

Fundamentals of Medical & Case Management of Drug-Susceptible TB



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AGENDA

All times are listed in Pacific Standard Time

- | | |
|----------------|---|
| 12:00-12:05 PM | Welcome and Introductions

Presenter: Ann Scarpita, MPH, MSN, BSN, RN, TB Nurse Consultant, Tuberculosis Program, Colorado Department of Public Health and Environment

Moderator: Lisa True, RN, MS, Nurse Consultant, Curry TB Center |
| 12:05-1:35 PM | Medical & Case Management of Drug-Susceptible TB <ul style="list-style-type: none">• Patient Experience Video• Overview Case Management, TB Treatment Regimens, and Duration• Adverse Reactions, Drug Interaction, Treatment Failure and Relapse• Case Management Fundamentals• Baseline Evaluation and Monitoring• DOT |
| 1:35-1:45 PM | Break |
| 1:45-2:20 PM | Case Management Case Study |
| 2:20-2:30 PM | Q&A and Wrap-Up |

LEARNING OBJECTIVES



By the end of this training, participants will be able to:

- describe the key components of TB case management
- identify the recommended regimens and first-line medications for treating drug-susceptible TB disease
- identify the baseline evaluations that should be obtained prior to starting treatment for drug-susceptible TB disease
- describe common side effects and the associated monitoring required for individual first-line anti-TB drugs
- monitor and document clinical findings to evaluate for response to TB treatment
- state several criteria for when treatment for drug-susceptible TB should be extended to at least 9 months

TB NURSE CASE MANAGEMENT CORE COMPETENCIES

This module supports the TB case manager's development of the following core competencies:

DOMAIN 1: Assessment & analytical skills - Essential knowledge & clinical skills:

- Identify recommended/ available TB treatment regimens (for DS-TB)
- Knowledge of treatment regimen recommendations for specific situations/ conditions (ERS, HIV, those at risk for tx failure)
- Assess infectiousness
- Evaluate the patient's medical and social history
- Be familiar with specific monitoring requirements for individual drugs
- Know vision testing, i.e., Snellen and Ishihara
- Recognize medication contraindications and adverse drug reactions
- Identify and report adverse effects
- Identify abnormal lab findings and when to refer patient for further evaluation
- Implement strategies that reduce barriers to treatment adherence
- Provide tx using DOT
- Adjust plan of care for management of treatment interruptions
- Evaluate and document clinical response to treatment
- Adhere to RVCT and HIPAA patient confidentiality requirements and exceptions
- Adhere to nursing documentation standards
- Coordinate clinical care with other providers to ensure safe and holistic care

DOMAIN 3: Education and Communication

- Ensure equitable goal setting
 - Establish equitable goals with the patient and patient's family by identifying and prioritizing treatment and care
 - Develop and communicate a written plan with the patient and the patient's family to achieve anticipated goals within a specified timeframe
 - Engage the patient and patient's family in implementing the plan of care
 - Provide an accurate, consistent, and clear message that is relevant to the intended audience
- Provide patient education
 - Assess patient's readiness to learn, level of health literacy, TB knowledge, attitudes and beliefs
 - Identify knowledge gaps and provide information
 - Tailor information to meet the needs and health literacy of the target audience
 - Develop messages that consider the language proficiency of the target audience
 - Disseminate educational materials in multiple formats
 - Limit the amount of information in each session
 - Provide an overview at the beginning and a summary at the end of each session
 - Encourage questions
 - Incorporate the use of support systems
 - Explain isolation process and limitations on visitors
 - Explain the role, responsibility, and legal authority of the health department

CASE MANAGEMENT CASE STUDY

On March 12, a hospitalist diagnosed Nancy, a 28-year-old Chinese-American female, with pulmonary TB disease. Nancy had the following tests results:

- **IGRA:** Positive
- **Chest X-Ray (CXR):** Showed cavities in the right upper lobe
- **Sputum Samples:** 2 sputum samples were smear positive on AFB smear (4+)
- **NAAT:** Not ordered
- **Cultures:** Awaiting results

On the same day the hospital, assuming Nancy had drug-susceptible TB, started her on the following medications:

- Isoniazid (INH) (Daily)
- Ethambutol (BID)
- Rifampin (BID)

The hospital's Infection Preventionist (IP) contacted your Local Public Health Agency (LPHA) on March 20 providing patient information and noting a discharge home on March 15. You are assigned as the case manager on March 22 and you visit Nancy's home on March 30.

When you make your home visit on March 30, you learn that Nancy works for a garment factory as a seamstress. She reports that she has been feeling much better and plans to return to work the following day, indicating that her family needs money for rent. During your visit you observe that there is very little food in the home and Nancy has a low BMI. Initially, Nancy denies having children, however, you observe that there is a baby sock in the corner and a few scattered toys. After discussion and education, Nancy discloses that she lives with her children (ages 1.5 and 3 years old), as well as her husband, mother, and sister in their 2-bedroom apartment.

You put together the following table to help yourself better understand the timeline and information you have already gathered.

Case Study

Date	Incident	Notes
March 12 th	Nancy was diagnosed with pulmonary TB disease by a hospitalist.	IGRA: Positive Chest X-Ray (CXR): Showed cavities in the right upper lobe Sputum Samples: 2 sputum samples were smear positive on AFB smear (4+) NAAT: Not ordered Cultures: Awaiting results
March 12 th	The hospitalist initiated treatment for drug-susceptible TB disease.	Isoniazid (INH) (Daily) Ethambutol (BID) Rifampin (BID)
March 15 th	Nancy was discharged from the hospital to her home.	
March 20 th	The Hospital IP contacted your LPHA to report TB disease.	
March 22 nd	You are assigned to be Nancy's case manager.	
March 30 th	You visit Nancy in her home.	During this visit you learn: Nancy works for a garment factory as a seamstress. Nancy plans to return to work tomorrow- if she doesn't return to work, Nancy fears they will be evicted from their apartment. Nancy lives with her mother, sister, husband, and children (ages 1.5 and 3) in a 2-bedroom apartment.

Case Study

1. What are the medical issues in the scenario, and follow up questions to ask?
2. What are the case management issues in the scenario, and follow up questions to ask?
3. What comments do you have about the timeline presented in the scenario?
4. What is your plan for follow-up with the hospitalist and IP?
5. How do you address Nancy's plans to return to work?
6. What are the educational needs for Nancy and her family? Explain how you will provide this education.

ASSESSMENT AND MONITORING TOOL FOR DRUG-SUSCEPTIBLE TB DISEASE

KEY	Baseline*	1	2	3	4	5	6	7	8	9	10	11	12	End of Treatment
TREATMENT¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	TBD	TBD	TBD	TBD	TBD	TBD	
Standard Treatment	Phase: INH, Rifampin, PZA, EMB, Vitamin B6			Continuation Phase: INH/Rifampin and Vitamin B6										
PATIENT EDUCATION²	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	TBD	TBD	TBD	TBD	TBD	TBD	<input type="checkbox"/>
LEGAL DOCUMENTS, INCLUDING ISOLATION²	<input type="checkbox"/>	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	
MICROBIOLOGY														
AFB Sputum smears, culture³	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	
Nucleic Acid Amplification Test ⁴	<input type="checkbox"/>													
Dug susceptibility ⁵	<input type="checkbox"/>													
IMAGING														
CXR or other imaging ⁶	<input type="checkbox"/>		TBD				TBD							<input type="checkbox"/>
CLINICAL ASSESSMENT														
Weight and height (BMI)	<input type="checkbox"/>													
Weight (to assess treatment response and adjust medication dose if warranted.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Symptoms ⁷	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Vision assessment (while on EMB) ⁸	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>											
MEDICATION MONITORING														
Direct Observed Therapy (Daily equals M-F OR 5 out of 7 days per week)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LABORATORY TESTING ⁹														
Interferon Gamma Release Assay (IGRA) There are two FDA approved IGRAs used in the U.S.: QuantiFERON (QFT)and T-Spot	<input type="checkbox"/>													
CMP, CBC	<input type="checkbox"/>	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	
HIV	<input type="checkbox"/>													
CD4 lymphocyte count and HIV RNA load if HIV positive.	<input type="checkbox"/>													
Diabetic screen (A1C if risk)	<input type="checkbox"/>				TBD				TBD					
Hepatitis B and C screen NOTE: Patients with hepatitis B and C risk factors (e.g., injection drug use, birth in Asia or Africa, or HIV infection) should have tests for these viruses.	<input type="checkbox"/>													
Uric Acid Level (if hx of gout, on PZA, and gout symptoms present)	TBD													
CONTACT INVESTIGATION														
Interviewing patient¹⁰	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	
Interviewing contacts¹¹														


ASSESSMENT AND MONITORING TOOL FOR DRUG-SUSCEPTIBLE TB DISEASE - KEY

Column1	Column2
Key	
* Baseline	Meeting and work to be performed within 24 hours of initial report of suspected or confirmed TB . Any laboratory or clinical testing that had not been done, should be scheduled within 48 hours of initial meeting with the patient. ANY TB MEDICATIONS should start after the collection of three respiratory specimens, but as soon as possible after determining TB medications are necessary. All medications are required to be given through the LPHA using directly-observed therapy.
1	Standard treatment is Rifampin (R), Isoniazid (I), Ethambutol (E), Pyrazinamide (Z), and Pyridoxine (Vitamin B6 50mg). IRZE is weight based dosing and is daily M-F. Contact TB nurse consultant for dosing recommendations. This regimen is sometimes referred to as RIPE.
2	Patient education and legal documents (treatment agreement, isolation education and agreement, etc.) shall be provided on initial visit with the patient. Education should cover the following topics: Diagnosis, treatment, directly-observed therapy, isolation agreement along with instructions on what isolation means (e.g., no leaving home other than for predetermined and approved doctor appointments or emergency room and no visitors in home, including family members who reside outside of patient's residence). Isolation will depend on several factors. Consult with the Colorado TB Nurse Consultant prior to this meeting to discuss possible timelines. This is also the time to assess the safety of the home, both for the patient and any co-inhabitants. Of Note: Isolation starts with a verbal agreement, which is documented in the patient record. If the patient is not complying to isolation agreement, educate the patient again and assess understanding. If the patient continues to not comply, a public health isolation order would be the next step. It is imperative that the RN case manager updates and consults with the Colorado TB Nurse Consultant whenever the patient is not complying.
3	Collect sputa every other week for AFB smear/culture until there are two consecutive negative cultures. The best specimens are 5mL or more, early-morning (NPO-including no brushing of teeth), and nurse-observed. It is recommended to collect every other Monday morning (after the initial three) to establish a routine. If the patient is relying on three negative smears to be released from isolation, this allows time to collect twice more (Wednesday and Thursday) in that same week with the hopes to release the patient from isolation by the weekend. IMPORTANT: Sputa must be collected M-TR only. Do not send any samples after Thursday morning as the specimen must be at the state lab prior to 9 am on Friday to test before the weekend. They do not accept samples on weekends. OF NOTE: resources, including instructions can be found on the Colorado TB Program website at https://cdphe.colorado.gov/tb-tools-lpha
4	Nucleic Acid Amplification Test (NAAT) should be performed on the two best initial samples; prefer positive smear, but not necessary to perform the NAAT. A geneXpert is one type of NAAT. Other possible rapid molecular testing includes PCR. If the patient is hospitalized, the nurse case manager or designee should contact the Infection Control Manager (ICP) to confirm this testing is ordered. If the patient is not hospitalized, the PHN will order this through the state lab.
5	Drug susceptibility testing can be performed at the state lab or at a reference lab. If the sample is not at the state lab, the nurse case manager or designee should contact the hospital ICP or microbiology lab to ensure that those are ordered and are being performed.
6	Chest Xray (or other imaging) is done initially and then upon request. Please consult with the Colorado TB Nurse Consultant regarding the need for further imaging.
7	Assess adherence and monitor the improvement of tuberculosis symptoms (e.g., cough, fever, fatigue, night sweats) as well as the development of medication side effects or adverse effects (e.g., jaundice, dark urine, nausea, vomiting, abdominal pain, fever, rash, anorexia, malaise, neuropathy, arthralgias). If a non-RN is providing DOT, then the RN must physically see the patient, minimum of monthly to perform full-assessment. This should be more often if warranted (patient change in status, complaints of side effects or adverse reactions, etc.).
8	Vision screening to include a Snellen and Ishihara initially and monthly while on Ethambutol, and more often if symptomatic. If the patient reports any changes in vision, the RN case manager should assist the patient in making an appointment to an optometrist to ensure a timely exam, and hold Ethambutol. Call the Colorado TB Nurse Consultant to provide update as soon as possible.
9	Serial labwork, including CMP or LFTs may be warranted if patient has abnormal baseline testing, lifestyle risk factors, pregnancy, or s/s associated with liver toxicity. Other testing such as A1C may be necessary.
10	The discussion of contacts needs to happen on the first visit to identify any high-risk contacts who may require immediate assessment and testing (e.g., children <5 years old, immune compromised, significant exposures, and those with respiratory symptoms who were exposed to this person). This should be a relatively quick conversation to start identifying those who need follow-up quickly. This is an ongoing conversation with the patient and may expand or change often. Contact the Colorado TB Nurse Consultant to discuss nuances and discuss timelines.
11	Any high-risk contacts should be interviewed and assessed in-person within 72 hours of report.

CASE MANAGEMENT RESPONSIBILITIES



REGIMENS FOR DRUG-SUSCEPTIBLE TB TABLE

Regimen	INTENSIVE PHASE		CONTINUATION PHASE		Range of total doses	Comments ^{3,4}	Regimen effectiveness
	Drugs ¹	Interval and Dose ² (Minimum Duration)	Drugs	Interval and Dose ^{2,3} (Minimum Duration)			
1	INH RIF PZA EMB	7 days/week for 56 doses (8 wks) OR 5 days/week for 40 doses (8 wks)	INH RIF	7 days/week for 126 doses (18 weeks), OR 5 days/week for 90 doses (18 weeks)	182 to 130	This is the preferred regimen for patients with newly diagnosed pulmonary tuberculosis.	<div> <p>Greater</p>  <p>Lesser</p> </div>
2	INH RIF PZA EMB	7 days/week for 56 doses (8 wks) OR 5 days/week for 40 doses (8 wks)	INH RIF	3 times weekly for 54 doses (18 weeks)	110 to 94	Preferred alternative regimen in situations in which more frequent DOT during continuation phase is difficult to achieve.	
3	INH RIF PZA EMB	3 x/week for 24 doses (8 wks)	INH RIF	3 times weekly for 54 doses (18 weeks)	78	Use regimen with caution in patients with HIV and/or cavitory disease. Missed doses can lead to treatment failure, relapse, and acquired drug resistance.	
4	INH RIF PZA EMB	7 days/week for 14 doses THEN 2 x/week for 12 doses ⁵	INH RIF	Twice weekly for 36 doses (18 weeks)	62	Do not use 2x/weekly regimens in HIV-infected patients or patients with smear-positive and/or cavitory disease. If doses are missed, then therapy is equivalent to once weekly, which is inferior.	

MANAGEMENT OF TREATMENT INTERRUPTIONS TABLE

Time Point of Interruption	Details of interruption	Approach
During intensive phase	Lapse is <14 days in duration	Continue treatment to complete planned total number of doses (as long as all doses are completed within 3 months)
	Lapse is ≥ 14 days in duration	Restart treatment from the beginning
During continuation phase	Received $\geq 80\%$ of doses and sputum was acid-fast bacilli (AFB) smear negative on initial testing	Further therapy may not be necessary
	Received $\geq 80\%$ of doses and sputum was AFB smear positive on initial testing	Continue therapy until all doses are completed
	Received <80% of doses and accumulative lapse is <3 months in duration	Continue therapy until all doses are completed (full course), unless consecutive lapse is > 2 months. If treatment cannot be completed within recommended timeframe for regimen, restart therapy from the beginning (i.e., restart intensive phase, to be followed by continuation phase) ^b
	Received <80% of doses and lapse is ≥ 3 months in duration	Restart therapy from the beginning, new intensive and continuation phases (i.e., restart intensive phase, to be followed by continuation phase)
<p>a According to expert opinion, patients who are lost to follow-up (on treatment) and brought back to therapy, with interim treatment interruption, should have sputum resent for AFB smear, culture, and drug susceptibility testing.</p> <p>b The recommended time frame for regimen, in TB control programs in the U.S. and in several European countries, is to administer all of the specified number of doses for the intensive phase within 3 months and those for the 4-month continuation phase within 6 months, so that the 6-month regimen is completed within 9 months.</p>		

RESOURCES ON TUBERCULOSIS

Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination (DTBE)

Guidelines: <https://www.cdc.gov/tb/hcp/clinical-guidance/>

Online Courses:

Self-Study Modules on Tuberculosis:

<https://www.cdc.gov/tb/hcp/education/self-study-modules-on-tuberculosis.html>

Core Curriculum on Tuberculosis: What the Clinician Should Know:

<https://www.cdc.gov/tb/hcp/education/core-curriculum-on-tuberculosis-continuing-education.html>

Curry International Tuberculosis Center (CITC)

Medical Consultation Warmline: <https://www.currytbcenter.ucsf.edu/consultation>

877-390-6682 (toll-free) or **415-502-4700**, leave a voicemail

Warmline inquiries can also be sent to the CITC email address: currytbcenter@ucsf.edu

8:00 AM to 4:30 PM (Pacific Time), Monday through Friday (excluding holidays). Voicemail is available to record incoming messages 24 hours a day, 7 days a week.

Online Products: <https://www.currytbcenter.ucsf.edu/products>

(selected highlights only—check the web page for the full list)

- *Nursing Guide for Managing Side Effects to Drug-resistant TB Treatment:*
<https://www.currytbcenter.ucsf.edu/products/view/nursing-guide-managing-side-effects-drug-resistant-tb-treatment>
- *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians, 3rd edition/2022 Updates:*
<https://www.currytbcenter.ucsf.edu/products/view/drug-resistant-tuberculosis-survival-guide-clinicians-3rd-edition>
- *Tuberculosis Infection Control: A Practical Manual for Preventing TB:*
<https://www.currytbcenter.ucsf.edu/products/view/tuberculosis-infection-control-practical-manual-preventing-tb>

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Online Courses & Presentations

(selected highlights only—check our website for more opportunities)

- *Practical Solutions for TB Infection Control: Infectiousness and Isolation:*
<https://www.currytbcenter.ucsf.edu/products/view/pediatric-tuberculosis-online-presentation>
- *Tuberculosis Radiology Resource Page:* <https://www.currytbcenter.ucsf.edu/trainings/tb-radiology-resource-page>

Archived Webinars: <https://www.currytbcenter.ucsf.edu/trainings/webinar-archive>

Classroom Trainings: <https://www.currytbcenter.ucsf.edu/trainings>

National Tuberculosis Controllers Association (NTCA)

Tuberculosis Nurse Case Management: Core Competencies

<http://www.tbcontrollers.org/resources/core-competencies/tb-nurse-case-manager/>

Interjurisdictional Transfers (Forms and resources):

<http://www.tbcontrollers.org/resources/interjurisdictional-transfers/#.XZUwIOhKhPY>

Interjurisdictional Transfers (Contacts):

<http://www.tbcontrollers.org/community/statecityterritory/#.XZUxHuhKhPZ>

California Tuberculosis Controllers Association (CTCA)

California Department of Public Health/CTCA Joint Guidelines:

<https://ctca.org/guidelines/cdph-ctca-joint-guidelines/>

CTCA Directory: <https://ctca.org/wp-content/uploads/CTCA-Directory.pdf>

Global Tuberculosis Institute

Tuberculosis Case Management: A Guide for Nurses:

<https://globaltb.njms.rutgers.edu/educationalmaterials/productfolder/tbcasenurse.php>

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Heartland National TB Center

Case Studies in Tuberculosis: Training in Nurse Case Management: https://www.heartlandntbc.org/wp-content/uploads/2021/12/case_studies_tb_ncm_training_tools.pdf

Resource

American Journal of Respiratory and Critical Care Medicine, *Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis: An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline, 2024*: <https://www.atsjournals.org/doi/10.1164/rccm.202410-2096ST>