



LABORATORY MEDICINE AS A PROFESSION AND CLINICAL SCIENCE – HOW TO PERFORM BOTH OF THEM WELL?

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Laboratory diagnostics is the medical discipline devoted to obtain, explore and employ knowledge about using various techniques for the analysis of body fluids composition and properties of cells and tissues, and interpretation of the results in relation to health and disease. It should be stressed that laboratory diagnostics or laboratory medicine is both the clinical discipline and the separate medical science. These two fields of laboratory diagnostics are tightly bound as in the case of other clinical sciences.

Laboratory tests are used in various stages of the diagnostic process in all fields of clinical medicine, being along with imaging studies, electrophysiological and other procedures the main source of information on the health status of the patient. It is estimated that laboratory results can be the basis of 60% -70% of medical decisions (1). In addition to routine diagnostics in symptomatic patients, laboratory tests are used for screening, treatment monitoring and medical jurisprudence. Thus, laboratory diagnostics generating around 10% of all healthcare costs is crucial for the healthcare decision-making process, contributing to improved outcomes and cost savings (1-4).

Advances in medical sciences and clinical practice cause the continuous increase in demand for laboratory testing related to their panel, the quantity and availability. Meeting this demand is possible thanks to the big methodological and technological progress in laboratory medicine over the past 20-30 years. This progress has brought the measuring picomole concentrations of various substances in body fluids and testing on the cellular and subcellular level, including genetic material. Moreover, the analytical quality has significantly improved together with an increase in laboratory efficiency and decrease in turn-around time (5,6).

However, despite this progress, a fundamental question still remains valid - how to properly perform laboratory tests, and ensure their accessibility, the adequate turn-around time, and the appropriate analytical quality? In other words – how should the laboratorians perform their work well?

Automation, consolidation, integration and centralization of laboratory procedures and manufactured on an industrial scale ready-to-use reagents have completely changed the nature of the work in diagnostic laboratories. Currently, the laboratory staff members must be familiar with often complex preanalytical phase of performed tests, analytical methodology and advanced measurement techniques and equipment, various electronic devices and information systems, which they use in daily practice. The automation of measuring systems developing very dynamically requires continuous updating of knowledge of analytical methodology and features of particular analyzers (maintenance and calibration, monitoring measurement system and electronics, trouble-shooting or error recognition, corrective action and others). Thus, the contemporary laboratorian should be also an expert in the field of advanced measurement techniques and equipment.

The remaining professional knowledge and skills have also become more complex. The preanalytical phase properly established for the continuously increasing number of performed tests should be based on the knowledge of

interfering factors influencing the obtained results (7). This knowledge is necessary for advisory functions including explaining the causes of erroneous results, which sometimes are obtained in laboratories. Moreover, the required qualifications must include an appropriate body of knowledge of the pathophysiology and diagnostics of diseases, allowing validation of the results before reporting and advisory functions offered by laboratories.

There are two key factors determining the respective competence of laboratory staff – professional training and appropriate human resources management. The required scope of the knowledge and skills is very wide and such high level of professional qualifications is not necessary for every diagnostician employed in given laboratory. According to the common organizational approach there are at least two categories of laboratory staff. Laboratory technicians familiar with analytical methodology and equipment are the operators of the analyzers and are responsible for the proper performing of tests. They are not involved in the validation of the results or the consultative and advisory functions of the laboratory. The next group comprises laboratory diagnosticians, which should be familiar with the preanalytical and analytical phase as well as with the pathophysiological, and diagnostic context of performed tests and obtained results. Their duties usually include supervising the work of technicians, validating the obtained results and releasing the lab reports and the contact with physicians ordering the tests (5,8). This contact is very important and useful for both laboratory diagnosticians and physicians and should have an organizational and technical support. The exchange of information is often helpful for validation of the results and their interpretation particularly in the case of erroneous results. On the other hand, doctors benefit of getting sometimes assistance in interpreting the results or in the appropriate choice of laboratory tests. Currently, the laboratory service includes the advisory and consultative functions and laboratory diagnosticians should be partners for physicians in the diagnostic process. To achieve this, they must have an appropriate level of professional qualifications including sufficient medical knowledge. Particularly important is that laboratory staff members' qualifications must be in line with current scientific and technological bases of laboratory medicine. Thus, laboratory diagnostics is the medical profession based on advanced analytical technologies, diagnostic expertise and medical knowledge.

Properly organized pre- and postgraduate training in all fields of laboratory medicine should ensure the acquisition of appropriate professional knowledge and skills by laboratorians (5,9). The syllabus for pre-graduate and post-graduate training in clinical chemistry and laboratory medicine should be similar to the syllabus prepared by EC4 committee (10,11). Moreover, laboratory diagnosticians should also have the ability of continuous updating professional knowledge and skills in order to raise qualifications through constant participation in training courses and medical research. They should have the ability of management in the area of laboratory medicine, taking individual and collective responsibility for their own profession along with its economic and social aspects. In order to meet these tasks, the main standards of pre- and postgraduate education for laboratory diagnosticians should ensure that:

- the study program includes basic and clinical science as well as laboratory professional training
- the basic contents are medically oriented, practical and adjusted to the needs of clinical training
- the educational facility is adequately equipped with laboratories, which must meet the quality standards for scientific and medical diagnostics laboratories
- the clinical diagnostics training should be carried out in hospital facilities by physicians familiar with laboratory medicine

Learning effects for the postgraduate education include advanced knowledge from the specialist field of laboratory medicine as well as skills and attitude to head specialist laboratories and be a consultant in the areas of diagnostic practice, prognosis and treatment monitoring.

Laboratory diagnostics or laboratory medicine is also a clinical science of a specific nature resulting from its location "across" all other clinical disciplines. Laboratory tests are an essential diagnostic tool, or the subject of numerous experimental, clinical and epidemiological studies. Laboratory medicine by its nature integrates the basic science, technical performance and clinical context for patient decision making but as the science provides a general rules of selection of tests for specific research tasks. Laboratory medicine creates also the rules of analysis and interpretation of the results and for evaluation of the diagnostic performance of laboratory tests. The scientific nature of laboratory diagnostics is best reflected in the evidence-based laboratory medicine (EBLM). According to the classical definition EBLM is the conscientious, explicit, and judicious use of current best evidence in making well-informed medical decisions (12,13). Thus, all clinical practice guidelines developed for the use of laboratory tests should be based on EBLM rules. On the other hand, EBLM serves the basis of studies designed to evaluate the use of laboratory tests in

defined clinical settings. It provides also useful tools to assess the study design, reliability of data and quality of systematic reviewing and metaanalyses (14). Altogether, laboratory medicine is the clinical science using advanced research tools and providing data relevant for clinical practice, published in highly valued scientific journals. It should be emphasized that progress in laboratory diagnostics, as in other clinical disciplines, is made not only through clinical studies, but also in daily practice. Diagnostic laboratories are a source of information that properly selected and analyzed can have high scientific value. For this reason, the institutions performing research in the field of laboratory medicine, in addition to co-operation with clinical units should be integrated with diagnostic laboratories. Separation of such institutions lowers the quality of both research and routine laboratory testing.

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