Laboratory Medicine Best Practices: Developing and Applying Systematic Evidence Review and Evaluation Methods for Quality Improvement

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Faculty/Author/Speaker Disclosure:
The faculty/speaker(s) for this live session do not have relevant financial relationships with commercial interests to disclose.

Credit Type: Continuing Medical Education
Number of Credits: 2.0
MOC Competencies (if Applicable): Not applicable
You will leave with the ability to:

- Compare and contrast conventional methods used to develop guidelines, standards and recommendations (i.e., consensus expert opinion) in laboratory medicine and evidence-based methods.

- Describe the A6 Cycle and the necessary steps to develop evidence-based recommendations that impact laboratory medicine decision making.

- Explain several examples where laboratory medicine best practice evidence reviews have been performed and describe the review, results and outcomes associated with the practices reviewed.
Introductory Remarks

Susan Snyder, Ph.D., MBA
Battelle Centers for Public Health Research and Evaluation

October 2011
What is LMBP?

An initiative sponsored by the Centers for Disease Control and Prevention (CDC) to develop and implement transparent evidence-based methods to evaluate the effectiveness of pre- and post-analytical quality improvement practices consistent with the Institute of Medicine’s healthcare quality aims.*

*safe, timely, effective, efficient, equitable, and patient-centered
What?

- **Evidence-based method**
  Strategy explicitly linking practice recommendations or guidelines to outcomes from scientific evidence of effectiveness

- **Effectiveness**
  Extent to which a specific intervention or practice works (i.e., achieves a desired change in one or more measurable outcome)
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 used to identify 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.
LMBP Methods Deliver Evidence-Based Results

LMBP evidence reviews begin with a topic area analytic framework with these components:

- **Review question** (> 1) that addresses a
- **Quality issue/problem** which can be
- **Improved/Prevented** and captured by
- **Outcome Measures** of effectiveness

**Review Question:**

*Do specific practices improve specified healthcare quality outcomes?*

LMBP methods transparently and systematically:

- Answer the review questions *and*
- Develop evidence-based ‘best practice’ recommendations.
## LMBP History

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convene LMBP Workgroup – multidisciplinary panel</td>
<td>Develop and pilot methods for evaluation and recommendation</td>
<td>Pilot review and evaluation methods (3 review topics)</td>
</tr>
<tr>
<td>Systematic review methods</td>
<td>Utilization of Expert Panels to complete evidence reviews</td>
<td>Pilot methods to obtain unpublished studies (outreach and recruitment)</td>
</tr>
<tr>
<td>Key terms, definitions, inclusion criteria (general)</td>
<td>Develop/test methods for inclusion of unpublished practice assessments</td>
<td>Partner with lab medicine organizations and leaders</td>
</tr>
<tr>
<td>Proof of concept test of the review methods</td>
<td>Evaluate implementation and sustainability options</td>
<td>Develop Implementation Strategy</td>
</tr>
<tr>
<td>Initial implementation and methods recommendations</td>
<td></td>
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</tr>
</tbody>
</table>

American Society for Clinical Pathology
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 and Battelle Staff / Review Team
- Scientific staff supporting data collection, abstraction, synthesis and evidence reviews

Consultants
- Contractor staff and experts who provide scientific and administrative support
<table>
<thead>
<tr>
<th>LMBP Present</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 4</strong></td>
</tr>
<tr>
<td><strong>2009-2010</strong></td>
</tr>
<tr>
<td>Finalize systematic review methods</td>
</tr>
<tr>
<td>Complete first 3 evidence reviews</td>
</tr>
<tr>
<td>LMBP Website futurelabmedicine.org information dissemination and submission of unpublished evidence</td>
</tr>
<tr>
<td>New topic identification and development</td>
</tr>
</tbody>
</table>

Outreach activities & Partnership models
Laboratory Medicine Best Practices:

Methodology for Translating Evidence into Action!

Robert H. Christenson, Ph.D., DABCC, FACB
Professor of Pathology
Professor of Medical and Research Technology
University of Maryland School of Medicine
Baltimore, MD

October 2011
Where have you seen the phrase “Evidence-Based Medicine?”

- Advertising?
- Internal marketing materials?
- Strategy documents?
- Training materials?
- Statements about culture or practices?

- The real question: Have you ever faced a decision about what practices and procedures work best, and wished you could confidently back up your choice?
Approaches to Decision-Making

Typical
- Intuition
- Unsystematic clinical observations
- Beliefs/theories of thought leaders

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

Consensus Opinion
- May reflect an incomplete review of evidence, bias (selectivity, minority viewpoints, perspective)

Evidence-based
- Systematic synthesis and appraisal of existing evidence

American Society for Clinical Pathology
Not All Evidence is Equal

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.”

Beliefs, anecdotes or poorly designed experiments don’t constitute good evidence.
Evidence-Based Laboratory Medicine

“A diagnostic test result should enable a decision to be made, which leads to an action being taken, yielding an improved outcome for the patient.”

Price and Christenson 2003
Challenge: Connecting Laboratory Testing to Outcomes

Demonstrating the value of lab tests on health or economic outcomes is reliant on linking the test with processes that directly impact outcomes.
Decision-making frequently driven by “opportunities for improvement”

What is the problem?
- Hospitals can be dangerous places.
- According to Institute of Medicine (IOM) report, 100,000 deaths per year related to medical errors.
- Safe, Timely, Effective, Efficient, Equitable, Patient Centered

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

How do we reduce risk and improve patient outcomes?
- Determine what works: Evidence-Based Laboratory Medicine (LMBP)
Approach: The A6 Cycle for EBLM

1. **Identified Topic**
2. **ASK**
3. **ASSESS**
4. **A 6 Cycle**
5. **ACQUIRE**
6. **APPLY**
7. **ANALYZE**
8. **APPRAISE**
An Evidence-Based Approach

Core Idea → Problem → Solution

- **The Core Idea**
  - Medical care for patients should be based to the greatest extent possible on evidence of effectiveness

- **The Problem(s)**
  - According to an Institute of Medicine report, up to 100,000 deaths per year result from medical errors
  - Large gaps exist between clinical practice and evidence supported by clinical research
  - Clinical validation of effective practices is lacking

- **The Solution**
  - Determine what is effective through evidence-based evaluation of practice
What is the Evidence?

The data that may be obtained from:

- Primary research, published individual studies
- Secondary research, that summarizes information from primary research
- Unpublished work (e.g., your own in-house quality improvement projects or assessments)
What is a systematic review?

**Definition:** A summary of the clinical literature. A systematic review is a critical assessment and evaluation of all research studies that address a particular clinical issue. The researchers use an organized method of locating, assembling, and evaluating a body of literature on a particular topic using a set of specific criteria. A systematic review typically includes a description of the findings of the collection of research studies. The systematic review may also include a quantitative pooling of data, called a meta-analysis.

Applying an Evidence-Based Approach to Laboratory Medicine

- Laboratorians can apply the principles of evidence-based laboratory medicine to answer questions and solve problems in providing patient-centered services
- An evidence-based approach is applied through the systematic synthesis (combination of information) and appraisal of existing evidence
- Using evidence to evaluate practice effectiveness can help laboratory professionals and healthcare stakeholders to:
  - Determine what is effective, for whom and in what setting(s)
  - Improve patient care and outcomes
  - Promote transparency and accountability
How Can Evidence Make a Difference?

- An Administrative Director wants to request new technology
  - The academic center where she works is considering implementing a bar-coding system to reduce patient specimen identification errors. She has been asked to evaluate the benefit of implementing this bar-coding system.

- How does this Director determine if this practice (bar-coding systems) is effective?

- How does cost effectiveness get considered?
Systematic Reviews

- A method of locating, collating and evaluating all of the available evidence on a specific topic using pre-specified criteria.

- Key Characteristics:
  - Clearly stated set of objectives
  - Explicit, reproducible methodology to locate, assemble and evaluate studies
  - Assessment of the validity of the findings of included studies
  - Standardized description of the findings from all included studies
  - Quantitative pooling of the data from included studies (meta-analysis)

LMBP Systematic Review Methods

- Adapted from validated evidence-based methods used in clinical medicine
- Pilot-tested (2006-2010) with input from practitioners and researchers in laboratory medicine, clinical medicine and health systems research
- Includes unpublished findings IF they meet the same standards applied to published data

LMBP Expert Panels

• Reach consensus on topic area evidence review quality and effect size rating categories

• Apply and provide feedback on evaluation methods to produce ratings for individual study quality and effect size

• Evaluate individual practices’ overall strength of evidence, effect size consistency (i.e., direction and magnitude)

• Develop final draft practice evidence summaries and draft recommendations to be presented to the LMBP Workgroup
LMBP Workgroup

Multidisciplinary group with oversight responsibility
5,000-foot view of LMBP Process

Topic Selection / Analytic Framework

CDC Review Team with guidance from LMBP Workgroup and Expert Panelists

Systematic Review

CDC Review Team / Expert Panels

Evidence-Based Recommendations

Recommending Body (LMBP Workgroup) identifies best practices based on Expert Panel evaluation

Evidence Summaries

Consensus Ratings
LMBP's Review Cycle Methods: A-6 Steps

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

ACQUIRE
Identify sources and collect potentially relevant published and unpublished studies

APPRAISE
Create an evidence base by applying screening and evaluation/rating criteria to standardized information from individual studies

ANALYZE
Synthesize and rate overall strength of body of evidence (quality, effect size, consistency)

APPLY
Disseminate findings for review and local implementation

AUDIT/ASSESS
Activities to measure and monitor targeted outcomes
If you ask the wrong question, why would you expect to get the right answer?

"A prudent question is one-half of wisdom." - Francis Bacon
Formulate an Answerable Question
the PICO system

- **P**opulation/patient
- **I**ndicator/intervention/test
- **C**omparator/control
- **O**utcome
Can I use the plasma BNP test to rule-in or rule-out decompensated heart failure in patients presenting with dyspnea to urgent care?
Formulate an Answerable Question
diagnostic accuracy

- **P** - breathless patients in primary care
- **I** - plasma BNP
- **C** - two cardiologists review
- **O** - ‘rule-in’ or ‘rule-out’ heart failure
**ASK**: Patient Specimen Identification

**Healthcare Quality Issue:**

- Patient specimen identification errors may contribute to adverse patient events and wasted resources.

**Evidence Review Question:**

- What interventions/practices are effective in reducing patient/specimen identification errors?
Lab Medicine Best Practice
the PICO system

- Practice
- Indicator/intervention/test
- Comparator/control
- Outcome
**Published Literature**

- **Initial Search Results**
  - 1677 references

- **30 Full Text Articles**

- **14 pre abstraction articles**

**Unpublished Assessments**

- **1647 Excluded**
  - Title/abstract did not meet inclusion criteria

- **20 Excluded**
  - Did not meet criteria

- **9 found by hand searching, 5 excluded**

- **Venipuncture**
  - 0 submitted

- **Phlebotomy Teams**
  - 5 submitted
  - 2 included

- **Prepackaged prep kits**
  - 2 submitted
  - 0 included

**Results by Practice:**

- 7 Venipuncture (vs. catheter)
- 6 Phlebotomy team
- 4 Prep Kits
APPRAISE  Individual Study Design and Findings

- **Initial screen** of search results (exclusion criteria)
- **Abstract, standardize and summarize** studies meeting inclusion criteria
- **Evaluate and rate/score**
  - Study quality (4 elements in quality checklist)
  - Effect size (substantial, moderate, minimal/none)
- **Synthesize** into a practice body of evidence
LMBP Study Quality Appraisal Checklist

**Study Setting**
- Is information about the study setting provided? (e.g., ICU, ED)

**Practice**
- Is there a practice description that includes requirements and components for operations?
- Is the duration (start and end dates) for the practice reported?

**Sample population**
- Is the sample population identified (e.g., patients, samples, tests)?
- Are number(s) and description(s) of participants or specimens provided (e.g., blood, urine)?
- Is the selection criteria for participants or specimens provided (what was included and excluded)?

**Comparator Practice**
- Is there a comparison practice or standard (status quo)?
- Are key characteristics (in relation to practice) described?

**Outcome Measures**
- Are measurement(s) to assess practice impact identified and defined (e.g., length of stay)?
- Are the measure(s) relevant to the review question?
- Is the method of data collection described?

**Results**
- Are findings described and supporting data provided?
- Have appropriate analysis been performed?
- Are reported findings clearly related to the practice of interest?
LMBP – APPRAISE
Abstract, Standardize, Summarize and Rate Evidence Summary Table

Quality Domains

Bibliographic Information
- Author(s)
- Yr Published/Submitted
- Publication
- Author Affiliations
- Funding

Quality Domains Points

2 2 1 3

- Two reviewers/abstractors independently review evidence
- Results of abstractions are compared
- Meeting to resolve Abstractor discrepancies
- Individual study quality ratings are based on four dimensions of study quality:
  » Study
  » Practice
  » Outcome measures
  » Results/Findings
Insights: Common Study Quality Problems

Information commonly missing or inadequate in laboratory medicine quality improvement project write-ups:

**Sample size:** The description of the study population that is the unit of analysis (patients, specimens, etc.) is incomplete or the setting is too distinctive to generalize

- **Total number for sample size,** e.g., number of patients, number of tests and or number of samples in total, is inadequate to allow a robust analysis of the practice

- **Inadequate description** of tests or samples included in the study (e.g. all tests within a given time period, stratified random sample of tests or a convenience sample)

- The project period **start and end dates** including the start and end dates for the intervention is missing or too short to allow for a robust estimate of the impact

- **The description of the intervention** isn’t sufficient to allow it to be replicated

- **Outcome measure** description is inadequately described

- **Statistical methods** were not applied to characterize results

- The **results reported cannot be clearly attributed** to the intervention
### LMBP – APPRAISE

**Synthesize – Aggregate Body of Evidence**

#### 1 – Study Quality Rating

<table>
<thead>
<tr>
<th>Practice A</th>
<th>Study Characteristics (3 pts)</th>
<th>Practice Characteristics (2 pts)</th>
<th>Outcome Measures (2 pts)</th>
<th>Results (3 pts)</th>
<th>Overall Study Quality Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Study 2</td>
<td></td>
<td></td>
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<td>...</td>
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<tr>
<td>Study n</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Good**: 8-10 pts
- **Fair**: 5-7 pts
- **Poor**: ≤ 4 pts

#### 2 – Study Effect Size Rating

<table>
<thead>
<tr>
<th>Study Ratings</th>
<th>Study Quality Rating</th>
<th>Study Effect Size Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td></td>
<td>Substantial</td>
</tr>
<tr>
<td>Study 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study n</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Substantial**
- **Moderate**
- **Minimal/None**

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**Individual Study Ratings**

<table>
<thead>
<tr>
<th>Study Ratings</th>
<th>Study Quality Rating</th>
<th>Study Effect Size Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>Good</td>
<td></td>
</tr>
<tr>
<td>Study 2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study n</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ANALYZE the Overall Body of Evidence

From the APPRAISE step, rate:
1. Individual study quality
   - Good, Fair, Poor
2. Effect size magnitude
   - Substantial, Moderate, Minimal/None
3. Evaluate for consistency
   - Yes/No
4. Translate into a practice’s overall strength of evidence rating
   - High, Moderate, Suggestive, Insufficient
5. Best Practice recommendation
   - Recommend, No recommendation, Recommend Against
LMBP Expert Panels

- Reach consensus on topic area evidence review quality and effect size rating categories
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## Meta Analysis

Evaluate Consistency & Standardized Effect Size

<table>
<thead>
<tr>
<th>Study name</th>
<th>Odds ratio</th>
<th>Lower limit</th>
<th>Upper limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1 (2001)</td>
<td>2.32</td>
<td>1.11</td>
<td>4.87</td>
</tr>
<tr>
<td>Study 2 (2000)</td>
<td>1.94</td>
<td>0.79</td>
<td>4.78</td>
</tr>
<tr>
<td>Study 3 (2004)</td>
<td>1.78</td>
<td>0.93</td>
<td>3.41</td>
</tr>
<tr>
<td>Study 4 (2005)</td>
<td>0.98</td>
<td>0.39</td>
<td>2.47</td>
</tr>
<tr>
<td>Study 5 (2002)</td>
<td>0.94</td>
<td>0.34</td>
<td>2.62</td>
</tr>
<tr>
<td>Study 6 (2003)</td>
<td>0.32</td>
<td>0.12</td>
<td>0.85</td>
</tr>
<tr>
<td>Summary Effect Estimate</td>
<td>1.22</td>
<td>0.70</td>
<td>2.12</td>
</tr>
</tbody>
</table>

Odds ratio and 95% CI

Test more effective, p < .05

Test less effective, p < .05

Favors Standard Practice

Favors Test Practice
Consistency (Yes/No)

Overall Evidence Rating

<table>
<thead>
<tr>
<th>Individual Study Quality</th>
<th>Individual Effect Size</th>
<th>Consistency (Yes/No)</th>
<th>Overall Strength Rating</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td># Good: # Fair:</td>
<td>Substantial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Good: # Fair:</td>
<td>Moderate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Good: # Fair:</td>
<td>Minimal / None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Good: # Fair:</td>
<td>Adverse</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Statistics for each study**

<table>
<thead>
<tr>
<th>Study name</th>
<th>Std diff in means</th>
<th>Standard error</th>
<th>Lower limit</th>
<th>Upper limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study A (2007)</td>
<td>0.85</td>
<td>0.11</td>
<td>0.62</td>
<td>1.07</td>
</tr>
<tr>
<td>Study E (2009)</td>
<td>0.64</td>
<td>0.03</td>
<td>0.59</td>
<td>0.69</td>
</tr>
<tr>
<td>Study B (2007)</td>
<td>0.47</td>
<td>0.06</td>
<td>0.36</td>
<td>0.58</td>
</tr>
<tr>
<td>Study C (2008)</td>
<td>0.34</td>
<td>0.06</td>
<td>0.21</td>
<td>0.46</td>
</tr>
<tr>
<td>Study F (2010)</td>
<td>0.07</td>
<td>0.05</td>
<td>-0.04</td>
<td>0.17</td>
</tr>
<tr>
<td>Study D (2009)</td>
<td>-0.28</td>
<td>0.06</td>
<td>-0.40</td>
<td>-0.17</td>
</tr>
</tbody>
</table>

Summary effect estimate: 0.34 ± 0.16

Favors Standard Practice

-1.00 -0.50 0.00 0.50 1.00

Favors Test Practice
# Overall Strength of Evidence

## Overall Evidence Rating

<table>
<thead>
<tr>
<th>Individual Study Quality</th>
<th>Individual Effect Size</th>
<th>Consistency (Yes / No)</th>
<th>Overall Strength Rating</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td># Good: # Fair:</td>
<td>Substantial</td>
<td></td>
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</tr>
<tr>
<td># Good: # Fair:</td>
<td>Adverse</td>
<td></td>
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</tbody>
</table>

## Combined Evidence Minimum Criteria

<table>
<thead>
<tr>
<th>Strength Ratings</th>
<th>Combined Evidence Minimum Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>#Studies</strong></td>
<td><strong>Effect Size Rating</strong></td>
</tr>
<tr>
<td>High</td>
<td>≥ 3</td>
</tr>
<tr>
<td>Moderate</td>
<td>≥ 2 or ≥ 3</td>
</tr>
<tr>
<td>Suggestive (Low)</td>
<td>≥ 1 or ≥ 2 or ≥ 3</td>
</tr>
<tr>
<td>Insufficient (Very Low)</td>
<td>All others</td>
</tr>
</tbody>
</table>

*Note: This table provides a guideline for determining the overall strength of evidence based on the combined evidence minimum criteria. The specific criteria and ratings are based on the number of studies, effect size, and study quality. The recommendation is based on the overall strength of evidence.
<table>
<thead>
<tr>
<th>Recommendation Categories</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommend</strong> (‘Best Practice’)</td>
<td>Consistent and high or moderate overall evidence of effectiveness strength rating of desirable effects</td>
</tr>
<tr>
<td><strong>No recommendation for or against</strong></td>
<td>Insufficient evidence to determine effectiveness</td>
</tr>
<tr>
<td><strong>Recommend against</strong></td>
<td>Consistent and high or moderate overall evidence of effectiveness strength rating adverse effects</td>
</tr>
</tbody>
</table>
LMBP Systematic Review to LMBP Evidence-based Recommendation

Expert Panel

A6 Cycle

ASK

ACQUIRE

APPLY

ANALYZE

Recommendation Categories
- Recommend
- No recommendation for or against
- Recommend against

LMBP Workgroup
Evidence ⟷ Action!
Laboratory Medicine Best Practices:

Patient Identification: “Holy Grail” of the Pre-Analytical Phase

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Professor and Vice Chair, Clinical Services, Pathology
Loyola University Medical Center
Maywood, IL, USA

October 2011
Presentation Objectives

Following this presentation, the learner will be able to:

• Describe why patient specimen identification (PSID) is the ‘Holy Grail’ of laboratory medicine
• Understand how the ‘A6’ Cycle can be used in the PSID analytic framework to determine if there are evidence-based recommended LMBP’s
• List evidence-based recommended LMBP’s for PSID
PSID ... Lab Medicine’s “Holy Grail”

• Improving patient and sample identification at the time of specimen collection, analysis and resulting remains the #1 PSG of CAP

• Improving accuracy of patient identification remains the #1 TJC NPSG as it has been for years … this includes laboratory and pathology specimens

• Misidentification is expensive … e.g., a mislabeled specimen cost one provider $15K excluding legal fees

• A mislabeled specimen could lead to a patient fatality

• The #1 ‘zero tolerance’ error in lab medicine
Many have searched for the “Holy Grail”
Where PSID errors may occur ...

- Speci-Man was created in 2004 in a project named ‘Label Liability: Tubes on the Loose’
- Multidisciplinary team of 2 residents, 2 nurses, 2 faculty and 2 medical students
- Loyola University Health System’s ‘Innovations in Leadership’ program
- Collected ‘hypothetical extra charges data’ as estimation of the $ impact of specimen mislabeling
- 14 actual cases, eliminated 2 outliers (~ $15K, $60)
- Mean add’l charges per case: $ 712
  \[ \times 150 \text{ cases per month} \times 12 \text{ months} \]

= $1.28 M per year
**Specimen Labeling**

When should you call on **Speci-Man**?

*When... Somewhere a Patient Escapes Correct Identification*

Follow these steps to ensure proper handling of specimens...

- **S**tart with the order.
  - Verify the test, patient, and ordering physician.

- **P**ick the supplies.
  - Use the correct tube/container and labels.

- **E**nsure identity.
  - Use two patient identifiers.

- **C**ollect specimen.
  - Obtain correct amount at correct date and time.

- **I** am responsible.
  - Attach correct labels to correct specimen.

**Don't let your tube on the loose.**

**Call on Speci-Man**
Focusing on PSID in the LUHS

- Bedside glucose testing (2003 - 2011)
  - With connectivity ~ 4.3 Sigma; Without connectivity … who knows?
- FMEA in ED (2006)
  - Mislabels down 50%, but it has always come back up
  - Captures all unlabeled specimen occurrences to focus on specimens submitted without proper identifiers
  - Monthly Specimen Exception Reports down 30% - 101 down to 70
- Recent lab recommendations:
  - Implement bedside barcode labeling (7 yrs!!)
  - Work with nursing education to improve collection training
  - Expand unit based monitoring of non-conformances
  - ‘Toe the line’ on compliance with specimen collection policy

Working on PSID in a provider setting is like playing ‘Whack-A-Mole’ ….
Others Have Searched for the Grail ... LMBP’s PSID Expert Panel

- **Corinne Fantz**, Co-Director of Core Laboratories (Emory Hospital); Medical Director of Support Services and Director of POCT for Emory Healthcare
- **Julie Gayken**, Administrative Director of Laboratory Services in Anatomic and Clinical Pathology, Regions Hospital
- **Denise Geiger**, Laboratory Director, John T. Mather Hospital
- **David Hopkins**, Medical Epidemiologist, Community Guide Branch, CDC
- **Stephen Kahn**, Associate Director, Clinical Laboratories; Director of Core Laboratory Services and POCT, Loyola University Health System
- **James Nichols**, Director, Clinical Chemistry Department of Pathology, Bay State Health Systems
- **Stephen Raab**, Director, Cytopathology Laboratory, U Colorado Cancer Center
- **Paul Valenstein**, Director of Clinical Microbiology, St. Joseph Mercy Hospital
Analytic Framework

Patient Specimen and Test Identification Errors

Quality Problem
Patient specimen/test identification (ID) errors may result in adverse patient outcomes and wasted resources.

Preventability/Improvement
All ID errors are preventable. Error rates range from < 1% to > 50%.*

*Some variation due to different measurement methods

Practices/Interventions
- Barcoding systems for specimen labeling
- Point-of-care test (POCT) barcoding

Intermediate Outcomes
- ID error rates (specimen and test)
- Wasted lab and healthcare resources (testing and error resolution)

Healthcare/Health Outcomes
- Diagnostic and treatment delays
- Diagnostic and treatment errors
- Increased care time (e.g. length of stay)
- Additional testing
- Costs associated with above

Harms
ID errors - other barcodes

Mortality
LMBP “A6” Steps

Are patients in an environment with a particular lab practice likely to be better off than similar patients who are not?
ASK the Question

Frame focused question(s) to be answered by evidence review
Patient Specimen Identification

Healthcare Quality Issue:

- Patient specimen identification errors may contribute to adverse patient events and wasted resources

Evidence Review Question:

- What interventions/practices are effective in reducing patient/specimen identification errors?

Evidence Review Question (Focused):

- Are barcoding practices effective at reducing patient specimen and test identification errors?
Selected Potential Outcome Measures

- **PSID Errors:**
  - Number (%) of mislabeled and/or misidentified specimen per total # specimen collected (mismatch between specimen label and patient or specimen collected from wrong patient)
  - Number (%) of mismatches between pathology specimen parts requisitions and patient information per total pathology specimen requisitions
  - Number (%) of mismatches between pathology specimen cassettes and laboratory tag for patient information per total pathology specimen cassettes

- **PIEs: Number (%) of misidentified patients per total number of point of care tests (POCT)**
  - mismatches between patient info on wrist or armband and information on POCT device

- **Specimen Rejection Rate:**
  - Percentage of blood specimens rejected by the laboratory due to missing patient identification / Total number of patient blood specimens

- **Unnecessary Repeat Phlebotomies:**
  - Number of repeat phlebotomies due to mislabeled specimen / Total # of patient specimens
  - Blood loss due to excessive draws is a strategic blood management issue
Key Practice Definitions

• **Bar Coding Systems**
  – Electronic bar coding on patient and specimen used to establish positive i.d. of specimen belonging to patients. Uses bar-code scanners and portable label printing devices

• **Point-of-Care Bar Coding Systems**
  – Automated patient and sample identification system using bar-coded patient armbands and bar scanners when diagnostic testing is conducted at or near to the patient
ACQUIRE the Evidence

Identify sources and collect potentially relevant studies
Searching for the Evidence

• Strategy: focus on relevant literature that categorizes/defines I.D. errors and/or identifies potential interventions/practices to reduce them

• Top 5 search term hits:
  – patient specimen identification (260)
  – laboratory identification errors (187)
  – identification errors AND patients AND specimen (25)
  – Reducing patient identification errors (16)
  – Strategies to reduce identification errors (10)

• Sources of evidence – The ‘Usual Suspects’

• Standard LMBP method – as described .................
## Study/Submission Screening Criteria Checklist – i.e., ‘Standard Method’

### 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
Inclusion Criteria

• Specific intervention/practice identified in the literature
  – Is actually in use and available for application
  – Can be performed and reproduced in other comparable patient care settings
  – Impacts a defined group of patients
  – Identifies a potential improvement in an outcome that can be related to at least one of these aspects of patient care:
    - Effective
    - Efficiency
    - Equitable
    - Patient-centered
    - Safe
    - Timely
Exclusion Criteria

• Upon review of an article’s title and abstract (or unpublished data submission), it was excluded if one or more of the following criteria were applicable:
  – No practice was assessed (i.e., no outcome measures were identified)
  – The practice was not sufficiently described
  – The article was a commentary or opinion piece
APPRAISE the Evidence

Create an evidence base by applying screening criteria related to topic, questions, practices, and outcomes
How to Appraise Evidence?

• Essential to appraise ALL of the evidence critically

• Apply PICO criteria

• Assess degree to which evidence is affected by bias

• Utilize existing appraisal tools, scales or checklists
Evidence Search Outcomes

Systematic Review Flow Diagram

Phase 2 Pilot Test Results

Identification

Screening

521 Total References
- 506 PubMed, CLSI, Cochrane
- 15 Hand Search

449 References Excluded
- 244 review title or abstract
- 205 did not meet requirements

72 Full-Text Review
- 28 PubMed, CLSI, Cochrane
- 15 Hand Search
- 29 Background Articles

56 References Excluded
- 44 e-search
- 12 hand search

22 Full-Text Studies Meeting Inclusion Criteria
- 16 Published Studies
  - 6 Unpublished practice submissions
    - 4 Barcode Systems (Central Lab)
    - 2 Barcode Systems (POCT)

Results: 17 Studies Included

Barcoding systems: 10
Point-of-care testing barcoding systems: 7

Phase 3 Pilot Test Results

Identification

Screening

81 Total References
- 74 PubMed (4 studies overlap from Phase 2)
- 6 Phase 2 studies
- 1 Snowball sampling (Referenced by other authors)

72 Excluded
- 50 review title or abstract
- 22 did not meet requirements

5 Excluded
study quality criteria not met

Included
# Overall ‘Strength of Evidence’ Ratings

<table>
<thead>
<tr>
<th>Strength Ratings</th>
<th>Combined Evidence Minimum Criteria</th>
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<td>Insufficient (Very Low)</td>
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on a case-by-case basis
# Evidence Summary Table 2011: Standardize, Summarize & Rate the Studies

<table>
<thead>
<tr>
<th>Practice: Bar Coding Systems</th>
<th>Study</th>
<th>Practice</th>
<th>Measures</th>
<th>Results</th>
<th>Total</th>
<th>Rating</th>
<th>Effect Size Rating</th>
<th>Overall Consistency</th>
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</table>

*not in meta-analysis

### 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**

<table>
<thead>
<tr>
<th>Bibliographic Information</th>
<th>Study</th>
<th>Practice</th>
<th>Outcome Measures</th>
<th>Results/Findings</th>
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<tr>
<td>- Author(s)</td>
<td>- Design</td>
<td>- Design</td>
<td>- Type of Findings</td>
<td>- Pretest-Posttest</td>
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<td>Killeen JP, Chan TC, Johnson J, and Guess DA</td>
<td>- Facility/Setting</td>
<td>- Description</td>
<td>- Barcoding system</td>
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<tr>
<td>- Yr Published/Submitted</td>
<td>- UCSD Medical Center, San Diego CA</td>
<td>- Barcoding system</td>
<td>Number of mislabeled specimens / number of specimens (per specimen)</td>
<td>Pretest: 2.56 per 1000 [CI: 1.94 to 3.32] (0.00256%); 57/22,243; ID errors: 41 mislabeled and 16 unlabeled</td>
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<tr>
<td>- Publication</td>
<td>- Before-after</td>
<td>- 8 months duration, no dates provided</td>
<td>Posttest: 0.49 per 1000 [CI: 0.24 to 0.87], (0.00049%); 11/22,574; ID errors: 8 mislabeled and 3 unlabeled</td>
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<td>- Author Affiliations</td>
<td>- Facility/Setting</td>
<td>- Training: not discussed</td>
<td>- Staff/Other Resources</td>
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<td>- Cost: not reported</td>
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<td>- Funding</td>
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<td>- Sample: All Emergency Department (ED) patients during study period (age census: 40,000)</td>
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<td>- Publication</td>
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<td>- Comparator: Imprint stamp sticker labels on specimens and</td>
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## Evidence Summary Table 2011: PSID

### Standardize, Summarize & Rate Studies

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*not in meta-analysis

**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: Poor

<table>
<thead>
<tr>
<th>Study</th>
<th>Practice</th>
<th>Outcome Measures</th>
<th>Results/Findings</th>
</tr>
</thead>
</table>
| - **Design:** Non-comparative study | - **Description:** Barcoding for transfusion linking patient wristbands with blood component labels. Consists of the handheld PC/bar-code scanner with a frequency port to a portable printer. Software checks for the operator’s electronic signature (personal ID badge bar code), the patient’s name and medical record # (wristband); (i) the component (compatibility bar code); and (iv) the blood component (whole blood # (blood bag bar code). | - **Outcome Measures:**
1. Positive identification rate. 
2. Number of bar-code-labeled blood sample tubes and certification forms were legible with complete information.
 | **Results/Findings:**
- Non-comparative Study, Time series (average): 
- **Findings/Effect Size:**
1. “All (100%) patients, blood samples, and blood components for transfusion were positively and accurately identified.”
2. “All (100%) bar-code-labeled blood sample tubes and certification forms were legible with complete information.”
- Stat. Significance/Test(s): None
- Results/conclusions bias: The
Results/findings (3 pts maximum): 0
- Insufficient sample. Statistical power not discussed and sample size too small
- Data insufficient to allow effect size calculation (non-comparative study)

---

**Study (3 pts maximum): 1**
- Complete study time period reported
- Transfusion study may be distinctive to be generalizable

**Practice (2 pts maximum): 0**
- No practice duration specified
- Recording not adequately described

---

**Study (3 pts maximum): 1**
- Complete study time period reported
- Transfusion study may be distinctive to be generalizable

**Practice (2 pts maximum): 0**
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---

**Study (3 pts maximum): 1**
- Complete study time period reported
- Transfusion study may be distinctive to be generalizable

**Practice (2 pts maximum): 0**
- No practice duration specified
- Recording not adequately described
## Turning a Poor Study into a Good One

### Register of nurses:
- **Time Period:** 10/02- no end date provided
- **Sample:** 125 tests, all blood samples and blood components for transfusions.
- **Comparator:** Not reported
- **Study bias:** Small sample size, no comparison data or complete time period provided. The number of patients represented by transfusions is not reported.

### Record if (including): (iv) the blood component (compatibility barcode); and (iv) the blood centre's whole blood # (blood bag barcode).
- **Duration:** 10/02 - ?(no end date)
- **Training:** provided during 1-hour session including written and instruction review on how to use the system.
- **Staff:** Nurses
- **Cost:** not reported

### Education forms logbook with complete information
- **Recording Method:** electronic medical record

### Information:
- **Stat. Significance/Test(s):** None
- **Results/conclusions biases:** The stated purpose was to focus on nurses who transfuse blood infrequently, yet no statistics presented for these results (suggest that these nurses perform more poorly than nurses who transfuse frequently). Results focused on subjective ratings.

<table>
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<tr>
<th>Study (3 pts maximum): 1; Complete study time period not reported</th>
<th>Practice (2 pts maximum): 1; No practice duration specified</th>
<th>Outcome measures (2 pts maximum): 1; Recording method is not adequately described</th>
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<tbody>
<tr>
<td>Insufficient sample: Statistical power not discussed and sample size too small</td>
<td>Data insufficient to allow effect size calculation (non-comparative study)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Specify 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
ANALYZE the Evidence

Standardize, summarize and rate strength of body of evidence (study characteristics, quality, effect size, and consistency)
# Body of Evidence – Bar Coding Systems

<table>
<thead>
<tr>
<th>Practice: Bar Coding Systems</th>
<th>Study</th>
<th>Practice</th>
<th>Measures</th>
<th>Results</th>
<th>Total</th>
<th>Rating</th>
<th>Effect Size Rating</th>
<th>Overall Consistency</th>
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</thead>
<tbody>
<tr>
<td><strong>Published</strong></td>
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<tr>
<td>Bologna 2002</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
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<td>Fair</td>
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<td>5 Studies = Good/Substantial</td>
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<tr>
<td>Brown 2010</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>9</td>
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<td></td>
<td>2 Studies = Fair/Substantial</td>
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<tr>
<td>Hayden. 2008</td>
<td>3</td>
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<td>Good</td>
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<td>1 Study = Good/Moderate</td>
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<td>2 Studies = Fair/Moderate</td>
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<td>Kileen 2005</td>
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<td>3 Studies = Poor - Excluded</td>
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<td>Morrison 2010</td>
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<td>Turner 2003</td>
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<tr>
<td>LBJ 2009</td>
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<td>2</td>
<td>8</td>
<td>Good</td>
<td>Moderate</td>
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<tr>
<td>U of MN 2009</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>5</td>
<td>Poor</td>
<td>N/A</td>
<td></td>
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</tr>
<tr>
<td>U of WA*</td>
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<td>2</td>
<td>2</td>
<td>1</td>
<td>7</td>
<td>Fair</td>
<td>Substantial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unpub A 2009</td>
<td>1</td>
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<td>1</td>
<td>2</td>
<td>6</td>
<td>Fair</td>
<td>Substantial</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*not in meta-analysis

---

**American Society for Clinical Pathology**

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**LABORATORY MEDICINE**

**Best Practices**
### Standardize & Summarize Studies For Practices Reducing PSID Errors

#### Patient Specimen Identification: Bar Coding Systems

<table>
<thead>
<tr>
<th>Study name</th>
<th>Group</th>
<th>Odds ratio</th>
<th>Lower limit</th>
<th>Upper limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bologna 2002</td>
<td>Fair</td>
<td>2.57</td>
<td>0.83</td>
<td>7.97</td>
</tr>
<tr>
<td>Morrison 2010</td>
<td>Fair</td>
<td>1.70</td>
<td>1.23</td>
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</tr>
<tr>
<td>Unpublished A</td>
<td>Fair</td>
<td>12.00</td>
<td>1.56</td>
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</tr>
<tr>
<td>Random-Effects Mean – Fair</td>
<td>Fair</td>
<td>2.43</td>
<td>1.10</td>
<td>5.39</td>
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<tr>
<td>Brown 2010</td>
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<td>12.95</td>
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<td>26.58</td>
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<tr>
<td>Hayden 2008</td>
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<td>6.58</td>
<td>5.26</td>
<td>8.22</td>
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<tr>
<td>Hill 2010</td>
<td>Good</td>
<td>3.67</td>
<td>3.30</td>
<td>4.08</td>
</tr>
<tr>
<td>Killeen 2005</td>
<td>Good</td>
<td>5.27</td>
<td>2.76</td>
<td>10.06</td>
</tr>
<tr>
<td>LBJ 2009</td>
<td>Good</td>
<td>6.50</td>
<td>0.36</td>
<td>117.61</td>
</tr>
<tr>
<td>Zarbo 2009</td>
<td>Good</td>
<td>2.68</td>
<td>1.55</td>
<td>4.63</td>
</tr>
<tr>
<td>Random-Effects Mean – Good</td>
<td>Good</td>
<td>5.44</td>
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<td>7.74</td>
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<tr>
<td>Random-Effects Mean – Overall</td>
<td>Overall</td>
<td>4.39</td>
<td>3.05</td>
<td>6.32</td>
</tr>
</tbody>
</table>

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

Source: Laboratory Medicine Best Practices
### Bar Coding Systems ... LMBP

<table>
<thead>
<tr>
<th>Specific practice</th>
<th>Bar Coding Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Recommendation Statement</td>
<td><strong>Recommend</strong>: The LMBP’s Workgroup recommends use of a bar coding process to <strong>consistently link</strong> patients and their specimen through the entire testing process to reduce or eliminate PSID errors. This is based on the strength of evidence for this practice and consistency of observed effects</td>
</tr>
<tr>
<td>Strength of evidence rating</td>
<td><strong>High: Adequate</strong> volume of evidence is available that includes consistent evidence of substantial healthcare and safety changes from well-designed, well conducted studies</td>
</tr>
</tbody>
</table>
### Bar Coding Systems ... LMBP

<table>
<thead>
<tr>
<th>Topic Area</th>
<th>Bar Coding Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable Disease/Condition, Patient Safety, Coordination of Care</td>
<td>Potential threat of duplicative testing, misdiagnosis, or delayed or unnecessary treatment</td>
</tr>
<tr>
<td>Patient population(s) of interest</td>
<td>Both IP’s and OP’s may be affected</td>
</tr>
<tr>
<td>Applicability</td>
<td>Based on consistency of study results, bar coding is a practice with a high level of applicability across diverse settings and patient groups (e.g., inpatient and outpatient, general medical, emergency, pediatric, and anatomic pathology)</td>
</tr>
</tbody>
</table>
Laboratory Medicine Best Practices in Patient Specimen Identification - #1

- LMBP Workgroup recommends use of a bar coding process to consistently link patients and specimens through the TTP to reduce or eliminate PSID errors based on:
  - Strength of Evidence is High
  - Consistency of observed effects
  - On average, there was a 90% reduction in PSID errors (n = 10, range of PSID error reduction 60 – 100%)
## Evidence Summary Table 2011: PSID
### Point-of-Care Bar Coding Systems

<table>
<thead>
<tr>
<th>Practice: POCT Bar Coding Systems</th>
<th>Study Quality Rating</th>
<th>Effect Size Rating</th>
<th>Overall Consistency</th>
<th>Overall Strength of Body of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colard 2005</td>
<td>3 2 1 2 8</td>
<td>Good</td>
<td></td>
<td>5 Studies = Good/Substantial</td>
</tr>
<tr>
<td>Nichols et.al 2004</td>
<td>2 2 1 0 5</td>
<td>Poor</td>
<td>N/A</td>
<td>1 Study = Fair/Substantial</td>
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<td>Rao et al. 2005</td>
<td>2 2 1 2 7</td>
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<td></td>
<td>1 Study – Fair/Moderate 2 Studies = Poor-Excluded</td>
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<td>Unpublished</td>
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<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Geisinger 2009</td>
<td>2 2 2 1 7</td>
<td>Fair</td>
<td>Substantial</td>
<td></td>
</tr>
<tr>
<td>Kenmore Mercy Hospital 2011</td>
<td>3 2 2 3 10</td>
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<td>Substantial</td>
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<tr>
<td>Mercy Hospital of Buffalo 2011</td>
<td>3 2 2 3 10</td>
<td>Good</td>
<td>Substantial</td>
<td></td>
</tr>
<tr>
<td>Sisters of Charity Hospital Buffalo 2011</td>
<td>3 2 2 3 10</td>
<td>Good</td>
<td>Substantial</td>
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<tr>
<td>Sisters of Charity Hosp. St. Joseph 2011</td>
<td>3 2 2 3 10</td>
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<td>Substantial</td>
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<tr>
<td>Unpub B 2009</td>
<td>1 2 2 0 5</td>
<td>Poor</td>
<td>N/A</td>
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</tbody>
</table>
### Point-of-Care Bar Coding Systems

#### Patient Specimen Identification: Point-of-Care-Testing Bar Coding Systems

<table>
<thead>
<tr>
<th>Study name</th>
<th>Subgroup within study</th>
<th>Odds ratio</th>
<th>Lower limit</th>
<th>Upper limit</th>
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</thead>
<tbody>
<tr>
<td>Geisinger 2009</td>
<td>Fair</td>
<td>5.94</td>
<td>5.26</td>
<td>6.71</td>
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<td>Rao 2005</td>
<td>Fair</td>
<td>4.75</td>
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<td>88.73</td>
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<td>Random-Effects Mean - Fair</td>
<td>Fair</td>
<td>5.94</td>
<td>5.26</td>
<td>6.71</td>
</tr>
<tr>
<td>Colard 2005</td>
<td>Good</td>
<td>14.72</td>
<td>13.47</td>
<td>16.08</td>
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<tr>
<td>Sisters St. Joseph 2011</td>
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<td>5.61</td>
<td>6.60</td>
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<td>Mercy 2011</td>
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<td>5.23</td>
<td>4.98</td>
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<td>Kenmore 2011</td>
<td>Good</td>
<td>3.85</td>
<td>3.56</td>
<td>4.16</td>
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<td>Sisters-Buffalo 2011</td>
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<td>5.83</td>
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<td>Random-Effects Mean - Overall</td>
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<td>5.93</td>
<td>5.28</td>
<td>6.67</td>
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</tbody>
</table>

Pooled effect of bar-coding. Odds ratios right of the vertical line that runs from 0 provides evidence of an effect of bar-coding.
## Point-of-Care Bar Coding Systems

<table>
<thead>
<tr>
<th>Specific practice</th>
<th>Point of Care Bar-Coding Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Recommendation Statement</td>
<td><strong>Recommend:</strong> The LMBP’s Workgroup recommends point of care bar coding as a practice to reduce or eliminate PSID errors</td>
</tr>
<tr>
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</table>
# Point-of-Care Bar Coding Systems

<table>
<thead>
<tr>
<th>Topic Area</th>
<th>Point-of-Care Bar Coding Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable Disease/Condition, Patient Safety, Coordination of Care</td>
<td>Potential threat of duplicate/redundant testing, misdiagnosis, or delayed or unnecessary treatment</td>
</tr>
<tr>
<td>Patient population(s) of interest</td>
<td>Both IP’s and OP’s may be affected</td>
</tr>
<tr>
<td>Applicability</td>
<td>Based on consistency of study results, POC bar coding is a practice with a high level of applicability across diverse settings and patient groups (e.g., IP and OP, general medical, emergency, pediatric, and primary care clinics)</td>
</tr>
</tbody>
</table>
Laboratory Medicine Best Practices in Patient Specimen Identification - #2

- LMBP Workgroup recommends bar coding at the POC as a practice to reduce or eliminate PSID errors based on:
  - Strength of Evidence is High:
  - Consistency of Observed Effects
  - On average, there was a 75% reduction in POCT PSID errors (n=7, range of error reduction 37–100%)
APPLY the Evidence

Report and disseminate the findings
Please note ...

Reporting and disseminating the evidence is actually happening even as you read this slide

Thank you for participating in the process
ASSESS or AUDIT

Did the intervention work?
Implementation Considerations — Bar Coding Systems

• **Feasibility of Implementation:** Practice is currently in use, available for immediate application, and can be used in a variety of inpatient and outpatient settings. No significant barriers to implementation have been identified:
  - Time involved in verifying patient specimen identification does not change
  - Both nursing and medical staff found no difficulty in using the device. New staff required supervision only during their initial two or three sessions of use
  - Problems in 12% of episodes of use, mostly related to battery failure leading to scanning or printing errors
  - Wristbands reported to be inconvenient method for identifying patients in operating theaters because they are not always available for checking
  - High staff satisfaction with the electronic process

• **Economic Evaluation:** The cost of implementing the practice is similar to other software implementation projects. The studies that provided cost data indicate start-up costs ranging from $100,000 to $1.2 million:
  - Annualized estimated cost savings (due to implementation of the practice) of $129,000; Return on investment of 3.8 years
  - Bar coding approach saved staff resources, requiring only one staff member to complete the task whereas two staff members were needed by the conventional second checker system
  - System development cost (2004) HK1,250,00 with HK50,000 annual recurrence as compared to HK0 second-checker system
Implementation Considerations — Bar Coding Systems

- **Applicability to Specific Care Settings:**
  - Practice is suitable for use across a range of IP ns OP care settings

- **Associated Harms and Benefits:**
  - Evidence base does not identify any associated harms with the practice.
  - Some studies report higher staff satisfaction with use of a bar-coding system
  - Although not identified in the evidence base, one hypothetical scenario involving technology failures would suggest a potential harm (and associated threat of misidentification, need for specimen recollection, and possible misdiagnosis/treatment) if there were no backup technology to assure positive PSID
Implementation Considerations—Point-of-Care Bar Coding

• **Feasibility of Implementation:**
  – Practice is currently in use and available for immediate application, and can be used in a variety of inpatient and/or outpatient settings
  – No significant barriers to implementation have been identified

• **Economic Evaluation:**
  – Point of Care Bar Coding studies we examined did not report costs

• **Applicability to Specific Care Settings:**
  – Practice is suitable for use across a range of IP and OP care settings (e.g., general medical, emergency, primary care, and pediatric services)

• **Associated Harms and Benefits:**
  – We do not detect any associated harms with the practice
Thank You

skahn@lumc.edu
Laboratory Medicine Best Practices:
Reducing Blood Culture Contamination

Susan Snyder, Ph.D., MBA
Battelle Centers for Public Health Research and Evaluation

October 2011
LMPB Quality Issue/Problem

• Blood culture contamination can produce false positive cultures that lead to inappropriate patient follow-up and treatment.

• According to the American Society for Microbiology, contamination rates should not exceed 3%.

• Reported contamination rates vary from 1.1% to 5.2%.
Perspective

• Approximately 750,000 cases of sepsis occur each year in the United States.
• A blood culture is the standard method to detect septicemia.
• Reliable blood culture results depend on correct sample collection.
• Adults: It is estimated that false positive cultures comprise up to half of all positive blood cultures in adult patients.
• Pediatrics: High contamination rates are common in pediatric patients due to the use of intravenous access devices.
Clinical Utility

- False positive blood cultures lead to errors in clinical interpretation with subsequent consequences:
  - Administration of unnecessary antimicrobial therapy.
  - Performance of additional cultures and other diagnostic tests.
  - Unnecessary hospitalization or extended length of stay (LOS).
  - Increased health care costs.
  - Undue burden on patient.

When germ relationships go bad

You make me SICK!
Acknowledgments

LMBP Blood Culture Contamination Expert Panel Members

• Roberta Carey, Acting Division Director, Division of Laboratory Science and Standards, Centers for Disease Control
• Dennis Ernst, Director, Center for Phlebotomy Education
• Dana Grzybicki, Department of Pathology, University of Colorado Denver
• Margret Oethinger, Director Pathology Department, Providence Portland Medical Center
• Stephen Raab, Director, Cytopathology Laboratory U Colorado Cancer Center
• Ronald Schifman, Acting ACOS for Research Southern Arizona VA Healthcare System
• Ann Vannier, Director, Southern California Regional Reference Laboratory, Kaiser-Permanente Healthcare Systems
• Melvin Weinstein, Department of Medicine, University of Medicine, Dentistry of New Jersey-Robert Wood Johnson Medical School
## Acknowledgments

### Additional LMBP Review Team Members

<table>
<thead>
<tr>
<th>Battelle</th>
<th>CDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert Black</td>
<td>Abrienne Patta</td>
</tr>
<tr>
<td>Robert Christenson</td>
<td>Colleen Shaw</td>
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<tr>
<td>James Derzon</td>
<td>Susan Snyder</td>
</tr>
<tr>
<td>Paul Epner</td>
<td>Malaika Washington</td>
</tr>
<tr>
<td>Alessandra Favoretto</td>
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</tbody>
</table>
Methods

- **ASK** focused question(s) and develop supporting quality issue analytic framework.

- **ACQUIRE** relevant evidence/studies from published sources and unpublished quality improvement studies

- **APPRAISE** acquired studies by:
  1. Applying screening (inclusion/exclusion) criteria.
  2. For all studies included in the practice evidence base, systematically abstract, standardize and rate study quality and effect size magnitude.

- **ANALYZE** the body of evidence by synthesizing the individual studies and evaluating and rating the consistency, quality and effect size of the evidence, to produce an overall strength of evidence rating for a “best practice” recommendation.
LMBP Review Question

ASK

• What interventions/practices are effective at reducing blood culture contamination?
**ASK - Evidence Review Question:** What practices are effective for reducing blood culture contamination?

**Blood Culture Contamination Analytic Framework**

- **Pre analytic sources of blood culture contamination**
  - Pre-collection practices
    - Aseptic technique
    - Antiseptic agent
    - Gloves
    - Proper drying time
  - Collection site

- **Interventions**
  - Venipuncture vs. Intravenous catheters
  - Phlebotomy Teams vs. non-phlebotomy staff
  - Prep kit vs. no prep kit

- **Preventability/ Improvement**
  - BCC rate range 1.1%-5.2%
  - Standards of the American Society for Microbiology (rate not to exceed 3%)

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

- **Care-Related Outcomes**
  - Unnecessary antibiotic therapy
  - Unnecessary hospital admissions
  - Increased hospital length of stay
  - Associated Incremental costs of care

- **Health-Related Outcomes**
  - Hospital Acquired Infection
  - Other additional tests
  - Mortality

- **Harms**
  - Increased risk of occupational needle stick injury: 1-vs. 2-needle
  - Patient infection due to collection site/technique.
ACQUIRE
Search Results

Published Literature

Initial Search Results
1677 references

1647 Excluded
Title/abstract did not meet inclusion criteria

30 Full Text Articles

20 Excluded
Did not meet criteria

14 pre abstraction articles

9 found by hand searching, 5 excluded

14 Published Studies
2 Unpublished Studies

Results by Practice:
7 Venipuncture (vs. catheter)
6 Phlebotomy team
4 Prep Kits

Unpublished Assessments

Venipuncture
0 submitted

Phlebotomy Teams
5 submitted
2 included

Prepackaged prep kits
2 submitted
0 included
1. Screen (at least one finding for a relevant practice and outcome)
2. Study quality ratings based on:

<table>
<thead>
<tr>
<th>Study Setting</th>
<th>Comparator Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Description of where practice implemented? (e.g. ICU, ED)</td>
<td>✓ Description of comparison practice or standard (status quo)</td>
</tr>
<tr>
<td></td>
<td>✓ Key characteristics (in relation to practice)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Practice description includes requirements and components for operations that are replicable?</td>
</tr>
<tr>
<td>✓ Duration (start and end dates)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample population</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Description (e.g. patients, samples, tests)</td>
</tr>
<tr>
<td>✓ Number(s) and description(s) of participants or specimens (e.g. blood, urine)</td>
</tr>
<tr>
<td>✓ Selection criteria for participants or specimens</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Definition of the measurement(s) used to assess practice impact (e.g. error rate, length of stay)</td>
</tr>
<tr>
<td>✓ Method of data collection described</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Findings described with supporting data provided</td>
</tr>
<tr>
<td>✓ Appropriate analysis</td>
</tr>
</tbody>
</table>
ACQUIRE
Search Results

Published Literature

Initial Search Results
1677 references

1647 Excluded
Title/abstract did not meet inclusion criteria

30 Full Text Articles

20 Excluded
Did not meet criteria

14 pre abstraction articles

9 found by hand searching, 5 excluded

14 Published Studies
2 Unpublished Studies

Results by Practice:
7 Venipuncture (vs. catheter)
6 Phlebotomy team
4 Prep Kits

Unpublished Assessments

Venipuncture
0 submitted

Phlebotomy Teams
5 submitted
2 included

Prepackaged prep kits
2 submitted
0 included
ANALYZE

From the APPRAISE step, rate:

- Individual study quality
  - Good, Fair, Poor
- Effect size magnitude
  - Substantial, Moderate, Minimal/None

Evaluate for consistency

- Yes / No

Translate into a practice’s overall strength of evidence rating

- High, Moderate, Suggestive, Insufficient

Best Practice recommendation

- Recommend, No Recommendation, Recommend Against
## Results

LMBP Blood Culture Contamination Systematic Review - Preliminary Results

**Venipuncture (versus Intravenous Catheter) Collection Site**

**Body of Evidence: 7 Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Quality Rating</th>
<th>Effect Size Rating</th>
<th>Overall Consistency</th>
<th>Overall Strength of Body of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>Study Practice Measure Results Total Rating</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McBryde 2005</td>
<td>3 2 2 3 10</td>
<td>Good Substantial</td>
<td>YES</td>
<td>HIGH</td>
</tr>
<tr>
<td>Norberg 2003</td>
<td>2 2 1 3 8</td>
<td>Good Substantial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Martinez 2002</td>
<td>3 2 1 1 7</td>
<td>Fair Substantial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Everts 2001</td>
<td>2 2 2 3 9</td>
<td>Good Substantial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desjardin 1999</td>
<td>3 1 2 3 9</td>
<td>Good Moderate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beutz 2003</td>
<td>3 2 2 2 9</td>
<td>Good Moderate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ramsook 2000</td>
<td>2 2 1 2 7</td>
<td>Fair Moderate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Study characteristics

- **Practice description**: (Maximum points = 3)
- **Outcome Measure**: (Maximum points = 2)
- **Results of Study**: (Maximum points = 3)

**Study characteristics**

- **Good**: 8 - 10 total points
- **Fair**: 5 - 7 total points
- **Poor**: <= 4 total points
### Venipuncture (versus Intravenous Catheter) Meta-Analysis

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Odds Ratio</th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>McBryde 2005</td>
<td>5.60</td>
<td>3.61</td>
<td>8.69</td>
</tr>
<tr>
<td>Norberg 2003</td>
<td>3.46</td>
<td>2.55</td>
<td>4.69</td>
</tr>
<tr>
<td>Martinez 2002</td>
<td>2.57</td>
<td>1.12</td>
<td>5.89</td>
</tr>
<tr>
<td>Everts 2001</td>
<td>2.12</td>
<td>1.32</td>
<td>3.40</td>
</tr>
<tr>
<td>DesJardin 1999</td>
<td>1.88</td>
<td>0.95</td>
<td>3.74</td>
</tr>
<tr>
<td>Beutz 2003</td>
<td>1.88</td>
<td>0.88</td>
<td>3.99</td>
</tr>
<tr>
<td>Ramsook 2000</td>
<td>1.70</td>
<td>1.01</td>
<td>2.85</td>
</tr>
<tr>
<td></td>
<td>2.63</td>
<td>1.85</td>
<td>3.72</td>
</tr>
</tbody>
</table>

◆ = Venipuncture summary effect size

**Venipuncture is associated with lower blood culture contamination rates**

Odds Ratio = 2.63 (95% CI = 1.85 – 3.72)

Venipuncture is 2.63 times as successful as the comparison practice (intravenous catheter)

Boxes proportional to study size.
## Phlebotomy Team

### Body of Evidence: 6 Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Study</th>
<th>Practice</th>
<th>Measure</th>
<th>Results</th>
<th>Total</th>
<th>Rating</th>
<th>Effect Size Rating</th>
<th>Overall Consistency</th>
<th>Overall Strength of Body of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weinbaum 1997</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>9</td>
<td>Good</td>
<td>Substantial</td>
<td>YES</td>
<td>HIGH</td>
</tr>
<tr>
<td>Sheppard 2008</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>8</td>
<td>Good</td>
<td>Substantial</td>
<td></td>
<td>5 studies: Good/Substantial</td>
</tr>
<tr>
<td>Geisinger 2009</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>9</td>
<td>Good</td>
<td>Substantial</td>
<td></td>
<td>1 study: Fair / Substantial</td>
</tr>
<tr>
<td>Gander 2009</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>9</td>
<td>Good</td>
<td>Substantial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Providence-Everett 2009</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>9</td>
<td>Good</td>
<td>Substantial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surdulescu 1998</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>Fair</td>
<td>Substantial</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

### Rating
- Good: 8 -10 total points
- Fair: 5-7 total points
- Poor: <=4 total points
<table>
<thead>
<tr>
<th>Study name</th>
<th>Subgroup within study</th>
<th>Odds ratio and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Odds</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ratio</td>
</tr>
<tr>
<td>Weinbaum 1997#</td>
<td>Combined</td>
<td>5.78</td>
</tr>
<tr>
<td>Sheppard 2008</td>
<td>N/A</td>
<td>4.83</td>
</tr>
<tr>
<td>Geisinger 2009</td>
<td>N/A</td>
<td>2.52</td>
</tr>
<tr>
<td>Gander 2009</td>
<td>N/A</td>
<td>2.51</td>
</tr>
<tr>
<td>Providence 2009</td>
<td>Combined</td>
<td>2.44</td>
</tr>
<tr>
<td>Surdulescu 1998*</td>
<td>N/A</td>
<td>2.09</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.53</td>
</tr>
</tbody>
</table>

Phlebotomy teams are associated with lower blood culture contamination rates.

Odds Ratio = 2.53 (95% CI = 2.28 – 2.81)

Phlebotomy team is 2.53 times as successful as the comparison practice (without phlebotomy team)
## Prepackaged Prep Kits

**Body of Evidence: 4 Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Quality Rating</th>
<th>Effect Size Rating</th>
<th>Overall Consistency</th>
<th>Overall Strength of Body of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Study</td>
<td>Practice</td>
<td>Measure</td>
<td>Results</td>
</tr>
<tr>
<td>Trautner 2002</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Weinbaum 1997</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>McLellan 2008</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Wilson 2000</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

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

- **Effect Size Rating**
  - Good: 8 - 10 total points
  - Fair: 5 - 7 total points
  - Poor: ≤4 total points

- **Overall Consistency**
  - YES

- **Overall Strength of Body of Evidence**
  - INSUFFICIENT

---

American Society for Clinical Pathology

**LABORATORY MEDICINE Best Practices**
### Prepackaged Prep Kits Meta-Analysis

<table>
<thead>
<tr>
<th>Study name</th>
<th>Subgroup within study</th>
<th>Odds ratio and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Odds</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ratio</td>
</tr>
<tr>
<td>Trautner 2002</td>
<td>Prep v Usual prx</td>
<td>3.68</td>
</tr>
<tr>
<td>Weinbaum 1997</td>
<td>Combined</td>
<td>3.51</td>
</tr>
<tr>
<td>McLellan 2008</td>
<td>Combined</td>
<td>1.03</td>
</tr>
<tr>
<td>Wilson 2000</td>
<td>Combined</td>
<td>1.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.15</td>
</tr>
</tbody>
</table>

◆ = Prep kits summary effect size

Prepackaged prep kits are not associated with lower blood culture contamination rates.
Odds Ratio = 1.15 (95% CI = 1.02 – 1.30)
Prep kits are about as successful as the comparison practice (without prep kits)

Boxes proportional to weights

---

American Society for Clinical Pathology

Laboratory Medicine
Best Practices
Conclusions

Using the LMBP systematic review methods to evaluate the overall strength of evidence of effectiveness for reducing blood culture contamination rates for each practice, the LMBP Blood Culture Contamination Expert Panel and Workgroup recommended the following:

• **Best Practice**: Use of **venipuncture** as the preferred technique for sample collection in the clinical setting, when this option exits

• **Best Practice**: Use of phlebotomy **teams** to collect blood culture specimens

• No recommendation for or against the use of **prepackaged prep kits** (as a best practice.)
The Future

To continue to disseminate evidence-based practice recommendations to reduce blood culture contamination and improve patient and public health outcomes:

• Application of these practices should continue to be assessed so that these LMBP practice evidence reviews and recommendations can be updated with new study results.

• New evidence reviews and recommendations related to additional practices are needed, and requires acquisition of evidence not currently available.
In this activity you learned about

- Comparing and contrasting conventional methods used to develop guidelines, standards and recommendations (i.e., consensus expert opinion) in laboratory medicine and evidence-based methods.

- The A6 Cycle and the necessary steps to develop evidence-based recommendations that impact laboratory medicine decision making.

- Three examples where laboratory medicine best practice evidence reviews have been performed and had described the review, results and outcomes associated with the practices reviewed.
Lab-Centered

vs.

Patient-Centered

The lab report just came in.

The lab is in fine shape!
Evidence-Based Laboratory Medicine
Quality Improvement

ANSWERS
What works? What makes patients better off?
What improves public health?

ADDRESSSES
Important, well-defined gaps with
Measurable outcomes that impact health

USING
Transparent, evidence-based methods and data
<table>
<thead>
<tr>
<th>LMBP Present</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 4</strong> 2009-2010</td>
</tr>
<tr>
<td>Finalize systematic review methods</td>
</tr>
<tr>
<td>Complete first 3 evidence reviews</td>
</tr>
<tr>
<td>LMBP Website futurelabmedicine.org</td>
</tr>
<tr>
<td>Information dissemination and submission of unpublished evidence</td>
</tr>
<tr>
<td>New topic identification and development</td>
</tr>
<tr>
<td><strong>Phase 5</strong> 2010-2011</td>
</tr>
<tr>
<td>LMBP Methods published <em>Clinical Chemistry</em> June 2011</td>
</tr>
<tr>
<td>3 evidence review manuscripts for publication 2012</td>
</tr>
<tr>
<td>On-line educational modules/tutorials</td>
</tr>
<tr>
<td>Begin 3 new evidence reviews with new Expert Panels</td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
</tr>
<tr>
<td>Complete and publish 3 new evidence reviews</td>
</tr>
<tr>
<td>Partnerships with professional, accreditation and lab organizations and leaders</td>
</tr>
<tr>
<td>Dissemination and refinement of LMBP evidence-based products and tools</td>
</tr>
<tr>
<td>Evaluation of impact</td>
</tr>
<tr>
<td>Outreach activities &amp; Partnership models</td>
</tr>
</tbody>
</table>
LMBP Website
www.futurelabmedicine.org

About LMBP

The Laboratory Medicine Best Practices (LMBP) initiative was launched in 2006 by the CDC, Laboratory Science, Policy and Practice Program Office (formerly Division of Laboratory Systems). The Initiative’s goal is to establish an evidence-based process for identifying best practices for quality improvement. This initiative is supported by Battelle Memorial Institute (Battelle). Systematic evidence reviews are conducted by staff from CDC and Battelle under the guidance of a 15-member multidisciplinary Workgroup.

Why Apply Evidence-based Decision Making in Laboratory Medicine

Within the last decade, systematic review methods have improved evidence-based decision-making and made it more transparent. Existing approaches do not apply to laboratory medicine quality improvement practices, because published literature is limited and laboratory practices vary widely. To address this, LMBP systematic evidence reviews include the collection of unpublished data from quality improvement projects. Using evidence to evaluate practice effectiveness allows laboratory professionals...
LMBP: Get Involved!

What you can do

Get Involved

There are multiple ways to be involved in the Laboratory Medicine Best Practices initiative:

- Register to receive updates and notifications of new evidence reviews
- Submit data for evidence reviews
- Submit suggestions for future evidence reviews

Battelle conducts the project described on this website for the Centers for Disease Control and Prevention under contract W911NF-07-D-0001/D0 0191/TCN 07235

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# LMBP Quality Improvement (QI) Project/Study Summary Form Example

## Background Information

<table>
<thead>
<tr>
<th>LMBP Topic Name:</th>
<th>Patient Specimen/Test Result Identification – POCT Barcoding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem or Quality Issue Description:</td>
<td>In 2007, patient ID errors in POCT specifically with glucometers were over 2%. This resulted in delay of reporting, loss of charges, inability to identify the individual performing the testing and perhaps even inaccurate reporting of patient tests.</td>
</tr>
<tr>
<td>Submitter(s) and Organizational Affiliations:</td>
<td>Mercy Hospital of Buffalo, Catholic Health System, Buffalo, New York (Jarnot J and Weber A)</td>
</tr>
<tr>
<td>Funding Source(s):</td>
<td>Self-funded</td>
</tr>
</tbody>
</table>

## QI Project/Study

<table>
<thead>
<tr>
<th>QI Project/Study Design/Type:</th>
<th>Before-After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility Description (include size):</td>
<td>Mercy Hospital of Buffalo, Buffalo, NY; teaching hospital; &gt; 300 beds.</td>
</tr>
<tr>
<td>QI Project/Study Setting:</td>
<td>Hospital inpatient units including the ED.</td>
</tr>
<tr>
<td>Study Sample/Population (size and description, Pre and Post if applicable):</td>
<td>All hospital inpatient and Emergency Department POCT glucose tests</td>
</tr>
<tr>
<td>Pre: 249,667</td>
<td>Post: 517,744</td>
</tr>
<tr>
<td>Comparison Practice (dates and description):</td>
<td>Patient wristband with typed patient identifying information (name, date of birth, medical record number)</td>
</tr>
<tr>
<td>Sources of bias/confounders:</td>
<td>None noted</td>
</tr>
</tbody>
</table>

## QI Practice

<table>
<thead>
<tr>
<th>Practice Description:</th>
<th>POC glucose tests with barcoded patient ID wristbands with account/billing number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice Duration (start/end and other dates relevant to implementation):</td>
<td>Start: 5/28/2008 – 5/31/2011; Practice is ongoing</td>
</tr>
<tr>
<td>Training:</td>
<td>Training, re-training and communication/feedback using data reports; also included internal competition. POC glucose barcoding implemented as an upgrade to pharmacy barcoding which first introduced nurses to the process of scanning a barcode prior to actions.</td>
</tr>
</tbody>
</table>

## Outcome Measures

<table>
<thead>
<tr>
<th>Outcome Measure(s) Description (each separately):</th>
<th>Patient ID error rate (%): # Patient ID errors / total # POC glucose tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Error: Patient ID # from glucometer does not match current patient)</td>
<td></td>
</tr>
<tr>
<td>Recording method (how data was collected):</td>
<td>Glucometer data management system audit of daily testing log flags ID #s not matched to patients. Monthly review of ID errors by the POC department.</td>
</tr>
<tr>
<td>Comparative statistics provided for each nurse manager. Same recording practice pre-and post-barcoding.</td>
<td></td>
</tr>
</tbody>
</table>

## Results/Findings

<table>
<thead>
<tr>
<th>Results/Findings (related to outcome measures, e.g., Pre and Post):</th>
<th>Patient ID error rate:</th>
<th>Pre: 2.24% (5,589 / 249,667)</th>
<th>Post: 0.44% (2,256 / 517,744)</th>
</tr>
</thead>
<tbody>
<tr>
<td>81% reduction</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Analysis/Statistical Methods/Significance Test(s):</th>
<th>None reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conclusions:</td>
<td>None noted</td>
</tr>
</tbody>
</table>

---
## Educational Modules

### On-line for CEU Credit

<table>
<thead>
<tr>
<th>Module</th>
<th>Name</th>
<th>Module Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>The A-6 Cycle: Review and Evaluation Methods for Quality Improvement</strong></td>
<td>This is the first in a series of modules that will introduce the use of systematic reviews. The free online course explains how LMBP uses the A-6 model in completing evidence reviews. The course can be taken for continuing education credit, which is administered through <a href="https://www.cdc.gov">CDC Training and Continuing Education Online</a>. To take the course for credit, you must register on the CDC Training and Continuing Education website and then register for the course. Click <a href="https://www.cdc.gov">here</a> to register with CDC.</td>
</tr>
<tr>
<td>2</td>
<td><strong>Key Steps for Planning Quality Improvement Projects</strong></td>
<td>COMING SOON!</td>
</tr>
</tbody>
</table>
LMBP
Current evidence review questions

**Hemolysis**
Among Emergency Department (ED) patients, what practices are effective for reducing blood sample hemolysis?

**Cardiac Biomarker Testing**
Among ED patients presenting with symptoms suggestive of Acute Coronary Syndrome, what practices associated cardiac troponin testing effectively increase accurate myocardial infarction diagnosis, reduce time to treatment, and improve patient outcomes?

**Rapid Identification of Bloodstream Infections**
What practices are effective at increasing timeliness of providing targeted therapy for inpatients with diagnosed bloodstream infections to improve clinical outcomes (LOS, morbidity, mortality)?
LMBP

Current evidence reviews

**Hemolyzed Blood Specimen Reduction in Emergency Departments (ED)**
- Venipuncture vs. IV start
- Draw from antecubital fossa
- Largest gauge needle
- Low-vacuum tubes
- Dedicated phlebotomists
- IV start with syringe
- Duration of applied tourniquet

**Cardiac Biomarkers for Diagnosing Acute Myocardial Infarction (AMI) in ED Patients**
- Biomarker assay selection
- Serial sampling
- Point-of-care testing
- Concentration threshold criteria

**Blood Stream Infections: Timely Targeted Therapy for Inpatients**
- Rapid Gram stain
- Gram stain and PNA-FISH
- Chromogenic agar
- PCR
- Direct tube coagulase, thermonuclease, and other direct methods

Communication practices:
- Critical value call from lab to pharmacy
- Critical value call to provider lab report comment
- Other forms of rapid (electronic) communication
LMBP Partner Organizations

American Society for Clinical Laboratory Sciences

Consortium on Office Laboratory Accreditation

I ideas for ASCP Collaboration?
Questions and Answers

Dr. Robert H. Christenson – rchristenson@ummm.edu
Dr. Stephen E. Kahn - skahn@lumc.edu
Dr. Susan R. Snyder– snydersu@battelle.org

For more information:
www.futurelabmedicine.org