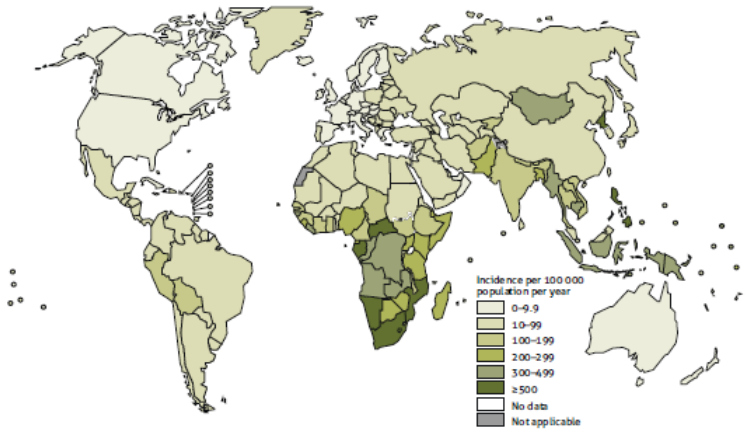

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Case Studies: NTCA Guidelines for Respiratory Isolation and Restrictions to Reduce Transmission of Pulmonary Tuberculosis in Community Settings

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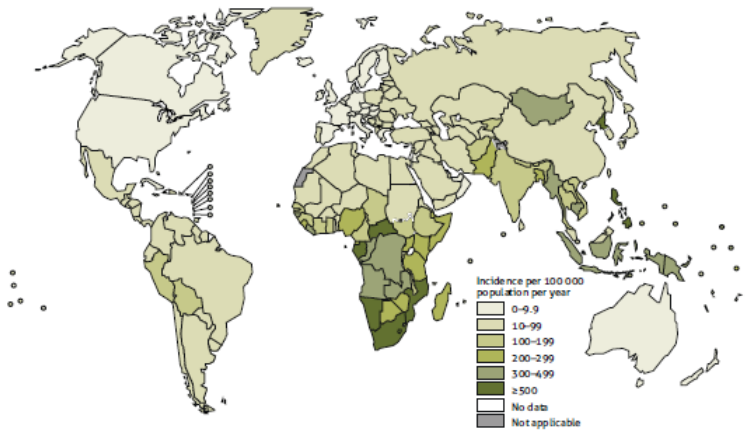

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Accessing the guidelines and commentary: CID

Table 1: Summary of the Recommendations

Table 1. Recommendations for Community-Based Respiratory Isolation and Restriction for Persons With Tuberculosis

Recommendation 1: Goals of RIR	1.1. The decision to recommend TB RIR should consider the potential benefits and harm for both the community and the PWTB.
Recommendation 2: Defining RIR (Table 2)	2.1. RIR in community settings should be conceptualized as a spectrum of tailored restrictions that are individualized for specific circumstances (Table 2).
Recommendation 3: Determining infectiousness and transmission risk (Figure 1)	3.1. Prior to effective[a] ATT initiation, PWTB with higher respiratory bacterial burden (ie, sputum smear and/or NAAT positivity, cavitation on chest imaging) may be considered as relatively more infectious than those with lower bacterial burden, with individual variability. 3.2. PWTB on less than 5 days of effective ATT should be considered relatively more infectious than those on longer durations of effective[a] therapy. 3.3. PWTB on effective[a] ATT for at least 5 days should be considered noninfectious or as having a low likelihood of infectiousness, regardless of sputum bacteriologic status during ongoing ATT (ie, smear microscopy or culture status), with certain exceptions.[b] 3.4. Overall risk of transmission to others should consider both a PWTB's infectiousness, as well as other factors including the environment of potential exposures, durations of exposure, and biological susceptibility of contacts.
Recommendation 4: Determining RIR (Table 3)	4.1. RIR is not recommended for persons with noninfectious forms of TB (ie, localized extrapulmonary TB without pulmonary involvement, as confirmed by sputum bacteriologic studies and/or chest imaging). 4.2. People with pulmonary TB on effective[a] ATT and a low likelihood of infectiousness should not have restrictions in most circumstances (ie, RIR should be removed, if present),[b] with individual exceptions for situations involving higher-risk community settings and populations (eg, children <5, immunosuppressed individuals). 4.3. Community-based RIR may be considered for PWTB who have higher infectious potential in which there is judged to be higher risk of transmission to the community.
Recommendation 5: Determining level of RIR (Table 3)	5.1. When community-based RIR is indicated for a PWTB, a moderate or midlevel range of RIR (Table 2) should be considered appropriate in most circumstances, with individual exceptions. 5.2. Specific RIR levels (eg, low, moderate, or extensive; Table 2) and duration for PWTB should be reassessed routinely (at least weekly) and may be modified based on individual considerations or changing circumstances. 5.3. When RIR is implemented, support should be provided to patients to mitigate anticipated and experienced harms.

Guidelines and Commentary: Clinical Infectious Diseases Available as Advance Articles

NTCA Guidelines:
https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciae199

https://tinyurl.com/NTCAisolation

Invited Commentary: Drs Caitlin Reed and Neela Goswami

JOURNAL ARTICLE ACCEPTED MANUSCRIPT

Duration of Effective Tuberculosis Treatment, not Acid-Fast Bacilli (AFB) Smear Status, as the Determinant for Deisolation in Community Settings FREE

Neela Goswami, MD, MPH, Caitlin Reed, MD, MPH

Clinical Infectious Diseases, ciae198, https://doi.org/10.1093/cid/ciae198

Published: 18 April 2024 **Article history** ▾

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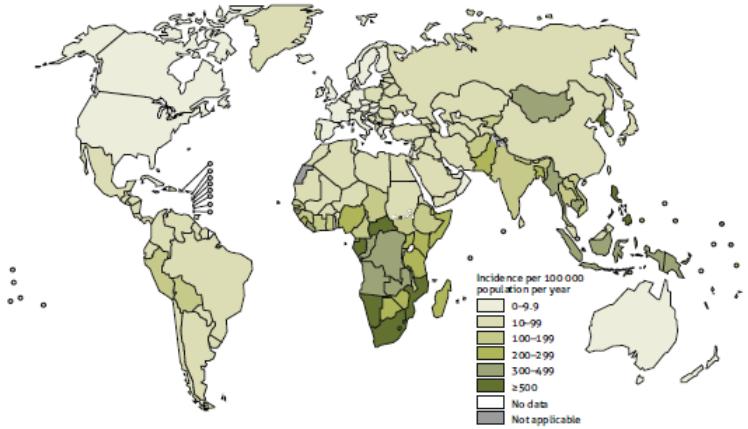
Issue Section: INVITED COMMENTARY

Invited Commentary:
https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciae198

https://tinyurl.com/IsolationCommentary

IDSA Endorsement:

- *Endorsed by the Infectious Diseases Society of America, May 2024*.



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Implementing NTCA guidelines

Baltimore: Table 4 and 5 Implementation templates within NTCA guidelines

Table 4. Implementation Aid for Initial Determination of Community-Based Respiratory Isolation and Restriction for Newly Diagnosed Persons With Tuberculosis

Step	Assessment	Notes and Recommendations
1. Assess infectiousness and transmission risk (see Rec 3)	1. Review initial chest imaging: presence or absence of cavitation	1. Individuals without prior imaging or bacteriologic evaluation of TB involvement in the respiratory tract should have assessment that includes a chest radiograph and expectorated sputum evaluation using smear microscopy, NAAT, and culture, when possible.
	2. Review initial sputum or respiratory bacteriologic studies	2. Individuals with pretreatment cavitation or sputum smear or NAAT positivity may have a higher initial bacterial burden and may be relatively more infectious than individuals with sputum smear and/or NAAT-negative samples (see Rec 3.1). Children under 10 y, particularly those with limited bronchial, laryngeal, or pulmonary involvement and minimal cough, are not generally regarded as infectious.
	3. Review initial DST and treatment regimen	Molecular DST should be used, when possible, to rapidly assess at least rifamycin susceptibility (eg, GeneXpert MTB/RIF [Cepheid Inc, Sunnyvale, California]). If rapid molecular or phenotypic DST is unavailable, initial drug selection and determination of ATT effectiveness is based on the epidemiologic likelihood of drug resistance and may consider clinical response to treatment. Individuals with suspected or identified drug resistance should have additional evaluation (eg, CDC Molecular Detection of Drug Resistance testing; phenotypic DST to first- and second-line drugs) to confirm the effectiveness of a chosen ATT regimen.
	4. Consider risk of transmission to the community (answering yes to 1 or more suggests relatively higher risks of community transmission; see Figure 1, chart B)	(See Rec 3.4; see Figure 1, chart B) 1. Assess housing—Is there shared ventilation with individuals who have not been previously exposed? If so, assess if transmission risks can be mitigated (ie, wear a surgical mask or minimize time spent in shared environment with others), or consider alternative housing options. 2. Assess employment, school setting, social activities, and other settings where PWTB will spend time—Is there likely to be prolonged (eg, multiple hours) or repeated contact in close proximity (eg, same room) with others, particularly previously unexposed?[a] 3. Is there likely to be contact with vulnerable populations (children, immunosuppressed individuals, such as in healthcare settings)? 4. Are there higher-risk environments (consider ventilation, space, density of occupants) where the PWTB is anticipated to spend time?
2. Determine whether community-based RIR is indicated (see Rec 4)	1. Does the PWTB have evidence of pulmonary TB? 2. Is the individual infectious and at high risk of transmission in the community? 3. Assess potential harms of RIR for PWTB	1. RIR is not indicated for individuals with localized extrapulmonary TB in whom TB of the respiratory tract has been excluded (see Rec 4.1). 2. Community-based RIR is indicated for most PWTB with pulmonary or respiratory involvement who have not completed at least 5 days of effective treatment (see Rec 4.3). Table 5 outlines decisions for the duration of community-based RIR. 3. The decision to recommend RIR should consider the potential benefits and harm for both the community and the PWTB (Rec 1.1).

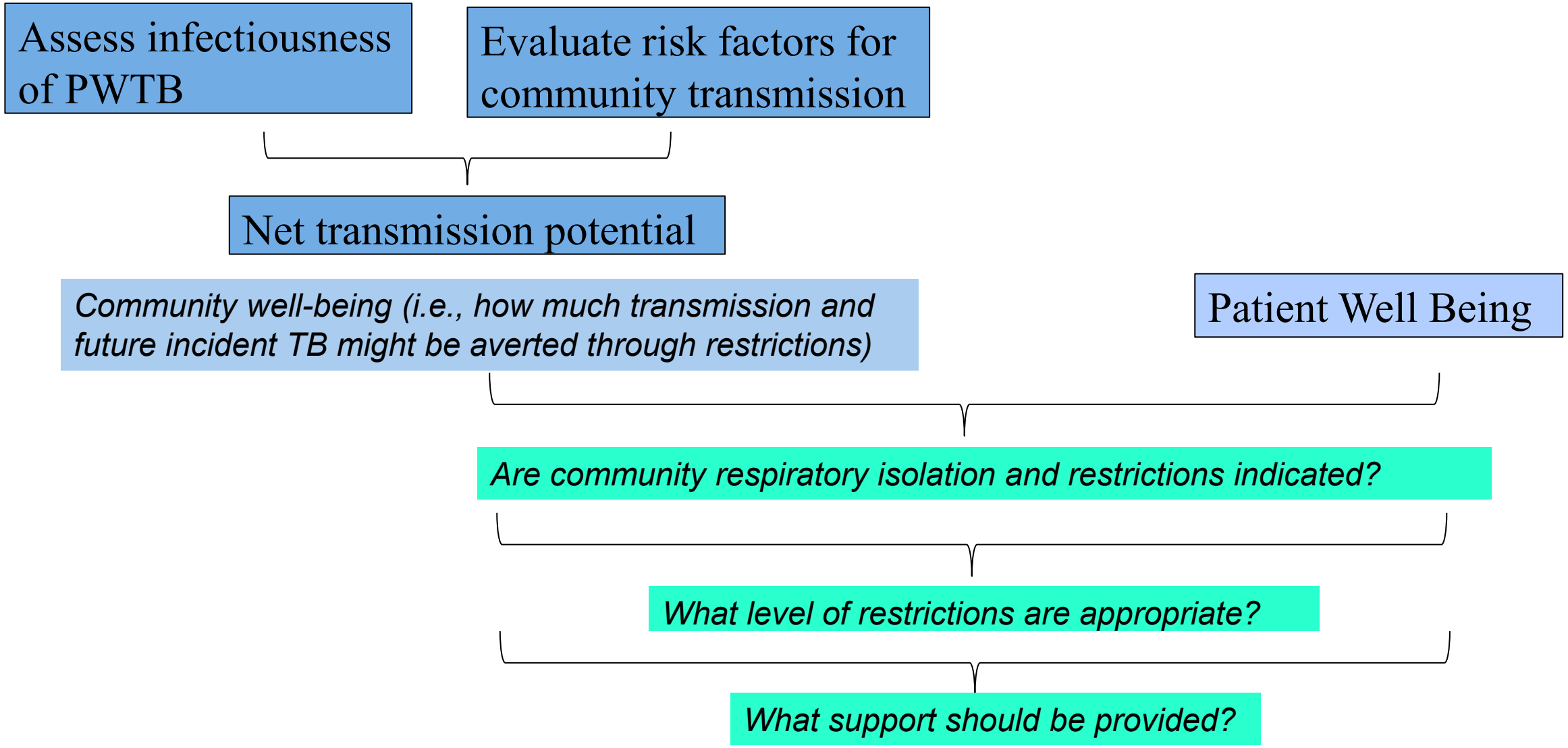
Initial Evaluation (prior to treatment)

Table 5. Implementation Aid to Assess Duration of Restrictions for Persons With Tuberculosis for Whom Community-Based Respiratory Isolation and Restriction Has Been Implemented

Step	Assessment	Notes and Recommendations
1. Assess how long PWTB has been under community-based RIR	1. Has PWTB been under community-based RIR for more than 5 days?	1. Decisions should be reassessed at least weekly, as well as with change in assessment of infectiousness, and changing circumstances related to patient and community benefits and harms (see Rec. 5.2). 2. Consider additional expert consultation or review when RIR duration has extended longer than 14 days, while ensuring adequate support for PWTB (see Rec 5.3).
2. Assess PWTB infectiousness	1. Assess duration of verified (ie, DOT or vDOT) treatment. 2. Was ATT considered effective? 3. Infectiousness is expected to progressively decline with ongoing ATT; alternatively prolonged duration of RIR is expected to result in harm for PWTB	1. Effective ATT is defined as a multidrug regimen to which the organism is susceptible or anticipated to be susceptible. If full DST is unavailable, decisions may be made based on available information (eg, rifamycin susceptibility) and clinical assessment of probability of drug resistance. 2. Most individuals completing at least 5 days of effective ATT have low infectious potential (see Recs 3.2–3.3), and RIR may be discontinued (see Rec 4.2). a. While ATT rapidly reduces a PWTB's infectiousness there may be individual variability. Available bacteriologic tests do not reliably predict infectious potential during ATT. b. In some instances of high initial bacterial burden (eg, pretreatment, sputum AFB smear-positive, cavitation), longer treatment durations (eg, 5–14 d) are expected to further reduce a PWTB's infectious potential (see Figure 1, chart A). c. Clinicians may use individualized judgment in assessing infectiousness based on pre-ATT bacterial burden (ie, initial sputum AFB smear status and cavitation), clinical response to ATT, drug susceptibility, adherence, and duration of ATT. d. Available data do not support repeated sputum smear microscopy and NAAT testing solely to assess ongoing infectiousness during ATT. Some clinicians may consider repeat sputum bacteriologic labs to monitor ATT response. However, changes to sputum smear, culture, and NAAT test results on ATT may not correlate with a PWTB's infectious potential.

Re-evaluation (on treatment)

Implementing NTCA guidelines

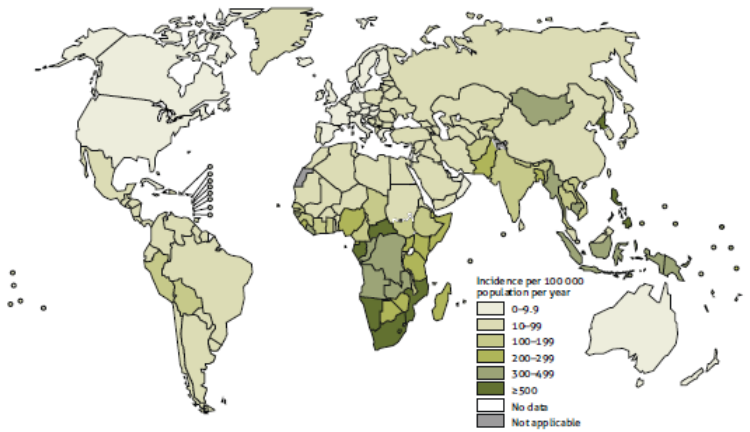


Initial Evaluation Template:

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[low, moderate, high]	
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB, High concern, Uncertain or confirmed DR-TB]	
c) Initial community risk assessment	[Low/Moderate/High/Variable]	
d)Assessment of Pre-Treatment infectiousness (NTCA Table 3):	[Non-infectious, Lowest, Low, Moderate, Highest]	
f)Concerns about restrictions:	[low (none), moderate, high]	
g) Initial Restriction determination (Table 2):	None/Low/Moderate/Extensive	
h) Restriction start date:	Overall and Community restrictions	
i.) treatment and treatment start date:		

Weekly reevaluation

WEEKLY REEVALUATION ON TREATMENT (or sooner)		
1.How long has PWTB been under community-based and total		
2.How long has PWTB been on effective therapy? 2.b Is there evidence of txt effectiveness? 2.c Are they tolerating medications? Is there concern of holding medications?		
3.Assess PWTB Infectiousness	Non-infectious, Lowest, Low, Moderate, Highest]	
4. Assess Community Risk Factors for Transmission (ENV)	[Low/Moderate/High/Variable]	
5.Assess potential harms to PWTB associated with TB diagnosis, treatment, and isolation:	Financial:Y/N, Stigma: Y/N, Housing: Y/N, Food: Y/N, Mental Health: Y/N	
Determine if RIR should be continued	[Continue, Discontinue, Modify]	
RESTRICTION SUMMARY		
a)Any Restriction start date		
b))Hospital restriction start date		
c)Hospital restriction end date		
d)Community restirction start date		
e)Community restriction end date		
f)All restriction end date:		
g)Total duration (days) of restriction:		



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Background Principles

What makes public health interventions (and guidelines) different?

- Public health policy for community based isolation has ethical and legal considerations
  - Public health has multiple dimensions: “preventing disease, prolonging life, and promoting health through organized efforts of society”
  - Closing the public health ethics gap: “public health decision makers haven’t always been transparent…failing to explain the reasoning behind their decisions about interventions such as mask mandates, quarantine and isolation policies, …”

- Burdens and sacrifices on the part of some persons (PWTB) to protect the health of the public

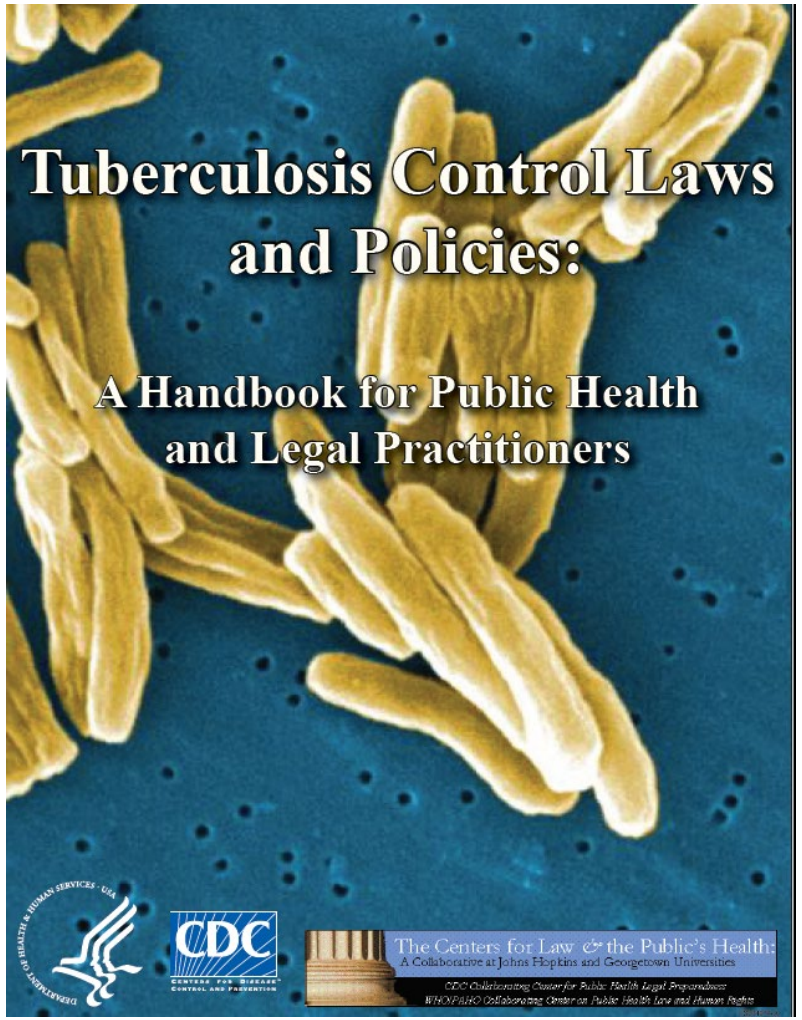
- Public health guidelines are unique because the values and preferences may differ based on the lens

Boon et al. Challenges in applying GRADE approach in public health guidelines: a concept article from GRADE public health group, JCE 2021
Parasidis et al. Closing the public health ethics gap, NEJM Sept 2022

2009: TB Control Laws and Policies—a Handbook for Public Health and Legal Practitioners

- Review the basic legal framework for control of communicable diseases

- Limitations of government powers:
  - "Concerning powers to control TB and other communicable diseases, public health authorities must balance the magnitude of the public health risk against the rights of the individuals or groups."
  - "prohibit government from depriving individuals of "life, liberty, or property without **due process of law**
  - "least restrictive means" should be used that achieves the purposes of the restrictions



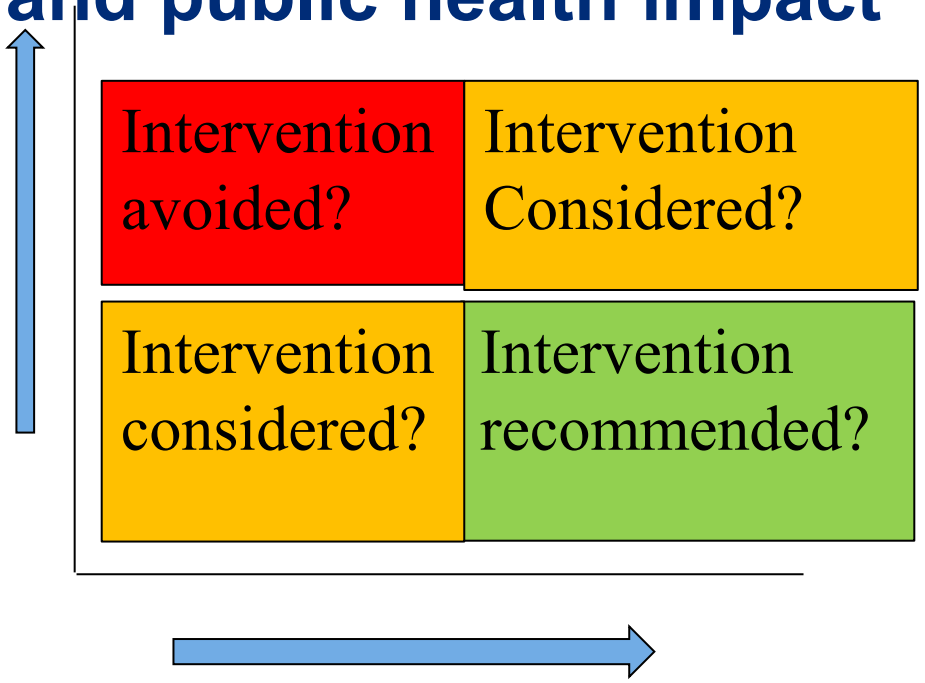
Recommendation 1: Goals of respiratory isolation and restrictions

1.1: The decision to recommend TB respiratory isolation and restriction (RIR) should **consider the potential benefits and harm** for both the **community and the PWTB.**

- Formalizes the ethical and legal principle that decisions about RIR must consider both:
  - Individual Well Being: Duties as a health care professional to maximize health of the patient (“Do no harm”)
  - Community Well Being: Responsibilities as a public health professional to minimize transmission and negative health outcomes for others

Evidence to recommendations: weighing relative individual and public health impact

Impact on patient Autonomy, rights, health, economics



Public Health Benefit from isolation

Guideline Development Group

Discussed Values and Preferences in constructing the guidelines

"A third function of the Constitution is to limit the ability of the government to violate individual rights, freedoms, and liberties, even when attempting to protect the public's health. Tensions arise when government actions to protect the public's health infringe on individual interests and autonomy. ***Resolving the tension between population-based regulations and individual rights requires trade-offs."***

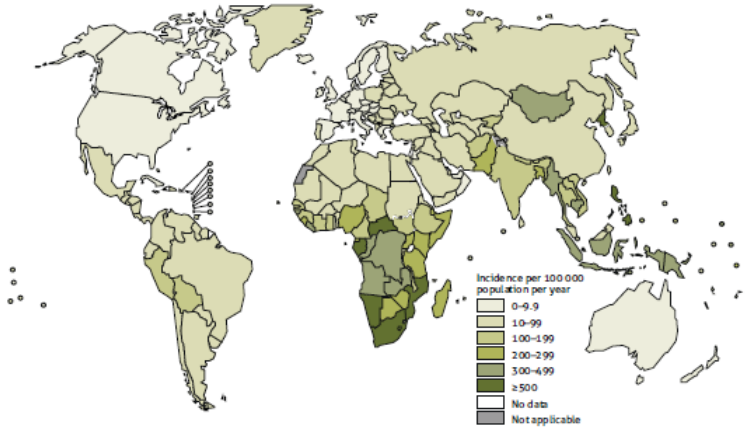
2009: TB Control Laws and Policies—a Handbook for Public Health and Legal Practitioners

More information on legal and ethical principles

- QR codes

Case Studies: *Disclosure- These case-examples reflect my individual perspectives on interpreting and implementing the NTCA guidelines*

- *Scenario 1: low bacterial burden, low/modest community risks, low harm*
- *Scenario 2: high bacterial burden; moderate community risks, low harm*
- *Scenario 3: moderate bacterial burden, moderate risks, high harm*
- *Scenario 4: high bacterial burden, high risks, high harm*



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General framework: Case 1

Recommendation 4: Determining whether community based RIR is indicated

- ***4.1: RIR is not recommended for persons with non-infectious forms of TB (i.e., localized extrapulmonary TB without pulmonary involvement, as confirmed by sputum bacteriologic studies and/ or chest imaging).***

- Foundational principle that persons not considered infectious should not have isolation or restrictions of liberties

Example 1: Low initial bacterial burden, low community risks

- 34 year old M, from Honduras, works on local farm and presents to the hospital with intermittent fevers and cough for 3 months with weight loss, and diagnosed with pulmonary TB.
  - Smear-Negative
  - GeneXpert Positive (rpoB negative)
  - No Cavity
  - No concerns for drug resistance epidemiologically

General approach to application of Recommendation 1

Community Benefits (based on averting transmission)

1.*Is the PWTB infectious?*

- *Pre-treatment bacterial burden*
- *Duration of treatment*

2.*If infectious, is there significant risk of transmission in the community?*

3.*Will isolation meaningfully prevent transmission and improve population outcomes*

Impact on patient:

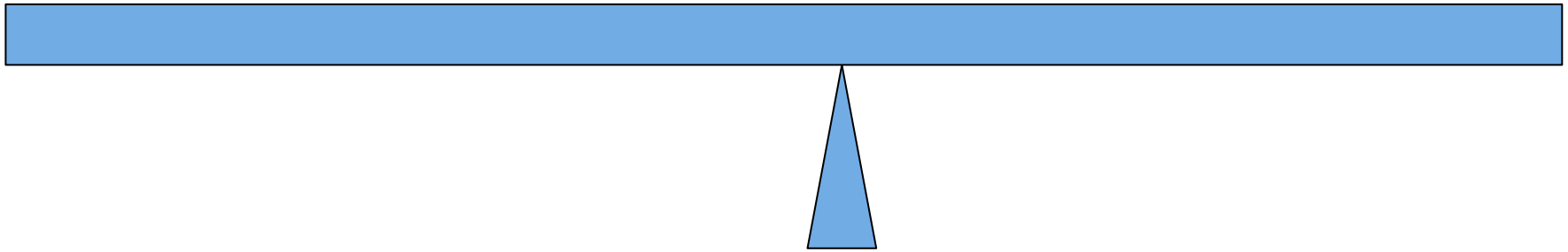
1.Mental Health

2.Financial/Employment

3.Food

4.Housing

5.Social/Stigma

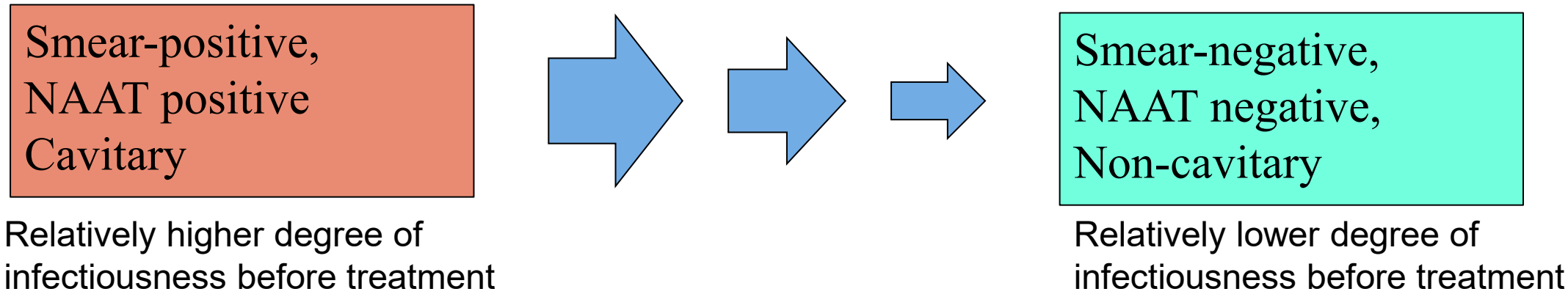


Steps

- Step 1: Determine infectiousness (Recommendation 3)
  - *What is the pre-treatment bacterial burden (and degree of infectiousness)?*

Recommendation 3: Determining infectiousness and transmission risk

- 3.1 *Prior to effective treatment initiation, PWTB with higher respiratory bacterial burden (i.e., sputum smear and/or NAAT positivity, cavitation on chest imaging) may be considered as relatively more infectious than those with lower bacterial burden, with individual variability.*
  - Strong recommendation, Moderate certainty of evidence



Steps

- Step 1: Determine infectiousness (Recommendation 3)
  - *What is the pre-treatment bacterial burden (and degree of infectiousness)?*
  - *What is the duration of effective treatment?*

Assess infectiousness and overall community risks

Approach	Result	Notes/Thoughts
1.Infectiousness prior to treatment: --sputum smear-microscopy --sputum culture --sputum NAAT --Imaging --Cough	• Smear-negative, • GeneXpert MTB/RIF-positive • No Cavity • Has Cough	Person is not on treatment (at their highest infectious potential) Bacterial burden is low (relatively lower infectious potential)

Health Department Assessment

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	LOW	
b) Review Initial DST and the Treatment Regimen		
c) Initial community risk assessment		
d)Assessment of current infectiousness (NTCA Table 3):		
f)Concerns about restrictions:		
g) Initial Restriction determination (Table 2):		
h) Restriction start date:		
i.) treatment and treatment start date:		

Assess infectiousness and overall community risks

Approach	Result	Notes/Thoughts
1.Infectiousness prior to treatment: --sputum smear-microscopy --sputum culture --sputum NAAT --Imaging --Cough	• Smear-negative, • GeneXpert MTB/RIF-positive • No Cavity • Has Cough	Person is not on treatment (at their highest infectious potential) Bacterial burden is low (relatively lower infectious potential)
2.Review available drug susceptibility testing	• GeneXpert MTB/RIF—no rpoB mutation detected • No known contacts to MDR-TB	• Presumed drug susceptible • Clinical decision to treat with standard RHZE, based on risks for drug resistance

Health Department Assessment

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[low,	Smear neg, GXP positive, no cavity
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c)Assessment of current infectiousness (NTCA Table 3):		
d) Initial community risk assessment		
f)Concerns about restrictions:		
g) Initial Restriction determination (Table 2):		
h) Restriction start date:		
i.) treatment and treatment start date:		

Table 3: Decision Aid

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated? [4]	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

4. The decision to recommend TB RIR should consider the potential benefits and harm for both the community and the PWTB. (Recommendation 1.1)

Recommendation 3: Determining infectiousness and transmission risk

- ***3.2: PWTB on less than five days of effective treatment should be considered relatively more infectious than those on longer durations of effective therapy***
  - Strong recommendation, Moderate certainty of evidence

Health Department Assessment of infectiousness: influenced by lack of treatment at this point in time

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[low,	Smear neg, GXP positive, no cavity
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c)Assessment of current infectiousness (NTCA Table 3):	[Moderate]	Pre-Treatment
d) Initial community risk assessment		
f)Concerns about restrictions:		
g) Initial Restriction determination (Table 2):		
h) Restriction start date:		
i.) treatment and treatment start date:		

Recommendation 3: Determining infectiousness and transmission risk

- ***3.4: Overall risk of transmission should consider BOTH a PWTB's infectiousness, AS WELL AS other factors including environment of potential exposures, duration of exposures, and biological susceptibility of contacts***

Steps

- Step 1: Determine infectiousness (Recommendation 3)
  - *What is the pre-treatment bacterial burden (and degree of infectiousness)?*
  - *What is the duration of effective treatment?*

- Step 2: Evaluating community risk factors for transmission (*assuming PWTB is infectious)*
  - *Frequency of contact to new individuals*
  - *Duration of contact to new individuals*
  - *Proximity of contact to new individuals*
  - *Host susceptibility to infection (children < 5, immunosuppressed)*

Transmission depends on more than infectiousness of a person with pulmonary TB

- Different environments and activities are anticipated to have different transmission risk, independent of infectiousness of PWTB
- Studies suggest that the risk of transmission is lower with outdoor activities and those with natural ventilation, compared to shared ventilation indoors
- There is no minimum duration of exposure that is required for infection, but studies suggest that longer durations have greater risk than shorter
  - 120 contact hours per month has been used to stratify risk in prior contact investigation guidelines
  - 8 hours of close exposure in closed space has been used (derived from limited evidence related to air travel)
- ***Individual circumstances and community context is important for assessing the expected benefits from isolation decisions***.

Guidelines for the investigation of contacts of persons with infectious tuberculosis. Recommendations from the National Tuberculosis Controllers Association and CDC. MMWR Recomm Rep **2005**; 54(Rr-15): 1-47

Assess infectiousness and overall community risks

Approach	Result	Notes/Thoughts
1.Infectiousness prior to treatment: --sputum smear-microscopy --sputum culture --sputum NAAT --Imaging --Cough	• Smear-negative, • GeneXpert MTB/RIF-positive • No Cavity • Has Cough	Person is not on treatment (at their highest infectious potential) Bacterial burden is low (relatively lower infectious potential)
2.Review available drug susceptibility testing	• GeneXpert MTB/RIF—no rpoB mutation detected • No known contacts to MDR-TB	• Presumed drug susceptible • Clinical decision to treat with standard RHZE

3.Assess overall community risks	• Lives with 4 roommates
	• Works in open spaces
	• No expected contact with children or immunosuppressed
		• Overall risks of transmission to new previously unexposed individuals is **low**
		  • Frequency of new contacts
		  • Duration of new contacts
		  • Intensity of new contacts

Health Department Assessment

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[low,	Smear neg, GXP positive, no cavity
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c)Assessment of current infectiousness (NTCA Table 3):	[Moderate]	Pre-Treatment
d) Initial community risk assessment	[Low]	Limited social circle, employment outside
f)Concerns about restrictions:		
g) Initial Restriction determination (Table 2):		
h) Restriction start date:		
i.) treatment and treatment start date:		

Steps

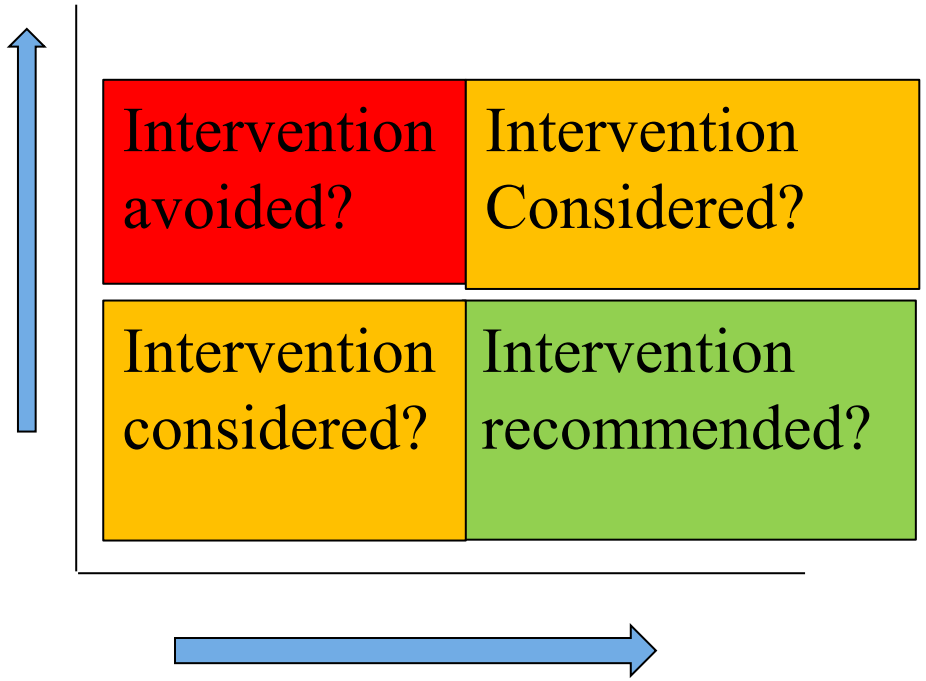
- Step 1: Determine infectiousness (Recommendation 3)
  - *What is the pre-treatment bacterial burden (and degree of infectiousness)?*
  - *What is the duration of effective treatment?*

- Step 2: Evaluating community risk factors for transmission (*assuming PWTB is infectious)*
  - *Frequency of contact to new individuals*
  - *Duration of contact to new individuals*
  - *Proximity of contact to new individuals*
  - *Host susceptibility to infection (children < 5, immunosuppressed)*

- Step 3: Is community based respiratory isolation and restrictions indicated?

Evidence to recommendations: weighing relative individual and public health impact

Impact on patient Autonomy, rights, health, economics

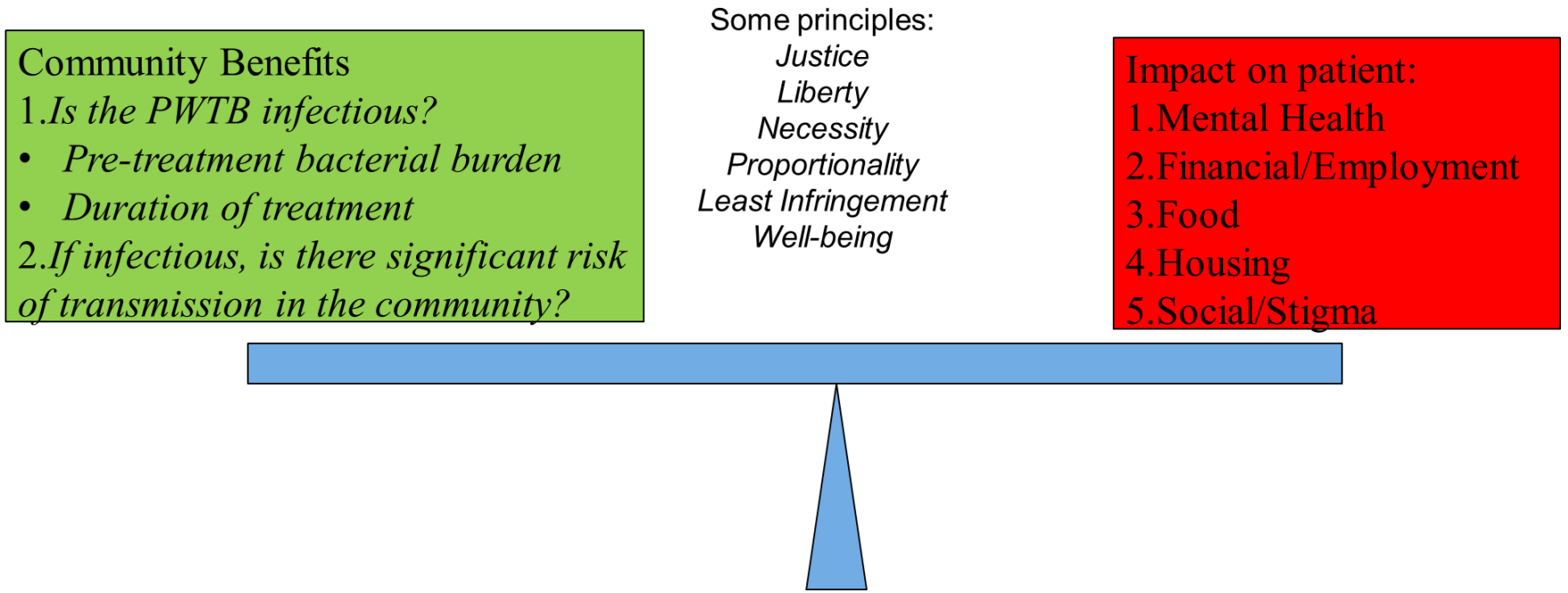


Public Health Impact

What is the evidence for recommending Restrictions of PWTB?

Determine whether community based RIR is indicated: *assess benefits and harms*

- Community based RIR is indicated for most persons with pulmonary TB or TB of the respiratory tract who have not completed at least 5 days of effective treatment (Assumption: *overall benefits are expected to outweigh harms in most situations*)



Step 3: Determine whether community based RIR is indicated: *assess benefits and harms*

- Formally assess **potential harms** of RIR for PWTB to aid decision-making:
  - **Financial stability**: *Patient indicates he can take a few days off of work but expresses concern that his employer will not retain him if he misses extended time*
  - **Housing stability**: *Patient has a home with multiple adult roommates (previously exposed), none of whom are immunosuppressed*
  - **Food stability**: *Patient indicates his roommates can assist with obtaining food*
  - **Mental health**: *multiple scales and tools available (PHQ-9, GAD-7)*
  - *Appendix 1 of the guidelines includes some possible signaling questions (not a validated tool, but represents possible questions derived from literature review)*

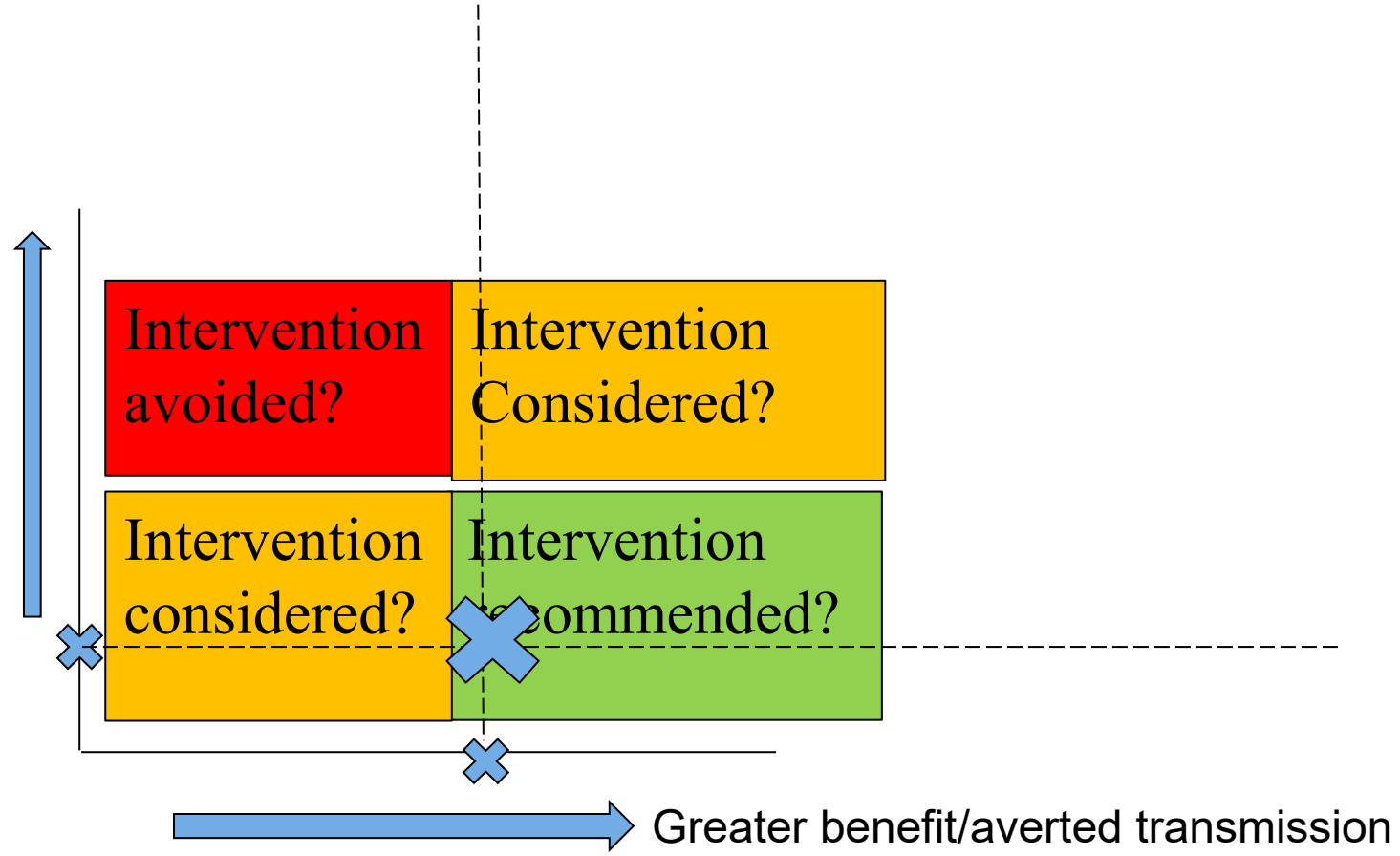
NTCA Guideline appendix: *assess patient impact*

HOUSING	1. Do you have a consistent and safe place to live while receiving TB treatment? ☐ Yes ☐ No 2. Are you worried that you will be asked to move due to TB treatment or isolation ☐ Yes ☐ No 3. Do you have children under the age of 5 at home? ☐Yes ☐No 4. Are there any individuals in the home that are immunocompromised? ☐Yes ☐No
FOOD	1. In the past year were you ever hungry but did not eat because there wasn't enough money for food? ☐Yes ☐ No 2. Are you concerned about access to food? ☐Yes ☐ No
JOBS	1. Do you have a job? ☐ Yes ☐ No (If yes, complete additional questions below) 1a. Do you think you may lose your job if you need to take time off from work due to TB treatment or isolation)? ☐ Yes ☐ No 1b. Do you work outside your home? ☐ Yes ☐ No 1c. Are you able to work remotely? ☐ Yes ☐ No
MENTAL HEALTH	1. Do you use drugs or drink at least 4 drinks of any kind in a single day? ☐ Yes ☐ No 2. Have you experienced any of the following problems within the past 2 weeks? • Feeling down ☐ Yes ☐ No • Feeling depressed ☐ Yes ☐ No • Feeling worried or frightened? ☐ Yes ☐ No • Any thoughts of harming yourself? ☐ Yes ☐ No
FINANCES	1.) In the past year- have you had trouble paying for Rent /Mortgage? ☐Yes ☐ No • Medical care? ☐Yes ☐No • Other bills? ☐Yes ☐N 2.) Have you borrowed any money this year? ☐Yes ☐No
SOCIAL	1.) Are you afraid to tell your family/friends about your diagnosis of TB? ☐Yes ☐No 2.) Are there activities you are worried you will not be able to do because of TB? ☐Yes ☐No Comments_____
GENERAL	Do you anticipate any challenges to being isolated? ☐Yes ☐No Comments:

Health Department Initial Assessment: Documentation

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[low,	Smear neg, GXP positive, no cavity
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c) Initial community risk assessment	[Low]	Limited social circle, employment outside
d)Assessment of current infectiousness (NTCA Table 3):	[Moderate]	Pre-Treatment
f)Concerns about restrictions:	[Low, but concerned for prolonged isolation]	Has access to food, housing, and some days off from work
g) Initial Restriction determination (Table 2):		
h) Restriction start date:		
i.) treatment and treatment start date:	RHZE (XXXX)	

Weighing relative individual and public health impact



Determine level of RIR-Recommendation 5.1

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

Individuals may be at their highest infectious potential prior to starting therapy. Specific provisions of RIR should balance community and individual benefits and harms
Support should be provided for any anticipated harms form RIR (Recommendation 5.3)

Recommendation 4: Determining whether community based RIR is indicated

- ***4.3: Community-based RIR may be considered for PWTB that have higher infectious potential in which there is judged to be higher risk of transmission to the community***
  - ***Conditional recommendation, Low Certainty of Evidence***

- **"Desirable consequences of RIR probably outweigh undesirable consequences in most situations"**
- Based on considerations of weighing values and preferences related to community and individual well being and harm.

Recommendation 5: Determining level of RIR

- ***5.1: When considering restrictions for PWTB, a moderate or mid-level range of RIR should be considered appropriate in most circumstances, with individual exceptions***

- Determination of RIR is based on weighing benefits and harms to the community and the individual
- Principle of “least restrictive means” to achieve the desired public health goals
- Moderate restrictions allows for some outdoor activities where there is lower transmission risk.
- Extensive restrictions may be considered in circumstances with higher infectious potential (e.g., prior to treatment initiation) and high community transmission risks or consequences (e.g., concern for transmission of drug-resistant TB)

Recommendation 2: Defining RIR

- 2.1 Respiratory isolation restrictions in community settings should be conceptualized as a **spectrum of tailored restrictions** that are individualized for specific circumstances

  - **Extensive Restrictions**:
    - Individuals limit movement to agreed upon location (e.g., home)
    - Exceptions are discussed with health department
    - Avoid visitors (previously unexposed)
  - **Moderate Restrictions**:
    - Spend *majority* of time at agreed upon location
    - Most activities in settings with good or natural ventilation (e.g., outdoors) allowable with discussion with health department
      - Avoid prolonged (e.g., multiple hours), or repeated close-contact, particularly those previously unexposed, particularly in indoor settings
      - Other risk mitigation strategies may be considered (i.e., surgical masks, KN95, N95)
  - **No restrictions**

Step 4: Assess needs for support

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

Evaluate needs for financial, housing, food support

Health Department Initial Assessment: Documentation

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[low,	Smear neg, GXP positive, no cavity
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c) Initial community risk assessment	[Low]	Limited social circle, employment outside
d)Assessment of current infectiousness (NTCA Table 3):	[Moderate]	Pre-Treatment
f)Concerns about restrictions:	[Low, but concerned for prolonged isolation]	Has access to food, housing, and some days off from work
g) Initial Restriction determination (Table 2):	**[Moderate]**	Patient may be discharged to the home
h) Restriction start date:	XXXX	Started isolation XXX in hospital, Community Isolation YYY
i.) treatment and treatment start date:	RHZE (XXXX)	

Case-example continued: Initial Evaluation Summary

- 34 year old with newly diagnosed pulmonary TB started on HRZE by hospital and discharged to home
  - Pre-treatment smear negative, GXP positive with no rpoB mutation
  - **Tolerating medication and has taken 3 days by DOT/vDOT**
  - Contact investigation was initiated by the health department
    - Four household contacts
    - No employment related contacts identified
    - Identifies five close friends he has spent time with regularly
  - **Health department recommended home-isolation (moderate restrictions)**
    - **Indicated he could go outdoors for exercise provided he had limited to no contact with previously unexposed individuals**
  - No concerns for food or housing
  - **Expresses concerns for missing work, as he is paid on an hourly basis. Is worried employer will not retain him if he misses too many days of work**

Recommendation 3: Determining infectiousness and transmission risk

- ***3.2: PWTB on less than five days of effective treatment should be considered relatively more infectious than those on longer durations of effective therapy***
  - Strong recommendation, Moderate certainty of evidence

Step 1-2: Assess duration of treatment and reassess infectiousness 3 days of HRZE by time of initial Health Dept evaluation

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

PWTB with low initial treatment burden is anticipated to have rapid decline in infectiousness

Step 3-4: Reassess indication for RIR—balance community and patient benefits and harms

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

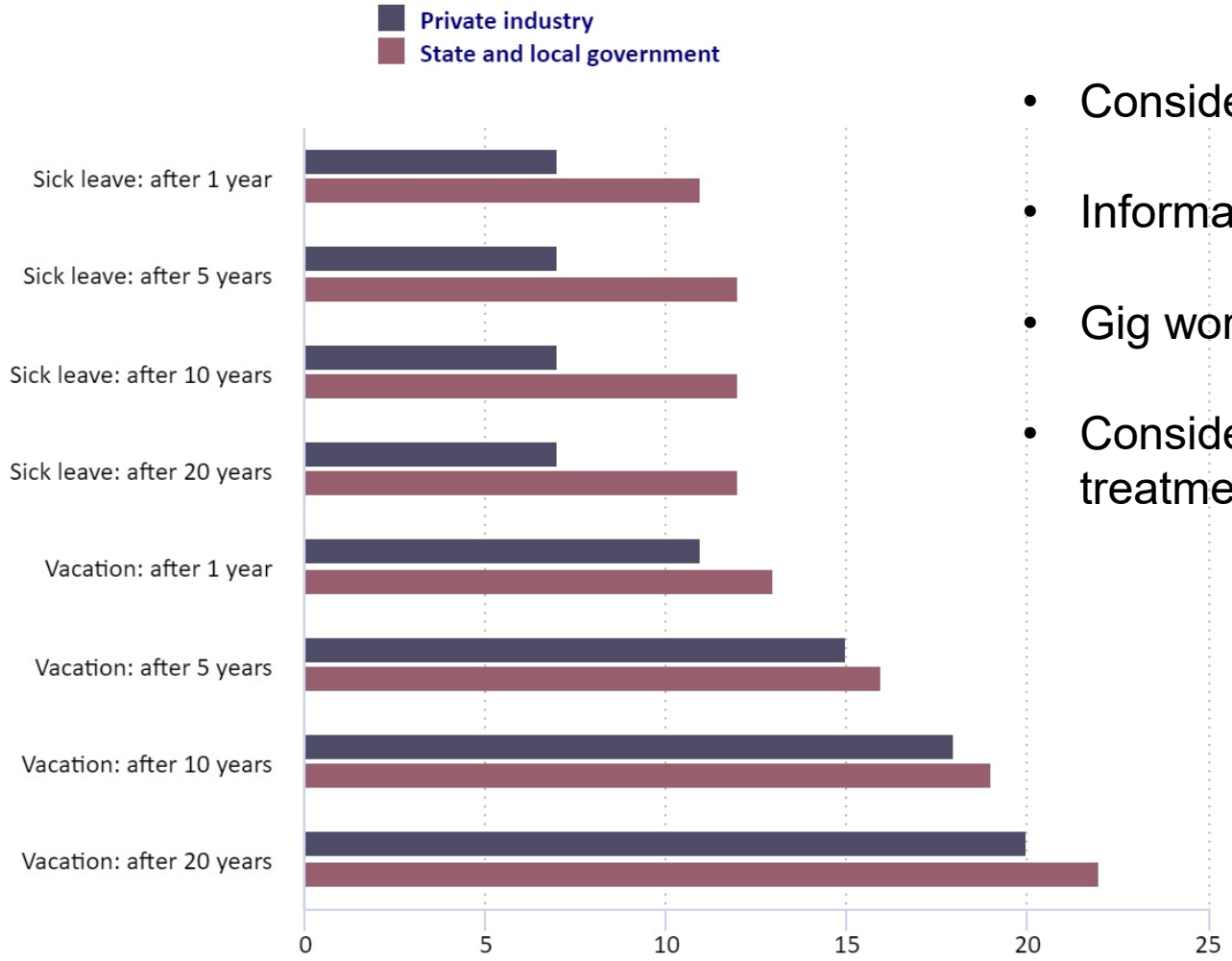
Evaluate needs for financial, housing, food support. Consider details of restrictions—outdoor employment could be considered (with masks if coming into close contact with others)

Case-example continued: > 5 days of treatment

- 34 year old with newly diagnosed pulmonary TB
  - Pre-treatment smear negative, GXP positive with no rpoB mutation
  - **Has completed 5 days of HRZE with DOT/vDOT** and is clinically improving
  - **Has remained in home isolation during this time**
  - **Growing anxious about ongoing missed days of work**

Average sick days off in the US: Department of Labor

Paid leave benefits: Average number of sick and vacation days by length of service requirement, March 2023



Source: U.S. Bureau of Labor Statistics.

- Consider individual circumstances
- Informal employment
- Gig work (ride-share, delivery, etc)
- Consider need for missed employment during treatment course

Recommendation 3: Determining infectiousness and transmission risk

- ***3.3: PWTB on effective[1] treatment for at least five days should be considered non-infectious or low likelihood of infectiousness, regardless of sputum bacteriologic status during treatment (i.e., smear-microscopy, NAAT or culture status), with certain exceptions[2]***
  - Conditional recommendation, Moderate certainty of evidence

1. Effective treatment is defined as a recommended multi-drug regimen to which the organism is susceptible or anticipated to be susceptible
2. No single test or treatment duration universally predicts non-infectiousness. Available evidence suggests **most** PWTB are unlikely to transmit to others within the first few (24-72hours) days after treatment initiation. Other factors to consider may include pre-treatment bacterial load, adequacy and adherence to treatment regimen, and/or adherence and clinical response to treatment.

Are bacteriologic studies (smear, culture) after treatment initiation associated with M. tuberculosis transmissibility?

- Observation on microscopy may not correspond to viability (culture)
- Detection in laboratory culture (viability, culture positivity) may not correspond to infectiousness (transcriptomic, gene-expression studies)
- Recent analysis:
  - Mean time to smear-conversion 34 days +/- 26 days (SD)
  - Mean time to culture conversion 38 days +/- 32 (SD)

- **There was no evidence of an association between smear-status or culture-status and infectiousness in available experimental or epidemiological studies of individuals on effective treatment.**

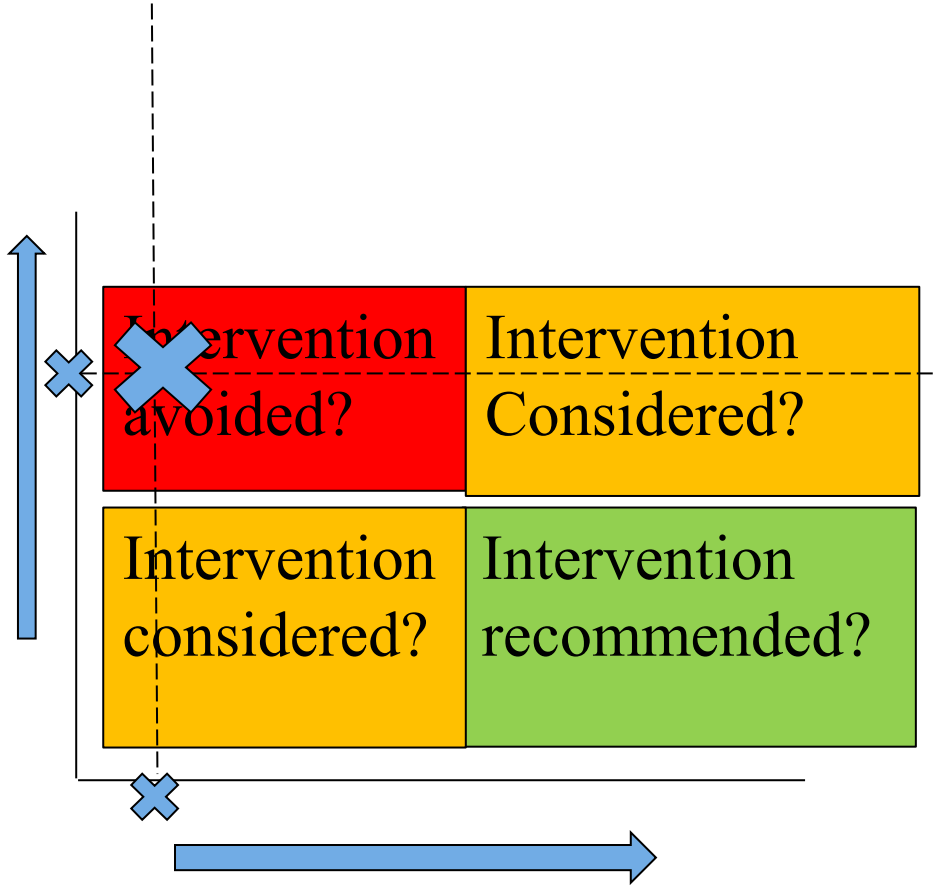
Fortun et al. AAC 2007
NTCA isolation guidelines, 2024

How much treatment is needed to reduce *M. tuberculosis* transmissibility?

- **Not all time points have been uniformly evaluated and there is no single biomarker**
- Laboratory studies: 90% decline in viable bacteria within first 48 hours
  - "If no other factor other than elimination of viable *M. tuberculosis* were to account for infectivity, majority of patients who receive treatment for as few as 2 days of RHZE could be assumed to have an infective potential that averages 10% of that at the time of diagnosis*"
- Human to guinea pig studies: the treatment effect is "prompt and striking"
  - Effect in some studies appears almost immediate (24-72 hours)
- Transcriptomic/Gene-expression studies: changes in 1-4 days of treatment
- Observational/Epidemiologic studies: majority evaluated transmission after 1-2 weeks of treatment
- Madras RCT: no difference comparing those in isolation, with those with home based treatment (ongoing exposure)

*Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America

Weighing relative individual and public health impact



Impact on patient Autonomy, rights, health, economics

Public Health Benefit

How much transmission is expected to be averted?

- Non-infectious or low level infectiousness
- Low level of community risk factors

Expected impact

- Financial
- Housing

Step 4: Determine indication for RIR—RIR can be discontinued in most situations after 5 days of treatment

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
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	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

Case-example continued: > 5 days of treatment

- 34 year old with newly diagnosed pulmonary TB
  - Pre-treatment smear negative, GXP positive with no rpoB mutation
  - **Has completed 5 days of HRZE with DOT/vDOT** and is clinically improving
  - **Has remained in home isolation during this time**
  - **Growing anxious about ongoing missed days of work**

- **Weekly Assessment:**
  - **Infectious:** non-infectious or low likelihood of infectiousness (5 days of effective therapy)
  - **Community risks:** low or modest
  - **Patient harms:** patient experiencing stress/anxiety, financial insecurity

Recommendation: Discontinue respiratory isolation and restrictions

WEEKLY REEVALUATION		
1.How long has PWTB been under community-based and total isolation	3 days (hospital); 2 days (home)	
2.How long has PWTB been on effective therapy? 2.b Is there evidence of txt effectiveness? 2.c Are they tolerating medications? Is there concern of holding medications?	a)5 days (DOT), 2 days (self-admin) b)Yes, clinical improvement (no cough) c)Tolerating medicine: Yes	
3.Assess PWTB Infectiousness	Lowest	
4. Assess Community Risk Factors for Transmission	[Low]	Works outdoors
5.Assess potential harms to PWTB associated with TB diagnosis, treatment, and isolation:	Financial: Yes Stigma: No Housing insecurity: Yes Food insecurity: No, Mental Health: No	
Determine if RIR should be continued	Discontinue	

Snapshot of documentation

****
ISOLATION
(Assessment based on NTCA Guidelines for Respiratory Isolation and Restrictions to Reduce Transmission of Pulmonary Tuberculosis in Community Settings, February 2024)
a) Initial pre-treatment infectiousness: LOW
b) Initial community risk assessment: LOW
c) Is there drug-susceptibility testing? NO
If not, is there any concern for drug resistance based on epi risks? NO
d) Initial Restriction level: MODERATE
e) Restriction start date: 3/28/2024

WEEKLY RE-EVALUATION
a) Duration of effective treatment: 9 DAYS
b) Assessment of infectiousness: LOWEST
c) Restriction end date: 4/1/2024
d) Restriction evaluation dates: 4/5/2024
e) Restriction harm assessment:
--Financial: YES
--Stigma: UNK
--Housing: YES
--Food: UNK
--Mental Health: UNK
f) Current level of RIR: NONE

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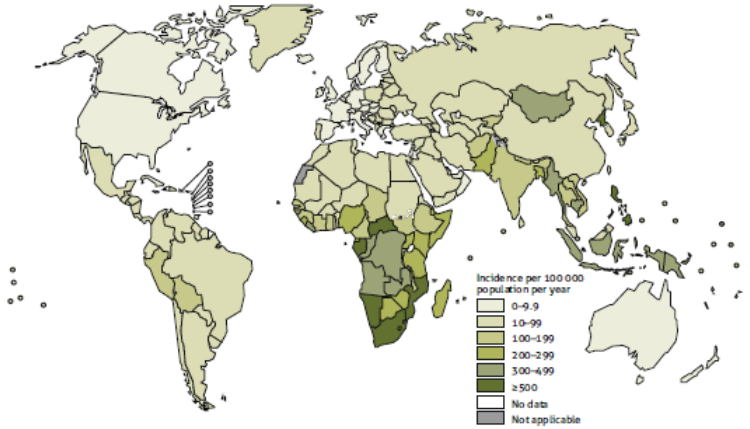


JOHNS HOPKINS MEDICINE

Case-study 2: high bacterial burden; moderate community risk, low patient harm

Case 2 : High pre-treatment bacterial burden

- 55 year old F, diagnosed with pulmonary TB after presenting with fevers x 2 weeks and productive cough.
  - Microbiology: Smear-positive, GeneXpert MTB/RIF positive (no rpoB)
  - Coughing
  - Cavity on chest imaging
  - Intermittent cough for 3 months
- Social History:
  - Born in India, living in the US since 2003,
  - Works in IT: 20 coworkers in single-floor office
  - Married with 3 children
  - Attends church on weekends (~50 individuals)

High initial bacterial burden, moderate community risks

- 55 year old F, born in India, living in the US since 2003, and works in IT, diagnosed with pulmonary TB after presenting with fevers x 2 weeks and productive cough.

Step	Result	Notes/Thoughts
1.Infectiousness prior to treatment: --sputum smear-microscopy --sputum culture --sputum NAAT --Imaging --Cough	• Smear-positive, • GeneXpert MTB/RIF-positive • Cavity • Has Cough	Person is not on treatment (at their highest infectious potential) **Bacterial burden is high** **High level of pre-treatment infectiousness**
2.Review available drug susceptibility testing	• GeneXpert MTB/RIF—no rpoB mutation detected	• Presumed drug susceptible • Clinical decision to treat with standard RHZE

High initial bacterial burden, moderate community risks

- 55 year old F, born in India, living in the US since 2003, and works in IT, diagnosed with pulmonary TB after presenting with fevers x 2 weeks and productive cough.

Step	Result	Notes/Thoughts
1.Infectiousness prior to treatment: --sputum smear-microscopy --sputum culture --sputum NAAT --Imaging --Cough	• Smear-positive, • GeneXpert MTB/RIF-positive • Cavity • Has Cough	Person is not on treatment (at their highest infectious potential) **Bacterial burden is high** **High level of pre-treatment infectiousness**
2.Review available drug susceptibility testing	• GeneXpert MTB/RIF—no rpoB mutation detected	• Presumed drug susceptible • Clinical decision to treat with standard RHZE
3.Assess overall community risks: **MODERATE**	• 3 children (10,13, 16) and husband in the house • ~20 coworkers in an office with shared ventilation (closed windows, cubicles); same people (already exposed) • Attends church on weekends (~50 individuals)	

Step 4: Determine indication for RIR—Pre-treatment

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

Recommendation 5: Determining level of RIR

- ***5.1: When considering restrictions for PWTB, a moderate or mid-level range of RIR should be considered appropriate in most circumstances, with individual exceptions***

- Determination of RIR is based on weighing benefits and harms to the community and the individual
- Principle of “least restrictive means” to achieve the desired public health goals
- Moderate restrictions allows for some outdoor activities where there is lower transmission risk.
- Extensive restrictions may be considered in circumstances with higher infectious potential (e.g., prior to treatment initiation) and high community transmission risks or consequences (e.g., concern for transmission of drug-resistant TB)

Health Department Initial Assessment: Documentation

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[high]	Smear pos, GXP positive, cavitation
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c) Initial community risk assessment	[Moderate]	Indoors, close proximity, high frequency/duration
d)Assessment of current infectiousness (NTCA Table 3):	[Highest]	Pre-Treatment
f)Concerns about restrictions:	[Low]	Has access to food, housing, and ability to telework
g) Initial Restriction determination (Table 2):	**[Extensive/Moderate]**	Moderate once started on therapy
h) Restriction start date:	XXXX	Started isolation XXX in hospital, Community Isolation YYY
i.) treatment and treatment start date:	RHZE (XXXX)	

Re-evaluation: High initial bacterial burden, moderate community risks, on therapy

- 55 year old F with smear-positive, GXP positive (rpoB negative), cavitary, pulmonary TB initiated on HRZE, with **moderate restrictions**
  - Moderate RIR: Agreed to limit movement to the home. When she feels up for it, she has permission to telework. She asks friends not to visit while she is ill.
    - She indicates good family support and is in good spirits
    - No concerns for housing, food, or financial insecurity
  - On HRZE with good adherence and has taken 5 days of treatment (DOT+vDOT)
  - Fevers have subsided, but still has a cough
  - Contact investigation has not yet been initiated at the site of employment

Determine indication for RIR—RIR can be discontinued in most situations after 5 days of treatment

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

2. May consider initial bacterial burden, adherence and response to treatment when assessing infectiousness
3. Additional restrictions or longer duration may be considered in scenarios of higher-risk community settings, **balancing community well-being and patient impact.**

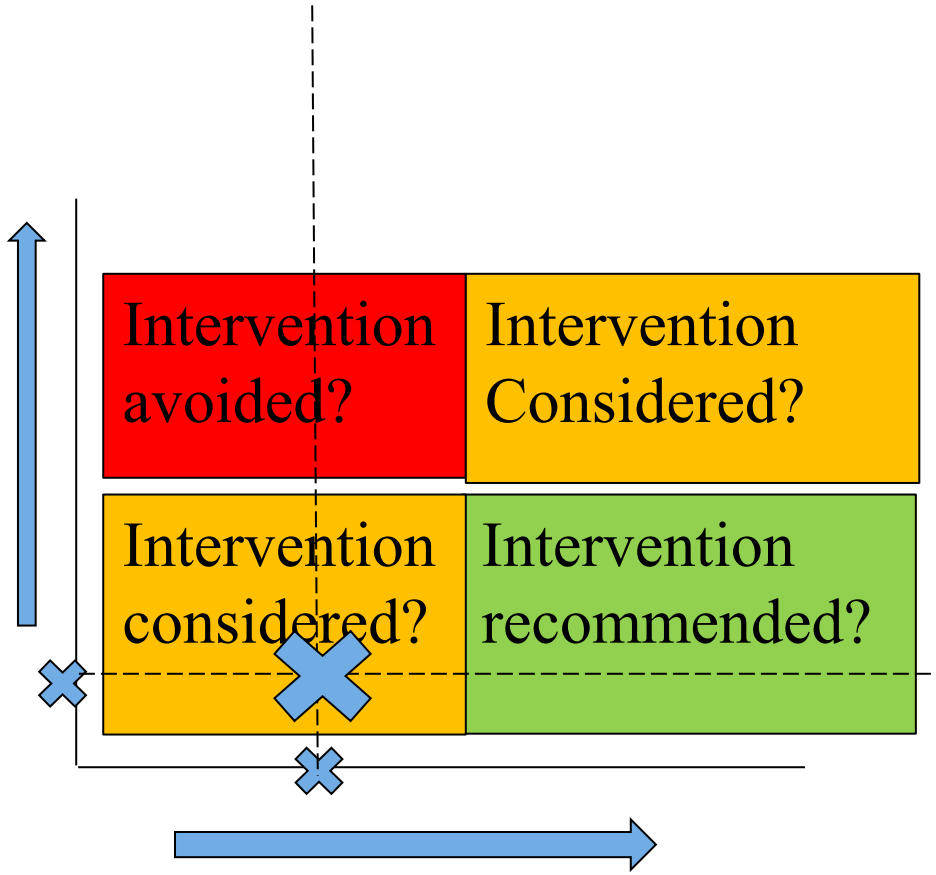
Example 2: High initial bacterial burden, moderate community risks

- Steps in reevaluation:
  - **Assess infectiousness**: **low or moderate/low** (five days of effective therapy)
    - Given individual variability, high pre-treatment bacterial burden, and ongoing cough may consider person as moderate/low infectiousness
  - **Assess community risks**: **Moderate**
    - Employment: prolonged (6-8 hours) contact with daily frequency with ~20 individuals in shared space daily, though most have been previously exposed
    - Social: weekly contact (~2 hours) with members of her church in close proximity
  - **Assess patient harms** as a result of community based RIR: LOW
    - Good support without concern for significant harms to mental health, stigma, finances, housing, or food

Recommendation 1.1: The decision to recommend TB respiratory isolation and restriction (RIR) should **consider the potential benefits and harm** for both the **community and the PWTB.**

Weighing relative individual and public health impact

Impact on patient Autonomy, rights, health, economics



Public Health Benefit

How much transmission is expected to be averted?

- Low/moderate level infectiousness
- Moderate level of community risk factors

Expected impact

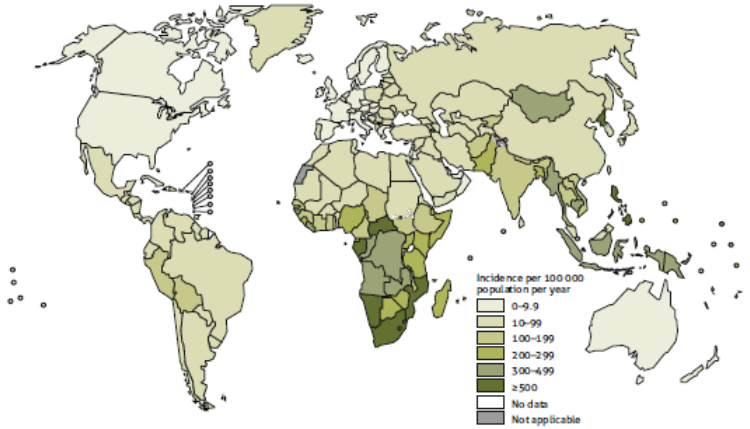
- Financial: low
- Housing: low
- Stigma/Social: low
- Food: Low

Example 2: High initial bacterial burden, moderate community risks

- 55 year old F with smear-positive, GXP positive (rpoB negative), cavitary, pulmonary TB initiated on HRZE
  - Implemented moderate RIR for five days
  - Reassessment after five days of effective treatment:
    - Likely low level of infectiousness, but given individual variability and higher initial bacterial burden
    - Moderate/higher community risks given employment in setting of closed ventilation and frequent prolonged contact with others
    - Assessment of patient harms
  - **Public health decision: Continue moderate RIR for another week and reassess**
    - Patient to tele-work
    - Avoiding social activities

Reevaluation: 12 days of treatment and clinical improvement

- 55 year old F with smear-positive, GXP positive (rpoB negative), cavitary, pulmonary TB initiated on HRZE x 12 days (one week later)
  - Moderate RIR now for 12 days during which she has taken walks outside of suburban home, but no other contact with others
  - Contact investigation has been initiated at employment and among social contacts
  - Clinically: feeling better, with mild intermittent non-productive cough (improved from prior)
- Assessment:
  - *Infectiousness*: likely non-infectious based on 12 days of therapy
  - *Community risks*: same as prior, but conditional on patient being infectious (highest risk to most employment and social contacts was prior to treatment initiation)
  - *Patient harms*: reveals she is starting to feel stressed and ‘couped’ up, and asking when she can return to work and church, but is concerned about infecting others
- Public Health decision making: balance community and patient well being
  - Discontinue RIR
  - Consider masking when in employment or community settings until cough resolves



JOHNS HOPKINS MEDICINE

Case-study: Moderate bacterial burden, moderate risks in the community; moderate/high patient harm

Example : Initial history

- 24 year old HIV negative born in Nicaragua, presented with abdominal pain and found to have pulmonary and GI TB
  - Microbiology: Sputum Smear-negative, GeneXpert MTB/RIF positive (no rpoB)
    - Stool AFB smear (culture positive)
  - Not Coughing
  - 1cm nodule, diffuse tree-in-bud opacities throughout lung fields 1.4cm cavity RUL
- Social History:
  - Born in Nicaragua and entered US 2022
  - Reports brother treated for PTB 2 years ago
  - Works part-time in a mail room (alone)

Example 2: Moderate initial bacterial burden, low/moderate community risks

- 24 yo w pulmonary smear-negative TB, stable housing, works mostly alone

Step	Result	Notes/Thoughts
1.Infectiousness prior to treatment: --sputum smear-microscopy --sputum culture --sputum NAAT --Imaging --Cough	• Smear-negative, • GeneXpert MTB/RIF-positive • Small Cavity • No Cough	Person is not on treatment (at their highest infectious potential) **Bacterial burden is low/moderate** **Infectiousness: moderate/high (before treatment)**
2.Review available drug susceptibility testing	• GeneXpert MTB/RIF—no rpoB mutation detected	• Presumed drug susceptible • Clinical decision to treat with standard RHZE
3.Assess overall community risks:	3 roommates in rented house Part-time work	• Low/Moderate risk: works alone, but poor ventilation

Step 4: Determine indication for RIR—Pre-treatment

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
Pre-treatment	High	Highest (Rec. 3.1)	Yes (Rec 4.3)	Extensive	Support should be provided to mitigate harm to PWTB (Rec 5.3).
	Low	Moderate (Rec 3.1)	Yes (Rec 4.3)	Extensive or Moderate (Rec 5.1)	
Treatment <= 5 days	High	Moderate (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
	Low	Moderate/Low (Rec 3.2)	Yes (Rec 4.3)	Moderate (Rec 5.1)	
Treatment > 5 days	High	Low (Rec 3.3) [2]	Not indicated in most situations (Rec 4.2)[3]	None	Individual exceptions to continue RIR may be considered (Rec 5.2) [3]
	Low	Lowest (Rec 3.3)		None	

Health Department Initial Assessment: Documentation

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[Low/Moderate]	Smear neg, GXP positive, cavitation
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c) Initial community risk assessment	[Low/Moderate]	Indoors, close proximity, high frequency/duration
d)Assessment of current infectiousness (NTCA Table 3):	[Highest]	Pre-Treatment
f)Concerns about restrictions:	[Moderate]	Has access to food, housing, worried about work
g) Initial Restriction determination (Table 2):	**[Extensive/Moderate]**	Moderate once started on therapy
h) Restriction start date:	XXXX	Started isolation XXX in hospital, Community Isolation YYY
i.) treatment and treatment start date:	RHZE (XXXX)	

Example : Re-evaluation

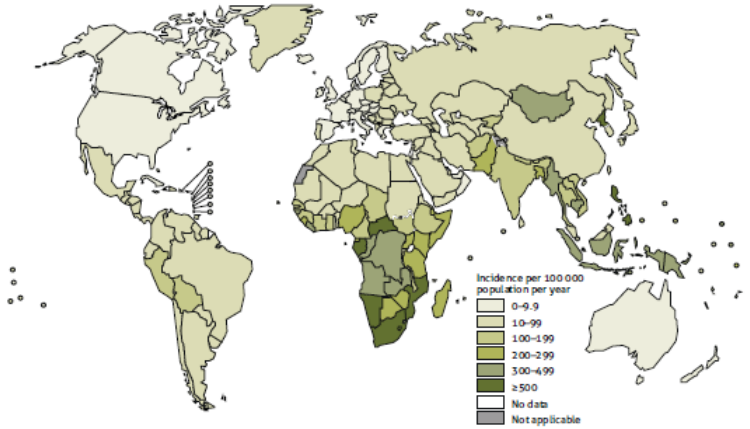
- Patient initiated on treatment in hospital and discharged Hospital Day 2 with weekend supply
- Home visit done on day 4 and we didn’t have the hospital treatment records
- Community risk assessment: Less certainty about mailroom based on description, but felt to be likely low risk for prolonged exposure to new individuals
- Patient harm: Expressing concern for financial and housing security if he missed any more time at work
- Decision: 5 days of isolation after verified treatment

WEEKLY REEVALUATION		
1.How long has PWTB been under community-based and total isolation	5 days (hospital); (only one verified dose) 4 days (home)	
2.How long has PWTB been on effective therapy? 2.b Is there evidence of txt effectiveness? 2.c Are they tolerating medications? Is there concern of holding medications?	a)5 days (DOT), 2 days (self-admin) b)Yes, clinical improvement (no cough) c)Tolerating medicine: Yes	
3.Assess PWTB Infectiousness	Low OR Lowest	
4. Assess Community Risk Factors for Transmission	[Low OR Moderate]	
5.Assess potential harms to PWTB associated with TB diagnosis, treatment, and isolation:	Financial: Yes Stigma: No Housing insecurity: Yes Food insecurity: No, Mental Health: No	
Determine if RIR should be continued	Discontinue after 5 verified doses + 2 self administered	

Document Isolation Summary

- **III. ISOLATION SUMMARY**
- A. Hospital Isolation Start date: **3/23/2024**
- B. Hospital Isolation End date: **3/28/2024**
- C. Duration of Hospital Isolation: **5 DAYS** (1 verified dose(s))
- D. Community Isolation Start date: **3/29/2024**
- E. Community Isolation End date: **4/1/2024**
- F. Community Isolation Duration: **4 DAYS** (5 verified doses)
- G. Total Isolation: 9 days

Note, that often persons have been in isolation for several days before treatment started which can have an impact



JOHNS HOPKINS MEDICINE

Case-study: High bacterial burden, Moderate/High Community Risk, high patient harm

Example : Initial history

- 47 year old HIV-negative, non-diabetic, Non-USB from Laos with ETOH use (7beers/day) with new diagnosis of PTB.
  - Microbiology: Smear-positive, GeneXpert MTB/RIF positive (no rpoB)
  - Coughing
  - Extensive Cavitation on CXR (5.9cm x 5.8cm)
  - Other Symptoms: Fevers, weight loss (20lbs)

- Social History:
  - Works as a dishwasher in a restaurant
  - 6 individuals in the household: none with HIV, no children

- Initial Assessment to harm: Moderate/High (concerns about finances and missing work)

Example: High initial bacterial burden, moderate community risks

- 47 yo w smear positive, cavitary TB, expressing concerns for any isolation

Step	Result	Notes/Thoughts
1.Infectiousness prior to treatment: --sputum smear-microscopy --sputum culture --sputum NAAT --Imaging --Cough	• Smear-positive, • GeneXpert MTB/RIF-positive • Cavity • Has Cough	Person is not on treatment (at their highest infectious potential) **Bacterial burden is high**
2.Review available drug susceptibility testing	• GeneXpert MTB/RIF—no rpoB mutation detected	• Presumed drug susceptible • Clinical decision to treat with standard RHZE
3.Assess overall community risks:	• 6 individuals in the house • Unclear # of co-workers	• **MODERATE/HIGH** • Presume poor ventilation and long durations in close proximity

Step 4: Determine indication for RIR—Pre-treatment

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
Treatment Status	Pre-treatment Respiratory bacterial burden[1]	Assessment of individual infectiousness*	Is RIR indicated?	What level of RIR to choose? (Rec. 2, Table 2)	Specific Recommendations should balance community and patient risks and benefits (Rec 1)
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	Low	Lowest (Rec 3.3)		None	

Health Department Initial Assessment: Documentation

Questions	Assessment	Notes
INITIAL EVALUATION FOR RESPIRATORY ISOLATION (Prior to treatment)		
a) Initial pre-treatment bacterial burden	[high]	Smear pos, GXP positive, cavitation
b) Review Initial DST and the Treatment Regimen	[Low/No Concern for DR-TB,]	GXP rpoB negative, no prior treatment history
c) Initial community risk assessment	[Moderate/High]	Indoors, close proximity, high frequency/duration
d)Assessment of current infectiousness (NTCA Table 3):	[Highest]	Pre-Treatment
f)Concerns about restrictions:	Moderate]	Has access to food and housing. **FINANCIAL AND EMPLOYMENT CONCERNS**
g) Initial Restriction determination (Table 2):	**[Extensive/Moderate]**	Moderate once started on therapy
h) Restriction start date:		
i.) treatment and treatment start date:		

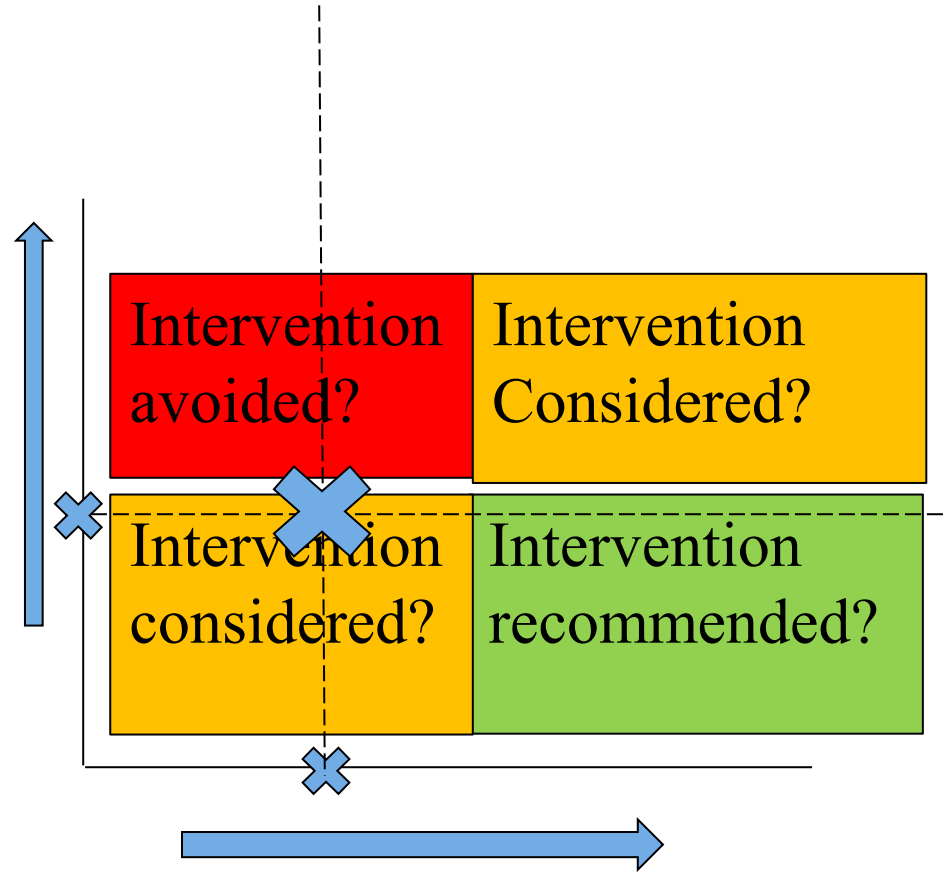
Re-evaluation: High initial bacterial burden, moderate community risks, on therapy

- Patient started isolation in hospital pending evaluation (DAY 1)
- **Started therapy Day 4:**
- **Discharged Day 9:** (5 days of treatment)
- Weigh initial high bacterial burden with higher community risk:
  - Decision to CONTINUE **moderate restrictions (no work)**
  - Moderate RIR: Agreed to limit movement to the home.
    - Very concerned for housing, food, and financial insecurity
  - Contact investigation has not yet been initiated at the site of employment

- Clinical: Decision to dose intensify Rifampin to achieve improved EBA

Weighing relative individual and public health impact

Impact on patient Autonomy, rights, health, economics



Public Health Benefit

How much transmission is expected to be averted?

- Low/moderate level infectiousness
- Moderate/High level of community risk factors

~~Expected~~ impact

- Financial: High
- Housing: High
- Stigma/Social: High
- Food: Low

Determine indication for RIR > 5 days on therapy

Recommendation 3: Determining infectiousness			Recommendation 4: Determining RIR	Recommendation 5: Level of RIR	Notes
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	Low	Lowest (Rec 3.3)		None	

2. May consider initial bacterial burden, adherence and response to treatment when assessing infectiousness
3. Additional restrictions or longer duration may be considered in scenarios of higher-risk community settings, **balancing community well-being and patient impact.**

Day 14: High initial bacterial burden, moderate community risks

- Steps in reevaluation:
  - **Assess infectiousness**: **low** (fourteen days of therapy)
    - Given high pre-treatment bacterial burden, desire for additional certainty about treatment efficacy
    - Micro: remained smear-positive—*Not expected to reliably correlate with infectiousness*
      - *Smear grade declining*
    - Reached out to lab: DST now available—pan-S (molecular)
    - Clinically: cough improving on dose intensified therapy
  - **Assess community risks**: Low/**Moderate**
    - Employment: prolonged (6-8 hours) contact but plan is for a contact investigation
  - **Assess patient harms** as a result of community based RIR: HIGH
    - Did lose employment, experience stigma at workplace
- Decision: Continue moderate restrictions until 14 DOT/vDOT doses, and then discontinue. Wear mask in any crowded areas.

Summary (my annotated take-home points)

- Recommendation 1: Decisions on restrictions and isolation should consider the overall community and individual benefits and harms
- Recommendation 2: Respiratory isolation and restrictions should be conceptualized as a spectrum of tailored interventions
- Recommendation 3: Treatment rapidly reduces infectiousness among PWTB, irrespective of bacteriologic studies (i.e., smear) collected during treatment
- Recommendation 4: Most PWTB can be removed from community based RIR after 5 days of effective treatment, with some exceptions for higher risk scenarios (e.g., very high pre-treatment bacterial burden, and anticipated exposure to vulnerable populations).
- Recommendation 5: Moderate restrictions are appropriate when community based RIR is indicated. PWTB should be offered support to mitigate harms of RIR.

Coming Soon….a series of manuscripts in JID and CID

- Review article on Determinants of Infectiousness (JID)
- Systematic review of the impact of isolation on population and patient outcomes (CID)
- Building an ethics-informed framework for public health guidelines (JID)
  - Presentation: Oxford Global Health and Bioethics International Conference
- Legal considerations for tuberculosis restrictions (JID)
- History of TB isolation practices (JID)

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Guidelines and Commentary: Clinical Infectious Diseases Available as Advance Articles

NTCA Guidelines:
https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciae199

Caitlin Reed Invited Commentary:
https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciae198