Laboratory Medicine Best Practices

CLIAC Presentation

September 5, 2007

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Laboratory Medicine Best Practices Presentation Outline

- Introduction
- Workgroup & Project Team
- Overview: Process and Development
- Process Constructs
- Review Methods
- Proof of Concept
- Evaluation Methods
- Results & Recommendations
- Next Steps
- Discussion Questions

Laboratory Medicine Best Practices Introduction

CDC Objective

Address an unmet need for a concerted national effort to apply an evidence-based approach to improve quality in laboratory medicine consistent with Institute of Medicine (IOM) recommendations

Goal

Create a process to review and evaluate evidence on existing pre- and post-analytic practices and policies in laboratory medicine

Strategy

Developed by CDC and Battelle Project Teams with the assistance of external multidisciplinary experts: Laboratory Medicine Best Practices Workgroup

Laboratory Medicine Best Practices Workgroup Members

Raj Behal, MD, MPH	University HealthSystem Consortium
Nancy Elder*, MD, MSPH	AAFP, Univ. of Cincinnati
John Fontanesi, PhD	Univ. of California San Diego
Julie Gayken, MT (ASCP)	Regions Hospital, CLMA
Cyril ("Kim") Hetsko*, MD, FACP	AMA, COLA, Univ. of Wisc.
Lee Hilborne*, MD, MPH	UCLA, RAND, ASCP
Michael Laposata*, MD, PhD	Mass. Gen. Hosp., Harvard Medical
James Nichols*, PhD	Bay State Medical Center , NACB
Mary Nix, MS, MT(ASCP)SBB	AHRQ
Stephen Raab*, MD	Univ. of Pittsburgh Medical School
Fatema Salam, MPH	National Quality Forum (NQF)
Ann Watt, MBA, RHIA	The Joint Commission
Ex-officio members:	
Sousan S. Altaie, PhD	FDA
James A. Cometa	CMS

*Current/Former CLIAC Members

Laboratory Medicine Best Practices Project Staff

CDC Team

- Susan Snyder, Project Leader
- Julie Taylor, Co-Leader, emeritus
- Colleen Shaw
- Pam Thompson
- Emily Reese

Management:

- Joe Boone
- Devery Howerton

Battelle Team

- Laura Puzniak, Project Leader
- Ed Liebow
- Diana Mass*
- Robert Black

Laboratory Medicine Best Practices
Basic Process Overview
Expert Multi-disciplinary Panel

Review Methods

- Analytic framework
- Search strategy
- Initial exclusion criteria
- Group practices
- Review/abstract data
- Topic/practice-specific inclusion criteria
- Identify practice-specific gaps for investigation
- Investigation: Focused search for additional evidence
- Summarize **evidence**

Evaluation Framework

- Rate **evidence** using criteria:
  - Impact:
    - Effectiveness
    - Feasibility
  - Strength of Evidence
- Consider other factors
- Convene recommending expert body

"Best Practice" Recommendations

- Strongly Recommend
- Recommend
- No recommendation (insufficient evidence for or against)
- Recommend against

Laboratory Medicine Best Practices Workgroup Process Development

- First Meeting – January 2007

Key Terms & Definitions → Inclusion/ Exclusion Criteria → Classification Scheme → Priorities - Criteria - Topics → Review & Evaluation Methods

- Second Meeting – June 2007

Review Methods → Proof of Concept → Evaluation Framework → Structure & Implementation Issues

Laboratory Medicine Best Practices Key Terms & Definitions

Best Practices are practices integral to the provision of laboratory medicine services that increase the probability of beneficial patient outcomes, considering scientific evidence and, when needed, expert opinion that support the IOM quality domains.

Laboratory Medicine encompasses testing services and associated practices for the assessment, diagnosis, treatment, management, or prevention of health-related conditions.

Laboratory Tests include any test or examination of materials derived from the human body for the purpose of making patient care decisions and improving public health.

Laboratory Medicine Best Practices Minimum Practice Inclusion Criteria

- Currently used and available for immediate application
- Reproducible in other comparable settings
- Impacts a defined group of patients
- Minimum evidence required: supported by expert opinion reached through a systematic, multidisciplinary derivation process
- Relates to at least one aspect of health care:
  - Assessment/Screening
  - Diagnosis
  - Treatment
  - Management
  - Prevention
- Potential improvement in outcome(s) related to an aspect of patient care:
  - Effectiveness
  - Efficiency
  - Patient-centeredness
  - Safety
  - Timeliness
  - Equity

Laboratory Medicine Best Practices Classification Scheme

Models reviewed

- Clinical conditions (e.g., diabetes, heart disease)
- Healthcare settings (e.g., hospital, physician office)
- Laboratory total testing process (pre- , analytical, post-)
- National healthcare quality priorities (e.g., NQF, IOM, AHRQ)
- Functional Model (based on disease continuum of care)
- IOM continuum of care across the life span
- Hybrid model combining laboratory total testing process and national healthcare priorities (Behal's evidence-based review of laboratory medicine guidelines and performance measures)

Consensus: Comprehensive, Multidisciplinary Framework

Hybrid model: laboratory total testing process grounded in national health priorities (IOM/NQF) and consistent with IOM performance measurement design principles (Behal 2006)

Laboratory Medicine Best Practices Priorities: Criteria and Topics

- Workgroup reviewed priority-setting criteria from multiple models using evidence-based methods for health-related systematic reviews and recommendations
- Combined criteria from models:
  - Burden of the problem
  - Preventability
  - Availability of existing knowledge
  - Potential effectiveness
  - Operational management
  - Economic benefit
- Workgroup identified 20 priority topics (separately from above criteria); from these patient/specimen identification topic selected for “Proof of Concept”

Laboratory Medicine Best Practices Process Methods

- Workgroup sub-groups:
  (1) Review Methods & (2) Evaluation Framework
- Purpose:

  To support an evidence-based recommendation process using explicit, transparent, accountable and consistent methods to ensure independence and integrity

- **Review Methods**: Key Components of Full Evidence Review
  - ☑ Analytic framework of key questions
  - ☑ Comprehensive literature search
  - ☑ Critical evaluation
  - ☑ Qualitative and/or quantitative synthesis
  - ☑ Detailed documentation of methods and findings

Source: U.S. Preventive Services Task Force 2007

Laboratory Medicine Best Practices Methods Proof of Concept

Review Methods
(sub-Workgroup)

Conceptual Approach (Topic)
Analytic framework, topic-specific quality issues/gaps, priorities

Methods Development
Search/inclusion strategies, data abstraction and evidence summary content/format, revisions

Review Completion
(CDC Team)
Organize results of search, identify practices, apply inclusion criteria, abstract, summarize

TOPIC AREA
Expert Panel
(Workgroup)

Review/Select Candidate Practices (and Evidence)

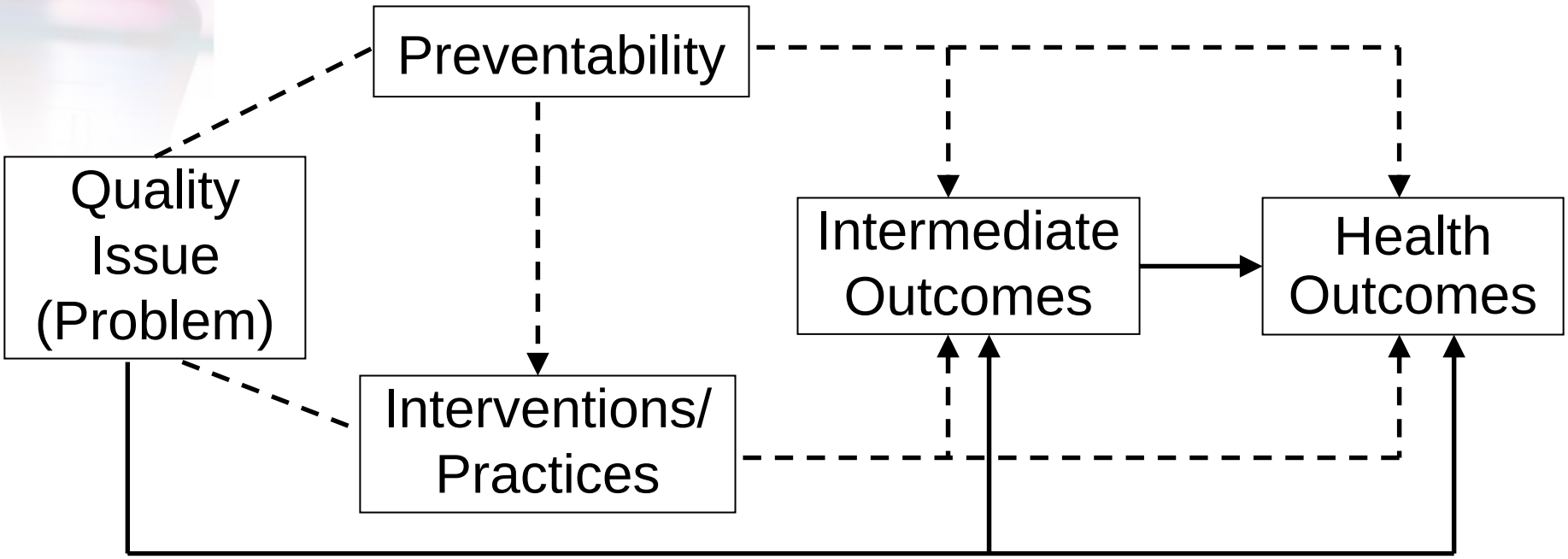
Recommend changes to review methods

Evaluation/ Recommendation Framework
(sub-Workgroup)

Evaluation Criteria
- Impact
  - Effect
  - Feasibility
- Strength of Evidence

Recommendations
- Strongly Recommend
- Recommend
- No recommendation
- Recommend against

Laboratory Medicine Best Practices
Basic Analytic Framework



Purpose

Define and clarify the scope of a topic area to facilitate a structured, methodological approach which is transparent, can be consistently applied and externally reviewed

Patient/Specimen Identification Proof of Concept Topic Analytic Framework

Quality Issue/Problem
Patient/Specimen Identification (ID) Errors

Preventability
- ~100% preventable
- Error rate range: <1% to > 50%
- Not consistently defined

Interventions/Practices
- Barcoding
- Dedicated phlebotomy
- Education program
- Incident reporting
- Lock out practices
- Marketing campaign
- Zero-tolerance policy
- Wristband monitoring

OUTCOMES

Intermediate/Process
- ID errors/error rates
- Diagnosis errors/delays
- Treatment errors/delays
- Process compliance
- Patient satisfaction
- Unnecessary testing
- Length of stay
- Associated costs

Health-related
- Error-associated health consequences

Review Methods
Literature Search Strategy

Reference Sources

- PubMed, Cochrane, professional guidelines, electronic databases (e.g., CLSI, ISO, NACB)
- Handsearching relevant journals, reports, conference proceedings, reference lists on relevant sources
- Consultation with sub-Workgroup members and key informants

Screening

- 1996 and later
- English language
- Search strategy inclusion/selection criteria met

CDC Review Team Process

Screen/Inclusion Criteria

Reference title and abstract screened independently by two reviewers using topic/practice inclusion criteria to identify for possible full review, plus additions from follow-up searches

Organize/Group

References for full review grouped by defined practice areas (some contained multiple practices)

Abstract/Evaluate

- Articles fully abstracted independently by at least 2 reviewers using Data Abstraction Form developed using existing models
- Evaluated for inclusion
- Content critically evaluated using standardize methods
- Reviewer discrepancies resolved by consensus

Literature Search & Inclusion Criteria Patient/Specimen Identification (ID)

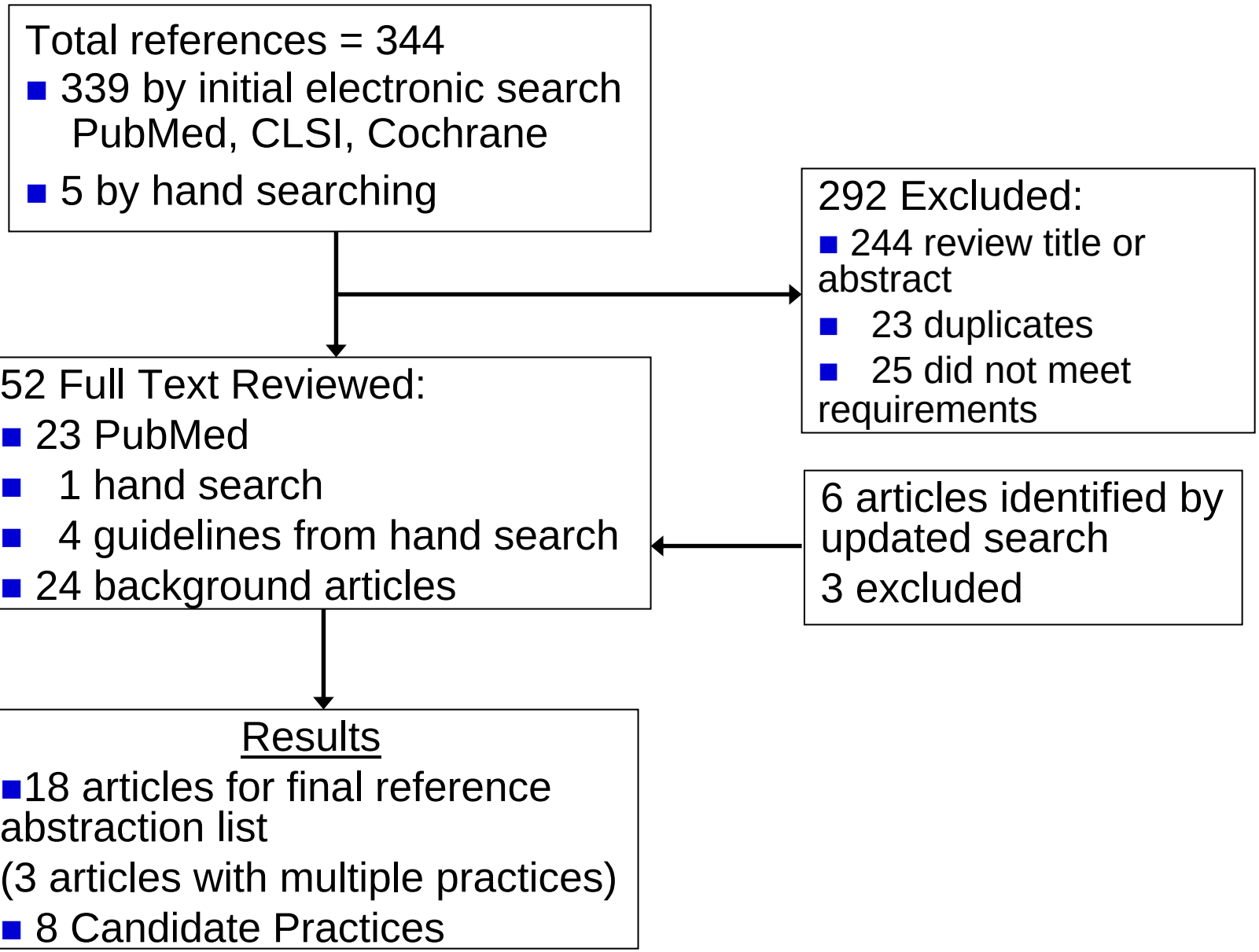
Initial Search Terms

- Laboratory ID errors
- ID errors AND patient AND specimen
- Laboratories AND ID systems AND specimen misidentification
- Specimen labeling errors
- Information systems AND hospitals AND reduce ID errors

Initial Inclusion/Selection Criteria - Title/Abstract addresses:

- ID errors in laboratory medicine/approaches for reducing ID errors (including case studies, guidelines, frameworks)
- Patient/specimen ID errors
- ID Error detection methods or frequency of specimen/patient ID errors
- Quality improvement programs/patient safety initiatives to reduce ID errors
- Technology to improve processes in laboratory medicine

Literature Review Results for Patient/Specimen Identification



Review Methods
Summarizing Results

Evidence Summary Table

Synthesis of evaluation of search results

- Standardized format developed using existing models; includes: practice description, study design, time period, sample, outcome measure, internal/external validity, effect size, practice link to results, feasibility, cost
- Table for each practice based on Review Team consensus on included references using these categories:
  - ☑ **Evidence**: Results include practice-specific quantitative effect measure
  - ☑ **Feasibility Only**: No quantitative effect results; practice implementation and/or cost information
  - ☑ **Related Information**: Deemed relevant to context of practice

Evidence Summary Tables
Patient/Specimen Identification

Candidate Practices	Evidence of Effect	Feasibility Only
Barcoding ID systems	3	4
Dedicated phlebotomy services	1	1
Education program	1	1
Incident reporting	1	1
Lock out practices	2	0
Marketing campaign	1	0
Zero-tolerance policy	2	0
Wristband monitoring	2	0

Laboratory Medicine Best Practices Evaluation Methods

Primary Sources

- Performance Measures

  AHRQ, NQF, AMA Physician Consortium

- Evidence-based Guidelines/Recommendations

  USPSTF, Community Guide, NACB, Oxford Centre for Evidence-based Medicine

Assumptions

- Practices not likely studied in controlled trials
- Evidence available to assess practice effectiveness is most likely to come from observational studies.
- Evidence for effectiveness of a specific practice may be limited

Laboratory Medicine Best Practices Evaluation Criteria

FEASIBILITY

EFFECT SIZE

STRENGTH OF EVIDENCE

Laboratory Medicine Best Practices Evaluation Criteria

FEASIBILITY of implementation assessment involves:

- Costs of intervention (monetary, non-monetary quantitative information)
- Barriers to implementation
- Benefits (in addition to outcomes)
- Potential harms (in addition to outcomes)

Ease and feasibility of implementation categorical scale:

- HIGH
- MEDIUM
- LOW

Laboratory Medicine Best Practices Evaluation Criteria

EFFECT SIZE assessment involves:

- Practice effects defined by one or more of the following:
  - Clinical outcomes
  - Operational / process outcomes (e.g., error rate,)
  - Economic outcomes (e.g., cost and associated outcomes)
- Effects (outcomes) consistently measured over time
  - Effect size is reported, AND
  - Statistical analysis (e.g., P-value) reported

Effect size is qualitatively expressed in categorical terms :

- SUBSTANTIAL
- MODERATE
- MINIMAL
- ADVERSE

Laboratory Medicine Best Practices Evaluation Criteria

STRENGTH OF EVIDENCE assessment involves:

- Number of studies involving the same procedure/practice
- Aggregate sample size of multiple studies
- Study sample groups comparable for multiple studies
- Measurement methods comparable for multiple studies
- Confounding factors addressed
- Consistency of findings reported for multiple studies

Strength of evidence categorical scale:

- STRONG
- MODERATE
- SUGGESTIVE
- INSUFFICIENT

Laboratory Medicine Best Practices Evaluation Framework

Impact Assessment			
Effect Size	**Feasibility**		
	High	**Medium**	**Low**
Substantial	Positive	Positive	Neutral
Moderate	Positive	Positive	Neutral
Minimal/ None	Neutral	Neutral	Negative
Adverse Effect	Negative	Negative	Negative

Laboratory Medicine Best Practices Evaluation Framework

Recommendation Grid

Impact Rating	Strength of Evidence Rating			
	Strong	**Moderate**	**Suggestive**	**Insufficient**
Positive	Strongly recommend	Recommend	Recommend	No recommendation for or against
Neutral	No recommendation for or against	No recommendation for or against	No recommendation for or against	No recommendation for or against
Negative	Recommend against	Recommend against	Recommend against	Recommend against

Laboratory Medicine Best Practices Results and Recommendations

WORKGROUP RECOMMENDATIONS – PHASE I

METHODS

- Address and incorporate non-traditional evidence that is not readily accessible for filling evidence gaps
- Create an **investigational component and process loop** into review methods
- Use focused and targeted outreach to access and develop evidence of practice effectiveness
- Set evidence criteria (including non-traditional evidence) *a priori*
- Re-visit candidate topics with advisory group
- Involve stakeholder organizations using multi-tiered approach

Laboratory Medicine Best Practices Workgroup Recommendations

MESSAGE

Do not wait for the evidence to catch up - Create a new approach to evidence reviews

- Use proactive methods to obtain evidence to address the effectiveness evidence gaps (e.g., calls for practices, identification of practice leaders/experts/centers)
- Rely on practice-specific outreach to practitioners and expert groups with practice experience and knowledge
- Develop explicit, systematic and transparent methods (i.e., study protocols, data collection and analysis) to incorporate non-traditional evidence in reviews

Laboratory Medicine Best Practices Results and Recommendations

WORKGROUP RECOMMENDATIONS – PHASE 1

STRUCTURE & IMPLEMENTATION

- Have CDC manage the process and data repository
- Evidence database should be open-source
- Overall coordinating/governing body with expert topic area panels
- Finance by government sources
- Modify an existing organizational model, involving an advisory group
- Establish an official publication for the Laboratory Medicine Best Practices

Laboratory Medicine Best Practices NEXT STEPS

Consistent with Workgroup recommendations and the Final Report, the CDC and Battelle are moving forward with Phase II which involves:

- Refining and developing process methods
- Creating a laboratory network for soliciting and creating practice evidence
- Pilot testing the process
- Evaluating organizational structure alternatives for implementation

Laboratory Medicine Best Practices NEXT STEPS

Phase II

Strategic Components

- Laboratory Medicine Best Practices Advisory Workgroup
- Collaboration with National Quality Forum (NQF), and laboratory medicine stakeholders
- Development of process investigational component
- Expert workgroups on 2-3 topic areas, each to evaluate at least 3 practices
- Plan for operationalizing Laboratory Medicine Best Practices

Laboratory Medicine Best Practices

Vision: A systematic process for evaluating laboratory medicine practices to improve the quality of patient care and health outcomes.

Workgroup Strategy for Process Development

Key terms & definitions → Inclusion/ Exclusion criteria → Classification scheme → Priorities
- Criteria
- Topics

→ Review methods & Evaluation framework
- Criteria/Ratings
- Recommendation levels

→
- Proof of Concept
- Structure & Implementation issues

→ Revise Process
Draft Report
External Review
Final Report
End of Phase 1

Challenges

- Coordination among multiple disciplines
- Variations in practice associated with technologies and settings
- Disconnected systems of care and communication
- Limited scientific evidence as basis for guidance/practice
- Health information technology variation
- "Best practices" not systematically identified
- Connecting laboratory to patient care decisions and outcomes
- Evidence demonstrating practice effectiveness

Proposed Laboratory Medicine Best Practices Process

TOPIC AREA
Expert Panel (multi-disciplinary) with staff

→ Review Methods
- Conceptual model
- Analytic framework
- Search strategy
- Initial inclusion/ exclusion criteria
- Organize information
- Group candidate practices
- Systematically review/abstract data
- Topic/practice-specific inclusion criteria
- Summarize evidence
- Identify practice-specific gaps for investigation

↔ Investigation
Conduct focused search for additional evidence
- Expert opinion
- Call for practices

↕ Select candidate practices for complete review

→ Review Completion
- Systematically analyze/summarize practice evidence
- Apply evidence-related exclusion criteria

→ Not met: Excluded Practices

Candidate practices for evaluation →

→ Evaluation Process
- Rate candidate practice evidence using evaluation framework criteria:
  - Impact:
    - Effectiveness
    - Feasibility
  - Strength of Evidence
- Identify/consider other factors
- Convene recommending expert body

→ **"Best Practice" Recommendations**
- Strongly Recommend
- Recommend
- No recommendation (insufficient evidence for or against)
- Recommend against

→ Identify areas for further research

Laboratory Medicine Best Practices
Discussion Questions

- Should the review and recommendation process and/or recommending body be named Laboratory Medicine Best Practices? (e.g., U.S. Preventive Services Task Force and the Guide to Clinical Preventive Services)
- As described, is the Laboratory Medicine Best Practices process a feasible solution for developing transparent, evidence-based recommendations?
- Who should convene and support the Laboratory Medicine Best Practices recommendation process?
- Is there a role for CLIAC? If so, what should it be?

Laboratory Medicine Best Practices
Discussion Questions (continued)

- How can appropriate and balanced representation be achieved (including multi-disciplinary experts, payers, and patients)?
- How should stakeholders be engaged?
- How should priorities for topic areas and practices be set?
- What needs to be modified or addressed from Phase I that is not in Phase II? Are there additional or alternative components that need to be addressed?