Evidence to Practice: Building the Evidence for Quality Improvement in Laboratory Medicine

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Over the past decade, healthcare has become more outcome-oriented, patient-focused, and evidence-based. Evidence-based practice is applied through the systematic synthesis and appraisal of data to answer questions and solve problems. Laboratory professionals should generate outcomes data from continuous quality improvement activities in standardized formats so that the data add to the evidence-based body of knowledge for laboratory medicine.

Background

Today's clinical laboratory professional may wonder about the relevance of an evidence-based approach in laboratory medicine as well as how to integrate this approach in day-to-day practice. The underlying premise of an evidence-based approach is that decisions for healthcare delivery are guided by the synthesis and appraisal of evidence from well-designed studies balanced with clinical expertise and individual patient preferences.[1] Challenges to practicing evidence-based laboratory medicine (EBLM) include the lack of evidence from well-designed studies, misconceptions about practicing and contributing to EBLM, and lack of institutional support for mentoring and implementing an evidence-based approach.

The objectives of this article include:

- Provide a brief overview of the principles of an evidence-based approach/practice;
- Describe the contribution of laboratory quality improvement data to evidence-based laboratory medicine; and
- Highlight the evidence-based practice methods that laboratory managers should integrate into the design of continuous quality improvement processes.

The underlying method used in the development of evidence-based practice recommendations is the conduct of systematic reviews. A systematic review collates and analyzes the findings from well-designed studies and pools the results from individual studies to reduce bias and maximize the interpretation of the conclusions.[2] When the results of multiple individual studies are statistically combined, this is called a "meta-analysis." Various terms are used for systematic reviews, including "comparative effectiveness" and "patient-centered outcomes research," but the common objective is to use available data to make optimal decisions for patient care. Systematic review methods consist of key steps to address a problem about the quality of a practice (see Table 1).

Table 1: Key Steps of a Systematic Review Process

1. Pose an explicit statement of one or more clinical questions
2. Develop a search strategy for published primary studies
3. Review titles and abstracts generated by the search
4. Select and review full papers and extract relevant data
5. Analyze data including use of meta-analytic tools
6. Summarize findings
7. Identify further research needed

Within laboratory medicine practice, systematic reviews can provide information to support decision making about health outcomes achieved from use of a diagnostic test (diagnostic accuracy is determined with different methods) and additional outcomes that influence cost and quality of patient care (e.g., patient length of stay, earlier treatment).

In 2006, the Centers for Disease Control and Prevention initiated the Laboratory Medicine Best Practices (LMBP) Initiative to develop and apply evidence-based methods to the review of quality improvement (QI) studies. Within this initiative, systematic review methods developed by governmental agencies and others were adapted for laboratory medicine, considering that evidence generated in this field primarily derives from observational studies rather than randomized controlled trials. The LMBP A-6 Methods are applied to conduct reviews that assess the effectiveness of practices in improving the quality of laboratory medicine service delivery.[3] Current LMBP systematic reviews are focused on the effectiveness of pre- and post-analytic practices. (Visit **www.futurelabmedicine.org/our_findings** for more information.) Through the LMBP systematic review process, unpublished QI data are incorporated with data from the peer-reviewed literature.

Key findings from pilot phases of LMBP A-6 Methods development (carried out 2006-2010) highlighted the limited availability of well-designed studies published in the peer reviewed literature that are eligible for inclusion in LMBP reviews. As a result it was determined that unpublished laboratory QI projects, which are routinely performed for continuous quality improvement, provided eligible data for systematic reviews. These quality improvement data typically are not disseminated through the peer-reviewed literature process.

Table 2: Key evidence-based practice principles to improve QI projects

1. Frame quality problems as clinical questions using the PICO format
2. Conduct literature searches
3. Apply elements of research study design to QI project design
4. Capture and disseminate project results

Applying Evidence-Based Principles to Laboratory Practice

While individual laboratories may not find it feasible to undertake systematic reviews, they can contribute QI findings to benefit a larger community of practice. Literature is available that provides guidance on the conduct of systematic reviews.[3,4,5] The focus of this article is on the principles that may be applied to improve the rigor of QI projects so they meet the criteria for inclusion in systematic reviews.

Applying principles of evidence-based practice may assist laboratory professionals to:

- Make a business case for a quality improvement project;
- Support clinical, managerial, and policy decisions;
- Design quality improvement projects that meet the standard for inclusion in systematic reviews;
- Organize information to share within facilities such as through storyboards and meetings;
- Document quality improvement projects for publication;

The PICO approach refers to the use of four components that frame a systematic review question: The population of interest (P), which represents who or what is being studied; the new intervention or practice of interest (I) that is being evaluated; the comparator (C), which is the standard or usual practice; and the outcome (O), a measure of the impact or success of the practice of interest.

- Provide data for the conduct of economic evaluations; and
- Contribute to development of evidence-based guidelines.

Key elements that may be applied to QI projects are shown in Table 2 (page 17) on previous page.

Steps to Using Evidence-based Principles Framing the Quality Question

A systematic review is designed to answer a clearly stated question. The PICO approach refers to the use of four components that frame a systematic review question: The population of interest (P), which represents who or what is being studied; the new intervention or practice of interest (I) that is being evaluated; the comparator (C), which is the standard or usual practice; and the outcome (O), a measure of the impact or success of the practice of interest (see Table 3).

Asking the question in a structured way concisely describes the quality issue to be evaluated and communicates this across work units and areas of specialty. For example: *When drawing blood samples for laboratory testing from patients in the Emergency Department (P), will using a syringe (I) versus a vacuum tube (C) for drawing blood using IV starts be more effective in reducing hemolysis rates (O) among these samples?*

Table 3: Types of PICO Questions[4,5,6]

QUESTION TYPE	MEASURE COMPARED
Intervention	What practice, policy, or therapy leads to the best outcome
Diagnostic	Which test is more accurate and precise in diagnosing a condition
Prognosis	The likelihood of a particular outcome for a population with specific changes observed in the results of laboratory questions

Conducting Literature Searches to Inform Practice

When conducting a systematic review, extensive literature searches are performed to identify all published literature on a topic. When planning quality improvement projects, literature searches may be used to help determine whether there are existing standards or guidelines for optimal practice and to gain ideas for conducting a QI project. PubMed is a free reference database that is available for laboratorians to identify primary studies that have been published. Selected sources for identifying primary studies, systematic reviews, and guidelines are listed in Table 4.

Table 4: Sources for Literature Searches

REFERENCE DATABASES
• **PubMed** (www.pubmed.gov) – Medical and life sciences literature, widely used for quick searches, free and produced by the U.S. National Library of Medicine.
• **Cochrane Library** (www.cochrane.org) – Extensive database of systematic reviews, primarily therapeutic and interventional trials. Reviews not conducted by Cochrane are indexed in Cochrane's Database of Abstracts of Reviews of Effects (DARE).
• **DARE** – Lists diagnostic systematic reviews relevant to clinical chemistry
PROFESSIONAL GUIDELINES AND SYSTEMATIC REVIEW RESOURCES
• **Agency for Healthcare and Research (AHRQ), National Guideline Clearinghouse** – A public resource for evidence-based clinical practice guidelines. www.guideline.gov/index.aspx
• **AHRQ's National Quality Measures Clearinghouse (NQMC)** – A public resource for evidence-based quality measures and measure sets. http://qualitymeasures.ahrq.gov, http://qualitymeasures.ahrq.gov/browse/by-topic.aspx
• **AHRQ Innovations Exchange** – A database of evidence-based innovations and tools for a range of healthcare settings and populations. www.innovations.ahrq.gov
• **Clinical and Laboratory Standards Institute** – A resource for laboratory practice procedures and guidelines. www.clsi.org/
• **National Academy of Clinical Biochemistry (NACB)** – Consensus-based guidelines for the laboratory evaluation and monitoring of patients with specified disorders. www.aacc.org/MEMBERS/NACB/LMPG/Pages/default.aspx#
• **Laboratory Medicine Best Practices (LMBP)** – Conduct of systematic reviews (initiated in 2011) to identify effective laboratory medicine practices. www.futurelabmedicine.org/our_findings/

Applying Elements of Research Study Design to QI Project Design

There is an opportunity in laboratory medicine to utilize quality improvement data to make evidence-based laboratory decisions. This is possible by improving the design of QI projects

Table 5: LMBP Study Quality Appraisal Checklist[3]

STUDY SETTING
☐ Is information about the study setting provided? (e.g., intensive care unit, emergency department)
☐ Is the duration of the QI project or study (start and end dates) noted?
PRACTICE
☐ Is there a practice description that includes requirements and components for operations?
☐ Is the duration (start and end dates) for the practice reported?
SAMPLE SIZE
☐ Is the sample population identified (e.g., samples, tests)?
☐ Is the total number of observations for the sample size provided (e.g., total number of phlebotomy service blood collections)?
☐ Is the selection criteria for participants or specimens provided (what was included and excluded)?
COMPARATOR PRACTICE (ORIGINAL OR USUAL PRACTICE)
☐ Is there a comparator practice or standard (status quo)?
☐ Are key characteristics of the original practice described?
OUTCOME MEASURES
☐ Are the measurement(s) to assess practice impact identified and defined (e.g., length of stay)?
☐ Are the measure(s) relevant to the QI question?
☐ Is the method of data collection described?
RESULTS
☐ Are the study results described and supporting data provided?
☐ Are reported results clearly related to the practice of interest?

as well as collating the results of multiple projects through the systematic review process. Most of the problems that make QI projects ineligible for systematic reviews include a lack of the following elements of sound research design—explicit focused purpose of the study, defined sample size, defined practice of interest, collection of baseline data or data on the usual (or current) practice (comparator), and defined outcome measures. The LMBP Initiative features a review team that developed a critical appraisal checklist for evaluating the study quality of published primary studies and unpublished QI projects. The checklist can serve as a guide to plan and document QI projects." Scenario 1 (see sidebar) provides an example of the checklist used to develop a QI project.

Disseminating QI Project Findings

Sharing the findings of quality improvement projects is integral to EBLM. This facilitates identification of effective practices through systematic reviews and contributes to an evidence-based body of knowledge that can inform laboratory medicine decision making. Sharing results also returns value for the time, effort, and funds expended. Methods of sharing the results of projects include internal meetings, message boards, and storyboards; presentations and posters at local, regional, national, and international conferences; and professional newsletters and submissions for peer-reviewed publication. The LMBP Study Quality Appraisal Checklist[3] (see table 5) and other sources[7,8] provide templates for preparing a publication about the findings of a project.

Clinical laboratory scientists have been leaders in quality assurance practice and now have an opportunity to further improve patient outcomes. Through the LMBP Initiative, the collective laboratory quality improvement work across organizations can be shared to achieve optimal service delivery. For ongoing LMBP systematic

Scenario 1

Staff at a hospital laboratory conducts a quality improvement project to assess whether employing rapid technology (rPCR) with direct communication of results improves the time to report identification of microbes causing suspected blood stream infections. The project involves just one hospital, and compares reporting times before and after the deployment of the rPCR with direct communication.

SAMPLE POPULATION

All adult inpatients with a positive blood culture result for Staphylococcus aureus bacteremia admitted during study time period; **pre rPCR** = 74 patients, **post rPCR** = 82 patients.

PRACTICE EVALUATED

Rapid technology (PCR) with communication; rPCR result paged to ID PharmD Monday – Friday 8 a.m. – 5 p.m. or logged by laboratory and reviewed by ID PharmD next business day.

COMPARISON PRACTICE

Gram stain, final identification and antibiotic susceptibility completed in 24-72 hours and reported in electronic medical record without notification to physician.

In this scenario a probable outcome could be reduction in time to targeted therapy, but it would be important to list the definition of this outcome and how it was recorded.

OUTCOME	MEASUREMENT	SOURCE/ RECORDING
Reduction in time to targeted therapy	Time from identification of positive blood culture to receipt of targeted antimicrobial therapy for patient for specific type of blood stream infection	Chart review

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reviews, de-identified data may be easily submitted online, including background information to support institutional review board (IRB) approval if required at your institution (**www.futurelabmedicine.org**). This website also features a submission form to list QI problems that are being addressed in your laboratory, free tutorials, and information about systematic reviews.

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