US CDC’s role for scaling up programmatic management of LTBI

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Technical Consultation Meeting on the Programmatic Management on Latent Tuberculosis Infection

1 September 2017
Seoul, South Korea
How Do We Improve LTBI Testing and Treatment?

**TB Prevention Cascade**

- Who do we test?
- Can we make diagnosis more efficient?
- Can we improve treatment completion?

<table>
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<tr>
<th>% of Population at high risk for LTBI</th>
<th>All individuals with LTBI</th>
<th>Engaged in care</th>
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US CDC Division of TB Elimination (DTBE) LTBI Activities

- Mathematical modeling
  - Impact of LTBI treatment on achievement of TB elimination (Hill et al, 2012)
  - Cost-effectiveness of different testing and treatment strategies (NEEMA consortium)
- Research: TB Trials Consortium (TBTC) and TB Epidemiologic Studies Consortium (TBESC)
  - Treatment trials
    - 3HP clinical trial (Sterling et al, 2011)
    - 3HP DOT vs. SAT (Belknap et al, pending)
    - 6 week daily RPT clinical trial to launch 2018
  - Epidemiologic studies
    - Predictive value of IGRA and TST diagnostic tests
    - Use of latent class analysis for LTBI prevalence and test characteristics
    - IGRA reproducibility studies
US CDC Division of TB Elimination (DTBE) LTBI Activities (II)

- **Operational research**
  - Post-marketing 3HP project (Sandul et al, etc.)
  - Program-level system to measure the TB Prevention Cascade and improve the cascade through implementation research (STEMS)
  - Engaging with community providers to measure TB Prevention Cascade in high-risk populations

- **Surveillance**
  - Molecular epidemiology to identify recent transmission vs. reactivation
  - Develop LTBI Infection surveillance system (TBLISS)

- **Policy**
  - U.S. Preventive Service Task Force Recommendations for LTBI testing

- **Training** – 5 Regional Training and Medical Consultation Centers (RTMCC)
US CDC LTBI Activities that Support LTBI Programmatic Management Globally

- Operational research
  - Post-marketing 3HP project (Sandul et al, etc.)
  - Program-level system to measure the TB Prevention Cascade and improve the cascade through implementation research (STEMS)
  - Engaging with community providers to track TB Prevention Cascade

- Surveillance
  - Molecular epidemiology to identify recent transmission vs. reactivation
  - Develop LTBI Infection surveillance system (TBLISS)

- Policy
  - U.S. Preventive Service Task Force Recommendations for LTBI testing

- Training – 5 Regional Training and Medical Consultation Centers (RTMCC)
Barriers To TB Elimination

- Health departments mainly focus efforts on TB cases
- LTBI is not a national reportable condition (some states report)
- Lack of a gold standard test for LTBI diagnosis
- Less than 50% LTBI treatment completion nationally
- Lack of a standard LTBI data collection system
Feasible Solution to Measure and Improve the Cascade

- A comprehensive LTBI data collection and management system that can be used at the national, state and local levels

- A system that can also be compatible with the proposed TB Latent Infection Surveillance System (TBLISS)

- A system that allows electronic data transfer from other electronic health records
Using the Cascade for Programmatic Improvement/Case Management

TB Prevention Cascade

- All individuals with LTBI
- Engaged in care
- Tested for LTBI
- LTBI/no TB
- Started LTBI treatment
- Completed LTBI treatment

% of Population at high risk for LTBI

- LTBI not diagnosed
- LTBI rx not started
- LTBI rx not completed
SURVEILLANCE FOR TUBERCULOSIS ELIMINATION MANAGEMENT SYSTEM (STEMS)

This instruction manual provides a reference guide for how to use and navigate STEMS.

STEMS INSTRUCTION MANUAL

U.S. Department of Health and Human Services

Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of Tuberculosis Elimination
Tuberculosis Epidemiologic Studies Consortium (TBESC)

August 1, 2017
Important Features of STEMS

- Free for programs
- User-friendly web-application
- Generates customized reports
- Able to track patients from referral through discharge
- Data can be uploaded from existing electronic health record systems
- Data can be downloaded for local analysis
- Can interface with TBLISS
Minimum data elements (MDEs)

- Date of birth
- Country of birth
- Primary reason the patient is being evaluated
- Diabetes mellitus at the time of diagnostic evaluation
- Test type (TST, QFT, T-SPOT)
- Test Results
- Diagnosis/ATS classification
- LTBI regimen
- LTBI treatment completion
- Adverse event
Timeline of STEMS Development

- **Part B protocol Development**: March 2014
- **NG starts STEMS build**: November 2015
- **Part B protocol Finalized**: March 2016
- **Official STEMS Release**: January 2017
- **Development of Minimum Data Elements**: March 2014
- **Beta Testing**: February 2016
- **Pilot Testing**: September 2016
The latest version 1.2.1 was released on July 31, 2017
STEMS, Part of a Larger Process

STEMS plays two key roles

- As an LTBI patient management system that can be used by TB clinics to ensure optimal patient management
- As part of a larger mission, it will provide information for the national LTBI surveillance system, TBLISS
LTBI Surveillance History (pre-2016)

- National TB Controllers Association (NTCA) surveyed TB programs, which revealed substantial support for national LTBI reporting if:
  - Reporting system was efficient and effective
  - Resources were adequate
- Advisory Council for the Elimination of TB’s LTBI Reporting Workgroup provided input in 2015
- TBESC transitioned to a new focus on improving LTBI reporting and on the TB Prevention Cascade
LTBI Surveillance History (2016)

- DTBE Surveillance Team adopted a 5-year goal to implement a TB Latent Infection Surveillance System (TBLISS) by 2020
- National TB Controllers Association (NTCA) established an LTBI reporting workgroup
- Early discussions between DTBE and NTCA
  - Both workgroups were very early in their respective processes
  - Sense was that working on separate, parallel tracks would be advisable with the intent to reconnect later
Capability Gap

- TBLISS would track and report LTBI data not currently available in order to facilitate:
  - Establishment of strategic partnerships to monitor LTBI
  - Identification of surveillance infrastructure gaps and needs
  - Creation of LTBI prevalence baselines, indicators, and targets
  - Focusing of attention on TB control program efforts to reduce LTBI prevalence
Stakeholders

- CDC
- State and local TB control programs and clinics
- Private and public healthcare providers
- Clinical laboratories
- Policymakers
- Nongovernmental organizations that serve at-risk populations
### Logic Model

#### Inputs
- Adequate data collection infrastructure (data standards, data collection tools)
- Accurate, complete, timely, and secure data on LTBI cases
- Motivated and trained staff
- Policies, guidelines, and agreements
- Monitoring and evaluation plan and tools
- Concept of Operations (ConOps) document
- Quality assurance procedures and tools
- Technical requirements

#### Activities
- Ensure functional state of surveillance system – TBLISS implementation
- Validate data
- Train site personnel (consultants, managers, data entry)
- Analyze LTBI data
- Conduct ongoing evaluation efforts to improve data elements
- Continue data sharing with TBESC sites and others
- Provide technical assistance to sites
- Disseminate surveillance data

#### Outputs
- Accurate reports on LTBI trends and characteristics
- Epidemiological research studies
- Evaluation reports
- Presentations
- Slide sets
- LTBI benchmarks and performance indicators
- Fact sheets
- Training manuals
- LTBI annual reports

#### Short Term
- Improved understanding of the epidemiology of LTBI:
  - Improved understanding of the obstacles to completion of LTBI treatment
  - Better understanding of the risk factors associated with LTBI

#### Intermediate
- Increase the number of LTBI patients completing treatment
- Inform the development of better programs to serve the LTBI population

#### Long-Term
- Decrease in the number of LTBI cases that will develop into TB disease

### TB Elimination

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- Decrease in the number of LTBI cases that will develop into TB disease
Potential TBLISS Data Sources

1. Programs with existing LTBI reporting systems
   - Local TB/LTBI CMS
   - Maven
   - ATLAS Worldcare
   - Other systems
   - Multiple external systems

2. Healthcare Provider Electronic Health Records
   - Epic
   - NextGen
   - Centricity
   - Other systems
   - Multiple external systems

3. Programs with LTBI data but no reporting systems
   - NTSS Case Report LTBI Reporting Module
   - CDC web-based system

4. Surveillance for TB Elimination Management System (STEMS)
   - Patient Registration
   - Case Management
   - Appointments
   - ATS Classification
   - Relationships
   - Clinical Documents
   - Alerts/Notifications
   - Contact Management
   - CDC web-based system with State review

TB Latent Infection Surveillance System

- Descriptive Analytics
- Quality Assurance
- Reporting

Programs that want a clinic-based LTBI patient management system

- Opportunity to benefit from TBESC Research and Tools
- Configurable
- Clinic-based
- Comprehensive LTBI Case Management System
Data Elements

- Near-term need to establish standard data elements for collection
  - STEMS variable definitions will greatly influence TBLISS definitions
  - Need to adhere to RVCT definition where there is overlap
- Need to assess ability of potential reporting areas to submit data using TBLISS standard definitions
TBLISS Proposed Data Elements to be Collected — Core

- Date Reported
- Reporting Address
- Patient Referral Information
- Primary Reason Evaluated for LTBI
- Date of Birth
- Sex at Birth/Gender Identity
- Race/Ethnicity
- Country of Birth
- Country of Birth of Parents

- TST/IGRA Results
- Chest Radiograph Result
- HIV Status
- Homeless/Incarcerated/LTCF
- Substance Abuse
- Primary Occupation
- Additional TB Risk Factors
- LTBI Treatment Information
- Progression to TB Disease
Conclusion

- US CDC portfolio for LTBI activities span surveillance, research, modeling, policy, and training
- TB Prevention Cascade allows measurement of LTBI activities for surveillance and program needs
- Standardized elements and definitions for TB Prevention Cascade crucial
- Feasible to use STEMS for case management
- TBLISS to collect LTBI data from different sources to track LTBI diagnoses and treatment for national program
Acknowledgements

- Surveillance team
  - Adam Langer
- TBESC
  - Thara Venkatappa
  - Dolly Katz
  - Pei-Jean Feng
  - Jim Wu
  - Matt Whipple
- NG database developer
  - Kumar Batra
- SEOIB
  - Tom Navin
TBESC-II: Focus on LTBI

Part A: Comparing Predictive Value of LTBI Tests

Part B: Measuring the TB Prevention Cascade

Part C: Closing the Gaps in the Cascade

Part D: Ultra-short LTBI Regimen Trial

10 years

2011 2016 2021