

# Reporting for TB Infection (LTBI): Step 1 Establishing a case definition

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# Objectives

Who we are and how did we get here

Discuss strategy for TB infection (LTBI) Surveillance

Purpose of TB infection Surveillance

Defining a “case” of TB infection (LTBI)

Scenarios and advice based on common questions

Where does the CDC fit?

Future plans!

# Some clarification on language

The language used to describe the pre-disease/non-symptomatic state of Tuberculosis is currently the subject of a lively discussion within the TB public health community.

Historically, its called Latent TB Infection, or LTBI, which is well known but not technically accurate.

I will be referring to this state as “TB Infection” and the (often) symptomatic phase as “TB Disease”

# Some background on TB Surveillance

“I thought TB was already reportable? Hasn’t the case definition already been established?”

**TB Disease (“Active TB”)** is reportable everywhere and reportable to CDC. The case definition was last revised in 2008

**TB Infection (“LTBI”)** is not reportable to CDC, and reporting varies widely by jurisdiction. No official case definition has previously been established

# Other Definitions

NTCA = National TB Controllers Association

SETC = Society for Epidemiology in TB  
Control (subset of NTCA)

IGRA = Interferon Gamma Release Assay – a relatively recently developed TB blood test

TST = Tuberculin Skin Test – An intradermal purified protein derivative (PPD) injection, the standard test for TB infection for 100+ years

# LTBI Surveillance Workgroup

NTCA tasked the Society for Epidemiology in TB Control (SETC) to form a workgroup

Approached the task like Epi's

- Defined a purpose and approach
- Study some existing infrastructure and programs. Look at literature.
- Start tackling ideas one at a time, establishing a roadmap

# Who we are

Very important to have as broad and representative a group as possible

So Far

Everyone Welcome!

**17** States

**2** Counties

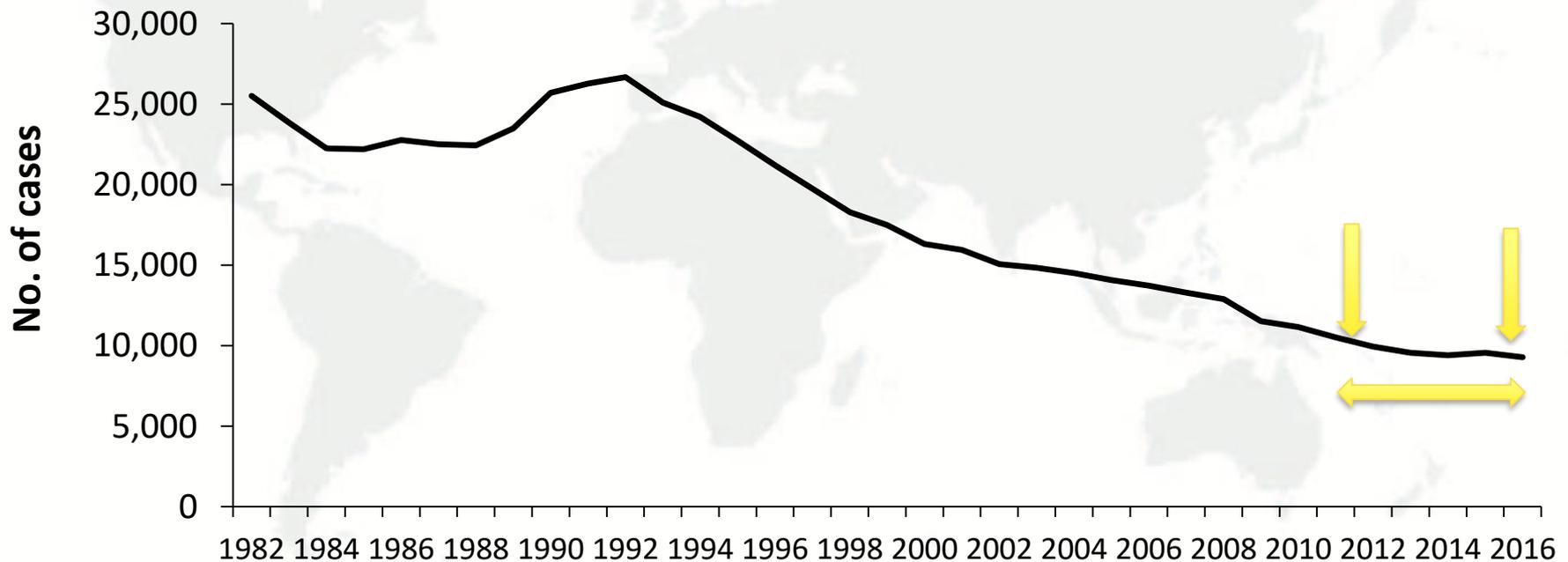
**1** City

and the CDC!

More interest all the time

# Why is everyone talking TB Infection all of a sudden?

## Reported Tuberculosis (TB) Cases United States, 1982–2016\*



\*As of June 21, 2017.

## TB Morbidity United States, 2011–2016

<b>Year</b>	<b>No.</b>	<b>Rate*</b>
2011	10,509	3.4
2012	9,940	3.2
2013	9,561	3.0
2014	9,398	3.0
2015	9,547	3.0
2016	9,272	2.9

\* Cases per 100,000 population; as of June 21, 2017.

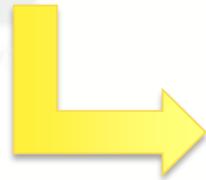
# Purpose and Scope – In general

It is the purpose of this working group to consider fully the idea and practice of surveillance for TB infection, to come to a representative consensus as to the direction and priority of such surveillance activities and to promote the agreed upon position of this workgroup to all partners

# A Roadmap

**Start:** Why are we doing surveillance?

What is TB infection?



What's happening already?

Data elements needed?

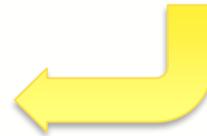
(Reporting & Outcomes)



Construct a framework

(Tiers, Key elements etc.)

**End:** Promote strategy



# Why do Surveillance for Infection?

Open with discussion of possible reasons for TB infection surveillance.

Settled on 3 categories:

1. Quantify the burden of TB Infection
2. To improve case finding for TB Disease
3. Improve treatment completion for TB Infection – Reducing case rates for TB Disease

# Standards

As work progressed it became clear that not everyone knew what we were talking about when we said

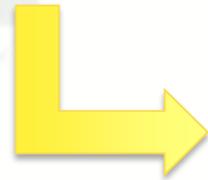
**LTBI**

Or rather... we all knew what **WE** were talking about

# A Roadmap

**Start:** Why are we doing surveillance?

What is TB infection?



What's happening already?

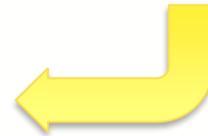
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# Establishing a Case Definition

Establishing a definition for TB infection requires a general shift in thinking.

Two overall ways to think about it

1. Define TB infection clinically
2. Define TB infection for surveillance

# Constellation of Possibilities

When do we start to count a  
“Case” of TB infection?  
(And who reports it?)

ELR reporting of positive blood tests

Clinician reporting of all positive TB tests

Clinician reporting of all positive TB tests  
+ evaluation

# We're Epidemiologists so...

Defined TB infection for surveillance

**ONLY!!!!**

Definition drafted, revised, widely distributed and presented, feedback solicited and incorporated and finally...

Presented to and adopted by CSTE at the  
2017 annual meeting

# TB infection Definition Highlights

## Diagnostic Testing Criteria for TB Infection

- A positive tuberculin skin test (TST)
- A positive interferon gamma release assay (IGRA)

# In Combination With

## Clinical Criteria for TB Infection

No clinical evidence compatible with active tuberculosis (TB) disease including:

No signs or symptoms consistent with TB disease

**AND**

Chest imaging without abnormalities consistent with TB

**OR**

Abnormal chest imaging that could be consistent with TB disease with microbiologic testing that is negative for MTB complex and where TB disease has been clinically ruled out

# Establishing Classifications

## **Suspected TB Infection**

A case that meets one or more of the diagnostic testing criteria

**AND**

*M. Tuberculosis* complex was not isolated from a clinical specimen  
(IF ONE WAS COLLECTED)

## **Confirmed TB Infection**

A case that meets one of the diagnostic testing criteria for TB infection

**AND**

*M. Tuberculosis* complex was not isolated from a clinical specimen  
(IF ONE WAS COLLECTED)

**AND**

Meets the clinical criteria for TB Infection as defined

# Case Definition Exclusions

- Persons who have been previously diagnosed and/or treated for TB infection
- Persons who have been previously diagnosed or treated for TB disease

While this may result in some under-reporting, especially in the shorter term, we emphasize that this is a surveillance definition. Treatment of previous positive individuals would remain the same.

# Case Definitions Next Steps

Getting the word out!

- Distribution & Promotion & Education
  - Alerting partners, newsletters, word of mouth
  - Presentations, webinars, Q&A sessions
- Monitor Usage & Evaluation
  - Partnership with CDC on next steps
  - Utilization in existing reporting infrastructure
  - Craft an evaluation plan for definition uptake and effectiveness
- Solicit feedback and modification

# A Case Definition Applied - 1

Scenario: Our patient did not come in for their evaluation to rule out TB disease after having a positive Skin Test/IGRA result. Would this still fit with the definition?

Answer: Yes! There are myriad situations (ELR?) where a patient's test result might be known but the status of the evaluation is not.

Classification: Suspected TB Infection

# A Case Definition Applied - 2

Scenario: I have a patient with both a skin test and an IGRA and the results don't match. What do I do?

Answer: Strictly speaking, by this case definition either test being positive is enough to trigger the classification system.

However....

# A Case Definition Applied - 3

Scenario: I have a low-risk patient with a positive result and I don't believe it. Should I apply the definition?

Answer: The definition allows for the classification of positive results. If a result doesn't seem accurate, diagnostic guidelines from the ATS and CDC should be followed to establish veracity. False positive test results would be treated as negative.

# A Case Definition Applied - 4

Scenario: I have a patient being treated presumptively for TB infection without a positive test result. How would they fit in?

Answer: Because the definition requires a diagnostic test to be positive, this patient would not meet the case definition criteria. This should not change clinical management of the case

# A Case Definition Applied - 5

Scenario: I have a patient that has been treated for suspected TB disease for 2 months, but was determined not to have active disease after being culture negative. Can I still count them?

Answer: Yes! The case definition would still apply, as soon as the patient has a positive test and has had TB disease ruled out clinically, in this case, two months later.

# Other work and looking ahead...

**Start:** Why are we doing surveillance?

What is TB infection?

**What's happening already?**

Data elements needed?  
(Reporting & Outcomes)

Construct a framework  
(Tiers, Key elements etc.)

**End:** Promote strategy

# A Path to National Notification

Any path to mandated reporting will of necessity include:

1. Some sort of tiers based infrastructure development path (not all jurisdictions are created equal)
2. A common language of key data elements for use between jurisdictions
3. A commitment to collecting outcomes data as well as reporting data

# So What's the End Game?

Ultimately – The goal is to eliminate TB

We posit that this will be achievable with effective public health action against TB infection at some level.

But how do we measure that?

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- NTCA
- CSTE
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- Mass. DPH
- Many more

# Questions?

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