

## Heartland National Tuberculosis Center (HNTC) Regional Medical Consultation Services Plan

**PURPOSE:** This plan identifies roles and responsibilities and establishes guidelines for the delivery of HNTC medical consultation services within the Heartland Region. In addition, it addresses the associated issues of communication both within the HNTC and between the HNTC and individuals/organizations in the states that comprise the Heartland Region; the exchange of medical expertise as part of the medical consultation process and capacity development within the Heartland Region; regional marketing activities to increase awareness of consultation services; and evaluation of the quality of consultation services and their value to the end-user and the Heartland Region.

### CORE REFERENCES:

An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy, American Thoracic Society; American Journal of Respiratory and Critical Care Medicine, Volume 174, pp 935-952, 2006

Availability of an Assay for Detecting Mycobacterium tuberculosis, Including Rifampin-Resistant Strains, and Considerations for Its Use – United States, 2013

Controlling TB in the United States, MMWR™ November 4, 2005, Vol. 54, No. RR-12

Diagnosis of Tuberculosis in Adults and Children: Official ATS/IDSA/CDC Clinical Practice Guidelines, October 2016

Drug-Resistant Tuberculosis: A Survival Guide for Clinicians, Francis J. Curry National Tuberculosis Center, 2016

Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, MMWR™ December 23, 2005, Vol. 54, No. 50

Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection – United States, 2010, MMWR™ June 25, 2010, Vol. 59, No. RR-5

#### Infection Control:

Additional Frequently Asked Questions (FAQ) for Clarification of recommendations in the “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005”, CDC/Division of Tuberculosis Elimination, April 18, 2007

American Academy of Pediatrics Red Book, 31<sup>st</sup> Edition, 2018 (pending publication)

Aidsinfo - <https://aidsinfo.nih.gov/guidelines>

Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, 2005, MMWR™ December 30, 2005, Vol. 54, No RR-17

NTCA and APHL – Consensus statement on the use of Cepheid Xpert MTB/RIF assay in making decisions to discontinue airborne infection isolation in healthcare settings, 2016

Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of American Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis, 2017

World Health Organization – The use of bedaquiline in the treatment of multidrug-resistant tuberculosis, Interim policy guidance, 2013

World Health Organization – The use of delamanid in the treatment of multidrug-resistant tuberculosis, Interim policy guidance, 2014

World Health Organization – WHO treatment guidelines for drug-resistant tuberculosis, 2011 with 2016 update

Latent Tuberculosis Infection: A Guide for Primary Health Care Providers, Francis J. Curry National Tuberculosis Center, 2010

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

Provisional CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Fumarate (Sirturo) for the Treatment of Multidrug-Resistant Tuberculosis, 2013

Radiographic Manifestations of Tuberculosis: A Primer for Clinicians, 2nd Edition (includes Continuing Education Credit Application and Evaluation), Francis J. Curry National Tuberculosis Center, 2010

Recommendations for Use of an Isoniazid –Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium tuberculosis Infection, MMWR™ December 9, 2011, Vol. 60, No. 48

Reported TB in the United States, 2016, CDC/Division of Tuberculosis Elimination, 2017

Severe isoniazid-associated liver injuries among persons being treated for latent tuberculosis infection, MMWR™ March 5, 2010, Vol. 59, No. 8

Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, MMWR™ June 9, 2000, Vol. 49, No. RR-6

Treatment of Tuberculosis, MMWR™ June 20, 2003, Vol. 52, No. RR-11

Tuberculosis (TB) Risk Assessment Worksheet, Appendix B, CDC/Division of Tuberculosis Elimination, September 27, 2006. Supplement to the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, 2005

Tuberculosis Infection Control: A Practice Manual for Preventing TB, Francis J. Curry National Tuberculosis Center, 2011

Updated guidelines for the use of nucleic acid amplification tests in the diagnosis of tuberculosis, MMWR™ January 16, 2009, Vol. 58, No. 1

**PERSONNEL STRUCTURE:**

1. Medical Director/ Medical Consultant: Barbara Seaworth, MD
2. Assistant Medical Director/Medical Consultant: Lisa Armitige, MD, PhD
3. Nurse Consultants: Catalina Navarro, RN, BSN; Iris Barrera, RN; Marybel Monreal, RN, BSN
4. Project Support Specialist: Alysia Wayne

**Note:** Heartland Medical Consultant Group is composed of physicians and other health care practitioners with expertise in specific areas of tuberculosis prevention and control activities and comprise a “consultation network” that can be called upon by the medical and nurse consultants to provide consultation and/or technical assistance in their particular areas of expertise.

**RANGE OF SERVICES:** Both medical and nursing consultation, as well as technical assistance in various aspects of TB prevention and control will be provided at no cost to physicians, nurses and other health care professionals in the 10 states and one Big City that comprise the Heartland Region. HNTC consultants will maintain expertise and the ability to respond to requests for medical and nursing consultation and/or technical assistance in the following areas:

1. Diagnostic evaluation of persons with possible tuberculosis
2. Treatment of TB infection and TB disease
3. Treatment of drug resistant TB, including MDR and XDR and contacts of these persons
4. Evaluation and management of:
  - a. Delayed bacteriologic, clinical and/or radiographic response to therapy
  - b. Treatment failure
  - c. Relapse of TB disease
  - d. Adverse drug effects: GI upset, rash, hepatitis, other

5. Diagnosis and treatment of LTBI and TB disease in children and adolescents
6. TB in the setting of HIV infection
7. Management of tuberculosis in persons with significant coexisting conditions: renal insufficiency, hepatic disease, pregnancy, other
8. Non-adherence with treatment
9. Investigation, evaluation and treatment of contacts to an infectious TB case
10. Evaluation and response to a tuberculosis outbreak
11. Infection control measures to reduce transmission of tuberculosis
12. Nurse case management

**ACCESSING SERVICES:** Health care providers may access consultation and technical assistance services by one of several methods:

1. Referral from the existing medical consultation process within each state
2. Referral from the CDC Call Center
3. Referral from other COE's
4. Contacting the HNTC directly via telephone. Calls preferably come to either a dedicated toll-free warm-line telephone number in San Antonio (800-TEX-LUNG or 800-839-5864) or to a nurse consultant: Catalina Navarro (210-531-4569); Iris Barrera (210-531-4539); Marybel Monreal (210) 531-4539. Clinicians may also contact one of the HNTC Medical Consultants directly. Phone numbers are provided on the HNTC website, as well as promotional literature.
5. Contacting the medical consultants ([barbara.seaworth@uthct.edu](mailto:barbara.seaworth@uthct.edu), [lisa.armitige@uthct.edu](mailto:lisa.armitige@uthct.edu)) or the nurse consultants ([catalina.navarro@uthct.edu](mailto:catalina.navarro@uthct.edu), [iris.barrera@uthct.edu](mailto:iris.barrera@uthct.edu), or [marybel.monreal@uthct.edu](mailto:marybel.monreal@uthct.edu)), directly via email. Email addresses are provided on the HNTC website and in promotional literature.
6. \*NEW\* Send an email to the nursing team at [heartlandconsultation@uthct.edu](mailto:heartlandconsultation@uthct.edu)

**WARM LINE USAGE:** Greater than 90% of calls will be answered the same day or within 24 business hours, however, the HNTC consultant line is a warm-line that is staffed during business hours and is a non-emergency line. If there is an urgent medical issue and you need to reach a consultant outside of business hours, please e-mail a medical consultant (e-mail addresses noted above). If an attempt to

reach an HNTC Medical Consultant is not successful or an immediate response is needed, please refer to emergency support within your community or state.

**HOURS OF OPERATION:** Monday – Friday, from 8:00 AM until 5:00 PM, Central Time. After business hours, voice mail service is available. Voice-mail messages left after 4:00 pm will be returned by the medical or nurse consultant within one business day.

**CONSULTATION PROCESS:** CDC guidance discourages “curbside consultation” by a COE. HNTC agrees that complete information provides the best opportunity to make the best recommendations. Although some requestors may prefer to contact the Consultant directly by telephone or email as described above, it is anticipated that the majority of requests seeking consultation or technical assistance will be by telephone call or e-mail and will be routed through a nurse consultant first to facilitate collection of pertinent data and prioritization of the request. The following process describes the most likely scenario:

1. At least 90% of calls not answered initially by a nurse consultant or medical consultant will be returned within one business day.
2. Evaluate appropriateness of the request and refer to other resources, if necessary. See “State Specific Consultation Processes” (below) for additional guidance. Requests may also be referred to another COE, if appropriate.
3. Determine case information required. Potential case information to be collected is described below. The extent of information to be collected will be based upon the complexity of the case and the reason for the consultation request:
  - a. Contact information for individual requesting consult, to include:
    1. Name
    2. Discipline
    3. Organization
    4. Phone number
    5. Fax number
    6. Email address
    7. Mailing address
    8. If other than treating physician, the name of the treating physician and his/her contact information
  - b. Patient’s name and date of birth (if caller is willing to provide this information)
  - c. Reason for consult request
  - d. History of present illness: review of events from patient’s initial presentation proceeding chronologically up to the present time. Depending on the nature of the consult, this may be

relatively uncomplicated or may be highly complex. Copies of state reporting forms, hospital admission history and physical, hospital discharge summary and any other consults accomplished may also be requested.

- e. Prior history of TB exposure, infection, or disease:
  - 1. Tuberculin skin test (TST) history, current TST date and results, and IGRA results and dates
  - 2. Chest x-ray/CT/Other diagnostic imaging: request written reports
  - 3. AFB smear and culture results, molecular test results, culture base drug susceptibility results with dates of each, antibiotic sensitivity results, and pathology results
  - 4. Treatment regimen(s), including start, stop and restart dates. Review of the following information: directly observed therapy (DOT), self-administration, adherence, intolerance, adverse drug reactions, etc.
  - 5. Laboratory monitoring/HIV status: baseline and periodic laboratory monitoring results. Copies of laboratory reports may be requested, if indicated. If HIV seropositive, request viral load(s) and CD4 count(s).
  - 6. Medical history/Co-morbid conditions/Surgical history, if applicable
  - 7. Medication history (prescription, over-the-counter, folk, herbal), concentrating on medications that increase risk of progression to active TB disease, have drug-drug interactions with drugs used to treat TB or increased risk of TB medication toxicity
  - 8. Social and individual risk factors for LTBI and/or TB disease
  - 9. Current weight, to include gain or loss in response to therapy
  - 10. Summary of contact investigation if pertinent to consult
  - 11. How the caller became aware of HNTC consultation services (CDC website, HNTC website, referral from state or local health department, etc.)
  
- f. A consultation summary will be sent by the requestor to the HNTC nursing staff along with accompanying documentation as requested by the HNTC consultation team (lab reports, radiographs, etc.).
  - 1. HNTC nursing staff will review the summary and documentation provided by the requestor and will:
    - a. Summarize case orally or via e-mail for the medical consultant
    - b. If more than one consult request is pending, determine priority of request with input from the medical consultant.
    - c. Organize and coordinate collection of additional information as requested by the medical consultant.
  
  - 2. Complete initial entry in the Medical Consultation Database (MCD) within two weeks post consultation.
    - a. Date of consult request
    - b. Demographic information (name of requestor, requesting agency, address, etc.) and requestor contact information
    - c. Contact attempts

- d. Indication of pediatric related calls
  - e. Bedaquiline information
  - f. Call category
  - g. Summary of the question
  - h. Linked calls
  - i. Date of initial response to consult request
  - j. Consultant response
- g. Once the medical consultant has contacted the requestor, the HNTC response to the inquiry is determined by the nature of the request and the stated preference of the requestor. Recommendations may take the form of a written consult, an email reply or telephone consultation. All consultations will be followed by a written consultation summarizing the clinical information, HNTC response and recommendations. Per CDC guidance, states will be notified of requests for consultation on persons with disease within 2 business days.
1. Written consult:
    - a. Written responses will be prepared within three to five business days following the date of the initial request (within three days for at least 80% of requests).
    - b. Most written responses will be completed via e-mail.
    - c. Once the consult is dictated by the medical consultant, the project support specialist produces a written draft and returns it to the medical consultant for review. Following the medical consultant's review, the consult is prepared by the project support specialist in final form for signature.
    - d. Once the consult is signed by the medical consultant, the project support specialist distributes copies to the requestor, the treating physician or other health care provider, the local health department and the TB Controller or other appropriate public health authority of that state via e-mail. The original consult is mailed to the requestor (Note: see "End-User Satisfaction" described below). A copy of the consult is forwarded to the nurse consultant for review and retained for the patient record.
    - e. If a consultation is judged by the medical consultant to be of significant public health importance, e.g., an extensive contact investigation surrounding a case of multi-drug resistant TB, he/she may elect to communicate directly with the State TB Control Program to facilitate the public health response.
  2. Email reply: The medical consultant incorporates the recommendations in an email to the requestor. A copy of the email is sent to the TB Controller or other appropriate public health authority of that state and to the nurse consultant for review and eventual inclusion in the patient's consultation record.
  3. Telephone consultation: The medical consultant will summarize the discussion and recommendations on the telephone consult worksheet. A copy of the worksheet is forwarded to the nurse consultant for review and eventual inclusion in the patient's consultation record. If indicated, an email will be sent to the TB Controller or other

appropriate public health authority of that state to inform them of the recommendations made.

4. Each nurse consultant is responsible for opening and maintaining records as identified (complex cases, MDR-TB cases, etc.). This record includes all documentation received or developed in the process of preparing the consult and the HNTC reply (written consult, email reply, telephone consult worksheet).

**CONFIDENTIALITY:** All patient information is maintained and communicated in a secure and confidential manner.

**REPORTING:**

1. CDC reporting: semi-annual (January, July) reporting will be in the format required by the CDC and will be based primarily upon analysis of the data entered in the MCD and the end-user satisfaction survey response spreadsheet.
2. TB COEs are required to provide documented medical consultation on a minimum of 20% of patients with TB disease reported for each state in their region. If, for any particular states, the TB COE is not involved in at least 20% of TB cases, justification may be provided and considered sufficient to meet the requirement. TB COEs are also required to respond to LTBI-related consultation requests.
  - a. Justification may include reasons such as:
    - i. Excellent state TB medical consultant fielded the majority of questions on TB cases this past year;
    - ii. State X had less than 5 relatively straightforward TB cases this past year and did not need further medical expertise for management, etc.
3. State programs need to be notified about patients with TB disease within 2 business days of consult provision.
4. Full consult notes need to be logged into the medical consultation database (MCD) within 2 weeks of consult date.
  - a. If the consult note is logged within 2 business days, this will result in automatic notification to the local state TB program, and will meet both requirements.
5. In addition to quantity and timeliness, consultations will also be evaluated for quality.
  - a. Consult reports will be expected to reflect lab report and chest radiograph review, as relevant to the consult question.
  - b. Consultation reports will also be expected to reference appropriate CDC DTBE Guidelines, TB COE products, and/or other literature relevant to the consult question.
  - c. Consultations marked with “circumstances of public health significance” may be evaluated more carefully than others.

- d. LTBI consults may be evaluated by when/where they come from (e.g. after training event in high-risk area)

**STATE SPECIFIC CONSULTATION PROCESSES:** Each state within the Heartland Region maintains some level of capability to provide medical consultation and technical assistance for TB control activities and the medical management of TB patients within the state’s jurisdiction. Some state TB Control Programs have a salaried TB Physician Consultant who may serve as the State TB Controller/Control Officer. Other states have identified and entered into formal or informal agreements for consultation services with physicians in various academic and/or private practice settings who have expertise in the medical management of TB patients.

The goal of the HNTC medical consultation service is to compliment and not supplant the existing state consultation and technical assistance process. In that light, HNTC medical consultation staff will align their activities with the state specific processes described in the State Specific Consultation Processes.

**MEDICAL CONSULTATION REGIONAL MARKETING ACTIVITIES:** General and targeted marketing activities are instrumental in increasing awareness and utilization of HNTC medical consultation services in the Heartland Region. Ongoing marketing activities will include:

1. Excellence in Customer Service and Meeting Customer Expectations: Although activities geared to increasing awareness of services are important, developing the processes necessary to respond in a timely manner to the needs of our customers and instilling credibility and confidence in our medical consultations are crucial to endorsement of our services and referral of cases for consultation by TB Control Program staff in the Region, particularly TB physician consultants. The COE Medical Consultants support marketing activities through acknowledgment of the value of the consultation service and regularly communicate this to other clinicians within their states.
2. Activities at Workshops and Conferences:
  - a. Brochures describing training, product development and medical consultation services will be available at each HNTC-sponsored training event. These will be reinforced by HNTC staff announcements and accompanying PowerPoint presentations. Similar activities will be conducted at national and regional programmatic conferences as these opportunities arise (NTCA, Midwest and Four Corners TB Controllers Meeting, North American Regional Union meeting, etc.).
  - b. TB Program staff throughout the HNTC Region will be encouraged to provide information about HNTC services when they appear before groups within their jurisdiction (local health department staff, physician groups, infection control practitioners, laboratorians, school nurses, correctional health care personnel, etc.).
3. Web-Based/Internet Activities: HNTC has developed and will maintain an extensive website describing available medical consultation services. This is the primary responsibility of the HNTC Website Coordinator with input from the medical and nurse consultants. A link to each state’s

TB Program website and the consultation services will be included. TB Controllers and programs are encouraged to post a link to the HNTC website on their state TB Program website, as well as on the websites of academic partners and other stakeholders in their state.

4. Products and Tools: Wide dissemination of products and clinical tools to assist in the medical management of patients with TB infection or TB disease serves to market HNTC medical consultation services by highlighting the nursing and medical expertise available through the Heartland Center. In addition, the collaborative relationships which develop between HNTC staff and our partners within the HNTC Region during the development and field testing of these products also highlights and broadcasts the expertise and services available through HNTC.
5. Clinical and Programmatic Mini-Fellowships: Although primarily intended to enhance the skills of medical providers and other TB Program staff, these fellowships also serve to increase the awareness and the utilization of consultation services as attendees interact with HNTC staff and TCID clinicians and develop the basis for an ongoing consultative relationship once they return to their home state.

**MEDICAL CONSULTATION SERVICES EVALUATION:** The evaluation of medical consultation services occurs in three separate but interrelated realms of activity, (1) internal assessment of the quality of the consult and the process which produced it, (2) measurement of end-user satisfaction with the consultation services received, and (3) evaluation of overall value to the Heartland Region.

1. Quality Assurance:
  - a. The Medical Consultation Database is the primary tool used to assess timeliness of responses to requests for consultation and technical assistance. Data entry is described above in "Consultation Process". The database provides aggregate data for determining average time to initial and final responses. The HNTC goal is to provide an initial response within one business day of the initial request for consultation and a written response within 3-5 business days. The nurse consultant will compile this metric as a component of the required CDC semiannual reporting.
  - b. TB Medical Consultants from the component states and other physicians providing expertise in the medical management of TB patients in the HNTC Region are networked into an informal group referred to as the Heartland Medical Consultant Group. Members of this group are targeted for distribution of products and clinical tools, the quarterly e-newsletter, clinical updates, and are invited to participate in periodic case teleconferences. Selected members of this larger group also attend periodic meetings/targeted training in San Antonio with the HNTC Medical Consultants.
  - c. Five written consults generated by the HNTC Medical Consultants will be reviewed once a quarter, by selected Texas Center for Infectious Disease staff physicians. HNTC nursing staff will ensure that a review will occur on each HNTC consultant at least once by the end of the year. This review will consider measures such as completeness of recommendations,

usefulness of recommendations, and adherence of recommendations to accepted guidelines and/or best practices. Records selected for review will consist of a longitudinal consultation, a consultation with public health significance, and a review of a consultation provided by any new medical consultant added to the consultation service. The reviewer's comments will be documented on a cover sheet attached to the consultation, returned to the HNTC Medical Consultant for review. The cases reviewed will be noted in the Medical Consultation Database as required by CDC for external reporting. Nurse consultations are continuously reviewed by the HNTC Medical Consultants throughout the year.

- d. The quality of pediatric consultations is enhanced by incorporating the expertise of four pediatric specialists, Dr. Lisa Armitige, Dr. Jeff Starke, Dr. Andrea Cruz, and Dr. Kim Smith when complex pediatric cases are encountered by the HNTC Medical Consultant. As necessary, the HNTC Medical Consultant asks these pediatric specialists to review the case and offer opinions prior to final recommendations being made by the HNTC Medical Consultant.
- e. The quality of consultations is enhanced by incorporating the knowledge of consultants with expertise in technical advice, programmatic issues, epidemiology, and laboratory issues: Drs. Annie Kizilbash, Adriana Vasquez, Sean O'Neil, Wendy Chung, and laboratorians Ed Graviss, and Ken Jost. As necessary, the HNTC Medical Consultant asks these specialists to review the case and offer opinions prior to final recommendations being made by the HNTC Medical Consultant.

**HEARTLAND REGION MEDICAL CONSULTATION CAPACITY DEVELOPMENT:** Efforts to increase medical consultation capacity within the Region are focused primarily on the HNTC Medical Consultants Group, whose members are identified by TB Controllers and HNTC Medical Consultants. These activities include:

1. HNTC clinical mini-fellowships conducted at the Texas Center for Infectious Disease or off-site in coordination with one of our partner states
2. TB Intensive Course
3. Electronic distribution of the quarterly HNTC e-newsletter, clinical updates, clinical tools and other products to facilitate the medical management of TB patients
4. Expert Network Calls hosted by CDC
5. Periodic meetings of selected members of the HNTC Medical Consultant Group to identify and prioritize activities for capacity development and make recommendations to the HNTC Advisory Committee
6. Targeted training for medical consultants at regional meetings and through the annual HNTC medical consultant meeting.