Workflow Analysis of the New Jersey Public Health Mycobacteriology Laboratory

Dana Woell¹, Thomas Kirn²

Presented by:
Tunisia King, Senior Laboratory Technician Microbiology, NJ Department of Health

1. Association of Public Health Laboratories Infectious Disease Fellow
2. New Jersey Department of Health
INTRODUCTION

• Background: For Mycobacterium tuberculosis (TB) infections, timely identification and rapid detection of drug resistance is critical to ensure proper treatment and infection control measures. Culture remains the gold-standard for TB isolation and identification, and as a slow-growing organism cultures need to be monitored for up to 6 weeks. Additionally, repeated specimens need to be tested over a period of days or weeks for monitoring of disease progression and treatment response. With multiple specimens needing to be monitored for such a prolonged time, efficient management of laboratory processes to streamline testing is essential for the timely and accurate identification of TB.

• Objectives: A workflow analysis of the Mycobacteriology lab in the New Jersey Public Health and Environmental Laboratory (PHEL) was undertaken to increase timeliness of reporting and decrease testing burden on staff.

• Methods: A process map of all TB lab workflows was drawn to diagram and clarify the algorithm by which specimens are processed, tested and reported. This process map was used to identify key gaps in current practices and areas that could be improved. Key indicators, such as turnaround time (TAT) data, was retrospectively queried to identify areas that were not meeting our benchmark goals.

• Results: Four key areas were identified that hold the potential for improvement: Initial identification of specimens, antimycobacterial susceptibility testing (AST), recording and reporting of results, and media contamination. In order to improve these key areas, between three and five actionable recommendations were made for each. Key indicators were assigned to monitor each of these metrics quantitatively, including monitoring of turnaround time for individual steps in the process map, overall turnaround times, rates of reporting error, and contamination rates. As individual changes are implemented on an ongoing basis, continued monitoring of these indicators will be compared to baseline to see which changes are useful in improving laboratory processes and efficiency.
GOALS

Focus Area 1: Reduce Identification Turnaround Time
• CDC Benchmark for Identification is ≥74% of isolates identified within 21 days of receipt
• Baseline: in 2017 only 30.4% overall of MTBC positive specimens met the 21 day goal

Focus Area 2: Improve AST Turnaround Time
• CDC Benchmark for AST is ≥69% of rifampin results reported within 17 days of identification
• Baseline: In 2017 44.3% of all specimens which were tested met this goal

Focus Area 3: Reduce contamination rates
• Issue: Media contamination increases turnaround time and makes it harder to differentiate mycobacteria from contaminating non-AFB. Reducing contamination will decrease burden on testing staff and simplify workflow.
Focus Area 4: Simplify workflow, paperwork and reporting

• Issue: Much of the TB lab’s work is recorded on paper work cards in addition to our laboratory information system (LIS). The microbiology worksheet in the LIS was cluttered and did not collect all relevant data fields, making it difficult to use for decision making. Additionally, data entry into the LIS was not uniform, as result options were outdated and did not reflect the most commonly entered results.

• Simplifying the LIS interface, updating order choices, and standardizing operating procedures and reporting between all staff will aid in improving efficiency, reduce error rates, and cut down on unnecessary testing.
METHODS

Workflow diagram of steps performed in the NJ TB lab to identify MTBC from clinical isolates and test for drug susceptibilities.

Three distinct steps identified

- Growth and identification of suspect AFB
- Complex identification by DNA Probe
- Inoculation of Antimycobacterial susceptibility testing
  - If AST is not inoculated within 5 days of positivity, specimens need to be subcultured to get a fresh culture

Average time to detection (TTD) highlighted for key processes
Implications and Recommendations

1. **Time to culture growth is a major barrier for 21 day identification TAT** (Figure 1)
   - Due to workflow considerations, 18 days was determined to be the maximum number of days a specimen can grow and still achieve a 21 day turnaround
   - 35% of all positive specimens in 2017 took more than 18 days to grow to positivity

2. **A gap exists between when a culture becomes positive and when DNA probe testing is performed** (Figure 2)
   - This is due to multiple factors, including day of the week the specimen becomes positive, testing volume and batching of specimens, and if the patient has previous history of positive cultures which determines what species are to be tested.

3. **Delaying probe testing causes specimens to need subculture prior to AST**
   - AST requires the culture to be within 5 days from initial positivity

4. **Subculturing adds ~10 days to the AST procedure- severely limiting the likelihood of achieving a 17 day turnaround** (Figure 3)
   - 44% of all specimens needing AST in 2017 were subcultured prior to inoculating

5. **Repeating AST more than doubles the time to final report** (Figure 4)
   - 47% of AST specimens in 2017 were repeated. Justified repeats include per protocol repeats due to unavoidable testing defects. Confirmatory repeats are done to confirm when drug resistance is detected. However, 8% of specimens overall were repeated in error or were not justified by standard protocols.

Recommendations:

1. Increase frequency of DNA probe testing to improve identification TAT and reduce the need for subcultures for AST turnaround
2. Simplify workflow and standardize probe criteria to reduce ambiguity about when a specimen should be tested
3. Inoculate AST directly from positive media as often as possible
4. Standardize criteria for when to repeat AST to reduce extra testing
THEN AND NOW: PROCESS IMPROVEMENTS

- Workflow changes introduced:
  
<table>
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<th>October 2017</th>
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<tr>
<td>- Eliminated extra testing to discriminate between subtypes of non-tuberculous mycobacteria</td>
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<td>- Wrote a document stating the standard criteria for performing DNA probe on a specimen</td>
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<td>- Simplified LIS test order list and report options</td>
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<td>- Ordered pre-made plates and buffer to reduce contamination</td>
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<tr>
<td>- Increased frequency of genetic probe testing to twice weekly on standard days</td>
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<td>- Standardized criteria for repeating AST for per protocol and confirmatory results</td>
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Results:

1. **Time from positive culture to probe was reduced from 8.3 days to 6.2 days**

2. **Overall Identification turnaround time improved from baseline**
   - Still only 40% of specimens meet the 21 day goal; have not yet achieved the benchmark of ≥74%

3. **Subculturing was dramatically reduced in 2018**
   - Only 17% of specimens which received AST had to be subcultured in order to inoculated, compared to 44% in 2017

4. **Unnecessary Repeats were eliminated in 2018 to date**
   - No unjustified or out of protocol repeats were performed in 2018
   - Confirmatory repeats was reduced from 17.8% to 13% due to stricter protocol as to what needs to be confirmed and what can be reported directly

5. **No overall reduction in AST turnaround time observed (yet!)**
   - Due to a testing issue in February 2018, the number of justified repeats increased dramatically (11% in 2017 to 39% in 2018TD) for troubleshooting
   - Because of these extra repeats, there has not been any discernable change in AST turnaround times despite quicker inoculation times
NEXT STEPS

• Continued monitoring of turnaround time and other indicators will be performed
• Additional recommendations to improve workflow have been made but not yet implemented
• There will be ongoing quality improvement initiatives to continue the upward trends already happening as well as to identify and reduce the impact of additional trouble spots
ACKNOWLEDGMENTS

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