Laboratory Medicine Best Practices: Developing an Evidence-Based Review and Evaluation Process

Final Technical Report 2007: Phase I

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Acknowledgments

The following report represents the collective efforts of many people dedicated to improving the quality of laboratory medicine. The authors would like to recognize several people whose support, guidance, expertise, and commitment have made it possible to develop an evidence-based process for identifying best practices.

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Laboratory Medicine Best Practices: Developing an Evidence-Based Review and Evaluation Process

Final Technical Report 2007: Phase I

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Executive Summary

Clinical laboratory services play a vital role in the delivery of individual health care and public health in the United States. The U.S. Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services (CMS) certifies over 200,000 laboratories in the United States under the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[1] These laboratories provide more than 1,000 laboratory tests for human conditions; about 500 of these tests are used daily.[2]

The Centers for Disease Control and Prevention (CDC) is committed to organizing a national effort to promote the use of best practices in laboratory medicine. In response to the Institute of Medicine's call to improve quality in medicine,[3] CDC's Division of Laboratory Systems (DLS) is supporting the development of a systematic, evidence-based process to identify best practices in laboratory medicine.

This effort was undertaken in October 2006 when DLS convened the Laboratory Medicine Best Practices Workgroup, a multidisciplinary advisory panel including experts in laboratory and clinical medicine, health systems and policy research, performance measurement, and standard setting. The Workgroup was supported by a team from DLS and a contractor, Battelle Memorial Institute (Battelle). The goal of the effort is to develop a process for making best practice recommendations that will assist professional organizations, government agencies, laboratory professionals, clinicians, and others who provide, use, regulate, or pay for laboratory services.

The process focuses on improving laboratory medicine by identifying and evaluating best practices that achieve the following:

- Enhance the quality of laboratory services and patient outcomes.
- Reduce redundancy and waste.
- Enable laboratories to define opportunities for quality improvement.

To date, the Laboratory Medicine Best Practices development process has two phases.

Phase I (October 2006 – September 2007)

The key steps involved in Phase I of this project included the following:

- Establish key terms and definitions related to best practices in laboratory medicine.
- Develop inclusion and exclusion criteria for candidate laboratory medicine practices.
- Create a classification scheme for organizing candidate practices.
- Identify priority criteria and topic areas for candidate practices.
- Develop systematic review methods to comprehensively search the literature and other relevant information sources, screen references, abstract data, and summarize results.
- Create an evaluation framework for making best practice recommendations on the basis of assessment of a practice's potential impact (effect size and feasibility) and the strength of evidence.
- Conduct a proof of concept exercise to test the review methods and evaluation framework.

- Assess results of the proof of concept and make necessary revisions to the process methods.
- Define strategic organizational and implementation constructs.
- Determine the next steps for Phase II.

Developing methods for identifying and evaluating candidate practices was challenging because of the limited availability of peer-reviewed, published, and accessible evidence related to laboratory medicine practices. As the Support Team and Workgroup progressed through the proof of concept exercise, the need to modify standard systematic review methods to address the state of evidence in the field of laboratory medicine became apparent. Members of the Workgroup agreed that considerably more evidence that is not accessible by conventional means might be available.

To address the need to find and incorporate more evidence into the process, the Workgroup recommended that a systematic and transparent methodology be created to include unpublished evidence that is not readily accessible. This methodology includes an "investigational component" to review, in a systematic fashion, evidence from sources that are not traditionally considered in the evaluation of medical evidence of effectiveness. This component incorporates a process loop to refine the evidence base over time as additional data become available.

Phase II (October 2007 – September 2008)

In Phase II, the key components are to

- Refine and develop process review and evaluation methods.
- Develop the investigational component recommended in Phase I.
- Develop a laboratory network for soliciting practices and evidence.
- Pilot test the process.
- Evaluate alternative organizational structures for implementing and sustaining this process.

Once Phase II is completed, the process will be more refined, and a new investigational component will be added to address the evidence gap in the literature. Efforts are under way to ensure that the Laboratory Medicine Best Practices recommendation process is sustainable and facilitates dissemination of best practices to relevant stakeholders.

Background

Laboratory medicine is an essential part of health care systems. More than 200,000 U.S. laboratories are certified by the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) under the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[1] CLIA regulations set minimum quality standards for clinical laboratory testing.

National initiatives that address all areas of health care should include laboratory practices. The Agency for Healthcare Research and Quality (AHRQ) has led national efforts to review and compile available information in its National Guidelines Clearinghouse and National Quality Measures Clearinghouse. AHRQ also is building a database of health service delivery innovations for its new initiative, the AHRQ Health Care Innovations Exchange. Laboratory medicine practices that satisfy AHRQ's inclusion criteria may be included in these databases.[4] The National Quality Forum (NQF) is conducting numerous projects to endorse consensus-based recommendations for health care-related performance measures and practices that include screening, diagnosing, and treating various chronic and infectious diseases, and patient safety practices.[5]

In laboratory medicine, efforts to develop guidelines, standards, policies, and best practice recommendations have typically been independent ventures that serve specific fields or professions. Professional organizations and industry associations, such as the College of American Pathologists (CAP), the Clinical and Laboratory Standards Institute (CLSI), and the Clinical Laboratory Management Association (CLMA), have developed approaches to recommending and disseminating quality practices. In some cases, government agencies and accrediting bodies have recognized these recommendations as meeting regulatory and accreditation requirements.

A more global approach to evidence-based recommendations is needed because many processes affect quality in laboratory medicine. Errors can be introduced in selecting and ordering appropriate clinical tests, obtaining patient specimens, conducting tests, reporting results to clinicians, and interpreting laboratory results.[6]

The following commonly encountered errors[7] can reduce patient safety or otherwise contribute to adverse health outcomes for patients, and diminish health care quality and patient satisfaction:

- Ordering the incorrect sequence of tests.
- Incorrectly identifying the patient and specimens.
- Performing laboratory tests improperly.
- Interpreting results incorrectly.
- Communicating results inaccurately.
- Misinterpreting or failing to understand the clinical significance of test results.

The potential consequences of these errors, virtually all of which can be reduced or prevented through changes in systems and processes, demonstrate the need for an evidence-based model for recommending laboratory medicine practices. Reinforcing this need is the continual evolution of medical technology, the emergence of entirely new fields of testing

(e.g., pharmacogenomics), and the discovery of new applications for existing laboratory tests. A systematic approach is needed to identify laboratory practices that are effective in reducing error rates, improving patient outcomes, and increasing efficiency.

Recognizing these opportunities for errors in the multifaceted process of clinical laboratory testing, CDC's Division of Laboratory Systems (DLS) is leading a concerted national effort to apply an evidence-based approach to evaluating and recommending best practices in laboratory medicine, consistent with Institute of Medicine (IOM) recommendations.[3,8] No single evidence-based model for recommending practices in laboratory medicine exists, although the number of laboratories operating in the United States and the volume of laboratory tests available certainly warrant such a model. Of more than 1,000 laboratory tests for human conditions, about 500 are used daily.[2] These tests help health care practitioners and patients make decisions about disease prevention, assessment, diagnosis, treatment, and management and are key components in clinical decision making.[9]

In evidence-based medicine, clinical anecdotes and expert opinion can be taken into consideration in evaluating the effectiveness of an intervention, service, or practice, but only in conjunction with a body of scientifically valid, peer-reviewed evidence.[10] The term *evidence-based medicine* first appeared in the literature in 1990 and began to flourish in 1993, with the publication of a 25-part series in *JAMA* titled *The User's Guide to Medical Literature.*[11] Evidence-based medicine applies criteria to interpreting and evaluating the validity of evidence and the value of clinical information before clinical decision making.[6,12,13]

Laboratory medicine best practice recommendations should be supported by evidence-based evaluations. Yet evidence demonstrating the effect of laboratory testing on health outcomes or even on intermediate clinical outcomes and process outcomes is extremely limited. Laboratory tests and associated practices are part of a more encompassing total testing process,[14] and health outcomes are affected by a combination of multiple steps in this process. In addition, more basic evidence of effectiveness is missing for some well-accepted practices, standards, recommendations, and requirements because historical application is taken as ample support in lieu of well-designed studies.

As part of an initiative to improve quality in laboratory medicine, DLS convened a multidisciplinary 14-member Laboratory Medicine Best Practices Workgroup, which was charged with developing an evidence-based process to identify, evaluate, and recommend best practices in laboratory medicine. This process addresses how to make best practice recommendations that would provide guidance to professional organizations, government agencies, laboratory professionals, clinicians, and others who provide, use, regulate, or pay for laboratory services. The process is designed to improve laboratory medicine by identifying and evaluating best practices that

- Enhance the quality of laboratory services and patient outcomes.
- Reduce redundancy and waste.
- Enable laboratories to define opportunities for quality improvement.

Efforts are under way to ensure that the Laboratory Medicine Best Practices recommendation process is sustainable by building an infrastructure that is based on partnerships and facilitates dissemination of best practices to relevant stakeholders.

Methods

Process Development

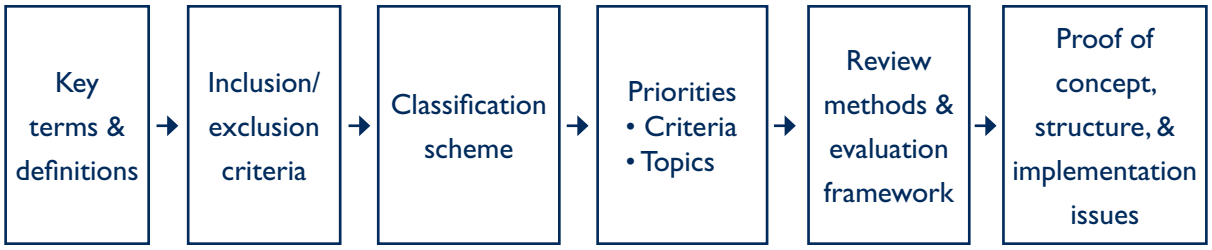
This report describes DLS' initial development of a systematic, evidence-based process for making best practice recommendations. A Support Team that included CDC and Battelle staff worked with the Laboratory Medicine Best Practices Workgroup to develop the overall approach, which involved the following steps:

1. Establish key terms and definitions related to best practices and laboratory medicine.
2. Develop inclusion/exclusion criteria for candidate laboratory medicine practices.
3. Create a classification scheme for organizing candidate practices.
4. Identify priority criteria and topic areas for candidate practices.
5. Develop systematic review methods to comprehensively search the literature and other relevant information sources, screen references, abstract data, and summarize results.
6. Create an evaluation framework for making best practice recommendations based on assessment of a practice's potential impact (effect size and feasibility) and the strength of evidence.
7. Conduct proof of concept to test the review methods.
8. Assess results of the proof of concept and make necessary revisions.
9. Define strategic structural and implementation constructs.
10. Determine the next steps to be included in Phase II.

Development Process At a Glance

Oct 2006	CDC DLS launches effort to recommend best practices
Dec 2006	Workgroup kickoff phone conference
Jan 2007	First Workgroup In-Person Meeting
Feb–Mar 2007	Initial development of review methods and evaluation framework
Apr–May 2007	Review of literature/proof of concept for review methods
Jun 2007	Second Workgroup In-Person Meeting
Jul–Nov 2007	Report developed and next steps determined
Dec 2007	Final Report

The following schematic depicts the team's approach to developing this process. See Appendix A for a more detailed illustration.



Expert Workgroup Selection

To be effective, the Laboratory Medicine Best Practices process needs to be developed by stakeholders representing a broad array of scientific, practitioner, payer, and patient communities. Thus, CDC convened a multidisciplinary panel of experts to create this process (see Appendix B). Members of the Laboratory Medicine Best Practices Workgroup were recruited and selected on the basis of their experience, interest, and expertise in one or more of the following categories:

- Performance measurement
- Health systems
- Health policy research
- Clinical practice
- Standard setting
- Laboratory management

Workgroup members were asked to participate in two face-to-face 2-day meetings and multiple conference calls. They also provided e-mail feedback in response to specific queries and document drafts. The 14-member Workgroup was supported by staff from DLS and Battelle (Support Team).

In-Person Workgroup Meetings

The goal of the first Workgroup meeting (January 2007) was to gain input on the conceptual approach for the methodology that members would use to develop the process. Workgroup members discussed and offered recommendations on working definitions, inclusion and exclusion criteria, classification systems, topic priorities, and review and evaluation methods. The Workgroup had the opportunity to comment on the conceptual approach during the meeting and to answer directed questions in a follow-up inquiry.

After the first Workgroup meeting, two subgroups were created—one focusing on developing a methodology for evidence reviews (Review Methods Subgroup) and the other focusing on developing an evaluation framework (Evaluation Subgroup). These subgroups worked via e-mail and conference calls.

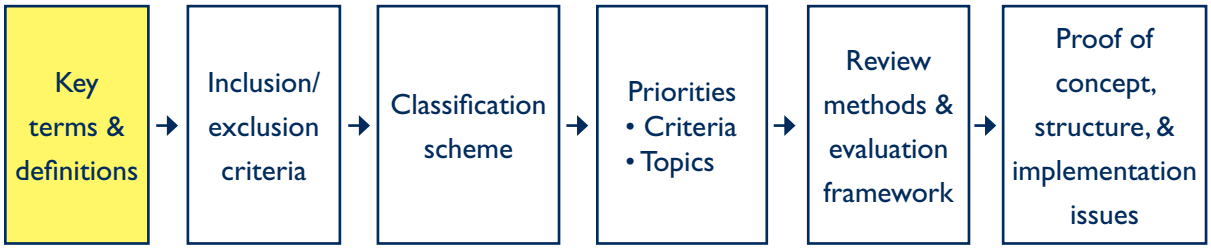
The objectives of the second Workgroup meeting (June 2007) were to review work completed on the methodology for evidence reviews and the evaluation framework, and to make recommendations for further development. Meeting discussion included 1) review and refinement of methods for identifying and reviewing candidate best practices, 2) general criteria for evaluating and recommending best practices, and 3) next steps for pilot-testing the process and disseminating recommendations.

The Workgroup used a series of proof of concept exercises to apply proposed methods to reviewing and evaluating candidate practices in the topic area of patient/specimen identification, a priority area identified by the Workgroup. Members also addressed specific conceptual and operational features for the process, especially as these features related to an organizational structure.

Workgroup members had the opportunity to comment on the meeting summaries and to provide an overall evaluation of the process, the in-person sessions, and the facilitation of the sessions.

Process Development Constructs

Definitions



Working definitions for best practices and laboratory medicine were reviewed and revised by the Workgroup during the kickoff call and at the first in-person meeting. The Workgroup emphasized the need for simple and comprehensible definitions.

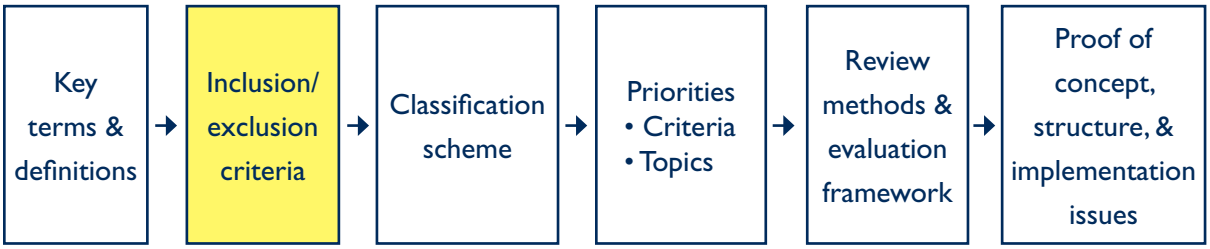
Workgroup members expressed concerns about using the term *best* to describe practices, and suggested alternatives such as *quality*, *effective*, and *preferred*. The term *quality* was rejected because laboratory practices may not match the domains of quality assessment and management as these are understood in the broader health care system. *Effective* was excluded out of concern that it implied a linkage that might not be available between the practice and some favorable health outcome, and because it might not capture other domains. *Preferred* was excluded because it raised questions about who prefers the practice and implies endorsement of one practice or policy over another. In the end, members of the Workgroup decided to use the term *best practices* because it is commonly used and widely understood in the field.

The Workgroup members agreed that *laboratory medicine* should be defined in an inclusive manner and opted to categorize laboratory medicine testing services into "assessment, diagnosis, treatment, management, or prevention of health-related conditions" instead of trying to list individual types of testing. Moreover, by adding "any test or examination of materials derived from the human body," the definition for *laboratory medicine* includes the realm of testing and also focuses on human laboratory tests in contrast to environmental, veterinary, or other types of laboratory testing.

Laboratory Medicine Best Practices Definitions

- ***Best Practices*** are practices integral to the provision of laboratory medicine services that increase the probability of beneficial patient outcomes, as demonstrated by scientific evidence (or in the absence of such direct evidence, consensus expert opinion) that the practice in question supports the Institute of Medicine's (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.
- ***Practices*** are protocols, procedures, policies, techniques, processes, systems, standards, incentives, activities, and interventions that are used to provide health care to patients.

Inclusion/Exclusion Criteria



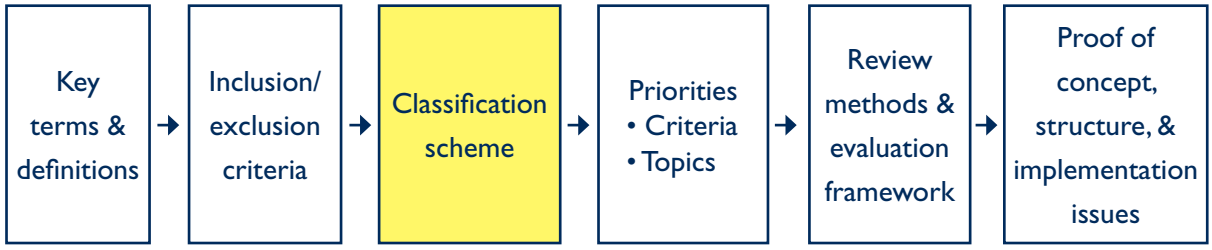
Minimum Inclusion Criteria

- The practice is in current use and available for immediate application.
- The practice can be reproduced in other comparable settings.
- The practice impacts a defined group of patients.
- The practice relates to at least one of the following aspects of care for a health condition:
  - Assessment/Screening
  - Diagnosis
  - Treatment
  - Management
  - Prevention
- The practice identifies a potential improvement in an outcome that can be related to at least one of the following aspects of patient care (IOM domains):
  - Effectiveness
  - Efficiency
  - Equity
  - Patient-centeredness
  - Safety
  - Timeliness
- The practice is supported by some evidence of effectiveness or by expert opinion reached through a systematic, multidisciplinary derivation process.

Workgroup members were asked to develop the minimum criteria for a practice to be considered for the Laboratory Medicine Best Practices process. These parameters represent the basic criteria for a practice to be considered for further and more detailed evaluation. Key components of the inclusion criteria are that the practice is current, replicable, population-based, has potential to improve outcomes, and is supported by direct evidence of effectiveness or by expert opinion. The Workgroup discussed the limited quantity and quality of scientific evidence available for laboratory medicine practices and the difficulty creating a hierarchical model for rating these practices.

Members agreed that the "opinions of respected authorities based on clinical evidence, descriptive studies of clinical reports, or reports of expert committees" would be an acceptable minimum level of evidence for a candidate practice in lieu of some level of direct evidence. However, the Workgroup members expressed a preference for a systematic, multidisciplinary evaluation process.

Classification Scheme



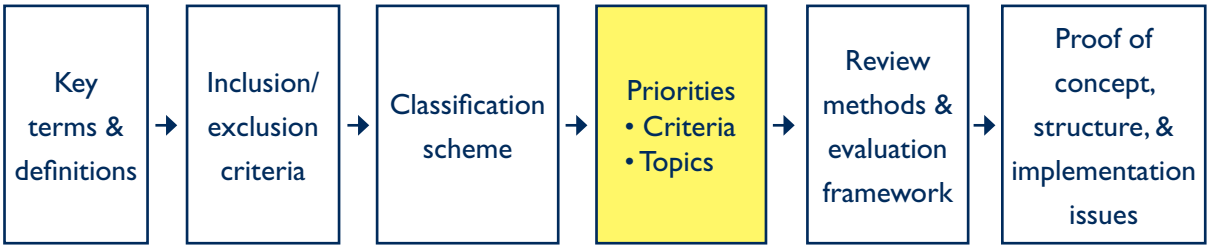
The Workgroup reviewed the following classification schemes:

- Clinical conditions (e.g., diabetes, heart disease, infectious disease).
- Health care settings (e.g., hospital, physician office, point-of-care, nursing home).
- Laboratory total testing process (pre-analytical, analytical, post-analytical).

- National health care quality priorities (e.g., NQF, IOM, AHRQ).
- Functional model (based on the continuum of care for analytical individual patient testing within a single disease process).
- IOM continuum of care across the life span based on the developmental periods of a patient's life (i.e., newborn, adolescent, adult).
- Hybrid model based on a report issued by NQF,[15] which combines the laboratory total testing process and national health care quality priorities based on an evidence-based review of guidelines and performance measures associated with laboratory tests.

The Workgroup members reached a general consensus to use an expanded version of the total testing spectrum of laboratory medicine similar to the hybrid model in the NQF report. They recommended focusing on the pre-analytic and post-analytic components of the total testing process, with particular attention to communication between the laboratory and clinicians to ensure that test results are appropriately interpreted. This focus should be balanced with a global perspective on the testing process through the health care continuum, which encompasses all areas of laboratory medicine. The Workgroup also acknowledged that such a hybrid model would be more useful than a linear model.

Priorities



The Workgroup considered several methodological models for identifying priority topic areas for evidence-based systematic reviews and recommendations. These included *The Community Guide*,[16] the National Academy of Clinical Biochemistry's (NACB) *Laboratory Medicine Practice Guidelines (LMPG)*,[17] the U.S. Preventive Services Task Force's (USPSTF) *Guide to Clinical Preventive Services*,[18] and the Oxford Centre for Evidence-Based Medicine's *Levels of Evidence*.[19] When the criteria for setting priorities used in these models are compared, considerable overlap becomes apparent. Although the terminology used differs among the models, they have the following constructs in common:

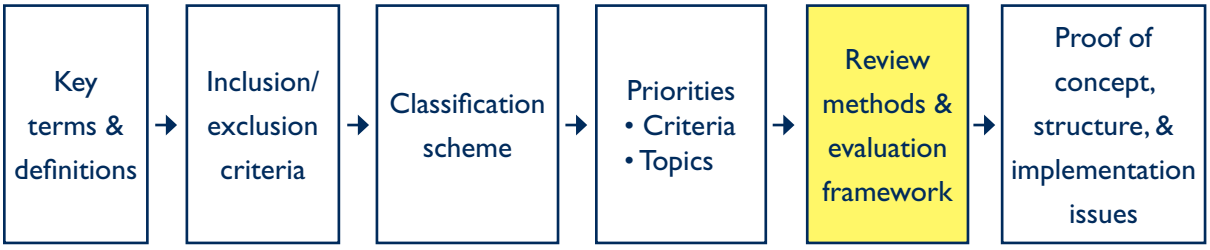
- Burden of the problem
- Preventability
- Availability of existing knowledge
- Potential effectiveness
- Operational management
- Economic benefit

The Workgroup completed an exercise intended to identify topic areas for development of best practices. From this list, *lack of accurate patient identification and labeling of specimens* was chosen as the topic area for completing the Phase I proof of concept, a preliminary test of this process. This topic area offered some evidence of the effectiveness of practices and many challenges that are not unique to this topic area (e.g., lack of standardized definitions and practices). Thus, this topic area offered a good first test of the process methods.

Workgroup Priority Topics (January 2007)

- Identification of organizational structures that promote good management.
- Lack of accurate patient identification and labeling of specimens.
- Accurate incorporation of results into patient treatment plan.
- Communication between laboratory and ordering physician about which test to select and clinical significance of results.
- Electronic display of laboratory data (i.e., how it will be displayed).
- Accessibility of laboratory services.
- Post-analytic reporting of results.
- Read back of critical value test results and test ordering.
- Challenge of integrating laboratory information with other clinical data to optimize patient safety.
- Identification of practices that have high probability for improving quality care.
- Finding the best way to handle information transmissions between laboratory and offices.
- Reporting results to the patient.
- Appropriate blood product selection.
- Promoting the value of laboratories (to the general public and clinicians).
- Standardized policies for training and continual training on how to collect samples.
- Setting up a Computerized Physician Order Entry system for ordering laboratory services.
- Ensuring that laboratory goals (National Quality Agenda) are met consistent with national health care priorities.
- Ensuring an appropriate and trained workforce.
- Ensuring monitoring of follow up of patients on the basis of laboratory results.
- Introduction and dissemination of new techniques to laboratories and physicians.
- Communication to patient before laboratory testing to ensure patient is aware of the process.

Review Methods



To develop the review methods needed to recommend best practices, the CDC Review Team completed a comprehensive review of methodology consistent with an evidence-based evaluation and recommendation process. With guidance from the Review Methods Subgroup, methods were developed, including an analytic framework, a literature search strategy, a data abstraction form, and an evidence summary table for each practice. These methods were then applied to the topic of patient/specimen identification. Workgroup members reviewed this work and provided recommendations on the review methods at their second in-person meeting.

Analytic Framework

An analytic framework (see Figure 1) shows how quality improvements in laboratory medicine can lead to positive outcomes. In the systematic review and assessment of evidence, an analytic framework is essential because it helps reviewers specify the issue/problem, determine how it can be prevented or performance improved, and identify interventions and practices that may ultimately improve health outcomes. The analytic framework also explicitly encompasses the identification of potential harms associated with the practice or intervention.

An analytic framework defines and clarifies the scope of a topic area (or subtopics within a topic area) so that it can be consistently applied by workgroups/teams. Putting these concepts and their relationships into a simple framework creates a structured approach to implementing review methods that will be adequately transparent and understandable to external reviewers. An application of the analytic framework for the quality issue of patient/specimen identification errors is illustrated in Figure 2.

Figure 1: Analytic Framework for Laboratory Medicine Topic

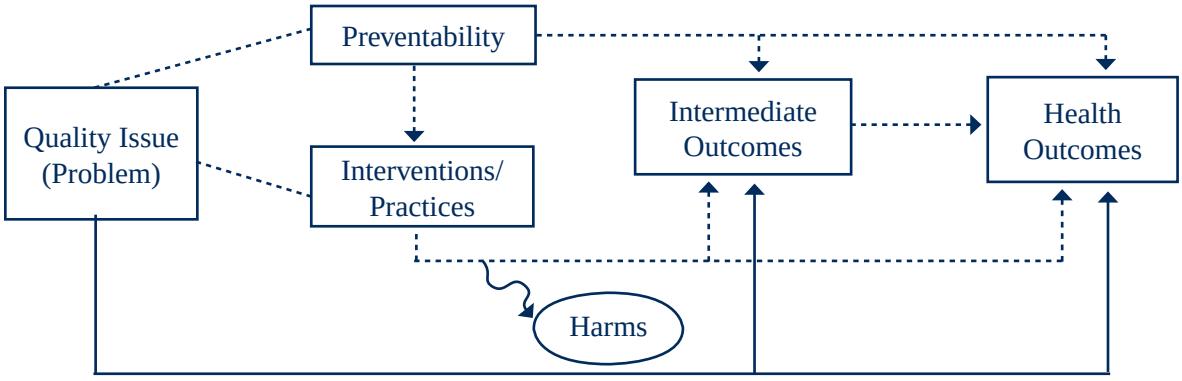
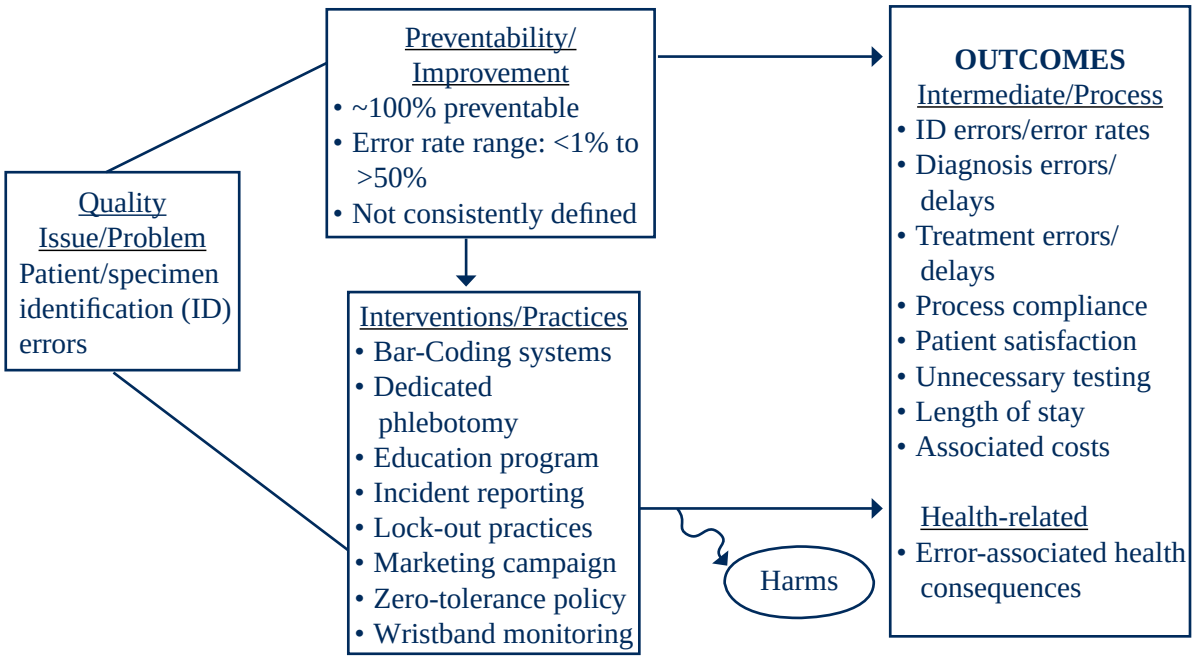


Figure 2: Patient/Specimen Identification Topic Analytic Framework



Initial Search Terms for Patient/Specimen ID Candidate Practices

- Laboratory identification (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.

Literature Search Strategy

The CDC Review Team developed a comprehensive literature search strategy to systematically review the literature and identify candidate best practices. Team members developed applicable search terms for the review topic of patient/specimen identification. The search strategy was limited to English language literature with publication dates no earlier than 1996.

Multiple databases were used to search the literature, including the following:

- PubMed
- Cochrane databases
- Professional guidelines electronic databases (e.g., CLSI, ISO, NACB)

The team members manually searched journals, reports, conference proceedings, guidelines, technical reports of relevance to the review topic, and reference lists of relevant publications. The search strategy also included consulting with Review Methods Subgroup members to identify further research and information relevant to the review.

Selection Criteria for Patient/Specimen ID Review Topic

The title or abstract of the article addresses

- ID errors in laboratory medicine/approaches for reducing ID errors.
- Error-detection methods for specimen/ID errors or frequency of errors.
- Patient/specimen ID errors.
- Quality improvement programs/patient safety initiatives to reduce specimen/ID errors.
- Technology to improve processes in areas of laboratory medicine.
- Literature that addresses specific case studies, guidelines, or conceptual frameworks for reducing ID errors.

Inclusion/Exclusion Criteria

Two reviewers independently screened titles and abstracts of identified literature using the initial topic-specific selection criteria and the minimum criteria for candidate practices developed by the Workgroup. These references were compiled to generate a table of pre-data abstraction references, which were grouped by practice area.

Full text copies of 58 relevant references were screened and reviewed independently by at least two reviewers using standard exclusion criteria developed by the CDC Review Team. Applying the standard exclusion criteria, 17 references were selected for full data abstraction. The selection process and review results are summarized in a flow diagram in Appendix C.

Standard Exclusion Criteria

- Practice not sufficiently described.
- Article/study did not assess practice.
- Article/study is commentary or opinion article.

Data Abstraction and Synthesis

A Data Abstraction Form was developed to consistently identify and then synthesize key components from the references (see Appendix D). The fields selected for abstraction were based on the information needed to summarize and evaluate the evidence. The abstraction form was primarily based on criteria established by *The Community Guide*,[16] the National Academy of Clinical Biochemistry,[17] and the U.S. Preventive Services Task Force.[18]

Components included in the abstraction form were

- Reference information
- Practice description and characteristics
- Implementation context
- Study description (e.g., design, sample size and characteristics, dates/time period, setting, comparators)
- Outcome measure types and descriptions
- Effect size
- Statistical analysis
- Internal and external validity
- Feasibility
- Cost
- Barriers
- Benefits (other than outcome measures)
- Potential harms (other than outcome measures)

Internal and External Validity

Internal Validity Rating: Based on how many of the following abstraction criteria were met:

- Outcome variable(s) clearly specified.
- Study sample groups comparable (e.g., pre- and post-intervention).
- Measurement methods comparable.
- Confounding factors addressed.

External Validity Rating: Based on a combination of the internal validity rating and how many of the following abstraction criteria were met:

- Finding(s) can be transferred to locations beyond those specifically included in the study.
- Identified practice can be applied to additional settings.

Most studies involving pre- and post-analytical laboratory medicine are likely to be practice-oriented research using nonrandomized, quasi-experimental, or observational designs. Compared with randomized controlled studies, these designs are considered to have greater limitations with respect to internal validity. By the same token, findings of observational and quasi-experimental study designs may be more broadly generalizable (i.e., have greater external validity) than are the findings of narrowly designed randomized studies.[20] Consequently, some assessment of the internal and external validity of studies included in the review was deemed appropriate to characterize the quality of the studies. Summary ratings of internal validity and external validity were developed on the basis of study characteristics reported in each article reviewed.

For the patient/specimen identification topic proof of concept, 17 references were selected for full review. Each reference was abstracted by at least two independent members of the CDC Review Team using the Data Abstraction Form, and the information was summarized using an evidence summary table for each practice. These were case studies or longitudinal studies. Three of the references included more than one practice and were used in evaluating multiple practices.

The references identified the following eight candidate best practices for reducing patient/specimen identification errors:

- Bar-coding identification systems
- Dedicated phlebotomy services
- Education program
- Incident reporting
- Lock-out practices
- Marketing campaign
- Zero tolerance policy
- Wristband monitoring

Evidence Summary Tables

The review team faced several expected challenges, including limited quality and quantity of evidence and the lack of clearly defined data elements that could be used to evaluate the candidate practices. As a solution, the review team created the following three categories of review information to account for the limited evidence on practice effectiveness:

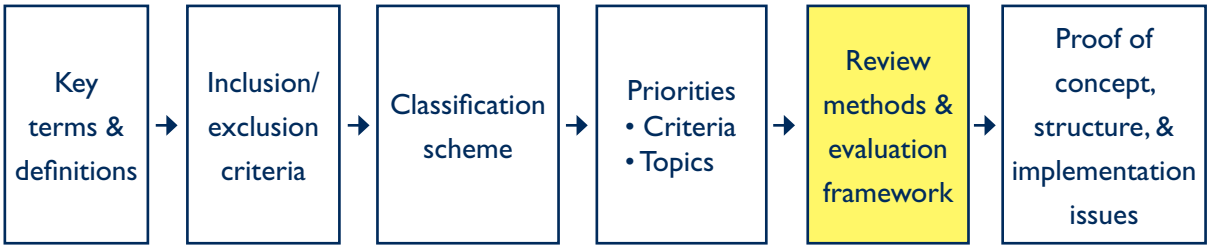
- *Evidence* includes articles that reported some quantified information related to the effect of a practice (i.e., effect size).
- *Feasibility Information Only* includes articles that reported information specific to practice implementation and/or cost.
- *Related Information* includes articles that were relevant to the practice but did not contain any data elements that could be consistently evaluated. However, these articles might offer contextual or other supporting information related to the practice.

An evidence summary table format was developed that included characteristics for each reference. The *Evidence* category of references included these characteristics:

- Citation information
- Practice description
- Study design
- Time period
- Study population/sample and sample size
- Outcome measure
- Internal/external validity
- Effect size
- Practice link to results
- Feasibility
- Cost
- Benefits and harms

Evidence summary tables were completed for each of the eight patient/specimen identification practices. (See Appendix E for a sample completed evidence summary table related to Bar-Coding identification systems.)

Evaluation Framework



Two primary sources were used to develop the evaluation methodology for recommending best practices in laboratory medicine: performance measures and evidence-based guidelines. The latter were considered most relevant given their relative similarity and applicability to practices. Multiple organizations such as *The Community Guide*,[16] National Association of Clinical Biochemistery (NACB),[17] Oxford Centre for Evidence-based Medicine,[19] U.S. Preventive Services Task Force (USPSTF),[18] and others[21] have specified methodologies for evaluating and recommending practices, interventions, and guidelines. During the first in-person Workgroup meeting, an overview of these existing models was provided to the Workgroup. Although none of these methods was tailored to laboratory medicine, they provided an array of constructs that facilitated Workgroup discussion about what might work for laboratory medicine.

Evaluation Subgroup

To continue development of an evaluation framework, the Evaluation Subgroup was formed within the Workgroup. The subgroup developed assumptions, criteria, and ratings for evaluating candidate practices and recommending best practices for laboratory medicine by searching the literature and consulting with content experts to develop an evaluation framework tailored to laboratory medicine.

Assumptions

Three key assumptions guided development of an evaluation framework for this process.

- **Laboratory medicine interventions or practices are not likely to have been studied in randomized controlled trials.** To date, trials in which individual patients or individual sites are assigned randomly to intervention or control groups for a laboratory procedure or practice evaluation are not typically available, primarily because of practical difficulties associated with conducting such trials.
- **The evidence available to assess a candidate practice's effectiveness is most likely to come from observational studies.** Two kinds of study designs are most likely to be available: 1) observational study designs, such as case-control studies, cohort studies, or hybrid case-cohort studies that examine the potential impact of the practice on patient outcomes, and 2) operations research/management science studies (e.g., case studies), including those conducted in a quality management framework, such as Failure Mode and Effects Analysis (FMEA), Lean,[22] or total quality management (TQM). These management approaches are likely to focus on intermediate or process outcomes that can be linked by a chain of inference to patient outcomes.
- **Evidence for effectiveness of a specific practice might be limited**. The basis for evaluating the practice will be a structured, descriptive analysis or a systematic review of the available evidence combined with consensus expert opinion, the specific nature and composition of which will be formalized as this process is developed.

Evaluation Criteria

Candidate practices for the evaluation framework are identified by using review methods (such as those previously described) that characterize evidence of a practice's effectiveness. For a practice to be considered a candidate, it must satisfy the minimum inclusion criteria (specified in the Inclusion/Exclusion Criteria section of this report), and there must be some indication that the practice has the potential to improve outcomes likely to affect the quality of patient care and health outcomes.

The Workgroup recommended the following three evaluation criteria for rating the body of evidence for an individual practice or intervention to be considered a best practice:

1) Effect size (i.e., the magnitude of change in an outcome measure attributable to the practice).
2) Feasibility of implementation.
3) Strength of evidence (i.e., the degree of confidence in the evidence/judgments).

General descriptions of the practice evaluation criteria and their corresponding rating and recommendation methods are provided in the next sections of this report. These descriptions constitute the first stage of developing the Laboratory Medicine Best Practices evaluation framework. The specific strategies for determining the overall ratings for each of the three criteria, and for rating their respective individual characteristics and how they are combined to determine the overall rating, were not fully developed at the end of Phase I.
In Phase II, more detailed specifications for the evaluation criteria and rating methods, required for completing the development of a transparent and consistent process for making recommendations, will be addressed. In a proof of concept exercise, Workgroup members applied the evaluation framework to assess the practice of using Bar-Coding systems for patient/specimen identification to refine their recommendations for the Laboratory Medicine Best Practices evaluation methods.

Effect Size Assessment

Effects (outcome variables) are clearly defined in terms of at least one of the following:

- Clinical outcomes.
- Operational/process outcomes (e.g., error rates).
- Economic (e.g., cost of test/procedure, treatment, associated outcomes).

Effects (outcomes) are consistently measured over time

- Effect size is reported.
- Statistical analysis (e.g., p-value) is reported.

Effect size is qualitatively expressed in categorical terms (e.g., adverse effect, no effect, minimal, moderate, substantial).

Effect Size

Effect size is determined by measuring a practice's results in terms of outcomes that are likely to affect the quality of patient care and/or health outcomes. Quantifying the effect size can be difficult because of sparse evidence and often heterogeneous data. Therefore, the Evaluation Subgroup developed a categorical rating for assessing effect size using four levels: *substantial*, *moderate*, *minimal/none*, and *adverse*.

These rating levels are not intended to correspond to uniformly specified values, but instead will be determined by the practice-relevant context. The first three levels refer to a desirable effect. Effect size assessment involves evaluating practice outcome measures, their size, importance, and quality.

Feasibility of Implementation

Evaluating the feasibility of implementing a practice encompasses an assessment of its availability for immediate application, its applicability for multiple types of patients and settings, and its sustainability. Each of these characteristics is given a rating of *high*, *medium*, or *low*. In addition, barriers to implementation and benefits and harms of implementing the practice are characterized. On the basis of the minimum inclusion/exclusion criteria, if the practice is not in current use or immediately available for application, it is excluded from further analysis. An overall feasibility rating of *high*, *medium*, or *low* is developed for the practice.

Feasibility Assessment

Feasibility of implementation involves assessment of

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

Ease and feasibility of implementation can be assigned to a categorical scale (e.g., high, medium, low) based on information reported and ratings related to the characteristics above.

Impact Assessment

After a practice's ratings for effect size and feasibility of implementation are established, recommendations may be developed in a two-stage process: 1) assessing impact and 2) assessing the strength of evidence. In the impact assessment, results from the evaluation ratings for effect size and feasibility of implementation for a candidate practice are combined into a single impact rating. Impact assessment ratings can be *positive*, *neutral*, or *negative*. The following grid shows the impact assessment ratings associated with each combination of ratings for size of effect and feasibility.

Best Practices in Laboratory Medicine
Impact Assessment Rating:
Size of Effect x Feasibility

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

- A positive impact rating signifies that the practice or procedure will likely do more good than harm and is demonstrably (or shows promise of being) implementable and sustainable.
- The neutral impact rating signifies that there are important trade-offs between the effect size, benefits/harms, and feasibility, or it is not clear whether the practice or procedure does more good than harm. Thus, its feasibility rating is not sufficient to offset its lack of effect size.
- The negative impact signifies that the practice or procedure does not clearly do more good than harm and that it would not be considered a candidate for best practice recommendation. A negative impact rating also could signify that even though the practice or procedure is likely to have a minimal desirable effect, its feasibility rating is low.

Strength of Evidence

The strength of evidence for a practice's body of evidence is evaluated in the second stage of developing recommendations. The following criteria are examples of the various criteria that should be evaluated to determine the strength of evidence:

- The number of studies involving the same or similar procedure/practice.
- The internal and external validity of these studies.
- The aggregate sample size of multiple studies.
- The comparability of study sample groups among multiple studies.
- The comparability of measurement methods among multiple studies.
- The assessment of confounding factors.
- The consistency of findings reported among multiple studies.

Randomized control trials, cohort studies, and case-control studies are not the evidence norm for laboratory medicine. Therefore, the evaluation must be based on a less definitive set of categorical criteria. The Workgroup agreed on the following four categories of evidence:

- A *strong* designation would be for well-designed, multisite operations case studies or other more rigorous study designs that report effect size in quantitative terms and use an appropriate statistical analysis.
- A *moderate* designation would be given to descriptive evaluation studies and case reports with consistent results.
- A *suggestive* designation would be given for qualitative or weak quantitative evidence (i.e., opinions of respected authorities consistent with supported models, on the basis of clinical experience, descriptive studies and case reports, or reports of expert committees).
- An *insufficient* designation would be given when there is no evidence-based support for recommendation (i.e., expert opinion only, with no specific case study data).

Recommendations

Recommendations are formulated in accordance with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group findings[23] to reflect the extent to which one can be confident that following the recommendations will do more good than harm.

The Workgroup agreed on the following four classifications for recommendations:

- A practice receiving a rating of *strongly recommend* should be implemented in appropriate care settings.
- A practice with a rating of *recommend* should be implemented, taking into account case study or narrative data concerning the sensitivity of outcomes to variations in implementation and/or care settings.
- A practice with a rating of *no recommendation for or against* has a potentially favorable effect on health care outcomes and/or error reduction, but is not sufficiently supported by evidence to indicate that it should be implemented in appropriate care settings. Additional studies may be warranted to strengthen the relevant evidence base for this practice.
- A practice with a rating of *recommend against* 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.

The following grid shows how ratings for the impact assessment and strength of evidence are both considered to determine the recommendation rating.

Best Practices in Laboratory Medicine Recommendation Rating: Impact Assessment (Effect/Feasibility) x Strength of Evidence				
Impact Assessment 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

Nontraditional Evidence

The Workgroup also discussed criteria needed to evaluate "nontraditional" evidence and ways that this type of information could be integrated into the evaluation framework. The process should encompass consensus expert opinion, unpublished institutional assessments of proposed practices, and a targeted outreach or investigational component to collect evidence concerning practice effectiveness. This outreach component might encompass such mechanisms as calls for practices issued through professional societies, identification of leaders in a particular practice, or development of practice evaluation networks by using common protocols to collect evidence concerning the effectiveness of practices that meet a minimum threshold of study quality. Members of the Workgroup recommended that specific *a priori* criteria for evaluating evidence collected through such mechanisms should be set so that an expert panel can review the data using unbiased, systematic methods.

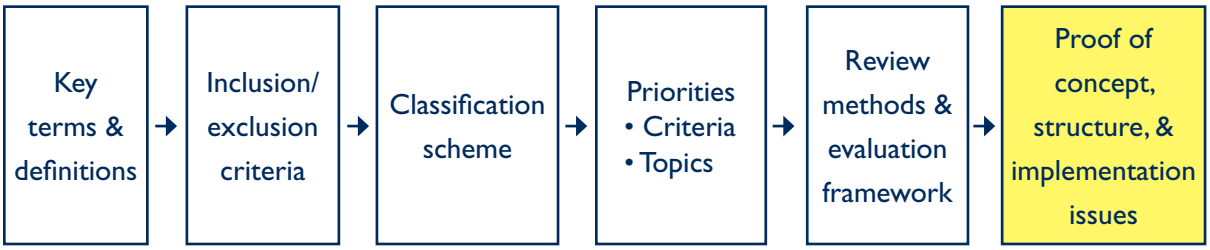
Economic Evidence

The Workgroup discussed the use of economic evaluation evidence such as cost-effectiveness and cost-benefit studies in the evaluation framework. In most of the existing frameworks for making recommendations (e.g., *Guide to Clinical Preventive Services* and the *Community Guide*), no explicit criteria are given to address economic evidence. If economic evaluation evidence is available, it is generally addressed in summarizing recommendations and evidence.

Workgroup members concluded that similar to the other models, economic evidence should be a consideration but not an explicit evaluation criterion. Members recognized that cost-related information is generally highly valued by policy and decision makers, and such information is often the primary driver behind decisions to adopt practices. Therefore, economic evidence must be considered.

Results and Recommendations

Proof of Concept



For purposes of evaluating the proposed review methods and recommending changes, the Workgroup completed a proof of concept exercise during the second in-person meeting. Members assessed this application of the proposed review methods and evaluation framework to eight candidate practices on the topic of patient/specimen identification.

Although the CDC Review Team attempted to provide the Workgroup with the largest possible number of studies and practices to consider in this exercise, some of the studies did not include adequate information on the practice or its effects. During the proof of concept exercise, the Workgroup applied basic relevance criteria to determine the appropriateness of including the study/practice in subsequent steps of the evaluation.

The Workgroup discussed the various patient/specimen identification practices and determined which candidate practices should continue on to the evaluation framework. They made this decision on the basis of their opinion of how the available evidence for each practice met the following criteria:

- Relevance to topic
- Adequate specification
- Consistent definition (if multiple studies)
- Relevance of outcome measure for assessing practice effectiveness
- Relevance of reported results for assessing practice effectiveness

The Workgroup advised moving the majority of the evidence articles and practices forward through the evaluation framework (excluding only two of the eight practice areas: marketing campaign and zero tolerance policy because of insufficient information for evaluation).

In completing the proof of concept, the Workgroup encountered several challenges. For instance, multiple practices and systems can be simultaneously involved and/or implemented, and measurement approaches and definitions vary greatly, making the actual primary outcome measure of identification error rates uncertain (e.g., ranging from 1% with self-reporting to 63% with direct observation).[24] In addition, no standardized data are available to measure identification errors or to determine their effects on patient care or health outcomes. Consequently, the costs of identification errors are largely unknown.

The Workgroup applied the proposed evaluation framework to the practice selected for evaluation: bar-coding identification systems. The Workgroup provided the following overall ratings:

- *Feasibility of implementation:* medium
- *Effect size:* moderate
- *Overall impact rating:* positive

The Workgroup did not provide a definitive rating of the strength of evidence for bar-coding identification systems. Specific issues in applying the process—how to weight information from different types of studies, how to account for nontraditional evidence in the framework, and how to place clinical relevance into the recommendation—were discussed at length. Although the Workgroup began applying the evaluation framework to this practice, the exercise did not include completing the process to the point of making a recommendation.

The Workgroup's evaluation framework proof of concept exercise highlighted the need to develop detailed specifications that can be consistently applied by expert panels to assess the relevant practice evidence characteristics that make up the three overall criteria ratings (feasibility of implementation, effect size, and strength of evidence). Clearly specified criteria and rating methods are required to achieve the goal of a Laboratory Medicine Best Practices recommendation process that is evidence-based and transparent.

Review and Evaluation Methods

As the Workgroup progressed through the proof of concept exercise, it became increasingly apparent that the lack of peer-reviewed, published, and accessible evidence for laboratory medicine practices required a new and innovative approach. Members realized that although the Laboratory Medicine Best Practices process needs an evidence base, current standard systematic review methods and evidence-based recommendation models would have to be modified to take this lack of accessible information into account. The collective sense of the Workgroup was that considerably more evidence might be available that is not accessible by conventional means.

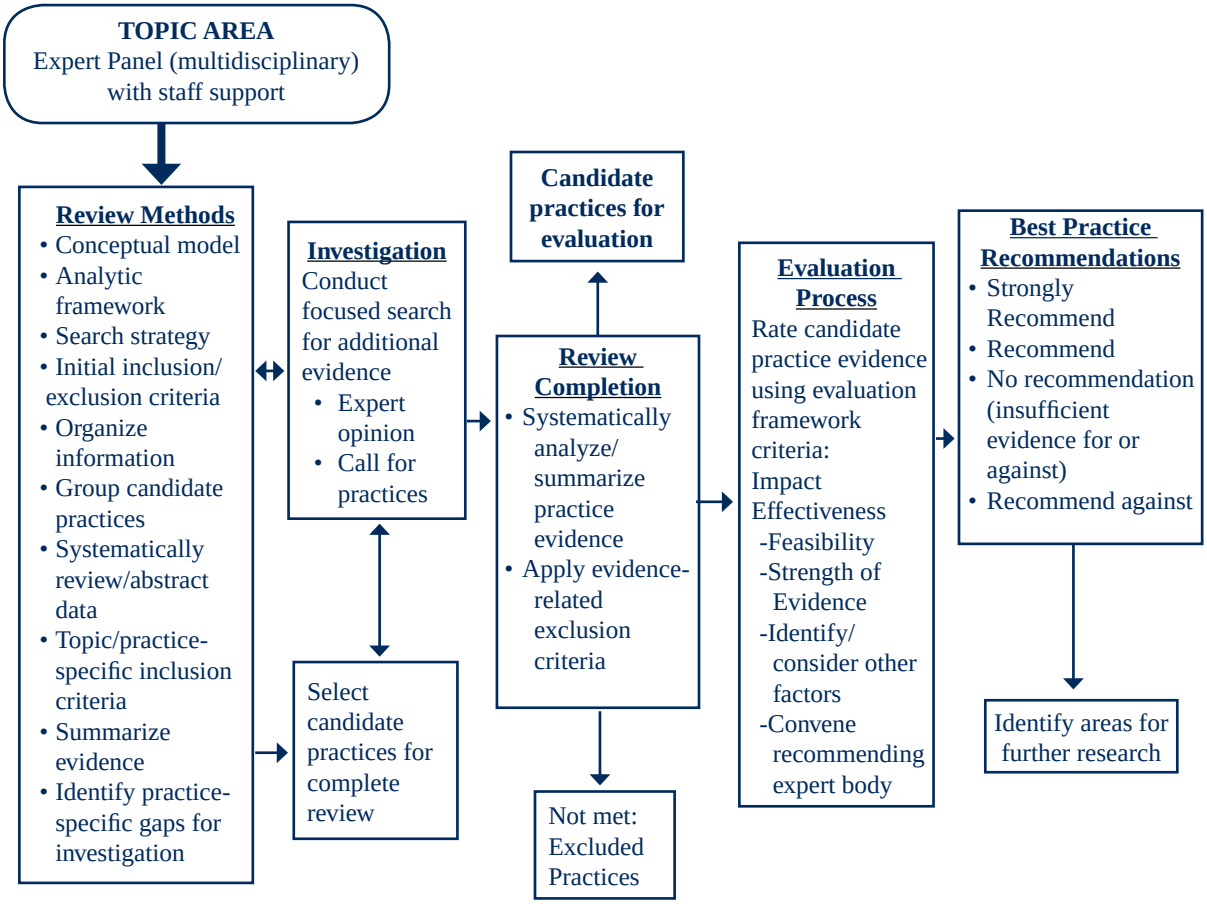
Laboratory Medicine Best Practices
Workgroup Methods Recommendations

- Address and incorporate nontraditional evidence that is not readily accessible for filling evidence gaps.
- Create an investigational component and process loop for review methods.
- Use focused and targeted outreach to access and develop evidence of practice effectiveness.
- Set evidence criteria (including nontraditional evidence) *a priori*.
- Revisit candidate topics with advisory group.

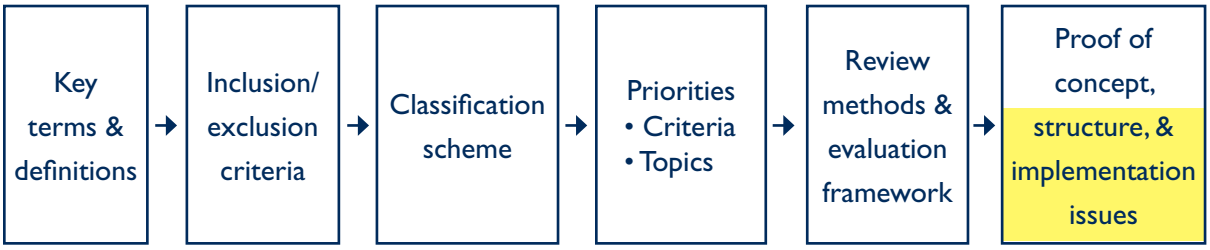
To address the need to find and incorporate more evidence into the process, the Workgroup recommended that an investigational component be added to the process to systematically review evidence from "nontraditional sources." The innovative features of this modified process are a systematic approach to incorporating evidence from sources other than peer-reviewed publications, and a process loop to refine the evidence base over time as evidence evolves.

The Workgroup's recommendation is not to wait for the evidence to catch up. Instead, they suggested that a process be developed to address gaps in the literature that can be filled by practitioners and expert groups with knowledge of institutional practices and unpublished studies. This nontraditional evidence can be gathered through focused and targeted outreach (e.g., identification of practice leaders, experts, and centers as well as calls for practices). This process is depicted in Figure 3.

Figure 3: Proposed Process for Identifying Best Practices in Laboratory Medicine



Structure and Sustainability



At their June 2007 in-person meeting, Workgroup members addressed a series of conceptual and operational questions regarding implementation and sustainability of the Laboratory Medicine Best Practices recommendation process. The Workgroup members were provided an opportunity to provide individual, written feedback concerning many of these constructs in a follow-up inquiry after the June meeting.

Before these sessions, three presentations were made to provide background information to the Workgroup, along with opportunities for discussion on related methods and processes. The first presentation was by Raj Behal, MD, MPH, and was based on his work for the NQF that summarized evidence and introduced a framework for laboratory medicine performance measures. Two other presentations provided overviews of evidence-based recommendation processes; these presentations were given by David Hopkins, MD, MPH, of *The Community Guide* and James Nichols, PhD, of the NACB.

The Workgroup provided recommendations on conceptual and operational structures and definitive next steps during the in-person meeting and by follow-up inquiry after the meeting. In the judgment of the Workgroup, CDC should retain control and direction of the process for developing best practices recommendations and is the appropriate organizational home for a data repository that might be developed as a result of the process. Workgroup members agreed that the data should be openly accessible and in an electronic, secure repository that protects the integrity of the work.

Laboratory Medicine Best Practices
Workgroup Operational Recommendations

- Have CDC manage the process and data repository.
- Ensure that evidence database is open sourced.
- Involve stakeholder organizations using multi-tiered approach.
- Establish an official publication to disseminate information about best practices in laboratory medicine.
- Establish an overall coordinating/governing body with expert topic area panels.
- Finance the efforts with government sources.
- Use existing organizational structures, including an advisory body.

The Workgroup agreed that multiple organizations should be stakeholders in the Laboratory Medicine Best Practices process and have a vested interest in its success. These organizations include pathology groups, accrediting organizations, hospitals, physicians, other health care providers, payers, and patients. To engage stakeholders and maintain interest in the process, the Workgroup recommended a multi-tiered approach that includes calls for practices, Listserv announcements, a Web site, and newsletters.

Establishing an official publication to disseminate and document Laboratory Medicine Best Practices process methods and recommendations also was recommended to provide interested parties with a consistent method to obtain up-to-date information. The Workgroup identified specific organizations that would have an interest, including the National Academy of Clinical Biochemistry (NACB), American Society for Clinical Pathology (ASCP), College of American Pathologists (CAP), Clinical Laboratory Standards Institute (CLSI), American Association for Clinical Chemistry (AACC), Clinical Laboratory Management Association (CLMA), International Federation of Clinical Chemistry (IFCC) – Evidence-Based Laboratory Medicine Committee, National Quality Forum (NQF), the Joint Commission, and patient advocacy groups.

The Workgroup recommended an overall coordinating/governing body to spearhead the continuing effort to develop the best practices process with expert panels for each topic area. They recommended that the effort be federally funded to ensure that its focus remains on a broad public health agenda. The Workgroup considered several barriers to successful implementation, including limited resources, competition, and varying interests.

The Workgroup considered existing structural models in developing recommendations for an organizational structure and by-laws. Various existing organizational models and their structural components and similarities were discussed. The Workgroup identified issues that could be relevant to the proposed methodology for the process of identifying best practices. They recommended that a single advisory committee or task force be used for implementing the Laboratory Medicine Best Practices recommendation process. If an appropriate committee or task force does not already exist, one with open nominations and term limits should be established.

These recommendations represent the conclusion of Phase I and the transition to Phase II in creating the Laboratory Medicine Best Practices recommendation process. As many other health organizations are at various stages of creating evidence-based best practices, guidelines, performance measures, and quality indicators, this initiative can benefit from their experiences. This effort is a large undertaking that will require sustained effort and collaboration.

Next Steps

Consistent with the Laboratory Medicine Best Practices Workgroup's recommendations, CDC is moving forward with Phase II, which involves the following key steps:

- Refine and develop process methods.
- Develop a laboratory network for soliciting and creating practice evidence.
- Pilot test the process.
- Evaluate alternative organizational structures for implementing the process.

A key outcome of Phase II will be the additional refinement of the process, which will include the development of a new investigational component to fill the evidence gap in the literature. Work will again rely on the external Laboratory Medicine Best Practices Workgroup. Phase II will begin with the solicitation of professional and private sector groups interested in participating in a network to identify and evaluate candidate practices. This network will be fundamental in identifying potential studies, data sources, and participants to evaluate candidate practices in priority areas of laboratory practices or services.

Pilot tests of at least three candidate practices in each of two topics (e.g., patient/specimen identification, critical values reporting, or reducing blood culture contamination) will be conducted. For each pilot test topic area, an expert panel will be convened whose primary function is to develop review protocols and complete evidence review for evaluating the candidate practices. The evaluation protocol will address guidance on evaluating both published and unpublished evidence of practice effectiveness. The result will be a refined evaluation process based on pilot-test findings. Evaluation of existing organizational models and structural components will provide a basis for making the Laboratory Medicine Best Practices evidence-based recommendation process operational.

CDC's DLS is committed to fulfilling the recommendations of the IOM to "reduce burden of illness, injury, and disability and to improve the health and functioning of the people of the United States"[3] in the field of laboratory medicine. The Laboratory Medicine Best Practices recommendation process provides an opportunity to identify and promote evidence-based practices that ultimately can lead to better health outcomes.

Phase I set the groundwork for developing the process and revealed the need to develop a new approach—a more inclusive model that integrates traditional and nontraditional evidence. This process offers a broad based opportunity to systematically integrate and disseminate evidence by using explicit and transparent methods in a way that has not been done historically in the field of laboratory medicine. A primary focus of CDC's efforts in Phase II and subsequently will be on ensuring that the recommendation process is sustainable and facilitates dissemination of best practices to relevant stakeholders.

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

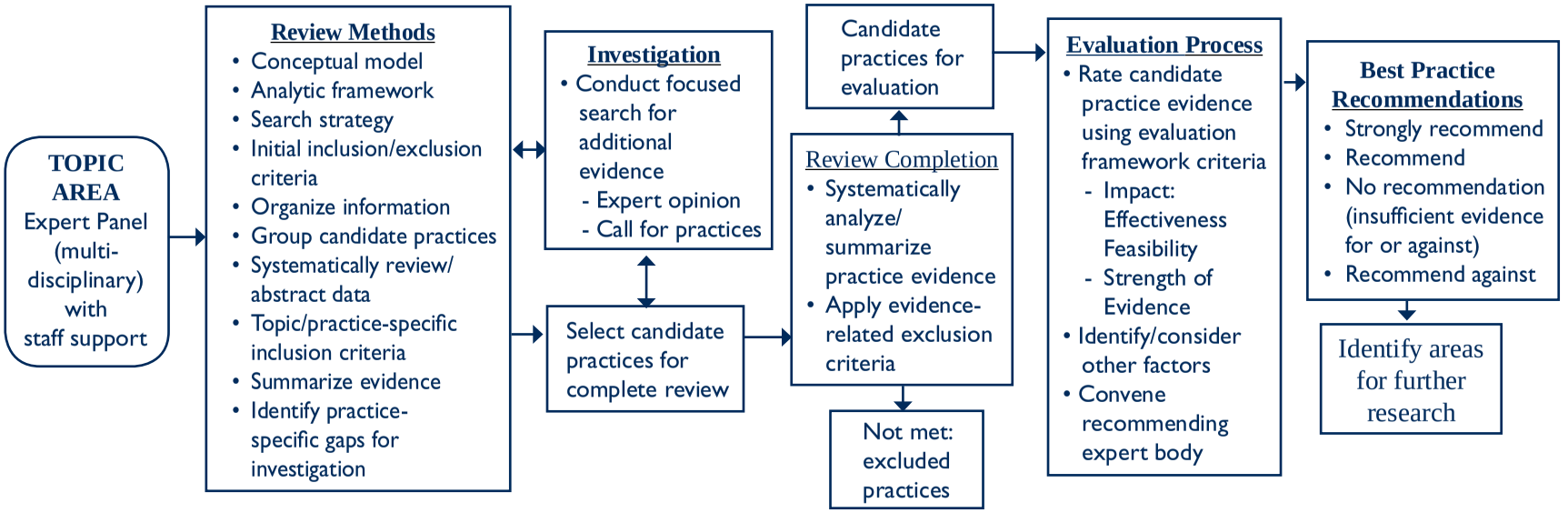
Workgroup Strategy for Process Development

Key terms & definitions → Inclusion/ exclusion criteria → Classification scheme → Priorities • Criteria • Topics → Review methods & evaluation framework → Proof of concept, structure, & implementation issues → • Revise process • Draft report • External review • Final report • End of Phase I

Challenges

- Lack of 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.
- Variations in health information technology.
- Best practices not systematically identified.
- Need to connect laboratories to patient care decisions and outcomes.
- Need for evidence demonstrating practice effectiveness.

Proposed Process for Identifying Best Practices in Laboratory Medicine



APPENDIX B

Laboratory Medicine Best Practice Workgroup Roster

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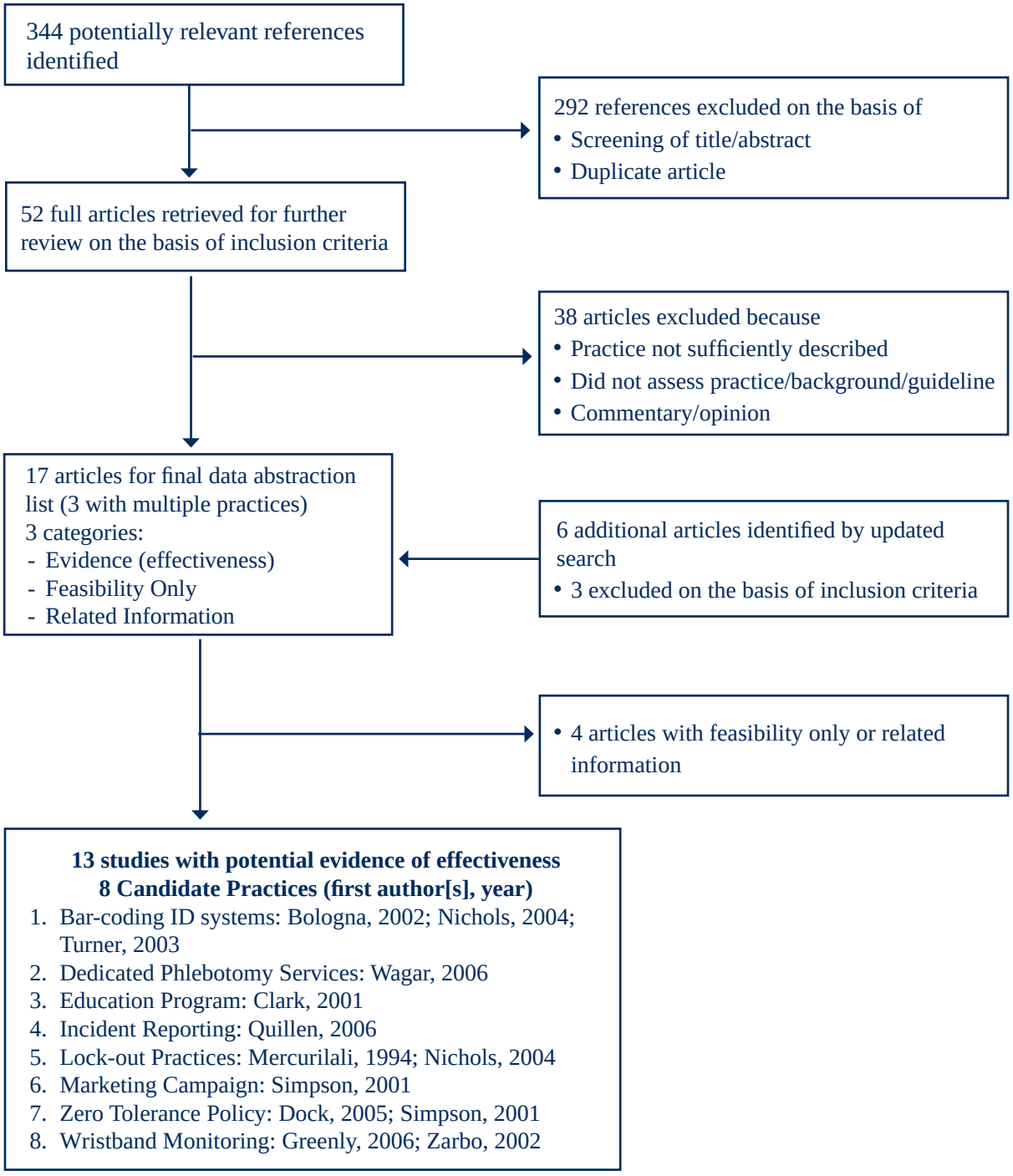
APPENDIX C

Selection Process for Study Inclusion and Review Results

Patient/Specimen Identification



APPENDIX D
Data Abstraction Form

Reviewer's Notes

- For all multiple-choice options, check all responses that apply.
- Indicate the page or table number from the article where data are located to aid in checking the information.

I. Classification Information

1. Reviewer Name _____

1.1 Review Completion Date _____

2. Topic: Patient/specimen identification errors

2.1 Subtopic _____
2.2 Practice _____

3. Citation (author[s], title of article, and publication date) _____
_____

4. Author(s) Affiliation _____

5. Study Funding
❏ Not performed or studied by a manufacturer
❏ Supported by a manufacturer
❏ Performed by a manufacturer
❏ Other, specify _____

6. Reference Type

❏ Published article	❏ Technical report	❏ Presentation
❏ Book/book chapter	❏ Professional guidelines	❏ Conference proceeding

❏ Other, specify _____

7. Intervention

Practice Type(s): ❑ Technology Device/equipment ❑ Procedures/protocols

a. **Description.** Describe the potential practice service, materials that were delivered, or policies implemented.

b. How Delivered/Implemented. Describe how the intervention was delivered.

c. Where/Who and other information. Include major characteristics of study, sample/ population, and other information relevant to the applicability or validity of the results.

d. Comparator(s). Description intervention was compared to (such as "status quo," "no program").

II. Study Description

8. Study Design

- ❑ Randomized control study
- ❑ Nonrandomized controlled trials
- ❑ Multi-institutional study with comparison groups
- ❑ Cross-sectional (e.g., ID errors and related factors measured at a specific point in time in a defined population)
- ❑ Case-Study descriptive (detailed profile of subject and experience)
- ❑ Case-Study evaluative (data to evaluate the merit of a practice or event)
- ❑ Longitudinal Study (observations of same items over time)
- ❑ Other, specify _____

9. Sample size and characteristics (Note differences when applicable for pre- and post- intervention or comparison groups.)

Size_____

_____

_____

_____

Characteristics_____

_____

_____

_____

Comments_____

_____

_____

_____

10. Location of study

❏ USA (specify state[s] and city[ies]) _____

❏ Other country (specify state[s] and city[ies]), provinces) _____

11. Time period of study (specify beginning and end dates, if available, and follow-up periods)

_____

12. Audience (Specify the projected users of the study results.)

❏ Practitioners or health care providers
❏ Payers
❏ Manufacturers
❏ Laboratory professionals
❏ Health administrators
❏ Patients
❏ Other, specify _____

13. Setting

❏ Hospital outpatient
❏ Hospital inpatient
❏ Laboratory
❏ Clinic
❏ Physician office
❏ Other, specify _____

III. Results

14. Describe outcome measure(s). Provide definition used by authors.

❏ Clinical outcome(s) (direct or intermediate) (e.g., patient received appropriate care, morbidity)

❏ Operational/Process of care outcome(s) (direct or intermediate) (e.g., error rate reduction, time of treatment, length of stay)

❏ Economic outcome(s) (direct or intermediate)

15. Describe effect size as reported by the author(s).

_____
_____
_____

16. Statistical analysis reported

❏ None
❏ P-value, specify _____
❏ Other, specify _____

Comments: _____
_____
_____

IV. Study Quality

17. Was the intervention adequately described in terms of what was done, how it was delivered, and where it was done? Is it consistent with inclusion/exclusion criteria for this practice?

❏ Yes, specify why _____
_____

❏ No, specify why not _____
_____

18. Internal validity (The comparison groups are selected and compared in such a manner that the outcome is likely to be attributable to the effect under investigation.)

❏ Outcome variable(s) clearly specified
❏ Study sample groups comparable (e.g., pre- and post-intervention)
❏ Measurement methods comparable
❏ Confounding factors addressed

Comments _____
_____
_____

19. External validity (generalizability)

❏ Findings can be transferred to locations beyond those specifically included in the study
❏ Identified practice can be applied to additional settings

Comments _____
_____
_____

V. Other Issues

20. Feasibility and other key issues addressed in the paper. Check off any of the following issues that are described by the authors. Flag issues that might be of importance in describing the intervention or implementation. Include the page numbers where this information can be found.

❏ Costs of the intervention (monetary, nonmonetary, or human resources)

❏ Barriers to implementation

❏ Benefits (in addition to outcomes detailed in results)

❏ Potential harms (in addition to outcomes detailed in results)

Citation • Authors • Title • Publication • Date	Practice/Intervention • Description • Objective	Study Design • Design • Time period • Setting • Sample/ Population • Sample size	Outcome Measure • Definition • Comparable measure • Internal validity • External validity	Effects/Results • Size • Analysis • Practice link to results	Other Factors • Feasibility • Costs • Benefits • Harms	Comments/ Notes
• Bologna LJ, Mutter M. • Life after phlebotomy deployment: reducing major patient and specimen identification errors. • *J Healthc Inf Manag.*16(1):65–70. • 2002 • Bologna LJ, Lind C, Riggs RC. • Reducing major identification errors within a deployed phlebotomy process. • *Clin Leadersh Manag Rev.* Jan–Feb;16(1):22–26. • 2002	• Bar-code identification system consisting of handheld portable data terminals, central server that communicates with hospital laboratory information systems (LIS) and personal computers at each unit's nursing work station. • Reduction in error rates for: 1) Misidentified patients 2) Incorrect/ incomplete label of specimens 3) Incorrect specimen container 4) Unnecessary phlebotomy 5) Improve patient satisfaction with phlebotomy service	• Case study • 1997–2000 • Valley Hospital in New Jersey (about 400 beds). • Total patient phlebotomies in 10 patient care centers. • Total phlebotomies: Pre-intervention = 69,432 Post-intervention = 59,490	• Percentage error rate changes in four specimen identification error types. • Pre- and post-intervention percentage error rate changes for four specimen identification error types. • Internal validity: Fair • External validity: Good	• Average rate of error reduction: 77% overall in four error types: 1) Misidentified patients: 94% 2) Incorrect/ incomplete label: 59% 3) Incorrect specimen container: 52% 4) Unnecessary phlebotomy: 89% • No p-values • No other factors considered	• Savings in length of stay and legal costs not quantified. • Hard costs savings noted as modest; annual savings $129,000. • Number of unnecessary phlebotomies reduced, increasing patient satisfaction.	• No criteria for error types included

Citation • Authors • Title • Publication • Date	Practice/Intervention • Description • Objective	Study Design • Design • Time period • Setting • Sample/ • Population • Sample size	Outcome Measure • Definition • Comparable measure • Internal validity • External validity	Effects/Results • Size • Analysis • Practice link to results	Other Factors • Feasibility • Costs • Benefits • Harms	Comments/ Notes
• Nichols JH, et al. • Reducing medical errors through bar-coding at the point of care • *Clin Leadersh Manage Rev.* Nov/Dec:328–334. • 2004	• Automated patient Bar-Coding point of care testing (POCT) device scans patient wristband bar-code to read 9-digit patient account number and 5-digit operator number in ICU. • Reduction in POCT identification error rates (associated with operator data entry).	• Longitudinal study • 15 months; Nov. 2002–Jan. 2004 • Baystate Health System in western Mass.; (>850 inpatient beds in 3 hospitals); 1 million POCTs/ yr. by >2,000 clinical operators. • Intensive Care Unit (ICU) blood gas and glucose POCTs; no estimate given for ICU sample size; only system-wide volume of nearly 600,000/year.	• 9-digit patient account number and 5-digit operator number identification (ID) errors (no other specification). • Monthly identification errors compared pre- and post-implementation for glucose meter and blood gas device POCT; 2 pre-implementation comparators (status quo and operator lock-out). • Internal validity: Good • External validity: Good	• ID errors decreased from average 26/month to 1/month for glucose ($p = 0.0007$) and from average of 4.6–1.7/month for blood gas $p = 0.048$ after implementation of bar-coding. Figures 1 and 2 show final ID errors for bar-coding only sustained at 12 months for glucose and 6 months for blood gas. • No other effect size estimates provided. • Confounding factors addressed in text; not in data or analysis.	• Improved interdepartmental communication. • Reduces billing losses due to incorrect patient ID. • Doesn't verify wristband ID number is correct. • Operators had intermittent problems reading bar-coded wristbands; generated initial increase in ID errors when resorted to manual data entry.	Results of POCT ID errors: either stopped by the data management system before reaching medical record or results transferred to the wrong patient's medical record.

Citation • Authors • Title • Publication • Date	Practice/Intervention • Description • Objective	Study Design • Design • Time period • Setting • Sample/ • Population • Sample size	Outcome Measure • Definition • Comparable measure • Internal validity • External validity	Effects/Results • Size • Analysis • Practice link to results	Other Factors • Feasibility • Costs • Benefits • Harms	Comments/ Notes
• Turner CI, Casband AC, Murphy ME. • Bar-code technology: its role in increasing the safety of blood transfusion. • *Transfusion.* 43:1200–1209. • September 2003	• Bar-code patient ID system for blood sample collection compatibility and blood administration using hand-held scanners that scan PDF bar-codes. • Establish if use of bar-code technology could reduce error rates in blood transfusion procedures based on British Committee for Standards in Hematology (BSCH) guidelines.	• Case study • None given • Hematology outpatient clinic Oxford Radcliffe Hospital in Oxford, UK. • 51 first-unit red blood cell (RBC) transfusions in hematology outpatient clinic.	• Improvement in following BSCH criteria for blood transfusions. • Specific audit measures (comparators) useful for specimen identification topic: 1) Sample tube labeled immediately with hospital number, surname, first name, date of birth (DOB), sex, and sample date. 2) Number of patients wearing a wristband. 3) Number of patient surname, DOB, and hospital number on wristband checked. 4) Patient ID on blood pack checked.	• Comparitors: 1) 50% increase (50%–100% based on 30 samples) 2) 10% increase (88%–98% based on 51 samples) 3) 67% increase (33%–100% based on 30 samples 4) No change (100% based on 51 samples) • By exact test of independent proportions: 1) $p < 0.0001$ 2) No p-values given for comparators 2, 3, and 4 • Internal validity: Good • External validity: Good	• High costs may be deterrent. • About $750,000 for 1,500-bed hospital. • Multifunctional uses of system (medication administration). • Staff felt more confident and preferred new system. • Increased patient satisfaction. • System also showed improvement in blood compatibility checking.	Numerous other transfusion checks were included in this study.

FEASIBILITY INFORMATION ONLY			
Citation • Authors • Title • Publication • Date	**Practice/Intervention** • Description • Objective	**Feasibility Information** • Implementation • Cost	**Comments/Notes**
• Coyle GA, Heinen M. • Scan your way to a comprehensive electronic medical record. Augment medication administration accuracy and increase documentation efficiency with bar-coding technology. • *Nurs Manage.* 33(12):56, 58–59. • 2002	• The Martinsburg Veteran Affairs Medical Center (VAMC) implemented bar-coded medication administration (BCMA) point-of-care software. • Improve medication administration accuracy.	• Setting: By 1999 all 163 Veteran Affairs medical centers had begun implementing bar-code medication administrations, a point-of-care software solution for validating and documenting medication administration. The software allows comparison of bar-code information from a patient's wristband to patient medication, order, time, dosage, and route. • The cost for implementation at one Veteran Affairs medical center is listed as $181,110 (at a 247- bed center; costs include personnel and equipment). • Reports that implementation of BCMA requires ongoing training, especially for equipment use.	Veteran Affairs encountered challenges with hardware and supplies that proved to be unreliable, untested, or unavailable. Through trial and error, they identified batteries, scanners, and other compatible supplies.

• Waton K. • Paean to process. • *Health care Management Technology.* 27(3):26–28. • 2006	• Automated patient identification system using bar-coded wristbands for blood specimen collection (BD Diagnostics BD.id patient identification system). • Save time: reduce by 50% the order-to-collect time and the time spent on specimen recollects or other laboratory issues. • Reduce errors: reduce 8.4% wrong container rejection rate to 2.0%, and actual errors from 0.6 errors per month to 0.	• Implementation information: - Location: Jackson-Madison County General Hospital; a 662-bed tertiary care hospital in Tennessee; laboratory has more than 190 employees, including 48 phlebotomists, and billed 1.25 million tests in 2005. - Chronology: BD.id patient system chosen in March 2005; 15 pocket PCs, docking stations, and small battery-operated printers were purchased; staff spent summer 2005 fine-tuning interface between the LIS and ID system; hospital implemented September 26, 2005. - Steps: Streamlined blood specimen collection system with the following seps: • Specimen collection order entered into hospital LIS. • Order downloaded to BD.id server. • Order transmitted to a pocket PC that contains a bar-code scanner. • Phlebotomists scan own ID badge first and then scans patient's bar-coded wristband to verify patient identity. • Printer produces specimen label at the bedside with patient and phlebotomist names, date, time of collection, container type and test ordered. • Phlebotomist draws blood and labels the tube. • Tube sent to laboratory via pneumatic tube at nurses' station. • Via placement is a docking station, pocket PC uploads collection information to the LIS indicating sample is on its way to the laboratory for test.	Tennessee hospital laboratory's dedication to process improvement culminates in patient ID system that streamlines the specimen collection process and reduces errors.

• Woeste S. • Technology to reduce specimen collection errors. • Arch Pathol Lab Med. Aug;8(35):471–474. • 2004	Bar-coding system; BD.id System	• BD.id system and implementation information: Three institutions where this system has been implemented are 1) The Valley Hospital, Ridgewood, NJ (Bologna, et. al article included in evidence table), 2) South Georgia Medical Center in Valdosta, GA, and 3) Swedish American Hospital in Rockford, IL. Initial data published in 2001. • BD.id System features: Hand-held computer that scans bar-codes. Patient identification by scanning patient's wristband. Interfaces with hospitals LIS. Scans specimen container for verification of correct container for specimen. Mechanism to print bar-coded labels at bedside.	Article supported by manufacturer. No cost information provided.
• Wright AA, Katz IT • Bar-coding for patient safety. • NEJM 353(4);329–331. • 2005	• Bar-coding ID system: - Protect patients and reduce costs associated with adverse events.	• Implementation information: - Partners HealthCare system (includes Massachusetts General Hospital, Brigham, and Women's Hospital); each nurse has a wireless laptop computer, a battery-operated scanner, and a cart, and they have adapted to using the system and recognize its ability to catch errors. - Cost information: $10 million in start-up expenses (about half spent on training) and about $1 million annually to maintain. - Performance: Early data from the hospital pharmacy suggest bar-coding has reduced drug errors by more than 50%, preventing about 20 adverse drug events per day.	Concerns include the risk of disrupting nursing work-flow patterns, limiting nursing autonomy, and too slow to respond to rare clinical emergencies (related to medication).
RELATED INFORMATION			
• Nichols JH, et al. • Sources of bar-code scanner failure on POCT devices. • Point of Care. 3(3):140–146 • 2004	An investigation of sources of POCT bar-code scanner failure to determine why they were failing and how to obtain more reliable scanning. Effects examined included wear, lighting, distance, and angles of orientation on rates of successful scanning.		