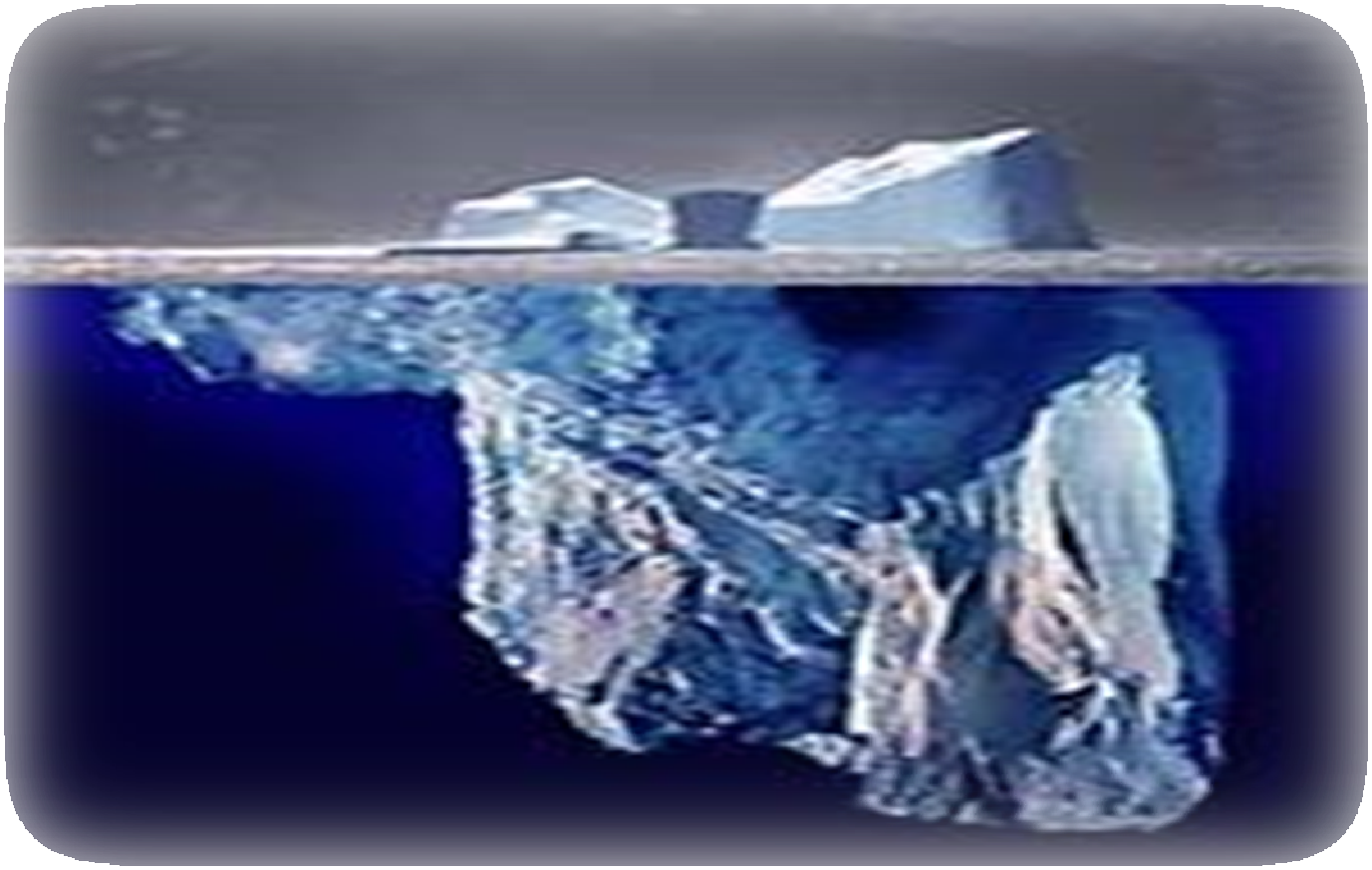
Georgia Department of Public Health



Tuberculosis Policy and Procedure Manual 2014

Georgia Department of Public Health
Division of Health Protection
Office of Immunization and Infectious Disease
Tuberculosis Program
http://dph.georgia.gov/tuberculosis-tb-prevention-and-control

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INTRODUCTION

These guidelines were created to assist state, district and local health departments in controlling, monitoring, treating, notifying, and testing tuberculosis (TB) disease and infection for the State of Georgia. It is not possible for any guideline to address all situations for individuals; therefore, clinical judgment must always be exercised. Tuberculosis standards have been well established by nationally accepted scientific authorities, such as the American Thoracic Society (ATS), the Infectious Diseases Society of America (IDSA) and the U.S. Centers for Disease Control and Prevention (CDC), as well as generally recognized TB control experts such as the National Tuberculosis Nurse Coalition (NTNC) and National Tuberculosis Controllers Association (NTCA). The standards of care for the medical treatment and control of TB are published jointly by ATS, IDSA, and CDC. Georgia follows these national standards and recommendations and in addition, has state-specific standards for TB control and prevention. References to these standards are listed below:

Nurse Protocols for Registered Professional Nurses in Public Health, current edition. Located on the DPH web pages at
http://dph.georgia.gov/nurse-protocols

Georgia Tuberculosis Reference Guide, current edition. Located on the TB web pages at
http://dph.georgia.gov/tb-publications-reports-manuals-and-guidelines

NTCA, NTNC. Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second Edition.2011. Each district health office and county health department was sent a copy in 2012. Additional copies may be purchased by contacting the National TB Controllers Association at http://tbcontrollers.org/

CDC. Core Curriculum on Tuberculosis: What the Clinician Should Know, 2011. Each district health office was sent a copy in 2012. It can also be ordered from CDC or downloaded at http://www.cdc.gov/tb/education/corecurr/

ATS, CDC, IDSA. “Treatment of Tuberculosis” (MMWR 2003;52[No. RR-11]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf

CDC, NTCA. “Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC” (MMWR 2005;54 [No. RR-15]). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf

CDC. “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Healthcare Settings, 2005” (MMWR 2005;54[No. RR-17]). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

CDC. “Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection” (MMWR 2000;49[No. RR-6]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf

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ATS, CDC, IDSA. “Diagnostic Standards and Classification of Tuberculosis in Adults and Children” (Am J Respir Crit Care Med 2000;161[4 Pt 1]). Available at: http://www.thoracic.org/statements/resources/archive/tbadult1-20.pdf

TUBERCULOSIS PROGRAM CONTACT INFORMATION:

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ACKNOWLEDGEMENTS

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Table of Contents

1. Mission and Responsibilities

Table of Contents

RESPONSIBILITIES FOR TUBERCULOSIS CONTROL

MISSION

The mission of the Georgia Tuberculosis (TB) Program is to control transmission, prevent illness and ensure treatment of disease due to tuberculosis. This is accomplished by the following:

- Identify and treat persons who have active TB disease
- Locate, evaluate and treat contacts
- Screen high-risk populations

The TB Program has the legal responsibility for all TB clients in Georgia regardless of who provides the direct services.

Tuberculosis services in Georgia are provided on a cooperative basis by local county health departments, district health offices, the private medical sector, other public agencies and the Georgia Tuberculosis Program.

LEGISLATIVE AUTHORITY

Copies of the laws and regulations can be downloaded from these links:

Official Code of Georgia Annotated (O.C.G.A.)
http://www.lexisnexis.com/hottopics/gacode/

Title 31-2A, 31-12-2, 31-12-4, and 31-14

Rules and Regulations: Department of Public Health, Tuberculosis Control, Chapter 511-2-3 http://rules.sos.state.ga.us/cgi-bin/page.cgi?g=Georgia_Department_of_Public_Health%2Findex.html&d=1

REPORTING REQUIREMENTS

In Georgia, all tuberculosis must be reported immediately to the local county health department. Physicians, hospitals, laboratories and other health care providers are required to report any of the following:

- Any child less than 5 years discovered with Latent TB Infection
- Any confirmed case of TB
- Any suspected case of TB
- Any person being treated with two or more anti-tuberculosis drugs
- Any positive culture for *Mycobacterium tuberculosis*

HOW TO REPORT

- Report cases electronically through the State Electronic Notifiable Disease Surveillance System (SendSS)
- Complete a Notifiable Disease Report Form and mail in an envelope marked CONFIDENTIAL, or...
- Call your County Health Department
- If your County Health Department cannot be reached, call the Georgia Department of Public Health at 404-657-2588.

RESPONSIBILITY OF THE STATE TB PROGRAM

STATE MEDICAL CONSULTANT

Provide medical consultation to district contract physicians, local health departments, private physicians, other providers and agencies and provide recommendations for treatment of tuberculosis as requested.
Provide clinical updates to district contract TB physicians and district TB coordinators through official memoranda, conference calls, and other educational venues, as needed.

Review all TB cases and TB suspects to ensure quality and appropriate treatment regimens by attending local/district case reviews and state cohort reviews.

Monitor and approve all requests for use of second-line TB medications.

Review and update TB nurse protocols and the Georgia TB Reference Guide as requested by the Georgia TB Program.

EPIDEMIOLOGY

Collect, manage, analyze and interpret TB surveillance and genotyping data to describe tuberculosis morbidity and mortality trends, demographic characteristics and risk factors of TB cases, and the incidence of TB among high-risk populations. Interpret data to assist in development of program policies and procedures.

Manage state genotype database, notify districts of genotype clusters in their districts, conduct genotype cluster investigations, and recommend measures to control TB transmission.

Monitor resistance levels to anti-TB drugs.

Evaluate implementation of core TB program strategies and attainment of program outcome measures such as completion of therapy among active TB cases, directly observed therapy, completed contact evaluations, and completion of treatment for TB infection among contacts.

Conduct outbreak investigations, other epidemiologic studies and evaluation of special project interventions.

Review secondary data sources (e.g., hospital discharge summaries, AIDS registries, laboratory reports) to detect failure to report TB cases.

Review completeness, accuracy and timeliness of surveillance data.

Produce the annual Georgia TB Report, annual progress reports and program management reports. Respond to inquiries on TB statistics.

STATE TUBERCULOSIS PROGRAM STAFF

Formulate and distribute state tuberculosis guidelines, procedures and protocols based on best practices.

Consult with district health departments, correctional facilities, hospitals, and all other health care providers on general concerns regarding tuberculosis management and/or specific tuberculosis cases. Provide consultation to the districts regarding the complete care of complex cases. Provide social service consultation and assessment on patients as needed.

Maintain listing of current educational materials and information on proper management and treatment of tuberculosis and act as a resource to provide these materials and information, as requested.

Maintain the tuberculosis web pages with current and accurate information on the Department of Public Health web site.

Conduct training for the district and local staff. Provide train-the-trainer courses to increase the local and district capacity for training. Maintain up-to-date training tool kits.

Provide program evaluation, technical consultation and support. Conduct site visits to local county health departments and district facilities to conduct technical consultation, quality assurance and quality improvement. Lead state case reviews and cohort reviews.

Maintain budget and financial data of all state funds and federal funds. Manages grant deliverables.

Establish, update and maintain charts for all tuberculosis suspects and tuberculosis cases. Maintain medical records on TB cases for at least 21 years. Information should include the following: Name, birth date, county of residence, medications, drug susceptibilities, and record of disposition.

Obtain documentation for out-of-state TB cases and/or contacts. Provide information to requesting district/county health departments.

Maintain the TB patient management module of the State Electronic Notifiable Disease Surveillance System (SendSS) and monitor the status of immigrants and refugees in the Electronic Disease Notification System (EDN). Provide consultation and technical support to end users on these systems.

Monitor accuracy of data, establish files and internal databases, back up files, enter data and maintain tuberculosis documentation. Verify and count all cases of tuberculosis for the State of Georgia and transmit surveillance statistics to CDC.

Facilitate the process for court-ordered treatment/confinement.

Recertify covered entities for 340B TB drugs annually or as scheduled by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs.

RESPONSIBILITY OF THE DISTRICT TB PROGRAM

DISTRICT HEALTH DIRECTOR

Has the ultimate responsibility for ensuring appropriate TB management in their district. Implement TB guidelines, policies, procedures, and protocols in county health departments within the district. Provide supervision and delegate activities to staff and may delegate certain medical acts such as tuberculin skin testing, venipuncture and sputum collection to trained unlicensed public health staff.

Mediate between health care providers, the local health department, the contract TB physician and the state office to facilitate best practices for TB programs in the district.

Produce and deliver health order directives as first legal step to ensure compliance for evaluation and/or treatment of tuberculosis.

Develop and maintain a working relationship with the county's attorney, the sheriff's office, hospitals and other community organizations in the district to facilitate access to needed resources, assist with patient adherence issues, and/or court-ordered therapy or confinement.

DISTRICT CONTRACT PHYSICIAN/CONSULTANT

Provide for the overall medical management of clients in the county health department TB programs. Conduct and participate in regular, routine, case reviews and cohort reviews.

Remain knowledgeable on current recommendations regarding the clinical management of TB disease and infection.

Consult with the State TB Program when making recommendations for the treatment of multi-drug resistant (MDR) tuberculosis (TB resistant to at least isoniazid and rifampin) before prescribing second-line drug regimens.

Monitor the care and treatment of clients with TB disease and infection being followed by private physicians. Consult as needed with healthcare providers to ensure appropriate medical treatment.

Provide recommendations on the following clients within the specified time frame after the client is referred to them:

- TB suspect/case within 48 hours
- Close contact to TB cases/suspects and all children within 48 – 72 hours
- All other clients within two weeks

When contract physician is not available, provide back-up physician for consultation.

DISTRICT TB COORDINATORS

Provide oversight, consultation and assistance to county health departments.

Provide consultation and assistance to other health care providers (e.g., hospitals, nursing homes, private physicians, correctional facilities, etc.).

Collaborate with physicians, hospitals, substance abuse centers, correctional facilities and community organizations to promote best practices, foster continuity of care, and provide needed social services for TB clients.

Facilitate hospitalization and/or discharge planning with social worker and/or infection control nurse.

Become a state certified TB Trainer and conduct TB Update and Skin Test (TST) Certification courses, Contact Investigation/DOT courses, TB Case Management courses and other educational activities for public health staff, correctional facilities and private sector providers within the district. Ensure TST certification is maintained by all public health staff who provide direct TB clinical services. Submit all rosters, evaluation summaries and registration forms to the State TB Program within two weeks of each class.

Provide in-service training on tuberculosis to county health departments, local communities and other agencies.

Serve as the point of contact for counties needing emergency and long-term housing services for infectious, homeless or non-compliant clients. Identify and establish partnerships with local resources to provide placement as needed.

Monitor the care and case management of all TB clients to ensure outcomes are achieved according to established state indicators and time frames.

Develop district policies, procedures and protocols to include infection control plan for health departments under direction of the Health Director.

Promote and conduct regular case reviews with local staff and contract physician.

Facilitate court-ordered TB treatment as needed.

Participate in conference calls, in-person meetings, attend state sponsored meetings and trainings, and disseminate the information obtained to the county health department TB staff. Assign a representative to participate in these activities if the coordinator cannot participate.

Promote and conduct program evaluation activities. Perform chart audits and send summaries of findings to the state TB Office. Promote and attend state cohort reviews.

Maintain a current listing of all Public Health TB facilities that receive TB drugs through the 340B TB Drug Pricing Program. Include the National Provider Identifier (NPI) numbers, the physical address of the facility and information regarding the contact person (e.g., name, title, phone/fax numbers, email address, etc.) who will verify 340B TB status during the state TB Office recertification period, unless a District pharmacist or pharmacy technician is already maintaining this listing. Maintain records and ensure proper documentation of all clients receiving 340B TB drugs.

Coordinate the submission of patient data to the state office. The state patient records should mirror the district patient records.

District Coordinators are to submit the following to the State TB office:
Client information on all TB cases and suspects including but not limited to the following:

- Consent and treatment plans
- Physicians' notes
- Progress reports
- Admission and discharge summaries
- Bacteriology results and laboratory reports
- Radiology results
- Any additional supporting documentation

District coordinators should refer to the case management timeline for a complete list of time-sensitive case management documents to report to the state office.

Grant-in-Aid quarterly reports are due to the state office on the 15th of the month following the end of each quarter. Grant-in-Aid annual report is due to the state office by July 15th of every year.

RESPONSIBILITY OF THE COUNTY TB PROGRAM

County Health Departments are responsible for the medical supervision and case management of all known TB cases and suspects in order to prevent the spread of

tuberculosis within their county. Each county health department should have a designated TB nurse with the following responsibilities.

TB NURSE

Collaborates with local physicians, local hospitals, substance abuse centers, correctional facilities and community organizations to promote TB education, best practices, foster continuity of care, and provide needed social services for TB clients. Facilitates hospitalization and/or discharge planning with social worker and/or infection control nurse. Provides tuberculin skin testing as requested. Collaborates with community organizations and facilities to perform targeted high risk TB screening and education about TB.

Ensures submissions of all isolates from local hospitals and laboratories to state laboratory for genotyping.

Upon notification of a TB case/suspect, a home visit within 24 – 48 hours is needed to assess the home environment for home isolation. If the patient is hospitalized, the home visit may be done within 24- 48 hours after discharge. Legal agreements and consents should be signed at this time.

Provides case management and follow-up of all known TB clients (cases, suspects, contacts, LTBI) to ensure timely and appropriate treatment. Appropriate treatment on the recommended four drug therapy should be started and completion of treatment should be within 12 months unless medically indicated otherwise. TB clients will be assessed for adverse reactions to medications at every encounter. Clinic visit, clinical status, and adherence shall be monitored and documented monthly. Directly observed therapy (DOT) is the standard of care for all cases, all children under the age of five with active TB disease or LTBI and for all HIV-infected persons with active TB disease or LTBI. Conversion of positive cultures to negative cultures will be documented. Drug susceptibilities will be completed on all initial specimens.

Cooperates with and assist private physicians treating tuberculosis clients. Obtains information from physicians assuring the private provider completes the “Initial Report on Clients with TB” form 3141 and “Follow-up Report on Clients” form 3142 monthly.

Facilitates the enforcement, when necessary, of tuberculosis laws and regulations to protect the health of the public.

Thorough contact investigations should be done to elicit and completely evaluate identified contacts. Infected contacts should be started on appropriate therapy with completion of treatment within 12 months.

Provides documentation for and participates in local, district and state case reviews, cohort reviews, chart audits and other program evaluation activities.

Receive reports of TB suspects/cases from other health care providers and promptly submit these reports (physicians' notes, progress notes, admission and discharge notes and bacteriology and radiology results) to the district TB Coordinator.

COMMUNICABLE DISEASE SPECIALIST (CDS)/OUTREACH WORKER (ORW)
If the county does not have CDS/ORWs, the TB Nurse is responsible for these duties.

Assists with contact investigation on cases and suspects to elicit and completely evaluate identified contacts.

Trained CDS/ORW may provide tuberculin skin testing, venipuncture and sputum collection if these acts are delegated by the District Health Director.

Provides directly observed therapy (DOT). TB clients will be assessed for adverse reactions to medications at every encounter. In the event of an adverse reaction, medication should be discontinued and the TB Nurse contacted immediately.

Follows-up and locates TB clients who miss appointments.

Coordinates transportation for clinic appointments.

Educates communities, clients and families about tuberculosis.

Provides reports to TB nurse and/or to the district TB coordinator as requested.

NATIONAL TB INDICATORS

For tuberculosis (TB) programs, quality of care is measured by means of objectives and standards. Such objectives and standards are used as yardsticks to direct the program and measure its success. Objectives reflect outcomes or results and program desires. Programs require objectives to define expected outcomes and results for case management activities. Standards are an accepted set of conditions or behaviors that define what is expected and acceptable regarding job duties, performance, and provision of services. The TB control program works to achieve objectives through a series of standards.

National TB Indicators with State Targets

Objective Categories	Objectives and Performance Targets
1. Completion of Treatment	For patients with newly diagnosed TB for whom 12 months or less of treatment is indicated, increase the proportion of patients who complete treatment within 12 months to 93.0%. • **State target 88%**
2. TB Case Rates	
• **U.S.-born Persons**	Decrease the TB case rate in U.S.-born persons to less than 0.7 cases per 100,000. • **State target: 2 per 100,000**
• **Foreign-born Persons**	Decrease the TB case rate for foreign-born persons to less than 14.0 cases per 100,000. • **State target: 16 per 100,000**
• **U.S.-born non-Hispanic Blacks**	Decrease the TB case rate in U.S.-born non-Hispanic blacks to less than 1.3 cases per 100,000. • **State target: 4 per100,000**
• **Children Younger than 5 Years of Age**	Decrease the TB case rate for children younger than 5 years of age to less than 0.4 cases per 100,000. • **State target: 1 per 100,000**
3. Contact Investigation	
• **Contact Elicitation**	Increase the proportion of TB patients with positive acid-fast bacillus (AFB) sputum-smear results who have contacts elicited to 100.0%. • **State target 95%**
• **Evaluation**	Increase the proportion of contacts to sputum AFB smear-positive TB patients who are evaluated for infection and disease to 93.0%. • **State target 80%**
• **Treatment Initiation**	Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) who start treatment to 88.0%. • **State target 80%**
• **Treatment Completion**	For contacts to sputum AFB smear-positive TB patients who start treatment for newly diagnosed LTBI, increase the proportion that complete treatment to 79.0%. • **State target 75%**

Objective Categories	Objectives and Performance Targets
4. Laboratory Reporting • **Turnaround Time** • **Drug-susceptibility Result**	Increase the proportion of culture-positive or nucleic acid amplification (NAA) test-positive TB cases with a pleural or respiratory site of disease that have the identification of *M. tuberculosis* complex reported by laboratory within N days from the date the initial diagnostic pleural or respiratory specimen was collected to n%. Increase the proportion of culture-positive TB cases with initial drug-susceptibility results reported to 100.0%. • **State target 98%**
5. Treatment Initiation	Increase the proportion of TB patients with positive AFB sputum-smear results who initiate treatment within 7 days of specimen collection to n%. • **State target 88%**
6. Sputum Culture Conversion	Increase the proportion of TB patients with positive sputum culture results who have documented conversion to sputum culture-negative within 60 days of treatment initiation to 61.5%. • **State target 62%**
7. Data Reporting • **RVCT** • **ARPEs** • **EDN**	Increase the completeness of each core Report of Verified Case of Tuberculosis (RVCT) data item reported to CDC, as described in the TB Cooperative Agreement announcement, to 99.2%. • **State target 95%** Increase the completeness of each core Aggregated Reports of Program Evaluation (ARPEs) data items reported to CDC, as described in the TB Cooperative Agreement announcement, to 100.0%. • **State target 100%** Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreements announcement, to n%. • **State target 85%**
8. Recommended Initial Therapy	Increase the proportion of patients who are started on the recommended initial 4-drug regimen when suspected of having TB disease to 93.4%. • **State target 90%**
9. Universal Genotyping	Increase the proportion of culture-confirmed TB cases with a genotyping result reported to 94.0%. • **State target 90%**
10. Known HIV Status	Increase the proportion of TB cases with positive or negative HIV test result reported to 88.7%. • **State target 95%**

Objective Categories	Objectives and Performance Targets
11. Evaluation of Immigrants and Refugees • **Evaluation Initiation** • **Evaluation Completion** • **Treatment Initiation** • **Treatment Completion**	For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiate medical evaluation within 30 days of arrival to n%. • **State target 70%** For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who complete medical evaluation within 90 days of arrival to n%. • **State target 75%** For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., increase the proportion who start treatment to n%. • **State target 85%** For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S. and started on treatment, increase the proportion who complete LTBI treatment to n%. • **State target 75%**
12. Sputum-culture Reported	Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 years or older that have a sputum-culture result reported to 95.7%. • **State target 95%**
13. Program Evaluation • **Evaluation Focal Point**	Increase program evaluation activities by monitoring program progress and tracking evaluation status of cooperative agreement recipients. Increase the percent of cooperative agreement recipients that have an evaluation focal point
14. Human Resource Development Plan	Increase the percent of cooperative agreement recipients who submit a program-specific human resource development plan (HRD), as outlined in the TB Cooperative Agreement announcement, to 100.0%. Increase the percent of cooperative agreement recipients who submit a yearly update of progress-to-date on HRD activities to 100.0%.
15. Training Focal Point	Increase the percent of cooperative agreement recipients that have a TB training focal point.

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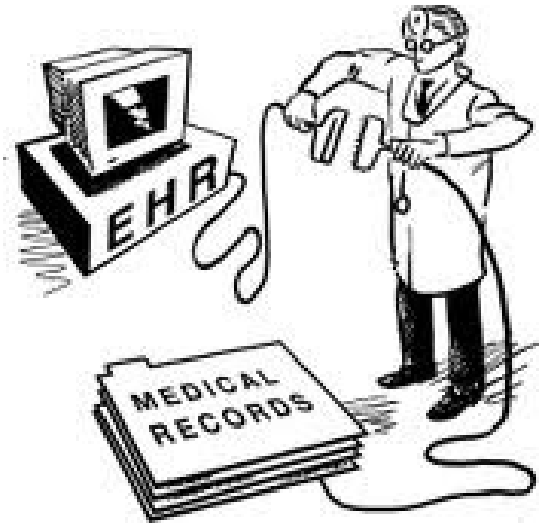
2. Medical Records and Surveillance



SendSS

Table of Contents

MEDICAL RECORDS AND SURVEILLANCE

All tuberculosis records are confidential. Their release to health and non-health agencies (excluding agencies within DPH) and Quality Service Agreements should be made only with a signed authorization to release information. Health Insurance Portability and Accountability Act (HIPAA) guidelines must be followed. Public Health does have some exceptions. See letter from Commissioner of Public Health on following page. Additional information about HIPAA is available on the DPH website: http://dph.georgia.gov/notice-privacy-policies.

The district TB coordinators are to coordinate the submission of patient data to the state office. The state patient records should mirror the district patient records.

RETENTION OF MEDICAL RECORDS

The Georgia Archives maintains the record retention timelines and is located at http://www.georgiaarchives.org/InformationForGovernmentAgencies/Records_laws_and_regulations/LGRetentionSchedules2011.pdf

Record Title	Description	Retention
(Cases/Treatment)	All documents relating to health services provided to tuberculosis patients; "cases" includes those clients with active TB infection and/or with TB infection (TBI) and an abnormal chest x-ray	21 years from the date of the last service
Tuberculosis Records (Negative x-rays)		10 years from End of calendar year in which x-ray was taken
Tuberculosis Records (Positive x-rays)		10 years from end of calendar year in which x-ray was taken
Tuberculosis Records (Prophylaxis/ Prevention)	All documents relating to health services provided to tuberculosis clients; "prophylaxis" includes those clients with TBI and a normal chest x-ray	21 years from date of last service

Brenda Fitzgerald, MD, Commissioner
Nathan Deal, Governor
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RE **"Public Health" Exceptions to HIPAA**

Dear Colleague:

From time to time, we receive questions from physicians and other health care providers who are concerned that federal privacy regulations prevent them from reporting patient information to local health departments or to the Department of Public Health.

The "Health Insurance Portability and Accountability Act" (HIPAA), enacted by Congress in 1996, protects the confidentiality of the patient's personal health information. However, HIPAA and its accompanying regulations strike a balance between a health care provider's duty of confidentiality and the need to protect the public health. Federal HIPAA regulations provide that patient health information may be provided to state public health authorities, with or without the patient's consent, in many different circumstances. Those circumstances include the following:

- A health care provider "may disclose protected health information for the public health activities and purposes described in this paragraph to a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions," 45 C.F.R. § 164.512(b)(1)(i); and

- A health care provider "may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the [provider] in good faith believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat," 45 C.F.R. § 164.512(j)(1)(i).

I hope this information will facilitate your support of our unwavering efforts to protect the public health. If you have any questions, please feel free to contact our legal department.

With best regards, I am

Yours very truly,

Brenda Fitzgerald, M.D.
Commissioner of Public Health
State Health Officer

TB SURVEILLANCE

STATE ELECTRONIC NOTIFICATION DISEASE SURVEILLANCE SYSTEM (SendSS)

Approved users of the TB module in the State Electronic Notification Disease Surveillance System (SendSS) can report TB cases, TB suspects, LTBI in children younger than 5 years old, and contacts of TB cases, electronically at http://sendss.state.ga.us

Update the case verification status of all TB suspects in SendSS as a verified TB case or not a TB case within 90 days from date of report.

REPORTING AND COUNTING CASES OF *M. TUBERCULOSIS*

The district TB coordinator or designee shall report new suspects/cases of tuberculosis within 24 hours of notification to the state TB Program office using the TB patient management module in SendSS. The state TB program reviews each TB case to ensure that it meets CDC's surveillance case definition criteria. All cases that meet the surveillance definition of a verified TB case and cases whose TB diagnosis are certified by a licensed health provider are included in Georgia's annual TB morbidity count. Timely reporting of information is imperative to ensure that all verified cases are counted in the year the patient's diagnosis was verified.

Information concerning TB/HIV co-infected patients, MDR cases, airline flight exposures, clusters of TB cases, children suspected of, or diagnosed with TB, or any instance that might precipitate media attention, is to be immediately reported to the district TB Coordinator who will in turn, report it to the state TB program office.

CRITERIA FOR TB SUSPECT

TB suspects are persons for whom there is a high index of suspicion for active TB (e.g., a known contact to an active TB case or a person with signs or symptoms consistent with TB) who is being evaluated for TB disease. A TB suspect may be referred to as Class V TB. See Appendix 1: Classification System for Tuberculosis in Tuberculosis Nursing: A Comprehensive Guide to Patient Care, 2nd Edition.

The TB suspect will have a prescription for two or more TB drugs and one or more of the following:

- Signs/symptoms of tuberculosis
- Positive AFB smear
- Abnormal chest x-ray
- History of exposure to tuberculosis
- Initial sputum reports, microbiology reports, prescriptions, chest x-ray reports and other provider notes are reviewed by the state medical consultant. If the client meets the above criteria, they will be placed on the State TB Program's active

suspect list. TB suspects from districts with contract physicians are placed on the list based on recommendations from clinic notes. State TB program staff enter refugees and immigrants with a Class B1 or B2 (non-LTBI) status as TB suspects in SendSS and county health departments should complete their evaluation within 90 days of arrival in Georgia to rule out TB.

CASE DEFINITIONS

1. Laboratory confirmed case
   Isolation of *M. tuberculosis* complex from clinical specimen by culture, or
   Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test.

2. Clinical case
   In the absence of a laboratory confirmation of *M. tuberculosis*, a person must meet all of the following criteria to be considered a clinical case of tuberculosis:
   - Positive tuberculin skin test or IGRA
   - Signs and symptoms compatible with TB (e.g., abnormal chest x-ray, abnormal chest CT scan, or clinical evidence of current disease such as fever, night sweats, cough, weight loss, hemoptysis)
   - Receiving treatment with two or more anti-tuberculosis medications.

3. Provider Diagnosis
   If a case does not meet the laboratory or clinical definition, the case may be counted as a verified case of TB by provider diagnosis if clinical evidence of TB is present and a client shows clinical improvement with TB medications.

4. Recurrent TB cases
   A new record in SendSS should be created for all recurrent TB cases, whether the recurrent case occurred 12 months before or after treatment completion or closure from supervision by a county health department. However, a case should not be counted twice within a 12-month period. An active TB case diagnosed in a previously verified TB case within 12 months after completion of therapy or after being closed to supervision is not counted as a new case for surveillance purposes. Active TB diagnosed in a previously verified TB case should be counted as a new case if more than 12 months has elapsed since the patient completed treatment or was closed to supervision by the county health department.

5. Non-tuberculous Mycobacterial Disease (NTM)
   A person who has disease attributed to or caused by NTM only should not be counted or reported as a case of tuberculosis.
   A person who has tuberculosis disease diagnosed with both *M. tuberculosis* and other NTM shall be counted and reported as a case of tuberculosis.

6. Tuberculosis case diagnosed after death
   Tuberculosis cases reported to health departments should be reported and counted

as a case if evidence of current disease was present at time of death.

REPORTING LATENT TB INFECTION (LTBI)

The finding of latent TB infection (LTBI) in a child less than five years of age is a reportable disease. When LTBI in a child less than five years of age is reported, public health personnel will initiate a contact investigation to identify the source of the infection, recommend treatment for latent TB infection, follow-up the child to ensure completion of LTBI treatment by directly observed therapy, and monitor for development of active disease. Early identification of TB infection and treatment in children can prevent progression to active disease. The contact investigation of a young child with LTBI may identify a previously undiagnosed and untreated case of active TB.

SendSS REPORTING REQUIREMENTS AND TIMELINES

TB CASES AND TB SUSPECTS:

- Patient's basic demographic information (name, birth date, age, sex, race/ethnicity, address) will be entered in the Patient tab of the SendSS within 24 hours after public health (county, district or state level) is notified of a TB suspect/case started on treatment for active TB. Other data in the Patient tab that are not available at time of notification will be updated in SendSS within 24–72 hours after the missing data are received by the end user responsible for data entry in SendSS.
- Data for the Assessment tab in SendSS and the patient's initial drug regimen for the Medication tab in SendSS will be entered within 24 hours after a patient is diagnosed as a verified case of TB by a county health department or within 24 hours after information of the patient's TB diagnosis is received by the end user responsible for data entry in SendSS. Other data in the Assessment or Medication tab that are not available at time of diagnosis will be updated in SendSS within 24–72 hours after the missing data are received.
- The Report of Verified Case of TB (RVCT) form should be generated (by clicking the Generate button) when data for the Patient, Assessment, and initial drug regimen in the Medication tab have been entered in SendSS.
- Initial TST/IGRA, chest radiographs, chest CT scans, bacteriology and drug susceptibility test results will be entered in SendSS within 24 hours after results are received. After entering the initial drug susceptibility test results, the end user should click the Generate button in SendSS to generate the RVCT Follow-up 1 form.
- Information on whether the patient moved while on TB treatment and the reason for stopping TB treatment (found in the Medication tab) and DOT information (found in the DOT tab) will be entered in SendSS within 24–72 hours after the client has completed therapy or within 24–72 hours after the county health department has determined that the patient can not complete therapy because patient died, is lost to follow-up or has moved, etc. After entering this information, the end user should click the Generate button in SendSS to generate the RVCT Follow-up 2 form.

CONTACT INVESTIGATION AND LTBI TREATMENT:

- Contact's basic demographic information will be entered in SendSS within 72 hours after contacts are identified or 72 hours after the data are received by the end user responsible for data entry of contacts in SendSS.
- Results of contact evaluations will be updated within 24 hours after receiving the first TST/IGRA result, within 24 hours after receiving the follow-up TST/IGRA results, and within 24 hours after the initial chest radiograph reading is obtained.
- The start date for LTBI treatment will be entered within 24 hours after contacts start LTBI therapy or within 24 hours after receipt of this information.
- The date LTBI treatment was stopped will be entered within 24–72 hours after contact stops treatment or within 24-72 hours after receipt of this information.

OTHER TB PROGRAM REPORTING REQUIREMENTS AND TIMELINES

District TB Coordinators for Health Districts receiving Grant-in-Aid (GIA) allocations from the Georgia TB Program should submit the GIA Quarterly Report to the state TB Office by the 15th of October, January, April, and July.

The GIA Annual Report is to be completed and submitted to the state TB Office by July 15 each year.

GIA District Education Reports are to be submitted quarterly.

Copies of all current contracts and memorandums of understanding/agreement (e.g., medical consultative, radiology, laboratory, etc.) funded with GIA dollars should be on file at the state TB Office.

Submit all TB program reports to the state TB program point of contact.

INTERJURISDICTIONAL TRANSFERS

The district office should submit an Interjurisdictional Notification form to the state TB program's point of contact when a TB patient who is still on TB treatment moves to another district or state. If the TB patient moves to another country while still on treatment, the district office should submit an International TB Notification form to the state TB program's point of contact. The state office will send the Interjurisdictional or International TB Notification form to the TB program of the patient's new state or country of residence, respectively. The state office will also refer patients who move to Mexico to CureTB and refer patients who move to countries other than Mexico to TBNet, for treatment follow-up. The state office is responsible for following up treatment completion data from the state TB program of the patient's new state of residence and entering the data in SendSS. The state office will inform CDC's Atlanta Quarantine Station of patients who have moved to another country to request their assistance to follow-up treatment abroad and/or request CDC to place the patient on a Do Not Board list.

The Interjurisdictional Notification form can be found on the Georgia TB program web pages at https://dph.georgia.gov/tb-public-health-clinic-forms.
The International TB Notification form can be found on CDC's Division of TB Elimination webpage at: http://www.cdc.gov/tb/programs/international/internat_proces.htm
Referral forms to TBNet can be found at the Migrant Clinician's Network website at: http://www.migrantclinician.org/files/HN-Enrollment-Packet_English.pdf#

When patients move to another district, state or country, the District TB coordinator or their designee should document the move in SendSS by the following procedure;

a. Enter the patient's new address in the Patient Information Tab in SendSS
b. Open the Meds tab and select "Yes" where it asks ""Did the patient move during TB therapy?"
c. Enter the new county, state, or country where the patient has moved

For foreign-born TB patients who have immigrated to the U.S. in the last five years, District TB coordinators and county health department nurses are encouraged to identify a patient's family member or point of contact from the patient's country of origin, to avoid the difficulty of locating patients that move back to their country of origin without a forwarding address.

DISTRICT- TO-DISTRICT TRANSFER
When a TB patient plans to move (or has moved) from one District to another, District TB Coordinators or their designee should complete an Interjurisdictional Notification form and fax it to the Medical Records Operations Analyst at the state TB program office, inform the District TB Coordinator of the District the patient is moving to about the transfer, and document the transfer in SendSS.

OUT-OF-STATE TRANSFER
When a TB patient plans to move (or has moved) from Georgia to another state, District TB Coordinators or their designee should complete an Interjurisdictional Notification form and fax it to the Medical Records Operations Analyst at the state office who will in turn notify the TB control program of the patient's new state of residence. The state office will fax all pertinent medical documents to that state and respond to any additional request for information. District offices or county health departments in Georgia should communicate directly with the county health department in the other state to provide detailed information on TB treatment, laboratory reports and clinical notes, to ensure continuity of care. District TB Coordinators or their designee should document the transfer in SendSS.

OUT-OF-THE-U.S. TRANSFERS
When a TB patient plans to move (or has moved) to another country while still on treatment, or has moved before TB diagnosis was confirmed, or before TB treatment was started, District TB Coordinators should call or email the TB Program Director directly, or in the Director's absence, the TB epidemiology unit. Patient can travel internationally if they have three consecutively negative sputum AFB smears, have

completed at least two weeks of appropriate TB medications, and do not have MDR-TB/XDR-TB. If these criteria are not met, the TB Program Director or TB epidemiologist will contact CDC's Division of Global Migration and Quarantine (DGMQ) to discuss whether the patient should be placed on a federal Do Not Board list or other means to restrict travel. For patients who move to Mexico, Districts should fill out an International TB notification form and fax it to the state TB program Medical Records Operations Analyst who will contact CureTB for follow-up. For countries other than Mexico, Districts should fill out both the International TB notification form and TBNet referral forms and fax them to the state TB program Medical Records Operations Analyst who will contact TBNet for follow-up. The Immigration and Customs Enforcement (ICE) agency is responsible for referring undocumented immigrants on TB treatment under ICE custody to CureTB or TBNet on deportation.

REFUGEE OR IMMIGRANT CLASS B1 OR B2

CDC Electronic Disease Notification (EDN) System notifies the Georgia State TB Program of aliens arriving in Georgia with a Class B1/B2 TB condition which is assessed during their screening abroad by U.S. Department of State panel physicians. Newly arrived immigrants, refugees, parolees[1] and asylees[2] with a B1/B2 TB classification should receive thorough and timely TB evaluations to ensure prompt detection of TB disease. Appropriate treatment should be completed to prevent future cases.

CLASS B CONDITION
A classification based on clinical evaluations performed abroad indicating findings consistent with a specific disease:

B-1 Tuberculosis, clinically active, not infectious
B-2 Tuberculosis, not clinically active, not infectious
B-2 Latent TB Infection

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[1]Parolees: A parolee is an alien, appearing to be inadmissible to the inspecting officer, allowed into the United States for urgent humanitarian reasons or when that alien's entry is determined to be for significant public benefit. Parole does not constitute a formal admission to the United States and confers temporary status only, requiring parolees to leave when the conditions supporting their parole cease to exist.

[2]Asylee: An alien in the United States or at a port of entry who is found to be unable or unwilling to return to his or her country of nationality, or to seek the protection of that country because of persecution or a well-founded fear of persecution. Persecution or the fear thereof must be based on the alien's race, religion, nationality, membership in a particular social group, or political opinion. For persons with no nationality, the country of nationality is considered to be the country in which the alien last habitually resided. Asylees are eligible to adjust to lawful permanent resident status after one year of continuous presence in the United States. These immigrants are limited to 10,000 adjustments per fiscal year.

INSTRUCTIONS TO COUNTY HEALTH DEPARTMENTS: B1/B2 NOTIFICATIONS

1. Upon receipt of the Class B1/B2 notification from the state TB program, contact the refugee and immigrant immediately and instruct him/her to report to the county health department for a TB skin test and clinical evaluation.
2. Assess the alien for TB signs and symptoms.
3. Administer tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA)
4. Read TST after 48-72 hours
5. Order chest radiograph if TST is greater than or equal to10 mm or the IGRA is positive
6. After TB evaluation is completed, treat appropriately if diagnosed with LTBI or active TB
7. Complete TB Follow-up Worksheet when evaluation is completed and fax the worksheet to District TB Coordinator who will submit the worksheet to the Georgia TB Program Office
8. If person was started on LTBI treatment, update the section on LTBI treatment on the same TB Follow-up Worksheet when the person completes LTBI treatment or stops treatment, and submit the worksheet to the District TB Coordinator who will submit the updated worksheet to the Georgia TB Program

B1/B2 SendSS PROCESSING PROCEDURES FOR DISTRICT TB COORDINATORS

Aliens with a B1 or B2 classification should be located and TB evaluation initiated within 30 days of arrival.

State TB Program staff enter all B1 and B2 (non-LTBI) aliens into SendSS as TB suspects.

Some B2 aliens are classified as having LTBI (depending on their country of origin) and therefore are not entered in SendSS as TB suspects, but should still be evaluated by the county health department.

Alien TB suspect status should be changed in SendSS within 90 days of date reported.

SendSS DATA ENTRY FOR CLASS B1/B2

The case verification status of B1/B2 TB suspects should be updated in SendSS when data on their final diagnosis become available.
To update the case verification status in SendSS:

- Open the Diagnosis Tab
- Enter correct diagnosis from the Case Verification Status drop down box
- Click on the Add button
- Open the RVCT tab
- Click on the Generate button

TB ALIEN FOLLOW-UP WORKSHEET COMPLETION

State TB program staff enters the TB Follow-up Worksheet data in CDC's Electronic Disease Notification (EDN) software. DeKalb County TB Program staff enters their own data directly in EDN.

The highlighted fields in the follow-up worksheet are mandatory fields needed to successfully upload the data in EDN.

Submit the completed worksheet to state TB Medical Records with attention to Medical Records supervisor.

Resubmit the completed worksheet when the alien completes therapy, if applicable.

ELECTRONIC DISEASE NOTIFICATION SYSTEM QUALITY IMPROVEMENT PROCEDURES

A monthly report of un-submitted TB Alien Follow-up Worksheets and missing worksheet data is distributed by TB Epidemiology staff to District TB Coordinators.

A quarterly report of unclassified TB suspects greater than or equal to 90 days that include B1/B2 TB suspects is sent out to District TB Coordinators by Medical Records.

3. Overview of Tuberculosis Services

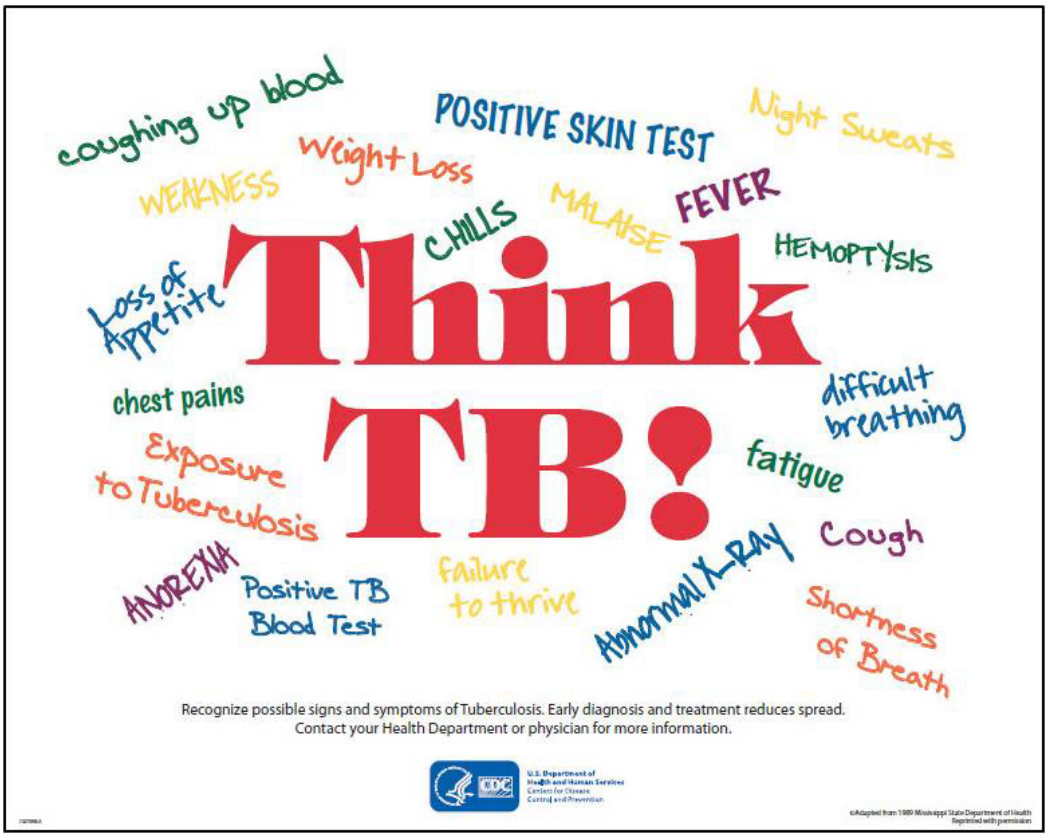


Table of Contents

TUBERCULOSIS SERVICES

Active tuberculosis is a public health threat. Latent TB infection (LTBI) is a reservoir for future active TB cases. TB prevention and control programs need to address both active TB and LTBI to protect the health of the community. TB services must be rendered at the time of client presentation regardless of the client's ability to pay.

Medicaid and third party payers may be billed for all TB services but should not bill for TB medicines or the PPD solution which are purchased by the state at a discount from the federal 340B TB Drug Pricing Program and provided to all District TB programs. TB services can be billed according to the county sliding fee scale, however, treatment may not be refused if the patient is unable to pay. All out of pocket payments for TB suspects, confirmed TB cases, converters, contacts to TB suspects or cases, and children under five years of age with LTBI are to slide to zero dollars ($-0-). For clients who fall outside these parameters (screening for employment, school, etc.), if the client does not have the money on the day of service, the client can be billed for service.

It may be possible for contracts or MOUs to be executed with local facilities that frequently send employees or students to the health department for TB screening as a way to generate funds to cover these services.

Ideally, clients from high risk populations should not incur or only incur minimal charges from a county health department TB clinic because the benefit of providing TB services to them to prevent a future case far outweighs the cost of the service. An example would be a client who is enrolling in a substance abuse program and needs a TST or chest x-ray in order to be accepted to the program.

MEDICAL CARE

Each health district in Georgia has a District Health Director and a contract with a practicing physician for oversight in providing medical care to TB clients. The district varies widely in how the oversight is implemented. Some districts have the physician see every TB client, while in others; the physicians never see the clients but review the charts on a regular basis and provide consultation to the nurses. If the direct care is provided by a private physician, the county TB nurse is to obtain monthly reports to maintain oversight.

The nurse protocols describe the management of uncomplicated pulmonary TB and LTBI. Anything that falls outside of the protocols is to be managed by the contract physician and the nurse will work under those orders and will not be working under protocol. The district contract physician will write the order and sign off on the chart. The district pharmacy or contract pharmacy will dispense the medication. If a patient is being co-managed by a private physician in the community, the district contract physician will have to collaborate for care and write the orders for any health department involvement. This is especially important concerning medications. Public health nurses do not work under community physician's orders. They can only work

under the Georgia Standard Nursing Protocol or the district contract physician's orders. A registered professional nurse or physician's assistant is only authorized to dispense pursuant to an order issued in conformity with a nurse protocol or job description, not a prescription or an order written on a chart or phoned in by a physician. For more information, please see the "Drug Dispensing Procedure" in the *Nurse Protocols for Registered Professional Nurses in Public Health, current edition.* Located on the web pages at https://dph.georgia.gov/sites/dph.georgia.gov/files/related_files/site_page/Drug%20Dispensing%20Procedure.pdf

Diagnostics, treatment, clinical care, case management and infection control guidelines and standards should be available for reference by each TB staff member. Instead of repeating these guidelines in this document, please refer to the following sources:

Nurse Protocols for Registered Professional Nurses in Public Health, current edition. Located on the TB web page at https://dph.georgia.gov/nurse-protocols

Georgia Tuberculosis Reference Guide, current edition. Located on the TB web page: https://dph.georgia.gov/sites/dph.georgia.gov/files/TB-Pub-GATBReferenceGuide2014.pdf

NTCA, NTNC. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second Edition.2011.* Each district health office and county health department was sent a copy in 2012. Additional copies may be purchased by contacting the National TB Controllers Association at http://tbcontrollers.org/

CDC. *Core Curriculum on Tuberculosis: What the Clinician Should Know, 2011.* Each district health office was sent a copy in 2012. It can also be ordered from CDC or downloaded at http://www.cdc.gov/tb/education/corecurr/

ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003; 52[No. RR-11]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf.

CDC, NTCA. "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC" (*MMWR* 2005; 54 [No. RR-15]). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf .

CDC. "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Healthcare Settings, 2005" (*MMWR* 2005;54[No. RR-17]). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

CDC. "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection" (*MMWR* 2000;49[No. RR-6]). Available at: http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf .

ATS, CDC, IDSA. “Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America” (*MMWR* 2005; 54[No. RR-12]). Available at: http://www.cdc.gov/MMWR/PDF/rr/rr5412.pdf

ATS, CDC, IDSA. “Diagnostic Standards and Classification of Tuberculosis in Adults and Children” (Am J Respir Crit Care Med 2000;161[4 Pt 1]). Available at: http://www.thoracic.org/statements/resources/archive/tbadult1-20.pdf

OFFICE VISITS

All legal forms are to be completed at the first office visit. This includes consent for treatment, treatment plan, medication information, DOT agreement and/or refusal of care.

Gather as much locating information as possible. Some examples would be emergency contact information, email address, cell phone number, screen name, face book or other social network. Upon evaluation of non-US born, "recent" (past 5 years) immigrants, please identify a family member or another close contact in their home of origin, as an emergency contact. This will assist in locating patients that are "lost" while infectious.

All persons on treatment are expected to have a clinic visit at least once a month. More frequent clinical visits may be needed depending on the complexity of the case.

See Section 7: Nursing Evaluation and Monitoring for specific information.

HOME VISITS

All active TB cases are expected to have at least one home visit to evaluate the living situation of the client to determine the suitability of home isolation, the presence of children and to educate and build rapport with the client and the client’s family.

SCREENING FOR TB

When a client has a tuberculin skin test (TST) placed at an HIV clinic or a correctional facility and comes to the health department for it to be read, it would be advisable to read the TST without any barriers, i.e., not to bill for the TST reading, as HIV and TB programs often collaborate in the case management of clients. Other facilities may place a TST and tell the client to go to the health department for it to be read. In these cases, collaboration with the facilities would be encouraged to assure proper placement and a possible MOU might be feasible.

Interferon Gamma Release Assay (IGRA) may be available through contracts with laboratories.

All health departments have the ability to administer and read TSTs. Persons who perform and/or interpret this test should have obtained initial TST certification when newly hired and have it maintained by completing the recertification requirements every two years.

TUBERCULIN SKIN TESTING BY UNLICENSED PUBLIC HEALTH PERSONNEL

Georgia law permits physicians to delegate the administration of TSTs to unlicensed medical assistants (O.C.G.A. 43-34-44) that they supervise. The law does not require on-site supervision by the delegating physician at all times. District Health Directors (DHD) may delegate the administration and/or reading of tuberculin skin tests (TST) to unlicensed public health personnel when all of the following criteria have been met:

1. The DHD has reviewed and approved the standard training curriculum for the *TB Update and Skin Test Certification* course.
2. The DHD has a written delegation signed by the DHD and the unlicensed public health personnel outlining the specific parameters of the delegation.
3. The DHD has a system in place in which the skill competency of the individual can be validated on an annual basis.
4. The individual has obtained TST certification from the Georgia Tuberculosis Program and maintains certification by timely renewal every two years.

The DHD can set up any system to validate the skill competency of the individual in any way that is feasible for the district. It might be feasible to have a skill competency day at the district health office once a year at which time all unlicensed public health staff could be observed at one time. In other districts, it might be reasonable for an individual in the field to be observed while performing and reading the test. TST-certified nurse trainers can supervise the administration and reading of the TSTs by unlicensed personnel, consistent with usual practice in county health departments, if it is difficult or impractical for DHDs to do so. While unlicensed public health personnel may administer and/or read a TST, they must refer any induration to a licensed medical professional for interpretation of the induration.

The current standard training curriculum for the *TB Update and Skin Test Certification* course can be obtained from the program director of the Georgia Tuberculosis Program at 404-657-2634 or by sending an email to tbnurse@dhr.state.ga.us. For unlicensed public health personnel, the process includes a full day course which covers didactics regarding tuberculosis and testing process, a video demonstrating the correct procedure and a practicum where the participant must provide a return demonstration of the proper procedure. After the class, the participant is required to perform 10 satisfactory administrations and 10 satisfactory readings under supervision in his/her clinic setting. Validation of completion of all steps must be sent to the Georgia Tuberculosis Program prior to a certificate being issued. The Georgia Tuberculosis Program issues a paper certificate once all components of the TST certification process are complete. Each individual may be required to submit a copy of his/her current certification to the DHD at the time of signing the annual delegation document.

SAMPLE MEDICAL DELEGATION

The signatures below indicate a mutual agreement between the delegating physician(s) and the unlicensed public health (PH) personnel who are authorized to perform administration of tuberculin skin test (TST) and reading (measurement) of tuberculin test for the purpose of screening for active TB and latent TB infection.

All public health personnel whose signatures appear on this page:

1. Have been adequately trained to perform the delegated act of administering and/or reading tuberculin skin tests

2. Have obtained certification in TST reading and administration from a certified instructor for the Tuberculosis Program, Georgia Department of Public Health AND maintain and renew their TST administration and reading certification every two years, AND , and such training is documented by a state certification form in each person's training file.

3. Have immediate access to a licensed medical professional for consultation and for referral of any induration read for interpretation.

4. Participate in an annual skill competency event that is observed by the delegating physician.

5. Have been given an opportunity to have questions answered.

_____ _____
Signature of Delegating Physician Date

_____ _____
Signature of PH Personnel Date

_____ _____
Signature of PH Personnel Date

_____ _____
Signature of PH Personnel Date

_____ _____
Signature of PH Personnel Date

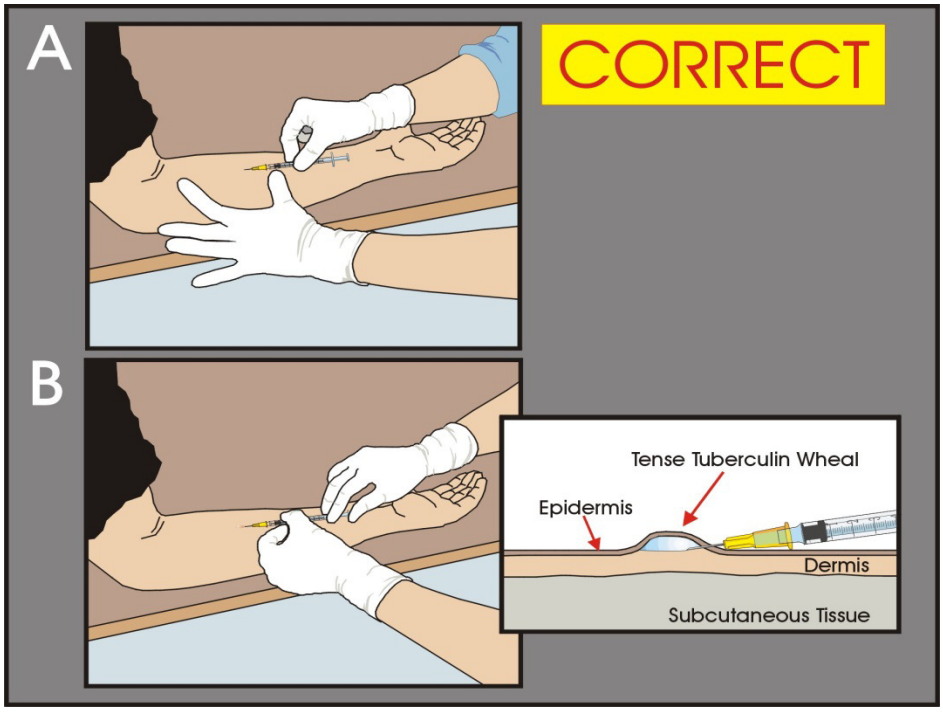
ADMINISTRATION OF MANTOUX TUBERCULIN SKIN TEST (TST)

Purpose of test: To determine whether a person has become infected with the TB germ. This test cannot determine whether the person has active TB disease or Latent TB infection.

Supplies:
Tuberculin syringe
27 gauge needle
½" or 3/8" needle length
5 Tuberculin unit strength PPD solution
Alcohol pads
Cotton ball
Gloves (Note: gloves may or may not be worn according to facility)

Procedure:

1. Draw up 0.1 ml of PPD solution into tuberculin syringe
2. Expel excess air bubbles
3. Clean area of forearm (dorsal or volar surface) with alcohol pad. Let dry.
4. With bevel of needle facing upwards, inject the solution intradermally (just under the 1st layer of skin). A tense wheal (bubble) approximately 6 - 10 mm should be visible at the injection site.
5. Withdraw the needle and dispose into SHARPS container.
6. Patient (or nurse if wearing gloves) may "dab" any spot of blood appearing at the site with a cotton ball. Do not place a Band-Aid on the site.
7. Instruct patient to return in 48 – 72 hours for reading.

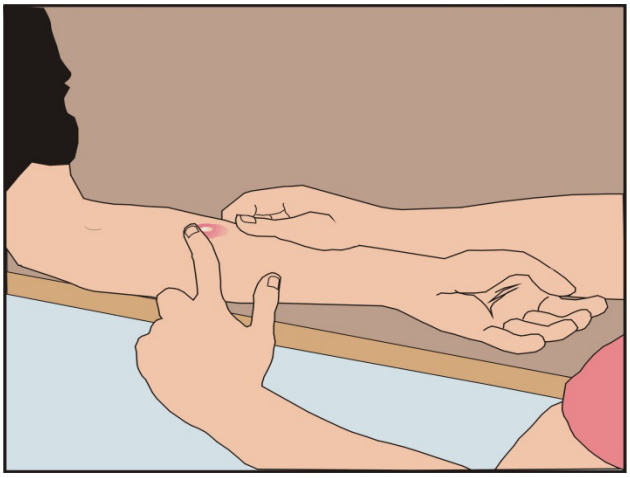


MEASUREMENT OF THE MANTOUX TUBERCULIN SKIN TEST (TST)

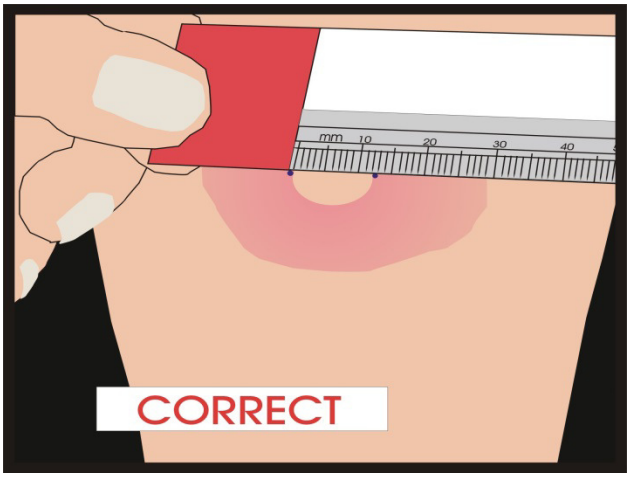
Purpose: To determine a reaction to the tuberculin solution and measure the size of the induration (raised hardened area)

Procedure:

1. Test is read by a trained healthcare worker 48 – 72 hours after the TST Placement. If a patient fails to show up for the scheduled reading, a positive reaction may still be measurable up to 1 week after testing. However, if a patient fails to return within 72 hours and shows no induration, the TST should be repeated.
2. The area of induration (palpable raised hardened area) around the site of injection is the reaction to tuberculin that is to be measured. Erythema (redness) and soft tissue swelling are not to be measured.
3. Palpate the injection site for induration. The borders of the induration can be marked with a ball point pen or with the fingernail.
4. Using either a flexible ruler or caliper ruler with millimeter markings, measure across the forearm (perpendicular to the long axis or transversely). All reactions should be recorded in millimeters (e.g. 12 mm). If no induration is found, "0 mm" should be recorded.



Palpation of the induration



Measurement of the induration

INTERPRETATION OF THE MANTOUX TUBERCULIN SKIN TEST (TST)

Purpose: Skin test interpretation depends on the measurement of the induration and the person's risk of being infected with TB and /or progression to disease if infected.

Procedure:

1. Match the measurement of the induration with the person's risk factors from the chart below.
2. **Record** the size of the induration in millimeters (mm)
   • Don't write "negative" or "neg" but record as 00 mm or 7 mm, etc.
   • Do write positive results as a number, not positive," such as 10 mm, 12 mm
3. Give client official documentation of results

Induration of ≥ 5 mm is considered positive in	**Induration of ≥ 10 mm is considered positive in**	**Induration of ≥ 15 mm is considered positive in**
• Human immunodeficiency virus (HIV)-positive persons • Recent contacts of TB case patients • Persons with fibrotic changes on chest radiograph consistent with prior TB • Patients with organ transplants and other immunosuppressed patients (Receiving the equivalent of ≥15 mg/d of prednisone for 1 month or more. Risk of TB in patients with corticosteroids increases with higher dose and longer duration.)	• Recent immigrants (i.e., within the last 5 years) from high-prevalence countries • Injection drug users • Residents and employees† of the following high-risk congregate settings: prisons and jails, nursing homes and other long-term facilities for the elderly, hospitals and other health care facilities, residential facilities for patients with acquired immunodeficiency syndrome (AIDS), and homeless shelters • Mycobacteriology laboratory personnel • Persons with the following clinical conditions that place them at high risk: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head, neck, or lung),weight loss of ≥10% of ideal body weight, gastrectomy, and jejunoileal bypass • Children < 4 years of age, or infants, children and adolescents exposed to adults at high-risk	• Persons with no known risk factors for TB

† For persons who are otherwise at low risk for TB and who are tested at the start of employment, a reaction of ≥15 mm is considered positive.

CHEST X-RAYS

Health districts and/or county health departments may have on-site radiology services or the services may be provided through contracts with local facilities.
Chest x-rays should be performed on the following persons:

- Person with signs and/or symptoms of active TB regardless of TST or IGRA result
- Contacts with a positive reaction to a TST (greater than or = 5 mm induration) or IGRA
- Contacts to cases that have a previous positive TST
- Contacts with HIV infection
- Contacts for whom window period treatment is being considered
- Persons with documented evidence of converting from a negative TST to a positive TST within the past 2 years
- Persons on LTBI treatment that develop signs and/or symptoms of active TB
- Children under five years of age with a positive TST referred for a chest x-ray to diagnose LTBI or rule out TB

Chest x-rays for follow up of an initial positive skin test as a result of routine testing or in conjunction with employment, school, etc. may be provided through memorandums of agreement or at a nominal cost according to local health department policies. All fees should be based on the county sliding fee scale. Annual chest x-rays for previous TST positive clients are not recommended (although some facilities will still require them). The use of a clinical symptom screen is recommended to document the symptom screen. Education about signs and symptoms so that the person knows when to seek health care can be found at https://dph.georgia.gov/tb-educational-resources-general-public. This document can be signed and kept with the facility's annual screening paperwork.

A clinical symptom screen is required for all clients who have a lapse in LTBI treatment. A repeat chest x-ray evaluation is required for clients who are symptomatic or who have had a lapse in therapy for two months or more.

OTHER IMAGING AND/OR NECESSARY MEDICAL PROCEDURES

The state TB Program is to be notified immediately of any necessary medical procedures that are not in the state nursing protocols. The state medical consultant must approve all procedures. The county will pay for the procedure at the current Medicaid rate.

LABORATORY TESTING

Certain blood and microbacteriology testing is required to diagnose and monitor TB cases and LTBI. Detailed information about the tests required can be found in the *Standard Nurse Protocols for Public Health Nurses* and in Section 7 of this document.

Laboratory results not performed by the State Laboratory are done through a contract with a local laboratory and county and/or district. For more information about the state laboratory, please refer to the *2012 Laboratory Services Manual* found at https://dph.georgia.gov/lab. For more information on individual laboratory tests, please see the section on List of Laboratory Services.

HIV test results should be documented on all patients receiving TB care through the health departments. An opt-out approach is recommended. This means the patient is informed of the laboratory tests that will be performed, including an HIV test. The patient can decline the HIV test; otherwise, the test will be performed. Documentation of a patient's refusal should be in the medical record. During the course of treatment, HIV testing should continue to be offered until results can be obtained. If a client continues to refuse, have the client a "Refusal of HIV Testing" form (located at the end of this section) and notify the contract physician. For more information and background on this approach, please refer to CDC's *"Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings"* at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.

INCENTIVES AND ENABLERS

Incentives and enablers for TB patients and contacts on LTBI treatment are available from the American Lung Association (ALA) of Georgia through a contract with the Georgia TB Program. Refer to the *Alternative Housing Project for Homeless Tuberculosis Patients in Georgia* brochure available from ALA, or call ALA at 770-434-5864 for current procedures to request and obtain incentives/enablers. Districts may request approval from the state TB program director or deputy director to use unexpended GIA funds to purchase incentives and enablers. On occasion, there may be incentive/enabler monies available from the state TB Program. Contact the TB program deputy director at 404-657-2634 to request these funds. Ensure is also supplied without charge to supplement the nutritional status of patients. Contact the TB Program to order Ensure.

MEDICAL INTERPRETATION SERVICES

The State of Georgia has a statewide contract with AT&T Language Line to provide medical interpretation services to the clients of Georgia. No person should be turned away because of the inability to speak or understand English. Family members of the client are not to be used to interpret for the client and staff. Information packets can be requested from AT&T free of charge by calling the customer service number 1-800-752-6096.

PROCEDURE FOR USE OF AT&T LANGUAGE LINE

- Place the non-English speaker on hold
- Dial 1-866-874-3972
- Enter your client ID [513565] on the keypad or stay on the line for assistance
- Press 1 for Spanish or

- Press 2 for all other languages
- Speak the name of the language at the prompt
- An interpreter will be connected to the call
- Brief the interpreter. Summarize what you wish to accomplish and give any special instructions.
- Add the non-English speaker to the line
- Conduct your business

HOSPITALIZATION

The state office TB Program is to be notified immediately of any pending hospitalization of a TB suspect/case. If the client has no insurance or Medicaid/Medicare, then the county is expected to negotiate with the local county hospital to use the hospital indigent care funds.

HOUSING HOMELESS CLIENTS

Each county and district should maintain a current listing of single occupancy motels in their area. The American Lung Association (ALA) has a contract to verify suitable housing for homeless clients. Refer to the *American Lung Alternative Housing Project for Homeless Tuberculosis Patients in Georgia: Operations Procedures.* This document is distributed with this policy and procedure manual.

STATE TB SOCIAL SERVICES

Contact the state TB Program Social Services Provider for assistance with referrals and consultations on complicated clients.

What can the State TB Social Service Provider do?

1. Provide psychosocial assessments (to determine the problem(s), level of functioning and appropriate services and treatment plans for the patient)
2. Provide referral/linkage to appropriate resources
3. Provide direct services/counseling to patients and families
4. Provide phone consultation to districts on complex cases
5. Provide onsite consultation to districts on complex cases
6. Provide educational programs to District staff regarding social service issues
7. Provide assistance to districts with resource development and coordination by collaborating with local agencies and organizations
8. Provide assistance to districts by collaboration with ALA on complex patients
9. Provide assistance to districts on special projects

Who can be referred to the State Social Service Provider?

1. Patients referred to ALA for services
2. Patients with complex psychosocial problems (homeless, uninsured, no income, substance abuse, mental health, undocumented, etc.)

Items needed for referral to State Social Service Provider:

1. Georgia Department of Public Health Form 3121-R, Tuberculosis Services and Client Referral Form located on the TB web pages at https://dph.georgia.gov/tb-public-health-clinic-forms
2. Social service referral form (completely filled out with relevant information i.e., infectious status, insurance type, family members, family support, next of kin, income, unemployment history, etc.)
3. Any other referrals or social services notes from hospital and/or community agencies

It would also be very helpful to refer complex patients to the state social worker the same time they are referred to ALA for services. See American Lung Association section.

PROGRAM EVALUATION

Program evaluation is a core activity of TB control. Self-evaluation is needed in order to identify key intervention points during therapy in which action can be taken to promote optimal patient outcomes. The TB Program encourages participation in the Office of Nursing Quality Assurance/Quality Improvement initiative. During each grant cycle, an evaluation plan is developed and implemented.

CASE REVIEWS

The district and local jurisdictions are expected to perform regular case reviews. The state medical consultant and other state office personnel will attend one case review per district per year. The Medical Records Supervisor will work with each district to set a date and time.

COHORT REVIEWS

The state office will conduct four cohort reviews per year. Usually, these will be in the high morbidity districts. he state office nurse consultant will coordinate with each selected district to conduct these reviews.

For more information on program evaluation expectations, processes and procedures, please refer to *Tuberculosis Program Evaluation Guidelines* available at http://www.health.state.ga.us/programs/tb/publications.asp .

Refusal of HIV Testing

Name_____ Date of Birth _____

☐ I have been exposed to an active TB case

☐ I have been diagnosed with latent TB infection (LTBI)

☐ I have been diagnosed with an active case of TB or suspected case of active TB

CDC recommends HIV screening for all TB clients. This includes persons who have been exposed to an active case of TB (contacts), persons diagnosed with latent TB infection (LTBI) and those persons either suspected to have active TB or those persons confirmed to have active TB.

TB is particularly dangerous for people with HIV infection. Active TB can accelerate the progression of HIV in persons living with HIV. Having HIV infection when exposed or diagnosed with LTBI can increase the progression of latent TB infection to an active case of TB.

After having the recommendations and risks explained to me, I have decided to refuse a test for HIV. I have been told the signs and symptoms of active TB are cough lasting more than 3 weeks, fever, night sweats, coughing up blood, chest pain, fatigue and unexplained weight loss. I understand that if I develop any signs and symptoms of active TB, I need to seek medical care immediately. I understand that TB is an infectious disease that can be passed to others. I also understand that legal steps can be taken if I develop active TB and I do not seek medical care, but expose others to becoming infected and/or sick.

_____ _____

Client's signature Date

_____ _____

Public Health Representative Signature Date

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4. Pharmacy

Table of Contents

MEDICATIONS

The state provides TB medications free of charge to all TB clients treated through the local health departments. Clients, Medicaid and insurance companies are not to be charged under any circumstance for TB medications or PPD solution. Any client receiving medications through the county health department must be clinically assessed at least monthly by a registered nurse, advance practice registered nurse, physician's assistant or medical doctor for clinical improvement and adverse reactions to the medications. Each patient on TB medications should have a monthly clinical assessment.

For the current formulary, ordering procedures and storage considerations, please refer to Division of Public Health, Office of Pharmacy, Pharmaceutical Supply Catalog, July 1, 2010 available from the Office of Pharmacy.

TRANSPORT OF DANGEROUS DRUGS

The DOT agreement signed by the client authorizes the DOT staff person to act as an agent of the client and gives permission for them to transport the client's medication. This medication is dispensed and labeled with the patient's information. PPD solution is not dispensed but is carried in bulk (multi-dose vials) to perform contact investigations. The Standard Nurse Protocols allows Registered Nurses to transport PPD solution to a non-public health clinic site. Non-licensed public health staff is not allowed to transport PPD solution into the field.

340B INFORMATION AND DRUG DISPENSING PROCEDURE

Refer to the Nurse Protocols for Registered Professional Nurses in Public Health, current edition, "Georgia Department of Public Health Drug Dispensing Procedure." Located on the Office of Nursing web page at http://dph.georgia.gov/nurse-protocols.

MEDICATIONS REQUIRING APPROVAL BY STATE MEDICAL CONSULTANT

- Second-line anti-TB medications
- Corticosteroids for patients with TB meningitis or pericarditis

Steps to complete to receive second-line TB drugs:

- Email the State Medical Consultant, the TB Program Manager and the State Office TB Nurses with a synopsis of the patient.
- Fax the following documentation to the State TB Office (404-463-3460):
    1) Copy of the prescription for all TB medications
    2) Progress Note stating the need for the alternate regimen
    3) The *Second-Line Therapy Authorization Form* can be found on the TB web pages at https://dph.georgia.gov/tb-public-health-clinic-forms.

- The state TB Nurse will verify the documentation and consult with the State Medical Consultant. Additional information may be requested.
- Once the State Medical Consultant has signed the approval, the State Office TB Nurse will supply a copy of the signed authorization to the state Office of Pharmacy and back to the requestor.
- The requestor will contact the district drug coordinator or pharmacy to have the order placed into Cardinal.com (district drug coordinator or pharmacist sends an e-mail to the State Pharmacy Section verifying the order was placed).
- Once the State Pharmacy Section receives the signed second-line approval form and the e-mail from the district drug coordinator/pharmacist, the pending order can be approved (if the product is not on hand locally). The pharmacist can dispense the order. If there is no district pharmacist, seek contracted pharmacy services to dispense since there is no nurse protocol for ordering and dispensing second-line drug treatment.

5. Directly Observed Therapy

Table of Contents

Tuberculosis (TB) treatment can seem difficult – it requires taking multiple medications for at least 6 months. Most people have trouble remembering to take their medicines, especially after symptoms of the disease improve or have disappeared completely. Directly Observed Therapy (DOT) is an essential element for the prevention of further transmission of infection and disease. The ultimate purpose is to have each patient fully complete his/her first-ever TB treatment. Having every initial treatment fully completed, patients can be cured of TB and relapses are kept to minimum. This is the only effective means to avoid MDR-TB and XDR-TB, which, in developing, high burden countries, is still almost incurable. DOT entails the direct observation of the patient's self-administering and swallowing the correct dose of anti-tuberculosis medications at the proper time for the complete period of therapy by a designated, trained and responsible agent of the patient. However, DOT is not just providing medication. DOT involves front line interaction with the patient. The DOT worker has the opportunity to make a genuine contribution not only to the patient's physical health but also his or her well-being. Frequently, the DOT worker will identify social service or personal needs that could interfere with completion of treatment. Helping the patient resolve these problems not only helps achieve program outcomes but it also helps the patient find the assistance needed with their problems. Directly Observed Therapy (DOT) is the standard of care in Georgia to ensure an individual who has been prescribed medication for the treatment of active tuberculosis (TB) disease or latent TB Infection (LTBI) completes the recommended course of drug therapy by taking all the medication.

DEFINITIONS

1. DOT – directly observed therapy is the assistive and supportive act of providing the anti-tuberculosis medication directly to the patient for self-administration and observing him or her swallow the medication(s) as prescribed for the treatment of TB or LTBI. The DOT worker may not always be directly observing the very young child self-administering medications, but may be assisting/observing the parent or guardian in giving the medication. DOT does **not** entail dispensing or administering any medication.
2. TB – tuberculosis is a disease caused by the *Mycobacterium tuberculosis* complex that can affect any part of the body, but usually affects the lungs. The general symptoms are fever, night sweats, weight loss, and fatigue. Pulmonary TB symptoms may include productive cough and/or coughing up blood. Extrapulmonary TB may include pain or other symptoms related to the site of the disease.
3. LTBI –Latent TB infection is characterized by a positive reaction to a tuberculin skin test, the absence of symptoms of active TB disease, and a chest x-ray that is not suggestive of active TB disease.

GENERAL PROVISIONS

1. DOT is <u>required</u> for:
    - All suspected and/or confirmed active cases disease.

- All children being treated for LTBI/presumptive LTBI less than 5 years of age
- All persons being treated for LTBI/presumptive LTBI who are co-infected with HIV
- All persons being treated for LTBI/presumptive LTBI on an intermittent dosing regimen
- All persons on the combined isoniazid and rifapentine regimen for LTBI

2. If financial resources allow, DOT is strongly recommended for:
    - Persons infected with LTBI/presumptive LTBI that are at risk for active disease (e.g., close contacts, immunocompromised persons, converters, etc.)
    - All children five to fifteen (5 – 14) years of age being treated for LTBI/presumptive LTBI
    - Any person being treated for LTBI/presumptive LTBI that has adherence problems
3. Each person (or legal guardian) on DOT should sign and have a copy of a DOT agreement.
4. DOT is considered to be given Monday through Friday except in the case of MDR-TB or XDR-TB. Only DOT doses are counted towards completion of treatment.
5. DOT provision sites: DOT can be carried out at any site mutually agreed upon by the patient and DOT provider
6. The standard *DOT Screening Questions* regarding TB symptoms, medication side effects and adverse reactions is to be completed at each DOT visit. The results are to be documented on the DOT sheet, in the appropriate computer system and communicated to the nurse.
7. Each dose is to be documented and counted on the DOT sheet, at the time of ingestion. Each dose is to be transferred to the electronic database (SendSS) in a timely manner if data entry resources allow.
8. Education should be provided to the patient at each visit.
9. The DOT worker is expected to be alert for information concerning any identified or unidentified contacts, early warning signs of adherence problems and possible relocation of the patient and to communicate this information to the TB Nurse Case Manager promptly.
10. Any missed DOT appointments will be brought to the attention of the TB Nurse Case Manager and will be dealt with promptly according to procedures.
11. Who can provide DOT
    - Supervised and trained licensed or non-licensed employees of local and regional health departments.
    - Any supervised and trained responsible person mutually agreed upon by the patient and the health department including (but not limited to) health care personnel, employers, school staff, clergy, staff of a drug treatment center, fireman or staff of a CBO.
    - Employees of institutions responsible for the TB care of their residents.
    - As a rule, DOT cannot be provided by a family member.

- For complex regimens including IV/IM medications or twice daily dosing, home care agencies may provide DOT or share responsibilities with the local health department.

12. Personnel without a nursing license are not allowed to pour medications from bottles, pour pills out of packets, crush pills, or mix pills with food or liquids. They are to support the patient in self preparation and self-administration of his/her own medications.
13. DOT providers are required to complete the orientation and education process outlined in the current Georgia Tuberculosis Program Policy and Procedure Manual. DOT training must be documented on the DOT Provider Agreement and kept at the clinic level. All DOT workers are to sign a Provider Agreement.
14. Supervisors or TB Nurse case managers will accompany DOT providers on field visits each quarter for quality assurance purposes.
15. All medications must be stored and delivered according to the current Georgia Tuberculosis Program Policy and Procedure Manual.
16. Case conferences between the DOT worker and the TB Nurse Case Manager should be held at least weekly to share information concerning the patient's care.

DIRECTLY OBSERVED THERAPY (DOT) EDUCATION

All training must be verified and documented. These documents are to be kept at the local level and are to be available to the state office upon request.

SECTION A: The public health employee or contractor whose **primary** duty is to provide DOT

1. Complete the current CDC Self Study Modules on Tuberculosis available online at http://www.cdc.gov/tb/pubs/ssmodules/default.htm. These modules can be completed either online or using hard copies. The Supervisor must verify completion of each module and assess knowledge retained.
    - Introduction to course # SS3035
    - Module 1: Transmission and Pathogenesis of Tuberculosis
    - Module 2: Epidemiology of Tuberculosis
    - Module 3: Targeted Testing and Diagnosis of Latent TB Infection and Tuberculosis Disease
    - Module 4: Treatment of Latent TB Infection and Tuberculosis Disease
    - Module 5: Infectiousness and Infection Control
    - Introduction to course #SS3036
    - Module 6: Contact Investigation for Tuberculosis
    - Module 7: Confidentiality in Tuberculosis Control
    - Module 8: Tuberculosis Surveillance and Case Management in Hospitals and Institutions
    - Module 9: Patient Adherence to Tuberculosis Treatment
2. Complete a DOT class provided by the state office, district or local personnel.
3. Demonstrate a skills check to include (but not limited to) the following:
    - Be issued and fit-tested for correct N-95 respirator. Describe when and how to replace issued masks.
    - Demonstrate the correct procedure for donning an N-95 Respirator.
    - Demonstrate correct procedure for a self-check of fit of an N-95 mask.
    - Describe when an N-95 respirator must be worn during a visit for DOT.
    - Identify an N-95 mask and a surgical mask.
    - Correctly name and identify each TB medication after visual inspection.
    - Correctly confirm the number of pills needed for the following dosages of each TB medication they will deliver:
        i. Isoniazid 300 mg; 900 mg
        ii. Rifampin 600 mg
        iii. Pyrazinamide 1000 mg; 1500 mg; 2000 mg; 3000 mg; 4000 mg
        iv. Ethambutol 800 mg; 1200 mg; 1600 mg; 2000 mg; 2800 mg; 4000 mg
        v. Pyridoxine (B6) 25 mg; 50 mg
    - Explain the difference between a medication side effect and an adverse reaction.

- Describe side effects of the medications and possible actions to take.
- Describe adverse reactions to the medications and actions to take.
- Identify when to call the TB Nurse Case Manager and how to reach him/her.
- Accurately and legibly complete a DOT sheet (form 3130 or comparable).
- Describe process of turning in DOT sheets and where they are to be kept.
- Be knowledgeable and able to provide basic education on the following "12 Points of Tuberculosis (TB) Patient Education":
    - Transmission of TB
    - Differences between LTBI and Active TB disease
    - Progression of LTBI to Active TB
    - Signs and symptoms of disease
    - Importance of HIV testing
    - Respiratory isolation and use of masks
    - Infectious period
    - Importance of chemotherapy as prescribed
    - Side effects and adverse medication reactions
    - Directly Observed Therapy
    - Importance of regular medical assessments
    - Importance of contact investigation

4. Complete a minimum of 2 weeks of observation in the field of a qualified DOT worker.
5. Complete a minimum of 2 weeks of performance in the field supervised by the DOT worker's supervisor.
6. Sign a DOT Provider Agreement.

SECTION B: The DOT worker who is not a public health employee or contractor, but is a mutually agreed upon person by the patient and the health department OR a public health employee whose regular job does not involve providing DOT, but who is acting as a lay DOT worker.

All training must be verified and documented. These documents are to be kept at the local level and are to be available to the state office upon request.

1. Attend a one-on-one educational session with the TB Nurse Case Manager or District TB Coordinator. Review the following:
    a. "12 Points of Tuberculosis (TB) Patient Education" handout.
    b. Review the specifics of case.
    c. Show the medications and dosages.
    d. Discuss the DOT Screening Questions Checklist and actions, side effects and adverse reactions, how to reach the TB Nurse Case Manager and when to seek help.
    e. Review, demonstrate and discuss the applicable skills needed from the following list:

- Be issued and fit-tested for correct N-95 respirator.
- Describe when and how to replace issued masks.
- Demonstrate the correct procedure for donning an N-95 Respirator.
- Demonstrate correct procedure for self-check of fit of an N-95 mask.
- Describe when an N-95 respirator must be worn during a visit for DOT.
- Identify an N-95 mask and a surgical mask.
- Correctly name and identify each TB medication after visual inspection.
- Correctly confirm the number of pills needed for the dosages of each TB medication they will deliver. Repeat this each time the medication changes.
- Explain the difference between a medication side effect and an adverse reaction.
- Describe side effects of the medications and possible actions to take.
- Describe adverse reactions to the medications and actions to take.
- Identify when to call the TB Nurse Case Manager and how to reach him/her.

f. Show how to document on the DOT sheet. Set up the process to turn in the sheets each month.

2. Arrange to have the DOT worker observe several DOT visits with the patient and then have the DOT worker perform the visits under supervision until all parties feel comfortable.
3. Discuss where and how the medications will be stored.
4. Have the DOT worker sign the DOT Provider Agreement and the DOT consent with the patient.
5. Complete the DOT Instruction Sheet and give to DOT Worker. Update as needed.
6. Allow plenty of time for questions and encourage questions.
7. Make sure the DOT Worker knows how to reach the TB Nurse Case Manager or designated person.

DIRECTLY OBSERVED THERAPY (DOT) PROCEDURE

Directly Observed Therapy (DOT) is the standard of care in Georgia to ensure an individual who has been prescribed medication for the treatment of active tuberculosis (TB) disease or latent TB infection (LTBI) completes the recommended course of drug therapy by taking all the medication.

GENERAL PROVISIONS

1. Responsibilities
    a. All anti-tuberculosis medications shall be issued pursuant to one of the following:
        - A prescription from a licensed practitioner authorized to prescribe
        - An order issued in conformity with a nurse protocol or job description. A registered professional nurse is only authorized to dispense pursuant to an order issued in conformity with a nurse protocol or job description, not a prescription or an order written on a chart or phoned in by a physician.
    b. The physician, pharmacist or RN working under protocol is responsible for assuring each medication is dispensed according to state pharmacy law and Nurse Protocols Drug Dispensing Procedures. The nurse in charge of medications or the TB Nurse Case Manager is to verify that the medications match the medication orders, that there is adequate medication for each dose, place all of the patient's medication bottles into one bag labeled with the patient's name and date of birth, keep a log of medications distributed to the DOT provider, inform the DOT provider of any changes in medications and to coordinate with the DOT provider to assure proper delivery to the right patient on the right schedule. The TB Nurse Case Manager will assess the need for the patient's isolation and inform the DOT Provider regarding the need of using an N95 mask during DOT visits.
    c. The DOT provider, acting as an agent of the patient, is to obtain the patient's medications from the nurse according to local health department policies and procedures and to transport the medications to the correct patient. Each time DOT is provided, the observer should verify that the right medications are delivered to the right patient in the right amount. If this cannot be confirmed, do not give the medication and notify the TB Nurse Case Manager. The DOT provider is to observe and support the patient in the self-administration of his/her medication, maintain required documentation and communicate all observations, issues or information obtained to the TB Nurse Case Manager or Physician.

2. Storage and handling of medications
    a. All medications are to be stored in a secured area (under lock and key when not in actual use). A complete and accurate record of all drugs on

hand, received, dispensed, issued, removed or otherwise disposed of is to be kept in accordance with the record-keeping requirements of the Board of Pharmacy. All records pertaining to drug accountability (from order and receipt of drug to actual patient administration) must be kept on file and available for inspection.

b. All drugs shall be stored in designated areas within the facility that are sufficient to insure the proper sanitation, temperature, light, ventilation, moisture control, segregation and security. These conditions must also be considered when drugs are being transported. Medications kept in a car during DOT will not be in direct sunlight or visible from windows. The car doors are to be locked when medications are present. No medications can be stored in a car over 8 hours.

3. DOT Counseling and Education
    a. The TB Nurse Case Manager will provide the initial explanations of DOT, TB treatment and the "12 Points of Tuberculosis (TB) Patient Education":

- Transmission of TB
- Differences between LTBI and Active TB disease
- Progression of LTBI to Active TB
- Signs and symptoms of disease
- Importance of HIV testing
- Respiratory Isolation and use of masks
- Infectious period
- Importance of chemotherapy as prescribed
- Side effects and adverse medication reactions
- Directly Observed Therapy
- Importance of regular medical assessments
- Importance of contact investigation

    b. The DOT provider will reinforce the counseling and education provided by the TB Nurse Case Manager and physician. The DOT provider will establish rapport with patient and encourage the exchange of information. He/she should learn as much as possible about the patient's beliefs and attitudes about TB, sources of social support and barriers to treatment. The DOT worker has the opportunity to make a genuine contribution not only to the patient's physical health but also his or her well-being. Frequently, the DOT worker will identify social service or personal needs that could interfere with completion of treatment. Helping the patient resolve these problems not only helps achieve program outcomes but it also helps the patient find the assistance needed with their problems. The DOT worker is expected to be alert for information concerning any identified or unidentified contacts, early warning signs of adherence problems and possible relocation of the patient and to communicate this information to the TB Nurse Case Manager promptly.

4. Documentation
    a. DOT visits are to be documented completely on the DOT sheet daily.
    b. DOT may be required to be documented in each health department computer system according to local policy.

c. DOT visits may be documented in the SendSS DOT calendar.
d. Anything out of the ordinary (additional contact identification, social circumstances, emotional status, adverse reactions to medications, etc.) are to be documented in the patient's chart daily and are to be verbally reported to the TB Nurse Case Manager upon return to clinic after visit.

5. Missed Appointments
    a. The DOT worker and the patient negotiate dates, places, and times for DOT services to be provided, and both sign a document stating such agreements. In the event that either the patient or the DOT worker is unable to keep the appointment, they should call the other party and arrange for an alternative date and time. Unavoidable missed appointments will be handled according to the Treatment Interruption guidelines listed later in this chapter.
    b. Any missed DOT appointments will be brought to the attention of the TB Nurse Case Manager and will be dealt with promptly.
    c. These steps will be followed until DOT has been reinstituted. Document efforts and results of those efforts daily. Verbally discuss with the TB Nurse Case Manager on a daily basis.
        - On the day of the missed appointment, the DOT worker will call all known telephone numbers for the patient. If unsuccessful, the DOT worker will go to the patient's house at the end of his/her work day to see if contact can be made.
        - On the second day, in addition to efforts stated above, telephone calls will be made to all known emergency contacts, employer and friends of the patient. Leave a note in a plain, sealed envelope with the patient's name on it. The note should only contain a short message such as "John, Missed you yesterday. Call me at 555-555-5555. Thanks. Mary." Slide the note under the door if possible. Do a community search of known hangouts, neighbors and friends.
        - On the third day, in addition to the efforts stated above, a certified letter should be sent to the patient's home. A team conference should be held to decide what steps should be taken from this point, including legal action.

6. Confidentiality
    a. The DOT provider must demonstrate understanding of patient confidentiality laws and observe them at all times.
    b. Any patient information or record will be kept in a file or folder except when in use.
    c. When performing a community search, do not give out information or explain why you are looking for a particular person. Just ask them "If you see Jim, please ask him to Call Mary."
    d. Written communication left at a patient's home due to a missed appointment should be in a plain, sealed envelope with the patient's name on the outside. Inside provide only minimal information such as "John, Missed you today. Call Mary at 555-555-5555."

7. Incentives and Enablers
    a. Definitions and examples
        - Incentives are small rewards given to patients to encourage them to take their medication, keep DOT and clinic appointments and to complete treatment. Examples are restaurant or grocery gift cards, clothing or personal products, books, snacks or visiting time by the DOT worker.
        - Enablers are things that make it possible or easier for the patients to receive treatment by overcoming barriers. Examples are gas vouchers, bus tokens, cab fare, transportation, interpretation services and timing of DOT or clinic visits.
    b. Incentives and Enablers should be individualized according to the patient's needs. Discussion by the team members during team conferences may be needed to identify pertinent incentives for each patient.
    c. Be aware of local, district, state and national resources that are available.
    d. Follow local procedures to obtain and maintain accountability of each incentive or enabler.

PROCEDURE

1. Obtain the medication bag for each patient from the TB Nurse Case Manager or Medication Nurse. Look at each bottle inside the bag to verify that the name matches the name on the outside of the bag and that there is enough medication to cover the day's dosage. Don't borrow medications from other patient's bottles. Tell the nurse if medications are needed. Make sure DOT sheet, form #3130-R has the right patient's name on it and is in the right medication bag. Place all labeled medication bags in a carrying container.
2. Obtain information regarding isolation and the need for masks for each patient from the TB Nurse Case Manager. Make sure you have your N95 mask and a supply of surgical masks for the patients, if needed for clinic appointments.
3. Provide the clinic with an itinerary of your DOT visits for the day before leaving the clinic. Observe field safety rules. Follow local procedures for maintaining contact throughout the day.
4. Place the carrying container in your car where the medications are not visible from the windows. Place them in the cooler section of the car out of direct sunlight. During the summer keep the air conditioner on. Never put medication in the trunk. Follow local procedures to insure the proper sanitation, temperature, light, ventilation, moisture control, segregation and security. Lock the car doors whenever you exit the vehicle.
5. When you arrive at the DOT site, greet the person. Verify the identity of the patient and that you have the right medication for that patient.
6. Put on N95 mask, if needed.
7. Ask the patient how he/she is doing. Administer the *DOT Screening Questions Checklist* and take actions as indicated. If you identify any adverse reaction, hold the medication and immediately call the TB Nurse Case Manager. If you are the

RN, assess the patient, hold the medication and call your District contract physician. Document on the DOT sheet (form #3130-R).

8. If no adverse reactions are reported, proceed with the DOT visit. Make sure the patient has something to drink and a snack if needed. Give the patient the medication bag with all the medication bottles in them.
9. Observe the patient taking the pills from each bottle and verify he/she has the correct number of pills for each medication. Once the patient has removed the pills from the bottles, maintain visual contact with the pills. Avoid the patient leaving your sight, answering the phone, picking up a child or clothing.
10. Watch the patient take and swallow the medication. Make sure the patient actually swallows the medication and does not "cheek" it or hide the pills in his/her hand, clothing or furniture. Do not leave the pills with the patient to take at a later time. The first line anti-TB medications should be taken together as a single oral dose rather than divided doses. This leads to a higher and potentially more effective peak serum concentration. It is preferable for the medications to be taken on an empty stomach if tolerated. However, if the patient experiences epigastric distress or nausea when taking the medication, dosing with a snack or food is recommended. If the patient (or child) cannot swallow the pills, he/she (or parent) can crush the pills and empty the capsules into one or two teaspoons of non-sugary liquid or food. Follow with the ingestion of non-medicated food or liquid.
11. It is recommended that the DOT Provider remain with the patient at least 5 minutes after the medication has been ingested, to assure that there is no regurgitation of the medication. During this time, build rapport and trust with the patient by engaging in interaction. Listen and try to understand the patient's knowledge, beliefs, and feelings about TB disease and treatment. Adopt and reflect a nonjudgmental attitude about behaviors that the patient may participate in that you may not agree with (e.g., drug use). Identify potential barriers to adherence and involve the patient in identifying possible solutions. Note any items or ideas that could be used as incentives or enablers for your patient.
12. Reinforce TB education from the "12 Points of Tuberculosis (TB) Patient Education" and answer any questions the patient has regarding the disease or treatment. Prepare the patient for the next step in treatment.

The 12 Points of Tuberculosis (TB) Patient Education:

- Transmission of TB
- Differences between LTBI and Active TB disease
- Progression of LTBI to Active TB
- Signs and symptoms of disease
- Importance of HIV testing
- Respiratory Isolation and use of masks
- Infectious period
- Importance of chemotherapy as prescribed
- Side effects and adverse medication reactions
- Directly Observed Therapy
- Importance of regular medical assessments
- Importance of contact investigation

13. The DOT worker is expected to be alert for information concerning anything out of the ordinary (additional contact identification, social circumstances, and

emotional status) and to communicate this information to the TB Nurse Case Manager promptly. For example, in casual conversation the patient may mention participating in a hobby at a previously undisclosed location. The DOT worker could probe a little bit and find out when the last time the patient participated in the hobby and which friends were there. It would be important to relay this information to the TB Nurse Case Manager for follow-up in the contact investigation.

14. After the patient has completed taking all of his/her medication, have the patient initial on the DOT sheet (form #3130-R) and place your initials beside them.
15. Have the patient put the medication bottles back into his medication bag and hand it to you. Place the completed DOT sheet in the bag with the patient's medications.
16. Confirm the next DOT appointment, the next clinic appointment and transportation to the clinic. Answer any questions or concerns of the patient.
17. Offer words of support and encouragement to the patient for his/her involvement in treatment and getting better. Offer any incentive or enabler and thank the patient for the visit.
18. Take the medication bag with you and leave the DOT site.
19. Return to your vehicle and complete any notes and documentation about the DOT visit and observations made.
20. Place the notes and DOT sheet in the patient's medication bag and place bag into carrying container.
21. When you get back to the clinic, return the medications to designated person in designated area. DO NOT KEEP IN CAR. Place DOT sheets in designated place.
22. Communicate with the TB Nurse Case Manager about the patients you observed today. Coordinate any new interventions or strategies with the TB team.
23. Complete any computer documentation or other patient record documentation.

DIRECTLY OBSERVED THERAPY (DOT) PROVIDER AGREEMENT

I, _____ agree to provide DOT for the treatment of tuberculosis (TB) patients for 6 – 9 months in order to help prevent further transmission of infection and disease and prevent development of drug resistance. I understand that I will support and observe the client with the self-administration of his/her medication. I will act as the patient's agent to transport his/her medication that has been prescribed and dispensed according to Georgia law.

1. I will keep information obtained or learned confidential among the patient, myself and the health care team.
2. I will deliver the prescribed, pre-packaged medication on the days and times agreed upon in the DOT agreement signed by the patient and myself.
3. I understand DOT is the act of providing the anti-tuberculosis medication directly to the patient for self-administration and observing him or her swallow the medication(s) as prescribed for the treatment of TB or LTBI. DOT does **not** entail dispensing, administering, pouring or altering any medication.
4. Prior to observing the patient take his/her medication, I will ask the questions on the *DOT Screening Questions Checklist* at each visit and will follow the actions to take. If I am unsure of further actions, I will contact the TB Nurse Case Manager.
5. I will watch the patient swallow all of the prescribed medication.
6. I will document the visit on the DOT Sheet.
7. I will store and transport all medications according to the current Drug Dispensing Protocol.
8. I will immediately report to the nurse or physician immediately any missed doses or anything out of the ordinary observed during each visit.
9. I will be alert for information concerning any identified or unidentified contacts, early warning signs of adherence problems and possible relocation of the patient and communicate this information to the TB Nurse Case Manager promptly.
10. Other_____
    _____

This agreement acknowledges that _____ has completed a DOT

Training session conducted by _____ on _____.

There have been _____ field visits supervised by _____.

DOT Provider_____ Date _____

Supervisor_____ Date _____

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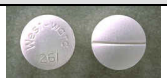
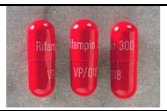
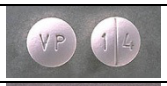
DOT INSTRUCTION SHEET

Date medication started _____

	Name	Address	Main phone	Cell phone
Patient				
DOT Worker				
TB Nurse Case Manager				

Medications:

Medication name and dosage	Picture of medication	Number of Pills to take	Number of Days / week
Isoniazid _____ mg			
Rifampin _____ mg			
Pyrazinamide _____ mg			
Ethambutol _____ mg			
Pyridoxine (B6) _____ mg			

DOT Days (circle): Monday Tuesday Wednesday Thursday Friday

DOT Time: _____ Mask Needed? No ☐ Yes ☐

DOT Location: _____

DOT Documentation Sheet ☐ **DOT Screening Questions** ☐ **Medications** ☐

Check in with nurse (day and time): _____ **Phone**: _____

Next Clinic appointment for client: _____

Additional Instructions:

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DOT SCREENING QUESTIONS CHECKLIST

A. TB Symptoms

1. "Are you experiencing coughing, coughing up blood, tiredness or fatigue, chest pain, fever, chills or night sweats?" If the answer is yes, ask "Has it gotten better since starting your medication?"

Action: → TB Symptoms should get better after being on medication for 2 – 3 weeks. Notify TB Nurse Case Manager if symptoms do not get better or if they come back after having been resolved.

B. Side effects – Some side effects are expected to occur in some people.

1. Do you experience nausea when taking your medication? If yes, ask "Does it get better after you eat or later in the day?"

Action: → Should resolve with time and supportive measures. Suggest the patient try taking the medication with a snack or food. Notify the TB Nurse Case Manager.
If it does not resolve or if it escalates into vomiting, ***immediately*** notify the TB Nurse Case Manager.

2. What color is your urine?

If answers "orange/red" this is an expected side effect of Rifampin. Action: → Let patient take medication.

If answers "dark, maple syrup colored or coffee colored" – this could be an adverse reaction.
Action: → DO NOT GIVE MEDICATION! Call the TB Nurse Case Manager ***immediately*** for instructions.

C. Adverse Reactions – May indicate toxicity.

Do you have any of the following symptoms now or since the last time you saw your nurse or doctor?

1. Nausea, vomiting, abdominal pain, coffee colored urine, jaundice (yellowing of eyes or skin), fatigue, loss of appetite or flu-like symptoms
2. Skin rash, tingling in extremities
3. Changes in hearing or changes in vision
4. Bleeding problems, joint pain
5. Unsteady when walking, behavioral changes, headache

Action: → DO NOT GIVE MEDICATION! Call the TB Nurse Case Manager ***immediately*** for instructions.

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Directly Observed Therapy (DOT)
QA/QI Field Visit

Date _____

Name of DOT Worker _____

	Excellent	Acceptable	Needs Improvement
Consistent and proper use of verification processes			
Prioritized field visits geographically			
Organization of medications, records and supplies			
Itinerary completed and left at clinic			
Storage and transport of medications			
Observes field safety and personal safety			
Maintains patient's confidentiality			
Verifies patient's identity matches medication bag			
Establishes rapport with patient			
Communicates at patient's level of understanding			
Gives factual information			
Uses "DOT Screening Questions Checklist" appropriately			
Ensures patient has drink before handing medication			
Observes and verifies the patient taking the correct number of pills from each bottle			
Watches the patient swallow all pills and is alert for tricks			
Has patient initial DOT sheet and completes documentation			
Remains with patient at least 5 minutes after ingestion			
Reflects a non-judgmental attitude			
Asks open-ended questions			
Recognizes problems communicated by patient			
Effectively elicits information from patient			
Recognizes discrepancies in previous responses			
Picks up on clues from patient and probes appropriately			
Re-enforces patient education			
Acknowledges barriers and works with patient to resolve			
Offers support and encouragement to patient			
Confirms and prepares patient for next step/visit			

Leaves patient with positive motivation			
Stores and transports medications appropriately			
Observes field safety and personal safety			
Maintains patient's confidentiality			
Returns medications to designated place and person			
Communicates with TB Nurse Manager about observations made today			
Completes necessary documentation			

SUMMARY and FEEDBACK:

FOLLOW-UP PLAN:

Signature of DOT Worker _____ Date_____

Signature of Reviewer _____ Date_____

DOSE COUNTING

Dose counting is a method to count and document TB medication doses. It is helpful in determining if a patient is on track to complete treatment within the recommended time frame and it aids in determining when a patient has completed treatment. Dose counting to determine completion of treatment is only definitive when the patient is on Regimen 1 or Regimen 2. These are the only treatment regimens allowed under nurse protocol. All other regimens require the contract physician's clinical judgment to determine when treatment is complete. Dose count for the month and dose count to date should be placed on each DOT sheet as it is completed.

Weekend self-administered medications do not count in the final dose tally. Self-administered doses during short vacations and out of town trips do not count in the final tally.

Weekly and intermittent dosing can be counted together. Five (5) weekly doses equal two (2) twice weekly doses equal three (3) thrice weekly doses. Convert weekly and intermittent doses to follow the guidelines below.

The initial phase of treatment is counted first to determine completion of the intensive period of treatment. This count must be complete before moving on to the continuation phase of treatment. Ethambutol doses do not need to be counted and the Ethambutol may be dropped from the regimen as soon as the drug susceptibilities show no resistance.

Regimen 1	Regimen 2
Initial phase • (INH + RIF + PZA + EMB) 5 days/week • 40 doses over 8 weeks • Should be completed within 3 months	Initial phase • (INH + RIF + PZA + EMB) 5 days/week • 10 doses for 2 weeks **PLUS** • (INH + RIF + PZA + EMB) 2 days/week • 12 doses over 6 weeks • should be completed within 3 months
Continuation phase (INH + RIF) 2 days/week X 36 doses over 18 weeks should be completed within 9 months	Continuation phase (INH + RIF) 2 days/week X 36 doses over 18 weeks should be completed within 9 months

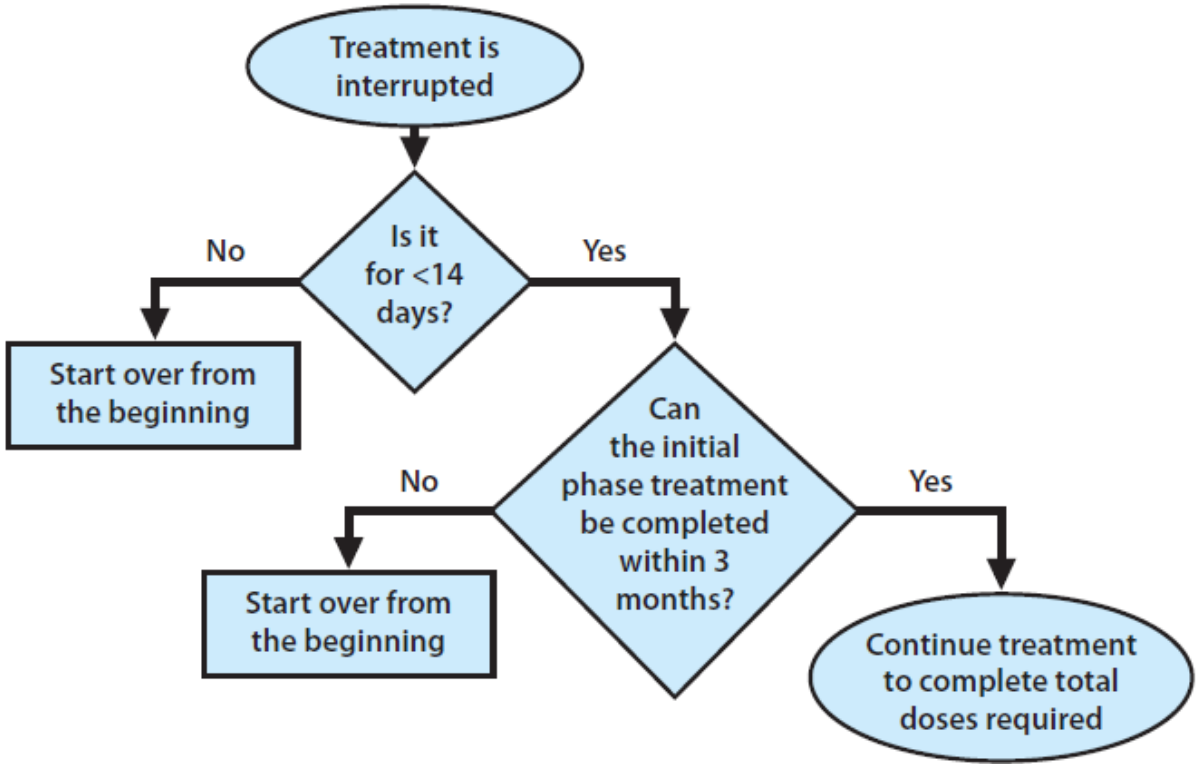
INTERRUPTIONS IN TREATMENT

Interruptions in treatment can lengthen the time of treatment or may cause the patient to have to start treatment over.

INITIAL PHASE

The initial phase of treatment is considered the first two months when the patient is receiving four medications. During this intensive time, If the interruption lasts more than 14 days, the patient must start treatment over. If it is less, then time must be added to the treatment to assure the correct number of doses for the initial phase.

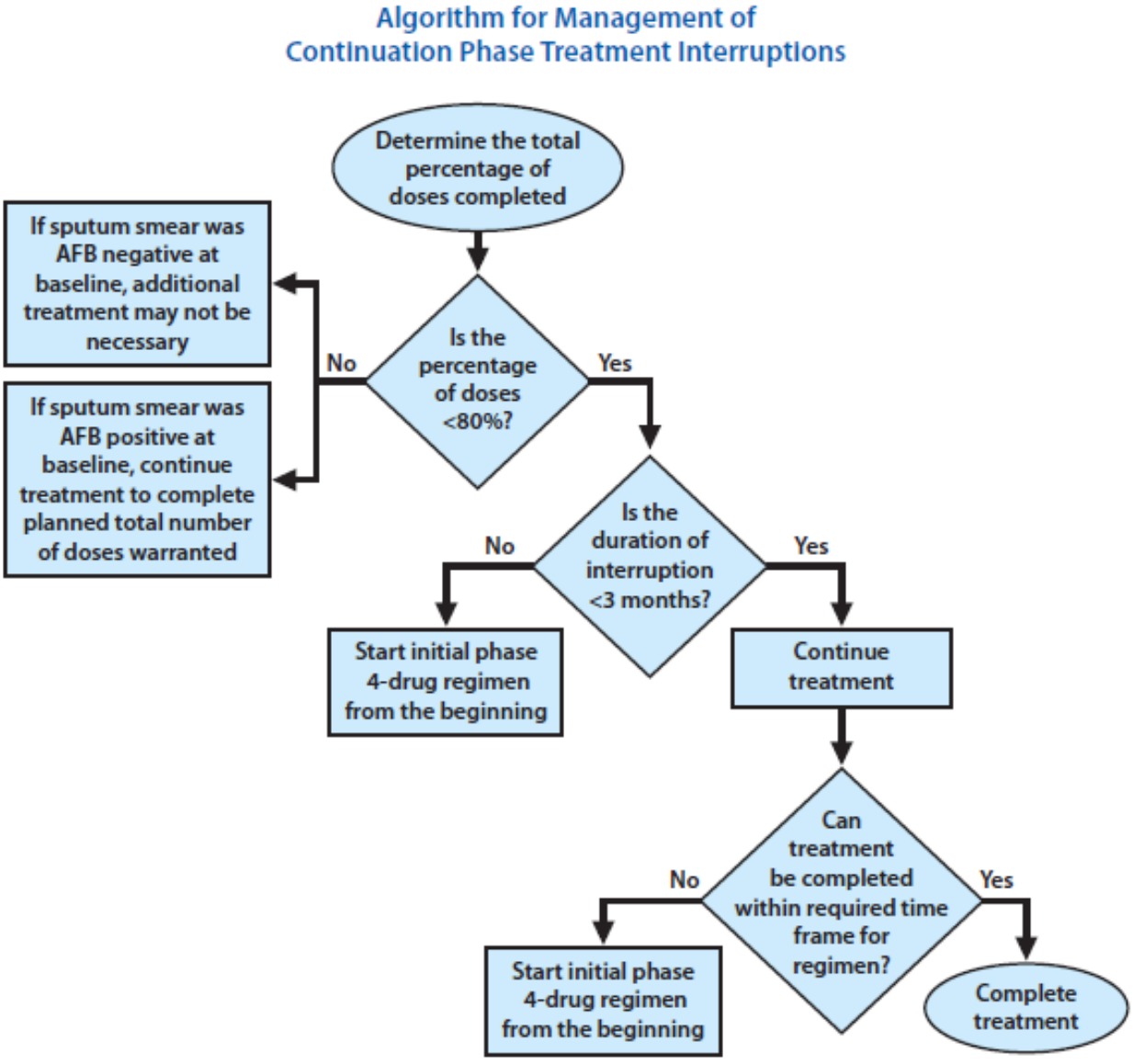
Algorithm for Management of Initial Phase Treatment Interruptions



CONTINUATION PHASE

The continuation phase is after the patient completes the intensive portion of treatment and the drug susceptibilities are known. During this time, if the interruption is more than three months, the patient will have to start treatment over. If it is less than three

months, then time will have to be added to the treatment to assure the correct numbers of doses are taken to complete treatment.



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6. Contact Investigation

Table of Contents

DEFINITIONS AND BACKGROUND

Contact investigations serve as an important means of preventing further TB transmission. The evaluation of contacts of cases of infectious TB is one of the most productive methods of identifying adults and children with LTBI who are at high risk for progression to TB disease and persons already in the early stages of TB disease.

The TB cases we have identified are just the tip of the iceberg. Each infected person is what lies underneath the surface, waiting to emerge and become our next case. Every single TB case began as someone's contact. On average, 10 contacts are identified for each person with infectious TB in the U.S.; 20-30 percent of contacts have latent TB infection and one percent of contacts have active TB disease. Of those contacts who develop disease, approximately one-half will do so within the first two years after exposure.

Below are common terms used during contact investigations:

Suspect	A person believed to have active TB disease, but has not been confirmed to have TB disease
Case	A person diagnosed with active TB disease
Index patient	The first TB suspect or active TB case reported to the health department around whom a contact investigation is done
Source Case	The person who infected another person with *M. tuberculosis*; this may be referenced when a child less than age five is reported to the health department and a source case investigation is done to look for the person who infected the child
Secondary Case	Any additional suspects or cases found during the course of a contact investigation
Exposure	The condition of being vulnerable or susceptible to infection due to proximity to an infectious person; not every person who is exposed to TB becomes infected with TB
Infectious period	Time frame when exposure may have occurred. Starts three months prior to TB diagnosis or onset of symptoms
Contact	A person who has been exposed to an infectious case of TB
Elicitation	The naming and identifying of a person who has been exposed

Evaluation	Complete evaluation for a contact consists of: a symptom screen, an initial tuberculin skin test (TST)/IGRA, a follow-up TST/IGRA 8-10 weeks later if initial TST/IGRA is negative, and a chest x-ray (CXR) after any positive reaction of 5 mm or more
TST/IGRA	Tuberculin skin test /Interferon-Gamma Relay Assay; these are tests to determine if a person has become infected with *M. tb*
NAAT	Nucleic Acid Amplification Test; a rapid test to determine whether *M. tb* is present in a specimen

The national goals for contact investigation are below, along with Georgia's targets:

1. **Contact Elicitation** = Increase the proportion of TB patients with positive acid-fast bacillus (AFB) sputum-smear results who have contacts elicited to 100.0%. State target = 95%.
2. **Contact Evaluation** = Increase the proportion of contacts to sputum AFB smear-positive TB patients who are evaluated for infection and disease to 93.0%. State target = 80%
3. **Treatment Initiation** = Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) who start treatment to 88.0%. State target = 80%
4. **Treatment Completion** = For contacts to sputum AFB smear-positive TB patients who start treatment for newly diagnosed LTBI, increase the proportion that complete treatment to 79.0%. State target = 75%

While there are specific steps in a contact investigation, information is obtained at inconsistent rates which may alter the sequence of events; however, all steps will be covered in a complete investigation. The steps are as follows:

1. Medical record review (Pre-interview preparation)
2. Index patient interviews
3. Field investigation
4. Risk assessment for *M. tuberculosis* transmission
5. Identification of priority contacts
6. Evaluation of contacts
7. Treatment and follow-up of contacts
8. Determining the need to expand the investigation
9. Evaluation of contact investigation activities

For in depth information about each step, refer to the following resources:

CDC's "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis" at http://www.cdc.gov/tb/publications/guidelines/ContactInvestigations.htm.

NTNC's *Tuberculosis Nursing: A Comprehensive Guide to Patient Care"* located in each health department.

CDC's *Self Study Modules*, "Module 6: Contact Investigation" at http://www.cdc.gov/tb/education/ssmodules/default.htm

A contact investigation plan is a work in progress and will change as more information is obtained.

Who needs a contact investigation plan?

- Children less than five years old with LTBI
- Clients with extrapulmonary TB
- Clients with active TB disease

CHILDREN LESS THAN AGE FIVE WITH LTBI

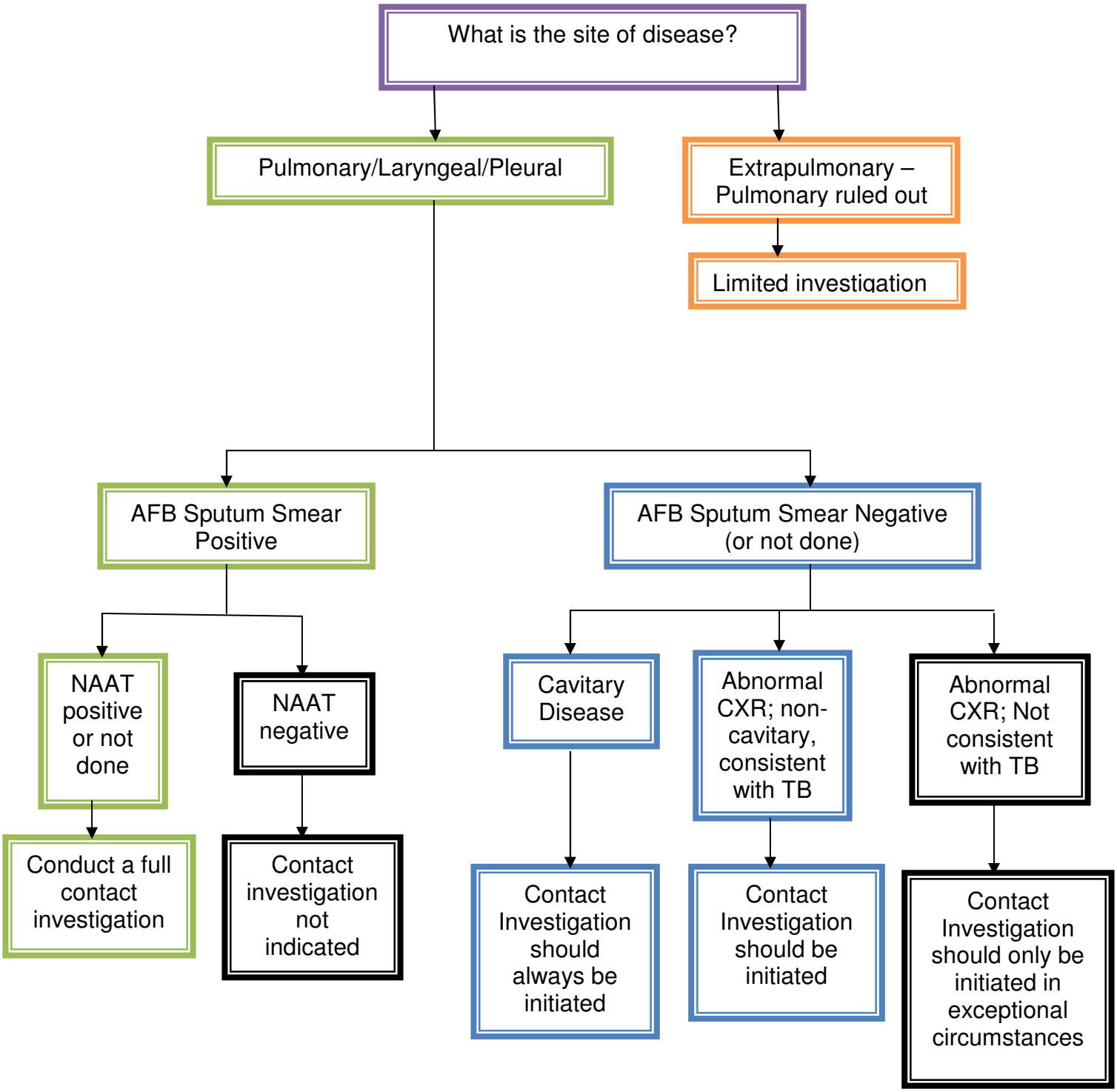
In Georgia, LTBI in children younger than five years old is reportable to public health authorities. Health departments must conduct a source case investigation, which entails looking for the person who may have infected the child. We know that infection had to be fairly recent (within the child's life). Most often, the child is infected by a household member. A contact investigation for these children should be completed within a week in order to prevent further transmission of TB. The investigation consists of inquiring of the parents about any caretaker or family member who has signs and symptoms of TB and to placing and reading one TST/IGRA on each household member. A positive IGRA or a TST result of 5 mm or more is followed with a chest x-ray (CXR). If the CXR is normal or negative, then the initiation and completion of LTBI treatment is encouraged.

PATIENTS WITH EXTRAPULMONARY TB

TB patients that do not have pulmonary, laryngeal, or pleural disease are considered to have extrapulmonary TB and are not infectious; however, sometimes a person will have pulmonary TB along with extrapulmonary TB. Pulmonary TB must be ruled out by collecting three diagnostic sputum specimens and performing a CXR. A limited contact investigation should be done within 30 days. This investigation consists of asking the patient if they have a household member with signs and symptoms of TB. If not, no further action is needed. If a household member is identified with signs and symptoms of TB, that person should be completely evaluated for TB. The household members would then receive one TST/IGRA. A positive IGRA or a TST result of 5 mm or more is followed with a chest x-ray (CXR). If the CXR is normal or negative, then treatment initiation for LTBI and treatment completion is encouraged.

PATIENTS WITH ACTIVE TB DISEASE

Clients with active TB disease will have the most comprehensive contact investigations. The first question to be answered is "What is the site of the disease?"



Indications that a patient is infectious include the following:

- Symptoms of TB (cough that lasts three weeks or longer, fever, weight loss, night sweats, coughing up blood, weakness or fatigue)
- A positive AFB Sputum Smear
- A positive NAAT
- Cavitary disease
- An abnormal CXR consistent with TB

Once a contact investigation is initiated, certain time frames must be met.

Activity	Suspects with indications of infectiousness	Suspects without indications of infectiousness
First Index Patient Interview Interview the index patient in person within this number of days following notification	≤ 1 Working day from notification	≤ 3 Working days from notification
Residence Visit Visit the place of residence of the index patient within this number of days following the first index patient interview	≤ 3 Working days after the first interview	3 working days after the first interview
Field Investigation Visit all potential settings for transmission (school, work, church, leisure, etc) within this number of days following the initiation of the contact investigation	5 Working days after the start of the investigation	5 Working days after the start of the investigation
Index Patient Re-interviews Re-interview the index patient one or more times for clarification and additional information within this number of weeks after the first interview	1 or 2 Weeks after the first interview	1 or 2 Weeks after the first interview

Source: Centers for Disease Control and Prevention, National Tuberculosis Controllers Association. Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC. MMWR 2005:54(No. RR-15):7-8.

For additional information on interviewing the index patient, please see the following resources:

TB Interviewing for Contact Investigation: A Practical Resource for the Healthcare Worker (New Jersey Medical School Global Tuberculosis Institute Web site; at http://www.umdnj.edu/globaltb/tbcontrol.htm

Effective TB Interviewing for Contact Investigation: Self-Study Modules. CDC http://www.cdc.gov/tb/publications/guidestoolkits/Interviewing/default.htm

CONTACT PRIORITY

The following is adapted from NTCA/NTNC *Tuberculosis Nursing: A Comprehensive Guide to Patient Care*, Appendix III, Priority of Exposed Contacts (Washington State):

Contacts are classified into three groups (High, Medium, Low) according to the priority of their need for follow-up. Priorities may change as you learn more information about the case and/or the contact and/or the environment.

Remember: No matter what their category, always prioritize the follow up of contacts. First address the persons who are considered a medical risk. These are defined as those who are at particularly high risk of developing TB disease once infected with *M. tuberculosis*. These contacts include the following in Georgia:

- Immunosuppressed, e.g., HIV infection, prolonged corticosteroid therapy, organ transplant, TNF blockers
- Less than age five
- Have diabetes mellitus, silicosis, end stage renal disease, gastrectomy, jejunoileal bypass, leukemia, lymphoma or cancer of the head or neck.

An initial encounter needs to be made with each identified contact in order to assess the person for signs and symptoms of tuberculosis.

EXPOSURE CATEGORY 1

The County Health Department (CHD) should focus on the highest priority contacts:

- Those exposed to persons with acid-fast bacilli (AFB) sputum smear positive or cavitary tuberculosis.

Contacts to these cases are categorized as follows:

(High) = Case is sputum smear positive or cavitary chest x-ray and contact is:

1. A household member
2. Less than 5 years of age
3. Has medical risk factors (i.e., HIV)
4. Was exposed during a medical procedure (i.e., bronchoscopy)
5. Was exposed in a congregate setting
6. Exceeds duration environment limits

(Medium) = Case is sputum smear positive or cavitary chest x-ray and contact is:

1. 5 - 15 years of age
2. Exceeds duration environment limits

(Low) = Case is sputum smear positive or cavitary chest x-ray and contact is:

1. All other contacts that do not fall under the preceding categories (e.g. individual visiting outdoors once or twice a week during the infectious period)

Category 1 Time Frames for Contact Evaluation and Treatment Initiation				
Priority	**Working Days from listing of a Contact to Initial Encounter**	**Working Days from Initial Encounter to Completion of Initial Medical Evaluation**	**Considered for Presumptive LTBI treatment during window period**	**Working Days from completion of Medical evaluation to treatment initiation**
High Priority without medical risk	3 Working Days after being listed as a contact	5 Working Days	No	10 Working Days
High Priority with a medical risk or age less than 5 years	3 Working Days after being listed as a contact	5 Working Days	Yes	Continue treatment for a full course if infected.
Medium Priority	3 Working Days after being listed as a contact	10 Working Days	No	10 Working Days
Low Priority	10 Working days after being listed as a contact	30 Calendar Days	No	10 Working Days

EXPOSURE CATEGORY 2

- Those exposed to persons with acid-fast bacilli (AFB) sputum smear negative tuberculosis or,
- Those exposed to persons suspected of having TB disease due to an abnormal chest x-ray that is consistent with TB disease.

AFB Sputum Smear Negative (or not done)

Abnormal CXR; non-cavitary, consistent with TB

Contacts to these cases are categorized as follows:
(High) = Case is sputum smear negative and contact is:

1. Less than 5 years of age
2. Has medical risk factors (e.g., HIV)
3. Was exposed during a medical procedure (e.g., bronchoscopy)

(Medium) = Case is sputum smear negative and contact is:

1. A household member
2. Was exposed in a congregate setting
3. Exceeds duration environment limits

(Low) = Case is sputum smear negative and contact is:

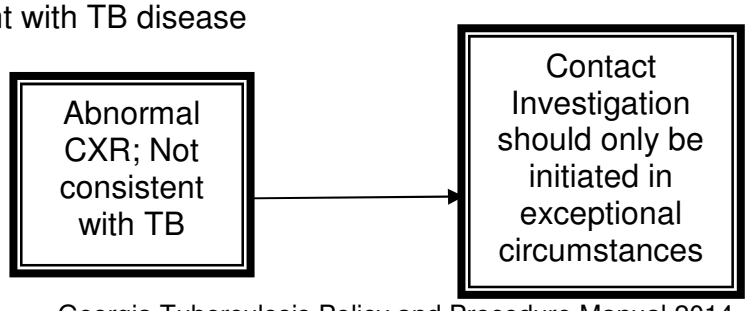
1. All other contacts that do not fall under the preceding categories

Category 2 Time Frames for Contact Evaluation and Treatment Initiation				
Priority	**Working Days from listing of a Contact to Initial Encounter**	**Working Days from Initial Encounter to Completion of Initial Medical Evaluation**	**Considered for Presumptive LTBI treatment during window period**	**Working Days from completion of Medical evaluation to treatment initiation**
High Priority without medical risk	3 Working Days after being listed as a contact	10 Working Days	No	10 Working Days
High Priority with a medical risk or age less than 5 years	3 Working Days after being listed as a contact	10 Working Days	Yes	Continue treatment for a full course if infected.
Medium Priority	3 Working Days after being listed as a contact	10 Working Days	No	10 Working Days
Low Priority	10 Working days after being listed as a contact	May consider waiting until 8 weeks after last exposure to perform TST/IGRA	No	

EXPOSURE CATEGORY 3

The CHD should provide follow up on these contacts according to resource availability (time, staff, etc.)

- Those exposed to persons with suspected TB with abnormal chest x-rays not consistent with TB disease



CONTACT EVALUATION

The evaluation of a contact is much more than simply administering a tuberculin skin test. The contact must be completely evaluated based on good decision making and best practices. The following format for the evaluation and monitoring of TB patients is used to be consistent within this document. This format can assist the nurse in charting and in determination of correct CPT evaluation and management codes.

CHIEF COMPLAINT
HISTORY OF PRESENT COMPLAINT
PERTINENT HISTORY
REVIEW OF SYSTEMS
PHYSICAL EXAMINATION
DECISION MAKING
COUNSELING / CARE COORDINATION / EDUCATION
TESTS AND PROCEDURES
EVALUATION AND MANAGEMENT LEVEL

CHIEF COMPLAINT

Patient has been exposed to an active TB case. This person may be a named contact by the index case or may be discovered during the course of the investigation. Not everyone who is exposed to an active case of TB becomes infected or progresses to disease.

HISTORY OF PRESENT COMPLAINT

It is important to gather a pertinent history from contact/patient to perform a thorough evaluation, but it will also aid in conducting a thorough contact investigation.

CONTACT TO A CASE
When eliciting the details about the exposure, document all of the following:

- Location and environment of the exposure – Where did the exposure take place? Was it at school or work? If so, document the name of the workplace or school and describe the exact location of the exposure. Describe the environment.
- Amount of time spent with TB case – How much time is spent with the TB Case?
- Frequency of time spent with TB case – How often do the contact and the TB Case spend time together? Is it every day, once a week?
- Physical space between contact and TB case – What is the physical proximity of the contact and the TB Case? Six inches? 20 feet?

For example, “Ms. Smith and the TB Case share a 45 minute lunch break together in the ABC company break room. The break room is a 12 foot by 14 foot room with one

table which seats 10 people. Ms. Smith states she sat at the same table with the TB case approximately 18 inches apart. They would eat lunch together at least 4 days a week."

PREVIOUS TB HISTORY
It is very important to know if the contact/patient has ever been diagnosed with active TB disease or latent TB infection before because this will impact how he/she is evaluated for this exposure. Document dates of diagnosis or testing, location where the diagnosis or testing took place and what treatment was offered or completed.

Also document date, and location of any BCG vaccination given to the patient.

PERTINENT MEDICAL HISTORY
It is necessary to determine if there is any medical history or condition that may indicate the contact would be at a high risk of progression to TB disease if infected with TB. Document the history of any of the following:

- HIV infection*
- Prolonged corticosteroid therapy
- Organ transplant
- Tumor necrosis factor (TNF) blockers
- Diabetes mellitus
- Silicosis
- End stage renal disease
- Gastrectomy
- Jejunoileal bypass
- Leukemia
- Lymphoma
- Cancer of the head or neck
- Less than 5 years of age

*CDC recommends HIV testing **all** contacts, no matter the HIV status of the case. ***However, if the index TB case is HIV+, then it is vital to have the adult contacts tested for HIV.***

Any of the above conditions would make the contact a high priority contact with a medical risk. This means the healthcare provider will need to assess the need to place the contact on presumptive latent TB infection treatment during the window period.

REVIEW OF SYSTEMS

A limited review of systems is done to assess whether the patient has any signs and symptoms of active TB disease and whether there is any contraindication to performing a TST.

CONSTITUTIONAL
Does the patient have any unexplained weight loss, fever, chills, weakness or fatigue, night sweats, and/or loss of appetite?

SKIN
Does the patient have a rash, itching, scaring or tattoos on arm?

RESPIRATORY
Does the patient have any shortness of breath, cough or sputum?

ALLERGIC/IMMUNOLOGIC
Does the patient have asthma? Has he/she had hives or anaphylaxis as a result of exposure to anything? Does he/she have an allergic response to materials, foods or animals?

PHYSICAL EXAMINATION

A very limited physical examination is made.

- Observe characteristics of breathing; note any coughing or shortness of breath
- Observe overall skin texture
- Examine skin of arm for scarring, tattoos, veins, turgor

DECISION MAKING

Use all of the information obtained during the history, review of systems and physical examination to make your decision on how to handle this patient.

ARE THERE ANY SIGNS OR SYMPTOMS OF POSSIBLE ACTIVE TB?
Does the patient need a complete evaluation for active TB?
Does the patient need a referral for a physician, Chest x-ray, etc.?
Does the patient need to be isolated?
Dose the patient need a mask?
Do sputum specimens need to be collected?

WHAT METHOD OF EVALUATION IS BEST?
Is a TST or IGRA needed?
Is there any contraindication to placing a TST, IGRA?
Is the patient able to return to the clinic in 48-72 to have the TST read?
Does the patient need a chest x-ray instead of a TST, IGRA?

WHAT IS THE PRIORITY OF THE PATIENT?
Is this patient at high risk of progression to TB disease if infected?
Does the patient need a chest x-ray along with a TST, IGRA?
Will the patient need any follow-up after this test?
Does this contact need to be placed on presumptive latent TB infection treatment?

COUNSELING/CARE COORDINATION

GENERAL EDUCATION OF A CONTACT

Regardless of the method of evaluation for the patient, any contact to a case is bound to have questions and the healthcare provider needs to be able to educate the contact on the following:

- The difference between exposure, infection and disease
- Purpose of an evaluation and the methods (TST, IGRA, Chest X-Ray)
- Limitations of testing
- Discuss follow-up testing in 8 – 10 weeks. Emphasize the significance of the follow-up TST/IGRA. Discuss best way to remind patient of follow-up test. Obtain alternative contact information for the patient.
- Explain the need for HIV status and the relationship between HIV and TB
- Discuss the patient's risk factors and why the test was chosen

TUBERCULIN SKIN TEST

- Do not rub, scratch or pick at injection site
- Do not cover injection site with a Band-Aid
- It is alright to get the injection site wet
- Set appointment for the patient to return in 48-72 hours to have the test read

CHEST X-RAY

- For previous positive patients, explain why a TST is not indicated and why a chest x-ray is being done
- For patients with a medical risk, explain why a chest x-ray is needed regardless of the TST or IGRA result
- Set appointment for chest x-ray
- Complete referral forms
- Give instructions to patient as to where to go, what time and what will occur
- Set appointment for follow-up to review the results of the chest x-ray

HIGH PRIORITY CONTACTS WITH A MEDICAL RISK

- Explain how the medical risk can lead to a progression to disease if the contact is infected
- Discuss window period and presumptive latent TB infection treatment

PROCEDURES

Chose the appropriate procedures needed to evaluate the patient. Identify and take credit for everything you do. All procedures need to be coded accurately.

- Administer a TST
- QFT
- T-Spot

- HIV
- Screening for HIV
- Venipuncture
- Handling / Conveyance of specimen
- Chest X-Ray
- Risk Reduction Interventions (15 min.)
- Risk Reduction Interventions (30 min.)

EVALUATION AND MANAGEMENT

The evaluation and management is sometimes referred to as the office visit code. Be sure to select the most appropriate evaluation and management code.
LPN: TST reading; no follow-up
RN; straightforward
RN; arrange for CXR; high risk for progression

This same procedure should be followed in 8 – 10 weeks when the follow-up evaluation is done.

PRESUMPTIVE LATENT TB INFECTION TREATMENT

Presumptive LTBI treatment is the practice of providing window period prophylaxis treatment for presumed *M. tuberculosis* infection to high-risk contacts of infectious TB cases, when the contact has an initial TB skin test reaction of less than 5mm or initial negative IGRA result and the testing was performed less than 8 weeks from the contact's last exposure to the source case.

Contacts at particularly high risk of developing TB disease once infected with *M. tuberculosis* include: children less than 5 years of age and persons with immune systems compromised by HIV infection, immunosuppressive medications (prednisone, cancer chemotherapy, anti-rejection drugs for cancer therapy, tumor necrosis factor alpha agents antagonists) and certain medical conditions (diabetes mellitus, silicosis, end stage renal disease, cancer of the head and neck, reticuloendothelial diseases [e.g., lymphoma, leukemia], gastric or jejunoileal bypass surgery).

Candidates for presumptive LTBI who would benefit from a full course of LTBI treatment are immunosuppressed due to the following conditions:

- HIV infection.
- Prolonged corticosteroid therapy.
- Persons with organ transplants.
- Persons on TNF-alpha inhibitors

Candidates for presumptive LTBI who can stop treatment after the window period if the follow-up TST/IGRA is negative include contacts that are children less than 5 years of age and persons with any of the following conditions:

- Diabetes mellitus.
- Silicosis.
- End stage renal disease
- Gastrectomy
- Jejunoileal bypass
- Leukemia
- Lymphoma
- Cancer of the head or neck

TREATMENT OF INFECTED CONTACTS

All contacts diagnosed with LTBI will be offered treatment unless contraindicated. Contacts will be encouraged to start and complete LTBI treatment. The TB Coordinator should review the contact investigation forms on a regular basis. All contacts will be entered into SENDSS according to the time frames stated in the Medical Records/ Surveillance Section. The following codes are to be used:

CODES		
a) Reason LTBI Treatment Stopped:	b) Reason why CI not completed for contact	c) Reason why no contacts entered
1. Completed Therapy 2. Death 3. Moved 4. Active TB Developed 5. Adverse Reaction 6. Chose to Stop Lost to Follow-Up 7. Provider Decision	1. Still following up 2. No TST2 or IGRA2 because 1st TST/IGRA done 8-10 weeks after exposure 3. No TST2 or IGRA2 because extra- pulmonary source case 4. No TST2 or IGRA2 because sputum/culture negative source case 5. Refused/uncooperative 6. Moved 7. Lost to follow up 8. Died 9. Other	1. Contact investigation was not done 2. Case died or too ill to interview. No surrogate interviewee available. 3. Case uncooperative/refused to identify contacts. No surrogate interviewee available. 4. Case moved/lost-to follow-up. No surrogate interviewee available. 5. Contacts identified but cannot be located 6. Contacts uncooperative/refused 7. Contacts moved/lost to follow-up 8. Shares same contacts with an index case whose contacts have already been entered. 9. Mass screening done. Cannot distinguish between close and casual contacts. 10. Other

INVESTIGATIONS ACROSS JURISDICTIONS

CONTACT INVESTIGATIONS ACROSS HEALTH DISTRICTS

District TB Coordinators should notify other district TB coordinators of cross-district contact investigations and continue to monitor follow-up to ensure all contacts of cases from their district are identified and evaluated. Local health department TB nurses should complete the contact investigation form with full name and location information. This form should be forwarded to the receiving county health department for evaluation who in turn should return the completed form to the originating health department. The district of the source case for the contacts is ultimately responsible for entering the contact investigation results in SENDSS, but may request help from other districts or the state epidemiology unit if the data entry task overwhelms their district's capacity to enter all contact information.

1) Requesting County should send a letter of notification to the identified contact which informs them of the exposure, refers them to their local health department, and lets them know that a health department employee may be contacting them.

2) Requesting County completes Form 3126 with the following information:
   - Index patient information
     - Patient's clinic number
     - State registry number
     - Patient's county
     - Disease site
     - Infectious period
     - Initial sputum results and date collected
   - Contact information
     - Exposure environment
     - Name, phone number, complete address
     - Race
     - Sex
     - Date of birth and age
     - Relationship to index patient
     - Last exposure date
     - Priority

3) Fax with a copy of the letter sent to the contact to the Receiving County and to the state office

4) Receiving County needs to act within stated time frames for evaluating contacts:

HIGH PRIORITY
Initial encounter within 3 or less days after notification with medical evaluation completed within 5 days of initial encounter (10 days if smear negative)

MEDIUM PRIORITY
Initial encounter within 3 days after notification with medical evaluation completed within 10 days of initial encounter

LOW-PRIORITY
Initial encounter 10 days after notification with medical evaluation completed within 30 days.

5) Receiving County completes Form 3126 with documentation and faxes back to Requesting County by the timeframes indicated for the priority of the contact so first TST can be entered into SENDSS.

6) Requesting County telephones Receiving County at the time when the 2nd TST is due to give a friendly reminder. Remember, it is the Requesting County who is responsible.

7) Receiving County completes Form 3126 with documentation and faxes back to the Requesting County and to the state office.

CONTACT INVESTIGATIONS ACROSS STATES

Contacts to Georgia cases that move out of state should be referred to that state for follow-up by submitting an interjurisdictional notification form to the State TB Program, which will notify the new state. When the follow-up information is received from the new state, the TB Program will forward the information to the District TB Coordinator. When the Georgia TB Program is notified of contacts entering Georgia from other states, the information is forwarded to the appropriate District TB Coordinator. When follow-up information is returned to the TB Program, it is forwarded to the original state that submitted the contact information.

EXPANDING THE INVESTIGATION

A contact investigation may need to be expanded if there is evidence of recent and/or continuing transmission.

- Unexpectedly large rate of infection in high priority contacts
- Evidence of a secondary case of TB disease
- Infection in any contact < 5 years
- Contacts with change in TST status (converters)

EXAMPLE OF INFECTION RATE

Eleven high priority contacts were identified for a reported TB case. One contact had a documented previous positive skin test. The other 10 contacts did not have documented previous skin tests. These 10 contacts were recently tested in connection with the contact investigation with the following results: 7 had a positive reaction and 3 had a negative reaction.

Summary:

- 11 contacts were identified
- 1 contact had a documented previous positive skin test
- 10 contacts had no documented previous skin test
  - 7 of the 10 contacts had a newly identified previous positive skin test
  - 3 of the 10 contacts had a newly identified negative skin test

1. Determine the number of contacts with a newly identified positive skin test.

- Subtract the number of contacts with a documented previous positive skin test from the total number of contacts with positive skin tests (new or previously documented)

8 contacts with positive skin tests (new or previously documented)
-1 contact with a documented previous positive skin test
7 contacts with newly identified positive skin tests

2. Next, determine the total number of contacts without a documented previous positive skin test.

- Subtract the number of contacts with a documented previous positive skin test from the total number of contacts

11 total number of contacts identified
-1 contact with a previous positive skin test
10 contacts without a documented previous skin test

3. Finally, determine the infection rate.

- Divide the number of contacts with a newly identified positive skin test by the total number of contacts without a documented previous positive skin test
- Multiply by 100; the resulting percentage is the infection rate for the group of contacts

$$\frac{\text{7 contacts with a new positive skin test}}{\text{10 contacts without a documented previous skin test}} \times 100 = \textbf{\textit{70\% Infection rate}}$$

4. Decide on expansion of testing.

Yes, you would expand testing since our background infection rate = 2-3%

EXAMPLE OF SECONDARY CASE

During the course of your investigation, 14 contacts are evaluated. One of those contacts has signs and symptoms of active TB. This contact becomes a TB suspect and has a complete evaluation for a TB case. A contact investigation will now begin around this second suspect/case. At this point, it cannot be determined if the index case transmitted the disease to the contact or if the contact is the source case. Either way, recent transmission has taken place and now there is a secondary case of TB. The investigation of the index case should now be expanded.

EXAMPLE OF LATENT TB INFECTION IN PERSON < 5 YEARS

The contact investigation includes the household members. The index case has a wife, an eight-year old son and a three-year old toddler. The wife and the son have a 0 millimeter TST (negative), but the three-year old has a 6 mm TST (positive). This indicates recent transmission and calls for an expansion of the investigation.

EXAMPLE OF TST CONVERTER

An index case has exposed 22 co-workers. There is an annual TB screening in the workplace and each of the 22 contacts had a TST within the last year that was 0 mm (negative) at that time. When tested after the exposure, one co-worker had a result that was 12 mm. This co-worker is said to have converted from a negative result to a positive result. The definition of conversion is an increase of 10 mm within a two year period.

SUMMARY

In the absence of evidence of recent transmission, an investigation should not be expanded to lower priority contacts. When program-evaluation objectives are not being achieved, a contact investigation should be expanded only in exceptional circumstances, generally those involving highly infectious persons with high rates of infection among contacts or evidence for secondary cases and secondary transmission. Expanded investigations must be accompanied by efforts to ensure completion of therapy.

Decisions about expanding contact investigations should be made by clinical and supervisory staff, the TB coordinator, and sometimes the state office.

7. Evaluation and Monitoring

Table of Contents

Each TB patient is to have a physical evaluation according to these programmatic guidelines prior to receiving services. Regardless of which service is provided, there are components that will remain the same. Each patient will have to give a medical history, have a review of systems and a physical examination. Whether these components are limited or in-depth depend on why the patient is being evaluated.

The evaluation of a patient needing a TB screening would be limited and focused in scope. A patient who is beginning treatment for active TB disease would need a very detailed and in-depth evaluation. A patient beginning treatment for LTBI would have an evaluation similar to the TB suspect/case but not quite as detailed.

EVALUATION FOR TB SCREENING

PERTINENT HISTORY

PREVIOUS TB HISTORY
It is very important to know if the patient has ever been diagnosed with active TB disease or latent TB infection before because this will impact how he/she is evaluated. Document dates of diagnosis or testing, location where the diagnosis or testing took place and what treatment was offered or completed.

Also document date, and location of any BCG vaccination given to the patient.

PERTINENT MEDICAL HISTORY
It is necessary to determine if there is any medical history or condition that may indicate the patient would be at a high risk of progression to TB disease if infected with TB. Document the history of any of the following:

- HIV infection
- Prolonged corticosteroid therapy
- Organ transplant
- TNF blockers
- Diabetes mellitus
- Silicosis
- End stage renal disease
- Gastrectomy
- Jejunoileal bypass
- Leukemia
- Lymphoma
- Cancer of the head or neck
- Less than 5 years of age

REVIEW OF SYSTEMS

A limited review of systems is done to assess whether the patient has any signs and symptoms of active TB disease and whether there is any contraindication to performing a TST.

CONSTITUTIONAL
Does the patient have any unexplained weight loss, fever, chills, weakness or fatigue, night sweats, and/or loss of appetite?
SKIN
Does the patient have a rash, itching, scaring or tattoos on arm?

RESPIRATORY
Does the patient have any shortness of breath, cough or sputum?

ALLERGIC/IMMUNOLOGIC
Does the patient have asthma? Has he/she had hives or anaphylaxis as a result of exposure to anything? Does he/she have an allergic response to materials, foods or animals?

PHYSICAL EXAMINATION

A very limited physical examination is made.

- Observe characteristics of breathing; note any coughing or shortness of breath
- Observe overall skin texture
- Examine skin of arm for scarring, tattoos, veins, turgor

EVALUATION FOR TREATMENT

PERTINENT HISTORY

A thorough and complete medical and social history needs to be taken. The Tuberculosis Services form #3121 R can be used to record much of the information obtained.

DEMOGRAPHICS
Certain demographic information is needed to help direct the focus of the contact investigation and the case management of the patient. Some of the demographic information is for reporting purposes to CDC.

SOCIAL HISTORY
A social history is helpful in determining any special needs that may need to be addressed in order to provide prompt and continuous treatment to completion. Living arrangements, transportation and employment information is needed to provide comprehensive case management. Substance use is a major cause of treatment interruption and needs to be addressed throughout treatment. One way is to perform a Screening, Brief Intervention and Referral to Treatment (SBIRT) for Substance Use:

1. *Screen: How many times in the past year have you had X drinks or more in a day? X= 5 drinks for men, 4 for women. How many times in the past year have*

you used an illegal drug or used a prescription medication for non-medical reasons?

2. Provide feedback "*What connection (if any) do you see between your drinking and this visit?"*
3. *Provide a brief intervention to enhance motivation, discuss pros and cons, assess patient readiness*
4. *Referral to treatment*

More information can be found here:
SAMSA-HRSA Center for Integrated Health Solutions: Implementing SBIRT in Community health and Community Behavioral Health Centers:
http://www.thenationalcouncil.org/cs/center_for_integrated_health_solutions
The patient can be referred to the state social worker for an in-depth assessment and intervention if needed.

MEDICAL HISTORY
A thorough medical history is needed to determine if there are any complicated acute or chronic medical conditions including (but not limited to): diabetes, renal insufficiency with estimated creatinine clearance less than 50 ml/min., end-stage renal disease on hemodialysis that will impact treatment. An alcohol and substance abuse assessment is needed. If HIV status is not documented, a test is indicated. Current prescriptions and over the counter medications need to be listed. Note any allergies and current immunization status.

PREVIOUS TB HISTORY
It is very important to know if the patient has ever been diagnosed with active TB disease or latent TB infection before. Document dates of diagnosis or testing, location where the diagnosis or testing took place and what treatment was offered or completed. Document whether this patient was named as a contact to another TB case. Was he/she a contact to a known drug resistant case?

Also document date, and location of any BCG vaccination given to the patient.

REVIEW OF SYSTEMS

A review of systems is indicated when a patient is starting on medication for active TB disease or latent TB infection. A clear picture of the patient's current health status is needed. This is necessary to provide a baseline for later assessment of possible adverse drug reactions. It is important for the patient to be able to describe a change from his/her "normal" baseline. In TB disease, it is also to determine the severity of symptoms and establish how ill the person is as a baseline for documenting clinical improvement with treatment.

CONSTITUTIONAL
Does the patient have any unexplained weight loss, fever, chills, weakness or fatigue, night sweats, and/or loss of appetite? How severe are they?

HEENT
Does the patient have any vision loss, blurred vision, double vision or trouble distinguishing colors? Does he/she wear glasses?
Does the patient have any hearing loss or ringing in the ears? Does he/she wear a hearing aid?

SKIN
What is the normal color of skin? Are there any rashes or itching? If so, what is the cause? Is there any bruising? Does the patient bruise easily?

CARDIOVASCULAR
Does the patient have any chest pain, chest pressure/chest discomfort, palpitations or edema?

RESPIRATORY
Is the patient experiencing any shortness of breath, cough or sputum? Is this something new or is this a chronic condition? Is the patient coughing up blood?

GASTROINTESTINAL
Does the patient have anorexia, heartburn, nausea, vomiting or diarrhea or abdominal pain? Does anything relieve it? Does anything precipitate it? What color are his/her stools? Is there any blood in the stool?

GENITOURINARY
What color is the patient's normal urine? Does he/she have bladder or kidney infections? Have they ever had a problem with kidney function?

NEUROLOGICAL
Does the patient have headaches? What kind and what relieves them? Does he/she have dizziness, syncope, paralysis, ataxia, numbness or tingling in the extremities? Is there any problem with memory or cognition?

MUSCULOSKELETAL
Does the patient have muscle and/or back pain? Does he/she have any arthritis, joint pain or stiffness? Is there any weakness in his/her limbs or any problem with gait and movement? Have they every had signs of gout?

HEMATOLOGIC
Does the patient have anemia, bleeding or bruising? Are they on aspirin therapy?

LYMPHATICS
Has the patient ever had enlarged nodes or a history of splenectomy?

PHYSICAL EXAMINATION

A nursing physical examination will establish how ill the person is as a baseline for documenting clinical improvement with treatment. It also serves as a baseline to assess adverse drug reactions.

VITAL SIGNS
Temperature, Pulse, Respiration, blood pressure, height, current weight (compare to normal weight), BMI

EYES
Check color of sclerae. Check pupils for size and reaction to light. Perform a vision test for acuity and color discrimination.

SKIN
Observe the overall color of skin. Check trunk and back for bruising or rash. Check turgor and examine extremities for bruising.

GASTROINTESTINAL
Check abdomen for tenderness.

RESPIRATORY
Collect sputum specimens. Observe characteristics of cough (if any).

MUSCULOSKELETAL
Observe the patient's movements and gait. Check for joint swelling or redness.

NEUROLOGICAL
Observe for dizziness, syncope, paralysis, ataxia when moving, or getting up and down. Check for any memory difficulty or change in cognition.

MONTHLY TREATMENT MONITORING

Every TB patient receiving treatment through the health department is to be closely monitored for adverse drug reactions and response to treatment. The same format for evaluation is used during the monthly monitoring sessions. Is there anything preventing optimal treatment? What can you do to improve treatment? For active TB suspects/cases, review DOT (Section 5) and contact investigation (Section 6).

PERTINENT HISTORY

An update of any changes in medical history should be made. In addition, document the treatment regimen, the duration of treatment and number of doses taken to date. Verify that the patient is on track to complete treatment within guidelines. Has there been any alcohol or substance abuse? How is the patient complying with the prescribed regimen?

REVIEW OF SYSTEMS

It is important for the patient to be able to describe a change from his/her "normal" baseline. The review of systems is primary to check for any adverse drug reactions. The patient education materials at the end of this chapter can be used to aid in this monthly review.

CONSTITUTIONAL
Does the patient have any unexplained weight loss, fever, chills, weakness or fatigue, night sweats, and/or loss of appetite? How severe are they?

HEENT
Does the patient have any vision loss, blurred vision, double vision or trouble distinguishing colors? Does he/she wear glasses?
Does the patient have any hearing loss or ringing in the ears? Does he/she wear a hearing aid?

SKIN
What is the normal color of skin? Are there any rashes or itching? If so, what is the cause? Is there any bruising? Does the patient bruise easily?

CARDIOVASCULAR
Does the patient have any chest pain, chest pressure/chest discomfort, palpitations or edema?

RESPIRATORY
Is the patient experiencing any shortness of breath, cough or sputum? Is this something new or is this a chronic condition? Is the patient coughing up blood?

GASTROINTESTINAL
Does the patient have anorexia, heartburn, nausea, vomiting or diarrhea or abdominal pain? Does anything relieve it? Does anything precipitate it? What color are his/her stools? Is there any blood in the stool?

GENITOURINARY
What color is the patient's normal urine? Does he/she have bladder or kidney infections? Have they ever had a problem with kidney function?

NEUROLOGICAL
Does the patient have headaches? What kind and what relieves them? Does he/she have dizziness, syncope, paralysis, ataxia, numbness or tingling in the extremities? Is there any problem with memory or cognition?

MUSCULOSKELETAL
Does the patient have muscle and/or back pain? Does he/she have any arthritis, joint pain or stiffness? Is there any weakness in his/her limbs or any problem with gait and movement? Did they every have signs of gout?

HEMATOLOGIC
Does the patient have anemia, bleeding or bruising? Are they on aspirin therapy?

LYMPHATICS
Has the patient ever had enlarged nodes or a history of splenectomy?

ALLERGIES
Does the patient have a history of asthma, hives, eczema or rhinitis, allergic response to food, material medication or environment? What are the causes? What relieves it?

PHYSICAL EXAMINATION

VITAL SIGNS
Temperature, Pulse, Respiration, blood pressure, height, current weight (compare to normal weight), BMI

EYES
Check color of sclerae. Check pupils for size and reaction to light. Perform a vision test for acuity and color discrimination.

SKIN
Observe the overall color of skin. Check trunk and back for bruising or rash. Check turgor and examine extremities for bruising.

RESPIRATORY
Collect sputum specimens. Observe characteristics of cough (if any).

GASTROINTESTINAL
Check abdomen for tenderness.

MUSCULOSKELETAL
Observe the patient's movements and gait. Check for joint swelling or redness.

NEUROLOGICAL
Observe for dizziness, syncope, paralysis, ataxia when moving, or getting up and down. Check for any memory difficulty or change in cognition.

LAB QUICK REFERENCE SHEET

CLASS 3 - TB DISEASE
CLASS 4 - OLD TB DISEASE
CLASS 5 - TB SUSPECT

These patients are usually started on a four-drug regimen of isoniazid, pyrazinamide, ethambutol and rifampin. When the **initial** four-drug regimen is used, it is important to perform the following monthly lab assessments for the duration of the four-drug treatment.

Isoniazid - monthly hepatic/liver function test
Pyrazinamide - monthly uric acid levels and creatinine
Ethambutol - monthly vision/color exam
Rifampin - monthly CBC with differential

In addition to the above labs**,** a baseline serum glucose should be drawn. If the results are abnormal, a Hgb A1C should be drawn at the next visit.

The hepatic/liver function test, the serum glucose and creatinine levels can be ordered as a comprehensive metabolic panel instead of ordering each individual lab in an effort to save money**.**

On all known diabetic patients, obtain a Hgb A1C with baseline labs.
The above labs are sent for processing to the lab provider for your county.

HIV testing should be done on all patients. TB patients *may* qualify for Oraquick, if not, do venipuncture for HIV.

Hepatitis C ab should be drawn on all adults initially.

Hepatitis B profile should be drawn on all adults and anyone less than 18 years old who is foreign-born.

The above three labs are sent for processing to the state lab.

During the initial phase of treatment assess the patient monthly for any signs or symptoms of gout or change in kidney function. If any signs or symptoms are present, continue to draw uric acid levels for gout and creatinine for kidney function. If the patient is asymptomatic for gout or kidney issues, then these labs do not have to be drawn every month.

During the continuation phase of treatment while the patient is on isoniazid and rifampin, monthly hepatic/liver function test and CBC with differential will be drawn monthly and **sent for processing to the lab provider for your county**.

CLASS 2 – LATENT TB INFECTION, NO DISEASE

If the patient is on isoniazid, baseline hepatic/liver function test is done. Then monthly (if indicated by protocol) hepatic/liver function test is done.

If the patient is on rifampin, baseline hepatic/liver function test and CBC with differential is done. Then monthly CBC differential is done and monthly (if indicated by protocol) hepatic/liver function test is done.

The above labs are sent for processing to the lab provider for your county.

HIV testing should be done on all patients. TB patients *may* qualify for Oraquick, if not, do venipuncture for HIV and send for processing to the state lab.

TELEPHONE NURSE MONITORING PROGRAM (TNMP)

OBJECTIVE

1. To facilitate latent TB infection treatment adherence by making the medications available at minimum inconvenience to the patient.
2. To leverage existing technology to facilitate treatment adherence despite decreases in resources
3. To improve completion rates for latent TB infection treatment.

CONCEPT

- Patients being treated for latent TB infection with self-administered isoniazid for nine months, and who are at low risk for hepatic complications may be considered for the telephone nurse monitoring program.
- Patients will have baseline laboratory tests done at the initial clinic visit.
- Patients will have the initial clinic visit and the first three follow-up monthly clinic visits monitored by the nurse at the health department clinic and will pick-up their monthly supply of isoniazid at the clinic.
- If no adverse side effects to isoniazid are identified during the first three clinic visits, telephone monitoring may begin after the third follow-up visit to the health department clinic and a 90-day supply of medication will be issued.
- Follow-up monitoring by telephone calls interspersed with in-person clinic visits.

Refer to the "*Guidelines for Public Health Nurses Practicing in Telehealth / Telenursing / Telemedicine, January 2013*" available from the Office of Nursing. Nurses must have read the above guidelines, have practiced under the TB Nurse Protocol for two years or more, have demonstrated mastery of communication skills and have been endorsed by their supervisor to participate in TNMP.

CLIENT ELIGIBILITY

- Be age eighteen years or older
- Has been on LTBI treatment for at least two months, has not missed a clinic appointment and states compliance with taking medication
- Identified as being at low risk for hepatic complications while receiving anti-TB medications (e.g., does not consume alcohol, does not have any liver problems, does not have hepatitis, does not have HIV)
- Baseline laboratory tests are at normal levels
- Able to communicate by telephone with the nurse directly or with translation assistance through the language line
- Able to have a stable telephone number where they can be reached
- Able to read instructions on the medication label
- Able to demonstrate knowledge about the side effects and adverse reactions to the medications
- Able to demonstrate understanding about the signs and symptoms of active TB disease
- Able to demonstrate when and how to call the nurse should adverse reactions occur

PROCEDURE

NOTE: All encounters will follow the same format outlined under *Telephone Call Process.*

1. The initial evaluation will be face-to-face at the health department clinic. Baseline laboratory tests will be done. If there is no contraindication to isoniazid, a 30-day supply of isoniazid will be ordered and dispensed.

2. The first follow-up evaluation (end of month one) will be face-to-face at the health department clinic. If there is no adverse reaction to isoniazid and the baseline laboratory tests were within normal limits, a 30-day supply of isoniazid will be ordered and dispensed to the patient. If adverse reactions are identified, the medication will be stopped and follow-up actions taken according to the Standard Nurse Protocols for latent TB Infection.

3. The second follow-up evaluation (end of month two) will be face-to-face at the health department clinic. If there is no adverse reaction to isoniazid, a 30-day supply of isoniazid will be ordered and dispensed to the patient. If adverse reactions are identified, the medication will be stopped and follow-up actions taken according to the Standard Nurse Protocols for latent TB Infection.

4. The third follow-up evaluation (end of month three) will be face-to-face at the health department clinic. If there is no adverse reaction to isoniazid, the patient has not missed any clinic visits and has missed minimal pills, the patient may be

considered for enrollment in the TNMP. If adverse reactions are identified, the medication will be stopped and follow-up actions taken according to the Standard Nurse Protocols for latent TB Infection.

- Verify the patient's eligibility to enroll in TNMP
- Describe the TNMP and explain the benefits to patients deemed eligible
- Explain criteria for enrollment
- Discuss importance of having access to a stable working telephone where he/she can be reached
- Explain the TNMP follow-up schedule and that medication would be issued in 90-day supplies.
- Discuss the following logistics with the patient:
  - Verify the ability to receive and/or make telephone calls in private
  - Verify and record the telephone numbers to be used by patient and nurse.
  - The need to have both patient and nurse in the state of Georgia at the time of the telephone calls.
  - The privacy of the patient's information and the need to verify the identity of both the patient and nurse when the telephone calls are made. Mutually decide on a code name/phrase and response.
- Continue to conduct patient education on the signs and symptoms of adverse reactions. Demonstrate to the patient how to articulate degree and severity of possible findings.
- Have the patient demonstrate how to completely and accurately describe the reactions.
- Instruct the patient on adverse reactions to the medications which need to be reported immediately to the health department. Explain that the patient will need to be seen in the clinic for any adverse reaction.
- A 90-day supply of isoniazid will be ordered and dispensed to the patient.

5. The first Telephone Nurse Monitoring Program (TNMP) call will be made 25-30 days (end of month four) after the third follow-up clinic visit. If there is no adverse reaction to isoniazid, the patient will be instructed to continue with the medication. If there is an adverse reaction, the patient is to stop the medication immediately and come to the clinic for further evaluation.

6. The second TNMP call will be made 30 days (end of month 5) after the first TNMP call. If there is no adverse reaction to isoniazid, the patient will be instructed to continue with the medication. If there is an adverse reaction, the patient is to stop the medication immediately and come to the clinic for further evaluation.

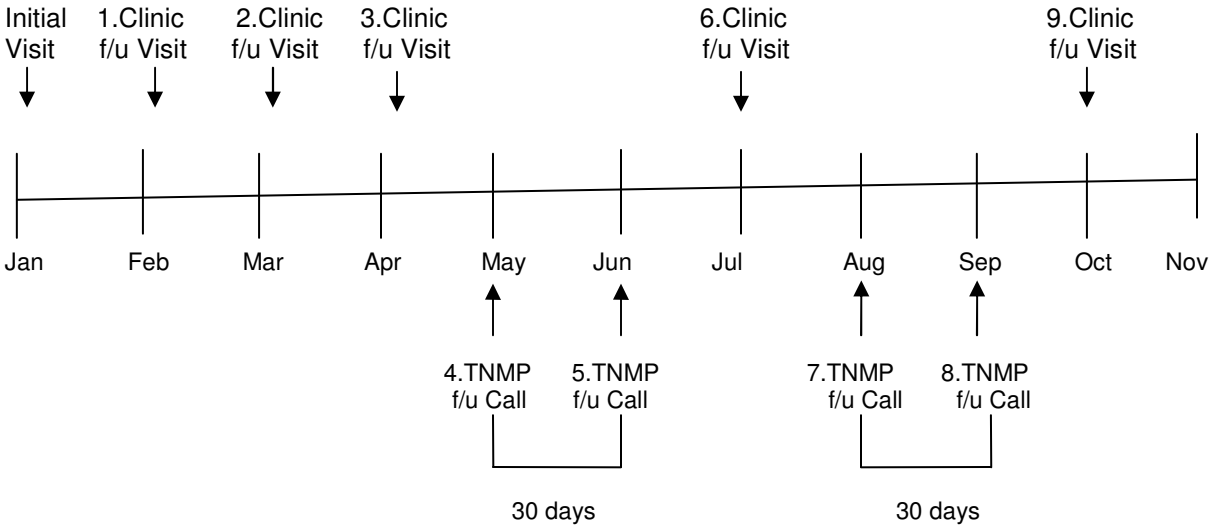
7. The fourth follow-up visit will occur in the health department clinic for a face-to-face evaluation (end of month six). If there is no adverse reaction to isoniazid, a 90-day supply of isoniazid will be issued to the patient. If adverse reactions are identified, the medication will be stopped and follow-up actions taken according to the Standard Nurse Protocols for latent TB Infection.

8. The third TNMP call will be made 25-30 days (end of month 7) after the clinic visit. If there is no adverse reaction to isoniazid, the patient will be instructed to continue with the medication. If there is an adverse reaction, the patient is to stop the medication immediately and come to the clinic for further evaluation.

9. The fourth TNMP call will be made 30 days (end of month 8) after the third TNMP call. If there is no adverse reaction to isoniazid, the patient will be instructed to continue with the medication. If there is an adverse reaction, the patient is to stop the medication immediately and come to the clinic for further evaluation.

10. The fifth and final follow-up visit will occur in the health department clinic for a face-to-face evaluation (end of month nine). If there is no adverse reaction to isoniazid and the patient has finished taking his medication, then the patient's treatment is considered complete and closed out.

TNMP Diagram



TELEPHONE CALL PROCESS

1. Review the patient's record before the call and keep the record open to document the call as you progress.

2. Call the patient at or within 15 minutes of the scheduled time.

3. Request to speak to the patient.

4. Ask the agreed upon security question to verify the identity of the patient and ask where the patient is currently located (must be within the borders of the state of Georgia).

5. Ask the patient whether the time is still appropriate.
   - If no, arrange another time with the patient (preferably within 30 to 60 minutes, but at least within 24 hours) and give the patient the option of initiating the call within this time frame
   - If yes, continue with the call

6. Following the format outlined in the previous section, complete a brief present history including asking about any missed pills.

7. Complete a pertinent history.

8. Perform a review of systems and document all answers in the patient record.

9. Identify any adverse reactions and discuss any change in the review of systems and the actions to be taken by the patient in response to the changes.

10. Discuss whether the patient is to continue or discontinue the medication.

11. Discuss any concerns identified by the patient.

12. Perform counseling/care management as indicated.

13. Verify the date and time of the next monitoring call.

14. Document the telephone monitoring call in the patient record using the applicable CPT codes.
    - Telephone assessment and management (5 – 10 min.)
    - Telephone assessment and management (11 – 20 min.)
    - Telephone assessment and management (21 – 30 min.)

15. Include the following documentation in the patient record:
    - The time and outcome of the TNMP call
    - Who initiated the call—the nurse or the patient

- The date and the time for the next TNMP call

16. If the patient was not reached, then document the following actions and responses:
    - If the patient does not answer, make 2 to 3 additional attempts to reach the patient within the 30 minute period of time.
    - Document failed attempts in the patient's chart.
    - Make an attempt to reach patient by telephone each day until contact is made.
    - If contact is not made by telephone within one week, make a home visit to the client to re-evaluate placement in TNMP.
    - At the discretion of the nurse, the patient may be discontinued from TNMP for lack of telephone availability.

Nurses may telephone patients not enrolled in TNMP for missed appointments, counseling and follow-up of referrals and education. The same CPT codes would apply.

DISCONTINUING TELEPHONE MONITORING SERVICE

Conditions under which a patient should be discontinued from the TNMP and returned to regular monthly clinic monitoring are as follows:

- Patient no longer has a working telephone
- Patient missed several TNMP calls and has not been reached in 15 days of the first missed scheduled contact
- Patient developed side effects that need closer monitoring
- Patient developed active disease and is placed on multiple drug treatment
- Patient requests to be discontinued from TNMP

PATIENT EDUCATION

Nurses should provide counseling and education at every encounter. The patient needs to understand the disease process of tuberculosis and their individual treatment plan. The *12 Points of Tuberculosis Patient Education* and the *Tuberculosis Education Record* are excellent tools to use for content and documentation. These are located on the TB webpages.

It is imperative that the client be thoroughly educated on the potential side effects of TB medications and the symptoms of adverse reactions. It is also vital that the patient know how to describe each symptom and that the nurse understand each description.

Side effects of medications are those things which are anticipated to happen to people taking certain medications. Most of the side effects are manageable and do not require stopping the medication.

Adverse reactions of medications are those things which are severe and may indicate harm to the patient. Adverse reactions warrant stopping the medication and consulting the contract physician.

Refer to the *Standard Nurse Protocols* and the *12 Points of Tuberculosis Patient Education* for drug specific information and actions.

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Use the patient education sheets (located at the end of this section) as you go through the review of systems. Demonstrate how to use the rating scales for each question for assessment during the first three months. This will assist the nurse and the patient understanding each other's vocabulary and what each other mean. This type of communication will carry over to the telephone and assist the nurse in making her assessment if the patient becomes enrolled in the TNMP.

On the patient education sheets, a scale is used with each symptom. Most of the scales are labeled from 0 to 10 with 0 being "none" of the symptom and 10 being "severe" symptom.

Example 1: Rudy and the nurse go over the patient education sheets about GI disturbances and Rudy denies having any nausea and vomiting. They rate this as 0 and discuss that if he feels nausea, he might rate it as 1, but if he begins to vomit dark, coffee ground material, then he would need to immediately alert the nurse and describe it as 10.

Example 2: When asked what color his urine is, Tom points to the orange urine. The nurse and Tom discuss how the medication rifampin turns secretions orange in color. They compare the normal yellow and the rifampin orange to the dark, maple syrup colors. Together they agree that if Tom's urine begins to look dark like that, he will immediately alert the nurse and describe it as 8 – 10.

Example 3: Jeri states she had some nausea and vomiting. The nurse would discuss the number of events (Jeri states one time); the color of the vomit (Jeri states it looked like her dinner) and when the events took place (Jeri vomited shortly after eating) and when the last dose of medication (she had taken her pill that morning, 6 hours earlier). Together the patient and the nurse would discuss if there were any lingering feelings and how the patient feels at this moment. If Jeri states she felt better after vomiting and did not have any other problems at the time and that she feels great today, then they would discuss that "2 or 3" could describe this event and that it is unlikely to be related to medication. The nurse explains that if Jeri continues to vomit in the next couple of days or if she begins to vomit dark, coffee ground material, then she would need to immediately alert the nurse and describe it as 10.

There are numerous patient education materials available for use in addition to what is covered here. People learn in different ways, so having information presented in writing, by speaking, in pictures, in video and by demonstration all assist in retaining what is learned.

CONSTITUTIONAL

Unexplained elevated temperature for three or more days

0__I__I__I__I__I__I__I__I__I__I__10
98° **101°**

Unexplained weight loss

0__I__I__I__I__I__I__I__I__I__I__10
None **Severe**

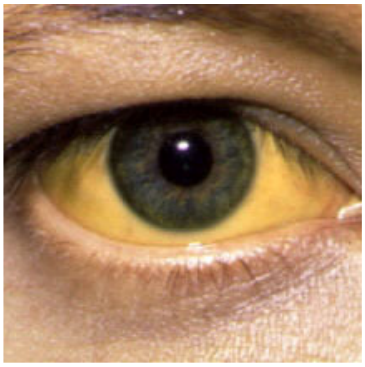
Tired, don't feel well, malaise, weakness

0__I__I__I__I__I__I__I__I__I__I__10
None **Severe**

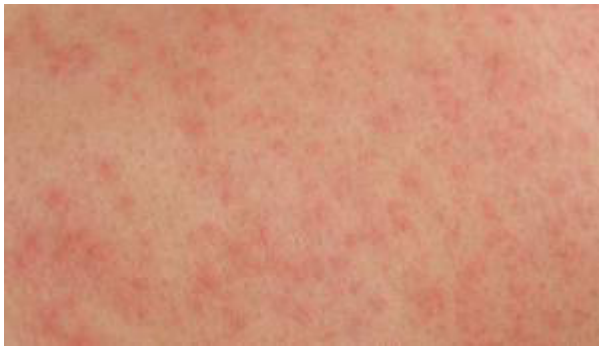
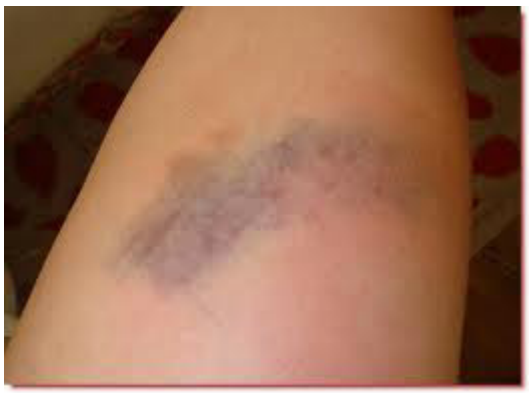
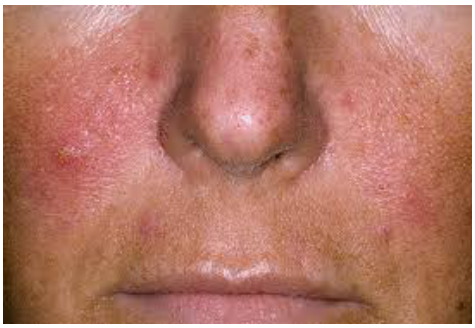
Chills and/or night sweats

0__I__I__I__I__I__I__I__I__I__I__10
None **Severe**

HEAD, EYES, EARS, NOSE, THROAT (HEENT)

	**Vision changes** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Color of sclera** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Hearing loss, ringing in ears** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**

SKIN

	**Yellowish skin** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Rash or itching** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Bruising** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Flushing** Avoid eating cheeses and meats, soy sauce, soy beans. Miso soup, fava beans, snow peas, sauerkraut, yeast, wine or beer **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**

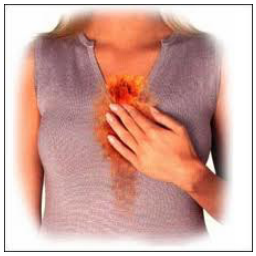
CARDIOVASCULAR

	**Chest Pain** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**

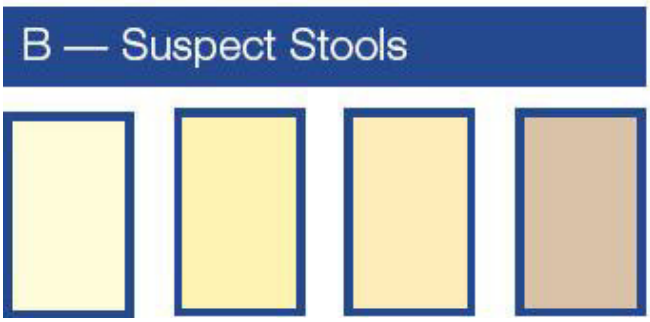
RESPIRATORY

	**Shortness of Breath** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Coughing** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Coughing up blood** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**

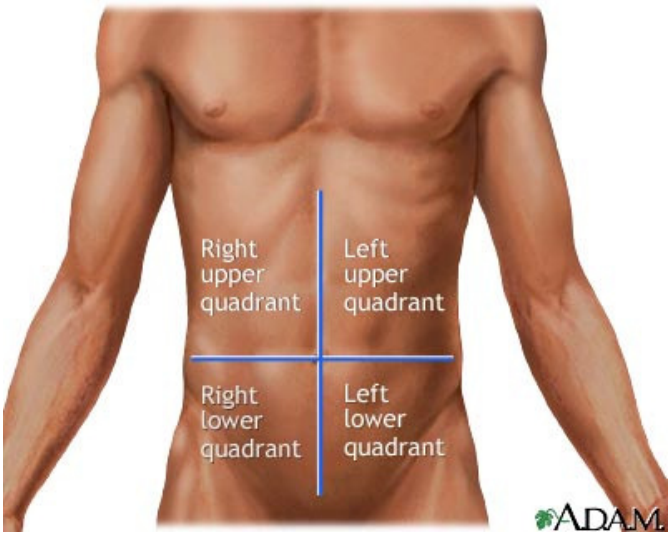
GASTROINTESTINAL, 1

	**Loss of appetite** **0__I__I__I__I__I__I__I__I__I__10** **None** **Severe**
	**Nausea** Small snack with pill or suck on hard candy **0__I__I__I__I__I__I__I__I__I__10** **None** **Severe**
 	**Nausea and Vomiting** Dark brown, coffee grounds material **0__I__I__I__I__I__I__I__I__I__10** **None** **Severe**
	**Heartburn** Do not take antacids 1 hour before or 1 hour after your pill **0__I__I__I__I__I__I__I__I__I__10** **None** **Severe**
	**Diarrhea** **0__I__I__I__I__I__I__I__I__I__10** **None** **Severe**

GASTROINTESTINAL, 2

<table>
<tr>
<td> 
</td>
<td>Pale or clay-colored stools

0__I__I__I__I__I__I__I__I__I__1
0
Dark Brown White</td>
</tr>
<tr>
<td>  </td>
<td>Abdominal Pain
Cramping, belly pain

0__I__I__I__I__I__I__I__I__I__1
0
None Severe</td>
</tr>
<tr>
<td> 
</td>
<td>Right upper quadrant tenderness

0__I__I__I__I__I__I__I__I__I__1
0
None Severe</td>
</tr>
</table>

GENITOURINARY

	**Normal** Urine is light yellow to a deep yellow in color **0__I__I__I__I__I__I__I__I__I__10** **Light, clear deeper, cloudy**
	**Normal** Urine is light to deep orange with Rifampin **0__I__I__I__I__I__I__I__I__I__10**
	**Abnormal** **Persistently dark urine** **Urine the color of maple syrup or coca cola** **0__I__I__I__I__I__I__I__I__I__10** **Yellow Maple syrup**
Change in kidney function Lethargy, feeling of being unwell, flu-like feelings but no fever, weakness, shortness of breath, appetite loss, nausea, weight loss, itching, dry skin and generalized swelling may occur	**Kidney function** **0__I__I__I__I__I__I__I__I__I__10** **No symptoms Symptoms**

NEUROLOGICAL

Peripheral Neuropathy

- A burning or prickling sensation
- Tingling or numbness, skin crawling, or itching
- A feeling of "pins and needles"

Taking Vitamin B6 will help decrease

0__I__I__I__I__I__I__I__I__I__I__10
None Severe

Headache

0__I__I__I__I__I__I__I__I__I__I__10
None Severe

Dizziness

0__I__I__I__I__I__I__I__I__I__I__10
None Severe

Cognitive and memory problems

0__I__I__I__I__I__I__I__I__I__I__10
None Severe

MUSCULOSKELETAL

	**Joint pain, Stiffness, Gout** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Sore Muscles** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**
	**Weakness in legs or difference in walking** **0__I__I__I__I__I__I__I__I__I__I__10** **None Severe**

12 Points of Tuberculosis (TB) Patient Education

Transmission of TB

- TB is a disease caused by the TB germ. The disease is mainly in the lungs (pulmonary TB), but the germ can travel to other parts of the body (extrapulmonary TB) and sometimes can be in multiple parts of the body (miliary or disseminated TB).
- TB is spread when someone who is sick with TB in his/her lungs coughs, sneezes, talks or sings and sprays the TB germ into the air. When someone spends time with that person, he/she can breathe in the TB germ and become infected. One usually has to be around a person with infectious TB for a long time and share the same airspace to be infected.
- Infectiousness decreases after the person has been on treatment for a while.
- You can NOT get TB by sharing drinks, toys or personal items.
- When a person is exposed to the TB germ and becomes infected, the person's own immune system will usually build a wall around the TB germs, keeping them from growing and multiplying. This is called latent TB infection or LTBI. The germs can remain dormant in a person's body throughout his/her lifetime.
- A TB skin test (Mantoux) can be given to see if someone has been infected with the TB germ. If the skin test is positive, a chest X-ray and sputum test will be done to make sure the person does not have TB disease. The skin test only determines latent TB infection. A positive result does not necessarily mean the person has TB disease.
- Once TB disease is ruled out, the doctor may prescribe a preventive medicine called Isoniazid (INH). INH can prevent TB by killing the TB germs.

Differences between LTBI and Active TB disease

- Both can have a positive skin test
- LTBI has no symptoms and the person feels fine; but in active TB disease, the person usually feels sick and has symptoms of TB.
- In LTBI, the chest x-ray is normal; in active TB disease, it is usually abnormal.
- LTBI can NOT transmit the germs to others; in active TB disease, the germs can be transmitted to other people.
- Both can be treated

Progression of LTBI to Active TB

- A person who is exposed and becomes infected with TB has a 10% chance of developing active TB disease. The most critical time period is the first 2 years after becoming infected.
- When the body's immune system is weak, the wall around the TB germs begins to break down. The TB germs wake up and start multiplying; growing and attacking the body, making the person feel sick and develop symptoms.

- Anyone can get TB, but some people are at greater risk than others. These include:
    - Persons living with someone who has active TB of the lungs
    - Persons who had TB disease in the past but didn't receive or complete their treatment
    - Persons who are elderly
    - Persons with weakened immune systems

Signs and symptoms of disease

- The early signs and symptoms of TB develop slowly and may go unnoticed for a long time. These include:
    - Cough
    - Chest pain
    - Loss of appetite
    - Weight loss
    - Tiredness
    - Fever/chills/night sweats
- The symptoms should get better after the person is on medication for a couple of weeks. If they don't or if they come back after getting better, the nurse or physician needs to be notified.

Importance of HIV testing

- All patients in TB clinics should be tested for HIV. This includes TB suspects, patients, and contacts.
- People infected with HIV (the virus that causes AIDS) are more likely than uninfected people to get sick with other infections and diseases. Tuberculosis is one of these diseases.
- HIV infection weakens the immune system. If a person's immune system gets weak, latent TB infection can activate and become TB disease. Someone with latent TB infection and HIV infection has a **very high risk** of developing TB disease. Without treatment, these two infections can work together to shorten the life of the person infected with both.
- HIV infection is the most important known risk factor for progression from latent TB infection to TB disease. Progression to TB disease is often rapid among HIV-infected persons and can be deadly. In addition, TB outbreaks can rapidly expand in HIV-infected patient groups.

Respiratory Isolation and use of masks

- It is important for the patient to remain at home on isolation. As much as possible, he/she should stay away from other people in the house by staying in a separate room or wearing a surgical mask when leaving the room. Separate bedrooms or beds are highly recommended, if possible. The patient cannot travel, go to work, go to school, go shopping or participate in any other activity where there is contact with other people.

- The patient needs to cover his/her mouth and nose with a tissue when coughing or sneezing. These tissues should be flushed, burned or placed in a sealed leak proof bag before disposal.
- The patient cannot leave home except to keep medical appointments. He/she must wear a surgical mask to the clinic and doctor's offices.
- The patient should not allow anyone, other than those living with him/her or those individuals providing care to him/her, into the home and should stay away from young children.
- These isolation instructions remain in effect until the patient is told by the health department that he/she no longer has to stay in isolation.
- The isolation instructions may be placed back in effect again after the patient has been told that he/she is no longer infectious should the clinical situation change.
- Keep doors and windows open as much as possible.
- DOT visits will be conducted outdoors, beside open windows and as efficiently as possible in order to reduce exposure time.
- The DOT worker will wear an N95 mask during the time the patient is considered infectious.
- Go outside to collect sputum specimens. The DOT worker should wear an N95 mask anytime sputum is being collected.

Infectious period

- The infectious period is the time when a patient sick with active TB can pass the germs to other people.
- The infectious period begins 3 months prior to the onset of symptoms or clinical sign of TB.
- The infectious period continues until all of the following criteria is met:
    1. Three consecutive smear negative specimens
    2. The patient is on appropriate medications
    3. The patient is getting better
- The infectious period is important to determine in order to focus the contact investigation

Importance of chemotherapy as prescribed

- Having TB should not keep someone from leading a normal life. When TB patients are no longer infectious or feeling sick, they can do the same things they did before they had TB. The medicine does not affect strength, sexual function or the ability to work. If the TB medicine is taken as directed, the medicine will kill all the TB germs and prevent the patient from becoming sick with TB again.
- It is necessary to take several different TB medications because there are many TB germs to be killed. Taking three to four different TB medications will stop the TB germs from becoming resistant to the medication.
- The most common medications are Isoniazid; Rifampin; Pyrazinamide and Ethambutol.
- The patient will usually take several tablets of four different medications every day (M-F) for the first two months. Then the patient may be able to take several

tablets of just two medications twice a week until treatment is completed (another 4-7 months).

- TB is almost always curable if the patient adheres to the treatment regimen of taking several special medications for six to nine months. The medication must be taken continuously and uninterrupted for the duration of treatment.
- The treatment takes this long because the TB germs grow very slowly and are slow to die. The combination of these medications delivered by DOT can cure the disease in less than a year.
- Prolonged illness, disability or possible death are avoided
- Risk of developing MDR-TB or XDR-TB is decreased

Side effects and adverse medication reactions

Side effects *of medications are those things which are anticipated to happen in people taking certain medications. Most of the side effects are manageable and do not require stopping the medication.*

Medication	Side Effect	Action
Isoniazid	Dizziness; tingling/numbness around the mouth or in the extremities	Proactively B6 is usually given; report any mild signs or symptoms to the nurse or physician
	GI distress; nausea when taking the pills but feels better later in the day;	Alter time of day pills are given; try giving pills with a small snack or food; report to nurse or physician
Rifampin	Discoloration of bodily fluids; urine, sweat or tears may be orange or reddish	Prepare the patient to see this; have him/her switch to hard contact lenses or glasses because staining can occur of soft contact lenses
	Drug interactions; can interfere with birth control pills or implants; can alter effectiveness of methadone	Counsel patient to use an alternative or back-up method of birth control (e.g., copper-bearing IUD such as ParaGard, condoms, diaphragm) when rifampin is prescribed, it reduces effectiveness (degree depending on method) of combined oral contraceptives, progestin-only oral contraceptives, levonorgestrel implants, Depo-Provera, patch and ring. Advise condom back-up. Make sure nurse and physician are aware of all medications the patient is taking
	Sun sensitivity; frequent sunburn	Counsel patient to avoid prolonged exposure to sun and to wear adequate sunblock

	Easy bruising; slow blood clotting GI distress; nausea when taking the pills but feels better later in the day	Avoid bruising; do not take aspirin unless ordered by a physician; tell healthcare provider about medications prior to any procedure that might cause bleeding Alter time of day pills are given; try giving pills with a small snack or food; report to nurse or physician
Pyrazinamide	GI distress; nausea when taking the pills but feels better later in the day; Joint aches	Alter time of day pills are given; try giving pills with a small snack or food; report to nurse or physician Cold packs or heat packs; report to nurse or physician
Ethambutol	Can cause blurred or changes vision; changes in color vision	Monitor and test eyes monthly

Adverse medication reactions *are side effects of medications that are severe and warrant stopping the medications to avoid harm or damage to the patient.*

Medication	Adverse Reaction	Action
Isoniazid	Dizziness; tingling/numbness around the mouth or in the extremities Hepatitis: nausea; vomiting; yellowish skin or eyes; abdominal pain; dark, maple syrup or coffee colored urine; abnormal liver function tests; fatigue; fever >3 days; flu-like symptoms; lack of appetite	Stop medication if severe or seems to be worsening; notify nurse or physician Stop medication and notify nurse or physician
Rifampin	Easy bruising; slow blood clotting Hepatitis: nausea; vomiting; yellowish skin or eyes; abdominal pain; dark, maple syrup or coffee colored urine; abnormal liver function tests; fatigue; fever >3 days; flu-like symptoms; lack of appetite	Stop medication and notify nurse or physician Stop medication and notify nurse or physician
Pyrazinamide	Severe stomach upset; vomiting; lack of appetite Hepatitis: nausea; vomiting; yellowish	Stop medication and notify nurse or physician Stop medication and notify

	skin or eyes; abdominal pain; dark, maple syrup or coffee colored urine; abnormal liver function tests; fatigue; fever >3 days; flu-like symptoms; lack of appetite	nurse or physician
Ethambutol	Any changes in visions noted	Stop medication and notify nurse or physician

Other warnings to tell clients taking TB medications

- Limit alcohol use when taking TB medication. Combining alcohol and TB medicine can cause liver damage.
- Tell the nurse if other medications are being taken. TB medication can interfere with certain prescription drugs.
- Report any complaints to the nurse.

Directly Observed Therapy

- Most TB patients start feeling well after only a few weeks of treatment but the TB germs are still alive in the body
- It is very dangerous for a TB patient to stop taking medicine early or not to take it regularly. The TB germs begin to grow again and patients may become infectious and remain sick much longer.
- Stopping treatment too early or taking treatment irregularly could cause the TB germs to become resistant to the TB medicine. If this happens, new and different medicines will be needed to kill the TB germs. These new medicines have to be taken for a longer time and usually have more serious side effects.
- DOT helps prevent these problems by making sure that treatment is complete.

Importance of regular medical assessments

- It is very important to have regular check-ups at the clinic at least monthly.
- Blood tests can be done to make sure the medications are not harming the liver.
- Chest x-rays may be done to see if there is improvement.
- Sputum tests will be done to ensure medications are working. The sputum results also help decide when a patient is no longer infectious and can return to his/her normal life.

Importance of contact investigation

- When a patient has TB disease, they are doing the right thing by sharing the names of people they spent time with when they were able to pass TB germs to others (infectious period). By helping the healthcare worker do a contact investigation, they are helping their family and friends stay well. And they are helping to make sure their community stays healthy.
- The healthcare worker will ask for the names of contacts, people the patient spent time with before getting treatment—when the TB germs could be passed on to others.
- The healthcare worker will call or visit people to let them know they should be tested for TB. Together the healthcare worker and patient make a list of all

contacts. Contacts are family members, friends, neighbors, co-workers, and others who spent time with the patient when they were sick.

- Give the names of the contacts to your healthcare worker. Don't let being embarrassed keep you from listing people you may have given TB germs. Think of how you are helping those around you stay well. Protect your family and friends.
- Questions the healthcare worker may ask the patient:
    - "How long have you been coughing? When did you first feel sick?"
    - "Where did you spend time when you were feeling sick and coughing? Where did you live? Did you go to school? Where did you hang out when you were not at home or working?"
    - "Who are the family members, friends, neighbors, and co-workers you spent time with while coughing?"
- The healthcare worker will decide which people need to be contacted based on the information given. It is important for the healthcare worker to be in touch with people who may have been given TB germs. These friends, family members, co-workers, or classmates may have latent TB infection. This means they have dormant (sleeping) TB germs in their body, so they may not feel sick. If they get treatment for latent TB infection, they won't get sick with TB disease. If they already have TB disease, they will need treatment right away.
- Some people with TB disease are afraid they will lose their job if others learn they passed TB germs to people at work. Others may be worried their friends and family will reject them. What you need to know is that the information you share with the healthcare worker is kept private and confidential.
- The healthcare worker will call or visit the people named. He/she may talk to a group of people at the patient's work, school, or place of worship. The healthcare worker will suggest the contact get a TB skin test and will provide information on where to get tested.

8. Adherence, GA TB Laws and Court-Ordered Treatment

Table of Contents

ADHERENCE

For in-depth information on adherence, please read Chapter VII in *Tuberculosis Nursing: A Comprehensive Guide to Patient Care* and Module 9 of CDC's *Self Study Modules on Tuberculosis.*

Adherence means "sticking to" or "being faithful to," such as your *adherence* to your diet even when chocolate cake is around, or patients' *adherence* to TB treatment — they continue to take medication even when they are feeling better. TB treatment takes at least six months and could last for up to two years. Most patients begin to feel better early in the treatment. This makes it difficult for them to continue to take medication that may make them feel bad. It can be challenging for the public health staff to help keep the patient on treatment.

Understanding how the patient feels about TB disease and treatment will help the healthcare worker begin to support the patient. Accepting different perceptions while presenting valid health information can be challenging. All education and information must be tailored to the patient's knowledge and readiness to accept new information. The *12 Points of Patient Education* can be presented using videos, pictures, written material or through conversation. The patient education section in this manual contains pictures that can be used as well as the *12 Points of Patient Education*. The county health departments have DVDs and videos. Web presentations and other patient resources can be found online on the DPH TB Program's web site at https://dph.georgia.gov/tb-educational-resources-general-public.

From the first encounter, the patient needs to understand what is expected during the course of TB treatment and the consequences if those expectations are not met. Tell the patient about non-adherence and why it might occur. Explain the consequences of non-adherence are treatment failure and continued TB transmission. Set the expectation that public health is here to support the patient in completing a full course of therapy until treatment completion. The expectations should be reinforced at each encounter with the patient until they are fully understood. This can best be done by the health care worker listening carefully to the patient and quickly identifying any possible barriers to adherence. Once identified, the barriers need to be addressed and mutually resolved.

During the first visit, the consent to treatment form (3609.TB) and the treatment plan (3144) should be explained and agreements signed. In addition, a DOT agreement (603 DOT) needs to be negotiated and signed. At every patient encounter, adherence should be checked and documented. The TB Case Manager should analyze the patient's adherence rate during monthly evaluation sessions and more frequently as needed. Episodes need to be dealt with promptly and efforts and results of efforts need to be documented as they occur.

The local clinic staff must assess how the patient is adhering to treatment, quickly recognize when a patient is not on course and make rapid interventions to minimize interruptions in treatment. It is important for the staff to identify the specific reasons a patient is not adherent and address them with the patient. An individualized plan to overcome the barriers to treatment needs to be made and negotiated with the patient. At times, an additional agreement may need to be written and signed by the patient.

The following are some examples of non-adherent episodes:

- Patient on five day per week DOT and misses three DOT appointments in a two-week period.
- Patient on twice weekly DOT and misses two DOT appointments in a two-week period.
- Patient misses a clinic appointment
- Patient breaks isolation while still infectious
- Failure to disclose adequate information to identify contacts
- Substance abuse during treatment causing interruption in TB treatment

Each episode of non-adherence must be documented in the patient record. All actions taken and the results of those actions must be thoroughly documented in the patient record.

It is important be as pro-active as possible when dealing with patients. Break down the length of treatment into manageable steps and use individualized incentives for reaching set milestones. Provide positive reinforcement for keeping appointments. Make DOT appointments that fit into the patient's lifestyle and are easy to keep. Send reminders for clinic appointments. Help the patient identify a buddy that can provide additional support during treatment.

Negotiation and assisting the patient to come up with solutions before small incidents become major issues can help to avoid having to take a patient to court. Listening carefully to the patient and acting on clues during conversation can decrease episodes of non-adherence. For instance, during the course of a conversation, the patient may mention leaving town to visit with a family member. The public health staff should act on that information and get details about the possible visit. Answer questions of *who, when, where* and work with the patient to work out a mutually satisfactory way to make sure the patient continues treatment without interruptions while visiting the family.

Adherence should methodically be assessed and documented on a monthly basis at a minimum. Results should be discussed during the regular case reviews with the staff and/or TB Coordinator. Strategies to address issues should be discussed, implemented, evaluated and documented before they become a major problem.

ASSESSMENT TOOL

1. Take the ***actual*** number of events and divide by the ***scheduled*** number of events then multiply by 100 to get percentage of adherence for each of the following:

    - DOT doses in a month
    - Clinic visits to date
    - Referrals made for social services or medical care to date

    Examples:

DOT	65 scheduled DOT visits, showed up for 42 visits 42 divided by 65 = .646 X 100 = 64.6% DOT adherence
Clinic appointments	5 scheduled clinic visits, showed up for 2 visits 2 divided by 5 = .4 X 100 = 40% clinic appointment adherence
Referrals	Referred to HIV clinic for testing, substance abuse counselor & social security disability. Showed up for HIV testing 1 divided by 3 = .33 X 100 = 33% referral adherence

2. Review the number of episodes of non-adherence to date. Have the methods to address those episodes been effective? Are there other steps that need to be taken?

3. Is the patient on track to complete treatment within one year? Do a current dose count and project treatment completion. Minimum amount of time is 26 weeks and maximum time is 52 weeks.

4. Assesses patient's TB knowledge, attitudes, and beliefs concerning drug efficacy and severity of TB disease; reviews patient education progress on the Tuberculosis Education Record.

ESCALATION OF ISSUES

Unfortunately, patient situations can be complex and timeliness of interventions is needed. Below are guidelines for bringing potential problems to resolution in a prompt manner so that interruptions to treatment are minimized. Remember, documentation is key in these matters.

LOCAL TB NURSE

- Assesses for potential conflicts in approach to TB treatment and naming of exposed persons; identifies nature of differences and addresses patient-centered approach with patient and in written plan
- Outlines, verbally and in writing, patient and provider responsibilities so that each understands important details about how patient's TB will be managed: legal parameters, method of treatment administration, methods of airborne infection control, methods of communication (e.g., phone numbers)
- Assesses for potential treatment barriers; selects, with patient's input, mutually acceptable enablers to overcome barriers;
- Negotiates incentives to reward successful accomplishment of treatment milestones
- Performs initial telephone calls, home visits, and certified letters to gain cooperation and compliance

DISTRICT TB COORDINATOR

- Assists TB nurse with follow up actions, field visits, and location strategies for missing patients
- Supports TB Nurse in negotiation and information sessions with patient to stress patient care plan; adherence; and strategies to overcome barriers
- Discusses with State Office developing situations and possible strategies

DISTRICT TB HEALTH DIRECTOR

- Issues Health Director Orders for compliance
- Notifies county attorney of possible court action; works with attorney through the court process

STATE TB OFFICE

- Support TB Coordinator in strategies to overcome issues
- Support district staff through the court process
- Liaison to GeoCare if confinement is needed

COURT-ORDERED TREATMENT AND/OR CONFINEMENT OF NON-ADHERENT TB PATIENTS

All court proceedings should be through the District TB Coordinator. The state office TB Program is to be notified immediately of any pending legal issue with a TB case. The county attorney, the client's attorney and all associated court fees are to be paid by the county health department.

The state office TB Program is to be notified immediately of any pending confinement case. Approval must be obtained from the TB Program Director. The health district is expected to pay the confinement facility. Paid invoices can then be submitted to the state office TB Program for reimbursement.

Typical Court-Ordered Treatment Process:

1. District Health Officer or TB Coordinator sends a certified letter to non-adherent patient with specific instructions on TB treatment and isolation, e.g., wear a surgical mask in public.
2. If no letter has been sent, but the County Health Department (CHD) has documentation that they gave specific instructions to the patient, patient agreed and signed a treatment plan, patient did not comply with these instructions and is a public health threat because of potential disease transmission, the District or CHD can proceed to ask for court-ordered compliance with CHD instructions.
3. CHD should contact the county attorney's office for an Emergency Commitment Hearing Order (Form 3 in Court Order Templates). The county attorney will have a judge sign the order.
4. With this order, a court hearing is scheduled within 7 days from the day the order is signed. The county sheriff will pick-up the patient and confines him in a jail or hospital with respiratory isolation facilities until the court hearing. The sheriff's office can contact other counties to confine the patient if their county jail or local hospital does not have an appropriate isolation room.
5. The patient is assigned a lawyer, the county attorney represents the CHD, and CHD health providers appear in court to testify.
6. The judge can order the patient to follow very specific instructions, e.g., wear a mask in public until sputum smear negative 3x and until he has taken 2 weeks of medicines, and comply with DOT. The judge can state that if patient does not comply, he will be in contempt of court and can be detained/committed by court order to a facility approved by the state TB program like a county jail with respiratory isolation units or GeoCare (previously JustCare) in South Carolina.
7. If the county attorney does not have a lot of experience with these kinds of orders, s/he can consult with the county attorneys from Fulton, DeKalb, Gwinnett or Cobb, who are experienced with such procedures.

The Georgia Department of Public Health and GeoCare Inc. in South Carolina have a memorandum of understanding (MOA) regarding court-ordered non-adherent TB

patients referred by county health departments to GeoCare for detention. The MOA has the following stipulations:

FUNDING FOR ADMISSION OF GEORGIA TB PATIENTS AT GEOCARE:
Charges incurred by clients involuntarily committed will be invoiced to the client's county health department. The DPH TB Program will provide allocations to the respective district for charges incurred by the client(s) admitted to GeoCare. These allocations will be made within 30 days of receipt of an invoice.

a) Services under this MOA will be invoiced to each district at a daily per person rate of $260.00 while in isolation and $189.00 out of isolation (2012 rates).
b) After the first year of this MOA, on the anniversary date, the price will adjust for each additional year, in an amount equal to the most recently available annual change in the *Bureau of Labor Statistics Consumer Price Index for the South, Medical Care Component,* which is the most accurate measure of the cost increases CRCC experienced delivering services.
c) The DPH TB Program will assist GeoCare, when requested, in collecting past due invoices from respective districts.

RESPONSIBILITIES OF THE DPH TB PROGRAM FOR GEOCARE REFERRALS:

a) The DPH TB Program will ensure that all clients referred for admission to GeoCare have a legal commitment order prior to admission.
b) The DPH TB Program will ensure that GeoCare receives a completed *Medical Data Summary Sheet* on each pending admission.
c) The DPH TB Program will ensure that each client will arrive with a signed *Medical Care Plan*, a copy of his/her current medical record along with a 3-month supply of prescribed TB medications.
d) The DPH TB Program will ensure that the balance of prescribed TB medications to complete the client's treatment regimen will be provided.
e) The DPH TB Program will routinely monitor the care, treatment and clinical status of each TB client committed from Georgia.
f) The DPH TB Program will provide technical assistance, guidance, educational materials as requested.

RESPONSIBILITIES OF GEOCARE REGARDING SERVICES AND DELIVERABLES:

a) GeoCare agrees to provide rooms that are secure and ensure safety at all times and that are appropriate for clients involuntarily committed to the facility for failure to adhere to a treatment regimen.
b) GeoCare agrees to follow the *Medical Care Plan* which accompanies the client from Georgia.
c) GeoCare agrees to consult the DPH TB Program Medical Consultant prior to any change in the prescribed treatment plan.
d) GeoCare agrees to obtain prior approval from the DPH TB Program Medical Consultant or a designee before any referral to another facility for services, with the exception of a medical or life-threatening emergency. The DPH TB Program will be notified as soon as possible after the occurrence.
e) GeoCare will provide monthly x-rays as ordered.

f) GeoCare will provide *Monthly Medical Status Reports* to the DPH TB Program and local county health department.
g) GeoCare will provide Airborne Infection Isolation (AII) rooms/special negative pressure rooms for the specific purpose of isolating persons who might have suspected or confirmed infectious TB disease.
h) GeoCare will provide three nutritious meals along with snacks daily.
i) GeoCare will provide opportunities for recreation in the courtyard.
j) GeoCare will provide transportation for external medical appointments, if required.

SPECIAL CIRCUMSTANCES:

a) In the event of the death of the TB client committed from Georgia, GeoCare shall notify the state TB Program Manager or designee as soon as possible after the event.
b) The DPH TB Program will notify the county health department of the client's death.
c) The DPH TB Program will discuss any burial plans with the respective county health department and with family members, if available.
d) If the TB client is deemed homeless and after due diligence to identify family none is found, the client will be buried in accordance with the procedures of GeoCare.
e) A statement to the effect of the above item d will be faxed to the GeoCare General Manager.
f) The cost of burial will be included in the client's last invoice.

REPORTING REQUIREMENTS:

a) GeoCare will submit monthly invoices for each client's charges to the respective District TB Coordinator by the 15th of each month for the preceding month.
b) GeoCare will submit a *Monthly Medical Status Report* to the DPH TB Program's State Office for each TB client in their custody. Reports should be received by the 15th of each month for the preceding month.
c) GeoCare will provide the DPH TB Program with a thorough *Discharge Summary* within two weeks after the client's discharge from their facility. The *Discharge Summary* will be inclusive of a synopsis of the hospital course, special procedures performed, consultations performed, abnormal laboratory studies and a complete list of medications prescribed at discharge.
d) GeoCare will provide a 7-day supply of TB medications, if the patient is still under treatment at the time of discharge from the facility.

DELINQUENT REPORTS:

a) GeoCare will submit reports/client updates as required by the DPH TB Program by the designated due dates as outlined in this MOA.
b) DPH TB Program reserves the right to withhold payments for services performed under this MOA, after notice to GeoCare and an opportunity for a meeting with a DPH TB Program representative.

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Sample Medical Care Plan for GeoCare Referral

(Type the Medical Care Plan on your County Health Department's letterhead/stationery)

Current Date:
Patient's Name:
Patient's Date of Birth:
Patient's Social Security Number:
Diagnosis: Laboratory-confirmed, active pulmonary TB
Medications:
(Provide detailed directions. For PRN medications, add reason for administration)
Initial TB drug regimen (for current weight = xx lbs.)

Isoniazid 300 mg daily for 56 doses by DOT
Rifampin 600 mg daily for 56 doses by DOT
Ethambutol xxxx mg daily for 56 doses by DOT
Pyrazinamide xxxx mg daily for 56 doses by DOT
Pyridoxine 25 mg daily for 56 doses by DOT

Continuation TB drug regimen

Isoniazid 900 mg twice weekly for 36 doses by DOT
Rifampin 600 mg twice weekly for 36 doses by DOT
Pyridoxine 50 mg twice weekly for 36 doses by DOT

Chest x-ray frequency:

Only if indicated

Laboratory Testing: (Frequency of sputum examination, liver enzymes, vision tests, etc.)

- Monthly hepatic function panel, or as needed if signs or symptoms of hepatic toxicity
- Sputum AFB smear/culture daily x 3 then weekly until sputum conversion, then monthly

Miscellaneous:
(ID consult, negative pressure isolation room, frequency of recording patient's weight, social services referral if substance abuse counseling/drug rehabilitation is indicated, etc.)

- Baseline and monthly visual acuity testing and red/green color discrimination
- Negative pressure room needed until 3 consecutive negative sputum smears collected on different days, 2 weeks of TB medication and signs of clinical improvement
- Biweekly weight checks
- Refer to social services related to substance abuse

Interchange:
Please send monthly reports of normal findings re:
1. Medical evaluation
2. Laboratory results
3. General condition and miscellaneous

Please notify us as soon as possible re:
1. Abnormal laboratory findings
2. Adverse reactions to medications
3. Any other pertinent abnormal findings

Physician's signature and date signed needed at end of sheet
Type physician's name and title underneath signature.

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GEORGIA CODE

*** Current Through the 2013 Regular Session ***

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TITLE 31. HEALTH

CHAPTER 14. HOSPITALIZATION FOR **TUBERCULOSIS**

§ 31-14-1. "Active **tuberculosis**" defined; declaration of policy

(a) As used in this chapter, the term "active **tuberculosis**" means a diagnosis demonstrated by clinical, bacteriologic, or diagnostic imaging evidence, or a combination thereof. Persons who have been diagnosed as having active **tuberculosis** and have not completed a course of anti-tuberculosis treatment are still considered to have active **tuberculosis** and may be infectious.

(b) Active **tuberculosis** is declared to be dangerous to the public health.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 1; Code 1933, § 88-701, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 2005, p. 1513, § 1/SB 56.
Title Note

§ 31-14-2. Petition for commitment

When the county board of health or the Department of Public Health has evidence that any person has active tuberculosis and is violating the rules and regulations promulgated by the department or the orders issued by the county board of health and thereby presents a substantial risk of exposing other persons to an imminent danger of infection, after having been directed by the county board of health or the department to comply with such rules, regulations, or orders, the county board of health or the department shall institute proceedings by petition for commitment, returnable to the superior court of the county wherein such person resides or, if such person is a nonresident or has no fixed place of abode, in the county wherein such person may be found. The petition executed under oath shall state the specific evidence supporting the allegations, that the evidence has existed within the preceding 30 days, that the person named therein has active tuberculosis and is violating the rules and regulations of the

department or the orders of the county board of health and presents a substantial risk of exposing other persons to an imminent danger of infection, after having been directed by the county board of health or department to comply with such rules, regulations, or orders, and that the public health requires commitment of the person named therein. The petition must be accompanied by a certificate of a physician stating that the physician knows or suspects that the person named therein may have active tuberculosis, the evidence which forms the basis of this opinion, and whether a full evaluation of the person is necessary.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 4; Code 1933, § 88-704, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1995, p. 1231, § 1; Ga. L. 2005, p. 1513, § 1/SB 56; Ga. L. 2009, p. 453, § 1-4/HB 228; Ga. L. 2011, p. 705, § 6-3/HB 214.

§ 31-14-3. Hearing on petition; notice; physical examination; court costs; attorney's fee; conduct of hearing

(a) Immediately upon the filing of a petition pursuant to Code Section 31-14-2, the judge of the superior court shall set the matter for a full and fair hearing on the petition. Such hearing shall be held no sooner than seven days and no later than 12 days, excluding Saturdays, Sundays, and holidays, subsequent to the time of filing of the petition. The court shall serve personal notice of the hearing upon the person named in the petition and upon the petitioner. The notice required by this Code section shall include the time and place of the hearing; notice of the person's right to counsel, that the person may apply for court appointed counsel if the person cannot afford counsel, and that the court will appoint counsel unless the person indicates in writing that he or she does not wish to be represented by counsel; and notice that the person may waive his or her rights to a hearing under this Code section. A copy of the petition and physician's certificate filed under Code Section 31-14-2 shall be attached to the notice. The judge shall, where prayed for in the petition, provide for the examination of the person named therein by a physician licensed under Chapter 34 of Title 43, which examination shall include sputum examinations by a laboratory approved by the department and a recent chest X-ray of good diagnostic quality interpreted by a physician licensed to practice under Chapter 34 of Title 43, as a part of the order setting the matter for hearing; the order shall require the person or persons named therein to make such examination. Any X-ray and accompanying report or any written report as to a sputum examination shall be admissible as evidence without the necessity of the personal testimony of the person or persons making such examination and report. A physician may rely upon this evidence as the basis for the diagnosis of active tuberculosis and the defendant may offer opposing evidence on this issue by testimony or otherwise. All court costs incurred in proceedings under this chapter, including costs of examinations required by order of court but excluding any examinations procured by the person named in the petition, shall be borne by the county wherein the proceedings are brought. The fee to be paid to an attorney appointed under this Code section to represent a person who cannot afford counsel shall be paid by the county board of health instituting proceedings for commitment.

(b) A full and fair hearing shall mean a proceeding before a hearing examiner under Code Section 31-14-8.1 or before the superior court in a proceeding under subsection (a) of this Code section. The hearing may be held in a regular court room or in an informal setting, in the discretion of the hearing examiner or the court, but the hearing shall be recorded electronically or by a qualified court reporter. The person named as defendant shall be provided with the opportunity for the assistance of counsel. If the defendant cannot afford counsel, the court shall appoint counsel for the defendant or the hearing examiner shall request that the court appoint such counsel; provided, however, that the defendant shall have the right to refuse in writing appointment of counsel. Both parties shall have the right to confront and cross-examine witnesses, to offer evidence, and to subpoena witnesses. Both parties shall have the right to require testimony before the hearing examiner or in court in person or by deposition from any physician upon whose evaluation the decision of the hearing examiner or the court may rest. The hearing examiner and the court shall apply the rules of evidence applicable in civil cases, except as otherwise provided for in this chapter. The burden of proof shall be upon the party seeking commitment of the defendant. The standard of proof shall be by clear and convincing evidence. At the request of the defendant, the public may be excluded from the hearing. The defendant may waive his or her right to be present at the hearing. The reason for the action of the court or the hearing examiner in excluding the public or permitting the hearing to proceed in the defendant's absence shall be reflected in the record.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 5; Code 1933, § 88-705, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1985, p. 620, § 1; Ga. L. 1995, p. 1231, § 1; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-4. Service of copy of petition and order; penalty for failure to comply

A copy of the petition and order shall be served on the person named in the petition. Any failure of such person to comply with the order or with the notice by the persons appointed therein to make examination shall be enforceable by attachment for contempt.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 7; Code 1933, § 88-707, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-5. Circumstances allowing custody pending hearing

Where a danger exists that the person named in the petition may abscond or conceal himself or herself or where the person is conducting himself or herself so as to present a substantial risk of exposing other persons to an imminent danger of infection, the

court may, as a part of the order made pursuant to Code Section 31-14-3, direct the sheriff or the sheriff's deputies to take such person into custody pending hearing and impose such confinement as will not endanger other persons. An affidavit shall be attached to the petition containing the specific facts supporting the need for custody pending hearing.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 6; Code 1933, § 88-706, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1995, p. 1231, § 2; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-6. Report of persons making examination; service of copies

The person or persons appointed by the order to make the examination shall file a report thereof, in triplicate, in the court wherein the proceeding is pending. The clerk of the superior court shall forthwith make service of one copy on the agency instituting the proceeding and one copy on the party named as defendant therein and the defendant's attorney, which service shall be personal or by certified mail or statutory overnight delivery.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 8; Code 1933, § 88-708, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1995, p. 1231, § 2; Ga. L. 2000, p. 1589, § 3; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-7. Results of hearing; commitment to hospital or facility; dismissal of petition and release from custody; costs of transportation; review of commitment order

(a) Upon the hearing set in the order, if the court finds that the person has active tuberculosis, is violating the rules and regulations promulgated by the department or the orders issued by the county board of health after having been directed by the county board of health or the department to comply with such rules, regulations, or orders, presents a substantial risk of exposing other persons to an imminent danger of infection, and there is no less restrictive available alternative to involuntary treatment at a hospital or facility approved by the department for the care of tubercular patients, then the court shall issue an order committing the defendant to the custody of the sheriff of the county or the sheriff's deputies to be delivered to the designated hospital or facility, where the defendant shall be admitted for care and treatment not to exceed two years. If the court does not find that the above standards are met, then the court shall dismiss the petition and the defendant shall be released from custody if taken into custody pursuant to Code Section 31-14-5. The costs of transporting such person to the hospital or facility shall be paid out of county funds.

(b) An order for commitment shall be subject to review at the instance of either party by

appeal.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, §§ 9, 10; Code 1933, §§ 88-709, 88-710, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1985, p. 620, § 2; Ga. L. 1995, p. 1231, § 2; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-8. Period of confinement of patients committed under chapter

Upon commitment the patient shall be confined in a hospital or facility approved by the department for the care of tubercular patients for a period not to exceed two years unless, before the expiration of such two-year period, the designated responsible physician of the tuberculosis inpatient unit determines that the following conditions no longer exist:

(1) The patient has active tuberculosis; or

(2) The patient has active tuberculosis and there is a substantial likelihood of future noncompliance with a proposed treatment plan which will predictably lead to the development of infectious drug-resistant tuberculosis. The likelihood of noncompliance must be based upon a history of noncompliance with treatment; provided, however, that short emergency leaves in the event of death or critical illness in the family or short therapeutic leaves may be granted under conditions which would not adversely affect the public health and in accordance with rules and regulations established by the department.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 11; Ga. L. 1957, p. 271, § 1; Code 1933, § 88-711, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1985, p. 620, § 3; Ga. L. 1995, p. 1231, § 2; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-8.1. Continuation of confinement of patient; report required; hearing

(a) If it is necessary to continue confinement of a committed patient beyond a period of two years ordered by a court or hearing examiner or authorized under subsection (d) of this Code section, the designated responsible physician of the tuberculosis inpatient unit shall review and update the patient's treatment plan and shall prepare a report giving evidence of the necessity of such continued confinement. The report shall be prepared so as to allow sufficient time for the hearing authorized by this Code section to be conducted before the expiration of the two-year period of confinement. The report shall specify that, based upon clinical or X-ray evidence:

(1) The patient is a person having active tuberculosis requiring continued

commitment; or

(2) The patient is a person having active tuberculosis with a substantial likelihood of future noncompliance with a proposed treatment plan which will predictably lead to the development of infectious drug-resistant tuberculosis. The likelihood of noncompliance must be based upon a history of noncompliance with treatment.

(b) Such report shall be filed in the patient's medical record. A copy of the report shall be personally served on the patient along with a statement that the patient may, within 15 days after service of the report, file a request for a hearing to be conducted in accordance with the procedure for contested cases under Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act,' except as otherwise provided in this chapter, that the patient has a right to counsel at the hearing, that the patient may apply immediately to the superior court in the county where the committed patient is confined to have counsel appointed if the patient cannot afford counsel, and that the court will appoint counsel for the patient unless the patient indicates in writing that he or she does not desire to be represented by counsel or has made his or her own arrangements for counsel. Payment for such court appointed representation shall be made by the department. The hearing may be continued as necessary to allow the appointment of counsel.

(c) If a hearing is requested within 15 days of service of the report on the patient, the hearing examiner shall set a time and place for the hearing to be held within 15 days of the time the hearing examiner receives the request. The hearing examiner may set a hearing if a request is made later than 15 days after service of the report if good cause is shown for the delay in making the request. Notice of the hearing shall be personally served on the patient, the hospital or facility, and, when appropriate, on counsel for the patient. Such hearing shall be a full and fair hearing, as described in Code Section 31-14-3, before a hearing examiner. After such hearing, the hearing examiner may issue any order which the court is authorized to issue under Code Section 31-14-7.

(d) If a hearing is not requested within 15 days of service of the report on the patient, the department shall be authorized to continue confinement of the patient for an additional period not to exceed six months.

HISTORY: Code 1981, § 31-14-8.1, enacted by Ga. L. 1995, p. 1231, § 2; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-8.2. Appeal from orders of superior court or hearing examiner; costs; right to counsel

Either party may appeal any order of the superior court or hearing examiner in a proceeding under this chapter. An order of the superior court may be appealed to the Court of Appeals and the Supreme Court as provided by law but shall be heard as expeditiously as possible. The appeal of an order of a hearing examiner shall be to the

superior court of the county in which the proceeding was held. The review shall be conducted by the superior court without a jury and shall be confined to the record. The court, upon request, may hear oral argument and receive written briefs. The patient must pay his or her costs upon filing any appeal authorized under this Code section or must make an affidavit that he or she is unable to pay costs. The parties shall retain all rights of review of any order of the superior court, the Court of Appeals, and the Supreme Court, as provided by law. The patient shall have a right to counsel on appeal or, if unable to afford counsel, shall have counsel appointed for the patient by the court. The appeal rights provided in this Code section are in addition to any other appeal rights which the parties may have.

HISTORY: Code 1981, § 31-14-8.2, enacted by Ga. L. 1995, p. 1231, § 2; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-9. Procedure for securing discharge; petition for habeas corpus

(a) At any time after commitment and not more often than once every six months, the patient or any friend or relative having reason to believe that the patient no longer has active tuberculosis or that the patient's discharge will not endanger the public health may institute proceedings by petition in the superior court of the county wherein the confinement exists, whereupon the judge shall set the matter for a hearing to occur within 15 days requiring the person or persons to whose care the patient was committed, or their duly authorized agents, to show cause on a day certain why the patient should not be discharged. The judge shall also require that the patient be allowed the right to be examined prior to the hearing by a licensed physician of the patient's own choice and at the patient's own personal expense. Thereafter all proceedings shall be conducted in the same manner as are proceedings for commitment.

(b) In addition to the above procedure for securing discharge, the patient or a friend or relative on behalf of such person may petition, as provided by law, for a writ of habeas corpus to question the cause and legality of detention and to request a court of competent jurisdiction to issue a writ for release, provided that a copy of the petition along with the proper certificate of service shall also be served upon the presiding judge of the court ordering such detention and upon the county board of health or the Department of Public Health which initiated the petition for commitment pursuant to Code Section 31-14-2, which service shall be made by certified mail or statutory overnight delivery.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 12; Code 1933, § 88-712, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1995, p. 1231, § 2; Ga. L. 2000, p. 1589, § 3; Ga. L. 2005, p. 1513, § 1/SB 56; Ga. L. 2009, p. 453, § 1-4/HB 228; Ga. L. 2011, p. 705, § 6-3/HB 214.

§ 31-14-10. Enforcement of rules and regulations by county boards of health

The county boards of health or their duly authorized agents shall, within their respective limits, enforce rules and regulations adopted by the department for the protection of the public against active tuberculosis.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 3; Code 1933, § 88-703, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1985, p. 620, § 4; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-11. Unauthorized leave of committed person from hospital or facility

Any person who leaves a hospital or facility approved by the department for the treatment of tuberculosis to which he or she has been committed by court order, without having been discharged by the medical staff of the tuberculosis inpatient unit or the community tuberculosis control unit, shall be taken into custody and returned thereto by the sheriff of any county where such person may be found, upon affidavit being filed with the sheriff by the designated responsible official of the hospital or facility to which such person has been committed.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 14; Code 1933, § 88-714, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1985, p. 620, § 5; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-12. Applicability of commitment provisions to persons who obey rules and regulations of department

No person having active tuberculosis who, in his or her home or other place, obeys the rules and regulations of the department and county boards of health for the control of active tuberculosis or who voluntarily accepts care in a hospital or facility operated for the care of tuberculosis, in his or her home, or in another place and who obeys the rules and regulations of the department and completes the prescribed course of therapy for the control of active tuberculosis shall be committed as prescribed in this chapter.

HISTORY: Ga. L. 1953, Nov.-Dec. Sess., p. 348, § 13; Code 1933, § 88-713, enacted by Ga. L. 1964, p. 499, § 1; Ga. L. 1985, p. 620, § 6; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-13. Order directing compliance with plan of evaluation or outpatient treatment; contempt

(a) In lieu of the petition for commitment as authorized by Code Section 31-14-2, the county board of health or the department may petition the court for an order directing the person to comply with a plan of evaluation or outpatient treatment. The department may also petition the court for an order directing the parents, guardians, or custodians of persons under the age of 18 who have been exposed to tuberculosis to allow screening for tuberculosis by public health authorities or to provide evidence of such screening by a licensed physician. Proceedings, evidence, and hearings thereon will be in the same manner as with commitment petitions, and upon the hearing the court may dismiss the petition or order the person to comply with the screening, evaluation, or outpatient treatment plan. The court may also modify the plan prior to ordering compliance.

(b) A petition for outpatient treatment as authorized by subsection (a) of this Code section may also be initiated by a county board of health or the department where a previously hospitalized, diagnosed, or committed patient's condition no longer requires hospitalization or commitment but where protection of the public health requires continued treatment on an outpatient basis of said patient.

(c) Any person known or suspected to have tuberculosis who fails to comply with a plan of evaluation or outpatient treatment ordered pursuant to this Code section, or any parent, guardian, or custodian of a person under the age of 18 who fails to comply with screening ordered pursuant to this Code section or who aids or abets such failure may be punished as for contempt. Contempt proceedings may be initiated by the filing of a petition by the county board of health or by the department with the superior court of the county of the patient's residence or the county where the patient may be found if a nonresident or without a fixed place of abode.

HISTORY: Code 1981, § 31-14-13, enacted by Ga. L. 1985, p. 620, § 7; Ga. L. 2005, p. 1513, § 1/SB 56.

§ 31-14-14. Immunity from liability

Any physician, peace officer, attorney, or health official, or any hospital or facility official, agent, or other person employed by a private hospital or facility or at a hospital or facility operated by the state, by a political subdivision of the state, by a county board of health, or by a hospital authority created pursuant to Article 4 of Chapter 7 of Title 31, who acts in good faith in compliance with the admission and discharge provisions of this chapter shall be immune from civil or criminal liability for his or her actions in connection with the admission of a patient to or the discharge of a patient from a hospital or facility approved by the department for the care of tubercular patients.

HISTORY: Code 1981, § 31-14-14, enacted by Ga. L. 1995, p. 1231, § 3; Ga. L. 2005, p. 1513, § 1/SB 56.

CHAPTER NOTES

CROSS REFERENCES. --Designation of department as agency responsible for supervision and administrative control of state hospitals for treatment of tubercular patients, § 37-1-21.

ADMINISTRATIVE RULES AND REGULATIONS. --Tuberculosis control, Official Compilation of the Rules and Regulations of the State of Georgia, Department of Human Resources (now the Department of Community Health for these purposes), Public Health, Chapter 290-5-16.

LAW REVIEWS. --For note on 1995 amendments and enactments of Code sections in this chapter, see 12 Ga. St. U.L. Rev. 247 (1995).

TITLE NOTES

LAW REVIEWS. --For article, "The Aftermath of Baby Doe and the Evolution of Newborn Intensive Care," see 25 Ga. St. U.L. Rev. 835 (2009). For article, "The Problem of Non-Identity in Valuing Newborn Human Life," see 25 Ga. St. U.L. Rev. 865 (2009). For article, "Baby Doe: Does It Really Apply Now? Palliative Care of the Ill Neonate," see 25 Ga. St. U.L. Rev. 901 (2009). For article, "Why the Capta's Baby Doe Rules Should Be Rejected in Favor of the Best Interests Standard," see 25 Ga. St. U.L. Rev. 909 (2009). For article, "Personal Reflections on Extremely Premature Newborns: Vitalism, Treatment Decisions, and Ethical Permissibility," see 25 Ga. St. U.L. Rev. 931 (2009). For article, "Medical Futility," see 25 Ga. St. U.L. Rev. 985 (2009). For article, "The Baby Doe Regulations and Tragic Choices at the Bedside: Accepting the Limits of 'Good Process'," see 25 Ga. St. U.L. Rev. 1019 (2009). For article, "Rescuing Baby Doe," see 25 Ga. St. U.L. Rev. 1043 (2009). For article, "Playing God with Baby Doe: Quality of Life and Unpredictable Life Standards at the Start of Life," see 25 Ga. St. U.L. Rev. 1061 (2009). For article, "Baby Doe and Beyond: Examining the Practical and Philosophical Influences Impacting Medical Decision-Making on Behalf of Marginally-Viable Newborns," see 25 Ga. St. U.L. Rev. 1097 (2009).

For note, "Baby Doe at Twenty-Five," see 25 Ga. St. U.L. Rev. 801 (2009). For note, "Phase Six Pandemic: A Call to Re-Evaluate Federal Quarantine Authority Before the Next Catastrophic Outbreak," see 44 Ga. L. Rev. 803 (2010).

JUDICIAL DECISIONS

CITED in Tuck v. State, 122 Ga. App. 649, 178 S.E.2d 305 (1970); Montega Corp. v. Grooms, 128 Ga. App. 333, 196 S.E.2d 459 (1973).

RULES OF THE DEPARTMENT OF HUMAN SERVICES: PUBLIC HEALTH

http://rules.sos.state.ga.us/cgi-bin/page.cgi?g=Georgia_Department_of_Public_Health%2FTUBERCULOSIS_CONTROL%2Findex.html&d=1

511-2-3-.01 Purpose.
(1) The purpose of this chapter is to prevent spread of tuberculosis and to prevent the development of new cases.
(2) The Georgia Department of Public Health or its designee (Department) has the responsibility of developing procedures to ensure that persons with suspected cases of tuberculosis receive prompt diagnostic tests and persons with confirmed cases are given written treatment plans and an adequate oral explanation thereof which, if observed, can prevent the disease from spreading and lead to the recovery of the patient.
(3) A person with pulmonary tuberculosis, and positive sputum, who refuses to take prescribed chemotherapy is a threat to the health of the community. Each time this individual coughs or sneezes, living virulent tubercle bacilli are dispersed on droplet nuclei into the area. By inhaling these virulent bacilli, any individual living or being in close contact with this diseased person over a period of time may become infected with the disease. Furthermore, any person with tuberculosis who refuses to take the full recommended course of therapy is a threat to the community due to the possibility of that person developing drug resistant tuberculosis.
Authority: O.C.G.A. Secs. 31-2A-6, 31-14-1, 31-14-10, 31-14-12. **History:** Original Rule entitled “Purpose” adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

511-2-3-.02 Reporting.

(1) In-patient or out-patient treatment of a case of active tuberculosis and treatment of a suspected case with two or more anti-tuberculosis drugs shall be reported to the Epidemiology and Prevention Branch of the Department through the local county health department or its designee (LCHD). The report shall state whether the case is still under treatment, the address of the case, the clinical status, treatment of the disease, the dates and results of sputum examinations and x-rays, instances of patient noncompliance with the treatment plan and any other information required by the Department. Said reporting should be done either by the attending physician or by the designated person at a treating hospital or clinic, if any. Also laboratories shall report to the Epidemiology and Prevention Branch of the Department and the LCHD all confirmed cultures of mycobacterium tuberculosis.
(2) A physician who attends a case of active tuberculosis shall examine or cause to be examined all persons working or living in close proximity to the patient who have a significant risk of infection, and shall forward the results of said examinations to the Epidemiology and Prevention Branch of the Department and the LCHD. In the alternative, such physician may refer such persons to the LCHD for examination. An

examination required by this section shall include such tests as may be necessary to diagnose the presence of tuberculosis.
Authority: O.C.G.A. Secs. 31-2A-6, 31-14-1, 31-14-10, 31-14-12. **History:** Original Rule entitled “Reporting” adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

511-2-3-.03 Duties and Responsibilities of the County Health Departments
(1) It is the general responsibility of the LCHD to see that proper and reasonable measures are put into effect to prevent the spread of tuberculosis from any person capable of spreading it. In order to fulfill its responsibility the LCHD shall:
(a) ensure that all available tuberculosis control services are accessible to all residents;
(b) secure the prompt reporting of all diagnosed or suspected cases of tuberculosis;
(c) ensure effective treatment and continuing medical supervision of suspected and diagnosed cases of tuberculosis;
(d) ensure that contacts are identified and brought to examination, diagnostic conclusion and appropriate treatment if needed;
(e) provide for the discharge from supervision of patients whose treatment has been successfully completed; and
(f) keep each referring physician or institution informed as to the treatment of each referred patient.
(2) The LCHD shall promptly interview all reported or known persons who have a confirmed or suspected case of contagious tuberculosis.
(3) If, upon information obtained by an agent, the LCHD has reasonable cause to conclude that a person has a suspected or confirmed case of tuberculosis which needs prompt medical evaluation, the LCHD shall issue to the person a written order directing him/her to appear at a specified time and place to comply with a written plan of evaluation. The LCHD shall attach to the order a statement containing its factual basis and shall inform the person of the right to respond in writing to allegations in the statement prior to the scheduled time of the evaluation.
(4) If the person fails to submit to the planned evaluation and has not presented to the LCHD satisfactory reasons why such an evaluation is unnecessary, the LCHD may, in its discretion, file either a petition for an order of compliance or commitment.
(5) If, upon information obtained by an agent of the LCHD, the LCHD has reasonable cause to conclude that a minor may have been exposed to tuberculosis, the LCHD shall issue an order to the parent, guardian or custodian of the minor directing him/her at a specified date and place either to allow tuberculosis screening of the minor by the LCHD or to provide evidence of such screening by a licensed physician. The LCHD shall attach to the order a statement setting forth its factual basis and shall inform the parent, guardian or custodian of his/her right to respond in writing to allegations in the statement prior to the specified date of the screening, or submission of evidence thereof.
(6) If on the specified time the parent, guardian or custodian fails to submit the minor for screening and has not presented medical evidence or other written evidence that such screening is unnecessary, the Department may at its discretion file a petition for the screening of a minor in superior court.

(7) After it has identified a confirmed or suspected case of tuberculosis, the LCHD shall seek to implement a written plan of treatment which shall be explained to the patient who will be given an opportunity to consent to it in writing.
(8) The written plan of treatment shall contain a detailed description of the required cooperation of the patient and the set time schedule of any directly observed intake of prescribed drugs.
(9) The LCHD shall also explain orally and in writing to the patient the value of treatment and why drugs must be taken for the patient's recovery, control of cough, the prevention of the possible emergence of drug resistant organisms, and to prevent the spread of the disease to others.
(10) If, upon information obtained by an agent of the LCHD, the LCHD has reasonable cause to conclude that a patient is failing to comply with a plan of treatment, the LCHD shall issue a written order to the patient directing him/her to present evidence of an intention to comply with the plan of treatment by a specified date. The LCHD shall attach to the order a statement setting forth its factual basis and shall inform the person of his/her right to respond in writing to the allegations in the statement prior to the specified date.
(11) If by the specified date, the patient fails to present to the LCHD evidence that he/she has complied or intends to comply with the plan of treatment, the LCHD may in its discretion issue a quarantine order against the patient or file a judicial petition for an order of compliance or commitment. No such action, however, shall be taken against a patient who voluntarily accepts inpatient treatment recommended by the LCHD.
(12) Notwithstanding the provisions of any other regulation in this chapter, if the LCHD is unable to locate the person to be named in the petition after a good faith effort to do so, or if an imminent danger to public health exists, the LCHD may in its discretion file for a petition for commitment or compliance or issue a quarantine order without first issuing an order to the person.
(13) If a person fails to comply with a quarantine order or a judicial order, the LCHD may institute contempt, injunction, or other judicial enforcement action against the person as is authorized by law.
(14) The LCHD must notify the Director of the State Tuberculosis Control Program or his designee of the intent to initiate commitment proceedings and obtain confirmation of the availability of a bed for such patient before instituting commitment proceedings.
Authority: O.C.G.A. Secs. 31-2A-6, 31-14-1, 31-14-10, 31-14-12. History: Original Rule entitled “Duties and Responsibilities of the County Health Departments” adopted.. F. Sep. 20, 2013; eff. Oct. 10, 2013

511-2-3-.04 Hospitalization of Committed Patients
(1) Upon commitment by court order of the superior court, individuals with tuberculosis are to be admitted to a facility approved by the Department for the treatment of tuberculosis patients (approved TB facility).
(2) At the approved TB facility, each patient shall receive the following:
(a) a complete medical and laboratory evaluation upon admission by a licensed physician;
(b) monthly x-rays as ordered;

(c) monthly observed sputum examinations with cultures and sensitivity studies as required;
(d) orders for prescribed drug regimens in the patient's chart and signed by a licensed physician;
(e) a medical evaluation at least once a month on the need for further commitment.
1. A copy of the monthly evaluation shall be forwarded to the committing LCHD.
(3) If a committed patient's behavior becomes unmanageable, he or she may be placed in the proper detention area for further treatment and counseling. If the approved TB facility's detention facilities prove inadequate, the patient may be transferred to more secure facilities designated for the care of tuberculosis by the State TB Control Program.
(4) Acutely ill patients may be transferred to an appropriate medical center for more intensive care.
(5) While these patients are in the hospital, no leaves of absence will normally be granted except for death or critical illness in the immediate family, medical reasons, or for other good cause approved by appropriate staff.
(6) Committed patients shall not be deprived of any social or recreational privilege granted other patients unless the patient is confined to a detention area. Patients confined to a detention area shall not be permitted off-unit privileges except as approved by medical staff.
Authority: O.C.G.A. Secs. 31-2A-6, 31-14-1, 31-14-10, 31-14-12. History: Original Rule entitled “Hospitalization of Committed Patients” adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

511-2-3-.05 Discharge of Committed Patients
(1) The physical status of a patient shall be reviewed by the medical staff on no less than a monthly basis. If no review has taken place within the past month, the patient or his representative may request such a review. If, after such review, it is determined by the designated responsible physician at the approved TB facility or the Tuberculosis Control Program that a committed patient no longer has contagious tuberculosis or his/her discharge will not endanger the public health, he/she shall be discharged if consistent with the order of commitment.
(2) At least fifteen days prior to discharge, the LCHD or its designee must approve a suitable living environment in the community to which the patient is to be discharged.
(3) Upon discharge, the LCHD shall assume responsibility for directly observed therapy, certified sputum collections, chest x-rays and other clinical evaluations. If discharged patients are found to be noncompliant after discharge they are eligible for re-admission either as voluntary or recommitted patients.
(4) The discharging physician must notify and file notice of intent to discharge a committed person from the hospital fifteen days prior to granting a discharge with each of the following:
(a) Director of Tuberculosis Control Program, Department of Human Resources; and
(b) Responsible LCHD from which the individual was committed.

Authority: O.C.G.A. Secs. 31-2A-6, 31-14-1, 31-14-10, 31-14-12. **History:** Original Rule entitled “Discharge of Committed Patients” adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

511-2-3-.06 Judicial Petitions

(1) The Department has concurrent authority with LCHD to file judicial petitions for commitment, orders of compliance, or contempt.

(2) When filing a petition for commitment which asks that the person be taken into custody by the sheriff or his/her deputies prior to the judicial hearing, the LCHD, the Department or their designees shall attach to the petition either an affidavit signed by an agent which alleges that person named in the petition may abscond or conceal himself/herself and the factual basis thereof or an affidavit signed by a physician which alleges that such person is an imminent danger to the public health and the factual basis thereof.

Authority: O.C.G.A. Secs. 31-2A-6, 31-14-1, 31-14-10, 31-14-12. History: Original Rule entitled “Judicial Petitions” adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

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COURT ORDER TEMPLATES

Commitment Order

Consent Commitment Order

Emergency Commitment Hearing Order

Emergency Petition for Confinement of Tuberculosis Client

Modification of Consent Commitment Order

Physician's Certification for Tuberculosis Confinement

Verification

Consent Order for Court-Ordered TB Treatment)

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COMMITMENT FOR TUBERCULOSIS TREATMENT

IN THE SUPERIOR COURT OF _____ COUNTY

STATE OF GEORGIA

_____ COUNTY BOARD OF HEALTH	*	
Plaintiff,	*	
	*	**CIVIL ACTION**
v.	*	**FILE NO.**
_____,	*	
Defendant,	*	

COMMITMENT ORDER

The Plaintiff having filed a Petition for Commitment to a hospital of a client with active tuberculosis on _____, 200__, the Court having appointed a hearing officer to hear the Plaintiff's Petition and counsel to represent the Defendant, the Plaintiff and the Defendant having agreed to the following Consent Order for Confinement and the hearing officer having agreed to this Consent Order; the hearing officer finds the following:

The Defendant, _____, is a _____-year old male/female who has active tuberculosis as defined by O.C.G.A. 31-14-1. From 200__, the Defendant was under the supervision of the _____Board of Health's Tuberculosis Clinic for treatment of his/her active tuberculosis. During this time, the Defendant did not comply with Board of Health orders to consistently take his/her medication and remain confined so that he/she would not spread the disease. The inconsistent treatment of tuberculosis poses the risk to_____ and the general public of creating a resistant tuberculosis strain that would not be treatable for the Defendant or for any person who might contract this resistant strain. Since the Defendant's

involuntary confinement on _____, 200__, at _____, the Defendant's tuberculosis has responded to treatment and the level of bacteria in his/her sputum has reduced dramatically. Although he/she shortly will become non-infectious for active tuberculosis, he/she would subject himself/herself to a relapse if the tuberculosis treatment were not confined for the length of time as prescribed by his/her physician, which could result in a resistant or multi-resistant tuberculosis strain.

Based upon the above-described facts, the hearing officer hereby finds that the Defendant should remain confined to a facility that will ensure he/she consistently takes his/her medication for active tuberculosis. The period of confinement shall be for six (6) months unless an extension of the confinement is granted pursuant to O.C.G.A 31-14-8.1. The place of confinement shall be _____, a facility that has been approved by the Department of Human Resources for the care of tubercular clients. The Defendant's confinement at _____ shall begin only after the Defendant no longer has active tuberculosis as determined by his/her physician. While the client still has active tuberculosis, he/she shall remain confined at _____ under the _____ County Sheriff's supervision. When it is determined that he/she no longer has active tuberculosis, the Sheriff of _____ County or his/her deputies will transport the client to _____ in _____, _____, and release him/her into the custody of and care of _____.

SO FOUND this _____day of _____, 200_____.

_____

Hearing Officer appointed by

Superior Court Judge

_____

Consented to and approved by:

_____

Attorney for Defendant

_____

Attorney for Plaintiff

_____

Defendant

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IN THE SUPERIOR COURT OF _____ COUNTY

STATE OF GEORGIA

_____ COUNTY	*	
BOARD OF HEALTH	*	
Plaintiff,	*	**CIVIL ACTION**
v.	*	**FILE NO.**
_____,	*	
Defendant,	*	

CONSENT COMMITMENT ORDER

The hearing officer that was appointed by this Court having approved a Consent Commitment Order for the confinement of the Defendant, this Court hereby approves the Commitment Oder that was entered into by the hearing officer on the _____ day of _____, 200___.

THEREFORE, the Defendant is ORDERED to be confined pursuant to **O.C.G.A 31-14-1, et seq.,** and to _____ for a period of _____(_____) months to ensure that he/she regularly takes his/her tuberculosis treatment. While at _____, the Defendant will comply with all the orders of _____ for the treatment of tuberculosis, Board of Health orders regarding his/her treatment for tuberculosis, and the orders of medical professional whose care he/she is under. The Defendant's confinement for the treatment and care for his/her disease shall not exceed _____ (___) months, unless that time period is extended by hearing as provided in **O.C.G.A. 31-14-8.1.**

The Defendant's confinement at _____ shall begin only after he/she is negative for active tuberculosis. Until the Defendant is negative for active tuberculosis, he/she shall remain in the custody of the _____County Sheriff or his/her lawful deputies at _____ Hospital.

SO ORDERED this _____ day of _____, 200___.

_____

Judge

Superior Court _____ County

Prepared and presented by:

_____

Attorney for _____

Approved by:

_____

Attorney for _____

_____

Defendant

IN THE SUPERIOR COURT OF _____ COUNTY

STATE OF GEORGIA

_____ COUNTY

BOARD OF HEALTH

Plaintiff,	*	**CIVIL ACTION**
v.	*	**FILE NO. _____**
_____	*	
Defendant,	*	

EMERGENCY COMMITMENT HEARING ORDER

The plaintiffs' Emergency Petition for Confinement of Tuberculosis Client having come before this Court, and after hearing ex parte evidence presented by the Plaintiff, the Court finds the following:

1.

The Defendant, _____, has active tuberculosis

2.

The Defendant has violated the _____ County Board of Health orders to remain confined in the Defendant's residence and has further defied the Board of Health orders to consistently take his/her medicine.

3.

The Defendant poses a flight risk because (state documented basis for allegation – he/she does not have a stable address, has a drug problem, is used to living on the streets).

4.

Based upon the above listed conclusions, the evidence presented to the Court and the Physicians Certificate attached to the Plaintiff's Petition, and the verified Petition, the Court holds the following:

a. Because the Defendant may abscond or conceal himself/herself and because his/her violation of Board of Health orders makes him/her a substantial risk of exposing other person to an imminent danger of infection, the Court directs the Sheriff or his/her deputies to take the Defendant into custody pending the hearing that is required pursuant to **O.C.G.A. 31-14-3.** This shall be under the supervision of Board of Health personnel or other medical personnel to ensure the safety of the Sheriff's deputies.

b. The Defendant shall remain in custody until he/she has a full and fair hearing on the Plaintiff's Petition for Confinement. This initial confinement shall be at a facility appropriate for TB treatment.

c. The Court hereby sets a hearing date on the Plaintiff's Petition for the _____day of _____, 200_ at _____ ___. The hearing shall be conducted at _____.

d. _____ is entitled to appointed counsel. The Court will appoint counsel unless _____ indicates in writing he/she does not want counsel. The Court will appoint counsel unless _____ indicates in writing he/she does not want counsel. The Court hereby appoints _____ as Counsel for the Defendant to represent him/her in this matter.

e. During the Defendant's initial confinement pursuant to this Order, the Defendant shall remain confined so that he/she does not infect the general public with tuberculosis and he/she

shall take his/her medications as directed by the Board of Health and any health professional whose care he/she is under.

f. The Defendant shall further submit himself/herself to appropriate medical examinations to determine whether and when the tuberculosis is no longer active.

SO ORDERED this _____ day of _____, 200_.

_____

_____, Judge

Superior Court of County

Prepared and Presented by:

_____

Attorney for Plaintiff

Ga. Bar No. _____

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IN THE SUPERIOR COURT OF _____ COUNTY

STATE OF GEORGIA

_____ COUNTY	*	
BOARD OF HEALTH	*	
Plaintiff,	*	**CIVIL ACTION**
v.	*	**FILE NO._____**
_____	*	
Defendant,	*	

EMERGENCY PETITION FOR CONFINEMENT OF TUBERCULOSIS CLIENT

COMES NOW, the _____ **COUNTY BOARD OF HEALTH** to file this Petition for Commitment of a Person with Active Tuberculosis pursuant to **O.C.G.A. 31-14-1, et seq.,** and shows the Court as follows;

1.

The Defendant, _____, resides at _____in _____ County, and is therefore subject to the jurisdiction of this Court.

2.

The Defendant has active tuberculosis as defined in **O.C.G.A. 31-14-1 (a).**

3.

The Defendant is violating orders of the Department regarding treatment of his/her active tuberculosis having missed _____ (_____) out of his/her last _____ (_____) scheduled doses. The Defendant has also violated specific Board of Health orders by not confining himself/herself to his/her residence, thus exposing himself/herself to the general

public. The Defendant, by violating these orders of the Board of Health presents a substantial risk of exposing other persons to an imminent danger of infection. The Defendant was released from _____ Hospital on _____, 200_, with active tuberculosis and was referred to the _____County Board of Health Tuberculosis Clinic for follow-up treatment.

5.

The Defendant's chest x-ray and medical examinations and sputum examination confirm that the Defendant has active tuberculosis. The state medical lab has confirmed the sputum test.

6.

The general public's health requires commitment of this person to prevent exposing the general public to tuberculosis.

7.

The Defendant was formerly a homeless person, but since his/her release from _____ Hospital, has resided with _____at _____. This person may be unaware of their risk for TB infection due to continued contact with the Defendant therefore screening may be necessary. Because he/she has no stable address, the Defendant presents a risk of concealing himself/herself from the _____ County Board of Health. He/She has also conducted himself/herself in a manner to expose the general public by disregarding the Board of Health orders to remain confined in_____'s house and to regularly take his/her medication.

8.

Because the Defendant is a flight risk and is conducting himself/herself in a manner to expose others to imminent danger of infection, emergency commitment is necessary to protect the general public.

WHEREFORE, the Plaintiff respectfully requests that this Court:

a. Direct the Sheriff or Sheriff's Deputies to take the Defendant into Custody pending a hearing on the Petition for Confinement so he/she will not endanger other persons pursuant to **O.C.G.A 31-14-5.**

b. That the Court schedules a hearing no sooner than _____ (__) days and no later than _____ (__) days to determine whether the Defendant should be confined.

c. That the Court appoints the Defendant counsels to represent him/her at this hearing.

d. That the Court give the Plaintiff such further relief as the Court deems necessary.

Respectfully submitted,

_____

_____

Attorney for Plaintiff

Ga.Bar No._____

Address

Phone Number

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IN THE SUPERIOR COURT OF _____ COUNTY

STATE OF GEORGIA

_____ COUNTY BOARD OF HEALTH,	*	**CIVIL ACTION**
Petitioner	*	
v.	*	**FILE NO. _____**
_____,	*	
Respondent.	*	

MODIFICATION OF CONSENT COMMITMENT ORDER

The Plaintiff and the Defendant having come before this Court with a Consent Modification of this Court's Consent Commitment Order dated _____, 200_, the Court hereby amends its Order of _____, 200__, as follows:

1.

The _____ County Sheriff is relieved of his/her responsibility of maintaining the Defendant in his/her custody at _____ Hospital until further order of this Court. The _____ County Sheriff or his/her lawful deputies are still responsible for transporting the Defendant to _____ in _____, _____. No other terms of the Consent Commitment Order or the Commitment Order of the hearing officer is altered or amended or superseded by this amendment.

_____

Judge,____ County Superior Court

(Signatures continued on following page.)

Consented to by:

_____
Attorney for Plaintiff

Ga. Bar No._____

_____
Attorney for Defendant
Ga. Bar No._____

IN THE SUPERIOR COURT OF _____ COUNTY

STATE OF GEORGIA

_____ COUNTY BOARD OF HEALTH	*	
Plaintiff,	*	**CIVIL ACTION**
	*	**FILE NO. _____**
_____	*	
Defendant,	*	

PHYSICIAN'S CERTIFICATION FOR TUBERCULOSIS CONFINEMENT

COMES NOW, _____, **M.D.,** who after being duly sworn states the following:

1.

Affiant is a Physician licensed to practice medicine in the State of Georgia and is the Primary Physician for the Defendant.

2.

The Defendant is a _____ year old man/woman with presumptive active Tuberculosis (TB). This diagnosis is based upon a physical examination of the client and reviewing _____'s medical records, including his/her chest x-ray, which shows an anomaly, and positive AFB sputum smears.

3.

The client should be strictly monitored to ensure that he/she takes his/her medication for the TB as prescribed to ensure his/her infection is not infectious and that he/she does not develop drug-resistant TB.

4.

Since _____'s TB is contagious, he/she should be confined so he/she does not

come into contact with the general public.

FURTHER AFFIANT SAYETH NOT.

_____

Print Physician Name

Sworn to and subscribed
before me this _____
day of _____, 200_.

_____
NOTARY PUBLIC

[seal]

STATE OF _____

COUNTY OF _____

VERIFICATION

_____, DIRECTOR, TB CLINIC, _____ COUNTY BOARD OF HEALTH being first duly sworn on oath, deposes and say that he/she is the **Coordinator of the TB Clinic for the _____ County Board of Health,** that he/she has read the foregoing **Emergency Petition for Confinement of Tuberculosis Client** and knows the contents thereof, and that the contents of the Petition are true and correct to the best of his/her knowledge.

_____

DIRECTOR OF _____ COUNTY BOARD OF HEALTH

Sworn to and subscribed before me this _____ day of _____, 200 ___.

_____
NOTARY PUBLIC

[SEAL]

IN THE SUPERIOR COURT OF _____COUNTY

STATE OF GEORGIA

_____COUNTY BOARD OF HEALTH,	**:**	
Petitioner	**:**	**CIVIL ACTION**
v.	**:**	**FILE NO. XX-X-XXXXX-XX**
John Doe	:	
Respondent	**:**	

CONSENT ORDER FOR COURT-ORDERED TB TREATMENT

The petition of the _____County Board of Health having been filed with this court to bring John Doe under court order for treatment of active tuberculosis, and it appearing to the court that John Doe has agreed to be brought under court order, and it further appearing to the court that it is appropriate to make such arrangement the order of this court, it is hereby

CONSIDERED, ORDERED, AND ADJUDGED as follows:

1.

Jurisdiction and venue are proper.

2.

Respondent John Doe has active tuberculosis and is presently a threat to public health. Respondent has missed scheduled treatment and presents a substantial risk of exposing other persons to an imminent danger of infection. Protection of the public health requires treatment of respondent on an outpatient basis.

3.

By his execution of this consent order, respondent John Doe has indicated that he is aware of his right to a hearing in this matter and his right to seek the assistance of counsel, and has freely and voluntarily waived his right to both.

4.

Respondent John Doe shall undergo directly observed therapy ("DOT"), whereby personnel from the _____County Board of Health ("CBOH") will observe him in taking his medications. Respondent shall make himself available on a daily basis for such treatment unless otherwise directed by the CBOH Tuberculosis clinic.

5.

Respondent shall attend monthly clinic visits at the CBOH Tuberculosis clinic, with address at _____, as directed by the CBOH Tuberculosis clinic staff.

6.

Respondent shall submit sputum specimens as directed by CBOH Tuberculosis clinic staff.

7.

Respondent must stay at his home at _____ and not allow any new visitors into his home unless and until he is released to do otherwise in writing by the CBOH infectious disease physician. This release may take place after three negative sputum samples and two weeks of treatment. Otherwise, respondent shall not leave his home except for emergencies and monthly CBOH Tuberculosis clinic visits. Respondent shall wear a surgical mask when he is out of the home.

8.

Respondent shall undergo routine blood work, chest x-rays, and other tests directed by the CBOH infectious disease physician.

9.

Respondent shall cooperate fully with the CBOH Tuberculosis clinic staff in informing them of names, addresses, telephone numbers, places of work, and any other identifying information as to those persons with whom he has had contact.

10.

Respondent shall remain under treatment pursuant to this order unless and until he is released in writing by the CBOH infectious disease physician. Respondent shall undergo any necessary follow-up after treatment as directed by the CBOH Tuberculosis clinic staff.

11.

Failure by respondent to comply with any provisions of this order shall subject him to the contempt powers of this court.

SO ORDERED this ___th day of _____, 20__.

_____

Judge, Superior Court

_____County Judicial Circuit

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AMERICAN LUNG ASSOCIATION®
IN GEORGIA

ALTERNATIVE HOUSING PROJECT FOR HOMELESS TUBERCULOSIS PATIENTS IN GEORGIA

Operational Procedures

2452 Spring Road
Smyrna, Georgia 30080
(770) 434-5864

Revised
July 2010

TABLE OF CONTENTS

Alternative Housing for Homeless Tuberculosis Patients in Georgia Overview

The closure of the TB Unit at Northwest Georgia Regional Hospital (NWGRH) required public health to identify alternative housing for homeless patients discharged from acute care hospitals within the State of Georgia. These patients, some of whom are infectious, need stable housing in which to receive Directly Observed Therapy (DOT), meals and referrals for social services. Working in collaboration with Metro TB Task Force, the American Lung Association in Georgia (ALAG), Grady Health System and the Atlanta TB Prevention Coalition (ATPC), this plan addresses these public health needs for the statewide TB program.

The Division of Public Health, Epidemiology and Prevention Branch utilized partial funds from the redirection of the closure of the In-Patient Unit at NWGRH to contract with the ALAG to provide alternative housing (including meals, personal supplies, transportation [non TB clinic appointments are coordinated through sub-contracted vendors and MARTA tokens for non-infectious patients] and referrals for social services for the homeless TB patients). Through the contract with ALAG, the State Director, two Program Managers, manage this Project.

More than 749 tuberculosis patients utilized the Alternative Housing Project since 1996. The Project utilizes inexpensive motels, trailers, duplexes, apartments and houses. The health departments provide DOT and transportation to TB and Ryan White clinic appointments. July 1, 2005, American Lung Association of Georgia began to extend its services to provide housing services for non-infectious clients.

The plan to place homeless patients in area housing requires frequent communication among ALAG area hospitals, and county TB clinics. In addition to the formal agreements between ALAG and rental establishments, letters of agreements are on file from all participating districts. These letters demonstrate a commitment to the Alternative Housing Project by each district TB Program. Monthly patient care reviews are mandatory to ensure that continuity of care is maintained and other needed services are being provided. A designated outreach worker (ORW provide DOT and patient follow-up.

Procedures for Alternative Housing Project

Purpose:

Funds are provided by the Georgia Department of Community Health, Division of Public Health, TB Unit, to the American Lung Association in Georgia (ALAG) to provide assistance for temporary housing and to facilitate Directly Observed Therapy (DOT) to ensure completion of therapy among homeless TB patients.

Organizational Roles:

ALA in Georgia	Health District	Georgia DCH – TB Control Program
Provide technical assistance in locating appropriate housing for 18 health districts	Assess tuberculosis patients for housing placement and financial assistance	Consultation
Conduct monthly case review with health districts	Participate in monthly case review with ALAG	Technical Assistance
Participate/facilitate multidisciplinary team conferences to maintain patient continuity of care after hospital discharge	Provide directly observed therapy and TB medical management	Administrative Support
Establish goals that can be used to measure progress	Provide transportation to the TB, Ryan White and Infectious Disease clinics	Disburse Funds
Preserve and ensure lines of communications	Preserve and ensure lines of communications	Preserve and ensure lines of communications

Project:

I. The Project will enable homeless TB patients to complete TB therapy by assisting with housing, meals, non-TB clinic transportation substance abuse/mental health referrals and DOT.

II. The ALAG staff will assist the District TB coordinators by identifying temporary housing for appropriate individuals based on medical status and housing needs. Negotiations with potential housing providers must be initiated prior to the identification of homeless patients.

III. ALAG coordinates and approves housing services for the state of Georgia. Funds will be disbursed for housing by check to the leasing agent only. No funds will be issued to the client or family members. The maximum amount allowable at one time is one month's rent. ALAG will not be responsible for paying rent and/or utilities prior to

client entering Project. Clients should be evaluated monthly and monthly assessments should be reported to ALAG to determine the continued need for housing services or referrals to other housing programs.

Process:

I. **Identify Housing Resources**

Temporary housing may be a motel, hotel, efficiency, apartment, trailer, personal care home or rooming house. Reasonable utilities additionally will be paid, if not included in the rental agreement.

Housing Options *

Options include home for patients who can return to a stable home and three levels of facilities for those without a stable home.

Levels of Housing

Level 1:	Acute care hospitals Alternative Housing Project - smear positive, medically stable and clinical improving
Level 2:	Shelters – ones that require negative smears; trained staffs provide DOT. Alternative Housing Project - smear positive, medically stable and clinical improving
Level 3:	Shelters that require negative cultures (extra-pulmonary cases); trained staff for DOT Alternative Housing Project – negative cultures (pulmonary cases)

* Georgia Tuberculosis Reference Guide, 2005. Emory University School of Medicine, Department of Medicine, Division of Infectious Diseases, and Georgia Department of Human Resources, Division of Public Health, TB Program, 2005.

II. **Patient Assessment**

It is the responsibility of the health department to assess all possibilities for housing before requesting assistance through the Project.

A. Eligibility

Patient should be a suspect or an active case of tuberculosis and must demonstrate that he/she has an unstable home environment.

Financial Assistance

If a patient is unable to work because of infectiousness, ALAG will assist

with monthly financial obligations; this is based on the availability of funds and patient's financial status. Funds will immediately cease once the patient has three negative smears. If a patient is living with a family member, all funds will be distributed to the leasing agent and utility company. ALAG will only pay the patient's portion of rent and/or utilities.

Housing Placement -without income

Type of Placements	Infectious or Status Unknown	Non-Infectious	Extra Pulmonary	Latent TB Infection
Hotel	No	Yes	Yes (based on funding availability)	No Services
Motel	Yes	No	Yes (infectious status unknown)	No Services
Personal Care Homes	No	Yes (based on medical condition)	Yes (based on medical condition)	No Services
Rooming House	No	Yes	Yes (based of funding availability)	No Services
*Food	Yes	Yes	Yes	No Services

*Once a client convert to smear/culture negative. He/she will have 30 days to apply for the Food Stamp Program. Client MUST provide ALAG written documentation at that time.

Housing Placement-with income (including food stamps) not to exceed $500.00

Type of Placements	Infectious or Status Unknown	Non- Infectious	Extra Pulmonary	Latent TB Infection
Hotel	No	Yes	Yes (based of funding availability)	No Services
Motel	Yes	No	Yes (infectious status unknown)	No Services
Personal Care Homes	No	Yes (based on medical condition and income amount)	Yes (based on medical condition and income amount)	No Services
Rooming House	No	Yes	Yes (based of funding availability)	No Services
Food	No (ALAG will provide transportation to store with mask)	No (ALAG will provide transportation to store)	No (ALAG will provide transportation to store)	No Services

ALAG has the right to make determinations of eligibility outside the above guidelines.

B. Administrative Procedures

1. The District Health TB Coordinators notifies ALAG, via fax or in Person, with the following completed forms:

   A. Alternative Housing/Social Service Referral;
   B. Patient Health Department Agreement for Temporary Housing;
   C. Temporary Housing Fund Application; and
   D. Patient-Provider Therapeutic Contract; or Patient-Provider Therapeutic Contract for Financial Assistance.

All forms must be completed and signed by the appropriate persons.

2. Once the forms have been submitted, ALAG will respond in writing with the approval time and date within 48 hours. Once the time and date have been set, it is the responsibility of the health district to inform ALAG of any change. If both parties have not confirmed a time and date, ALAG will not be responsible for groceries, supplies and/or rent for that day.

THERE ARE NO PLACEMENTS ON FRIDAYS.

3. During the first week, **supervised** sputums must be collected by the designated health professional three times, thereafter once a week until three consecutive negative. Sputum containers should never be left with the patient nor should the patient receive sputum mailers.

4. For additional funding of current patients, the health districts MUST submit a new **Temporary Housing Fund Application** along with a **Monthly Assessment**. It is not the responsibility of ALAG to request additional funding for existing patients. **If the necessary paperwork is not submitted, no funds will be disbursed**.

5. If the patient misses any DOTs, specimen collections, and/or TB clinic appointments, please complete the Alert Form and submit it to ALAG within 48 hours. Please also submit an Alert Form for any change in the patient's status.

6. Once the patient is ready for other housing, it is the responsibility of the Health District to transport patient. Any patient completing treatment or violating the contract is responsible for his/her own transportation. A Health District representative must be present at the time of the move.

In the Metro-Atlanta area, ALAG will meet the Health District representative at the designated site. All parties must be there at the agreed time. Keys will be collected by ALAG at that time.

District Health TB Coordinators MUST adhere to the above protocols to ensure funding in a timely manner to secure patient's retention in this Project.

Housing Facility Guidelines for Infectious Patients

1. The housing establishment must have prompt availability of housing, a willingness to provide housing and to receive payment on a bi-weekly and monthly basis.

2. The American Lung Association in Georgia and the health districts will provide TB education and skin testing for housing facility staff.

3. The rental unit (motel) will have at minimum, a bed, table, chair, clothing chest, rack for hangers, refrigerator, stove/microwave and television. The room will be clean and without noticeable pest or odors.

4. The room will have a linen change at least once a week. To minimize the risk of exposure to the hotel staff, the linen should be left for the patient to change.

5. The room will be accessible only from a door leading to the outside, not to a public hallway or another room.

6. The entrance door will have a lock on the inside that the client can set manually and a peephole for safety.

7. The room will have its own toilet, bath or shower with hot running water.

8. The room will have its own independent air conditioner that vents to the outside.

9. The selected motel will have a clean appearance on the outside, excluding areas that are under renovation.

Housing Facility Guidelines for Non-Infectious Patients

1. The housing establishment must have prompt availability of housing, a willingness to provide housing and to receive payment on a biweekly and monthly basis.

2. The rental unit (hotel, motel, personal care home or a rooming house) must have at a minimum, a bed, a clothing chest, and a rack for hangers. The room will be clean and without noticeable pest or odors.

3. The housing site must be at least within walking distance of a laundry mat or on the bus route.

4. The entrance will have a lock on the inside that the client can set manually and a peephole for safety.

5. The room will be accessible to a toilet, bathroom with hot running water.

6. The selected housing facility will have a clean appearance on the outside, excluding areas that are under renovation.

Forms

AMERICAN LUNG ASSOCIATION IN GEORGIA

SOCIAL SERVICES REFERRAL
TB Alternative Housing Project

Patient's Name:_____County/District:_____

Age:_____ Race:_____ Gender: □ Female □Male

Previous/Current Address:_____

Address Was: □ Street □ Shelter* □ Abandoned Building □ Family/Friends □ Home

*Name of Shelter_____

Reason for services:_____

****

Lab Status: (Must have lab work to process referral)

	Smear				Culture		
Case	1+	2+	3+	4+	□ No Growth	□ MTB	□ Atypical
					Type of specimen:_____		
Suspect	1+	2+	3+	4+	□ Pending at _____weeks		

Expected TB Completion Date:____/____/___ Site of TB_____

Chest x-ray Status:

€ Abnormal € Normal Date:____/___/____

****

Mental Health Status

Past Psychiatric History Yes No

Diagnosis (where, when, name of Doctor/Therapist) _____

_____

****

Income Status:

□	Employment (Where)_____	$_____
	Can Patient return to work □ Yes □ No	
□	Food Assistance	$_____
□	General Assistant	$_____
□	SSI Disability	$_____
□	TANF	$_____
□	Veterans Benefits	$_____
	TOTAL MONTHLY INCOME	**$**_____

****

Substance Abuse:

□ Alcohol □ Amphetamine □ Cocaine □ Crack □ IV Drug

□ Marijuana □ Denied

****

Services Requested:

□ Housing □ Food □ Funds for Rent/Utilities □ Social Services

****

Anticipated move-in date:_____ TB Representative:_____ Date_____

****

For ALAG Use Only

□ Approved □ Denied _____

Signature and Date

Move in Date:_____

All sections must be completed in its entirety to be processed.

AMERICAN LUNG ASSOCIATION®
IN GEORGIA

PATIENT-HEALTH DEPARTMENT AGREEMENT FOR TEMPORARY HOUSING
TB Alternative Housing Project

I, _____certify that I have no fixed, regular, and/or adequate residence at this time and I am unable to provide 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 (infectious or not infectious) to others. I understand that District Public Health and the _____ will provide temporary housing during treatment and I must:

1. Be at _____ on _____ at _____ am/pm to take my medicine.
2. Keep clinic appointments and have laboratory tests as necessary.
3. Notify the TB nurse of any problems with TB medicine or other emergencies.
4. Avoid alcohol and/or other drug use.
5. Not to participate in any illegal activity at the residential facility.
6. Not visit with other people in the housing area or other indoor areas until the TB nurse tells me I am not infectious to others.
7. Follow lease conditions by not having anyone else stay overnight, unless pre-approved in the lease.
8. Not to make any charges to the housing; and not make any long distance phone calls charged to the housing.
9. Allow the health department to identify me by name to the housing agent if needed.
10. Will hold the American Lung Association in Georgia its agents from **any and all liability.**

I understand that if I violate any of the above, I may lose the housing and I may be confined to another appropriate facility to complete my TB disease treatment.

Client: _____ TB Representative: _____

Date: _____

****

The housing agent hereby agrees to comply with the following and thereby, will hold harmless the American Lung Association in Georgia and its agents from **any and all liability**.

Infectious Patients:

1. Provide housing that meets infection control guidelines.
2. Provide housing with an exit that leads directly to the outside or to a hallway that leads directly outside.
3. Provide single occupancy housing and will report TB patient violations to the TB representative and ALAG.
4. Allow no housing employee to enter the client's room until 24 hours after the client is determined to be noninfectious by the TB nurse. Housekeeping and linen supply arrangements are as follows:

_____

Non-Infectious Patients:

1. Provide single occupancy housing and will report TB patient violations to the TB representative and ALAG.
2. Provide TB patient with clean linen at least once a week if patient is residing at a hotel, motel or a personal care home. Clients residing at a rooming house will be responsible for their own linen.

Housing Agent: _____ TB Representative:_____

Date: _____

TEMPORARY HOUSING FUND APPLICATION
TB Alternative Housing Project

Patient's Name:

Address:

****

TB Coordinator Name:

District:

Health Department:

Address:

County: Telephone #:
Fax #:

****

Housing Vendor:

Federal ID Number:

Contact Person:

Address:

County: Telephone #:
Fax #:

Charges for Housing $ _____ Monthly from _____to_____
$ _____ Bi-weekly from _____to_____
$ _____ Weekly from _____to_____

****

Signature of TB Representative: _____ Date: _____

Signature of Housing Vendor: _____Date: _____

*If there is not a vendor signature, Coordinator must provide official documentation of the amount and address.

All Sections must be completed in its entirety to be processed.

AMERICAN LUNG ASSOCIATION®
IN GEORGIA

PATIENT-PROVIDER THERAPEUTIC CONTRACT
TB Alternative Housing Project

The following is a statement of what is expected of each patient who agrees to accept temporary housing paid for by the American Lung Association in Georgia. Please read guidelines carefully and if you agree to abide by the conditions listed, please sign at the bottom.

1. Lodging will be temporarily provided for you during your treatment for TB. The length of time the room will be made available to you will depend on your medical needs, your cooperation and continued participation with follow-up provided by District Public Health.
2. During your stay, you are expected to keep your room clean and undamaged. At the end of your stay, the room must be left in good condition.
3. You should have **no** visitors at any time.
4. If it is determined that you need food assistance, food vouchers/certificates may be made available to you so that your family or friends may purchase food for you.
5. You must remain in your room until District Public Health informs you otherwise.
6. Your outreach worker or nurse will visit with you once a day, usually in the morning. Other unannounced visits will be made.
7. Participation in Directly Observed Therapy (DOT) is required in order to stay at the residential facility. DOT will be provided to you by a designated health care professional. Failure to participate in a scheduled DOT session, may lead to the immediate termination of your room rental. As a part of your treatment, you may be transported from time to time to the Health Department for test, or to see physicians.
8. Use of illegal drug or other illegal activities by you and/or any guest(s) in your room will result in the immediate termination of your room rental.
9. Any behavior deemed detrimental and or inappropriate (determined by ALAG, the District Public Health and/or the vendor) to your health, the health of others or the property will result in the immediate termination of your room rental.
10. If your room rental is terminated due to inappropriate behavior by you or your guest(s) or by your inability to comply with DOT, you must return the room key immediately to the outreach worker, TB nurse or designated staff and vacate the premises.
11. If you are diagnosed as **not** having TB, you will be released from the Project within 48 hours.
12. ALAG will seek, when possible, to involve and educate family and friends in your aftercare so that they will have a better understanding of how to assist you while you are in the motel and later when you are able to find alternate housing.

Signature: _____ Date: _____

PATIENT-PROVIDER THERAPEUTIC CONTRACT
For Financial Assistance
TB Alternative Housing Project

The following is a statement of what is expected of each patient who agrees to accept financial assistance for (name services) _____ paid for by the American Lung Association in Georgia. Please read guidelines carefully and if you agree to abide by the conditions listed, please sign at the bottom.

1. The length of time that ALAG will provide financial assistance will be determined by any financial changes, your medical needs, your cooperation and continued participation with follow-up provided by District Public Health.
2. You should not have visitors until Public Health informs you that you are no longer infectious to others. At that time visitors must wear a mask.
3. Your TB representative will visit with you weekly. Other unannounced visits will be made.
4. Participation in Directly Observed Therapy (DOT) is required in order to receive financial assistance. DOT will be provided to you by a designated health care professional. Failure to participate in a scheduled DOT session may lead to the immediate dismissal from the Project. As a part of your treatment, you may be transported from time to time to the Health Department or another site for tests or to see physicians.
5. Any behavior deemed detrimental to your health or the health of others will result in the immediate termination of the agreement.
6. If you or your inabilities to comply with DOT terminate the agreement due to inappropriate behavior, ALAG will immediately cease from providing financial assistance.
7. When you have completed the project or have **three negative smears**, ALAG will **immediately cease** from financial assistance.
8. If you are diagnosed as <u>not</u> having TB, ALAG will immediately cease financial assistance.
9. We will seek, when possible, to involve and educate family and friends in your aftercare so that they will have a better understanding of how to assist you while you are enrolled in the Project.

Signature: _____ Date: _____

ALERT FORM
TB Alternative Housing Project

Date: _____

Patient's Name: _____

Location:_____

Date of field visit: _____ Time: _____

Name of person conducting field visit:_____

Reason for field visit:

- ☐ Collect Sputum
- ☐ DOT
- ☐ Transportation to TB Clinic
- ☐ Routine visit
- ☐ Other

****

Reason for Alert:

- ☐ Patient not at designated site
- ☐ Patient was hospitalized
- ☐ Patient refused DOT
- ☐ Patient has unauthorized visitors
- ☐ Patient left Project
- ☐ Patient incapable of living along

Concerns: _____
_____

Plan of Actions: _____
_____

Submitted by:
_____Date:_____

Note: Form must be faxed to American Lung Association in Georgia's Alternative Housing Project within 48 hours of the event. Fax: (770) 319-0349, Office (770) 434-5864

MONTHLY ASSESSMENT
TB Alternative Housing Project

MONTH: _____

PATIENT'S NAME: _____ DATE OF BIRTH: _____

ADDRESS: _____

COUNTY OF RESIDENCE:_____ DISTRICT: _____

LAST CLINIC EVALUATION:_____ ANTICIPATED CLOSURE DATE:_____

****

LAB STATUS:

DATE	SMEAR (Please check box)	CULTURE (Please check box)
1. _____	- ☐ 1+ ☐ 2+☐ 3+☐ 4+ ☐	No Growth ☐ MTB ☐ Pending ☐
2. _____	- ☐ 1+ ☐ 2+☐ 3+☐ 4+ ☐	No Growth ☐ MTB ☐ Pending ☐
3. _____	- ☐ 1+ ☐ 2+☐ 3+☐ 4+ ☐	No Growth ☐ MTB ☐ Pending ☐
4. _____	- ☐ 1+ ☐ 2+☐ 3+☐ 4+ ☐	No Growth ☐ MTB ☐ Pending ☐
5. _____	- ☐ 1+ ☐ 2+☐ 3+☐ 4+ ☐	No Growth ☐ MTB ☐ Pending ☐
6. _____	- ☐ 1+ ☐ 2+☐ 3+☐ 4+ ☐	No Growth ☐ MTB ☐ Pending ☐

How Results Obtained: Sputum ☐ Culture ☐ Induced ☐ Other ☐ _____

(Please Check Appropriate Boxes)

****

CURRENT TREATMENT REGIMEN - DOT:

Daily ☐ Biweekly ☐ 3x weekly ☐ Total Number of DOT's _____
(for the entire month)

If DOT's missed, please give explanation: _____

_____

Number Delivered: _____ Number Taken/Observed _____

****

PATIENT PHYSICAL STATUS: Full time ☐ Part time ☐ Not able to work ☐

SUMMARY/RECOMMENDATIONS: _____

Submitted by: _____ Date: _____

All sections must be completed before submitting Monthly Assessment Form.

10. Tuberculosis Laboratory and Mycobacteriology Tests

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Table of Contents

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LABORATORY TESTS

Alanine Aminotransferase (ALT/ SGPT)

Alkaline Phosphatase

Aspartate Aminotransferase (AST/ SGOT)

Bilirubin

Complete Blood count (CBC with differential)

Creatinine

Glucose

Helper T. CD4 (CD4)

Hemoglobin A1C (Hgb A1C)

Hepatic Function Panel (LFP)

Hepatitis B Profile

Hepatitis C Virus

Human Immunodeficiency Virus (HIV)

Quanti-FERON GIT (QFT)

T-Spot

Tuberculin Skin Test (TST)

Uric Acid

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Alanine Aminotransferase (ALT/SGPT)	
Specimen:	Serum (preferred) **or** plasma
Volume/Min.Vol.	1 ml/ 0.5 ml
Container:	Red-top tube, gel-barrier tube, green-top (heparin) tube, or lavender-top (EDTA) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions:	Maintain specimen at room temperature
Why run this test?	To screen for liver damage and/or to help diagnose liver disease
What is being tested?	Alanine aminotransferase (ALT) is an enzyme found mostly in the cells of the liver and kidney; much smaller amounts of it are also found in the heart and muscles. In healthy individuals, ALT levels in the blood are low. When the liver is damaged, ALT is released into the blood stream, usually before more obvious symptoms of liver damage occur, such as jaundice. This makes ALT a useful test for detecting liver damage.
How is this test used?	The alanine aminotransferase (ALT) blood test is typically used to detect liver injury. It is often ordered in conjunction with aspartate aminotransferase (AST) or as part of a liver panel to screen for and/or help diagnose liver disease. AST and ALT are considered to be two of the most important tests to detect liver injury, although ALT is more specific than AST. Sometimes AST is compared directly to ALT and an AST/ALT ratio is calculated. This ratio may be used to distinguish between different causes of liver damage. ALT values are often compared to the results of other tests such as alkaline phosphatase (ALP), total protein, and bilirubin to help determine which form of liver disease is present
What does the result mean?	Normally, levels of ALT in the blood are low, (per reported parameters). Very high levels (per reported parameters) of ALT (more than 10 times the highest normal level) are usually due to acute hepatitis, often due to a virus infection. In acute hepatitis, ALT levels usually stay high for about 1–2 months but can take as long as 3–6 months to return to normal. Levels of ALT may also be markedly elevated as a result of exposure to drugs or other substances that are toxic to the liver as well as in conditions that cause decreased blood flow (ischemia) to the liver. Other causes of moderate increases in ALT include obstruction of bile ducts, cirrhosis (usually the result of chronic hepatitis or bile duct obstruction), and with tumors in the liver.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comments(s)	Both Isoniazid and Rifampin can cause an elevation of hepatic enzymes (ALT and AST) ALT is less sensitive than is AST to alcoholic liver disease. Increased ALT is found with obesity.

Alkaline Phosphatase	
Specimen:	Serum (preferred) **or** plasma
Volume/Min.Vol.	2 ml / 0.5ml
Container:	Red-top tube, gel-barrier tube, or green-top (heparin) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection. If a red-top tube or green-top tube is used, transfer separated serum or plasma to a plastic transport tube.
Storage Instructions	Maintain specimen at room temperature or refrigerate
Why run this test?	To screen for or monitor treatment for a liver or bone disorder.
What is being tested?	Alkaline phosphatase (ALP) is an enzyme found in several tissues throughout the body, including liver, bone, kidney, bowel (intestine), and in the placenta of women who are pregnant. However, the highest concentrations ALP are present in the cells that comprise the bone and liver. ALP in bone is produced by special cells called "osteoblasts" that are involved in the formation of bone. Elevated levels of ALP in the blood are most commonly caused by liver disease or bone disorders. Levels of the enzyme can be greatly increased, for example, in cases where one or more bile ducts are blocked. Smaller increases of blood levels are seen in liver cancer and cirrhosis, with use of drugs toxic to the liver, and in hepatitis.
How is this test used?	The alkaline phosphatase test (ALP) is used to help detect liver disease or bone disorders. In conditions affecting the liver, damaged liver cells release increased amounts of ALP into the blood. This test is often used to detect blocked bile ducts because ALP is especially high in the edges of cells that join to form bile ducts. If one or more of them are obstructed, for example by a tumor, then blood levels of ALP will often be high. Any condition that affects bone growth or causes increased activity of bone cells can affect ALP levels in the blood. An ALP test may be used, for example, to detect cancers that have spread to the bone or to help diagnose Paget's disease. This test may also sometimes be used to monitor treatment of Paget's disease or other bone conditions, such as vitamin D deficiency. If ALP results are increased but it is not clear whether this is due to liver or bone disease, then tests for ALP isoenzyme tests may be done to determine the cause. A GGT test (Gamma-glutamyl Transferase) and/or a test for 5'-nucleotidase may also be done to differentiate between liver and bone disease. GGT and 5'-nucleotidase levels are increased in liver disease but not bone disorders.
What does the result mean?	High ALP usually means that either the liver has been damaged or a condition causing increased bone cell activity is present. If other liver tests such as bilirubin, aspartate aminotransferase (AST), or alanine aminotransferase (ALT) are also high, usually the ALP is coming from the liver. If calcium and phosphorus measurements are abnormal, usually the ALP is coming from bone. If a GGT or 5'-nucleotidase is also increased, and then the high ALP is likely due to liver disease. If either of these two tests is normal, then the high ALP is likely due to a bone condition.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comment: Some drugs: (clofibrate, azathioprine, estrogens and estrogens in combination with androgens) lower serum ALP activity. Hepatitis: Moderate increases in alkaline phosphatase occur in viral hepatitis, but greater elevations of the transaminases (AST (SGOT), ALT (SGPT)) are usually found. ***Used alone, alkaline phosphatase may be misleading.***	

Aspartate Aminotransferase (AST/SGOT)	
Specimen:	Serum (preferred) **or** plasma
Volume/Min.Vol.	1 ml / 0.5 ml
Container:	Red-top tube, gel-barrier tube, green-top (heparin) tube, or lavender-top (EDT) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instruction	Maintain specimen at room temperature
Why run this test?	To detect liver damage and/or to help diagnose liver disease
What is being tested?	Aspartate aminotransferase (AST) is an enzyme found in cells throughout the body but mostly in the heart and liver, and to a lesser extent in the kidneys and muscles. In healthy individuals, levels of AST in the blood are low. When liver or muscle cells are injured, they release AST into the blood. This makes AST a useful test for detecting liver damage. A number of conditions can cause injury to liver cells and may cause increases in AST levels. The test is most useful in detecting liver damage due to hepatitis, drugs toxic to the liver, cirrhosis, and alcoholism. AST, however, it is not specific for the liver and may be increased in conditions affecting other parts of the body.
How is this test used?	The blood test for aspartate aminotransferase (AST) is usually used to detect liver damage. It is often ordered in conjunction with another liver enzyme, alanine aminotransferase (ALT), or as part of a liver panel to screen for and/or help diagnose liver disorders. AST and ALT are considered to be two of the most important tests to detect liver injury, although ALT is more specific than AST. Sometimes AST is compared directly to ALT and an AST/ALT ratio is calculated. This ratio may be used to distinguish between different causes of liver damage. AST levels are often compared with results of other tests, such as alkaline phosphatase (ALP), total protein, and bilirubin to help determine which form of liver disease is present. AST is often measured to monitor treatment of persons with liver disease and may be ordered either by itself or along with other tests for this purpose. Sometimes AST may be used to monitor people who are taking medications that are potentially toxic to the liver. If AST levels increase, then the person may be switched to another medication.
What does the result mean?	Normally, levels of AST in the blood are low. Very high levels (above reported parameters) of AST (more than 10 times the highest normal level) are usually due to acute hepatitis, often due to a virus infection. In acute hepatitis, AST levels usually stay high for about 1–2 months but can take as long as 3–6 months to return to normal. Levels of AST may also be markedly elevated as a result of exposure to drugs or other substances that are toxic to the liver as well as in conditions that cause decreased blood flow (ischemia) to the liver. When an increased AST is from the liver, it is more likely to relate to disease of the hepatocyte.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comment: ***Drugs:*** A large number of commonly used drugs have been reported to elevate AST: isoniazid, phenothiazines, erythromycin, progesterone, anabolic-androgenic steroids, halothane, methyldopa, opiates, indomethacin, salicylates in children, and other drugs. Hepatotoxicity from drugs may cause high aminotransferase activity with elevation of AST: ALT ratio.	

Bilirubin, Direct	
Specimen	Serum (preferred) **or** plasma
Volume/Min.Vol.	1 ml / 0.5 ml
Container:	Red-top tube, gel-barrier tube, or green-top (lithium heparin) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions	Refrigerate
Why run this test?	To screen for or monitor liver disorders or hemolytic anemia (increased destruction of RBCs)
What is being tested?	Bilirubin is an orange-yellow pigment, a waste product primarily produced by the normal breakdown of heme, a substance found mainly in the protein hemoglobin in red blood cells (RBCs). It is ultimately processed by the liver to allow its elimination from the body. This test measures the amount of bilirubin in the blood in order to evaluate liver function or to help diagnose anemia caused by the increased destruction of RBCs (hemolytic anemia). RBCs normally degrade after about 120 days in the circulation. As the heme in hemoglobin is broken down, it is converted into bilirubin; this form is also called unconjugated bilirubin. Unconjugated bilirubin is not very soluble in water, so it is carried by proteins to the liver, where sugars are attached (conjugated) to it to form water-soluble conjugated bilirubin. The breakdown products of bilirubin give stool its characteristic brown color.
How is this test used?	In adults and older children, bilirubin is measured to diagnose and/or monitor liver diseases, such as cirrhosis, hepatitis, or gallstones. It is also used to evaluate people with sickle cell disease or other causes of hemolytic anemia who may have episodes when excessive red blood cell destruction takes place, increasing bilirubin levels. Bilirubin can be measured as a total level and/or as conjugated and unconjugated levels for these purposes. More commonly, the laboratory uses a chemical test to detect water-soluble forms of bilirubin, termed direct bilirubin, which is an estimate of the amount of conjugated bilirubin. By subtracting this from the total bilirubin, an indirect estimate (indirect bilirubin) of unconjugated bilirubin is obtained.
What does the result mean?	*Adults and children:* Increased total bilirubin that is mainly unconjugated (indirect) bilirubin may be a result of:1) Hemolytic or pernicious anemia, 2) Transfusion reaction, 3)Cirrhosis, 4) A common metabolic condition termed Gilbert syndrome, due to low levels of the enzyme that attaches sugar molecules to bilirubin. If conjugated (direct) bilirubin is elevated more than unconjugated (indirect) bilirubin, there typically is a problem associated with decreased elimination of bilirubin by the liver cells. Some conditions that may cause this include:1) Viral hepatitis, 2) Drug reactions, 3) Alcoholic liver disease. Conjugated (direct) bilirubin is also elevated more than unconjugated (indirect) bilirubin when there is some kind of blockage of the bile ducts. This may occur, for example, with: 1) Gallstones getting into the bile ducts, 2) Tumors, 3) Scarring of the bile ducts
How to order this test/cost?	Order from your local contract laboratory. Cost: N/A
Comment: Drugs or infections that cause hepatotoxicity may alter bilirubin levels. Measurement of direct bilirubin is usually not necessary when the total bilirubin is <1.2 mg/dL.	

Complete Blood Count (CBC) With Differential	
Specimen:	Whole blood
Volume/Min.Vol.	Fill tube to capacity / 0.5 mL
Container:	Lavender-top (EDTA) tube
Collection:	Invert tube 8 to 10 times immediately after tube is filled at the time of collection.
Storage Instructions:	Maintain specimen at room temperature
Why run this test?	To determine general health status and to screen for and monitor a variety of disorders, such as anemia
What is being tested?	The Complete Blood Count (CBC) test is an automated count of the cells in the blood. A standard CBC includes the following: 1) number of white blood cells (WBC), 2) number of red blood cells (RBC), 3) hemoglobin content (Hgb), 4) hematocrit (Hct) , 5)mean corpuscular volume (MCV), 6) mean corpuscular hemoglobin (MCH), 7) mean corpuscular hemoglobin concentration (MCHC), 8) platelet count and volume
How is this test used?	The complete blood count or CBC test is used as a broad screening test to evaluate overall health, detect and/or identify a wide range of hematologic disorders such as anemia, infection, and many other diseases. It is actually a panel of tests that examines different parts of the blood and includes the following: 1) White blood cell (WBC) count is a count of the actual number of white blood cells per volume of blood. Both increases and decreases can be significant, 2) White blood cell differential looks at the types of white blood cells present. There are five different types of white blood cells, each with its own function in protecting us from infection. The differential classifies white blood cells into each type: neutrophils (also known as segs, PMNs, granulocytes, grans), lymphocytes, monocytes, eosinophils, and basophils, 3) Red blood cell (RBC) count is a count of the actual number of red blood cells per volume of blood. Both increases and decreases can point to abnormal conditions, 4) Hemoglobin measures the amount of oxygen-carrying protein in the blood, 5) Hematocrit measures the percentage of red blood cells in a given volume of whole blood, 6) The platelet count is the number of platelets in a given volume of blood. Both increases and decreases can point to abnormal conditions of excess bleeding or clotting.
What do the results mean?	Presence of one or more of the following may be indication for further investigation: hemoglobin <10 g/dL, hemoglobin >18 g/dL, MCV >100 fL, MCV <80 fL, MCHC >37%, WBC >20,000/mm^3, WBC <2000/mm^3, presence of sickle cells, spherocytes, Pappenheimer bodies, basophilic stippling, stomatocytes, schistocytes (fragmented RBCs), target cells, oval macrocytes, teardrop red blood cells, abnormal cell populations, nucleated red blood cells in other than the newborn..
How to order this test/cost	Order from your local contract laboratory
Comment: Rifampin is known to cause thrombocytopenia. Mean corpuscular volume (MCV) is a measurement of the average size of a RBC. Mean corpuscular hemoglobin (MCH) is a calculation of the average amount of oxygen-carrying hemoglobin inside a red blood cell. Mean corpuscular hemoglobin concentration (MCHC) is a calculation of the average concentration of hemoglobin inside a red blood cell. Red cell distribution width (RDW) is a calculation of the variation in the size of RBCs	

What does the test result mean?

The following table explains what increases or decreases in each of the components of the CBC may mean.

Components of the CBC

TEST	NAME	INCREASED/DECREASED
WBC	White Blood Cell	May be increased with infections, inflammation, cancer, leukemia; decreased with some medications (such as methotrexate), some autoimmune conditions, some severe infections, bone marrow failure, and congenital marrow aplasia (marrow doesn't develop normally)
% Neutrophil	Neutrophil/Band/Seg/Gran	This is a dynamic population that varies somewhat from day to day depending on what is going on in the body. Significant increases in particular types are associated with different temporary/acute and/or chronic conditions. An example of this is the increased number of lymphocytes seen with lymphocytic leukemia. For more information, see Blood Smear and WBC.
Lymphs	Lymphocyte	
% Mono	Monocyte	
% Eos	Eosinophil	
% Baso	Basophil	
Neutrophil	Neutrophil/Ban/Seg/Gran	
Lymphs	Lymphocyte	
Mono	Monocyte	
Eos	Eosinophil	
Baso	Basophil	
RBC	Red Blood Cell	Decreased with anemia; increased when too many made and with fluid loss due to diarrhea, dehydration, burns
Hgb	Hemoglobin	Mirrors RBC results
Hct	Hematocrit	Mirrors RBC results
MCV	Mean Corpuscular Volume	Increased with B12 and Folate deficiency; decreased with iron deficiency and thalassemia
MCH	Mean Corpuscular Hemoglobin	Mirrors MCV results
MCHC	Mean Corpuscular Hemoglobin Concentration	May be decreased when MCV is decreased; increases limited to amount of Hgb that will fit inside a RBC
RDW	RBC Distribution Width	Increased RDW indicates mixed population of RBCs; immature RBCs tend to be larger

TEST	NAME	INCREASED/DECREASED
Platelet	Platelet	Decreased or increased with conditions that affect platelet production; decreased when greater numbers used, as with bleeding; decreased with some inherited disorders (such as Wiskott-Aldrich, Bernard-Soulier), with Systemic lupus erythematosus, pernicious anemia, hypersplenism (spleen takes too many out of circulation), leukemia, and chemotherapy
MPV	Mean Platelet Volume	Vary with platelet production; younger platelets are larger

Creatinine, Serum	
Specimen:	Serum (preferred) **or** plasma
Volume/Min.Vol.	1 ml / 0.5 ml
Container:	Gel-barrier tube, red-top tube, green-top (heparin) tube, or lavender-top (EDTA) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection.
Storage Instructions	Maintain specimen at room temperature.
Why run this test?	Routinely as part of a comprehensive or basic metabolic panel to monitor kidney function
What is being tested?	This test measures the amount of creatinine in your blood and/or urine. Creatinine is a waste product produced in your muscles from the breakdown of a compound called creatine. Creatine is part of the cycle that produces energy needed to contract your muscles. Both creatine and creatinine are produced by the body at a relatively constant rate. Almost all creatinine is excreted by the kidneys, so blood levels are a good measure of how well your kidneys are working. Creatinine concentrations will be slightly higher in men than in women and children. Results from a blood creatinine test and a 24-hour urine creatinine test may be used to calculate creatinine clearance.
How is this test used?	The creatinine blood test is used along with a BUN (blood urea nitrogen) test to assess kidney function. Both are frequently ordered as part of a basic or comprehensive metabolic panel (BMP or CMP), groups of tests that are performed to evaluate the function of the body's major organs. BMP or CMP tests are used to screen healthy people during routine physical exams and to help evaluate acutely or chronically ill patients in the emergency room and/or hospital. If the creatinine and BUN tests are found to be abnormal or if you have an underlying disease, such as diabetes, that is known to affect the kidneys, then these two tests may be used to monitor the progress of kidney dysfunction and the effectiveness of treatment. Serum creatinine measurements (along with your age, weight, and gender) also are used to calculate the estimated glomerular filtration rate (eGFR), which is used as a screening test to look for evidence of kidney damage.
What does the result mean?	Increased creatinine levels in the blood suggest diseases or conditions that affect kidney function. These can include:1) Damage to or swelling of blood vessels in the kidneys (glomerulonephritis) caused by, for example, infection or autoimmune diseases , 2) Bacterial infection of the kidneys (pyelonephritis), 3) Death of cells in the kidneys' small tubes (acute tubular necrosis) caused, for example, by drugs or toxins,4) Prostate disease, kidney stone, or other causes of urinary tract obstruction, 5) Reduced blood flow to the kidney due to shock, dehydration, congestive heart failure, atherosclerosis, or complications of diabetes.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comment(s)	**Drugs**: If there is renal impairment dosage adjustment of EMB, PZA may be needed. **High** creatinine*:* Renal diseases and insufficiency with decreased glomerular filtration, urinary tract obstruction, reduced renal blood flow including congestive heart failure, shock, and dehydration; rhabdomyolysis can cause elevated serum creatinine. **Low** blood levels of creatinine are not common.

Glucose, Plasma	
Specimen:	Plasma
Volume/Min.Vol.	Entire collection / 0.5ml
Container:	Gray-top (sodium fluoride) tube
Collection:	Label specimen as plasma. Mix well
Storage Instructions	Maintain specimen at room temperature
Why run this test?	To determine if your blood glucose level is within a healthy range; to screen for, diagnose, and monitor high blood glucose (hyperglycemia) or low blood glucose (hypoglycemia), diabetes, and pre-diabetes; to check for glucose in your urine
What is being tested?	This test measures the amount of glucose in the blood or urine. Glucose is the primary energy source for the body's cells and the only energy source for the brain and nervous system. A steady supply must be available for use, and a relatively constant level of glucose must be maintained in the blood. During digestion, fruits, vegetables, breads and other carbohydrates are broken down into glucose (and other nutrients); they are absorbed by the small intestine and circulated throughout the body. Using glucose for energy production depends on insulin, a hormone produced by the pancreas. Insulin facilitates transport of glucose into the body's cells and directs the liver to store excess energy as glycogen for short-term storage and/or as triglycerides in adipose (fat) cells.
How is this test used?	The blood glucose test may be used to:1) Screen for both high blood glucose (hyperglycemia) and low blood glucose (hypoglycemia) 2) Help diagnose diabetes, 3) Monitor glucose levels in persons with diabetes. Depending on the purpose of testing, glucose may be measured on a fasting basis (collected after an 8- to 10-hour fast), randomly (anytime), post prandial (after a meal), and/or as part of an oral glucose challenge or tolerance test (OGTT/ GTT *Screening:* Blood glucose is often measured as part of a group of tests, such as a CMP (Comprehensive Metabolic Panel), during routine physicals. This is done to screen for diabetes, which often causes no symptoms early in its course, and for pre-diabetes – moderately increased blood glucose levels that indicate an increased risk of developing type 2 diabetes. For screening purposes, a CMP or blood glucose test is performed on a fasting basis (fasting blood glucose, FBG).
What does the result mean?	High levels (per reported parameters) of glucose most frequently indicate diabetes, but many other diseases and conditions can also cause elevated blood glucose.
How to order this test/cost	Order from your local contract laboratory
Comment: Blood should be drawn in the morning after an overnight fast (no caloric intake for at least eight hours), during which time the individual may consume water.	

Helper T Lymphocyte Marker CD4	
Specimen:	Whole blood
Volume	Fill tube(s) to capacity
Container:	Lavender-top (EDTA) tube and yellow-top (ACD-A) tube
Collection:	Invert tube 8 to 10 times immediately after collection. To preserve cellular viability, collect specimen so it will arrive in the laboratory Monday through Friday and within 48 hours of collection. Please indicate date and time of venipuncture on the tube(s) and on the test request form.
Storage Instructions	Maintain specimen at room temperature
Why run this test?	Most often, this test is done to measure the strength of your immune system if you have been diagnosed with HIV infection
What is being tested?	CD4 and CD8 cells are lymphocytes that have markers on the surfaces of the cells called CD4 and CD8. They are types of white blood cells that fight infection, and they play an important role in your immune system function. CD4 and CD8 cells are made in the spleen, lymph nodes, and thymus gland, and they circulate throughout the body in the bloodstream. CD4 cells are sometimes called T-helper cells. They help to identify, attack, and destroy specific bacteria, fungi, and viruses that affect the body. CD4 cells are a major target for HIV, which binds to the surface of CD4 cells, enters them, and either replicates immediately, killing the cells in the process, or remains in a resting state, replicating later. As the HIV virus gets into the cells and replicates, the number of CD4 cells in the blood gradually declines. The CD4 count decreases with HIV disease progression. This process may continue for several years before the number of CD4 cells drops to a low enough level that symptoms associated with AIDS begin to appear. As treatment reduces the amount of HIV present in the body and slows progression, the CD4 count will increase and/or stabilize.
How is this test used?	Monitor patient's helper/inducer T-cell status. If you have been diagnosed with HIV, a CD4 test by itself, a CD4 percent, or a CD4/CD8 ratio is used to help evaluate and track the progression of HIV infection and disease. CD4 cells are the main target of HIV, and the number of CD4 cells will decrease as HIV progresses. Since CD4 cells are usually destroyed more rapidly than other types of lymphocytes and because absolute counts can vary from day to day, it is sometimes useful to look at the number of CD4 cells compared to other types of lymphocytes.
What does the result mean?	In general, the CD4 count goes down as HIV disease progresses. Any single CD4 count value may differ from the last one even though your health status has not changed. According to public health guidelines, preventive therapy should be started when an HIV-positive person who has no symptoms registers a CD4 count under 200 cells per cubic millimeter of blood. Some physicians will opt to consider treatment earlier, at 350 cells/mm^3. CDC considers HIV-infected persons who have CD4 counts below 200 cells/mm^3 to have AIDS, regardless of whether they have any signs or symptoms.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comment: For patients with CD4 counts <50 cells/mm3, ART should be initiated within 2 weeks of starting TB treatment (**AI**) For patients with CD4 counts ≥50 cells/mm3 with clinical disease of major severity as indicated by clinical evaluation (including low Karnofsky score, low body mass index [BMI], low hemoglobin, low albumin, organ system dysfunction, or extent of disease), the initiation of ART within 2 to 4 weeks of starting TB treatment (**BI** for CD4 count 50–200 cells/mm3 and **BIII** for CD4 count >200 cells/mm3). For other patients with CD4 counts ≥50 cells/mm3, ART can be delayed beyond 2 to 4 weeks but should be initiated by 8 to 12 weeks of TB therapy (**AI** for CD4 count 50–500 cells/mm3; **BIII** for CD4 count >500 cells/mm3). Rating of Recommendations: A = Strong; B = Moderate; C = Optional	

Hemoglobin (Hbg) A1C	
Specimen:	Whole blood
Volume/Min.Vol.	7 ml Pediatric EDTA whole blood tubes may be used. Please place the entire tube in a transport tube for shipment to the laboratory.
Container:	Lavender-top (EDTA) tube or green-top (lithium heparin) tube. Other anticoagulants have not been tested or found acceptable
Collection:	The usual precautions in the collection of venipuncture samples should be observed. The sample must be free of clots.
Storage Instructions	Maintain specimen at room temperature
Why run this test?	To monitor a person's diabetes and to aid in treatment decisions; to screen for and/or diagnose diabetes and prediabetes
What is being tested?	The A1c test evaluates the average amount of glucose in the blood over the last 2 to 3 months. It does this by measuring the concentration of glycated (also often called glycosylated) hemoglobin A1c. Hemoglobin is an oxygen-transporting protein found inside red blood cells (RBCs).. Hemoglobin A can be further subdivided, with one of the subcomponents known as hemoglobin A1c. As glucose circulates in the blood, some of it spontaneously binds to hemoglobin A. The glucose-hemoglobin molecules formed are said to be glycated. The higher the concentration of glucose in the blood, the more glycated hemoglobin is formed. Once the glucose binds to the hemoglobin, it remains there for the life of the red blood cell - normally about 120 days. The combination of glucose and hemoglobin A is referred to as HbA1c or A1c. A1c is produced on a daily basis and slowly cleared from the blood as older RBCs die and younger RBCs (with non-glycated hemoglobin) take their place
How is this test used?	The A1c test and eAG calculation are used to monitor the glucose control of diabetics over time. The goal of those with diabetes is to keep their blood glucose levels as close to normal as possible. This helps to minimize the complications caused by chronically elevated glucose levels, such as progressive damage to body organs like the kidneys, eyes, cardiovascular system, and nerves. The A1c test and eAG result give a picture of the average amount of glucose in the blood over the last few months. A1c is frequently used to help newly diagnosed diabetics determine how elevated their uncontrolled blood glucose levels have been.
What does the result mean?	For monitoring glucose control, A1c is currently reported as a percentage, and it is recommended that diabetics aim to keep their A1c below 7%. The report for your A1c test also may include an estimated Average Glucose (eAG), which is a calculated result, based on your A1c levels. The purpose of reporting eAG is to help you relate your A1c results to your everyday glucose monitoring levels. The formula for eAG converts percentage A1c to units of mg/dL or mmol/L so that you can compare it to your glucose levels from home monitoring systems or laboratory tests. The closer a diabetic can keep their A1c to 6% without experiencing excessive hypoglycemia, the better their diabetes is in control. As the A1c and eAG increase, so does the risk of complication.
How to order this test/cost?	Order from your local contract laboratory. Cost: N/A
Comment: Any cause of shortened erythrocyte survival will reduce exposure of erythrocytes to glucose with a consequent decrease in Hb A_{1c} (%). Causes of shortened erythrocyte lifetime might be hemolytic anemia or other hemolytic diseases, homozygous sickle cell trait, pregnancy, or recent significant or chronic blood loss.	

Hepatic Function Panel (LFP)	
Specimen:	Serum (preferred) **or** plasma
Volume/Min.Vol.	1 ml / 0.5 ml (**Note:** This volume does **not** allow for repeat testing
Container	Red-top tube, gel-barrier tube, **or** green-top (heparin) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions	***Stable*** at room temperature for up to seven days or refrigerated for up to 14 days.
Why run this test?	To screen for, detect, evaluate, and monitor for liver inflammation and damage
What is being tested?	A liver panel is a group of tests that are performed together to detect, evaluate, and monitor liver disease or damage. The liver is one of the largest organs in the body and is located in the upper right-hand part of the abdomen and behind the lower ribs. The liver metabolizes and detoxifies drugs and substances that are harmful to the body. It produces blood clotting factors, proteins, and enzymes; helps maintain hormone balances, and stores vitamins and minerals. Bile, a fluid produced by the liver, is transported through ducts directly to the small intestine to help digest fats or to the gallbladder to be stored and concentrated for later. The liver panel measures enzymes, proteins, and substances that are produced or excreted by the liver and are affected by liver injury. When performed together, these tests give a snapshot of the health of the liver, an indication of the potential severity of any liver injury, change in liver status over time, and a starting place for further diagnostic testing.
How is this test used?	A liver panel may be used to screen a person for liver damage, especially someone who has a condition, or is taking a drug, that may affect the liver. A Comprehensive Metabolic Panel (CMP) may be ordered instead of a liver panel for routine screening. This group of tests includes most of the liver panel as well as additional tests that evaluate other organs and systems within the body. Abnormal tests on a liver panel may prompt a repeat analysis to see if the elevation or decrease persists and/or may indicate the need for additional testing to determine the cause of the liver dysfunction.
What do the results mean?	The liver panel test results are not diagnostic of a specific condition; they indicate that there may be a problem with the liver. In a person who does not have symptoms or identifiable risk factors, abnormal liver test results may indicate a temporary liver injury or reflect something that is happening elsewhere in the body – such as in the skeletal muscles, pancreas, or heart. It may also indicate early liver disease and the need for further testing and/or periodic monitoring.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comment: Drugs: Isoniazid, Rifampin and Pyrazinamide have an adverse effect on the liver. Tests include: Alanine aminotransferase (ALT/SGPT); albumin, serum; alkaline phosphatase, serum; aspartate aminotransferase (AST/SGOT); bilirubin, direct; bilirubin, total; protein, total, serum.	

This table shows examples of some combinations of results that may be seen in certain types of liver conditions or diseases.

Type of liver condition or disease	**Bilirubin**	**ALT and AST**	**ALP**	**Albumin**	**PT**
Acute liver damage (due, for example, to infection, toxins or drugs, etc.)	Normal or increased usually after ALT and AST are already increased	Usually greatly increased; ALT is usually higher than AST	Normal or only moderately increased	Normal	Usually normal
Chronic forms of various liver disorders	Normal or increased	Moderately increased	Normal to slightly increased	Normal	Normal
Alcoholic Hepatitis	Normal or increased	AST is usually at least twice the level of ALT	Normal or moderately increased	Normal	Normal
Cirrhosis	May be increased but this usually occurs later in the disease	AST is usually higher than ALT but levels are usually lower than in alcoholic disease	Normal or increased	Usually decreased	Usually prolonged
Bile duct obstruction, cholestasis	Normal or increased; increased in complete obstruction	Normal to moderately increased	Increased; often greater than 4 times what is normal	Usually normal but if the disease is chronic, levels may decrease	Usually normal
Cancer that has spread to the liver (metastasized)	Usually normal	Normal or slightly increased	Usually greatly increased	Normal	Normal
Cancer originating in the liver (hepatocellular carcinoma, HCC)	May be increased, especially if the disease has progressed	AST higher than ALT but levels lower than that seen in alcoholic disease	Normal or increased	Usually decreased	Usually prolonged
Autoimmune	Normal or increased	Moderately increased	Normal or slightly increased	Normal or decreased	Normal

If a person is taking drugs that may affect their liver, then abnormal test results may indicate a need to re-evaluate the dosage or choice of medication. When a person with liver disease is being monitored, then the doctor will evaluate the results of the liver panel together to determine if liver function in worsening or improving. For example, increasingly abnormal bilirubin, albumin, and/or PT may indicate deterioration in liver function, while stable or improving results of these tests may indicate liver function preservation or improvement.

Hepatitis B Routine Screen	
Specimen:	Whole blood
Volume/Min.Vol.	6 ml
Container:	Red-top tube no additives
Collection:	Allow blood specimen to clot undisturbed at room temperature for at least 30 minutes. Transport immediately or place specimen in refrigerator until transporting. Do not hold over 7 days.
Storage Instructions:	Refrigerate
Why run this test?	To detect and diagnose an infection with a hepatitis virus.
What is being tested?	Hepatitis B is a liver infection caused by the hepatitis B virus (HBV). It is one of several various causes of hepatitis, a condition characterized by inflammation and enlargement of the liver. Other causes of hepatitis include, for example, certain drugs, inherited disorders, and autoimmune diseases. HBV is one of five "hepatitis viruses" identified so far. The other four are A, C, D, and E. The course of HBV infections can vary from a mild form that lasts only a few weeks to a more serious chronic form lasting years. Sometimes chronic HBV leads to serious complications such as cirrhosis or liver cancer. Some of the various stages or forms of hepatitis B include:1) Acute infection - presence of typical signs and symptoms with positive screening test, 2) Chronic infection — persistent infection with the virus detected by lab tests accompanied by inflammation of the liver, 3) Carrier (inactive) state — persistent infection but no liver inflammation (a carrier is someone who may appear to be in good health but harbors the virus and can potentially infect others.
How is this test used?	Hepatitis B tests may be used for a variety of reasons. Some of the tests detect antibodies produced in response to HBV infection; some detect antigens produced by the virus, and others detect viral DNA. Generally, one set of tests is used to determine the cause of acute symptoms while another set of tests may be used after a diagnosis is made, to monitor possible progression of the disease, to detect chronic infection and/or carrier status. The following is a list the main uses for HBV tests: 1) To detect acute hepatitis B infection: hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), IgM and sometimes hepatitis B e antigen (HBeAg), 2) To diagnose chronic HBV hepatitis: HBsAg, hepatitis B virus (HBV) DNA, and sometimes HBeAg , 3) To monitor chronic hepatitis B infection and its treatment: HBsAg, hepatitis B e antigen (HBeAg), hepatitis B surface antibody (anti-HBs) IgG, hepatitis B e antibody (anti-HBe) IgG and HBV DNA , 4)To detect previous exposure to hepatitis B, in a person who is immune compromised (when the virus can become reactivated): hepatitis B core antibody (anti-HBc) total and anti-HBs.
What does the result mean?	The tests for hepatitis B may be ordered individually, but are often ordered in some combination depending on the reason for testing. Results of the tests are typically evaluated together. Sometimes the meaning of one result depends on the result of another test.
How to order this test/cost	Order from the GPHL. The Ga. Public Health Laboratory does not charge the county health departments for this procedure.
Comment: Test includes**:** HBsAg; HBeAg; anti-HBc, total; anti-HBc, IgM; anti-HBe; anti-HBs	

The table below summarizes possible interpretations of some common patterns of results.

Hep B surface antigen (HBsAg)	**Hep B surface antibody (Anti-HBs)**	**Hep B core antibody (Anti-HBc IgM)**	**Hep B core antibody Total (Anti-HBc IgG+IgM)**	**Hep B e antigen (HBeAg)*See note**	**Hep B e antibody (Anti-HBe)**	**Interpretation / Stage of Infection**
Negative	Negative		Negative			No active or prior infection; not immune — may be good candidate for vaccine; possibly in the incubation stage
Positive	Negative	Negative	Negative	Positive	Negative	Early acute infection
Positive	Negative	Positive or Negative	Positive or Negative	Positive	Negative	Acute infection, usually with symptoms; contagious
Positive	Negative	Positive	Positive	Negative*	Positive	Late in the acute stage of infection (seroconversion)
Negative	Negative	Positive	Positive	Negative*	Positive	Acute infection is resolving (convalescent)
Positive	Negative	Negative	Positive	Positive	Negative	Usually indicates an active chronic infection (liver damage likely)
Positive	Negative	Negative	Positive	Negative*	Positive	Chronic infection but low risk of liver damage — carrier state
Negative	Positive	Negative	Positive	Negative*	Positive	Infection resolved (recovery); immunity due to natural infection
Negative	Positive		Negative			Immunity due to vaccination

*Note: There are some types (strains) of HBV that do not make e-antigen. In areas where these strains of HBV are common (in the Middle East and Asia), testing for HBeAg is not very useful. In these cases, a negative HbeAg result does not necessarily mean that the antigen is not present or that the person is not infectious; it may be that the person is infected with a strain that does not make the e-antigen

Hepatitis C Virus (HCV) Antibody	
Specimen:	Whole blood
Volume/Min.Vol.	6 ml
Container	Red-top tube no additives
Collection:	Allow blood specimen to clot undisturbed at room temperature for at least 30 minutes. Transport immediately or place specimen in refrigerator until transporting. Do not hold over 7 days.
Storage Instructions:	Refrigerate
Why run this test?	To screen for and diagnose a hepatitis C virus (HCV) infection and to monitor treatment of the infection.
What is being tested?	Hepatitis C (HCV) is a virus that causes an infection of the liver that is characterized by liver inflammation and damage. It is one of five "hepatitis viruses" identified so far, including A, B, D, and E, that is known to cause the disease. HCV is spread by exposure to contaminated blood, primarily though the sharing of needles by intravenous drug users, but also by sharing personal items contaminated by blood such as razors, through sex with an infected person, via health care occupational exposure, and from mother to baby during childbirth. Before tests for HCV became available in the 1990s, HCV was often transmitted by blood transfusions. While HCV is not as contagious as Hepatitis B, there is currently no vaccine to prevent infection. Hepatitis C infection is a common cause of chronic liver disease in North America; about 2% of all adults in the United States have been exposed to the virus, and up to 85% of those who have it will become chronically infected after their acute infection resolves. According to the CDC, an estimated 3.2 million people in the U.S. have a chronic HCV infection. Many of those who are infected have no symptoms and are not aware of the condition.
How is this test used?	Hepatitis C tests are used to detect and diagnose an infection and/or to monitor the treatment of hepatitis C virus (HCV). Tests are used to detect the condition if a person: 1) Has been exposed to someone with HCV , 2) Participates in high risk behaviors such as injecting street drugs , 3) Has abnormal liver function tests, 4) Has symptoms associated with liver disease, such as jaundice, dark urine, nausea, or unexpected weight gain or loss , 5) Test blood safety
What do the results mean?	In general, if the HCV antibody test is strongly positive, then someone has likely been infected at some time with hepatitis C. If the HCV RNA test is positive, then the person has a current infection. If no HCV viral particles are detected, then the person either does not have an active infection or the virus is present in very low numbers.
How to order this test/cost?	Order from the GPHL. The GA Public Health Laboratory charges the county health department a fee of $10 for this procedure.
Comment: Since as many as 90% of commercial intravenous immunoglobulin's test positive for hepatitis C antibody, an artifactual positive can result briefly after transfusion.	

Human Immunodeficiency Virus 1 (HIV-1), Qualitative, RNA	
Specimen:	Plasma **or** serum
Volume/Min.Vol.	1 ml 0.5 ml
Container:	Lavender-top (EDTA) tube, yellow-top (ACD) tube, red-top tube, or gel-barrier tube
Collection:	N/A
Storage Instructions	Refrigerate or Freeze
Why run this test?	To determine if you are infected with Human immunodeficiency virus (HIV)
What is being tested?	This test detects HIV antibodies in blood or other body fluids. HIV, human immunodeficiency virus, is the virus that causes AIDS (acquired immunodeficiency syndrome), which destroys the immune system and leaves the body vulnerable to debilitating infections. When HIV enters the body, such as through contact with an infected individual or contaminated needle, the immune system responds by producing antibodies directed against the virus. These antibodies can be detected about 3 to 8 weeks after exposure to the virus. If exposure to the virus is more recent, then antibody levels may be too low to detect. It may be necessary to perform a p24 antigen test or an HIV RNA (viral load) test in order to detect the virus.
How is this test used**:**	HIV antibody testing is used to screen for and diagnose HIV infections. Early treatment of HIV infection and immune system monitoring can greatly improve long-term health. Also, knowing your HIV status may help you change behaviors that would put you and others at risk.
What do the results mean?	A healthy individual has no antibodies to HIV. However, a negative screening test means only that there is no evidence of disease at the time of the test. It is important for those who are at increased risk of HIV infection to have screening tests performed on a regular basis to check for possible exposure to the virus. If you test positive for HIV antibodies on both the ELISA and the Western Blot tests, you are considered to be infected with HIV. HIV cannot be cured, but early diagnosis allows for treatment that can help to suppress levels of virus in your body (viral load) and slow progression of the disease.
How to order this test/cost	Order from the GPHL. The GA Public Health Laboratory charges the county health departments a fee of $10 for this procedure.
Comment: Antibodies to the HIV virus are often detected by a screening test called an ELISA. The ELISA test is repeated if positive. The ELISA method is very sensitive but requires another test, a Western Blot, to confirm the results because false positives can occur. These tests can be done on blood, urine or oral sample in a local clinic. There are several rapid tests available in which results are generated in about 20 minutes. However, these too must have confirmatory testing before a final diagnosis can be made.	

QuantiFERON Gold-in-tube (Interferon-Gamma Release Assay or IGRA)	
Specimen:	Whole blood
Volume/Min.Vol.	1 ml x three tubes (see Container) /0.8 ml x three tubes.
Container:	The QuantiFERON® collection kit contains instructions for the draw of three special QuantiFERON® collection tubes (one each): (1) gray-top (with white ring), uncoated (nil); (2) red-top (with white ring), TB antigen-coated; (3) purple-top (with white ring), mitogen-coated.
Collection:	**REFER TO COLLECTION INSTRUCTIONS INCLUDED WITH DRAW KIT.** Special specimen collection kit contains three gel-barrier tubes: gray-top/white ring (nil), red-top/white ring (TB antigens), and purple-top/white ring (mitogen). All three tubes are required for a single test result. Each tube is designed to draw only 1 ml and fill time may be longer than other blood collection tubes. Following proper fill, shake tubes vigorously for five seconds; frothing will occur. **Do not centrifuge or refrigerate** specimens. To preserve cellular viability, specimens should be collected and sent same day, at room temperature, so as to arrive at the lab as soon as possible and within 14 hours of draw. Please indicate date and time of venipuncture on the tubes and on the test request form.
Storage Instructions	Maintain specimen at room temperature (17°C to 27°C). Do **not** centrifuge, refrigerate, or ship tubes on ice.
Why run this test?	To help determine whether or not you may have a latent or active infection with the ***Mycobacterium tuberculosis*** bacteria.
What is being tested?	Tuberculosis (TB) screening tests help to determine whether a person has become infected with *Mycobacterium tuberculosis* bacteria, the cause of TB. The screening tests measure the body's immune response to antigens derived from the bacteria – either directly as a skin reaction to a tuberculin skin test (TST) or indirectly with an interferon gamma release assay (IGRA) blood test. TB, once called consumption, has been recognized as causing illness for thousands of years. This bacterial infection may affect many body organs, but it primarily targets the lungs. TB may cause an inactive (latent) infection or an active, progressive disease. The immune system of about 90% of the people who become infected with TB manage to control its growth and confine the TB infection to a few cells in the body. The bacteria in these cells are inactive but still alive. The person does not have any symptoms and they are not infectious, but they do have a "latent TB infection." If, after some time, the person's immune system becomes weakened (compromised), the mycobacterium may begin to grow again, leading to an active case of tuberculosis disease. Active TB does cause illness in the person and it can be passed to others through respiratory secretions such as sputum or aerosols released by coughing, sneezing, laughing, talking, singing or breathing.
How is this test used?	The QuantiFERON®-TB Gold test is an in vitro assay to aid in the diagnosis of both latent and active infection with *Mycobacterium tuberculosis.* TB screening tests are not used as a general population screens but are used to screen certain people who are at high risk for TB exposure.
What does the result mean?	Test results are reported either as: 1) **positive,** an indication of infection with *Mycobacterium tuberculosis is likely,* 2) **negative***, an indication of* infection with *Mycobacterium tuberculosis is* unlikely, *(however, in contact investigations, negative results obtained on recent contacts of persons with infectious tuberculosis prior to 8 weeks typically should be confirmed by repeat testing 8-10 weeks after the end of exposure), or 3)* **indeterminate***, indicating an uncertain likelihood of Mycobacterium tuberculosis infection.*
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comment: QuantiFERON®-TB Gold test does not give a **false positive** response in people who have received bacilli Calmette-Guerin (**BCG**) as a vaccine or for cancer therapy. Since the test requires viable white blood cells, the IGRA blood sample must be received and tested by the laboratory within a designated window of time.	

T-Spot (Interferon-Gamma Release Assay or IGRA)	
Specimen:	Whole Blood
Volume/Min.Vol.	The guidelines for the volume of blood are: Adults and children 10 years old and over 6 ml, children 2 to 9 years old 4 ml, children up to 2 years old 2 ml
Container:	Collect the blood specimen(s) in a standard green top tube (lithium or sodium heparin). No special collection tubes are required
Collection:	**DO NOT USE** a blood collection tubes that contain the anti-coagulant EDTA. EDTA affects the secretion of interferon gamma. *Read package insert for complete instructions.*
Storage Instructions	Do **NOT** refrigerate or freeze blood samples. Blood samples to be processed with the T-SPOT.*TB* test must be used within 8 hours post venipuncture. Samples can be used up to 32 hours post venipuncture with the addition of the T-Cell *Xtend* reagent prior to running the T-SPOT.*TB* test. Whole blood samples should be maintained between 18°C and 25°C until processed. *Read package insert for complete instructions.*
Why run this test?	To help determine whether or not a person has latent TB infection or active TB disease with the *Mycobacterium tuberculosis* bacteria.
What is being tested?	The screening test measure the body's immune response to antigens derived from the bacteria. Peripheral blood mononuclear cells (PBMCs) are separated from a whole blood sample and washed to remove any sources of background interfering signal. The PBMCs are then counted so that a standardized cell number is used in the assay. This ensures that even those who have low T cell titers due to weakened immune systems (the immunocompromised and immunosuppressed) have adequate numbers of cells added to the microtitre wells.
How is this test used?	The T-SPOT ***TB*** test is a blood test, also known as an **Interferon Gamma Release Assay**, or IGRA, for TB infection. The test was approved by the FDA in 2008. The T-SPOT.***TB*** test is an ***in vitro*** diagnostic test that enumerates the response of effector T cells that have been sensitized to ***Mycobacterium tuberculosis***. The T-SPOT.***TB*** test is an indirect test for ***M. tuberculosis*** infection (including disease) and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluations.
What does the result mean?	Test results are reported either as: 1) **Positive,** = or > 8 spots, an indication of infection with Mycobacterium tuberculosis **is likely***, 2)* **Borderline,** 5,6,or 7 spots**,** *i*ndicating *an* **uncertain likelihood** *of* infection with Mycobacterium tuberculosis, 3) ***negative***, = or < 4 spots*,* indicating *t*hat Mycobacterium tuberculosis is **not likely,** *(*however, in contact investigations, negative results obtained on recent contacts of persons with infectious tuberculosis prior to 8 weeks typically should be confirmed by repeat testing 8-10 weeks after the end of exposure*), or* 4*)* **indeterminate***,* indicating an **uncertain likelihood** *of Mycobacterium tuberculosis* infection.
How to order this test/cost	Order from Oxford Immunotec
Comment: The T-SPOT.*TB* assay should be used and interpreted only in the context of the overall clinical picture. A negative test result does not exclude the possibility of exposure to or infection with *M. tuberculosis.* There is no association with BCG vaccination and T-SPOT.***TB*** test results. The test utilizes two ***M. tuberculosis*** specific antigens (ESAT-6 and CFP 10) that do not cross react with the BCG vaccine or most common non-tuberculosis mycobacteria (NTMs), with the exception of *M. kansasii*, *M. szulgai*, *M. marinum*3,4 and *M. gordonae.*	

Tuberculin Skin Test, Mantoux (TST)	
Specimen:	N/A
Volume:	N/A
Container:	N/A
Collection:	N/A
Storage Instructions:	Refrigerate
Why do this test?	To help determine whether or not you may have a latent or active infection with the ***Mycobacterium tuberculosis*** bacteria
What is being tested?	Tuberculosis (TB) screening tests help to determine whether a person has become infected with ***Mycobacterium tuberculosis*** bacteria, the cause of TB. The screening tests measure the body's immune response to antigens derived from the bacteria – either directly as a skin reaction to a tuberculin skin test (TST) or indirectly with an interferon gamma release assay (IGRA) blood test. The tuberculin skin test involves two steps: the injection of a small amount of purified protein derivative (PPD) solution under the first layer of skin of the forearm and an evaluation of the injection site conducted by a health care worker at 48 and/or 72 hours to see if a local skin reaction has occurred.
How is this test used?	TB screening tests are not used as a general population screens but are used to screen certain people who are at high risk for TB exposure such as: those who have signs and symptoms consistent with active tuberculosis, those with diseases or conditions that weaken the immune system, such as those with HIV or AIDS, that make them more vulnerable to a TB infection, those who are in confined living conditions such as homeless shelters, migrant farm camps, nursing homes, schools, and correctional facilities, health care workers and others whose occupations bring them in close contact with those who may have active TB, Those who have been in close contact with someone who has an active case of TB, those who come from or have lived for a period of time in a foreign country where TB may be more common, those who inject illegal drugs.
What does the result mean?	A health care worker will interpret your tuberculin skin test results by looking at the injection site on your forearm at 48 or 72 hours (in most cases). A **positive** result will form a red and swollen circle at the site of the injection. The size (diameter) of the swollen raised circle determines whether exposure to TB has occurred. Positive TST results are also commonly seen in those who have received a BCG vaccination. **Negative** results for may mean that a person has not been exposed to TB, that the person is not infected with tuberculosis, that their immune system has not responded to the antigen in the test, or that it is too early to detect exposure. It takes about 6 weeks after infection before a person demonstrates a positive reaction to TB screening tests. If you want to confirm a negative or indeterminate result, you may repeat the same test or do either the TST or IGRA as an alternate follow-up test.
How to order this test/cost?	N/A
Comment: Repeated TSTs do not produce hypersensitivity. TST does cause a false positive reaction in persons who has received BCG (Bacille Calmette-Guérin). Incorrect administrations of TST can produce negative result.	

Uric Acid, Serum	
Specimen:	Serum (preferred) **or** plasma
Volume/Min.Vol.	1ml 0.5ml
Container:	Red-top tube, gel-barrier tube, green-top (heparin) tube or lavender-top (EDTA) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions	Maintain specimen at room temperature
Why run this test?	To detect high levels of uric acid in the blood, which could be a sign of the condition gout or to monitor uric acid level
What is being tested?	Uric acid is produced by the breakdown of purines, which are nitrogen-containing compounds found in the body in substances such as DNA. Purines enter the blood primarily from the normal breakdown and turnover of cells in the body and to a lesser extent from the digestion of certain foods (such as liver, anchovies, mackerel, dried beans and peas) and drinks (alcoholic beverages like beer and wine). Most uric acid is removed from the body by the kidneys and is excreted in the urine; the remainder is eliminated in the stool. If too much uric acid is produced or not enough is excreted, it can accumulate in the body and cause increased levels in the blood (hyperuricemia). The presence of excess uric acid can cause gout, a condition characterized by inflammation that occurs in joints when crystals derived from uric acid form in the joint (synovial) fluid. Excess uric acid can also lead to kidney disease.
How is this test used?	The uric acid blood test is used to detect high levels of this compound in the blood in order to help diagnose gout. The test is also used to monitor uric acid levels in people undergoing chemotherapy or radiation treatment. Rapid cell turnover from such treatment can result in an increase in uric acid. The uric acid urine test is used to help diagnose the cause of recurrent kidney stones and to monitor people with gout for stone formation.
What does the result mean?	Higher than normal uric acid levels (per reported parameters) in the blood is called hyperuricemia and can be caused by the over-production of uric acid in the body or the inability of the kidneys to clear out enough uric acid. The doctor will need to investigate further to determine the cause of the overproduction or decreased excretion of uric acid. There are several genetic inborn errors that effect purine metabolism. Metastatic cancer, multiple myeloma, leukemias, and cancer chemotherapy can cause increased production of uric acid. Chronic renal disease, acidosis, toxemia of pregnancy, and alcoholism can cause decreased excretion.
How to order this test/cost?	Order from your local contract laboratory. Cost: N/A
Comment	Drugs causing increased uric acid concentration include diurectics, pyrazinamide, ethambutol, and nicotinic acid.

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MYCOBACTERIOLOGY LABORATORY TESTS

7H11 Agar Plate

Acid-Fast Stain (AFB)

Genotyping

Gen-Probe AccuProbe DNA Probe Test

High Performance Liquid Chromatography (HPLC)

Lowenstein-Jensen Agar (LJ Slants)

Mycobacteria Growth Indicator Tube (MGIT)

Nucleic Acid Amplification Test (NAAT) using the Amplified Mycobacteria Tuberculosis Direct Test (MTD)

NAAT using the Cepheid GeneXpert MTB/RIF Assay

Polymerase Chain Reaction (PCR)

Restrict Fragment Length Polymorphism (RFLP)

Drug Susceptibilities

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7H11 Agar Plate	
How does it work?	7H11 agar is a transparent agar-based media for the isolation and colony morphology of mycobacterium. Oleic acid, albumin, and pancreatic digest of casein are the key ingredients which aid in the growth of the tubercle bacilli.
When would this media be used?	When a broth culture exhibits growth, the laboratory uses this media to obtain growth of the mycobacterium on solid media.
How long before growth is obtained?	Visible growth can occur in as few as 3 to 5 days with the rapid-growing mycobacterium. With M. tuberculosis, and some of the other slow-growing bacteria, it can take up to 4 weeks before growth is obtained.
How are the results classified?	Positive for growth Negative for growth Contaminated
What do the results mean?	When growth is observed on the 7H11 media, the technologist determines if the growth is a mycobacterium or if it is some other organism. If the growth is a mycobacterium, HPLC is run to identify the mycobacterium. If the growth proves to be an organism other than a mycobacterium, then the plate is considered to be contaminated and no further studies are performed. If no growth is seen on the 7H11 agar, it is reported as negative.
Are other tests needed?	The TB Lab will initiate identification procedures if the growth is a mycobacterium species.
How would this test be ordered?	NA
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this procedure.

Acid-Fast Stain (AFB Smear)	
How does it work?	Mycobacterium is able to form stable complexes within certain stains such as Auramine O. Although the exact nature of the acid-fast staining reaction is not completely understood, phenol in the primary stain allows the stain to penetrate into the cell wall. The cell wall mycolic acids retain this primary stain even after washing with acid-alcohol. This resistance to decolorization with acid-alcohol is what causes mycobacteria to be called "acid-fast." • A drop of processed sputum is spread on microscope slide and placed on a 70˚ C slide warmer for 2 hours. • The slide is then moved to a staining rack and Auramine O stain is applied to the slide for 15 minutes. • The slide is washed with acid-alcohol for 2 minutes. • Acridine orange, a counterstain, is applied to the slide for 2 minutes. • The slide is then rinsed with distilled water, allowed to air dry and examined using a fluorescent microscope. Mycobacterium appears as green fluorescing bacilli against a red-orange background.
When is this test run?	Monday through Friday
How long before results are ready?	Results are usually available within 24 hours.
How are the results classified?	<u>Number of bacteria seen</u> — <u>Interpretation</u> No fluorescing bacteria seen — No AFB found 1-3 fluorescing bacteria seen on entire slide — +/- 4-36 fluorescing bacteria seen per 100 fields — 1+ 4-36 fluorescing bacteria seen per 10 fields — 2+ 4-36 fluorescing bacteria per field — 3+ >36 fluorescing bacteria per field — 4+
What do the results mean?	• The higher the number (4+), the higher the bacteria load. • The higher the number, the more infectious the patient is to others. • Begin TB treatment with 4 drugs until TB is confirmed or ruled out. • Any patient with a positive AFB smear needs to be on respiratory isolation.
Are other tests needed?	Yes, a culture and sensitivity if the culture grows MTB.
When would this test be used?	• To quickly determine if TB is a possibility. • To determine the degree of infectiousness.
How would this test be ordered?	This test is automatically done on all clinical specimens.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or district for this test.

Genotyping	
How does it work?	The genotype of an organism refers to the specific genetic makeup of that organism, usually in the DNA. This "internally coded, inheritable information" is used as a blueprint or set of instructions for building and maintaining a living creature. These instructions are written in a coded language (the genetic code) and they are copied at the time of cell division or reproduction and are passed from one generation to the next. Genotyping describes a great variety of techniques that are used to identify the primary localization and mapping of genes.
When is this test run?	The State Lab does not perform this test. Isolates are sent to the Michigan State Genotyping Lab for analysis.
How long before results are ready?	Results are usually available 2 to 3 weeks after the Michigan State Genotyping Lab receives the isolate.
How are the results classified?	NA
What do the results mean?	The results show a mapping of the gene.
Are other tests needed?	NA
When would this test be used?	• To rule out cross-contamination of specimens. • To determine reactivation vs. reinfection of a patient. • To determine if two or more patients are infected with strains of M. tuberculosis possessing identical genotypes.
How would this test be ordered?	Isolates on all first-time MTB positive patients are automatically sent to Michigan for genotyping. Physicians can request this test by calling the Georgia Public Health TB Lab.
How much would this test cost?	There is no charge for this test.

Gen-Probe AccuProbe DNA Probe Test	
How does it work?	• The Gen-Probe identification test is rapid DNA probe test which uses nucleic acid hybridization for the identification of certain mycobacterium. Gen-Probe manufactures four Accuprobe kits to test for the following organisms: M. tuberculosis complex, M. avium complex, M. gordonae, and M. kansasii. • Ribosomal RNA is released from the test organism by sonication. A single-stranded DNA probe (specific for the target* organism) with a chemiluminesecent label combines with the ribosomal RNA to form a DNA: RNA hybrid. The hybrids are then measured in a luminometer. Results are measured in relative light units.
When is this test run?	This test serves as a "back up" for HPLC testing and is only run when the HPLC instrument is "down" for maintenance.
How long before results are ready?	Results are available the day the test is run.
How are the results classified?	Positive, Negative, and Indeterminate for the target organism.
What do the results mean?	Positive: The isolate is identified as one of the target organisms. Indeterminate: The test is inconclusive and must be repeated. Negative: The isolate is not one of the target organisms.
Are other tests needed?	If the isolate is identified as M. tuberculosis, and if this is the first time the patient has had a positive MTB culture, drug susceptibility testing should be ordered. This is automatically done by the TB Lab.
When would this test be used?	To identify growth on solid media or growth in liquid media as M. tuberculosis complex, M. avium complex, M. kansasii, or M. gordonae.
How would this test be ordered?	This test is ordered by the TB laboratory technologists when it is indicated.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

* The target organism is the organism the test kit is designed to identify. For example, if you were using the Accuprobe M. kansasii test kit, the target organism would be M. kansasii, or if you were using the Accuprobe M. tuberculosis complex test kit, the target organism would be M. tuberculosis complex.

High-Performance Liquid Chromatography (HPLC)	
How does it work?	HPLC is used to identify mycobacterium by analysis of mycolic acids. Mycobacterium contain large amounts of mycolic acids in their cell wall. The type and amount of the mycolic acids vary in each species of mycobacteria. HPLC testing generates chromatographs based on the mycolic acids that are present in the test organism. By comparing these graphs with known reference chromatograph patterns, the organism can be identified.
When is this test run?	Monday through Friday
How long before results are ready?	Results are available the day after the test is performed.
How are the results classified?	HPLC testing should identify the mycobacterium being tested.
What do the results mean?	The results identify the mycobacterium.
Are other tests needed?	If the organism is identified as *M. tuberculosis*, and if this is the first time MTB has been isolated from the patient, then a drug susceptibility test should be ordered. This is automatically done by the TB Lab.
When would this test be used?	To identify an isolate as a mycobacterium.
How would this test be ordered?	This test is ordered by the TB laboratory technologists when it is indicated.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

Lowenstein-Jensen Agar (LJ Slants)	
How does it work?	Lowenstein-Jensen agar is a relatively simple formulation that requires the addition of supplements in order to support the growth of mycobacterium. Glycerol and egg mixture are added to provide the fatty acids and protein which are required for the metabolism of mycobacterium.
When would this agar be used?	After undergoing the decontamination/concentration process, all specimens received in TB Lab for routine culture are inoculated onto this media.
How long before growth is obtained?	Visible growth can occur in as few as 3 to 5 days with the rapid-growing mycobacterium. With M. tuberculosis, and some of the other slow-growing bacteria, it can take up to 4 weeks before growth is obtained.
How are the results classified?	Positive for growth Negative for growth Contaminated
What do the results mean?	When growth is observed on the LJ slant, the technologist determines if the growth is a mycobacterium species or if it is some other organism. If the growth is a mycobacterium species, identification procedures are started. If the growth proves to be an organism other than a mycobacterium, then the LJ is considered to be contaminated and no further studies are performed. If no growth is seen on the LJ slant, it is reported as negative.
Are other tests needed?	The TB Lab will initiate identification testing. Susceptibilities will be ordered by the lab when indicated.
How would this test be ordered?	NA
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

Mycobacteria Growth Indicator Tube (MGIT)	
How does it work?	The MGIT Tube is intended for the detection and recovery of mycobacterium using the BACTEC 960 equipment. The tubes contain 7 ml of modified Middlebrook 7H9 broth and are flushed with 10% CO2. A fluorescent compound is embedded in silicone on the bottom of the round bottom MGIT tubes. The fluorescent compound is sensitive to the presence of oxygen dissolved in the broth. Initially, the large amount of dissolved oxygen quenches emissions from the compound and little fluorescence can be detected. Later, actively growing organisms consume the oxygen and allow the fluorescence to be detected. Tubes are monitored by the BACTEC 960 every 60 minutes for increasing fluorescence. Analysis of the fluorescence is used to determine if the tube is positive.
When would this media be used?	MGIT tubes are inoculated each day that clinical specimens are received in the lab. After undergoing the decontamination/concentration process, all specimens received for routine culture are inoculated into this media.
How long before growth is obtained?	For mycobacterium, from 1 week to 6 weeks. Negative (no growth) MGITs are held for 6 weeks before reporting as negative.
How are the results classified?	Positive, Negative, or Contaminated
What do the results mean?	Positive: Growth noted. Identification procedures are started. Negative: No growth Contaminated: Growth other than mycobacterium is present.
Are other tests needed?	The TB Lab will initiate identification testing if the MGIT is positive. Susceptibilities will be ordered by the lab when indicated.
How would this test be ordered?	NA
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

Nucleic Acid Amplification Testing (NAAT) using the Amplified Mycobacteria Tuberculosis Direct Test (MTD)	
How does it work?	The Amplified *Mycobacterium tuberculosis* Direct Test (MTD) is a target-amplified nucleic acid probe test for the detection *of M. tuberculosis* complex rRNA in concentrated specimen sediments prepared from sputum, bronchial specimens (BAL or bronchial aspirates), or tracheal aspirates. The MTD test is intended for use only with specimens from patients showing signs and symptoms consistent with active pulmonary tuberculosis. Patients who have received no antituberculous therapy, or less than 7 days of such therapy, or have not received such therapy in the last 12 months may be evaluated with this test. MTD testing does not take the place of culture. A negative MTD test does not exclude the possibility of isolating M. tuberculosis from culture.
When is this test run?	This testing serves as a backup for the Cepheid GeneXpert and is only run when the Cepheid GeneXpert is "down" for maintenance.
How long before results are ready?	Results are usually available the same day the test is run.
How are the results classified?	Positive, Negative, and Indeterminate.
What do the results mean?	Positive: *M. tuberculosis complex* rRNA is detected. Negative: *M. tuberculosis complex* rRNA is not detected. Indeterminate: Equivocal results. Test must be repeated.
Are other tests needed?	A culture for M. tuberculosis must be performed.
When would this test be used?	CDC Updated Guidelines for the Use of NAAT state: Nucleic acid amplification testing (NAAT) should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities.
How would this test be ordered?	By checking Nucleic Acid Amplification Testing (NAAT) on a TB Submission Form and sending the form and specimen to the State Lab.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

Nucleic Acid Amplification Testing (NAAT) using the Cepheid GeneXpert MTB/RIF Assay	
How does it work?	The Cepheid GeneXpert MTB/RIF Assay is a diagnostic test that can identify *Mycobacterium tuberculosis* (MTB) in clinical specimens from respiratory sources. The GeneXpert purifies, concentrates, amplifies (by real-time PCR), and identifies targeted nucleic acid sequences in the TB genome. The GeneXpert MTB/RIF Assay does not take the place of culture. A negative MTB/RIF Assay does not exclude the possibility of isolating *M. tuberculosis* from culture.
When is this test run?	Monday through Friday.
How long before results are ready?	Results are usually available the same day the test is run.
How are the results classified?	Positive, Negative, and Indeterminate.
What do the results mean?	Positive: *M. tuberculosis* is detected. Negative: *M. tuberculosis* is not detected. Indeterminate: Equivocal results. Test must be repeated.
Are other tests needed?	A culture for *M. tuberculosis* must be performed.
When would this test be used?	CDC Updated Guidelines for the Use of NAAT state: Nucleic acid amplification testing (NAAT) should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities.
How would this test be ordered?	By checking Nucleic Acid Amplification Testing (NAAT) on a TB Submission Form and sending the form and specimen to the State Lab.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

NOTE: This assay also detects rifampin resistance although we are not reporting those results at the present time. As soon as our validation studies are complete, we will begin reporting the rifampin results.

Polymerase Chain Reaction (PCR)	
What is PCR?	A technique for amplifying DNA sequences in vitro by separating the DNA into two strands and incubating it with oligonucleotide primers and DNA polymerase. It can amplify a specific sequence of DNA by as many as one billion times and is important in biotechnology, forensics, medicine and genetic research.
How does it work?	There three major steps are involved in a PCR. These three steps are repeated for 30 or 40 cycles. The cycles are done on an automated cycler, a device which rapidly heats and cools the test tubes containing the reaction mixture. Each step -- denatauration (alteration of structure), annealing (joining), and extension -- takes place at a different temperature: 1) **Denaturation:** At 94 C (201.2 F), the double-stranded DNA melts and opens into two pieces of single-stranded DNA. 2) **Annealing:** At medium temperatures, around 54 C (129.2 F), the primers pair up (anneal) with the single-stranded "template" (The template is the sequence of DNA to be copied.) On the small length of double-stranded DNA (the joined primer and template), the polymerase attaches and starts copying the template. 3) **Extension:** At 72 C (161.6 F), the polymerase works best, and DNA building blocks complementary to the template are coupled to the primer, making a double stranded DNA molecule.
Why run this test?	To do PCR, the original DNA that one wishes to copy need not be pure or abundant. It can be pure but it also can be a minute part of a mixture of materials. So, PCR has found widespread and innumerable uses -- to diagnose genetic diseases, do DNA fingerprinting, find bacteria and viruses, study human evolution, clone the DNA of an Egyptian mummy, establish paternity or biological relationships, etc.. Accordingly, PCR has become an essential tool for biologists, DNA forensics labs, and many other laboratories that study genetic material
How long before the results are ready?	N/A
What does the result mean?	There are thousands, millions or billions of copies of the original specimen submitted
How to order this test?	N/A
How much would this test cost?	The GA Public Health Laboratory does not charge for this service
Comment(s)	With one cycle, a single segment of double-stranded DNA template is amplified into two separate pieces of double-stranded DNA. These two pieces are then available for amplification in the next cycle. As the cycles are repeated, more and more copies are generated and the number of copies of the template is increased exponentially.

Restriction Fragment Length Polymorphism (RFLP)	
How does it work?	Restriction Fragment Length Polymorphism (RFLP) is a molecular technique in which organisms may be differentiated by analysis of patterns derived from cleavage of their DNA by restriction endonuclease. If two organisms differ in the distance between sites of cleavage of a particular restrictions endonuclease, the length of the fragments produced will differ. The similarity or the difference of the patterns can be used to differentiate species of mycobacteria from one another.
When is this test run?	The State Lab does not perform this test. Isolates are sent to the Michigan State Genotyping Lab for analysis by PCR.
How long before results are ready?	Results are usually available within 3 weeks after the Michigan Genotyping Lab receives the isolate.
How are the results classified?	NA
What do the results mean?	The results show a mapping of the restriction fragment.
Are other tests needed?	No
When would this test be used?	• To rule out cross-contamination of specimens. • To determine reactivation vs. reinfection of a patient. • To determine if two or more patients are infected with strains of *M. tuberculosis* possessing identical genotypes.
How would this test be ordered?	Physicians can request this test if approved by the TB Program.
How much would this test cost?	There is no charge for this test.

MTB Susceptibility Testing	
How does it work?	*M. tuberculosis* isolates are tested for sensitivity/resistance to isoniazid, rifampin, and ethambutol using the BACTEC MGIT 960 susceptibility method. If resistance is detected in any of the three drugs, the susceptibility is repeated and streptomycin is added to the drug panel. All isolates showing resistance are submitted to CDC for confirmation. • A standardized suspension of MTB is added to 4 MGIT tubes. Tube 1 is a growth control (contains no antibiotics), Tube 2 contains isoniazid, Tube 3 contains rifampin, and Tube 4 contains ethambutol. • The MGIT tubes are placed in the BACTEC 960 which scans the tubes for growth once every hour. • When the growth control tube has reached 400 growth units, the BACTEC 960 performs a final scan on tubes 2, 3, and 4 to check for growth and then prints out a final report. • Based on growth units, it can be determined if the MTB isolate is sensitive or resistant to each of the drugs tested. • If the MTB is sensitive to a drug, there would be no growth in that MGIT tube. If the MTB is resistant to a drug, then the MTB would grow in the MGIT tube and the growth units would be registered on the BACTEC 960 report.
When is this test run?	Monday through Friday
How long before results are ready?	4 to 13 days after the actual susceptibility testing is started. Isolates must meet certain criteria before susceptibility testing can be performed. This can add up to 7 days to the turn-around-time for the susceptibility results.
How are the results classified?	Sensitive, Resistant, or Contaminated
What do the results mean?	Sensitive: The drug can be used to treat the MTB isolate. Resistant: The drug has no effect on MTB isolate. Contaminated: The susceptibility is contaminated with an organism other than MTB and will have to be repeated.
Are other tests needed?	No, unless multi-drug resistance is demonstrated. Then the isolate is sent to CDC for an expanded panel of drug testing.
When would this test be used?	• To determine the susceptibility of an MTB isolate to isoniazid, rifampin, ethambutol, and in some cases to streptomycin. • When a patient is not responding to treatment and the physician feels that the susceptibility should be checked again. • Every 3 months for as long as a patient's cultures remain MTB positive.
How would this test be ordered?	Through the State TB Lab. Susceptibilities are automatically run on all first-time MTB positive cultures.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

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