Achieving Treatment Completion for Drug Susceptible TB December 11, 2024



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- State the criteria considered when determining how long a patient should be treated for drug-susceptible TB (DS-TB) disease and when their treatment is considered complete
- Assess for and anticipate potential barriers to successful treatment completion
- Incorporate strategies to address adherence barriers and to minimize interruptions in TB treatment

Treatment Length & Completion

UNDERSTAND THE CRITERIA USED TO DETERMINE THE DURATION OF TREATMENT AND TREATMENT COMPLETION FOR DS-TB DISEASE

Definition: Treatment Duration

How long your patient is expected to be on TB treatment

Typically stated in weeks or months (26 weeks or 6 months of treatment)



Definition: Completion of Therapy

The determination of whether or not treatment has been completed is based on the <u>total number of doses taken</u> – not solely on the duration of therapy.

The total number of doses is then used to calculate *treatment weeks*

ATS/CDC/IDSA Clinical Practice Guidelines for Drug-Susceptible TB page 22

DOT – The Standard of Care

Directly Observed Therapy (DOT): direct visual observation of swallowing medication by a HCW or another trained person

Digital adherence programs (eDOT/VDOT): video enabled electronic devices which confirm ingestion of medication constitutes DOT

Self administered (SA) : No observed doses

Both DOT and SA: Any dose self administered





Criteria Used to Determine Treatment Length



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Criteria	Examples/Additional Info
TB disease site	TB meningitis (12 months), bone/joint may be 9 months
Smear/culture conversion	Culture conversion >60 days with cavitation – 9 months
Drug susceptibilities	PZA resistance (9 months)
PZA for 8 weeks	9 months of treatment if less than 8 weeks PZA
Chest X-ray/CT	Cavitation with delayed culture conversion – 9 months
Treatment interruptions	See details re: treatment extension/restart
Provider choice	Low body weight, diabetes, age, medication interactions





Criteria Used to Determine Treatment Completion

- Consider the prescribed regimen and its expected length
- What treatment documentation exists? Is there a DOT record to calculate doses?
- What about this individual and their treatment course may warrant a treatment extension?
- Measure whether any gaps in treatment warrant an extension*



Why The Focus on Completion?

- Risk of relapse
- Risk of acquired drug resistance
- Risk of transmission to others

Successful treatment of tuberculosis has benefits both for the individual patient and the community in which the patient resides.



Drug Regimens for Drug-Susceptible TB Disease

	INTENSIVE PHASE		CONTINUATION PHASE		Range		Regimen	
Regimen	Drugs ¹	Interval and Dose ² (Minimum Duration)	Drug	Interval and Dose ^{2,3} (Minimum Duration)	of total doses	Comments ^{3, 4}	effectiveness	
1	INH RIF PZA EMB	7 days/week for 56 doses (8 weeks) OR 5 days/week for 40 doses (8 weeks)	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.	Greater	
2	INH RIF PZA EMB	7 days/week for 56 doses (8 weeks) OR 5 days/week for 40 doses (8 weeks)	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.	Τ	
3	INH RIF PZA EMB	3 x/week for 24 doses (8 weeks)	INH RIF	3 times weekly for 54 doses (18 weeks)	78	Use regimen with caution in patients with HIV and/or cavitary 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 doses⁵	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 cavitary disease. If doses are missed, then therapy is equivalent to once weekly, which is inferior.	Lesser	

Source: Adapted from 2016 ATS/CDC/IDSA Clinical Practice Guidelines: Treatment of Drug-susceptible Tuberculosis, Table 2 Washington State Department of Health | 10

Treatment Frequency

Treatment weeks ≠ calendar weeks. Calculate treatment weeks using a simple formula

<u>Total doses taken (10)</u> = Total treatment weeks (2) Frequency of administration (5)

Daily DOT can mean 7 days/week or 5 days/week (Mon-Fri) - OR BOTH!!

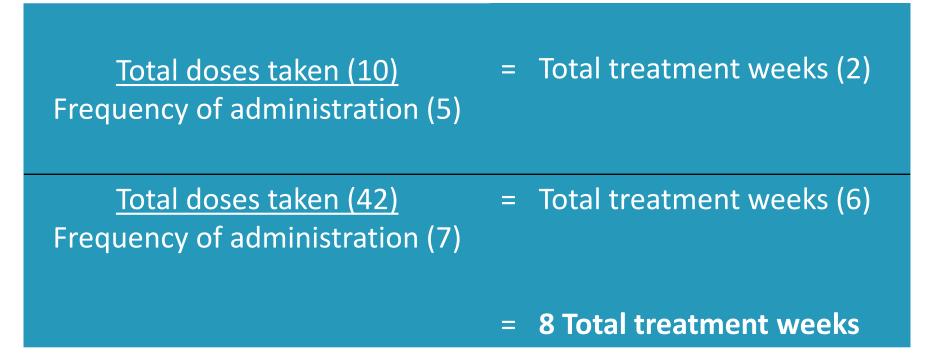
• When DOT is used, drugs may be given 5 days per week and the necessary number of doses adjusted accordingly. Although there are no studies that compare 5 with 7 daily doses, extensive experience indicates this would be an effective practice. DOT should be used when drugs are administered < 7 days per week.

ATS/CDC/IDSA Clinical Practice Guidelines for Drug-Susceptible TB pages 4-6

Treatment Frequency

Frequency changes during therapy

Remember - daily DOT can mean 7 days/week or 5 days/week (Mon-Fri) - OR BOTH!!



Treatment Frequency

What happens when things get complicated?

Your patient has had frequent side effects from their medication and has had to pause their meds for a couple of days two different times. The patient wants to know when they can stop taking so many pills and go down to just the two because it's been 8 weeks.

> Total doses taken (36) = Total treatment weeks (7.2) Frequency of administration (5)

Length of Treatment

How many weeks in a year? 52!

How many weeks in 9 months? 39!

How many weeks in 6 months? 26!

People often think of a month as 4 weeks, but this is usually not the case.

Formula

52 x 0.5 (half the year) = 26 weeks for 6 months tx 52 x 0.75 (three quarters of the year) = 39 weeks for 9 months tx 52 x 1.0 (whole year) = 52 weeks for 12 months tx

54 y/o male with culture positive TB has cavitary disease and RIPE was started April 1. The first 8 weeks were five days weekly, he completed 40 DOT doses and moved to a five times weekly continuation phase of INH and RIF.

Over the next 11 weeks he received meds five times weekly and completed 50 doses of this regimen.

The patient is asking if he is on track to complete treatment in 26 weeks. Choose the best answer to his question.

- 1. Yes, he has received all doses to date and is on track to complete in 26 calendar weeks
- 2. No, he missed 5 doses and needs an additional week of five times weekly treatment
- 3. Yes, his cough has improved & he's feeling better
- 4. No, he has only taken 40 doses of PZA and he needs 56

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Extending Treatment Length

Known risk for relapse:

Positive culture *after* 2 months of therapy (end of intensive phase)

AND

Cavitation on CXR at beginning of treatment

Extend continuation phase with INH and RIF for a continuation phase of 7 months *for a total of 9 months of therapy*

Treatment may also be extended to 9 months for

- Discontinuation of PZA before 8 weeks of treatment
- being >10% below ideal body weight;
- being an active smoker;
- having diabetes, HIV infection, or any other immunosuppressing condition;
- having extensive disease on chest radiograph

ATS/CDC/IDSA Clinical Practice Guidelines for Drug-Susceptible TB page 7

Management of Treatment Interruptions

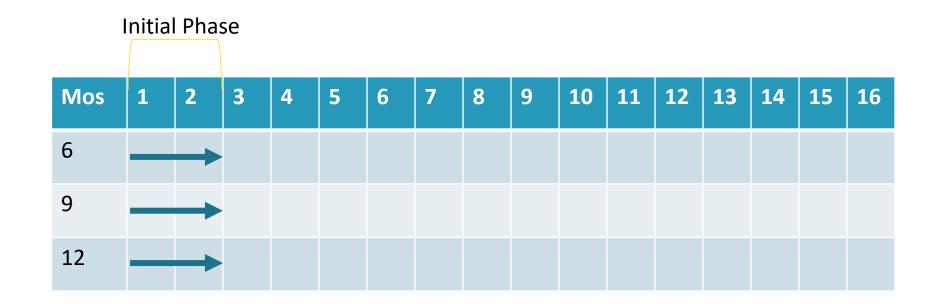
When Interruption Occurs	Situation	Guidelines	
During initial phase	Lapse is <14 days in duration	Continue treatment to complete planned total number of doses (as long as all doses are completed within 3 months)	
	Lapse is ≥14 days in duration	Restart treatment from the beginning	
During continuation phase	Received ≥80% of doses and sputum was AFB smear negative on initial testing	Further therapy may not be necessary	
	Received ≥80% of doses and sputum was AFB smear positive on initial testing	Continue therapy until all doses are completed	
	Received <80% of doses and lapse is <3 months in duration	Continue therapy until all doses are completed (full course)	
		If treatment cannot be completed within recommended timeframe for regimen, restart therapy from the beginning	
	Received <80% of doses and lapse is ≥3 months in duration	Restart therapy from the beginning, new initial and continuation phase	

Core Curriculum on Tuberculosis: What the Clinician Should Know. 6th Ed, 2013 Pg 161

Regimen Interruptions

All regimens for drug susceptible TB disease

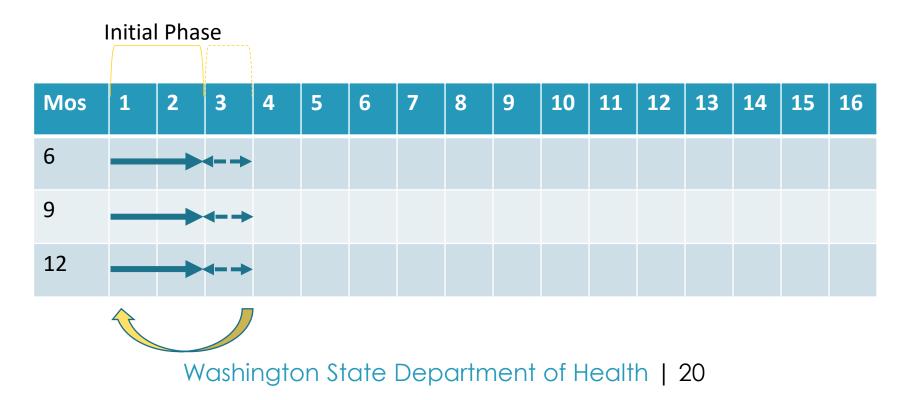
Initial 2-month phase must be completed in 3 months.



Regimen Interruptions

All regimens for drug susceptible TB disease

- Initial 2-month phase must be completed in 3 months. If not restart the entire treatment course. If \geq 14-day interruption (not cumulative) restart treatment
- If 8 weeks of treatment with PZA is not completed extend to 9 months



The greatest risk for non-adherence occurs at what point in treatment?

- 1. Before you start treatment
- 2. At the very start of treatment
- 3. 2 4 weeks after starting treatment
- 4. 8 10 weeks into treatment
- 5. 16 20 weeks into treatment
- 6. The last few weeks of treatment

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Hitting the Wall Behavior

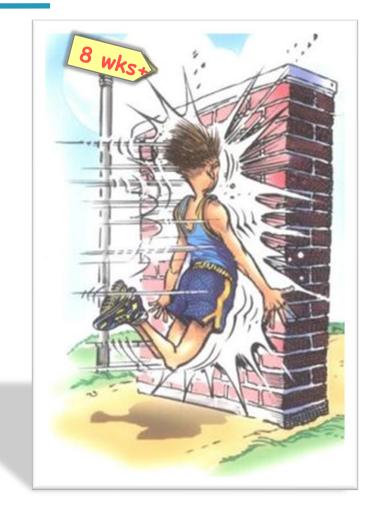
Feeling better

Alleviated feelings of fear

Return to normal

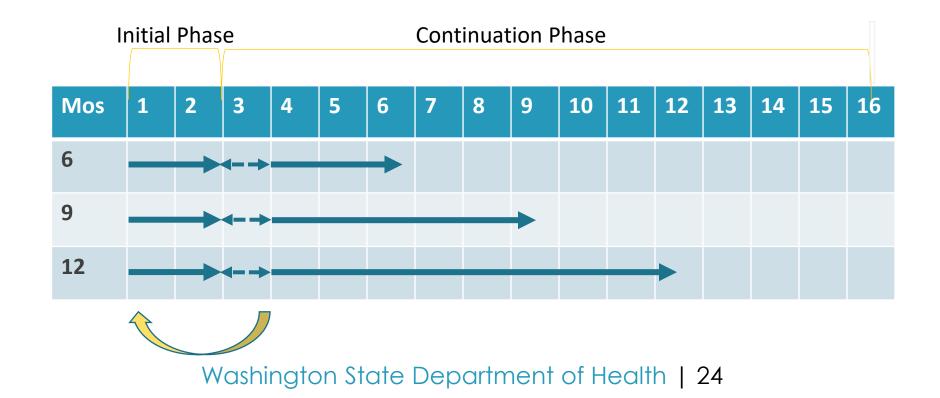
Stigma of health department visits Resume alcohol or drug behaviors

How much longer?



Regimen Interruptions

Management of interruptions in the continuation phase is dependent upon initial sputum smear results, duration of interruption and whether 80% of treatment has been completed



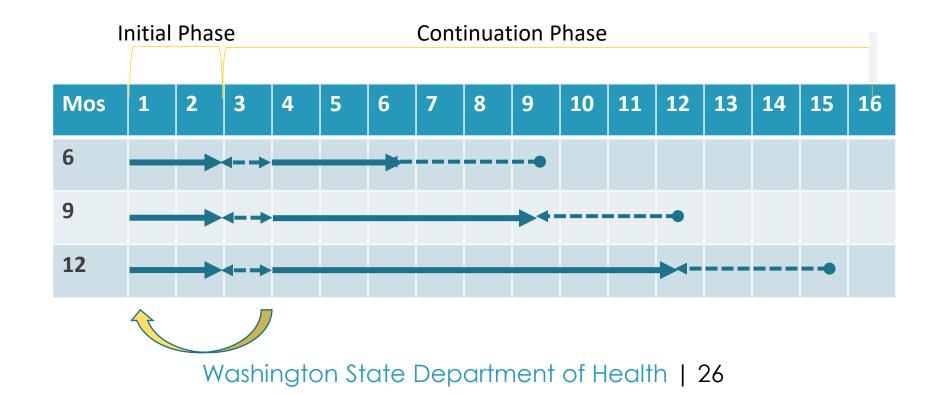
Continuation Phase Interruptions

Interruption of doses taken	Approach
> 80% taken, initially smear neg	Further therapy may not be necessary
> 80% taken, initially smear pos	Continue therapy until completed
< 80% taken, cumulative lapse of 3 months	Continue therapy until completed, unless continuous gap is >2 months
	Restart entire regimen if therapy can not be completed within the recommended timeframe
< 80% taken, lapse is >3 months	Restart entire regimen

Adapted from Table 6, IDSA Treatment of Drug Susceptible TB Guidelines

Regimen Interruptions

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When deciding if TB treatment is completed you must: (select all that apply)

- 1. Confirm which doses were given
- 2. If cavitary, be certain that treatment was 12 months
- 3. Calculate treatment weeks by counting weeks on a calendar
- 4. Ensure treatment was completed in the required length of time
- 5. Calculate treatment weeks by dividing the doses taken by the frequency of administration

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Your client has their treatment extended to 9 months. What could have occurred to require extending treatment from 6 to 9mos. Choose any that apply.

- 1. Bilateral cavitary disease
- 2. Sputum culture conversion to negative the 67th day after treatment began and the chest x-ray had a cavitary lesion in the RUL
- 3. Susceptibilities were not available until 15 weeks after treatment began
- 4. Required doses of PZA were completed in 11 weeks
- 5. TB disease was found in both the lungs and the spine

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Reporting Treatment Completion

	Case Outcome
* Sputum culture conversion documented	✓
* Did patient move during therapy?	~
* Reason therapy stopped or never started 🖬	Completed treatment
	Lost
	Patient choice (uncooperative or refused)
	Adverse treatment event
	Not TB
	Died Died
	Dying (treatment stopped due to imminent death, regardless of cause of death)
	Other
	Unknown
Reason TB disease therapy extended >12 months (select all that apply)	✓
Treatment administration (select all that apply)	DOT (Directly Observed Therapy, in person)
	EDOT (Electronic DOT, via video call or other electronic method)
	Self-administered
Type of outpatient health care provider	✓
* Did the patient die (either before diagnosis or at any time while being followed by TB program)?	✓
* LHJ close case 🗸	
Comments	

Health Equity and Stigma

IDENTIFY THE IMPACT OF HEALTH INEQUITIES ON TB CARE

Credit to Omid Bagheri Garakani, Seattle Tuberculosis Nursing Workshop: Health Equity and Social Justice, July 2023

What is Health Equity?



Health equity is the state in which everyone has a fair and just opportunity to attain their highest level of health.

Health inequities are preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been disadvantaged by their social or economic status, geographic location, and environment.

Achieving health equity requires ongoing societal efforts to:

- Address historical and contemporary injustices;
- Overcome economic, social, and other obstacles to health and health care; and
- Eliminate preventable health disparities.
- Change the systems and policies that have resulted in the generational injustices that give rise to health inequities

Credit to Omid Bagheri Garakani, Seattle Tuberculosis Nursing Workshop: Health Equity and Social Justice, July 2023

Overview - TB and Health Equity

Populations experiencing health inequities and TB:

- People with low-income living in rural and urban environments
- Immigrants, particularly those who recently immigrated
- Black, Indigenous, and communities of color, particularly those experiencing economic marginalization
- People incarcerated, and people unhoused
- Others?

From CDC:

- In <u>2023</u>, **90.1% of the TB cases** reported in the United States occurred among persons who identified as racial and ethnic minorities..
- The percentage of TB cases occurring in non-U.S.—born persons was 75.8% of the national case total in 2023.

Credit to Omid Bagheri Garakani, Seattle Tuberculosis Nursing Workshop: Health Equity and Social Justice, July 2023 Washington State Department of Health | 34 Every patient has a relationship to the social determinants of health and **cannot be separated** from their environment

Every social determinant of health is **created by** unfair and unjust systems based on race, gender, ability, class, nationality, sexual orientation, religion, and indigenous heritage.

Healthy People 2030 Social Determinants of Health



PRACTICAL TIP: Because of the inequities within the healthcare system, be curious to know their entire social and environmental context to better understand the limitations they have and identify opportunities for support. Ask about what challenges they face in making appointments, completing treatment, taking medications, etc.

> Credit to Omid Bagheri Garakani, Seattle Tuberculosis Nursing Workshop: Health Equity and Social Justice, July 2023 Washington State Department of Health | 35

TB Stigma & Other Challenges

TB diagnosis is scary: misunderstood disease course, fear of social isolation

• Although not new to the world, Tuberculosis remains the world's deadliest infectious disease. It is also curable and preventable.

Latent TB infection: If there are no symptoms, then what are you treating?

• Global treatment differences: Some countries only track and treat active infections; explain the different TB approaches instead of allowing them to fill in the blanks (e.g. their ethnicity/nationality)

Side effects of treatment: I feel fine, why take meds that will make me feel unwell?

• Side effects even mild, must not be minimized. Explain treating it now can prevent TB disease later

Tuberculosis Series: Approach to Patients - EthnoMed

PRACTICAL TIPs:

- Treat the diagnosis of tuberculosis with the same sensitivity and confidentiality you would reserve for sexually transmitted diseases and HIV.
- Educate your patient about the curable nature of tuberculosis and emphasize the good health that will result from treating the disease.
- Take time to discuss the social ramifications of the disease. If the patient is not infectious, reassure [them] that full social participation should continue
- Use anti-stigma language, such as the "<u>Stop the Stigma: Eliminating Stigmatizing Language</u>" Guide from Heartland National TB Center
 Credit to Omid Bagheri Garakani, Seattle Tuberculosis Nursing Workshop: Health Equity and Social Justice, July 2023

Stop the Stigma: Eliminating Stigmatizing Language

HNTC Survey Results

Not that.....

Language suggested by participants

Use this.....

Non-hurtful Replacement Language

Key Terms suggested by the Stop TB Partnership

Use this	Not that
Adherence / Non-adherence	Compliance / Non-compliance
Person lost to follow up	Defaulter
TB Prevention and Care	TB Control
Person to be evaluated for TB	TB Suspect
HIV-Positive	HIV-infected

TB Infection	Latent TB	Person la
Lack of housing; Under-housed;	Homeless/Homelessness	TB Preve
People experiencing homelessness		Person t
Immigrant	Alien	HIV-Posi
Undocumented	Illegal; Illegal alien	
Person with TB disease	TB case	
Treatment failed	Treatment failure	
Missed doses/Non-adherent	Delinquent	
Contact Analysis; Contact Elicitation;	Investigation; Investigate	
Contact Identification		
Exposed to TB	TB contact	
Tuberculosis	Consumption; White Plague	

Assess Resources/ Adherence Checklist

Name		
Phone		
Signifi	cant:	
1.	Are you worried about your appointment today?	Yes No
2.	How do you feel that you have been treated today in the health un	iit?
2	Great Don't Know Poor	
3.	How are you feeling about your recent diagnosis of tuberculosis?	
	😀 🙂 😐 😫	
	Great Don't Know Poor	
4.	Has tuberculosis disease been explained to you?	Yes No
Barrie	rs:	
5.	Do you have reliable transportation?	Yes No
6.	Do you know someone that can help you with transportation?	Yes No
7.	Are you worried about gas costs when attending appointments?	Yes No
8.	Do you have somewhere reliable and safe to stay each night?	Yes No
9.	Do you have enough food to eat each day?	Yes No
10.	Do you have family/friends to talk to when you have problems?	Yes No
11.	Are you from this area?	Yes No
12	Do you have a lot of stress in your life right now?	Yes No

Case Study & Discussion

Case Study:

A person born in a TB endemic country is missing follow up medical appointments after being released from the hospital with a diagnosis of pulmonary TB and started on treatment.

A co-worker shares- "This family and other families in that apartment complex don't keep morning appointments because they sleep until 2pm".

Questions:

- 1. What are barriers to attending medical appointments that this person could be experiencing?
- 2. What are questions you could ask to sort it out the issue?
- 3. What support and ideas could you offer?

Case Study & Discussion

Case Study:

Your patient is US-born person who is experiencing housing instability, with a history of incarceration and past military service. The client is an elder and is resistant to taking medication directly observed. They are also reluctant to tell you where they sleep at night (i.e. possible couch surfing). The client has been missing doses of their TB treatment and not taking medication for diabetes but goes to all their primary care appointments.

Questions:

- 1. What are possible barriers this person could be experiencing in missing doses and taking medication?
- 2. What are ways you could ask to sort it out?
- 3. What support and ideas could you offer?

Promoting Adherence & Preventing Treatment Failure

UTILIZE TOOLS TO ASSESS AND INCORPORATE STRATEGIES TO ADDRESS NON-ADHERENCE TO IMPROVE PATIENT OUTCOMES

Remember

The responsibility of treatment success is assigned to the healthcare professional not the patient

Assessing for Adherence

Is the client keeping appointments?

Is the client communicating with you and/or others on the care team?

How is their relationship with friends/family?

Any major life changes for the patient recently?

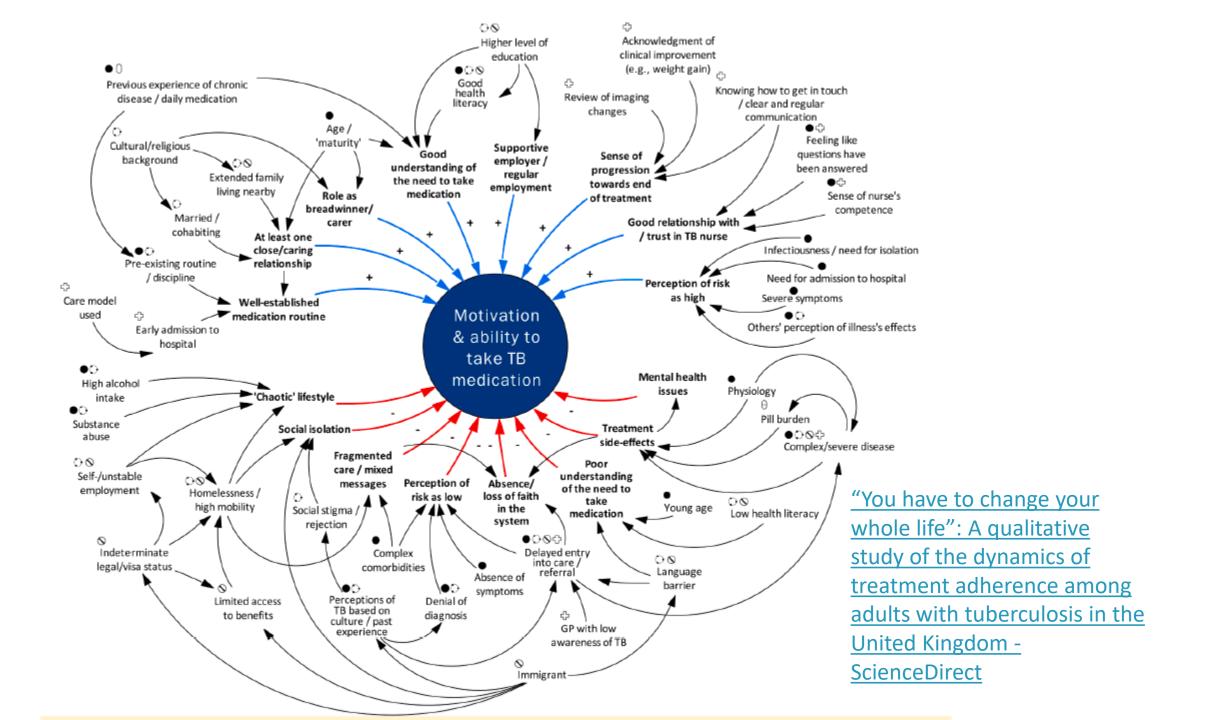
Is the client swallowing the meds?

Is there clinical improvement?

Are sputum results improving?

Achieving culture conversion?





Predicting Adherence: Examining Implicit Bias

Gender

Race

Nationality

Ethnicity

Sexual Orientation

Religion

Level of education

Ability

Housing status

Age

There is no way to predict adherence based on these characteristics and there are no patient characteristics that will guarantee adherence to treatment

Risk factors for non-adherence

Re-activation, re-treatment, past treatment failure Previous non-adherence to TB or LTBI treatment Drug resistance or medication intolerance Behavioral health including drug use Health beliefs Level of treatment literacy Citizenship status Mental health, memory loss, developmental disability

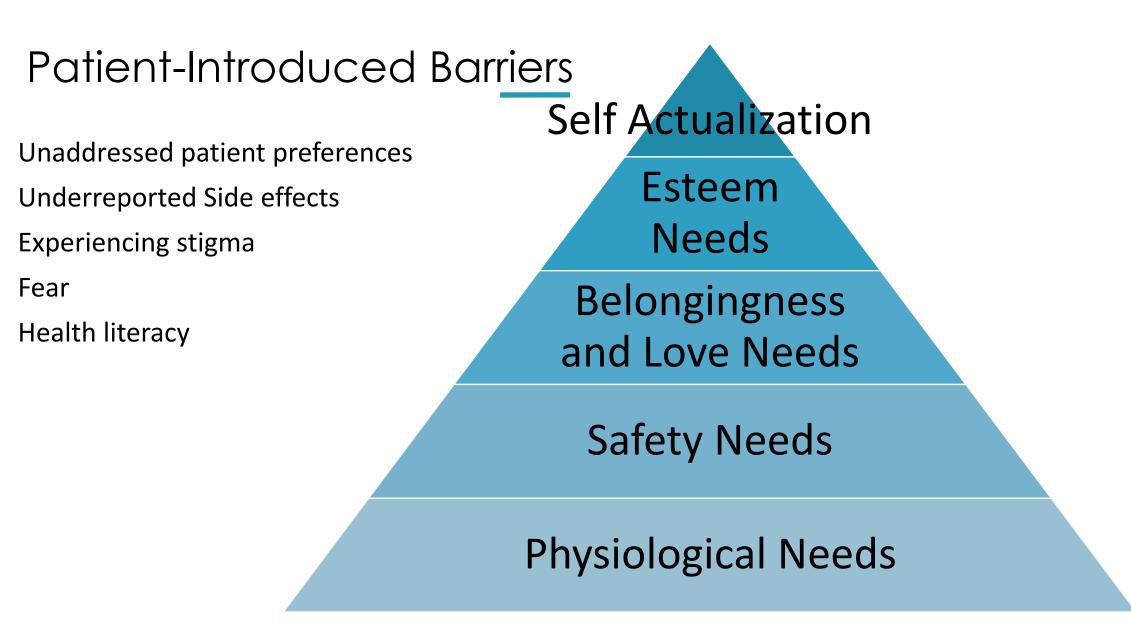


Barriers to Successful Treatment Completion

• Barriers may come from

- The patient
- The care team
- The treating and/or managing organization
- The healthcare system in general





Clinician-Introduced Barriers

Lack of knowledge or bias toward patient preferences Health education delivery

Lack of culturally or linguistically appropriate care

Inappropriate treatment length

Incorrect dosages of medications

Less than 8 weeks of PZA



Assuring susceptibility results are obtained and shared

Discontinuing first line drugs if there are side effects without a re-challenge

Organizational-Introduced Barriers

Lack of protocol for when to begin VDOT vs. in-person DOT and when to remove VDOT

Multiple programs, multiple responsibilities

Time constraints

Resource constraints- no incentives or enablers

Misunderstanding of TB nurse case management role

Missed communication opportunities- policies and procedures

Calm after the storm

Perceived low priority

Others?

System-Introduced Barriers

- Lack of flexibility with scheduling options
- Under or uninsurance impacting ability to access services
- Lack of culturally or linguistically appropriate care
- Delays in medication access due to cost
- Lack of transportation options to get to appointments
- Lack of childcare options



Polling Question 5

Select which strategy most positively impacts completion of treatment?

- 1. Experienced public health staff
- 2. DOT
- 3. Incentives and enablers
- 4. Monitoring of side effects
- 5. TB nurse case management
- 6. Appropriate TB regimen
- 7. Clear policies and procedures

Polling Question 5

Select which strategy most positively impacts completion of treatment?

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Lost to Follow-up

Have a protocol with stepped approach including letters and home visits

- Patient look up tools
- Inmate look up
- Internet sleuthing
- Neighbors, co-workers, friends

- Syndromic data
- Social research and photos on social media
- Shelters, jails, hospitals
- Postal Service: CFR 265.6(d)(5)(i) – Disclosure of names & addresses

Incentives and Enablers

Examples of incentives (O) and enablers (O)



Oregon Health Authority resource on Incentives and Enablers



Source: Adapted from CDC Self Study Training Module 6 Managing Tuberculosis Patients and Improving Adherence, Tuberculosis (TB) [Internet]. Centers for Disease Control and Prevention; 2017 [cited 20170ct25]. Available from: <u>https://www.cdc.gov/tb/education/ssmodules/default.htm</u>

Legal Interventions

Escalating and increasing severity

- Signed agreements (least restrictive)
- Health Officer Order
- Emergency detention
- Formal involuntary isolation order

Documentation is vitally important to success

- Build from the beginning
- Must show that the Health
 Department has made every effort
- Document all attempts

Considerations

- Individual liberty vs protecting public health – Must look for "least restrictive means"
- Cannot *force* clients to take medicines
- Very costly: attorney fees, court hearing
- Deemed non-infectious
- Other ways to apply supportive measures

A case study

Group Exercise

When you are in your virtual breakout room...



Turn on your camera during small groups



If you need help: Come back to the main room – hover over the bottom right corner to see a "Leave Breakout Room" button



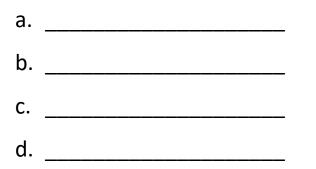
If you do not have a microphone, switch to phone audio or use the Chat to ask questions and contribute

Instructions

- Break into assigned groups with facilitators
- 35 minutes
 - 5 minutes: round the room introductions
 - 25 minutes: group case discussion
 - 5 minutes: summary and wrap-up
- Select one person as a spokesperson, another as a scribe
- Read case details
- Activity debrief and discussion will follow back in the main room

Case Discussion

- 1. Start big picture- Identify 3 social and environmental areas of this person's situation that you anticipate engaging in during treatment of TB.
- 2. With these 3 social and environmental areas, use the two tools provided (Assess Resources & Adherence checklist), to identify questions that you would use to increase your understanding of this patient's experience.
- 3. List 4 areas of concern for adherence to treatment



 For each concern describe 2 potential interventions to improve adherence. Each person in the group should provide an answer that is realistic in their state/region.

Thank you!

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