HEALTH SERVICES POLICY & PROCEDURE MANUAL

North Carolina Department Of Correction
Division Of Prisons

SECTION: Clinical Practice Guidelines

POLICY # CP-4

SUBJECT: TB Infection/TB Disease

EFFECTIVE DATE: April 2011
SUPERCEDES DATE: September 2007

References

Related ACA Standards **4th Edition Standards for Adult Correctional Institutions 4-4350, 4-4355**

These guidelines are based on the recommendations of the American Thoracic Society Infectious Disease Department, Center for Disease Control and Prevention and the NC Tuberculosis (TB) Policy Manual developed by the TB Control Branch of the NC Department of Health and Human Services (DHHS).

The Mantoux tuberculin skin test (TST) is the most accurate test for determining TB infection and is the only skin test recommended. The TST should be repeated when interpretations are ambiguous or inconclusive. Under nursing law, an RN or LPN may not delegate the administration or reading of a TST to an unlicensed person. The TST may be read by the LPN and/or RN. Persons with abnormal readings, per the NC TB Control Guidelines, will be screened immediately for signs or symptoms of active disease. Abnormal findings will be assessed and verified by an RN. Healthcare workers will receive training in TB transmission, pathogenesis, treatment and prevention relevant to their job responsibilities on hire and annually. Nurses who place or read TST's will have competency verification in those tasks.

A. Administration
1. Use 0.1cc of 5TU Purified Protein Derivative (PPD)
2. Use tuberculin syringe with 3/8 inch 26 – 27 gauge needle.
3. Clean volar or flexor surface of left forearm approximately 2 – 4 inches below the elbow; allow to dry completely.
4. Give intradermal injection with needle bevel upward; a tense white wheal of 6-10mm in diameter should be produced.
5. Repeat injection at another site at least 2 inches away if part of the antigen is lost or the injection is given too deeply and no wheal is formed.
6. Follow guidelines for standard precautions.
7. Administer TST prior to or simultaneously with live virus vaccines, e.g., measles, mumps, rubella, smallpox, and chicken pox. If TST is not given simultaneously, wait 4 – 6 weeks before giving the TST.
8. There is no contraindication to repeating a TST that was previously positive; a TST should be administered if there is no documentation of a prior mm reading.
9. TST is safe throughout the course of pregnancy.
10. TST is not contraindicated for individuals who have been vaccinated with BCG.

B. Reading
1. Read TST in 48 –72 hours. Positive TST reactions after 72 hours are considered valid. Negative TST reactions should be repeated when individuals fail to return within 72 hours.
2. Locate induration (not redness) by palpating in a crosswise motion.
3. Measure transversely (crosswise) to the long axis of the forearm and record as a single measurement in millimeters (mm).
4. Cold packs or over the counter topical steroid preparations may be used at the injection site for the relief of pruritus and local discomfort.

C. Interpretation
1. A reaction $\geq$ 5 mm in duration is considered positive for:
    a. Close contacts of a known or suspected infectious TB case
    b. Individuals with HIV infection

c. Chest X-ray with fibrotic lesions or consistent with prior TB
d. Individuals suspected of having TB disease based on clinical and/or chest x-ray evidence.
e. Individuals with organ transplants or other immunosuppressed patients.

2. A reaction ≥ 10 mm in duration is considered positive in all other inmates.

D. Candidates for TST

1. Inmates will be given TST upon admission to the DOC and annually thereafter on the anniversary date of their incarceration.
2. Inmates having a past positive TST and a documented mm reading will be screened for signs and symptoms of TB upon admission and annually on the anniversary of their incarceration.

E. Inmates with a New Positive TST Reaction or converter

1. Screen for symptoms of TB disease. If signs and symptoms of active TB disease are present refer to HCPM Policy TX IV-4D.
2. Obtain Chest x-ray (posterior-anterior view) within 7 days if no S/S of active disease.
3. Offer HIV antibody testing unless inmate has a positive HIV test result documented.
4. Counsel inmate on the risks/benefits of LTBI therapy.
5. Obtain baseline hepatic panel. Monthly lab testing is no longer needed for individuals with normal results.
6. Refer to physician for continued evaluation and/or orders for preventive therapy.
7. If there is an increase in reaction of ≥10 mm within a 2 year period, it should be recorded as converter.

F. Inmates with clinical signs and symptoms of active TB disease shall be:

1. Given surgical mask to wear continuously until placed in an AII room.
2. Evaluated promptly and placed in an AII room as soon as possible.
3. Transferred to the appropriate treatment facility per DOP HCPM policy TX-IV.
4. Placed in a separate area away from other inmates until transfer to an appropriate facility can be arranged.
5. Provided education to include use of tissues and covering mouth and nose during coughing or sneezing.

G. Inmates with History of BCG Vaccinations

1. TST is not contraindicated in an individual with a history of BCG vaccination.
2. An individual with a positive TST reaction should be considered infected with mycrobacterium TB regardless of their BCG history.
3. Evaluate all BCG vaccinated individuals with a positive TST for preventive therapy.
4. TB reactivity caused by BCG wanes with time and is unlikely to persist >10 years after vaccination in the absence of mycobacterium TB infection or exposure.

H. Inmates with documented History of TB Infection or TB Disease without signs and symptoms of active TB disease:

1. Verify past positive mm reading and completion of treatment for preventive or active disease. If necessary, contact the health department in order to obtain verification.
2. If verified, individuals with a previously documented positive TST and a negative chest x-ray should have a repeat x-ray only when symptoms for TB disease are present.
3. Screen inmate for symptoms that would indicate active TB: productive cough, SOB, night sweats, fever, weight loss, hemoptysis, appetite loss (Complete DC- 928) and annually thereafter.
4. If prior therapy is complete and inmate does not have symptoms indicative of TB, screen annually for symptoms and refer to physician for evaluation if symptoms occur.
5. If unable to verify treatment completion, complete the following
   a. Obtain chest x-ray within seven days and refer to physician for evaluation and treatment orders.

b. Obtain medical history including any previous reaction to TB drugs
c. Review current medical conditions that would contraindicate preventive therapy

I. Treatment for Latent Tuberculosis Infection (LTBI)

1. All inmates with a positive TST shall be evaluated for preventive treatment.
2. Age is no longer a criteria used for determining whether or not to provide treatment for LTBI or when to do laboratory testing.
3. Every effort will be made to counsel and educate the inmate regarding the benefits of risk reduction for active disease with LTBI treatment.
4. The inmate has the right to refuse LTBI preventive therapy, and a signed refusal should be obtained.
5. Refer to provider for evaluation and treatment orders.
6. Prior to initiation of LTBI therapy, active disease must be ruled out.

J. Treatment Regimens for LTBI

1. Directly Observed Therapy must be used for the treatment of LTBI as well as TB disease.
2. Treatment Regimens will follow current NC TB Control Guidelines. These are:

   a. INH for 9 months is the preferred regimen. Nine months of INH offers approximately 90% protection against the progression of TB infection to TB disease. Dosage is 5mg/kg of weight with a maximum of 300mg daily (270 doses) or 15mg/kg of weight with a maximum of 900mg twice weekly (78 doses) for total nine months taken within a twelve month period of time.

   b. INH for 6 months is recommended when 9 months can not be completed. It is an adequate course of treatment for LTBI. It offers approximately 70% protection in individuals who complete a full course of therapy. Dosage is 300mg daily (180 doses) or 900mg twice weekly (52 doses) for total of six months taken within a nine month period of time.

   c. INH for LTBI is contraindicated for individuals with active hepatitis or end stage liver disease

   d. Rifampin for 4 months should be offered only if intolerance to INH develops or the individual is a close contact to an INH resistant case of TB. Dosage of Rifampin is calculated according to body weight and rounded up to the next available dosage. (Dosage is 10 mg/kg of weight with a maximum of 600 mg daily.) Daily Rifampin (120 doses) should be given for a total 4 months within a 6 month period of time. Obtain LFT's and CBC prior to initiation of Rifampin. **Rifampin may not be given on a twice weekly schedule.**

3. If administering twice weekly medication, Tuesday and Friday or Monday and Thursday are the recommended days for administering twice-weekly medications.
4. **HIV Infected Inmates:** Nine months of INH is the treatment regimen for treating individuals who are known to be HIV positive. HIV positive individuals treated with INH should receive pyridoxine (B6) 25 mg daily or 50 mg twice a weekly on the same schedule as INH. Providers should consult with ID specialist for all inmates who are receiving antiretroviral therapy prior to initiating treatment for LTBI.

K. Pyridoxine

1. Peripheral neuropathy is associated with the use of INH, but is uncommon at doses of 5 mg/kg of body weight. Pyridoxine (B6) 25 mg daily or 50mg twice weekly should be given on the same schedules as INH if the following risk factors are present:
   a. Pregnancy (if prenatal vitamin does not contain at least 25mg of B6).
   b. Diabetes mellitus
   c. History of an average alcohol use of > 3 drinks per day
   d. Malnutrition
   e. Seizure disorder
   f. HIV infection

L. Monitoring Inmates on Treatment for LTBI (Use Chronic Disease Flow Chart Form DC-817)

1. Pretreatment Evaluation
   a. Assess inmate initially for signs and symptoms that may indicate conversion to active TB disease. These signs may include productive cough, recent weight loss, anorexia, unexplained fever, night sweats, shortness of breath, or chest pains.
   b. Reassess monthly for signs or symptoms of adverse reactions to medications. (See DC-817)
   c. If signs and symptoms of drug interactions occur, hold medications, obtain hepatic function panel and refer to physician for further evaluation.
2. Medication Monitoring
   a. TB medication shall be directly observed therapy (DOT). DOT is the actual observation of medication ingestion by a Healthcare worker.
   b. Tuesday and Friday or Monday and Thursday are the recommended days for administering twice-weekly medications.
   c. In order to insure that all doses are administered, make up any self administered or missed doses. This will ensure adequate therapy.
   d. Number each dose given on the MAR beneath the dose given.
3. Obtain hepatic function panel monthly on the following individuals:
   a. Baseline hepatic function panel results are abnormal.
   b. Pregnant women
   c. Women up to 3 months postpartum or in the immediate postpartum period (i.e., within 3 months of delivery).
   d. Those with symptoms of adverse reactions
   e. Persons taking potentially hepatotoxic drugs
   f. Persons with chronic active hepatitis B or hepatitis C.
   g. Those with HIV infection

   Hold therapy if signs and symptoms of hepatotoxicity are present, draw hepatic function panel and consult physician.

4. Elevations of liver enzymes can and typically do occur. Manage individuals with no signs and symptoms of hepatotoxicity as follows:
   a. ALT are 2-3 times the Upper limit of normal (ULN), consult physician. In most cases INH should be continued.
   b. ALT is 3-5 times ULN, consult physician. In most cases INH should be continued. Repeat ALT every 2 weeks as long as ALT remains 3-5 times ULN.
   c. ALT > 5 times ULN, stop INH and consult physician.

5. If initiating Rifampin therapy for LTBI due to INH intolerance or close contact of INH resistant TB case, obtain baseline CBC with platelets and hepatic panel prior to the initiation of therapy. If any of these are abnormal consult provider before initiating therapy. Obtain hepatic function panel monthly on individuals who had abnormal baseline results and those with symptoms of adverse reactions.

M. Treatment of Active TB Disease in consultation with ID specialist when needed.

1. Treat for 6 months minimum or at least for 4 months after culture conversion, whichever is longer. Conversion is defined as "the first complete set of three (3) negative cultures obtained in a series". If the individual is unable to produce sputum and an attempt is made under nursing supervision and documented this can be counted as the first complete set of negative cultures obtained in a series.
2. If cavitation is present on the initial chest radiograph and sputum culture remains positive after 2 months of treatment, individuals will need to be treated for 7 additional months for a total of 9 months.
3. Isoniazid (INH), Rifampin (RIF), Pyrazinamide (PZA) and Ethambutol (EMB) are the initial treatment of choice for all HIV negative and non-pregnant individuals.
4. All dosage of TB drugs should be calculated according to mg/kg body weight and rounded up to the next available dose supplied by the manufacturer. Consultation with ID specialist or TB Control Program is recommended when needed.
    a. Initial phase (first 8 weeks) consists of four-drug therapy: INH, RIF, PZA, EMB, daily for 8 weeks. If PZA is not included within the first 2 weeks of treatment or PZA is contraindicated, a minimum of nine months of daily INH and RIF is required.
    b. Continuation phase (last 18 weeks) consists of two drug therapy: INH and RIF daily for 18 weeks.
    c. Discontinue EMB when initial culture results confirm fully susceptible organisms or cultures return negative and individual is clinically improving.
    d. Discontinue PZA after 8 weeks if culture results confirm fully susceptible organisms or cultures return negative and individual is clinically improving.
    e. Peripheral neuropathy (see Section K above).
    f. HIV Infected Inmates: Providers should follow the recommendations for treatment of HIV negative patients when treating the HIV positive client. HIV positive inmates with CD4 < 100 are to be on daily therapy rather than twice weekly.
    g. All TB medications are to be given at the same time, no split doses.

N. Monitoring Inmates on Active Disease Treatment (Use Form DC-817)

1. All items listed in Section L above.
2. Report all active cases to local health department. Complete and forward report Communicable Disease Report Card (DHHS 2124).
3. Collect-supervised sputum regardless of prior specimen obtained elsewhere. The individual should be instructed to provide two additional sputums on consecutive days in the early morning.
4. In addition to hepatic panel and HIV tests, baseline labs should be obtained for bilirubin, serum creatinine, serum uric acid and CBC with differential.
5. Baseline visual acuity (Snellen) and red-green color perception should be obtained for inmates treated with ethambutol.
6. Baseline hearing test should be obtained for inmates being treated with streptomycin. Reassess every two months until discontinued.
7. Prior to initating medications, calculate and verify each prescribed medication dosage based on inmate's weight.
8. Obtain a chest x-ray during the final two (2) weeks of therapy on all individuals with pulmonary TB disease.
9. Assess monthly for hepatotoxicity and adverse drug reactions.

10. Inmates who are slow to respond to therapy, have significant residual radiographic findings upon completion of therapy or who are immunocompromised should be re-evaluated as needed every six (6) months.

O. Sputum Specimen Collection and Monitoring
1. If initial sputum smear was positive, collect sputum after two weeks of daily DOT therapy.
2. Obtain a set of three consecutive early morning sputum specimens every 2 weeks until cultures convert to negative. Supervise the collection of one specimen in each set.
3. Obtain chest x-ray after 2 months of treatment if pre-treatment sputum culture results were negative. Consult with physician to determine if continued TB treatment is recommemded.

P. Isolation
1. Transmission of TB is dependent upon four factors:
   a. Number and/or viability of bacilli expelled in the air
   b. Susceptible host (contacts)
   c. Environment (shared air)
   d. Duration and/or frequency of exposure (time)
2. Inmates with clinical signs and symptoms that are suspect for laryngeal or pulmonary tuberculosis will be placed in respiratory isolation (AII room) until:
   a. They have three consecutive sputum specimens at least 8 hours apart found to be smear negative for AFB.
   b. They have been compliant on TB medication to which the organism is judged to be susceptible and
   c. There is evidence of clinical improvement on therapy.

Q. Documentation
1. Inmate's positive TB skin test will be appropriately documented on the problem list in the medical record and in OPUS
2. Inmates who are identified as close contacts to active TB cases will have this close contact documented on the problem list in medical record and in OPUS
3. When charting on MAR place the number under the healthcare worker's initial to identify dose given and to provide an ongoing accurate count of doses i.e. 1, 2, 3, …

R. Record Keeping
1. Document TST (mm reading), sputums, laboratory tests, x-rays, treatment and discharges on the DC-928 (Immunization Record/TB Skin Test)
2. Update OPUS with screening results. Inmates with past positive screenings should have PP (past positive) appear before mm reading when entering information into OPUS. Update the Problem list in OPUS (MS08 screen) with evaluation results, verification of findings, treatment plan and resolution.

S. Releases:
1. LTBI preventive treatment – Complete DC-516 (Community TB Referral) and fax or mail to local county health. department where inmate is being released. Give inmate a copy of DC-516 and one week supply of medication upon release with instructions to follow-up at the local health department the next business day for additional medication . Place original DC-516 in Health Services Record section II.

2. Active treatment – Complete DC 516 and notify by telephone the TB nurse in the county where the inmate is being released of inmate's scheduled discharge. Fax or Mail copy of completed form to health department. Instruct inmate that he is required to report to the health department on the next business day for his next dose of medication. At that time, the health department will provide additional instructions.

3. Refer to HCPM Policy #CC-8 Aftercare Planning for Inmate in Health Services – Continuity of Care

(*) Inmates may refuse preventive therapy. If preventive therapy is indicated inmates should be counseled regarding the benefits of preventive therapy and encouraged to accept and complete the prescribed treatment; however, the final decision to take medication lies with the inmate. The "Refusal of Treatment Form" (DC-442) shall be completed and filed in the inmate's medical record.

The above are intended as minimum standards. Many situations are not addressed. Primary care physicians may consult by phone with the DHHS TB Control Physician (919) 733-7286 when necessary

5/26/11

Paula Y. Smith, MD, Director of Health Services Date

SOR:

A. NC Administrative Codes 10ANCAC41A.025 "Control Measures- Tuberculosis" and 10ANCAC41A.0206 "Infection Control HealthCare Settings".

B. NC Tuberculosis Control Manual 10th edition April 2007 available at http://www.epi.state.nc.us/epi/gcdc/tb/manual.html

C. NC DOC Safety, Occupational & Environmental Health Policy E-6 "Occupational Exposure to TB" effective 1/1/07.

D. "Guidelines for Preventing the Transmission of Mycrobacterium Tuberculosis (MTB) in Health Care Settings " 2005, CDC, MMWR, December 30, 2005. Vol. 54. RR 17

E. "Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC" July 7, 2006, Vol. 55 No. RR-9.