ANALYTICAL BASIS OF CLINICAL LABORATORY DIAGNOSTICS

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The laboratory examination of a patient is usually divided into three stages: pre-analytical, analytical and post-analytical. The analytical stage takes place entirely in the laboratory, while the other two stages have a rather significant extra-laboratory component. It is important to realise that, as in any sphere of human activity, mistakes made in clinical diagnostic laboratories are inevitable. The objective of each laboratory is to establish, through a quality assurance system, a robust set of tools to identify errors and to implement targeted interventions to minimise them.

Keywords: the diagnostic value, laboratory tests, laboratory services, haemolysis, lipemia;

Quality assurance refers to a set of planned and systematic activities necessary to provide confidence that the diagnostic information contained in an authorised report meets defined quality requirements. Undoubtedly, the patient is interested in the high quality of laboratory services. Clinical laboratory diagnosticians are also interested in the quality of their products. As for representatives of any other type of activity, for them it is important to be confident in a well-done job on a daily basis.

Motivation for quality work is one of the components of professionalism. The next group of stakeholders is clinicians as the main consumers of diagnostic information, including laboratory follow-up data. The share of laboratory indicators in the whole flow of diagnostic information used by clinicians reaches 70-80%. The issue of standardisation of laboratory tests in general, and at this stage in particular, is quite acute. Laboratory examination begins with the clinician prescribing a list of analytes whose measurement is necessary for diagnosis or monitoring of the patient's condition. One of the common causes of error is inadequate laboratory reporting. An obviously valuable test is of no value if the result of the test is not used in any way. Causes of inappropriate prescription of laboratory tests:

– the diagnostic value of the test;

– the variability of reference values;

– negative results and evaluation of the whole sum of tests (comparing the results

of more than one test);

– course of the disease;

– duplication of laboratory tests;

– sufficiency of diagnostic information.

The physician must realise that laboratory tests prescribed to confirm or exclude a disease may do more harm than good. It is obvious that there is no ready-made unified standard for the pre-analytical stage, and, apparently, there will not be (the wide specificity of medical and preventive institutions and, accordingly, clinical diagnostic laboratories serving them). There are differences in the organisation of work of a centralised laboratory and a laboratory serving a hospital. In this case, each medical and preventive institution, based on recognised international and domestic standards and recommendations, should develop and approve a standard for this stage of laboratory testing. Preparation of the patient for laboratory tests is one of the most important components of the pre-analytical stage. Certain actions must be performed here:

– The clinician should explain to the patient the need for the laboratory test;

– the nurse should inform the patient about how to prepare for the test.

The laboratory part of the pre-analytical phase begins when the sample and requisition are delivered to the laboratory. The following stages of this part are distinguished:

– organising the receipt of samples and applications (registration of patient samples);

– Sample identification, centrifugation;

– If necessary, the conditions and timing of sample storage prior to analysis;

– detection of influences (haemolysis, lipemia) and impurities (drug metabolites, contaminants);

– distribution of samples to workplaces, execution of the study.

It is recommended to organise a place of reception of biological material in the laboratory. Upon receipt of material in the laboratory, the registrar checks the compliance of samples with the directions, condition of samples, time of collection and delivery of material. The clinical laboratory diagnostician should define and approve the criteria for refusal to accept the material for testing (e.g., discrepancy between the application and the label on the tube, inability to read the application, material taken with the wrong anticoagulant or preservative, exceeding the delivery time, presence of clots in whole blood with anticoagulant, etc.). After centrifugation, the most frequent failure criteria are haemolysis and turbidity of the sample. Centrifugation is used to centrifuge various materials, which are to be used for laboratory tests in the future. Centrifugation time evaluation is primarily a determination of whether the centrifugation time and conditions are appropriate for the type of material being

centrifuged. The main form of control of the pre-analytical stage is periodic external and internal checks.

However, this form of control cannot be recognised as effective. The problem of controlling this stage of laboratory research remains one of the most serious problems of modern laboratory medicine. In modern clinics, clinical diagnostic laboratories about 90-95% of blood and other biological samples are collected using vacuum systems. Comparing the costs of open blood collection (blood collection by syringe), secondary tubes for analysers, syringes, needles, detergents and disinfectants, electricity, additional equipment for washing tubes, accounting for glass breakage, purchase of necessary reagents (anticoagulants: EDTA, citrate, heparin) and staff remuneration, on the one hand, the purchase of modern systems for the collection of biological material (blood, urine), on the other hand, the economic costs are commensurate.

But the factor of significant reduction in the risk of infection of personnel with hepatitis and HIV when using systems for blood collection (during the whole time of blood collection the sterility of the collected sample is observed, contact with the blood of the patient is excluded, guaranteeing the protection of medical personnel and the patient, safe transportation of biomaterial) in comparison with the procedure of open blood collection (blood collection by syringe) cannot be ignored.

Thuse, without the introduction of vacuum or other systems for the collection of blood and biological fluid samples in widespread practice, we cannot expect to improve the pre-analytical stage, and most importantly, to ensure the quality of laboratory research in general.

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