IX. Selected Resources

A. American Lung Association (ALA) Incentive Funds

1. Funds are available to health department TB nurses to purchase or provide incentives to ensure treatment completion for tuberculosis and latent TB infection.
2. The health department must develop a policy on how the funds will be accessed by the nurse. The check will be written to the health department.
3. Incentives may be used to cover the basic needs of the patient, such as, food, transportation, and purchase of other prescription medications, assistance with utility bills, or other needs identified by the TB nurse. Alcohol or tobacco products may not be provided with these funds
4. The base request amount is $50 in rare instances a larger amount may be approved. A letter of justification must accompany any request for more than $50.
5. Procedure for TB nurse:
   - Complete the incentive fund application legibly.
   - Provide all information requested on the application.
   - Complete a W-9 form (https://www.irs.gov/pub/irs-pdf/fw9.pdf)for the health department. This only has to been done once so that the ALA will have the information on file.
   - Fax the application and W-9 form if applicable to your regional TB nurse consultant.
   - Maintain a copy of the application in the health department files.
   - When the $50 has been spent, complete the incentive fund application/expenditure report form; attach receipts and fax, mail or e-mail to your regional TB nurse consultant.
   - If additional funds are needed indicate on the form that you are requesting another $50.
6. Procedure for N.C. TB control nurse consultants:
   - The regional TB nurse consultants will review and approve applications.
   - The regional TB nurse consultant will maintain a record of incentive program applications.
   - The regional TB nurse consultant will approve the application and fax or e-mail the application to the American Lung Association (ALA).
   - After the regional TB nurse consultant receives the receipts from the health department, she/he will forward the receipts to the ALA.
7. Procedure of the American Lung Association:
   - After receiving an application approved by the regional nurse consultant the ALA will mail a check to the health department indicated on the application form.
   - The ALA will give N.C. TB Control a report of incentive funds on a monthly basis.

B. Housing Funds

1. Housing fund application form A must be completed and signed by the local health department nurse and the landlord/rental agent.
2. The landlord/rental agent must submit a W-9 form (https://www.irs.gov/pub/irs-pdf/fw9.pdf)
3. Housing fund application form B must be completed and signed by the local health department nurse and the patient.

4. Housing must be the lowest cost available, have prompt availability, and be safe for the TB nurse to visit. The following criteria must also be met if the patient is sputum smear positive:
   - No shared air space with other leased areas.
   - An exit or hallway that leads directly outside.
   - No housing employee shall enter the patient's room until eight hours after the patient is considered non-infectious. Housekeeping arrangements must be worked out for individual situations.
5. Housing funds may not be used for deposits for apartments or utilities, a lease for an extended period of time or payments to family members or the patient.
6. A new application must be completed after 30 days.
7. A signed treatment agreement should be in place.
8. Priority will be given to smear positive or homeless persons.
9. Procedure for the local health department TB Nurse:
   - Call to discuss the situation with the regional TB nurse consultant. If no other options exist for housing the regional TB nurse consultant will ask the health department nurse to complete the housing fund application.
   - Identify appropriate housing and have the rental agent or landlord sign the application – Form A.
   - Explain criteria for getting housing funds to the patient and have the patient sign the application – Form B.
   - Fax the completed application (Forms A and B) to the regional TB nurse consultant.
   - Refer the patient to social services and/or other resources to assist patient in meeting his own housing needs.
   - Re-submit a new housing fund application each time rent is due.
   - If the housing agent is unable to wait for payment from the ALA the health department may pay for the housing and ask the ALA to reimburse the health department with the regional nurse consultants approval.
10. Procedure for N.C. TB Control:
    - The regional TB nurse consultant will review and approve housing fund applications and fax the application and W-9 form to the ALA.
    - The regional TB nurse consultant will maintain a file of housing funds applications.
11. Procedure for the ALA:
    - After receiving a housing fund application that has been approved by the regional TB nurse consultant the ALA will issue a check to the rental agent.
    - The ALA will give N.C. TB Control a report of housing funds on a monthly basis.

C. <u>Funds for Utility Bills</u>

ALA funds may be used to pay for utilities.

1. Procedure for the local health department nurse:
   - Complete form C;
   - Attach a copy of the utility bill; and
   - Fax the application to the regional TB nurse consultant.
2. Procedure for NC TB Control:
   - Review the application and if approved fax to the ALA.
3. Procedure for the ALA:
   After receiving an application for payment of utility bills the ALA will issue a check to the utility company along with a copy of the bill.

Incentive Fund Application/Expenditure Report

Grant Number 5040-NCTB-4219

Fax to Regional TB Nurse Consultant

County Health Department: _____
Make check payable to: _____ Attention: _____
Address: _____
City, State, Zip: _____
Phone: _____ ext.: _____ Fax: _____
County TB Nurse: _____ Email: _____

****

☐ **Check here if Initial Application for the Incentive Program**

I wish to participate in the incentive program and hereby request an initial check for $50.00.

I understand that I may use these funds for patient compliance with TB disease treatment or treatment of LTBI.

If I leave my present position, I will:

- submit an expenditure report of the funds expended and the remaining local fund balance
- notify the regional TB Nurse Consultant of the name and address of the agency nurse who has the balance of unused funds to continue the local incentives program.

****

☐ **Check here if Expenditure Report with Receipts Attached**
From (date) _____ through (date) _____

Indicate what previous funds were used for				Amount(s):
			Beginning balance	**$ _____**
Food:	☐meals/fast food	☐groceries	☐nutrition (Ensure, etc)	$_____
Transportation:	☐bus fare	☐taxi fare	☐gasoline reimbursement or gas cards	$_____
Other:	☐	☐special incentives for children	☐gift certificates for necessary items	$_____
	☐	☐	☐	$_____
			Total expenditures:	**$_____**
			Balance of funds	**$_____**

# helped_____	# Cases:_____	# Contacts:_____	# Reactors:_____	Total #_____

☐ **Check here if you are requesting another $50.00 incentive check**

My signature certifies that the funds have been expended in accordance with Enabler and Incentive Fund guidelines.

_____ _____
County Nurse Signature Date

_____ _____
TB Nurse Consultant Signature Date

Housing Fund Application
FORM - A
Grant Number 5040-NCTB-4221
Fax to Regional Nurse Consultant

Nurses' Name: _____County Health Department: _____
Address: _____
City, State, Zip: _____
Phone: _____ext. _____ Fax: _____
Email: _____
****

Payment Request for Housing ☐ Initial Request ☐ Subsequent Request

Amount: $ for _____ through _____
(Note: Cannot exceed 30 days) Date Date

Contact person for housing (landlord/rental agent) _____
Phone: _____ extension: _____ Fax: _____
Check to be written to: _____
Federal Tax ID number: _____
Address: City,State,Zip: _____
County (if different from HD): _____
****

The housing agent hereby agrees to comply with the following, and thereby, will hold harmless NC DHHS, American Lung Association, the health department and its agents from liability:

1. Provide housing with no shared air space with other leased areas
2. Provide housing with an exit that leads directly to the outside or to a hallway that leads directly to outside
3. Allow no housing employee to enter the client room until 8 hours after the client is determined by the PH Nurse to be non-infectious. Housekeeping and linen supply arrangements are as follows:
   -
4. Provide single occupancy housing and report any patient problems to the health department nurse
5. Maintain the confidentiality of the individual for whom housing is being provided

The above housing agent has agreed to provide housing for the above costs.

- I have been given a copy of this agreement.
- I agree to the above conditions as housing agent and understand that the confidentiality of the individual is legally protected and that anyone who violates the person's confidentiality may be subject to prosecution.

_____ _____
Signature of Health Department Nurse Date

_____ _____
Signature of Housing Agent Date
(Required only on Initial Payment Request)

Regional Nurse Consultants Approval Signature _____

FORM - B

Grant Number 5040-NCTB-4221

Client – Health Department Agreement for Housing

I, _____, certify that I have no fixed, regular and/or adequate night-time residence at this time and I am unable to provide current shelter for myself.

I understand that I have confirmed or suspected active TB disease and treatment is necessary. I understand that, at this time, I am considered

☐ infectious to others ☐ not infectious to others

I understand that the arrangements have been made for temporary housing during treatment and that I must:

1. Be at _____on _____ at _____am/pm to take my medicine.

2. Keep clinic appointments and have necessary laboratory tests.

3. Notify the health department nurse of any problems with the medicine or other emergencies.

4. Avoid alcohol or other drug use.

5. Not visit with other people in the housing area or other indoor areas until the health department nurse tells me I am no longer infectious to others.

6. Follow housing conditions by not having anyone else stay overnight, unless prearranged in the lease; not make any charges to the housing; and not make any long distance phone calls charged to the housing.

7. Allow the health department to identify me by name to the housing agent, N.C. TB Control and American Lung Association, if needed.

8. If the infectious to others box is checked, I cannot leave the rental unit except to go outside, until the health department nurse says I am no longer infectious to others.

****

- I have been given a copy of this agreement.
- I understand that I will be responsible for any damage to the rental property.
- I understand that if I violate the above I may lose the housing and may be subject to prosecution for violation of TB control measures which is a misdemeanor offense pursuant to G. S. 130A-25, punishable by incarceration until TB disease treatment is complete.

Client: _____ _____

Signature Date

Heath Department Nurse: _____ _____

Signature Date

Emergency Funds for Utilities - Form C
Grant Number 5040-NCTB-4221
Fax to Regional Nurse Consultant

Nurses' Name: _____
County Health Department: _____

Address: _____

City,State,Zip: _____

Phone: (__ __)___ _____extension: __ ____
Fax: _____

Email: _____
****

Payment Request for Utilities ☐ Initial Request ☐ Subsequent Request

☐ Electricity ☐ Phone (basic service only)

☐ Other (Specify):_____

Check to be written to _____

Account number _____

Amount: $ _____

Address: City ,State ,Zip: _____

A new form must be completed each time a utility bill needs to be paid. Deposits and past due / late fees cannot be paid using ALA funds. Attach a copy of the utility bill.

_____ _____
Signature of Patient Date

_____ _____
Signature of Health Department Nurse Date

_____ _____
Signature of Regional Nurse Consultant Date

D. N.C. TB Control Program - Contact Information

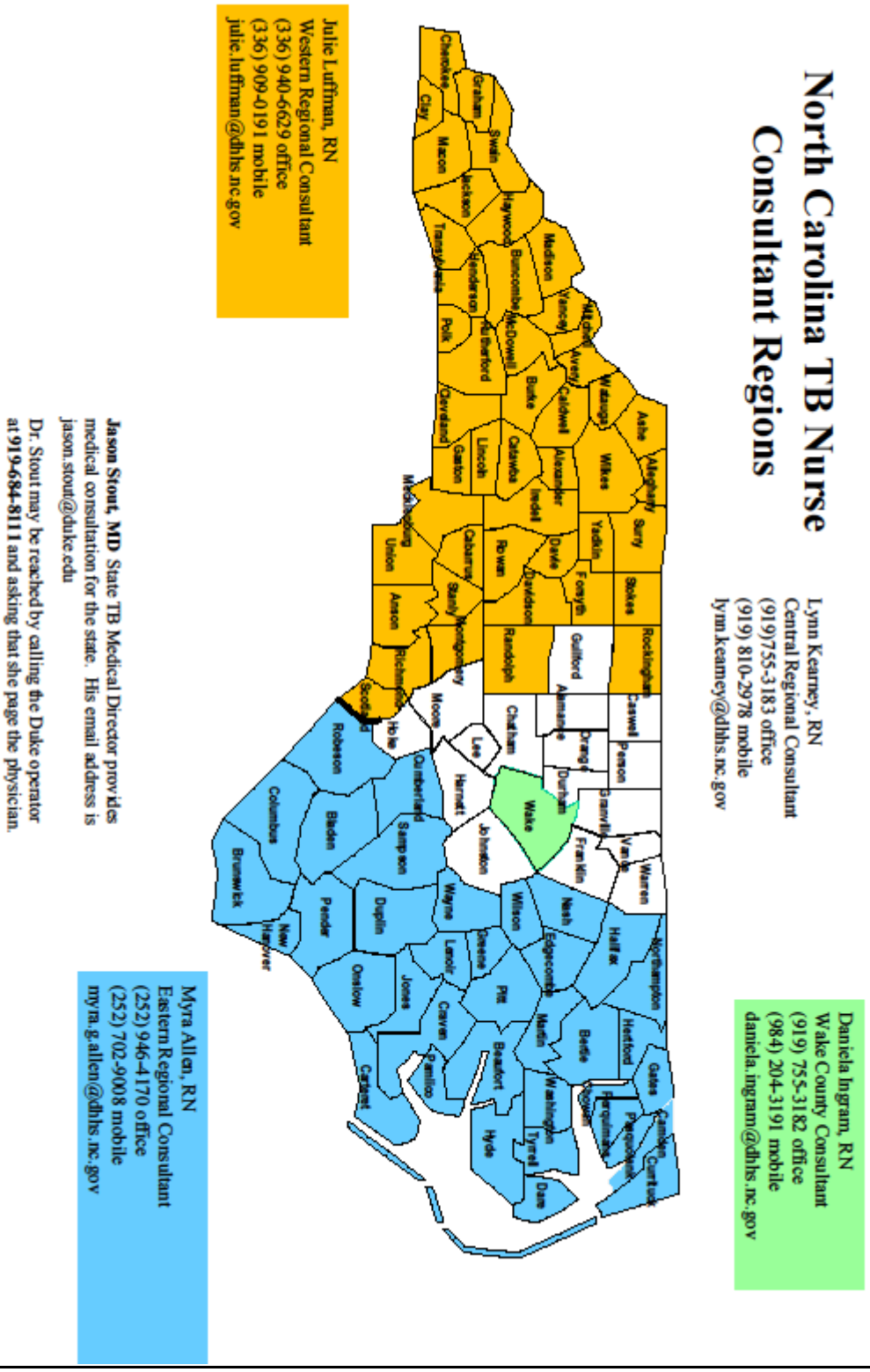
1. Medical Director services include:

   a. Telephone consultation with health departments (HD), private medical doctors (PMD) and other health care providers about diagnosis, treatment and medical management of TB infection and disease.
   b. Education for any health care provider regarding TB medical management.
   c. Chest film consultation to HDs/PMDs for abnormal chest films when TB is suspected or to be ruled out.
   d. Contact information for the State Medical Consultants:
      - Dr. Jason Stout is available for consultation for all adult patients and may be reached by calling the Duke University operator at 919-684-8111 and asking that s/he page Dr. Jason Stout.
      - Fax # for Dr. Stout is 919-681-7494
      - Mailing address is:
        - Duke University Medical Center
          Division of Infectious Diseases
          Box 102359 DUMC
          Durham, NC 27710
      - To send x-rays by FedEx, UPS, etc., please send to:
        - Dr. Jason Stout
          Duke University Medical Center, Div. of Infectious Diseases
          Room 186
          First floor, Hanes House
          330 Trent Drive
          Durham, NC 27710
      - Contact Dr. Amina Ahmed for pediatric consultations:
        - Department of Pediatrics
          Levine Children's Hospital
          1000 Blythe Blvd.
          MEB 4th Floor
          Charlotte, NC 28203
          Phone: 704-381-6803
          Fax 704-381-6841
          Pager 704-337-1065

2. Nurse consultant services include:

   a. Quality assurance for local TB programs including annual assessments.
   b. Consultation regarding community TB surveillance and patient management.
   c. Orientation and educational programs for health departments and other health care providers.
   d. Contact information for nurse consultants (see map next page)

2. <u>Map of TB Nurse Consultant Regions</u>



E. Charges for Services

G. S. 130A-144(e) specifies that "the local health department shall provide, **at no cost to the patient**, the examination and treatment for tuberculosis disease and infection and for sexually transmitted diseases. . . "

1. TST Fees

   a. A patient may not be charged for a TST if state-supplied PPD is used.

   b. The patient may be charged for a TST as a single service using privately purchased PPD for:
      - Employment requirement;
      - Residential requirement;
      - Immigration or citizenship requirement; and
      - Physical exam for college entry, insurance, sports activity or marriage.

   c. The patient may be charged for completion of Record of Tuberculosis Screening (DHHS 3405).

   d. A fee per TST or an hourly rate contract may be established with other agencies, institutions or businesses for the health department to provide TST using privately purchased PPD. **No fee** may be charged for a TST for:
      - Contact investigation;
      - HIV positive individuals as required by Rule .0202;
      - Epidemiologic investigations to identify a source case; and/or
      - Tuberculosis suspects.

2. Chest x-ray patient fees

   a. **No fee** may be charged for chest x-rays on newly identified TST positive individuals, suspected or confirmed TB cases, and their contacts.

   b. The patient may **not** be charged by private facilities that provide contractual x-ray services for the health department.

3. Third-Party Billing

   a. The Medicaid Interagency Agreement allows health departments:
      - To bill for services provided to cases, suspected cases being evaluated to diagnose or rule out disease, contacts and reactors.
      - For information about billing Medicaid for TB services see https://files.nc.gov/ncdma/documents/files/1D-3_0.pdf

   b. Health departments may bill private insurers using CPT codes. Private facilities that provide contractual x-ray services for the health department may bill private insurers and/or other third party payers.

b. Address questions regarding billing to the administrative consultant that serves your county.

F. Class A/B Refugee and Immigrant TB Follow-up Protocol for Local Health Department (LHD) TB Programs

Immigrants and Refugees are required to have a pre-departure exam prior to coming to the U.S. If there are any concerns related to TB, the person is given a Class A or B classification. The TB program in the state that the person is traveling to is notified and provided with information about the person. These immigrants/refugees are categorized as follows:

Class A. TB disease active, pulmonary or extra-pulmonary. Immigrants and Refugees with a class A condition must complete treatment for TB prior to coming to the U.S. Exemptions are only given in extreme circumstances and must be given by the state TB Medical Consultants.

Class B- 0. No tuberculosis exposure, not infected. Persons in this class have no history of exposure and a negative reaction to the tuberculin skin test.

Class B -1. Tuberculosis exposure, no evidence of infection. Persons in this class do have a history of exposure but have a negative reaction to the tuberculin skin test. Action taken for persons in this class depends mainly on the degree and recency of exposure to M. tuberculosis. If there has been close exposure within 3 months, follow-up is required, and preventive therapy should be considered.

Class B- 2. Tuberculous infection, no disease. Persons in this class have a positive reaction to the tuberculin skin test, negative bacteriologic studies (if done), and no clinical or radiographic evidence of tuberculosis. Preventive chemotherapy may be indicated in some persons in this group.

Class B- 3. Tuberculosis: clinically active. Class 3 includes all patients with clinically active tuberculosis whose diagnostic procedures are complete. To fit into Class 3, a person must have clinical and/or radiographic evidence of current tuberculosis. This is established most definitively by isolation of M. tuberculosis. In the absence of a positive culture for M. tuberculosis, persons in this class must have a positive reaction to the tuberculin test. A person who had past tuberculosis and who currently has clinically active disease belongs in Class 3. A person remains in Class 3 until treatment for the current episode of disease is completed.

Class B- 4. Tuberculosis: not clinically active. This classification is defined by a history of previous episode(s) of tuberculosis or abnormal stable radiographic findings in a person with a positive reaction to tuberculin skin test, negative bacteriologic studies (if done), and no clinical and/or radiographic evidence of current disease. Persons in Class 4 may never have received chemotherapy, may be receiving prevention chemotherapy, or may have completed a previously prescribed course of chemotherapy

When N.C. TB Control is notified about a person with a Class A/B condition an event will be created in NCEDSS. Medical evaluation forms will be scanned and attached to the event. When the event is created the person will appear in the workflow called Class A/B County Acknowledgement Needed. This will serve as the county notification about the person. The county can clear this workflow by answering yes to the question: Remove this event from the class A/B workflow. This question is located in the administrative question package under the blue heading labeled Reporter Information.

The following procedures should be followed:

- An initial phone call (with someone available – if necessary – to communicate with the person in his/her native language) should be made to the sponsor/relative's home within five working days after receiving the notification. An arrangement should be made for the person to come in for screening during clinic hours.
- If the person does not visit the TB clinic within ten working days of phone call, a letter (if necessary, in the person's native language) should be sent to the home of the sponsor/relative.
- If the person does not visit the TB clinic within ten working days of the letter, a field visit (with someone available – if necessary – to communicate with the person in his/her native language) should be made to the home of the sponsor/relative.
- If the person has moved, obtain the forwarding address and contact the state TB program with the new address so the event can be transferred to the correct jurisdiction.
- It is the responsibility of the LHD to assure that this individual complies with the instructions to report to the LHD within one month of arrival. If this does not occur, the LHD must report this to the state TB Control Program which will, in turn, report this information to the Division of Quarantine. This may prevent the immigrant from getting a change of status change to a permanent citizenship.
- The person should be fully evaluated for TB disease, including a TST and chest x-ray if not done overseas. If a chest x-ray was taken overseas, repeat the x-ray if the original is of poor quality, x-ray is > 6 months old, there are any symptoms, or there is any question about validity of the X-ray. If indicated, sputum should be obtained for smear and culture. When TB disease is ruled out, consider treating for LTBI if indicated.
- When any immigrant/refugee comes into the clinic, the Epi form (DHHS 1030 found on the State TB Control Program website) should be completed.
- Provide skin test (TST) if not done overseas, regardless of BCG history, and read skin test in 48-72 hours. Record results in mm of induration. Provide this information to the patient. Persons 6 months or older should receive a TST unless reliable documentation of a prior positive TST or history of previous disease is available. Disregard BCG history when reading the TST and making treatment decisions. Pregnancy is not a contraindication for TST. Provide TST for children 6 months or under if the child has HIV infection or the child was exposed to an individual with active TB disease.

Schedule a child under 6 months who is not HIV+ or a close contact for a TST after his/her 6 month birthday.

- A local physician or radiologist should review the overseas chest X-ray – if the overseas X-ray is not available, is technically inadequate, was taken more than six months ago, or there are questions about the validity of the X-ray, then a new X-ray must be done. If patient is symptomatic (cough, fever, hemoptysis, night sweats, weight loss, etc.) a new X-ray should be done.
- Asymptomatic persons with LTBI and normal chest X-rays are candidates for treatment of LTBI.

In accordance with CDC guidelines, the patient's evaluation should be initiated within 30 days of their arrival into the United States. If the evaluation is not initiated within the 30 days, the event will show up in the workflow titled Class A/B Evaluation Initiation Past Due (30 days). The event will show up in the Class A/B Evaluation Completion Past Due (90 days) workflow when the Class A/B Disposition Date and the Disposition have not been entered into the wizard within 90 days.

A TB Follow-up worksheet wizard should be completed in NCEDSS after you have evaluated the patient and made a determination about whether he or she has active or latent tuberculosis and if treatment is needed. This is considered the "disposition" and the date this was determined is the "disposition date." You may go to the print document icon in NCEDSS to print the TB Follow-up Worksheet after you complete the wizard. All fields in the TB Follow-up Worksheet wizard should be completed (regardless of diagnosis) within 90 days of the LHD receiving the forms. If something was not done it should be marked as not done, rather than leaving the field blank. **If the immigrant/refugee does not report to the TB clinic for clearance, this should be indicated in the wizard and a disposition date should be entered as the date it was determined that the patient was lost to follow-up.** Examples of this would be: if they moved to another jurisdiction, returned to country of origin, the address provided is insufficient to locate them, or unknown (lost to follow-up).

Once you have entered the disposition completion date and the disposition into the wizard, this will put the event into a workflow for the state to review. Since it is usually a LTBI event you cannot assign it to the state. If treatment is not recommended, the state will close the event if all information needed has been entered. If treatment is recommended, the case will remain open until one of the following occurs:

- The treatment regimen stop date is entered in the TB follow-up worksheet wizard.
- The reason treatment not initiated is entered into the TB follow-up worksheet wizard.
- The treatment regimen start date is entered in the TB follow-up worksheet wizard but treatment is not completed for some reason and as a result, reason for incomplete therapy is indicated in the TB follow-up worksheet wizard.

Once one of the above occurs, this will put the event into a workflow for the state to review. At that point, if everything is entered for this patient, the state will close the event (only the State TB Registrar should close class B events in NCEDSS).

When the patient completes treatment the completion date should be entered into NCEDSS. If a treatment stop date is not entered within 12 months of treatment start date, you will be notified through the Class A/B Treatment Started 1 Year Ago and Completion Status Not Recorded workflow. To clear this workflow you must complete the treatment information.

G. Laboratory Services

1. State Public Health Laboratory / Mycobacteriology

a. Submitting specimens:
- Use DHHS 1247 to order supplies from:
  Laboratory Mailroom, Division of Laboratory Services
  P. O. Box 28047
  Raleigh, NC 27611-8047
  Courier # 52-41-41
  Phone: 919-733-7656
- Provide all requested information, including Medicaid number and social security number.
- Consult the State Laboratory Manual **SCOPE** for detailed information.

b. Laboratory results:
- First-time smear positive results are reported by telephone to the provider who submitted the specimen on the day the specimen is processed.
- Smear results are reported as:
  - No acid-fast bacilli found.
  - Acid-fast bacilli found (<1 **or** 1-10 **or** >10 per field).
- Preliminary culture results are reported as:
  - Growth suggestive of Mycobacterium tuberculosis.
  - Growth suggestive of non-tuberculosis mycobacterium (NTM).
- Final culture results are reported as:
  - "Growth identified as Mycobacterium tuberculosis complex" (M. tuberculosis, M. bovis, M. africanum).
  - "Growth identified as Mycobacterium (species name)."
  - "Contaminated", indicating overgrowth with bacteria or other microorganisms.
- No further action is required for NTM results UNLESS the patient is currently under treatment as a TB suspect.

c. Susceptibility testing:
- Performed on all initial positive M. tuberculosis cultures for:
  - Isoniazid
  - Rifampin
  - Pyrazinamide
  - Ethambutol

- Performed for second line drugs if resistance to any first-line drug is present.
- Reported as "S" for Susceptible or "R" for Resistant for liquid media (e.g. Bactec).
- Reported as a percent (%) resistance (colony count) for solid media results.
- Performed for rifabutin, ofloxacin, amikacin by special request.

d. Notification to the health department:
- Original report sent to the health department on specimens submitted by the health department.
- "County copy" sent to the health department for smear positive and/or M. tuberculosis culture specimens that were submitted by other health care providers.
- Reported by Electronic Laboratory Report (ELR) in NCEDSS.

e. M. tuberculosis cultures are retained by the laboratory for one year.

2. North Carolina is participating in a universal genotyping program through the State Public Health Lab. Therefore, private and hospital-based laboratories that process their own cultures need to forward one specimen per M.tb culture positive patient to the State Public Health Lab. Local TB nurses need to help ensure that this process takes place.

3. Private Laboratory Mycobacteriology

a. All laboratories are required by G. S. 130A-139 to report positive smears and M.tuberculosis cultures within seven days of obtaining the result.

b. Reports from private and commercial laboratories (Report of Positive Smear (AFB) and/or Positive Culture of M. tuberculosis - DHHS 3005) are sent to N.C. TB Control (see sample in this chapter).

c. N.C. TB Control forwards these reports to the patient's county of residence.

d. Contact the local nurse consultant with questions upon receipt of results from a private laboratory.

e. As noted above, one specimen per M.tb culture-positive patient should be forwarded to the State Public Health Lab for genotyping.

4. Nucleic Acid Amplification Testing (NAA) For Tuberculosis: North Carolina State Laboratory of Public Health Testing and General Guidelines for Interpretation:

a. In some instances NAA test results can provide a more rapid diagnosis of tuberculosis (or exclude such a diagnosis), allowing practitioners to make more informed decisions regarding treatment and the need for isolation. NAA tests are designed to supplement, rather than to replace,

standard mycobacterial culture for confirmation of diagnosis and the test is not suitable for all specimens.

b. Types of NAA tests available:
- MTD (Gen-Probe®) is FDA approved for detecting AFB in smear-positive AND smear-negative respiratory specimens from patients suspected of having tuberculosis.
- Amplicor® is another type of NAA test but it is **only** FDA approved for detecting AFB smear-positive respiratory specimens; potential advantages of NAA tests include more rapid diagnosis, but, as noted above, they do NOT replace AFB smear or mycobacterial culture, and do not replace clinical judgment.
- Some labs perform their own formulated real time-polymerase chain reaction (RT-PCR) NAA test after validating the process. This is the type of test the North Carolina State Laboratory of Public Health (N.C. SLPH) validated and uses.

c. The N.C. SLPH will perform a RT-PCR on undigested primary clinical specimens only (i.e., directly on the sample, not on samples already set up for culture). The sample will undergo routine processing to determine if it is AFB smear-positive or negative.

- RT-PCR will be performed on all first-time AFB smear-positive specimens for each patient (whether requested or not).
- RT-PCR will only be performed on smear negative specimens in special circumstances.

d. When submitting respiratory specimens to the SLPH submit three spontaneous or induced sputum specimens initially (early morning samples are best), or a sample from BAL in addition to a pre and post-BAL specimen. Specimens will be processed as follows:

- **AFB smear-positive specimens**. As noted earlier, RT-PCR will be performed on the first AFB smear positive specimen for each patient.
    - If the RT-PCR is positive, no other RT-PCR tests will be performed on subsequent specimens (see Interpretation section below). Specimens will, however, be cultured and TB isolates tested for drug susceptibility as usual.
    - If the RT-PCR result is negative on any AFB smear-positive specimen, then testing for inhibitors will be performed, and specimens will be cultured and TB isolates tested for drug susceptibility as usual.
    - **AFB smear-negative specimens.** As noted earlier, smear-negative specimens will only be tested in special circumstances
- **extra-pulmonary specimens:**
    - Selected specimens from extra-pulmonary sites can be submitted for RT-PCR testing. Specimens appropriate for testing include lymph node aspirate or biopsy, tissue biopsy,

and urine. RT-PCR has a high specificity on smear-positive specimens and can confirm a diagnosis of active TB in such instances. However, the sensitivity is much lower, especially on smear-negative specimens, so the **RT-PCR test result cannot be used to exclude a diagnosis of active TB if the specimen is AFB smear-negative**. Therefore, unless you have specifically discussed with the SLPH and gotten approval, only smear-positive tissue specimens will be tested using RT-PCR.

- Specifically, pleural fluid and cerebrospinal fluid (CSF) are generally not appropriate specimens for RT-PCR testing, as these specimens are generally smear-negative and RT-PCR has very low sensitivity. Smear-positive pleural fluid or CSF can be submitted for testing.

e. Interpretation of RT-PCR and other NAA tests

- NAA tests can be very useful to rapidly determine whether or not a patient poses an infectious risk to others, particularly in instances where a patient would otherwise be isolated waiting for culture confirmation of a diagnosis (e.g. in a hospital setting). A negative RT-PCR on these samples does not completely exclude the presence of TB; however, a negative test does indicate that the quantity of M. tuberculosis in the sputum is a very low level, so the patient is less likely to be contagious. It should not be used in place of sound clinical judgment when determining matters of infectivity or the need for isolation.

- NAA tests are **not licensed** for use on non-respiratory tissues or specimens (e.g., cerebrospinal fluid, lymph node tissue), should be interpreted with extreme caution if ordered for one of these non-licensed uses, and should not be used to “rule-out” TB in these circumstances. Also, NAA tests have not been tested in pediatric populations.

- Interpretation of an NAA test done on an approved specimen: In general, a “positive” NAA test should be considered evidence of M. tuberculosis disease, while awaiting final culture results;

AFB Smear – positive specimens

- A “positive” NAA test should be considered evidence of M. tuberculosis disease, while awaiting final culture results.
- A negative NAA test does NOT necessarily rule-out TB and should be interpreted with caution using experienced clinical judgment.
- If the RT-PCR test result is negative on an AFB smear-positive specimen, then testing for inhibitors will be performed:
    - If inhibitors are found, the RT-PCR test result is of no diagnostic assistance for that specimen. Up to two more samples can be tested.

- If no inhibitors are found, testing will continue on other samples. If a second RT-PCR test result on an AFB smear-positive specimen is also negative, the patient can be assumed to have a diagnosis of non-tuberculosis mycobacterial disease (NTM).

AFB Smear – negative specimens

- If the RT-PCR test result is positive on any AFB smear-negative specimen, up to two more specimens can be tested. If another specimen also tests positive by RT-PCR, then the patient can be considered to have active TB.
- If the RT-PCR test result is negative on all three AFB smear-negative specimens, the patient can be assumed to be not contagious, and likely does not have TB, though the AFB culture is the final definitive result.
- If the RT-PCR test result is positive on only one specimen, the result is considered indeterminate, and clinical judgment must be used to determine the need for treatment, isolation, and further diagnostic workup.

For more information about NAA testing, contact your regional TB Nurse Consultant, or refer to the MMWR January 16, 2009 / 58(01);7-10 (https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm?s_cid=mm5801a3_e)

5. Sputum Collection Procedure

a. The first sputum specimen should be collected under supervision if possible, with the health care worker wearing an N-95 mask.

b. instruct the patient/family as follows:
   - Thoroughly rinse mouth with water before collecting specimen
   - Collect only material coughed up from the lungs – not saliva or post-nasal drainage.
   - Collect specimen(s) upon arising on three successive days.
   - Inhaling steam, e.g. hot shower, may help induce sputum production.
   - Collect at least 5 ml of sputum (1 teaspoon).
   - Expectorate directly into the plastic tube and thoroughly dry the lip of the tube before screwing the cap on tightly.
   - Refrigerate the specimen until able to mail the State Public Health Laboratory or deliver to the health department.

c. Label plastic specimen tube with the patient's name and identification number that matches the requisition form DHHS 1247.

d. The completed DHHS 1247 (see sample in this chapter) should be placed around the outside of the inner metal container.

e. The local health department must affix first class postage for patient mailing.

6. Sputum Induction Protocol

a. The purpose of sputum induction is to obtain a sputum specimen for diagnostic or sputum conversion purposes from a patient unable to produce a specimen naturally.

b. This procedure can be done outside patient's home or within the home in a well-ventilated area.

c. If procedure is performed in a healthcare facility, a room, booth or enclosed area must have negative pressure. Airflow must be from the corridor into the sputum induction room then exhausted to the outside.

d. Equipment required:
- Nebulizer and disposable "neb kit" (tubing, mouthpiece, plastic chamber for sterile hypertonic saline);
- Sputum container properly labeled;
- Sterile, non-bacteriostatic (no preservatives) 3%-10% hypertonic saline (5-10cc); and
- N95 respirator or equivalent.

e. Preparation of equipment:
- Inspect nebulizer for cleanliness. If necessary, wipe nebulizer surfaces with a 10 percent bleach solution.
- Place hypertonic saline in the nebulizer chamber.
- Connect mouthpiece to tubing (including chamber) and connect tubing to machine.
- Test nebulizer by turning equipment on and observing mist production.

f. Preparation of patient:
- Explain procedure to patient and demonstrate nebulizer function
- Have patient rinse mouth out with a disposable cup of water.
- Instruct patient to place his/her lips around the mouthpiece and inhale the aerosol, through the mouthpiece, using slow, deep breaths for 10-15 minutes.
- Instruct patient to cough vigorously if spontaneous coughing does not occur; the patient should cough several times and expectorate all sputum into the container.
- Instruct patient to keep sputum container closed until ready to expectorate; direct patient to close container securely after the specimen has been collected.
- Caution patient not to leave the sputum induction area until coughing has completely stopped.
- Instruct patient to shut the door after leaving the sputum induction room.

g. Staff role

- Staff must wear properly fitted respirator while in the sputum induction room.
- Verify patient is using nebulizer correctly.
- It is not necessary for staff to remain with patient during procedure.
- Staff must remain nearby to assist patient if necessary and to ensure patient remains in the sputum induction room until coughing has stopped.

h. Preparation of specimen:
- Sputum may appear watery. Send to lab regardless of appearance.
- Properly label plastic container with patient's name and identification number that matches the requisition form DHHS 1247.
- Check "induced sputum" on the lab requisition.
- Prepare two sputum containers for patient to take home, making sure they are properly labeled.
- The induction procedure may cause patient to produce sputum later. If patient produces a specimen later in the day (following induction), the specimen should be sent to the lab.

i. Care of equipment and area:
- To determine length of time required to decontaminate air, refer to Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Facilities, MMWR 1994/ 43(RR13), page 72.
- If staff enters room any time prior to the end of the time period determined in "a" above, a properly fitted respirator must be worn.
- Never reuse disposable nebulizer tubing or mouthpiece. Seal used articles in a plastic bag and discard in biohazardous receptacle.

7. Gastric Aspiration Procedure

Gastric aspiration is the recommended method of collection of respiratory secretions for the bacteriologic diagnosis of TB disease in children who are unable to expectorate sputum. Compared with bronchoalveolar lavage (BAL), gastric aspiration is less invasive, has fewer potential complications, and is an excellent method for confirming a bacteriologic diagnosis. The specimens should be collected as follows:

a. Patients should be hospitalized whenever possible to ensure proper collection and processing of gastric aspirates. If done on an outpatient basis it should be done before the patient takes anything by mouth, sits up or ambulates.

b. The microbiology laboratory should be notified of the anticipated collection of specimens and a technician should be identified to facilitate processing of the specimens.

c. Early morning specimens should be collected on three consecutive mornings.

d. The patient should fast 6 to 8 hours before the procedure. He/she should have no intake of food (solids, liquids, etc.) from 10 p.m. until after the specimen is collected at 6 a.m. the following morning.

e. A feeding tube (8 FR) should be placed into the stomach while the patient is recumbent, preferably while still asleep or immediately upon awakening. Once the location of the tube is verified a minimum of 5 ml of gastric contents should be aspirated with a 10-20 ml syringe.

f. A minimum of 5 ml of gastric contents is needed for processing. If less than 5 ml are aspirated, 20-30 ml of non-bacteriostatic sterile water (not tap water) should be inserted through the tube and the gastric contents should be aspirated. The feeding tube should then be removed.

g. Specimens should be placed in a sterile container and **immediately** adjusted to a neutral pH with 100 mg of sodium carbonate (Na_2CO_3) salt or with 3 ml of a sodium bicarbonate solution (100 mg/ml). The neutralization step may be completed at the bedside or the specimen may be transported **immediately** to the laboratory and neutralized on arrival.

h. All specimens should be transported to the microbiology laboratory **immediately** or, if neutralized at the bedside, should be refrigerated until transport to the laboratory.

8. Serum Concentration Levels for TB Drugs

- Serum drug levels (SDL)should be considered for the following patients:
- HIV-infected patients with a CD4 count of < 100 who are taking isoniazid and/or rifampin as part of the TB regimen.
- Apparent treatment failure (recurrent positive culture during therapy). Meanwhile add two new drugs.
- Patients who have completed a full course of TB treatment and who experience TB relapse within two years
- Persistently positive AFB smear or culture after 12 weeks of DOT (85 percent of patients should have negative cultures within eight weeks).
- Known gastrointestinal conditions, surgical procedures or abnormalities likely to interfere with medication absorption, e.g., partial gastrectomy, Crohn's disease, resection of small intestine.
- Send specimens to the Infectious Disease Pharmacokinetics Laboratory at the University of Florida. The cost for each assay is $80. The Southeastern TB Center may have funds to pay for this. This can be billed to the health department or the health department can send a check with the specimen. To have it billed to the health department, write in the health department's name, address, phone and fax numbers in the responsible party section and they will bill you. Call your TB Nurse Consultant if you want to access these funds. Complete one column of information for each drug to be

assayed. Make as many photocopies as you need. All specimens sent to the laboratory should conform to all Federal and IATA shipping regulations. If you have any questions call the Infectious Disease Pharmacokinetics Laboratory at (352) 273-6710. The requisition form and instructions can be found at the following link https://idpl.pharmacy.ufl.edu/forms-and-catalog/

9. The NC State Laboratory Mycobacteriology requisition form (DHHS 1247) can be found at: https://slph.ncpublichealth.com/Forms/1247-Mycobacteriology-TB-20170801.pdf

10. The Report of Positive (AFB) and/or Positive Culture of M.tuberculosis (DHHS 3005) can be found at: https://epi.publichealth.nc.gov/cd/tb/docs/dhhs_3005.pdf

H. Reporting TB to NC TB Control

1. General Information:

   a. The Report of Verified Case of Tuberculosis (RVCT) is submitted to the to the regional Nurse Consultant in NCEDSS and includes:
      - Initial two-page form (CDC 72.9A)
      - Follow-up Report 1 (CDC 72.9B)
      - Follow-up Report 2 (CDC 72.9C)

   b. The state that officially counts the TB case is responsible for completion of all parts of the RVCT.

   c. Use the North Carolina Disease Surveillance System (NCEDSS) to report TB to N.C. TB Control.

   d. A reporting tool must be completed on all suspect or confirmed TB cases by using the reporting tool wizard in NCEDSS and then re-assigning the event to the regional TB nurse consultant within seven days of a patient being identified as a TB suspect.

   e. Report confirmed cases of new active TB disease by completing the RVCT wizard and re-assigning the event to the regional TB Nurse Consultant within 12 weeks of initiation of disease treatment.

   f. Susceptibility results must be entered into NCEDSS if a patient has a positive culture for M. tb. This will populate the fields needed for the follow-up 1 in NCEDSS. This must be entered by the time the RVCT is submitted.

   g. A follow-up 2 must be completed within four weeks of the patient completing therapy by completing the follow-up 2 wizard in NCEDSS and re-assigning the case to the regional TB nurse consultant.

h. “Unknown” is an unacceptable response for most questions; the requested information must be retrieved prior to submission of the report.

i. Call your TB nurse consultant for questions regarding report completion.

I. RVCT Page 1

Patient's Name _____ (Last) (First) (M.I.)

Street Address _____ _____ (ZIP CODE)

REPORT OF VERIFIED CASE OF TUBERCULOSIS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES-
FORM APPROVED OMB NO. 0920-0026 Exp. Date 05/31/2011

REPORT OF VERIFIED CASE OF TUBERCULOSIS

1. Date Reported

Month ☐☐ Day ☐☐ Year ☐☐☐☐

2. Date Submitted

Month ☐☐ Day ☐☐ Year ☐☐☐☐

3. Case Numbers

	Year Reported (YYYY)	State Code	Locally Assigned Identification Number	Reason:
State Case Number	☐☐☐☐	☐☐	☐☐☐☐☐☐☐☐☐	
City/County Case Number	☐☐☐☐	☐☐	☐☐☐☐☐☐☐☐☐	
Linking State Case Number	☐☐☐☐	☐☐	☐☐☐☐☐☐☐☐☐	☐
Linking State Case Number	☐☐☐☐	☐☐	☐☐☐☐☐☐☐☐☐	☐

4. Reporting Address for Case Counting

City ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Within City Limits *(select one)* ☐ Yes ☐ No

County ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ZIP CODE ☐☐☐☐☐ — ☐☐☐☐

5. Count Status *(select one)*

Countable TB Case

☐ Count as a TB case

Noncountable TB Case

☐ Verified Case: Counted by another U.S. area (e.g., county, state)

☐ Verified Case: TB treatment initiated in another country *Specify*_____

☐ Verified Case: Recurrent TB within 12 months after completion of therapy

6. Date Counted

Month ☐☐ Day ☐☐ Year ☐☐☐☐

7. Previous Diagnosis of TB Disease *(select one)*

☐ Yes ☐ No

If YES, enter year of previous TB disease diagnosis: ☐☐☐☐

8. Date of Birth

Month ☐☐ Day ☐☐ Year ☐☐☐☐

9. Sex at Birth *(select one)*

☐ Male ☐ Female

10. Ethnicity *(select one)*

☐ Hispanic or Latino

☐ Not Hispanic or Latino

11. Race *(select one or more)*

☐ American Indian or Alaska Native

☐ Asian: *Specify*_____

☐ Black or African American

☐ Native Hawaiian or Other Pacific Islander: *Specify*_____

☐ White

12. Country of Birth

"U.S.-born" (or born abroad to a parent who was a U.S. citizen) *(select one)* ☐ Yes ☐ No

Country of birth: *Specify*_____

13. Month-Year Arrived in U.S.

Month ☐☐ Year ☐☐☐☐

14. Pediatric TB Patients (<15 years old)

Country of Birth for Primary Guardian(s): *Specify*

Guardian 1_____

Guardian 2_____

Patient lived outside U.S. for >2 months? *(select one)* ☐ Yes ☐ No ☐ Unknown

If YES, list countries, *specify*: _____

15. Status at TB Diagnosis *(select one)*

☐ Alive ☐ Dead

If DEAD, enter date of death: Month ☐☐ Day ☐☐ Year ☐☐☐☐

If DEAD, was TB a cause of death? *(select one)*

☐ Yes ☐ No ☐ Unknown

16. Site of TB Disease *(select all that apply)*

☐ Pulmonary

☐ Pleural

☐ Lymphatic: Cervical

☐ Lymphatic: Intrathoracic

☐ Lymphatic: Axillary

☐ Lymphatic: Other

☐ Lymphatic: Unknown

☐ Laryngeal

☐ Bone and/or Joint

☐ Genitourinary

☐ Meningeal

☐ Peritoneal

☐ Other: Enter anatomic code(s) *(see list)*: 1 ☐☐ 2 ☐☐ 3 ☐☐

☐ Site not stated

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Information contained on this form which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used only for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

NC -

J. RVCT Page 2

REPORT OF VERIFIED CASE OF TUBERCULOSIS

17. Sputum Smear *(select one)*

☐ Positive ☐ Not Done
☐ Negative ☐ Unknown

Date Collected: Month Day Year

18. Sputum Culture *(select one)*

☐ Positive ☐ Not Done
☐ Negative ☐ Unknown

Date Collected: Month Day Year

Date Result Reported: Month Day Year

Reporting Laboratory Type *(select one)*: ☐ Public Health Laboratory ☐ Commercial Laboratory ☐ Other

19. Smear/Pathology/Cytology of Tissue and Other Body Fluids *(select one)*

☐ Positive ☐ Not Done
☐ Negative ☐ Unknown

Date Collected: Month Day Year

Enter anatomic code *(see list)*:

Type of exam *(select all that apply)*: ☐ Smear ☐ Pathology/Cytology

20. Culture of Tissue and Other Body Fluids *(select one)*

☐ Positive ☐ Not Done
☐ Negative ☐ Unknown

Date Collected: Month Day Year

Enter anatomic code *(see list)*:

Date Result Reported: Month Day Year

Reporting Laboratory Type *(select one)*: ☐ Public Health Laboratory ☐ Commercial Laboratory ☐ Other

21. Nucleic Acid Amplification Test Result *(select one)*

☐ Positive ☐ Not Done
☐ Negative ☐ Unknown
☐ Indeterminate

Date Collected: Month Day Year

Date Result Reported: Month Day Year

Enter specimen type: ☐ Sputum
OR
If not Sputum, enter anatomic code *(see list)*:

Reporting Laboratory Type *(select one)*: ☐ Public Health Laboratory ☐ Commercial Laboratory ☐ Other

Initial Chest Radiograph and Other Chest Imaging Study

22A. Initial Chest Radiograph *(select one)*

☐ Normal ☐ Abnormal* (consistent with TB) ☐ Not Done ☐ Unknown

* For ABNORMAL Initial Chest Radiograph: Evidence of a cavity *(select one)*: ☐ Yes ☐ No ☐ Unknown
Evidence of miliary TB *(select one)*: ☐ Yes ☐ No ☐ Unknown

22B. Initial Chest CT Scan or Other Chest Imaging Study *(select one)*

☐ Normal ☐ Abnormal* (consistent with TB) ☐ Not Done ☐ Unknown

* For ABNORMAL Initial Chest Radiograph: Evidence of a cavity *(select one)*: ☐ Yes ☐ No ☐ Unknown
Evidence of miliary TB *(select one)*: ☐ Yes ☐ No ☐ Unknown

23. Tuberculin (Mantoux) Skin Test at Diagnosis *(select one)*

☐ Positive ☐ Not Done
☐ Negative ☐ Unknown

Date Tuberculin Skin Test (TST) Placed: Month Day Year

Millimeters (mm) of induration:

24. Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis *(select one)*

☐ Positive ☐ Not Done
☐ Negative ☐ Unknown
☐ Indeterminate

Date Collected: Month Day Year

Test type:
Specify _____

25. Primary Reason Evaluated for TB Disease *(select one)*

☐ TB Symptoms
☐ Abnormal Chest Radiograph (consistent with TB)
☐ Contact Investigation
☐ Targeted Testing
☐ Health Care Worker
☐ Employment/Administrative Testing
☐ Immigration Medical Exam
☐ Incidental Lab Result
☐ Unknown

NC

K. RVCT page 3

Patient's Name _____ State Case No. _____
(Last) (First) (M.I.)

REPORT OF VERIFIED CASE OF TUBERCULOSIS

REPORT OF VERIFIED CASE OF TUBERCULOSIS

26. HIV Status at Time of Diagnosis *(select one)*

☐ Negative ☐ Indeterminate ☐ Not Offered ☐ Unknown
☐ Positive ☐ Refused ☐ Test Done, Results Unknown

If POSITIVE, enter:
State HIV/AIDS Patient Number: ☐☐☐☐☐☐☐☐☐☐ City/County HIV/AIDS Patient Number: ☐☐☐☐☐☐☐☐☐☐

27. Homeless Within Past Year *(select one)*

☐ No ☐ Yes ☐ Unknown

28. Resident of Correctional Facility at Time of Diagnosis *(select one)* ☐ No ☐ Yes ☐ Unknown

If YES, *(select one)*:
☐ Federal Prison ☐ Local Jail ☐ Other Correctional Facility
☐ State Prison ☐ Juvenile Correction Facility ☐ Unknown

If YES, under custody of Immigration and Customs Enforcement? *(select one)*
☐ No ☐ Yes

29. Resident of Long-Term Care Facility at Time of Diagnosis *(select one)* ☐ No ☐ Yes ☐ Unknown

If YES, *(select one)*:
☐ Nursing Home ☐ Residential Facility ☐ Alcohol or Drug Treatment Facility ☐ Unknown
☐ Hospital-Based Facility ☐ Mental Health Residential Facility ☐ Other Long-Term Care Facility

30. Primary Occupation Within the Past Year *(select one)*

☐ Health Care Worker ☐ Migrant/Seasonal Worker ☐ Retired ☐ Not Seeking Employment (e.g. student, homemaker, disabled person)
☐ Correctional Facility Employee ☐ Other Occupation ☐ Unemployed ☐ Unknown

31. Injecting Drug Use Within Past Year *(select one)* ☐ No ☐ Yes ☐ Unknown

32. Non-Injecting Drug Use Within Past Year *(select one)* ☐ No ☐ Yes ☐ Unknown

33. Excess Alcohol Use Within Past Year *(select one)* ☐ No ☐ Yes ☐ Unknown

34. Additional TB Risk Factors *(select all that apply)*

☐ Contact of MDR-TB Patient (2 years or less) ☐ Incomplete LTBI Therapy ☐ Diabetes Mellitus ☐ Other *Specify* _____
☐ Contact of Infectious TB Patient (2 years or less) ☐ TNF-α Antagonist Therapy ☐ End-Stage Renal Disease ☐ None
☐ Missed Contact (2 years or less) ☐ Post-organ Transplantation ☐ Immunosuppression (not HIV/AIDS)

35. Immigration Status at First Entry to the U.S. *(select one)*

☐ Not Applicable
- "U.S.-born" (or born abroad to a parent who was a U.S. citizen)
- Born in 1 of the U.S. Territories, U.S. Island Areas, or U.S. Outlying Areas

☐ Immigrant Visa ☐ Tourist Visa ☐ Asylee or Parolee
☐ Student Visa ☐ Family/Fiancé Visa ☐ Other Immigration Status
☐ Employment Visa ☐ Refugee ☐ Unknown

36. Date Therapy Started

Month ☐☐ Day ☐☐ Year ☐☐☐☐

37. Initial Drug Regimen *(select one option for each drug)*

	No	Yes	Unk		No	Yes	Unk		No	Yes	Unk
Isoniazid	☐	☐	☐	Ethionamide	☐	☐	☐	Moxifloxacin	☐	☐	☐
Rifampin	☐	☐	☐	Amikacin	☐	☐	☐	Cycloserine	☐	☐	☐
Pyrazinamide	☐	☐	☐	Kanamycin	☐	☐	☐	Para-Amino Salicylic Acid	☐	☐	☐
Ethambutol	☐	☐	☐	Capreomycin	☐	☐	☐	Other	☐	☐	☐
Streptomycin	☐	☐	☐	Ciprofloxacin	☐	☐	☐	*Specify* _____			
Rifabutin	☐	☐	☐	Levofloxacin	☐	☐	☐	Other	☐	☐	☐
Rifapentine	☐	☐	☐	Ofloxacin	☐	☐	☐	*Specify* _____			

Comments:

_____
_____
_____
_____

L. RVCT Follow-up Report 1

Patient's Name _____ (Last) (First) (M.I.)

Street Address _____ (Number, Street, City, State) _____ (ZIP CODE)

REPORT OF VERIFIED CASE OF TUBERCULOSIS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL
AND PREVENTION (CDC)
ATLANTA, GEORGIA 30333
FORM APPROVED OMB NO. 0920-0026 Exp. Date 05/31/2011

REPORT OF VERIFIED CASE OF TUBERCULOSIS

Initial Drug Susceptibility Report (Follow Up Report – 1)

Year Counted	State Case Number	City/County Case Number

Submit this report for all culture-positive cases.

38. Genotyping Accession Number

Isolate submitted for genotyping *(select one)*: ☐ No ☐ Yes

If YES, genotyping accession number for episode:

39. Initial Drug Susceptibility Testing

Was drug susceptibility testing done? *(select one)* ☐ No ☐ Yes ☐ Unknown

If NO or UNKNOWN, do not complete the rest of Follow Up Report –1

If YES, enter date FIRST isolate collected for which drug susceptibility testing was done:

Month Day Year

Enter specimen type: ☐ Sputum

OR

If not Sputum, enter anatomic code *(see list)*:

40. Initial Drug Susceptibility Results *(select one option for each drug)*

	Resistant	Susceptible	Not Done	Unknown
Isoniazid	☐	☐	☐	☐
Rifampin	☐	☐	☐	☐
Pyrazinamide	☐	☐	☐	☐
Ethambutol	☐	☐	☐	☐
Streptomycin	☐	☐	☐	☐
Rifabutin	☐	☐	☐	☐
Rifapentine	☐	☐	☐	☐
Ethionamide	☐	☐	☐	☐
Amikacin	☐	☐	☐	☐
Kanamycin	☐	☐	☐	☐

	Resistant	Susceptible	Not Done	Unknown
Capreomycin	☐	☐	☐	☐
Ciprofloxacin	☐	☐	☐	☐
Levofloxacin	☐	☐	☐	☐
Ofloxacin	☐	☐	☐	☐
Moxifloxacin	☐	☐	☐	☐
Other Quinolones	☐	☐	☐	☐
Cycloserine	☐	☐	☐	☐
Para-Amino Salicylic Acid	☐	☐	☐	☐
Other *Specify* _____	☐	☐	☐	☐
Other *Specify* _____	☐	☐	☐	☐

Comments:

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Patient's Name _____ (Last) _____ (First) _____ (M.I.)

Street Address _____ (Number, Street, City, State) _____ (ZIP CODE)

REPORT OF VERIFIED CASE OF TUBERCULOSIS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GEORGIA 30333
FORM APPROVED OMB NO. 0920-0026 Exp. Date 05/31/2011

REPORT OF VERIFIED CASE OF TUBERCULOSIS

Case Completion Report

(Follow Up Report – 2)

Year Counted	State Case Number	City/County Case Number

Submit this report for all cases in which the patient was alive at diagnosis.

41. Sputum Culture Conversion Documented *(select one)* ☐ No ☐ Yes ☐ Unknown

If YES, enter date specimen collected for FIRST consistently negative sputum culture:

Month ☐☐ Day ☐☐ Year ☐☐☐☐

If NO, enter reason for not documenting sputum culture conversion *(select one)*:

☐ No Follow-up Sputum Despite Induction ☐ Patient Refused ☐ Patient Lost to Follow-Up
☐ No Follow-up Sputum and No Induction ☐ Other *Specify* _____
☐ Died ☐ Unknown

42. Moved

Did the patient move during TB therapy? *(select one)* ☐ No ☐ Yes

If YES, moved to where *(select all that apply)*:

☐ In state, out of jurisdiction *(enter city/county)* *Specify*_____ *Specify*_____
☐ Out of state *(enter state)* *Specify*_____ *Specify*_____
☐ Out of the U.S. *(enter country)* *Specify*_____ *Specify*_____

If moved out of the U.S., transnational referral? *(select one)* ☐ No ☐ Yes

43. Date Therapy Stopped

Month ☐☐ Day ☐☐ Year ☐☐☐☐

44. Reason Therapy Stopped or Never Started *(select one)*

☐ Completed Therapy ☐ Not TB
☐ Lost ☐ Died
☐ Uncooperative or Refused ☐ Other
☐ Adverse Treatment Event ☐ Unknown

If DIED, indicate cause of death *(select one)*:

☐ Related to TB disease ☐ Unrelated to TB disease
☐ Related to TB therapy ☐ Unknown

45. Reason Therapy Extended >12 months *(select all that apply)*

☐ Rifampin Resistance ☐ Non-adherence ☐ Clinically Indicated – other reasons
☐ Adverse Drug Reaction ☐ Failure ☐ Other *Specify* _____

46. Type of Outpatient Health Care Provider *(select all that apply)*

☐ Local/State Health Department (HD) ☐ IHS, Tribal HD, or Tribal Corporation ☐ Inpatient Care Only ☐ Unknown
☐ Private Outpatient ☐ Institutional/Correctional ☐ Other

Comments:

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Information contained on this form which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used only for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

N. RVCT Follow-up Report 2, page 2

Patient's Name _____ (Last) (First) (M.I.) State Case No. _____

REPORT OF VERIFIED CASE OF TUBERCULOSIS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GEORGIA 30333
FORM APPROVED OMB NO. 0920-0026 Exp. Date 05/31/2011

Case Completion Report - *Continued* (Follow Up Report – 2)

47. Directly Observed Therapy (DOT) *(select one)*

- ☐ No, Totally Self-Administered
- ☐ Yes, Totally Directly Observed
- ☐ Yes, Both Directly Observed and Self-Administered
- ☐ Unknown

Number of weeks of directly observed therapy (DOT) ☐☐☐

48. Final Drug Susceptibility Testing

Was follow-up drug susceptibility testing done? *(select one)* ☐ No ☐ Yes ☐ Unknown

If NO or UNKNOWN, do not complete the rest of Follow Up Report –2

If YES, enter date FINAL isolate collected for which drug susceptibility testing was done:

Month ☐☐ Day ☐☐ Year ☐☐☐☐

Enter specimen type: ☐ Sputum

OR

If not Sputum, enter anatomic code *(see list)*: ☐☐

49. Final Drug Susceptibility Results *(select one option for each drug)*

	Resistant	Susceptible	Not Done	Unknown
Isoniazid	☐	☐	☐	☐
Rifampin	☐	☐	☐	☐
Pyrazinamide	☐	☐	☐	☐
Ethambutol	☐	☐	☐	☐
Streptomycin	☐	☐	☐	☐
Rifabutin	☐	☐	☐	☐
Rifapentine	☐	☐	☐	☐
Ethionamide	☐	☐	☐	☐
Amikacin	☐	☐	☐	☐
Kanamycin	☐	☐	☐	☐

	Resistant	Susceptible	Not Done	Unknown
Capreomycin	☐	☐	☐	☐
Ciprofloxacin	☐	☐	☐	☐
Levofloxacin	☐	☐	☐	☐
Ofloxacin	☐	☐	☐	☐
Moxifloxacin	☐	☐	☐	☐
Other Quinolones	☐	☐	☐	☐
Cycloserine	☐	☐	☐	☐
Para-Amino Salicylic Acid	☐	☐	☐	☐
Other *Specify* _____	☐	☐	☐	☐
Other *Specify* _____	☐	☐	☐	☐

Comments:

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O. Health Education/Audiovisual Materials

1. Audiovisual and educational materials available from NC TB Control

Artificial Arms For TST Reading -The two arms will help you teach health professionals how to read a TST. Each arm has a card indicating the mm induration. Please clean both arms before returning. See mm answers for each arm and cleaning instructions inside the box. **These are only available to health department staff. Call 919-755-3184.**

P. The requisition for Tuberculosis Control Materials (DHHS 2407) can be found at: https://epi.publichealth.nc.gov/cd/tb/docs/dhhs_2407.pdf

Q. The CDC TB Materials Order Form can be found at: https://www.cdc.gov/tb/publications/default.htm#ordering

R. New TB Nurse Orientation Checklist

Goal	Given instruction	Observed	Competent
Is knowledgeable about N.C. TB Control Policies as set forth in manual			
Is knowledgeable about local TB control policies			
Demonstrates correct use of TB control forms:			
• Tuberculosis Drug Record- DHHS 1391			
• Tuberculosis Flow Sheet- DHHS 2810			
• Tuberculosis Epidemiological Record- DHHS 1030			
• Nursing record of Tuberculosis Contacts – DHHS 1662			
• Understands how to proceed when a Refugee Notification of Arrival notice is received in NCEDSS.			
• Record of Tuberculosis Screening – DHHS 3405			
Demonstrates knowledge of TB case management:			
• Organizes and prioritizes workload.			
• Works with private or health department provider to develop a treatment plan and obtain physician's orders.			
• Makes initial hospital and/or home assessment and subsequent home visits as required.			
• Is knowledgeable about cultural/language barriers including reading ability and obtains the services of an interpreter when needed.			
• Provides or arranges for DOT.			
• Directs and supervises a contact investigation (CI) for laryngeal, pleural, and pulmonary TB cases.			
• Obtains sputum specimens and completes requisition.			
• Provides follow-up care for TB cases/suspects/TLTBI in a timely manner.			
• Is knowledgeable about policy on clients that are lost to follow-up			
• Is able to correctly place and read a PPD			
• Is knowledgeable about Interferon Gamma Release Assays (IGRA).			
Has read and understands the General Statutes for the control measures for communicable disease GS 130A-144 and NC Administrative Code 15 A NCAC 19A.0205.			
Is knowledgeable about how to initiate a TB Treatment Agreement and /or an Isolation Order.			
Is knowledgeable on how to use NCEDSS to manage TB using the workflows for reports, such as, the reporting tool, RVCT, follow-up one and two reports, reviewing labs, and reporting about contacts and class B immigrants			
Is knowledgeable about incarceration procedures for health law violators.			
Administers intramuscular injections properly.			
Performs venipunctures correctly.			
Performs vision screening test for acuity and colorblindness.			

Is able to perform basic audiometry tests for hearing acuity.			
Knowledgeable of baseline testing requirements.			
Knowledgeable about infection control measures, including how to use a N-95 respirator, elements of a tuberculosis infection control policy and risk classifications.			
Is knowledgeable about x-ray findings that may indicate TB.			
Is knowledgeable about how to order TB medications through N.C. TB Control.			
Is knowledgeable about TB medications including side effects; drug interactions, especially with HIV/AIDS medications, mental health medications, contraceptives or adverse reactions.			
Teaches client/family/significant others about:			
• Confidentiality			
• DOT for TB cases/suspects/ and some TLTBI			
• Transmission/pathogenesis of infection and disease			
• Concept of infection vs. disease			
• Prevention of spread of TB			
• Process of contact investigation and identification of source case, if child or HIV/AIDS client involved.			
• Purpose and importance of LTBI treatment for contacts.			
• Importance of regular ingestion of TB medications for both active disease and LTBI treatment.			
• Importance of completing full-course of treatment to cure.			
• Importance of at least monthly medication and monitoring visits with TB nurse to assess progress, adherence and side effects.			
• Signs/symptoms of TB disease to report to RN including hemoptysis, sputum production, weight loss, fatigue and / or failing to clinically improve.			
• Provides written literature about TB to client (in language client can understand).			
• Teaches client/family/significant others about TB medications and interactions with other medicines.			
• Discusses side effects, such as; fever, GI disturbances, loss of appetite, skin rash/itching, numbness/tingling of hands and feet, and headache.			
• Assesses adherence to medications on each visit.			
• Counsels patient on the importance of HIV testing and performs test with patient consent. Refers patient for appropriate follow-up if HIV positive and obtains CD4 count.			
Knowledgeable about appropriate resources for patients, such as ALA incentive and housing funds.			

S. Clinical Pathway For Managing Tuberculosis Suspects/Cases

CLINICAL PATHWAY FOR MANAGING TUBERCULOSIS SUSPECTS/CASES	NAME _____ ID # _____ DOB _____

VISIT	INITIAL AND DATE AFTER COMPLETING EACH TASK	INITIAL	DATE
Day 1	Obtain medical history including recent exposure, previous infection, risk factors, signs, symptoms & duration of symptoms of TB disease. Use Tuberculosis Epidemiologic Record (DHHS 1030).		
	Collect and send sputum specimen for AFB smear & culture. Provide patient with two more sputum containers and give instructions on how to obtain a sputum specimen. If unable to get a specimen provide or schedule induction.		
	Place PPD or obtain IGRA/ Obtain weight/ Perform baseline visual acuity testing for red-green color blindness if taking EMB/ Complete flow sheet -DHHS 2810.		
	Provide HIV counseling and testing. If HIV positive get CD4 count and assure patient is in HIV care. Obtain baseline test/results for hepatic function panel, creatinine, CBC, platelet count, as ordered. If streptomycin is used, also need baseline BUN and audiogram. Second-line drugs need additional monitoring.		
	Provide educational information about TB, including TB Booklet with contact phone numbers and plan for future care including need for monthly clinic visits to see physician or nurse/have patient sign TB Treatment Agreement.		
	Obtain a posterior-anterior view chest x-ray plus lateral if < 5 yr		
	Discuss TB medications/side effects/hepatotoxicity/DOT/		
	Obtain prescriptions for standard four drug regimen (RIF, INH, PZA, EMB) and administer first dose of daily DOT. All meds should be given at the same time. Set up schedule for daily DOT. Document DOT on Tuberculosis Drug Record (DHHS 1391).		
	Begin contact investigation.		
Day 2	Obtain sputum smear results in the afternoon if the State Lab received the specimen this am. Obtain second sputum specimen.		
	Continue contact investigation and daily DOT		
	Review chest x-ray report/chest x-ray film with physician		
Day 3	Read PPD on day 2 or 3 and record results in chart.		
	Obtain sputum smear/NAA results and third sputum specimen.		
	Continue contact investigation and daily DOT.		
Day 5-14	Continue daily DOT.		
	Continue educating patient and contacts about TB.		
	Continue contact investigation.		
	Report initial findings about case to the TB nurse consultant using the reporting tool wizard in N.C. EDSS within seven days.		

VISIT	INITIAL AND DATE AFTER COMPLETING EACH TASK	INITIAL	DATE
Week 3			
	Obtain two sputum specimens for smear and culture every two weeks until there are two consecutive negative cultures. Isolation can be discontinued after getting two consecutive negative smears.		
Week 4	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
Weeks 5 to 7	Contact State Lab for sensitivity results if these have not yet been obtained. If sensitive to all medications, ask physician to discontinue EMB. If any resistance, consult physician.		
	Continue collection of q 2 wk sputum specimens until culture negative x 2.		
	Continue DOT.		
Week 8	Complete monthly assessment. (DHHS 2810) If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Discontinue PZA after eight weeks if fully sensitive.		
	Cultures and susceptibility results should be final. If initial culture is positive this should be reported as a TB case by completing a RVCT wizard in NCEDSS and assign to TB nurse consultant.		
	If cultures are negative consult with physician about diagnosis. Obtain a chest x-ray. If decision is made to treat as a culture negative case of TB based on improved symptoms and chest x-ray, continue RIF and INH for a total of 16 weeks of therapy.		
	For most patients, therapy can begin thrice weekly. This should consist of isoniazid and rifampin thrice weekly (dosage will change) DOT for 18 weeks (54 thrice-weekly doses). A week may be counted if at least two DOT doses are ingested during that week. It is recommended that patients with HIV infection, positive acid-fast sputum smears, and/or cavitary disease on plain chest radiographs continue daily therapy until completion.		
	Repeat PPD's for contacts that were negative initially.		
Week 9 to 11	Continue DOT and collection of sputum specimens if still culture positive.		
Week 12	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Assess for response to treatment. If response (clinical or bacteriological is slow or sub-optimal consult TB Nurse Consultant. Treatment should be lengthened to include at least four months of treatment following sputum conversion. If the patient does not convert sputum cultures to negative by eight weeks and had a cavity on the initial x-ray, treatment should be extended to nine months.		

Clinical Pathway for Managing Tuberculosis Suspects/Cases Page 3	Name _____ DOB _____

VISIT	INITIAL AND DATE AFTER COMPLETING EACH TASK	INITIAL	DATE
Week 13 to 15	Continue DOT, and collection of every two weeks sputum specimens until **culture** negative x two.		
Week 16	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
Week 17 to 19	Continue DOT.		
Week 20	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
Week 21 to 23	Continue DOT.		
Week 24 to 25	Complete monthly assessment (DHHS 2810). If there are side effects, hold meds, draw appropriate labs and consult physician.		
	Obtain monthly hepatic function panel on high risk individuals.		
	Continue DOT.		
	Obtain end-of-treatment chest x-ray for a comparison film for future reference for all pulmonary cases unless treatment is going to be extended		
	Schedule patient to receive end of treatment evaluation by a physician or mid-level provider		
Week 26	Complete final week of DOT if treatment was not lengthened due to missed doses, slow sputum conversion, or resistance.		
	Complete Certificate of Completion for TB Treatment card and give to patient along with instructions to return to clinic if symptoms of TB occur.		
	Complete RVCT follow-up 2 wizard in NCEDSS and assign to TB nurse consultant.		

Initials	**Signature**

T. North Carolina TB Control Guidelines for the Management of TB Suspects/Cases in Correctional and Detention Facilities

1. TB Evaluation and Diagnosis

   a. Each correctional facility, camp or center that has a suspected case of TB should promptly notify their local county health department TB program, as soon as they begin evaluation, diagnosis, or treatment of any inmate suspected of having TB.
   b. TB airborne precautions should be initiated for any inmate who has signs or symptoms of TB disease and should remain in effect until TB is ruled out, or the inmate has documentation of three consecutive negative sputum smears.
   c. Local TB nurses are available to assist the correctional facility as requested with the evaluation and diagnosis of inmates suspected of having TB in their county.
   d. Local health department TB nurses are available to provide direct TB evaluation to inmates at detention centers that do not have access to nursing care.
   e. The correctional facility or other detention facility may request sputum specimen containers from the local health department to assist with the evaluation of an inmate suspected of having TB. However, because ongoing sputum collection may be necessary, the facility should follow the DOC policy and place an order for any additional sputum collection containers with the State Laboratory of Public Health.
   f. TB expertise is available from the State TB medical consultant upon request for the diagnosis of TB suspects incarcerated in North Carolina. Dr. Jason Stout may be contacted by calling the Duke University operator at 919-684-8111and have the physician paged.

2. TB Suspect/Case Notification

   a. Once an inmate is considered a TB suspect/case in a correctional or detention facility, the local health department should be notified within 24 hours just as the local health department would be notified by the hospital or any other health care facility when TB is suspected.
   b. Local health department nurses will notify their regional TB Nurse Consultant of the incarcerated TB suspect/case using the TB Report Tool/electronic reporting (within seven days) as they would with any other TB suspect.
   c. The NC Department of Correction (N.C. DOC) Infection Control Nurse will notify the N.C. TB control nurse consultants when they are notified of a TB suspect within the correctional system as soon as it is brought to their attention by phone call or email.
   d. Once the TB nurse consultant has been notified of a suspect case she can assure the appropriate local health department TB nurse has also been notified of the suspect.

3. TB Suspect/ Case Reporting

a. Persons who reside in local, state, federal, or military correctional facilities may frequently be transferred or relocated within and/or between various correctional facilities. TB in those persons should be reported to the local health authority and counted by the locality where the diagnosis was made, and treatment plans were initiated.
b. The reporting health department will assume the responsibility of completing the TB RVCT/electronic reporting for case counting of this individual.
c. The correctional facility will provide all TB related medical information requested by local health departments or N.C. TB Control for the reporting and the monitoring of the TB treatment of TB suspects/cases in the correctional system. The N.C. DOC infection control nurse is available to assist the local health departments in obtaining information as needed on inmates housed in the state prison system. At the current time the phone number is 919-733-0800 ext. 587.

4. TB Treatment and Monitoring

a. The treatment of TB cases that are incarcerated will be provided and directly observed by the correctional facility nurse unless the facility does not have access to nursing services. If that is the case, the local health department TB nurse can provide the medication and directly observed therapy (DOT).
b. It is the responsibility of the local health department TB nurse that is reporting or counting the TB case to monitor the treatment provided by the correctional facility nurses to the incarcerated cases (appropriate drugs, appropriate dosages and appropriate length of treatment, appropriate monthly monitoring, lab testing and microbiologic testing).
c. The monthly monitoring for adverse reactions, provision of any necessary lab work and collection of sputum or other specimens for mycobacteriology will be the responsibility of the correctional facility nurse.
d. In order to monitor treatment, the local health department nurse needs to receive and review at least monthly the inmate's medication administration records and monthly adverse reaction symptom review checklist.
e. One of the TB nurse consultants will routinely review the records of TB suspects/cases housed at N.C. Correctional facilities and will assist in obtaining copies of the medication administration records and the monthly symptom reviews for the inmates housed here.
f. The regional TB nurse consultants as well as the state TB medical consultants are available to assist the local health department nurses in monitoring the appropriateness and adequacy of TB treatment provided by the correctional facility.
g. The correctional facility will keep the TB nurse consultants, the reporting health department, and any other involved health departments advised of the TB case's location.
h. Inmates with M. TB may be moved to other correctional facilities when:
   - Adequate therapy has begun;
   - Pulmonary cases have had two consecutive negative sputum smears; and

- Records, including lab tests and medication administration records have been sent to the new correctional facility, the health department, and if applicable, the DOC infection control nurse.

5. Contact Investigations

   a. The contact investigation within the correctional facility will be conducted by the correctional facility in collaboration with the local health department.
   b. Local health departments and N.C. TB Control will provide assistance in correction facility contact investigations as requested by the correctional facility.
   c. The correctional facility will notify the reporting county health department of ongoing TB contact investigations and provide a list of the released inmates (contacts) needing TB follow-up. This list should include each contact's county of residence, last known address, phone number and/or their emergency contact information. The reporting county health department will oversee the TB follow-up of these contacts.
   d. The reporting county health department TB nurse will notify the other local health department TB nurses of the contacts residing in their counties needing TB follow-up. The appropriate regional TB nurse consultant is available to assist in this notification as needed.
   e. The local health department TB nurse will send a letter to notify each contact residing in their county of their TB contact in the correctional facility and the need for TB follow-up. This letter will advise the contact to bring the letter to their local health department to receive the recommended TB follow-up at no charge.
   f. The local health department TB clinics will provide necessary TB follow-up at no charge to contacts to correctional facility TB cases residing in their counties, including TST, chest x-ray, treatment for latent TB infection (LTBI), mycobacteriological testing, HIV testing, or required lab work. Results of the contact's evaluation will be reported back the reporting county health department TB nurse.
   g. Investigation of contacts to correctional cases residing outside of the correctional system will be the responsibility of the local health department TB clinic in their county of residence.
   h. Results of health department's contact investigation will be made available to the correctional facility by the reporting county, so the correctional facility may evaluate their own contact investigation.
   i. The correctional facility will provide the reporting health department with the results of their contact investigation, as the reporting health department is ultimately responsible for overseeing the entire contact investigation.

6. Continuity of Treatment and Discharge Planning for Individuals with TB Disease Upon Release from Prison

   a. To ensure uninterrupted treatment, discharge planning for inmates diagnosed with TB should begin as soon as it is determined that they will not complete their treatment in prison. It is the responsibility of the

correctional facility to initiate discharge planning with the local health department.

b. The correctional facility's infection control nurse should notify the N.C. TB Control TB nurse consultant when an inmate with TB will be released prior to the completion of his/her TB treatment.
c. Once it is determined which county the inmate will be residing upon their release the TB nurse consultant will notify that local health department.
d. The correctional facility should forward a copy of the inmate's prior TB treatment and pertinent medical records to the county health department that will be continuing the inmate's TB treatment prior to the inmate's release.
e. Upon the inmate's discharge from the state prison system the correctional facility will complete their referral form (DC 516 N.C. DOC Community TB Referral) and this form will be sent to the county assuming care for the TB case.
f. Upon the inmate's discharge the health department will assume full responsibility for the inmate's TB care management including DOT with appropriate drugs, with appropriate dosages and the appropriate length of treatment, appropriate monthly monitoring, lab testing and mycobiological testing.
g. The correctional facility will be responsible for informing the reporting county (if different from the county assuming treatment responsibility) that the inmate has been released from prison and will be completing treatment elsewhere.
h. The county health department that completes the inmate's TB treatment is responsible for completing the RVCT follow-up 2 form and sending it to the reporting county.

7. Continuity of Treatment and Discharge Planning for Individuals Receiving Treatment for LTBI Upon release from Prison

a. To ensure uninterrupted treatment, discharge planning for inmates diagnosed with LTBI should begin as soon as it is determined that they will not complete their treatment in prison.
b. Upon the inmate's discharge from the state prison system the correctional facility will complete their referral form (DC 516 N.C. DOC Community TB Referral) and send this form to the county assuming the inmate's LTBI treatment along with any other records pertinent to the inmate's continued LTBI treatment.
c. The DOC facility nurses or medical records staff will be available to assist the local health department in acquiring records to assume the LTBI treatment from the correctional facility if necessary. (N.C. DOC Medical Records (919) 715-1570).
d. The health department upon the inmate's discharge will assume full responsibility for the inmate's LTBI treatment and monitoring.

8. Oversight

a. TB nurse consultants will periodically review the records of known TB

b. suspects/cases at N.C. facilities. The DOC infection control nurse will send periodic updates on the TB suspects receiving treatment or evaluation for TB.
c. The N.C. TB Control staff will meet with N.C. DOC infection control staff annually to discuss TB patient care issues.
d. Correctional facility medical staff will be invited to participate in all N.C. TB control educational trainings.
e. One of the TB nurse consultants will be designated to serve as the correctional facility liaison with the N.C. DOC. At the current time (October 2018), this is Lynn Kearney lynn.kearney@dhhs.nc.gov 919-755-3183.

U. North Carolina TB Control Program Hurricane/Disaster Action Plan

Optimizing the continuity of care for patients with active tuberculosis can be challenging in the setting of a natural disaster, which may displace patients, disrupt communications, and interfere with infrastructure essential for drug distribution and dispensing. A coherent but simple action plan is important to deal with problems arising from natural disasters. This action plan is outlined below.

1. Essential points
   - Tuberculosis is rarely an acutely life-threatening problem and missing a small number of medication doses in the setting of a natural disaster is unlikely to cause significant harm to patients or induce drug resistance.
   - A natural disaster has the potential to concentrate large numbers of persons in close quarters (e.g. shelters). Tuberculosis usually requires prolonged, close contact for transmission, but potential for transmission exists from infectious cases to persons with intense exposure to these cases at close quarters.
   - The top priority for tuberculosis control should therefore be establishing the whereabouts of the most infectious cases (i.e. smear-positive cases), separating these cases from uninfected/susceptible persons where possible, and assuring that these cases continue anti-tuberculous treatment (which reduces infectiousness).
   - Second priority for tuberculosis control is to assure continuation of medication for less contagious (i.e. smear-negative) and noncontagious (i.e. extra-pulmonary) tuberculosis cases.
   - Persons with latent tuberculosis are unlikely to suffer any significant harm from temporarily halting latent tuberculosis treatment in the setting of a natural disaster and should therefore be considered low priority in this setting.

2. Action Plan
   - If a severe weather condition or other disaster is expected, the TB control program nurse consultants should ensure that they have an up-to-date list of active TB cases in their regions.
   - If an unexpected disaster occurs, the nurse consultants should obtain a list of active TB cases in their regions as soon as possible from the NCEDSS system, focusing on county of residence, site of disease, acid-fast smear status, current TB drugs with doses, and duration of treatment received.

- In the case of a potential/expected disaster, the county TB control staff should be instructed to do the following:
    - Elicit emergency contact information for all of their active cases, including location/phone for where the cases plan to go if they need to leave their current location.
    - Provide all active cases with a one-week supply of anti-tuberculous medications for daily self-administration, in case of disruptions that would exclude the possibility of directly observed therapy.
    - Provide their nurse consultant with emergency contact information for key personnel in case of a disaster affecting health department communication infrastructure.
- After an emergency, the nurse consultants should contact the relevant TB nurse/provider in all counties in their region with active cases as soon as possible.
- If disruptions in infrastructure have occurred that limit the ability of a county to provide treatment to patients, the nurse consultant should facilitate communication with nearby, unaffected counties to determine whether these unaffected counties can provide assistance. For example, TB drugs are normally delivered directly to the county by Cardinal. In the case of infrastructure disruptions preventing such delivery, the nurse consultant will communicate with nearby counties to determine whether drugs could temporarily be delivered to a nearby county.
- Nurse consultants will assist the county nurses in finding ways to isolate infectious TB cases from congregate living settings (e.g. shelters). Potential resources to achieve this isolation are as follows:
    - American Lung Association funds to pay for temporary hotel rooms; and
    - Hospitalization at local facilities if absolutely necessary.
- If TB cases are displaced from their home counties, county TB nurses (assisted by N.C. TB nurse consultants if necessary) will communicate with TB control personnel in the new jurisdiction (another county in NC or out of state) to assure continuity of care. If the displacement is expected to last less than one week, an interjurisdictional transfer form should be sent to the new jurisdiction.

V. North Carolina Cohort Review Policies and Procedure

Background

Cohort Review (CR) is a systematic review of tuberculosis cases and their contacts to evaluate treatment outcomes and identify areas for improvement. Implementing CR is part of North Carolina's CDC Cooperative Agreement

Objectives of Cohort Review

1. To ensure that patients with active tuberculosis in North Carolina receive appropriate evaluation and treatment
2. To provide a mechanism for continuous quality improvement for state and local tuberculosis control programs
3. To track progress toward meeting state, local, and national program objectives
4. To provide regular opportunities for real-time, patient-relevant education of local health department staff regarding optimal management of patients with suspected or confirmed tuberculosis disease

Procedures

1. Reviews are conducted annually on all cases and current suspects identified since the previous review that meet the following criteria:
    a. Class b events with TB disease
    b. Drug resistant cases
    c. HIV co-infected
    d. Pediatric cases less than 5 years of age at the time of diagnosis
    e. Cases who took longer than 60 days to convert
    f. Persons with more than one episode of TB (includes treatment failures, relapses)
    g. Persons treated for greater than 365 days
    h. Person who had serum drug levels obtained, regardless of the reason
    i. Anyone started on less than or more than the standard 4 drugs
    j. Persons who are dead at diagnosis or die during therapy
    k. Person with serious drug intolerances
2. Suspects in whom TB was ruled out will not be reviewed even if they received TB treatment. If a case was reviewed before, it is not reviewed again unless there are problems or the TB nurse has issues to discuss

Timeline of events

1. The nurse consultants coordinate the timing of the reviews with the NC TB Medical Director and the county and set the review schedule several months in advance.
2. If the review will be done by phone, the nurse consultant obtains and distributes the conference call phone number
3. The county TB nurse schedules the room for the review if the review is being done at the LHD. He or she invites local physicians who are prescribing TB treatment to patients whose cases will be reviewed.
4. Three weeks prior to the review, the nurse consultant provides a list of patients to be presented and emails it to the county nurse to be verified.

5. The TB nurse completes the Cohort Review Case Presentation Form. This can be done at any point prior to review, for example, the nurse can start filling it out as soon as the case is confirmed.
6. The nurse consultant may print out all the RVCT forms on the patients to be reviewed. During the review, she can compare what the TB nurse presents to what was entered into NCEDSS; this is a quality control measure.

During the review

1. The TB nurse presents the information in the order that it appears on the Cohort Review Form. Cohort Review differs from a case conference during which there may be detailed discussion about the case's history and family, etc. The TB nurse's cohort review presentation should take about 3 minutes. Those present at the review discuss the case.

After the review

1. The state TB Medical Director or Consultant writes a draft report on the review and sends it to the nurse consultant for review. The TB Medical Consultant then finals the review and sends it to the nurse consultant for distribution to the TB nurses.
2. Copies of the cohort review letters should be sent to TB Epidemiologist for the year end reports.

Summary of participants' roles and responsibilities

1. County TB nurses: Enter all required information into NCEDSS. Schedule room for cohort review. Complete the Cohort Review Case Presentation Form. Invite providers (if different from the county TB physician) who are prescribing/managing the cohort review patients. Verify the list of patients provided by the nurse consultant for the review. At the review session, verbally present the information. Respond to participants' questions.
2. County TB physician and /or the provider who is prescribing/managing the TB: Participate in review and responds to participants' questions.
3. State tuberculosis medical director: Provides guidance on standards of care, treatment guidelines, monitoring, case management and research. Provides cohort review report to county TB nurses via the state TB nurse consultant the review.
4. State tuberculosis nurse consultant: Assists with cohort review training. Coordinates the review date with the NC TB physicians and the county. Obtains conference call phone number if needed. Provides a list of patients to be presented and emails it to the county TB nurse to be verified. Participates in review. Reviews draft cohort review report. Distributes final report to the TB nurses.

North Carolina Cohort Review Case Presentation

Patient Information:

TB Nurse:_____

Date:_____ County:_____ Provider:_____ NEDSS ID:_____

Patient name:_____ Jurisdiction if not same county as on Line 1:_____
Last First

Age:_____ Sex:____ Foreign born (check one)? ❒Yes ❒ No If yes, birth country: _____

Arrived in USA (date): _____ Circle one: Class A B1 B2 N/A

Race: (Check one or more):

❒ American Indian or Alaska Native ❒ Asian ❒ Black or African American

❒ White ❒ Native Hawaiian or other Pacific Islander (specify):

Ethnicity (Check one): ❒ Hispanic or Latino ❒ Not Hispanic or Latino

HIV status: pos / neg / unknown on _____ (date) If unknown, reason (check one): ❒refused ❒not offered

- If HIV positive, is patient in care? ❒Yes (location:_____)
  ❒No (circle reason): doesn't want care / can't afford care / other_____
- CD4 count: _____ on _____(date) If <200, taking PCP prophylaxis (Septra DS/ Bactrim DS/ trimethoprim sulfamethoxazole; Dapsone; Mepron/atovaquone; aerosolized pentamidine)? Yes No
- Viral load: _____ on _____(date)
- Was pt started on anti-retroviral meds during TB treatment? ❒ Yes ❒ No If yes, list meds on Page 2

TB Information:

Factors associated with increased risk from therapy (Check all that apply):

❒ chronic active Hepatitis B ❒ Hepatitis C ❒ end-stage renal disease

❒ Patient was a contact to a case

Smear & Culture Results

Is this a clinical case of TB (all cultures negative)? ❒ Yes ❒ No

If "Yes," check all that apply: ❒ TST ____mm ❒ IGRA positive ❒ CXR c/w TB
❒ signs/symptoms c/w TB ❒ improved on TB meds

If "No," check one or both: ❒ Pulmonary ❒ Extra-pulmonary

If pulmonary (check specimen source):
❒ sputum ❒ bronch
❒ lung tissue ❒ gastric aspirate

If Extra-pulmonary (check):
❒ pleural ❒ lymphatic ❒ genitourinary
❒ meningeal ❒ peritoneal ❒ laryngeal
❒ bone and/or joint ❒other: _____

Pulmonary smear result collected on_____(date): ❒ Pos ❒ Neg ❒ N/A ❒ Unknown	Extra-pulmonary smear result collected on _____(date): ❒ Pos ❒ Neg ❒ N/A ❒ Unk
Initial pulmonary culture result: ❒ MTB ❒ Neg/NTM ❒ Pending ❒ N/A ***OR*** ❒ PCR positive ❒ PCR negative	Initial extra-pulmonary culture result: ❒ MTB ❒ Neg/NTM ❒ Pending ❒ N/A ***OR*** ❒ PCR positive ❒ PCR negative

Initial susceptibility of pulmonary/extra-pulmonary specimen: ❒ Pansensitive ❒ Resistant to: _____

If positive sputum culture initially, was culture status documented every 2 weeks until culture conversion to negative? (Check one): ❒Yes ❒No ❒Sputum culture has not converted yet

If "No," why not? Check: ❒ lost ❒died ❒moved ❒no sputum despite induction ❒other:_____

Sputum culture conversion date: _____

Did sputum culture convert to negative within 60 days? ❒ Yes ❒ No ❒ Pending ❒ N/A

Initial chest x-ray results (Check one): ❒ normal ❒ abnormal consistent with TB

If abnormal (check): ❒ cavity ❒ miliary ❒ other (specify): _____

For a child with TB, was the source case found? ❒ Yes ❒ No ❒ Pending ❒ N/A

Treatment Information:

If sputum smear-positive, was treatment started within 7 days of specimen collection?	❒ Yes ❒ No ❒ N/A	*If "No," why not? (check):*	❒ lost ❒ died ❒ moved ❒ delay in locating pt ❒ delay in receiving smear report

Medication Regimen: Drug regimen started on (date): _____ Weight _____ lbs/kg
(check): ❒ current ❒ complete Baseline serum creatinine: ____ mg/dL
(check): ❒ initial ❒ continuation

Drug	Daily dose (mg)	Number of weeks of daily DOT	2x/week or 3x/week dose (mg)	Number of weeks of 2x/week or 3x/week DOT	Total number of weeks of DOT received
INH					
RIF					
PZA					
EMB					

Was therapeutic drug monitoring (TDM) done? ❒Yes ❒ No *If "yes," check result:*
❒therapeutic, no dose change ❒sub-therapeutic, dose(s) changed ❒follow-up TDM done: ❒therap ❒sub-ther

Missed doses/treatment interruption? ❒Yes ❒ No
If "yes," number of missed doses _____
If "yes," check reason(s): ❒ vomited ❒held ❒partial dose during reintroduction ❒ lost ❒ moved
❒ refused ❒not home ❒ no show at clinic ❒ drug toxicity/adverse reaction
If drug toxicity/adverse reactions (check all that apply): ❒nausea ❒ vomiting ❒rash ❒itching
❒hepatotoxicity ❒ fever ❒headache ❒ other_____

Was therapy completed within 12 months? ❒ Still on meds ❒ Yes ❒ No *If "No," check all that apply:*
❒ rifampin resistance ❒ non-adherence ❒ clinically indicated ❒ adverse drug reaction ❒ failure ❒ other

Expected therapy completion date: _____
End of treatment CXR & Provider Evaluation (Check one): ❒ scheduled ❒ done

Medications that patient is taking (or new since last review or taken when on TB treatment): _____
_____

Were all of patient's other meds (including OTC & dietary supplements) reviewed & assessed for potential drug interactions between them & TB meds and for increased hepatotoxicity risk? ❒ Yes ❒ No
If yes, describe the interaction(s) and list the meds causing increased hepatotoxicity risk:_____
_____
_____
If yes, describe what was done to avoid/compensate for the interaction(s)/increased hepatotoxicity risk:
_____
_____

Were baseline tests (hepatic function, CBC with platelets, & creatinine) completed? ❒Yes ❒ No
Were baseline labs abnormal? ❒Yes ❒ No
If yes, were follow-up labs done? ❒Yes ❒ No
If follow-up labs were done, what was outcome (check all that apply): ❒Follow-up labs were normal
❒Follow-up labs were abnormal ❒Patient will have monthly labs ❒ Treatment interruption

Contacts (List number of high & medium priority contacts for each category)

In subsequent reviews, update this section since last review.

	High Priority	Medium Priority
Number of contacts identified		
Number of contacts with prior positive TST		
Number of contacts with new positive TST		
Number of contacts who were fully evaluated[1]		
Number of contacts with active TB		
Number of contacts with LTBI		
Number of contacts with LTBI who started TLTBI		
Number of contacts with LTBI who completed TLTBI		

[1]Fully evaluated: TST placed and read; if initial TST negative, repeated in 8 weeks; if TST positive, chest x-ray done. For prior positive TST: symptom screen done.

W. North Carolina Video Directly Observed Therapy Policies and Procedures

Purpose:
To provide guidelines for the use of video directly observed therapy (video DOT) by public health providers in North Carolina. Video DOT is defined as the use of remote video (e.g. streaming video using a service such as Skype or Facetime) by a **healthcare worker** to observe a patient ingesting medications.

Policies:
1) Public health staff may use video DOT to supervise ingestion of medications for selected patients with active or latent tuberculosis who meet the inclusion criteria listed below
2) For TB control/program purposes, video DOT is considered equivalent to in-person directly observed therapy
3) Patient adherence with video DOT should be continuously monitored, and if any concerns arise there should be a low threshold to resume conventional directly observed therapy
4) Monthly in-person monitoring visits will be conducted by the local health department TB nurse

Policy:

Administrative Requirements

The following administrative requirements must be met prior to initiation of video DOT:
1) Signed order by the attending public health/tuberculosis physician
2) Signed treatment agreement

Technological Requirements
1) Patient must have a working mobile phone with videophone (e.g. Facetime) capability that can interface with corresponding technology at the local health department OR
2) Patient must have a working computer with broadband internet connectivity and a webcam capable of transmitting sound and video

Patient Selection

Video DOT may be offered to adult (18 and over) patients with active TB that meet the following criteria:
1) Good response to treatment, as judged by the treating clinician. Examples of a good response would be decreasing degree of sputum smear positivity and/or improved signs and symptoms.
2) Motivated to complete treatment with psychosocial support to attain this goal.
3) No prior problems with missed DOT doses, missed appointments, or nonadherence.
4) Patient has demonstrated successful swallowing of all pills within a five-minute period.
5) No treatment interruptions due to medication toxicity or intolerance.
6) Stable residence and living conditions.
7) Able to communicate directly with TB program staff using appropriate language skills
8) Patient must be able to clearly identify by name and quantity each drug as it is ingested while provider maintains a clear view of the patient's face and mouth.
9) There is no known resistance to any of the first-line anti-tuberculous drugs (isoniazid, rifampin, pyrazinamide, or ethambutol); if drug resistance is identified the state nurse consultant should be contacted regarding whether continued VDOT is appropriate.
10) In-person DOT is strongly recommended for at least the first 14 doses of treatment for most patients with pulmonary TB, particularly smear-positive TB.
    Patients with latent TB may be offered Video DOT at the start of latent TB treatment at the discretion of the patient and treating clinician.

Video DOT Procedure

1) Patient and public health provider will establish a standing video DOT appointment time and contact procedure that is mutually convenient prior to initiation of video DOT.
2) Patient will be informed that video DOT is voluntary and may be discontinued (with resumption of face-to-face DOT) at any time at the discretion of the patient or provider.
3) Patient and public health provider will test the video connection prior to administration of the first video DOT dose. For a mobile phone setup, this should consist of a test video call between the patient and provider while the patient is in the clinic. For a home computer setup, this should consist of a test video call at a time mutually convenient for the patient and provider.
4) Key elements to be verified during the test call:
    a. Video is of adequate quality to observe pills and to visualize the patient's open mouth
    b. Patient and public health provider have correct mutual contact identifiers (e.g. phone numbers, Skype ID, etc.)
5) Video DOT should not be initiated until a successful test call has been conducted
6) The patient should be advised to perform video DOT in a private location to preserve confidentiality. Confirmation of the confidentiality of the setting by the video DOT provider is strongly recommended at the beginning of the first few calls, at a minimum. If others are present in the room, the provider should confirm that the patient wants to proceed with video DOT while those individuals are present in the room.
7) A successful video DOT call should consist of the following elements:
    a. Provider verifies the identity of the patient by visual recognition
    b. Provider visualizes the pills to be taken and verifies that the doses and medications are correct
    c. Provider directly visualizes the patient swallowing all of the pills
    d. After the last pill is swallowed, patient will display the empty mouth on the video to verify that no pills remain in the mouth
    e. Provider will speak with the patient for at least 30 seconds after ingestion of the last pill as a second check that no pills remain in the mouth. The patient should speak during this time and reciting a standardized phrase (e.g. the alphabet) is encouraged.
    f. Provider will document the DOT visit in NCEDSS per standard procedure
8) If the patient wishes to discuss private information with the healthcare provider via video DOT, the provider should remind the patient that video DOT (like telephone and internet communication) is not completely secure and confirm that the patient wishes to proceed with the discussion via video DOT. Other means of communication (e.g. telephone, face-to-face) should always be offered if the patient prefers these to video DOT.
9) Patients should be provided no more than a thirty-day supply of medication, and a face to face visit should occur on at least a monthly basis. Medications should be provided labeled in appropriate containers in accordance with NC Pharmacy regulations.

X. TB Contacts in Other U.S. States and Territories

The National TB Controllers Association (NTCA) maintains a current list of interjurisdictional contacts for each state and large city. These are public health professionals that oversee the exchange of pertinent information about TB patients and/or TB contacts. The following link will take you to the NTCA website listing:
http://www.tbcontrollers.org/community/statecityterritory/#.VW3awEaqFIw

The NTCA also has the Interjurisdictional forms and instructions on their website. The interjurisdictional form should be used to make referrals to other TB programs. The interjurisdictional form should be sent to the appropriate contact person listed and a copy should also be sent to the NC TB Control Registrar. The following link will take you to NTCA's website where the forms and instructions can be found:

http://www.tbcontrollers.org/resources/interjurisdictional-transfers/#.VW3ZaUaqFIw