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Pre-analytical variability in laboratory studies. Monitoring and evaluation of pre-analytical error on the example of collected data at the West Pomeranian Cancer Center in Szczecin in Poland

Bartosz Rodziewicz[1, A], Marcin Kołodziej[2, B], Bartłomiej Pala[3, C ✉], Michał Spieszny[4, D], Maciej Sołtysiński[5, E], Tomasz Pala[3, F], Bartosz Kołodziej[6, G], Michał Piotrowiak[7, H]

[1] West Pomeranian Cancer Center, Laboratory Diagnostic Facility, Strzałowska 22, 71-730 Szczecin, Poland
[2] Pomeranian Medical University Hospital No. 1, Pediatric, Oncology and Child Immunology Department, Unii Lubelskiej 1, 71-252 Szczecin, Poland
[3] Pomeranian Medical University Hospital No. 1, Department of Pediatric Neurosurgery and Neurosurgery, Unii Lubelskiej 1, 71-252 Szczecin, Poland
[4] Pomeranian Medical University Hospital No. 1, Pediatric Emergency Department, Unii Lubelskiej 1, 71-252 Szczecin, Poland
[5] Independent Public Provincial Complex Hospital in Szczecin, Department of Gastroenterology and Internal Medicine, Arkońska 4, 71-455, Szczecin, Poland
[6] University of Warmia and Mazury in Olsztyn, Michała Oczapowskiego 2, 10-719 Olsztyn, Poland
[7] Piotrowiak Clinic, Strzelców Karpackich 20, 71-806 Szczecin, Poland

[A] ORCID: 0000-0002-4939-2821; [B] ORCID: 0000-0002-1216-4905; [C] ORCID: 0000-0002-4156-6604; [D] ORCID: 0000-0002-2992-5424; [E] ORCID: 0000-0002-5602-6782; [F] ORCID: 0000-0002-3169-9905; [G] ORCID: 0000-0003-3578-3159; [H] ORCID: 0000-0001-8591-1716

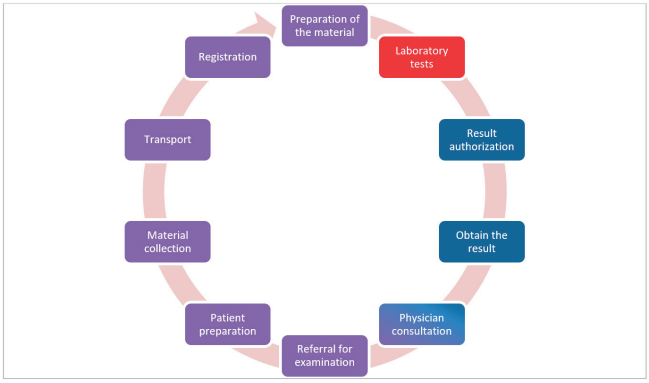
✉ pala.b@edu.pum.edu.pl

ABSTRACT
Pre-analytical phase in laboratory studies may be influenced by multiple factors, which can be categorized into patient-related, patient-independent, and interfering factors. The first group includes diet, physical activity, body position, medicines, and stimulants. These are the most important factors because here the patient can consciously influence the laboratory results. Second group are the patient-independent factors such as gender, population, age, and pregnancy are beyond the control of the patient. The last category includes conditions such as hemolysis, lipemia, and hyperbilirubinemia. They can alter the results of coagulation tests and other biochemistry studies. Hence, clots in a specimen and the presence of hemolysis and the most common factors account for 80% of pre-analytical phase laboratory errors. It is absolutely necessary to implement procedures for monitoring and assessing pre-laboratory error as well as medical staff training regarding the collection, storage, and transport of samples.
Keywords: pre-analytical error; laboratory studies; diagnostic laboratory; oncology; analytical errors.

INTRODUCTION

Reliable laboratory test results are one of the key elements in the health care system. On their basis, over 70% of decisions regarding treatment and possible hospitalization of patients are made. That is the reason why it is so important that a laboratory result is as reliable as possible [1]. A diagnostic process can be divided into 3 phases: pre-analytical, analytical, and post-analytical. These phases are closely related and are part of the so-called Lundberg cycle. Their duration is the waiting time for the result referred to as turnaround time. Figure 1 shows the phases of the diagnostic cycle. The pre-analytical phase is a set of activities carried out before the tests are performed. It includes activities such as filling in a referral for a medical examination, preparation of a patient for examination, collection of biological material, transport of samples to the laboratory, identification, and registration of samples, and preparation of material for testing. Performing these steps correctly ensures that patient samples do not change characteristics prior to testing. The next phase is the analytical stage, during which laboratory tests are performed. Ensuring the reliability of research at this stage includes supervision over the apparatus and monitoring the obtained results. For this purpose, the evaluation of analytical correctness is applied through the mechanism of intra-laboratory and extra-laboratory quality control of laboratory tests. Appropriate results of control tests allow the confirmation of the correctness of the results obtained from samples taken from patients. The post-analytical phase is the last stage of laboratory research, during which the result of laboratory tests is generated. All test results are checked for reliability and consistency by an authorized laboratory diagnostician who, if necessary, supplements the report with necessary laboratory comments. The authorized result is then communicated to the physician in paper and/or electronic form. At each of these stages, it is possible to make mistakes that can significantly affect the doctor's decision. According to literature data, errors in laboratory tests occur most often at the pre-analytic stage. It is estimated that they account for 80–90% of all errors in laboratory tests. Therefore, the task of the laboratory is to monitor errors and implement standards to minimize their occurrence. To ensure the proper quality of laboratory tests, recommendations are needed for the laboratories that perform them. One of the basic and obligatory documents defining the requirements that a laboratory should meet is the Regulation of the Minister of Health of 23 March 2006 (amended) on the quality standards for medical diagnostic and microbiological laboratories [2, 3]. An additional document recommended for medical

diagnostic laboratories is the European standard PN-EN ISO 15189 "Medical laboratories – Requirements for quality and competence". The purpose of this study is to analyze errors in the pre-analytical phase on the example of data collected at the Department of Laboratory Diagnostics (DOLD) at the West Pomeranian Cancer Center (WPCC) in Szczecin in Poland.



purple – pre-analytical phase; red – analytical phase; blue – post-analytical phase
FIGURE 1. Phases of the diagnostic cycle (Lundberg cycle)

TYPES OF FACTORS INFLUENCING THE TEST RESULT

The pre-analytical phase can be influenced by numerous factors, which can be categorized into: patient-related factors, patient-independent factors, and interfering factors [4]. All of them can have a negative effect on the result of a laboratory test [5, 6, 7, 8, 9].

FACTORS INDEPENDENT OF THE PATIENT

Population

An example of population-based differences is the difference in blood morphology results between sub-Saharan and European populations, with the former having significantly lower leukocyte counts and much higher activity of creatine kinase, and levels of creatinine and vitamin B12 [10].

Sex

The most striking differences between the 2 sexes concern the concentration of hormones, but also some differences in certain biochemical and hematological parameters. Men have a higher concentration of substances such as hemoglobin, iron, creatinine, and creatine kinase.

Age

Age significantly affects the concentration of many parameters in both blood and urine, therefore the reference values are different for children and adults. In newborns, a number of erythrocytes, as well as hemoglobin level, are much higher than in adults, which in turn increases the level of bilirubin. Alkaline phosphatase activity, which is an indicator of osteoblast growth, also decreases with age.

Pregnancy

Certain parameters change during pregnancy. In pregnant women, the mean plasma volume changes, increasing from about 2.6 L to 3.9 L. During the first 10 weeks of pregnancy, there are slight changes in the concentration of various biochemical parameters. Then, the changes increase until the 35th week, and then they stabilize. Therefore, it is important to interpret a test result depending on the stage of pregnancy.

PATIENT-DEPENDENT FACTORS

Diet

Failure to remain in the fasted state before blood sampling for tests significantly increases the concentration of many determined parameters. These changes are caused by absorption of measured substances, including glucose, phosphate, and triglycerides. After a meal, the metabolism of substances such as urea and ammonia changes. Certain food ingredients can interfere with laboratory testing. Samples should not be taken during a fasting period as free fatty acids, uric acid, adrenocorticotropic hormone (ACTH) increase, and on the other hand, insulin and triglyceride levels decrease. For this reason, it is important that the patient comes to the examination on an empty stomach, i.e. 12 h after the last meal. In addition, in case of some tests, the patient should follow a special diet, eliminating from it, for example, chocolate and bananas, consumption of which affects the results of a test of catecholamines and their derivatives.

Physical activity

During exercise, water is lost with sweat, and body fluids are displaced between the intravascular and interstitial spaces. This results in an increase in adrenaline, cortisol, ACTH, and a decrease in insulin levels. Moreover, during intense exercise, the concentration of uric acid, lactate, and the activity of creatine kinase in the serum increase. Regular exercise contributes to the growth of muscle mass, which in turn increases the concentration of creatinine in plasma and its excretion into urine. In hematological tests, an increase in the number of thrombocytes can be observed. On the other hand, in coagulation tests, there is an increase in D-dimers and a decrease in prothrombin time (PT) and activated partial thromboplastin time (APTT). However, all these changes normalize after a couple of days.

Body position

Tests results may vary depending on whether they are performed in a sitting or lying position. The plasma volume of the patient in the vertical position compared to the horizontal position can be reduced by up to 12%. Such change may lead to a difference in the concentration of many tested substances.

Medicines

Medicines taken by the patient may interfere with the method of determining a given parameter through its direct action or its

metabolites. Some medications can also affect the functions of various organs. One example is the use of ascorbic acid, which can interfere with chemical reactions in urine strip tests. Also, metronidazole may cause low levels of plasma transaminases, and ibuprofen may increase the concentration of potassium in plasma. In addition, certain dietary supplements as well as bioactive substances can also affect our metabolism and alter laboratory results (f.e. curcumin, resveratrol, silymarin). For instance, genistein might affect the human body because of its estrogen-like activity. It is implicated in increasing high-density lipoprotein and lower low-density lipoprotein cholesterol levels as well as alterations of calcium ions due to its osteoporosis prevention properties. In addition, the ceruloplasmin blood concentration can be affected by genistein, thus changing the copper serum levels. Another important bioactive substance is silymarin which is specifically associated with increased release of certain cytokines such as interleukin 10, tumor necrosis factor α as well as interferon γ, hence induced inflammatory state might have an impact on various acute-phase proteins [11, 12].

Stimulants

Alcohol abuse causes liver damage, which in turn contributes to an increase in liver enzymes such as GGT, aspartate aminotransferase, alanine transferase, and a decrease in vitamin B6 and folic acid levels. Nicotine increases the number of leukocytes in the blood and the carcinoembryonic antigen tumor marker level. Caffeine increases levels of adrenaline, noradrenaline, and cortisol in plasma. In addition, the regular use of drugs such as marijuana increases levels of potassium, chloride, sodium, urea, and insulin, and lowers the concentration of glucose and creatinine in the blood.

INTERFERING FACTORS

The most common interfering factors that significantly influence the results of laboratory tests are hemolysis, lipemia, and hyperbilirubinemia [1].

Hemolysis

Hemolysis is one of the most common abnormalities that disqualify a test specimen. In its case, components contained in erythrocytes are released into plasma or serum. Hemolysis can occur at any stage of the pre-laboratory phase. *In vitro* hemolysis can be caused by factors such as excessive storage time, freezing, and incorrect sampling. In contrast, *in vivo* hemolysis may be a result of a disease process such as hemolytic reaction after blood transfusion, thalassemia, and lead poisoning. Hemolysis is most often recognized by the visible red color of the centrifuged sample. The red color is a result of hemoglobin being released from erythrocytes. The color is visible when the hemoglobin concentration exceeds the value of 200 mg/L. Hemolysis interferes with spectrophotometric methods due to an increase in the absorbance of light in the wavelength range of 300–500 nm. In addition to hemoglobin, other substances are also released from erythrocytes, in particular potassium, phosphates, lactic dedydrogenase, acid phosphatase, and proteins. Therefore, when measuring these substances, it should be remembered that their concentration in a sample with hemolysis will be inflated. However, hemolysis does not always affect the concentration of the tested parameter. Determinations of biochemical parameters such as chlorides, calcium, iron-binding capacity, creatinine, urea, and cholesterol are not sensitive to the presence of hemolysis [13].

Lipemia

After hemolysis, lipemia is the second most common interference that affects test results. The cause of lipemia in the collected blood sample may be a failure to observe the correct time from eating a meal to blood collection by the patient, alcohol consumption, diabetes, hypertriglyceridemia, chronic renal failure, hypothyroidism, pancreatitis, multiple myeloma, primary biliary cholangitis, lupus erythematosus, and parenteral nutrition. Plasma turbidity is visible when the triglyceride concentration rises is above 3.4 mmol/L and whole blood above 11.3 mmol/L. Measurement disruptions caused by lipemia are due to mechanisms such as the scattering and absorption of light by lipids in spectrophotometric methods, as well as increasing the non-aqueous phase and partitioning effects between polar and non-polar phases. Lipemia may affect the analysis result by interfering with photometric measurements, especially glucose levels and the activity of transaminases. It happens that in the case of high lipemia it may not be possible to obtain the result due to the disturbance of the linearity of the measurement method. Lipemia can be removed, unlike other interfering factors such as hemolysis. There are many methods for removing lipids from serum or plasma. The simplest and most frequently used method is ultracentrifugation of samples with the use of micro-centrifuges [14, 15, 16, 17].

Hyperbilirubinemia

Hyperbilirubinemia may significantly influence the results of biochemical and coagulation tests. Serum yellowing caused by high levels of bilirubin may be a result of excessive destruction of red blood cells, and disturbance of the liver or biliary function. Hyperbilirubinemia can interfere in 2 ways. Spectral interferences, when during testing turbidity methods are used (e.g. in coagulology), or chemical interferences leading to disturbances in the determinations based on the peroxidase method, i.e. glucose, creatinine, and urea concentration [13, 15].

TYPES OF ERRORS

Pre-analytical errors

A pre-laboratory error is defined as a change in the concentration of the determined substance in a given biological material in relation to the initial concentration, which occurred as a result of improper preparation of the patient for testing or

incorrect handling of the material before its delivery to the laboratory. These errors are not dependent on the activities performed in the laboratory. The cause of pre-analytical errors is primarily incorrect preparation of the patient for laboratory tests. Most often it is the wrong time to collect a specimen. Other causes of pre-laboratory errors are errors made by the sampler. These errors include putting the specimen in the wrong tube, incorrect collection site, using a tourniquet for too long, collecting blood diluted with a previous infusion, collecting incorrect material, incorrect labeling of patient samples preventing identification of the collected material, mistaking patients, and inadequate protection of samples or transport of a specimen in inappropriate conditions [18].

Analytical errors

Analytical errors are errors related directly to activities of performing the tests in the laboratory. These types of errors do not necessarily mean a mistake in performing an analysis. They define a degree to which the obtained result is distant from the real value. These are errors that cannot be avoided even with the utmost diligence in performing the tests. Among them, we can distinguish random error, systematic error, and maximum permissible error [9, 10].

Random error

Random error, called the precision error, is a measure of the repeatability of the determination. It determines a dispersion of obtained results around the real value in the tested material. The precision error is quantified as the standard deviation of the method, which should be a constant value for each concentration range of the analyte. The precision of a method should not be confused with the accuracy of a method. Precision defines the degree of reproducibility of the obtained results when the measured substance is repeatedly determined in the same test material.

Systematic error

Systematic error is the deviation of the obtained result from the expected value. In order to detect a presence of a systematic error in the analysis, the result obtained should be compared with the result obtained by another method of determination. There are 2 types of systematic error:

— laboratory systematic error, most often caused by a calibration error in the reagents or equipment used,

— systematic error of the method, which may be due to its low specificity strictly related to determination methodology or to interference caused by interfering substances.

Systematic error can also be caused by an inadequate sampling or the loss of some biological material.

The permissible error

The permissible error is the maximum error that does not significantly alter the clinical interpretation of the result. Its size is only influenced by the biological variability of the determined parameter.

Post-analytical errors

Post-analytical errors are related to improper handling of a test result. Most errors in this phase are caused by the too long processing time and authorization. They also arise during transcription of the results from the analyzers to the laboratory information system and when relevant comments are not entered in final reports.

MATERIALS AND METHODS

In order to estimate the number of pre-laboratory errors, DOLD implemented the pre-laboratory error monitoring and assessment procedure, which included 6 quality indicators (QI) disqualifying the sample and the test group in which the error could occur. These indicators were developed on the basis of the model proposed by the Working Group on Laboratory Errors and Patient Safety, established by the International Federation of Clinical Chemistry. Quality indicators and a study group are presented in Table 1.

TABLE 1. Sample disqualifying factors and study groups

Quality indicators	Research group
Presence of a clot in the sample with an anticoagulant (QI-1)	biochemistry, morphology, ESR, coagulation system, serology, gasometry
Wrong anticoagulant-sample ratio (QI-2)	biochemistry, morphology, ESR, coagulation system, serology, gasometry
Hemolysis (QI-3)	coagulation system, serology, biochemistry
Improper marking of samples (QI-4)	all test groups
Samples not taken for testing (QI-5)	all test groups
Improper transport/storage of samples (QI-6)	all test groups

ESR – erythrocyte sedimentation rate; QI – quality indicators

The analysis of pre-analytical errors was performed on the basis of data collected at the DOLD of the WPCC in Szczecin. Data were collected from 3 hospital departments (Department of Clinical Oncology, Department of Clinical Radiotherapy, and Department of Oncological Surgery) and a DOLD collection point. The analysis was made by compiling all pre-analytical errors from the first 6 months of 2020 and comparing them to the data collected in the first half of 2019. It was carried out for the entire WPCC and separately for each unit. Then

the data from all units were compiled and compared. This allowed determining which errors and in which hospital unit are the most common reason for disqualifying samples for laboratory tests. The obtained results were presented in the form of a report that was handed over to the quality representative and ward nurses.

RESULTS

Error analysis in West Pomeranian Cancer Center

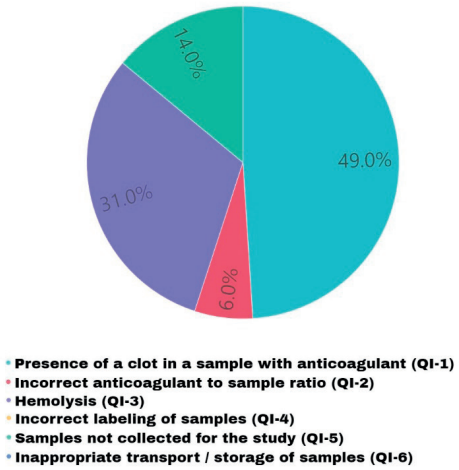
In the first half of 2020, a total of 47,480 samples were assessed at the Laboratory Diagnostics Department, including 46,188 whole blood samples and 1,292 urine samples. Out of 46,188 whole blood samples, 21,709 were biochemical samples, 18,148 hematological samples, 2,076 serological samples, 4,032 coagulation samples, and 223 samples for erythrocyte sedimentation rate.

A total of 26,404 samples was ordered by the departments of Oncological Surgery, Clinical Oncology, and Clinical Radiotherapy, 8,047, 12,417, and 5,940 samples were collected, respectively. The remaining part, of 21,076 samples, was collected at the sampling point of the Laboratory Diagnostics Department (Tab. 2).

In the first half of 2020, out of 47,480 samples delivered to the Laboratory Diagnostics Department, 196 were disqualified, which constitutes 0.41% of all samples. Of the 46,188 samples taken for the anticoagulant, 97 samples were rejected due to a clot and 12 samples were rejected due to an incorrect anticoagulant-sample ratio, which was 0.21% and 0.03%, respectively. Hemolysis was found in 60 samples (0.22%), 27 samples were not taken for testing (0.06%) – Table 3.

The largest number of samples were disqualified due to the presence of a clot in the sample with an anticoagulant, which accounted for 49% of all errors. Samples with hemolysis accounted for 31% of all pre-analytical errors and it was the second largest reason for disqualification. Failure to collect the sample for analysis accounted for 14% of all errors. An inadequate ratio between blood and anticoagulant accounted for 6% of the disqualification. There were no errors related to incorrect labeling and transport of the material for testing. The percentage distribution of errors in the first half of 2020 is shown in Figure 2.

Compared to the first half of 2019, in the first half of 2020, a decrease in the number of errors related to the presence of hemolysis, a clot in the anticoagulant sample, an incorrect anticoagulant-sample ratio, and incorrect sample labeling was observed. Errors related to failure with obtaining a sample for analysis remained the same. However, during both 6-month periods, no errors were found regarding the storage and transport of the tested samples (Fig. 3).



QI – quality indicators

FIGURE 2. Percentage distribution of errors in the first half of 2020

ERROR ANALYSIS FOR INDIVIDUAL WEST POMERANIAN CANCER CENTER UNITS

Oncological Surgery Department

In the first half of 2020, 8,047 samples were collected at the Department of Oncological Surgery, of which 50 were rejected, which constituted 0.62% of all samples. The most common reason for disqualifying the material for testing was a clot in the sample with the anticoagulant. For this reason, 29 out of 8,021 samples were disqualified, which constituted 0.36%. Hemolysis was the second cause of disqualification. For this reason,

TABLE 2. Number of samples collected by individual units in the hospital

Sample / Hospital unit	Oncological Surgery	Clinical Oncology	Clinical Radiotherapy	Department of Laboratory Diagnostics	Total
Biochemistry	2538	5301	2540	11330	21709
Hematology	2293	5290	2371	8194	18148
Coagulation	1870	544	678	940	4032
General analytics	26	876	121	269	1292
Serology	1319	389	227	141	2076
ESR	1	17	3	202	223
Total	8047	12417	5940	21076	47480

ESR – erythrocyte sedimentation rate

TABLE 3. Total number of errors in the first half of 2020

Quality indicators	Total quantity of the samples assesed	Number of disqualified samples	Percentage of samples disqualified [%]
The presence of a clot in the sample with the anticoagulant (QI-1)	46188	97	0.21
Inappropriate anticoagulant-sample ratios (QI-2)	46188	12	0.03
Hemolysis (QI-3)	27817	60	0.22
Incorrect labeling of samples (QI-4)	47480	0	0.00
Samples not taken for testing (QI-5)	47480	27	0.06
Improper transport/storage of samples (QI-6)	47480	0	0.00
Total number of samples	47480	196	0.41

QI – quality indicators

13 out of 5,727 samples were rejected, which was 0.23%. The abnormal amount of whole blood relative to the anticoagulant was the third reason for sample rejection. For this reason, 5 out of 8047 samples were rejected, representing 0.06%. Samples not collected for the examination and ordered by a physician accounted for 0.04%. There were no samples that were stored and transported improperly, nor samples that were incorrectly labeled (Tab. 4).

Among all the pre-analytical errors recorded at the Department of Oncological Surgery, the error related to the presence of a clot in the sample with an anticoagulant was the most common. It accounted for 58% of all errors. Hemolysis in samples was 26%. Inappropriate anticoagulant-sample ratios were found in 10% of disqualified samples. The lowest percentage of errors concerned samples not collected for the study, it constituted 6% of all errors (Fig. 4).

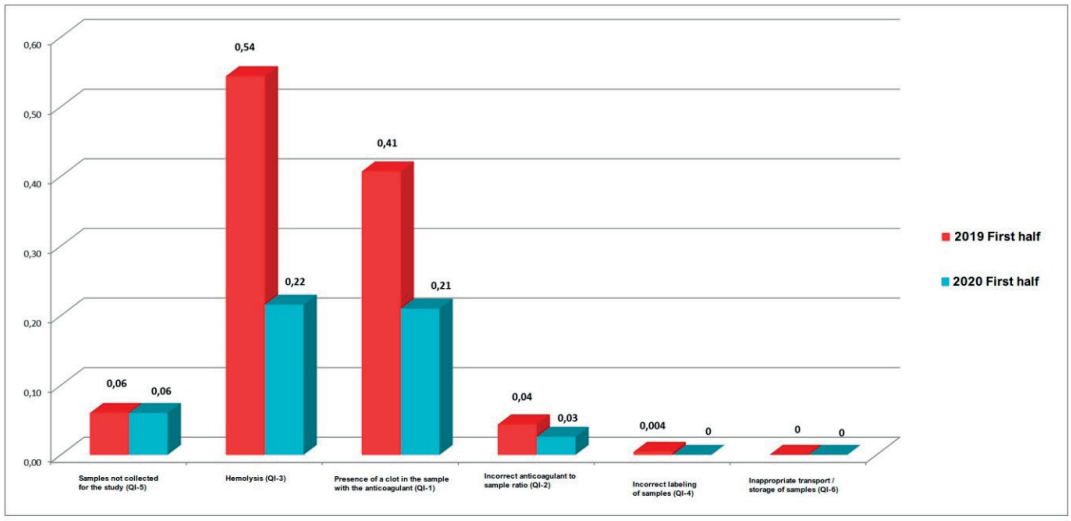
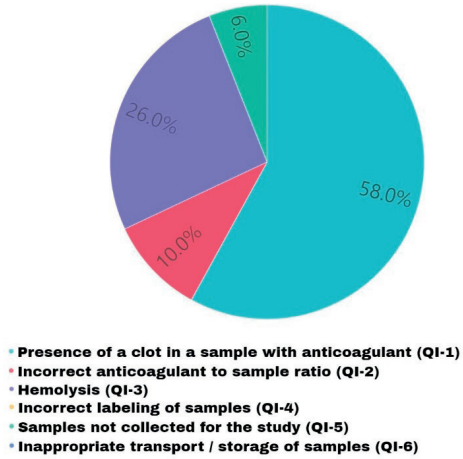


FIGURE 3. Comparison of the first half of 2019 and the first half of 2020

TABLE 4. The number of disqualified samples in the Department of Oncological Surgery and the percentage of errors in relation to all samples

Quality indicators	Number of disqualified samples	Total quantity of the samples assessed	Percentage of samples disqualified [%]
The presence of a clot in the sample with the anticoagulant (QI-1)	29	8021	0.36
Inappropriate anticoagulant-sample ratios (QI-2)	5	8021	0.06
Hemolysis (QI-3)	13	5727	0.23
Incorrect labeling of samples (QI-4)	0	8047	0.00
Samples not taken for testing (QI-5)	3	8047	0.04
Improper transport/storage of samples (QI-6)	50	8047	0.00
Total number of errors	50	8047	0.62

QI – quality indicators



QI – quality indicators

FIGURE 4. Percentage distribution of errors in the Department of Oncological Surgery in the first half of 2020

Comparing the first half of 2020 with the first half of 2019, the percentage of samples with hemolysis and improper labeling has decreased in the Surgery Department. There was a slight increase in the number of specimens with clots in the anticoagulant tubes, abnormal blood-to-anticoagulant ratio, and non-sampled samples (Fig. 5).

Department of Clinical Oncology

Out of 12,417 samples collected at the Department of Clinical Oncology, 75 were rejected due to deviations from pre-analytical requirements. It accounted for 0.60% of all samples. The most common cause of disqualification was hemolysis. For this reason, 31 samples were rejected, representing 0.50% of all samples. A clot was found in 25 out of 6,234 samples (0.98%). It was the second most frequent cause of disqualification. The third was the lack of a sample, found in 14 cases, which constituted 0.11%. Abnormal anticoagulant-sample ratio was found in 5 samples (0.04%). At the Department of Clinical Oncology, no errors were made with storage and transport of the material for testing and with incorrect labeling (Tab. 5).

In the Department of Clinical Oncology, the largest number (41%) of samples was rejected due to hemolysis. A clot in the sample with an anticoagulant accounted for 33% of all disqualification reasons. Nineteen percent of the 75 rejected samples were not collected for the study. The lowest error rate, 7%, was related to the incorrect ratio between the sample and the anticoagulant (Fig. 6).

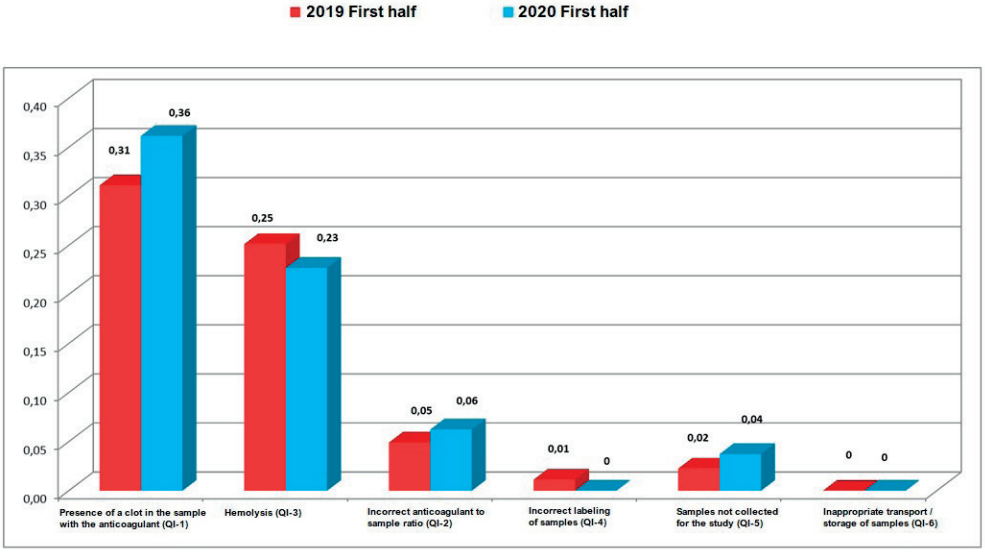
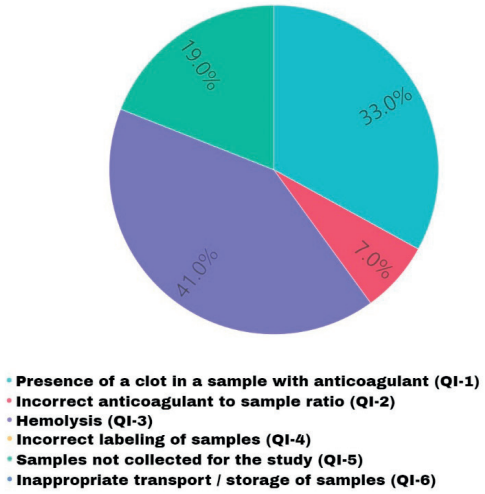


FIGURE 5. Comparison of the first half of 2019 and the first half of 2020 at the Department of Oncological Surgery

TABLE 5. The number of disqualified samples in the Department of Clinical Oncology and the percentage of errors in relation to all samples

Quality indicators	Number of disqualified samples	Total quantity of the samples assessed	Percentage of samples disqualified [%]
The presence of a clot in the sample with the anticoagulant (QI-1)	25	11541	0.22
Inappropriate anticoagulant-sample ratios (QI-2)	5	11541	0.04
Hemolysis (QI-3)	31	6234	0.50
Incorrect labeling of samples (QI-4)	0	12417	0.00
Samples not taken for testing (QI-5)	14	12417	0.11
Improper transport/storage of samples (QI-6)	0	12417	0.00
Total number of errors	75	12417	0.60

QI – quality indicators



QI – quality indicators

FIGURE 6. Percentage distribution of errors in the Department of Clinical Oncology in the first half of 2020

In the first half of 2020, the Department of Clinical Oncology showed a decrease in all types of pre-analytical errors compared to the first half of 2019 (Fig. 7).

Department of Clinical Radiotherapy

In the first half of 2020, 5,940 samples were collected at the Clinical Radiotherapy Department, 52 of which were rejected (0.88%). The most common reason for disqualification was the clot found in 35 samples, which was 0.60%. There were 10 samples with hemolysis, which constituted 0.29% of all samples. The third most frequent error was the failure to collect a sample for the study, found in 0.12% of cases. The abnormal anticoagulant-sample ratio was found in 2 cases (0.04%). Samples that were improperly labeled, stored, and with an inadequate anticoagulant-sample ratio were not found (Tab. 6).

The collected data show that 3 types of pre-analytical errors were recorded in the Department of Clinical Radiotherapy. Of all the errors, as many as 67% were samples with an anticoagulant in which a clot was found. Hemolysis was observed in 19% of cases. The smallest percentage, amounting to 14%, were samples not collected for analysis (Fig. 8).

Compared to the first half of 2019, the percentage of samples with a clot, hemolysis and an incorrect anticoagulant-sample ratio at the Radiotherapy Department decreased. The number of samples that were not taken for testing increased slightly. Both in the first half of 2019 and 2020, no samples were found improperly stored and transported (Fig. 9).

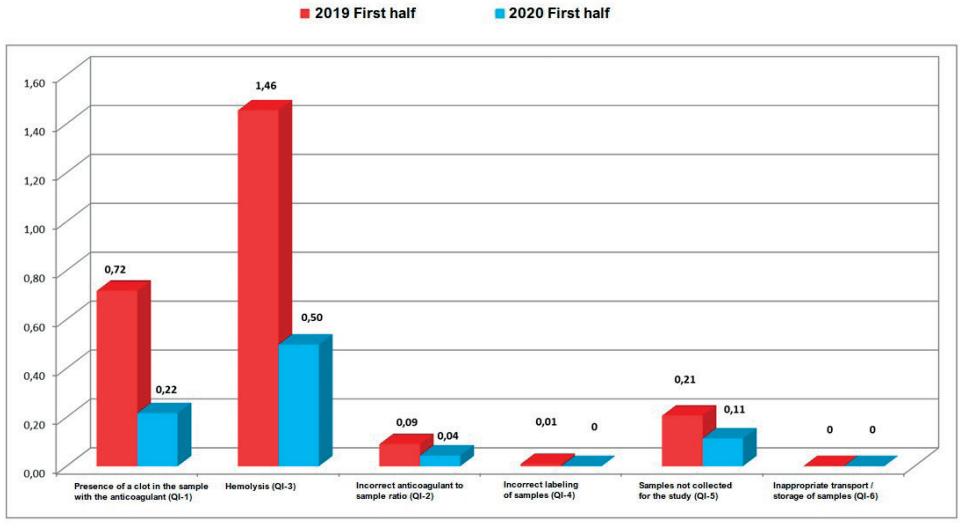


FIGURE 7. Comparison of the first half of 2019 and the first half of 2020 at the Department of Clinical Oncology

TABLE 6. The number of disqualified samples in the Department of Clinical Radiotherapy and the percentage of errors in relation to all samples

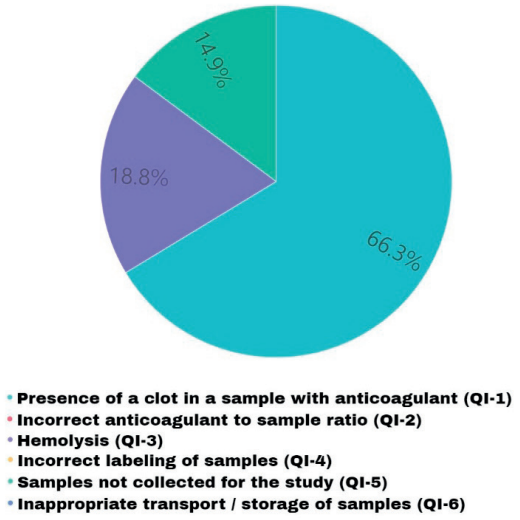
Quality indicators	Number of disqualified samples	Total quantity of the samples assessed	Percentage of samples disqualified [%]
The presence of a clot in the sample with the anticoagulant (QI-1)	35	5819	0.60
Inappropriate anticoagulant-sample ratios (QI-2)	0	5819	0.00
Hemolysis (QI-3)	10	3445	0.29
Incorrect labeling of samples (QI-4)	0	5940	0.00
Samples not taken for testing (QI-5)	7	5940	0.12
Improper transport/storage of samples (QI-6)	0	5940	0.00
Total number of errors	52	5940	0.88

QI – quality indicators

TABLE 7. The number of disqualified samples in Department of Laboratory Diagnostics and the percentage of errors in relation to all samples

Quality indicators	Number of disqualified samples	Total quantity of the samples assessed	Percentage of samples disqualified [%]
The presence of a clot in the sample with the anticoagulant (QI-1)	8	20807	0.04
Inappropriate anticoagulant-sample ratios (QI-2)	2	20807	0.01
Hemolysis (QI-3)	6	12411	0.05
Incorrect labeling of samples (QI-4)	0	21076	0.00
Samples not taken for testing (QI-5)	3	21076	0.01
Improper transport/storage of samples (QI-6)	0	21076	0.00
Total number of errors	19	21076	0.09

QI – quality indicators



QI – quality indicators

FIGURE 8. Percentage distribution of errors in the Department of Clinical Radiotherapy in the first half of 2020

Laboratory Diagnostics Department

In the first half of 2020, at the DOLD collection point, only 19 out of 21,076 samples were disqualified, which accounted for 0.09% of all samples. The most frequently rejected samples showed hemolysis. These were 6 samples (0.05%). The clot in the samples taken for the anticoagulant was the second cause of disqualification and it was 8 samples, which was 0.04%. Three samples were not taken for the tests, 0.01% of all the samples. Two samples were rejected due to inadequate anticoagulant to blood ratio [19]. No errors were found in the scope of improper storage and labeling of the sample (Tab. 7).

In DOLD, 42% of the pre-analytical errors were samples with the anticoagulant showing the presence of a clot. Hemolysis was the cause of disqualification in 32% of errors. The lack of a sample for testing was found in 16% of all errors. The lowest percentage of errors were samples with an inadequate anticoagulant-sample ratio (Fig. 10).

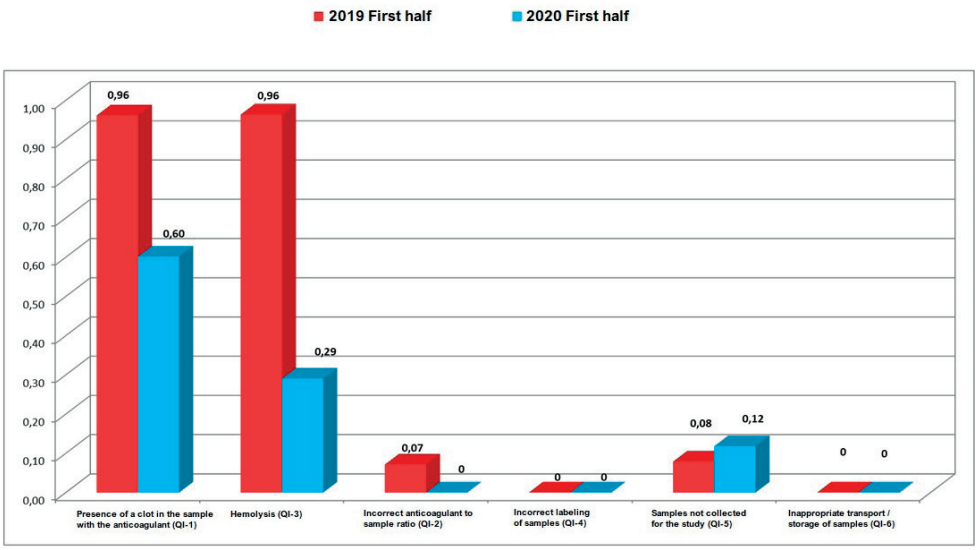


FIGURE 9. Comparison of the first half of 2019 and the first half of 2020 at the Department of Clinical Radiotherapy

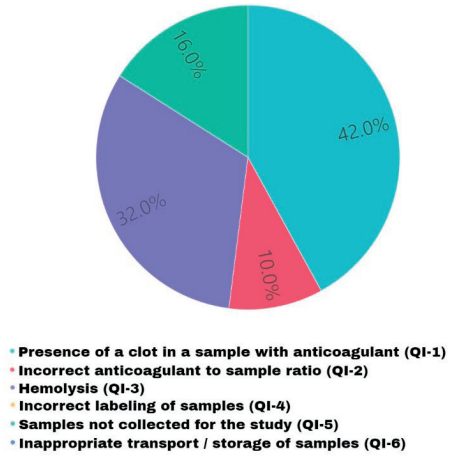
TABLE 8. Number of errors in the first half of 2020 in individual hospital units

Hospital unit	Clinical Radiotherapy	Clinical Oncology	Oncological Surgery	Department of Laboratory Diagnostics
Total number of samples taken	5940	12417	8047	21076
Number of rejected samples	52	75	50	19
Percentage of errors	0.88	0.60	0.62	0.09

TABLE 9. Percentage share of individual preanalytical errors divided by hospital units

Quality indicators	Oncological Surgery		Clinical Oncology		Clinical Radiotherapy		Department of Laboratory Diagnostics	
	no. of errors	%	no. of errors	%	no. of errors	%	no. of errors	%
The presence of a clot in the sample with the anticoagulant (QI-1)	29	0.36	25	0.22	35	0.60	8	0.04
Inappropriate anticoagulant-sample ratios (QI-2)	5	0.06	5	0.04	0	0.00	2	0.01
Hemolysis (QI-3)	13	0.23	31	0.50	10	0.29	6	0.05
Incorrect labeling of samples (QI-4)	0	0.00	0	0.00	0	0.00	0	0.00
Samples not taken for testing (QI-5)	3	0.04	14	0.11	7	0.12	3	0.01
Improper transport/storage of samples (QI-6)	0	0.00	0	0.00	0	0.00	0	0.00

QI – quality indicators



QI – quality indicators

FIGURE 10. Percentage distribution of errors in the Laboratory Diagnostics Department in the first half of 2020

In the first half of 2020, compared to the first half of 2019, the number of samples with hemolysis and a clot in the sample with the anticoagulant decreased. The number of errors related to incorrect anticoagulant-sample ratio and non-sampled samples increased slightly. No errors were found related to improper labeling of the sample and its storage (Fig. 11).

Comparison of pre-analytical errors between hospital units

When comparing hospital units in the first half of 2020, it was shown that the highest percentage of samples that were disqualified was collected at the Department of Clinical Radiotherapy. Out of 5,940 samples, 52 samples were rejected, which is 0.88%. Out of 8,047 samples collected at the Department of Oncological Surgery, 50 were rejected, which accounted for 0.62% of all samples. Out of 12,417 samples collected in Clinical Oncology, 75 samples, 0.60%, were rejected. The fewest errors were recorded at the DOLD collection point. Out of 21,076 samples taken there, 19 were disqualified, which accounted for 0.09% of all the samples. The data are summarized and presented in Table 8.

The clot in the sample with the anticoagulant was most common in the samples from the Department of Clinical Radiotherapy, 0.60%. Next: Oncological Surgery 0.36%, Clinical Oncology 0.22%, DOLD 0.04%. Inadequate anticoagulant-sample ratios were most often observed in test tubes from the Department of Oncological Surgery: 0.06%. Respectively: Clinical Oncology 0.04%, DOLD 0.01%. No errors of this kind were reported at the Department of Clinical Radiotherapy. Samples rejected due to hemolysis mainly concerned the Department of Clinical Oncology, they constituted 0.50% of all samples collected there. Next, from the Department of Clinical Radiotherapy 0.29% of the samples, Surgery Oncology 0.23% of the samples, and DOLD 0.05% of the samples. The pre-analytical error resulting from the lack of sample collection for the tests was: 0.12% of all samples in the Department of Clinical Radiotherapy, 0.11% in the Department of Clinical Oncology, 0.06% in the Department of Oncological Surgery and 0.01% of all samples in the Department of Oncological Surgery. In the first half of 2020, no errors related to improper labeling and storage of material for testing were found. The table below shows the number and percentage of pre-analytical errors, taking into account the QI, at individual hospital wards and the DOLD collection point (Tab. 9).

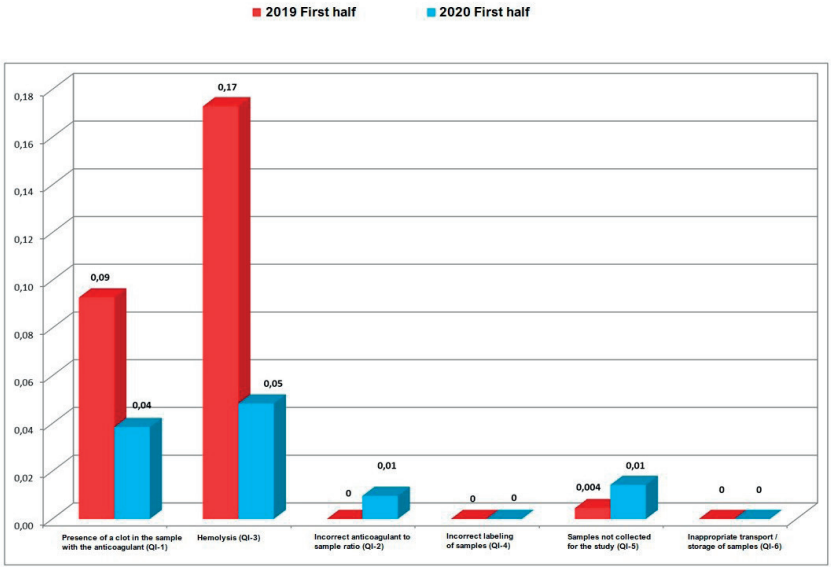


FIGURE 11. Comparison of the first half of 2019 and the first half of 2020 at the Department of Laboratory Diagnostics

CONCLUSIONS

Pre-analytical phase errors are a significant problem in laboratory diagnostics. Therefore, it is important that they are constantly monitored. The analysis of the recorded errors allows for the introduction of corrective actions, which undoubtedly contributes to reducing the occurrence of this type of errors. This in turn translates into patient safety and lower labor costs. In WPCC, the 2 most common reasons for specimen disqualification due to deviation from quality requirements were a clot in a specimen with an anticoagulant and the presence of hemolysis. These irregularities are most often caused by improper collection and mixing of the sample. Compared to other pre-analytical errors, they accounted for 80% of all disqualifications. Therefore, a periodic training of personnel in this area is especially important. In order to minimize the probability of error occurrence, it is also necessary to introduce quality standards in the form of appropriate procedures. For this reason, the WPCC has implemented procedures for monitoring and assessing pre-laboratory error, which involve the control and training of hospital staff in collection, storage and transport of samples for testing. This type of action allowed to obtain low error values, at the level not exceeding 1%.

However, it is still an excessively high value in comparison with other medical centers, where the preanalytical error is estimated at 0.43% [20].

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