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Commentary

Evidence in action; commentary

The underlying principles of evidence-based medicine (EBM) are now becoming accepted in the practice of laboratory medicine [1–4], and with this is coming a paradigm shift in the practice of laboratory medicine, as well as a host of new challenges. A key objective of EBM, which has a strong resonance in laboratory medicine, is the emphasis on improving the quality of the information on which decisions are based [5], highlighting the role of the laboratory as an information provider. An important note about EBM, both in its principles and in its practice, is that it is "…not about mechanisms, but about outcomes…." [5]; this is particularly apposite for laboratory medicine, often considered as the scientific basis of medicine. It points to a need, beyond the quality of information provided, to encompass how information is used in the interests of individual patients. Therefore the paradigm shift, and the challenges that this engenders, lie in the linkage between the information (and the quality of this information) provided by laboratory medicine and its impact on patient outcomes. However, this notwithstanding, it is also important to recognize that the practice of medicine, and within that laboratory medicine, comprises the integration of a complexity of processes and therefore optimal performance has to take into account more process orientated outcomes.

This paradigm shift broadens the perspective of the laboratory professional beyond the core boundaries of the generation and delivery of reliable information — the result. Early evidence from laboratory quality improvement programs such as the Q-probe initiative highlighted the need for the laboratory professional to investigate the pre- and post-laboratory influences on laboratory performance [6,7]. More recent analysis of errors in laboratory medicine has clearly demonstrated that the highest proportion of errors occurs in the pre- and post-analytical phases of laboratory practice [8–10]. Studies of the quality of healthcare provision have also shown errors in provision across the care pathway — with both errors of commission as well as of omission [11–13]. Broadly speaking errors can occur as the result of a poorly performed element of a process, a poorly conducted process, the use of an inappropriate process, or the absence of the use of any process when one is warranted.

A well recognized definition of EBM is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" [14]. In practical terms this can be summarized as "doing the right thing(s) right" to deliver the best outcome for the individual patient; see Table 1. The concept of "doing the right thing right" embraces a number of important facets (i) relevance — the individual patient context, (ii) process – an integrated sequence of information-driven steps – the intervention, (iii) the consequence — the outcome, and (iv) cost. The cascade of steps listed in Table 1 illustrates the complexity of the "diagnostic process", as well as the challenge of integration into the broader "care process" in which it resides. It is the successful integration of the "diagnostic process" within the "care process" that is essential to realizing the goals of EBM, and herein lie many of the challenges faced in evidence-based laboratory medicine (EBLM).

From the patient's perspective, "doing the right thing right" can be described in terms of a process of assessment, diagnosis and action – and of which there may be several iterations – in the process from presentation to treatment and outcome [15]. The determination of what is "right" should be based on evidence of effectiveness, but this is challenging when trying to determine what is effective in a multifaceted, complex process. Thus, while it is relatively straightforward to evaluate the "intervention" in a single step process, evaluation of a multistep process requires careful thought and planning There are enumerable approaches to the design of studies to generate evidence of effectiveness, as well as approaches to evaluating the quality of evidence, but little has been published in relation to evidence of the effectiveness of diagnostic tests [16]. It is now recognized that in order to establish the effectiveness and value of a diagnostic test, the impact on the patient outcome has to be investigated; this requires evaluation of the "care process", rather than simply the "diagnostic process"; in other words, at a minimum, a "test and act" intervention [17–19]. However, whether we are considering the experimental or routine practice settings, it is expected that all of the process elements that comprise the intervention will be delivered to an optimal level. We know that this level of delivery is not always the case; thus at the highest level adherence to clinical guidelines is variable [11,12], as is the case in the use of tests [20,21].

Much of the detail on the delivery of many of the integral processes of laboratory medicine as a routine service has evolved supported by elements of best practice, for example, in relation to the quality of analytical performance. This has included significant contributions from both informal and formal quality improvement programs. Clearly, it can be challenging (both experimentally and financially) to design studies that identify the impact of the procedural aspects of a process on a health outcome — although asking the question is totally appropriate. Thus determining the impact of bar coding of specimens is a valid question — and one that is undoubtedly asked at the time when the initial investment is proposed; the question has been addressed in one of the reviews published in this special issue [22]. Similarly, it is important to have confidence in systems employed to alert clinicians to critical results, another of the topics addressed in this special issue [23]. These are topics that should be part of ongoing quality management and quality improvement programs.

It is interesting therefore that Christenson et al. have pointed out that no approaches have been designed to encompass data from observational quality improvement studies in relation to laboratory medicine practice [24]. Laboratory medicine is part of a complex process of clinical decision making, with many steps which can all impact on the patient outcome. Thus the elements of the process outlined in Table 1

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Table 1
Doing the right thing right; laboratory medicine as part of the care process. Key elements of practice that impact on the patient outcome, and for which performance requirements are important.

RIGHT	Elements of practice and performance requirements
Problem recognition	Understanding of the problem (the clinical question)
Patient	Age, gender, pre-existing conditions
	Signs and symptoms
	Pre-test probability
Test	Right test
	Diagnostic performance
	Evidence of effectiveness
Sample	Right patient, right sample
	Appropriate specimen e.g. absence of hemolysis, no contamination
	Timing of collection e.g. relevant to other processes (ward round etc)
	Transportation and storage
Timing	According to clinical practice requirement e.g. drug treatment
Analysis	Required analytical performance
Result	Methodological and physiological interferences
	Quality control
Reporting	Timely
	Critical limit alerts
	Interpretation inc post-test probability
Decision	Timely
	Appropriate
	Patient involvement
Action	Timely
	Appropriate
	Patient involvement
Outcome	Patient satisfaction
	Process efficiency

can all be converted into questions, e.g., how do we minimize the risk of blood culture contamination, and of hemolysis during blood collection? These issues are addressed in this special issue [25,26]. This was recognized by the CDC's Division of Laboratory Science and Standards through support of the Laboratory Medicine Best Practices Initiative [27]. Christenson et al. have described a process for collecting and evaluating data from quality improvement studies relating to elements of the practice of laboratory medicine [24]. It is effectively an incremental approach to assessing the performance of elements of a complex process, and offers a practical alternative to the rigors of a randomized controlled trial. In some cases the outcome of the process is some measure of the efficiency or the effectiveness of that process. However, it should be stressed that if the process outcome (or improvement) triggers a downstream effect on later stages of the diagnostic OR the care process, e.g., the time at which a clinical decision can be made or action taken, then the subsequent actions have to be part of the evaluation — and any subsequent process change. An example here is in the use of point-of-care testing (POCT) where there is a significant change in both the "diagnostic process" and the role it plays in the "care process"; i.e., there has to be a care process change as a result of the rapid delivery of the result [13,28]. In other words, to state the obvious, improvement in laboratory medicine practice can invariably require a complementary change in clinical practice in order to deliver the benefit.

This special issue features some of the first outputs from the use of the methodology for reviewing the evidence in laboratory medicine practice as described by Christenson et al. [22–26], and which address specific elements of laboratory practice listed in Table 1. The methodology is founded on that used in EBM and EBLM in which the first, and critical, step is identifying the nature of the problem or question. The methodology progresses through to application of evidence and review of practice (essentially the same as performance management and continuous quality improvement) [19], illustrating the breadth of application of the core principles of EBM and EBLM, particularly on how to evaluate some of the process aspects of the practice of laboratory medicine.

There are some interesting general points to be gained from these reports, the first being the importance of a consistent approach to study design, data collection and reporting of results. This bears out the benefits envisaged from the STARD initiative, as well as from the methodology used in evidence-based laboratory medicine and this laboratory best practices initiative [3,4,24,29]. Snyder et al. [22] make the point that much of the data is observational and therefore is at risk of bias due to the less structured approach to quality improvement work; this may warrant further attention as this project progresses. However, while the observational nature of the studies might be a weakness, the extraction of data from quality management and quality improvement programs is a strength in that it represents routine (or close to routine) practice. The extent and strength of the evidence should be of value to any laboratory manager currently making a case for specimen or patient barcoding technology. In addition the coverage of the topic to include point-of-care testing (POCT) is a valuable contribution as the use of POCT gathers pace, particularly outside of the hospital setting.

The review on critical value reporting illustrates the complexity of issues embodied in what might be considered a simple task [23]. It also highlights the issue of responsibility for the delivery of important information in a complex organization; one might argue an issue which offers an opportunity for the laboratorian to embed him/herself in the clinical team. This is a far more complex issue, and while the authors focussed on the use of automated alerts and call centers the extent and quality of evidence were insufficient to make any clear recommendation about automated alerts. That said, the exercise itself identified the need for further work as well as informing the reader as to the issues that needed to be taken into consideration — including being aware of the potential risks (in particular) associated with the use of automated alert systems.

Snyder et al. have addressed the issue of reducing contamination of blood cultures, where there are three major solutions available in the literature. This issue represents a significant amount of work for anyone seeking a solution, needing to delineate between the choice of sampling technique (venipuncture or use of a catheter sample), experience of the person collecting the specimen, and the approach to patient preparation [25]. It would appear that the use of a venipuncture by an experienced phlebotomist is supported by strong evidence from several studies.

The study on the impact of blood collection methods on hemolysis is, again, a commonly asked question, and in which, as the authors noted, practice (particularly in the emergency room) is heavily influenced by personal preference — as well as the urgency of the moment [26]. The review favors the use of the straight needle, as well as the use of sampling from the antecubital vein (rather than more distant sites) if an IV start is employed. Awareness of these recommendations will be helpful to more junior staff required to collect blood specimens.

The value of the four reviews reported in this special issue is that they address important practical questions. However, in addition, the authors have set out the methodological approach in detail, and furthermore they have identified the limitations of their work. Thus, while there are still questions to be addressed with regard to the use of the observational data from quality improvement studies, this initiative offers a transparent process for communicating the quality of processes expected in laboratory best practice guidelines. These studies also offer helpful insights into the design and conduct of future quality improvement exercises that will enhance the practice of important steps in assuring the quality of the contribution of laboratory medicine to patient care.

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