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Background on TB Laboratory Aggregate Report

- Is published every two years
- Contains analysis of self-reported TB testing data from CDC TB Elimination Cooperative Agreement (CoAg) public health laboratory (PHL) awardees
- Aggregates PHL TB workload and performance indicator data, including:
  - *Mycobacterium tuberculosis* complex (MTBC) culture positivity
  - Nucleic acid amplification testing (NAAT)
  - Turn around time (TAT) trends
  - Testing methods
Purpose

- Provides data back to CoAg awardees in aggregate, and evaluates trends
- Encourages laboratories to:
  - Review national averages and trends
  - Evaluate laboratory specific data against peer data
  - Monitor/assess internal workload and TAT indicators
  - Track progress and set goals
Assessment

- TB laboratory supervisors or their designees were invited to participate in an evaluation of the Fourth Edition of the report, in April of 2017
  - Survey contained 13 multiple choice and 6 free-text questions
- Response rate was 72% (42/58)
- PHLs used the report to:
  - Compare internal laboratory culture positivity and TAT data to data reported by other PHLs
  - Document accomplishments within the laboratory
  - Increase local awareness of PHL TB laboratory services, and of the impact of these lab services within the state
Assessment (2)

- Data assisted PHLs to:
  - Update specimen criteria protocols
  - Monitor turnaround time data more effectively
  - Suggest or implement new methodologies including IGRA, molecular assays, and Maldi-TOF

- Suggested elements/domains to add to future reports included:
  - IGRA testing (location of testing in the TB lab vs another lab; choice of specific test used)
  - Staffing levels for TB testing in PHL
  - 5-year trends of NAAT and identification (ID) methods
  - Drug susceptibility testing (DST)
  - Barriers/challenges to meeting national TB benchmarks for PHLs

- Information was used by CDC to plan for the Fifth Edition
# Change in National Workload, 2015–2017

<table>
<thead>
<tr>
<th>Description</th>
<th>Three Year Change No. (% change)</th>
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<tbody>
<tr>
<td>Clinical specimens(^a) received</td>
<td>-5,644 (-2.7)</td>
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<tr>
<td>Patients for whom a specimen was submitted</td>
<td>-5,469 (-5.9)</td>
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<tr>
<td>Patients culture positive for MTBC</td>
<td>+149 (3.9)</td>
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<tr>
<td>Patients culture positive for MTBC that were NAAT positive</td>
<td>-168 (-7.9)</td>
</tr>
<tr>
<td>Patients tested by NAAT or other rapid test(^b)</td>
<td>+150 (0.7)</td>
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<tr>
<td>Patients NAAT positive for MTBC(^b)</td>
<td>-704 (-21.7)</td>
</tr>
<tr>
<td>Patients for whom a reference isolate was submitted(^c)</td>
<td>+339 (2.2)</td>
</tr>
<tr>
<td>Patients with a reference isolate identified as MTBC</td>
<td>+71 (2.1)</td>
</tr>
<tr>
<td>Patients for whom DST was performed</td>
<td>-334 (-5.6)</td>
</tr>
<tr>
<td>IGRA</td>
<td>+17,310 (18.9)</td>
</tr>
</tbody>
</table>

\(^a\) Processed and cultured, not including isolates referred from other laboratories, \(^b\) Includes sediments received only for NAAT, \(^c\) Received to either rule out or confirm the identification of MTB
Nationally, in 2017 approximately 4.6% culture positivity was seen for MTBC among PHL. The range of culture positivity was broad, from a low of 0% to a high of approximately 32.2%.
Trends in NAAT Utilization and Performance, 2015–2017

- Number of patients with MTBC positive culture (Workload Indicator 2a): 3293, 3297, 3578
- Number of patients with MTBC positive culture with a positive NAAT (Workload Indicator 2b): 1884, 1778, 1762 (45%)
- Number of patients with MTBC positive culture with a positive NAAT reported within 48 hours (Healthy People 2020): 1476 (45%), 1498 (45%), 1558 (44%)

Legend:
- 2015 (n=52)
- 2016 (n=48)
- 2017 (n=50)
Turnaround Times, 2017

- Specimen Receipt: % w/in 1 day
  - *67%
  - 46%
  - 53%
  - 48%
  - National Target: 57%

- Smear: % w/in 1 day
  - *92%
  - 85%
  - 91%
  - 93%
  - National Target: 95%

- ID: % w/in 21 days
  - *74%
  - 72%
  - 72%
  - 77%
  - National Target: 81%

- DST: % rifampin w/in 17 days of ID
  - *69%
  - 57%
  - 77%
  - 52%
  - National Target: 53%

Ranges of clinical specimens received:
- <2,000 (n=25; n=23 DST & ID)
- 2,001-5,000 (n=21)
- 5,001-8,000 (n=7)
- >8,001 (n=5)
NAAT Methods, 2018

- Cepheid Xpert MTB/RIF, 36
- Real-time PCR, 15
- Pyrosequencing, 1
- Hologic Amplified MTD, 2
- Referred, 4
Hologic Accuprobe, 30
Maldi-TOF, 5
Real-time PCR, 6
HPLC, 7
Cepheid Xpert MTB/RIF, 2
Fujirebio INNO-LiPA, 2
Sequencing, 2
Referred, 2
PRA, 1
PCR Melting Curve Analysis, 1
First-line DST Methods, 2018

- Referred—DST Reference Center, 14
- Referred—Other Laboratory, 4
- Indirect AP, 1
- Thermo Scientific Sensititre, 1
- Bactec MGIT, 38
Molecular Testing for Detection of Drug Resistance, 2018

- Targeted Sequencing, 5
- Cepheid Xpert MTB/RIF*, 2
- Whole Genome Sequencing*, 1
- Bruker MTBDRplus Line Probe Assay, 1

*Performed on culture growth
None, 28

Qiagen QuantiFERON in Mycobacteriology Laboratory, 8

Qiagen QuantiFERON in other section of PHL, 20

Oxford Immunotec T-Spot.TB, 2
Final Thoughts

- Public Health TB Laboratory role differs
- Decreasing specimen volume and increasing culture positivity
- Shifting test methodologies
- Self-reported data were analyzed for this report
- Important to monitor your laboratory specific data, and to compare findings with national data
- All reports/editions are available on the internet: https://www.cdc.gov/tb/publications/reportsarticles/labreports.htm
- Fifth Edition Aggregate Report will be released later this year
- Thank you for evaluation responses and feedback
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.