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Measuring the impact of laboratory medicine on clinical management and patient outcomes

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All who work in laboratory medicine have anecdotal evidence of the value of laboratory medicine in delivering safe and effective patient care and improving individual patient outcomes by enabling faster, more accurate diagnosis and effective treatment. However, systematic evidence of the contribution of laboratory medicine to the clinical process has been much harder to obtain – understandably so, in view of the multitude of factors that are involved in reaching a diagnosis or planning treatment for an individual. Laboratory medicine has also had a broader impact upstream of diagnosis and management, playing a key role in areas such as risk assessment and screening of healthy subjects for latent disease. These areas are becoming increasingly important with the recognition that early diagnosis and intervention reduces overall healthcare costs for a wide range of common diseases.

The so-called "70% claim" is commonly cited to indicate the value of laboratory medicine. It occurs in various forms, most commonly that "Laboratory medicine data influences 70% of clinical decisions" (1), or minor variations around this figure. Unfortunately, the data on which this claim was based represents unpublished studies and anecdotal observations (2), and cannot now be objectively verified.

We need more specific and evidence-based measures of the added value of laboratory medicine, which in turn require better designed studies and better use of existing biomarkers. The IFCC Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes was established by the Executive Board in 2012 to evaluate the available evidence supporting the impact of laboratory medicine in health care, and to develop the study design for new and prospective studies to demonstrate the contribution made by laboratory medicine to improving outcomes.

The Task Force has recently published its report (3), which summarizes the existing evidence and indicates the gaps in our understanding. It also identifies deficiencies in current utilization, suggests potential solutions and offers a vision of a future in which laboratory medicine is used optimally to support patient care. This special issue of eJIFCC explores the central issues in more detail, with contributions from acknowledged experts in the field.

Rapid, accurate diagnosis of the patient's presenting condition is essential to obtaining the best outcome, and there has been much

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emphasis on recent years in reducing diagnostic error. The work of Plebani's group has clearly shown that, where diagnostic error arises from laboratory testing, the pre- and post-analytical phases are much more vulnerable to error than the actual analytical phase (4), which implies that laboratories need to refocus their efforts on error reduction toward the total testing process rather than simply on the analytical aspects of their work. Mario Plebani develops these ideas in the first article in this issue *"Diagnostic Errors and Laboratory Medicine – causes and strategies"*. He emphasises the importance of focussing on appropriate test utilization and accurate result interpretation to reduce the overall risk of laboratory-related diagnostic errors and improve patient care.

Danielle Freedman takes up this theme in our second article *"Towards better test utilization – strategies to improve physician ordering and their impact on patient outcomes"*. She discusses the factors that influence test ordering by physicians, and describes proven strategies for achieving change which improve laboratory utilization and have a direct effect on patient outcomes. Influencing the behaviour of individual physicians is important, but physicians are increasingly reliant on evidence-based international guidelines for effective diagnosis and management of disease, and the laboratory community must ensure that it is represented when these guidelines are prepared if the uses and limitations of laboratory tests are to be properly understood. Howard Morris' article *"Collaborating with International Clinical Organizations"* describes IFCC's role in working with international clinical organizations to enhance the effective translation of developments in laboratory medicine to improve patient care and clinical outcomes, and ensure their adoption into routine clinical practice via inclusion in relevant clinical guidelines.

However good a laboratory test, it cannot affect the individual patient outcome if the result never reaches the clinician who is responsible for delivering care. Joanne Callen and colleagues address the topic of "*The impact for patient outcomes of failure to follow up on test results. How can we do better?"*, and outline potential solutions to the widespread problem of missed results. Solving that problem requires the laboratory to get involved in establishing and maintaining resilient governance approaches, and creating a culture dedicated to ensuring reliable and safe patient care.

Having explored in detail what needs to be done to ensure that laboratory tests are ordered and used appropriately, the other two presentations in this issue focus on how the value of laboratory medicine can be measured and demonstrated. Bruce Jordan and colleagues discuss *"The clinical and health economic value of clinical laboratory diagnostics",* using as exemplars three disease areas that represent substantial health care burdens for society – heart failure, Alzheimer's disease and asthma. Finally, Patrick Bossuyt and Parvin Tajik's article *"Evaluating biomarkers for guiding treatment decisions"* presents a theoretical framework for evaluating treatment decisions and summarizes study designs for evaluating treatment selection markers. It is vitally important that new markers receive robust outcome-based evaluations before they are introduced into clinical practice, in exactly the same way that new drugs are evaluated before they are licensed. The European Group on Tumor Markers has recently published a proposal on evaluation of new tumor markers (5), which describes a four-phase approach, similar to the process used by the FDA and others for the evaluation of new drugs.

The report of the IFCC Task Force (3) concludes that work is required in five areas to ensure that laboratory medicine is firmly focussed on improving outcomes:

1. Improved utilization of existing and new tests. This requires determination of optimum testing strategies based on patients' presenting complaints, development of interventions to support appropriate test ordering/requesting, proper sample collection, transport and storage, effective strategies for transmission of test results, agreement on clinically-appropriate triggers for critical result notification and consultative services and comments to ensure that results are properly applied.
2. Defining new roles for laboratory professionals that are focussed on optimizing patient outcomes by adding value at all points of the diagnostic brain-to-brain cycle and auditing the effectiveness of these roles and the overall diagnostic process.
3. Development of standardized protocols for prospective patient-centred studies of biomarker clinical effectiveness or extra-analytical process effectiveness.
4. Benchmarking of existing and new tests in specified situations with commonly accepted measures of effectiveness including post-implementation audit. This must include the effects of pre- and post-analytical components of the testing process, and must consider the overall impact of the testing process on all relevant clinical outcomes.
5. Agreed definition and validation of effectiveness measures and use of checklists for articles submitted for publication.

Laboratory doctors and scientists of the future must be involved in producing guidelines for investigation, advising clinical staff on the best strategy for individual clinical presentations and the further tests needed to confirm a diagnosis, and ensuring that results are not misinterpreted or missed and that resources (human, technical and financial) are used to do the right test on the right person at the right time. It's a daunting challenge, but getting this right means better use of tests, better patient care, lower health care costs, improved job satisfaction for laboratory workers and enhanced ability to recruit and retain good scientists in laboratory medicine. That's a goal worth working for, and the Editors hope that the Task Force report and the contents of this special issue will inspire and equip laboratorians across the world to rise to the challenge!

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