# 8th National Conference on Laboratory Aspects of Tuberculosis - 2013

The Shifting Role of the Clinical Laboratory

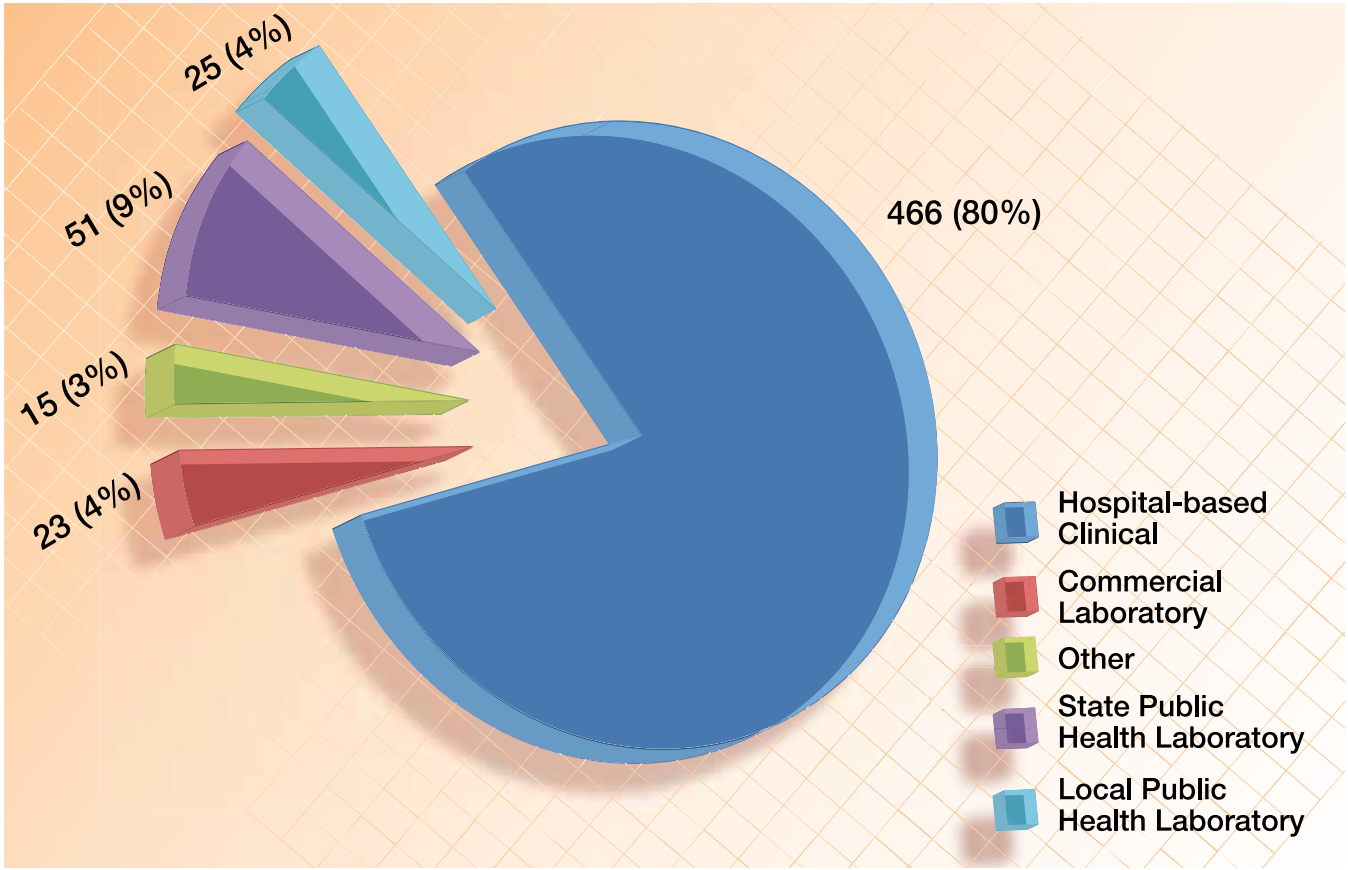
# Goals

- Current state
- Current challenges
- Current solutions
- Future opportunities

# National TB Services Survey Report

- 2002:  CDC/APHL Task Force on the Future of TB Laboratory Services recommended comprehensive assessment of TB services in US laobratories:  public, hospital, commercial.
- APHL/CDC launched the 118-question National TB Laboratory Services Survey in 2010 – 2011.
- Results summarized June, 2012.

# TB Diagnostics in Hospital-based Clinical Laboratories




Distributed to 1444 laboratories; 656 (45%) responded.

National TB Services Report, Diagnosing TB. APHL, 2012.

# Characteristics of 466 Hospital Laboratories

| In-house service | Number (%) performing |
|---|---|
| AFB-smear microscopy | 466 |
| AFB Culture | 364 |
| MTBC Identification | 121 |
| First-line DST | 26 |
| Second-line DST | 4 |
| Direct Detection | 33 |
| IGRA | 35 |

# Hospital Laboratories Performing AFB Smear Microscopy

| # AFB Smears per Week | Hospital Laboratories |
|---|---|
| <5 | 93 |
| 6-14 | 115 |
| 15 - 25 | 80 |
| 26 - 50 | 87 |
| 51 - 100 | 60 |
| >100 | 28 |

National TB Services Report, Diagnosing TB. APHL, 2012

# Current challenges - smears

- Maintaining competency with low volume
- Laboratory labor cost

# Current challenges - NAAT

- Access to NAAT needed
- Very few hospital laboratories provide this service in-house
  - Expense per test
  - Validating/verifying assay
  - Highly skilled technologists required for laboratory-developed tests or the commercial assays that have been available.

# Progress in Hospital Laboratories

- Little change in vast majority of hospital laboratories.
- Many hospital laboratories are giving smear results within 24 hours
- Many hospital laboratories identifying MTBC are doing so within 21 – 28 days
- Many hospital laboratories performing TB AST have first line results within 28 – 35 days

# Current and future consideration

- Use of Xpert MTB/RIF assay
- Creative collaboration between hospital and public health laboratories

# Future Consideration:  Xpert MTB/RIF

- Not commercially available in US until this summer
- Initial FDA classification was as a Class III device because there was no predicate device.
- FDA Advisory panel recommended Class II two years ago and change was made just a few weeks ago.

# Future Consideration: Xpert MTB/RIF #2

- Role: Given the low incidence of tuberculosis in the United States, is it really cost-effective and clinically relevant to run this test on every specimen or every patient?

# Future Consideration: Xpert MTB/RIF #3

- Previous NAAT(s) for tuberculosis required sophisticated medical technologists
- Not all molecular testing requires highly skilled technologists now

# Future Consideration: Xpert MTB/RIF #4

- Simple, rapid
- Able to be done by wide range of hospital labs, not just those with molecular diagnostics

# Future Consideration: Xpert MTB/RIF #5

- Could we think about this test differently – not as an addition to what we are already doing but as a replacement for smears?
- Specificity

# Future Consideration: Xpert MTB/RIF #6

- Labor (small volume hospitals) replacing smears, not performing this test in addition to smears
- No requirement for highly skilled technologists once test is operational
- Specificity – what is the cost of a hopsital isolation room and 4 drugs, or directly observed therapy for a patient who is smear positive?

# Future considerations: Hospital and public laboratory collaboration

- Scarce resources and shifting priorities on both sides
- Stroger – IDPH ad hoc collaboration

# Future considerations: Hospital and public laboratory collaboration #2

- Creative collaborations between public health and hospital laboratories, especially as both laboratories can provide fewer services with smaller budgets.

# Thank-you!

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15% of laboratories perform direct detection for rapid identification of MTBC from a clinical specimen. Of these, 55% were public health laboratories. Current CDC recommendations encourage the use of nucleic acid amplification testing on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test results would alter case management or TB control activities (3).