Colorado Department of Public Health and Environment

Colorado: The Perspective of a Big Network

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Objective

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- 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

Background

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- 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

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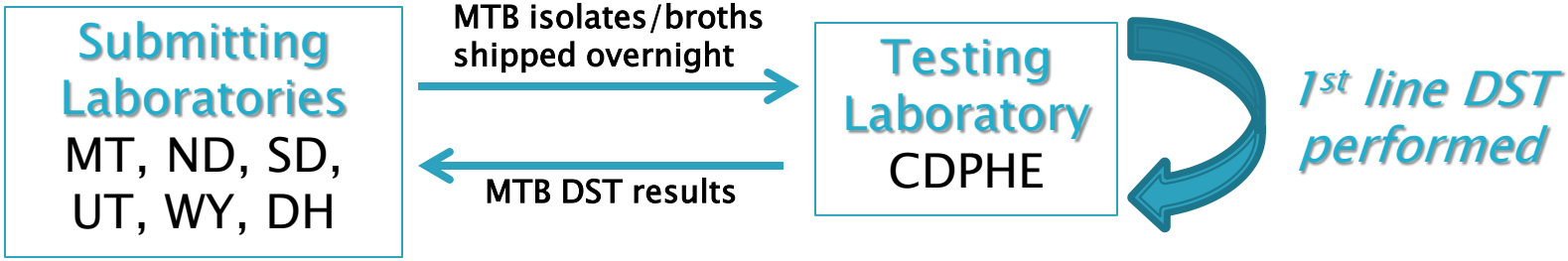
- Shared Services Model



Study Design

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- 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

Study Design

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- 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

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- MTB DST testing at submitting laboratories

Submitting Laboratory	MTB 1st line DST method
MT	In-house
ND	refer
SD	In-house
UT	refer
WY	refer
DH	In-house

- Results and turnaround times from CDPHE and submitting laboratories are compared

Results: DST Turnaround times

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- Project Timeline: July 2012 – June 2013

	CO	MT	ND	SD	UT	WY	DH
Role	Testing lab	Submitting lab	Submitting lab	Submitting lab	Submitting lab	Submitting lab	Submitting lab
Volume	9	2	10	7	7	0	12
Average Standard DST TAT[1]	36.5	39.8	88.3	10	39.3	n/a	25
Average CDPHE DST TAT[2]	36.5	28	37.8	20.7	33.5	n/a	25

[1]Time (days) between culture ID as MTB and generation of DST result
[2]Time (days) between receipt at CO lab and generation of DST result

Results: TAT from specimen receipt in submitting lab to final DST result

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	CO	MT	ND	SD	UT	WY	DH
Role	Testing lab	Submitting lab	Submitting lab	Submitting lab	Submitting lab	Submitting lab	Submitting lab
Average specimen receipt to DST at submitting lab TAT[1]	n/a	67 (40–119)	56.1 (38–86)	24 (24–28)	64.3 (48–75)	n/a	46 (23–122)
Average specimen receipt to DST at CDPHE DST TAT[2]	36.5 (21–65.5)	46 (13–76)	64.8 (29–118)	47.7 (34–57)	92.7 (26–174)	n/a	52 (25–111)

[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

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- Shipment times varied by location

	MT	ND	SD	UT	WY	DH
Average specimen transit time	2	16.7	8.86	36.1	n/a	5.2
Specimen transit time range	1–5 (1) [1]	1–69 (15)	2–20 (11)	2–87 (25)	n/a	1–15 (8)

[1]Median 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

Sources of variation: specimen type

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- 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

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- Control tube growth issues (poor growth/over growth)
- 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

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- 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 ins 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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