Laboratory Medicine: Value for Patients Is the Goal

To the Editor:

Bossuyt et al. (1) make interesting points regarding the major transformations in laboratory medicine in recent decades. They also underline the new competencies required by laboratory professionals to address current challenges, including the need to give “comprehensive consultative support” to clinicians. I would like to emphasize that the evolution of clinical laboratories into knowledge services is the key not only for their survival but, even more relevant, for improving patient safety.

A body of evidence has been collected in the last few years to demonstrate that a large percentage of laboratory errors occurs in the pre- and postanalytical steps (2), in particular at the beginning (pre-analytical phase) and at the end (post-analytical phase) of the total testing process. These errors are especially related to requests for an inappropriate test and errors in patient and sample identification, data interpretation, and actions taken on behalf of the patients. In particular, studies during the past 30 years have documented that clinicians ignore or overlook 25%–60% of abnormal routine and STAT tests (2); a more recent study demonstrated that a much smaller but still high percentage (3.5%) of abnormal results are not documented in the patient medical report (3).

Clinical laboratories should, therefore, assume some responsibility for the whole cycle of testing, including appropriateness of test request and interpretation, so that the reported data may result in effective patient management and, ultimately, satisfactory clinical outcomes (4). This responsibility, however, should be achieved only through a close liaison with and the involvement of clinicians and other healthcare professionals in the quality loop. Commodification, outsourcing, and the establishment of megalaboratories that simply spew out analytical results undermine the effective governance of the total testing process, and thus increase the number and risk of errors in laboratory medicine.

The report by Bossuyt et al. (1) is also welcome because it may prevent the eventual rapid spreading of a new condition, the “Alamo syndrome”. Under the increasing economic pressure affecting the delivery of laboratory services, some professionals seem to seek refuge in a closed environment (i.e., consolidated structures and megalaboratories), focusing on the mere reduction of the cost per test and on other efficiency indicators within the laboratory walls. Yet, as we all know, no one defending the Alamo survived the siege. The survival of clinical laboratories should be achieved by opening effective channels in the clinical context in which tests are required and used; laboratory services should be planned, commissioned, and delivered within a network, as part of an integrated healthcare system, and in relation to their impact on the patient’s “journey”. A focus on these processes should lead to the revision of and improvement in the timeliness, efficiency, and effectiveness of delivering laboratory information. This process must occur in the wider context of integrated clinical pathways for meeting real clinical needs, including more multidisciplinary efforts, identifying opportunities for cooperative approaches for delivering clinical information (e.g., integrating information from laboratory and imaging techniques), and streamlining training and education toward these aims.

Four main principles should therefore underpin changes in the delivery of laboratory services: (a) the goal must be value for patients and for public health; (b) laboratory services must be organized around medical conditions and care cycles; (c) clinical and economic outcomes must be measured; and (d) competition between different laboratories must hinge on the best possible quality and value in patient care, not solely upon cost per test result.

Finally, some comments should be made regarding the statement “services offered by clinical laboratories are more and more perceived as homogeneous, because many tests are performed on automated instruments using commercially available reagents” (1). As a matter of fact, current evidence shows that analytical quality is still a major issue, and data from internal quality control and from external quality assessment programs do not consistently demonstrate that the results from clinical laboratories meet evidence-based quality specifications (2). Therefore, technology is a fundamental, but not a unique feature in assuring analytical quality. Laboratorians should make more efforts to implement and communicate to clinicians the value of quality specifications, their relationships with clinical needs, and their relevance for appropriate interpretation and use of laboratory results (5).

The pathway for the future is to stimulate competition based on value and to provide knowledge services with analytical excellence as their mandatory starting point. If this mission is achieved, the interpretation and utilization of laboratory information will be more effective, and the Alamo syndrome will be banished.

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References

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Nanotechnology and Immunoassay

To the Editor:

The roots of nanotechnology can be traced back to colloid science in the mid-19th century. Francesco Selmi, often credited with the first true research in the field, studied the behavior of various metallic and acidic emulsions in the 1840s (1). Shortly thereafter, Michael Faraday and Thomas Graham, two scientific pioneers known primarily for their work with electricity and diffusion of gases, respectively, contributed further to the analysis of nanoparticulate suspensions, i.e., colloids. Faraday’s studies in electrochemistry naturally led him to the first experiments with colloidal gold (2), and Graham coined the term “colloid” after noting that certain substances showed slow diffusion rates through porous membranes (3).

Early applications of nanostructures in analysis included the use of colloidal gold and silver (i.e., nanosized gold and silver particles) as part of histologic stains (4). Since then, the scope of analytical applications of nanotechnology has increased considerably (5). One branch of analysis in which nanotechnology has had a significant impact is immunoassays.

A broad range of nanostructures (e.g., spheres and tubes) are being used to push the detection limits and throughput of immunoassay technology. Metallic and semiconductor nanoparticles, for example, are gaining popularity as highly sensitive labels (e.g., in fluorescent detection and Raman tagging), and magnetic nanoparticles are being used as solid supports for immunoassays. In addition, the fabrication of nanobarcodes structures has recently opened the door to the development of high-throughput multiplexed assays. Finally, the optimized design of self-assembled monolayer and nanoimprinted substrate surfaces has yielded precisely organized surface-immobilized antibodies, further improving the performance of immunoassays.

We have compiled a database of recent references that encompasses the body of research that lies at the intersection of nanotechnology and immunoassays, covering the period from 2005 to mid-2007. This database is intended to provide a comprehensive view of nanotechnology’s expanding role in immunologic techniques as well as spark a more focused effort in this area of study.


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References


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Use of a Bone Marrow Transplantation Model System to Demonstrate the Hematopoietic Origin of Plasma S100B mRNA

To the Editor:

The analysis of circulating RNA in plasma opens up new possibilities for the noninvasive monitoring of a variety of physiological and pathological conditions (1). In this study, we demonstrate the usefulness of a bone marrow transplantation (BMT) model system for ascertaining the tissue origin of plasma RNA species. These data were generated as part of a project to develop plasma nucleic acid markers for brain injury. Because brain injury, such as stroke, involves cell death and disruption of the blood-brain barrier, we hypothe-