Colorado: The Perspective of a Big Network

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Objective

- To explore centralization of drug susceptibility testing (DST) for *Mycobacterium tuberculosis* (MTB) in the northern plains and intermountain region.

Collaborating Laboratories

- **CO**: Colorado Department of Public Health & Environment (CDPHE)
- **MT**: Montana Public Health Laboratory
- **ND**: North Dakota Dept of Health; Laboratory Division– Microbiology
- **SD**: South Dakota Public Health Laboratory
- **UT**: Utah Unified State Laboratories: Public Health
- **WY**: Wyoming Public Health Laboratory
- **DH**: Denver Health, Public Health Laboratories
TB cases are on the decline in the US, as a result of effective Public Health measures.

Public Health laboratories are facing declining funding.

Northern plains and intermountain states continue to see declining TB testing specimen.

Maintaining services and technical proficiency for all aspects of TB testing is increasingly expensive.
Study Design

- Shared Services Model

**Submitting Laboratories**
MT, ND, SD, UT, WY, DH

MTB isolates/broths shipped overnight

**Testing Laboratory**
CDPHE

MTB DST results

1st line DST performed


Study Design

- Responsibilities of testing laboratory
  - Coordinate conference calls and other communication
  - Provide FedEx number and submission forms
  - Initiate DST within 24h of receipt of specimen
  - Provide DST results as they become available
  - Collect and evaluate data from CDPHE and submitting laboratories

- Responsibilities of submitting laboratories
  - Perform DST testing in parallel on all referred specimen
  - Ship MTB isolates/broths to CDPHE within 72 hours of identification
  - Complete submission forms and data tracking spreadsheets
  - Participate in conference calls and other communication
MTB DST testing in the CDPHE laboratory
- 1st line DST is performed on MTB positive isolates
- BACTEC™ MGIT™ 960 System

CDC/CLSI guidelines for critical test concentrations:
- Streptomycin (1.0 µg/ml)
- Isoniazid (0.1 µg/ml)
- Rifampin (1.0 µg/ml)
- Ethambutol (5.0 µg/ml)
- Pyrazinamide (100 µg/ml)
Study design

- MTB DST testing at submitting laboratories

<table>
<thead>
<tr>
<th>Submitting Laboratory</th>
<th>MTB 1st line DST method</th>
</tr>
</thead>
<tbody>
<tr>
<td>MT</td>
<td>In-house</td>
</tr>
<tr>
<td>ND</td>
<td>refer</td>
</tr>
<tr>
<td>SD</td>
<td>In-house</td>
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<td>UT</td>
<td>refer</td>
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<tr>
<td>WY</td>
<td>refer</td>
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<tr>
<td>DH</td>
<td>In-house</td>
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</table>

- Results and turnaround times from CDPHE and submitting laboratories are compared
## Results: DST Turnaround times

- **Project Timeline:** July 2012 – June 2013

<table>
<thead>
<tr>
<th>Role</th>
<th>CO</th>
<th>MT</th>
<th>ND</th>
<th>SD</th>
<th>UT</th>
<th>WY</th>
<th>DH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
<td>Testing lab</td>
<td>Submitting lab</td>
<td>Submitting lab</td>
<td>Submitting lab</td>
<td>Submitting lab</td>
<td>Submitting lab</td>
<td>Submitting lab</td>
</tr>
<tr>
<td>Volume</td>
<td>9</td>
<td>2</td>
<td>10</td>
<td>7</td>
<td>7</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Average DST TAT&lt;sup&gt;1&lt;/sup&gt;</td>
<td>36.5</td>
<td>39.8</td>
<td>88.3</td>
<td>10</td>
<td>39.3</td>
<td>n/a</td>
<td>25</td>
</tr>
<tr>
<td>Average CDPHE DST TAT&lt;sup&gt;2&lt;/sup&gt;</td>
<td>36.5</td>
<td>28</td>
<td>37.8</td>
<td>20.7</td>
<td>33.5</td>
<td>n/a</td>
<td>25</td>
</tr>
</tbody>
</table>

<sup>1</sup> Time (days) between culture ID as MTB and generation of DST result

<sup>2</sup> Time (days) between receipt at CO lab and generation of DST result
# Results: TAT from specimen receipt in submitting lab to final DST result

<table>
<thead>
<tr>
<th>Role</th>
<th>CO</th>
<th>MT</th>
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<th>SD</th>
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<th>WY</th>
<th>DH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average specimen receipt to DST at submitting lab TAT$^1$</td>
<td>n/a</td>
<td>67 (40–119)</td>
<td>56.1 (38–86)</td>
<td>24 (24–28)</td>
<td>64.3 (48–75)</td>
<td>n/a</td>
<td>46 (23–122)</td>
</tr>
<tr>
<td>Average specimen receipt to DST at CDPHE DST TAT$^2$</td>
<td>36.5 (21–65.5)</td>
<td>46 (13–76)</td>
<td>64.8 (29–118)</td>
<td>47.7 (34–57)</td>
<td>92.7 (26–174)</td>
<td>n/a</td>
<td>52 (25–111)</td>
</tr>
</tbody>
</table>

$^1$Time (days) between receipt of specimen in submitting lab and submitting lab DST result

$^2$Time (days) between receipt of specimen in submitting lab at DST result at CO (includes transit time)
Sources of variation: shipment

- Shipment times varied by location

<table>
<thead>
<tr>
<th></th>
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<th>UT</th>
<th>WY</th>
<th>DH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average specimen</td>
<td>2</td>
<td>16.7</td>
<td>8.86</td>
<td>36.1</td>
<td>n/a</td>
<td>5.2</td>
</tr>
<tr>
<td>transit time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen</td>
<td>1–5</td>
<td>1–69</td>
<td>2–20</td>
<td>2–87</td>
<td>n/a</td>
<td>1–15</td>
</tr>
<tr>
<td>transit time</td>
<td>(1)</td>
<td>(15)</td>
<td>(11)</td>
<td>(25)</td>
<td></td>
<td>(8)</td>
</tr>
</tbody>
</table>

1Median transit time (days)

- Some early shipments were sent in batches which increased lag time
- CO requested specimen be shipped immediately upon obtaining an MTB positive culture
- Shipment times improved during the course of the funding period
Culture type:

- We observed that broth/slant cultures yielded significantly improved turnaround times in comparison to sediments.

- Requests for cultures (instead of sediments) improved turnaround times.
Sources of variation: Other

- Control tube growth issues (poor growth/overgrowth)
- Discordant results with CDC (repeat required)
- Minimal growth on submitted slant (required additional growth time prior to DST set up)
- Contamination (NTB, cocci, yeast)
- Problems with PZA assay (repeat required)
- Equipment problems at submitting lab
Conclusions

- The shared services model can be successful for providing timely, cost effective TB DST testing in a low volume region such as the northern plains and intermountain states.

- Successful shared services plans should include:
  - Strict guidelines for sample submission
    - Specimen should be sent immediately upon obtaining a positive culture (no batch shipments)
    - Preferred specimen type: broth cultures (sediments & slants result in delayed DST results)
  - Capability to perform molecular DST methods would significantly reduce DST times and decrease the impact of delays such as contamination and poor growth.
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  - Michael Wilson
  - Ginger Hildred

- APHL

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