sciendo

Letter to the Editor

The evaluation of the preanalytical phase- a continuous challenge for clinical laboratories

DOI:10.2478/rrlm-2021-0038

To the Editors,

Evaluation of the preanalytical phase remains a challenge for laboratory staff. Most steps of the preanalytical phase take place outside the laboratory. What quality indicators (QIs) a laboratory should use is stated by the Preanalytical Phase Working Group of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM WG-PRE) [1]. Collected data should be compared with the results obtained in a different period of time as part of the process of quality improvement, as suggested in the ISO 15189: 2013 Standard [2]. Data may also be compared with the results obtained in peer laboratories if the results are published,as part of a benchmarking activity [3]. A survey concerning the preanalytical phase was distributed in European countries by the EFLM WG-PRE and the results were published in two open access papers[3,4]. Only three participants from Romania were registered and results were not included in the general statistics [3]. In the US, as part of the Q-probe program organized by the College of American Pathologists (CAP), different aspects of the preanalytical phase are prospectively followed and results are published [5,6]. In this paper, we aimed to fill the gap and evaluate by survey how laboratories in Romania use the preanalytical phase QIs and what results are obtained, in order to allow comparisons between peer laboratories, if needed.

To evaluate what QIs are used in Romanian laboratories, a series of three questionnaires were distributed via email to members of the Romanian Association for Laboratory Medicine (RALM). Also, members were invited to participate by placing an announcement on the RALM website. The participation was voluntary and the consent was implied for all participants that completed the questionnaire. The questionnaires are available as online material.

Although RALM has more than 200 registered members, only 36 members completed Q1, 24 completed Q2 and 4 members completed Q3.

Comments

Q1

Patient identification has a critical role in the laboratory. However, in most laboratories affiliated to a health instituion, patients are identified in the clinical wards with no control from the laboratory staff. Clear guidelines about patient and sample ID are given in the CLSI document for sample collection and in ISO 15189 Standard. Not all laboratories that participated in the survey are accredited according to this Standard, but with one exception, they all have a written procedure for patient ID. A proper identification of patients is made by addressing at least two open questions (such as name and age) to patients who are able to communicate. For patients who are unable to communicate (e.g. newborns, infants, comatose patients), a bracelet for correct ID is recommended[6]. Only half of the laboratories that completed the survey use a combination of the two.

A second critical step is to correctly identifiy the specimens. A sample label is supposed to have at least two elements for identification: name and unique code or barcode. All laboratories that participated in our survey declare they have

at least two such sample ID elements, but one large hospital (>1000 beds) surprisingly reported using only handwritten labels. The importance of correct patient and sample ID would perhaps be better understood if the laboratory had a risk-based approach on the matter: in a laboratory that performs > 1 milion tests/year, a patient with 2 presentations/ year and 10 tests/ presentation, has a 10% "chance" to receive the wrong result due to identification errors [3]. In our survey, only 50% of the laboratories monitor labeling quality and only 40% do not accept re-labeling of the specimen.A similar proportion of laboratories included in the CAP study (66%) allow sample re-labelling (7). A mean of 10 erroneous labels/1000 labels is reported by laboratories, corresponding to a 3.9 Sigma Score: a good performance, but not excellent and far from the 6 Sigma Score that such a critical step is supposed to have. In the US, in a mandatory survey performed in 147 laboratories under CAP regulations, a number of 1.31 mislabeled specimens/1000 labels was reported (7). The issue of patient and sample ID is also addressed by the EFLM:3 out of the 16 QIs of the preanalytical phase refer to patient or physician ID and specimen label (1). The most common labeling defect reported in our study was the spraying of labels with disinfectants. We can only assume that this renders the labels illegible. This defect accounted only for 6% of the defects reported by the CAP study cited earlier. However, given that our surveys were performed during the COVID-19 pandemic, it could be speculated that the increased use of disinfectants, justified or compulsive, may have also impacted this aspect.The most common defect stated in the CAP study was missing labels. A noteworthy case in our study was a laboratory that admitted to identifying the patient by process of elimination in case of unlabeled samples. We strongly emphasize that this is against all recommendations.

In Q1 the issue of how laboratories use the information collected in the process of evaluating the preanalytical phase was also adressed. Most laboratories use only handwritten forms to document the process and 38% do not use a numerical indicator to quantify these defects. Thus, it may be assumed that this information has little use in daily practice for the laboratories. As in the survey published by the EFLM-WG (1), 30% of the laboratories do not evaluate this information and 25% do not take any action after evaluation. As stated by the EFLM-WG, in order to improve the total testing process, the errors must be documented, analysed periodically, and communicated to the clinicians (1,2).

Q2

An important part of the QIs proposed by the EFLM WG-PRE address the issue of test requests. A laboratory test should be performed at the right time, for the right patient, on the right specimen. More so, according to ISO regulations, the laboratory staff should offer consultations on test requests and judicious use of laboratory resources. According to our survey, only 50% of laboratories routinely monitor test requests. Most laboratories (85%) accept additional requests, but one should consider that a high number of such requests may indicate that the initial request was not complete. The laboratory should make a clear distinction between the tests that are accidentally overlooked and those requests performed after evaluation of the initial results. In a study performed in the US in 56 laboratories, a median of 6.7 cancellations/ 1000 requests was reported. The main reason for test cancellation besides preanalytical issues was duplicate test ordering. An interesting conclusion of the questionnaire is that 50% of laboratories store an aliquot of the initial sample. It is unclear to us whether this aliquot is kept only for additional requests or it has other purposes. If this is the case, one must ask: is this practice cost effective? Also, when

performing additional tests, can the aliquot be traced without a doubt to the initial sample?

Q3

Regarding Q3, considering that only four laboratories completed the survey, we cannot draw any general conclusion. From the completed surveys, it seems that laboratories evaluate and document more the quality of samples, transport and conditions that influence the results in the preanalytical phase than other factors. This tendency was also observed in the EFLM survey: most laboratories are interested in preanalytical sources of error such as interfering substances, analyte sample stability, and compliance to specimen collection guidelines (1) .

Although a small number of laboratories completed our survey, it is clear that some aspects of the preanalytical process are more closely evaluated than others. For instance, as we demonstrated in a previous study, hemolysis has influence on routine coagulation tests, but does not have any clinical significance in subjects without anticoagulant therapy (8). The EFLM WG-PRE has provided the tools for evaluating the preanalytical phase. It is also true than not all QIs can and need to be documented in all laboratories. What preanalytical QIs should be used is a decision that must be made by each individual laboratory after proper evaluation of its current practices.

Oprea R. Oana[1,2*], Manescu I. Bogdan[1,2], Gyorfi Imola[1,2]

1. Dept Clinical Biochemistry and Immunology, UMFST George Emil Palade Targu Mures, Romania
2. Central Laboratory, Distr Emergency Hospital Targu Mures, Romania

Received: 20th October 2021
Accepted: 30th November 2021
Published: 15th December 2021

Corresponding author

Oprea R. Oana
E-mail: oanacalugar@yahoo.com

Conflicts of interests

The authors declare no conflict of interests.

References

1. Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Biochem Rev. 2012 Aug;33(3):85-8.
2. Standard 15189:2013. Standard specific pentru calitate si competenta in laboratoare medicale. ASRO 4. 2013.
3. Westgard JO. Six Sigma. https://www.westgard.com/six-sigma-qc.htm
4. Cadamuro J, Lippi G, von Meyer A, Ibarz M, van Dongen E, Lases5, et al. European survey on preanalytical sample handling - Part 1: How do European laboratories monitor the preanalytical phase? On behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE). Biochem Med (Zagreb). 2019 Jun 15;29(2):020704. DOI: 10.11613/BM.2019.020704
5. Cadamuro J, Lippi G, von Meyer A, Ibarz M, van Dongen E; Lases5, et al. European survey on preanalytical sample handling - Part 2: Practices of European laboratories on monitoring and processing haemolytic, icteric and lipemic samples. On behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE). Biochem Med (Zagreb). 2019 Jun 15;29(2):020705. DOI: 10.11613/BM.2019.020705
6. Darcy TP, Barasch SP, Souers RJ, Perrotta PL. Test Cancellation: A College of American Pathologists Q-Probes Study. Arch Pathol Lab Med. 2016 Feb;140(2):125-9. DOI: 10.5858/arpa.2015-0022-CP
7. Wagar EA, Stankovic AK, Raab S, Nakhleh RE, Walsh MK. Specimen labeling errors: a Q-probes analysis of 147 clinical laboratories. Arch Pathol Lab Med. 2008 Oct;132(10):1617-22. DOI: 10.5858/2008-132-1617-SLEAQA
8. Binzari E, Zaharia M, Barbu S, Oprea OR, Dobreanu M. Hemolysis has no influence on routine coagulation tests in subjects without anticoagulant therapy - a referral Romanian emergency hospital laboratory experience. Rev Romana Med Lab. 2019;27(4):375-82. DOI:10.2478/rrlm-2019-0034