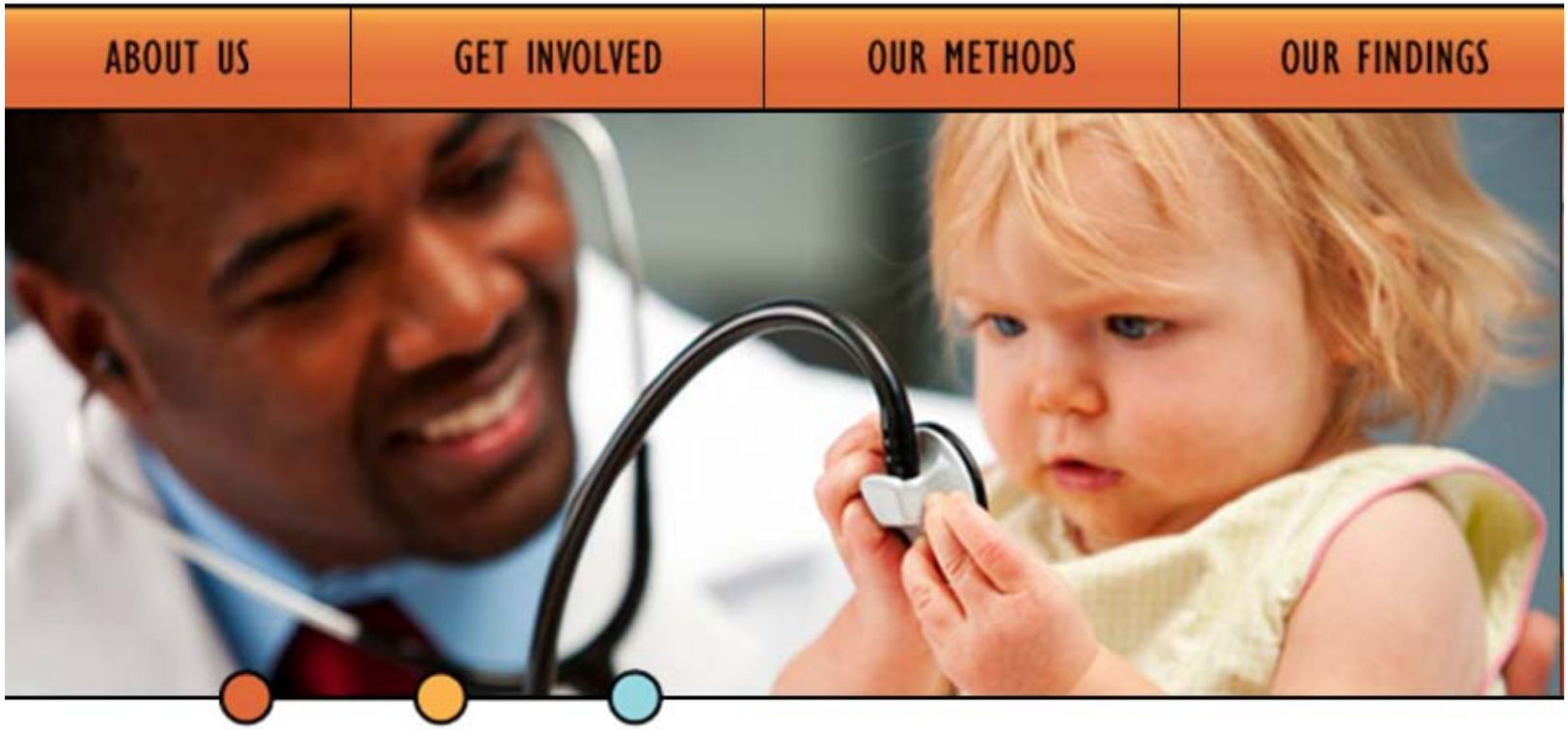
Laboratory Medicine Best Practices: Transparent Methods for Patient-Centered, Evidence-Based Quality Improvement

LABORATORY MEDICINE
Best Practices



Presented by

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Today's Objectives

- Describe differences between AHRQ and LMBP Efforts.
- Discuss the need for the use of evidence based laboratory medicine to insure patient-centered outcomes.
- Describe the LMBP A-6 Cycle that includes published studies and unpublished findings.
- Review the LMBP topic selection process and a pilot study of practices to reduce blood culture contamination rates.
- Note LMPB on-line tutorials to educate laboratory professionals about quality improvement study designs.
- Describe key efforts to sustain the LMBP Initiative and gain support from official bodies.

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LMBP Systematic Review Steps

ASK

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

ACQUIRE

Identify sources and collect potentially relevant studies

APPRAISE

Create an evidence base by applying screening and evaluation/ rating criteria

ANALYZE

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

APPLY

Disseminate findings for review and local application

AUDIT/ASSESS

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Evidence Based Systematic Reviews

Medical Test Reviews-AHRQ

Laboratory Medicine Best Practices-CDC

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Medical Test Reviews-AHRQ

Writing the Report

- Follow a standard template for the overall report:
  - Abstract and Executive Summary
  - Chapter 1. Introduction
  - Chapter 2. Methods
  - Chapter 3. Results
  - Chapter 4. Discussion
- Ordering of subsections may vary but:
  - Should adhere to principles of clarity
  - Should be consistent with key questions
  - May be guided by PICOTS

PICOT(S) = population, intervention, comparator, outcome, time frame, and study design or setting

Agency for Healthcare Research Quality

- Medical Test Reviews
- Test-A medical test is a kind of medical procedure performed to detect, diagnose, or evaluate disease, disease processes, susceptibility, and determine a course of treatment

Laboratory Medicine Best Practices

- Patient-centered, transparent systematic reviews
- Practices- Protocols, procedures, policies, techniques, processes, systems, standards, incentives, activities, and interventions that are used to provide healthcare to patients.

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AHRQ Topic Development

- Topic development begins with a claim
  - Testing strategy's impact on health outcome
  - Test's clinical role
  - Potential advantages over existing test or strategy

LMBP Topic Development

- Topic development begins with:
  - IOM priorities: Safe, Timely, Effective, Efficient, Equitable, Patient-Centered
  - *Evidence*: At least modest; *Outcome measure(s)*: At least one relevant outcome; *Practices*: At least *3* practices affecting performance or outcomes related to a quality issue.

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LMBP

Formulate an Answerable Question

the PICO system

- **Population (Patient Description)**
- **Indicator (Practice)**
- **Comparator (Control practice)**
- **Outcome (Health-related, Economic)**

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AHRQ

Formulate an Answerable Question

the PICOT(S) system

- **Population (Description of patients)**
- **Indicator (test, intervention)**
- **Comparator (Control, Gold Standard)**
- **Outcome (Detect, Diagnose, evaluate)**
- **Time Frame (when to test)**
- **Study Design or Setting (RCT, ED)**

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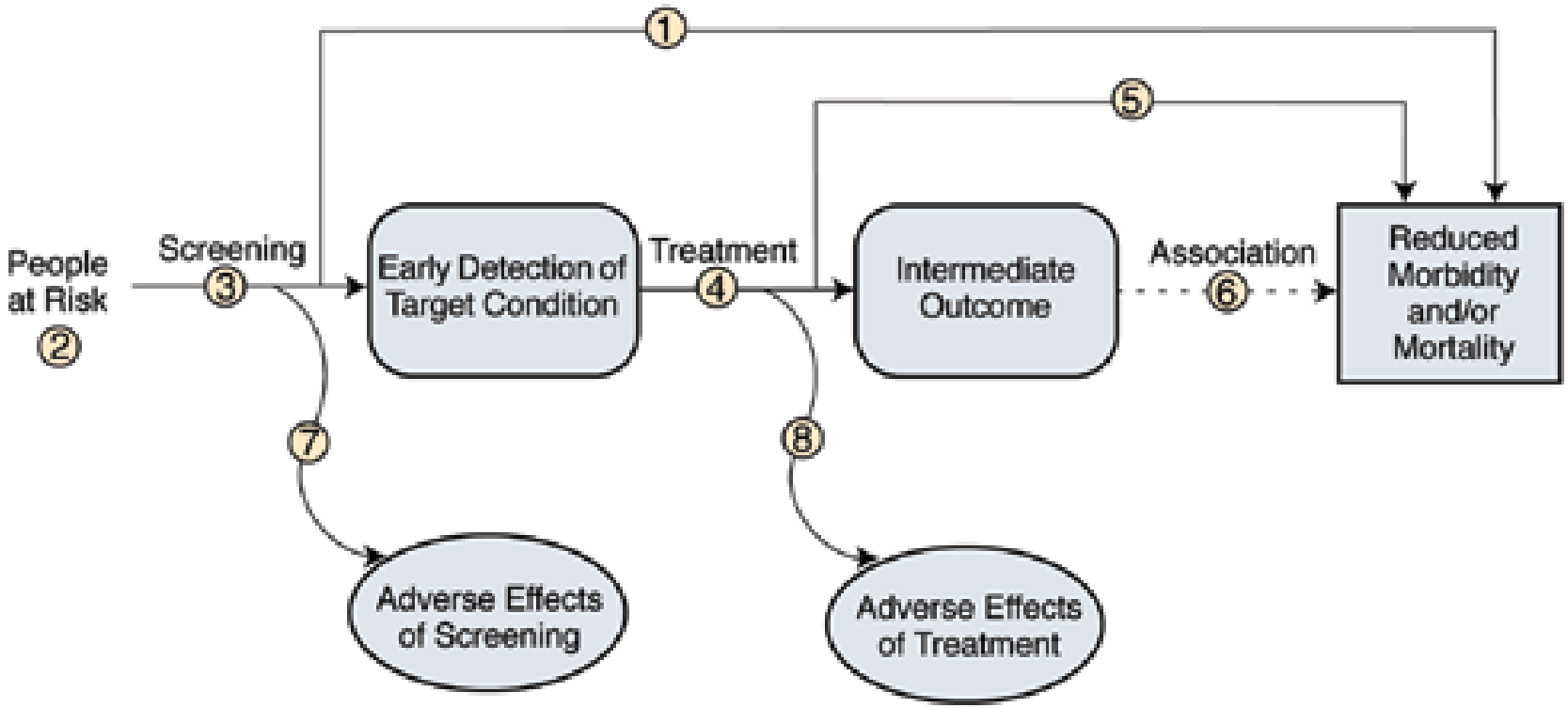
US Preventive Services Task Force Analytic Framework



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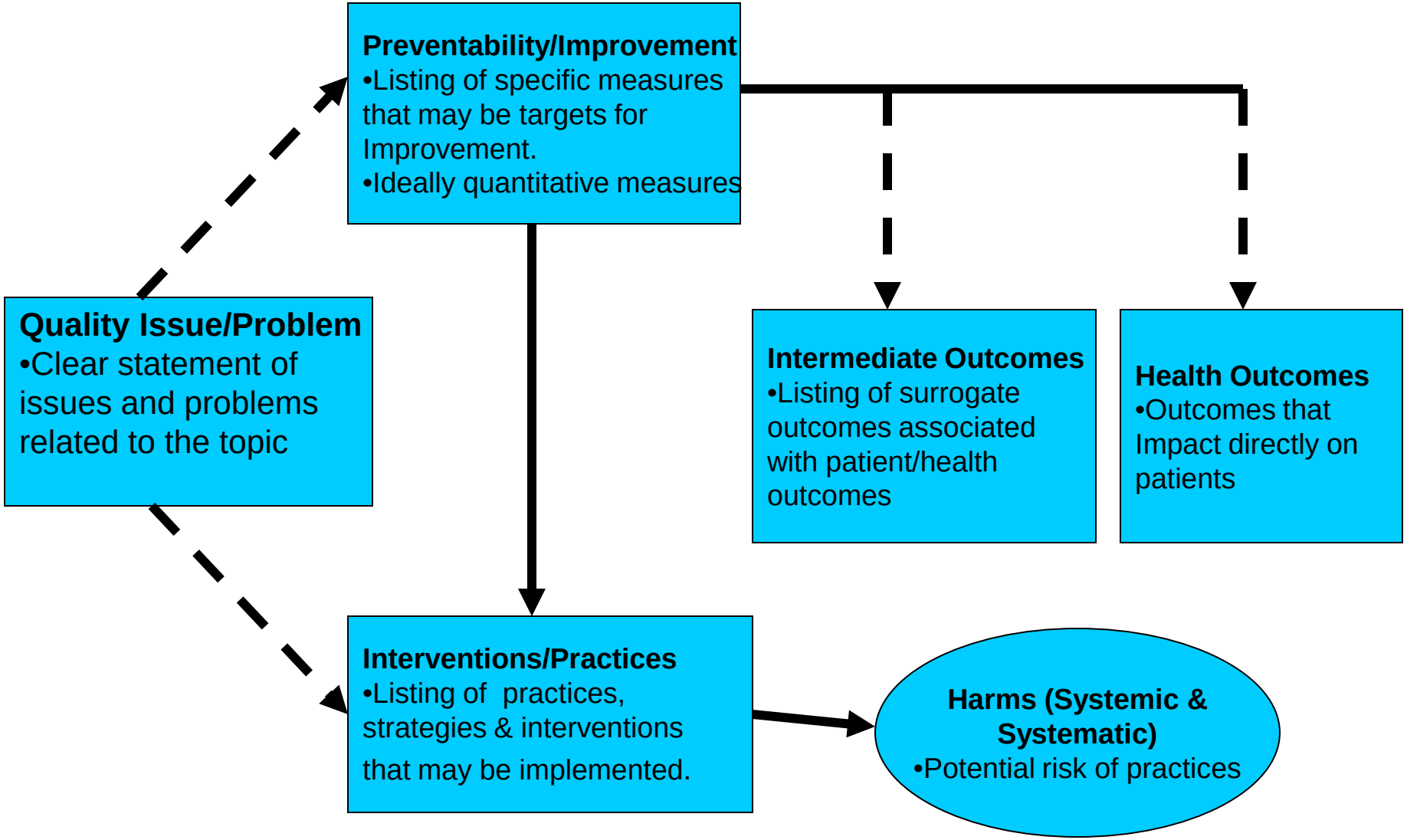
LMBP Analytic Framework



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Medical Test Review

Claim: health outcome, clinical role, advantages

Do patients having the test fare better than similar patients who do not have the test?

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Lab Medicine Best Practices

Safe, Timely, Effective, Efficient, Equitable and Patient-Centered

Do patients at institutions using the laboratory medicine best practice recommendations fare better than similar patients where the best practice recommendations are not implemented?

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LMBP and Arthur Rubinstein?

A guy once asked pianist Arthur Rubinstein "Pardon me sir, but how do I get to Carnegie Hall?" and Rubinstein replied

- Practice
- Practice
- Practice

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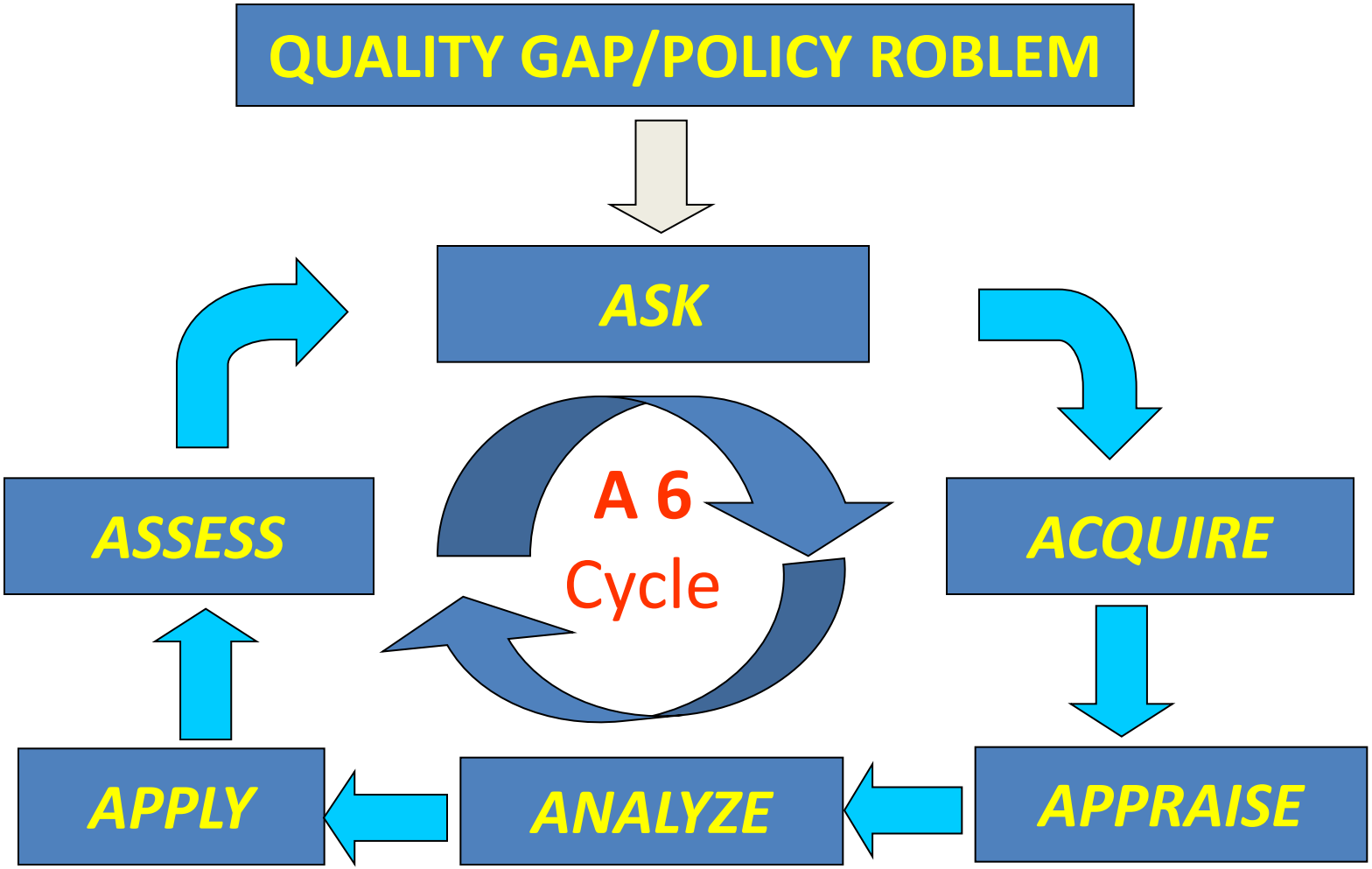
LMBP Systematic Review Methods
A-6 Cycle



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LMBP

Formulate an Answerable Question

the PICO system

- **Population (Patient Description)**
- **Indicator (Practice)**
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- **Outcome (Health-related, Economic)**

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LMBP: Form as a Review Question

Example Topic: Communicating Critical Values

Example Review Question: For hospitalized patients, what practices are effective for communicating laboratory critical value results in a timely and accurate fashion to the licensed caregiver who can act on them?

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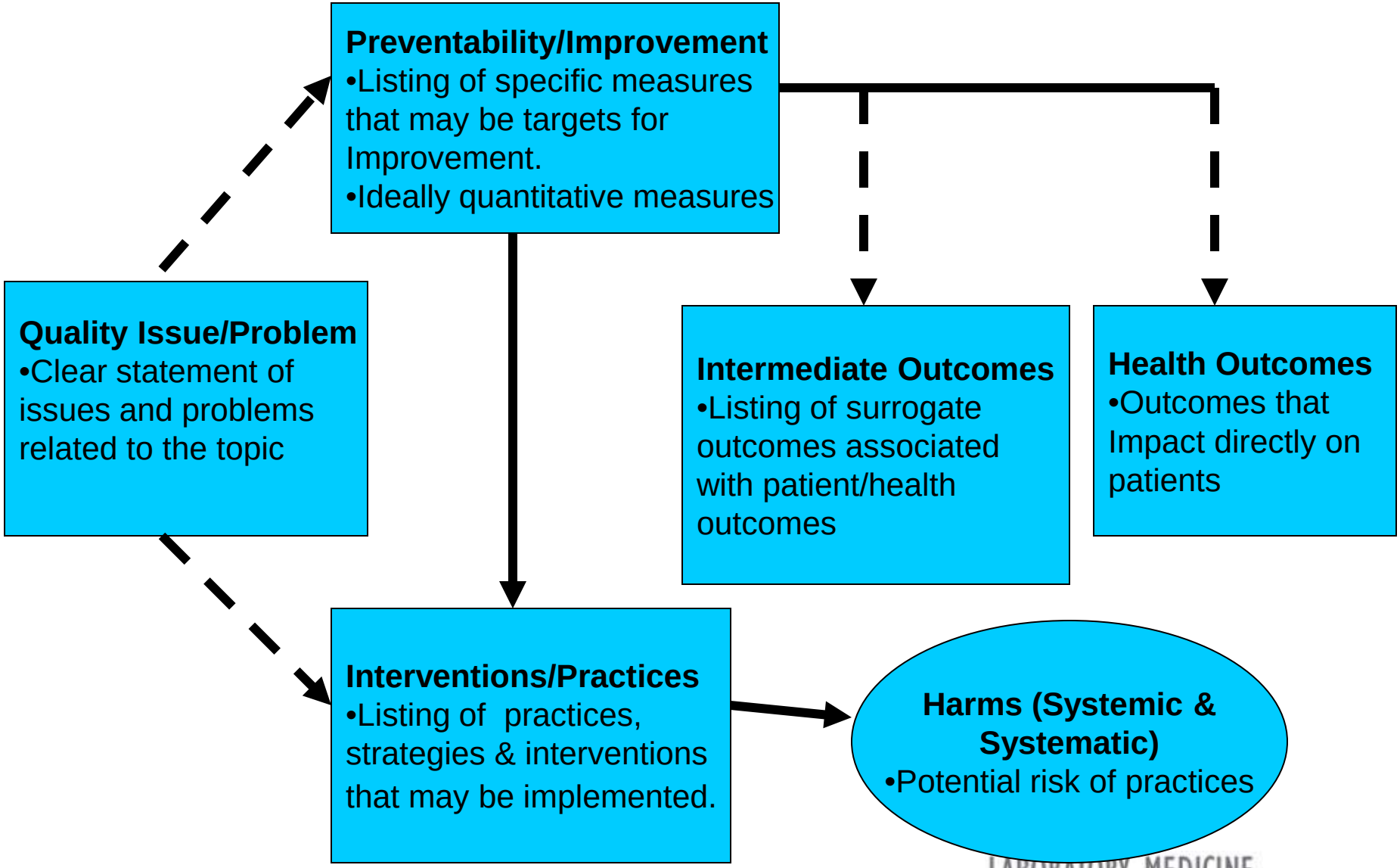
LMBP Analytic Framework



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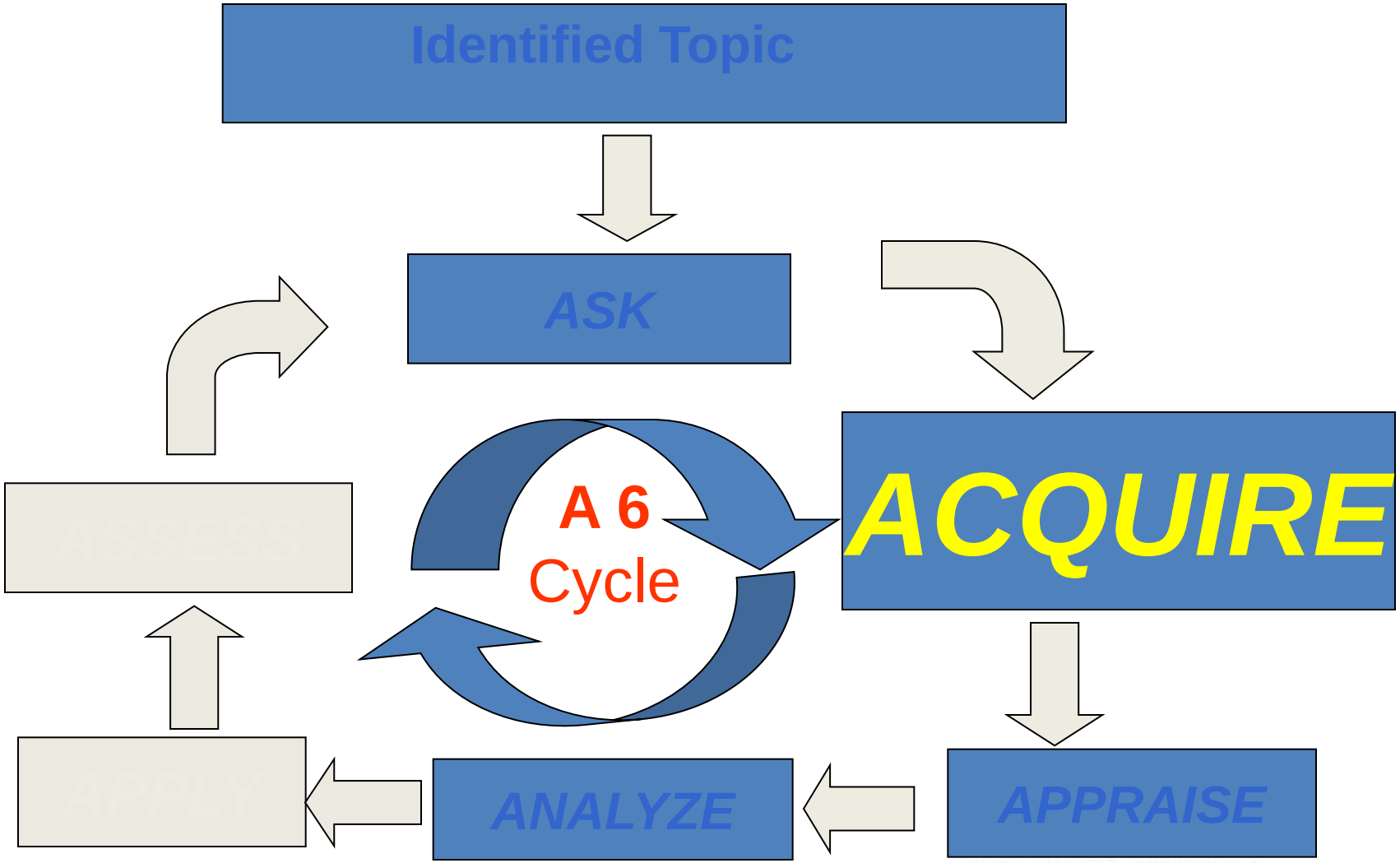
ACQUIRE: Identify sources and collect potentially relevant studies



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ACQUIRE: Identify sources for evidence to address the specific question

- Reference Databases (e.g. Medline AND EMBASE, Cochrane)
- Hand-searching key journals
- Meeting Abstracts or conference proceedings
- Special Databases (grey literature)
- Reference lists and citation searching
- Commentaries (may lead to other sources)
- Contacting Experts (unpublished studies)
- The Internet
- Unpublished studies

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- Meeting Abstracts or conference proceedings
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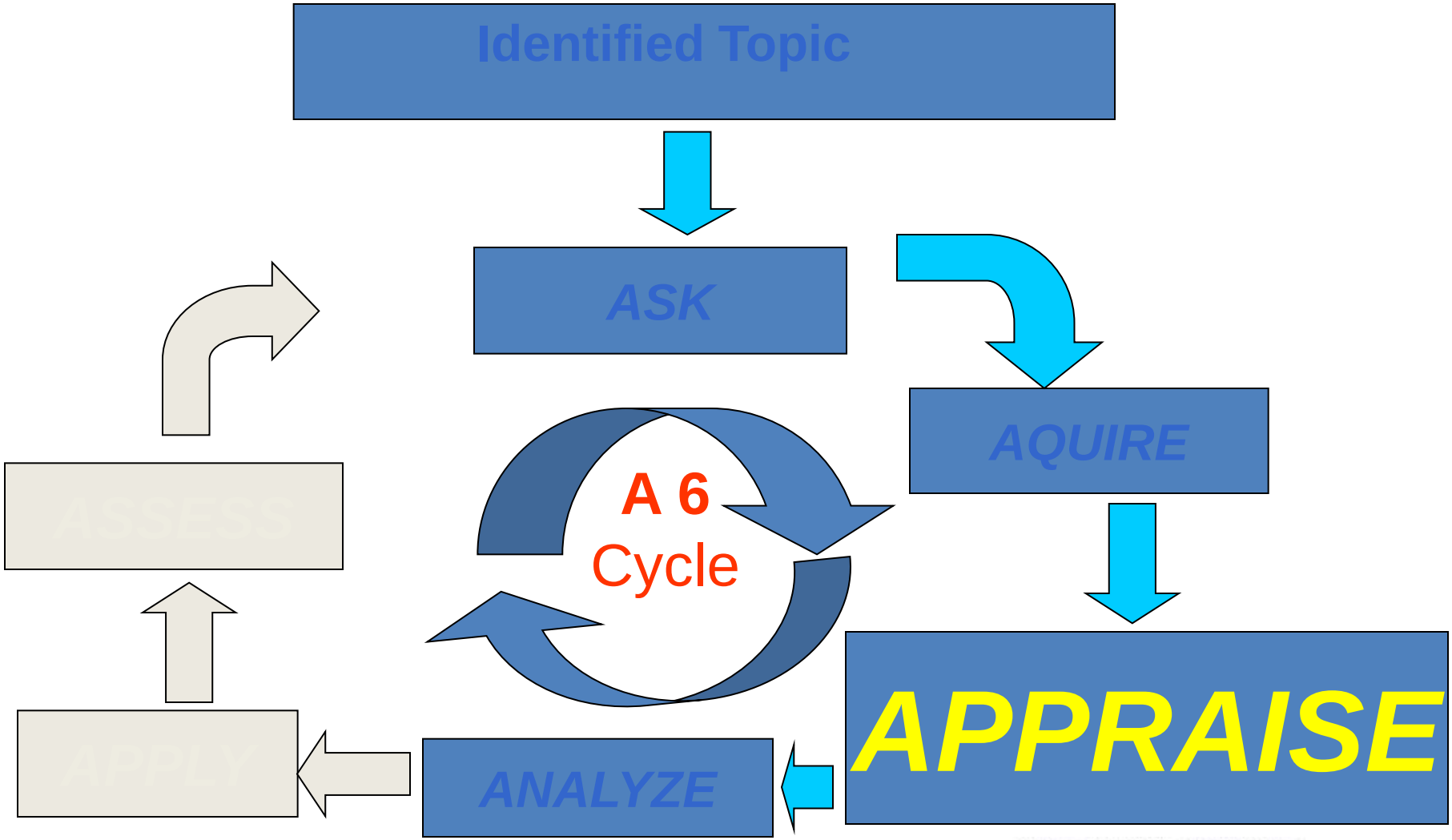
- Reference lists and citation searching
- Commentaries (may lead to other sources)
- Contacting Experts (unpublished studies)
- The Internet
- **Unpublished reports and studies**

Expert Panels

Each topic area Expert Panel have 7-9 panelists:

- 2-3 Work Group members with relevant topic area content expertise
- 2-3 topic area content experts who are not Work Group members
- 1 specialist in evidence review methods
- 2 specialists in laboratory management, including administrative and laboratorian specialties

Appraise: Create an evidence base by applying screening and evaluation/ rating criteria



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LMBP APPRAISE STEP (A3) Process Summary

- **Initial screen** of search results (exclusion criteria)
- **Abstract, standardize and summarize** studies meeting inclusion criteria
- **Evaluate and rate/score**
  - Study quality
  - Effect size
- **Synthesize** into a practice body of evidence

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LMBP APPRAISE STEP (A3) Overview

- **Purpose**

  Evaluate the search results (published and unpublished) from the ACQUIRE (A2) step to identify and qualify studies for potential inclusion as evidence of practice effectiveness that address the focused review question(s) framed in the ASK (A1) step.

- **Process**

  Initial screening of individual published and unpublished search results against LMBP study inclusion and exclusion criteria to full abstraction and evaluation of candidate studies, including rating of study quality and effect size, for a specific practice's evidence base using a minimum of two reviewers

- **Results**

  A practice-specific aggregate body of evidence (evidence base) of effectiveness studies for use in the ANALYZE (A4) step, including evaluation of effect size and consistency and meta-analysis using individual study results

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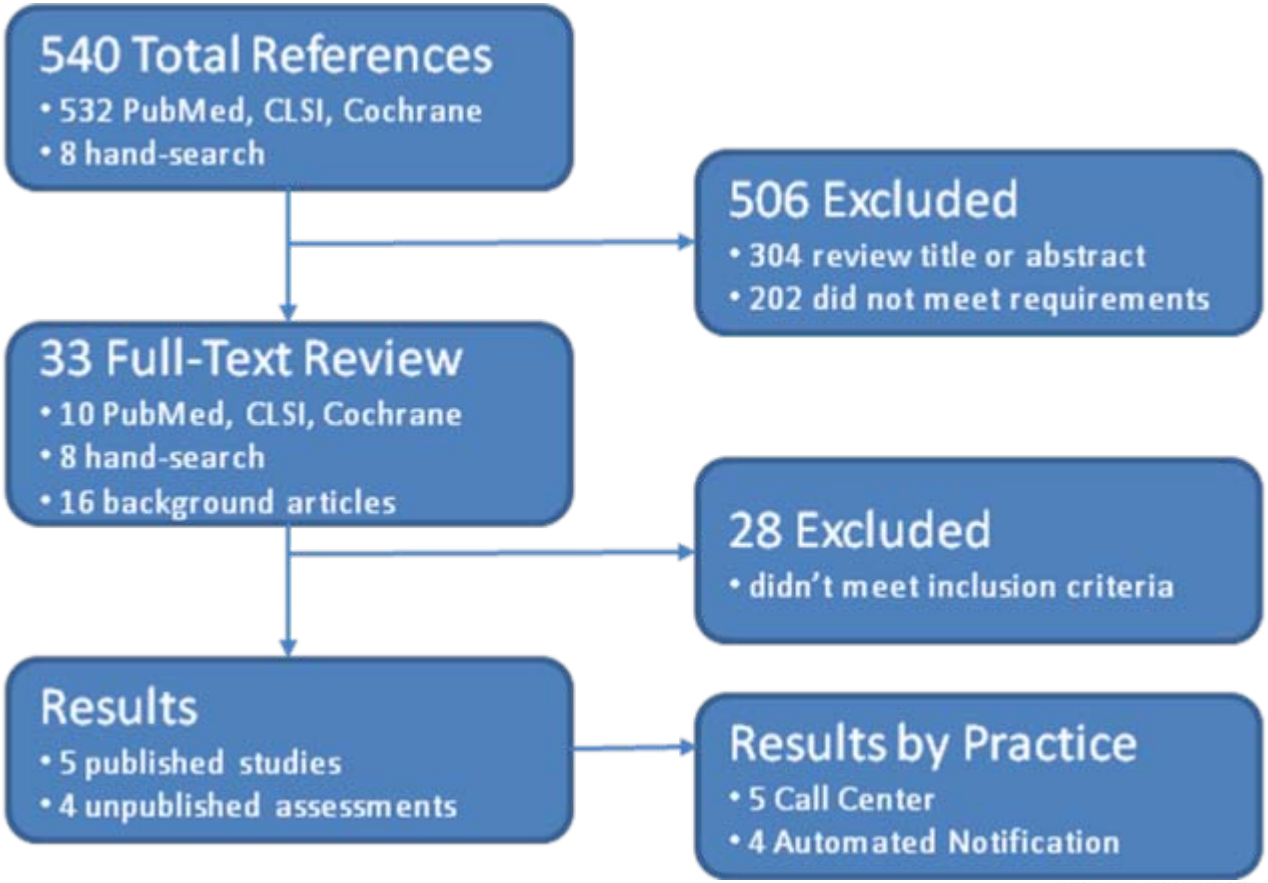
Report search strategy and account for and the sources

- Inclusion / exclusion criteria for the topic



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Evidence Summary Table

	Quality Domains			
Bibliographic Information - Author (s) - Yr Published/Submitted - Publication - Author Affiliations - Funding				
Quality Domains Points	2	2	1	3

- Two Abstractors independently review evidence
- Results of abstractions are compared
- Meeting to resolve Abstractor discrepancies

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Appraise

Step 1 – Study Quality Rating

Practice A	Study Characteristics (3 pts)	Practice Characteristics (2 pts)	Outcome Measures (2 pts)	Results (3 Pts)	Overall Study Quality Rating
Study 1	2	2	1	3	8
Study 2	2	1	1	1	5
...					
Study n					

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

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Combine Appraise Steps 1 & 2

1 – Study Quality Rating

Practice A	Study Characteristics (3 pts)	Practice Characteristics (2 pts)	Outcome Measures (2 pts)	Results (3 Pts)	Overall Study Quality Rating
Study 1	2	2	1	3	8
Study 2					
...					
Study n					

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

2 – Study Effect Size Rating

Study Ratings	Effect Size
Study 1	Substantial
Study 2	
...	
Study n	

- Substantial
- Moderate
- Minimal/None

Study Ratings	Study Quality Rating	Study Effect Size Rating
Study 1	Good	
Study 2	1	2
...		
Study n		

Individual Study Ratings

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Standardize, Summarize and Rate Studies

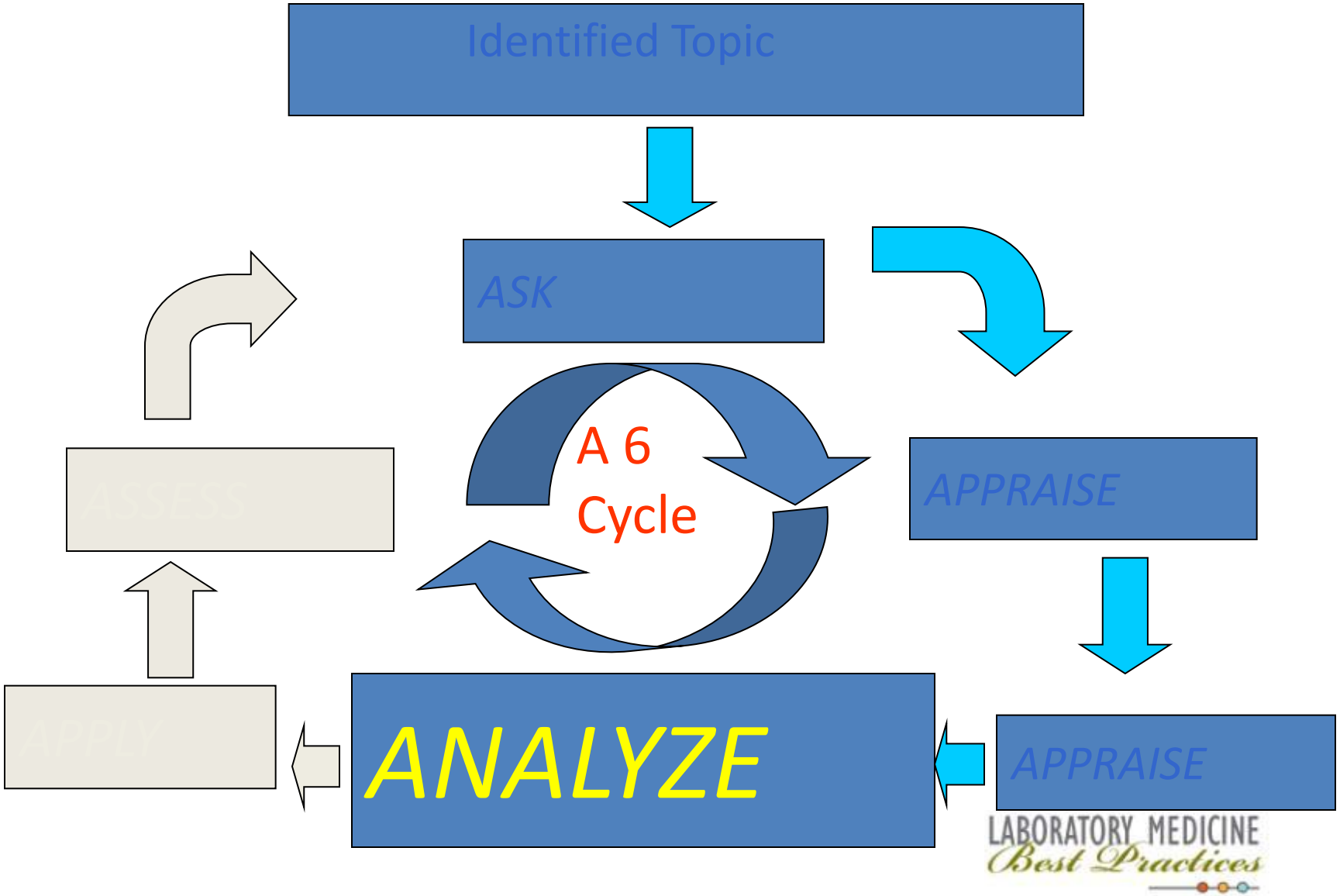
Practices reducing patient specimen identification errors

Practice: Bar-coding Systems	Study Quality Rating						Effect Size Rating
Evidence	Study	Practice	Outcome Measure	Results	Total	Rating	
Bologna 2002	2	2	2	2	8	Good	Substantial
Hayden et al. 2008	3	2	2	3	10	Good	Substantial
	2	2	2	3	9	Good	Substantial
Sandler et al. 2005	1				3	Poor	n/a
Turner et al. 2003	1				4	Poor	n/a
Zarbo et al. 2009	2				9	Good	Moderate
Unpub A 2009	3				7	Fair	Substantial
U of MN 2009	1				5	Fair	Substantial
U of WA 2009	2				8	Good	Substantial
LBJ 2009	2				8	Good	Substantial

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

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

LMBP – ANALYZE (A-4): Body of Evidence



Appraise

Study Quality Rating

Practice A	Study Characteristics (3 pts)	Practice Characteristics (2 pts)	Outcome Measures (2 pts)	Results (3 Pts)	Overall Study Quality Rating
Study 1					
Study 2					
...					
Study n					

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

Study Effect Size Rating

Study Ratings	Effect Size
Study 1	
Study 2	
...	
Study n	

- Substantial
- Moderate
- Minimal/None

	Study Quality Rating	Study Effect Size Rating
Study 1	1	2
Study 2		
...		
Study n		

Individual Study Ratings

Analyze

Overall Evidence Rating

Individual Study Quality	Individual Effect Size	Consistency (Yes / No)	Overall Strength Rating	Recommendation
# Good: # Fair:	Substantial	3	4	5
# Good: # Fair:	Moderate			
# Good: # Fair:	Minimal / None			
# Good: # Fair:	Adverse			

1 2

Individual Study Ratings

Overall Evidence Ratings

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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

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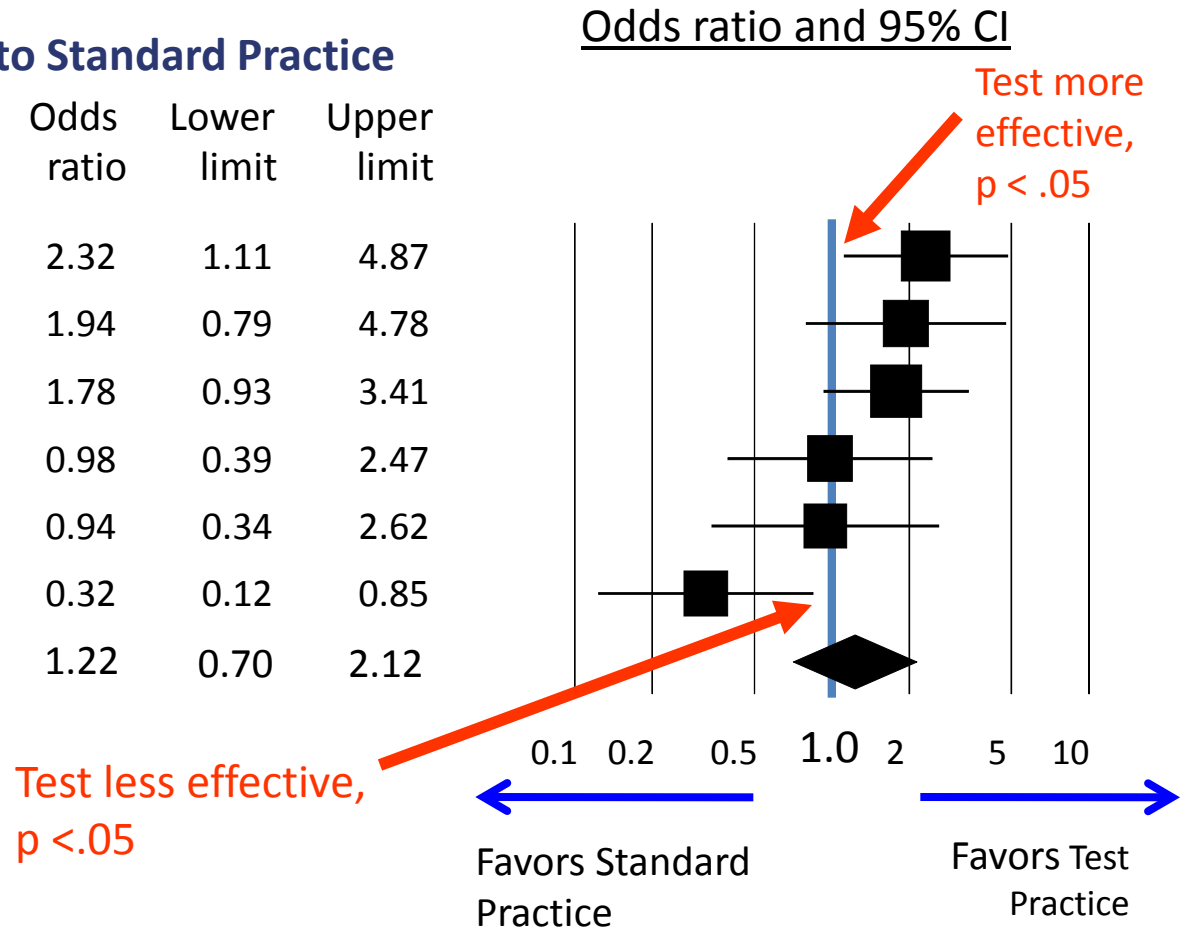
Meta Analysis
Evaluate Consistency & Standardized Effect Size

Test Practice Compared to Standard Practice

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



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Consistency (Yes/No)

Overall Evidence Rating				
Individual Study Quality	Individual Effect Size	Consistency (Yes / No)	Overall Strength Rating	Recommendation
# Good: # Fair:	Substantial			
# Good: # Fair:	Moderate			
# Good: # Fair:	Minimal / None			
# Good: # Fair:	Adverse			

1

2

3

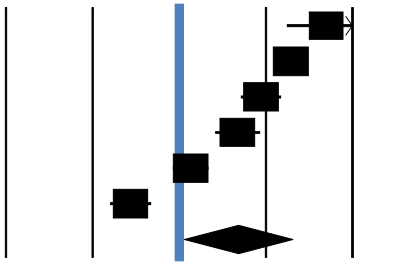
Yes / No

4

5

Study name	Statistics for each study			
	Std diff in means	Standard error	Lower limit	Upper limit
Study A (2007)	0.85	0.11	0.62	1.07
Study E (2009)	0.64	0.03	0.59	0.69
Study B (2007)	0.47	0.06	0.36	0.58
Study C (2008)	0.34	0.06	0.21	0.46
Study F (2010)	0.07	0.05	-0.04	0.17
Study D (2009)	-0.28	0.06	-0.40	-0.17
Summary effect estimate	0.34	0.16	0.03	0.66

Std diff in means and 95% CI



-1.00 -0.50 0.00 0.50 1.00

Favors Standard Practice

Favors Test Practice

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Overall Strength of Evidence

Overall Evidence Rating				
Individual Study Quality	Individual Effect Size	Consistency (Yes / No)	Overall Strength Rating	Recommendation
# Good: # Fair:	Substantial	3 Yes / No	4	5
# Good: # Fair:	Moderate			
# Good: # Fair:	Minimal / None			
# Good: # Fair:	Adverse			

1

2

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

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Practices

Laboratory Medicine Best Practices Evidence-Based Recommendations

Recommendation Categories	Definition
Recommend ('Best Practice')	**Consistent** and **high** or **moderate** overall evidence of effectiveness strength rating of desirable effects
No recommendation for or against	Insufficient evidence to determine effectiveness
Recommend against	Consistent and **high** or **moderate** overall evidence of effectiveness strength rating adverse effects

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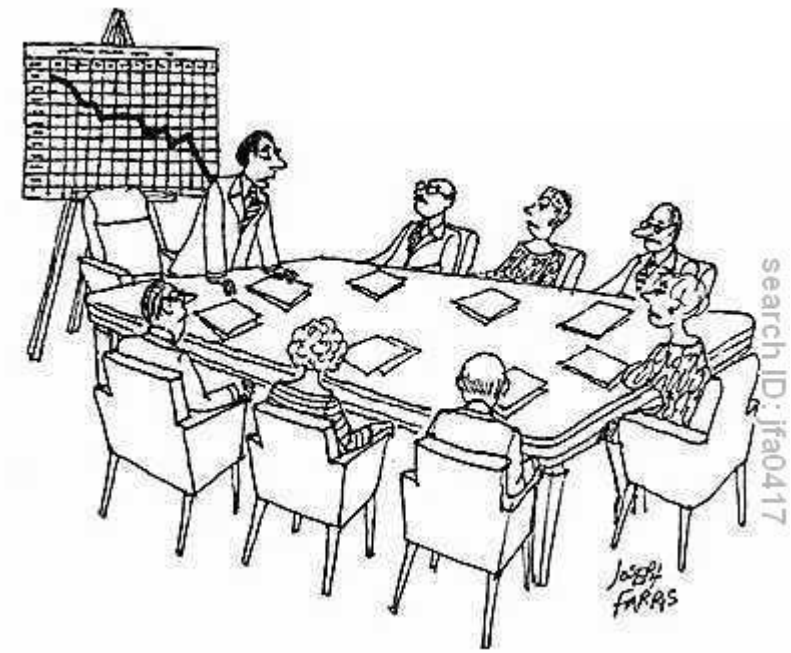
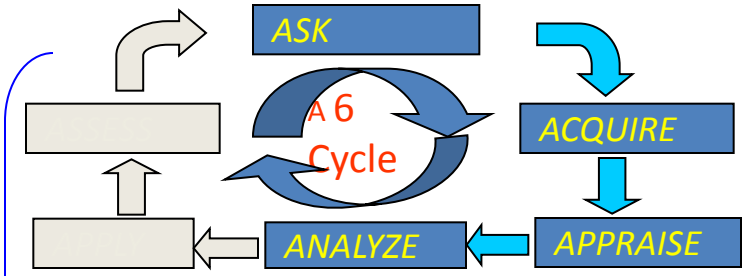
LMBP Evidence-based Recommendation



Workgroup

Expert Panel



Overall Evidence Rating				
Individual Study Quality	Individual Effect Size	Consistency (Yes / No)	Overall Strength Rating	Recommendation
# Good: # Fair:	Substantial	3	4	5
# Good: # Fair:	Moderate			
# Good: # Fair:	Minimal / None			
# Good: # Fair:	Adverse			

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

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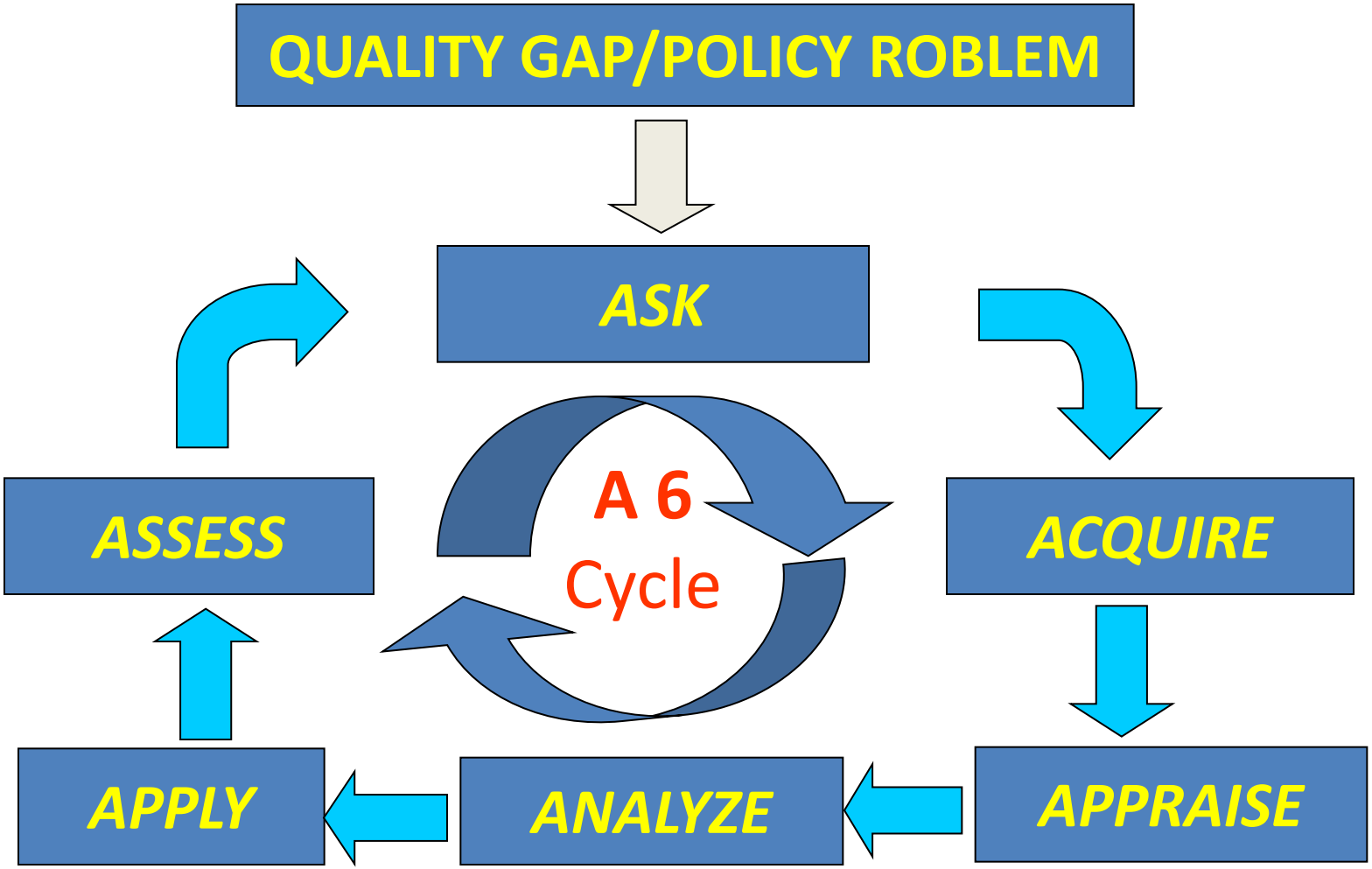
LMBP Systematic Review Methods A-6 Cycle



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Meeting Laboratory Practitioners' Needs

COMMON SCENARIOS THAT REQUIRE EVIDENCE-BASED DECISION MAKING

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An Administrative Director wants to request new technology

- Patient specimen identification errors continue to be a major problem despite the implementation of new identification guidelines. The medical center is considering a bar-coding system to reduce patient specimen identification errors.
- The Laboratory Administrative Director is requested to evaluate the benefits of this new technology.

Question: How does the Administrative Director determine if this practice (bar coding systems) has been effective in other settings?

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An Emergency Department physician wants the laboratory to improve MRSA testing turn-around-time

- Patient admissions with potential infectious conditions are on the rise, and the bed management coordinator needs information in a timelier manner to make room assignments. These patients remain in the ED for an extended period of time until the laboratory results are reported. This creates a longer waiting time for new patients arriving in the emergency department.
- The Microbiology Supervisor is requested to evaluate new tests that may result in an improvement in TAT.

Question: How does the Microbiology Supervisor evaluate other tests on the market that will result in effective patient admissions?

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A Diabetes Center Manager wants to change the mode of delivery of care

- The clinicians at a Diabetes Center want to improve patient compliance. They have read that HbA1c is available in a point of care testing (POCT) device and can improve the management of the patient's condition by providing test results at the time of patient consultation and thus improve patient outcomes.
- The Manager is asked to contact the hospital laboratory's Chemistry Supervisor to help evaluate the effectiveness of POCT device in other settings and its potential implementation.

Question: How does the Chemistry Supervisor evaluate the evidence on the use of POCT for HbA1c.

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Applying an Evidence-Based Approach to Laboratory Medicine

Using evidence to evaluate practice effectiveness can help laboratory professionals and healthcare stakeholders to:

- Determine what practices are effective, for whom and in what settings(s)
- Inform clinical decision making
- Improve patient care and outcomes
- Promote transparency and accountability

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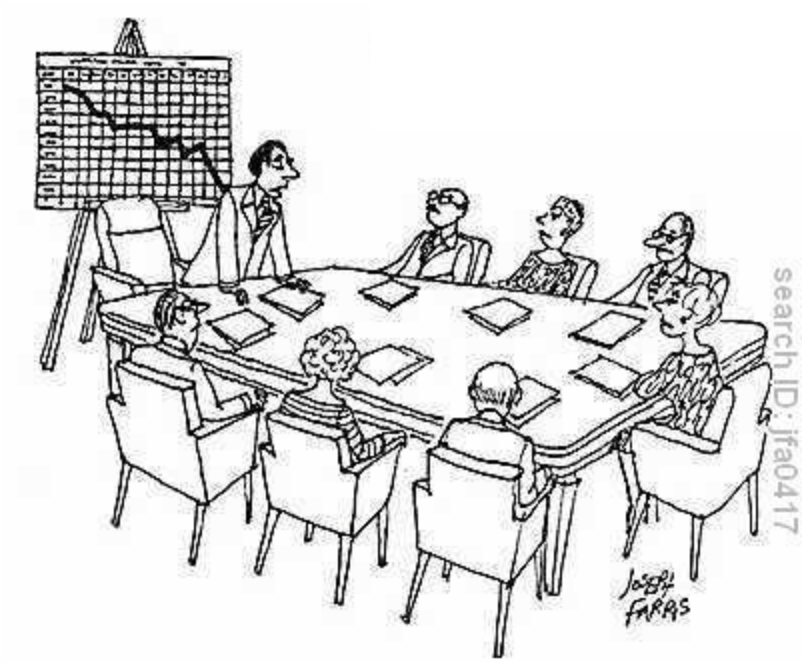
How are Topics Identified?

Two Groups of Advisors



Let's keep the big picture in mind

Workgroup

"We're getting down to nuts and Bolts"

Expert Panel

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How Are Topics Identified? Additional Input:

- Personnel from LMBP Team (CDC/Battelle)
- Professional Organizations
- Accrediting Agencies
- LMBP Website
- Communications with Laboratory Professionals

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Major Criteria for Topic Selection

Consistent with one or more of IOM Aims

- Patient-centered
- Safe
- Effective
- Efficient
- Equitable
- Timely

Topic represents a practice in the pre- or post-analytic stage of testing process

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Topics Completed in Methods Validation Phases

- Reporting critical values
- Patient specimen identification
- Reducing blood culture contamination

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Practices to Reduce Blood Culture Contamination

Example of LMBP A-6 Process Applied

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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

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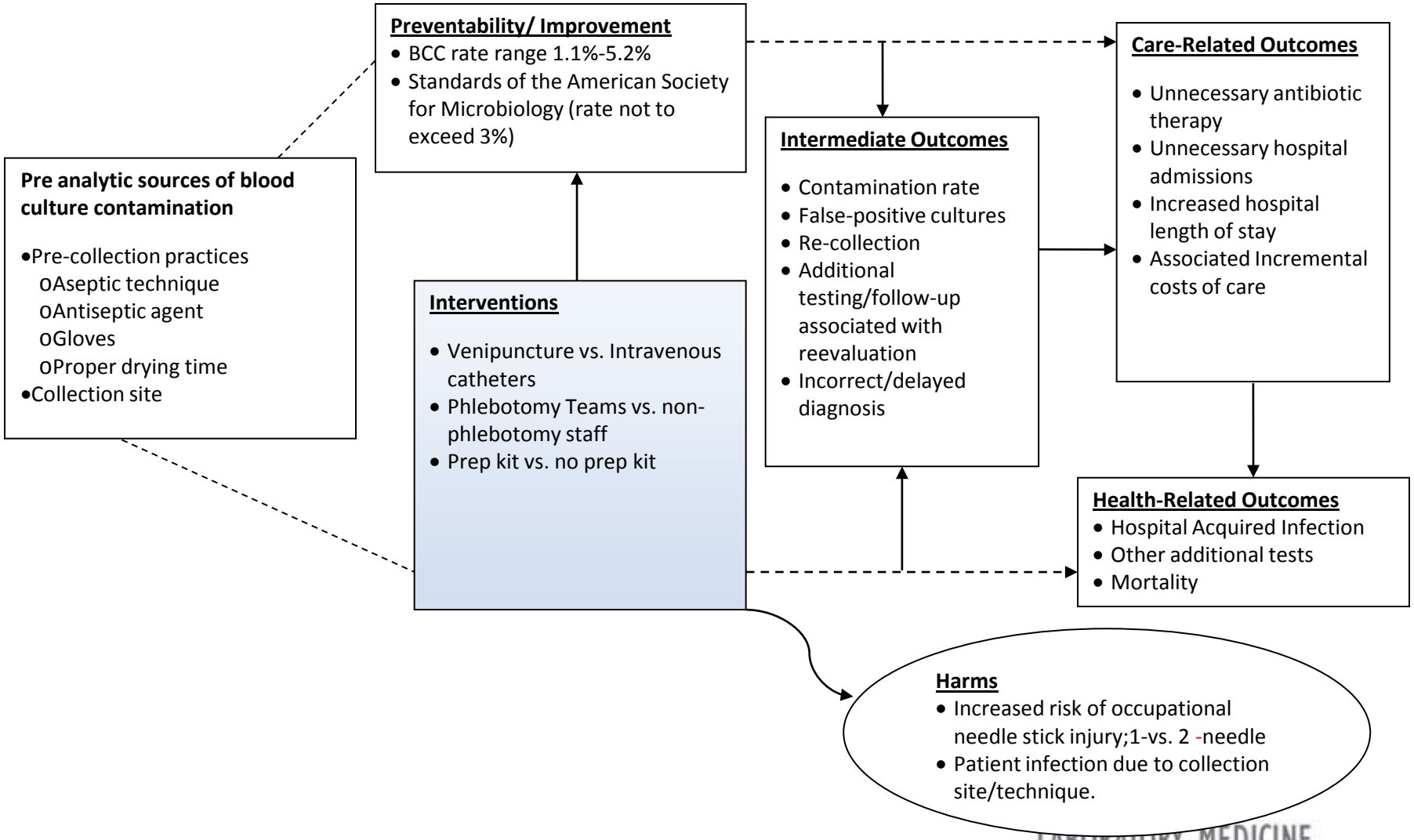
LMBP Review Question

ASK

- What interventions/practices are effective at reducing contamination of blood cultures drawn from hospitalized patients?

ASK - Evidence Review Question: What interventions/practices are effective at reducing contamination of blood cultures drawn from hospitalized patients?



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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

9 found by hand searching, 5 excluded

14 pre abstraction articles

Unpublished Assessments

Venipuncture
0 submitted

Phlebotomy Teams
5 submitted
2 included

Prepackaged prep kits
2 submitted
0 included

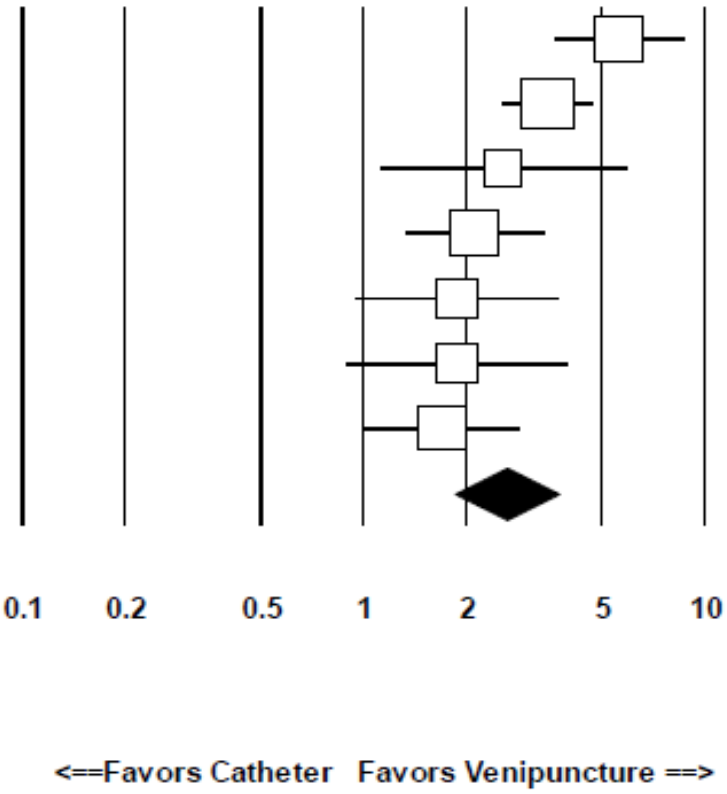
14 Published Studies
2 Unpublished Studies

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

Venipuncture (versus Intravenous Catheter) Meta-Analysis

Study name	Statistics for each study		
	Odds ratio	Lower limit	Upper limit
McBryde 2005	5.60	3.61	8.69
Norberg 2003	3.46	2.55	4.69
Martinez 2002	2.57	1.12	5.89
Everts 2001	2.12	1.32	3.40
DesJardin 1999	1.88	0.95	3.74
Beutz 2003	1.88	0.88	3.99
Ramsook 2000	1.70	1.01	2.85
	2.63	1.85	3.72

Odds ratio and 95% CI



◆= 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.

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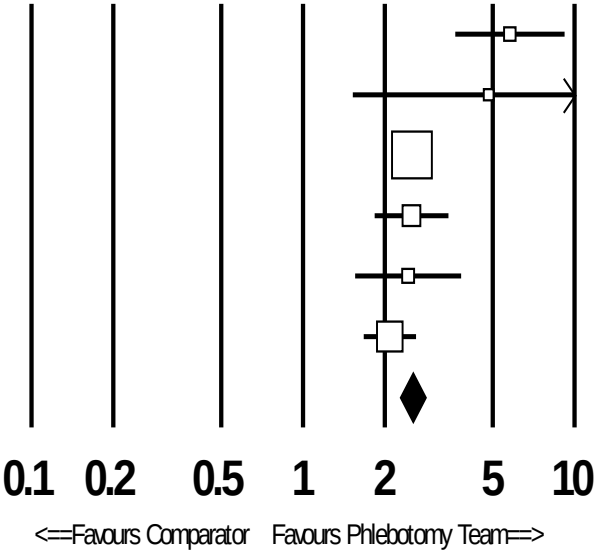
Phlebotomy Team
Meta-Analysis

Study name	Subgroup within study	Odds ratio	Lower limit	Upper limit
Weinbaum 1997#	Combined	5.78	3.64	9.17
Sheppard 2008	N/A	4.83	1.53	15.26
Geisinger 2009	N/A	2.52	2.18	2.91
Gander 2009	N/A	2.51	1.84	3.43
Providence 2009	Combined	2.44	1.56	3.82
Surdulescu 1998*	N/A	2.09	1.68	2.61
		2.53	2.28	2.81

Odds ratio and 95%CI



Boxes proportional to weights

◆= Phlebotomy team summary effect size

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)

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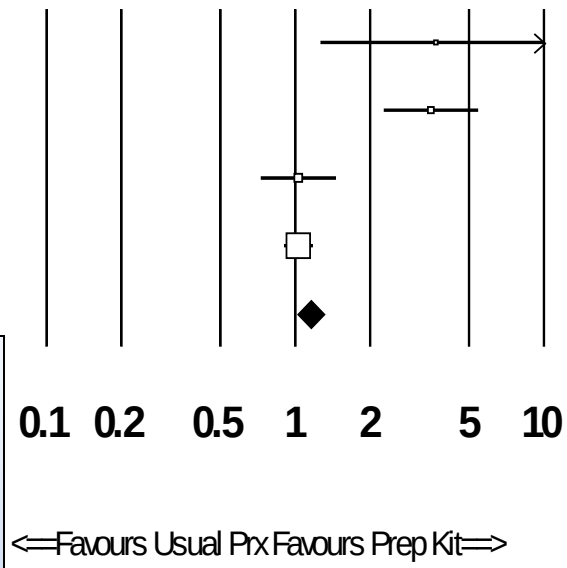
Prepackaged Prep Kits
Meta-Analysis

Study name	Subgroup within study	Odds ratio	Lower limit	Upper limit
Trautner 2002	Prep v Usual prx	3.68	1.26	10.74
Weinbaum 1997	Combined	3.51	2.27	5.45
McLellan 2008	Combined	1.03	0.73	1.46
Wilson 2000	Combined	1.03	0.90	1.18
		1.15	1.02	1.30

Odds ratio and 95% CI



◆= Prep kits summary effect size

Prepackaged prep kits are <u>not</u> 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

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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.

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Future plans for blood culture topic

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

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LMBP Initiative is Fighting These Culprits For You

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Additional LMBP Pilot Project Findings

- New LMBP methods can be used for systematically reviewing and evaluating quality improvement practices
- Quality improvement projects and efforts routinely conducted by laboratories generate relevant data for inclusion in systematic evidence reviews
- Data from quality improvement projects can be used as evidence of practice effectiveness
- Many quality improvement projects fail to meet minimum research standards for good study design

LMBP Educational Objective

- Develop and implement an education / curriculum strategy that familiarizes laboratory professionals with methods for improving the quality of unpublished process improvement / quality assurance studies so that data from these studies are consistently available to inform best practice recommendations.

LMBP Educational Activity

Development of a four-part, self-guided tutorial to:

- Increase awareness about new LMBP evidence-based methodology for conducting systematic evidence reviews, and
- Increase the competence in application of evidence-based principles to quality improvement (QI) projects or research
- Online Module 1 anticipated 1st quarter of 2011 at www.futurelabmedicine.org

Building a Curriculum for Evidence-based Laboratory Medicine

Solving a clinical problem using an evidence-based approach is a cyclical process that begins with generating an answerable question and ends with assessing the process.

Core Skills

- Designing outcomes projects
- Formulating answerable questions
- Searching the literature
- Critical appraisal of data
- Interpret analysis of data / meta-analysis
- Writing papers

Sustainability

Gerald O'Hara (Thomas Mitchell): On Sustainability

Do you mean to tell me, Katie Scarlett O'Hara, that Tara, that land doesn't mean anything to you?
Why, land is the only thing in the world worth workin' for, worth fightin' for, worth dyin' for,

because it's the only thing that lasts.

LMBP systematic reviews get as close the truth as possible. Worth workin' for, worth advocatin' because it's the only thing that lasts.

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Sustainability

- Enlisting partners to support dissemination and uptake of best practices
- Topics in the pipeline
- Suggestions for panelists and feedback on topics: ASM
- Formal recognition of the need for the application of systematic review methods and the use of evidence-based best practices in LM

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LMBP Partner Organizations

American Society for Clinical Laboratory Sciences

Consortium on Office Laboratory Accreditation

Sustainability

- Enlisting partners to support dissemination and uptake of best practices
- Topics in the pipeline
- Suggestions for panelists and feedback on topics: ASM
- Formal recognition of the need for the application of systematic review methods and the use of evidence-based best practices in LM

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Proposed new review topics

- **Hemolysis**: What practices are effective at reducing rejection by the clinical laboratory of samples drawn from in-patient and ED patients due to hemolysis as a sample quality issue?
- **Cardiac Biomarker Testing**: Will the adoption of serial point of care testing of cardiac troponin effectively increase accurate myocardial infarction diagnosis, reduce time to treatment, increase appropriate patient disposition and improve patient outcome among ED patients presenting with symptoms suggestive of Acute Coronary Syndrome?
- **Rapid Identification of Bloodstream Infections**: What practices are effective at increasing timeliness of providing targeted therapy for in-patients with diagnosed bloodstream infections to improve clinical outcomes (LOS, morbidity, mortality)?

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Sustainability

- Enlisting partners to support dissemination and uptake of best practices
- Topics in the pipeline
- Suggestions for panelists and feedback on topics: ASM
- Formal recognition of the need for the application of systematic review methods and the use of evidence-based best practices in LM

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Review Questions from ASM Workshop

- **What practices are effective at increasing timeliness of providing targeted therapy for inpatients with diagnosed bloodstream infections *(positive blood cultures?)* to improve clinical outcomes (LOS, morbidity, mortality)?**
- What practices following specimen collection are effective at reducing false positive diagnoses of Urinary Tract Infections (UTI)?

Sustainability

- Enlisting partners to support dissemination and uptake of best practices
- Topics in the pipeline
- Suggestions for panelists and feedback on topics: ASM
- Formal recognition by CLIAC of need for a sustainable mechanism of applying systematic review methods and the use of evidence-based best practices in laboratory medicine.

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Questions for the Committee

- Does the Committee agree that the LMBP approach to selecting and qualifying topics for evidence reviews is appropriate for identifying important evidence-based best practices in Lab Medicine?
- Would the Committee please comment on the list of new topics proposed for systematic reviews?
- Would the Committee please comment on other key topic areas, focusing on pre- and post-analytic stages of the total testing process, that it would like to see the LMBP Initiative add to its future calendar?
- Would the Committee consider formally recognizing the value of continuing the LMBP Initiative in a sustained fashion ?

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Thank You

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For more information: www.futurelabmedicine.org

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