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С. В. Котлика

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ANALYSIS OF RESEARCH METHODS IN CLINICAL AND DIAGNOSTIC LABORATORY

Sydorko 1.1., Baitsar &. I.

Забезпечення якості лабораторних досліджень є однією з центральних проблем сучасної лабораторної медицини. Тільки завдяки точній організації та якісному лабораторному тестуванню можна очікувати, що кожен результат, про який повідомляється в санкціонованому звіті, може бути використаний лікарем для прийняття діагностичних рішень та відповідного лікування. Дуже важливо забезпечити точність та узгодженість результатів досліджень. Тільки за чіткої організації та якісного проведення лабораторних досліджень можна очікувати, що кожен результат, відображений в авторизованому звіті, може бути використаний лікарем для прийняття діагностичних рішень або рішень, які змінюють схему лікування. Одним зі способів визначення компетентності клініко-діагностичних лабораторій та якості їх досліджень є проведення незалежної оцінки якості.

Ensuring the quality of laboratory research is one of the central problems of modern laboratory medicine. Only through accurate organization and quality laboratory testing can it be expected that every result reported in an authorize4 report can be used by a physician to make diagnostic decisions and appropriate treatment. It is important to ensure the accuracy and consistency of test results Only with a clear organization and quality of laboratory tests can we expect that each result reflected in the authorized report can be used by a physician to make diagnostic decisions or decisions that change the treatment regimen. One of the ways to determine the competence of clinical diagnostic laboratories and the quality of their research is to conduct an independent quality assessment.

Clinical laboratory diagnostics (laboratory medicine) is one of the most important components of the health care system, which provides medical - diagnostic care to patients in assessing health status, diagnosing diseases, monitoring treatment results, further prognosis, and quality of life. Today, the process of reforming medicine and bringing it closer to EU standards in the country has just begun, it will also affect the quality system in clinical diagnostic laboratories. Special attention is required to measurement procedures in the structure of laboratory diagnostics as a tool for objective assessment of the patient's condition. The initial procedure for laboratory research is the measurement, which together with quality management is the fundamental basis of any laboratory. In addition, the clinical diagnostic laboratory, as a subject of market relations, must solve the problem of implementing and ensuring a quality system as an element of ensuring

the conformity assessment procedure. During treatment, patients undergo a laige number of different types of diagnostic tests. Among them, clinical laboratory studies occupy an important place. According to the results of laboratory tests, doctors clarify the diagnoses of patients, conclude the level of compliance of important parameters of human life, its organs with regulatory values and their changes during the treatment process and prognosis for quality of life in the future. Therefore, the reliability of the results of such specific conformity assessments is directly related to health and life.

Scientific publications of domestic and foreign specialists in the field of laboratory work are mainly devoted to the introduction or improvement of a method of laboratory diagnostics, ignoring the problem of organizing the laboratory service system as a subsystem of health care.

The main strategic direction of the development of modern laboratory diagnostics in Ukraine is to improve the quality of clinical laboratory research.

The quality of clinical laboratory tests is understood as the presence of confidence that the test correctly and timely assigned to the patient is. per r formed at a sufficient analytical level with the appropriate rate of accuracy of analysis in biological samples.

Quality control should inel ude a permanent system of internal laboratory control and external quality assessment of laboratory tests. The existence of a system of internal laboratory control and external evaluation of the qual- ^{A} ity of laboratory tests is one of the basic confirmations of the competence of the laboratory and its accreditation. Poor quality laboratory tests lead to misdiagnosis, inappropriate and incomplete treatment, and risk to patients. Clinical laboratory tests are a major factor in assessing human health and clinical diagnosis of diseases. They study the composition of samples of biological materials taken from the examined patients. The purpose of clinical laboratory research is to obtain objective information about the internal environment of patients, to establish the presence or absence of changes in the composition of biological materials, which are characteristic of abnormal organs and systems of the examined patient in the presence of certain forms of pathology. Laboratory tests occupy the main position in the overall picture of the patient's condition, which is essential for diagnosis, assessment of pathology, and dynamics of the disease, deciding on the application of necessary treatment measures.

Laboratory medicine provides 70-80 % of the information needed to make decisions about the diagnosis, treatment, and prevention of diseases. Providing reliable information to clinicians is an important requirement

for the quality of clinical laboratory tests of clinical diagnostic laboratories, which ensures the correct and timely appointment of the analysis for the patient. Only with a quality laboratory test can you count on the correct diagnostic decisions and proper treatment. One of the ways to determine the competence of clinical diagnostic laboratories and the quality of their research is to conduct an independent quality assessment [11.

For the quality of the research results, serious problems are created by a large number of objective and subjective factors. To eliminate the problematic factors, the course was aimed at developing national standards in the field of laboratory medicine using international experience that regulates the require ments for the organization of clinical diagnostic laboratories an d laboratory analytical institutions. An acute problem of laboratory tests is to ensure the accuracy of the results. The main requirement for such research is to provide reliable information to consumers. First of all, it determines the requirement for the quality of clinical and diagnostic laboratory tests, which ensures the correct and timely appointment of the patient's analysis performed at the appropriate analytical level, with the necessary information for interpretation. One way to determine the competence of clinical and diagnostic laboratories and the quality of the ir research is to conduct an independent quality assessment.

One of the main requirements for laboratory tests is the ability to meet medical requirements with analytical reliability, clinical information, and timeliness. Many traditional and new trends in the clinical diagnostic laboratory (CDL) require constant correction of the interaction, but most importantly - to remain objective in laboratory research. A significant amount of research falls on general clinical laboratory tests, a little less on biochemical, even less on bacteriological, cytological studies, the least on sanitary- genetic.

The structure of laboratory research in modem medicine is multifaceted, meets the basic practical requirements - the maximum objectivity of the results. To solve the problem of maximum objectivity of the results of laboratory research in general - it is customary to rely on numerous standards (regulations), which, in turn, change dynamically and depend on many factors.

To objectify th e results and more efficient operation of general clinical and specialized laboratories, as well as laboratory centers, it is planned to test the system, starting with preparing patients for laboratory tests, biomaterials, accurate laboratory tests, compliance with delivery rules, compliance with pre-processing results, design and providing results. Given the

significant number of circumstances and factors that affect the objectivity of laboratory tests, it is possible to predict ways to optimize them. The purpose of this work is to assess the gen eral problems of the objectivity of laboratory tests and to suggest ways of their ratio nal solution.

The rational choice of a technique is extremely important for the estimation of the quality of research. Its essence is the criteria of analytical suitability. These include specificity, accuracy, relevance, reproducibility, correctness, selectivity, and sensitivity. Specificity - the property of the method to qualitatively and quantitatively identify a single substance. Accuracy - the quality of measurements that reflect the closeness of the results of the content of the analyte to its true concentration. Conformity - the proximity of the results of the study, performed under the same conditio ns. Reproductiveness characterizes the proximity to each other of the results of studies performed in different conditions. Correctness — the correspondence of a certain result to its true value. Selectivity - the quality of separation of a particular substance from impurities and the dependence on the concentration of the test material. Sensitivity- the ability of the method-to determine the smallest amount of analyte. There is a sensitivity threshold for each laboratory method.

The scientific and methodological basis of laboratory diagnostics is complex and uses theoretical and analytical capabilities of individual sub-disciplines of laboratory medicine: general clinical research, biochemistry, hematology, coagulatory, cytology, laboratory genetics, molecular biology, immunology, is serology, bacteriology, virology, mycology chemical and toxicological studies, therapeutic monitoring of drugs, etc.

To objectify the results and effective work of general and specialized laboratories, as well as laboratory centers, it is planned to test the system, starting with preparing patients for laboratory research, taking biomaterial, accurate laboratory research, compliance with delivery rales, compliance with biomaterials pre-treatment regulations actually laboratory research, registration and delivery of results (information for the doctor). Given the significant number of circumstances and factors that affect the objectivity of laboratory tests, it is possible to provide options for their optimization.

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Given the analysis of factors and techniques that affect the objectivity of laboratory tests, to achieve quality assurance of laboratory tests based on the improvement and high reliability of methods must comply with the following requirements for laboratory diagnostics:

- rational implementation of laboratory support in different conditions of medical care;
- careful training for clinical diagnostic laboratories and ensuring their professional competence;
- modem and timely logistical support of the laboratory (reagents, test systems, calibration materials);
- improvement of analytical technologies, laboratory researches with rational modernization of the basic techniques;
- rational financing and optimization of economic conditions of laboratories and laboratory departments [2].

The correct choice of research method in CDL is one of the main issues of biochemical analysis. From an economic, analytical, and diagnostic point of view, this plays an important role in organizing the work of the laboratory. Therefore, the choice of method, the accuracy of measurements that provide laboratory analytical equipment is always relevant. Organizational issues include the conditions of implementation of the method (toxicity), the cost of remuneration, additional staff training, purchase of new equipment, reagents, providing the method, the ability to transport and store biomaterials, research and quality control at the previous stage. It is also necessary to take into account the cost of reagents and equipment, staff salaries.

From an analytical point of view, the method characterizes sensitivity and specificity; accuracy and reproducibility, availability of standard samples, control materials, the possibility of quality control. These include the stability of the reagents and the number of substances.

The diagnostic value of the method is determined by its sensitivity and specificity, the ability to obtain results in the shortest possible time, the in

dependent organization of standardization, and external quality control, including control and post-analytical stages. When choosing a method, there are often conflicts between organizational problems, the analytical capabilities of the method, and diagnostic aspects, so it is necessary to compromise. The use of the express method does not always satisfy the sensitivity and specificity of clinical diagnostic analysis. The efficiency of the express method contradicts high accuracy The cost of research is one of the main reasons for the slow introduction of new technologies. The presence of automated equipment in the laboratory allows for diagnostic tests in a short period of time, but the use of biochemical auto analyzers does not guarantee quality results [3].

To implement a new diagnostic method, it is necessary to assess: the expected number of requests, the availability of reagents, equipment, consumables, calibrators, standard samples and control materials in the laboratory, the need for staff training, quality control, and more. This applies entirely to the development of new pharmacokinetic and enzyme-linked immunosorbent assays for CDL. Equipping CDL with optical equipment also influences the choice of analytical methods.

Undoubtedly, the analytical laboratory process as a whole is a unique working concept that allows us to detect and reduce errors, including in the initial stages, such as patient identification and selection of tests, and in the final stages, such as the method of transmission and interpretation of results. Teamwork is the quintessence of safety, especially if you need jo reduce' the number of errors in the choice of tests and increase the number of adequate responses to research results. The availability of support systems that provide information on diagnostic efficacy and on-site interpretation criteria may play a role, but collaboration between professionals is a prerequisite for such a patient - centered approach and error reduction. International projects aimed at developing quality indicators for all stages of the analytical process and establishing appropriate quality specifications can allow CDL to compare, control, and improve the quality of its daily work. When evaluating the activities of CDL, the results of internal laboratory quality control are considered first. These data really reflect many of the problems of laboratory work. Most CDLs focus on the analytical stage of quality control, paying insufficient attention to the pre- and post-analytical stages. It is no secret that the organization of quality control at the pre-analytical stage is the most difficult because the collection of biological material invol ved not only employees of the laboratory. From these positions, a good organization of the pre- and post - analytical stage of quality control deserves high praise.

According to the research results, priority areas for improving medicine at the present stage have been identified. In particular, there is a need for further close cooperation between public health institutions and numerous private institutions. This not only increases the level of competitiveness of all entities but also solves the problem of improving the quality of medical services.

Justification of the introduction of foreign experience, in particular the application of quality standards in the provision of medical services, consumer orientation, which over time raises the level of medical institutions to the European one. The analysis indicates the need for further attention to the issue of qual ity in the medical sector and the activities of CDL.

In laboratory medicine, the analysis of processes, registration, documentation of all procedures and processes is carried out in accordance with quality standards, in particular, DSTU EN ISO 15189: 2015 [4]. The latter is specifically designed for medical laboratories and is a key tool for changing and improving everyday clinical practice.

The problem of ensuring the quality of laboratory tests should be addressed at the national level in the Ministry of Health of Ukraine, in health care facilities, and at the level of each individual CDL. This can help to implement the requirements of the international standard "Medical laboratories. Requirements for quality and competence", which aims to create quality management systems for CDL and their subsequent accreditation. Participation in the Ministry of Health is part of this overall system of quality assurance of laboratory tests and increases their effectiveness in the diagnostic, preventive, and curative process. For the vast majority of laboratory studies, the exact implementation of techniques does not yet ensure the reliability of the results. This is due to the fact that the study of biological material is a complex multi-stage process that involves difficult to control operations that affect the accuracy of the results. Knowledge of errors that may occur at different stages of the patient's examination, sufficient theoretical and practical competence of physicians in the field of laboratory diagnostics, correct assessment of factors influencing the interpretation of results, will help to eliminate diagnostic defects and timely treatment. The main task of CDL is to provide clinically important information, not just to present the results of the study. Research methods can be different, the only goal is a comprehensive examination of the patient. Therefore, if the diagnosis is based on laboratory data, the doctor must be confident in the quality of the study. Establishing ongoing cooperation and mutual understanding between laboratory specialists and clinicians is a necessary condition for the

contribution of CDL to the activities of a medical institution to be truly significant and properly assessed.

Conclusions. For the objectivity of laboratory researches, it is necessary to define the general problems of the laboratory which is engaged in laboratory diagnostics, to improve the preparation of experts, to improve, modernize, rationalize laboratory researches with the application of ultramodern materials, systematic informing doctors about possibilities of laboratory medicine. The problem of ensuring the quality of laboratory research is one of the central problems of modern laboratory medicine. The main requirement for such studies is to provide reliable information to clinicians. This, first of all, determines the requirement for the quality of clinical laboratory tests, which ensures the correct and timely appointment of the analysis for the patient, performed at a sufficiently high analytical level with the necessary information for its interpretation. Only with a clear organization and quality of the laboratory study can we expect that each result reflected in the authorized report can be used by a doctor to make diagnostic decisions or decisions that change the treatment regimen. One way to determine the competence of laboratories and the quality of their research is to conduct'an independent quality assessment. Tests in CDL cannot be considered reliable without proper quality control. Analyzes in CDL cannot be considered reliable without quality control. The procedure for accreditation of CDL still does not meet a number of requirements recommended by EU experts. These requirements prescribe the need for their implement ation'in practice. The level of requirements for the competence of such laboratories is much higher than established in the international standard [4].

Modem laboratory research methods involve the creation of a multi - component system of material analysis, which corresponds to the high quality and objectivity of the results. Their constant analysis and improvement, according to organizational, analytical, diagnostic, and economic expediency expands the possibilities of diagnostic laboratories. The use of modem information technologies and methods allows the doctor to get fundamentally new opportunities for a reasonable choice of treatment tactics. The use of data analysis methods for the development of support systems for management decisions in clinical laboratory diagnostics opens new perspectives. Thus, modem laboratory research involves the creation of a multi-component system of material analysis, which corresponds to the high quality and objectivity of the results.

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