted if the side effects are minor and there is no evidence of liver toxicity and the physician orders the restarting.

7. If patient develops signs or symptoms of liver toxicity (such as unexplained fatigue, weakness, malaise, anorexia, nausea, vomiting, dark urine, jaundiced) discontinue medication, draw LFTs, document findings in the chart, and consult with the physician. Make an appointment for the patient to be seen in clinic by the physician if ordered by physician. If other signs or symptoms of serious side effects or toxicity are noted, discontinue medication and consult with physician immediately.

8. All high-risk TB Class I contacts (e.g., negative TST, from 0-4 mm) must have an initial normal chest x-ray. Those contacts that have a negative reaction to an initial TST must be retested 3 months after they were last exposed to the infectious TB index case. LTBI therapy may be discontinued if the repeat TST is negative if the patient is no longer being exposed to infectious TB, and, if the physician concurs.

   The duration of LTBI therapy for the HIV-positive Class I TB contact should be individualized. Consideration must be given to the likelihood of LTBI and the possibility of anergy. The physician must specify the length of LTBI therapy for these contacts.

   Note: It is the responsibility of the ERN to obtain the necessary information to determine that the patient is no longer exposed to an infectious TB index case before INH is discontinued.

9. During the course of LTBI therapy, medication dosages for children weighing less than 60 lbs should be adjusted based on weight. When the dosage is changed from the original order, a new prescription needs to be written on the form H-261 in Section 10, "NOTES" (e.g., Sig: INH 100mg ii p.o. daily
   disp: 60 tablets
   refill x 2)

   or in the Progress Notes (H-654) and signed by a physician within one week.
   NOTE: Any pediatric patient weighing ≥60 lbs should receive 300 mg of INH.

10. Close the patient to clinic follow-up when the patient has completed LTBI therapy as prescribed by the physician. If noncompliant see "broken appointment algorithm" in appendix for a summary of current recommendations. A "Tuberculosis Patient Discharge Status" card (H-1832) will be given to those patients completing LTBI therapy. This card may be given to the patient at the time the final refill is given if the patient is currently compliant with therapy. The patient must be counseled to contact the clinic immediately if any problems develop during the final month of therapy.

11. During the course of LTBI therapy, females of childbearing age should be assessed monthly for their last menstrual period (LMP) and the LMP date documented on the H-261. If pregnancy is suspected, the ERN should do a pregnancy test, document the results in the chart, and consult with the physician if the test is positive.

12. The physician must examine patients with an increased risk of liver damage before referral to the ERN (see Policy -ERN Caseload: C-5 p.2). These patients must have normal LFTs before referral to the ERN for LTBI therapy. Monthly LFTs must be obtained for at least 3 months after referral. Any abnormal LFT must be documented in the chart and the chart reviewed by the clinician. The need for further evaluation, including LFTs or other lab work, is at the discretion of the physician. The factors associated with an increased risk of liver damage include age ≥35 years, a history of hepatitis, laboratory results indicating hepatitis, liver disease, the daily use of alcohol, and injection drug use. Pregnant women on LTBI treatment should have LFTs near the time of delivery. During the first 6 months postpartum, women need monthly LFTs when on LTBI-therapy. Pregnant women and women in the first 6 months postpartum are not routinely placed on LTBI therapy unless they are at high risk of developing TB.

13. If there has been a break in LTBI therapy for over one month, consult with the TB physician per General Policy Statement – ERN Caseload: B-5, (p.2) before restarting INH.

E. CONDITIONS REQUIRING CONSULTATION WITH TB PHYSICIAN:

1. Persistent intolerance and/or signs and symptoms of INH toxicity such as unexplained anorexia, fatigue, weakness, malaise, nausea, vomiting, dark urine, or jaundice. Other possible side effects include rash, headache, dizziness, and fever.

2. Signs and symptoms of TB disease, e.g., chronic cough, night sweats, persistent low-grade fever, hemoptysis, unexplained respiratory complaints, and any unexplained weight loss in children or unexplained weight loss (greater than 10 pounds in 3 months) in adults

3. Patients having risk factors associated with an increased risk of liver damage (see D-11, p.11).

4. Signs and symptoms or a history of other medical problems, e.g., seizure disorders, cancer, high dosage of steroids, diabetes, etc.

For the above conditions, prior to consulting with the physician, the ERN needs to: stop the INH, obtain a thorough history about the problem(s) including an assessment of possible causes, document these findings in the patient's chart and then consult with the physician. The physician will evaluate the condition(s). The physician may wish to follow the patient, order laboratory test(s) and/or continue to hold the INH. The physician must order the restarting of therapy.

F. PATIENT EDUCATION

Emphasize the risk factors associated with being a high-risk contact or converter. Explain the presence of HIV infection as an important risk factor for developing clinical TB. Explain the meaning of a positive TST reaction. Discuss the difference between LTBI and TB disease, reason for taking medication, instructions for use, and importance of regular use. Explain possible adverse reactions to medication and procedure to follow if signs and symptoms occur (including stopping the medication until they can consult with the nurse or doctor). The principle of education is to emphasize the benefits of LTBI therapy and the infrequency of adverse reactions. Provide the patient with appropriate written material in the appropriate language. The education should be supplemented with flip charts or other audio-visual aids. Obtain verbal consent from patient to begin LTBI therapy. The record must also contain a signed, dated and witnessed consent before LTBI therapy is initiated.

G. RECORD KEEPING:

Clinic visits, medication dispensed, LTBI therapy surveillance, TST, chest x-ray, laboratory test results and broken appointment follow-up will be documented on form H-261. If additional space is needed to document problems and action(s) taken, a Progress Notes (H-654) may be used. The Progress Notes must reference the flow sheet (H-261) each time the H-261 is used. The SOAP format is to be used on the Progress Notes. All documentation in the chart must be done in accordance with the County of Los Angeles, Department of Health Services, Medical Records, Policy and Procedure Manual. The closure of all patients on LTBI therapy must be done on the H-304 and the appropriate copy submitted to the TB Control Program.

1. DOCUMENTATION SYSTEM (Excerpted from County Los Angeles, Department of Health Services, Medical Records, Policy and Procedure Manual).

a. POMR Charting System

The method used to record and codify medical information is the Problem Oriented Medical Record (POMR) charting system.

The POMR promotes meaningful recording of information usable by all the health team members. It provides mechanisms of collecting and recording data systematically so that rationale for action and outcome can be evaluated.

The POMR is based on four phases of medical action: data based collections, problem formulation, problem oriented plans and progress notes of each problem

Progress notes shall be recorded in the SOAP format of **S**ubjective, **O**bjective, **A**ssessment and **P**lan.

All patient encounters, including those that have the primary recording else-where, e.g., flow sheet, are noted in the progress notes with the date, problem and notation to which form contains the primary recording ("see flow sheet" and signature).

b. DHS Documentation Standards

DEFINITIONS:

Medical Record:	The legal document that records information regarding a patient's care and treatment at a DHS facility.
Provider:	The person who provides that care; can be a physician, nurse, technician, allied health professional, etc.
Documentation:	The information placed in the medical record that provides a description of the care provided, the patient's response to that care, the medical impressions about that care, and the recording of laboratory or diagnostic test results. Also included are flow sheet recordings of vital signs, etc.
Legibility:	The information must be readable.

1). Purpose of Documentation

- To create a record to document a patient's complaints, history findings, impressions, diagnoses, treatments and outcomes
- To provide a means of communication between various providers about the patient's condition
- To record diagnoses and procedures to justify third-party reimbursement

- To serve as a legal document to provide evidence of care rendered in the event of a legal dispute.

2). Information to Document
General Rules

- The patient's full name and medical record number must be on each page.
- Date, times, signatures and titles are required for each entry.
- Signatures must identify the signee by either being legible or by having the signee print his/her name below the signature.
- Entries must be legible.
- Entries must be made in blue or black ink.
- Errors may be denoted by drawing one line through the entry, writing "error" above the line, followed by the person's initials, date and time.
- NO WHITE OUT OR ANY OTHER OBLITERATION IS ALLOWED.
- Entries must correspond in time to the care provided.
- Late entries (notes recorded that are out of time sequence with prior existing notes) are acceptable only if the information is designated as a "late entry" and the note identifies the date and time of actual writing.
- Subsequent notes (notes used to document information that occurred previously, but do not qualify as a late entry) may be made if the information is required to clarify or correct previous written information. Subsequent notes must identify the date and time actually written and make reference to the date and time of the prior note that is being clarified.

3). Consistency

- Information recorded in the medical record must be accurate and factual and support conclusions and impressions. (e.g., if the provider documents a "delay in care," the note should include a depiction of critical times instead of just recording "delay").
- The provider must review previous notes by other providers at the time of documenting a progress note. This will ensure continuity and consistency in the record.
- The provider must review and correct dictated notes, which may include procedure and/or operative notes, prior to signing them.

4). Documenting Complications and/or Adverse Events

- Documentation of complications/adverse events must be objective, factual, accurate, and timely.
- Documentation should note that the patient and/or family was informed of complication/adverse event, when possible. If not informed, the reason should be noted.
- For complications/adverse events that involve a specific health care team, all members of that team should have access to the same set of facts concerning times and sequences of events.
- Clarify factual details and sequences, if needed. Inconsistencies should be avoided, if possible.

5). Documenting Disagreements

- The medical record is not to be used to express negative comments about medical care rendered by another provider.
- Disagreements between providers related to findings of exams or interpretation of diagnostic tests should be noted and resolved, if possible.
- Disagreements between providers on the treatment plan shall include the basis for any alternative treatment recommendations.

PROTOCOL # 2
MANAGING CLINICALLY INACTIVE TUBERCULOSIS CLASS IV

POLICY: Extended Role Nurses may implement LTBI therapy and supervise the treatment of LTBI in patients who have been inadequately treated or received no treatment for TB disease and are without evidence of current disease activity (TB Class IV). The medical record must have a completed TB EPI (screening) Report (H-304), the results of baseline liver function tests (LFTs) when the history reveals a potential for liver damage - see Protocol #2: D-8, (p.17), a prescription for LTBI treatment as written by the TB physician, and a signed order referring the patient to the ERN. The prescription is to be written on the form H-261 or TB Patient Clinical Summary (H-513). The patient with TB Class IV must be seen by the physician before referral to the ERN per General Policy Statement -ERN Caseload: C-4, (p.4).

PROTOCOL:

A. DEFINITION: TB Class IV – is TB not clinically active with a history of episode(s) of TB or abnormal but stable radiographic findings, a positive reaction to the TST (≥ 5mm), negative bacteriological studies (if done), and no clinical or radiographic evidence of current TB disease. History reveals the patient has not completed a prescribed course of chemotherapy or has had no previous treatment. The TB physician must have ruled out active TB disease.

B. DATA BASE:

1. Subjective: Asymptomatic.
2. Objective: TST and chest x-ray reading.

C. ASSESSMENT/DIAGNOSIS: Tuberculosis Class IV.

D. TREATMENT PLAN AND FOLLOW-UP:

1. Implement/continue LTBI therapy as prescribed by the TB physician. Medication may be dispensed using Protocol #4. The risks and benefits and the need for compliance must be explained to the patient at each visit before dispensing medication. The patient must give verbal consent before proceeding.

2. The patient will be seen monthly to monitor compliance, to determine how medication is being tolerated, signs and symptoms of toxicity, and the prescription refill.

3. The preferred LTBI treatment is INH and Rifampin (Rifamate) for 4 months. If Rifampin is not tolerated or is contraindicated, INH should be given for 9 months.

4. Discontinue medication if it is not tolerated due to side effects. After evaluating the patient, documenting in chart, and consulting with the physician, medication may be restarted if the side effects are minor, there is no evidence of toxicity, and the physician orders the restarting.

5. If patient develops signs or symptoms of liver toxicity, (such as anorexia, fatigue, weakness, malaise, dark urine or jaundice) discontinue medication, draw LFTs, document findings in the chart and consult with the physician. Make an appointment for the patient to be seen by the physician if ordered by physician. If other signs or symptoms of serious side effects or toxicity are noted, discontinue medication and consult with the physician immediately.

6. Children are rarely, if ever, diagnosed with TB Class IV. However, should a child be on LTBI therapy for TB IV, medication dosages for children weighing less than 60 lbs. should be adjusted based on weight as ordered by the physician. When the dosage is changed from the original order, a new prescription needs to be written on the form H-261 in Section 10 "NOTES" (e.g., Sig: INH 100mg ii p.o. daily
   disp: 60 tablets
   refill x 2)
   or on the TB Patient Clinical Summary (H-513), if applicable, or in the Progress Note (H-654) and signed by a physician within one week. **NOTE: Any pediatric patient weighing ≥ 60 lbs should receive 300 mg of INH. The Rifampin dosage for children is 10-20 mg/kg to a maximum of 600 mg daily.**

7. Close the patient to clinic follow-up when patient has completed LTBI therapy as prescribed by the physician. The physician must approve closure of TB Class IV patients (See "chest clinic broken appointment guidelines" in appendix 3 for a summary of current recommendations). A "Tuberculosis Patient Discharge Status" card (H-1832) will be given to those patients completing LTBI therapy, and may be given at the time of the final refill if the patient is currently compliant with his therapy. The patient must be counseled to contact the clinic immediately if any problems develop during the final month of therapy.

8. The physician must examine patients with an increased risk of liver damage before referral to the ERN (see General Policy Component ERN Caseload: C-5, p.2). These patients must have normal LFTs before referral to the ERN for LTBI therapy. Monthly LFTs must be obtained for at least 3 months after referral. Any abnormal LFTs must be documented in the chart and the chart reviewed by the clinician. The need for further evaluation including LFTs or other lab work is at the discretion of the physician. The factors associated with an increased risk of liver damage include age ≥35 years, a history of hepatitis, laboratory results indicating hepatitis, liver disease, or chronic liver disease, the daily use of alcohol, and injection drug use.

Pregnant women on LTBI treatment should have LFTs near the time of delivery. During the first 6 months postpartum, women need monthly LFTs when on LTBI therapy. Patients on INH and Rifampin should be monitored with monthly LFTs throughout treatment.

9. If there has been a break in LTBI therapy for over one month, consult with the TB physician per General Policy Statement - ERN Caseload: B-5, p.2 before restarting the medication.

10. During the course of LTBI therapy, females of childbearing age should be assessed monthly for last menstrual period (LMP) and the LMP date should be documented on H-261. If pregnancy is suspected, the ERN should do a pregnancy test, document the results in chart, and consult with physician if the test is positive.

E. CONDITIONS REQUIRING CONSULTATION WITH CHEST CLINICIAN:

1. Persistent intolerance and/or signs and symptoms of INH or Rifampin toxicity such as unexplained anorexia, fatigue, weakness, malaise, nausea, vomiting, abdominal pain, dark urine, or jaundice. Other possible side effects include rash, headache, dizziness and fever.

2. Signs and symptoms of TB disease, e.g. chronic cough, night sweats, persistent low-grade fever, hemoptysis, unexplained respiratory complaint or unexplained weight loss in children or unexplained weight loss (greater than 10 pounds in 3 months) in adults.

3. Patients having risk factors associated with an increased risk of liver damage (see D-8 p.17).

4. Signs and symptoms or a history of other medical problems, e.g., seizure disorders, cancer, high dosage of steroids, diabetes, etc.

For the above prior conditions to consulting with the physician, the ERN needs to stop the INH and obtain a thorough history about the problem(s) including an assessment of possible causes, document these findings in the patient's chart and then consult with the physician. The physician will evaluate the condition(s). The physician may wish to follow the patient, order laboratory test(s) and/or continue to hold the INH. The physician must reorder the restarting of therapy.

F. PATIENT EDUCATION:

Emphasize the significance of an abnormal chest x-ray and the increased risk of developing current TB disease. Explain the presence of HIV infection as an important risk factor for developing clinical tuberculosis. Explain the meaning of a positive TST reaction. Discuss the difference between LTBI and TB disease, reason for taking medication, instructions for use, and importance of regular use. Explain possible adverse reactions to medication and procedure to follow if signs and symptoms occur including stopping of medication until the patient can consult with the nurse or doctor. The principle of education is to emphasize the benefits of LTBI therapy and the infrequency of adverse reactions. Provide the patient with appropriate written materials in the appropriate language. The education should be supplemented with flip charts or other audio visual-aids. Obtain verbal consent from patient to begin LTBI therapy. The record must also contain a signed, dated, and witnessed consent before LTBI therapy is initiated.

G. RECORD KEEPING:

Clinic visits, medication dispensed, LTBI therapy surveillance, TST, chest x-ray, laboratory test results and broken appointment follow-up will be documented on the form H-261, or the TB Patient Clinical Summary (H-513) when both INH and Rifampin are used. If additional space is needed to document problems and action taken, the Progress Notes (H-654) may be used. The Progress Notes must reference flow sheets H-261 or H-513 each time the flow sheet is used. The SOAP format is to be used on the Progress Notes. All documentation in the chart must be done in accordance with the County of Los Angeles, Department of Health Services, Medical Records, Policy and Procedure Manual. The closure of all patients on LTBI therapy must be done on the H-304 and appropriate copy submitted to TB Control.

PROTOCOL # 3
MANAGING STABLE OR IMPROVING PULMONARY TUBERCULOSIS DISEASE (TB CLASS III)

POLICY: Extended Role Nurses may supervise the treatment of a patient who has stable or improving pulmonary TB disease (TB Class III). The patient must be on an effective treatment regimen and be improving clinically. The medical record must have a written physician's order referring the patient to the ERN and prescriptions for the patient's medications must be written on the TB Patient Clinical Summary (H-513) or Progress Notes (H-654). The ERN may follow patients on directly observed daily or intermittent therapy. Patients having drug-resistant TB, extra pulmonary TB disease, or who are HIV-positive must be followed by the physician per General Policy Statement - ERN Caseload: D, (p.2).

PROCOTOL:

A. DEFINITION: Pulmonary TB – is TB disease of the lung(s) that is clinically active with Mycobacterium tuberculosis complex on culture (if done) from the lung, plus clinical, bacteriological or radiographic evidence of current disease. The disease process must be stable or improving for the ERN to supervise the patient's treatment.

B. DATA BASE:

1. Subjective: Asymptomatic or clinically improving.

2. Objective: Chest x-ray reading, and clinical findings.

C. ASSESSMENT/DIAGNOSIS:

Pulmonary TB, Class III, stable.

D. TREATMENT PLAN AND FOLLOW-UP:

1. Check for compliance in taking medication.
2. Evaluate for signs or symptoms of side effects or toxicity.
3. Continue prescribed medications for the length of time specified by the physician.
4. Schedule patient for a clinic visit no less frequently than monthly to evaluate compliance, clinical progress and refill prescriptions.
5. Draw ordered laboratory tests including liver function tests (LFTs) during the clinic visit. Book the chart to the physician for review and evaluation if laboratory results are abnormal.
6. Perform vision screening each clinic visit if patient is receiving Ethambutol.
7. Obtain sputum specimen(s) for AFB smear(s) and culture(s) as outlined in the TB Control Manual. If patient is unable to raise sputum, obtain induced sputum.

8. Medication dosage for children should be adjusted based on weight and ordered by the physician.
9. Repeat chest x-ray at 3 months and at the end of the prescribed course of chemotherapy.
10. Book the chart to the physician for review and consultation before closing the patient to clinic follow-up.
11. The physician is to review and sign the chart within one week of each visit.

E. CONDITIONS REQUIRING CONSULTATION WITH CHEST PHYSICIAN:

1. Development of adverse reaction e.g., tingling, itching, headaches, rash, numbness, nausea, vomiting or symptoms of liver toxicity, etc. (per TB Control Manual).
2. Symptoms of progressive TB disease process: persistent cough, night sweats, persistent low-grade fever, hemoptysis, unexplained respiratory complaints, or weight loss.
3. Smear positive after 2 months or culture positive at 3 months or later after beginning of therapy.
4. Abnormal changes in laboratory results.
5. Worsening appearance on chest x-ray.
6. Signs and symptoms of other medical problems.
7. Patient requests consultation.

F. PATIENT EDUCATION:

Emphasize and explain the significance of TB disease. Appropriately interpret results of laboratory data. Reinforce the communicability of TB and the method of transmission. Explain reasons for taking medication, instructions for self-administration of medications or directly observed therapy, and the importance of regular use. Explain possible adverse reactions to medications and procedure to follow if signs and symptoms occur including stopping medication until consulting with nurses or physicians. The principle of education is to emphasize the benefits of medication (chemotherapy), the importance of taking medication as prescribed, and what to do about adverse reactions. Provide the patient with appropriate written material in the appropriate language. The education should be supplemented with flip charts or other audio-visual aids. The record must also contain a signed, dated, and witnessed consent form.

PROTOCOL # 3
MANAGING STABLE OR IMPROVING PULMONARY TUBERCULOSIS DISEASE (TB CLASS III)

G. RECORD KEEPING:

Clinic visits, medications dispensed, x-ray and laboratory test results and broken appointment follow-up will be documented on the TB Patient Clinic Summary (H-513). If additional space is needed to document problems and action taken, the Progress Notes (H-654) may be used. The SOAP format is to be used on the Progress Notes. All documentation in the chart must be done in accordance with the County of Los Angeles, Department of Health Services, Medical Records, Policy and Procedure Manual. The Progress Notes must reference the flow sheet (H-513) each time the flow sheet is used. The physician must order the closure of all TB (Class III) patients. Closure of all TB (Class III) patients must be done on the H-513 and the appropriate copy submitted to the TB Control Program.

LABELING AND DISPENSING PRESCRIBED MEDICATIONS

POLICY: Extended Role Nurses may label and dispense medication that has been prescribed by the physician for the management of TB. Medication should be dispensed in monthly allotments, unless otherwise specified. The physician must order any medication supply of greater than one month. The following drugs may be labeled and dispensed using the procedure below: Isoniazid, Ethambutol, Pyrazinamide, Rifamate, Rifampin, Rifabutin and Rifater.

PROCEDURE:

1. The prescription must be written and signed by the physician. The prescription will be written in the patient's record on the form H-261 or the TB Patient's Clinical Summary (H-513).

   NOTE: For some patients having TB II, uncomplicated by other medical conditions, the ERN may initiate daily INH before the order is signed per General Policy Statement - ERN Caseload: A (p.1). The prescription must be signed by the physician as soon as possible, but no later than one week after INH is initiated. The prescription must be written and signed in advance for some patients – refer to the General Policy Statement - ERN Caseload: A, B, C for guidelines.

2. The prescription must include
   - Date
   - Drug name and dosage
   - Size and quantity of medication to be dispensed
   - Direction for use
   - Number of refills permitted
   - Physician's signature

3. During the course of therapy, medication dosage for children weighing less than 60 lbs should be adjusted based on weight, (e.g. 10-15 mg/kg for INH and 10-20 mg/kg for Rifampin). All pediatric patients weighing 60 lbs or more should receive 300 mg of INH. See TB Control Manual (or the "First-Line TB Drug" table found in the appendix of this document) for the correct dosage of other TB drugs. When the dosage is changed from the original order, a new prescription needs to be written on the form H-261 in sec. 10, "NOTES"

   (e.g., Sig: INH 100mg ii p.o. daily
   disp: 60 tablets
   refill x 2)

   or on the TB Patient Clinical Summary (H-513), if applicable, or in the Progress Note (H-654) and signed by a physician within one week.

4. The pharmacy or warehouse furnishes the health center with medications in the manufacturer's container or appropriate package which includes the name of the drug, strength of drug, number and quantity supplied, the manufacturer, the expiration date and lot number. The prescription label is to be affixed to this container or appropriate packaging. All RN's may reduce from bulk container to smaller containers as long as the drugs are dispensed within the same clinic. If repackaged, the new container must list the above information.

5. The bottle must be labeled with the following information:

   - Patient name and record number
   - Drug name, strength and quantity dispensed
   - Directions for use
   - Date of issue
   - Expiration date (if not visible on the container or
   - another container is used)
   - Name, address and telephone number of the health center
   - Name of the prescribing physician
   - Initials of the nurse dispensing the drug
   - The manufacturer and lot # (if not visible on the container or another container is used)
   - A "side-effect" label (if available)

6. Record Keeping:
   The above information must be indicated on either the form H-261, the TB Patient's Clinical Summary (H-513) or the Patient Progress Note (H-654) per Policy #501.3 (Los Angeles County Department of Health Services. Public Health Center Nursing Procedures).

PATIENT EDUCATION:

Explain the reason for taking medication, instructions for self-administration of medication, or directly observed therapy, and the importance of regular use. Explain possible adverse reactions to medication and procedure to follow if signs and symptoms occur.

AUTHORITY: California Business and Professions Code: Section 2725, 2725.1, 4051.5 California Health and Safety Code Section 1206 (b). Opinion of the Attorney General of California, Volume 57 P. 93, 2-19-74.

ALGORITHM FOR ERN MANAGEMENT OF TB CLASS 1,2,3,4 or 5)

APPENDIX 2

TB CLASS 1 or 2

Converters/Reactors age 4-34 years old without medical problems

ERN to start daily INH & follow per Protocol #1

Length of therapy to be specified by physician

M.D. to sign prescription within one week of patient staring INH

All contacts – TB Class 1, 2

Reactors with high risk medical conditions or certain other risk conditions (E.4, p.12).

Pregnant or less than 6 months postpartum

Reactors with break in

M.D. Examination or M.D. Review of Chart before INH initiated

ERN may follow patient per Protocol #1 following M.D. order

HIV -positive

Contacts to drug-resistant TB

Increased risk of liver disease

Reactors <4 years old

M.D. Examination and Evaluation

ERN may follow patient per Protocol #1 following M.D. Order

TB CLASS 3, 4, or 5

TBCLASS 3 Pulmonary, Stable TB CLASS 4

M.D. Evaluation, Exam and Order

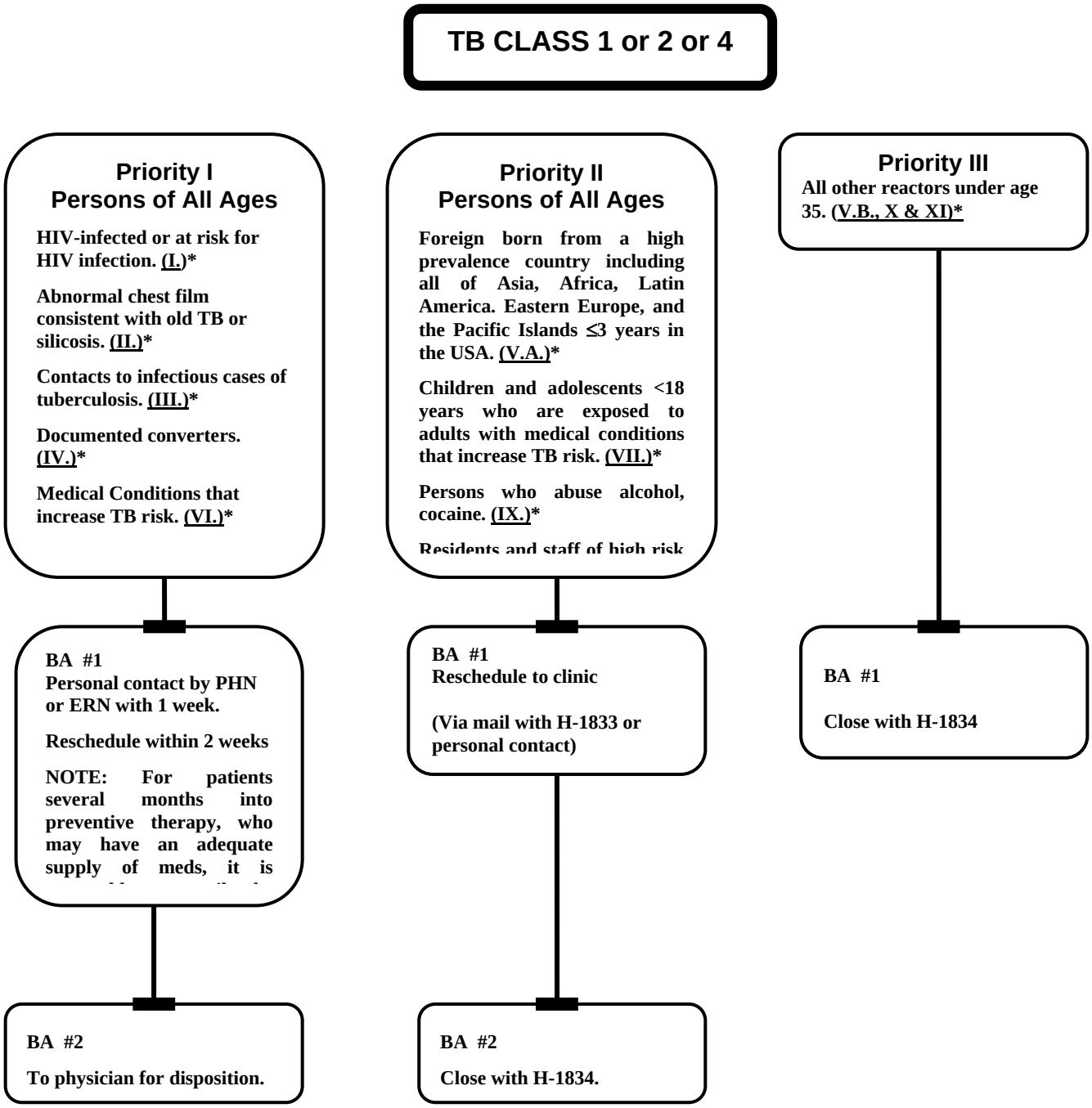
ERN may follow:
Protocol 2 (TB CLASS 4)
Protocol 3 (TB CLASS 3)

TB CLASS 3
TB CLASS 5
Unstable Pulmonary
Extra Pulmonary
Drug-Resistant
HIV-Positive

M.D. to Follow

CHEST CLINIC BROKEN APPOINTMENT (BA) GUIDELINES

TB CLASS 3 AND 5: All Charts Must be Reviewed by the Physician
Necessary Follow-up or Closure Must be Written by the physician



*Refers to Roman Numbers on pages 3 and 4 of the "Targeted Skin Testing and Treatment of Latent Tuberculosis Infection in Adults and Children." (Revised 11/2005)

First-Line TB Drugs

Drug	Dose in mg/kg (maximum Dose)						Adverse Reaction	Monitoring	Comments
	Daily		2 Times/Week *		3 Times/Week *				
	Children	Adults	Children	Adults	Children	Adults			
INH (Isoniazid)	10-15 (300mg)	5 (300mg)	20-30 (900mg)	15 (900mg)	not recommended	15 (900mg)	**More Common:** Hepatic enzyme elevation Hepatitis Peripheral neuropathy Mild effects on central nervous system **Less Common:** Rash, headache, dizziness, convulsions, fever **Drug Interactions:** Phenytoin (Dilantin)	Baseline hepatic enzymes (LFTs) for all persons at increased risk of liver damage (e.g. >35 yrs. history of hepatitis or liver disease, chronic liver disease, daily use of alcohol, injection drug use) & monthly for at least the first 3 months on INH. • Pregnant women –-LFTs near time or delivery • Postpartum women – LFTs monthly for first 6 months postpartum • Whenever patient has symptoms of adverse reactions	Hepatitis risk increase with age and alcohol consumption Pyridoxine can prevent peripheral neuropathy
RIF (Rifampin)	10-20 (600mg)	10 (600mg)	10-20 (600mg)	10 (600mg)	not recommended	10 (600mg)	GI upset Hepatitis Bleeding problems Flu-like symptoms Rash Drug interactions: Protease Inhibitors, estrogen (including oral contraceptives), methadone, coumadin derivatives, oral hypoglycemic agents, digitoxin, theophylline, anticonvulsants, cyclosporin, antiarrhythmic agents	Baseline lab measurements for adults • CBC and platelets • Hepatic enzymes Repeat measurements: • If baseline results are abnormal • If patient has symptoms of adverse reactions • Monthly if patient on more than one TB drug	Significant interactions with: • Protease inhibitors • Methadone • Birth control pills • Many other drugs Colors body fluids orange May permanently discolor soft contact lenses
PZA (Pyrazinamide)	15-30 (2 g)	20-25 (2 g)	50 (4 g)	40-50 (4 g)	not recommended	30-35 (3 g)	Hepatitis Rash GI upset Joint aches Hyperuricemia Gout (rare)	Baseline measurements for adults • Uric acid • Hepatic enzymes Repeat measurements monthly	Treat hyperuricemia only if patient has symptoms
EMB (Ethambutol)	15 (2.5g)	15	50	40-50	not recommended	25-30	Optic neuritis	Baseline and monthly tests • Visual acuity • Color vision	Not recommended for children too young to be monitored for changes in vision unless TB is drug resistant
SM (Steptomycin)	20-40 (1 g)	15 (1 g)	20 (1 g)	15 (1 g)	not recommended	15 (1g)	Ototoxicity (hearing loss or vestibular dysfunction) Renal toxicity Rash Fever	Baseline and repeat • Hearing (every 2 months • Kidney function (monthly)	Avoid or reduce dose in adults 60 years old

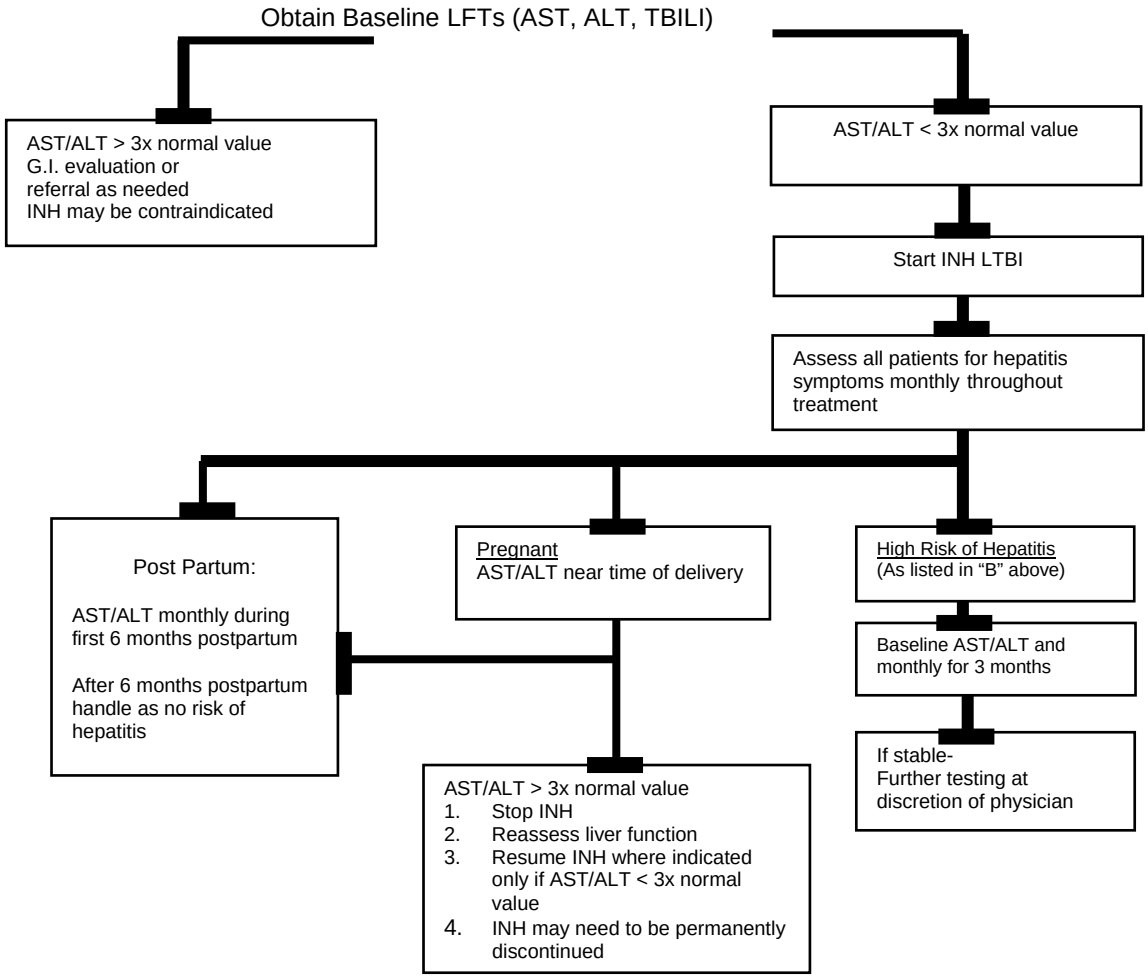
Notes: Adjust weight-based dosages as weight changes.
- All regimens should be used with DOT

Liver Function Monitoring during INH Therapy for LTBI

A. No Risk of Hepatitis
   1. No baseline LFTs
   2. Symptomatic monitoring monthly
   2. Stop INH when symptomatic and draw LFTs
   3. Resume INH where indicated only if AST is less than 3x normal value and M.D. reorders

B. High Risk of Hepatitis
   1. History of hepatitis, liver disease, daily use of alcohol, current or past injection drug use
   2. Pregnant or 3-6 months postpartum (including post abortion)*
   3. ≥ 35 years old **

Monitor the Patient at High-Risk for Hepatitis as Follows:



* LTBI therapy is not recommended unless other risk factors present. Hold until 3-6 months postpartum.
** LTBI therapy is not recommended for persons ≥ 35 years old with normal chest x-ray and no other risk factor.

Priorities for Targeted Skin Testing

TB CLASS 1 or 2 or 4

Priority I
Persons of All Ages

HIV infected or at risk for HIV infection. (I.)*

Abnormal chest film consistent with old TB or silicosis. (II.)*

Contacts to infectious cases of tuberculosis. (III.)*

Documented converters. (IV.)*

Medical Conditions that increase TB risk. (VI.)*

A. Injection drug use, regardless of HIV serostatus
B. Diabetes mellitus (especially insulin dependent)
C. Silicosis
D. End-stage renal disease
E. Chronic immunosuppression
   1. Transplant recipients
   2. Prolonged corticosteroid therapy (15 mg/day for 1 mo)
   3. Other immunosuppressive therapy
F. Hematological and reticuloendothelial diseases
G. Malnutrition & clinical situations associated w/rapid weight loss
   1. Cancer of the head and neck
   2. Intestinal bypass or gastrectomy
   3. Chronic malabsorption
   4. Low body weight (>10% below ideal body weight)

Priority II
Persons of All Ages

Foreign born from a high prevalence country including all of Asia, Africa, Latin America, Eastern Europe, and the Pacific Islands ≤3 years in the USA. (V.A.)*

Children and adolescents <18 years who are exposed to adults with medical conditions that increase TB risk. (VII.)*

Persons who abuse alcohol, cocaine. (IX.)*

Residents and staff of high risk congregate settings. (VIII.)*

Priority III
All other reactors under age 35.

1. Foreign born from a high prevalence country including all Asia, Africa, Latin America, Eastern Europe and Pacific Islanders ≥ 3 years in the USA (V.B.)
2. All other reactors except pregnant women (X & XI)

*** Refers to Roman Numbers on Page 3 of new Los Angeles County Standards for LTBI**

Revised 11/2005

County of Los Angeles Department of Health Services
Tuberculosis Control Program Standards

Targeted Skin Testing and Treatment of

Latent Tuberculosis Infection in Adults and Children

The following official LAC standards are based on CDC/ATS, California Tuberculosis Controllers Association, and California Department of Health Services, Tuberculosis Control Branch official guidelines

Recently published guidelines from the American Thoracic Society and Centers for Disease Control and Prevention have recommended a change in nomenclature. The terms "chemoprophylaxis" and "preventive therapy" will no longer be used. Instead, the phrase "treatment of latent tuberculosis infection (LTBI)" is recommended because it more accurately describes the intended intervention. This change in nomenclature will hopefully promote greater understanding of the concept for both patients and providers, resulting in more widespread use of this important tuberculosis (TB) control strategy. **(**see **Appendix 4 for Definitions and Abbreviations)**

Targeted TB Skin Testing

Targeted tuberculin skin testing for LTBI aims to identify individuals at high risk for TB who would benefit from treatment of LTBI. Persons for whom treatment of LTBI is indicated in this document are the same categories of persons who should be targeted for tuberculosis skin testing. Skin testing low risk populations will result in unnecessary testing and treatment because of false-positive test results.

High risk for developing TB disease is defined as:

(1) recent infection with *Mycobacterium tuberculosis*,
(2) the presence of clinical conditions that are associated with an increased risk of progression of LTBI to active TB (see **Appendix 1: Tables 1 and 2**) or
(3) increased morbidity if progression to TB disease occurs.

Definition of a positive tuberculin skin test

Previous vaccination with BCG is not a contraindication to tuberculin skin testing. Because most persons who have received prior BCG vaccination are from high prevalence areas of the world, previous vaccination should be ignored when interpreting a tuberculin skin test.

I. ≥ 5 mm of induration*****

A. Persons known or suspected to have HIV infection.

B. Recent contacts to an active case of pulmonary or laryngeal TB.

C. Persons with an abnormal chest radiograph consistent with TB disease.

D. Immunosuppressed individuals (See page 3 **Indications for Treatment of LTBI -TB2 and TB4**, VI-E)
***Note:** The California Department of Corrections considers all inmates high risk, and therefore treats for latent infection all inmates 5mm.

II. ≥ 10 mm of induration

All persons except those in I. above

Note: The CDC recommends using a 15 mm cutoff for low risk reactors. However, in California, public health departments do not recognize this cutoff because California is a high incidence state and the prevalence of nontuberculous mycobacterial infections is lower than other regions of the United States.

III. Tuberculin skin test conversion

TST conversion is defined as an increase of at least 10 mm of induration from < 10 mm to ≥ 10 mm within two years from a documented negative to positive TST.

Example: a TST of 4 mm that increases in size to 14 mm or more in induration would be considered a skin test conversion.

In some cases, the exact size (in mm) of the previous tuberculin skin test may not be known. In such cases, skin test conversion is defined as a change from a negative to positive tuberculin skin test within a 2-year period.

Evaluation for TB Disease - Symptom review and chest radiography

I. All persons who have a positive tuberculin skin test should undergo symptom review and have a chest radiograph.

A. If the radiograph is normal and the patient is asymptomatic, treatment of LTBI may be indicated (see **Appendix 2**).

B. If the radiograph is normal but the patient has a clinical presentation consistent with tuberculosis, further work-up is indicated and treatment of LTBI should be delayed until active tuberculosis has been ruled out.

II. Bacteriologic studies should be obtained for all persons with an abnormal chest radiograph consistent with tuberculosis even when the radiographic abnormalities appear stable. If bacteriologic studies are obtained, treatment of LTBI should not be initiated until final culture results are available.

Definition of persons eligible for treatment of LTBI (TB2 and TB4)

The following classes of persons are eligible for treatment of LTBI if they have not received a prior course of treatment for active TB or LTBI. In some cases, individuals may require another course of therapy if they have been exposed as a close contact to an infectious case of TB and have HIV/AIDS or are otherwise immunosuppressed.

I. TB2 - Tuberculosis infection, no disease:
Positive reaction to tuberculin skin test, negative bacteriologic studies (if done) and no clinical and/or radiographic evidence of tuberculosis.

II. TB4 - Tuberculosis, no current disease:

A. History of previous episode(s) of tuberculosis, or
B. Abnormal*, but stable, radiographic findings in a person with a positive tuberculin skin test, negative bacteriologic studies, and no clinical and/or radiographic evidence of current disease.

*Abnormal refers to radiographs with parenchymal abnormalities consistent with TB. It does not refer to isolated calcified granulomas or apical pleural thickening

Indications for Treatment of LTBI TB2 and TB4 (See **Appendix 2**)

Persons in the following categories including pregnant women, except when otherwise noted, should be treated if their tuberculin skin test is positive and they have not previously completed a course of therapy for tuberculosis or LTBI.

I. Persons known or suspected to have HIV infection, regardless of age.

II. Persons with an abnormal chest radiograph suggestive of tuberculosis and classified as a TB 4, regardless of age.

III. Recent close contacts to active pulmonary or laryngeal TB, regardless of age.

IV. Tuberculin skin test converters, regardless of age.

V. Persons from countries with high TB rates but no other risk factors, except for pregnant women.

A. Recent arrivals to the USA (arrived within the past 3 years or less), regardless of age.
B. Remote arrivals to the USA (resided continuously in the USA for more than 3 years), and are **NOT OVER 35 YEARS OF AGE.**

VI. Persons with the following conditions that have been associated with an increased risk of TB (See **Appendix 1, Tables 1 and 2**), regardless of age:

A. Injection drug use, regardless of HIV serostatus

B. Diabetes mellitus (especially insulin-dependent)

C. Silicosis

D. End-stage renal disease

E. Chronic immunosuppression

1. Transplant recipients

2. Prolonged corticosteroid therapy (15 mg/day for. 1mo)

3. Other immunosuppressive therapy

F. Hematological and reticuloendothelial diseases

G. Malnutrition and clinical situations associated with rapid weight loss

1. Cancer of the head and neck
2. Intestinal bypass or gastrectomy
3. Chronic malabsorption
4. Low body weight (>10% below ideal body weight)

VII. Children and adolescents < 18 years of age exposed to adults with any of the above high risk characteristics, except if pregnant.

VIII. Residents and employees of the following high risk congregate settings: prison and jails, nursing homes, and other long-term facilities for the elderly, residential facilities for patients with AIDS, and homeless shelters; other homeless persons; employees of hospitals and other health care facilities **regardless of age.**

IX. Persons with a positive tuberculin skin test not in the above categories who abuse alcohol, cocaine, and intravenously injected drugs who are tested and have LTBI **regardless of age.**

X. All other

XI. All persons who are tested and have LTBI and are **NOT OVER 35 YEARS OF AGE**, except for pregnant women.

Indications for Treatment of LTBI - TB1 (TB exposure but negative skin test) (See **Appendix 2**)

Close Contacts

In close contacts to infectious cases, the initial tuberculin skin test may be negative despite underlying infection with *M.tuberculosis* if the TST is placed before the contact has mounted an immune response to the tuberculin antigen. It takes 2-12 weeks after infection with *M. tuberculosis* to develop a positive TST reaction.

Close contacts (TB1) to an infectious case, who have a tuberculin skin test < 5 mm, should have a chest radiograph obtained, and once TB disease is excluded, should be started on therapy for LTBI regardless of age **IF:**

I. Circumstances suggest a high probability of infection. For example, evaluation of other contacts with a similar degree of exposure demonstrates a high prevalence of infection, documented converters, or secondary cases.

II. The contact is a child under 5 years of age, or is infected with HIV, or is otherwise immune-compromised.

For those individuals who are started on therapy with a TST < 5 mm, a repeat tuberculin skin test should be performed 10 to 12 weeks after contact with the infectious case has been broken, or the index case becomes non-infectious, to determine if the skin test has become positive. Decision on continuing therapy should be made once the result of repeat skin testing is available.

Note: In HIV infected contacts; treatment should be completed, regardless of the result of the repeat skin test.

Treatment Regimens for LTBI

(See **Appendix 3,** for intervals and duration, drug dosages, and treatment completion criteria)

The standard regimen is isoniazid (INH) as a single drug.

I. INH alone:

A. 6 month regimen (minimum) for immune-competent adults. 9 month regimen if twice-weekly

B. 9 month regimen for children and adolescents (up to age 16 - 18)

C. 9 month regimen for HIV-infected persons or persons suspected of having HIV infection

D. 9 month regimen for TB 4 (See also **IV** below)

Alternative regimens for special circumstances.

II. RIF and PZA for 2 months:

Approval from the TB Control Program is required before using this regimen.

This regimen is not to be used except in HIV infected persons who are at very high risk for tuberculosis and unlikely to take 6 – 9 months of INH. Particular caution is necessary in patients taking other medications associated with livery injury, and those with a history of alcoholism even if alcohol use is discontinued during treatment. Rifampin/pyrazinamide is contra-indicated for persons with underlying liver disease or for those who have had isoniazid –associated liver injury. Rifampin/pyrazinamide must be given by directly observed therapy (DOT).

III. Rifampin alone for 6 months:

Treat persons exposed to cases with mono-resistance to INH or intolerance to INH with 6 months of RIF. A 2-month regimen of RIF and PZA is not recommended.

IV. INH and RIF (Rifamate) or RIF alone for 4 months for TB 4.

Although there have been no randomized studies to document the efficacy of this regimen in persons classified as a TB 4, there is a great deal of experience with this regimen in the public health sector. Give this regimen to TB suspects who have been started on treatment for TB but are later determined to be TB 4. The time for treatment as a suspect case should be included in the total 4 months recommended for treating LTBI.

V. Rifabutin may be substituted for rifampin in the above regimens in situations where rifampin cannot be given such as in HIV-infected persons taking certain protease inhibitors or non-nucleoside reverse transcriptase inhibitors. Dosage adjustments may, however, be necessary. TB Control should be consulted before making this substitution.

VI. Regimens for Contacts to Drug Resistant Cases

A. INH mono-resistant source case

Refer to III above.

B. Multidrug resistant source case

Persons exposed to a multidrug resistant case of TB require consultation with TB Control for expert advice concerning appropriate treatment.

Daily vs. Intermittent Dosing

INH may be given daily or twice weekly when treating LTBI. When INH is given twice weekly it must be given by DOT and the length of therapy should be a minimum of 9 months.

Intermittent therapy should not be used with a 2 month RIF and PZA regimen except under an approved protocol from TBC**.**

A. Directly Observed Therapy

Directly observed therapy (DOT) for LTBI should be used in circumstances where the risk of nonadherence is judged to be high, the risk of progression to active disease is high, or when the treatment regimens are given intermittently. New short course regimens and intermittent dosing may make DOT more feasible.

Monitoring for Drug Toxicity and Adherence

I. Baseline Evaluation

A. Baseline laboratory testing is not routinely indicated for all persons at the start of treatment for LTBI. Such testing may, however, be considered on an individual basis. Persons with the following high-risk characteristics are required to have baseline laboratory testing:

1. HIV infection
2. History of, or at risk of, chronic liver disease
3. Alcoholism
4. Taking other hepatotoxic medications
5. All persons over 35 years of age
6. Pregnant women and those in the immediate post-partum period (3 – 6 months)

B. The baseline laboratory tests will depend on which drug regimen is being used.

1. Isoniazid-containing regimen - In persons taking isoniazid, baseline measurements of serum AST or ALT and bilirubin are indicated.
2. Rifampin (or rifabutin) -containing regimen - In persons taking a rifamycin, baseline measurements of complete blood count and platelets are recommended, in addition to liver function tests.
3. Pyrazinamide-containing regimen - same as rifampin-containing regimen. A baseline uric acid level is not necessary unless the patient has a history of gout.

II. Evaluation During Treatment

A. Clinical Evaluation - Patients being treated for LTBI should receive a clinical evaluation at least monthly, regardless of the regimen used. The evaluation should include careful in person questioning of the patient about side effects associated with the medications, particularly hepatitis (e.g., anorexia, malaise, abdominal pain, fever, nausea, vomiting, dark urine, icterus). In addition, the patient should be asked about adherence and educated about the possible side effects of the medications.

No more than a one-month supply of medication is to be dispensed at a time.

B. Rifampin and pyrazinamide containing regimens may require more frequent monitoring. Liver function studies including a serum aminotransferase (AT) and bilirubin must be done at baseline, weeks 2, 4, and 6 of therapy. Asymptomatic serum AT increases are expected but do not require that treatment be stopped unless the AT level is greater than three times the upper limit of normal range in which case the regimen should not be resumed . Treatment should also be stopped and not resumed if any of the following findings occur: AT greater than normal range accompanied by symptoms of hepatitis, or serum bilirubin greater than normal whether symptoms are present or not. Rifampin/pyrazinamide must be given by DOT.

C. Routine laboratory monitoring during treatment of LTBI is indicated for those whose baseline liver function are abnormal, for persons at high risk of hepatic disease, or persons with symptoms of hepatitis. The frequency of this monitoring will vary depending on the person's risk of liver disease and the severity of the liver function test abnormalities.

Note: Pregnant women and those in the immediate post-partum period (within 3 - 6 months of delivery) *must* have repeat liver function tests measured monthly.

III. When To Stop Medications Due to Drug-induced Hepatitis

Medications should be stopped if the transaminase levels exceed **3** times the upper limit of normal. Medication should be held pending further clinical and laboratory evaluation**.**

Completion of Therapy

Completion of therapy should be based on the total number of doses administered not duration of therapy. If treatment is interrupted the recommended number of doses of the regimen should be provided within a certain maximum time period (See **Appendix 3**). The entire regimen should be restarted if interruptions were frequent or prolonged enough to preclude completion of doses in the time frames specified. When therapy is restarted after an interruption of more than 2 months, a medical examination to exclude active disease is indicated.

The standard in LAC when closing a patient being treated for LTBI to the TB Registry is to include the total number of medication doses received over a specific period of time.

Note: No set of standards can cover all individual treatment situations that can and will arise. Thus, when questions on individual situations not covered by these standards do arise, consult with LAC TB Control Program.

These standards have been approved and are in effect as of February 2001:

Signed:

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Director, Health Protection and
Disease Control, Communicable Disease Control

Signed copied on file – TB Control Program

VII. Suggested Readings

1. American Academy of Pediatrics. 2000. Tuberculosis. *In* Red Book: Report of the Committee on Infectious Diseases, 25th ed. American Academy of Pediatrics, Elk Grove Village IL.

2. American Thoracic Society / Centers for Disease Control and Prevention. Treatment of tuberculosis and tuberculosis infection in adults and children. Am J Respir Crit Care Med 1994; 149: 1359-1374.

3. American Thoracic Society / Centers for Disease Control and Prevention. Targeted skin testing and treatment of latent tuberculosis infection. Am J Respir Crit Care Med. 2000 161: S221-S247.

4. American Thoracic Society / Centers for Disease Control and Prevention. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000; 161:1376-1395.

5. Centers for Disease Control and Prevention. Notice to readers. Updated guidelines for the use of rifabutin or rifampin for the treatment and prevention of tuberculosis among HIV-infected patients taking protease inhibitors or nonnucleoside reverse transcriptase inhibitors. MMWR 2000; 49:185-189.

6. Center for Disease Control and Prevention. Update: Fatal and Severe Liver Injuries Associated With Rifampin and Pyrazinamide for Latent Tuberculosis Infection, and Revisions in American Thoracic Society/CDC Recommendations-United States, 2001 MMWR 2001; 50(34);733-5.

7. Zuber PLF, McKenna MT, Binkin NJ, Onorato IM, Castro KG. Long-term risk of tuberculosis among foreign-born persons in the United States. J.A.M.A. 1997; 278:304-307.

Appendix 1

High Risk Populations

Table 1. Incidence of Active TB in Persons with a Positive TST by Selected Factors

Risk Factor	TB Cases/1000 person-years
Infection > 2 years past	**1.6**
Infection < 1 year past	**12.9**
HIV Infection	**35.0-162.0**
Injection Drug Use	
HIV seropositive	**76.0**
HIV seronegative or unknown	**10.0**
Silicosis	**68**
Radiographic findings consistent with old TB	**2.0-13.6**

Source: American Thoracic Society/Centers for Disease Control and Prevention, 2000

Table 2. Certain medical conditions associated with an increased risk of developing TB

Medical Condition	Relative Risk
Solid organ transplant	
Renal	**37**
Cardiac	**20-74**
Jejunoileal bypass	**27-63**
Silicosis	**30**
Chronic Renal Failure/Hemodialysis	**10.0-25.3**
Carcinoma of head and neck	**16**
Gastrectomy	**2-5**
Diabetes mellitus	**2.0-4.1**

Source: American Thoracic Society/Centers for Disease Control and Prevention, 2000

Appendix 2

CANDIDATES FOR TREATMENT OF LATENT TUBERCULOSIS INFECTION (LTBI) (adapted from Charles P. Felton National TB Center)			
Category of person tested	TST <5 mm	TST ≥ 5 mm	TST ≥ 10 mm
(1) Recent Contact to TB Case[1]			
1. Child <5 years and recent contact[2]	TREAT	TREAT	TREAT
2. HIV-infected and recent contact[2]	TREAT	TREAT	TREAT
3. Immunosuppressed and recent contact[2]	TREAT	TREAT	TREAT
4. Other recent contact of TB case	Do Not Treat	TREAT	TREAT
(2) No Recent Contact to TB Case			
1. Fibrotic changes on chest X-ray[3]	Do Not Treat	TREAT	TREAT
2. HIV-infected	Do Not Treat	TREAT	TREAT
3. Injection drug user with unknown HIV status	Do Not Treat	TREAT	TREAT
4. Other immunosuppressed persons[4]	Do Not Treat	TREAT	TREAT
5. Foreign-born persons from endemic country[5]	Do Not Treat	Do Not Treat	TREAT
6. Injection drug user known to be HIV negative	Do Not Treat	Do Not Treat	TREAT
7. Resident/Employee institutional setting[6]	Do Not Treat	Do Not Treat	TREAT
8. Mycobacteria lab personnel	Do Not Treat	Do Not Treat	TREAT
9. High-Risk clinical conditions[7]	Do Not Treat	Do Not Treat	TREAT
10. Children < 18 years of age exposed to adults at high risk	Do Not Treat	Do Not Treat	TREAT
11. Other persons depending on local epidemiology and resources	Do Not Treat	Do Not Treat	TREAT

Note: If a person meets more than one criteria for treatment, the lower TST cut point for therapy should be used (i.e. an immigrant from a TB endemic country who has fibrotic changes on chest radiograph should be treated if the TST is ≥5 mm induration

[1]Recent contacts to active case of pulmonary or laryngeal TB.

[2]Recent contacts who are initially TST-negative should have a TST repeated 8-12 weeks after last exposure to TB case (see Text). Treatment can usually be discontinued after negative second TST in children. HIV infected adults and children, however, should receive full course of therapy regardless of TST result.

[3]Abnormal, stable, radiographic findings (parenchymal abnormalities consistent with TB, not isolated calcified granuloma or apical pleural thickening). Bacteriologic studies should be obtained for all persons with an abnormal chest radiograph consistent with TB even when the radiographic abnormalities appear stable. When bacteriologic studies are obtained, treatment of LTBI should not be initiated until final culture results are available.

[4]Transplant recipients, prolonged corticosteroid therapy (∃15 mg/day for ∃1 month), other immunosuppressive therapy

[5] Persons who have resided in the U.S. for over 3 years should receive treatment if they are not over 35 years of age.

[6]Residents and employees of the following high risk congregate settings: prisons and jails*, nursing homes and other long-term facilities for the elderly, residential facilities for patients with AIDS, homeless shelters; other homeless persons; employees of hospitals and health care facilities.

*The California Department of Corrections considers all inmates high risk, and therefore treats for latent infection all inmates ∃5mm.

[7]Silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g. leukemias and lymphomas), other specific malignancies (e.g. carcinoma of the head and neck or lung), weight loss of ∃10% of ideal body weight, gastrectomy, jejunoileal bypass.

Pregnancy: Treat during pregnancy if either HIV-infected or recent *M.tb* infection.

Appendix 3

Recommended Drug Treatment Regimens For Treatment of LTBI

Drug	Interval & Duration	Adult Dose (max)	Pediatric Dose (max)	Criteria for Completion	Monitoring	Comments
INH	Daily for 6 mos	5 mg/kg (300 mg)		180 doses within 9 mos	Clinical monitoring monthly. Liver function tests[1] at baseline in selected cases[2] and repeat measurements if baseline tests are abnormal, patient is at high risk for adverse reactions, or patient has symptoms of hepatitis.	Preferred regimen for all immune-competent adults.
	Twice-weekly for 9 mos	15 mg/kg (900 mg)		76 doses within 12 mos		Alternate regimen for adults. DOT must be used with twice-weekly dosing
INH	Daily for 9 mos	5 mg/kg (300 mg)	10-20 mg/kg (300 mg)	270 doses within 12 mos		Preferred for children and HIV-infected adults. In HIV-infected patients, INH may be administered concurrently with NRTIs, protease inhibitors, or NNRTIs
	Twice-weekly for 9 mos	15 mg/kg (900 mg)	20-40 mg/kg (900 mg)	76 doses within 12 mos		Alternate regimen for children HIV-infected. DOT must be used with twice-weekly dosing
RIF plus PZA	Daily for 2 mos	RIF 10mg/kg (600 mg) PZA 15-20 mg/kg (2.0 g)	nr	60 doses within 3 mos	Clinical monitoring at baseline, weeks 2, 4, and 6. Liver function tests[1] at baseline and repeat measurements if baseline results are abnormal or patient has symptoms of adverse reactions. Requires TB Control approval Medications must be given by DOT.	Alternate regimen for HIV-infected adults unlikely to take 6-9 mos of INH. In HIV-infected patients, certain protease inhibitors or NNRTIs should not be administered concurrently with RIF; an alternative is rifabutin 300 mg daily.
RIF	Daily for 6 mos.	10 mg/kg (600 mg)	10-20 mg/kg (600 mg)	120 doses within 9 mos	Clinical monthly monitoring Complete blood count, platelets, and liver function tests[1] at baseline in selected cases[2] and repeated measurements if baseline results are abnormal or patient has symptoms of adverse reactions	For persons exposed to INH resistant, RIF susceptible TB and those who cannot tolerate INH.
INH plus RIF	Daily for 4 mos.	INH 5 mg/kg (300 mg) RIF 10mg/kg (600 mg)		120 doses within 6 mos	See INH and RIF	Alternate regimen for TB Class 4 (history of previous TB or abnormal but stable radiographic findings without evidence of active TB.)

Abbreviations: INH = isoniazid, RIF = rifampin, PZA = pyrazinamide, NRTIs = nucleoside reverse transcriptase inhibitors, NNRTIs = non-nucleoside reverse transcriptase inhibitors, DOT = directly observed therapy, mos. = months, nr = not recommended. **Pregnancy:** INH regimens preferred for pregnant women. Some experts would use RIF plus PZA as an alternate regimen in HIV-infected pregnant women. PZA should be avoided during the first trimester. **MDR-TB exposure**: For persons who are likely to be infected with INH and RIF (multi-drug) resistant TB and at high risk of reactivation, PZA and ethambutol or PZA and a fluoroquinolone are recommended depending on the sensitivities of the M. tb isolate. (Consult expert.)

[1] AST or ALT and serum bilirubin

[2] HIV Infection, history of liver disease, alcoholism, and pregnancy

Appendix 4

Definitions and Abbreviations

1. LTBI — Latent tuberculosis infection

2. TB1 — Tuberculosis exposure--no evidence of infection
   History of exposure
   Negative reaction to tuberculin skin test

3. TB2 — Tuberculosis infection--no disease
   Positive reaction to tuberculin skin test
   Negative bacteriologic studies (if done)
   No clinical, bacteriological, or radiographic evidence of current disease

4. TB3 — Tuberculosis disease--clinically active
   Mycobacterium tuberculosis cultured (if done)
   Clinical, bacteriological, or radiographic evidence of current disease

5. TB4 — Tuberculosis--not clinically active
   History of episode(s) of tuberculosis, or
   Abnormal but stable radiographic findings
   Positive reaction to the tuberculin skin test
   Negative bacteriologic studies (if done), and
   No clinical or radiographic evidence of current disease

6. TB5 — Tuberculosis disease suspected
   Diagnosis pending

7. CDC — Centers for Disease Control and Prevention

8. TST — Tuberculin skin test

9. LAC — Los Angeles County

10. DHS — Department of Health Services

11. TBC — Tuberculosis Control Program

12. DOT — Directly observed therapy

13. ATS — American Thoracic Society