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# Achieving Treatment Completion for Drug Susceptible TB

Lisa Ferguson, RN, BSN, MSc

Wednesday, September 27<sup>th</sup>

# Learning Objectives

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- state the criteria used to determine the duration of treatment for drug-susceptible TB (DS-TB) disease
- assess for and anticipate potential barriers to treatment
- be able to identify factors to consider towards determining 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: Completion of therapy

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Treatment for a defined duration without accounting for the number of doses taken can result in under-treatment.

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

**Then, calculating the total number of doses in  
TREATMENT WEEKS**

# DOT – The Standard of Care

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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



# Confirming Completion of Treatment

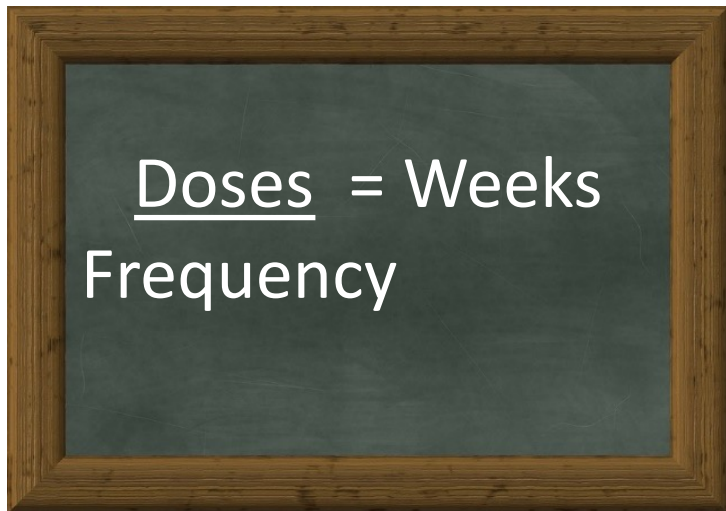
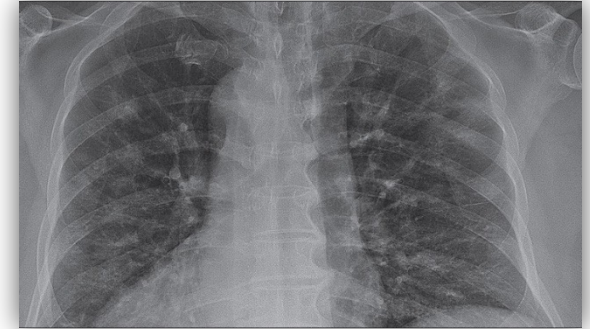
Consider the prescribed treatment regimen

Review DOT/treatment documentation

Calculate treatment weeks (not simply counting calendar weeks)

Recognize gaps in treatment to identifying the length of time it took to complete that regimen

Identify specific case characteristics



# Treatment Frequency

*Daily* DOT does not only mean 7 days/week. It often means 5 days/week (Rates of successful therapy are equivalent. pg 8)

Treatment weeks  $\neq$  calendar weeks. Calculate treatment weeks using a simple formula

$$\frac{\text{Total doses taken (10)}}{\text{Frequency of administration (5)}} = \text{Total treatment weeks (2)}$$

[ATS/CDC/IDSA Clinical Practice Guidelines for Drug-Susceptible TB](#) pages 4-6

# Length of Treatment

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6 months of treatment  $\neq$  24 weeks, it equals 26 weeks *because*

$$\frac{52 \text{ weeks}}{2} = 26 \text{ weeks}$$

Patient disease characteristics can alter the original ordered treatment length

- CNS involvement, treatment interruptions, drug resistance increases the length

Providers may choose a longer treatment length (sometimes shorter)

The number of doses of PZA must be  $\geq$  to 8 weeks

Treatment Interruptions: Many do not complete treatment by guidelines

- Initial phase  $\geq$ 14 days treatment interruption = start over
- Continuation phase  $\geq$ 2 consecutive months = extend?



# Polling Question 1

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 thrice weekly continuation phase of INH and RIF.

Over the next 11 weeks he received meds thrice weekly and completed 30 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 3 doses and needs an additional week of thrice 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

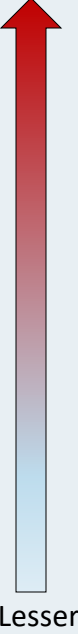
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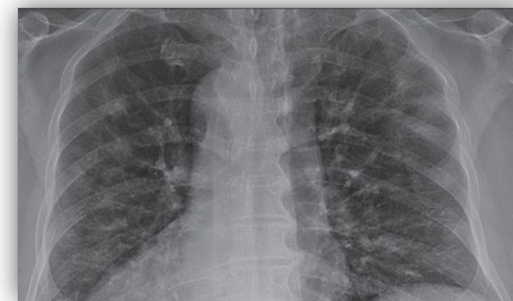
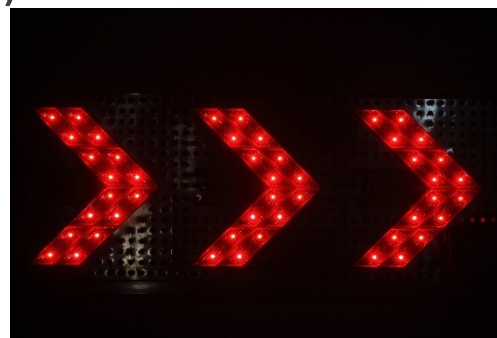
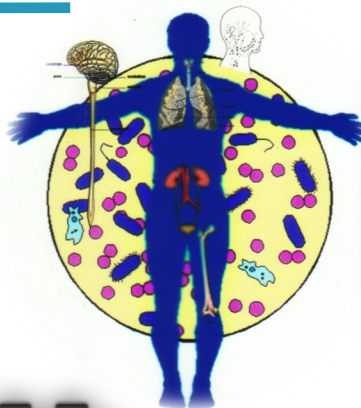
# Drug Regimens for Drug-Susceptible TB Disease

Regimen	INTENSIVE PHASE		CONTINUATION PHASE		Range of total doses	Comments <sup>3, 4</sup>	Regimen effectiveness
	Drugs <sup>1</sup>	Interval and Dose <sup>2</sup> (Minimum Duration)	Drug	Interval and Dose <sup>2,3</sup> (Minimum Duration)			
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.	 <p>Greater</p> <p>Lesser</p>
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.	
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 doses <sup>5</sup>	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.	

Source: Adapted from 2016 ATS/CDC/IDSA Clinical Practice Guidelines: Treatment of Drug-susceptible Tuberculosis, Table 2

# Case criteria used to determine treatment length

- ▶ TB site of disease (for example CNS TB)
- ▶ Sputa smear, culture/conversion status
- ▶ Drug Susceptible or Resistant
- ▶ PZA for 8 weeks (40/56 doses)
- ▶ Chest X-ray, CT
- ▶ Treatment interruptions



# Duration of Continuation Phase

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Risks for relapse:

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

**AND**

Cavitation on CXR

Extend continuation phase with INH and RIF for an additional 3 months (continuation phase of 7 months for a total of 9 months of therapy)

Treatment may also be extended to 9 months for

- Not taking PZA
- 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 <b>negative</b> on initial testing	Further therapy may <b>not</b> be necessary
	Received ≥80% of doses and sputum was AFB smear <b>positive</b> 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. 6<sup>th</sup> Ed, 2013 Pg 161

# Regimen Interruptions

All regimens for drug susceptible TB disease

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

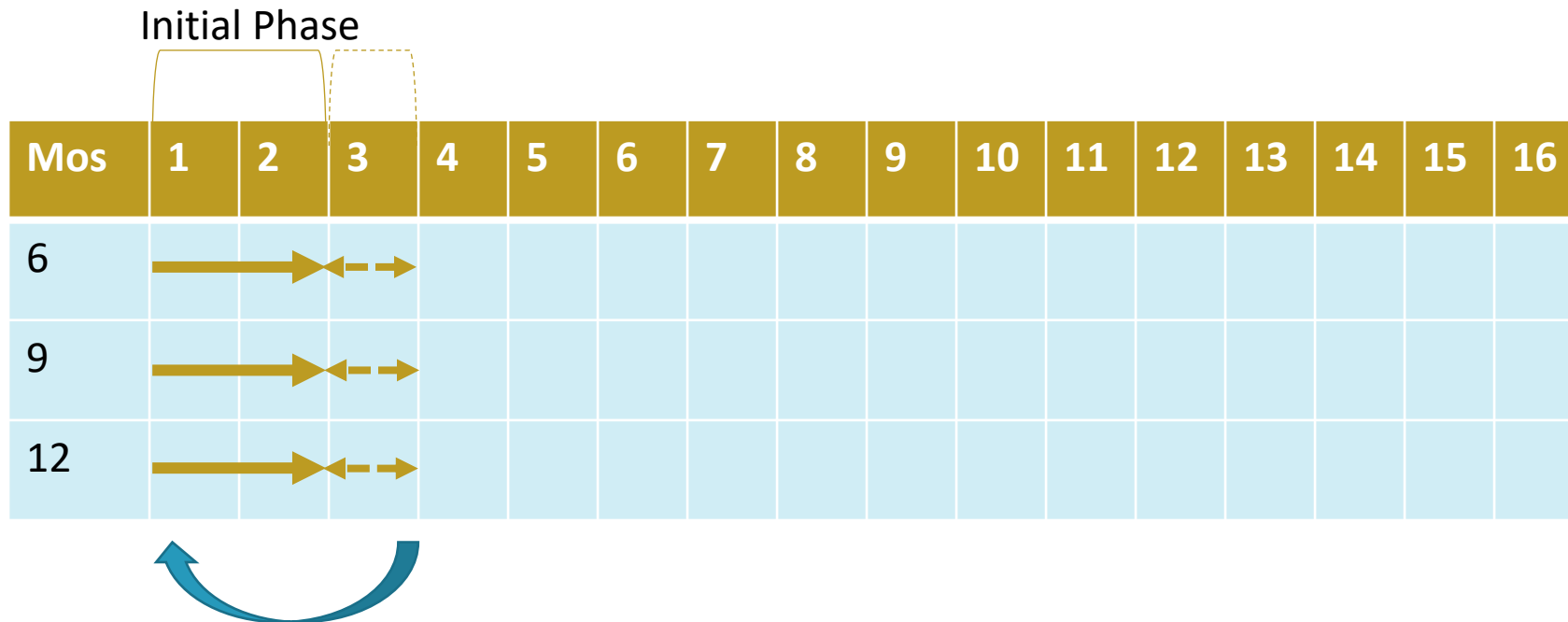
Initial Phase

Mos	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
6	→															
9	→															
12	→															

# 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





## Polling Question 2

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

## Polling Question 2

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

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5. **16 – 20 weeks into treatment**
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# Hitting the Wall Behavior

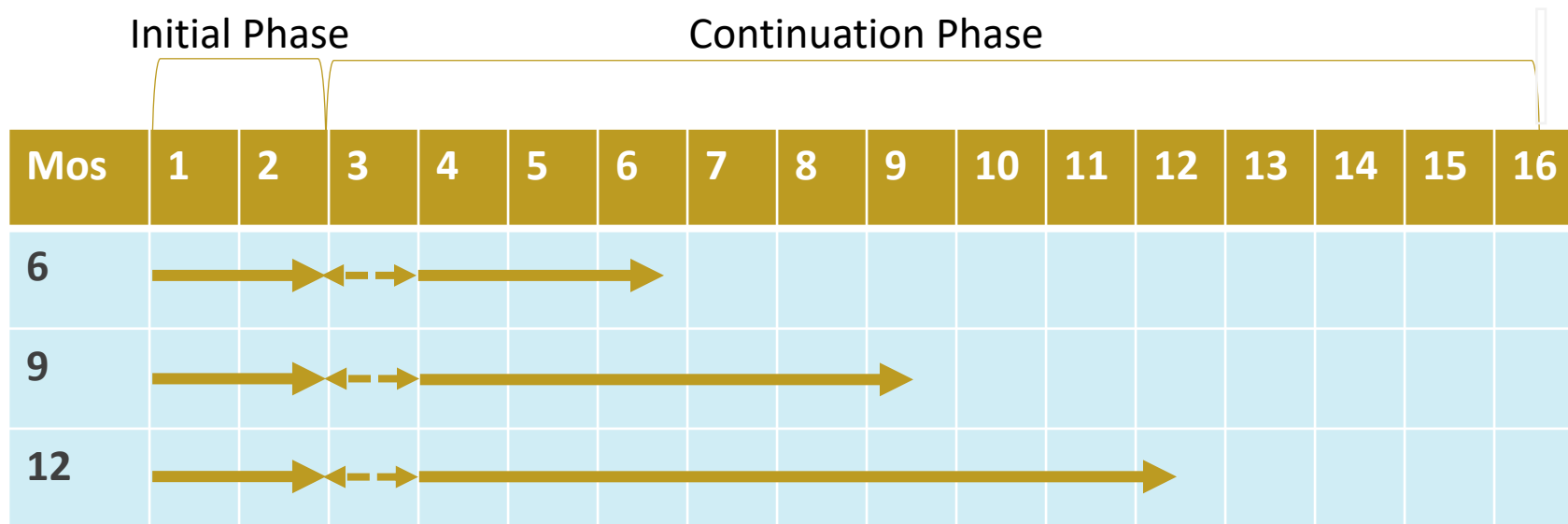
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- Feeling better
- Alleviated feelings of fear
- Return to normal
- Stigma of health department visits
- Resume alcohol or drug behaviors
- How much longer?



# 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

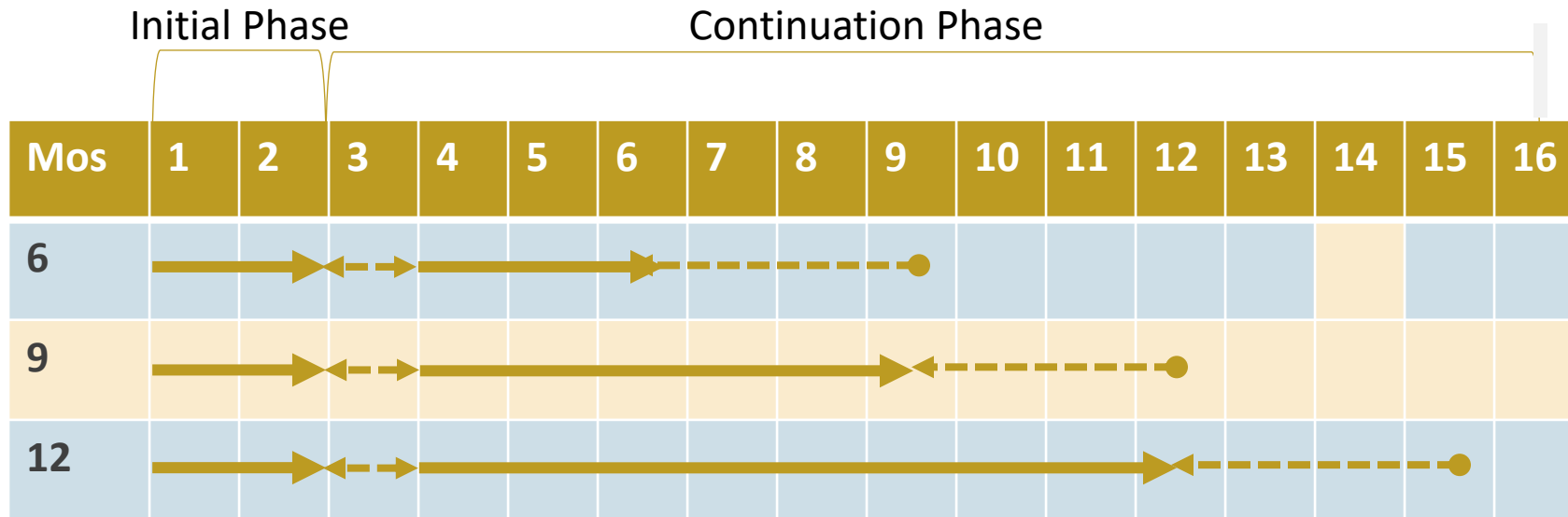
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Interruption of doses taken	Approach
≥ 80% taken, initially smear neg	Further therapy may not be necessary
≥ 80% taken, initially smear pos	Continue therapy until completed
< 80% taken, cumulative lapse of 3 months	Continue therapy until completed, 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

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.



# Polling Question 3

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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

# Polling Question 3

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## Polling Question 4

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 cavitory disease
2. Sputum culture conversion to negative the 67<sup>th</sup> day after treatment began and the chest x-ray had a cavitory 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

## Polling Question 4

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.

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# REPORTING COMPLETION OF TREATMENT

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

# Health Equity and Stigma

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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?

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**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 2022:**

- About 90% of the TB cases reported in the United States occurred among racial and ethnic minority groups.
- The percentage of TB cases occurring in non-U.S.-born persons was 73% of the national case total in 2022.

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

## Healthy People 2030 Social Determinants of Health

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.



**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

# TB Stigma & Other Challenges

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

- Although not new to the world, Tuberculosis remains one of the world's deadliest infectious diseases, second only to COVID-19. 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 "[Stop the Stigma: Eliminating Stigmatizing Language](#)" 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

### Language suggested by participants

Use this.....	Not that.....
TB Infection	Latent TB
Lack of housing; Under-housed; People experiencing homelessness	Homeless/Homelessness
Immigrant	Alien
Undocumented	Illegal; Illegal alien
Person with TB disease	TB case
Treatment failed	Treatment failure
Missed doses/Non-adherent	Delinquent
Contact Analysis; Contact Elicitation; Contact Identification	Investigation; Investigate
Exposed to TB	TB contact
Tuberculosis	Consumption; White Plague

## 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

# Assess Resources/ Adherence Checklist

## Patient Questionnaire To Assess Resources

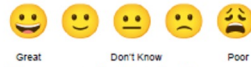
Name \_\_\_\_\_

Phone \_\_\_\_\_

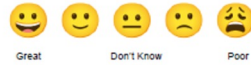
### Significant:

1. Are you worried about your appointment today? Yes \_\_\_ No \_\_\_

2. How do you feel that you have been treated today in the health unit?



3. How are you feeling about your recent diagnosis of tuberculosis?



4. Has tuberculosis disease been explained to you? Yes \_\_\_ No \_\_\_

### Barriers:

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 \_\_\_

13. If you are having trouble coping, feel sad or angry most of the time, or have any other issues that you feel you need help with then please let us know. We have Community Health Workers just waiting for your call so they can help you. 😊

# Case Study & Discussion

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## **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

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## **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

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

# Assessing for Adherence

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Is the client keeping appointments?

How is their relationship with friends/family?

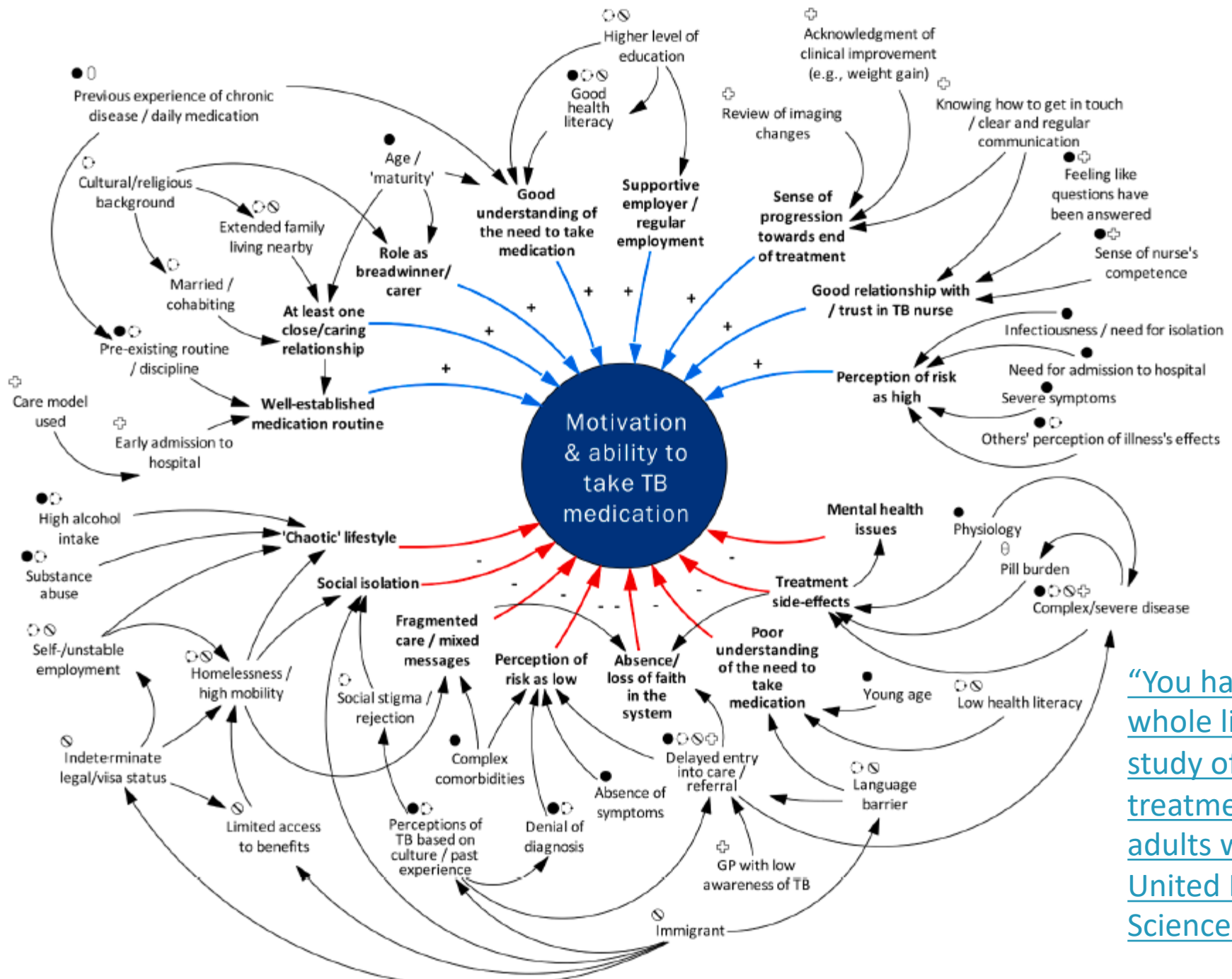
Any major life changes for the patient recently?

Is the client swallowing the meds?

Is there clinical improvement?

Are sputum results improving?

Achieving culture conversion?



[“You have to change your whole life”: A qualitative study of the dynamics of treatment adherence among adults with tuberculosis in the United Kingdom - ScienceDirect](#)



# Predicting Adherence: Examining Implicit Bias

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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

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Re-activation, re-treatment, past treatment failure

Previous non-adherence (Incomplete LTBI treatment, absconded)

Drug resistance or medication intolerance

Behavioral health including drug use

Health beliefs

Level of treatment literacy

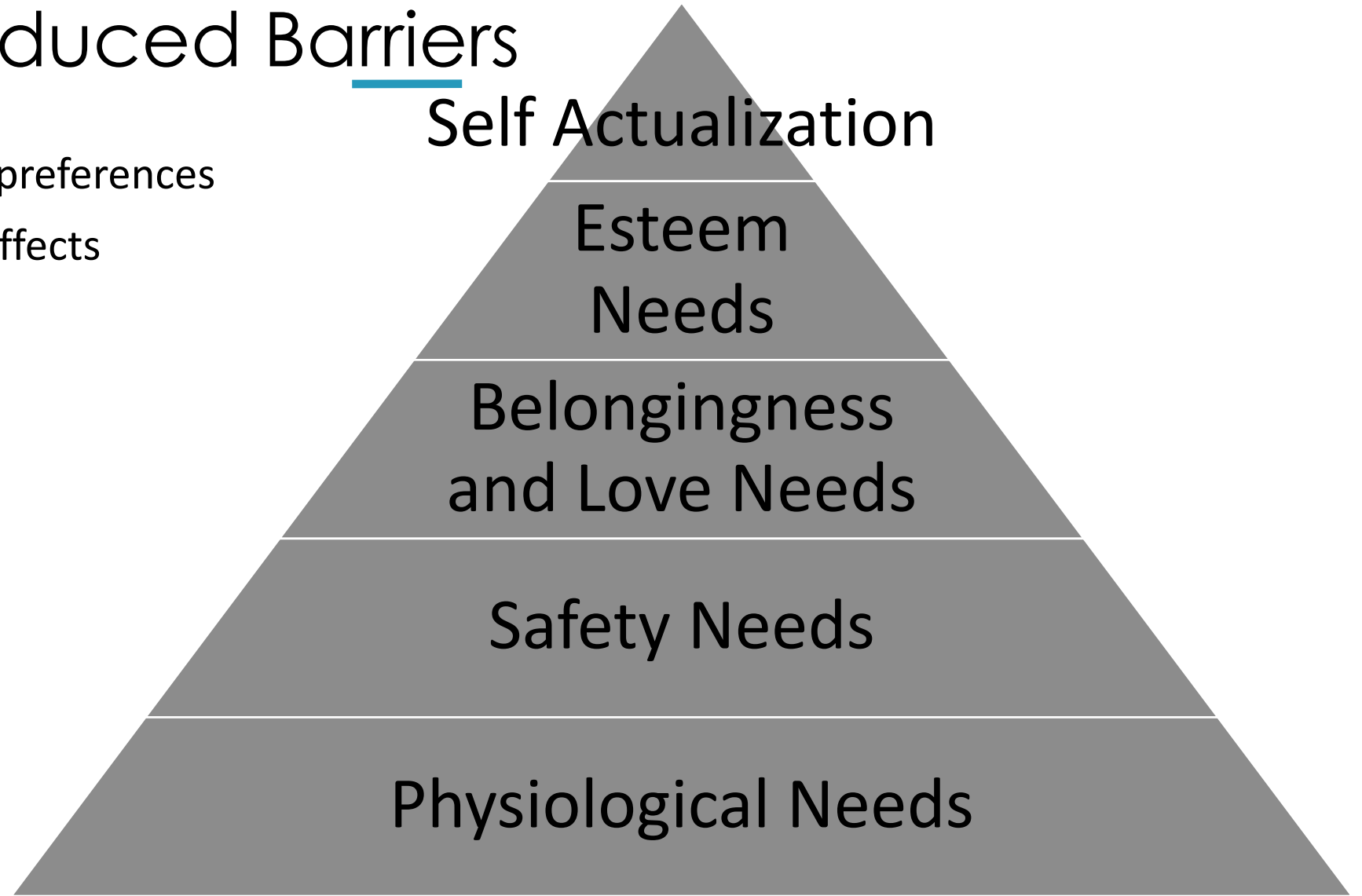
Citizenship status

Mental health, memory loss, developmental disability



# Patient Introduced Barriers

- Unaddressed patient preferences
- Underreported Side effects
- Experiencing stigma
- Fear
- Health literacy



# Clinician Introduced Barriers

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Lack of knowledge or bias toward patient preferences

Health education delivery

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?

# Polling Question 5

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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

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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

# 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

[Incentives and Enablers \(cdc.gov\)](https://www.cdc.gov)

Core curriculum chapter 6 adherence strategies.

## Enablers and Incentives

<b>Enablers</b> <i>Interventions to assist the patient in completing therapy</i>	<b>Incentives</b> <i>Interventions to motivate the patient tailored to individual patient wishes and needs, thus, meaningful to the patient</i>
Transportation Vouchers	Food baskets or snacks and meals
Convenient clinic hours and locations	Restaurant and grocery store coupons
Clinic personnel who speak the languages of the populations served	Assistance in finding or provision of housing
Reminder systems and follow-up of missed appointments	Clothing or other personal products
Social service assistance (referrals for substance abuse treatment and counseling, housing, and other services)	Books
Outreach workers (bilingual/bicultural as needed) can provide many services related to maintaining patient adherence, including provision of DOT, follow up on missed appointments, monthly monitoring, transportation, sputum collection, social service assistance, and education reinforcement	Stipends
Integration of care for tuberculosis with care for other conditions	Patient contract

# Legal Interventions

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## 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

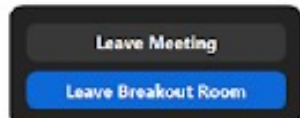
# Group Exercise

# When you are in your virtual breakout room...

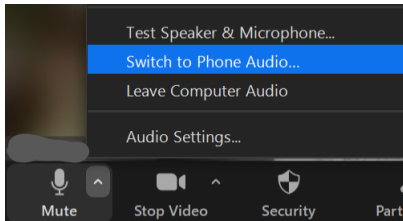
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Turn on your camera during small groups



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

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- 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

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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
  - a. \_\_\_\_\_
  - b. \_\_\_\_\_
  - c. \_\_\_\_\_
  - d. \_\_\_\_\_
1. 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.

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# Thank you!

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