Promoting innovation in Laboratory Medicine

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ABSTRACT
Laboratory Medicine represents an essential part of healthcare with a fundamental impact on the clinical management and outcome of the patient; it has undergone significant changes over time, switching from specimen- to patient-centered vision. The leitmotif of this evolution has been and is currently the innovation.

Key words: *innovation, education, laboratory medicine*

"It's far more important to know that person the disease has than what disease the person has".

Hippocrates 460 b.c.

This is nowadays the essence of the Medicine of the third millennium, which is focused on the patient and its health. Already Hippocrates 2500 years ago proposed the concept of considering the patient as a "whole" person underlying the idea that the patient must be considered as a unique human being and must be treated as such. In this scenario, Laboratory Medicine has a crucial role in allowing to practice Personalized Medicine. According to the European Commission, "*Personalized Medicine refers to a medical model using molecular profiling for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention"* (1). In other words, Personalized Medicine is focused on tailoring medical treatments to the characteristics of patient's profile stratified by biomarkers. Accordingly, Laboratory Medicine professionals are asked to play a primary role (2).

Nowadays, Laboratory Medicine is an indispensable part of modern healthcare with an essential impact on the clinical management and outcome of the patient. Indeed, laboratory testing is the single highest volume medical activity and is essential for the patient care, from the screening to the diagnosis, prognosis, therapy, and monitoring of both disease and therapy. It is recognized as fundamental to clinically cost-effective providers of healthcare since it is often the main basis for costly downstream care: admission to hospital or high-cost investigative procedures, such as biopsy or complex imaging (3). Laboratory Medicine has been defined as "*the nerve center of diagnostic medicine*" (4), and the Institute of Medicine (IOM) has included laboratory services in the 10 Essential Benefits Categories in the US healthcare system (5).

Noteworthy, Laboratory Medicine is a complex reality. It is enough to consider that a small-medium sized laboratory performs services in multiple fields (clinical chemistry, hematology, hemostasis and coagulation, immunology, pharmacology, molecular biology, microbiology, and virology autoimmunity), which require the support of different professionals (physician, biologist, biotechnologist, biomedical laboratory technician, chemist) with different but complementary skills, in a socio-political-economic context that is sometimes "schizophrenic". In addition, clinical laboratories are asked to constantly increase productivity, with fewer resources, but without compromising quality. Given that the health is a priceless asset, the resources used to maintain its integrity should be considered a value and not a cost.

It should be underlined that the role of Laboratory

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Medicine has undergone significant changes overtime, switching from specimen- to patient-centered vision. Patient-centered care is defined as "*providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions*" (5). For decades, Clinical Laboratories focused on the analytical aspect and, consequently, the laboratory was thought as a provider of numbers (6). In the last decades, the concept of Laboratory Medicine is evolving as a partner in patient care by actively collaborating with Clinicians to select and order tests and to interpret relative results, with the common aim of improving the patient's outcome.

The leitmotif of this evolution has been and is currently the innovation. Since the first clinical laboratory in 1896 at John Hopkins Hospital in Baltimore, laboratories underwent important changes, "*evolving from a small, crowded room in the hospital basement to an organization of marvelous complexity*", as stated by Conn (7). The innovation leads to the advancement in new technology, allowing the improvement in all laboratory's aspects, including quality of tests, organization, and turn-around time. The culture of innovation in Laboratory Medicine paves the way for an era of Personalized Medicine, adding significant value to the critical role of the laboratory within healthcare provision (8). Innovation can be declined into different aspects, including automation, which is the main feature of all modern Clinical Laboratories, allowing the reduction of error and the improvement of the quality of laboratory tests. The high-throughput technologies, such as microarray and next generation sequencing, openend the door to the era of "Omic Sciences".

In recent decades, the progress of biomedical and diagnostic technologies has brought great benefits in all sectors that aim to protect and improve human health; the future possibilities of these technologies are indefinable and their influence on the development of medicine and our society is of great importance.

Laboratory Medicine is a branch of Clinical Medicine characterized by rapid and continuous technological progress. The diffusion in healthcare facilities of an ever-increasing number of biomedical equipment and advanced technologies for diagnosis and therapy has radically changed the approach to healthcare, hyper-specializing technologies in the hospital setting and expanding the territorial scope up to the patient's home with telemedicine. This process of "technologicalisation" highlights the need to resort to specific skills and adequate organizational structures to guarantee the efficient and correct management of the technologies used.

The education to the innovation is fundamental. Indeed, facing with an increasingly vast and now indispensable distribution of these technologies, the healthcare facility will have to be able to choose the most appropriate ones, to use the instruments correctly, to guarantee the safety of patients and operators, as well as the quality of the service provided, optimizing purchase and management costs. Technological innovation in the biomedical field takes place according to models that are completely unique compared to what happens in other industrial contexts. Indeed, in the case of biomedical technologies, innovative processes take on a particular configuration due to the strong interaction required between different actors: clinicians, researchers, patients, technology producers, public institutions. The "path of innovation" involves different moments related to research and industrial development, market regulation and the evaluation of the clinical, economic, organizational, and ethical implications of the diffusion of technology in clinical practice. The adoption of biomedical technology in healthcare systems is therefore the result of a long process that involves various stakeholders with different roles. The final result expected by all the players involved is the production of innovation useful for the assistance processes, to be conveyed in the healthcare systems in the timeliest manner possible in safety and quality, compatibly with the economic constraints. The regulatory process represents, more than ever in this field, a valid support to facilitate the interaction between the actors active in the various processes so that industry, researchers, doctors, health managers, political structures, and citizens themselves can share and align the priorities and needs of the stakeholders involved. Actually, the results produced by clinical laboratories refer to an individual and are compared to reference intervals calculated on a "healthy" population, not considering features of the single individual that could modify its interpretation. Up to now, the use of values relating to a reference population has made it possible to guarantee an excellent quality of the health service offered, but the time seems to have come for a change of the paradigm for the interpretation of laboratory data, paying greater attention also to other individual features. One of us (9-10) has recently proposed to use also the intra-individual reference values for successive monitoring of each patient so to compare better the trends to a major severity or its decrease along one or more disease within the patient being cured. This will allow a more precise evaluation in Laboratory Medicine, particularly if the based values are taken in each subject very early in their life (18-25 years) and monitoring is followed by the family physician together with genomic predictive medicine for the predisposing asset (9-10).

In addition, we can now combine different information from the analysis of genomics, proteomics, metabolomics, and other omics, to provide optimal diagnosis and treatment. This new approach is being also more effective in case of multimorbidity as we said before, by defining the "personalized medicine". The transfer of this new rapidly developing scientific approach to the Health Service would allow for significant benefits to be obtained for patients, clinicians, and the health system itself.

Personalized medicine, therefore, relies based on the creation of therapeutic pathways based on molecular signatures of the patient. The innovative approach provided by Personalized Medicine involves a significant increase in innovative laboratory tests with a consequent increase in the volume of data to be collected, analyzed, and translated into information that will serve as a guide for clinical decisions. This implies a substantial initial investment in instrumentation, education, and training of laboratory personnel with consequent structural changes.

Another important innovation is to make diagnostic integration of several Professionals in Diagnostic Medicine (Laboratory Medicine, Pathology, Imaging Diagnostics) to produce a commented common report to the clinician, wherever this is possible.

The achievement of this goal is possible, not only by significant changes in the structure and organization of Laboratory Medicine, but also through the union of different skills and technologies and the organization of constructive collaboration among the various professionals working in the health system. A key role in the creation of networks, which are essential for the development and support of this new approach, is played by Laboratory Managers who place themselves between research activities and clinical applications and should be considered as a reference for the integration of different skills and the development of common and shared solutions.

CONFLICT OF INTEREST

None

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