Applying Evidence-based Methods to Quality Improvement Projects

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Learning Objectives

- Describe the steps of the Laboratory Medicine Best Practices systematic review methods
- Define assessment criteria for collecting evidence in a clinical setting
- Describe how quality improvement data can be used as evidence of practice effectiveness
- Develop strategies for increasing the quality of evidence collected in their own settings
To be Covered

- Purpose of the Laboratory Medicine Best Practices project
- Newly developed methods used by the LMBP project team
- Criteria for generating good quality evidence
- Strategies for increasing the quality of evidence collected in clinical settings

What is LMBP?

An initiative sponsored by the Centers for Disease Control and Prevention (CDC) to develop, pilot test and apply systematic review methods to evaluate evidence of the effectiveness of pre- and post-analytical laboratory medicine quality improvement practices consistent with the Institute of Medicine’s healthcare quality aims.*

*safe, timely, effective, efficient, equitable, and patient-centered
Cherished Beliefs in Medicine

- The idea that long-term hormone-replacement therapy would help prevent heart disease in women made sense.
- *JAMA 2002 Sep 4;288(9):1064.*
  “Postmenopausal hormone therapy should not be used to reduce risk for CHD events in women with CHD.”

Decision-making frequently driven by “opportunities for improvement”

What is the problem?
- Hospitals can be dangerous places.
- According to IOM report, 100,000 deaths per year related to medical errors.

Where do most errors in lab medicine occur?
- Pre-analytical and post-analytical phases.

How do we reduce risk and improve patient outcomes?
Approaches to Decision-making

Status Quo
- Intuition
- Unsystematic clinical observations
- Beliefs/theories of respected leaders

Expert Opinion
- May reflect uncertainties, anecdotes, bias (selectivity, minority viewpoints, perspective)

EBLM
- Systematic synthesis and appraisal of existing evidence

Fundamental Question in Our Laboratory Medicine Practices
Are patients in an environment with a particular laboratory practice likely to be better off than similar patients who are not?

Clinical or Policy Problems

ASK

ASSESS

A 6 Cycle

ACQUIRE

APPLY

ANALYZE

APPRAISE
LMBP Objectives

- Establish transparent systematic review methods to evaluate quality improvement practice effectiveness
- Improve healthcare quality and patient outcomes by disseminating completed evidence reviews of practice effectiveness identifying evidence-based laboratory medicine “best practices”
- Increase engagement of laboratory professionals in quality improvement research and data collection
- Encourage recognition of laboratory professionals as partners in healthcare policy and decision-making

Assumptions for LMBP Methods Development

- Laboratory medicine practices not likely studied in controlled trials
- Evidence available to assess practice effectiveness is most likely to come from observational studies
- Evidence for effectiveness for specific practices is frequently limited
- Must utilize many sources of evidence, including unpublished evidence
Who is involved?

LMBP Workgroup:
- 15-member Independent Body
- Multi-disciplinary composition: clinicians, pathologists, laboratorians, and health services researchers

LMBP Expert Panelists
- Invited experts in a particular topic area to participate in the systematic evidence review

CDC Staff / Review Team
- Scientific staff supporting data collection, abstraction, synthesis and evidence reviews

Consultants
- Contractor staff and experts who provide scientific and administrative support

LMBP “A6” Steps

ASK
Frame focused question(s) to be answered by the evidence review

ACQUIRE
Identify sources and collect potentially relevant studies

APPRaise
Create an evidence base by applying screening criteria related to topic, questions, practices, and outcomes

ANALyze
Standardize, summarize and rate strength of body of evidence (study characteristics, quality, effect size, and consistency)

APPLY
Disseminate findings for review and local application

AUDIT/ASSESS
LMBP Methods
ASK (A1)
Frame focused question(s) to be answered by the evidence review

Aim to answer the following questions:

• What practices are (not) effective for laboratory quality improvement as measured by specific key outcome measures?
• In which settings do practices work?
• What are the implementation considerations for adapting effective practices?

LMBP Topic Selection
Criteria Used

• Address laboratory medicine quality issues of broad stakeholder interest.

• Can be framed by at least one focused question related to practice effectiveness and its impact on relevant outcomes.

• Published literature identifies at least:
  • one potential practice,
  • one quantitative finding, and
  • outcome measures of effectiveness relevant to quality of patient care and/or health outcomes.
LMBP Pilot Test Review Topics

Systematic evidence reviews completed for 3 quality improvement topics, each with multiple practices:

- **Patient Specimen Identification**
  Review Question: “What practices are effective at reducing patient specimen identification errors?”

- **Critical Value Test Result Communication**
  Review Question: “What practices are effective for timely and accurate communication of critical value test results?”

- **Blood Culture Contamination**
  Review Question: “What practices are effective at reducing blood culture contamination?”

LMBP
ACQUIRE (A2)
Identify sources and collect potentially relevant studies

Graphic Source: Centre for Evidence-based Practice, presentation by Paul Glasziou, www.cebm.net
LMBP
ACQUIRE (A2)

Search for evidence should be comprehensive

• Pubmed and Cochrane databases
• Professional guidelines electronic databases (e.g., AHRQ, CLSI, ISO, NACB)
• Hand searching journals of relevance
• Conference proceedings, and technical reports
• Reference lists of relevant published studies
• Key informants
• Unpublished quality improvement assessments

Why Include Unpublished Studies?

• Supplement the limited availability of peer reviewed literature in laboratory medicine to enlarge the evidence base

• Improve the knowledge base of what works, for whom, and in what setting(s)

• Improve information exchange and inform decision-making
Unpublished Studies

- Web-based data collection form
- Available on website www.futurelabmedicine.org
- De-identified data
- Submitters may opt to remain anonymous

LMBP
APPRAISE (A3)

Create an evidence base by applying screening criteria

Graphic Source: Centre for Evidence-based Practice, presentation by Paul Glasziou, www.cebm.net
# LMBP Study/Submission Screening Criteria Checklist

## Study Setting
- ✓ Description of where practice implemented? (e.g. ICU, ED)

## Intervention
- ✓ Practice description includes requirements and components for operations that are replicable?
- ✓ Duration (start and end dates)

## Sample population
- ✓ Description (e.g. patients, samples, tests)
- ✓ Number(s) and description(s) of participants or specimens (e.g. blood, urine)
- ✓ Selection criteria for participants or specimens

## Comparator Practice
- ✓ Description of comparison practice or standard (status quo)
- ✓ Key characteristics (in relation to practice)

## Outcome Measures
- ✓ Definition of the measurement(s) used to assess practice impact (e.g. error rate, length of stay)
- ✓ Method of data collection described

## Results
- ✓ Findings described with supporting data provided
- ✓ Appropriate analysis

---

**LMBP ANALYZE (A4)**

Standardize, summarize and rate strength of body of evidence (study characteristics, quality, effect size and consistency)
### Standardize, Summarize and Rate Studies
Practices reducing patient specimen identification errors

#### Practice:
Bar-coding Systems

<table>
<thead>
<tr>
<th>Study Quality Rating</th>
<th>Effect Size Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence</td>
<td>Study Quality Rating</td>
</tr>
<tr>
<td>Bologna 2002</td>
<td>2</td>
</tr>
<tr>
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#### Study characteristics (Maximum = 3)
- Practice description (Maximum = 2)
- Outcome Measure (Maximum = 2)
- Results of Study (Maximum = 3)

#### Model Study name Statistics for each study Log odds ratio and 95% CI

#### Log odds ratio

#### Model Study name Statistics for each study Log odds ratio and 95% CI

#### Standardize & Summarize Studies
Practices reducing patient specimen identification errors

#### Odds ratios right of the vertical line that runs from 0 provides evidence of an effect of bar-coding

#### Boxes proportional to weights
LMBP
Overall ‘Strength of Evidence’ Rating

<table>
<thead>
<tr>
<th>Strength Ratings</th>
<th>Combined Evidence Minimum Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#Studies*</td>
</tr>
<tr>
<td>High</td>
<td>≥ 3</td>
</tr>
<tr>
<td>Moderate</td>
<td>≥ 2</td>
</tr>
<tr>
<td>Suggestive (Low)</td>
<td>≥ 1</td>
</tr>
<tr>
<td>Insufficient (Very Low)</td>
<td></td>
</tr>
</tbody>
</table>

*Evidence reviews and meta-analyses of multiple studies assessed on a case-by-case basis

LMBP
APPLY (A5)
Disseminate findings for review and local application

- Peer-review publications, trade publications and technical reports
- Website: www.futurelabmedicine.org
- Shared with LMBP Network participants and partners
- Conferences and other presentations (e.g., audioconferences)
LMBP
ASSESS (A6)

Activities to assess whether application of the evidence was effective:

• Measure and monitor targeted outcomes
• Quality assurance activities
• Intervention study
• Economic evaluation
• Registry

Key Criteria for Achieving Good Quality Evidence

• Explicit identification of the question to be answered
• Appropriate choice of patients and setting
• Use of robust measure of outcome
• Exclusion of confounding variables
• Description of methodology that can be reproduced

**LMBP Study/Submission Screening Criteria Checklist**

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Study characteristics (Maximum = 3)
- Practice description (Maximum = 2)
- Outcome Measure (Maximum = 2)
- Results of Study (Maximum = 3)

Good: 8 -10 points
Fair: 5-7 points
Poor: <=4 points
### Evidence Example: Good

#### Study characteristics

- **Study quality rating**: 8-10 points
- **Practice description rating**: 5-7 points
- **Outcome measure rating**: <=4 points

---

#### Standardize, Summarize and Rate Studies
Practices reducing patient specimen identification errors

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### Evidence Example: Fair

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<td>2</td>
<td>10</td>
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<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Sandler et al. 2005</td>
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<td>1</td>
<td>0</td>
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<td>1</td>
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**Study characteristics**
- **Evidence**: 8 -10 points
- **Practice description**: 5 - 7 points
- **Outcome Measure**: Maximum = 2
- **Results of Study**: Maximum = 3

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### Standardize, Summarize and Rate Studies

Practices reducing patient specimen identification errors

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<td>Good, Substantial</td>
</tr>
<tr>
<td>Sandler et al. 2005</td>
<td>1</td>
<td>Poor, n/a</td>
</tr>
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<td>1</td>
<td>Poor, n/a</td>
</tr>
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<td>Good, Moderate</td>
</tr>
<tr>
<td>Unpub A 2009</td>
<td>3</td>
<td>Fair, Substantial</td>
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<td>Good, Substantial</td>
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</table>

**Study characteristics**
- **Evidence**: 5 - 7 points
- **Practice description**: 5 - 7 points
- **Outcome Measure**: Maximum = 2
- **Results of Study**: Maximum = 3

---

**Legend**
- **Good**: 8 - 10 points
- **Fair**: 5 - 7 points
- **Poor**: <= 4 points
Evidence Example: Poor

<table>
<thead>
<tr>
<th>Study</th>
<th>Practice</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design: Non-compliant</td>
<td>Description: Barcodes for transfusion linking wristbands with blood labels. Consists of the PC barcode scanner frequency port to a printer. Software charts the operator’s electronic medical record (wristband), component (compatibility code), and (iv) the blood code.</td>
<td>Outcome (1) Rate of patients found in chart for transfusion were positively and accurately identified. (2) All (100%) blood samples and blood components for transfusion were positively and accurately identified.</td>
</tr>
<tr>
<td>Facility: Georgetown Hospital, Washington, D.C.</td>
<td>Time Period: 10/02 date provided</td>
<td>Findings/Effect Size:</td>
</tr>
<tr>
<td>Study Setting: Hematology-oncology, bone marrow transplant unit</td>
<td>Sample: 125 tests, all blood samples and blood components for transfusion</td>
<td>(1) &quot;All (100%) patients; blood samples and blood components for transfusion were positively and accurately identified.&quot;</td>
</tr>
<tr>
<td>- Design: Non-compliant</td>
<td>- Time Period: 10/02 date provided</td>
<td>(2) &quot;All (100%) bar-code labeled blood sample tubes and certification forms were legible with complete information.</td>
</tr>
<tr>
<td>- Facility: Georgetown Hospital, Washington, D.C.</td>
<td>- Sample: 125 tests, all blood samples and blood components for transfusion</td>
<td>- Stat. SignificanceTest(s): None</td>
</tr>
<tr>
<td>- Study Setting: Hematology-oncology, bone marrow transplant unit</td>
<td>- Design: Non-compliant</td>
<td>- Results/conclusions bias: The Results/findings (3 pts maximum):</td>
</tr>
<tr>
<td>- Time Period: 10/02 date provided</td>
<td>- Time Period: 10/02 date provided</td>
<td>0</td>
</tr>
<tr>
<td>- Sample: 125 tests, all blood samples and blood components for transfusion</td>
<td>- Sample: 125 tests, all blood samples and blood components for transfusion</td>
<td>- Insufficient sample: Statistical power not discussed and sample size too small</td>
</tr>
<tr>
<td>- Comparator: Not reported</td>
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<td>- Data insufficient to allow effect size calculation (non-comparative study)</td>
</tr>
<tr>
<td>- Study site: Small sample size, no comparison data or complete time period provided. The number of patients represented by transfusions is not reported.</td>
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<tr>
<td>- Complete study reported</td>
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<td>- Data insufficient to allow effect size calculation (non-comparative study)</td>
</tr>
<tr>
<td>- Transfusion study distinctive to be generalizable</td>
<td>- No practice duration specified</td>
<td>- Data insufficient to allow effect size calculation (non-comparative study)</td>
</tr>
</tbody>
</table>

Turning a Poor Study into a Good One

<table>
<thead>
<tr>
<th>Study (3 pts maximum): 1</th>
<th>Practice (2 pts maximum): 3</th>
<th>Outcome measures (3 pts maximum): 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Period: 10/02 no end date provided</td>
<td>No practice duration specified</td>
<td>Recording method: electronic medical record</td>
</tr>
<tr>
<td>Sample: 125 tests, all blood samples and blood components for transfusion</td>
<td>- Training: provided during 10002 - 10/02 no end date</td>
<td>- Specimen: provided with complete information</td>
</tr>
<tr>
<td>Comparator: Not reported</td>
<td>- Duration: 10002 - 10/02 no end date</td>
<td>- Recording Method: electronic medical record</td>
</tr>
<tr>
<td>Study site: Small sample size, no comparison data or complete time period provided. The number of patients represented by transfusions is not reported.</td>
<td>- Training: provided during 10002 - 10/02 no end date</td>
<td>- Specimen: provided with complete information</td>
</tr>
<tr>
<td>- Complete study time period not reported</td>
<td>- Study site: Small sample size, no comparison data or complete time period provided. The number of patients represented by transfusions is not reported.</td>
<td>- Recording Method: electronic medical record</td>
</tr>
<tr>
<td>- Transfusion study may be too distinctive to be generalizable</td>
<td>- No practice duration specified</td>
<td>- Specimen: provided with complete information</td>
</tr>
</tbody>
</table>

1. Specify the project period and duration of the practice
2. Increase sample size
3. Provide more description on the recording method
4. Apply statistical treatment to characterize results
Strategies for Generating Strong Evidence

• Formulate an answerable question

• Address key study quality issues

• Consider data collection and treatment early

Formulate an Answerable Question: The PICO System

• Population/patient
• Indicator/intervention/test
• Comparator/control
• Outcome
Project Design

Address how you will gather and analyze information to answer the QI project question.

This includes:

- Defining outcome measures
- Defining the sample population
- Statistical tests

Generating Good Quality Evidence

The following decreases study quality and generalizability of project results:

- Incomplete Project/Study time periods or dates
- Population sample
  - Total number of tests, patients and or specimens not documented
  - Too few observations, too small to allow a robust estimate of the impact of a practice
- Practice description
  - Requirements/components not identifiable
Generating Good Quality Evidence (continued)

Study Setting
- Too distinctive (e.g. pediatric oncology unit)

Measurement period
- Insufficient to allow a robust estimate of the impact

Results bias
- Results reported are not attributable to the practice

HOW TO PARTICIPATE

Organizations and Individuals can:
- Register to receive updates and notifications
- Submit topic suggestions/ideas
- Provide input on draft review topics and evidence reviews
- Submit quality improvement project data for current evidence reviews

www.futurelabmedicine.org
Acknowledgements

• Susan Snyder PhD, MBA – CDC Project Officer
  • Abrienne Patta, MPH,CHES
  • Malaika Washington, MSPH

• Ed Liebow, PhD – Battelle Project Lead
  • Robert Black, MPH
  • Robert Christenson, PhD, DABCC, FACB
  • James Derzon, PhD
  • Paul Epner, MEd, MBA
  • Alessandra Favoretto, MHS
  • Diana Mass, MA, MT(ASCP), CLS

Thank You

LMBP Network Participation
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Project Questions
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