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Preamble: 'Evidence in Action: The Laboratory Medicine Best Practice Initiative'

The purpose of this special section is to present findings from evidence-based systematic reviews conducted as part of the Laboratory Medicine Best Practices (LMBP) initiative from the United States Centers for Disease Control and Prevention (CDC) Division of Laboratory Science and Standards (DLSS). The systematic reviews comprising this special section examine various practices utilized by the clinical laboratory to provide information for care of patients. The term 'practices' as used in these reports represents protocols, procedures, policies, techniques, processes, systems, standards, incentives, activities, and interventions that are used to provide healthcare to patients. These systematic reviews are intended to address timely and pragmatic issues that are encountered frequently in the Laboratory Medicine environment. Laboratory practices in diverse topics are examined that include: use of barcoding for reducing patient specimen and test identification errors, reducing blood culture contamination in in-patient settings, timely critical value reporting in in-patient settings and blood collection techniques to reduce the rates of hemolysis in blood samples from the emergency department. The selection of topics for these and future best practice systematic reviews was guided, in part, by the Institute of Medicine (IOM) 'Crossing the Quality Chasm' report, which states that healthcare should be *safe, timely, efficient, effective, equitable* and *patient centered* to achieve substantial improvements in the quality of health care. Regarding patient safety specifically, it has been stated that nearly 100,000 deaths annually are attributable to medical error [1–3]; this information has prompted an increased emphasis on patient safety and quality improvement in medicine over the past decade, including in the specialty of Laboratory Medicine. The IOM Roundtable on Quality of Care classified threats to healthcare quality into three broad categories: overuse (receiving treatment of no value), underuse (failing to receive needed treatment), and misuse (errors and defects in treatment) [4]. Laboratory medicine testing can be viewed as consisting of three phases: preanalytical, analytical and postanalytical [5]. It has been established that most errors occur in the preanalytical and postanalytical testing phases [6–9]. For this reason laboratory practices in these phases are emphasized in the LMBP systematic reviews presented in this special section.

Fundamental principles for the LMBP systematic reviews include transparency, scientifically sound information, and fostering an inclusive process open to all relevant stakeholders and to the public. The LMBP review process methods are designed so that given the same evidence, the review findings can be replicated by an entirely different review team. To be effective, the reviews must be completed and disseminated in a timely fashion as the recommendations must be applied in practice while they are relevant. Work on LMBPs is accomplished in active collaboration with stakeholders representing germane specialties, professional societies and guideline-developing organizations. Collaborators and participating stakeholders have a substantive role in identifying the practices evaluated and outcomes considered in the evidence reviews. Best practice recommendations are issued by an independent recommending body that has fully disclosed potential conflicts of interest and is not subject to the influence of any particular faction, any sponsoring agency, or political consideration. The LMBP activity intentionally avoids duplicating ongoing efforts by integrating and interacting with organizations and existing efforts for conducting evidence reviews intended for the identification and dissemination of evidence-based practice recommendations.

Methodology for conducting LMBP systematic reviews was recently published [10]; a full text PDF of the article is available at the following link < http://www.clinchem.org/content/57/6/816.full.pdf+html>. The LMBP methods follow the process outlined by 6 steps that have been coined the 'A6 Cycle' displayed in Fig. 1: ASK the question–ACQUIRE the evidence–APPRAISE the evidence–ANALYZE the acceptable body of evidence–APPLY the findings–and ASSESS or audit the effectiveness of implementing the findings in practice. Developing a new methodology for conducting LMBP systematic reviews was necessary because even though more than 120 evidence–evaluation systems have been developed [11], none are designed to include observational quality improvement studies to identify evidence-based Laboratory Medicine practices. The LMBP methology was adapted to the Laboratory Medicine field from validated evidence-based medicine methods established by the USPSTF [12], AHRQ [13], and the Guide to Community Preventive Services [14]. It is important to note that there were several key modifications to these earlier methodologies: (i) inclusion of quality improvement study designs; (ii) the identification and evaluation of unpublished evidence for consideration, and (iii) combining individual study quality, effect size magnitude and relevance of outcome measure ratings to evaluate consistency of findings and transparently derive an overall strength rating for a body of evidence. The ASK, ACQUIRE, APPRAISE and ANALYZE steps are presented in the LMBP systematic reviews comprising this special section; the APPLY and ASSESS steps are obviated because they depend on dissemination and adaption of the practices.

Application of the LMBP methods requires coordinating the activities of several different groups, including an independent Workgroup that has oversight responsibilities, a staffed Review Team tasked with finding, appraising and analyzing available evidence, and a multidisciplinary Expert Panel specifically brought together for each topic. The Workgroup consists of experts in the field of Laboratory Medicine and other disciplines relevant to healthcare quality and evidence review methodology. The Workgroup is convened by the CDC and has final decision-making responsibility for all practice recommendations promulgated by the LMBP initiative. Review Team staff are trained in screening, abstracting, and rating studies for use as practice evidence. Expert Panelists comprise an eclectic group that is selected based on their knowledge in the review

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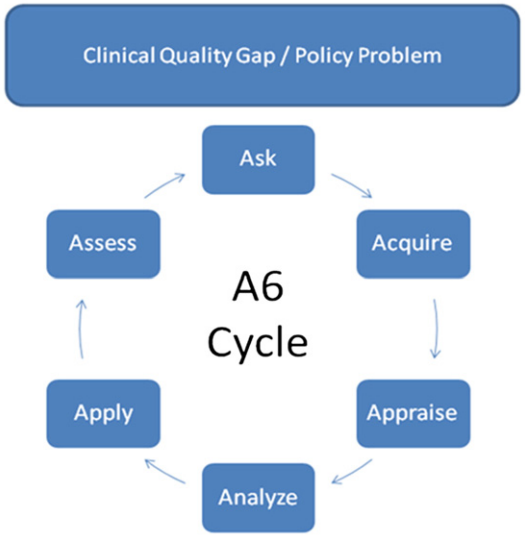

Fig. 1. The A6 evidence-based practice cycle adapted for laboratory medicine quality improvement. Reproduced with permission from reference [1].

topic area, evidence review methods and laboratory management. The evidence review results are used to identify evidence-based "best practices" by expert panels based on the effect size magnitude, consistency and relevance of outcome measures with information provided on applicability and implementation (e.g., practice cost, feasibility), when available. The Expert Panel utilizes the LMBP methods to review and evaluate the evidence synthesized and ratings drafted by the Review Team to assess the strength of evidence for each practice, finalize evidence review and evaluation findings for each practice, and translate findings into draft evidence-based recommendations with justification for consideration by the Workgroup.

The general structural outline of the LMBP Systematic Reviews included in this Special Section is displayed in Table 1. The introduction explains the background and importance of the topic area as well as Quality Gap, i.e. the difference between the current state of practice and the ideal state. The second methods section focuses on ASKing the relevant questions for the review, explaining how the evidence was ACQUIRED, and articulating how the evidence was APPRAISED and ANALYZED. The methodology also examines the practice effectiveness evidence and the body of evidence qualitative analysis. Use of meta-analytic techniques and presentation as forest plots communicate effect-size. The discussion section is intended to add insight into the findings of the systematic review including applicability of results, potential harms, additional benefits, feasibility of implementation, economic evaluation and so on. A discussion of future research needs is also included in the discussion. Finally, the conclusion and recommendations section succinctly lists recommendations from the workgroup on the topic of question.

These LMBP systematic reviews represent the first evidence-based effectiveness studies intended for the translation of successful practices into the routine of clinical laboratories, and demonstrate that the A6 LMBP methodology developed and adapted from validated systems can be applied for evaluating quality improvement practices. Other systematic reviews on topics in Laboratory Medicine are ongoing; these can be viewed <www.futurelabmedicine.org>. This website allows for the submission of unpublished data/evidence for reviewing these ongoing topics and also provides a mechanism for nomination of additional topics for future LMBP systematic reviews. The website contains other materials, including educational tools. It is crucial that readers carefully consider the information presented in these systematic reviews and how this evidence can be put into action for improving the healthcare delivered to patients.

Table 1
General structure of laboratory medicine best practice systematic reviews.

1.0 Introduction
1.1 *Quality Issue and Importance*
1.2 *Quality Gap*
2.0 Methods
2.1 *ASK: Review question, practice descriptions and analytic framework*
2.2 *ACQUIRE: Search for practice effectiveness evidence*
2.3 *APPRAISE: Screen, evaluate and rate available evidence*
2.4 *ANALYZE: Evidence review synthesis and results*
3.0 Evidence review synthesis and results
3.1 *Practice effectiveness evidence*
3.1.1 Body of evidence qualitative analysis
3.1.2 Meta-analysis (if appropriate)
4.0 Discussion
4.1 *Additional considerations*
4.1.1 Applicability
4.1.2 Harms
4.1.3 Additional benefits
4.1.4 Economic evaluation
4.1.5 Feasibility of implementation
4.2 *Future research needs*
4.3 *Limitations*
5.0 Conclusion and Recommendations

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Robert H. Christenson
Fax: +1 410 328 5880.
E-mail addres: RCHRISTENSON@umm.edu.