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Standing Delegation Orders and Procedures
Standing Medical Orders and Procedures
Issued by the Regional Director

Cover Sheet

For: Tuberculosis Services

Effective Date: _____Through_____

Authorizing Physician: _____

Signature: _____ Date: _____

Emergency Contact Information: _____

Staff authorized to perform the Standing Delegation Orders and Procedures:

Name/Title	Signature	Date

Texas Department of State Health Services
<<Health Service Region____ or Local Health Department>>
Standing Delegation Orders and
Standing Medical Orders for
Tuberculosis Prevention and Control

I. Definitions

A. Standing delegation orders (SDO) are defined as written instructions, orders, rules, regulations or procedures prepared by a physician and designed for a patient population with specific diseases, disorders, health problems or sets of symptoms.

B. Standing medical orders (SMO) are defined as orders, rules, regulations or procedures prepared by a physician or approved by a physician or the medical staff of an institution for patients that have been examined or evaluated by a physician. SMO are used as a guide in preparation for carrying out medical and surgical procedures or both. These orders, rules, regulations or procedures are authority and direction for the performance for certain prescribed acts for patients by authorized persons as distinguished from specific orders written for a particular patient.

II. Purpose

A. These standing delegation orders/standing medical orders are provided for <<Department of State Health Services or local health department name>> licensed registered nurses and vocational nurses providing services in <<Health Service Region ____ or local health department service area>>, under the medical supervision of the <<regional director or local medical director>>. All staff authorized to use these orders will review the SDO/SMO and sign a cover sheet annually. The SDO/SMO and the signature sheets will be retained by the agency for 25 years. It is the intent of all parties involved that the procedures done through them are in conformity with the Texas Medical Practice Act, the Texas Nurse Practice Act, and rules promulgated under those acts.

III. Process for development of these standing delegation orders/standing medical orders

A. Initially written and reviewed annually by staff at the Department of Health Services (DSHS) Central Office TB Program;
B. Reviewed by TB expert physician(s) who are recognized by the DSHS TB program;
C. Reviewed and approved by a Department of State Health Services TB/HIV/STD/Viral Hepatitis Medical Officer.
D. Sent electronically to DSHS regional TB program managers and local health department TB programs as a template for regional or local health department use.
E. Regional Medical Directors and local health department physicians review the template, make any changes they wish to make, sign them and distribute them for use by their registered and licensed vocational nurses to use when delivering TB services to individuals.

IV. Requirements for nurses performing these orders

A. Be registered nurses or licensed vocational nurses;
B. Have a current nursing license from the Texas Board of Nursing (each nurse's license will be reviewed for currency on an annual basis);
C. Receive training in accordance with appropriate clinical procedures and standards;
D. Receive initial and annual performance evaluations by the nurse's supervisor that document the person's ability to carry out these orders in the customary manner;
E. Maintain detailed patient medical record on each patient, including but not limited to:
    1. Nursing care delivered on each patient visit;
    2. Actions carried out under the SDO/SMO;
    3. Drugs or medications administered, provided or observed to be taken by the patient (directly observed therapy);
    4. Other information that is routinely noted on patient charts and files by physicians in their offices;
    5. Review the patient plan of care with the prescribing physician at a minimum of every 3 months while the patient is under care.

V. Place of service and method of contacting the physician

A. Authorized personnel can provide services under the SDO/SMO in the clinic when the physician is with the patient or in the building.
B. Authorized personnel can provide services under the SDO/SMO in the patient's home, in the clinic setting, or other field settings when a process for contacting the physician has been established.
C. Staff that provide services using these orders should contact the authorizing physician directly when medical direction or consultation is needed, when patient assessment data indicates deviations from normal limits, or as specified in any individual standing order. In an emergency situation, the authorized person is to call 911, provide first aid services, and contact the supervising physician.

VI. In addition, other clinic physicians may develop standing delegation orders/standing medical orders to be reviewed annually by the <<regional or local medical director>> and carried out by the <<regional or local>> nurses. For further information on the general authority of a physician to delegate, see the Texas Occupations Code, Chapter 157, Subchapter A, General Provisions, §157.001.

VII. The following documents must be readily available to the nurse both as an electronic file and in hard copy:
A. Controlling Tuberculosis in the United States, (ATS/CDC/IDSA), MMWR Vol. 54, No. RR-12, 2005. (http://www.cdc.gov/mmwr/PDF/rr/rr5412.pdf)
B. Treatment of Tuberculosis, (ATS/CDC/IDSA), 2003. (http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf)
C. An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy, Am J Respir Crit Care Med, Vol 174. pp 935-952, 2006 (http://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy-pdf)

D. Diagnostic Standards and Classification of Tuberculosis in Adults and Children, (CDC), 2000. (http://www.thoracic.org/statements/resources/archive/tbadult1-20.pdf)
E. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005, MMWR, Vol. 54, No. RR-17 (2005), (http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf)
F. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, MMWR Vo. 54, No. RR-15, 2005 (http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf)
G. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection-United States, 2010, MMWR 2010, 59 (RR-t); pp. 1-25 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=n5905a1_e)
H. Targeted Tuberculin Testing and Treatment of Latent TB Infection, (CDC), 2000. (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm)
I. Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC, MMWR, Vol. 55, No. RR-9, 2006, (http://www.cdc.gov/mmwr/PDF/rr/rr5509.pdf)
J. Update: Adverse Event data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003, MMWR 52 (No. 31) (http://www.cdc.gov.mmwr/preview/mmwrhtml/mm5231a4.htm)
K. Managing Drug Interactions in the Treatment of HIV-Related Tuberculosis, CDC, 2007, http://www.cdc.gov/tb/TB_HIV_Drugs/default.htm
L. Core Curriculum on Tuberculosis, 5thEdition, (CDC) 2011 and Interactive Core Curriculum on Tuberculosis: What the Clinician Should Know, (CDC), 2011 (http/www.cdc.gov/tb/education corecurr/pdf/corecurr_all.pdf)
M. Drug Information on Antituberculosis Drugs, PDR. (http://www.pdrhealth.com/drug_info/index.html)
N. Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents, Pediatrics, Vol. 114, No. 4, October 2004
O. Self Study Modules on Tuberculosis 1-5 and 6-9, (CDC) 2008 (http://www.cdc.gov/tb/educationssmodules/default.htm)
P. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings, (CDC) 2006
Recommendations for Human Immunodeficiency Virus (HIV) Screening in Tuberculosis (TB) Clinics, (CDC) 2007

VIII. In accordance with the above requirements, the public health nurse may:
A. Perform, assess, and record information about the following:
1. History, including but not limited to:
a. Personal health history including a list of all medical conditions that may increase risk of developing tuberculosis, other significant medical conditions, and all medications currently being taken.
b. Drug allergies or intolerances
c. Family health history
d. History of exposure to tuberculosis

e. History of tuberculin skin testing or testing with an FDA approved Interferon Gamma Release Assay for individuals aged 5 or older.
f. Prior treatment of tuberculosis disease or infection
g. Social history including alcohol and drug abuse or incarceration or institutionalization.
h. Pregnancy, history of pregnancy, date of last menstrual period for all women of childbearing age, currently utilized contraceptive method
i. Other risk factors for tuberculosis including birth or extended travel in countries with high prevalence of tuberculosis
j. History of liver disease or risk factors (including HIV infection, injecting drug use and birth in Africa, Asia or the Amazon basin) for viral hepatitis B and C or chemically induced hepatitis (alcohol or drug abuse)
k. If patient was referred, document reason, date, and source of referral and obtain copies of relevant medical information.
l. Obtain permission from patient and arrange for periodic follow-up information to be provided to the referring physician or primary care physician, as appropriate.
m. If the patient does not have a primary care physician, facilitate finding a source of basic health care for the individual.

2. Medical screening procedures, including but not limited to:
   a. Perform clinical assessment for tuberculosis medication toxicity (TB-205 or other reasonable facsimile developed locally)
      1) Vital signs (weight, height, temperature, blood pressure)
      2) Signs and symptoms of adverse drug reactions, recurrence of TB disease, and/or pregnancy
      3) Red/green color discrimination using Ishihara plates when ethambutol is prescribed
      4) Visual acuity using Snellen chart when ethambutol or rifabutin is prescribed
      5) Audiometry and a screen for balance when standing and walking, if injectables are used (amikacin, capreomycin, kanamycin, streptomycin)
   b. Palpate for enlarged cervical lymph nodes and question patient about any swellings in their armpits or groin (axillary or inguinal lymph nodes). If found, notify treating physician.
3. Collect specimens (sputum, blood or other body fluids) for laboratory procedures, including but not limited to:
   a. Bacteriology - smear and culture for acid fast bacilli (AFB) as indicated.
   b. For all adult patients suspected or known to have TB disease, baseline measurements of the following should be obtained
      1) aspartate amino transferase (AST)
      2) alanine aminotransferase (ALT)
      3) bilirubin
      4) alkaline phosphatase
      5) serum creatinine
      6) complete blood count (CBC)

7) a platelet count
c. HIV test using the opt out method (See procedure #6 for which individuals to test)
d. If infected with HIV, then the results of a CD4+ count should be obtained.

4. Tuberculosis screening procedures, including but not limited to:
   a. Mantoux skin test, interferon gamma release assay (IGRA) or other Food and Drug Administration (FDA) approved blood assay for tuberculosis that is adopted for use by the DSHS TB Services Branch
   b. Referral for chest x-ray or other radiographs as indicated
5. Educate patients regarding the following, obtain signature in accordance with agency policy, and document on the form or in progress notes that patient received copies of signed consents and privacy statement. If an interpreter was used, document the name of the interpreter.
   a. General Consent and Disclosure (L-36)
   b. Disclosure and Consent for Drug Therapy (TB-411, TB_411a, TB-415 or TB-415a, TB-415b), (A disclosure and consent form must be signed and documented in the medical record each time new drugs are added.)
   c. Order to Implement and Carry Out Measures for a Patient with Tuberculosis (TB-410, TB-410a or TB-410b)
   d. Acknowledgment of Understanding Provision of Antituberculosis Drugs Limited to Patients with MTB (TB-409)
   e. DSHS or locally developed privacy statement

B. Identify abnormal screening/laboratory results and refer to a physician.

C. Assess patient knowledge, provide education and counsel patients using tuberculosis services on the following:
   1. Transmission and pathogenesis of tuberculosis
   2. Treatment of disease/infection
   3. Patient management of the disease
   4. Rationale for DOT
   5. Mantoux tuberculin skin test or IGRA, sputum collection or other procedures
   6. Rationale for contact/source case/associate investigations
   7. Medication, risk/benefit and possible adverse reactions
      a. Patients should be educated about possible adverse reactions to the medications they will be taking and instructed to report immediately any possible adverse reactions
      b. Patients should be instructed to inform other physicians providing them with medical care that they are on drugs that may have significant interactions with other medications.
   8. High-risk groups for tuberculosis infection/disease
   9. Prevention of transmission of TB and infection control measures, if applicable
   10. HIV/AIDS and TB
      a. The impact of HIV infection on TB and its treatment
      b. Consult with a provider who is knowledgeable in the treatment of HIV and TB if a patient has both conditions
   11. Patients with hepatitis B or C should be instructed how to prevent transmission.

These patients should be encouraged to seek consultation and treatment for hepatitis B or C infection.

12. Educate female patients about the effect of the rifamycins on hormonal birth control methods and counsel the patient to add a barrier method to prevent pregnancy

D. Provide and monitor administration of antituberculosis medications through the following:

1. Provide or administer generic drug if particular drug order is not available by its trade name. Listed below are the abbreviations for antituberculosis drugs, as they appear on the TB-400B, followed by their generic names:
   INH & RIF - isoniazid and rifampin (Isonarif or Rifamate)
   INH - isoniazid
   RIF - rifampin
   PZA - pyrazinamide
   EMB - ethambutol
   Second line drugs that may be ordered:

CS - cycloserine	ofloxacin
ETH - ethionamide	amikacin
CAP - capreomycin	kanamycin
Cipro-ciprofloxacin	PAS - para-aminosalicylic acid
rifabutin	Lamprene (clofazimine)
Rifater	rifapentine
Levaquin (levofloxacin)	Avelox (moxifloxacin)
Linezolid	SM - streptomycin

2. Have an appropriate physician order on record including name of drug(s), dosage, frequency, route and method of administration (directly observed therapy [DOT] or self administered therapy [SAT]), length of treatment, and maximum number of refills:
   a. Written order on TB-400A or B or locally acceptable form, or
   b. Written order on a prescription form or physician letterhead
   c. Verbal order documented in the progress notes, counter signed and dated by the physician
   d. All prescriptions and verbal orders must be followed by appropriate TB form (TB-400A or B) with the prescribing clinician's signature faxed or mailed within 96 hours
   e. Antituberculosis drugs for cases/suspects (classification III, V) must be recorded in a DSHS approved electronic reporting system or on a TB-400B at least every 3 months with the prescribing clinician's signature. A TB-400B is required each time the drug regimen is changed (drugs added/deleted, frequency of DOT) or this information may be entered in a DSHS approved electronic reporting system.
3. Monitor for adverse effects of medications as follows in nursing management procedures
4. Perform nursing review and document the review at least monthly
5. Arrange for medical evaluation at least every 3 months or more often if indicated.

E. Provide nursing management for patients receiving tuberculosis services according to the following procedures:
   1. Nursing Management of Persons Exposed to *Mycobacterium tuberculosis*
   2. Nursing Management of Associates to a Child with Latent TB Infection (LTBI) Less than 2 Years of Age
   3. Nursing Management of Contact Investigations and Identified Contacts
   4. Nursing Management of Patients on Treatment for LTBI
   5. Nursing Management of Patients with Pulmonary and/or Extrapulmonary Tuberculosis
   6. HIV Testing
   7. Nursing Management of Persons on Treatment for LTBI With INH and Rifapentine by DOT, Weekly for 12 Weeks

Nursing Management of Persons Exposed to *Mycobacterium tuberculosis*
Procedure #1

1. Educate patient regarding the differences among tuberculosis exposure, infection and disease and document education on TB-203, equivalent form, or in progress notes.
2. Interpret skin test reading for a TB skin test based on patient's risk factors. Interpret interferon gamma release assay (IGRA) as positive, negative indeterminate or borderline.
   a. If indeterminate or borderline, repeat the test one time. If indeterminate or borderline the second time, consult with the physician treating the patient or an expert TB physician.
3. Palpate for enlarged cervical lymph nodes and question patient about any swellings in their armpits or groin (axillary or inguinal lymph nodes). If found, notify treating physician.
4. Record the following information on the patient's record and refer persons with possible LTBI for a chest x-ray and medical evaluation:
   a. Reason, date, and source of a referral to your clinic for an individual
   b. Reason for initial tuberculin skin test or IGRA
   c. Date administered, date read, and results in mm of tuberculin skin test or date specimen collected and results of IGRA
   d. History of TB exposure, testing and treatment
   e. Health history, including prior surgeries (If patient reports symptoms suggestive of TB disease, notify treating physician.)
   f. BCG vaccination, include year of last vaccination, if available
   g. List of medications and/or street drugs presently taking, and alcohol intake
   h. Allergies
   i. Smoking history
   j. List population risks for TB infection (e.g. immigration from or travel to a country with high prevalence of TB, history of incarceration/institutionalization, occupation serving high-risk population)
   k. List conditions that increase risk for progression from TB infection to disease (e.g. HIV, diabetes, use of medications that suppress the immune system etc.)
   l. Weight, temperature
   m. Blood pressure
   n. Symptoms of tuberculosis
   o. HIV test results, if known

5. Notify patient of x-ray results.
6. If treatment for LTBI is recommended, refer to: Targeted Tuberculin Testing and Treatment of Latent TB Infection, 2000; Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003; Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents, Pediatrics, Vol. 114, No. 4, October 2004, and Nursing Management of Patients on Treatment of LTBI, Procedure #4.
7. If treatment for LTBI is not started within three months of the chest x-ray showing no abnormalities indicative of tuberculosis or the patient begins to exhibit symptoms suggestive of tuberculosis, a new chest x-ray or other diagnostic procedures should be examined prior to

the start of therapy for LTBI. For persons at high risk of progressing to TB disease including those < 1 year of age, those coinfected with HIV, or those receiving immunosuppressive therapy, a repeat chest x-ray should be given before taking the first dose of medication if therapy for LTBI is not started within one month to ensure that TB disease has not developed.

8. If patient refuses treatment for LTBI, educate patient on importance of seeking medical evaluation for development of any symptoms suggestive of TB and document refusal in medical record (TB-415, TB-415a or local form).

Nursing Management of Associates to a Child with LTBI, Less than Two Years of Age
Procedure #2

1. When a child less than two years of age is identified with latent TB infection (LTBI) through screening not related to a known or suspected index case of TB, a source-case investigation and screening of household and other close associates is indicated. The purpose of associate screening is to identify anyone with TB disease who may be the source of infection and to identify associates that may have been infected by that source case.
2. Symptom screening and tuberculin skin testing or IGRA testing of associates to a child less than two years of age with latent TB infection (LTBI) shall be conducted for persons sharing a residence with the child and for those with equally close contact. The IGRA should only be used on individuals 5 years of age and older. The tuberculin skin test is to be used for children under 5 years of age.
3. Educate associates on testing procedure and rationale for testing.
4. Initiate Positive Reactor Work Sheet (TB-318) or Report of Contacts (TB-340) with a notation of associate testing in the comments section; maintain in patient's record. The tuberculin skin testing or IGRA testing of associates (e.g., family, close friends, baby sitter, and others as indicated) should be initiated within 7 days of notification of LTBI in a child less than two years of age.
5. Obtain a signed general consent on form (L-36 or equivalent) prior to placing a TB skin test or drawing blood for an IGRA test.
6. Refer all associates with a new positive tuberculin skin test or IGRA test result for a chest x-ray and a medical evaluation (see Procedure #1, section 4). Consult a physician for appropriate follow-up for infants and immune compromised associates.
7. Refer all associates with signs or symptoms of TB disease for immediate medical evaluation regardless of tuberculin skin test or IGRA results. Refer to Procedure #5.
8. If treatment of LTBI is recommended for adults, refer to Targeted Tuberculin Testing and Treatment of Latent TB Infection, 2000; Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003; and Standing Delegation Order for INH & Rifapentene
9. If treatment of LTBI is recommended for children <18 years of age, refer to Targeted Tuberculin Testing and Treatment of Latent TB Infection in Children and Adolescents, Pediatrics, Vol. 114, No. 4, October 2004, and Nursing Management of Patients on Treatment of LTBI, Procedure #4.

Nursing Management of Contact Investigations and Identified Contacts
Procedure #3

1. Criteria and time-line for beginning a contact investigation
   a. Begin the data gathering phase of the contact investigation as soon as TB is diagnosed or strongly suspected in a patient
   b. The contact investigation interview should be initiated no more than 3 working days after the suspect or case is reported to the health department. If the initial interview is not conducted in the home, then a home visit should be scheduled. Multiple interviews may be needed to identify and obtain locating information for high priority contacts. If the case is less than 5 years of age, the interview should focus on gathering information about anyone with symptoms of TB disease who may have spent time with the child and then focus on identifying and locating close associates of the child who may have been exposed to tuberculosis during the same time period as the child.
   c. At a minimum for all cases and suspects seek information about the following:
      1) Exposure of the presenting case to persons with known tuberculosis or symptoms of tuberculosis disease.
      2) Persons with potential exposure to infectious tuberculosis on the basis of risk as described below.
      3) Times to conduct follow-up interviews including visits to the home that are timely and maximize information about the physical environment and who lives or visits in the home or, as appropriate, visits to a congregate setting.
2. Determine the priority of the contact evaluation phase of each contact investigation based on the characteristics of the presenting case that increase infectiousness.
   a. (First Priority) For an index patient that has sputum smears positive for acid-fast bacilli (AFB) or evidence of a cavity on a chest radiograph, evaluate all high and medium priority contacts. Refer to Figure 2 in "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis," MMWR, Vol. 54, No. RR-15, which is on page 28 of this SDO document.
   b. (Second Priority) For an index patient with suspected or confirmed pulmonary/pleural TB, who has an abnormal chest radiograph consistent with TB disease, but sputum smears that are negative for AFB, evaluate all high and medium priority contacts. Refer to Figure 3 in "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis," MMWR Vol. 54, No. RR-15, which is on page 29 of this SDO document.
   c. (Third Priority) For all other index patients that meet the Texas reporting criteria for a case of TB, evaluate contacts that are living in the household, aged less than 5 years, have a medical risk factor, or were exposed during an unprotected medical procedure (such as bronchoscopy, sputum induction or autopsy).
      1) Testing of contacts with the most exposure to extrapulmonary cases confirms that there has been no transmission due to pulmonary involvement.
      2) Testing of contacts with the most exposure to cases aged less than 5 years may identify the source of the child's infection or other associates that may have been infected by that source case.
3. Within a given contact investigation determine and set priorities for testing individual contacts using the Concentric Circle approach that considers the duration and frequency of

exposure and the Social Networking approach that considers the place(s) where the index patient spent most of his or her time while infectious, and the characteristics of the contacts that would increase probability of progression to active disease, if infected.

4. Some congregate settings, such as correctional facilities and hospitals, will perform the testing of contacts in their facilities. The health department employee responsible for the contact investigation will need to coordinate activities and document collected information on the results of the evaluation of congregate facility contacts.
5. Since some of the contacts may live outside of the local health jurisdiction, a local health jurisdiction employee will also need to make referrals so that contacts in other health jurisdictions may be evaluated. The results of the evaluations and treatment of contacts that are infected should be documented at the local health jurisdiction that originated the contact investigation.
6. Initiate tuberculin skin testing or IGRA testing (for individuals 5 years of age and older) of high priority contacts within 7 days of identification. (Refer to Procedure #1 for nursing management of persons exposed to *Mycobacterium tuberculosis*.)
   a. Educate contacts on nature of disease, diagnostic and monitoring procedures involved.
   b. Enter each high priority contact identified in a DSHS approved electronic reporting system or on TB-340 or TB-341, document all identifying information for each contact, their relationship to case, priority category, previous TB skin testing or IGRA testing and disposition (e.g., placed on treatment of LTBI, identified as case, dismissed, etc.).
   c. Obtain pertinent history, including any symptoms consistent with TB disease or risk factors that would increase probability of progression to TB disease, from contact and document on Targeted Tuberculin Testing Screening Form (TB-207), Tuberculosis Health Assessment/History (TB-202) or an equivalent form.
   d. Obtain signed general consent on form (L-36 or equivalent) prior to placing TB skin test or drawing blood for an IGRA.
   e. Notify contact of skin testing results, refer for x-ray and medical evaluation as indicated and counsel accordingly.
   f. If treatment of LTBI is recommended for adults, refer to Targeted Tuberculin Testing and Treatment of Latent TB Infection, 2000; Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003; and Nursing Management of Patients on Treatment of LTBI, Procedure #4. If treatment of LTBI is recommended for children and adolescents under 18, refer to Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents, *Pediatrics*, Vol. 114, No. 4, October 2004.
   g. If the initial skin test result or IGRA test result is negative, a second test should be administered 8 to 10 weeks after the contact with the active case has been broken. An IGRA conversion is defined as a change in the test result from negative to positive. Break in contact is defined as physical separation of the contact from the presenting case or when the presenting case is no longer considered infectious due to response to treatment, (e.g., three consecutive negative sputum smears or for MDR-TB three consecutive negative cultures).
   h. Pregnancy is not a contraindication for skin testing or IGRA testing.
   i. Pregnant women must have the abdomen shielded appropriately during chest x-ray and

should usually have this procedure deferred until the second trimester unless active TB is suspected or the woman is at high risk of progression to active TB disease, if infected.

7. When *Mycobacterium bovis* is known or suspected to be the cause of disease, ask the index case about consumption of unpasteurized dairy products and evaluate persons who may have consumed dairy products from the same source.
8. Expanding testing to other-than-close contacts should occur if there is evidence of recent disease transmission as demonstrated by 1) a contact with TB disease, 2) infection in a child less than 5, or 3) skin test or IGRA test conversion from negative to positive between the first and second test in a close contact. If an unusually high percentage of high-priority contacts, whose prior skin test or IGRA history is unknown, are positive on the first test, then consider expanding the investigation.
   a. Educate other-than-close contacts regarding nature of disease and diagnostic procedures to be performed.
   b. Enter each other-than-close contact identified in a DSHS approved electronic reporting system or on TB-340 or TB-341 documenting all information as for close contacts.
   c. Notify contacts of screening results and counsel accordingly.
   d. Refer persons with LTBI and other high priority contacts (children 5 years of age and under, HIV infected or otherwise immunosuppressed), regardless of initial skin test results, for chest x-ray (anterior/posterior and lateral view for children) and medical evaluation.
   e. If treatment of LTBI is recommended, refer to the following: Targeted Tuberculin Testing and Treatment of Latent TB Infection 2000; Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003; and Management of Patients on Treatment of LTBI, Procedure #4.
9. High-priority contacts (includes both close contacts and/or high-risk contacts) that are initially skin test or IGRA test negative must receive a repeat tuberculin skin test or IGRA 8 to 10 weeks after the contact is broken. Break in contact is defined as physical separation of the contact from the presenting case or when the presenting case is no longer considered infectious due to response to treatment, (e.g., three consecutive negative sputum smears or for MDR-TB three consecutive negative cultures). The need to test initially or retest medium and low priority contacts should be based on whether there is evidence of recent transmission of infection in the high-priority contacts.
   a. If the repeat skin test or IGRA remains negative and contact with the presenting case has been broken, no further follow-up is needed.
   b. If the repeat skin test or IGRA is positive, follow-up with chest x-ray and medical evaluation.
   c. If chest x-ray and medical evaluation are not suggestive of tuberculosis disease, children 4 years of age or younger, HIV infected individuals, and other immunosuppressed persons who are identified as high priority contacts must be placed on treatment for possible LTBI (window period prophylaxis). If second skin test or IGRA, applied 8 to 10 weeks after contact is broken remains negative, medications may be stopped. If second skin test or IGRA converts to positive, maintain treatment of LTBI until the selected treatment regimen is completed. If signs or symptoms suggestive of TB develop at any site, refer for medical evaluation immediately.

d. If the second skin test or IGRA is negative, infants less than 6 months old as well as HIV infected individuals with advanced immunodeficiency should be evaluated for continuation of treatment for LTBI based on evidence of transmission of infection in other high priority contacts. Obtain a medical consultation with one of the DSHS approved TB experts.

10. Education of contacts

Provide education to the contacts regarding the epidemiology, transmission and pathogenesis of tuberculosis; rationale for contact investigation; confidentiality of patient information; steps in the diagnostic process; the difference between latent TB infection and TB disease; and signs and symptoms associated with TB disease.

11. HIV Testing

a. The following contacts to known cases and suspects should be tested for HIV infection using the opt out method. See procedure 6.
   Contacts to cases and suspects who are HIV+ and
   Contacts to cases and suspects who are HIV negative but have a history of substance abuse (injecting and non-injecting).
b. Local and regional health departments may not have the capacity to perform venipuncture for the above contacts evaluated under field conditions. Perform the HIV test when contacts come to a public health clinic for the purpose of contact evaluation services. For contacts who are evaluated outside of the public health clinic setting, offer HIV testing via referral to a local HIV testing resource. See procedure #6.
c. A person with a documented negative HIV test result from a specimen collected within the last 14 days would not need a repeat HIV test. A person with significant exposure to someone with TB disease may decline HIV testing; however, the health care worker should educate the person that knowledge of HIV status is important to the number and types of tests that should be performed to complete their evaluation for TB infection. See procedure #6.
d. Separate written consent and prevention counseling prior to HIV testing is no longer required.
e. Newly positive HIV test results shall be reported to the appropriate HIV/STD program. The patient shall be informed of newly positive HIV test results in person by a health care worker who is trained in post-test counseling. However, this function can be performed by an HIV/STD program health care worker who is trained in post-test counseling. For contacts who are HIV positive, the diagnostic process may require collection of appropriate specimens (such as sputum, etc.) in addition to obtaining a TST or IGRA and chest radiograph. Educate all HIV positive contacts about the risk of rapidly developing tuberculosis disease if infected with TB.
f. Obtain a chest x-ray for all recent TB contacts who are HIV infected regardless of the result of the skin test. Collect sputum samples or other specimens for all recent TB contacts that are HIV infected, especially those with significant immunosuppression.

12. Contact investigations for patients with MDR-TB or XDR-TB

a. Most contact investigations are initiated before the resistance pattern of the case is known; however, if drug resistance is strongly suspected or when drug resistance to at least INH and RIF is known, the presenting case should be interviewed for contacts more frequently and by different interviewers. The initiation of treatment and the treatment

regimen for contacts with latent TB infection must be based on a consultation with a TB expert physician.

b. Collect information about known previous TB exposure or history of spending time in an environment where TB exposure is a significant possibility (e.g., work or residence in a homeless shelter or correctional facility, travel or residence in countries with a high burden of TB incidence, as in an incidence of at least 20 per 100,000 population. If yes, the patient may have been previously infected by someone with disease susceptible to first-line medications. Inform the treating physician of the patient about the history responses, and ask for a medical decision regarding initiation of standard treatment for LTBI, if not previously treated, and conduct periodic follow up (symptom screening and chest x-ray) at 3, 6, 12, 18 and 24 months.

   1). If no, conduct periodic follow up (symptom screening and chest x-ray at 3, 6, 12, 18 and 24 months).

c. Consultation with a TB expert physician is required, especially for any contact suspected of having TB disease, who has a positive TST or IGRA or who is immune-compromised regardless of TST or IGRA result.

d. Obtain a consultation from a TB medical consultant regarding preventive treatment ofcontacts to an MDR or XDR case. Two years of medical and radiographic evaluation are generally recommended. The frequency of that follow up may be every 3 months if the patient is HIV positive or has other substantially high risk factors; if the contact is HIV negative and not at increased risk, the frequency of evaluation may be every 6 months. The expert physician will make the decision regarding the frequency of follow up medical and radiographic evaluation.

Nursing Management of Patients on Treatment for LTBI
Procedure #4

1. Administrative: Note: See procedure 7 for patients with LTBI who will take INH and Rifapentene
   a. Open a medical record.
   b. Obtain a written or verbal order for medication.
   c. On admission to service, initiate appropriate nurses' notes and baseline toxicity check.
   d. Obtain signatures for general consent and disclosure and consent for drug therapy of latent tuberculosis infection. Whenever a new drug is added to the regimen, obtain a new disclosure and consent statement.
   e. Contacts to MDR-TB cases must receive a medical consultation with one of the DSHS recognized consultants for appropriate management.
   f. Pregnant women should only be placed on treatment of LTBI when it has been determined that they are at high risk of progressing from infection to disease.
   g. Obtain permission from patient and arrange for periodic follow-up information to be provided to the referring physician or primary care physician, as appropriate. If the patient does not have a primary care physician, facilitate finding a source of basic health care for the individual.
   h. Complete the Hurricane/Natural Disaster Questionnaire with the patient, and review the information with the patient on a monthly basis.
2. Assessment:
   a. Obtain a medical history, in the preferred language of the patient or using an interpreter, to include but not limited to medications and prior exposure to tuberculosis, previous treatment, pregnancy, history of pregnancy, and date of last menstrual period for all women of childbearing age. The TB 202 is appropriate for this history.
   b. Palpate for enlarged cervical lymph nodes, and question patient about any swellings in their armpits or groin (axillary or inguinal lymph nodes). If found, notify treating physician.
   c. Do a baseline clinical assessment and document on the TB-205.
   d. Obtain a baseline assessment of co-existing liver disease or factors that increase risk for hepatotoxicity from TB medications on all individuals prior to initiating treatment of LTBI.
      1) Baseline liver function studies are required on women who are pregnant, less than 3 months postpartum, patients with a history of liver disease, hepatitis, jaundice, HIV infected individuals, substance abusers (alcohol, drugs), patients on hepatotoxic medications, patients with chronic medical problems (diabetes, CHF, chronic renal disease) or as recommended by attending physician.
      2) For children and adolescents <18 years of age, baseline liver-function tests are not indicated in the absence of risk factors for liver disease but are indicated for those with a history or physical findings of liver disease, alcohol or drug abuse, symptomatic HIV/AIDS, or those treated with potentially hepatotoxic drugs.
      3) If baseline liver function studies exceed the normal range, consult the physician. (Do not continue medication without a physician's order.)

4) Review signs and symptoms of adverse effects with patient and record on Clinical Assessment for Tuberculosis Medication Toxicity (TB-205) or other appropriate form.
5) When rifampin, or rifabutin is prescribed, baseline CBC and platelets shall be done.

e. Chest x-rays:
1) In children ≤6 years of age, two views (anterior/posterior and lateral) are strongly recommended.
2. In children and adolescents <18, both the anterior/posterior and lateral views are preferred.
3. In adults, the anterior/posterior view is usually sufficient for diagnosis and the lateral view should not be done without a specific order from the physician.
4, Pregnant women must have the abdomen shielded appropriately during this procedure and should usually have the chest x-ray deferred until the second trimester unless active TB is suspected, the woman is HIV infected or a recent contact to a person with active TB disease.

5. If treatment for LTBI does not begin within 3 months of the chest x-ray showing no abnormalities indicative of tuberculosis or the patient begins to exhibit symptoms suggestive of tuberculosis, a new chest x-ray or other diagnostic procedures should be examined prior to the start of therapy for LTBI.

6. When the person with LTBI is at high risk of progressing to TB disease (including those < 1 year of age, those coinfected with HIV, or those receiving immunosuppressive therapy), a repeat chest radiograph should be given if therapy for LTBI is not started within one month of the chest x-ray.

3. Monitoring:
a. Educate patient on signs and symptoms of drug toxicity and under what conditions they need to stop medications and report their symptoms to the person in charge of their care: nausea, vomiting, abdominal pain, fatigue, jaundice, brown urine.
b. On a monthly basis, monitor for adverse drug reactions and document on TB-205.
c. Perform monthly liver function studies (ALT and AST) on
1) Women who are pregnant, less than 3 months postpartum, or suspect pregnancy.
2) Patients with a history of liver disease, hepatitis, jaundice,
3) Patients with elevated baseline liver enzymes,
4) HIV infected individuals,
5) Substance abusers (alcohol, drugs),
6) Patients on hepatotoxic medications,
7) Patients with chronic medical problems (diabetes, CHF, chronic renal disease)
8) Or as ordered by attending physician.
d. If any of the liver function studies (AST and ALT) exceed 3 times upper limit of normal, stop medication and consult physician. Do not restart medication without a physician's order.
e. If at any time side effects are reported or noted, e.g., nausea, vomiting, vertigo, abdominal pain, brown urine, etc., take the appropriate steps as designated below.
1) Instruct patient to stop medication
2) Obtain liver function studies on the same day, if possible
3) Consult physician (do not restart medication without a physician's order)

4) If treatment of LTBI is restarted, continue monthly monitoring or more frequent monitoring as ordered by physician.
5) If treatment of LTBI is not restarted and at least 6 months of treatment have been completed, patient may be closed as adequately treated.
6) A medical evaluation and a chest x-ray should be obtained in the event the patient develops unexplained fever, night sweats, weight loss and/or respiratory symptoms. In pregnant women, the abdomen should be appropriately shielded during this x-ray procedure.
7) Educate patient regarding signs and symptoms of tuberculosis. The education process is especially important when patient has taken less than 6 months treatment of LTBI.

f. If symptoms of active disease occur, stop medication, complete a medical history (TB-202), obtain a chest x-ray, collect 3 sputum samples, at least two of which are obtained in the early morning on consecutive days, and consult physician for medical evaluation. (Refer to procedure #5).
g. Issue medication in accordance with attending physician's order (verify that they are in agreement with the current ATS/CDC/IDSA guidelines).
h. If at onset or during course of treatment, an individual refuses to complete therapy prescribed, review consequences of non-adherence and counsel regarding signs and symptoms of active disease. Document refusal in medical record.
   Note: All MDR-TB and XDR contacts with LTBI, whether on treatment of LTBI or not, need to be followed closely with clinical and radiographic evaluation for 2 years. The TB medical consultant will make the determination as to the frequency of that evaluation, (usually every 3 or 6 months, based on risk factors).Obtain a consultation from a TB medical consultant for follow up on these MDR and XDR TB contacts.
i. Monitor for adverse drug reactions based on drug(s) prescribed for treatment of LTBI.
j. If a physician chooses to withhold treatment of LTBI, educate patients about TB infection and disease and advise patient to seek medical evaluation immediately if any signs or symptoms of TB develop

4. Treatment:
   a. If treatment of LTBI is recommended for adults refer to Targeted Tuberculin Testing and Treatment of Latent TB Infection; and Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003.
   b. Patients exposed to INH resistant TB should be given a regimen containing rifampin.
   c. Patients exposed to RIF resistant, INH susceptible, TB should be given a regimen containing INH for 9 months.
   d. Provide directly observed therapy (DOT/DOPT) to household contacts of cases and other high-risk contacts of cases as resources permit. Educate patient on the need for special arrangements for DOT/DOPT during a natural disaster or emergency evacuation. Document patient's preparedness plan and review with patient monthly. In the event of evacuation, re-establish contact, as soon as possible, to confirm location and reinstitute DOT/DOPT or transfer to new jurisdiction for continuation of treatment..
   e. When presenting case is suspected of having or known to have MDR-TB or XDR TB, a DSHS recognized expert physician in the treatment of MDR-TB must be consulted to determine an appropriate treatment regimen and the appropriate follow-up of persons

with LTBI who are contacts to an MDR-or XDR TB case.

f. If treated, DOT/DOPT is shall be provided for the following contacts that are likely to have been infected by an MDR-or XDR TB case: children <18years of age, persons who are HIV +, persons who are immunocompromised.
g. Modifications necessary in a patient's drug regimen depend on how many doses, over what duration of time, and when in the course of treatment, the patient has missed medication. A general guideline for patients on INH therapy is that if a patient has minor interruptions in therapy, those missed doses should be added to the end of the treatment regimen. For interruptions of therapy lasting longer than two months, a medical examination for signs and symptoms of TB disease is indicated before resuming medication. If the patient cannot complete the prescribed 9 months of therapy (e.g., 270 daily doses of INH) within 12 months or the prescribed 6 months of therapy (e.g., 180 daily doses INH) within 9 months, then seek a consultation with a DSHS recognized TB medical expert before resuming medication. For patients with significant interruptions in therapy with drugs other than INH, seek a consultation with a DSHS recognized TB medical expert before resuming medication.
h. If treatment of LTBI is recommended for children or adolescents <18 years of age, refer to Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents," *Pediatrics*, Vol. 114, No. 4, October 2004.
i. For patients prescribed INH, provide pyridoxine (Vitamin B_6) supplementation for pregnant women, breastfed infants, children or adolescents on milk- and meat-deficient diets, patients with HIV/AIDS, patients with paresthesias during therapy, or as ordered by the physician.
j. Refer patients for other medical and social services as appropriate.

Nursing Management of Patients with Pulmonary and/or Extrapulmonary Tuberculosis
Procedure #5

1. Administrative:
   a. Open a medical record.
   b. Document the date, source and reason for initial report or referral.
   c. Document the dates and respiratory isolation status if the patient was hospitalized or in a congregate setting at diagnosis.
   d. Develop a treatment/case management plan.
   e. Obtain a written or verbal order for medication.
   f. Place signed disclosure and consent form(s) in the patient's medical record each time new medications are added. These forms should be in the preferred language of the patient or the nurse should document that an interpreter was used.
   g. Place a signed health authority's control order (TB-410 Order to Implement and Carry Out Measures For a Client with Tuberculosis or equivalent control order with provisions specific to the patient) in the patient's medical record and document that the patient received a copy.
      1) The health authority should sign the control order prior to the time that the nurse explains what the order requires the patient to do. A facsimile copy, photocopy or electronic image of the health authority's signature is acceptable.
      2) The nurse should document on the control order the date that the patient receives the order.
      3) The control order should be in the preferred language of the patient or the nurse should document that an interpreter was used.
      4) The patient should sign that they understand the order and acknowledge receipt. If the patient refuses to sign the control order, the nurse should document the refusal on the order and in the medical record progress notes.
      5) The patient should be given a copy of the control order and the original should be placed in the patient's medical record.
   h. Have suspects, pending definitive diagnosis of TB, read and sign the acknowledgment statement (TB-409) regarding the restricted use of TB medications once TB has been ruled out. See http://www.dshs.state.tx.us/idcu/disease/tb/forms/default.asp. These forms should be in the preferred language of the patient or the nurse should document that an interpreter was used.
   i. Obtain a review of classification within 90 days for persons reported as Class 5.
   j. Nursing review monthly, medical review and prescription renewal on a TB-400B signed by the physician, at least every 3 months or as changes in medication occur (proposed length of therapy should be documented on the physician's order). If resources allow, patients should see a physician on a face to face encounter at diagnosis and every month.
   k. Initiate appropriate nurses' notes on admission and enter comments as indicated/ appropriate.
   l. Obtain permission from patient and arrange for periodic follow-up information to be provided to the referring physician or primary care physician, as appropriate. If the patient does not have a primary care physician, facilitate finding a source of basic health care for the individual.

m. Complete the Hurricane/Natural Disaster Questionnaire with the patient, and review this information with the patient on a monthly basis.

2. Initial Assessment:
   a. In the preferred language of the patient or with an interpreter, collect medical and social history to include symptoms; risk factors for tuberculosis, HIV, hepatitis B and C; substance abuse (alcohol, drugs); history of prior exposure to TB; history of prior treatment of TB infection or TB disease; birth or extended travel in countries with a high prevalence of TB; history of incarceration/institutionalization, pregnancy, history of pregnancy and date of last menstrual period for all women of childbearing age; and a list of all medications currently being taken. The TB 202 is appropriate for this assessment.
   b. Palpate for enlarged cervical lymph nodes, and question patient about any swellings in their armpits or groin (axillary or inguinal lymph nodes). If found, notify treating physician.
   c. Perform baseline assessment for adverse side effects and document on TB-205
   d. Baseline clinical assessment
      1) For all adult patients, obtain baseline measurements of the following and consult physician regarding abnormal results.
         a) aspartate amino transferase (AST)
         b) alanine aminotransferase (ALT)
         c) bilirubin
         d) alkaline phosphatase
         e) serum creatinine
         f) CBC
         g) a platelet count
      2) Obtain laboratory viral hepatitis B (hepatitis B surface antigen) and C (hepatitis C antibody test) test results and consult physician regarding positive results for those patients with risk factors for viral hepatitis including the following:
         a) history of injection drug use
         b) birth in Asia, Africa, the Pacific Islands, Eastern Europe, or the Amazon Basin
         c) HIV infection
         d) sexual or household contact with individuals chronically infected with viral hepatitis
         e) chronic hemodialysis
         f) receipt of clotting factors before 1987
         g) symptoms of undiagnosed liver disease
         h) receipt of blood or solid organ transplants before 1992
         i) recent birth to a mother infected with viral hepatitis
         j) If the hepatitis C antibody test is positive, a hepatitis C viral test is needed to determine chronic infection.
      3) Assess red/green color discrimination using Ishihara plates and visual acuity using a Snellen chart when ethambutol is prescribed.
      4) Assess visual acuity using a Snellen chart when rifabutin is prescribed.
      5) Audiometry and a screen for balance when standing and walking, if injectables are used (amikacin, capreomycin, kanamycin, streptomycin).
      6) Assess renal function (serum creatinine) monthly while patient is on amikacin,

capreomycin, kanamycin or streptomycin.

e. Contact investigation information
f. Patient understanding of disease, medications and clinic/visit schedules
g. HIV screening
   1). Routine HIV screening shall be performed for all persons 13 years of age and older with newly diagnosed or suspected TB disease unless the patient already knows that he or she is HIV-infected or there is a documented negative HIV test result from a specimen collected within the last 14 days. Testing will be done by the opt-out method. See Procedure #6.
   2). Patient information about HIV testing shall be presented in the same manner as information about other routine tests. If the patient declines to be tested for HIV, provide education about the importance of knowledge about their HIV status to the medical management of their TB disease.
   3). Separate written consent and prevention counseling for HIV testing is no longer required.
   4). Newly positive HIV test results shall be reported to the appropriate HIV/STD program. The patient shall be informed of newly positive HIV test results in person by a health care worker who is trained in post-test counseling. However, this function can be performed by an HIV/STD program health care worker trained in post-test counseling. Note: HIV infection is a notifiable condition and must be reported to the appropriate HIV program within seven calendar days.
   5). For patients with TB disease who are also infected with HIV, results of a CD4+ count should be obtained.
h. Consult a DSHS recognized TB expert physician if 1) susceptibility results show resistance to INH or RIF or 2) the patient remains symptomatic or smear or culture positive after 2 months.

3. Monitoring:
   a. Perform a clinical assessment for improvement of symptoms at least monthly and document in progress notes.
   b. Bacteriology:
      Obtain three sputum specimens, 8 to 24 hours apart, prior to or at the initiation of therapy for the determination of acid fast bacilli (AFB) smear and culture. At least one of the samples should be collected early in the morning. Collect and ship specimens according to laboratory guidelines for AFB culture identification and susceptibility at: http://www.dshs.state.tx.us/lab/myco_guidelines.shtm#Myco and http://www.dshs.state.tx.us/lab/MRS_shipping.shtm
      1) . Patients with known or suspected extrapulmonary tuberculosis should be educated about sputum collection and try to produce three sputum specimens prior to or at the initiation of therapy.
      2) At least every two weeks, collect three sputum specimens (of which at least one should be an early morning specimen) for the determination of smears only until three consecutive smears are negative.
      3) Nucleic Acid Amplification Testing (NAAT) should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for

whom the test result would alter case management or TB control activities. (MMWR 2009; 58:01; 7-10.

4) Monthly, collect at least one sputum specimen for the determination of culture until all specimens collected for 2 consecutive months are culture negative. Monthly sputum must be collected from patients with isolates resistant to both isoniazid and rifampin (MDR-TB) throughout the treatment course.
5) Ideally, one of every three sputum specimens collected should be supervised, but at least:
   a) one initial specimen at start of therapy
   b) one at two months of therapy
   c) one to document conversion of sputum
   d) if a specimen is returned as insufficient amount or contaminated
5) Results of specimens (sputa, urine, biopsy) exhibiting M.TB complex. cultured in laboratories other than DSHS, must be reported to the local health authority. Part of the initial isolate should be submitted to the DSHS lab in Austin for genotyping. . If the specimen is positive for MDR or XDR TB, a consult must be obtained from a designated tuberculosis medical consultant.
6) Patients should have at least one further sputum collection at completion of therapy, if possible.
7) Collect additional follow-up sputum specimens during and after treatment as requested by the physician.
8) Collect specimens for extrapulmonary tuberculosis as requested by the physician.
9) At least one isolate for each culture confirmed case of tuberculosis must be submitted to the Texas Department of State Health Services Laboratory in Austin for genotyping.

c. X-rays:
   1) Initial chest radiography should be obtained at onset of treatment. (Patients with suspected or known extrapulmonary tuberculosis should receive a chest x-ray to assess for pulmonary tuberculosis in addition to extrapulmonary tuberculosis.)
   2) In patients with negative initial cultures, a chest x-ray is necessary after 2 months of treatment for comparison with the initial chest x-ray.
   3) If the patient is culture positive at diagnosis, a repeat chest radiograph at completion of 2 months of treatment may be useful but is not essential. This should be done at the discretion of the treating physician.
   4) A chest x-ray at completion of treatment is desirable as it provides a baseline for comparison with any future films.
   5) It is recommended that children ≤6 years of age and preferred that other children and adolescents up to 18 years of age receive both anterior/posterior and lateral views.
   6) Pregnant women should have the abdomen appropriately shielded during chest x-ray.
d. Perform a clinical assessment for adverse drug reactions at least monthly (document on TB-205) and collect information about signs and symptoms of adverse drug reaction prior to each DOT dose (document on TB-206).
e. Patients on ethambutol and/or rifabutin must be questioned monthly and at each DOT dose regarding changes in vision, blind spots in the fields of vision, blurred vision, changes in peripheral vision, eye pain, redness of the eye, or excessive tearing.

1) Patients on ethambutol should also receive vision screening using the Snellen chart and the Ishihara plates at baseline and monthly.
2) Patients on rifabutin should receive vision screening using the Snellen chart monthly.

f. Routine laboratory monitoring of liver or renal function should be done as recommended by the physician.

g. Nurse case management:
1) Initiate DOT on all cases. A notation of explanation in a DSHS approved electronic reporting system or in the comments section of the TB-400 or a letter from the physician is required if DOT is not ordered.
2) Educate patient on signs and symptoms of adverse drug reactions and document education in medical record. Reassess the patient's educational needs at least monthly. Instruct patients to discontinue medications and contact the case manager or physician if one or more of the following occurs: nausea, vomiting, abdominal pain, fatigue, jaundice, brown urine.
3) DOT providers should report to the nurse case manager any complaints or positive answers to screening questions regarding adverse drug reactions as reported by patient.
4) If adverse reactions occur (e.g., nausea and/or vomiting, abdominal pain, anorexia, etc.) stop medications, consult with physician immediately, and obtain blood the same day for liver function studies (AST and ALT) if indicated. Serious adverse reactions that result in hospitalization or death shall be reported to the DSHS TB/HIV/STD Unit within two working days.
5) Patients should be instructed to inform physicians providing them with medical care for other conditions that they are on drugs that may have significant interaction with other medications.
6) Assess clinical status and sputum reports at each encounter. At the first sign of non-compliance or questionable compliance, discuss with the physician and consider initiating court-ordered management.
7) Enter documentation on nurses' notes as indicated and document review of laboratory reports before placing them in the medical record.
8) Issue medications in accordance with attending physician's orders (assure that they are in agreement with the current ATS/CDC/IDSA guidelines, and dosage and frequency is correct for patient's current weight).
9) Educate patient on the need for special arrangements for sheltering and DOT during a natural disaster or emergency evacuation. Document patient's preparedness plan and review with patient monthly. Orders for patient to self-administer during a natural disaster or evacuation may be obtained from the ordering physician, if determined to be appropriate.
10) In the event of an evacuation, ensure appropriate transportation and placement of TB smear positive cases and suspects in coordination with Central Office. Re-establish contact with cases/suspects, as soon as possible after evacuation, to confirm their location and reinstitute DOT or transfer to new jurisdiction for continuation of treatment.

h. Schedule the patient for medical reviews with the physician at least every three months or as indicated for the following:

1) Assessment of patient clinical status
2) Drug prescription renewal or adjustments in treatment regimen as indicated
3) Other orders as indicated

i. Consults:
1) A consult with a DSHS recommended TB medical consultant must be requested on all cases where susceptibility studies indicate resistance to isoniazid and/or rifampin. TB medical consults should also be requested on patients who remain symptomatic or whose smears/cultures remain positive after 2 months of appropriate therapy.
2) Consultations on pediatric cases are encouraged but are left to the discretion of each physician.
3) Patients with HIV infection and TB should be strongly encouraged to obtain care from a provider who is knowledgeable in treatment of HIV. Treatment of TB and HIV should be coordinated.
4) If treatment is interrupted more than 2 weeks in the initiation phase of therapy or more than 2 months in the continuation phase of therapy, a consultation with a DSHS recognized TB expert physician should be considered before restarting therapy. Repeat cultures should also be performed. The patient must be evaluated by a physician before restarting therapy.

4. Treatment:
a. Refer to recommendations for treatment in Treatment of Tuberculosis, (ATS/CDC/IDSA), 2003
b. If resources allow, TB patients should see a physician in a face-to-face setting at the time of diagnosis and every month, for assessment and physical examination.
c. A complete treatment plan must include, but is not limited to:
1) Assignment of a nurse case manager to coordinate patient's care.
2) Use of DOT on all cases and suspects.
3) Use of incentives and enablers to assure adherence to therapy, when indicated.
4) Referring patients for other medical and social services as required.
5) Client education given in the client's preferred language by a clinic staff member who is fluent in that language or with the use of an interpreter. Document use of an interpreter in the client's medical record.

c. TB Drugs in Special Situations: Treatment of Tuberculosis, (ATS/CDC/IDSA), 2003
1) Drugs that can be safely used during pregnancy include: isoniazid, rifampin, and ethambutol.
2) PZA is usually not used during pregnancy in the United States, but substantial evidence regarding its safety has been gathered from extensive clinical experience. Consultation with a DSHS recognized TB expert physician is recommended when PZA or any second line drug is considered for use in treatment of a pregnant TB patient. If PZA is not included in the initial treatment regimen, the minimum duration of therapy is 9 months. Pyridoxine, 25 mg/day, should be given to pregnant women who are receiving isoniazid.
3) *Medications and Mother's Milk, Tenth Edition,* 2002 by Thomas Hale, Pharmasoft Publishing, is an important resource to improve the accuracy of estimating drug levels for treatment of patients during lactation.
4) *Mycobacterum bovis* is resistant to PZA. When *M. bovis* is identified in AFB culture

positive specimens, notify the physician so that the drug regimen may be adjusted for PZA resistance.

HIV Testing
Procedure #6

1. All TB cases and TB suspects 13 years of age and older shall be tested for HIV infection.

2. The following contacts to known TB cases and TB suspects shall be tested for HIV infection:
   a. contacts to cases and suspects who are reportedly HIV+, and
   b. contacts to cases and suspects who are HIV negative but have a history of substance abuse (injecting and non-injecting). HIV testing will be performed on the above individuals unless:
      1). There is documentation of the patient's HIV status
      2). There is a documented negative HIV test result from a specimen collected within the past 14 days.

3. HIV screening will be performed by the opt-out screening method recommended by the Centers for Disease Control and Prevention.
   a. Obtain the patient's consent on the general consent and disclosure form.
   b. List all of the blood tests that will be done today, including the HIV test.
   c. Note: Do not ask the patient if he/she wants an HIV test, as this would constitute opt-in screening.
   d. Ask the patient if he/she has any questions.
   e. Answer any questions the patient asks.
   f. If the patient does not decline the HIV test, draw blood for the HIV test along with the other appropriate lab work,

4. If the patient declines the test
   a. Discuss and address reasons for declining the test
   b. Provide education about the relationship between TB and HIV
   c. Explain that the treatment for TB may be different if the patient has HIV infection/AIDS.
   d. Provide the test if the patient agrees
   e. If the patient continues to decline the test, respect the patient's wishes
   f. Document the declination in the medical record.

5. Providing HIV test results
   a. Establish a relationship with the disease intervention specialist (DIS) with the STD/HIV program in your jurisdiction. Disease intervention specialists receive special training in notifying patients of positive results, partner notification and post-test counseling. Additionally, the DIS is knowledgeable about HIV treatment services and social services available to HIV + patients in the geographical jurisdiction. The goal is to be able to notify the DIS of patients with positive results, and arrange for the DIS to give the positive result to the patient. The DIS will also provide posttest counseling, partner notification services, and link the patient to HIV treatment and social resources.
   b. Negative test results may be given to the patient by the public health nurse in a face to face or telephone encounter.
   c. Positive test results are required by law to be given in a face to face encounter. Notify the

DIS of the patient with a positive result and request that he/she give the positive test result to the patient and refer the patient to the necessary HIV services in the patient's geographical jurisdiction.

d. The public health nurse will coordinate care with the medical provider of HIV treatment services.

6. Reporting positive HIV test results
   a. HIV infection is a reportable condition.
   b. All positive test results will be reported to the surveillance program at the appropriate local health department or DSHS regional health department HIV/STD program. The timeframe for reporting is seven calendar days. For a list of reportable conditions and timeframes for reporting, see the following websites:
      www.dshs.state.tx.us/idcu/investigation/conditions
      www.dshs.state.tx.us/hivstd/healthcare/reporting/regions

7. Documentation
   a. Positive or negative HIV testing results should be documented in the patient's confidential medical record in the progress notes and on the appropriate TB 400 form
   b. The HIV test result must be sent to the surveillance and reporting staff at the DSHS central office or entered into the current electronic reporting system .

8. Assess and document if the patient begins highly active antiretroviral therapy (HAART)
   a. If HAART is begun, notify the treating TB physician and obtain a consultation with an expert TB physician for a new regimen of TB medications that are compatible with the patient's antiretroviral therapy regimen.

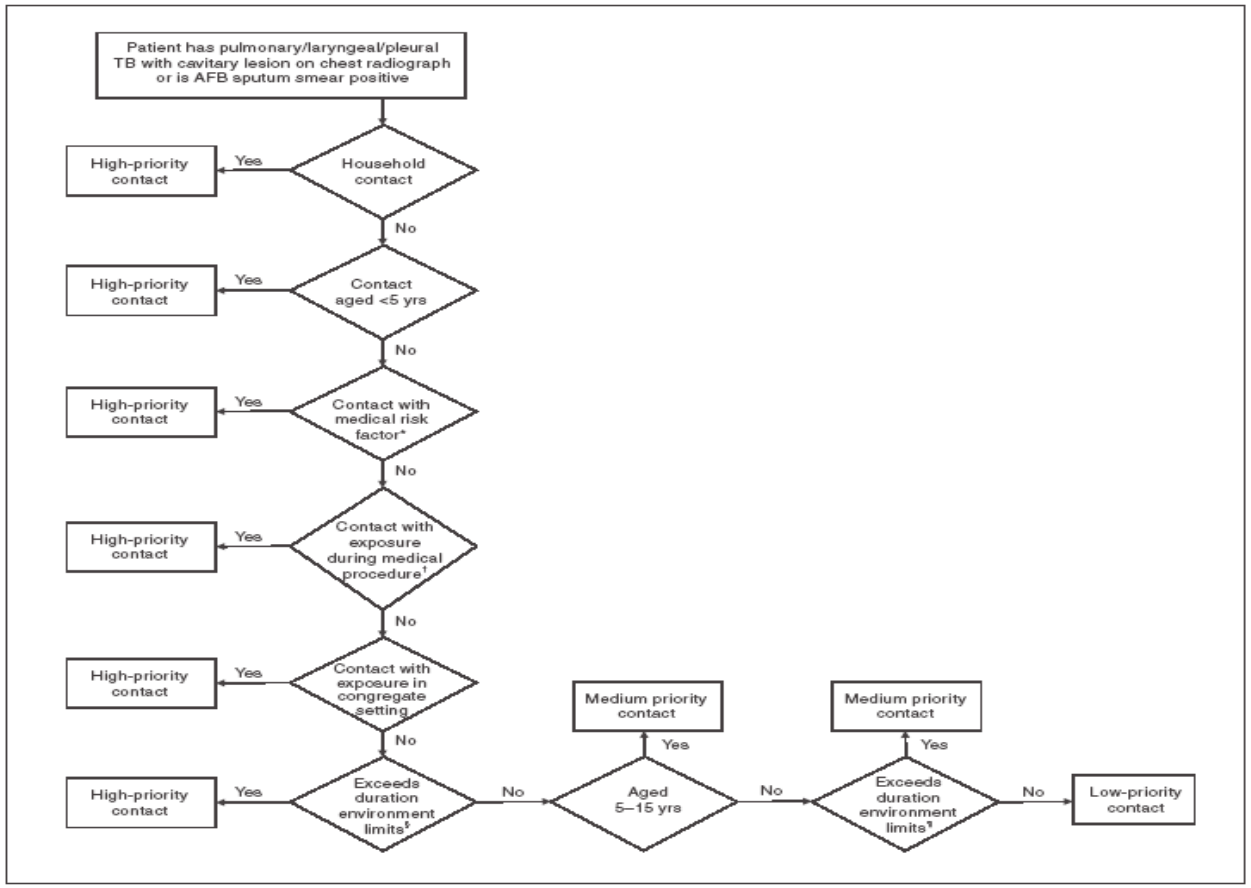
9. Verify during the monthly toxicity visit that the patient is actually taking his HIV medications and to alert the nurse if anything about their HIV medications change.

Acknowledgements

These model Standing Delegation Orders and Procedures were originally developed by the staff of the Public Health Region 1 prior to 1984 with additional contributions by the staff of Regions 4, and 6 between 1986-88, and by local and regional TB program staff in 1997, 2000, 2003, 2005, and 2006.

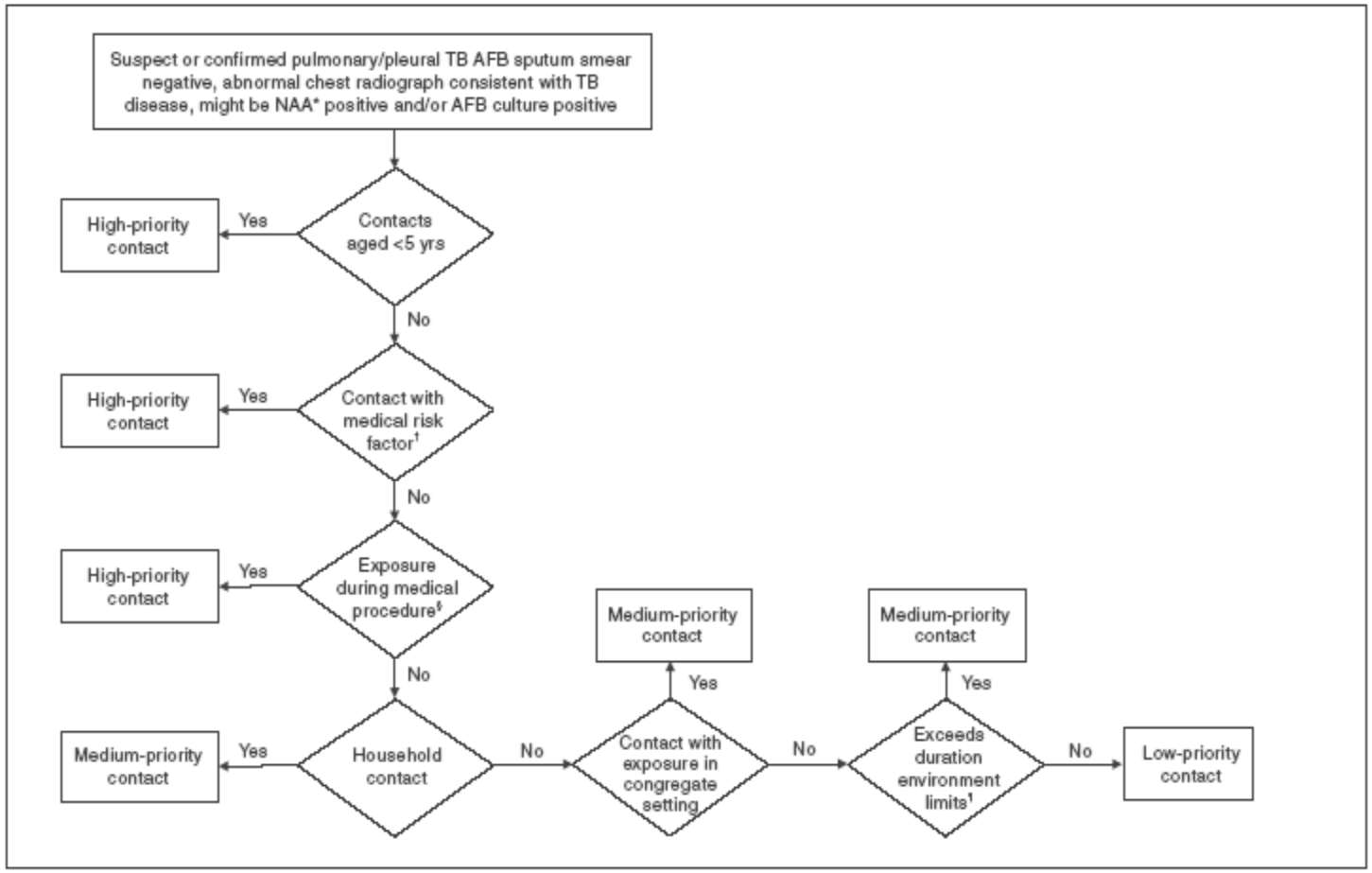
The latest coordination and revisions have been made by the Texas Department of State Health Services, TB/HIV/STD/Viral Hepatitis Unit following the recommendations of the American Thoracic Society, the Centers for Disease Control and Prevention and the Infectious Diseases Society of America as listed in Section VII, pages 2-3, of this document. Comments from all Public Health Service Regions were solicited and incorporated in 1997, 2000, 2003, 2005, and 2006.

FIGURE 2. Prioritization of contacts exposed to persons with acid-fast bacilli (AFB) sputum smear-positive or cavitary tuberculosis (TB) cases



* Human immunodeficiency virus or other medical risk factor.
† Bronchoscopy, sputum induction, or autopsy.
§ Exposure exceeds duration/environment limits per unit time established by the health department for high-priority contacts.
¶ Exposure exceeds duration/environment limits per unit time established by the health department for medium-priority contacts.

FIGURE 3. Priority assignments for contacts exposed to persons with acid-fast bacilli (AFB) sputum smear-negative tuberculosis (TB) cases



* Nucleic acid assay.
† Human immunodeficiency virus or other medical risk factor.
§ Bronchoscopy, sputum induction, or autopsy.
¶ Exposure exceeds duration/environment limits per unit time established by local TB control program for medium-priority contacts.