Texas Department of State Health Services
Austin, Texas
Inter-Office

TO: Directors, Health Service Regions
Directors, Local Health Departments
TB Program Managers, Health Service Regions, Local Health Departments
Directors of Nursing, Health Service Regions, Local Health Departments

FROM: Susan C. Penfield, M.D., Manager
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DATE: August 31, 2007

SUBJECT: Revised Standing Delegation Orders and Procedures for Tuberculosis Prevention and Control

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Attached are the revised Standing Delegation Orders (SDO) and Procedures.

These SDO and Procedures are only models and are available as an electronic file for local and regional health departments that wish to modify them to improve service to their patients. Our only concern is that you stay within the guidelines established by the Infectious Disease Control Unit and the Centers for Disease Control and Prevention Division of Tuberculosis Elimination to assure each patient receives quality care.

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Department of State Health Services
Health Service Region ___
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City, Texas, ZIP
( ) ###-####

Standing Delegation 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 for
Tuberculosis Prevention and Control

I. Standing delegation orders 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. They are reviewed, revised as needed, approved and signed annually by the regional or local medical director.

These standing delegation 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 and sign a cover sheet annually. 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.

In addition, other clinic physicians may develop standing delegation orders to be reviewed annually by the <<regional or local medical director>> and carried out by the <<regional or local>> nurses.

Training for personnel authorized to perform these orders is provided in coordination with appropriate clinical personnel. The supervisor will assure the performance of an initial and annual evaluation of staff competency with documentation in the <<DSHS or local>> performance evaluation.

Staff that provide services using these orders should contact the authorizing physician directly when medical direction or consultation is needed.

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.

II. The following documents must be readily available to the nurse:
   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. Diagnostic Standards and Classification of Tuberculosis in Adults and Children, (CDC), 2000. (http://www.cdc.gov/nchstp/tb/pubs/PDF/1376.pdf)
   D. 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)
   E. 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)

F. Guidelines for Using the QuantiFERON-TB Gold Test for Detecting *Mycobacterium tuberculosis* Infection, United States, MMWR Vo. 54, No. RR-15, 2005 (http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf)
G. Targeted Tuberculin Testing and Treatment of Latent TB Infection, (CDC), 2000.
H. 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)
I. 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)
J. Updated Guidelines for the Use of Rifamycins for the Treatment of Tuberculosis Among HIV-Infected Patients Taking Protease Inhibitors or Nonnucleoside Reverse Transcriptase Inhibitors (CDC), 2004. http://www.cdc.gov/nchstp/tb/tb_hiv_drugs/toc.htm
K. Core Curriculum on Tuberculosis, 4th Edition, (CDC) 2000 and Interactive Core Curriculum on Tuberculosis: What the Clinician Should Know, (CDC), 2004 (http://www.cdc.gov/nchstp/tb/webcourses/corecurr/index.htm).
L. Drug Information on Antituberculosis Drugs, PDR. (http://www.pdrhealth.com/drug_info/index.html)
M. Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents, Pediatrics, Vol. 114, No. 4, October 2004
N. Self Study Modules on Tuberculosis 1-5 and 6-9, (CDC) 1995 and 2000

III. 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
f. Prior treatment of tuberculosis disease or infection
g. Social history including alcohol and drug abuse, other behaviors that place one at risk for HIV infection, and incarceration or institutionalization.
h. Pregnancy, history of pregnancy, date of last menstrual period for all women of childbearing age
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 or Asia) for viral hepatitis B and C or chemically induced hepatitis
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. 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 as indicated for TB.
   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) CBC
      7) a platelet count
   c. HIV 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 or QuantiFERON-TB Gold test
   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 or TB-415), (A TB-411 or TB-415 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 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/sputum collection/or other procedures
6. Rationale for contact/source case/associate investigations
7. Medication, risk/benefit and side effects
   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. Need for pre and post HIV counseling and testing as indicated
    c. Need to consult with a provider who is knowledgeable in the treatment of HIV and TB
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.

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

1. Issue 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
   Less commonly used 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) gatifloxacin
moxifloxacin SM - streptomycin
Linezolid

2. Have an appropriate physician order on record including name of drug(s), dosage, frequency, route and method (DOT/SAT) of administration, length of treatment, and maximum number of refills:
   a. Written order on TB-400A or B or locally acceptable form
   b. Written order on a prescription form or physician letterhead
   c. Verbal order documented in the progress notes
   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 reordered 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 of LTBI
   5. Nursing Management of Patients with Pulmonary and/or Extrapulmonary Tuberculosis

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 Mantoux test based on patient's risk factors.
3. Palpate for enlarged cervical 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 QuantiFERON-Gold test
   c. Date administered, date read, and results in mm of tuberculin skin test or date specimen collected and results of QuantiFERON-Gold test
   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, 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)
   k. List conditions that increase risk for TB infection or disease (e.g. HIV or diabetes)
   l. Weight, temperature
   m. Blood pressure
   n. Risk factors for HIV
   o. HIV test results, if done
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 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 or local form).

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

1. Purpose of associate screening: 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 QuantiFERON-Gold 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.)
3. Educate associates on skin test 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 medical record. The tuberculin skin 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 a QuantiFERON-Gold test.
6. Refer all associates with a new positive tuberculin skin 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 results.
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 Nursing Management of Patients on Treatment of LTBI, Procedure #4.
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 Adolescence, 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.
   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 also in appendix A of this 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.
   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 exposure 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 the Social Networking approach that considers the place 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 collect and document 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 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 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 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.
   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 is negative, a second test should be administered 8 to 10 weeks after the contact has been 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).
   h. Pregnancy is not a contraindication for skin 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. 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 conversion between the first and second skin test in a close contact. If an unusually high percentage of high-priority contacts whose prior skin test 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: 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, Protocol #4.

8. High-priority contacts (includes both close contacts and high-risk contacts) that are initially skin test negative must receive a repeat tuberculin skin test 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 remains negative and contact with the presenting case has been broken, no further follow-up is needed.
   b. If the repeat skin test 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, applied 8 to 10 weeks after contact is broken remains negative, medications may be stopped. If second skin test converts to positive, maintain treatment of LTBI until 9 months of treatment is completed. If signs or symptoms suggestive of TB develop at any site, refer for medical evaluation immediately.
   d. If the second skin test is negative, infants less than 6 months old and HIV+ 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.
9. Offer HIV counseling (including education regarding the potential of rapidly developing TB disease in the presence of HIV infection) and testing to
   a. All recent contacts of persons with HIV infection and TB disease
   b. All recent TB contacts with risk factors for HIV infection.
10. 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.

Nursing Management of Patients on Treatment for LTBI
Procedure #4

1. Administrative:
   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.
2. Assessment:
   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.
   b. Palpate for enlarged cervical lymph nodes. If found, notify treating physician.
   c. Do a baseline clinical assessment and document on the TB-205.
   d. Baseline assessment of co-existing liver disease or factors that increase risk for hepatotoxicity from TB medications must be done on all individuals prior to initiating treatment of LTBI.
      1) Baseline liver function studies (AST and ALT) 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 (AST and ALT) 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, rifabutin or rifapentine is prescribed, baseline CBC and platelets shall be done.
   e. Patient's understanding of LTBI and TB disease, medications and clinic schedule
   f. HIV exposure and risk factors
   g. 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.

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.
   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 physician 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 (AST and ALT) 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 dismissed 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.
i. All MDR-TB contacts with LTBI, whether on treatment of LTBI or not, need to be followed closely with clinical evaluation every 3 months for 2 years and radiographic evaluations at 6, 12, and 24 months.
j. Monitor for adverse drug reactions based on drug(s) prescribed for treatment of LTBI.
k. 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.
   e. When presenting case is suspected of having or known to have MDR-TB, a DSHS recognized expert in the treatment of MDR-TB must be consulted to determine an alternative treatment regimen and the appropriate follow-up of persons with LTBI who are contacts to an MDR-TB case.
   f. If treated, DOT/DOPT is strongly recommended for contacts that are likely to have been infected by an MDR-TB case.
   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 expert before resuming medication. For patients with significant interruptions in therapy with drugs other than INH, seek a consultation with a DSHS recognized TB 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 required.

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 control order (Order to Implement Measures) in the patient's medical record and document that the patient received a copy. These forms should be in the preferred language of the patient or the nurse should document that an interpreter was used.
   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 TB Policy Manual, Section 6 - Consent Forms. 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 in a DSHS approved electronic reporting system or on the initial TB-400B).
   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.
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.
   b. Palpate for enlarged cervical lymph nodes. If found, notify treating physician.
   c. Perform baseline clinical assessment and document on TB-0205
   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) Assess red/green color discrimination using Ishihara plates and visual acuity using a Snellen chart when ethambutol is prescribed.
3) Assess visual acuity using a Snellen chart when rifabutin is prescribed.
4) Audiometry and a screen for balance when standing and walking, if injectables are used (amikacin, capreomycin, kanamycin, streptomycin).

e. Contact investigation information
f. Patient understanding of disease, medications and clinic/visit schedules
g. HIV counseling and testing should be offered to all patients. Results of a CD4 count should be obtained for all HIV infected patients.
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: (SHOULD BE SENT TO DSHS LAB)
      1) Obtain three sputum specimens prior to or at the initiation of therapy for the determination of smear and culture. At least two of the samples should be collected early in the morning on consecutive days. Ship specimens according to laboratory guidelines.
      2) At least every two weeks, collect three sputum specimens (of which two should be early morning specimens collected on consecutive days) for the determination of smears only until three consecutive smears are negative.
      3) 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 on MDR-TB cases throughout the treatment course.
      4) 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 drug resistance, cultured in laboratories other than DSHS, must be reported to the Infectious Disease Control Unit in Austin through the local program manager. There must be documented evidence that a consultation with a DSHS recognized medical expert on drug resistant TB has been obtained on all cases diagnosed with drug resistant TB (see Tuberculosis Policy Manual, Section 4 - Consultations).
      6) Patients should have at least one further sputum collection at completion of therapy, if possible.
      7) Additional follow-up 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 should be submitted to the Texas Department of State Health Services Laboratory for genotyping.

c. X-rays:
   1) Initial chest x-ray should be obtained at onset of treatment.
   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 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 patient educational needs at least monthly.
   3) DOT providers should report to the nurse manager any complaints or positive answers to screening questions regarding adverse drug reactions as reported by patient.
   4) If adverse reactions occur (nausea and/or vomiting) 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 Infectious Disease Control Unit within two working days.
   5) Patients should be instructed to inform other physicians providing them with medical care 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).

h. Medical reviews every three months as indicated for the following:
   1) Drug susceptibility results
   2) Assessment of patient clinical status
   3) Drug renewal or adjustments in treatment as indicated
   4) Other orders as indicated

i. Consults:
   1) A consult with a DSHS recommended expert physician must be requested on all cases where susceptibility studies indicate resistance to isoniazid and/or rifampin. Expert consults should also be requested on patients who remain symptomatic or whose smears/cultures remain positive after 2 months of appropriate therapy. (See Tuberculosis Policy Manual, Section 4 - Consultations).
   2) Consultations on pediatric cases are encouraged but are left to the discretion of each physician. (see TB Policy Manual, Section 4 - Consultations).
   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 must be obtained before restarting therapy. Repeat cultures should also be performed.

4. Treatment:
   a. Refer to recommendations for treatment in Treatment of Tuberculosis, (ATS/CDC/IDSA), 2003
   b. 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.

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, and 2005.

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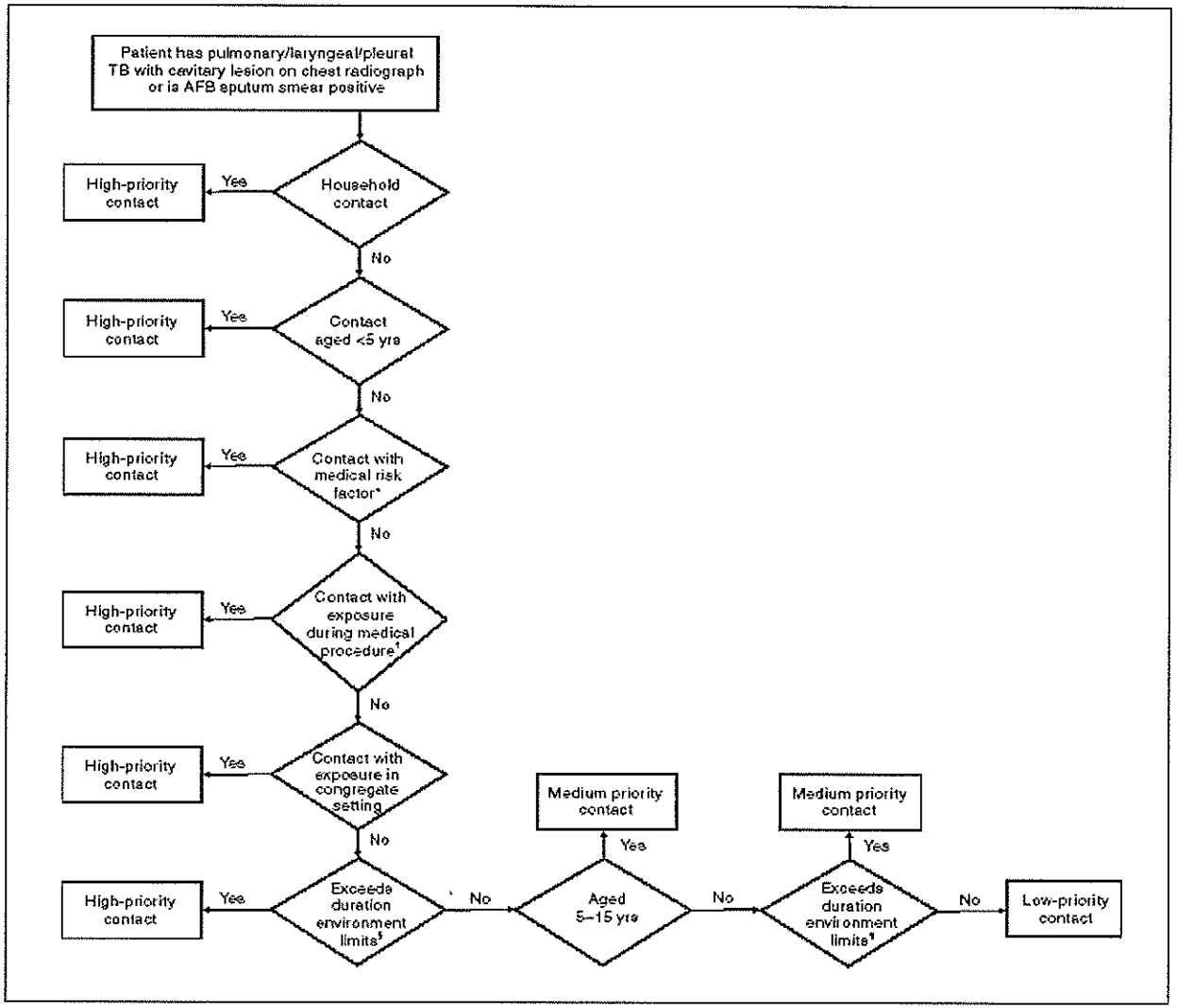
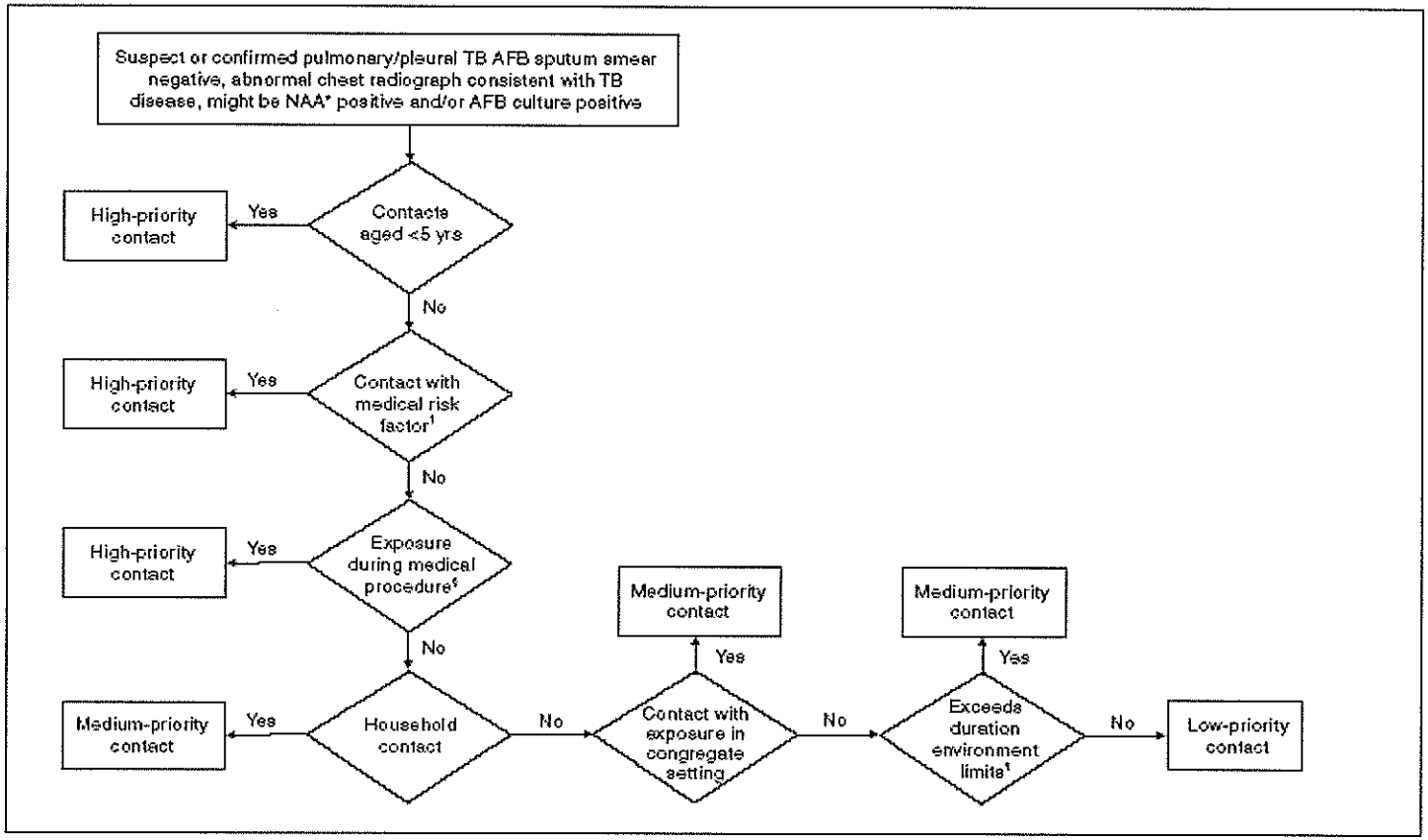
FIGURE 2. Prioritization of contacts exposed to persons with acid-fast bacilli (AFB) sputum smear-positive or cavitary tuberculosis (TB) cases



*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.