IJIMM, Volume 2, Issue 2, 2024 ISSN: 2995-5319
http://medicaljournals.eu/index.php/IJIMM/issue/view/3

INTERNATIONAL JOURNAL OF INTEGRATIVE AND MODERN MEDICINE

Quality Control in Clinical Laboratory Diagnostics

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Abstract: Quality control of clinical laboratory research is the creation and regular implementation of a system of measures to identify and prevent unacceptable errors that may occur in the course of laboratory research. Control of the analytical process is necessary to create confidence that analytical errors do not affect the clinical significance of the results.

Keywords: clinical diagnostic laboratory, quality control.

The quality control system is based on the principles of standardization of all stages of laboratory research and analysis of the results of in-laboratory quality control and external quality assessment. Quality assurance is understood as a set of planned and systematically carried out measures necessary to create confidence that the diagnostic information contained in an authorized report meets certain quality requirements. Quality control of clinical laboratory diagnostics is the creation and regular implementation of a system of measures to identify and prevent unacceptable errors that may manifest themselves in the process of performing laboratory tests.

The complete laboratory cycle consists of:

The quality control system is based on the principle of standardization of all stages of research.

1. Preanalytical stage

- preparation of the patient, appointment of the study, registration and collection of biomaterial, transportation to the laboratory, sorting of samples.

2. The analytical stage

- direct laboratory testing, including quality control measures.

3. Post–analytical stage

- validation of the obtained result of the study by the laboratory doctor, laboratory conclusion, issuance of the result to the patient or attending physician and solving a clinical problem based on the results of the study.

In Europe, the following definition has been adopted: quality, in relation to medical laboratories, is a correctly and timely prescribed test for a patient in need, performed at a sufficient analytical level with the necessary information for its interpretation.

Patient preparation for research is one of the important components of the extracurricular part of the stage. The doctor must necessarily explain to the patient the need for laboratory tests and inform the patient about how he needs to prepare for the research.

Unlike the pre- and post-analytical stages, where the main forms of control are periodic inspections (external and internal), the quality control of the analytical stage is, first of all, an assessment of the measurement results of control samples. As a result of any measurement, there is always an error or error - a deviation of the measurement result from the true value of the measured value. Even the best analytical methods for determining the concentration of a substance in a sample do not give the same result: when repeated measurements of the same substance, in the same sample, by the same method, there is always some variation in the results. Any measurement procedure performed in the laboratory includes a number of steps - preparation of samples and reagents, dosing, incubation, optical density

measurement, etc., while at each of them there is some error that affects the final result. The measurement result thus contains the contributions of all these errors. Convergence of measurement results is the proximity to each other of measurement results of the same quantity performed in the same analytical series.

It is important to understand that, as in any field of human activity, mistakes made in clinical diagnostic laboratories are inevitable. The task of each laboratory, using a quality assurance system, is to create a reliable set of tools that allows you to identify errors and carry out targeted measures that minimize them. Quality assurance is understood as a set of planned and systematically carried out measures necessary to create confidence that the diagnostic information contained in an authorized report meets certain quality requirements.

The recommendations of the International Organization for Standardization (ISO) and the national regulatory documents of Uzbekistan (State Standards in the field of laboratory medicine) provide standards and recommendations for quality assurance at all stages of laboratory research. Only with good organization and high-quality conduct of all stages of laboratory research - preanalytical, analytical and postanalytical - it can be expected that each result produced by the laboratory, presented in an authorized report, can be used by a doctor to make diagnostic decisions or decisions that change the treatment regimen.

The products of the medical laboratory are an authorized report containing the results of a laboratory study, as well as data about the patient (name, age, gender, diagnosis), the type of biological sample, the time of its collection and delivery to the laboratory, the current reference intervals for each analyte and other information. In other words, the laboratory produces and supplies the clinician with more or less reliable, often objective diagnostic information. The basis of quality assurance at the preanalytical stage is the development and strict compliance with the instructions on the quality of this stage of laboratory research, as well as maximum standardization of all the main points.

The non-laboratory part of the preanalytical stage begins with the appointment by the attending physician to a specific patient of a certain group of analyzes (component or characteristic of the sample to be measured) included in the laboratory study. It is he who forms an application with the list of analytes necessary for him, determines the conditions for preparing the patient (for example, on an empty stomach, the time of taking or collecting biological material), the test material (blood, urine, feces, sperm, etc.). Preparing the patient for research is one of the important components of the extra-laboratory part of the stage. The doctor must necessarily explain to the patient the need for laboratory tests and inform the patient about how he needs to prepare for the research. The qualitative collection of the material is one of the standardizing and determining moments of the entire laboratory study. An important role is played by the application form for tests. A well-designed and correctly filled out application form, firstly, simplifies the procedure for prescribing tests by a doctor to a specific patient, and secondly, minimizes the likelihood of errors due to the "human factor". During transportation, the stability of individual analytes is taken into account depending on time, temperature, and exposure to direct light.

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