Laboratory Medicine Best Practices (LMBP) Initiative Update

Clinical Laboratory Improvement Advisory Committee Meeting
August 30, 2012

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CDC Division of Laboratory Science and Standards
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.
Questions for CLIAC Consideration

- How can we generate new topics for discovery of laboratory best practices?
- What topic suggestions do you have?
- How can laboratory professionals become more engaged in quality improvement studies that...
  - advance on-site laboratory improvements?
  - support the broader evidence base for systematic reviews?
- What additional tutorials would help laboratory professionals learn about evidence-based practices and quality improvement study strategies?
- How can we more broadly communicate/disseminate best practices recommendations?
<table>
<thead>
<tr>
<th>Date</th>
<th>Presenter</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Sept 2006</td>
<td>Dr. Joe Boone</td>
<td>CDC</td>
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<tr>
<td>Feb 2007</td>
<td>Dr. Julie Taylor</td>
<td>CDC</td>
</tr>
<tr>
<td>Sept 2007</td>
<td>Dr. Susan Snyder</td>
<td>CDC</td>
</tr>
<tr>
<td>Sept 2008</td>
<td>Dr. Joe Boone</td>
<td>CDC</td>
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<tr>
<td>Feb 2009</td>
<td>Dr. Ed Liebow</td>
<td>Battelle</td>
</tr>
<tr>
<td>March 2011</td>
<td>Dr. Robert Christenson, Ms. Diana Mass</td>
<td>LMBP Workgroup</td>
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History/Goals

- CDC initiative, beginning in 2006 with contract assistance from Battelle

- Establish and use **transparent, systematic** review methods to evaluate evidence of laboratory practice effectiveness, especially in the pre- and post-analytical phases

- Improve healthcare quality and patient outcomes* through dissemination of evidence reviews of effectiveness which identify evidence-based laboratory medicine “best practices”

- Increase participation of laboratory professionals in quality improvement research and data collection

*Following Institute of Medicine’s quality domains: safe, timely, effective, efficient, equitable, and patient-centered
www.futurelabmedicine.org

Information and Activities:
• Tutorials, technical reports, systematic review findings
• Calls for evidence and for review topics
• Announcements of publications and meeting presentations
LMBP A6 Method


QUALITY GAP/POLICY PROBLEM

ASK

A 6 Cycle

ASSESS

ACQUIRE

APPLY

ANALYZE

APPRAISE
Accomplishments
2011-2012
Four Published Reviews, 2012


Systematic Reviews In Progress

- Use of Cardiac Biomarkers to Diagnose N-STEMI Myocardial Infarction in the Emergency Department

- American Society for Microbiology (ASM) Collaboration projects
  - Rapid diagnosis of blood stream infections
  - Urine collection and transport
  - *C. difficile* diarrhea diagnosis
Systematic Reviews In Progress in Conjunction with ASM

- Blood stream infections- Rapid Diagnostic Methods - conducted by CDC/Battelle with ASM expertise (At “Analyze” Step)
- Urine Transport - conducted by ASM with CDC guidance (At “Acquire” Step)
- *Clostridium difficile* - planned by ASM with CDC guidance (Starting “Ask” Step)
Evidence Based Approach-Systematic Reviews And The ASM Collaboration

**QUALITY GAP/POLICY PROBLEM**

**ASK**

**ASSESS**

A 6 Cycle

**ACQUIRE**

**APPLY**

**ANALYZE**

**APPRAISE**
<table>
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<tr>
<th>Date</th>
<th>Event/Activity</th>
<th>Comments</th>
</tr>
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<tr>
<td>May 2010</td>
<td>LMBP presentation at ASM annual meeting</td>
<td>ASM leadership identified team to select &amp; prequalify topics (ASM 7)</td>
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<tr>
<td>Feb 2011</td>
<td>ASM-CDC-Battelle workshop</td>
<td>Training on A6 method; ASM selected 3 topics</td>
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<tr>
<td>2011-2012</td>
<td>ASM staff/volunteers “shadow” review process for 1st topic</td>
<td>Rapid ID of blood stream infection review near completion</td>
</tr>
<tr>
<td>2012 -</td>
<td>ASM collaborating with CDC on 2nd topic</td>
<td>Urine collection and transport</td>
</tr>
<tr>
<td>2013 -</td>
<td>ASM takes lead for 3rd topic in collaboration with CDC</td>
<td><em>C. difficile</em> diarrhea diagnosis</td>
</tr>
</tbody>
</table>
LMBP Team-ASM 7 with CDC/Battelle
CDC & ASM Collaboration

ASM
- Committed to A-6 method; may supplement Cumitechs
- Will publish findings in *Clinical Microbiology Reviews*
- New ‘Evidence-based Practice Guidelines Committee’ (per ASM Professional Practice Committee) includes “ASM 7”
- Dr. Mark LaRocco hired as Review Coordinator for ASM Expert Panel’s systematic review work
- Librarian hired to support literature searches

CDC
- Liaisons - ensure fidelity to A-6 methods
- LMBP workgroup - reviews findings and recommends best practices
Systematic Review Topic Pipeline

Calling for suggestions:
- on LMBP website
- when presenting LMBP projects at meetings
- from LMBP Workgroup
- from CDC and Battelle staff
- from CLIAC members
Define a quality issue with an opportunity for improvement consistent with the six IOM healthcare quality aims*

Frame it with one, focused review question for a defined patient population

Identify at least three practices with potential to improve performance or quality outcomes associated with the defined quality issue

* Safe, Timely, Effective, Efficient, Equitable, and Patient-centered
Topic Identification and Selection Process: Guiding Principles

- Target outcome measures to assess practice effectiveness and have broad, stakeholder interest
- Evidence for effectiveness should be available from published sources (unpublished sources also possible using A-6)
- Prefer topics that are pre- and post-analytic issues – areas of most significant quality challenges
The LMBP Analytic Framework - ASK Step

Quality Problem
Clear statement of issues related to the topic

Preventability/Improvement
Measurable gap targeted for improvement

Interventions/Practices
May impact quality gap

Intermediate Outcomes
Measures that may precede or lead to health outcomes

Harms
Adverse effects of practices

Health/Healthcare Outcomes
End results of practices that directly impact patients and patient care
**ASK Step**

**Review Question:** Among hospitalized patients, what practices are effective for reducing blood culture contamination?

**Quality Problem**
Pre-collection practices (aseptic technique, agent, proper drying time) & collection site are sources of contamination

**Preventability / Improvement**
BCC rate range: 1.1-5.2%
ASM standard is rate not to exceed 3%

**Current Practices and Interventions**
- Venipuncture vs. intravenous catheters
- Phlebotomy teams vs. non-phlebotomy staff
- Prep kit vs. no prep kit

**Intermediate Outcomes**
- Contamination Rate
- False positive cultures
- Re-collection
- Additional testing / follow-up associated with re-evaluation
- Incorrect / delayed diagnosis

**Health / Care Outcomes**
- Unnecessary additional tests
- Unnecessary antibiotic therapy
- Unnecessary hospital admissions
- Hospital acquired infections
- Increased length of stay
- Additional incremental care costs

**Associated Harms and Benefits**
- Increased risk of occupational needle stick
- Patient / provider dissatisfaction
Topics in the Pipeline-for Pre-qualification

- Lipid profile testing in cardiovascular disease patients
- Using HbA1c/measurement as a diagnostic tool
- Coagulation testing/ hypercoagulation panel
- Effective diagnosis of sepsis
- Reflex molecular testing in microbiology
- Reducing blood utilization
Additional Lessons Learned

LMBP A6 Methods also evaluate quality improvement practices from unpublished data

- Builds the laboratory medicine evidence base
- Provides relevant data for systematic evidence reviews
- Data = evidence of practice effectiveness
- However, Many studies fail to meet minimum standards for good study design and implementation – Why?
Common Quality Improvement Study Problems

Information commonly missing in laboratory medicine quality improvement projects (communications and journal articles)

- Sample description
- Sample selection
- Data collection method
- Statistical methods
- Intervention
- Outcome measure
- Time period
- Cause and effect
Common Quality Improvement Study Problems, continued

- Frequently,
  - fewer than 3 articles published on same topic
  - probably due to journal’s desire for unique articles
  - at least 3 studies are needed for statistical significance

- Special groups of patients missing from studies;
  e.g., children (children are not little adults)
LMBP Educational Activity

A series of self-guided tutorials (with CE credit) which:

- Increase awareness about new LMBP A-6 methods for conducting systematic evidence reviews
- Increase competency for application of evidence-based principles to quality improvement (QI) projects or research
On-Line Training for Evidence-Based Laboratory Practice

- Module 1: An Overview of A-6 Methods - in use by the laboratory community
  https://www.futurelabmedicine.org

- Module 2: Application of A-6 Methods for Laboratory Practitioners – near completion

- Additional Modules: Concepts pending
  >Ideas from CLIAC members are welcomed
Future Focus: Apply (A5) and Assess (A6)
“Apply”

- Apply step (A5) involves dissemination and implementation of new practice in the field
- IOM states that it takes up to 17 years for a new guideline to become standard practice
- How can more rapid adoption be encouraged?
“Assess”

- Assess step (A6) measures the impact of the best practice recommendation on laboratory practice
  - collect measurement/data
  - submit to LMBP website
- How should QI projects be designed
  - to meet standards for systematic review
  - for inclusion in practice recommendation
  - to support A-6 cycle completion
Future Focus: QI Study Tools

Completed systematic reviews = templates for QI projects in other clinical laboratories

- Optimal study design featured in Discussion of published LMBP recommendations
- Optimal study design Checklist includes all required elements discovered during previous systematic review of topic
- Optimal study design and Checklist are on LMBP website “QI project in a box”
- Recruit clinical laboratory sites to participate in study using “QI project in box” model
Develop A Checklist With Required Elements For Systematic Review

<table>
<thead>
<tr>
<th>Background Information</th>
<th>QI Project/Study</th>
<th>QI Practice</th>
<th>Outcome Measures</th>
<th>Results/Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LMBP Topic:</strong> Hemolysis in the ED</td>
<td><strong>1. Problem/Quality Issue Description</strong></td>
<td><strong>5. QI Project Study Design/Type:</strong></td>
<td><strong>14. Outcome Measure(s) Description:</strong></td>
<td><strong>17. Results/Findings:</strong></td>
</tr>
<tr>
<td><strong>A. Practices (check all that apply):</strong></td>
<td><strong>Observational</strong></td>
<td><strong>Hemolysis Rate (how determined?):</strong></td>
<td></td>
<td><strong>(related to study design/outcome measure):</strong></td>
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<tr>
<td>- Straight needle venipuncture vs. IV start</td>
<td><strong>Pre-post Implementation</strong></td>
<td>Other – Describe:</td>
<td></td>
<td><strong>18. Data Analysis – Statistics:</strong></td>
</tr>
<tr>
<td>- Antecubital fossa vs. distal arm</td>
<td><strong>Spirit implementation (multiple sites)</strong></td>
<td>Other – Describe:</td>
<td></td>
<td>- Simple Association (not controlling non-test variables)</td>
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<tr>
<td>- Large vs. small gauge needle/catheter</td>
<td><strong>Case – Controls</strong></td>
<td>Other – Describe:</td>
<td></td>
<td>- Associations controlling for other variables</td>
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<tr>
<td>- Low vs. full vacuum tubes</td>
<td><strong>Randomized Assignment</strong></td>
<td>Other – Describe:</td>
<td></td>
<td>- Pair comparisons between two groups</td>
</tr>
<tr>
<td>- Syringe vs. tube when using IV start</td>
<td><strong>Other</strong></td>
<td>Other – Describe:</td>
<td></td>
<td>- Other</td>
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<tr>
<td>- Duration of applied tourniquet</td>
<td></td>
<td></td>
<td></td>
<td>Please Describe each checked method:</td>
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<td></td>
<td><strong>6. Facility Description (include size):</strong></td>
<td><strong>12. Intervention Duration Dates (pilot, pre/post, etc.) – List each phase with start and end dates:</strong></td>
<td></td>
<td><strong>13. Data Analysis: Significance</strong></td>
</tr>
<tr>
<td>- Hospital: Type/N Beds</td>
<td>Describe Phases:</td>
<td><strong>F Test</strong></td>
<td>For Pearson correlations</td>
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<td></td>
<td><strong>Chi square</strong></td>
<td><strong>T Test</strong></td>
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<td></td>
<td>Other – Describe:</td>
<td></td>
<td>Fisher Exact</td>
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<td><strong>7. QI Project/Study Setting:</strong></td>
<td></td>
<td>Chi-square</td>
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<td>- Emergency Department</td>
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<td>Other</td>
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<td>Other – Describe:</td>
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<td>Please Describe each checked method:</td>
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<td><strong>8. Overall Project/Study Timeframe (include pilot projects):</strong></td>
<td><strong>13. Resource Requirements/Costs:</strong></td>
<td></td>
<td><strong>16. Potential Sources of bias:</strong></td>
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<tr>
<td></td>
<td>start &amp; end dates:</td>
<td><strong>A. Staff / Training:</strong></td>
<td></td>
<td><strong>Patient characteristics: difficult / poor veins / poverty of injury</strong></td>
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<td><strong>Other – Describe:</strong></td>
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<td><strong>B. Equipment/Supplies:</strong></td>
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<td><strong>Gauge of needle/catheter</strong></td>
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<td><strong>Other – Describe:</strong></td>
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<td>Number of tubes drawn at once</td>
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<td>Other – Describe:</td>
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You can “check” boxes by double left clicking on them. If you do not have room to fill in the answer, use the next page and refer to question number.

**Developed by Nickolas Heyer, Battelle Institute**
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Receive notification of:
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- Calls for evidence, topics, public feedback
- Announcements of publications and meeting participation