ORIGINAL ARTICLE

The prevalence of pre-analytical errors in the laboratory of the Cantonal Hospital Zenica in Bosnia and Herzegovina

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ABSRTACT

Aim To identify rates of most common pre-analytical errors and to document possible (different) error rates between inpatients and outpatients.

Methods This retrospective study was conducted at the Department of Medical Biochemistry and Immunology Diagnostics, Cantonal Hospital Zenica, from December 2016 until March 2017. Data on rejected blood samples in the laboratory information system were analysed.

Results During the 3-month period 35,343 patient blood samples (25,545 inpatients and 9,798 outpatients) were received in the laboratory. The study identified 602 (1.70%) rejected samples because of pre-analytical errors, mostly due to haemolysis, 292 (48.50%), and clotted samples, 240 (39.87%). The remaining 70 (11.63%) samples were rejected because of inappropriate sample volume, inappropriate container and identification errors (7.81%, 2.16% and 1.66%, respectively). The proportion of inpatient rejected samples was 8.7-fold higher than in the outpatient samples. The proportion of inpatient rejected samples because of haemolysis, clotted samples, inappropriate sample volume and inappropriate containers were higher than in the outpatient samples (20.5-, 12.1-, 2.3- and 1.3-fold higher, respectively); proportion of rejected samples because of identification errors was 8.0-fold higher in the outpatient (collection sites outside the hospital) than in the inpatient samples.

Conclusion Higher pre-analytical sample error rates were connected with inpatient samples, while higher identification error rates were connected with outpatient samples. Establishment of periodic stuff training and introduction of information technology could reduce pre-analytical errors.

Key words: diagnostic errors, haemolysis, patient identification systems, pre-analytical phase

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INTRODUCTION

Diagnostic errors that affect both inpatients and outpatients appear to be the most common, costly and dangerous medical mistakes (1,2). They have an impact on every medical discipline as well as on laboratory medicine (3). Laboratory information plays an important role in medical decision making and it is crucial for diagnostic uncertainty (4). Accordingly, the latest version of the International Standard for medical laboratories accreditation (ISO 15189: 2012) emphasizes the need to "establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes" (5). According to the ISO 15189: 2012 the pre-analytical phase is defined as "steps starting in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins" (6).

Pre-analytical phase of the total testing process (TTP) is prone to more errors than analytical phase (7). Pre-analytical phase errors account for 50% to 75% of all laboratory errors (8). On the other hand, analytical phase errors record the significant decrease as a result of several improvements, especially in the internal and external quality control assurance programs (9).

It is widely accepted that the use of Quality Indicators (QIs) minimises the error risk. As basic monitoring and improvement tools they should be integrated in the laboratory improvement strategy (10). Quality Indicators are able to evaluate all key points of TTP including pre-analytical phase (11). The introduction of QIs of the TTP is "a must" in the accreditation process according to ISO 15189 standardisation of medical laboratories (6). Considered as an objective measures, they are fundamental for quantification of the laboratory services quality (11).

Model of Quality Indicators (MQI) proposed by the International Federation of Clinical Chemistry (IFCC) Working Group "Laboratory Errors and Patient Safety" (IFCC WG-LEPS) currently includes 57 QIs (35 pre-, 7 intra- and 15 post-analytical phases). Pre-analytical phase errors basically comprise two traditional QIs categories related to identification and sample problems. Each QIs with its own priority score (1 = Mandatory; 2 = Important; 3 = Suggested; 4 = Valuable) provides its gradual introduction into routine practice following the order of priority in accordance with their influence to the potential negative clinical outcomes (8,12).

Numerous studies have been conducted worldwide since 1989 in the attempt to demonstrate high pre-analytical phase error rate and how to reduce it (9). There are no studies evaluating pre-analytical errors in any laboratory in Bosnia and Herzegovina.

The aim of this study is to identify the rates of the most common, mandatory, sample and identification pre-analytical errors (haemolysis, inappropriate volume, clotted sample, inappropriate containers and identification errors) and to document possible (different) error rates between inpatients and outpatients.

MATERIALS AND METHODS

Materials and study design

This retrospective study was performed during a 3-month period, from December 2016 until March 2017 at the Department of Medical Biochemistry and Immunology Diagnostics, Cantonal Hospital Zenica (Zenica, Bosnia and Herzegovina), serving general and specialized clinical chemistry, haematology, immunology and coagulation testing services. The laboratory is not accredited by the ISO 15189 standard. Data on rejected blood samples in the laboratory information system (LIS) were analysed. The research was done respecting ethical standards of the Declaration of Helsinki. The study approval was obtained from the Ethics Committee of Cantonal Hospital Zenica.

Methods

For inpatients, phlebotomy was performed by the nursing staff in the clinical wards (outside of the laboratory) and samples were delivered to the laboratory by the hospital delivery personnel. Regarding outpatients, the Department of Medical Biochemistry and Immunology Diagnostics has an outpatient laboratory unit where phlebotomy is performed by laboratory technicians, but also receives (as a core laboratory) numerous samples transported from collection sites (services) outside the hospital, where phlebotomy is also performed by laboratory technicians. Test request forms are

registered into the hospital information system and then transferred into the LIS. Each sample taken from the patient was labelled with a barcode number which is used for identification of the name, surname, gender, age, the type of the tube, sample type, sample collection time and date, site of service where samples were collected, list of the requested tests and name of a doctor who requested tests. After being labelled, samples were subsequently centrifuged, aliquoted and distributed to different laboratory departments. Respective errors, encountered upon admission and later in the testing process, were entered into the LIS, stating that the sample was not processed. The rejected samples were stored in the laboratory for up to 24 hours.

The number and type of errors were retrieved retrospectively from the LIS. Two types of mandatory errors that are recorded into the LIS for every blood sample processed by the laboratory were evaluated: sample errors and identification errors.

As continuously recorded sample errors, according to the sample type (whole blood, serum, plasma) and type of containers for blood sampling, haemolysis, inappropriate volume, clotted sample and inappropriate containers were evaluated for the purpose of this study. Haemolysis was assessed visually by laboratory technicians, and was considered as a sample error, irrespective to the degree of the serum interference and type of test requested. According to the sample type, haemolytic and coagulated samples of any degree were considered unacceptable, and as such were rejected. Identification errors included missing or wrong patient identification data and sample misidentification for all patients and samples.

Statistical analysis

Data were presented as numbers and percentages. The error prevalence was calculated relative to the total number of errors for each category (sample type and container type) and expressed as a percentage.

RESULTS

During the 3-month period 35,343 patient blood samples (25,545 inpatient and 9,798 outpatient samples) were received in the laboratory, of which 602 (1.70%) were rejected because of errors in the pre-analytical phase of laboratory medicine. Stratification of data by the point of collection site revealed that the proportion of rejected samples was higher in the inpatients, 577 (2.26%) than in the outpatients, 25 (0.26%). However, after adjusting for the total number of samples submitted, the proportion of inpatient rejected samples was 8.7-fold higher than in the outpatient samples (Table 1).

Table 1. Distribution of evaluated and rejected inpatient and outpatient samples

Inpatients/ outpatients	Collection site	No (%) of samples	
		Received	Rejected
Inpatient	Clinical wards	24,968	577 (2.26)
Outpatient	Outpatient laboratory unit in hospital	4,882	11 (0.22)
	collection sites (services) outside of the hospital	4,891	14 (0.29)
	Total	9,773	25 (0.26)
TOTAL		34,741	602 (1.73)

Among outpatient samples 4,893 were collected in an outpatient laboratory unit in the hospital, while 4,905 were obtained from collection sites (services) outside the hospital. Stratification of data among outpatients revealed that the proportion of rejected samples was higher in outpatient collection sites outside the hospital, 14 (0.29%) than in the outpatient laboratory unit of the hospital, 11 (0.22%). After adjusting for the total number of samples submitted by both sites, the proportion of rejected samples in the collection sites outside the hospital was slightly (1.3-fold) higher than in the outpatient laboratory unit of the hospital (Table 2).

Table 2. Distribution of pre-analytical errors in inpatient and outpatient samples

Inpatients/ outpatients	Collection site	No (%) of samples with identified error					
		Haemolysis	Clotted sample	Inappropriate volume	Inappropriate container	Identification error*	Total
Inpatients	Clinical wards	284 (49.22)	237 (41.07)	44 (7.62)	10 (1.73)	2 (0.35)	577 (100)
Outpatients	Outpatient laboratory unit in the hospital	8 (32)	1 (4)	0	1 (4)	1 (4)	11 (44)
	collection sites (services) outside of the hospital	0	2 (8)	3 (12)	2 (8)	7 (28)	14 (56)
	Total	8 (32)	3 (12)	3 (0.14) (12)	3 (12)	8 (32)	25 (100)
TOTAL		292 (48.50)	240 (39.87)	47 (7.11)	13 (2.16)	10 (1.66)	602 (100)

*included missing or wrong patient identification data and sample misidentification

Further evaluation of data, according to the number and type of samples and containers showed that 292 (48.50%) out of 602 rejected samples were because of haemolysis, 240 (39.87%) because of clotting, 47 (7.81%) because of inappropriate volume, 13 (2.16%) because of inappropriate container, and the remaining 10 (1.66%) samples were rejected because of identification errors (Table 2). After adjusting for the total number of in- and outpatient samples, the proportion of inpatient rejected samples because of haemolysis, clotting, inappropriate volume and inappropriate container was 20.5-, 12.1-, 2.3- and 1.3-fold higher, respectively, than in the outpatient samples. The proportion of rejected samples because of identification errors was 8.0-fold higher in the outpatient samples (collection sites outside of the Hospital) than in the inpatient samples (Table 2).

DISCUSSION

We conducted this study with the primary objective of identifying rates of the most common, mandatory, sample and identification errors of blood samples that were rejected in our laboratory, generally and by the point of collection. To our knowledge, this is the first study evaluating these pre-analytical errors in any laboratory in Bosnia and Herzegovina. We detected an overall blood sample rejection rate of 1.70 % in our institution which was around 2.5 times higher than average rejection rate that was reported in similar studies: Atay et al. reported total rejection rate of 0.65 % in a one-year study (13), similar results, with 0.69% rejection rate, were found in an overview of the results of 4 years of the pre-analytical quality control program in 105 laboratories by Alsina et al. (14). The sample rejection rate of 0.3% to 0.8% had also been reported in data from multi-centre quality monitoring programs (15).

According to Joint Commission and the WHO Alliance for patient safety the first goal for clinical laboratories is “to improve patient and sample identification” (16); one of the leading causes of errors in laboratory medicine is identification errors. These errors, due to their potential for misdiagnosis and inappropriate treatment, can have significant consequences for patients, which are associated with the worst clinical outcome. Some studies demonstrate that the quality level of this fundamental step is unsatisfactory, with the misidentification rate of 1 in 1000 samples (17). Another study showed the misidentification rate of 1 in 2000 samples in transfusion medicine, while much higher rate, approximately 1 in 100, was found in clinical laboratory samples (18).

Bar-coding of sample tubes is recommended as an ‘’evidence-based best practice’’ since it has been shown that it reduces patient identification errors (19). Dikmen et al. reported 0.3% of misidentification rate in laboratory where electronic bar-coding system is used for identification of patients (20). This procedure is also applied in our institution, and it may be an explanation of far lower rate of 0.03% of identification errors in our laboratory comparing to the above mentioned studies.

The second category of pre-analytical errors includes sample problems. Haemolysis and clotted samples were the primary cause of errors in our laboratory (48.50% and 39.87%, respectively), which is in accordance with other studies. The most commonly reported types of pre-analytical errors in the study of Grecu et al. were also haemolysed samples (46.4%) and clotted samples (43.2%) of similar rate (21). Up to 40–70% haemolytic samples were found according to Lippi G at al. (22). In the study of Alsina at al. (14), 29% and 14% of all rejections were due to haemolysis and to clotted sample, respectively. The main reasons for appearance of haemolysis are vigorous mixing and pneumatic tube transport of the samples as well as forcing of blood through a large-bore needle of a syringe (23). The poor mixing of a content of the vacuum tubes after collecting the blood and keeping them in a horizontal instead the vertical position seems to be the most frequent reason of clotted sample occurrence. Clinical Laboratory Standards Institute (CLSI) recommends that test tubes should be slowly inverted for several times to enable the contact between blood and additives (24). Additionally, the delay of centrifugation for more than 10 minutes after the blood collection as well as use of the conventional syringe/needle/container system instead of vacuum tube system in the blood collection process are frequent reasons for high prevalence of sample coagulation (20).

All blood collection tubes must be filled to the specified volume on the test tubes ensuring the proper blood to additive ratio essential for proper analysis (25). Inappropriate sample volume is the third frequent reason of sample rejection

in our laboratory (7.81%). Other studies showed variation in frequency, from 2.9%, over 22% to 34% (13, 21, 26). Low rate of inappropriateness of container for blood samples in our laboratory (2.16%) is mostly in agreement with other studies (21) probably due to the use of colour coded closures of containers for blood sampling.

Usually, inpatient sample collection is not under control or performed by the laboratory staff. Far higher error rates are demonstrated with clinical ward rather than laboratory staff performing this procedure (27). Our study also showed that the proportion of rejected samples was higher in the inpatients (95.8%) than in the outpatients (4.2%) and that after adjusting for the total number of samples submitted by both sites, the proportion of inpatient rejected samples was 8.7-fold higher than in the outpatient specimens. Similar observations are confirmed in a study of Stark at al. with an error rate of 74.6% for inpatients and 25.4% for outpatients. The proportion of inpatient rejected samples was 5-fold higher than in the outpatient samples (15). We found that all pre-analytical errors, except identification errors, were the most common in inpatients. It is known that the venepuncture in new-borns, children, oncology and patients from intensive care units requires special training and skill (26). This could explain, to some extent, more frequent errors in inpatients. However, since the most common cause of errors is improper venepuncture and handling of blood samples, the reason for this could be insufficient education of the hospital nursing staff in the field of the pre-analytical phase of laboratory medicine. Lillo et al. reported that periodical training and education of the hospital nursing staff by laboratory specialists results in pre-analytical phase improvement (28). Li et al. noted that the incidence of the pre-analytical errors decreased from 1.36% to 0.94% after the step-by-step training program was established (29). Identification errors are far higher in outpatient samples collected outside of a hospital, probably due to the lack of electronic barcoding system. In such circumstances laboratories should rely on at least two independent identifiers for proper patient identification (30).

In conclusion, we detected higher overall blood sample rejection rate because of pre- analytical errors in comparison with that reported by others. The study results point the need of QIs introduction even in the non-accredited laboratories despite the lack of official written recommendations of our national scientific community about establishing the QIs for monitoring and evaluation of pre-analytical processes. Additionally, there is a need to establish regular, periodic training of clinical ward staff to reduce errors since higher pre-analytical error rates were demonstrated on samples collected at clinical wards in the hospital. Active participation of hospital workers and laboratory personnel in the process of improvement of pre-analytical quality will enable reduction of potential negative clinical outcomes. On the other hand, establishment of information technology can reduce pre-analytical errors mostly caused by the system-based shortages in outpatients from peripheral collection sites.

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TRANSPARENCY DECLARATION

Competing interests: None to declare.

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