PRINCIPLES OF QUALITY CONTROL OF LABORATORY DIAGNOSTICS

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Medical science enriched clinical practice with new, high-quality technologies and significantly changed the ideas of etiology, pathogenesis and treatment of many diseases, as well as raised a question of revising main aspects of the diagnosis and treatment process. Principles of evidence-based medicine enable the expansion of intuition and qualification of a physician in a making choice of optimal management in each particular situation.

This progress mainly results from achievements in the natural sciences, which provide a powerful tool for research into processes of the human organism at cell, sub-cell and molecular levels (*in vitro* diagnostics).

Today, the laboratory serves as a diagnostic department in a healthcare setting where patients are being managed: *in vitro* investigations (over 2000 types) of their biological samples help make laboratory diagnosis. The interpretation of laboratory results by a clinician skilled at *in vivo* diagnostics and possessing a good, clinical way of thinking contribute to our knowledge of an investigated object, including differential diagnosis and character of a disease phase, as well as providing a basis for monitoring the disease so that necessary corrections during treatment can be implemented.

The necessity of timely diagnosis that helps to make treatment more efficient and shorten its duration determines priorities of laboratory medicine development in world-wide medical practice.

Taking into account the growing interest of the medical society (both healthcare authorities and practitioners in laboratory medicine), it is necessary to make this process scientifically grounded and to take an active part in it.

Participants of these processes have their individual level of competence in determining tasks, which can be effectively solved only via consensus.

A main responsibility of laboratory specialists is, in collaboration with clinicians, to have a determining influence on the decisions of healthcare authorities and manufacturers of laboratory diagnostic products. A main (collective) goal is to contribute to our understanding of the possibilities of laboratory medicine in reorganizing the healthcare system.

A necessary component of this process is absolute adherence to quality principles of laboratory diagnosis through unified technological policy and management of both internal (according to Russian system of standards) and external quality control systems.

Taking into consideration the scientific and organizational potential accumulated by the metrological service for the assured accuracy of measurements, development of etalons and model measuring instruments, it seems particularly actual to establish reference laboratories within the system of the Ministry of Health and Social Development.

In metrology, defining error value, an important characteristic of a measuring instrument, is always performed relative to an actual meaning of the measured parameter. This approach allows us to obtain comparable results using instruments with different levels of accuracy and based on different methods of measurement.

A clinician is interested in comparing laboratory results with a population, group or individual norm. The accuracy in defining the boundary between norm and pathology determines the requirements for allowable error in measuring diagnostic parameters.

A laboratory specialist should not only provide a qualified performance of analysis but also participate in a collective diagnostic process.

These actions were aimed at methodologically ensuring one of the most challenging tasks of evidence-based medicine, namely providing a measure and units for measuring clinical parameters, including laboratory investigations as well as their comparability. Active implementation of the European Directive «In Vitro Diagnostics, IVD» seems a promising initiative. However, every action of this kind should be discussed in a dialogue of specialists in both laboratory diagnostics and metrology. It is useful to address an aphorism that biographers ascribe to Albert Einstein: exact sciences do what is possible in a proper way, while applied sciences do what is necessary in an available way.

International society has an enormous scientific and organizational potential for ensuring a proper accuracy of measurements, development of etalons, measuring instruments and standards. For effective cooperation of regulative organizations in the area of clinical laboratory diagnostics, the establishment of reference laboratories within the system of Russian Health Surveillance is needed. The reference laboratory responsible for STI diagnostics should have all the necessary facilities for identification of the whole range of infectious agents with the use of modern methods.

In addition, it appears to be particularly important that in a reference laboratory there should be specialists whose main responsibility would be research into the development of new, advanced technologies. The activity of a reference laboratory, which has to be accredited by the Russian Technical Regulation Agency, is in concordance with the «Agreement on cooperation of the Federal Technical Regulation and Metrology Agency and the Federal Health Surveillance and Social Development Service in the area of conformity, standardization and providing and receiving information» in the area of clinical laboratory diagnostics.

The Russian government approved the National Program «Health», which reflects basic principles of improvements in prophylaxis at national and regional levels.

The Program makes it possible to correct disproportional distribution of resources in the healthcare system: presently, the majority of resources are spent on hospital service, with much less resources being given to ambulatory service. It is obvious that the effectiveness of prophylaxis is mainly dependent on first contact medical services. For this reason, efforts should be made to improve the activity of primary healthcare services. Specialists of ambulatory settings (i.e. general practitioners) should have profound knowledge of laboratory medicine and they should have a clear idea of *in vitr*o diagnostic possibilities. Quality of STI diagnostics can be guaranteed with an active participation of a general practitioner in the laboratory analysis process. For quality control of this activity, both laboratory specialists and general practitioners have to learn and then introduce into practice principles of international regulatory document ISO/FDIS: Point-of-care testing — Requirements for quality and competence.

Because of his wide experience and encyclopedic knowledge in the area of laboratory medicine, the president of the Russian scientific society on clinical laboratory diagnostics, Professor V.V. Menshikov, was able to formulate national standards of laboratory diagnostics based on international standards:

- international standard ISO/FDIS 15189: Medical laboratories — Particular requirements for quality and competence (ISO 15189:2003);
- international standard ISO/FDIS 15195 ISO/TC 212: Laboratory medicine — Requirements for reference measuring laboratories;
- international standard ISO 17511-2003: Medical instruments for in vitro diagnostics — Measurement of parameters in biological samples — Metrological traceability of meanings ascribed to calibrators and control materials;
- international standard ISO 18153 – 2003: Medical instruments for in vitro diagnostics — Measurement of parameters in biological samples — Metrological traceability of catalytic concentration of enzymes ascribed to calibrators and control materials is an important milestone in implementing a system of voluntary certification of laboratory investigations.

At present, leading laboratories in Russia are actively involved in the process of voluntary certification in accordance with № 2493 order of Ministry of Healthcare (November 2, 2005) «Introduction of voluntary certification of laboratory investigations into the healthcare system». This work was commissioned to non-commercial partnership — Center of external control for quality of laboratory investigations. A regulatory document for microbiological laboratories is currently being developed.

It is reasonable to assume that the introduction of laboratory standards plays a key role in a basic change of status of laboratory product manufacturers and in implementing an accreditation system in the production consistent with ISO principles.

On the whole, the vector of laboratory medicine development is directed towards strong adherence to quality of clinical laboratory investigations. The national project «Health» gave this process a certain acceleration.