Indiana Department of Health

TB, CI, & LTBI – Oh My!

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Learning Objectives

- Understand the role of a Local Health Department (LHD)/Public Health Nurse (PHN) in case managing patients with tuberculosis (TB) and latent tuberculosis infection (LTBI)
- Understand the basics of conducting a TB contact investigation

Initial Notification (Initial Report)

- Receive the notification from one of the following sources:
  - Phone call from hospital/provider
  - Morbidity report in The National Electronic Disease Surveillance System (NEDSS) Base System (NBS)
  - Report of TB (State Form 10458) (faxed/secure e-mailed/mailed to LHD)
  - Essence alert
  - Interjurisdictional notification
  - Referrals for Class B examination, LTBIs, contact investigation

Example Patient Notification

REPORT OF TUBERCULOSIS
State Form 14058 (R11 / 5-23)
INDIANA DEPARTMENT OF HEALTH

This form contains confidential information per 410 IAC 1-2.5-78.

Submit form via NBS or fax completed form to Indiana Department of Health at (317) 233-7747.
Telephone: (317) 233-7434

TB Law: Every suspected and verified case of tuberculosis disease must be reported to the local health officer or health department within one (1) working day in accordance with 410 IAC 1-2.5.

1. **Patient name** *(Last, First, Middle Initial)*: Lunes, Domingo
2. **Address** *(number and street)*: 100 Main St.
   City: Goshen ZIP code: 46526
   County: Elkhart Telephone: (555) 111-2222
3. **Date of birth**: 01 - 10 - 1985 4. **At time of report**: ☑ Alive ☐ Dead
5. **Sex at birth**: ☑ Male ☐ Female
   If female, was individual pregnant at time of evaluation? ☐ Yes ☐ No
6. **Race** *(Check all that apply.)*
   ☐ American Indian or Alaska Native ☐ Asian *(specify)* _____
   ☐ Black or African-American ☐ Native Hawaiian or other Pacific Islander *(specify)* _____
   ☑ White ☐ Other Race *(specify)* _____
7. **Ethnicity**: ☑ Hispanic or Latino ☐ Not Hispanic or Latino
8. **Born in the United States?** ☐ Yes ☑ No
   If "No," country of birth: El Salvador
   Date arrived in the U.S. *(month, date, year)*: 01 - 01 - 2005
9. **Country of usual residence**: USA
10. **Lived outside of the United States for >2 months uninterrupted?** ☑ Yes ☐ No
    If yes, list countries: El Salvador
11. **Pediatric TB patients (<15 years old)**
    Country of birth for primary guardian(s) *(specify)*
    Guardian 1 _____
    Guardian 2 _____

FOR LOCAL HEALTH DEPARTMENT USE ONLY

Date local health department notified of TB Suspect / TB Case _____ *(month, day, year)*
Reported by _____ Telephone _____

FOR ALL NON-LOCAL HEALTH DEPARTMENT USE ONLY

Reported by: _____
Agency: _____
Telephone: _____
Attending Physician: _____
Telephone: _____

12. **Initial reason evaluated for TB disease** *(Select one.)*
    ☐ Contact investigation Name of case _____
    ☐ Screening
    ☑ TB symptoms
    ☐ Other _____

13. **Previous diagnosis of TB disease and/or Latent TB Infection?**

	TB Disease	Latent TB Infection
Previous diagnosis	☐ Yes ☑ No	☑ Yes ☐ No
Year of diagnosis		2005
Completed treatment?	☐ Yes ☐ No ☐ Unknown	☐ Yes ☑ No ☐ Unknown
Length of treatment		

Patient Name: Domingo Lunes

14. **HIV status at time of diagnosis** *(Select one.)*
    Date of HIV Test *(month, day, year)*: 04/10/2023
    ☐ Positive ☐ Indeterminate ☐ Refused
    ☑ Negative ☐ Pending ☐ Not Offered
    If HIV-Positive, was a CD4 Count test performed? ☐ Yes ☐ No
    Date collected *(month, day, year)* _____ Result: _____ cells/mm³

15. **Was the patient diabetic at the time of evaluation?** ☑ Yes ☐ No
    If yes, was an A1C test performed? ☑ Yes ☐ No
    Date collected *(month, day, year)*: 04/09/2023 Result: 9.8 %
    If yes, was a Fasting Blood Glucose Test performed? ☑ Yes ☐ No
    Date collected *(month, day, year)*: 04/09/2023 Result: 156 ml/dL

16. **Current smoking or vaping of nicotine products status at time of evaluation?**
    ☐ Current everyday smoker ☐ Current someday smoker
    ☑ Former smoker ☐ Never smoker
    ☐ Smoker, current status unknown

17. **Has the patient ever worked as one of the following?** *(Select all that apply.)*
    ☐ Health care worker ☑ Migrant / seasonal worker
    ☐ Correctional facility worker ☐ None of the above

18. **What is the patient's current occupation?**
    ☐ Health care worker ☐ Migrant / seasonal worker
    ☐ Correctional facility worker
    ☑ Other occupation *(specify)*: RV manufacturing
    Place of employment: Keystone Plant 57 Goshen
    ☐ Retired ☐ Unemployed
    ☐ Not seeking employment (e.g., student, homemaker, disabled person)
    ☐ Student School _____

19. **Has the patient been homeless in the past twelve (12) months?**
    ☐ Yes ☑ No
    If yes, name of facility _____

19a. **Has the patient ever been homeless?** ☐ Yes ☑ No
    If yes, name of facility _____

20. **Was the patient a resident of a correctional facility at time of evaluation?**
    ☐ Yes ☑ No
    If yes, name of facility _____
    Type of facility *(Select one.)*
    ☐ Local jail ☐ State prison ☐ Federal prison ☐ Juvenile correctional facility
    ☐ Other correctional facility

20a. **Was the patient ever a resident of a correctional facility?** ☑ Yes ☐ No
    If yes, name, location, and date *(month, day, year)* of most recent incarceration:
    Elkhart County Jail 03/08/2023

21. **Was the patient a resident of a long-term care facility at time of diagnosis?**
    ☐ Yes ☑ No
    If yes, name of facility _____
    Type of facility *(Select one.)*
    ☐ Nursing home ☐ Residential facility ☐ Alcohol or drug treatment facility
    ☐ Hospital-based facility ☐ Mental health residential facility
    ☐ Other long-term care facility

22. **Additional risk factors** *(select all that apply)*
    ☑ Contact of infectious TB patient (Two (2) years or less) Viernes Sabado
    ☐ End-stage renal disease at evaluation
    ☑ Heavy alcohol use in past twelve (12) months
    ☐ Immunocompromise (not HIV/AIDS)
    ☐ Injecting drug use in past twelve (12) months
    ☐ Noninjecting drug use in past twelve (12) months
    ☐ Post-organ transplantation
    ☐ TNF-α antagonist therapy
    ☐ Viral hepatitis B ever
    ☐ Viral hepatitis C ever
    ☐ Other *(specify)* _____

Patient Name: Domingo Lunes

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Example Patient Notification, Cont.

23. Inpatient (hospital) during TB workup? ☑ Yes ☐ No
If yes, name of hospital Goshen Hospital

24. Site of disease *(Select all that apply.)*
- ☑ Pulmonary
- ☐ Pleural
- ☐ Lymphatic: cervical
- ☐ Lymphatic: intrathoracic
- ☐ Lymphatic: axillary
- ☐ Lymphatic: other
- ☐ Lymphatic: unknown
- ☐ Laryngeal
- ☐ Bone and/or joint
- ☐ Genitourinary
- ☐ Meningeal
- ☐ Peritoneal
- ☐ Other
- ☐ Site Not Stated

25. Clinical symptoms *(Select all that apply.)*
- ☑ Prolonged productive cough
- ☑ Hemoptysis
- ☑ Chest pain
- ☑ Night sweats
- ☑ Fever
- ☑ Chills
- ☑ Weight loss
- ☑ Other weakness
- ☑ Fatigue
- ☑ Loss of appetite
- ☐ None

Date of onset of symptoms *(month, day, year)* 11/01/2022

26. TB skin test
☐ Positive ☐ Negative ☑ Not done
Date placed *(month, day, year)* _____
Date read *(month, day, year)* _____
Results _____mm

27. Interferon Gamma Release Assay (IGRA) test type
☑ QuantiFERON (QFT)
☑ Positive ☐ Negative ☐ Indeterminate ☐ Not done
☐ T-SPOT
☐ Positive ☐ Negative ☐ Borderline ☐ Invalid ☐ Not done
Date collected *(month, day, year)* 04/09/2023

28. Radiology / Other chest imaging study

Initial chest X-ray
☑ Consistent with TB ☐ Not consistent with TB ☐ Not done
If consistent with TB, evidence of cavity? ☑ Yes ☐ No
If consistent with TB, evidence of miliary TB? ☐ Yes ☑ No
Date of chest X-ray *(month, day, year)* 04/09/2023
Previous chest X-ray Date *(month, day, year)* 08/04/2020

Initial chest CT scan or other imaging study
☑ Consistent with TB ☐ Not consistent with TB ☐ Not done
If consistent with TB, evidence of cavity? ☑ Yes ☐ No
If consistent with TB, evidence of miliary TB? ☐ Yes ☑ No
Date of CT / other imaging *(month, day, year)* 04/09/2023
Previous CT / other imaging Date *(month, day, year)* _____

29. Laboratory performing testing
☐ Indiana Department of Health Lab
☑ Other lab *(specify)* Labcorp

30. Sputum smear *(Select one.)*
☑ Positive ☐ Negative ☐ Not done ☐ Pending
Date of collection *(month, day, year)* 04/09/2023

31. Sputum culture *(Select one.)*
☐ Positive ☐ Negative ☐ Not done ☑ Pending
Date of collection *(month, day, year)* _____

Patient Name Domingo Lunes

32. Nucleic Acid Amplification Test results *(Select one.)*
☑ Positive ☐ Negative ☐ Indeterminate ☐ Not done ☐ Pending
Date of collection *(month, day, year)* 04/09/2023
Specimen type ☑ Sputum
If not sputum, specify type of specimen _____

33. Smear / Pathology / Cytology of Tissue and other body fluids *(Select one.)*
☐ Positive ☑ Negative ☐ Not done ☐ Pending
Date of collection *(month, day, year)* 04/09/2023
Type of exam *(Select all that apply.)* ☐ Smear ☐ Pathology/Cytology
Specify type of specimen BAL

34. Culture of tissue and other body fluids *(Select one.)*
☐ Positive ☐ Negative ☐ Not done ☑ Pending
Date of collection *(month, day, year)* 04/09/2023
Specify type of specimen BAL

35. Initial drug regimen

☑ Isoniazid	Dose	250	Frequency	QD
☑ Rifampin	Dose	600	Frequency	QD
☑ Pyrazinamide	Dose	1000	Frequency	QD
☑ Ethambutol	Dose	800	Frequency	QD
☑ Vitamin B6	Dose	50	Frequency	QD
☐ Other *(specify)*				

36. Patient's current weight 110 pounds / 2.2 = 50 Kg

37. Date therapy started *(month, day, year)* 4/11/2023

Notes:
Works at Keystone finishing RV interiors, 8 persons in his work group
Lives at home with wife, 3 children, his parents, sister and sister's child
Held at Jail for one week in March (one month before hospitalization)
Preferred language Spanish, wife fluent in English.

Patient Name Domingo Lunes

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What do I do first? And when?

Review and decide on urgency within one working day

- Jurisdiction?
- Is this TB or LTBI?
- Who reported it?
- Why is the patient being evaluated for TB?
- Symptoms?
- Are the relevant labs attached?
- Chest imaging?
- Other relevant documents (progress notes, ID consult, etc.)?
- Has the patient been started on meds yet?
- Inpatient, at home or other (congregate setting, etc.)?
- Other notable risk factors or circumstances?

Contact Provider

- Contact the medical care provider within one working day of receipt of report
  - Establish rapport
  - Inform the provider about the case manager's roles/responsibilities and those of the local health department
  - Educate the provider about TB program services and oversight responsibility
  - Share resources – we can help!
- Request additional information
  - If a Report of TB (State Form 10458) is not initially provided, request this document from the reporting source. If the wrong form is initially submitted, request completion of the correct form.

Clinical Data Gathering

Collect medical documentation

- Sputum or other acid-fast bacteria (AFB) results (AFB/NAAT/Culture)
- Radiography (chest radiography (CXR), computed tomography (CT), other)
- Interferon Gamma Release Assay (IGRA) and/or tuberculin skin test (TST)
  - Keep in mind that a negative result does not on its own rule out TB
- Other lab tests
  - Examples: CD4 count, A1c, liver panel, etc.
- Hospital (if applicable) documentation
  - Examples: Infectious disease provider consultation notes, medication administration records (MARs), progress notes, er notes, etc.

Coordination with Hospital/Provider

In-patient

- Continuity of care is essential to successful TB treatment
- TB patient's local health department should be involved in discharge planning
- See Tuberculosis Hospital Discharge Planning Checklist for recommendations of items to be addressed before patient is discharged

Out-patient

- Individuals can be diagnosed with TB as out-patients
- Coordination primarily with provider

Isolation Guidance

- Generally, persons with pulmonary TB are isolated until they are deemed no longer infectious
- Persons with extrapulmonary TB only - generally do not need isolation
- Consider site of disease and any aerosolizing procedures or open wounds

Characteristics of a patient with TB disease that are associated with infectiousness

Factor	Description
Clinical	• Presence of cough, especially lasting three weeks or longer • Respiratory tract disease, especially with involvement of the larynx (highly infectious) • Failure to cover the mouth and nose when coughing • Inappropriate or inadequate treatment (e.g., drugs, duration)
Procedure	Undergoing cough-inducing or aerosol-generating procedures (e.g, bronchoscopy, sputum induction, administration of aerosolized medications)
Radiographic and laboratory	• Cavitation on chest radiograph • Positive culture for *M. tb* • Positive acid-fast bacilli (AFB) sputum smear result

Source: CDC Core Curriculum on Tuberculosis: What the Clinician Should Know, 7th edition, 2021

Environmental Factors that Enhance the Probability that *M. tb* will be Transmitted

Factor	Description
Concentration of infectious droplet nuclei	The more droplet nuclei in the air, the more probable that *M. tb* will be transmitted
Space	Exposure in small, enclosed spaces
Ventilation	Inadequate local or general ventilation that results in insufficient dilution or removal of infectious droplet nuclei
Air circulation	Recirculation of air containing infectious droplet nuclei
Specimen handling	Improper specimen handling procedures that generate infectious droplet nuclei
Air pressure	Lack of negative air pressure in infectious patient's room that causes *M. tb* organisms to flow to other areas

Source: CDC Core Curriculum on Tuberculosis: What the Clinician Should Know, 7th edition, 2021

Proximity & Exposure Factors that can Affect Transmission of *M. tb*

Factor	Description
Duration of exposure to infectious person	The longer the duration of exposure, the higher the risk for transmission
Frequency of exposure to infectious person	The more frequent the exposure, the higher the risk for transmission
Physical proximity to infectious person	The closer the physical proximity, the higher the risk for transmission

Source: CDC Core Curriculum on Tuberculosis: What the Clinician Should Know, 7th edition, 2021

Factors Associated with Infectiousness*

Factor Associated with Less Infectiousness	Factors Associated with More Infectiousness
No cough	Presence of a cough
No cavity in the lung	Cavity in the lung
No acid-fast bacilli (AFB) on sputum smear	Acid-fast bacilli (AFB) on sputum smear
Most extrapulmonary (non-pulmonary) TB disease	TB disease of the lungs, airway, or larynx
Receiving adequate treatment for 2 weeks or longer	Not receiving adequate treatment
Not undergoing cough-inducing procedures	Undergoing cough-inducing procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medications)
Negative sputum cultures	Positive sputum cultures

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*Infectiousness depends on a variety of factors. Clinicians should consider all these factors when determining whether a person with TB should be considered infectious.

Source: CDC Core Curriculum on Tuberculosis: What the Clinician Should Know, 7th edition, 2021

Isolation Guidance

- Heartland TB Center Guidance on Release from Hospital Tuberculosis Isolation

Guidance on Release from Hospital Tuberculosis Isolation[a]

Diagnostics:	Clinical Impression:	Under Airborne Isolation (AII) and discharging to:	Patient must meet all criteria:
Sputum **AFB Smear Positive** ***AND*** **NAAT Positive**	Active TB Disease	**Home—No** high risk individuals or individuals without prior exposure	• Follow-up plan has been made with local TB program and DOT has been arranged[b] • Started on standard TB treatment • All household members, who are not immunocompromised, have been previously exposed to the person with TB • Patient is willing to not travel outside the home until negative sputum smear results are received • No infants or children younger than 5 years of age or persons with immunocompromising conditions are present in the household who have not been evaluated and started on appropriate treatment
		Home—WITH high risk individuals OR **High-Risk/Congregate Setting**	Patients with infectious TB should NOT be allowed to return to a setting with high risk individuals. The patient can be *discharged* and is considered non-infectious if: • Three consecutive negative sputum smears from sputum collected in 8 - 24 hour intervals (at least one early morning specimen) ***AND*** • Started on drug regimen and tolerating for AT LEAST 2 weeks or longer ***AND*** • Symptoms have improved
Sputum **AFB Smear Negative** (or No Sputum AFB Smear Done) ***AND*** **NAAT Positive**	High likelihood of TB	**Home**—with/without high risk individuals OR **High-Risk/Congregate Setting**	• Three consecutive negative sputum smears from sputum collected in 8 to 24 hour intervals (at least one early morning specimen) • Started on standard TB treatment and tolerating for AT LEAST 5 days • A plan has been made to follow-up on culture results • No infants or children younger than 5 years of age or persons with immunocompromising conditions are present in the household who have not been evaluated and started on appropriate treatment
Sputum **AFB Smear Negative** ***AND*** **NAAT Negative**	High likelihood of TB	**Home**—with/without high risk individuals OR **High-Risk/Congregate Setting**	

AFB *- Acid-fast bacilli* ***AII*** *- airborne infection isolation* ***DOT*** *- Directly Observed Therapy* ***DST*** *- Drug Susceptibility Testing* ***MDDR*** *- Molecular Detection of Drug Resistance* ***MDR*** *- Multi-drug resistant* ***NAAT*** *- Nucleic Acid Amplification Test* ***TB*** *- Tuberculosis* ***XDR*** *- Extensively-drug resistant*

[a]Pulmonary Tuberculosis

[b]The hospital and/or treating clinician should contact the local health department prior to release of a patient with confirmed active TB disease.

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Isolation Locations

Acceptable Locations

- Home (no children under 5 or immunosuppressed adults)
- Negative air pressure rooms (Hospitals/Congregate Facilities)
- Motels (outward facing doors without shared ventilation)

Not Acceptable Locations

- Anywhere with young children (<5 years old) or immunosuppressed adults
- Jails/prisons (unless in negative pressure)
- Hotels
- LTC/assisted living (unless in negative pressure)
- Dorm rooms
- Group homes/shelters/treatment centers

Isolation Considerations

- Infectious patients must remain in isolation until the health department and clinician determine that isolation is no longer needed
  - Clinical visits for TB-related or other urgent medical concerns can be allowed with proper precautions and masking
- Public health nurses (PHNs) - wear fit tested N-95s when meeting with patients during the isolation period
  - Consider any additional personal protective equipment (PPE) needs for patient interview, directly observed therapy (DOT), etc.

Release from Isolation

- TB patients can be considered noninfectious when they meet all of the following three criteria:
  - They have three consecutive negative AFB sputum smears collected in 8- to 24-hour intervals (at least one being an early morning specimen).
  - Their symptoms have improved clinically (e.g., decreased frequency of cough, resolution of fever, weight gain, etc.).
  - They have received adequate treatment for two weeks* or longer.

* Criteria for smear positive TB

Isolation Letters

- Notice of isolation letter
  - To alert patient & potentially a workplace that the individual needs to remain in isolation for a period of time
- Release from isolation letter
  - To advise that a patient's period of isolation has ended
- Working with workplaces
  - Communication with a workplace may be needed via an isolation letter to advise that an individual needs to follow isolation protocols for a period of time due to a public health order
    - Don't need to mention specific condition – i.e. TB

Initial Patient Interview

Make initial contact with patient within one working day of report

Visit may be in hospital or at patient's home. Use appropriate PPE!

- Allow plenty of time, consider patient condition
  - May need to break up visit, information collection over a couple of visits depending on patient condition
  - Prioritize patient and family education, Isolation/DOT agreement and initial contact information
- Patient's chief concerns guide order of discussion topics
- Establish rapport
- Explain role of public health nurses, other staff involved in care
- Plan home visit if not already completed
  - Assess/discuss the home environment to determine suitability
  - Space, ventilation, presence of high-risk persons, safety concerns

*** Use your judgment regarding weekends/holidays, etc.**

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Initial Patient Interview

- Provide an overview of the TB treatment plan
  - Include discussion of medication side effects
  - Explain directly observed therapy (DOT), introduction of eDOT/VDOT
  - Anticipated length of treatment
- Patient and family education
  - Printed information in preferred language, language interpreter
- Collect information not included in provider notes
  - TB Investigation items: risk factors, preferred language, housing status, etc.
- Begin to collect information for contact investigation
- Discuss isolation, when isolation can be discontinued

Initial Patient Interview/Patient Education

Forms:

- LHD likely has a Consent to Treat/HIPAA forms
  - Consult manager/LHD attorney
  - This is NOT an IDOH form
- Isolation Agreement
- DOT Agreement
- VDOT/eDOT Agreement
- Consider use of a TB suspect/case management worksheet
  - Not an official form, only for taking notes
  - Not to be attached in NBS

Documenting a TB Investigation in NBS

- Open a Tuberculosis Investigation in NBS
  1) the patient has a positive PCR for MTB complex and/or a positive culture for MTB complex, **and/or**
  2) the patient has been started or will be starting RIPE or HPMZ therapy
- Variables within TB Investigation
  - Focus on Patient & Tuberculosis tab
  - Do not mark as “Unknown” if item is pending
  - Do not use “Unknown” if information can be obtained
  - Preferable to mark an item as “Not Done” vs. leaving blank
  - RNCs/TB Program can help when unsure how to answer items

Variables in NBS TB Investigation (Tuberculosis tab)

Complete as many investigation variables in NBS within one week as possible

- Reason for Evaluation
- Risk Factors
- TST/IGRA
- HIV
- Imaging
- Symptoms and Onset Date
- AFB labs (smear, culture, NAAT, cytology/path report)
- Initial Treatment Information
  - "Standard Therapy"/"Mark Rest No" buttons
  - Drugs/dosages
  - Patient weight

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IDOH will complete Reporting Information and Follow Up 1

Documenting a TB Investigation in NBS, Cont.

- Case Notes in NBS
  - Notes of importance documenting overall progress of investigation
  - Way for state partners to know how case is progressing, any challenges and changes
- Attachments
  - Please label clearly and separate documents
  - Should include Monthly Reports and DOT logs
  - Can also include documents affecting diagnosis, treatment
  - Chest imaging
  - Relevant visit/progress notes
  - AFB/Culture/NAAT labs
  - DO NOT include documents for contacts to patient (attach those within contact record or their own NBS investigation)

Notification

Notification should be submitted in NBS to officially count a TB case

- Submit when the patient has a positive PCR or culture for MTB *AND* the initial investigation is complete with all required variables
  - See NBS Quick Guide
- Communicate with RNC/TB Program as needed as you prepare notification

Notification is NOT needed for medication approval for TB disease

Notification functions different for LTBI and other communicable diseases

Documenting: NBS vs. LHD Internal Records

- NBS is an electronic disease reporting and case management platform used by IDOH
- LHD Internal Records:
  - Nurses Notes for day-to-day interactions
  - HIPAA Agreement
  - Consent to Treat
  - Isolation Agreement
  - DOT Agreement
  - Consult with LHD management/county attorney

Treatment

- Six months duration for **routine/uncomplicated** pulmonary TB disease
  - **Initial/Intensive phase**: Standard four drug regimen RIPE (INH, RIF, PZA, EMB), for 2 months (8 weeks)
  - **Continuation phase:** Additional 4-7 months (18-31 weeks) with INH and RIF if susceptible strain and evidence of clinical response to initial treatment
- Adjustments often needed based on sensitivity of isolate and medication tolerance of the patient. Treatment of drug resistant strains will depend on resistance pattern detected. Discuss with RNC/TB Program.
- Dosages may need adjusted as patient gains weight
- New 4-month RPT/MOX regimen, but its use has been limited due to drug supply challenges.

Ordering Medications

IDOH works with Purdue Pharmacy to provide TB medications for all TB patients.

- Initial shipment of medications sent overnight
- Subsequent refills shipped on Tuesday/Thursday. Order early to prevent interruptions in treatment
- Pharmacists knowledgeable and can assist with dosages, etc.

How to order:

E-prescribe

- In the electronic medical record (EMR) search for zip code 47907. Purdue University Pharmacy is the only pharmacy in this zip code OR you can search for West Lafayette and search for Purdue.
- In the free text of the script, please include the following:
  - The patient's county of residence – Purdue will send the medications to this local health department
  - The patient's language, if not English
  - The patient's weight

****Please remember you will still need to send a copy of the orders to the local health departments as well so they can administer the medications to the patients once the drugs are received from Purdue****

Directly Observed Therapy (DOT)

DOT is standard of care for ALL patients with TB

- Patient is observed swallowing each dose of TB meds
  - Check the medications before they are taken
  - Ask the patient if they are experiencing any side effects
  - Answer patient questions
- All patients should have in-person DOT for at least the first 14 days, longer in some circumstances
- DOT may be done by PHN or other healthcare personnel (not family)
  - DOT personnel need understanding of side effects, when to call provider

DOT, Cont.

- Patient need should be prioritized over LHD convenience when choosing time/location/modality of DOT
  - Time may change to accommodate various needs (other meds, meals, work hours)
  - Location may change
  - Patient privacy must be considered
- Consider pairing with incentive or enabler as needed

VDOT/eDOT

- VDOT/eDOT is acceptable alternative to in-person DOT if local policies and circumstances allow
- No minimum in-person vs. eDOT/VDOT visit requirement
  - Patient safety and nursing judgement should drive this decision
- Consider patient ability, comfort and preference
- Pros: Less invasive for patient, convenience and flexibility, less time for LHD staff
- Cons: Patient must have device/tech skills, patient must reliably answer eDOT calls, less contact with patient

More frequent in-person visits foster a closer rapport between the patient and LHD staff. This allows for better nurse case management.

eDOT Policies and Protocols

Health departments should develop their own policies and protocols on the use of eDOT with their TB patients.

Examples of inclusion criteria

- Stabilized on treatment for at least 2 weeks and noninfectious
- Motivated patient (as determined by case manager)
- Demonstrated adherence to treatment
- English speaking or ability to effectively communicate with the health care worker
- Drug-susceptible disease
- Converted sputum smear and culture to negative
- No current alcohol or drug use
- Managing physician accepts the eDOT approach
- Proficiency in using a smartphone or other technology
- Able to accurately identify each medication

Examples of exclusion criteria

- Infectious patients
- Adherence issues
- Language barriers
- Multidrug-resistance
- Minors without accompanying adult
- Immunocompromised
- Patient experiences adverse reactions
- Patients at risk for hepatic complications while receiving anti-TB medications
- Patients with disabilities that prevent full participation in eDOT such as hearing or vision disabilities, or physically challenged

Source: CDC Implementing an eDOT Program: A Toolkit for TB Programs

Sample DOT Agreement

Directly Observed Therapy Agreement for Tuberculosis Treatment

Patient Name _____ Date of Birth _____ Home Phone _____
Patient Address _____ Work Phone _____
City _____ ZIP _____ Cell Phone _____
Emergency Contact Person's Name _____ Telephone _____
Health Department _____ Date _____

I _____ **understand and agree that:**
(patient's name)

- ❑ The only way to get well is by taking my tuberculosis (TB) medicine exactly as my nurse or doctor tells me. If my disease goes untreated, there may be serious consequences: my illness may last longer or become more severe, I may spread TB to others, I may develop and spread drug-resistant TB, I may die from TB.
- ❑ I will be taking several medications for a long time (months or more) in order to kill the TB germs.
- ❑ I agree to cooperate with the supervised Directly Observed Therapy (DOT) program to help remind me to take my medicine and to make sure I complete my treatment and get well. In this program, a designated public health employee or a trained DOT worker is authorized as my agent to maintain possession of my medication and to be present when I take my TB medicine.
- ❑ I will participate in the DOT process.
- ❑ I will tell my DOT worker if I have any problems. I may be asked to go to _____ to meet with a doctor or nurse and/or to have tests during my treatment.
- ❑ I know that if I miss my visits and do not take my treatment as scheduled, legal action may be taken.

I, _____ **understand and agree that:**
(Name of Public Health Representative/Title)

- ❑ I will keep the patient's health data private.
- ❑ I will answer questions and concerns of the patient. I will help link the patient to other services as needed.
- ❑ I will promptly tell the doctor and/or nurse of anything out of the ordinary. I will give reports as needed.

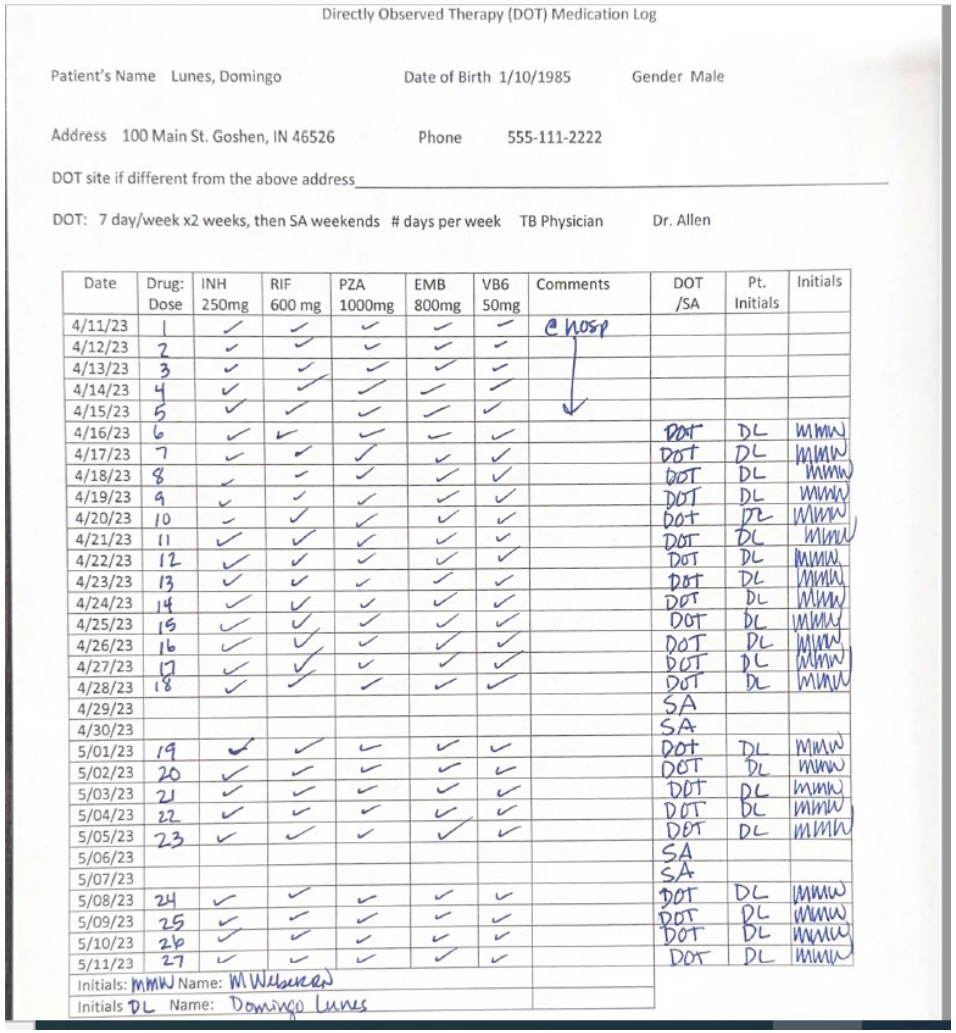
Patient Signature _____ Date _____

Public Health Nurse Signature _____ Date _____

DOT Provider Signature _____ Date _____

Indiana Department of Health

MARs – DOT/Log Record



Directly Observed Therapy (DOT) Medication Log

Patient's Name Lunes, Domingo Date of Birth 1/10/1985 Gender Male

Address 100 Main St. Goshen, IN 46526 Phone 555-111-2222

DOT site if different from the above address_____

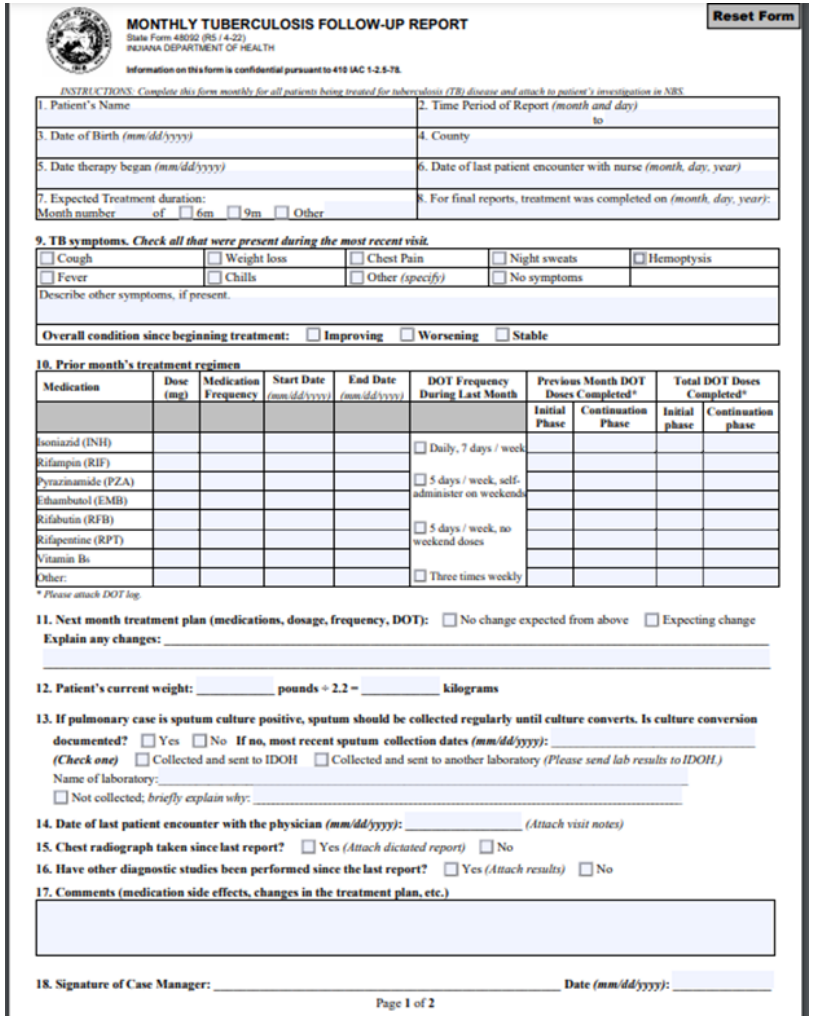
DOT: 7 day/week x2 weeks, then SA weekends # days per week TB Physician Dr. Allen

Date	Drug: Dose	INH 250mg	RIF 600 mg	PZA 1000mg	EMB 800mg	VB6 50mg	Comments	DOT /SA	Pt. Initials	Initials
4/11/23	1	✓	✓	✓	✓	✓	@ hosp			
4/12/23	2	✓	✓	✓	✓	✓				
4/13/23	3	✓	✓	✓	✓	✓				
4/14/23	4	✓	✓	✓	✓	✓				
4/15/23	5	✓	✓	✓	✓	✓				
4/16/23	6	✓	✓	✓	✓	✓		DOT	DL	MMW
4/17/23	7	✓	✓	✓	✓	✓		DOT	DL	MMW
4/18/23	8	✓	✓	✓	✓	✓		DOT	DL	MMW
4/19/23	9	✓	✓	✓	✓	✓		DOT	DL	MMW
4/20/23	10	✓	✓	✓	✓	✓		DOT	DL	MMW
4/21/23	11	✓	✓	✓	✓	✓		DOT	DL	MMW
4/22/23	12	✓	✓	✓	✓	✓		DOT	DL	MMW
4/23/23	13	✓	✓	✓	✓	✓		DOT	DL	MMW
4/24/23	14	✓	✓	✓	✓	✓		DOT	DL	MMW
4/25/23	15	✓	✓	✓	✓	✓		DOT	DL	MMW
4/26/23	16	✓	✓	✓	✓	✓		DOT	DL	MMW
4/27/23	17	✓	✓	✓	✓	✓		DOT	DL	MMW
4/28/23	18	✓	✓	✓	✓	✓		DOT	DL	MMW
4/29/23								SA		
4/30/23								SA		
5/01/23	19	✓	✓	✓	✓	✓		DOT	DL	MMW
5/02/23	20	✓	✓	✓	✓	✓		DOT	DL	MMW
5/03/23	21	✓	✓	✓	✓	✓		DOT	DL	MMW
5/04/23	22	✓	✓	✓	✓	✓		DOT	DL	MMW
5/05/23	23	✓	✓	✓	✓	✓		DOT	DL	MMW
5/06/23								SA		
5/07/23								SA		
5/08/23	24	✓	✓	✓	✓	✓		DOT	DL	MMW
5/09/23	25	✓	✓	✓	✓	✓		DOT	DL	MMW
5/10/23	26	✓	✓	✓	✓	✓		DOT	DL	MMW
5/11/23	27	✓	✓	✓	✓	✓		DOT	DL	MMW

Initials: MMW Name: M Wisneren

Initials DL Name: Domingo Lunes

IDOH Monthly Report Form



MONTHLY TUBERCULOSIS FOLLOW-UP REPORT

Reset Form

State Form 48092 (R5 / 4-22)
INDIANA DEPARTMENT OF HEALTH

Information on this form is confidential pursuant to 410 IAC 1-2.5-7.8.

INSTRUCTIONS: Complete this form monthly for all patients being treated for tuberculosis (TB) disease and attach to patient's investigation in NBS.

1. Patient's Name	2. Time Period of Report *(month and day)* to
3. Date of Birth *(mm/dd/yyyy)*	4. County
5. Date therapy began *(mm/dd/yyyy)*	6. Date of last patient encounter with nurse *(month, day, year)*
7. Expected Treatment duration: Month number ____ of ☐ 6m ☐ 9m ☐ Other	8. For final reports, treatment was completed on *(month, day, year)*:

9. TB symptoms. ***Check all that were present during the most recent visit.***

☐ Cough	☐ Weight loss	☐ Chest Pain	☐ Night sweats	☐ Hemoptysis
☐ Fever	☐ Chills	☐ Other *(specify)*	☐ No symptoms	
Describe other symptoms, if present.				
Overall condition since beginning treatment: ☐ **Improving** ☐ **Worsening** ☐ **Stable**				

10. Prior month's treatment regimen

Medication	Dose (mg)	Medication Frequency	Start Date *(mm/dd/yyyy)*	End Date *(mm/dd/yyyy)*	DOT Frequency During Last Month	Previous Month DOT Doses Completed*		Total DOT Doses Completed*	
						Initial Phase	Continuation Phase	Initial phase	Continuation phase
Isoniazid (INH)					☐ Daily, 7 days / week				
Rifampin (RIF)									
Pyrazinamide (PZA)					☐ 5 days / week, self-administer on weekends				
Ethambutol (EMB)									
Rifabutin (RFB)					☐ 5 days / week, no weekend doses				
Rifapentine (RPT)									
Vitamin B6									
Other:					☐ Three times weekly				

** Please attach DOT log.*

11. Next month treatment plan (medications, dosage, frequency, DOT): ☐ No change expected from above ☐ Expecting change
Explain any changes: _____

12. Patient's current weight: _____ **pounds ÷ 2.2 =** _____ **kilograms**

13. If pulmonary case is sputum culture positive, sputum should be collected regularly until culture converts. Is culture conversion documented? ☐ Yes ☐ No **If no, most recent sputum collection dates** ***(mm/dd/yyyy):*** _____
(Check one) ☐ Collected and sent to IDOH ☐ Collected and sent to another laboratory *(Please send lab results to IDOH.)*
Name of laboratory: _____
☐ Not collected; *briefly explain why:* _____

14. Date of last patient encounter with the physician ***(mm/dd/yyyy):*** _____ *(Attach visit notes)*

15. Chest radiograph taken since last report? ☐ Yes *(Attach dictated report)* ☐ No

16. Have other diagnostic studies been performed since the last report? ☐ Yes *(Attach results)* ☐ No

17. Comments (medication side effects, changes in the treatment plan, etc.)

18. Signature of Case Manager: _____ **Date** ***(mm/dd/yyyy):*** _____

Page 1 of 2

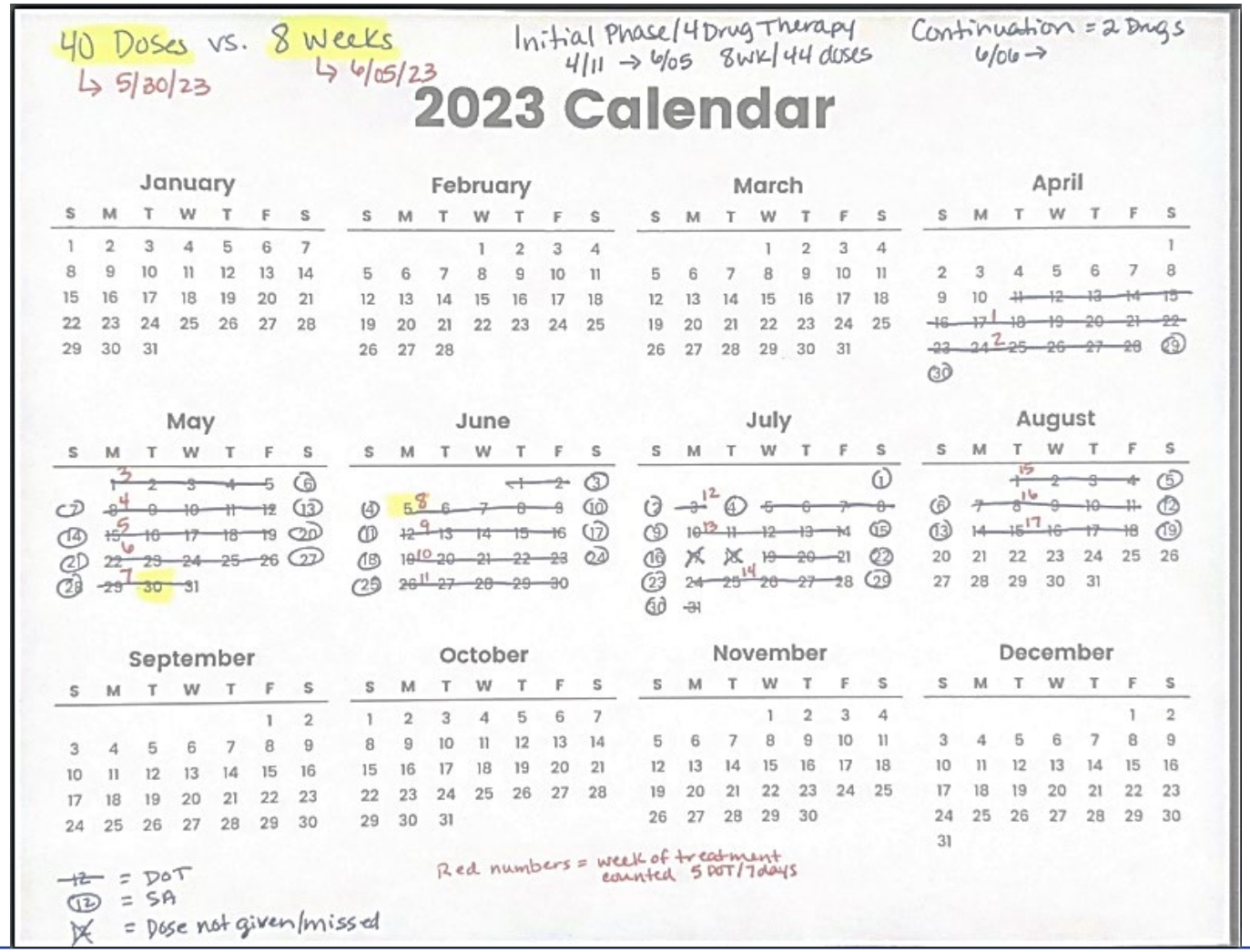
Monthly report & DOT logs are attached in NBS in the TB investigation for RNC to review each month (for those counties with a RNC).

Indiana Department of Health

Counting Doses

- Treatment completion calculated based on weeks of treatment ***and*** number of doses
- For one week to count toward treatment completion, minimum of 5 doses in 7 days must be observed either in-person or electronically
- Self-administered doses are NOT included in counted doses
- For weeks with holidays, a 5th dose should be scheduled on one of the days off
- For questions about counting number of doses/weeks, please consult RNC/TB program

Sample Dose Counting



Sputum Collection

- For diagnostic purposes, all persons suspected of having TB disease at any site should have sputum specimens collected for an AFB smear and culture, even those without respiratory symptoms
- At least three consecutive sputum specimens are needed, each collected in 8- to 24-hour intervals, with at least one being an early morning specimen
- If possible, specimens should be obtained in an airborne infection isolation (AII) room or other isolated, well-ventilated area (e.g., outdoors)

Sputum Collection

- Sputum is coughed up from deep inside the lungs
  - Different than saliva
- Ask the individual to take a very deep breath and hold the air for five seconds. Then, slowly breathe out. Ask them to take another deep breath and cough hard until some sputum comes up into their mouth. Have them spit the sputum into a cup.
- If an individual has trouble coughing up sputum, consider having them try breathing steam from a hot shower or a pan of boiling water
- GTBI Sputum Collection Videos

Sputum Collection/Shipping

- Submit specimens to the IDOH Lab within 24 hours of collection.
  - Specimens should be shipped to arrive at the lab Monday through Friday
  - Shipping specimens which will be in transit during the weekend or over a holiday is not recommended
- Do not hold specimens to batch them with specimens collected on subsequent days.
- Containers can be ordered from LimsNet

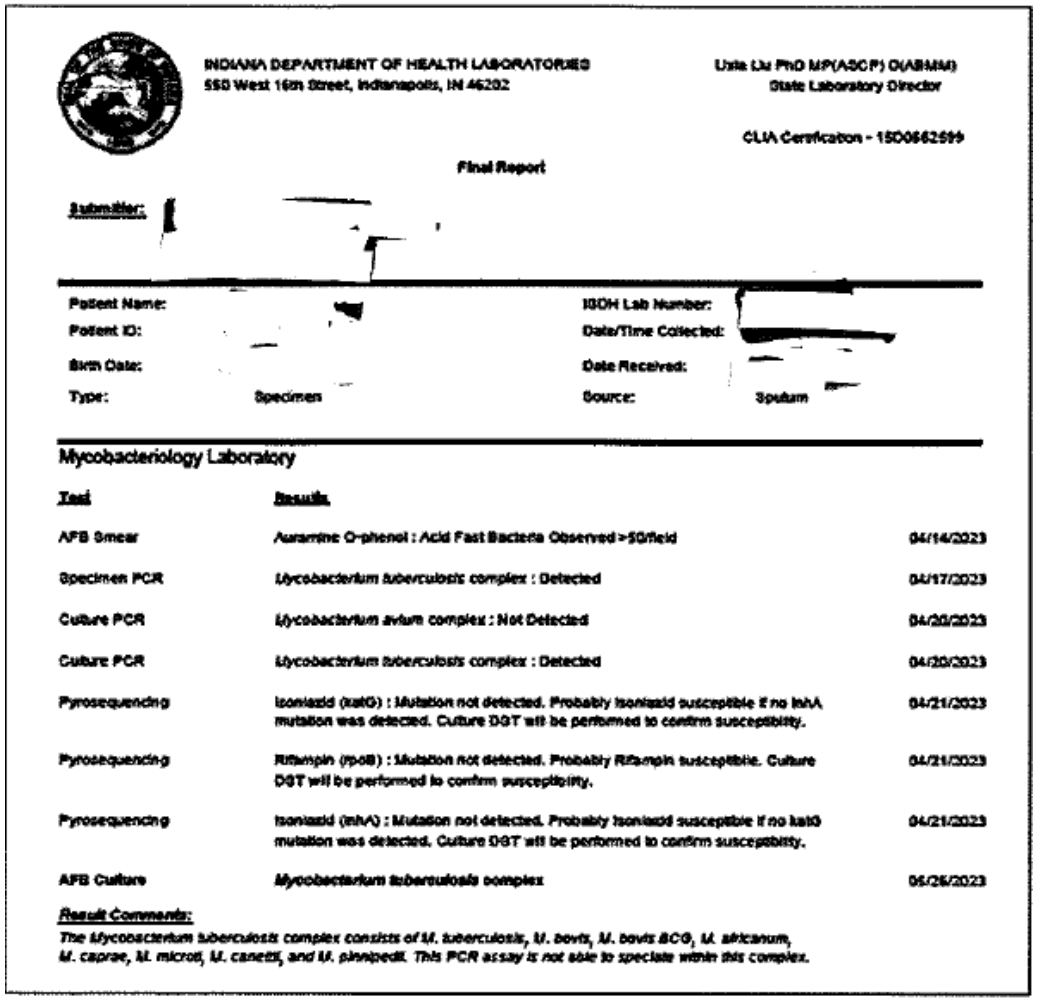
Sputum Monitoring

- For pulmonary TB patients, perform sputum monitoring at least monthly until 2 consecutive sputum cultures become negative.
- IDOH recommends consultation with a TB expert for anyone who is still sputum culture-positive at the end of the initial phase
- Resources
  - APHL Guidelines for Submission of Sputum Specimens for TB Testing
  - IDOH Lab TB Specimen Submission slide deck

Smear versus Culture

- The presence of acid-fast-bacilli (AFB) on a sputum smear (or other specimens for extrapulmonary disease suspicion) often indicates TB disease
- **Acid-fast microscopy** is easy and quick, but it does not confirm a diagnosis of TB because some acid-fast-bacilli are not *M. tuberculosis*
- Therefore, a **culture** is done on all initial samples to confirm the diagnosis
- A positive culture for *M. tuberculosis* confirms the diagnosis of TB disease. Cultures should be completed on all specimens, regardless of AFB smear results
- A positive culture is not always necessary to begin or continue empiric treatment for TB if the clinical suspicion is high based on other factors

Example sputum Smear Result (Limsnet/NBS)



INDIANA DEPARTMENT OF HEALTH LABORATORIES
550 West 16th Street, Indianapolis, IN 46202

Lixia Liu PhD MP(ASCP) DABMM)
State Laboratory Director

CLIA Certification - 15D0662599

Final Report

Submitter: [redacted]

Patient Name: [redacted]
Patient ID:
Birth Date:
Type: Specimen

ISDH Lab Number:
Date/Time Collected:
Date Received:
Source: Sputum

Mycobacteriology Laboratory

Test	Results	
AFB Smear	Auramine O-phenol : Acid Fast Bacteria Observed >50/field	04/14/2023
Specimen PCR	*Mycobacterium tuberculosis complex* : Detected	04/17/2023
Culture PCR	*Mycobacterium avium complex* : Not Detected	04/20/2023
Culture PCR	*Mycobacterium tuberculosis complex* : Detected	04/20/2023
Pyrosequencing	Isoniazid (katG) : Mutation not detected. Probably Isoniazid susceptible if no InhA mutation was detected. Culture DST will be performed to confirm susceptibility.	04/21/2023
Pyrosequencing	Rifampin (rpoB) : Mutation not detected. Probably Rifampin susceptible. Culture DST will be performed to confirm susceptibility.	04/21/2023
Pyrosequencing	Isoniazid (inhA) : Mutation not detected. Probably Isoniazid susceptible if no katG mutation was detected. Culture DST will be performed to confirm susceptibility.	04/21/2023
AFB Culture	*Mycobacterium tuberculosis complex*	05/26/2023

Result Comments:
The Mycobacterium tuberculosis complex consists of M. tuberculosis, M. bovis, M. bovis BCG, M. africanum, M. caprae, M. microti, M. canetti, and M. pinnipedii. This PCR assay is not able to speciate within this complex.

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Culture Conversion

- Sputum culture conversion means that a patient had a positive sputum culture before being treated for TB disease but after starting treatment their sputum culture became negative
- Conversion to culture-negative sputum is an indicator of the patient's response to TB treatment
  - This is important information to help determine the length of treatment

Sensitivities

- For all patients, the initial *M. tuberculosis* isolate should be tested for **routine TB drug sensitivity or resistance**. It is crucial to identify drug resistance as early as possible to ensure effective treatment
- Drug susceptibility patterns may be repeated for patients who do not respond adequately to treatment or who have positive culture results despite three months of therapy
- Initial empiric TB therapy may be based on the drug sensitivity profile of the likely source of TB exposure or based on the country of origin where they were likely exposed

Incentives and Enablers

- Incentives are small rewards given to the patient such as gift cards or food vouchers
- Enablers are anything that helps patients to complete therapy or show up for their DOT appointments
  - Examples of enablers include cab/ride share fare or bus fare
- IDOH will reimburse reasonable incentive and enabler expenses incurred by local health departments
  - Consult with your region's RNC/TB Program to obtain approval for significant incentive and enabler reimbursements before incurring expenses

Social Needs

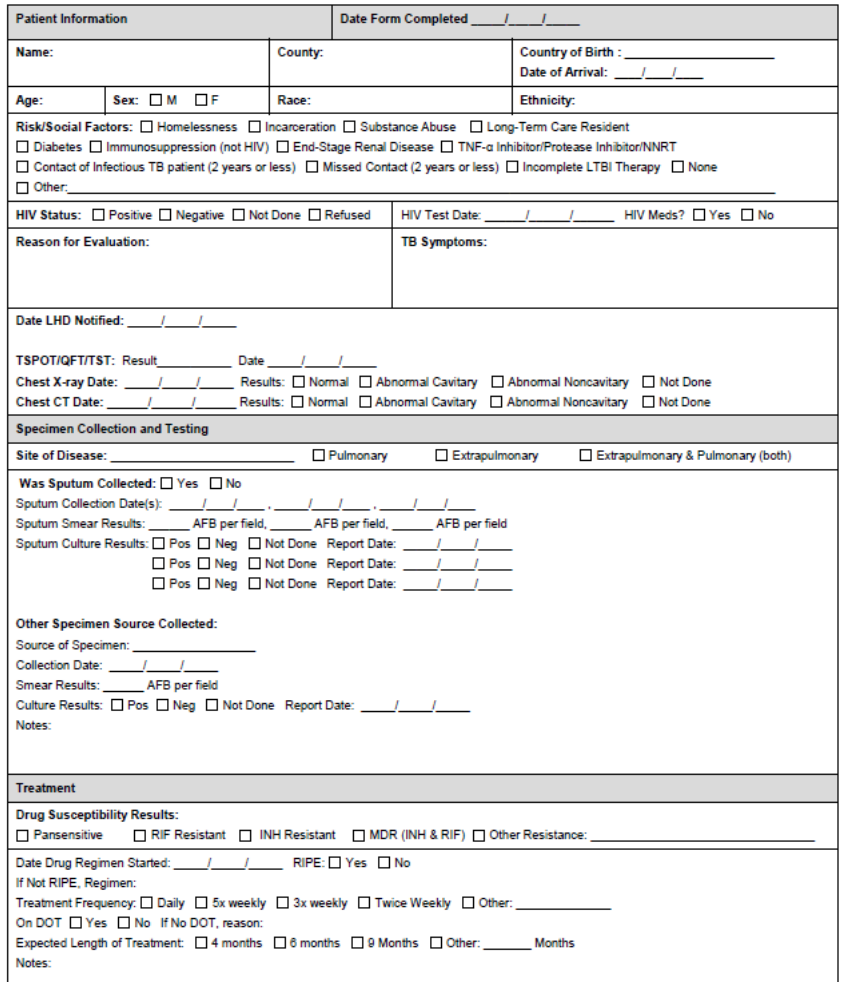
Consider the patient's social needs. Refer the patient to social services or community agencies as needed.

- Housing
- Food
- Transit
- Health insurance
- Income
- Substance use
- Mental health

Cohort Review

- Each TB case or suspect is reviewed at cohort typically four* months after identification

- The Cohort Chart Review form is prepared by the LHD PHN responsible for a TB case or suspect in preparation for the cohort review



Patient Information | **Date Form Completed** ____/____/____

Name: | **County:** | **Country of Birth :** _____ **Date of Arrival:** ___/___/___

Age: | **Sex:** ☐ M ☐ F | **Race:** | **Ethnicity:**

Risk/Social Factors: ☐ Homelessness ☐ Incarceration ☐ Substance Abuse ☐ Long-Term Care Resident
☐ Diabetes ☐ Immunosuppression (not HIV) ☐ End-Stage Renal Disease ☐ TNF-α Inhibitor/Protease Inhibitor/NNRT
☐ Contact of Infectious TB patient (2 years or less) ☐ Missed Contact (2 years or less) ☐ Incomplete LTBI Therapy ☐ None
☐ Other:_____

HIV Status: ☐ Positive ☐ Negative ☐ Not Done ☐ Refused | HIV Test Date: _____/_____/_____ HIV Meds? ☐ Yes ☐ No

Reason for Evaluation: | **TB Symptoms:**

Date LHD Notified: ____/____/____

TSPOT/QFT/TST: Result_____ Date ____/____/____
Chest X-ray Date: ____/____/____ Results: ☐ Normal ☐ Abnormal Cavitary ☐ Abnormal Noncavitary ☐ Not Done
Chest CT Date: ____/____/____ Results: ☐ Normal ☐ Abnormal Cavitary ☐ Abnormal Noncavitary ☐ Not Done

Specimen Collection and Testing

Site of Disease: _____ ☐ Pulmonary ☐ Extrapulmonary ☐ Extrapulmonary & Pulmonary (both)

Was Sputum Collected: ☐ Yes ☐ No
Sputum Collection Date(s): ____/___/___ , ____/___/___ , ____/___/___
Sputum Smear Results: _____ AFB per field, _____ AFB per field, _____ AFB per field
Sputum Culture Results: ☐ Pos ☐ Neg ☐ Not Done Report Date: ____/____/____
☐ Pos ☐ Neg ☐ Not Done Report Date: ____/____/____
☐ Pos ☐ Neg ☐ Not Done Report Date: ____/____/____

Other Specimen Source Collected:
Source of Specimen: _____
Collection Date: ____/____/____
Smear Results: _____ AFB per field
Culture Results: ☐ Pos ☐ Neg ☐ Not Done Report Date: ____/____/____
Notes:

Treatment

Drug Susceptibility Results:
☐ Pansensitive ☐ RIF Resistant ☐ INH Resistant ☐ MDR (INH & RIF) ☐ Other Resistance: _____

Date Drug Regimen Started: ____/____/____ RIPE: ☐ Yes ☐ No
If Not RIPE, Regimen:
Treatment Frequency: ☐ Daily ☐ 5x weekly ☐ 3x weekly ☐ Twice Weekly ☐ Other: _____
On DOT ☐ Yes ☐ No If No DOT, reason:
Expected Length of Treatment: ☐ 4 months ☐ 6 months ☐ 9 Months ☐ Other: _____ Months
Notes:

Indiana Department of Health

* For patients/suspects on the newer RPT/MOX treatment regimen, the cohort review would occur at two months.

Closing a TB Investigation

Do not change the Investigation to CLOSED within NBS

- Once a patient reaches a final outcome, complete the Follow up 2 variables within the TB Investigation:
  - Sputum Culture Conversion Documented (if applicable)
  - Moved Date & Reason Therapy Stopped
  - Type of Outpatient Health Care Provider
  - Directly Observed Therapy (DOT)
  - Final Drug Susceptibility Testing (if applicable)
- Document follow up or add other notes in Supplemental Note tab in NBS
- Email TB RNC/TB Program that the investigation is complete
- Provide treatment completion documents for patient

Preparation

- Things you can do now to prepare for a TB suspect/case
  - Obtain sputum containers from the IDOH Lab via LimsNet
  - Get fit tested for N-95 & order supply of properly sized masks
  - Plan for what to do when notified of a TB suspect/case
    - How/who will manage DOT
    - What is the backup plan when a PHN goes on vacation, is out sick, etc.
    - Prep DOT & Isolation agreements
    - Have a scale accessible
    - Have a list of resources/partnerships established to help meet patient's social needs

Contact Investigations

Indiana Department of Health

Overview

Contact investigations are a fundamental and extremely important strategy for the prevention and control of TB.

The LHD is responsible for assuring that a contact investigation is conducted and that all contacts are appropriately evaluated and treated within recommended timeframes.

Contact Investigations (CIs)….Why?

- To find and treat additional TB disease cases
  - 1% of contacts have TB disease
- To find and treat persons with LTBI to avert future cases
  - 10-20% of all contacts have LTBI
- On average, 15 contacts are identified for each person with infectious TB in the United States

Who are TB Contacts?

Contacts are persons who have shared airspace with a person with infectious TB disease.

These persons may include household members, friends, coworkers, classmates, and others.

Factors to Consider in Index Case

- Site of disease
- Sputum smear & culture results
- Radiographic findings
- Age
- HIV status
- Social characteristics

Factors that Predict Likely Transmission of TB

- Pulmonary, laryngeal, or pleural TB
- AFB positive sputum smear
- Cavitation on chest radiograph
- Adolescent or adult patient
- Frequent coughing, sneezing, singing
- Close social network

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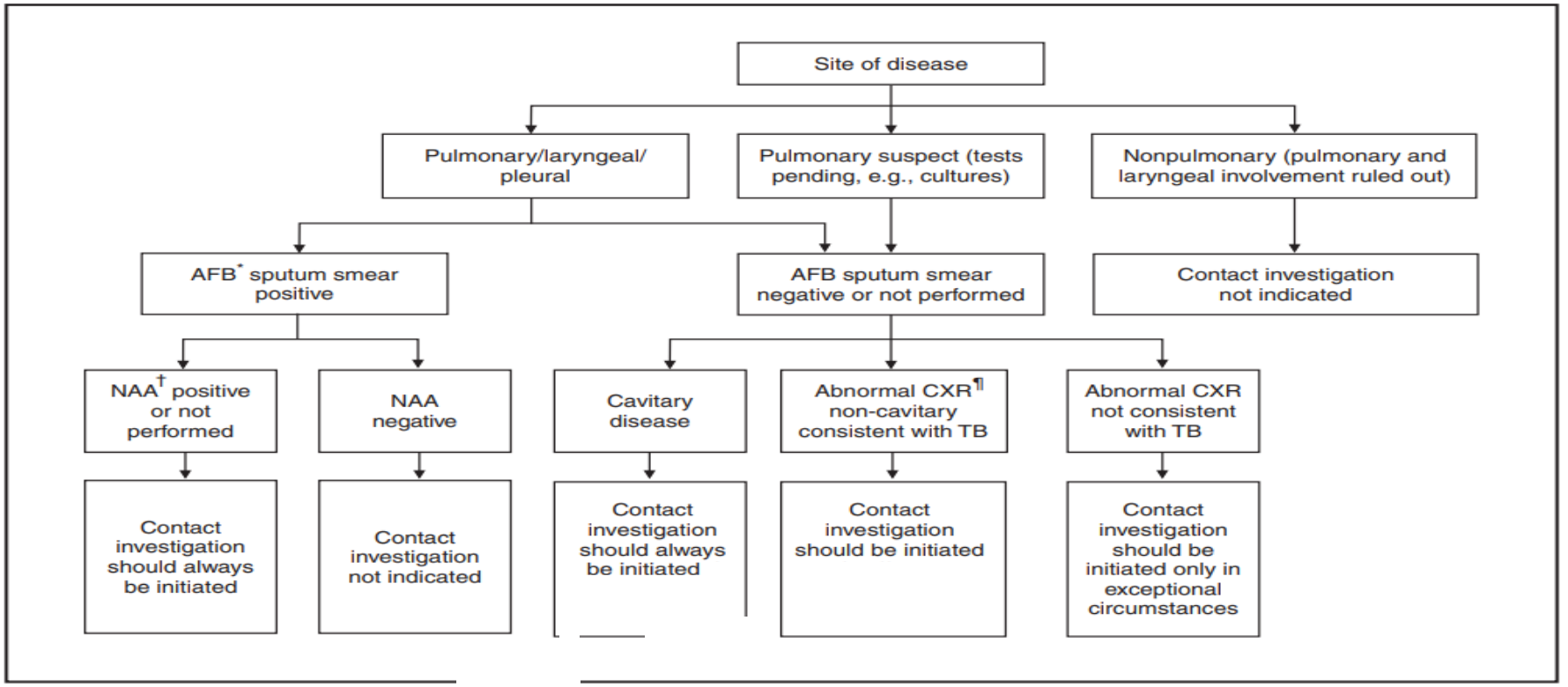
Source: CDC 2005 Contact Investigation Guidelines

Decision to Initiate a TB CI



* Acid-fast bacilli.
† Nucleic acid assay.
§ According to CDC guidelines.
¶ Chest radiograph.

Source: CDC 2005 Contact Investigation Guidelines

Determining the Infectious Period

- Used to identify contacts and determine testing timelines
- Based on onset of symptoms, sputa results, chest imaging
- Start date and end date
- Won’t know end date until patient is no longer considered infectious

Infectious Period Beginning

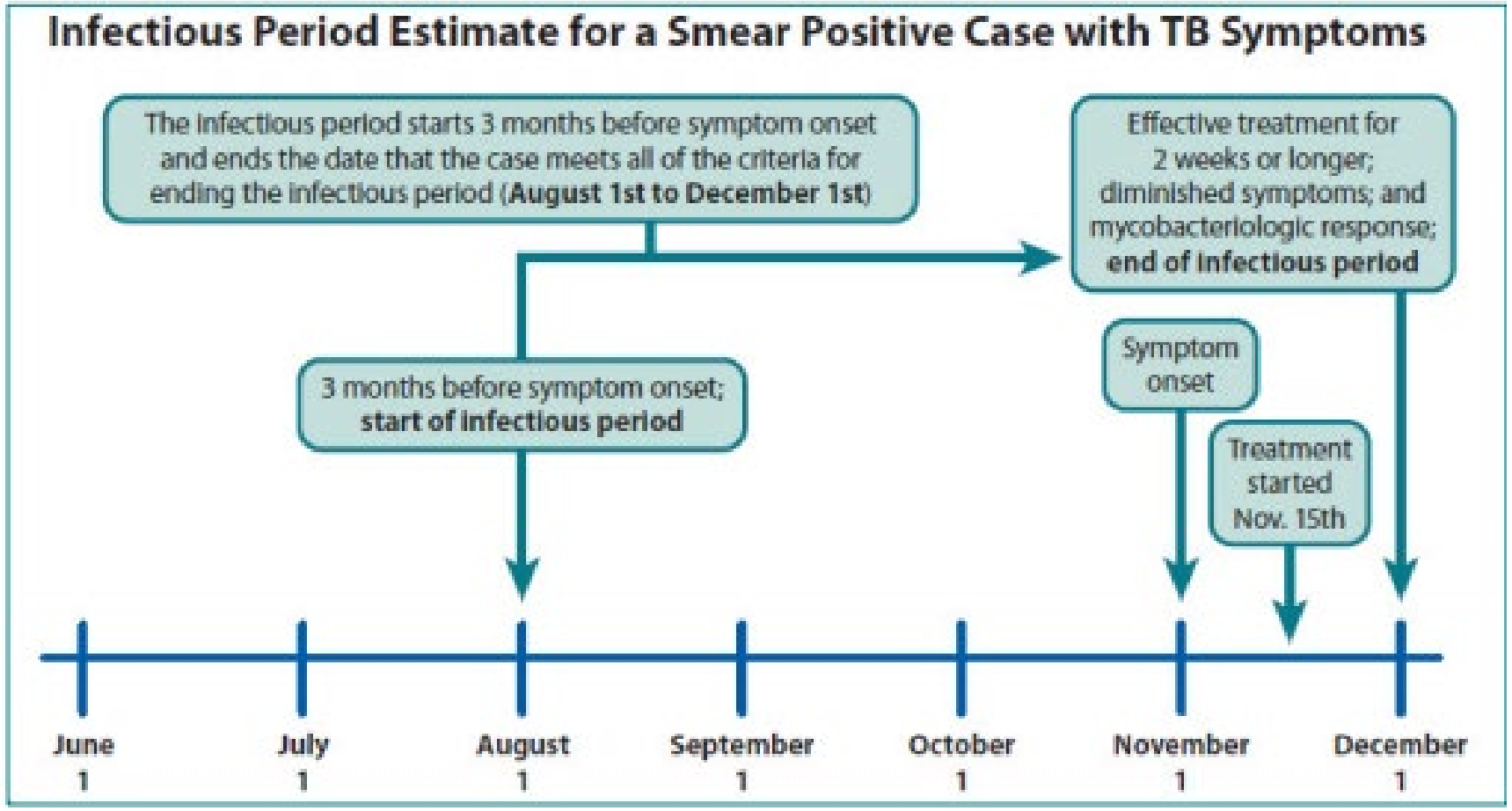
Recommendations for Estimating the Start of the Infectious Period

Characteristic of Case			Recommended Minimum Beginning of the Infectious Period
Respiratory TB Symptoms	Sputum Smear Positive	Pulmonary Cavity on Chest X-ray	
Yes	No	No	3 months before symptom onset or first finding consistent with TB disease, whichever is longer
Yes	Yes	Yes	3 months before symptom onset or first finding consistent with TB disease, whichever is longer
No	No	No	1 month (4 weeks) before date of suspected diagnosis
No	Yes	Yes	3 months before finding consistent with TB disease

Indiana Department of Health

Contact Investigation Guidelines, MMWR, 2005: 54 (No. RR-15): Table 2, p.7

Infectious Period Example



Contact Tracing Interview

- Conduct in patient's primary language or with an interpreter
- In person conversation
  - Hospital, TB clinic, patient's home, other place that accommodates patient's privacy
- Do not delay initiating conversation on contacts
  - Contacts may interpret delay as lack of importance
- Establish trust and rapport with patient, discuss confidentiality
- PHN notifies contacts confidentially
  - Not patient/family's job to notify contacts or explain what/why/when

First Interview

- Confirm known information, including infectiousness timeline
- Records sites of possible transmission
- Record dates/frequency of places of contact
- Gather list of known contacts
  - Stress importance of identification of all contacts
- Consider that an individual may have worked in more than one workplace, etc. during the infectious period
- Resource: GTBI Performance Guidelines for CI: The TB Interview

When?

- Part of Initial Interview
  - One day of notification
  - 3 days for sputum smear negative case
- Re-interview one to two weeks later
  - Confirm information obtained during first visit
  - Follow-up on any new information or questions
  - Obtain ‘remembered’ information
- Ongoing process (not one and done)
  - Keep in mind during discussions with patient and observations in the home during DOT, etc.
    - Ex. Extra pair of shoes in house, pictures in home, toys, etc.
  - As continue to build rapport, patient may feel more comfortable and share more

Possible Questions to Ask

- Who lives with you?
- Does anyone come & stay periodically? (kids, friends, family)
- Does anyone else come in your house regularly? (housekeepers, babysitters, neighbors)
- Where do you work/go to school?
- What is your work organization like?
- Do you have any other jobs?
- How do you get to work/school?
- Do you go to church?
- What do you do for fun?
- Do you go out to eat? Where?
- Are you in any clubs/organizations?
- What did you do for the holidays?
- Have you traveled anywhere for vacation? For work?
- Do you go to a gym?
- Do you have family that lives in the area?
- What healthcare appointments have you had?
- Hair/brow/nail salon/barber shop/massage or other spa services?

Field Investigation General Principles

- Site visit at place of possible transmission
  - Helps understand possible transmission
  - Essential and important step to contact investigation
  - Done even if patient has already been interviewed
  - Lack of site visits has contributed to TB outbreaks
  - Locations visited will depend on the suspect/case
    - Ex: work at a warehouse, hospital, casino, nail salon, etc.

Additional & Proxy Interviews

Proxy

- Used if patient cannot be interviewed or if additional information is needed that cannot be obtained from patient
- People familiar with patient's habits, behaviors, practices
- Consider patient confidentiality
- If unable to interview patient initially, may be able to later

May also need to interview IPs, facility staff, employers, etc. depending on the scenario

Testing & Evaluation of Contacts

All contacts should be tested with IGRA or TST as soon as possible, and again 8+ weeks after last exposure

- "Window period"
- Symptomatic contacts require urgent medical evaluation. Isolation precautions as appropriate.

- Contacts with positive TST/IGRA need CXR and medical evaluation to diagnose LTBI/TB. Follow LTBI/TB treatment protocols.
- Contacts with first round negative TST/IGRA and who are asymptomatic generally do not need CXR, sputum or medical evaluation and may continue their normal activities.
- Second round testing is at least 8 weeks after last contact. If positive on second round test, CXR and medical evaluation will be needed at that time.
- For contacts with ongoing contact (household) may need delayed or ongoing testing

High Risk Contacts

- Immunosuppressed contacts and children under age 5 and at higher risk of developing TB disease
- Prompt evaluation and starting on window prophylaxis is an early priority.
- Window Prophylaxis: Starting on LTBI treatment during “window” (incubation period)
  - TST or IGRA
  - Chest imaging
  - Medical evaluation
  - Consult with RNC/TB Program
- Pediatric testing algorithms vary by age group.

Documentation

NBS Contact Tracing Record

- Note all contacts even those that did not come in for testing
- Contact record
  - Locations and broad information about contacts, including names and test results go into the contact record as opposed to the patient record
- For any contacts noted to have LTBI, create a separate LTBI investigation
- Consider obtaining written documentation from anyone that declines testing

Large CIs

Contact RNC/TB Program to discuss potentially large CIs

- IDOH CI Toolkit
  - Includes Excel document for initial tracking of contacts
- IDOH can provide assistance
  - testing,
  - data tracking
  - media involvement
- Utilization of IDOH lab for IGRAs

Latent TB Infection

Indiana Department of Health

Types of Entities that may send LTBI Reports

- Providers
- Civil Surgeons
- Occupational health departments
- Dermatologists
- Rheumatologists
- Gastroenterologists
- Dialysis Centers
- Universities
- Hospitals

Outreach to Providers

- Raise awareness that LTBI is reportable in the State of Indiana
- Explain how to report LTBI
- Inform that free treatment is available through LHDs

Initial Notification

- Report of LTBI via official state reporting form
- LTBI Investigation in NBS
- Contact Investigation
- Positive IGRA lab report
- Essence alert
- Morbidity report in NBS
  - Could receive a morbidity report that is really supposed to be a NBS LTBI investigation

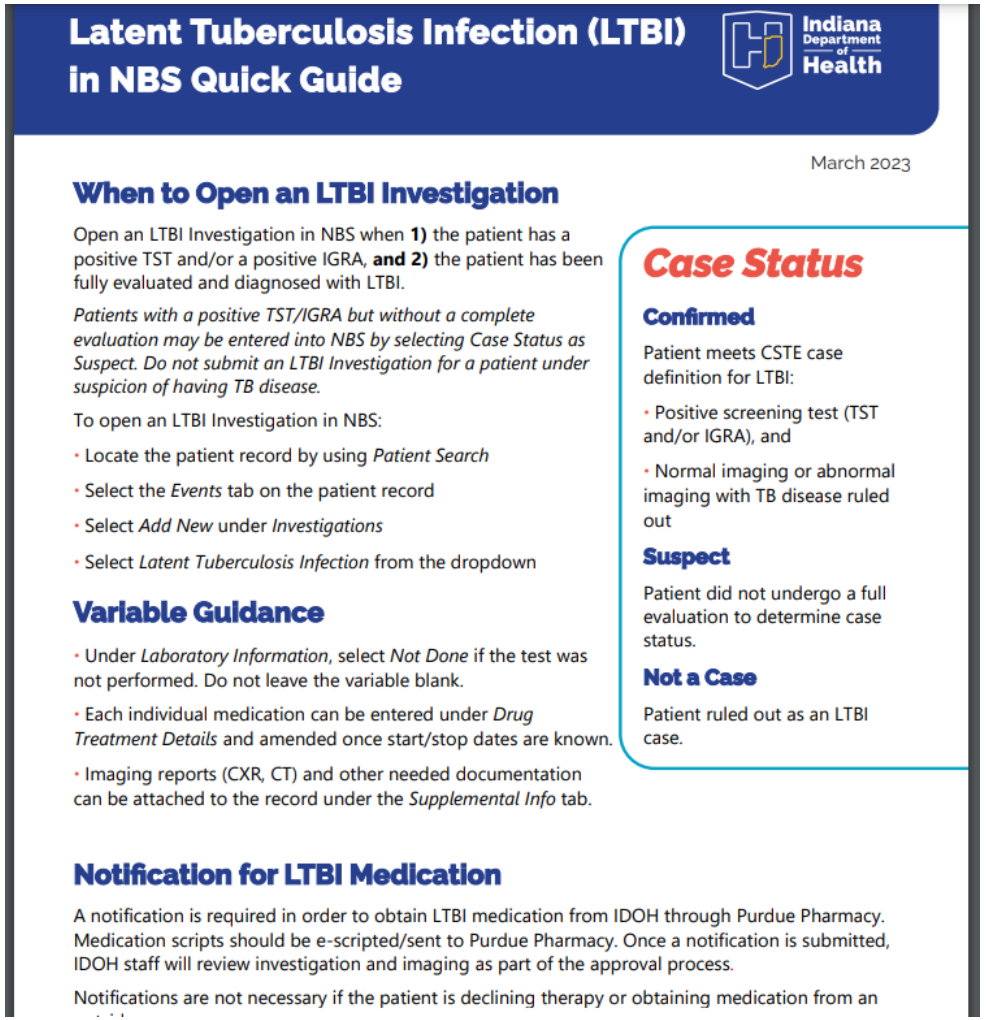
In the case of a positive IGRA report without complete evaluation/diagnosis of LTBI, LHDs can follow up with entities to provide awareness and encourage proper evaluation and treatment of LTBI.

When to Contact a Patient for LTBI

- Confirm with patient that information correct
- Provide patient education on LTBI, rationale for treatment
- Discuss LTBI/treatment options
  - Offer treatment at no cost through Purdue Pharmacy

- If patient declines treatment, add known variables to NBS and note declination of treatment. If patient changes their mind, they can receive treatment in future

LTBI Quick Guide



Latent Tuberculosis Infection (LTBI) in NBS Quick Guide

Indiana Department of Health

March 2023

When to Open an LTBI Investigation

Open an LTBI Investigation in NBS when **1)** the patient has a positive TST and/or a positive IGRA, **and 2)** the patient has been fully evaluated and diagnosed with LTBI.

Patients with a positive TST/IGRA but without a complete evaluation may be entered into NBS by selecting Case Status as Suspect. Do not submit an LTBI Investigation for a patient under suspicion of having TB disease.

To open an LTBI Investigation in NBS:

- Locate the patient record by using *Patient Search*
- Select the *Events* tab on the patient record
- Select *Add New* under *Investigations*
- Select *Latent Tuberculosis Infection* from the dropdown

Variable Guidance

- Under *Laboratory Information*, select *Not Done* if the test was not performed. Do not leave the variable blank.
- Each individual medication can be entered under *Drug Treatment Details* and amended once start/stop dates are known.
- Imaging reports (CXR, CT) and other needed documentation can be attached to the record under the *Supplemental Info* tab.

Case Status

Confirmed

Patient meets CSTE case definition for LTBI:

- Positive screening test (TST and/or IGRA), and
- Normal imaging or abnormal imaging with TB disease ruled out

Suspect

Patient did not undergo a full evaluation to determine case status.

Not a Case

Patient ruled out as an LTBI case.

Notification for LTBI Medication

A notification is required in order to obtain LTBI medication from IDOH through Purdue Pharmacy. Medication scripts should be e-scripted/sent to Purdue Pharmacy. Once a notification is submitted, IDOH staff will review investigation and imaging as part of the approval process.

Notifications are not necessary if the patient is declining therapy or obtaining medication from an

Can be found on website at:

www.tb.in.gov

https://www.in.gov/health/idepd/tuberculosis/training-and-education/tb-nbs-training-materials/#NBS_Training

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Reasons that Individuals may be Screened for LTBI

- Clinical reasons
  - Example: individuals that are going to start a TNF-α antagonist
- Contacts to person with infectious TB
  - Ensure proper documentation of source case and contact record in NBS
- Employment/Administrative testing
- Immigration
- Long-term care residents (upon entry)
- Targeted testing (which can include some of the other categories listed here)
- University students (by situation)

"Incidental" should never be used for Reason for LTBI Evaluation in NBS. TB testing is always done for some reason.

Evaluation

- Evaluate persons with TB symptoms (pulmonary or extra-pulmonary)
  - Collect sputum, more chest imaging, additional follow-up
  - Do not start treatment until the additional follow up is complete
- HIV testing
  - All LTBI patients should be offered HIV testing due to lifetime risk of developing TB disease

NBS Documentation

- Case status
  - Confirmed vs. Suspect vs. Not a Case
- Attach chest imaging to Supplemental Info
  - Imaging must be less than 6 months old to receive treatment

Required Variables for Notification

- Demographics
- Case Status
- Previous TB/LTBI
- Country of Birth
- TB Symptoms
- Imaging (with report file attached)
- TST/IGRA
- Primary Reason Evaluated
- HIV Status
- Risk Factors (as needed to ascertain case status)
- Patient Weight
- Medication Details (Name, MG, Frequency)

LTBI Treatment Regimens

Recommended Treatment Regimens for Latent TB Infection

	DRUG	DURATION & FREQUENCY	MAXIMUM DOSE	OTHER
PREFERRED	Isoniazid (INH)^ and Rifapentine (RPT)^^ (3HP)	Once Weekly for 3 months (12 weeks) Total Doses: 12	Adults and Children 12 years of age and over: **INH:** 15 mg/kg rounded to nearest 50 or 100 mg; 900 mg maximum (max) **RPT:** 10.0 – 14.0 kg; 300 mg 14.1 – 25.0 kg; 450 mg 25.1 – 32.0 kg; 600 mg 32.1 – 49.9 kg; 750 mg ≥ 50.0 kg; 900 mg max Children aged 2-11 years: **INH:** 25 mg/kg; 900 mg max **RPT:** see above	- Completion of therapy is defined as completing at least 11 weekly doses of treatment within 16 weeks. - Doses should be given at least 72 hours apart if weekly scheduled dosing variations occur. - Not recommended for pregnant women or women expecting to become pregnant during the treatment period.
PREFERRED	Rifampin (RIF)+ (4R)	Daily for 4 Months Total Doses: 120	Adults: 10 mg/kg; 600 mg max Children: 15-20 mg/kg*; 600 mg max	- Completion of therapy is defined as 120 daily doses within 6 months
PREFERRED	Isoniazid^ and Rifampin+ (3HR)	Daily for 3 Months Total Doses: 90	Adults: **INH:** 5 mg/kg; 300 mg max **RIF:** 10 mg/kg; 600 mg max Children: **INH:** 10-20 mg/kg*; 300 mg max **RIF:** 15-20 mg/kg; 600 mg max	- Completion of therapy is defined as 90 daily doses within 4 months
ALTERNATE	Isoniazid^ (6H/9H)	Daily for 6 Months (Total Doses: 180) **OR** Daily for 9 Months (Total Doses: 270)	Adults: 5 mg/kg; 300 mg max Children: 10-20 mg/kg#; 300 mg max	- Completion of therapy for the 6-month regimen is defined as 180 doses within 9 months. - Completion of therapy for the 9-month regimen is defined as 270 doses within 12 months.
ALTERNATE	Isoniazid^ (6H/9H)	Twice Weekly for 6 Months (Total Doses: 52) OR Twice Weekly for 9 Months (Total Doses: 76)	Adults: 15 mg/kg; 900 mg max Children: 20-40 mg/kg#; 900 mg max	- Directly Observed Preventative Therapy (DOPT) must be used for twice-weekly therapy. - Completion of therapy for the 6-month regimen is defined as 52 twice-weekly doses within 9 months. - Completion of therapy for the 9-month regimen is defined as 76 twice-weekly doses within 12 months.

^ INH is formulated as 100-mg and 300-mg tablets. INH liquid is commercially available but is not well tolerated by many children and is not generally recommended.

^^ RPT is formulated as 150-mg tablets in blister packs that should be kept sealed until use.

+RIF is formulated as 150-mg and 300-mg capsules.

Note 1: Directly-Observed Preventative Therapy (DOPT) is recommended for window prophylaxis treatment (see Note 2). DOPT should be considered for people who are at especially high risk for TB disease or who may have difficulty with treatment adherence. Decisions as to whether to use DOPT should be made on a case-by-case basis. Please consult with the regional nurse consultant as needed.

Note 2: Children younger than 5 years old and immunocompromised people exposed to someone with infectious TB, for whom TB disease has been ruled out, should be placed on LTBI treatment while waiting for post-exposure testing. This is called window prophylaxis treatment. Criteria for discontinuing window prophylaxis treatment can be viewed at http://www.cdc.gov/tb

Note 3: All treatment must be modified if the patient is a contact of an individual with drug-resistant TB disease. Consultation with a TB expert is advised if the known source of TB infection has drug-resistant TB.

Note 4: For people living with HIV/AIDS, please visit http://aidsinfo.nih.gov to view latest guidelines. Some rifamycins should not be taken with certain antiretrovirals. Consult with a TB expert or pharmacist if necessary.

Note 5: Pyridoxine (vitamin B6), 25-50 mg/day is given with isoniazid containing regimens such as 6H, 9H, and 3HR and at 50 mg/week with 3HP to people with risk factors for neuropathy (e.g., pregnant women, breastfeeding infants, individuals living with HIV, people with diabetes, alcoholism, malnutrition, or chronic renal failure, or people of advanced age) to prevent neuropathy. For people who develop peripheral neuropathy, experts recommend increasing pyridoxine dose to 100 mg/day.

*The American Academy of Pediatrics acknowledges that some experts use rifampin at 20-30 mg/kg for the daily regimen when prescribing for infants and toddlers (Source: American Academy of Pediatrics. Tuberculosis. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. Red Book: 2018 Report of the Committee on Infectious Diseases. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:829–53).

#The American Academy of Pediatrics recommends an INH dosage of 10–15 mg/kg for the daily regimen and 20–30 mg/kg for the twice weekly regimen.

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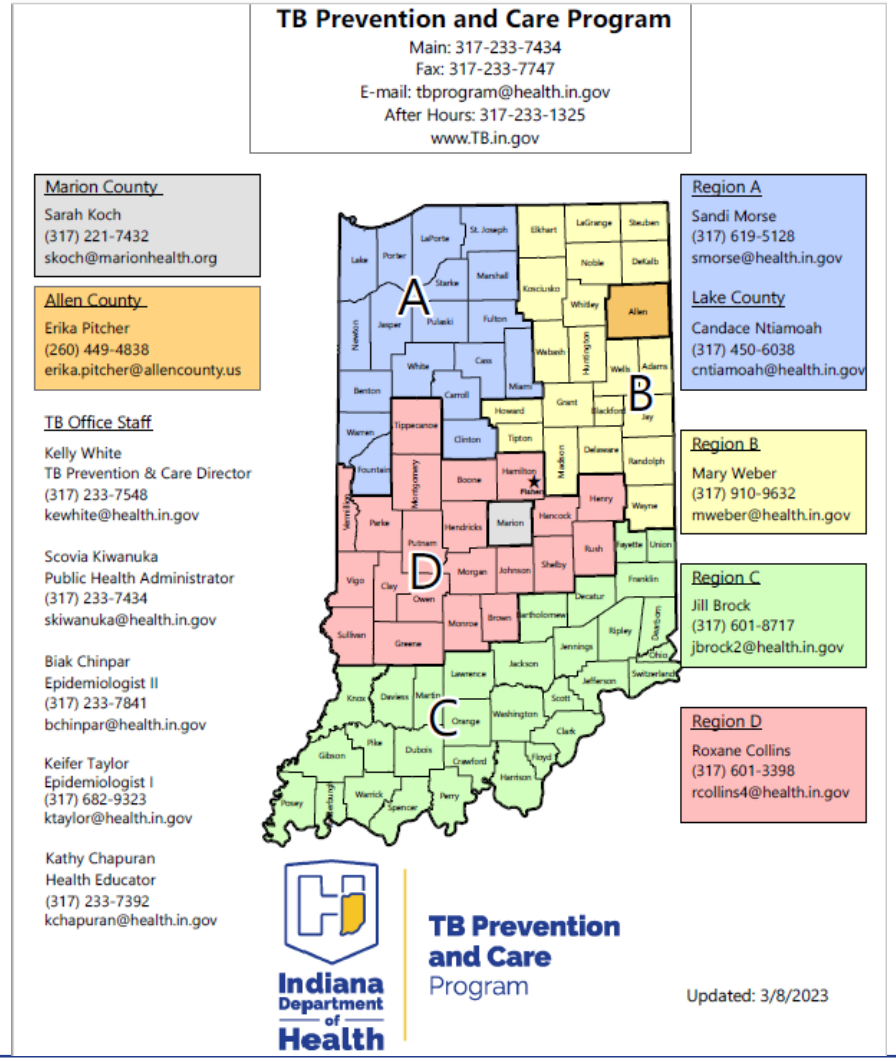
Obtaining LTBI Treatment

- Notification required for patients requesting meds from Purdue University Pharmacy
  - Include required variables and copy of chest imaging
- For counties with RNCs, they will approve medication orders in NBS when variables are complete and notification submitted
- If LTBI treatment is ordered through an alternative method (i.e. local pharmacy), treatment information still needs to be entered into NBS. **Does NOT require notification**
- Refills can be ordered early to prevent interruptions in treatment. Refills ship on Tuesday/Thursday for orders received by noon the day before

Closing a LTBI Investigation

- When patient reaches final outcome, complete the following variables in NBS:
  - Date Therapy Stopped (if applicable)
  - Reason Therapy Stopped or Never Started
  - Complete Overall Therapy section on Therapy page
- Provide patient with treatment completion document and instruct to not have testing in the future
- Ensure Case Status variable is up-to-date
- Change Investigation Status to closed
- Do NOT submit a notification for case closure (notification is used only for obtaining medications in LTBI investigations)

TB Program Regions



TB Resources

- IDOH TB Prevention & Care website (www.TB.in.gov):
  - General TB information
  - Quick guides/webinar recording on using NBS
  - TB/LTBI reporting forms
  - Indiana data
- CDC TB website (www.CDC.gov/TB):
  - TB educational materials & translated patient materials
  - TB guidelines
  - Infection control
  - National TB data

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Contact Information

TB Prevention & Care Program
317-233-7434
tbprogram@health.in.gov
www.tb.in.gov

Additional Resources

- HIPAA and Public Health Letter
- HIPPA Exemption
- IDOH Communicable Disease Reporting
- IDOH TB & LTBI NBS Training Materials
- IDOH LHD Materials
- GTBI Sputum Collection Videos