WA State MDR/XDR TB Workgroup 2012-2013

DOH 343-117 December 2014

Background

In 2012, the Local Health Jurisdiction (LHJ) Business Meeting was introduced for the first time at the Annual State Meeting. During this portion of the meeting, LHJs were encouraged to discuss TB related issues they feel were needed to be addressed in Washington State. Through this discussion it was determined that a statewide plan for managing drug resistant TB cases was needed.

All LHJs were invited to participate on a state-wide Multidrug-Resistant Tuberculosis – Extensively Drug-Resistant Tuberculosis (MDR/XDR TB) workgroup. The intent of the workgroup was to develop standard policy and procedures regarding logistics involved in effectively managing MDR/XDR TB patients and minimizing the risk of transmission. After the first workgroup call, three sub-workgroups were formed to focus on technical assistance, housing/isolation logistics, and financial logistics.

Outcomes

The technical assistance sub-workgroup implemented the Washington State MDR/XDR Technical Assistance Service. This service provides case consultation from a panel of TB experts. The consultation includes ongoing written treatment, isolation, and other case management recommendations.

The housing/isolation sub-workgroup created guidelines for isolating persons with MDR/XDR TB. The guidelines include pre-planning recommendations, information on working with the patient, and logistical requirements to consider when isolating an infectious person. These guidelines are a tool for assuring that the health of the public is protected while providing the infectious patient with adequate care.

The financial logistics sub-workgroup explored several options for paying for medical care for persons diagnosed with MDR/XDR TB. A policy development brief was written and presented to the Washington State Association of Local Public Health Officials (WSALPHO). WSALPHO will present the policy development brief to the legislature.

Acknowledgments

The following persons were active members of the WA State MDR/XDR workgroup:
Alice Simmons, Chris Spitters, Craig Colombel, Dave Park, David Miller, Diana Yu, Dorothy Gibson, Gary Goldbaum, Joseph Aharchi, Julie Tomaro, Kathy Lofy, Lara Strick, Lois Swenson, Masa Narita, Matthew Rollosson, Scott Lindquist, Shawn McBrien, Sheanne Allen, Sherry Carlson, Temple Parsons, and Tim McDonald.
Sincere appreciation is extended to all members for their hard work and time devoted to this workgroup!

Table of Contents

Washington State MDR/XDR Technical Assistance Service

Drug-resistant TB comprises a small percentage of Washington State TB cases, but requires lengthy and toxic drug regimens that require expertise not found in every LHJ. MDR-TB, is defined as Mycobacterium tuberculosis that is resistant to at least isoniazid and rifampin XDR-TB is defined as Mycobacterium tuberculosis that is resistant to isoniazid and rifampin (MDR) in addition to resistance to any of the fluoroquinolones and at least one of three injectable second line agents (kanamycin, amikacin, or capreomycin).

Due to higher morbidity and mortality, extended duration of therapy, high cost of treatment, and overall complexity associated with MDR/XDR TB cases, LHJ's face greater challenges with the management of MDR/XDR TB than with drug-sensitive disease. Washington State has implemented a Technical Assistance Service to assist LHJ's with case management of drug-resistant tuberculosis. This will be accomplished through a panel that provides experience with managing MDR/XDR TB cases, access to timely drug susceptibility testing and second line drug procurement and the ability to minimize other case management challenges. The prompt identification and successful treatment of drug-resistant TB cases can be facilitated by this technical assistance.

The Washington State MDR/XDR technical assistance service provides consultation on the following types of cases:

- Patients who have been diagnosed with MDR/XDR TB by either conventional drug susceptibility test or a molecular test for drug resistance.
- Patients who are currently on MDR/XDR TB treatment and have moved into Washington from another state or country.
- Patients who are thought to have MDR-TB because they are a close contact to an MDR/XDR TB case, but a clinical specimen for drug susceptibility testing was not available (e.g. child contact to an MDR/XDR TB case).

Objectives

1. Determine isolation requirements for 100% of all MDR/XDR patients including when to allow patients out of isolation. This includes recommendations for school and work.
2. Determination of appropriate treatment facility for 100% of all MDR/XDR patients.
    a. Hospital versus non hospital clinical setting.
3. Appropriate clinical and case management of all MDR/XDR TB cases.
    a. 100% will be on DOT at least 5 days/week for the duration of treatment.
    b. 100% will have HIV status documented.
    c. 100% will have a local case manager assigned for the duration of treatment.
4. Timely culture conversion, regular toxicity monitoring, and treatment completion.
    a. 80% will culture convert within 4 months of MDR-TB treatment start.
    b. 100% will have at least 80% of recommended toxicity monitoring completed.

    c. 85% will have a successful treatment outcome
5. Appropriate contact investigations for all infectious, pulmonary cases, including contact evaluation and treatment recommendations.
    a. 90% of infectious, pulmonary cases will have at least 1 contact identified.
    b. 85% of contacts will be fully evaluated to include TB screening, testing, radiographs, diagnostic labs and treatment recommendations.
    c. Completion of treatment will be measured.

MDR/XDR Technical Assistance Service panel composition

The service panel is comprised of physicians with clinical experience treating drug resistant TB. Each case will have at minimum 2 physicians with clinical and public health expertise on the panel. In addition, there is a Washington State TB nurse consultant, a Washington State Public Health lab representative, and a LHJ representative from the county of the patient's residence.

Case Consultation Process

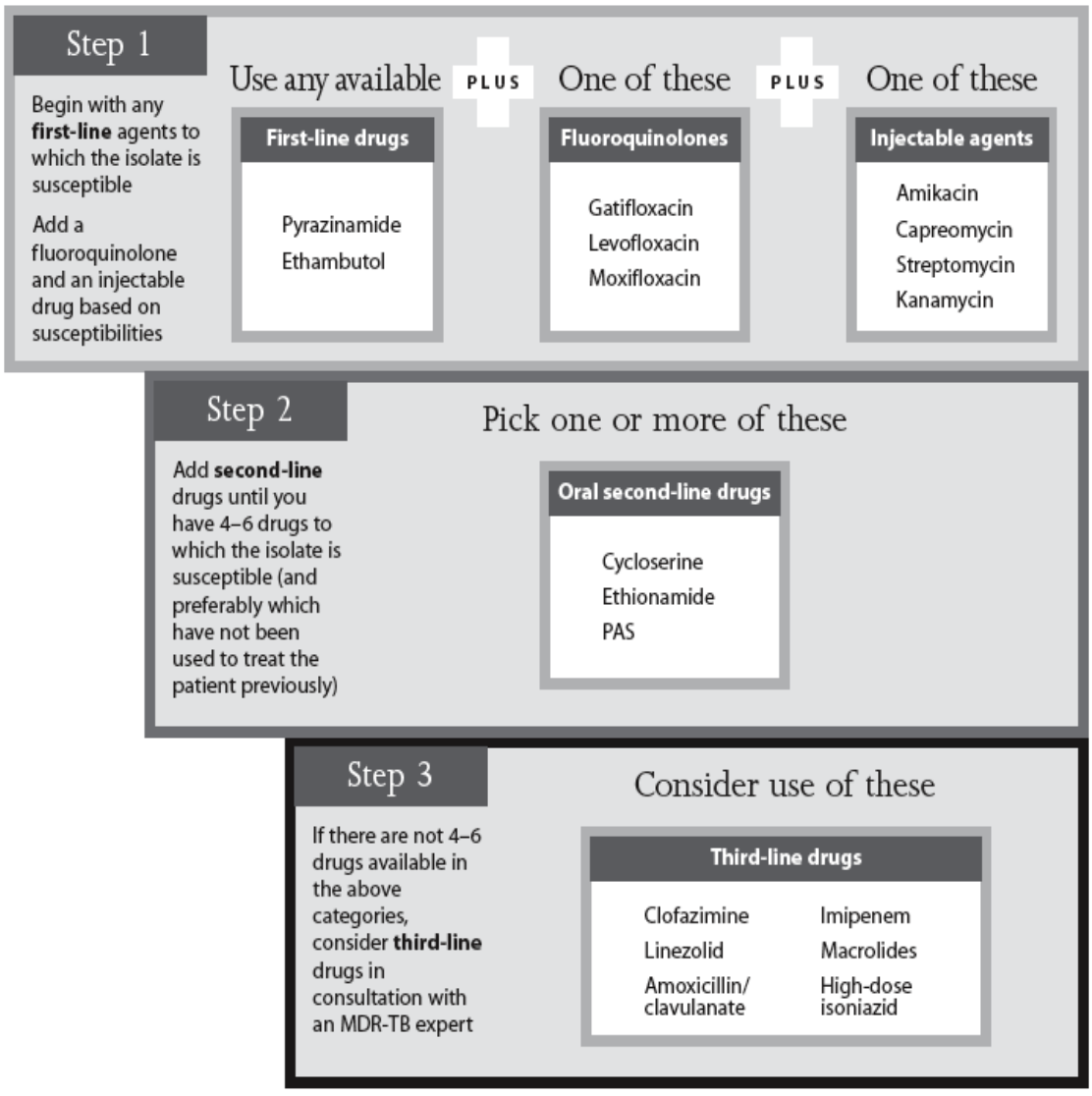
Following initial case notification, the Washington State TB Nurse Consultant will send an email informing all Technical Assistance service Panel of the new case. The nurse consultant will coordinate an initial teleconference and gather all relevant data as well as coordinate written service panel recommendations.

A full consultation provides on-going, written recommendations and updates to ensure appropriate treatment, management of side effects, and adherence throughout treatment. The Technical Assistance Service Panel will request copies of the treatment, bacteriology, laboratory, radiographic and contact investigation forms when a full consultation is requested to support preparation of Drug-o-Grams and other aspects of the consultation.

MDR/XDR Tuberculosis Management Quick Start Guide

1. Contact the Washington State MDR/XDR Technical Assistance Service Panel at 360-236-3443 for consultation and support in determining an appropriate drug regimen on the following types of cases:
    a. Patients who have been diagnosed with MDR/XDR TB by either conventional drug susceptibility test or a molecular test for drug resistance.
    b. Patients who are currently on MDR/XDR TB treatment and have moved into Washington from another state or country.
    c. Patients who are thought to have MDR/XDR TB because they are a close contact to an MDR case, but a clinical specimen for drug susceptibility testing was not available (e.g. child contact to an MDR/XDR TB case).

2. Use this table to guide you in determining an appropriate drug regimen for the patient:



3. Perform baseline and ongoing monitoring and laboratory testing:

On all patients:

- ☐ Weight (baseline and monthly)
- ☐ HIV test (baseline)
- ☐ Pregnancy test (baseline and as clinically indicated)
- ☐ Complete blood counts (baseline and as clinically indicated)
- ☐ Liver function tests (baseline and monthly)
- ☐ Creatinine (baseline and two weeks, then as clinically indicated)
- ☐ Mental health screening (baseline and as needed)

Patients receiving capreomycin or aminoglycosides:

- ☐ Creatinine (baseline and two weeks, then at least monthly)
- ☐ Potassium, calcium, and magnesium (baseline and monthly)
- ☐ Audiology and vestibular function (baseline and monthly)

Patients receiving ethionomide or PAS:

- ☐ Thyroid function (baseline and every 3 months)
- ☐ Electrolytes (PAS)

Patients receiving clofazamine or moxifloxacin:

- ☐ EKG QTc intervals (baseline and if symptomatic)

Patients receiving Bedaquiline:

- ☐ Lipase
- ☐ Alkaline phosphate
- ☐ Electrolytes
- ☐ EKG (at baseline, 2, 12 and 24 weeks or weekly if administered with clofazimine or moxifloxacin)
- ☐ Neuro exam

MDR/XDR Tuberculosis Isolation Quick Start Guide

The purpose of this document is to ensure the containment of MDR/XDR TB through measures designed to protect the public when an individual is suspected or known to have an infectious, drug-resistant strain (s) of TB.

1. Pre-planning for Isolation Preparedness
    a. Ensure that appropriate housing/facilities are able to provide the care and treatment for individuals who need isolation/airborne precautions that cannot be provided at their home or place of residence.
    b. Determine costs associated with implementing isolation/airborne precautions.

2. Evaluate patient
    a. Immediately or within 1 business day evaluate the patient for individual factors that may interfere with the patient's ability to maintain adherence to isolation/airborne precautions (e.g. substance abuse, mental health issues, social-psychological needs etc).

3. Instituting Airborne Precautions & Isolation
    a. Determine the appropriateness of the patient's living situation by using the Outpatient/Nontraditional Facility-Based TB Risk Assessment. If the living situation is not appropriate for isolation/airborne precautions arrange for an alternative living environment.

4. Patient Education
    a. Provide basic information about infectious TB and the need for isolation/airborne precautions.
    b. Review the treatment protocol for MDR/XDR TB patients and time involved to cure.
    c. Discuss DOT and have the patient sign a consent form.

5. Release from isolation
    a. The Technical Assistance Service Panel can assist you in determining when isolation can be discontinued.

6. Quality Assurance and Improvement

Purpose

The purpose of this document is to ensure the containment of MDR/XDR TB through measures designed to protect the public when an individual is suspected or known to have an infectious, drug-resistant strain(s) of TB.

Isolation Preparedness & Implementation

The local health department or district will require all persons with suspect or confirmed MDR/XDR infectious TB to exercise all reasonable airborne precautions to prevent the spread of infection to others. The health department will ensure that airborne precautions and isolation are provided for persons who have suspect or confirmed MDR/XDR infectious TB when the health officer decides these measures are necessary in order to prevent the spread of disease.

If persons can be safely maintained in their home environment without a danger to the health of the public, the health department will encourage and support.

Persons with infectious TB who live in congregate settings, are homeless, or live in a home that does not allow for isolation of the patient, he or she will be isolated in another facility until no longer infectious and can safely return to their former living arrangements.

It is the responsibility of the local health department to locate, evaluate, and initiate arrangements with agencies or businesses that can offer appropriate airborne isolation.

The local health department will work collaboratively with others in the community, both public and private, to prepare in advance for actions that are needed to provide voluntary and non- voluntary isolation/airborne safety measures. If a person is placed within the jurisdiction of another health department for care, the original health department retains responsibility for services and costs.

Legal Authority

The county health officer has statutory responsibility to investigate and enforce any Washington State Laws and Rules on Tuberculosis Control, to prevent or control the transmission of M. tuberculosis. The health officer is to investigate, make and enforce the necessary orders for any person with suspected or known infectious (pan-sensitive or drug-resistant) TB. If any person does not voluntarily comply with an isolation order issued by the local health officer, the health officer takes further legal actions to confine the person.

1. **Pre-planning for Isolation Preparedness**
    - Ensure that the appropriate facility(s) is (are) available that will provide the proper care and treatment of individuals who need isolation/airborne precautions that cannot be provided at their home or place of residence.
    - Identify potential locations in advance to provide isolation/airborne precautions (hospitals, university medical centers, nursing homes, county facilities, other community providers (infectious disease practices or pulmonologist) or correctional facilities for those who are under arrest or are convicted of crimes).
    - Discuss and secure an agreement, contract, or memo of understanding (MOU) for placement of individuals in need of isolation/airborne precautions. See Appendix A for Voluntary Home Isolation Recommendations.
    - For each person affected, the health department explores all possible ways to keep them at home if suitable environmental adjustments can be made.
    - For infectious individuals who cannot be isolated at home, ensure that the location chosen has a negative pressure room that meets requirements for isolation of infectious TB patients (minimum of six to twelve air changes per hour, vented directly outside with non-recirculating air, or with HEPA-filtered air) and a TB infection control plan that ensures competency in carrying out isolation/airborne precautions.
    - Other sites of isolation may also be motel room with outside venting, trailer home with outside venting, etc. See Appendix B for individuals who need inpatient care and are at high risk but not known to currently be infectious, determine that the facility is able to meet care and treatment needs, including if they become infectious.
    - Contact administrators of potential housing locations and/or community leaders in advance to develop a joint community education and preparedness plan. Schedule a meeting(s) with administrators and appropriate staff, such as social services, nursing, infection control and health educators.
    - Explain to community groups, organizations and/or residents that the health department has a responsibility regarding TB. Partnerships between community facilities, health care providers and nonprofit agencies are needed in order to protect everyone in the community in the case of active MDR/XDR TB.
    - Assess any costs associated with implementing isolation/airborne precautions and determine sources of payment.
    - Determine which third party payers may be appropriate for potential patients in the community including how to expedite Medicaid or health insurance eligibility requirements. Resolve potential third party payer issues early to foster acceptance of the affected person by medical and institutional providers.

WAC 246-100-045:

- The needs of a person isolated or quarantined must be addressed to the greatest extent possible in a systematic and competent fashion, including, but not limited to, providing adequate food, clothing, shelter, means of communication with those in isolation or quarantine and outside these settings, medication, and competent medical care;

- Premises used for isolation or quarantine must be maintained in a safe and hygienic manner to minimize the likelihood of further transmission of infection or other harm to persons isolated and quarantined;

- To the extent possible, cultural and religious beliefs should be considered in addressing the needs of individuals, and establishing and maintaining isolation or quarantine premises.

2. Evaluate the Patient

- Evaluate the risk of TB transmission immediately or within 1 business day upon receiving the verbal or written notification that an individual has been identified as having suspect or confirmed infectious MDR/XDR TB.
- Assess for individual factors that influence the person's ability to establish adherence to isolation/airborne precautions, such as:
    - Substance abuse.
    - Mental or emotional problems.
    - Chronic medical conditions that will increase the risk of transmission of TB,
        - Such as the need for dialysis, medical follow-up appointments, etc.
    - Consider language, cultural, and/or socioeconomic barriers. The individual
        - May have limited insight, understanding or acceptance of having TB disease,
            - Especially their understanding of the ability to transmit TB to others.
    - Previous treatment failures for TB, either active TB disease, or TB infection
        - Increases the risk of repeated failures.
- Support personnel are essential to assist the individual to maintain airborne precautions and to remain in isolation while getting their basic physiological and emotional needs met whether they will be in isolation at home or in an institution (grocery shopping, laundry, bill paying, medical or other appointments, obtaining medication, maintaining relationships, etc).
- Other priorities that the person is accustomed to may impact their ability or willingness to adhere to airborne precautions and/or medication therapy, such as having to maintain a strict diabetic or renal diet.
- Have the patient sign a Voluntary Isolation Agreement form.

3. **Instituting Airborne Precautions & Isolation**
   - Ensure that the health department staff who will have contact with the individual have been trained and are competent in following the health department's Infection Control Plan, including staff protective measures.
   - Assess the individual's environment for factors that increase the risk of TB transmission to susceptible persons.
   - Determine if the individual lives in a congregate setting with others that share the same air. The following types of settings are considered high risk for transmission of TB:
     - Correctional institutions
     - Hospitals
     - Nursing homes
     - Mental institutions
     - Drug treatment centers
     - Homeless shelters
   - Assess living accommodations, including apartment and/or single room occupancy . hotels, to determine if air is shared in common areas through the building ventilation system.
   - Determine if the individual lives with or has other close contact with persons at greater risk for TB disease, i.e. children under 5 years of age or immuno-suppressed persons.
   - Determine if the individual provides services to members of high-risk groups (i.e day care provider).
   - Determine the appropriateness of the living situation for this individual based on your assessment and by using the Outpatient/Nontraditional Facility-Based TB Risk Assessment.
   - Upon completion of the risk assessment, discuss findings with the local health officers and/or the WA State TB Medical Consultant regarding necessary actions.
   - In the event the current living situation is not appropriate, (e.g. congregate living site, or site where there is shared air through the building ventilation system or where infants and young children also reside), the health department will assist with arrangements and referrals necessary to secure an alternative living environment.

4. **Patient education**
   - Assess knowledge and provide information on TB disease and the need for isolation to the individual and any other relevant persons. Ensure sufficient early understanding to ascertain that they will maintain isolation/airborne precautions. Expand details of teaching and care as case management proceeds.

     - Provide basic education about TB, such as:
       - TB Disease transmission and pathogenesis.
       - How treatment for MDR/XDR TB is different from drug susceptible strains.

- The airborne nature of transmission and the risk to others with close, prolonged contact, including visitors or if the person were to go where there are other people.
- The importance of covering mouth and nose when coughing and sneezing. A mask worn by someone with TB does not protect others.
- Reviewing facts on and providing appropriate written materials in the person's own language and/or with use of an interpreter.
- Allow sufficient time for the person, family and other involved people to ask all questions.

- If there are any issues with the medical treatment plan, consult the patient's health care provider and/or the WA State TB Technical Assistance Team to meet both the necessary medical treatment goals and the needs of the individual. A verbal or written contract for adherence to the TB medical care plan may help the person and the family to understand what is expected.
- Essential points to review with patients/family and friends:
  - All MDR/XDR infectious TB patients must be on directly observed therapy (DOT).
  - Stress the importance of taking all medications.
  - Provide information about changes in signs and symptoms to report.
  - Provide at least one contact name and phone number for the person to call.
  - Obtain one or two contact names and phone numbers from the person in case you find them gone from home (someone who would know if they went to the hospital unexpectedly).
  - Stress the importance of staying at home or at the agreed location.
  - Assess and evaluate the individual's knowledge about the meaning and importance of isolation. Place emphasis on the importance of excluding previously unexposed persons until non-infectious.
- Identify personal and service needs required in supporting the individual in isolation (e.g. grocery shopping, laundry, mail, medical or other appointments, obtaining medication, etc.) Provide case management as necessary to meet these needs as well as psychosocial, emotional and spiritual needs.
- Discuss activities that the individual can safely do without exposing unexposed people (such as walking outside if it presents no risk) and help them to cope with issues related to isolation and airborne precautions. Work with the person to determine ways to maintain contact with significant others who cannot visit until the infectious period is over.
- Use incentives and enablers to promote cooperation and adherence.
- The health department staff will visit the individual daily to monitor the clinical condition, evaluate for medication side effects, and to monitor individuals for adherence with isolation. This may include unannounced home visits to assess adherence to isolation.

- Evaluate the care plan and the medical treatment plan, consulting the physician and the MXR/XDR Technical Assistance Team for any medical issues, to ensure that it is least disruptive to the individual's life and still supports the goals of individual treatment and protection of the community during case management.
- Evaluate the need for the health officer to issue an isolation or confinement order if the person does not voluntarily maintain isolation/airborne precautions.
- Health officer role for non compliant patients please refer to the Washington State Law Manual for Health Officers.

5. Release from Isolation

- There are several times during the treatment regimen when the issue of release from isolation will need to be discussed:

  - In the hospital environment, when discontinuation of negative-pressure isolation is contemplated.
  - When travel or transport to another facility is desired.
  - When discharge to the home environment is considered.
  - When transfer to a high-risk environment such as a congregate setting is the only option.
  - When home isolation may be discontinued.
  - For drug-susceptible TB, a patient receiving TB treatment is deemed to be non-contagious when he/she has produced 3 consecutive smear-negative sputa, has started an appropriate treatment regimen, and is clinically improved.
  - Particular care should be taken when considering if patients can return to settings where there are young children, immunocompromised individuals, and people who have co-morbidities.

Consider consulting the MDR/XDR Technical Assistance Service Panel before releasing person from isolation.

6. **Quality Assurance and Improvement**

- Perform regular review of data through case review to identify specific gaps and implement solutions to overcoming the gaps.

  - Chart reviews and case management reviews should be done on a weekly basis to ensure appropriate treatment and care.

Potential Sources for Patient Care and Treatment						
	Undocumented Alien	**Student/Employee Visa**	**Visitor/Temporary Visa**	**HIV/Co-morbidities**	**Homeless**	**Stable Environment**
Type of Isolation	ICE* or Federal Detention	Student Housing/Rental	Relative/Friends/ Rental	HIV Housing	Motel/Rental	Current Home
Funding Source	Federal Government	Medical Insurance (if any)/LHJ	LHJ**	HIV Patient Services/LHJ	LHJ	LHJ/Medical Insurance
Treatment Case Management	USPHS*** CDC**** LHJ MDR/XDR TB Team	LHJ Private Provider MDR/XDR TB Team	LHJ Private Provider MDR/XDR TB Team	LHJ Private Provider MDR/XDR TB Team	LHJ Private Provider MDR/XDR TB Team	LHJ Private Provider MDR/XDR TB Team
Food	Federal Government	LHJ/Student Services	LHJ/Family (if applicable)	LHJ/HIV Services	LHJ/Homeless Services	LHJ/Family (If applicable)
Contact Investigation	USPHS/CDC	LHJ	LHJ	LHJ	LHJ	LHJ

*ICE – Immigration and Customs Enforcement
**LHJ- Local Health Jurisdiction
***USPHS – United States Public Health Service
****CDC – Center for Disease Control and Prevention

Resources

Refer to “Improving Patient Adherence to TB Treatment” published by the Centers for Disease Control and Prevention (CDC) 1994.

For complete information on environment controls, refer to the CDC Guidelines at http://www.cdc.gov/tb/publications/factsheets/prevention/ichcs.htm.

For CDC Guidelines visit http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf .

American Thoracic Society. Diagnostic Standards and Classification of TB in Adults and Children. April, 2000.

American Thoracic Society. Targeted Tuberculin Testing and Treatment of Latent TB Infection. April, 2000.

California Department of Health Services and Executive Committee of the California TB Controllers Association. Guidelines for the Placement or Return of TB Patients into High Risk Housing, Work, Correctional, or In-Patient Settings. 1997.

Centers for Disease Control and Prevention. Core Curriculum on TB; Fourth Edition, 2000.
Centers for Disease Control and Prevention. Improving Patient Adherence to TB Treatment. 1994.

Centers for Disease Control and Prevention. Guideline for Isolation Precautions in Hospitals, January 1996.

Curry International TB Center. Drug-Resistant TB: A Survival Guide For Clinicians. 2011, 2nd edition.

Francis J Curry National TB Center, Institutional Consultation Services. Isolation Rooms: Design, Assessment and Upgrade. 1999.

Wisconsin Division of Public Health. Infection Control Plan for Local Health Departments (developed as a template for local health departments). 1998.

Appendix A

Recommendations for Voluntary Home Isolation

Recommendations for isolating potentially infectious TB patients depend on different factors such as: sputum smear results, site of disease, level of clinical suspicion that suspect has TB, drug sensitivity of the M. TB strain, the type of home setting; and the age, immune status and exposure status of household members.

Patients with initial sputum smear-positive (AFB+) pulmonary specimen:

1. Home Isolation with previously exposed children younger than five years old:
For patients with at least one positive AFB smear from a pulmonary specimen, have a high clinical suspicion of TB or positive NAAT, voluntary home isolation should be used when all of the following criteria are met:

- Children have been evaluated for TB and are receiving appropriate window prophylaxis by DOT.
- Patient is receiving and tolerating appropriate TB drug regimen by DOT.
- Patient, if primary care giver wears a surgical mask until DRSS or DST results are received and minimizes the time spent around the children.
- Patient, if breastfeeding mother, has consulted with the MDR/XDR-TB Technical Assistance Service Panel about continuing to breastfeed.
- Patient, if not the primary care giver, is separated from the children.

2. Home Isolation with previously exposed immunocompromised individuals five years and older:

- Immunocompromised family members must be evaluated for TB and receiving window prophylaxis and consult with the MDR/XDR TB Team about remaining in the household.
- Patient must be receiving and tolerating appropriate TB drug regimen by DOT.

Appendix B

Recommendations for Housing Patients with Confirmed or Suspected Infectious MDR/XDR TB who are homeless

The following guidelines should be considered when housing homeless patients who may have infectious MDR/XDR TB.

1. AFB sputum smear positive patients must be singly housed in self-contained housing units[1] that do not share air[2] with other units until:
   - Three (3) consecutive negative AFB sputum cultures from respiratory specimens have been collected, at least 8 hours apart, in which at least one was an early AM or induced sputum, or BAL; and
   - DRSS or DST results are obtained and patient has been on an appropriate treatment regimen for at least 14 daily doses of multi-drug, anti-TB therapy, taken by DOT and tolerated; and
   - They exhibit clinical improvement.[3]
   - Patients must be housed in self-contained housing units that do not share air with other units until the above conditions are met and expert clinical consultation has been sought from the MDR/XDR Technical Assistance Service Panel and the patient is determined to be no longer infectious.[4] (If such housing is not available, Airborne Infection Isolation in a health care facility should be used.)

2. Patients must receive DOT. Mechanisms must be in place to ensure that patients comply with DOT and infection control instructions.[5]

3. Incentives and enablers must be used to help the patient remain in the unit (e.g., television, radio, telephone for local calls).

4. It is the responsibility of the local health department to ensure the integrity of the isolation by requiring and ensuring the following:
   - Appropriate mechanisms are in place for the provision of food, laundry service, hygiene, and cleaning;
   - Staff, volunteers, and visitors do not enter the unit unnecessarily;
   - Anyone, including volunteers, needing to gain access to the housing unit must be trained in TB prevention methods;
   - Employees, volunteers and visitors entering the housing unit must use a NIOSH-certified respirator (employees' and volunteers' respirators must be fit- tested);
   - A sign must be conspicuously posted advising persons entering the housing unit to use respiratory precautions.

- Allowed sufficient time to pass before staff without respiratory protection enters a housing unit after a patient has been released to allow the space to be well ventilated and to clear any lingering AFB.

[1] A self-contained housing unit provides all facilities required for activities of daily living (i.e., sleeping, eating, and personal hygiene), to help ensure that contact with others does not occur.
[2] A housing unit that does not share air with other units has no ventilation system in common with other occupied units, nor any other means for air to move from one unit to another (e.g., under a door adjoining two units). If an exhaust air vent (any vent from which air is not supplied) is present, other than in the bathroom, it must be assumed that air is shared with other units).
[3] "Guidelines for the Assessment of TB Patient Infectiousness and Placement into High and Lower Risk Settings," CDPH/CTCA Joint Guidelines, 5/1/2009
[4] Amendment to Joint CDPH/CTCA "Guidelines for the Treatment of Active TB Disease" Page 17, Section E.2." and Appendix 3 - Algorithm for MDR-TB Cases and Hospital Discharge, " CDPH/CTCA Joint Guidelines, May 12, 2006
[5] Because the consequences of transmission of MDR-TB are severe, certain infection control practitioners might choose to keep persons with suspected or confirmed MDR-TB disease under airborne precautions during the entire hospitalization or until culture conversion is documented, regardless of sputum smear results ("Guidelines for Preventing the Transmission of Mycobacterium TB in Health Care Settings, 2005" MMWR 54(RR17):1-141.)

MDR/XDR Financial Workgroup Policy Development Brief

Summary

- RCW 70.30.045, RCW 70.30.055 and WAC 246-170-031 assign to local health jurisdictions (LHJs) financial responsibility for treatment and disease control management of all active TB cases, implicitly including MDR and XDR TB.
- Local health jurisdictions vary widely in their capacity to manage and pay for these rare forms of drug resistant TB. Although consultation from the State Department of Health (DOH) and partner LHJs can bridge the technical needs some LHJs will have, no mechanism exists to mitigate the financial impact of such cases, particularly on smaller LHJs. Furthermore, a high-cost MDR/XDR case would even be a financial challenge for the largest LHJ.
- MDR and XDR cases represent a statewide disease control interest. Almost all MDR/XDR cases were infected in places other than the LHJ of residence at the time of diagnosis; no local public health failure led to their occurrence. Furthermore, the potential for inter- county migration of untreated or inadequately treated cases presents a threat to neighboring LHJs.
- Expanded access to health insurance as set forth in the Affordable Care Act may mitigate some but not all of this financial risk. The proportion of such TB patients who would be eligible for coverage is uncertain. Furthermore, LHJs' non-clinical expenditures put forth in pursuit of disease control objectives (e.g., case management, rental assistance, food subsidies, other adherence facilitators) are not reimbursable by health insurers.

Medical Background

Some degree of drug resistance is present in 15-20% of the 185-200 TB cases occurring annually in Washington State. "Drug resistance" means that the TB germ infecting a specific case is able to continue growing in the presence of one or more antibiotics used to treat TB. Multidrug resistant (MDR) cases have resistance to the two main drugs used to treat tuberculosis (isoniazid and rifampin). Upon discovering that drug resistance is present, the appropriate medical and public health response is to change the treatment to drugs that are effective. Instead of the typical 6-9 month regimen used to treat drug-sensitive TB or isoniazid mono-resistant TB (involving the swallowing of approximately 750 pills cumulatively), treatment of MDR requires use of less potent, more toxic, and more expensive medications for 18-24 months (involving 80-100 injections and over 5000 pills cumulatively). Treatment success for drug sensitive disease is about 98% with a post-treatment risk of recurrence being less than 5%. Under the best circumstances, MDR treatment success is about 90% with an estimated relapse risk of 10-20% or higher. Extensive drug resistance (XDR) occurs when a MDR case is also resistant to two of the key alternative drug classes used for treatment of MDR, thus further increasing the complexity, toxicity and cost of therapy and further lowering success rates.

Scope of the Threat and Public Health Importance

About 1-2% of all TB cases in the United States are MDR; about 10% of these are XDR. Consequently, in a five-year period, Washington State is expected to have 10-20 MDR cases and 1-3 XDR cases. Ensuring completion of treatment for TB, particularly for MDR and XDR TB, is a public health priority. Prompt initiation of correct therapy and isolation interrupts transmission to others. Completion of therapy reduces risk of a relapse to an infectious state and future risk of transmission to others. TB treatment supervision by the local health jurisdiction involves not only administering the appropriate drug regimen and witnessing its ingestion, but also providing case management (usually via a public health nurse) to educate the patient about TB, ensure safety from severe side effects, assist in overcoming barriers to adherence with a long and arduous course of therapy, and testing close contacts for infection.

Treatment Costs

Estimated costs for treatment of MDR-TB (exclusive of LHJ labor and exclusive of the additional cost associated with surgery pursued in some cases) range from $20,000-$100,000 per case (compared to about $2,000 for an uncomplicated cases of drug sensitive TB). About 75% of these treatment costs are for the more expensive, "second-line" medications. In addition to medications, other costs include necessary laboratory and radiography examinations, support for temporary housing or rental assistance while patients are isolated and unable to work, similar subsidies for food while isolated, and other modest incentives and enablers (e.g., bus tokens, food vouchers) to facilitate compliance with the treatment schedule in the poorest patients.

Typical Cases

A 28 year-old east African woman and mother of four young children was diagnosed with TB of the lungs after experiencing two months of cough, fever, and night sweats with a 5-pound weight loss. She was placed in isolation at her home and was started on standard therapy. After several weeks of treatment and a poor response to therapy, the LHJ received results of drug susceptibility testing indicating multiple drug resistance (i.e., resistance to isoniazid and rifampin). The regimen was changed to an effective combination of second-line drugs. The patient experienced pain from the injections and nausea and severe headaches from the other medications. Also, respiratory isolation interfered with her ability to work and pay for her apartment, food, and childcare. After several months of therapy, she also developed depression as a side effect of one of the medications. Clinical adjustments were made to mitigate her discomfort and treat her depression while therapy continued. Meanwhile, temporary rental assistance and food subsidies were provided during the period of isolation. The LHJ also assisted her in applying for entitlements from DSHS that would mitigate her economic distress. After isolation was completed and she became strong enough, she enrolled in vocational training and English language coursework. Approximately 20 months after

initiating therapy, she completed treatment. Estimated clinical and non-clinical costs associated with her care (exclusive of labor) were $20,000.

A 20 y/o visiting foreign student attending college was diagnosed with TB of the lungs after presenting with a six-month history of productive cough progressing to fever, night sweats, anorexia and a 10-pound weight loss. He was placed in isolation in his apartment and started on standard therapy. A close associate was evaluated shortly after that and was found to have active TB, as well. Approximately six weeks later, results of drug susceptibility testing showed that both cases TB were resistant to all five "first-line" (standard) drugs used in TB treatment (including isoniazid and rifampin). DNA fingerprinting confirmed that the two cases were infected with the same strain. Their treatment regimens were adjusted to address the multiple drug resistant organism and a prolonged period of isolation ensued for the first case (6 months) that precluded the option of boarding an aircraft to return to the home country. Maintaining isolation required rental assistance and food subsidies due to lack of income. Side effects of nausea, stomach pain, agitation, and depression were witnessed in both cases, leading to difficulty in maintaining adherence and patient trust. Regimen manipulations to ensure patient safety and treatment with additional non-TB drugs were used to alleviate side effects and increase the patients' comfort. The first case's education was completely interrupted; he returned to his home country after completing 15 of 24 targeted months of treatment. The second case was unable to study due to adverse effects, but did finally complete therapy after 18 months and has subsequently resumed her college education in the same jurisdiction. Estimated costs for treatment and case management of both cases (exclusive of labor) were $60,000. Labor costs attributed to their care and case management were $90,000.

Request

- Modify statute and State Board of Health rule to explicitly indemnify LHJs against financial responsibility for treatment costs of MDR/XDR TB cases and assign that responsibility to DOH.
- Authorize DOH to reimburse LHJs on a cost basis for reasonable and appropriate expenditures for their treatment of MDR and XDR TB, delegating rule making for implementation of such to the SBOH.
- Appropriate sufficient funds for DOH to reimburse LHJs for MDR/XDR treatment expenditures.
- Estimated cost: $200,000-250,000 per year, on average.

MDR/XDR TB Workgroup Potential Funding Solutions Summary

RCW 70.30.045 states that each county is obligated to fund the cost of TB cases in their jurisdiction. Since 1977, a millage of 21 cents per $1,000 evaluation was instituted for each county that is broken into approximately: 1/3 to public health, 1/3 to TB, and 1/3 to hospital. While counties still receive these funds and may continue to use them as initially appropriated, there is no longer a requirement to do so. The concern is that the law requiring counties to fund TB was instated in 1943 (with last revision in 1999) based on a case with a standard four drug regimen, without the financial burden that MDR/XDR creates.

Possible ways to approach funding an MDR/XDR case:

- State splits 50/50 with the county managing the case
- State contributes based on level of need
- County agrees to fund up to certain amount, State funds rest (ex: county funds up to $100k)
- Create a funding pool comprised of contributions from each county (based on a pre determined formula)

After researching the suggested funding approaches, it was determined that the only feasible way to go about paying for such cases is to ask the legislature for Washington State to provide annual ongoing funding.

Brad Banks, a representative from WSALPHO, attended a call and was interested in pursuing this further and suggested that the group, with his assistance, approach the state asking for emergency funding for MDR/XDR cases. Brad asked if the group would provide a summary that includes:

- background of the issue
- examples of a recent cases as case studies
- costs associated with the cases

Brad presented this information at the WSALPHO meeting in June where it was supported by the group. The group will determine if it is a task for the administrators or health officers. The MDR/XDR Financial Workgroup determined that no further action was needed from the workgroup and the group has since ceased calls. The following Policy Development Brief will be presented to the legislature.