

# Evidence-Based Best Practices in Laboratory Medicine: Evidence Evaluation Methods

Clinical Laboratory Improvement Advisory Committee  
(CLIAC) Quarterly Meeting

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February 4, 2009

Atlanta, GA



*"Then we've agreed that all the evidence isn't in, and that even if all the evidence were in, it still wouldn't be definitive."*

# Balancing Need for Improvement with Knowledge of What Works

- Need is urgent, but so is need for confidence that recommended practices work
- “Following the leader” can incorrectly promote practices that do not work
- Investments in better practice evaluation are small compared with opportunity costs of widely implementing ineffective and harmful practices

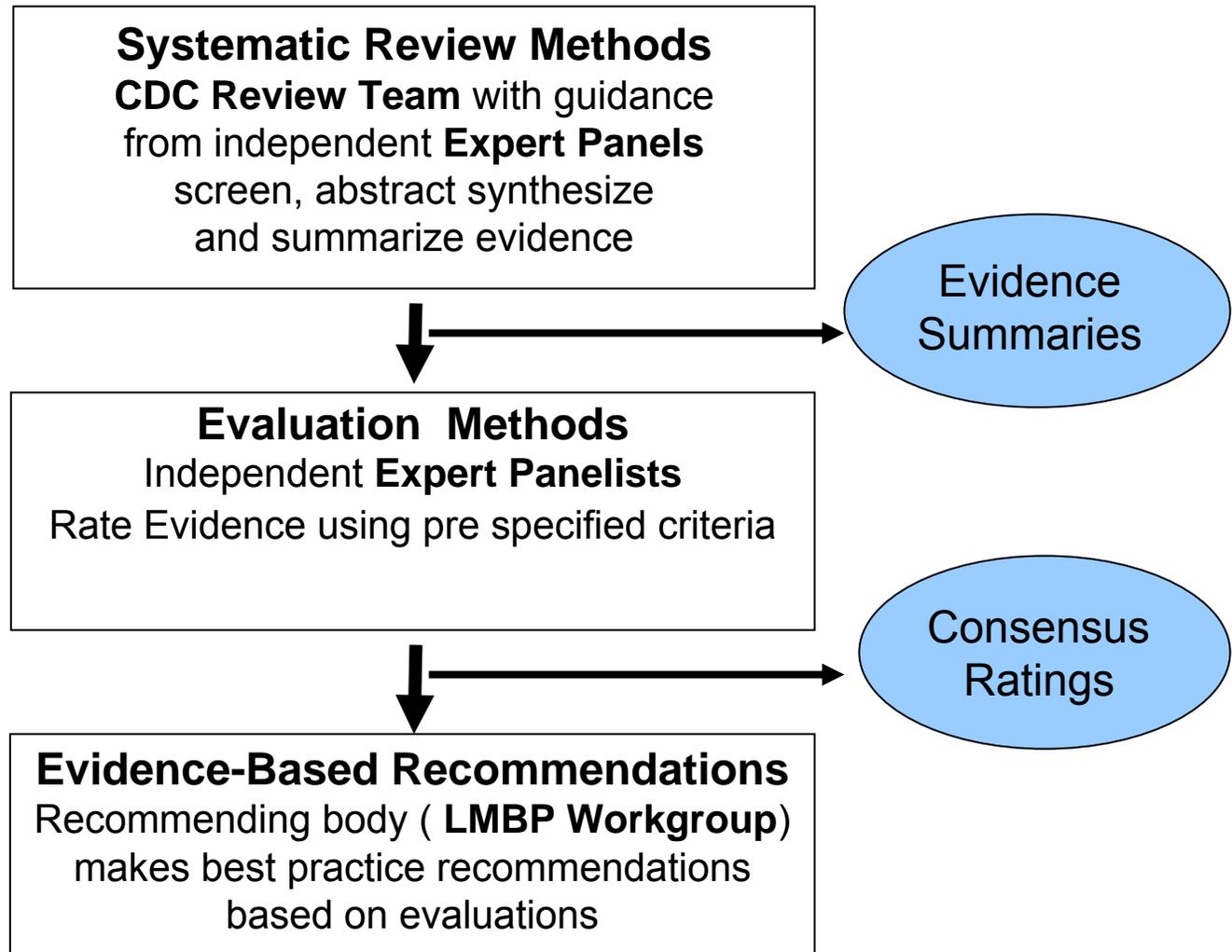
*Auerbach AD, Landefeld CS, Shojania KG. The Tension Between Needing to Improve Care and Knowing How to Do It, New England J Med 2007. 357(6):608-613.*

# Phase 2 (2007-08) Objectives

## Phase 2 builds on earlier Proof-of-Concept work (2006-07)

- Refine, develop, and pilot test methods
  - Utilize topic-specific Expert Panels to review and evaluate evidence
  - Develop criteria and guidance for rating individual studies and overall strength of evidence
- Test feasibility of developing a network to obtain unpublished studies
- Evaluate implementation and sustainability options
  - Key informant interviews with:
    - Guideline / recommending organizations
    - Laboratory medicine stakeholders
    - Pilot test LMBP Network participants

# Pilot Methods Overview



# Evidence Review Questions

## **Critical Values Reporting & Communication:**

*“What practices are effective for timely and accurate communication of laboratory critical test results to responsible / licensed caregivers?”*

## **Patient Specimen Identification:**

*“What are effective interventions / practices for reducing patient specimen identification errors?”*

# Laboratory Network

Aim to complement published evidence with UNPUBLISHED evidence, requiring development of a laboratory network:

- Initial endorsements: CLMA, The Joint Commission, ASCP, COLA, CAP
- Laboratory participation by invitation
- No new data - completed laboratory medicine studies (e.g., internal assessments, case studies, FMEA, Six Sigma, CQI)
- No patient-specific data or personal health information
- All data/studies submitted de-identified after abstraction
- Option to remain anonymous in summaries describing pilot and findings

# Evidence Exclusion Criteria

## Based on Analytic Framework and Evidence Review Question

- Title and abstract are not applicable to the topic area
- The practice is not sufficiently described
- Article or report is a commentary or opinion piece that contains no specific information on:
  - Cost
  - Benefits
  - Implementation
- No practice was assessed (i.e., no outcome measures of interest identified)

# Pilot Evidence Review

21 published studies, 8 unpublished studies

## **Critical Value Reporting (10 studies)**

### **Candidate Practices:**

- Read Back
- Automated Notification
- Call Center

## **Patient Specimen ID (19 studies)**

### **Candidate Practices:**

- Bar Coding Systems
- Bar Coding POCT
- Zero Tolerance Policy
- Education/Awareness Campaign

# Pilot Evidence Review

## **Evaluation Criteria:**

### **Individual Study Quality (4 domains)**

- Study setting, representativeness
- Practice description
- Relevance of outcome measures to review question
- Results and findings
- **Effect Size**
  - Magnitude of the effect of a practice ( adverse, small, medium, large)
  - Directness of outcome measure to address the review question
- **Overall Body of Evidence**
  - Consistency among study findings/results
  - Overall strength rating

# Pilot Evidence Review

- **Appointed 2 Topic-Specific Expert Review Panels**
  - Subject matter specialists
  - Specialists in evidence review methods
  - Laboratory management
- **Reviewed evidence of practice effectiveness**
  - Abstracted, standardized and summarized by CDC/Battelle Team
- **Drafted evidence-based recommendations**
  - Individual study quality
  - Overall consistency of study findings
  - Overall evidence of effectiveness strength

## 1 – Effect Size Rating

Study Ratings:	Effect Size(1)
Study 1 (Author Year)	
Study 2 (Author Year)	
.	
.	
Study n (Author Year)	

- Substantial
- Moderate
- None/Minimal
- Adverse

## 2 – Study Quality Rating

Practice A	Study Characteristics (3 points)	Practice Characteristics (2 points)	Outcome Measures (2 points)	Results/ Other (3 points)	Overall Study Quality Rating (2)
Study 1					
Study 2					
Study 3					
...					
Study N					

- Good: 8-10 points
- Fair: 5-7 points
- Poor: ≤ 4 points

### Individual Study Ratings

Study Ratings:	Effect Size(1)	Quality (2)
Study 1 (Author Year)	<b>1</b>	<b>2</b>
Study 2 (Author Year)		
.		
.		
Study n (Author Year)		

## Overall Evidence Rating

### Overall Evidence of Effectiveness

Effect Size Ratings (1)	Individual Studies #/Quality (2)	Consistency (3) (Yes/No)	Overall Strength Rating (4)	Recommendation (5)
Substantial	# Good: #Fair:	<b>3</b>	<b>4</b>	<b>5</b>
Moderate	# Good: #Fair:			
None/Minimal	# Good: #Fair:			
Adverse	# Good: #Fair:			

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### Recommendation Categories

- Recommend
- No recommendation for or against
- Recommend against

### Additional Considerations

- Feasibility of Implementation
- Economic Evaluation
- Applicability to Specific Care Settings
- Associated Harms and Benefits

Strength Ratings	Combined Evidence Minimum Criteria		
	# Studies*	Effect Size Rating	Quality Rating
High	≥ 3	Substantial	Good
Moderate	≥ 2	Substantial	Good
	≥ 3	Moderate	Good
Suggestive (Low)	≥ 1	Substantial	Good
	≥ 2	Moderate	Good
	≥ 3	Moderate	Fair
Insufficient (Very Low)	All others		

# Overall “Strength of Evidence” Rating

<u>Strength Ratings</u>	<u>Combined Evidence Minimum Criteria</u>		
	<u>#Studies*</u>	<u>Effect Size Rating (1)</u>	<u>Quality Rating (2)</u>
High	≥ 3	Substantial	Good
Moderate	≥ 2	Substantial	Good
	≥ 3	Moderate	Good
Suggestive (Low)	≥ 1	Substantial	Good
	≥ 2	Moderate	Good
	≥ 3	Moderate	Fair
Insufficient (Very Low)	All others		

\*Reviews and meta-analyses of multiple studies assessed on a case-by-case basis

# Overall “Strength of Evidence” Rating

- **High**: An adequate volume of evidence is available and includes consistent evidence of substantial healthcare and / or safety changes from well-designed, well-conducted studies.
- **Moderate**: Some evidence is available and includes consistent evidence of substantial to moderate healthcare and / or safety changes from well-designed, well-conducted studies.
- **Suggestive**: Limited evidence is available and includes consistent evidence of moderate healthcare and / or safety changes from a small number of studies of limited quality.
- **Insufficient**: Any estimate of a desirable effect is highly uncertain. Available evidence of effectiveness is:
  - Inconsistent or weak; OR
  - Consistent but with a minimal desirable effect; OR
  - Contained in an inadequate volume to determine effectiveness

# Recommendation Categories

- **Recommend**: The practice should be implemented in appropriate care settings, taking into account variations in implementation and/or care settings.
  - Recommendation results from a “High” or “Moderate” overall strength of evidence rating.
- **No recommendation for or against**:
  - Recommendation results from a “Suggestive” rating (appears to be consistent with effectiveness, but not sufficient to support a recommendation at this time)
  - Additional studies may be warranted to strengthen the relevant evidence base before making a recommendation
- **Recommend against**: consistent evidence of adverse effects
  - The practice should not be implemented because available evidence indicates it is not likely to result in more good than harm. Additional studies are not warranted to strengthen the relevant evidence base.

# Additional Considerations

Evidence reviews and Best Practice Recommendations should also report and consider information, where available, concerning:

- **Feasibility of Implementation**: Is the practice in current use and available for immediate application? Able to be used in a variety of inpatient and/or outpatient settings? Have significant barriers to implementation been identified?
- **Economic Evaluation**: Cost of implementing? Savings that are achieved with implementation? Any cost-effectiveness and/or cost-benefit assessments completed?
- **Applicability to Specific Care Settings**: Is the practice suitable for use across a range of inpatient and outpatient care settings? Targeted for point-of-care testing?
- **Associated Harms and Benefits**: Has the practice impacted patient satisfaction, provider satisfaction, ability to measure and monitor quality and process improvement, standardization of protocols across a healthcare network or system, or other outcomes that contribute to improvements in patient safety and healthcare quality?

# Results: Patient Specimen Identification

Practice	Recommendation Statement	Findings
<p><b>Point-of-Care Bar Coding Systems</b> Automated patient and sample identification system using bar-coded patient armbands and bar code scanners when diagnostic testing is conducted at or close to the patient <i>(3 published studies)</i></p>	<p><b>No recommendation for or against (overall strength of evidence rating of “insufficient”):</b></p>	<p>2 of 3 published studies received “Fair” quality ratings (no studies had a “Good” quality rating, and one study with a “Poor” quality rating was excluded). Both included studies received “Moderate” effect size ratings, resulting in a determination of a <b>consistent</b> effect.</p>
<p><b>Bar Coding Systems:</b> Electronic bar-coding on both patient and specimen used to establish positive identification of specimen as belonging to patient. This involves the use of scanners and capability to print labels. <i>(8 published studies)</i></p>	<p><b>No recommendation for or against (overall strength of evidence rating of “suggestive”):</b></p>	<p>6 of the 8 published studies received “Fair” quality ratings (no studies had a “Good” quality rating, and two studies with “Poor” quality ratings were excluded). 5 of 6 included studies received “Moderate” effect size ratings, 1 “Minimal/None”, resulting in a determination of a <b>consistent</b> effect.</p>

# Results: Patient Specimen Identification (continued)

Practice	Recommendation Statement	Findings
<p><b>Education-Awareness</b> Educational interventions and awareness campaigns among healthcare staff to improve accuracy of specimen labeling <i>(3 published studies, 1 unpublished study)</i></p>	<p><b>No recommendation for or against (overall strength of evidence rating of “insufficient”):</b></p>	<p>2 published and 0 unpublished studies received “Fair” quality ratings (0 studies rated “Good” quality). 1 “Moderate” and 1 “Minimal/none” effect size rating, resulting in a determination of a <b>consistent</b> effect.</p>
<p><b>Zero Tolerance</b> Policy for not accepting specimens with missing or incorrect information on labels <i>(2 published studies, 2 unpublished studies)</i></p>	<p><b>No recommendation for or against (overall strength of evidence rating of “insufficient”):</b></p>	<p>All 4 studies insufficient quality to be included in the evidence base. All four excluded studies received All four excluded studies received “Minimal/None” effect size ratings</p>

# Results: Critical Values Communication

Practice	Recommendation Statement	Findings
<p><b>Read Back</b> Documented repeat of correct telephone results by recipients to person who transmits it <i>(4 published studies)</i></p>	<p>No recommendation for or against (overall strength of evidence rating of <u>"insufficient"</u>)</p>	<p>1 out of 4 studies received a "Fair" quality rating (no studies had a "Good" or "Poor" quality ratings). The 1 "Fair" study received a "Moderate" effect size rating. The other studies received a "Minimal/None" effect size ratings.</p>
<p><b>Automated Notification</b> Automated alerting system or computerized reminders using mobile phones, pagers, email or other personal electronic devices to alert clinician of critical laboratory results. <i>(3 published studies)</i></p>	<p>No recommendation for or against (overall strength of evidence rating of <u>"insufficient"</u>)</p>	<p>2 of 3 published studies received "Fair" quality ratings and one received a "Good" quality rating (no studies had a "Poor" quality rating). Both "Fair" quality studies received "Moderate" effect size ratings, and the "Good" quality study received a "Minimal/None" effect size rating, resulting in a determination of a <b>consistent</b> effect.</p>

# Results: Critical Values Communication (continued)

Practice	Recommendation Statement	Findings
<p><b>Call Center</b> Notification process centralized in a unit responsible for communication of critical value results. Customer service centralization. <i>(1 published study, 1 unpublished study)</i></p>	<p>No recommendation for or against (overall strength of evidence rating of <u>"insufficient"</u>)</p>	<p>2 studies included, 1 received a "Good" quality rating and one unpublished study received a "Fair" quality rating (no studies had a "Poor" quality rating). The "Good" quality rated study received "Minimal/None" effect size rating and the "Fair" quality rated study received a "Moderate" effect size rating, resulting in a determination of a <b>consistent</b> effect.</p>

# Results: Organizational Sustainability

## **Explored organizational types for implementing the evidence-based recommendation process**

- **Attributes and Features of Similar Efforts**
- **Organizational Structure and Governance**
- **Initial network start-up and long-term sustainability**
- **Models for disseminating recommendations**

# Results: Organizational Sustainability

- Strong consensus: LMBP process is needed, and would be supported IF process:
  - Is open and transparent
  - Produces timely recommendations
  - Involves stakeholders in meaningful ways throughout
  - Has an *independent* recommending body
  - Has organizational commitment to sustainability over time (including funding commitment for staff)
  - Is integrated with (rather than duplicating) existing efforts (e.g., more need in pre- and post- analytic phases than in analytic)

# Topic Areas for Phase 3 and Beyond

- **Patient Specimen Identification and Critical Value Reporting**
  - Additional unpublished evidence for targeted practices may support recommendations
    - Bar Coding Systems and POCT Bar Coding Systems
    - Call Centers and Automated Notification
- **Blood culture contamination:** What practices are effective at reducing blood culture contamination rates?
  - Sample collection techniques
  - Antiseptic agents
  - Blood collection site
  - Collection supplies



- **Waived Tests:** What practices are associated with reducing error rates for tests whose compliance with CLIA regulations are waived
- **Genetic testing:** What practices in genetic testing are perceived as useful for achieving timely diagnosis and treatment by genetic counselors, clinicians, and patients?
- **Interpretive Reports/ Synoptic Reporting:** What practices are effective at assuring that synoptic reporting accurately communicates test results to treating clinicians?

## Potential Topic Areas (continued)

- **Laboratory Acquired Infections** – What practices are effective at minimizing the incidence of laboratory acquired infections?
  - Safety training
  - Surveillance
- **Direct-to-Consumer Testing - Genetic Testing**
  - Transparency
  - Provider education
  - Test and laboratory quality assurance
- **Cancer Testing**
  - Genetic Counseling
  - Communicating results
  - Patient management

# Implementation Phase Objectives

- Methods Development:

- further test and finalize review and evaluation methods

- Network Development:

- Expand / activate network of facilities and organizations willing to provide unpublished evidence
- Improve CDC's capacity to search for sources of relevant unpublished evidence

- Organizational Development:

- Develop organization to establish, implement and sustain Laboratory Medicine Best Practices as a continuing program that will produce transparent evidence-based reviews and recommendations with broad stakeholder participation

# Workgroup - 2008

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# Expert Panelists

## **Patient Specimen Identification Panelists**

- Stephen Raab (U Colorado Cancer Center)
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Thank You

Comments?  
Questions?