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Management of Suspect/Active TB Patients

Policy: The local public health agency (LPHA) is responsible for ensuring that adequate, appropriate diagnostic and treatment services are available, and are also responsible for monitoring the results of therapy. Suspect/active Tuberculosis (TB) patients may be managed in the private sector, by the local public health agency or jointly.

Purpose: To obtain appropriate treatment for the TB patient and to minimize the spread of TB within the community.

Procedure:

Upon notification of a suspect/active TB patient the local public health agency should follow the steps identified below. **Please notify the state TB nurse at: 573-751-6113 initially, and at any point in the process when you need assistance or have a question.**

1. **Upon notification of a patient with any of the following:**
   a. AFB (acid-fast bacillus) positive i.e. smear positive.
   b. Abnormal Chest X-Ray (CXR) consistent with TB.
   c. Physician suspicion of TB.
   d. Positive tuberculosis test (TST, blood test) – all patients with positive tests should be evaluated for TB disease before initiating treatment for Latent Tuberculosis Infection (LTBI). (Once disease is ruled out see section for treatment of LTBI.)
      1. Evaluate the patient for signs/symptoms of TB disease - **Tuberculosis Signs and Symptoms Checklist (see the *TB Manual*; *Appendices/Sample Forms* located at**: http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf).
      2. Ensure a CXR is ordered as soon as possible.
         - Diagnostic services can be utilized for physician's visit and CXR if patient has no insurance or means to obtain care.
      3. Collect 3 sputum specimens; at least one specimen being an early morning specimen and all three specimens collected at least 8 hours apart.
         - A physician's order is not needed to obtain a non-invasive sputum specimen. The specimen can be sent to the State Public Health Laboratory (SPHL) by the local health agency at no charge to the patient and/or the local health agency.

2. **The local public health agency should:**
   a. Complete patient interview within 3 days of notification of suspect TB.
      - It is highly recommended to schedule at least one home visit during the interview process. Follow up interviews are beneficial.

b. Initiate airborne isolation precautions, if pulmonary or laryngeal TB is suspected.
   - If the initial lab specimen is from an extra-pulmonary site, obtain 3 sputum specimens to check for potential pulmonary involvement.
   - If TB is confined to only extra-pulmonary site, the patient is not considered contagious.

c. Obtain a doctor's order for antituberculosis medications.
   - Ensure that an appropriate regimen is ordered. See the ATS/CDC/IDSA Tuberculosis Treatment Guidelines.
   - Fax prescription to contract pharmacy.
   - TB medication is provided at no charge by the state to ALL patients.

   Note: If patient has insurance, please include that information on the pharmacy form and the contract pharmacy can bill the insurance for the processing fee only. The patient WILL NOT receive a bill or be penalized by their insurer in any way.

d. Discuss Directly Observed Therapy (DOT) with both the physician and the patient. See section 4.04. DOT coupled with individualized case management leads to the best treatment results.

e. Assess the patient for risk factors for hepatotoxicity.
   - Arrange for liver function tests (LFT's) as ordered by the physician or as appropriate. Missouri Department of Health and Senior Services (MDHSS) will only pay for LFT's due to signs and symptoms of hepatotoxicity from TB medications which are approved by the Diagnostic Services Program (DSP) Manager on a case by case basis.

Complete Disease Case Report (CD-1) and TB History (TBC-10) and fax to the state TB nurse at (573) 526-0235 **(see the *TB Manual*; *Appendices/Sample Forms* located at**: http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf).

f. Contact/source case investigation should be initiated.
   - See CDC Module # 6 on "Contact Investigation for Tuberculosis".
   - http://www.phppo.cdc.gov/phtn/tbmodules/Default.htm

a. See instructions for Sputum Specimen Submission to the State Public Health Tuberculosis Lab and the Sputum Specimen Collection Flow Sheet below:

Please **do not** collect sputum specimens more frequently than what is recommended below. If the Tuberculosis Unit at the State Public Health Laboratory receives more specimens than what is recommended above, the specimens **will not** be processed. If the patient is not clinically improving, and additional specimens are needed, please contact DHSS TB Control Program nurse for your region.

b. If the patient is culture positive after two months of therapy the health care provider should be notified. If the patient has also shown cavitations on initial CXR, the length of treatment should be extended to 9 months per CDC/ATS recommendations.

Instructions for Sputum Specimen Submission to the State Public Health (SPHL) Tuberculosis (TB) Lab

Collect **three (3)** initial sputum specimens for all patients being evaluated for active TB.
All sputum specimens should be collected a minimum of **eight (8)** hours apart and at least one specimen must be an early morning specimen.
After the specimen is collected label all sputum specimen tubes with the patient's name, date of birth, date collected and time collected. **If this is not done the SPHL will discard the specimen(s).**

Submit the sputum specimen as each one is collected to the SPHL, do not wait until you have all **three (3)** specimens to submit to the SPHL.

1. If **one (1)** of the **three (3)** sputum smears are Acid Fast Bacilli (AFB) positive and Nucleic Acid Amplification (NAA) positive:

a. Wait **two (2)** weeks or **14 calendar days**, then
b. Collect **one (1)** early morning sputum specimen.
c. Label the specimen tube with the patient's name, date of birth, collection date and collection time.
d. Submit to the SPHL for processing.
e. Wait for results.

- If the **one (1)** sputum smear in **1 b. above,** is AFB ***negative:***

a. Collect **two (2)** more sputum specimens at least eight **(8) hours** apart.
b. Label each sputum specimen tube with the patient's name, date of birth, collection date and collection time.
c. Submit to the SPHL for processing.
d. Wait for results.

Do this until there are ***three (3) consecutive*** negative sputum smears and then,

See # 2 below for further instructions

- If the **one (1)** sputum smear in **1 b. above,** is AFB ***positive:***
  a. Wait **two (2)** weeks, then
  b. Collect **three (3)** sputum specimens, with **one (1)** being an early morning specimen and all **three (3)** collected at least **eight (8)** hours apart.
  c. Label each specimen tube with the patient's name, date of birth, collection date and collection time.
  d. Submit to the SPHL for processing.
  e. Wait for sputum smear results.

  If **any** of the **three (3)** sputum smears are AFB positive, continue to collect **three (3)** sputum specimens every **two (2) weeks**, with **one (1)** being an early morning specimen and all **three (3)** collected at least **eight (8)** hours apart.

Do this until there are ***three (3) consecutive*** negative sputum smears, then:

See # 2 below for further instructions

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2. After obtaining **three (3)** consecutive negative AFB sputum smears:
  a. Collect **one (1)** early morning sputum specimen monthly.
  b. Label the sputum specimen tube with the patient's name, date of birth, collection date and collection time.
  c. Submit to the SPHL for processing.
  d. Wait for the results.

Continue collecting **one (1)** sputum specimen **monthly** and submit to the SPHL until there are **two (2)** consecutive negative sputum ***cultures.***
Then **STOP** collecting!

- ***There are some exceptions in which more sputum specimens may be needed. Please notify your state TB nurse to discuss the exception before submitting anymore sputum specimens or they will be discarded.***

Do not continue to collect and submit sputum specimens to the SPHL after there are two (2) consecutive negative sputum cultures, they will not be processed.

TB Signs and Symptoms Checklist - (see the *TB Manual*; *Appendices/Other Resources* located at:
http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

Checklist for Active Disease Case: - (see the *TB Manual*; *Appendices/Other Resources* located at:
http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

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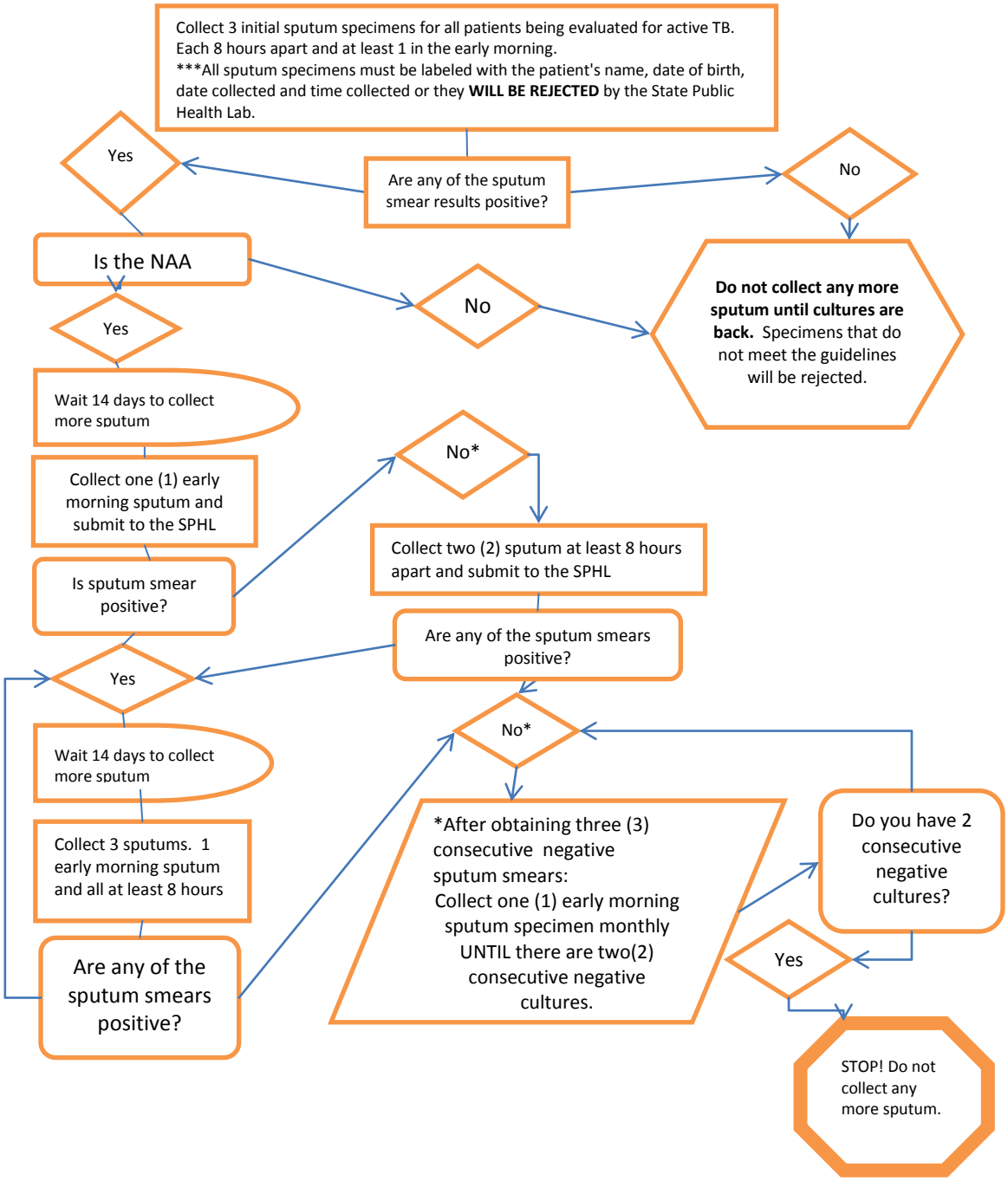

Please note: All sputum specimens must be labeled with the patient name, date of birth, date collected and time collected or the **WILL BE REJECTED** by the State Public Health lab.
DO NOT continue to collect specimens after 2 consecutive negative cultures have been obtained.
There are some exceptions in which more sputum specimens may be needed. Please notify your state TB nurse to discuss the exception before submitting any more sputum specimens or they will be discarded.

Obtaining TB Medications

Policy: To provide medications for the treatment of Tuberculosis (TB) disease and Latent Tuberculosis Infection (LTBI). Medications are provided at no charge to residents of Missouri as long as funding is available. **There are no financial eligibility requirements.**

Purpose: To eliminate all barriers in providing TB medications. To facilitate nursing case management of TB patients through the Local Public Health Agency (LPHA).

Procedure:

1. The local public health agency should complete the Tuberculosis Medication Request Form, TBC-8, (see appendix) and FAX along with the prescriptions for TB medications to the state contract pharmacy. Mail the original prescription to the pharmacy. A copy should be retained in the patient record.
2. The prescription may be written for the entire expected course of treatment. The pharmacy will dispense only ONE MONTH at a time.
3. Check the Five "R's" of medication before administering; Right medication, Right dose, Right patient, Right route, and Right time.
4. The medication is only to be administered to the patient and/or legal guardian.
5. When another health care provider is providing Directly Observed Therapy (DOT), i.e. nursing home, student health center and etc., the receiving LPHA nurse signs and accepts responsibility for the TB medications and transfers them to the health care provider.
6. The TB medications should be recorded on the tuberculosis drug monitoring record, TBC-1. (See appendix) All medications should be documented on the TBC-1.
7. Fax the TBC-1 to the State TB nurse each month.
8. For patients receiving their TB medications from an alternate source, ensure that the patient and physician understands the benefit of receiving the medications from the state pharmacy at no charge to the patient.
9. Nursing case management is available through the local public health nurse regardless of where the client obtains his/her medications.
10. If the patient and/or physician decline the use of the state pharmacy, the patient is still the responsibility of the LPHA. **The local public health agency should contact the patient and/or their physician at least monthly to monitor their progress.**

TB Medication Request Form (TBC-8) – (see the *TB Manual*; *Appendices/Sample Forms* located at: http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

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Monthly Patient Monitoring

Policy: All patients receiving medications for tuberculosis (TB) will receive at a minimum, a monthly review by the Public Health Nurse.

Purpose: To evaluate the response to therapy, to identify adherence problems, and monitor for adverse effects of treatment.

Procedure:

1. Schedule a visit (clinic or home) with the patient. This should be done at least once per month.

2. Monitor/document for medication toxicity utilizing the TBC-1 form. Notify the physician if signs or symptoms of toxicity are noted.

3. Assess patient for clinical response to the prescribe regimen. Symptoms should improve within a few days to a few weeks.
   - Decrease in frequency of cough
   - Less sputum production
   - Increased appetite
   - Weight gain
   - Reduction in fever
   - Decreased night sweats

   If the patient is not showing the expected clinical response, notify the health care provider promptly.

4. If client is exhibiting signs/symptoms of hepatotoxicity, liver function tests should be drawn.

5. If client has elevated liver enzymes or sign/symptoms of hepatotoxicity contact the health care provider promptly. If the health care provider is unavailable, have the patient hold medications until further notice (no more than 2-3 days).

6. Assess for adherence to the prescribed medication regimen.
   - Pill counts – count number of pills left in each medication bottle and document.
   - Ask patient how many times medications were forgotten or missed.
     - * If you believe the client is non-compliant try and determine reason. Attempt to correct for non-adherence through using incentives/enablers. See section 4.06.
     - * Directly Observed Therapy (DOT) is the standard of care for tuberculosis.

7. Provide patient education: Education should be provided in the patient's primary language and at an educational level appropriate for the patient. To include at least the following:
    - Tuberculosis disease process.
    - Expected outcomes of treatment.
        - Stress the importance of taking all medications exactly as prescribed. Taking only part of the medication or missing doses may result in drug resistance.
    - Benefits/adverse outcomes of drug regimens.
    - Discussion of infectiousness and infection control.
    - Methods of supervision i.e. DOT.

8. FAX/mail a copy of the Tuberculosis Drug Monitoring Record (TBC-1) to the state TB nurse each month.

Tuberculosis Drug Monitoring Record (TBC-1) – (see the *TB Manual*; *Appendices/Sample Forms* located at:
http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

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Directly Observed Therapy (DOT)

Policy: Directly observed therapy (DOT) is the standard of care for all persons being treated for tuberculosis disease.

Purpose: Standard of care. DOT coupled with individualized case management leads to the best treatment results.

Procedure: DOT involves providing the antituberculosis medications directly to the patient and watching as he/she swallows the medications.

1. **Initiating DOT**
   - DOT can be provided daily or intermittently in the office, clinic or in the "field" i.e. patient's home, place of employment, school, institutional settings such as hospitals, nursing homes and correctional facilities, or any other site that is mutually agreeable.
   - Careful attention must be paid to ensuring that ingestion of the medication is, in fact observed.
   - If the patient misses a scheduled appointment for DOT – the DOT provider must make immediate contact with the patient to schedule the next dose of medication, as soon as possible. This can include calling the patient or making a field visit.
   - All patients should continue to be monitored for signs and symptoms of treatment failure, and possible medication side effects.

2. **Documentation of DOT**
   - A medication record should be kept on each patient.
   - At completion of therapy document the number of DOT doses received.

3. **Process of DOT**
   - The local public health agency (LPHA), the observer, and the patient will set a mutually agreed upon schedule and site for observing the actual ingestion of the medication(s).
   - The observer may be a responsible person other than the patient, or one who is not subservient to the patient. Examples include: school or employee health nurses, work supervisors, clergy, or other responsible person, who does not have strong emotional ties with the patient.
   - If the case is a child, the observer cannot be the child's parent or family member.

The following steps should occur at each DOT encounter:

1. Check for medication side effects. The **observer** and the **patient** must be instructed by the local public health agency and have written materials regarding the potential adverse reaction(s) to the medication(s) that the patient is taking. Each time the observer and the patient meet for medication(s), the observer must check for any signs or symptoms of adverse reactions.

2. Verify the medication. Each time DOT is administered, the observer should verify that the right medications are administered to the right patient in the right amount. If this cannot be confirmed, do not give the medication to the patient. The local public health agency should be notified.

3. Watch the patient take the medications. The observer must actually see the patient swallow the medication(s). The observer should remain with the patient for approximately five (5) minutes after the medication has been ingested, to assure that there is no regurgitation of the medication(s).

4. Document the visit. The observer and patient must date and sign/initial for each dose of medication ingested. See medication administration record. This documentation then becomes part of the patient's medical record.

5. The observer must demonstrate understanding of patient confidentiality laws and observe them at all times. Confidentiality statement signed by the observer should be kept on file with the local agency.

6. If the patient misses even one (1) appointment to take the medication(s), the observer MUST notify the local public health agency immediately. The nurse then MUST immediately try to locate the patient and reinstitute DOT.

7. Sample agreements to utilize for DOT are located in the appendix.

Tuberculosis Medication Directly Observed Therapy Form (TBC -16) – (see the *TB Manual*; *Appendices/Sample Forms* located at:
http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

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Directly Observed Therapy (DOT)
Financial Assistance

Policy: To provide additional funding to Local Public Health Agencies (LPHA) to assist with providing DOT for Tuberculosis (TB) disease patients and or high-risk Latent Tuberculosis Infection (LTBI) patients. Funds are limited and subject to approval.

Purpose: To promote the use of DOT for TB disease patients and high-risk LTBI patients.

Procedure:

1. Financial Assistance is granted to LPHAs to assist them with the cost of traveling to the patient to provide DOT only, ***not*** for the patient to come to the LPHA for DOT.
2. Notify the Department of Health and Senior Services (DHSS) TB Control Program by email within five working days of initiating DOT, that the LPHA is interested in participating in the DOT Financial Assistance Program.
3. DHSS TB Control Program will approve and send a notice of approval to LPHA.
4. This program is only available to LPHAs that currently do not have a TB contract with Missouri Department of Health and Senior Services.
5. The LPHA can have up to no more than (4) patients at a time in the program for a maximum of $700 dollars per patient per calendar year, for successful completion of DOT.
6. If successful completion of DOT is not met by the end of the calendar year, the LPHA must send another request for the remaining months, prior to the start of the new calendar year.
7. The patient must receive at least 80% of TB medications by DOT provided in the field or location other than at the LPHA to receive DOT financial assistance.
8. The program has a fixed price billing as follows:

Standard Treatment	12 Dose Treatment
a. $142/month for the first two months (60 days) - $35.50 week.	a. $33.33 week/for three months (Once weekly for twelve weeks)
b. $104/month for the last four months - $26.00 week.	b. $400 per patient would be the maximum amount allowed.
c. $700 per patient would be the maximum amount allowed.	

9. LPHA must send an invoice for the funding to DHSS monthly to receive DOT financial assistance.
10. **During the monthly billing period the patient must receive at least 80% of their TB medications by DOT in the field or location other than at the LPHA.** Please see the billing template in this section to bill for services rendered.
11. Documentation of the DOT visit must be recorded on the Medication Record (MR). The patient and the nurse each sign the record and then initial each date the medication was given/received.
12. The individual observing the DOT has to adhere to all Department of Health and Senior Services (DHSS) policies regarding DOT. Please refer to section 4.0 in the policy manual, subsection DOT.

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Directly Observed Therapy (DOT) Billing Template

1. The Local Public Health Agency (LPHA) should use the following template when billing for DOT financial assistance from the Department of Health and Senior Services (DHSS). The billing cycle can be any 30-day period.

2. Documentation of the DOT visit will be recorded on the Medication Record (MR). The patient and nurse will each sign the record and then initial each date the medications was given/received. Leave patient name on the MR form.

3. The MR and billing form shall be sent to Jefferson City for processing.

4. Put the sample paragraph on an agency letterhead.

5. Sample paragraph:

   The Tuberculosis (TB) disease patient (do not use patient name on this form) residing in _____(county) received at least 80% of their TB medications by DOT provided in the field or location other than at the LPHA, as validated by the attached medication record (MR).

   _____
   Signature of County Staff or Signature of LPHA

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Tuberculosis Incentives and Enablers Program

Policy: To facilitate successful treatment for tuberculosis (TB).

Purpose: To improve compliance with therapy, through the use of incentives/enablers for those patients with tuberculosis disease or infection.

Incentives are small rewards given to patients to encourage them to keep their clinic or field Directly Observed Therapy (DOT) appointments.

Examples of Incentives

- Food vouchers for snacks or meals
- Groceries
- Restaurant coupons
- Clothing or personal products (i.e. soap, toothpaste)
- Books
- Retail store gift certificate (can NOT be redeemed for alcohol, cigarettes or ammunition)

Enablers are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties.

Examples of Enablers

- Transportation vouchers – cab fare
- Child Care – so patient can attend a doctor appointment
- Adjusted clinic hours and locations
- A person who speaks the languages of the populations served – Provider service
- Gas vouchers
- Health care supplies

Procedure:

1. When a patient is identified who could benefit from the use of incentives/enablers, request for incentives should be made through the state TB program.

2. An official request for incentive funds should be made on the local health agencies' letterhead or email. The following information should be included:
   - Patient name
   - What Incentive funds will be used for
   - TB disease
   - Requested item and cost
   - Agency and nurse making the request
   - Any additional information as needed
   - Date of service

3. Upon approval of the request by the TB Program Manager or their designee, the Bureau of Communicable Disease Control and Prevention (BCDCP) will prepare a mini initiative to guarantee payment to the requesting agency for the specific items listed in the mini initiative during the specific time period. The requestor should note that these funds may not be expended prior to receiving the signed mini initiative guarantee reimbursement of funds.

4. After expenditures are incurred, reimbursement request(s) shall be submitted in the form of an invoice, and supporting documentation, on the local public health agencies letterhead to the Missouri Department of Health and Senior Services, TB Control Program, PO Box 570, 930 Wildwood Drive, Jefferson City, MO 65102-0570. The total of all invoices may not exceed the authorized amount in the mini initiative. All invoices must be received by the date indicated in the mini initiative in order to be considered for payment.

5. Annual incentives in excess of $250.00 for an individual patient will generally not be approved. Exceptions can be made in extenuating circumstances with the approval of the TB Program Manager and/or the Chief.

6. First priority is given to purchasing incentives/enablers for patients with disease. Second priority is given to patients with infection who are high risk for breaking down with disease or who are a close contact to a tuberculosis case.

7. Incentives should be tailored to the patient's individual special needs and interests. Incentives are to be utilized to motivate the patient to complete his or her tuberculosis treatment.

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HIV/TB Case Supervision

Policy: To provide Human Immunodeficiency Virus (HIV) counseling and testing to all patients presenting with suspect/known Tuberculosis (TB) disease.

Purpose: To ensure appropriate care and services for persons co-infected with HIV and TB disease.

Procedure: Upon notification of a suspect/known TB case, the TB control staff person at the local health department will:

1. Provide HIV counseling and testing, regardless of patient age.
   a) Treating a patient with HIV/TB co-infection can alter the course of treatment. It is very important for the physician to know the patient's HIV status.

2. Contact the HIV care coordinator once official notification of a positive HIV test is obtained.

3. Coordinate the initial visit so both a TB staff person and an HIV care coordinator are both present with the patient at the same time.

4. Ensure that HIV care coordinators demonstrate understanding of the TB disease process and appropriate isolation precautions.

5. Report all newly diagnosed HIV cases to the Missouri Department of Health and Senior Services (DHSS) on a CD-1 form (see appendix) within 3 days of first knowledge.

6. Refer to Subsection 1.0 of this section for other care guidelines.

7. Refer to the Morbidity and Mortality Weekly Report (MMWR) "Treatment of Tuberculosis", June 20, 2003, section 8.0, page 50, for additional information on the treatment of TB/HIV patients. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm

8. Updates to HIV/TB treatment guidelines are made frequently. Please check the CDC website www.cdc.gov/nchstp/tb/ for the most recent information on the treatment of HIV/TB co-infection.

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Interjurisdictional Transfer

Policy: To provide prompt notification to the state, city, or county when a patient relocates.

Purpose: To ensure continuity of care when Tuberculosis (TB) patients relocate.

Procedure:

1. Moving within the state:
   a. Notify by phone the receiving jurisdiction as soon as possible when a patient is relocating. The receiving county should immediately contact the patient. If the receiving county cannot locate the patient – contact the original county and see if additional information is available.
   b. Provide a copy of the patient's record to the receiving health department.
   c. A signed release is NOT needed to transfer patient information to another health department.
   d. Notify the state TB Program of the patient relocation.

2. Moving outside the state:
   a. The Local Public Health Agency (LPHA) must notify the Bureau of Communicable Disease Control and Prevention (BCDCP)/TB Control Program when a patient moves outside the state of Missouri. An Interstate Reciprocal Notification of Disease form will be forwarded to the state to which the patient has moved.

3. Moving to Missouri from out of state:
   a. When a patient moves into Missouri, the state receives the Interstate Reciprocal Notification of Disease form from the originating state. The information will be passed to the LPHA where the patient is moving.

4. Patients moving to Mexico:
   a. Contact the BCDCP/TB Control Program if a patient is relocating to Mexico.
   b. CURE-TB is an organization that provides linkage between Mexico and the United States health departments. It helps improve continuity of care for TB patients traveling between the US and Mexico.
   c. For additional information the Cure-TB Program the web site is: http://www.sdcounty.ca.gov/hhsa/programs/phs/cure_tb/

5. Supervision in the county other than residence:
   a. If a patient receives a service in a LPHA other than his county of residence, notify the State TB Control Program.

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Interruption of Therapy – TB Disease

Policy: To provide the patient with the recommended treatment for Tuberculosis (TB) disease when interruptions in therapy occur.

Purpose: To provide recommendations on how to assure that the patient receives the recommended amount of medications for TB disease.

Background:

- Interruptions of therapy can occur for many reasons: intolerance of medication, increase in liver enzymes, and non-compliance of the patient ingesting the medication.
- Completion of therapy is based on the total number of doses administered – not on duration of therapy alone.
- Treatment is more important in the initial phase of therapy – when there is a high bacillary number.
- The earlier the break in therapy and the longer its duration, the more serious the effect and the greater need to restart the treatment from the beginning.

Procedure: When break in therapy occurs during the:

1. Initial Phase: First two (2) months
   - Lapse > 14 days in duration, treatment should be restarted from the beginning.
   - Lapse < 14 days the treatment can be continued.
   - In either case the total number of target doses to be given in the initial phase should be given.

2. Continuation Phase:
   - If the patient has received >80% of the planned total continuation phase doses given by Directly Observed Therapy (DOT), further treatment may not be necessary if:
   - Sputum was initially smear negative.
   - If sputum smear positive continued treatment is needed.
   - If patient received >80% of the planned total doses:
   - Lapse is > 3 months duration – TREATMENT SHOULD BE RESTARTED FROM THE BEGINNING.
   - Lapse is < 3 months in duration, treatment should be continued to complete a full course.

3. When the patient returns to treatment in either phase, sputum cultures should be obtained and repeat drug susceptibility testing performed.
   - **If positive cultures – treatment regimen must be restarted.**
   - If negative cultures – the patient could be treated as culture-negative TB and given an additional 4 months of combination therapy.

4. DOT should be used to ensure completion of therapy. Regardless of timing and duration of therapy interruption.

5. If already on DOT additional measures will be necessary to ensure completion of therapy. This could include incentives or involuntary commitment. (See Appendices ~~5~~—Missouri Statutes and Regulations Concerning Tuberculosis - Commitment - Definitions (*RSMo* 199.170 – 199.350) http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf

6. Please see the current 2003 CDC recommendations for "Treatment of Tuberculosis" for further information. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm

Annual Statement for Tuberculin Reactors Form - (see the *TB Manual*; *Appendices/Sample Forms* located at: http://health.mo.gov/living/healthcondiseases/communicable/tuberculosis/tbmanual/pdf/Appendices.pdf)

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Tuberculosis *(Mycobacterium tuberculosis)*

1. 2009 Case Definition

CSTE Position Statement Number: 09-ID-65

2. Clinical description

A chronic bacterial infection caused by *Mycobacterium tuberculosis*, usually characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

3. Clinical case definition

- A case that meets **all** the following criteria:
- A positive tuberculin skin test or positive interferon gamma release assay for *M. tuberculosis*
- Other signs and symptoms compatible with tuberculosis (TB) (e.g., abnormal chest radiograph, abnormal chest computerized tomography scan or other chest imaging study, or clinical evidence of current disease)
- Treatment with two or more anti-TB medications
- A completed diagnostic evaluation

4. Laboratory criteria for diagnosis

- Isolation of *M. tuberculosis* from a clinical specimen* OR
- Demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification test,** OR
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated.

5. Case classification

Confirmed: a case that meets the clinical case definition or is laboratory confirmed

Comment

A case should not be counted twice within any consecutive 12-month period. However, a case occurring in a patient who had previously had verified TB disease should be reported and counted again if more than 12 months have elapsed since the patient completed therapy. A case should also be reported and counted again if the patient was lost to supervision for greater than 12 months and TB disease can be verified again. Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in tuberculosis morbidity statistics unless there is concurrent tuberculosis.

*Use of rapid identification techniques for *M. tuberculosis* (e.g., DNA probes and mycolic acid high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion.

** Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species for clinical purposes. A culture isolate of *M. tuberculosis* complex is required for complete drug susceptibility testing and also genotyping. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations.

References

1. CDC. (2009, June) CDC Tuberculosis Surveillance Data Training: Report of Verified Case of Tuberculosis (RVCT) Instruction Manual. Atlanta, GA: U.S. Department of Health and Human Services, CDC. (Appendix A - Tuberculosis Case Definition for Public Health Surveillance) ftp://ftp.cdc.gov/pub/Software/TIMS/2009%20RVCT%20Documentation/RVCT%20Training%20Materials/RVCT%20Instruction%20Manual.pdf

See also:

1996 Case Definition
1990 Case Definition

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