A key objective of Evidence-Based Medicine (EBM), which resonates strongly in laboratory medicine, is the emphasis on improving the quality of the information on which decisions are based, highlighting the role of the laboratory as a key 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…”, and there are clear synergies in Evidence-Based Laboratory Medicine (EBLM). What is (or are) the outcome(s) of a laboratory investigation?

It is important in applying the principles of EBLM to understand the objectives of the laboratory medicine service. The value proposition, for any investigation is based on the unmet need, the benefit of the investigation and the beneficiary of the outcome. Benefits can broadly be categorised in clinical outcomes, process outcomes and economic outcomes. Thus, while the patient is the prime beneficiary, all of the stakeholders involved in the provision of healthcare will be beneficiaries – positively or negatively. Thus, it should be agreed that:

• an “appropriate” test [result] helps to satisfy an unmet need
• test results only generate a benefit when acted on
• appropriate test results should therefore [always] provide a benefit
• several stakeholders contribute to delivery of health care
• the unmet is likely to impact (+/-) on all stakeholders
• benefits are likely to impact (+/-) on all stakeholders
• all stakeholders share a responsibility to deliver the benefit.

The core of EBLM is the A5 cycle – ask, acquire, appraise, apply and audit. Asking the right question is the first step in problem solving and can be applied in many scenarios, (i) pre-analytical considerations for a test e.g. time of collection, (ii) analytical performance of a test e.g. impact of test imprecision on outcome, (iii) mode of delivery of a test e.g. use of point-of-care diagnostic performance of a screening test, (iv) use of a test for diagnosis e.g. rule in or rule out, (v) use of a test for prognosis, (vi) use of a test for treatment selection i.e. personalised medicine, (vii) use of test for treatment optimisation and compliance, (viii) health economics of a test, (ix) test utilisation i.e. audit/performance management, and (x) commissioning/decommissioning of tests.

In routine practice the question is structured to define the current clinical practice and patient setting, the test intervention and the expected outcome testing. There is a core to the question when applying the test to a clinical diagnostic problem based on the PICO formula, where P=patient, I=intervention, C=comparator and O=outcome. There are variants to this formula – typically specifying more detail related to the patient setting, e.g., T for timing of specimen collection, and C for change management (relevant to adoption of a test. The broader application of the structured question reflects the underlying use of a common approach to problem solving in innovation with adoption of new tests, quality control and performance management. However, recognising the benefit from the use of a test does not come from generation alone, but depends also on the decision made and action taken once the result has been delivered. So, the information required to define the patient setting (i.e., P) includes not only the patient characteristics (gender, age etc.) but also the setting in which the problem is found, e.g. the home, primary or secondary care etc. Similarly, there are characteristics of the intervention that need to be defined, e.g. whether the test is delivered from a central laboratory, or at the point of care, as well as other aspects like the analytical performance. In the case of the generation of evidence on the utility of a test then the comparator is the gold standard or reference method. In the case of quality improvement, the comparator is the clinical guideline in which the test result is employed.

Acquiring the evidence is the next step and a multifaceted activity. Crucial to this step is the definition of the pathway into which the test result contributes. Furthermore, it is important to collect the data relating to any element of resource that the test result may impact, tests and treatments, time to optimisation treatment, length of stay. In relation to generating evidence of effectiveness this data will cover the pathway that is expected with the use of the new test, while to comparator might include data relating to current practice – including the outcome measure that is being considered most relevant to the use of the new test.

In its broadest sense outcomes are measures related to the output healthcare delivery and can be categorised as clinical, operational or economic. All of the outcomes, and therefore outputs, of the delivery of healthcare can be used in the development, adoption, quality control and performance management of any care pathway in which laboratory medicine participates.
A key attribute in the practice of EBLM is critical appraisal. Critical appraisal has been described as ‘weighing up the evidence to assess its validity (closeness to the truth) and usefulness (clinical applicability). It is applied in clinical practice in the production of systematic reviews and clinical guidelines. However, it can also be applied in EBLM to inform research questions and the generation of evidence as well as in adoption of tests and in quality improvement. The attribute can be described in generic terms as applied to review of evidence:

- In the statement of the unmet need is the question clear?
- Are the results of the study valid? This is called internal validity.
- What are the results?
- Are the results relevant to my patient (or population)? This is called external validity.

Acknowledged barriers to adoption of new technologies in healthcare include the lack of an implementation plan, and an inability to disinvest in redundant resources. Using the principles of EBLM is therefore central to the application of evidence and audit of practice. EBLM therefore underpins innovation, quality control and performance management.