Essential Mycobacteriology Laboratory Services in the Era of MDR- and XDR-TB: A TB Controller’s Perspective

James Watt, MD, MPH

Acting Chief, Tuberculosis Control Branch California Department of Public Health
“The use of rapid, accurate mycobacteriology laboratory services and the prompt reporting of results to providers and the local health departments are essential to the control of tuberculosis.”

CDPH/CTCA/CAPHLD Joint Guidelines for Mycobacteriology Services in California, 1998/2008
“Public health laboratories should:

- assess and monitor the competence of laboratories that perform any testing related to ...TB within their jurisdictions;
- develop guidelines for reporting and tracking of laboratory results;
- educate ...health care providers, and public health officials about available laboratory tests, new technologies, and indications for their use.”

“Effective TB control depends on an integrated system that includes clinicians, laboratorians, and TB-control officials.”

General Characteristics

• The possibility of drug resistance increases the importance of making rapid and accurate diagnoses.
• Important characteristics for laboratory services
  – rapid
  – accurate (sensitivity and specificity)
Factors that Influence Rapidity and Accuracy

• Laboratory systems
  – specimen shipping
  – turn around times
  – information systems

• Specific tests
  – active TB—delay in diagnosis could result in transmission of drug resistant disease
  – latent TB infection (LTBI)—treatment decisions for MDR exposure difficult
Diagnosis of Active TB--Scenario

- 45 yo recent immigrant from Philippines
- previously treated for TB
- presents with 10 days of cough and fever
- CXR:
  - RUL scarring
  - RML infiltrate
- Sputum smear negative
Diagnosis of Active TB—Essential Services

• Assessment:
  – TB or non-TB pneumonia?
  – high risk for drug resistant TB
• Problem: possible transmission of drug resistant TB
• Objective: rapid, accurate diagnosis
• Important tests:
  – fluorescent microscopy
  – nucleic acid amplification tests
  – selective, liquid culture system
  – nucleic acid probes to identify *M. tb* complex
Diagnosis of LTBI--Scenario

- 17 yo high school student
- Culture confirmed MDR-TB
- Smear positive, cavitary CXR
- Urban high school
  - >3,000 students
  - 40% students foreign born
Diagnosis of LTBI—Essential Services

- Problem:
  - high background TST positivity
  - difficulty in assessing transmission
  - difficulties of treatment after MDR exposure
- Objective: increase the specificity of LTBI diagnosis
- Important test: IGRA
Services Specific to Drug Resistance

• Critical characteristics:
  – rapid
  – accurate

• Important tests:
  – rapid, molecular diagnosis
  – broth based first line susceptibility
  – standardized second line susceptibility
Other Important Tests

- Clinical monitoring of MDR-TB patients
  - drug levels
  - tests for toxicity
- Genotyping
Example of Consultation

- Annual testing employees (n=300)
- TST used in past (few positives)
- IGRA implemented
  - 9% positive
  - 7% indeterminate
- Collaborative investigation revealed high nil levels
- Repeat tests negative

Consultation

- Private laboratories
  - reporting and specimen submission
  - quality assurance
- Clinicians
  - appropriate testing
  - interpretation of results
  - resolution of complex situations
- TB control program
  - efficiency
  - prioritization
Summary—3 Aspects

• Importance of rapid and accurate laboratory services for TB control
• Specific tests related to drug resistance
• Consultative role of Public Health Laboratories
• Dialogue about creating an efficient and effective system for TB control
End Here
Essential Mycobacteriology Laboratory Services

- General tests
  - fluorescent microscopy
  - NAAT
  - broth culture system
  - IGRA

- Consultation

- Susceptibility tests
  - rapid, molecular diagnosis
  - broth based first line susceptibility
  - standardized second line susceptibility (reference)
Prompt, accurate diagnosis and effective treatment are not only essential for good patient care—
they are the key elements in the public health response to tuberculosis and the cornerstone of tuberculosis control. *International Standards for Tuberculosis Care, 2006.*