

TBeat

A newsletter produced by the Heartland National TB Center

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Four-Month Rifapentine Regimens with or without Moxifloxacin for Tuberculosis

S.E. Dorman, P. Nahid, E.V. Kurbatova, P.P.J. Phillips, K. Bryant, K.E. Dooley, M. Engle, S.V. Goldberg, H.T.T. Phan, J. Hakim, J.L. Johnson, M. Lourens, N.A. Martinson, G. Muzanyi, K. Narunsky, S. Nerette, N.V. Nguyen, T.H. Pham, S. Pierre, A.E. Purfield, W. Samaneka, R.M. Savic, I. Sanne, N.A. Scott, J. Shenje, E. Sizemore, A. Vernon, Z. Waja, M. Weiner, S. Swindells, and R.E. Chaisson, for the AIDS Clinical Trials Group and the Tuberculosis Trials Consortium

Abstract

BACKGROUND

Rifapentine-based regimens have potent antimycobacterial activity that may allow for a shorter course in patients with drugsusceptible pulmonary tuberculosis.

METHODS

In an open-label, phase 3, randomized, controlled trial involving persons with newly diagnosed pulmonary tuberculosis from 13 countries, we compared two 4-month rifapentine-based regimens with a standard 6-month regimen consisting of rifampin, isoniazid, pyrazinamide, and ethambutol (control) using a noninferiority margin of 6.6 percentage points. In one 4-month regimen, rifampin was replaced with rifapentine; in the other, rifampin was replaced with rifapentine and ethambutol with moxifloxacin. The primary efficacy outcome was survival free of tuberculosis at 12 months.

RESULTS

Among 2516 participants who had undergone randomization, 2343 had a culture positive for *Mycobacterium tuberculosis* that was not resistant to isoniazid, rifampin, or fluoroquinolones (microbiologically eligible population; 768 in the control group, 791 in the rifapentine–moxifloxacin group, and 784 in the rifapentine group), of whom 194 were coinfected with human immunodeficiency virus and 1703 had cavitation on chest radiography. A total of 2234 participants could be assessed for the primary outcome (assessable population; 726 in the control group, 756 in the rifapentine– moxifloxacin group, and 752 in the rifapentine group).

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Four-Month Rifapentine Regimens continued....

RESULTS CONTINUED

Rifapentine with moxifloxacin was noninferior to the control in the microbiologically eligible population (15.5% vs. 14.6% had an unfavorable outcome; difference, 1.0 percentage point; 95% confidence interval [CI], -2.6 to 4.5) and in the assessable population (11.6% vs. 9.6%; difference, 2.0 percentage points; 95% CI, -1.1 to 5.1). Noninferiority was shown in the secondary and sensitivity analyses. Rifapentine without moxifloxacin was not shown to be noninferior to the control in either population (17.7% vs. 14.6% with an unfavorable outcome in the microbiologically eligible population; difference, 3.0 percentage points [95% CI, -0.6 to 6.6]; and 14.2% vs. 9.6% in the assessable population; difference, 4.4 percentage points [95% CI, 1.2 to 7.7]). Adverse events of grade 3 or higher occurred during the on-treatment period in 19.3% of participants in the control group, 18.8% in the rifapentine–moxifloxacin group, and 14.3% in the rifapentine group.

CONCLUSIONS

The efficacy of a 4-month rifapentine-based regimen containing moxifloxacin was noninferior to the standard 6-month regimen in the treatment of tuberculosis. (Funded by the Centers for Disease Control and Prevention and others; Study 31/ A5349 ClinicalTrials.gov number, NCT02410772.)

Click here for the full journal article: https://pubmed.ncbi.nlm.nih.gov/33951360/



TAG Information Note: N-nitrosamines and Tuberculosis Medicines Rifampicin and Rifapentine

Written by: Sandrine Cloez and Mike Frick

Reviewed by: Jeremy Hill, Lindsay McKenna, Payam Nahid, Regina Osih, Chistophe Perrin, Tina Shah, Karin Turner and the staff of the Global Drug Facility

Background: N-nitrosamines and our medicines

In 2018, health authorities in the European Union, the United States, Canada, and other countries began investigating the presence of N-nitrosamine impurities in medicines. Initially, a type of N-nitrosamine called N-nitrosodimethylamine (NDMA) was identified in certain antihypertensive drugs. Since then, health authorities have identified N-nitrosamines in several other categories of drugs, including in common heartburn products (ranitidine, nizatidine), in antidiabetic drugs (metformin), and, more recently, in medicines used to treat and prevent tuberculosis (rifampicin, rifapentine).

This information note focuses on the presence of N-nitrosamines in tuberculosis (TB) medicines. The information provided is intended to help advocates, policymakers, and implementers understand how the identification of N-nitrosamines in rifampicin and rifapentine may affect the safety and supply of TB medicines and what this may mean for TB programs and patients. Key takeaway messages are presented first, immediately following this introduction, to focus readers' attention on priority actions; subsequent sections present the evidence behind these messages. Accompanying Q&A documents answer questions that people taking a course of TB preventive therapy (TPT) or a TB treatment regimen with either rifampicin or rifapentine would want to know about N-nitrosamines before beginning treatment. *Continued on next page...*



N-nitrosamines and TB Medicines continued....

Everyone has an intuitive sense of toxicology, or instinctual ideas about what is safe versus dangerous.1 Words such as "impurity," "carcinogen," and "toxicity" evoke strong emotions and may mean different things to different people. When considering any chemical risk—especially one only recently recognized, as in the case of N-nitrosamines and TB medicines—we need to train our 'intuitive toxicology' to judge risks not in isolation, but in the full context of what is known about the choices before us. In this spirit, this document shares information about N-nitrosamines and health in the context of TB, a life-threatening infectious disease. Not every question about TB medicines and N-nitrosamines has a simple answer, but as a community of people working to end TB, we can decide how to respond together if we are all well informed.

Click here for the full publication: https://www.treatmentactiongroup.org/wp-content/uploads/2021/02/nitrosamine-technical-brief-2021.pdf

Drug-resistant TB Clinical Trial Ends Enrollment Early after Positive Initial Data

A trial aiming to find a better treatment for multidrug-resistant tuberculosis (MDR-TB) has stopped enrolling patients early after its independent data safety and monitoring board indicated that the regimen being studied is superior to current care, and more patient data was extremely unlikely to change the trial's outcome.

TB-PRACTECAL, a phase II/III clinical trial sponsored by Médecins Sans Frontières/Doctors Without Borders (MSF), tested a six-month regimen of bedaquiline, pretomanid, linezolid and moxifloxacin, against the locally accepted standard of care. At the time of the interim analysis 242 patients had been enrolled in seven trial sites across Belarus, South Africa and Uzbekistan.

MSF is now preparing a dataset to share with the World Health Organization (WHO) as soon as possible, and full results will be submitted to a peer-reviewed journal in the coming months. MSF believes these findings will have the potential to change clinical practice.



Nanyanyiso Baloi holds her treatment regimen for pre-XDR-TB, which includes delamanid and bedaquiline. Khayelitsha, Western Cape, South Africa, 2016.

Transforming TB patient treatment

"This will be the first-ever multi-country, randomised, controlled clinical trial to report on the safety and efficacy of a six-month, all-oral regimen for drug-resistant TB," said Professor David Moore from the London School of Hygiene and Tropical Medicine and a member of the Trial Steering Committee. "The findings could transform the way we treat patients with drug-resistant forms of TB worldwide, who have been neglected for too long."

Click here for the full article: https://msf.org.uk/article/drug-resistant-tb-clinical-trial-ends-enrolment-early-after-positive-initial-data



Epidemiology and Clinical Characteristics of Childhood TB Identified Using Active and Passive Case Finding

S. Ikeda, A. T. Cruz, J. R. Starke—Department of Pediatrics, Baylor College of Medicine, Houston, Texas, USA

Click here for the full article: https://www.ingentaconnect.com/content/iuatld/ijtld/2021/00000025/00000006/art00010#

Abstract

BACKGROUND: Childhood TB cases can be found using passive case finding (PCF), i.e., by diagnosing children presenting with symptoms, or using active case finding (ACF), i.e., by identifying children with TB through contact tracing. Our study determined epidemiologic, clinical, and radiographic differences between these groups.

DESIGN/METHODS: Retrospective cohort study of children aged 0–19 years diagnosed with TB from January 1, 2012 to December 31, 2019 at a U.S. TB clinic, comparing clinical, radiographic, microbiologic, and epidemiological characteristics of children identified using PCF and ACF.

RESULTS: Of 178 eligible patients, 99 (55.6%) were diagnosed using PCF. Children identified using PCF were older (mean 8.9 vs. 6.1 years, P ¼ 0.003), more often non-US-born (OR 2.29, 95% CI 1.12–4.67), had more extrapulmonary disease (44.4% vs. 3.8%, OR 20.27, 95% CI 5.98–68.64) and severe intrathoracic findings (39.4% vs. 10.1%, OR 5.77, 95% CI 2.50–13.29). Children identified using ACF were often asymptomatic, had isolated hilar/mediastinal adenopathy, but had more availability of drug susceptibility data from a link to a source case.

CONCLUSION: Children identified using PCF had more severe manifestations, while those identified using ACF had greater availability of drug susceptibility data. Clinicians should be aware that clinical and radiographic presentations in children identified using PCF and those identified using ACF differ, and that the latter may be eligible for shorter treatment regimens.

Commentary from an Expert—Dr. Lisa Y. Armitiqe, Assistant Medical Director, Heartland National TB Center

Researchers at Baylor College of Medicine in Houston, Texas published a review of the epidemiology and clinical presentation of 178 children sorted by how they presented for evaluation. Children were characterized as being found by passive case finding (PCF) - meaning the children presented for evaluation due to illness, or active case finding (ACF) - meaning the children were found due to screening such as contact investigation or immigration screening.

In this publication, the authors noted several interesting findings. Children who presented by passive case finding (PCF) tended to be non-US born, older, sicker and more advanced in their disease progression. Children found by PCF were more likely to be symptomatic and to have a longer duration of symptoms. All children in this study requiring admission to the intensive care unit presented by PCF.

Children found by active case finding (ACF) were more likely to have less clinical and radiologic disease and to be asymptomatic or have minimal symptoms.

These findings are significant for many reasons. They validate the importance of contact investigation in identifying children early in the TB process *before* they get seriously ill. As the field is moving toward treating with shorter regimens, the authors identified children who could potentially be candidates for shorter treatment regimens such as those being studied in the SHINE trial conducted by the World Health Organization.

If you have any questions or just some thoughts, please feel free to reach out to us here at Heartland, we would love to hear what you are thinking! You can also contact the authors (Heartland's own consultants), Dr. Andrea Cruz or Dr. Jeffrey Starke.



Multistate TB Outbreak Linked to Suspected Contaminated Bone Graft Material Used in Surgery

HNTC has been consulted and involved in discussions with CDC regarding this outbreak.

We are available for consultation regarding any patients in the HNTC region who may have received one of the grafts.

On behalf of Dr. LoBue

Dear Colleague,

On May 25, 2021, CDC received notification of a cluster of patients at a single facility who developed *Mycobacterium tuberculosis* (MTB) surgical site infection following spinal fusion surgery. As of June 10, 2021, post-operative patients from multiple facilities in multiple states have developed surgical site infections (abscess, phlegmon, osteomyelitis, and/or discitis) or other manifestations of MTB infection (e.g., miliary, disseminated, meningitis). MTB was isolated from the wounds of multiple patients during post-operative evaluations.

The surgical procedures all used a single product lot of FiberCel, a bone allograft, manufactured by Aziyo Biologics and distributed by Medtronic (FiberCel lot NMDS210011). On June 2, the manufacturer issued a voluntary nationwide recall of the single lot of FiberCel linked to these patients.

The manufacturer reported that 154 units of this product, from a single donor, were shipped to more than 30 facilities in 20 states. CDC has worked with the affected state and local health departments to determine the disposition status of all distributed units of this lot and, where relevant, recipient patient clinical status. All facilities and states have been contacted and all unused products have been sequestered. If you have not been contacted, then there were no affected lots delivered to your jurisdiction.

There is **only one lot** that has been implicated in this investigation. The MTB isolate that was grown from affected patients was found to be susceptible to all first-line drugs (i.e., Rifampicin, Isoniazid, Pyrazinamide, Ethambutol (RIPE)). The genotype appears to be unique, but more information on genotyping and Whole Genome Sequencing will be shared as available. **CDC recommends that all patients who received this product lot immediately begin full treatment for TB disease.**

CDC encourages hospitals and providers to contact patients to notify them that the allograft material was contaminated and initiate full evaluation. Patients should be clinically evaluated as soon as possible both for post-operative infection as well as TB disease that may or may not have disseminated. Patients will need continued care from both surgical providers and TB providers to complete TB treatment.

Healthcare personnel may have been exposed to MTB via exposure to contaminated bone graft material during surgery or surgical revision or when providing patient care. It is important to rapidly identify and assess all exposed healthcare contacts for TB infection and disease.

Continued on next page...



Multistate TB Outbreak continued....

Facilities should report adverse health consequences to FDA's MedWatch Adverse Event Reporting Program:

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to

MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

Phone: (800) FDA-1088

If you have any questions, please reach out to your CDC project officer (list attached) or Sapna Bamrah Morris MD, FIDSA; Lead, Medical Officer Team; Field Services Branch Division of Tuberculosis Elimination; Centers for Disease Control and Prevention (sbmorris@cdc.gov).

Additional resources:

Request medical consultation through the <u>TB Centers of Excellence for Training, Education, and Medical Consultation</u>
Contact <u>State TB Control Programs</u>; Contact <u>CDC-INFO</u> (<u>cdcinfo@cdc.gov</u>) for all other inquiries.

I would like to thank the affected state and local TB programs for their continued assistance.

Sincerely,

Philip LoBue, MD, FACP, FCCP
Director
Division of Tuberculosis Elimination
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Awards and Elections in the Heartland Region

Congratulations to <u>Denese Scarlett Carrera</u> of becoming the 2021 Award Recipient of the National TB Controllers Association, **Unsung TB Hero**!

Congratulations to the newly elected (or continuing) members of the National TB Controllers Association (NTCA), and the National TB Nurse's Coalition (NSTC):

NTCA Treasurer—Sandra Morris, MPH, TB Controller, Texas Department of State Health Services

NTNC High Incidence Representative—<u>Elizabeth Foy, BSN, RN</u>, Nurse Administrator/Consultant, Texas Department of State Health Services

NTNC Medium Incidence Representative—<u>Eric Wicklund, BSN, RN</u>, TB Nurse Consultant, Oklahoma State Department of Health

NTNC Low Incidence Representative—Kristin Bertrang, RN, TB Program Manager, State of Nebraska



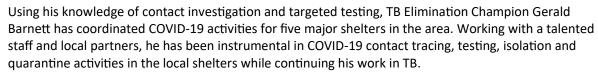
CDC TB Elimination Champions in the Heartland Region



Breathe Easy South Texas (B.E.S.T.) Project—San Antonio, Texas

Breathe Easy South Texas (B.E.S.T.) is a collaboration of governmental and private agencies specifically dedicated to performing targeted testing and treatment of latent TB infection. Not only are B.E.S.T partners continuing their direct care services to their TB patients during the COVID-19 pandemic, they are also putting their TB skills to use by assisting with early contact tracing and interviewing of patients with COVID-19.

Gerald Barnett, Contact Investigation/Special Populations Supervisor, Dallas County Health and Human Services







Dr. Otto F.W. Boneta, Tuberculosis Elimination Program Physician, Texas Department of State Health Services

Dr. Otto Boneta is a TB program and TB patient advocate. Dr. Boneta's innovative activities have helped the Texas Department of State Health Services continue their work to end TB during the COVID-19 pandemic. This TB Elimination Champion spearheaded a study to provide Clofazimine to Texas out patients with rifampin/multidrug resistance and authorized the use of video directly observed therapy. As a result, the team has been able to treat patients with MDR TB, while reducing COVID-19 exposure and travel time for staff and patients.

Harris County Public Health Tuberculosis Elimination Program, Texas

TB Elimination Champion, Harris County Public Health Tuberculosis Elimination Program, incorporated a signs and symptoms screening tool in response to COVID-19. They provide masks and gloves to patients and make use of their video directly observed therapy app to remind TB patients of their upcoming appointments.



Texas Department of State Health Services Region 4/5 North Tuberculosis Elimination Team, Tyler, Texas

The Texas Department of State Health Services Region 4/5 North Tuberculosis Elimination Team has worked to not only control and eliminate TB, but to also address COVID-19 in their community. Focusing on their collaborative mission while addressing both TB and COVID-19, they have continued to provide essential care for their patients. Although unable to host their annual World TB day conference, they have worked to ensure medical providers in their area remain mindful of the importance of testing for and treating TB.







TB Elimination Champions continued....

Texas TB Programs Supporting TB Services Along the Texas/Mexico Border—Harlingen, Texas

Texas Department of State Health Services' local and regional staff along the Texas/Mexico border in Harlingen worked to maintain core TB elimination services through mobile nursing, video directly observed therapy , and contact investigations, while supporting COVID-19 testing in high-risk areas.



A Message from our Director of Education

It has been a busy first half of the year for Heartland's Training and Education team! We began 2021 with our *Hot Topics in TB Webcast Series – New Healthcare Worker Guidelines and Practical Implications for Tuberculosis*, followed by our World TB Day webcast *What's Heartland Talking About*, which covered topics on TBTC Study 31; TB laboratory updates; Subclinical TB and new tools for providing patient-centered care. The webcast was very well received! Some of the comments shared by participants include "This was by far the best TB webinar that I have attended." "The patient testimonials were absolutely great!" "The testimonials were eye opening! Great patient perspectives." "I believe this is one of the best program presentations this year!" "This was a stellar conference!" To view archived materials for our trainings, please visit Training and Education - Heartland National TB Center (heartlandntbc.org).







Along with these courses, HNTC conducted an online *Clinical Pediatric TB Intensive*, hosting approximately 300 people. The participants remained engaged for the entirety of the 6-hour webinar. We are also focused on the development of new products including *Tips for Treating Latent TB Infection in Children Including Window Prophylaxis* (currently on our website) and *Screening, Diagnosis, and Treatment of Latent Tuberculosis Infection (LTBI) in Primary Care Settings: Tips for Coding and Billing* (available in the fall).

As we look forward to better days ahead, we have great topics lined up for 2022, including *TB Nurse Case Management, Clinical TB Intensive, Clinical Pediatric TB Intensive, MDR-TB Skills Immersion* and *TB Contact Investigation Interviewing Skills Course*. Please visit our new website at https://www.heartlandntbc.org/training.html for the latest updates.

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Message from the Director of Education continued....

<u>NEEDS ASSESSMENT</u> — In line with our continuous effort to improve our services and meet the needs of our region, we invite you to participate in a short survey. We greatly appreciate your feedback which will be used to guide the development of future products and trainings. Please contact **Delphina Sánchez** at <u>delphina.sanchez@uthct.edu</u> with any questions you may have.

Survey Link—https://www.surveymonkey.com/r/WPCCBJF

We appreciate the opportunity to serve our region with cutting-edge trainings and innovate products and hope to see you soon!

Delphina Sánchez, MA

Director of Education

Available Job Postings

<u>Coming Soon!</u> Heartland National TB Center

TB Nurse Consultant/Educator

Under the direction of the HNTC leadership team is responsible for the effective handling of a wide variety of multifaceted duties assigned within areas of nursing including, but not limited to: medical consultation, funded research studies, needs assessments, and educational product development. Position provides a strong foundation in public health policy and health assessment and promotion. Position participates in professional associations such as the National TB Controllers Association and the National TB Nurse Coalition and collaborates with local, regional and international partners in state, local, and federal agencies both nationally and internationally.

Heartland National TB Center

Training and Education Developer

Apply at: https://uthct.taleo.net/careersection/careers.uthealth.org/jobdetail.ftl?job=21000285&tz=GMT-05%3A00&tzname=America%2FChicago

Under the direction of the Administrative Services Officer (Director of Education), the Training and Education Developer performs highly complex administrative duties to plan, develop, coordinate, participate in and evaluate all aspects of education and training including identified special projects. Projects will include (not limited to) needs assessments; product development and review; translation efforts (Spanish, verbal and written); education activities; and other special projects as identified by organizational and grant opportunities.



Tips for Treating Latent TB Infection in Children—Now Available!



This double-sided fact sheet discusses the treating latent TB infection (LTBI) in children, including window prophylaxis.

Contents of the fact sheet include: Who should be treated?, What are the treatment regimens?, What are helpful administration tips?, and What are the monitoring recommendations?. On the reverse side is a quick-reference table regarding each of the preferred treatment regimens and the break down of dosing recommendations based on age.

Link to Book— https://www.heartlandntbc.org/assets/products/tip-for_treating_LTBI_in_children.pdf

Poster: Treatment of Drug-Susceptible Culture Confirmed Tuberculosis for Adults—Now Available!

This poster includes the first-line TB treatment regimens, dosing recommendations and frequency, and adverse reactions and monitoring

Link to poster: https://www.heartlandntbc.org/assets/products/Treatment_of_Drug-Susceptible_Culture_Confirmed_Tuberculosis_for_Adults.pdf



The fact-sheet and poster, as well as several other educational products are available via download from the HNTC website and can be printed in-house, or can be ordered by using the HNTC Product Order Form located at: https://heartlandntbc.org/products.html.

Resources

Centers for Disease Control and Prevention, Division of Tuberculosis Elimination—http://cdc.gov/tb/
Centers of Excellence (COE) TB Training and Education Products—https://sntc.medicine.ufl.edu/rtmccproducts.aspx
Find TB Resources—https://findtbresources.cdc.gov/

National TB Controllers Association—http://www.tbcontrollers.org

Program Collaboration and Service Integration (PCSI) - http://www.cdc.gov/nchhstp/programintegration/Default.htm
TB Education and Training Network—http://www.cdc.gov/tb/education/Tbetn/default.htm

Tuberculosis Epidemiologic Studies Consortium (TBESC) - http://www.cdc.gov/tb/topic/research/TBESC/default.htm

If your organization has any additional links for TB resources that you would like published, please send them to Alysia.Wayne@uthct.edu

Tra n g s

2021 HNTC Training Calendar		
Date(s)	Course	Location
Sept 9	Hot Topics in TB Webcast Series Tuberculosis and Pregnancy	Online
Sept 29—Oct 3	IDWeek 2021 Virtual Conference *conducted by the Infectious Disease Society of America www.idweek.org	Online
Oct 5—7*	TB Nurse Case Management	San Antonio, TX
Oct 8—12	American Academy of Pediatrics National Conference & Exhibition www.aapexperience.org	Philadelphia, PA
Oct 17—20	CHEST 2021 Annual Meeting *conducted by the American College of Chest Physicians www.chestmeeting.chestnet.org	Orlando, FL
Oct 19—22	52nd Union World Conference on Lung Health *conducted by the International Union Against Tuberculosis and Lung Disease www.theunion.org/our-work/conferences	Online
Oct 26—28*	TB Contact Investigation Interviewing Skills Course	San Antonio, TX
Nov 5	Bi-State Infectious Disease Conference	St. Louis, MO
Nov 18	Hot Topics in TB Webcast Series Diabetes and Tuberculosis—The Real Story	Online

^{*}if in-person trainings become allowed

This calendar is not inclusive of all available courses. Please refer to the website for any future trainings and detailed information.

Please visit our website: https://heartlandntbc.org/training.html

Proposed topics are subject to change; check website for the latest updates.

TRAININGS ARE POSTED TO THE WEBSITE AS THEY ARE CONFIRMED



Heartland National TB Center Staff

2303 Southeast Military Drive, San Antonio, Texas 78223

Tel: 800-TEX-LUNG (839-5864); Fax: 210-531-4500

www.heartlandntbc.org

Medical Director

Barbara Seaworth, MD

(210) 531-4541

barbara.seaworth@uthct.edu

barbara.seaworth@dshs.texas.gov

Medical Consultant

Megan Devine, MD

(903) 877-7380

megan.devine@uthct.edu

Director of Education and Training

Delphina Sanchez, MA

(210) 531-4528

delphina.sanchez@uthct.edu

Program Specialist

Alysia Wayne

(210) 531-4540

alysia.wayne@uthct.edu

Assistant Medical Director

Lisa Y. Armitige, MD, PhD

(210) 531-4548

lisa.armitige@uthct.edu

lisa.armitige@dshs.texas.gov

Nurse Consultant/Educator

Marybel Monreal, RN, BSN (210) 531-4539

marybel.monreal@uthct.edu

Training and Education Developer

RoShonda Booker, BS

(210) 531-4543

roshonda.booker@uthct.edu

Executive Director

Halbert 'Hal' Brown, DBA(c), MBA

(210) 531-4542

halbert.brown@uthct.edu

Nurse Consultant/Educator

Catalina Navarro, RN, BSN

(210) 531-4569

catalina.navarro@uthct.edu

Web Site Content Coordinator

Edgar Salinas, BBA

(210) 531-4520

edgar.salinas@uthct.edu

Administrative Assistant

Abe 'Tye' Thomas, II

(210) 531-4568

abe.thomasII@uthct.edu

The MISSION of the Heartland National TB Center is to build capacity with our partners. We will share expertise in the treatment and prevention of tuberculosis by: developing and implementing cutting-edge trainings, delivering expert medical consultation, providing technical assistance, and designing innovative educational and consultative products.

The VISION of Heartland National TB Center is to provide *excellence*, *expertise*, *innovation* in training, medical consultation, and product development to reduce the impact of tuberculosis in our region.