

Revised Technical Instructions for Civil Surgeons

October 9, 2018

Speakers



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Agenda

- Review of new technical instructions
- Latent TB infection overview
- Reporting and Referral
- Discussion

Civil Surgeon Tuberculosis Technical Instructions

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September 27, 2018

Agenda

During this portion of the webinar, I will explain:

- The reasons and process for the changes to the Tuberculosis Technical Instructions (TIs)
- Use of interferon gamma release assays (IGRA) in the US screening program
- When to refer or report applicants to health departments
- How to assign tuberculosis classifications to applicants

Helpful Definitions

- Immigrants: People who officially applied for and obtained US immigrant visas overseas and will become lawful permanent residents (LPR) upon arrival to the United States. Their full exam is done overseas by panel physicians. They can apply to become a US citizen after they have been an LPR for 5 years.
- Refugees: They are technically not LPRs yet when they arrive to the United States. They are here under a “protected status.” They are required to apply for adjustment of status at one year to become LPRs (<https://www.uscis.gov/greencard/refugees>). Most of the medical exam, including the tuberculosis screening, is completed overseas.

More Helpful Definitions

- Status adjusters: People applying for lawful permanent resident status while already in the United States on other terms. They must go through the full medical screening with a civil surgeon here in the United States. After 5 years of LPR status, they can apply to become a US citizen (<https://www.uscis.gov/greencard/adjustment-of-status>).
- The medical examination in the TIs can only screen for conditions relevant to US immigration law. It is not a complete medical evaluation.
- Becoming a US citizen is called [naturalization](#), not adjustment of status.

Process for TB TI Revision

- Joanna Regan (DGMQ) lead revision
- Input received from TB TI working group members
 - National Tuberculosis Controllers Association (Sarah Gordon, Lisa Armitage, and Jennifer Flood)
 - Advisory Council for the Elimination of Tuberculosis (Barbara Cole)
 - Stop TB USA (Randall Reves)
 - CDC Division of Tuberculosis Elimination (Terry Chorba)
 - DGMQ (Drew Posey)
- Input received from International Panel Physicians Association

Old IGRA Requirements for Civil Surgeons

- Updated October 2009
- Civil surgeons required to use IGRA or a TST in applicants 2 years of age or older

Current Recommendations for clinical use of IGRA in the United States

CID 2017;64(2):111–5; MMWR 2010;59(RR05);1–25.

- IGRA is recommended instead of TST in patients 5 years or older who
 - are likely to be infected with *M. tuberculosis*,
 - have a low or intermediate risk of disease progression,
 - it has been decided that testing for LTBI is warranted, and
 - either have a history of BCG vaccination or are unlikely to return to have their TST read.

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. 2018; 829–853.

- For children 2 years and older, either TST or IGRA can be used; but in people previously vaccinated with BCG, IGRA is preferred to avoid a false-positive TST.

Preliminary Data* on Health Department Use of IGRA

- Children ages 2–14 years diagnosed with LTBI overseas 2008–2014
- Total number of children in sample 45,951
- Majority (53%) with Class B2 LTBI retested after arrival
- If TST used overseas and retested stateside with IGRA, 69% IGRA-negative

**Preliminary, unpublished data courtesy Zanju Wang*

New IGRA Requirements for Civil Surgeons

- Effective October 1, 2018
- Civil surgeons must use IGRA instead of TST in all status adjusters 2 years of age and older

Civil Surgeon Responsibility for Testing

- New wording in Technical Instructions:

“Civil surgeons that are independent of health departments must not refer applicants to a health department for IGRA testing or chest x-ray; all IGRAs and chest x-rays ordered by civil surgeons must be performed independently of a health department.”

- Civil surgeons must
 - Perform IGRA test
 - Obtain a CXR if IGRA is positive

Civil Surgeon LTBI Required Reporting to Health Departments

- The old TB TIs recommended that civil surgeons report cases of LTBI to health departments.
- The new TB TIs require LTBI cases to be reported to health departments.
- The applicant's name, contact information, IGRA results, and chest x-ray results must be reported to the local health department of jurisdiction.
- Civil surgeons must proactively communicate with the health department of jurisdiction to coordinate referral and reporting.

For all applicants 2 years of age or older

- Medical history
- Physical examination
- IGRA

For those with a positive IGRA,
or signs or symptoms of tuberculosis,
or known HIV infection

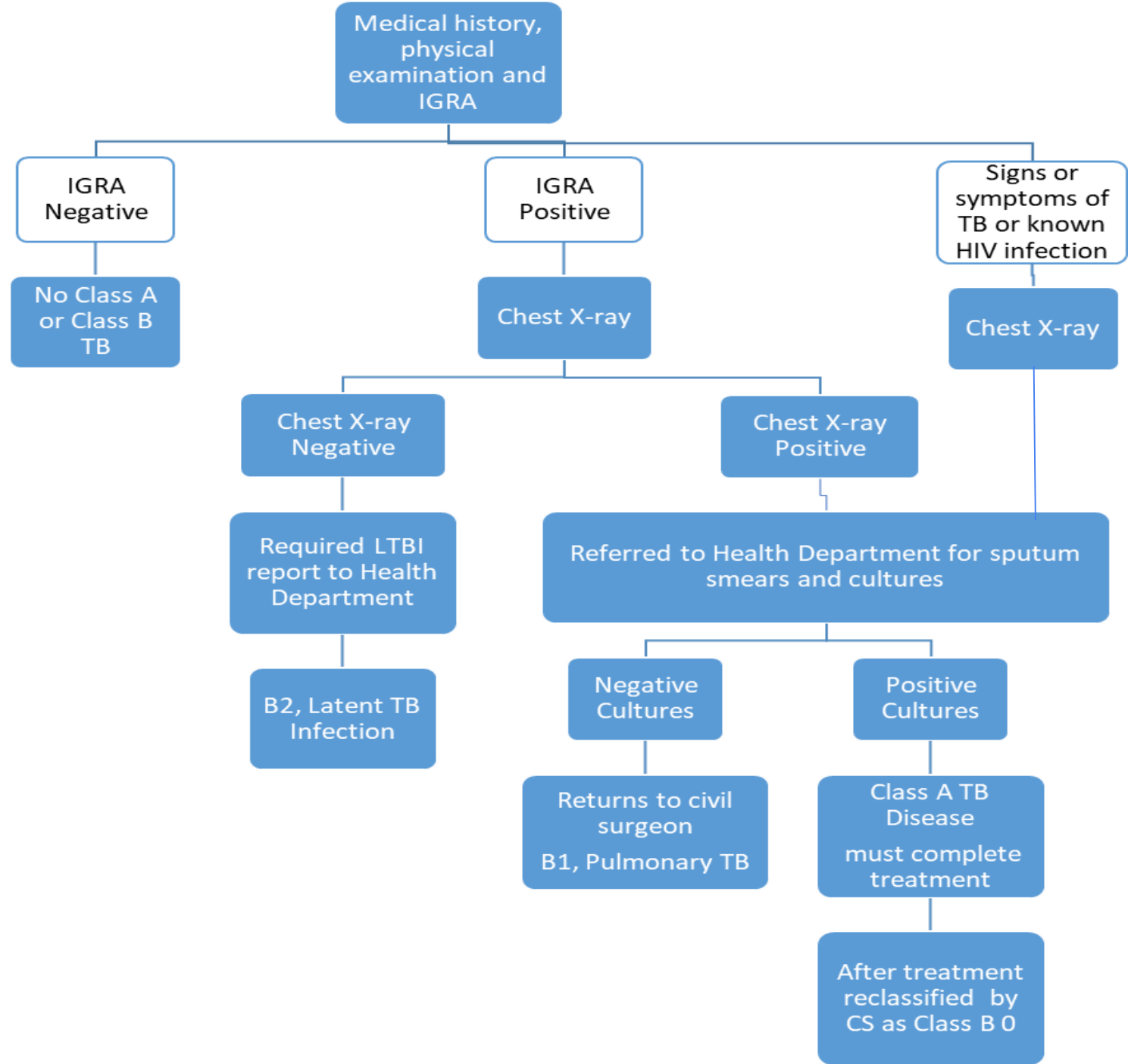
- Chest x-ray

For those with a chest x-ray suggestive of tuberculosis,
or signs or symptoms of tuberculosis,
or known HIV infection

- Required referral to health department of jurisdiction for further evaluation

For those with positive IGRA,
AND normal chest x-ray,
AND no signs or symptoms of tuberculosis,
AND no known HIV infection

- Required civil surgeon LTBI report to health department of jurisdiction



For Children Less than 2 Years of Age

- All applicants less than 2 years of age must have a physical examination and history provided by a parent or responsible adult who knows the child best.
- Only those who have signs or symptoms suggestive of tuberculosis disease or have known HIV infection
 - must have a TST or IGRA, and
 - must have a chest x-ray, and
 - must be reported to the health department of jurisdiction for further evaluation.

Thank you!
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For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.





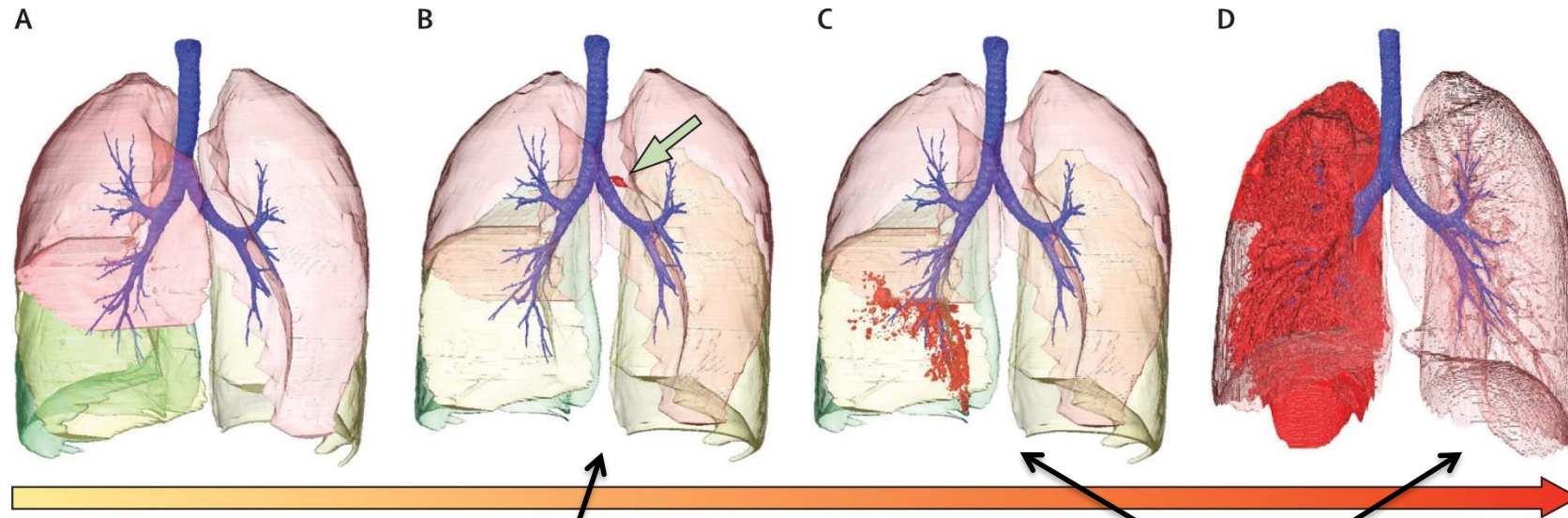
Latent Tuberculosis Infection: Opportunities for Preventing Tuberculosis

Revised Technical Instructions for Civil Surgeons

Shereen Katrak, MD, MPH
Medical Officer, TB Control Branch
October 9, 2018

1. Relevance of latent TB infection (LTBI)
2. Diagnosis of LTBI
3. Treatment of LTBI
4. Summary

Spectrum of disease



Latent TB Infection

- ***Absence of TB symptoms***
- Positive TST¹ or IGRA² result
- Chest radiograph normal
- Not infectious

¹TB skin test

²Interferon gamma release assay

Active TB Disease

- ***Symptoms such as cough, fever***
- TST or IGRA is usually positive
- Chest radiograph is usually abnormal
- Respiratory specimens usually culture positive (smear positive in about 50% of patients)

Why does LTBI matter?

- Risk factor for active disease
- Other health risks?
 - Compared with healthy controls, LTBI increases immune activation^{1,2}
 - Risk of other diseases, like MI?³
- Public health: reservoir for new cases

Why does LTBI matter?



Latent Tuberculosis Infection: Screening

Release Date: September 2016

Recommendation Summary

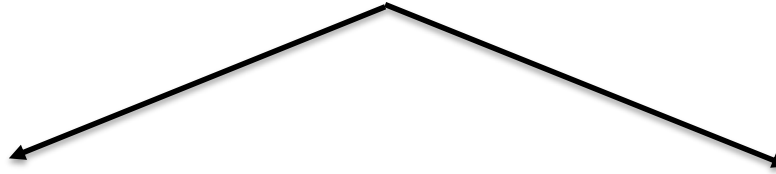
Population	Recommendation	Grade (What's This?)
Asymptomatic adults at increased risk for infection	The USPSTF recommends screening for latent tuberculosis infection (LTBI) in populations at increased risk.	



Prevent TB disease for patient and their family

1. Relevance of latent TB infection (LTBI)
- 2. Diagnosis of LTBI**
3. Treatment of LTBI
4. Summary

TB Lab Tests



TB skin test (TST)

1. TB Skin test



Interferon-gamma release assay (IGRA)

1. QuantiFERON[®]-TB Gold (QFT)
2. QuantiFERON[®]-PLUS (QFT-Plus)
→ replacing QFT-Gold
3. T-SPOT.TB (T-Spot)



No lab test can distinguish active from latent infection!

Tuberculin Skin Test (TST)

- How to read:
 - Measure induration (not erythema) at 48-72 h
 - Record millimeters
- Positive test:
 - $\geq 5\text{mm}$ for immunosuppressed including HIV, recent contacts
 - $\geq 10\text{mm}$ for all others with TB risk

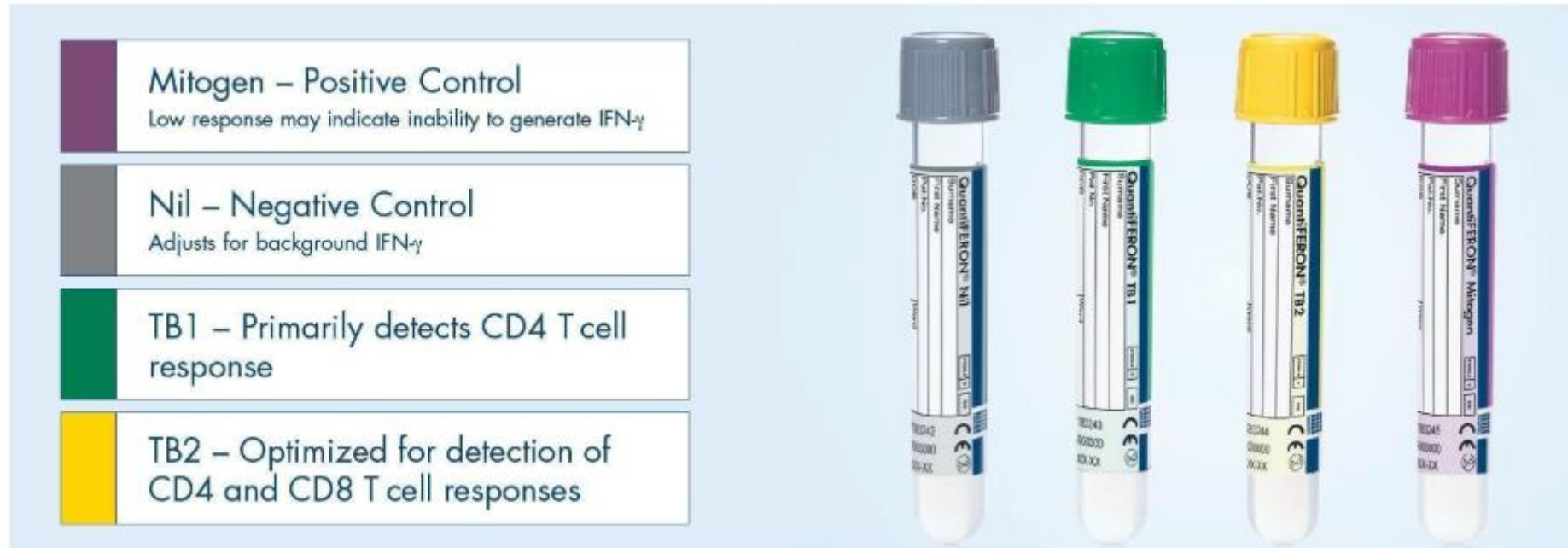


IGRA vs TB skin test advantages

- **IGRA** advantages over TST include...
 - Not affected by BCG vaccination
 - Not affected by most non-tuberculous mycobacteria
 - Interpretation is included with result
 - No return visit needed for interpretation



Quantiferon tests (QFT & QFT-Plus)



- Reporting : positive, negative, indeterminate
- Use in kids ≥ 2 , adults including pregnant women
- Okay to use in immunocompromised, but all tests (IGRA and TST) impacted by low CD4

T-SPOT



- Reporting : positive, negative, borderline
- Use in kids ≥ 2 , adults including pregnant women
- Okay to use in immunocompromised, but all tests (IGRA and TST) impacted by low CD4

Ruling out active disease



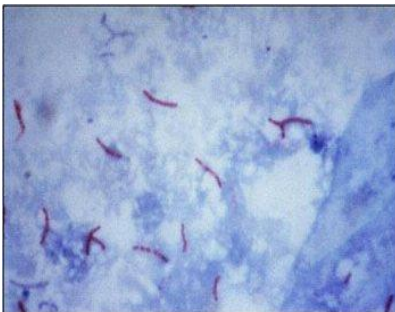
1. Symptom screen

- Cough
- Hemoptysis
- Weight loss
- Fevers/sweats
- Extreme fatigue



2. Chest x-ray

- Infiltrate
- Cavitory lesion
- Nodule
- Effusion
- Hilar LAD



3. Sputum collection

- AFB smear & culture
- MTB PCR

Key Points

1. IGRA (QFT-Plus or T-SPOT) should be used to diagnose TB infection
2. No lab test can distinguish between latent TB infection and active TB disease
 - Must rule out active disease before diagnosing & treating for LTBI

1. Relevance of latent TB infection (LTBI)
2. Diagnosing LTBI
- 3. Treatment of LTBI**
4. Summary

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

DECEMBER 8, 2011

VOL. 365 NO. 23



Three Months of Rifapentine and Isoniazid for Latent Tuberculosis Infection

	INH-RPT N=3,986	INH N=3,745	P-value
Effectiveness	1.9 per 1,000	4.3 per 1,000	Non-inferior
Completion	82.1%	69.0%	P<0.001
Hepatotoxicity	0.4%	2.7%	P<0.001

Treatment Regimens for Latent TB Infection

Medication(s)	Frequency	Duration	Doses
Rifapentine (RPT) + INH	Weekly	3 months	12
Rifampin	Daily	4 months (vs 3months)	120
Isonizaid (INH)	Daily	6–9 months	180 - 270

Summary

1. Testing & treating for LTBI is an opportunity to prevent TB
2. Use IGRA (QFT-Plus & T-SPOT tests)
3. Rule out TB disease before treatment
4. Shorter regimens such as INH + RPT (3HP) offer improved completion rates

Revised Technical Instructions for Civil Surgeons: Implementing Reporting to Health Departments

Pennan Barry, MD, MPH

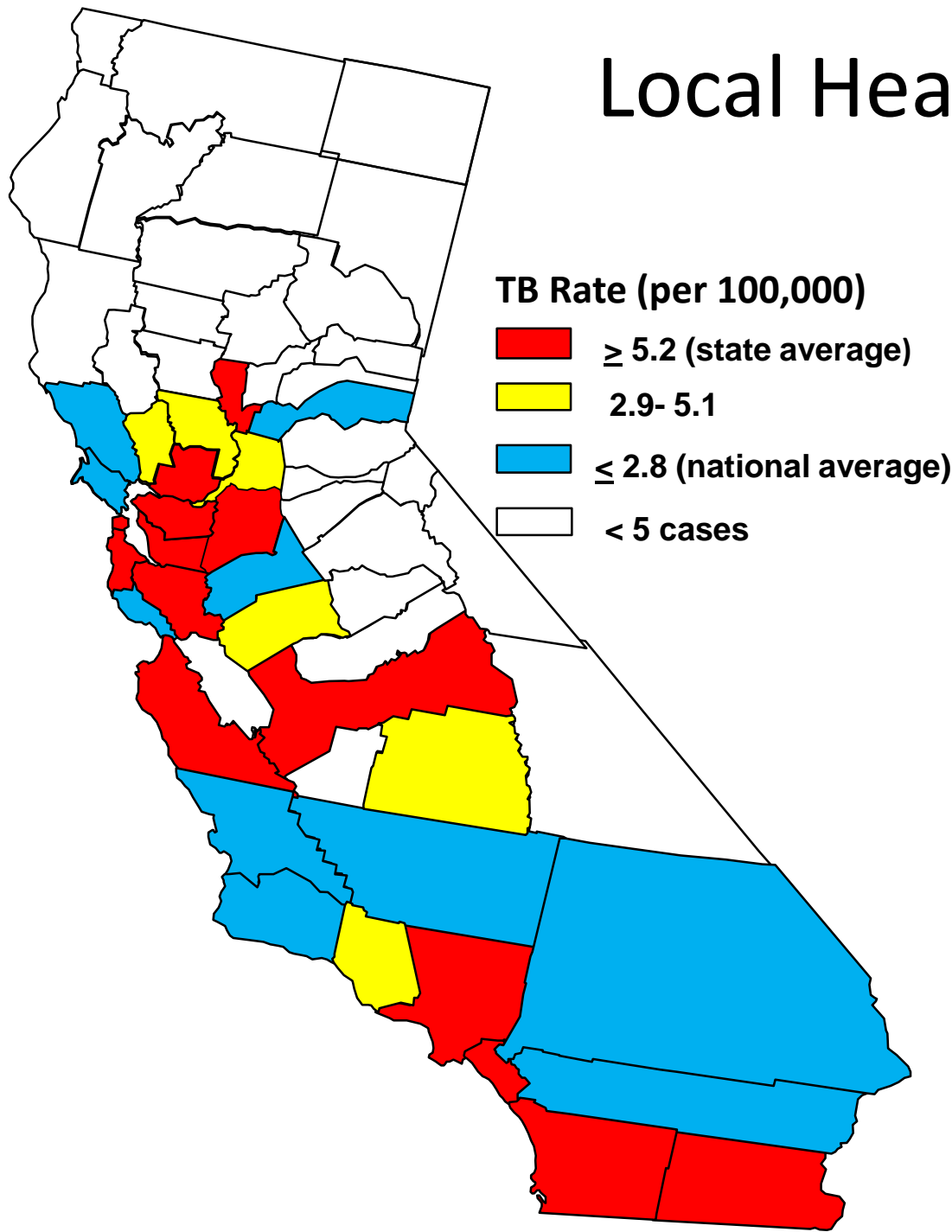
Chief, Surveillance and Epidemiology Section

October 9, 2018

Civil Surgeon LTBI Reporting

- Notification to LHD of LTBI diagnosis required
 - name, contact information, IGRA results, CXR results
 - Patient informed of reporting
 - Patient counseled on importance of LTBI treatment
 - LTBI treatment not required for medical clearance
 - Reporting exception: prior documented LTBI treatment completion, normal CXR, no symptoms
- *Referral* to LHD required for applicants with abnormal CXR, TB symptoms, HIV infection
 - Contact LHD directly

Local Health Departments (LHD)



- 61 jurisdictions
 - 58 counties plus Berkeley, Long Beach, Pasadena
- Report to jurisdiction where applicant resides

Contact your local TB program

- “civil surgeons must proactively communicate with health department of jurisdiction to coordinate referral and reporting”
- Contact info available here: <https://ctca.org/locations.html>

Reporting Mechanism

- Report to jurisdiction where applicant resides
- San Diego, San Francisco, Santa Clara:
 - report according to their instructions
- All other jurisdictions
 - Report using CalREDIE Provider Portal
 - Contact local program to get a Provider Portal account

CalREDIE Provider Portal

Submit reports to Health Departments electronically!

What is CalREDIE?

- California Reportable Disease Information Exchange (CalREDIE) is the California Department of Public Health's (CDPH) communicable disease reporting and surveillance system of record.
- It is used by state and local public health officials and healthcare providers for communicable disease reporting and surveillance.



**Civil Surgeon
submits
report
via PP**

What is the Provider Portal (PP)?

- Secure, web-based interface within CalREDIE
- Allows Civil Surgeons to electronically submit latent TB infection (LTBI) reports to Local Health Departments (LHDs)

Provider Portal Account Setup

- Civil Surgeon and staff:
 - submits Reporter Authorization form to LHD
 - Each person using the portal required to have own account (e.g., administrator, clerk)
- LHD:
 - verifies reporter account
 - submits to CalREDIE
- CalREDIE Help:
 - creates account
 - emails reporter their username and password

Webinar for Provider Portal Users

- Step by step how to use provider portal to report LTBI
- October 11, 2018 at Noon
- Register: <https://cdph-conf.webex.com/cdph-conf/onstage/g.php?MTID=e5474ce5c9145fb54692cacf955100c3c>



LTBI Treatment

- Coordinate LTBI treatment with local program
- Options may include:
 - Local TB public health clinic or clinics identified by local TB program (to be listed on CTCA.org website)
 - Applicant's established primary care provider
 - Civil surgeon's clinic

Referral for LTBI treatment

- Use template form to refer
(will be available at CTCA.org; coordinate with LHD)
 - Include printed IGRA report
(should include quantitative results)
 - Include printed CXR report
- Record referral in Provider Portal (if using)
- If treating at Civil Surgeon clinic,
report treatment completion/outcome to LHD

Notification Requirement: TB prevention opportunity

- Population with TB risk
- Already tested and TB ruled out
- Provide or link applicants to LTBI treatment to prevent future active TB disease

Reporting Resources

- CTCA Civil Surgeons Webpage:
 - <https://www.ctca.org/menus/civil-surgeons.html>
- LHD Contact Info:
 - <https://ctca.org/locations.html>
- CDPH TB Control Branch Website:
 - <https://cdph.ca.gov/tbcb>
- LTBI treatment information:
 - <https://cdph.ca.gov/LTBITreatment>
- CalREDIE Help:
 - <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CalREDIE-HELP.aspx>

Summary

- New technical instructions require
 - Use of IGRA instead of TST
 - Reporting to local health department
- Can report using the provider portal but check with your local health department first
- Help eliminate TB in California by referring your patients for LTBI treatment



Questions

- Resources are available at tbfreecalifornia.org
- Local health department contacts available at: ctca.org
- How to use the provider portal webinar: October 11 at Noon