



Indiana
Department
of
Health

RESPIRATORY ISOLATION RESTRICTIONS FOR COMMUNITY SETTINGS: UPDATED GUIDANCE

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OUR MISSION:

To promote, protect, and improve the health and safety of all Hoosiers.

OUR VISION:

Every Hoosier reaches optimal health regardless of where they live, learn, work, or play.



Learning Objectives

- Describe factors and conditions that increase/decrease likelihood of transmission of TB
- Review principles and evidence behind new guidance for modifying current isolation guidance
- Understand relationship between initiation of treatment and likelihood of transmission of TB
- Describe “adequate treatment”
- Discuss approaches to applying updated guidance to balance patient wellbeing and public safety

Review of Current Guidance

According to current Indiana Infection Control Measures, to be released from isolation (Smear positive/PCR positive sputa), patient must have all three:

- Three consecutive smear negative sputa
- 14 days of anti-TB meds
- Clinical improvement

Indiana code assigns authority of public health orders to local health officers (home rule).

Factors Related to Infectiousness

Patient Factors:

- Pulmonary or laryngeal disease
- Cavitory disease associated with higher likelihood of transmission
- Cough: More coughing=more likely to infect others
- Sputum AFB burden:
 - Presence of AFB on microscopy=possibility of transmission prior to treatment
 - Higher burden of AFB=higher likelihood of transmission
- Treatment with effective regimen has not been initiated

Environmental Factors:

- Closer proximity
- Poorer ventilation
- Longer duration of exposure
- Congregate settings and other situations that include high risk individuals

Why change now?

Goal of isolation is to prevent/reduce transmission of TB in a community.

PWTB bears all the burden of restrictions to potentially benefit community. This can cause harm to PWTB (financial, social stigma, mental health, family).

Harm vs. benefit: How many TB infections do Isolation restrictions prevent? Does this benefit the community? At what cost to PWTB?

Is there a way to protect the community and minimize or eliminate harm to PWTB?

Why change now?

New body of knowledge shows:

- Once effective regimen is initiated, rRNA synthesis of MTB quickly altered, decreasing pathogenicity within hours to a couple days
- Once an effective regimen has been initiated, potential for transmission rapidly decreases
- Most contacts who convert to TB positive exposed prior to initiation of treatment
- Sputum smears not predictive of infectiousness after treatment started

Conclusion: Once adequate treatment is started, risk of transmission rapidly decreases within hours to a few days.

Adequate Therapy

Adequate therapy must include:

- Reasonable assurance drug resistance is not a factor
 - Rapid molecular DST (pyrosequencing, GeneXpert, etc.)
 - IDOH lab building capacity for this
- Minimum **five days of treatment** with an effective regimen
- Doses given with DOT/eDOT/VDOT
- Doses appropriate for patient weight
- Doses tolerated
- Clinical improvement
- Assumption of no ongoing exposure

Respiratory Isolation Restrictions

Levels of RIR:

- Extensive, Moderate, None
- Levels can be used interchangeably in different situations
- Level of RIR should be regularly reassessed and changes made accordingly
- Sputum results no longer used as benchmark to determine infectiousness and make RIR decisions
- Local health officer has final discretion on RIR decisions. IDOH and patient's physician may be consulted

When to Consider Extending Precautions

Patient Factors:

- High AFB burden pre-treatment
- Cavitory lesions
- Cough
- Severe immunosuppression
- Malabsorption
- Poor or delayed clinical response
- Lack of molecular DST

Settings:

- Crowding
- Poor ventilation
- Public spaces (e.g., public transportation)
- High-risk settings

Contacts:

- Immunosuppressed contacts
- Children <5 years old

Extensive RIR

- Patient remains in one location (home).
- High-risk persons or PWTB may be rehoused to a different location
- Other persons who live with PWTB may be able to remain in the home
- No visitors to location
- PWTB only leaves location for emergency medical care/TB related appointments. Non-urgent care should be rescheduled
- Five days of “adequate therapy” before this might be discontinued
- May be combined with other levels of RIR depending on circumstance
- May be extended if concern for transmission remains
- Regularly reassess need for appropriate level of RIR

Moderate RIR

- Recognition that there could be some risk of transmission in certain circumstances
- Measures targeted to specific concern
- May be combined with other levels of RIR depending on circumstance
- Regularly reassess need for appropriate level of RIR
- Might include:
 - Masking of PWTB and/or others
 - Arranging for encounters in outdoor/very well-ventilated areas
 - Exclusion of high-risk persons or exclusion of PWTB from high-risk settings/situations
 - Other measures targeted to specific concerns

None-No Restrictions

- Risk of transmission of TB to others has been deemed minimal to none
- No infection control measures needed
- May be combined with other levels of RIR depending on circumstance
- Regularly reassess need for appropriate level of RIR

What happens after 5 days?

Generally, for pulmonary/laryngeal TB, Extensive RIR measures are in place for the first five days of treatment.

Once all criteria for “adequate therapy” have been met for 5 days:

- Assess patient progress-general improvement? Cough? Delayed response to treatment?
- Consider other factors associated with infectiousness (cavitation on chest imaging, immunosuppression, etc.)
- Drug resistance?
- Assess for high-risk circumstances/persons in patient’s life (work in healthcare, congregate or other high-risk setting? Spending time around high-risk persons?)
- Determine appropriate level of restriction needed to minimize transmission
- Determine if infection control measures can be used to decrease risk, targeting specific concerns

Scenario 1

Martha has a productive cough, pain in chest and weight loss. Her CXR has LUL opacity. Sputum is collected with results of 1-10 AFB/slide x3, PCR positive for MTB. She is diagnosed with Pulmonary TB.

She lives at home with her husband and teenage children. Martha works as a CNA at a skilled nursing facility.

Are RIR measures appropriate for Martha? What level?

What other pieces of information do you need to assess appropriate measures?

- Rapid molecular drug sensitivity information?
- Has Martha started treatment?
- How many days has she been on treatment?
- Is she tolerating meds?
- Appropriate doses/DOT?
- Is she experiencing clinical improvement?

Scenario 1 (con't.)

Martha begins taking RIPE on July 1. She is tolerating her medications. The dosages are appropriate for her weight. She is consistent with DOT. By July 5, the fifth day of treatment, her cough is noticeably improved and she is feeling better overall.

Can her RIR status be reassessed?

What information do you need?

On July 7, the lab reports pyrosequencing (inhA, katG and rpoB) results showing "No mutations."

How should her level of RIR be addressed?

- Release from RIR for "normal" activities.
- When can she return to work?
- Refer to heartland "Guidance on Release from Hospital Tuberculosis Isolation."

Scenario 2

Gwen has had an enlarged lymph node on her neck for the last four months. Six weeks ago, she had a biopsy and culture of the lymph node. The culture results are now positive for MTB. Gwen has had some night sweats and mild fatigue for six or seven weeks, but no respiratory symptoms. Her CXR is clear.

Is RIR appropriate for Gwen? Why?

Scenario 3

Claude has just been diagnosed with pulmonary TB. His sputum Xpert test results showed: MTB detected, RIF resistance not detected. His CXR has bilateral infiltrates and mild hilar adenopathy, but no cavitation. He is coughing, having chest pain and shortness of breath and night sweats.

Claude starts taking RIPE by DOT on July 1. He is consistent with weight appropriate doses of DOT and tolerating meds well.

Claude works as a self-employed landscaper. He has a partner who is with him every day, riding in the same vehicle from one home to another. The partner is an adult with no health concerns.

Claude is asking if he can continue to work, even before he completes 5 days of treatment. He states that if he does not continue to work, he will lose both pay and regular customers.

What level of RIR is appropriate? Is it reasonable to accommodate his work request? What mitigating measures can make this a safe option?

Scenario 4

Michael has become progressively ill over the last eight months. His CXR shows cavitary lesions bilaterally in upper lobes along with nodular opacities in LLL. He is experiencing productive cough, hemoptysis, 40-pound weight loss, poor appetite, fever/chills, night sweats, fatigue and chest pain. His QFT is indeterminate. His HIV is negative. He has a history of polysubstance abuse, incarceration, hepatitis C and type 1 diabetes. Sputum is collected and shows AFB > 50/field, PCR positive, cultures pending. He is started on RIPE on June 1. He is agreeable to **Extensive RIR** at a local motel, since he has a 3-year-old son at home.

June 3 : Michael reports severe nausea and vomiting x1 overnight. He denies abdominal pain and denies other signs of hepatotoxicity. After discussing with his physician, LFTs are collected but meds are continued pending those results.

June 4: His liver enzymes are within acceptable limits. He reports no new or worsening symptoms of hepatotoxicity. He states he has not vomited since the previous visit. Meds are continued. He states the night sweats have lessened slightly, but he has not noticed any improvement in fatigue, appetite, chest pain or cough.

Scenario 4 (cont.)

June 5: Day five since treatment started. Michael's pyro results are available, showing mutation detected on both inhA and katG; rpoB result is "no mutation detected". INH is discontinued, and Levofloxacin is added to his regimen starting today. You contact Michael's wife. She and the son have had TSTs. Her TST is positive and she is asymptomatic. The son has a negative TST and is asymptomatic. They have CXRs scheduled for later today.

Michael is eager to return home and is asking when he can leave the motel and rejoin his family.

You tell him he needs to remain at the hotel for now utilizing Extensive RIR measures for now. What are your reasons?

- Due to possible INH resistance and change in regimen, day five becomes first day on probable effective regimen
- Cavitation and high-grade AFB on sputa
- Minimal clinical improvement, particularly with cough
- High-risk person at home, not on appropriate treatment

How long do you anticipate he may need to stay in Extensive RIR?

Scenario 4 (cont.)

June 6: Michael reports vomiting 30 minutes after yesterday's DOT visit. He states he is still fatigued, but his temp has been below 100 degrees since June 4. His night sweats are greatly decreased. He states he has less chest pain. You notice he is still coughing as much as usual during your DOT visit.

June 7 and 8: He has not had any more vomiting. And reports no night sweats, fever/chills and you note a decrease in his cough. His wife and son have had CXRs, both "normal." His wife has an appointment with her PCP June 9 to fully rule out TB Disease and prescribe LTBI treatment. His son saw the pediatrician June 8 and INH was prescribed for window prophylaxis.

What do you need to do today?

June 9: His son's prescription was changed to RIF due to probable INH-resistance. The med should be available to start tomorrow. Michael is starting to feel much better and you note he is coughing a lot less. He states he is "going crazy being trapped in this motel." He would like to take a walk outside each day. Is this a reasonable accommodation? What precautions should be taken?

June 10: Michael continues to show clinical improvement and is tolerating his new regimen well. His son started taking RIF window prophylaxis today. His wife was able to pick up her prescription yesterday.

Scenario 4 (cont.)

June 11: Michael has been on his new regimen for seven days today. He continues to tolerate his meds and has enjoyed his walks. He is really missing his wife and son. Michael's wife reports her son misses his dad and is acting out at home. Michael is wondering if they can visit him at the park across the street from his motel. What precautions can make this possible?

June 12: Michael is doing well with his meds and feeling stronger each day. His wife has been bringing a home cooked meal to the park for him to eat at the motel and this has lifted his spirits, but he is anxious to get home.

June 13: Today Michael takes his 14th day of meds total. You arrive for DOT early in the morning just as he is waking up. You have him to collect one sample during your visit. You instruct him to collect one at bedtime and another one first thing in the morning tomorrow. You ship the first sputum sample to the lab.

June 14: Michael continues to do well and you ship the two remaining sputa.

June 15: Sputa results are back. 1) < 10 AFB/field; 2) 1-10 AFB/field; 3) < 1 AFB/field. Michael is tolerating meds well and feeling better each day.

Scenario 4 (cont.)

What level of RIR is appropriate for Michael now?

- Can Michael return home with his 3-year-old son?
- Can Michael resume other routine activities such as grocery shopping?
- Michael would like to go to his brother's wedding. It is an outdoor wedding at a friend's home. What information do you need to make recommendations to balance risk vs. harm?
- Michael volunteers as a soccer coach on the weekends. How soon can he resume this?
- Michael's sister just had twins and he would like to visit his sister and the babies. What do you recommend?

Role of Sputum Collection

- Sputum clearance ("smear negative sputa x3") is not necessarily predictive of risk of transmission but can provide general idea of patient progress
- Has appropriate use in determining lifting restrictions related to high-risk scenarios
- Culture conversion still important factor in determining length of treatment

Final thoughts

- Can be challenging shifting from “hard and fast” rules to “guidance”
- Flexibility allows for creative problem solving that serves PWTB better than concrete rules
- Balancing harm vs. benefit using common sense and compassion
- Local Health Officer makes final decisions about public health orders and actions including RIR
- IDOH Team available for discussions about situations where there are questions about what is the best thing to do

Fact Sheet/Quick Guide

- Quick reference guide available on the IDOH TB Care & Prevention team's website
- Can be found under isolation guidance on the local health department page



Should respiratory isolation restrictions (RIR) be used?

RIR should be used for patients with infectious TB. RIR is NOT appropriate for non-infectious TB.

What level of RIR should be used?

Least restrictive level of RIR should always be used. Always discuss with patient and base on individual considerations.

When should RIR be reassessed?

Specific RIR levels and duration of restrictions should be reassessed routinely (at least weekly) and may be modified based on individual considerations and changing circumstances.

When should RIR be discontinued?

RIR may be discontinued if patient has been on *effective therapy* for at least five days with certain exceptions.

Transmission Risk Factors:

- Pulmonary or laryngeal disease
- Cough
- Sputum AFB grade
- Cavitary disease
- Treatment not started
- Ventilation/proximity
- Presence of high-risk contacts

RIR Levels

Extensive RIR: Most restrictive level. Patient remains at location without high-risk persons. When patient leaves the primary site of RIR (such as for a healthcare visit), additional measures to reduce TB transmission risk may be warranted, including but not limited to, personal protective equipment (for close contacts, face masks for the PWTB, and efforts for improved ventilation. Visitors not living in the residence should be avoided.

Moderate RIR: Tailored restrictions targeted at specific concerns. Patient spends majority of time at an agreed-upon location, such as a home or residence. Patient may leave the location for most outdoor activities and some indoor activities deemed essential, as determined through discussion with public health department officials.

None: Patients have no restrictions and may engage in daily activities as usual, irrespective of setting or potential contacts.

Effective Therapy

- Multidrug regimen (i.e. RIPE) with appropriate dosages for patient weight
- Tolerating medications
- Doses given via Directly Observed Therapy (DOT)
- Reasonable assurance drug resistance is not a concern
- Clinical improvement noted

Guidance applies to community settings only. Do not use for healthcare, congregate or other high-risk settings.

Questions?

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