ASM presents the
Clinical Microbiology Portal’s
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METRICS IN MICROBIOLOGY

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Updated: April 2021
Washington Post: Medical Errors Now Third Leading Cause Of Death In United States

Core Laboratory Model

HENRY FORD HEALTH SYSTEM
Pathology & Laboratory Medicine
Service Line of Integrated Labs
Core Lab Operations

700,000 micro tests
52 Micro lab staff
50 courier runs/day
900 bed main campus
4 acute care hospitals
29 medical centers
8 emergency rooms

Photo provided by Linoj Samuel, Ph.D., D(ABMM).
Trend Towards Laboratory Consolidation

Percent Increase Test Volume vs FTE

- Lab #1
- Lab #2
- Lab #3
- Lab #4
Why Metrics in Clinical Microbiology?

- Specimens processed and Gram stains read 24/7.
- Cultures read out on two shifts.
- Use of multiple contingent and part time staff.
- Demands for higher productivity = increased risk of errors.
- Manual and subjective nature of microbiology testing.
How Are Others Using Metrics?

“You can’t manage what you don’t measure.”


The WG mission is to stimulate studies on the topic of errors in laboratory medicine, to collect available data on this topic and to recommend strategies and procedures to improve patient safety.

Additional Sources:


According to ISO 15189:2012

- **4.9 Identification and control of nonconformities:** The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes.

- **4.14.7 Quality Indicators:** The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.
Questions

• What tools can you use to monitor quality of work/training in your laboratory in real time?

• How far ahead of the curve are you in terms of anticipating problematic trends in your laboratory?

• How do you resist the tendency to patch, fix and move on?

• How can you use metrics to positively impact laboratory performance?
Questions

• How are we as a discipline using metrics?

• Do we have a standardized approach to collection, classification and analysis of metrics?

• Do we really have the ability to measure the quality of a lab and compare its performance to its peers?

• You can’t manage what you can’t measure!
Pre-analytic Metrics

- Unlabeled specimens.
- Miss-labeled specimens.
- Specimen labels not matching requisitions.
- Incorrect containers submitted for the tests ordered.
- Numbers of QNS specimens.
- Numbers of hemolyzed blood specimen.
- Numbers of specimens that leaked out of containers.
- Cancelled specimens.
- Lab utilization metrics.
Other Metrics

• Turnaround time.
• Blood culture contamination rate.
• AFB contamination rate.
• Sputum contamination rate.
• Interferon gamma release assay indeterminate rate.
• Molecular assay metrics: Invalid rates and positivity rates.
Some Common Metrics in Microbiology

• Urine culture contamination rate.
  – CAP Q-Probes study 2005\textsuperscript{1}.
  – Median institution had contamination rates ~15%.
  – Range from 0.8% to 41.7%.
  – Low rates associated with specimen refrigeration and patient instruction.

• Evidence Based Laboratory Medicine Practice Guidelines\textsuperscript{2}
  – No recommendation for or against is made for delayed processing of urine stored at room temperature, refrigerated, or preserved in boric acid.
  – No recommendation for or against is made for collection of midstream urine without cleansing.
  – Need more systematic studies!

\textsuperscript{1}Arch Pathol Lab Med Vol 132, June 2008.
\textsuperscript{2}CMR, January 2016 Volume 29 Number 1.
Blood Culture Contamination Rate

- Blood culture contamination rate.
  - What is the definition?
    - CAP Qprobes: A blood culture was considered to be contaminated if 1 or more of the following organisms were identified in only 1 of a series of blood culture specimens: coagulase-negative *Staphylococcus* species, *Propionibacterium acnes*, *Micrococcus* species, “viridans”-group streptococci, *Corynebacterium* species, or *Bacillus* species. A blood culture series was defined as 1 or more specimens collected serially within a 24-hour period to detect a bacteremic episode.\(^3\)
  - <3% recommended.
  - Median laboratory contamination rate was 2.89\(^3\).
  - Target rates <2%?
  - How do you calculate contamination rates - Lack of consistency in methods used.

\(^3\)Arch Pathol Lab Med Vol 129, Oct 2005.
Blood Culture Contamination Rate

• At one of our EDs, contamination rate was <3% however:
  – Nurses tended to draw multiple sets from single sticks or lines.
  – Multiple sets contaminated with coag neg staphylococci.
  – Not flagged as contaminant by laboratory algorithm.
  – In one quarter, 7/25 patients with such results received inappropriate therapy and diagnostic procedures.
  – Does blood culture contamination rate really tell us the whole story?
AFB Lab Metrics

• Manual decontamination process can be prone to variation.

• ~60% of Mycobacteria are lost during routine decontamination.\(^4\)

• Harsh decontamination can cause false negative cultures.

• Inadequate decontamination can cause contaminated cultures.

• Failure to review adequate number of fields can lead to false negative AFB smears.

• What metrics can we use in these settings?

\(^4\) WHO. Laboratory Services in Tuberculosis Control 1998.
AFB Lab Metrics

• What is the expected AFB culture contamination rate?
  – According to WHO: 2-3\%\(^4\).
  – According to CDC: 3-5\%\(^6\).
  – According to APHL:
    – For solid media 2-5\%\(^5\).
    – For liquid media 7-8\%\(^5\).

• AFB smear/culture correlation.
  – Smear positive specimens that are culture negative should be reviewed.
  – Percent of smear negative/culture positive specimens should be tracked (60-80\% correlation suggested).

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\(^4\) WHO. Laboratory Services in Tuberculosis Control 1998.

\(^5\) Mycobacterium tuberculosis-Assessing your laboratory, Association of Public Health Laboratories. 2009 Ed.

Gram stain/Culture Correlation

- Correlation between Gram stain and culture results can be a useful metric.
  - Measure of Gram stain quality.
  - May identify issues with culture processing.
  - May indicate inappropriate test ordering or specimen collection.

- Limited data on expected rate of Gram stain/Culture results.

- Anecdotal reports suggest high rate of correlation (>90%) between Gram stain and culture results for specimens that had moderate/many colonies on routine aerobic culture.⁶

Errors in Gram stain interpretation can have significant impact on patient care.\(^7\)

Interpretation of smears can be subjective especially in the presence of stained debris or thick smears.

Potential for contamination of slides with bacteria from water/reagents.

Limited data available on the incidence of Gram stain errors in routine specimens.

Gram Stain Errors Using Proficiency Testing

- Nancy Goodyear, PhD, Sara Kim, PhD, Mary Reeves, Michael L. Astion, MD, PhD, A 2-Year Study of Gram Stain Competency Assessment in 40 Clinical Laboratories, American Journal of Clinical Pathology, Volume 125, Issue 1, January 2006, Pages 28–33, https://doi.org/10.1309/40WD3015CH1RYH58


Gram Stain Errors With Positive Blood Cultures


Gram Stain Error Rate

• Limited data generated using proficiency test results.

• Variation between labs in processing steps and methods used for Gram stain: eg. methanol vs. heat fixation.

• Error rates with actual patient samples limited to single institutions and positive blood cultures.

• Only one study has examined multicenter Gram stain error rates.\(^6\)

Gram Stain Error Rate

• Examined error rates for Gram stains from sterile sites that had discrepant smear/culture results that met the following criteria.\(^6\)
  – Moderate/Many bacteria on smear and culture negative.
  – Moderate/Many bacteria on culture and smear negative.

• Collected data from four large laboratories serving tertiary care centers.

• Performed routine review of smears that met the study criteria.

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Smear/Culture Discrepant Results/Site

<table>
<thead>
<tr>
<th>Site</th>
<th>Discrepancy</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4%</td>
<td>96%</td>
</tr>
<tr>
<td>B</td>
<td>5%</td>
<td>95%</td>
</tr>
<tr>
<td>C</td>
<td>6%</td>
<td>94%</td>
</tr>
<tr>
<td>D</td>
<td>6%</td>
<td>94%</td>
</tr>
</tbody>
</table>
Incidence of Errors Among Discrepant Results

Site A: 91% (9%), 84% (16%)
Site B: 69% (31%), 55% (45%)
Site C: 91% (9%), 84% (16%)
Site D: 69% (31%), 55% (45%)
Gram Stain Errors

• Errors were caused by:
  – Improper smear preparation: Smear too thick or not enough material on the slide.
  – Failure to examine adequate number of fields.
  – Artifacts.

• Incidence of errors and the types of errors varied between laboratories suggesting that diverse issues are involved.
Example: Corrected Reports

- Corrected reports may indicate a failure in routine laboratory processes and should be followed up in a timely manner.
  - These include:
    - Gram stain interpretation errors.
    - Errors in organism identification.
      - Biochemical.
      - Colony morphology.
    - Result entry errors.
    - Specimen processing errors.
Corrected Reports

• Single institution study concluded that 6.7% of corrected reports have clinical impact.

Tracking Corrected Reports


Does Monitoring Corrected Reports Have an Impact?

Reduction in Pathologist Mis-Interpretations

Amended Reports per 10,000 cases

Source: Dr. Richard Zarbo
Corrected Reports


- Examined errors detected as part of routine supervisor review.
- Of 101,703 positive culture reports, 786 (0.8%) required 900 corrections.
- 302 (0.3%) of errors were potentially clinically significant.
- Errors from positive culture reports most commonly involved.
  - susceptibility (374 [42%]).
  - reporting (275 [31%]).
  - identification workup (217 [24%]).
Harrington et al examined error rates in 2229 sterile specimen culture reports spread across 4 independent full service laboratories.\(^7\)

Incidence of errors ranged from 4% to 19% with \(~25\%\) of errors having potential clinical impact.

The majority of errors were clerical (69%) but technical errors were more likely to have clinical impact.

Varied culture review processes may contribute to differences in error rates between labs.

\(^7\) Harrington et al. A Multicenter Assessment of Errors in Culture Reports. Poster presented ASM Microbe 2017
Tracking Corrected Reports in Microbiology

First Steps:

• Developed an mechanism that identifies corrected reports.

• Daily review by laboratory director/manager of corrected reports.

• Investigate each incident and determine whether laboratory was responsible for error.

• Identify staff involved and provide feedback as needed.

• Document and categorize by type of error.
### Tracking Corrected Reports

**Key**
- G = gram stain error
- I = identification error
- S = set up/labeling error
- P = error due to procedure

<table>
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<th>Feb</th>
<th>March</th>
<th>April</th>
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<tr>
<td></td>
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<td>I</td>
<td>S</td>
<td>P</td>
</tr>
<tr>
<td>Tech A</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tech B</td>
<td></td>
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<td><strong>Total</strong></td>
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<td>2</td>
<td>3</td>
<td>1</td>
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</table>
Types of Errors

• Organism identification errors:
  – *Corynebacterium* reported as *Coag neg staph*.

• Keystroke errors.

• Gram stain interpretation errors.

• Culture report in Gram stain field or vice versa.

• Just plain gibberish.
Corrected Reports

• Corrections made to reports are analyzed and tracked by technologists.

• Corrective action implemented if the situation meets certain criteria:
  – Three errors/quarter of same type.
  – Five errors/quarter of any kind.
  – Single incident of failure to follow lab policy for correcting detected errors.

• Corrective action may include:
  – Staged assessment.
  – Remedial training.
Challenges

• Lack of consensus on the definition of an error.
• Lack of standardized data collection system.
• Absence of systematic studies on the incidence of error rates in clinical microbiology laboratories.
• What constitutes an acceptable error rate?
Blood Culture Process

Potential Wasted Time / Areas For Improvement
Problem: Only 37% of positive blood cultures reported in <2hrs.
Time to Positive Blood Culture Gram Stain Report

- ≤2h: 37%
- 2-4h: 22%
- >4h: 27%

Goal: 95% ≤ 2h
Positive Blood Culture Gram Stain Reporting

After multiple interventions over several months and continuous data monitoring: Reached target of <2h and went on to improve to <1h.
# Example: Workload Metrics

<table>
<thead>
<tr>
<th></th>
<th>Henry Ford Health System</th>
<th>Microbiology Setup Times</th>
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<td>Pathology Informatics</td>
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<tr>
<td><strong>Hour</strong></td>
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<tr>
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<td>21</td>
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Note: The table above shows the workload metrics for different tests across different hours for the Henry Ford Health System and Microbiology Setup Times.
Tracking Specimen Deliveries

![Bar chart showing the number of deliveries by time of day]

- **Time of Deliveries by LSS**

<table>
<thead>
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<th>Time</th>
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<td>21:00</td>
<td>4</td>
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<td>20:00</td>
<td>2</td>
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<td>19:00</td>
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<td>18:00</td>
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<td>17:00</td>
<td>7</td>
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<tr>
<td>16:00</td>
<td>11</td>
</tr>
<tr>
<td>15:00</td>
<td>9</td>
</tr>
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</table>

*Number of Deliveries over 20 day period*
Tracking QNS Specimens

88.2% overall reduction in defects
Molecular Assay Metrics

- Data on positivity rate and invalid rates for point of care molecular assays separated by location.

<table>
<thead>
<tr>
<th>Site</th>
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<th>INAPCR</th>
<th>INBPCR</th>
<th>INVPCR</th>
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<tr>
<td><strong>Total</strong></td>
<td>4</td>
<td>1</td>
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</table>
metrics and cost impact

• Switched from testing 2 days/week to testing 4 days/week.

• Post intervention, TAT for HCV results was 90% <3 days.

• Timely results avoided wastage of expensive HCV medication.

• Even avoiding delayed lab results in 20 patients = $320,000 in savings for the institution.
Metrics Display Can Be as Simple as This:
Or Slightly More Complicated
The Trouble With Metrics

- Why track metrics if they have no impact on laboratory performance?
- Even useful metrics may have limited impact if not utilized appropriately.
- Large amounts of data generally lay around and do nothing.
- Reviewing metrics once a month offers limited opportunities for meaningful feedback or intervention in real time.
The Solution

• Pick a limited number of metrics.
• Set specific targets and timeframe for achieving that target.
• Delegate responsibility to specific individuals.
• Collect pre-intervention data.
• Review frequently: daily/weekly.
• Multiple rounds of interventions may be necessary.
• Collect post-intervention data at each stage.
• Move on to other metrics.
Finally:

• Need systematic studies to evaluate appropriate metrics and acceptable thresholds.
Thank You!

Questions? Contact Us.

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