LABORATORY CARE FOR PATIENTS

Laboratoryjna opieka nad pacjentem

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ABSTRACT

The objective of the present paper is to provide readers with good medical laboratory practice guidelines, in accordance with the Polish Code of Ethics and Conduct in Laboratory Medicine. We focus on the three phases of laboratory testing: the preanalytical phase, the analytical phase, and the post-analytical phase. In addition, we discuss the necessity of harmonious cooperation between health professionals, such as medical doctors, clinical laboratory personnel, and nurses, and the limitations of such cooperation.

Keywords: healthcare team, laboratory diagnostics, clinical laboratory care for patients

Słowa kluczowe: zespół opieki medycznej, diagnostyka laboratoryjna, laboratoryjna opieka medyczna

INTRODUCTION

The legal acts regulating Polish laboratory diagnostics were mostly developed in parallel to the corporatist organization of laboratory personnel established in 2001 on the initiative of Dr. Henryk Owczarek. It should be stressed that the first President of the National Chamber of Laboratory Diagnosticians, Dr. Henryk Owczarek and the corporatist organization of physicians were the initiators and main proponents of legal regulations on diagnostic laboratories. Those regulations specified the standards that a medical diagnostic laboratory and its personnel must meet. They introduced the following nomenclature:

- the term for laboratories conducting diagnostic tests is “medical diagnostic laboratories”;
- the term for laboratory occupation is “laboratory diagnostician” (higher education in a relevant field is a prerequisite);
- the term for procedures carried out in laboratories is “diagnostic laboratory procedures”;
- the term for university courses in this field is “medical analytics.”

The Laboratory Diagnostics Act specifies the competences of laboratory diagnosticians, including the head of a laboratory (who must be a specialist in an area compatible with the profile of the laboratory). The Laboratory Diagnostics Act defines the physical place for conducting diagnostic laboratory procedures, that is, a medical diagnostic laboratory, which also clearly shows that laboratory diagnosticians are to provide medical care for patients in a medical diagnostic laboratory.

The legal regulations concerning laboratory diagnostics in Poland are stipulated in the following documents:

- The Laboratory Diagnostics Act of July 27, 2001, as amended;
- The Regulation of the Minister of Health on quality standards for medical diagnostic laboratories of March 23, 2006, including Annexes 1 to 5, as amended;
- The Regulation of the Minister of Health on requirements for medical diagnostic laboratories of March 3, 2004, as amended.

3 The Regulation of the Minister of Health on requirements for medical diagnostic laboratories, www.kidl.org.pl (access: legal acts).
• The Regulation of the Minister of Health on the type of collected test material and persons who may collect it of November 3, 2004;

• The Regulation of the Minister of Health on specialization for laboratory diagnosticians of April 16, 2004.

The legal regulations have led to some significant changes in the laboratory medicine community, concerning, among others, the obligation to provide laboratory medical care for patients. This obligation follows from the premises specified below:

• Chapter 4 of the Laboratory Diagnostics Act: Obligations and rights of the laboratory diagnostican, art. 27: “Laboratory diagnosticians participate in diagnostic and preventive procedures and in treatment monitoring, so they should be part of healthcare teams in order to ensure quality in the process of treatment monitoring”;

• quality standards for medical diagnostic laboratories, Section 8: Presenting and issuing reports on laboratory tests, Subsection 8.2.10 on the laboratory interpretation of test results and the responsibility of the laboratory diagnostician for the test results;

• specialization programs (e.g., in medical laboratory diagnostics) and the competences of medical laboratory diagnosticians, which include participating in the formulation of algorithms for those medical procedures that involve laboratory tests, consulting in terms of test selection, testing techniques and result interpretation, and cooperating in preventive actions.

The quality standards adopted in medical diagnostic laboratories necessitate the existence of quality management systems. Consequently, some laboratories have decided to implement the PN-EN ISO 15189:2008 standard (Polish Standard PN-EN ISO 15189:2008, Medical laboratories, and in particular the requirements concerning quality and competence), which is specifically addressed to medical diagnostic laboratories. Section 5.1.4 of this standard states that the head of a laboratory (or another person in charge) should be able to advise persons who seek information (on the choice of tests, use of laboratory services, interpreting laboratory data) and be an active member of medical personnel within his or her specialization, if need be.

What is then the overarching objective of laboratory care for patients, what does it consist of, and what benefits does it offer to the patients and doctors?

The main objective of laboratory care for patients is producing valid and reliable laboratory test results, in accordance with the current state of knowledge and within the shortest possible time. Professional laboratory care for patients involves oversight of the preanalytical, analytical, and post-analytical phases of laboratory testing.

The preanalytical phase of laboratory testing consists of:

• an order form for laboratory tests;

• preparation of a list of tests offered by the laboratory;

• instructions on patient preparation for laboratory tests;

• instructions on collection of specimens;

• handling of the collected material (storage and transport of primary specimens, criteria for acceptance and rejection of primary specimens).

Laboratories are obligated to prepare order forms for laboratory tests in accordance with the Regulation of the Minister of Health on quality standards for medical diagnostic laboratories of March 3, 2004, as amended, which specifies the data that must be contained in the form. At the same time, the Regulation obligates the diagnostic laboratories to supply a sample form and instructions on how to fill it out to the persons ordering tests (usually physicians, but in some cases also patients). This precludes the possibility of ordering tests using a prescription form or other forms.

In practice, the requirements most often ignored by the ordering persons are: recording of the time of specimen collection and the collector identity; while that most often ignored by the laboratories is recording of the time of specimen receipt. Data on the time of testing are edited on laboratory test results. That gives the doctors information concerning the actual time elapsed.

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4 The Regulation of the Minister of Health on the type of collected test material and persons who may collect it, www.kidl.org.pl (access: legal acts).

5 The Regulation of the Minister of Health on specialization for laboratory diagnosticians, www.kidl.org.pl (access: legal acts).

between specimen collection and testing, which is critical to the clinical usefulness of the test results. In this way, one can also check whether the turnaround time (TAT)\(^7\) declared by the laboratory, that is, the time from ordering a test to obtaining its results, is observed.

The preanalytical phase of laboratory care for patients involves making sure that tests are ordered in accordance with the requirements specified by the laboratory through the procedures it formulates and supplies to the ordering persons, who should abide by such procedures (legal obligation). The physician’s choice of laboratory tests should be consistent with evidence-based medicine.\(^8\) For instance, it is common practice to order tests for hormones or hormone profile (urine cortisol) in the afternoon, while due to the circadian rhythm, such tests should be conducted in the morning. Laboratory care for patients in the preanalytical phase includes:

- requirements linked to patient preparation for laboratory tests;
- determination of procedures for specimen collection;
- recommendations concerning the handling of specimens before their delivery to the laboratory.

In accordance to the requirements of the Ministry of Health, medical diagnostic laboratories are obligated to prepare for all ordering persons (doctors or patients) procedures for the preanalytical phase, presenting them to the ordering persons, and obligating them to comply with these procedures.

Medical diagnostic laboratories are under the obligation to train medical personnel in terms of preanalytical procedures.

In practice, oversight over the preanalytical phase requires close cooperation and responsibility of the entire medical personnel: the doctor ordering a given test, the nurses collecting the specimens, and the personnel transporting the specimens to the laboratory.

It should be emphasized that, in accordance to the regulations of the Ministry of Health, all the requirements concerning the preanalytical phase of laboratory testing are primarily addressed to the ordering persons.

The best example of the need to formulate preanalytical phase procedures is the urine routine and microscopy test. An appropriately conducted test provides the physician with a considerable amount of useful information, which can confirm a hypothesized diagnosis on the condition that the test was carried out in accordance with the requirements and the results are reliable. The element that is most difficult to meet is recording the time of passing urine to monitor the time from passing urine (collecting a sample) to analysis. Few instruction notes for patients specify that they should write down the time of passing urine or give this information at the laboratory. Both laboratory personnel and physicians are aware of the fact that the time of passing urine is a fundamental parameter, but nevertheless, the test is usually carried out incorrectly. The very fact that the time of passing urine is not given makes it impossible to interpret the results analytically, and, by the same token, clinically. It is known that time influences urine pH, precipitation of non-morphotic elements of urine, degeneration of morphotic elements, and the presence of bacteria.\(^9\) This is basic knowledge to all physicians and laboratory diagnosticists, and yet it is often not put into practice.

Furthermore, invalid results generate considerable costs due to delays in making a diagnosis and ordering subsequent unnecessary tests, and, crucially, they prolong the patients’ suffering.

In monitoring the preanalytical phase, an important element is the transport of samples to the laboratory, which should take place under strictly defined conditions, specified by the medical diagnostic laboratory. Contrary to popular belief, this requirement is very challenging, and if it is met, then the laboratory and medical personnel may be deemed to work to high standards. In monitoring the transport of samples to the laboratory, the important factors are time, temperature, and sample type. For instance, in determining APTT \((\text{kaolin cephalin clotting time})\) in patients treated with heparin, it is important that the time from collecting whole blood to obtaining blood plasma be as short as possible, ideally less than 60 minutes, due to the anti-heparin factor being released from platelets. In turn, blood samples drawn for determination of lactate

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concentration must be transported in ice. In the case of acid-base status assessment, the time from collection of samples to analysis may not be longer than 30 minutes at room temperature. Urine bilirubin may be detected only if the urine sample is protected against light. The aforementioned requirements seem obvious, but in practice they are often ignored and thus constitute a source of errors in the pre-analytical phase, resulting in useless laboratory results.

This part of “laboratory care for patients” is the most difficult, because it is the cause of the greatest number of erroneous test results. Professional medical diagnostic laboratories monitor this stage and impose requirements on the ordering persons to ensure that the test results are valid. Then, the laboratories may take full responsibility for the quality of the results.

One of the responsibilities of laboratory diagnosticians is to provide help in selection of laboratory tests, if necessary. Obviously, it is the ordering person (most often a physician, or in some cases a patient) that makes the decision about the type, number, and frequency of tests. In the case of physicians this help mostly concerns new laboratory diagnostic methods or prescribing the place where they should be conducted. Often physicians’ expectations give rise to implementation of new tests, as laboratories should know the needs of their clients. Furthermore, the laboratory is required to give advice to patients who order diagnostic tests on their own initiative (consulting services).

The analytical phase directly involves the performance of laboratory tests. Currently, the great potential of laboratory diagnostics, the remarkable variety of laboratory methods and tests, and the technical possibilities of the analyzers used in laboratories have led to a situation where laboratory diagnosticians need to specialize. In response to the technical challenges of contemporary laboratory medicine, 13 specializations in various fields of laboratory diagnostics have been developed for laboratory personnel; they include: medical laboratory diagnostics, medical laboratory immunology, medical microbiology, medical laboratory transfusiology, medical laboratory genetics, public health, environmental health, medical cytromorphology, medical parasitology, medical laboratory hematology, and epidemiology. The selection of analytical techniques recommended by the International Federation of Clinical Chemistry (IFCC) must correspond to the expectations of the ordering physician or patient. This concerns two basic characteristics of a laboratory test, that is, sensitivity and specificity. All laboratories seek to use tests with the highest sensitivity and specificity possible, but in practice it is not easy because higher sensitivity leads to lower specificity of a test.

Even though laboratory tests are still classified as auxiliary procedures, nowadays there is no doubt that laboratory diagnostics plays a fundamental and leading role in the process of making a diagnosis by the physician. A very important element of the analytical phase is continuous monitoring of the measurement and auxiliary apparatus, which is the responsibility of each medical diagnostic laboratory.

Medical diagnostic laboratories use validated testing methods and have documents certifying compliance with the requirements imposed by the relevant laws with a view to ensuring the highest quality of services to their clients.

The last phase of “laboratory care for patients” is the post-analytical phase, which consists of:
• laboratory interpretation of test results;
• training, etc.;
• responses to ordering persons’ questions;
• patient training.

Part of the post-analytical phase of “laboratory care for patients” is laboratory interpretation of test results, which consist of communicating professional information to the ordering person. The most frequently used indications are H (high) or L (low) or outside (below) the testing range. It is a simple laboratory interpretation of test results.

Example 1 presents the complete blood count results for a patient with suspected polycythemia vera. The laboratory interpretation of the results includes neutrophilia with a left shift, erythrocytosis with microcytosis and hypochromia, and thrombocytosis.

Example 2 illustrates the case of a patient with suspected bacterial infection. The laboratory interpretation of these complete blood count results is neutrophilia with a left shift.

In both cases, a final clinical diagnosis may be made only by the physician based on history, physical examination, laboratory test results and interpretation, and possibly other additional diagnostic procedures.

The laboratory diagnostician’s obligation and right is to answer the physician’s question: “What do the test results suggest?” Of course, such an answer is not synonymous with making a diagnosis.

Laboratory care for patients, including laboratory interpretation of test results, also involves...
**Example 1.** Complete blood count with leukocyte differential (5diff) revealing neutrophilia (NEUT: 16450/µl), erythrocytosis (RBC: 7120000/µl), and thrombocytosis (PLT: 620000/µl)

**Example 2.** Patient with suspected bacterial infection; the laboratory interpretation of these complete blood count results is neutrophilia (NEUT: 13000/µl) with a left shift

*Source:* Training materials of the Laboratory Diagnostic Unit, Norbert Barlicki University Clinical Hospital No. 1 in Lodz
educating the patient in terms of reading laboratory test results, if appropriate. Physicians often request their patients to control a given laboratory parameter and to see them immediately in the case of abnormal test results. This is very common in diabetics (blood sugar testing) and in patients with chronic lymphocytic leukemia (lymphocyte count).

Patients often find it difficult to comply with such a request, and then the laboratory diagnostician’s role is to educate them (provide information) and make sure that they have an opportunity to consult with a medical diagnostic laboratory.

Post-analytical laboratory care for patients also includes regular check-ups of screening test devices. An example is the glucometer – the patient should have a plasma/serum glucose test conducted at a laboratory in parallel with a glucometer reading at least every six months. Another form of laboratory care for patients is development of profiles of laboratory tests commonly offered by medical diagnostic laboratories to facilitate ordering tests by physicians. The development of profiles, upon consultation with the ordering physicians, is most often based on organ and systemic diagnostics, while the use of abbreviated names should be readily understandable for the clients (mainly physicians). The most widely known and used names of laboratory test profiles include: the cardiac profile, the kidney profile, the liver profile, the allergic profile, the deficiency anemia profile. The use of such profiles greatly facilitates the physician’s work. For instance, the tests conducted within the iron deficiency anemia profile include complete blood count, microscopic examination of peripheral blood smear, reticulocytes, Fe, TIBC, UIBC, transferrin and transferrin saturation, and ferritin. In this way, the physician ordering one testing profile obtains results for all the individual tests subsumed under such a previously set profile (configured by the laboratory in cooperation with the physician).

It should be emphasized that the basis for laboratory care for patients is obtaining reliable test results in accordance with the current state of knowledge and within an acceptable time limit and communicating them to the authorized person, who is usually a physician.

Only valid results of laboratory tests are useful in conducting differential diagnostics and making a final diagnosis. Valid results of laboratory tests may form the basis for implementing a treatment, and are often indispensable for monitoring, continuing, or terminating the treatment implemented. On their basis, the physician may order further laboratory tests or implement preventive procedures.

The work of laboratory diagnosticians is regulated by acts of law applicable to laboratory diagnostics, which are enforced by the Team of Inspectors of the National Chamber of Laboratory Diagnosticians (KIDL).

A uniform and transparent legal system, the continuous monitoring of the quality of services offered by medical diagnostic laboratories, as well as the awareness, responsibility, and cooperation of the entire medical community ensures high quality of medical diagnostics and laboratory care for patients in Poland and makes it possible to meet the increasing requirements and expectations of physicians and patients.

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