

Wisconsin State Laboratory of Hygiene UNIVERSITY OF WISCONSIN-MADISON



Today's Program

- Update from WSLH
 - Laura Louison
- Update from DPH
 - Julie Tans-Kersten
- TB Control during COVID-19
 - Claire Leback
- Case Study
 - Rebecca Szydlowski











Updates from WSLH

- Wisconsin Mycobacteriology Laboratory Network (WMLN) activities
- Surveillance Data
- Current WSLH TB projects
- Effects of COVID-19 on TB laboratory



WMLN Laboratories





WMLN Activities

Site Visits

- 1 site visit completed in 2017
- 4 site visits completed in 2018
- 2019 and 2020....
- Hopefully will resume in 2021!



WMLN Activities

- Laboratory Survey
 - Last statewide survey conducted in 2014
 - Gather data
 - Test methods
 - Test volumes
 - Reagents
 - Specimen referral protocols
 - Complete by end of 2020 or early 2021



WMLN Surveillance Data

2019



TB Cases by county (2019)





MDR TB in WI





NTM isolations (2019)





CDC Aggregate Report Data

- CDC Tuberculosis Elimination and Laboratory Strengthening Cooperative Agreement
 - 58 Public Health Labs report workload and turnaround time data
 - Every 2 years an aggregate report is compiled and released to the participating laboratories



WSLH 2019 Workload Data

Clinical specimens received for AFB Smear and culture	3878 Total 1780 Individual Patients
Isolates received for AFB Identification	517 Total 413 Individual Patients
Number of patients tested directly by NAAT (PCR)	236
Number of patients for whom 1 st Line TB DST was performed	57
Number of patients tested by Molecular DST (GeneXpert)	40
Number of patients for whom MTBC genotyping was performed	51



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Figure 1. Distribution of Public Health Laboratory Testing Volumes Measured by Total Number of Clinical Specimens Received, 2015 and 2017.

Distribution of Clinical Specimens Received

2015 2017

*These jurisdictions referred all TB testing to another laboratory.

Note: DC=Washington, D.C., PHI=Philadelphia, SAN=San Diego, SFO=San Francisco, HOU=Houston, NYC=New York City, LAX=Los Angeles. All others are U.S. Postal Service abbreviations.



Figure 3. NAAT Algorithm, 2018. Testing per request only 13 New AFB smear positive patients (routinely only first smear positive specimen); AFB smear negative patients on request only New AFB smear positive patients (automatically testing >1 specimen per patient); AFB smear 2 negative patients on request only Combination of AFB smear status & non-clinical Indicators printed on submission form One specimen from all new patients regardless of AFB smear status All specimens received regardless of AFB smear status 1 except patient spreviously positive for MTBC All specimens received regardless of AFB smear 1 status and previous positivity 0 5 10 15 20 25 30 35 Number of PHL

Source: Centers for Disease Control and Prevention



Table 2. TAT Indicators, 2017.

TAT Measurement	Specimen receipt within 1 day of collection	AFB smear result within 1 day of receipt	ID of MTBC within 21 days of receipt*	DST within 17 days of ID of MTBC
National Target: (% of specimens that should meet the benchmark)	67% 68%	92% 93%	^{74%} 91%	^{69%} 82%
Number of laboratories meeting or exceeding national target	12	33	30	26
National Average (reported % of specimens meeting the benchmark)	49%	89%	72%	57%
Number of laboratories at or above national average	28	35	33	32

*Number of laboratories = 56 (2 laboratories had no MTBC identified)



Current Projects @ WSLH



June 2019: APHL releases RFP for WGS Project:



Request for Proposals: Whole Genome Sequencing (WGS) of Mycobacterium tuberculosis complex (MTBC) Positive Primary MGIT Culture

Application Due date: August 8, 2019



- WSLH TB Lab performs pilot study:
 - Extraction of DNA from primary MGIT tube of MTBC QC strains
 - Concentration of DNA extracted
 - Purity of DNA extracted
 - Viability studies on extraction procedure
 - Perform whole genome sequencing on extracted DNA
 - Bioinformaticians analyze WGS data



- Pilot Study a success!
 - Extraction procedure showed good quality yield and purity of DNA and effectively inactivated MTBC
 - Sequences showed good quality scores with high number of reads mapping to MTBC H37Rv genome
 - Things to consider: G:C content of MTBC, genome length of MTBC
- WSLH submits RFP to APHL for consideration



- WSLH was chosen as one of the awardees for the WGS study of MTBC from primary MGITs
 - At least 32 MTBC positive primary MGIT cultures to be sequenced (and up to 40 total)
 - Sequence data submitted to CDC/APHL for analysis
 - Still awaiting final analysis/report from CDC/APHL on the summary of the project as a whole



- WSLH is continuing to extract and sequence MTBC specimens to gather more data
- Future Uses ???
 - Molecular analysis of the genome for drug resistance markers
 - Identification of NTM and/or speciation of MTBC







TB/MAC PCR Assay Optimization

- Quality indicators lead to questions about internal PCR control
 - Is it possible to experience partial inhibition of PCR?
 - Could our assay be more sensitive?



TB/MAC PCR Optimization

- RNase P as the Internal Control?
 - RNase P—detection of human material in the sample. If not detected, PCR assay is considered "inhibited" and retested
 - Not standardized across specimens, amount present can vary widely
- Bloody or thick specimens?
 - Blood is a known inhibitor of PCR—without performing an extraction, could it be inhibiting the PCR amplification of TB?



TB/MAC PCR Optimization

- Validation of an internal plasmid control instead of the RNaseP
 - Bicoid developed at NYS Wadsworth Center
 - Plasmid containing control DNA target
 - Known concentration = expected cycle threshold (Ct) value in PCR assay
 - Can detect smaller amounts of inhibition that might be masked by a large amount of RNase P present





TB lab operations during COVID-19





Staffing for COVID testing

- Influx of specimens
- Testing expands to include Saturday and Sunday (comp time during the week)
- Staff still needs to be able to use vacation
- Some microbiologists have kids that can't go to school or daycare
- What about sick employees or quarantine periods?



Specimen volumes for AFB smear/culture

- 2019: Average 16 specimens per day
- 2020: Average 15 specimens per day
 - April 2020: Average 8 specimens per day
 - Some days only 1 specimen!
 - Other areas of CDD (other than virology!) were experiencing the same phenomenon!

Cross Train!



Staffing

- March 2020 5 Microbiologists for TB lab
 - 2 of the TB microbiologists also help cover Parasitology
- November 2020—7 Microbiologists for TB lab
 - 2 still cover Parasitology (1 is also trained in processing COVID-19 specimens)
 - 2 are fully trained in TaqPath COVID-19 assay
 - Starting with Panther COVID training
 - 1 is trained in data entry of COVID-19 specimens



WSLH TB Laboratory Team















Wisconsin Tuberculosis (TB) Program Updates

Julie Tans-Kersten Director, Wisconsin TB Program (WTBP) Wisconsin Mycobacteriology Laboratory Network Virtual Conference November 11, 2020

Topics

- TB epidemiology: global, U.S., Wisconsin
- Rifamycin issues
- New national TB guidelines
- New Wisconsin TB Program (WTBP) materials
- WTBP updates

TB Epidemiology: Global



https://www.who.int/tb/publications/global_report/en/

The Global Burden of TB 2019

Estimated number of cases Estimated number of deaths

All forms of TB	10.0 million	1.4 million (14%)*	
	10.0 million last year	1.5 million last year (15%)	
HIV-associated TB	820,000 (8.2%)	208,000 (25%)	
	862,000 last year (8.6%) 251,000 last year (29%)	
Multidrug-resistant TB & Rifampin resistance	465,000 (4.6%)	182,000 (39%)	
•	484,000 last year (4.8%)	214,000 last year (44%)	
Source: WHO Global Tubercu	ulosis Report 2020 * Includin	a deaths attributed to both HIV/TB	

The Global Burden of TB 2019

FIG. 4.4

Estimated TB incidence rates, 2019



Source: WHO Global Tuberculosis Report 2020

The Global Burden of TB 2019

FIG. 4.32

Estimated incidence of MDR/RR-TB^a in 2019, for countries with at least 1000 incident cases



Source: WHO Global Tuberculosis Report 2020
The Global Burden of TB

FIG. 2.5

Countries in the three high-burden country lists for TB, TB/HIV and MDR-TB being used by WHO during the period 2016–2020, and their areas of overlap



Table 2.4.

Source: WHO Global Tuberculosis Report 2018

TB Epidemiology: U.S.

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Tuberculosis (TB)

Reported Tuberculosis in the United States, 2019

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https://www.cdc.gov/tb/statistics/reports/2019/default.htm

CDC Key Findings 2019

- In 2019, 8,916 TB cases were reported in the United States, a 1.2% decrease from 2018.
- The national TB incidence rate decreased to 2.7 cases per 100,000 persons.

Progress Towards Tuberculosis (TB) Elimination, United States, 1983–2019



Majority of TB Cases Occur in Four States, United States, 2019





TB Cases and Rates Among U.S.-born versus Non-U.S.-born Persons, United States, 1993–2019



CDC Key Findings 2019

- Among U.S.-born people, TB disease disproportionately occurs among non-White persons.
- A disproportionate number of U.S. TB cases occur among people born outside of the United States.

Countries of Birth Among Non-U.S.–born Persons Reported with TB, United States, 2019 (N=6,364)



Percentage of TB cases among non-U.S.-born persons

39%



*Based on initial isolates from persons with no prior history of TB; multidrug-resistant TB (MDR TB) is defined as resistance to at least isoniazid and rifampin.

CDC Key Findings 2019

- The United States continues to have one of the lowest TB case rates in the world.
- The 2019 case count represents the lowest number of TB cases on record.
- Progress is too slow to eliminate TB in this century.
- Ending TB will require a dual approach:
 - maintaining and strengthening current TB control priorities
 - increasing efforts to identify and treat latent TB infection in populations at risk for TB disease

TB Epidemiology: Wisconsin





Case average

Wisconsin has had an average of 55 TB cases per year during the past 10 years.



Multi-drug resistance

Wisconsin's rate of multi-drug resistant TB is one of the highest in the U.S. Wisconsin treated 20 patients with MDR-TB in the past 10 years.



In 2019, five people died from TB or complications of the disease.

Reported TB Cases Wisconsin, 1982–2019



Average TB Incidence rates by Regions in Wisconsin 2010-2019



Number of TB Cases in U.S.-born vs. Foreign-born Persons, Wisconsin

■ US-Born ■ Foreign-Born



Countries of Birth Among Non-U.S.—Born Persons with TB Wisconsin, 2010–2019



TB rates for Top 10 Countries of Birth Wisconsin, 2010–2019



Number of TB Cases by Case Verification Criteria Wisconsin, 2005–2019



Wisconsin TB Summary

- 51 new patients were identified with TB in 2019.
- The 10-year average number of cases is 55 cases per year.
- Wisconsin TB incidence for 2019 (0.875) is below the national rate.
- There were no patients with MDR-TB in 2019.
- TB rates continue to be very low for homeless, long-term care, and correctional populations in Wisconsin.

Rifamycin Issues

Rifamycin Issues: Background

- Rifamycins are important drugs used in regimens for treatment of TB disease and latent TB infection (LTBI).
- There are two separate issues:
 - Shortage: rifapentine
 - Nitrosamine contamination: includes rifampin and rifapentine.
- WTBP sent messages in June and September regarding these issues.

Nitrosamine Contamination

- The US Food and Drug Administration (FDA) recently began testing for nitrosamines.
- Nitrosamines are potential carcinogens.
- Nitrosamine impurities were found in rifampin and rifapentine.

Nitrosamine Contamination (2)

- It is possible that nitrosamines were present in rifampin and rifapentine prior to introduction of FDA testing.
- The Centers for Disease Control and Prevention (CDC) is not aware of any data showing an association between cancer and use of rifamycins.
- FDA is allowing continued distribution of these medications.

Rifapentine Shortage

- Rifapentine (supplied as Priftin[®], manufactured by Sanofi) is part of a regimen for treating latent TB infection (LTBI).
- Priftin[®] is not available in generic form.
- A rifapentine shortage was announced by FDA in March 2020.
- The shortage is attributed to increased global demand and nitrosamine contamination.

WTBP Recommendations: Rifamycins for TB Disease

- There is no national shortage of rifampin at present.
- Providers should continue prescribing rifampin for treatment of TB disease per existing guidelines.

WTBP Recommendations: LTBI

- Patients who are already taking rifampin or rifapentine-containing regimens for LTBI should continue their treatment.
- If a clinician or a patient prefers to discontinue one of these regimens due to potential nitrosamine impurities, a complete regimen of 6 or 9 months of isoniazid can be started.

WTBP Recommendations: LTBI (2)

- The Wisconsin TB Dispensary pharmacy has rifapentine (Priftin[®]) in stock.
- The Wisconsin TB Dispensary will continue to supply rifapentine for patients that have already initiated their treatment using 3HP.

WTBP Recommendations: LTBI (3)

- WTBP will approve further use of 3HP through the Wisconsin TB Dispensary on a case-by-case basis, depending on the supply of medication.
- Providers can continue to prescribe the 4 months of daily rifampin (4R) LTBI regimen based on clinical indications and patient preference.
- See LTBI treatment options here: <u>P-01181</u>

New National TB Guidelines

New National TB Guidelines

Release	Name
Date	
07/2020	Essential Components of a Public Health Tuberculosis Prevention, Control and Elimination Program: Recommendations of the Advisory Council for the Elimination of Tuberculosis and the National TB Controllers Association. MMWR Recomm Rep 2020; 69(7); 1-27.
07/2020	Tuberculosis Screening, Testing and Treatment of US Health CarePersonnel. ACOEM and NTCA Joint Task Force on Implementation of the2019 MMWR Recommendations. Thanassi, et al., 2020. JOEM Vol. 62, No.7.
02/2020	Guidelines for the Treatment of Latent Tuberculosis Infection:Recommendations from the National Tuberculosis Controllers Associationand CDC, 2020.MMWR Recomm Rep 2020; 69(No. RR-1): 1-11.
09/2019	Treatment of Drug-Resistant Tuberculosis. American Journal of Respiratory and Critical Care Medicine, 2019.

New WTBP Materials



Nurse Case Management for Active Tuberculosis (TB) Disease

Wisconsin Tuberculosis Program | Bureau of Communicable Diseases | Division of Public Health | Department of Health Services

Phone: (608) 261-6319



Wisconsin Department of Health Services Division of Public Health P-00647 (Rev 09/19)

https://www.dhs.wisconsin.gov/tb/ provider-resources.htm

New WTBP Materials

Publication Number	Description
<u>P-42099B</u>	LTBI fact sheet, plain language
	(3 languages)
<u>P-42099</u>	TB fact sheet, plain language
	(3 languages)
<u>P-01181</u>	LTBI treatments
<u>P-02194A</u>	TB in Wisconsin, infographic
<u>P-00647</u>	Nurse Case Management for TB disease

New WTBP Materials: Screening and Testing of Health Care Personnel

Publication Number	Description
<u>P-02530</u>	Decision Tree: Tuberculosis Screening of Health Care Personnel (HCP) and Caregivers upon Hire
<u>P-02382</u>	Tuberculosis Screening and Testing: Health Care Personnel

Acknowledgements

- WSLH: for sponsoring and coordinating the annual WMLN conference
- Philip Wegner: for creating TB epidemiology slides
WTBP Staff



Tierney Hall



Julie Tans-Kersten



Pat Heger



Savitri Tsering



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Questions?

Effects of COVID-19 on State and National TB Programs

Claire Leback, MPH RN Nov 11, 2020





Plan

Early response and impact on program capacity

Current US & Wisconsin TB Program data

Predicted future impacts (global)

Plan

Early response and impact on program capacity

Current US & Wisconsin TB Program data

Predicted future impacts (global)

Early Events:



This did not exist for COVID...





How did this impact TB Program capacity?

Cronin AM, Railey S, Fortune D, Wegener DH, Davis JB. Notes from the Field: Effects of the COVID-19 Response on Tuberculosis Prevention and Control Efforts — United States, March–April 2020. MMWR Morb Mortal Wkly Rep 2020;69:971–972.

60–72% of CDC-funded TB programs reported partial or high impact on staffing capacity



Definitions

Partial impact

<50% of personnel time dedicated to COVID-19 response

or some changes made to program activity, but activity is still being performed

High impact

50–100% of personnel time dedicated to COVID-19 response

or major changes made to program activity or activity not being performed at the time of the program's response)

TB program activities with partial/high impact:

Diagnosis/treatment of TB (52%) Diagnosis/treatment of LTBI (68%) Contact investigations for TB (64%) Reporting & other surveillance (58%) Education/Training (94%) & Program evaluation (68%)

WI TB Program Staff



Julie Tans-Kersten



Claire Leback



Pat Heger



Tierney Hall



Philip Wegner



Savitri Tsering

April: Wisconsin TB Program released memo for guidance on public health prioritization of TB services during pandemic

Division of Public Health Information Upda

April 2020

Wisconsin Tuberculosis (TB) Program Informati Response

Background

As public health departments shift staff and resources to mee response, it is important to take steps to ensure that people w disease can continue their treatment, even if routine health ca Centers for Disease Control and Prevention (CDC) has <u>inform</u> emergencies in TB programs.

TB and COVID-19 Co-Infection

Patients with TB disease could become infected with COVIDcondition may unexpectedly deteriorate (e.g., new acute coug patients have respiratory compromise from their TB, making t COVID-19 infection. Therefore, respiratory <u>infection control</u> pr familiar with are of even greater importance. COVID 19 guids

Prioritize:

Evaluation and care of clients with active TB

Management of children on preventive antibiotics

Finishing of LTBI treatment

Exploration of telemed for needed directly observed therapy (DOT), treatment monitoring

Plan

Early response and impact on program capacity

Current US & Wisconsin TB Program data

Predicted future impacts (global)

CDC Prelim Data: New U.S. TB cases down in 2020





*As of 9/30/2020, compared to 2016-19 average

Possible causes:

Underreporting to or within public health

Underdiagnosis of TB (patient & provider behaviors, public health capacity)

True incidence decline? (decreased immigration, population behaviors with masks & social distancing)



Anecdotally...

Decreased call volume (all calls)

Fewer persons reported for evaluation of active TB

More reports from LHDs unable to do normal F/U, DOT for LTBI







For LTBI-Medication Reimbursement

The number of patients who took LTBI medications reimbursed by Wisconsin TB Dispensary dropped by ~40% in March–June 2020.



For Active TB...



The number of newly confirmed cases of active TB were below expected since March '20.



Plan

Early response and impact on program capacity

Current US & Wisconsin TB Program data

Predicted future impacts (global)

Long-term impact for Wisconsin and US not yet known



Global Modeling:

Focused on highburden countries (India, Kenya, Ukraine)

Looked at TB incidence and mortality over next five years

STOP TB Partnership, "The Potential Impact of COVID-19 Response on TB..."



The bad news...

Global TB incidence and mortality set back 5–8 years

+6.3 mil cases and +1.4 mil deaths between 2020–2025

STOP TB Partnership, "The Potential Impact of COVID-19 Response on TB..."

Multifactoral





With challenges, there is a call to action





Raise awareness of interruptions

Rebuild health systems

Restore funding

Stop TB: Civil Society Report on TB and COVID



TB Program Contact Information

Phone: 608-261-6319

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Email: dhswitbprogram@dhs.wisconsin.gov

Website:

https://www.dhs.wisconsin.gov/tb/index.htm


Tuberculosis and COVID-19 Coinfection

Rebecca Szydlowski, RN, Sauk County Public Health Tess Ellens, RN, Public Health Madison & Dane County

Client with Suspected COVID-19

21 year old female, from Peru

Arrived to U.S. in December 2019

Presented to local ED on 3/27 complaining of loose stools, abdominal pain, loss of appetite, weight loss, fever, chills, cough, and shortness of breath for past 2-3 weeks

Given tylenol, IVF, zofran, levophed, and hospitalized "due to concern for COVID-19"

Dx: pneumonia due to infectious organism- sepsis

Suspect Tuberculosis

COVID-19 negative from 3/27

Chest CT from 3/28 "Given the associated bronchiectasis and tree-in-bud nodularity atypical etiologies, such as fungal or mycobacterial, should be considered"

3/28: Quantiferon gold drawn

Sputum collection/QFT

3/29 sputum: mycobacterium tuberculosis DNA detected; 4+ AFB

3/30 sputum: 4+ AFB

Started on RIPE treatment on 3/30

Quantiferon gold: (resulted 3/31) TB1 minus NIL 0.53; TB2 minus NIL 0.52; Mitogen minus NIL 2.10; NIL 0.51

Communication with client

PHN, Spanish interpreter, and client had detailed discussion of what her diagnosis meant and what to expect in the next month(s)

Client began to clinically improve and was d/c'd home on 4/3.

4/4 and 4/5 home visits

Client was in bed sleeping upon arrival each day, reported feeling overall better but tired. PHN noted slight tachypnea and a cough. Patient did not get out of bed either visit.

4/6 home visit

Client reported feeling "fine" but PHN noted increased tachypnea and overall lethargy compared to past two days.

VS: BP 80/60, apical heart rate 144, RR 32, oral temperature of 101.8.

Client then reported chills and fatigue.

Housing Difficulties

"Principal diagnosis: Severe sepsis secondary to COVID-19 infection, superimposed on active tuberculosis"

Medical records reported "she remained afebrile for number of days, she remained without clinical decompensation and most of the last one third to a half of her hospitalization was in trying to find her adequate transitional housing and [an adequate] public health plan to continue monitoring her until she returns to Peru."

Stay at Lowell Center

Patient was d/c'd to Lowell Center from 4/15 to 5/6.

Throughout stay, client reported "feeling fine" but was continuously showing signs and symptoms inconsistent with her statements.

On the day client was intended to be transferred back to Sauk County, Tess noted that although client reports doing well, clinical picture was saying otherwise.

Admitted to St. Mary's from 5/6 to 5/11 for Sepsis, COVID infection, tachycardia, LLL pneumonia.

COVID testing timeline

- 3/27: negative NP swab for COVID-19
- 4/07: positive NP swab for COVID-19
- 4/21: positive sputum for COVID-19
- 4/28: positive sputum for COVID-19
- 5/05: negative sputum for COVID-19

AFB smear timeline

3/29 sputum: mycobacterium tuberculosis DNA detected; 4+ AFB 3/30 sputum: 4+ AFB 4/20: AFB smear; rare 4/21: AFB smear: moderate 4/27: AFB smear; rare 4/28: AFB smear; rare 4/29: AFB smear; rare 5/4: AFB smear: rare 5/6: AFB smear; rare

Cleaning up Communication

During hospitalization, client reports to provider that she has been cleared by PH to go back to Peru.

Many involved: client, sponsor, SCPH, WI TB program, MDCPH, Lowell Center, nurse in Peru, Peruvian consulate, campground

Post-hospitalization

Discharged from St. Mary's to local campground on 5/11

Released from isolation on 5/20

COVID testing timeline

```
3/27: negative NP swab for COVID-
19
```

```
4/06: <u>positive</u> NP swab for COVID-
19
```

```
4/21: positive sputum for COVID-19
```

```
4/28: positive sputum for COVID-19
```

```
5/05: negative sputum for COVID-19
```

AFB smear timeline

```
3/29 sputum: mycobacterium tuberculosis DNA detected; 4+
AFB
3/30 sputum: 4+ AFB
4/20: AFB smear; rare
                           5/11: No AFB seen
4/21: AFB smear; moderate
                           5/13: Rare
4/27: AFB smear; rare
                           5/18 - 5/20; no AFB seen
4/28: AFB smear; rare
4/29: AFB smear: rare
5/4: AFB smear; rare
5/6: AFB smear; rare
```

Where is she now?

Flight home on 6/17

Client contacted PHN recently with questions about paperwork. Client reports completing treatment in September and doing very well.

Planning to return to WI for school/work again in early 2021.



P.A.C.E Credits

- 2 Contact Hours
- P.A.C.E number: <u>035-050-20</u>
- Session Code: <u>2391</u>

ASCLS CE Organizer website: https://ceorganizer.ascls.org/login