

EFLM Position Paper

Edmée C. van Dongen-Lases, Michael P. Cornes, Kjell Grankvist, Mercedes Ibarz, Gunn B.B. Kristensen, Giuseppe Lippi, Mads Nybo and Ana-Maria Simundic*, on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Patient identification and tube labelling – a call for harmonisation

DOI 10.1515/cclm-2015-1089

Received November 7, 2015; accepted November 13, 2015; previously published online January 19, 2016

Abstract: Venous blood sampling (phlebotomy) is the most common invasive procedure performed in patient care. Guidelines on the correct practice of phlebotomy are available, including the H3-A6 guideline issued by the Clinical Laboratory Standards Institute (CLSI). As the quality of practices and procedures related to venous blood sample collection in European countries was unknown, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase conducted an observational study in 12 European countries. The study demonstrated that the level of compliance of phlebotomy procedures with the CLSI H3-A6 guideline was unacceptably low, and that patient identification and tube labelling are amongst the most critical steps in need of immediate attention and improvement. The process of patient identification and tube labelling is an essential safety barrier to prevent patient identity mix-up. Therefore, the EFLM Working Group aims to encourage

and support worldwide harmonisation of patient identification and tube labelling procedures in order to reduce the risk of preanalytical errors and improve patient safety. With this Position paper we wish to raise awareness and provide recommendations for proper patient and sample identification procedures.

Keywords: harmonisation; patient identification; patient safety; phlebotomy; preanalytical phase; tube labelling.

Background and aims

Venous blood sampling (also known as “phlebotomy”) is the most common invasive procedure carried out in healthcare. It involves several distinct processes, all of which are vulnerable to errors [1, 2] potentially putting the patient safety at risk. Guidelines on the correct practice of phlebotomy are available, including the H3-A6 guideline issued by the Clinical Laboratory Standards Institute (CLSI) in 2007 [3], recommendations issued by national societies [4, 5], or the guidelines on drawing blood published by the World Health Organisation (WHO) in 2010 [6].

As the quality of practices and procedures related to blood sample collection in European countries was unknown, the European Federation of Clinical Chemistry and Laboratory Medicine Working Group for the Preanalytical Phase (EFLM WG-PRE) conducted an observational study in 12 European countries [7]. The aims of this study were to: 1) assess the level of compliance of phlebotomy procedures with the CLSI H3-A6 guideline; and 2) identify the most critical steps for immediate attention and improvement in EFLM member societies by creating a risk occurrence chart based on the observed error frequency and severity scoring. The study found that the overall level of compliance of phlebotomy procedure with the CLSI H3-A6 guideline was unacceptably

*Corresponding author: Ana-Maria Simundic, University Hospital Sveti Duh, Department of Medical Laboratory Diagnostics, Sveti Duh 64, Zagreb 10000, Croatia, Phone: +385-1-3712-021, E-mail: am.simundic@gmail.com; amsimundic@kbsd.hr

Edmée C. van Dongen-Lases: Department of Clinical Chemistry, Academic Medical Center, Amsterdam, The Netherlands

Michael P. Cornes: Clinical Chemistry Department, New Cross Hospital, Wolverhampton, UK

Kjell Grankvist: Department of Medical Biosciences, Clinical Chemistry, Umea University, Umea, Sweden

Mercedes Ibarz: Laboratori Clínic Hospital Arnau de Vilanova, Lleida, Spain

Gunn B.B. Kristensen: Norwegian Clinical Chemistry EQA Programme, Bergen, Norway

Giuseppe Lippi: Section of Clinical Biochemistry, University of Verona, Verona, Italy

Mads Nybo: Department of Clinical Biochemistry and Pharmacology, Odense University Hospital, Odense, Denmark

low and that tube labelling and patient identification were the most critical steps during phlebotomy. The tube labelling process and patient identification are essential safety barriers to prevent patient identity mix-up. CLSI H3-A6 recommends that tube labelling is done after the blood sampling, in the presence of the patient [3]. In our survey, tube labelling was done after the blood sampling in only 53.4% of all phlebotomies observed (179/336), and even 29.6% of them were not done in the presence of the patient (53/179) [7]. Labelling blood tubes in the absence of the patient (regardless to whether it is done before or after the blood sampling) was assessed as possibly life threatening error.

According to CLSI H3-A6, patient identification is crucial and it is the responsibility of the phlebotomist to ensure that blood is drawn from the individual designated on the request form [3]. The frequency of patient identification error was 16.1% in our study and these errors were more frequent in emergency and outpatient departments than in clinical wards [7]. Identification errors are not always easily identifiable in clinical practice [8]. Nevertheless, several authors reported identification errors with unacceptable frequency in everyday work [9–11]. In their recent survey performed in Croatia, Dukic and Simundic have found that in almost 27% of cases, capillary blood gas samples were not labelled with the patient name [12]. Furthermore, identification errors were among the most frequent mistakes observed in a cross-sectional comparative study performed in three government hospitals in South Ethiopia from February to September 2012 [13]. Valenstein and colleagues categorised errors involving clinical laboratories from 120 institutions, and showed that up to 56% of identification errors were primary specimen label errors [14]. Although the prevalence of adverse events due to identification errors can be as high as 6%, more than 70% of them may result in significant patient inconvenience, with unknown change in treatment or outcome [14]. Therefore, the improvement of patient identification by decreasing the frequency of errors is a continuing challenge in all types of blood collection procedures and a crucial topic in many healthcare disciplines [15].

The EFLM WG-PRE is committed to promote the importance of preanalytical quality improvement and therefore, wishes to raise awareness about the need for immediate improvement of patient identification and tube labelling processes and call for the harmonisation of these important activities in the preanalytical phase. More specifically, the aim of this document is to provide EFLM WG-PRE recommendations for best practice in patient and sample identification.

Existing guidelines and EFLM WG-PRE recommendations

Patient identification is a key point in patient laboratory processing [16, 17]. Proper patient identification relies on at least two independent identifiers [18, 19]. The CLSI H3-A6 guideline describes requirements for identifying 1) a patient who is conscious, 2) a patient who is unconscious, too young, cognitively impaired, or does not speak the language of the phlebotomist, 3) a patient who is semi-conscious, comatose or sleeping, and 4) an unidentified emergency patient [3].

Whenever possible, patient identification (for a patient who is conscious) should be active and engage the patient by asking an open ended question (e.g. What is your name?, What is your date of birth?). EFLM WG-PRE recommends that the person who verifies the identity of the patient ('verifier') should use at least two and preferably three independent identifiers to identify a patient, one of which is the full name. The other identifiers may be date of birth, address, health insurance number, etc. The name of the person who has verified the identity of the patient should also be documented.

The CLSI H3-A6 guideline [3] also states that patient and patient's blood specimen must be positively identified at the time of collection. According to CLSI H3-A6 guideline, tubes should be positively identified after filling, not before, with a firmly attached label bearing at least the following:

- patient's first and last names;
- identification number;
- date;
- time (as required, e.g. therapeutic drug monitoring); and
- identification of the person collecting the specimen.

Moreover, the tube should be labelled with the above information before leaving the side of the patient. This may be accomplished by hand writing a label, computer-generated labels or a barcode label. Where possible, the labelled tube should be compared with patient's identification bracelet or have the patient verify that the information on the labelled tube is correct. In addition, there should be a mechanism to identify the person drawing the blood.

There has been a lot of debate about whether the tubes should be labelled before or after blood collection and some authors have argued that an undisputable evidence to support that recommendation does not exist [20]. Standard operating procedures for phlebotomy may

differ with local preferences and available technological resources in an institution [21]. EFLM WG-PRE recommends eliminating the requirement for tube labelling after collection. In our opinion, labelling before or after blood collection should be based on a prospective risk analysis of the phlebotomy process in each institution. Although some may argue that this could be too demanding, we still believe that risk based approach is the best way to establish a safe labelling policy and minimise risk of patient harm. Each institution should have a procedure to which all personnel should adhere. Tube labelling may also be performed prior to venepuncture, immediately after patient has been properly identified.

Regardless of the time when the blood tube is going to be labelled (before or after venepuncture), EFLM WG-PRE strongly recommends that tube labelling is done in presence of the patient. Otherwise, there is a risk that the tube will be left unlabelled and possibly mislabelled [4]. Actually, pre-labelling the tubes may even be more convenient since it allows that patient and sample identity are checked by comparing the information from the label with the patient identity, in the presence of the patient.

According to CLSI H3-A6 guideline, comprehensive information should be generated on the tube label for each venipuncture: 1) patient's full name, 2) patient's date of birth, 3) identification number, 4) time and date of sampling, and 5) identification of phlebotomist. EFLM WG-PRE recommends that the above mentioned essential information shall be registered within the laboratory in such a manner that the tube is traceable and unambiguously linked to patient, collected sample, phlebotomist and a verifier (if different from a phlebotomist). However, we believe it is not essential all these data be recorded on the tube. We are in favour of labelling the blood tube with a barcode, as barcodes can hold all the aforementioned information. If not on the tube, this information should be documented in paper records or laboratory information management system. We also recommend that a minimum of two independent identifiers should be used to identify the tube. Understandably, the more data used to identify the blood tube, the smaller is the chance of patient identification errors.

Ideally, the use of automated systems (e.g. electronic order entry, barcoding, radiofrequency identification and biometrics) is advisable to minimise patient identification errors. However, it should be stressed that these systems may eliminate many transcription and identification errors, but do not per se guarantee that the identity on the label correctly identifies the identity of the individual from whom the blood specimen was obtained. Positive patient identification (PPID) refers to the correct initial

identification of a patient and the absolute connection of all samples to that patient throughout the total examination process, including collection, analysis, and reporting [8]. The barcoded wristbands are increasingly worldwide used as a method for patient identification [21]. Both barcoding and radiofrequency identification could be used for electronic PPID. A barcode-based electronic PPID system includes barcoded patient wristbands, handheld computers onto which orders are downloaded, barcode scanners for confirming patient identity before blood sample collection, and portable printers to produce labels in the presence of the patient [22].

In addition, continuous education of the staff for venous blood sampling is highly advisable, since appropriate education of the personnel generates a better adherence to guideline recommendations for patient identification, tourniquet release, and test tube labelling [23, 24]. Feedback, discussions and reflection amongst phlebotomy personnel seem to be the best way to implement and sustain adherence to phlebotomy guideline practice and lead to long-term improvements in patient safety [25].

Finally, we recommend continuous monitoring of identification errors, preferably by repeated direct observations of phlebotomy practices and by using pre-analytical quality indicators [7, 26–28]. Ongoing monitoring is valuable, because it is strongly associated with a lower misidentification rate [14].

Final considerations and the way forward

EFLM aims to improve the level of harmonisation across the total examination process. The Federation, along with its WG-PRE, also wishes to take the lead in catalysing various European and possibly global harmonisation projects in the preanalytical phase of laboratory testing. Particularly, for patient identification and tube labelling steps, EFLM WG-PRE recommends the following:

- Healthcare institutions should have zero tolerance to patient identification errors;
- A minimum two and preferably three unique patient identifiers (one of which is the full name of the patient) should be used for patient identification;
- Patient and sample identity should always be checked in the presence of the patient;
- The institution should have a policy and a written standard operating procedure defining the patient and sample identification, which is followed by all personnel;

- The institution should have a system in place to continuously monitor and hopefully reduce the frequency of the identification error rate;
- A system should be in place for a continuous education for all professions involved in phlebotomy;
- EFLM member societies should adopt these recommendations and encourage their implementation among healthcare institutions at their national level;
- Standard writing bodies (CLSI, ISO) are encouraged to consider the present recommendations in the future revisions of their guidelines.

With this Position paper, the EFLM WG-PRE wishes to express continuing support to the worldwide harmonisation of phlebotomy practices. This document addresses two of the most critical steps in phlebotomy that need immediate attention: tube labelling and patient identification. We believe that harmonisation of these important steps could effectively decrease the potential risk of pre-analytical errors and improve patient safety.

Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.

Research funding: None declared.

Employment or leadership: None declared.

Honorarium: None declared.

Competing interests: The funding organisation(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

References

1. Lippi G, Salvagno GL, Montagnana M, Franchini M, Guidi GC. Phlebotomy issues and quality improvement in results of laboratory testing. *Clin Lab* 2006;52:217–30.
2. Lippi G, Mattiuzzi C, Guidi GC. Laboratory quality improvement by implementation of phlebotomy guidelines. *Med Lab Obs* 2006;38:6–7.
3. Clinical Laboratory Standards Institute. Procedures for collection of diagnostic blood specimens by venipuncture; approved guideline, 6th ed. CLSI document H3-A6. CLSI: Wayne, PA, 2007.
4. Nikolac N, Supak-Smolcic V, Simundic AM, Celap I. Croatian Society of Medical Biochemistry and Laboratory Medicine: national recommendations for venous blood sampling. *Biochem Med* 2013;23:242–54.
5. Lippi G, Caputo M, Banfi G, Buttarello M, Ceriotti F, Daves M, et al. Recommendations for collection of venous blood. *Biochim Clin* 2008;32:569–77.
6. World Health Organization. WHO guidelines on drawing blood: best practices in phlebotomy. WHO: Geneva, Switzerland, 2010.
7. Simundic AM, Church S, Cornes MP, Grankvist K, Lippi G, Nybo M, et al. Compliance of blood sampling procedures with the CLSI H3-A6 guidelines: An observational study by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE). *Clin Chem Lab Med* 2015;53:1321–31.
8. Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, et al. Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics. *Clin Chem Lab Med* 2009;47:143–53.
9. Grecu DS, Vlad DC, Dumitrascu V. Quality indicators in the preanalytical phase of testing in a stat laboratory. *Lab Med* 2014;45:74–81.
10. Atay A, Demir L, Cuhadar S, Saglam G, Unal H, Aksun S, et al. Clinical biochemistry laboratory rejection rates due to various types of preanalytical errors. *Biochem Med* 2014;24:376–82.
11. Giménez-Marín A, Rivas-Ruiz F, del Mar Pérez-Hidalgo M, Molina-Mendoza P. Pre-analytical errors management in the clinical laboratory: a five-year study. *Biochem Med* 2014;24:248–57.
12. Dukic L, Simundić AM. Institutional practices and policies in acid-base testing: a self reported Croatian survey study on behalf of the Croatian society of medical biochemistry and laboratory medicine Working Group for acid-base balance. *Biochem Med* 2014;24:281–92.
13. Melkie M, Girma A, Tsalla T. The practice of venous blood collection among laboratory and non-laboratory professionals working in Ethiopian Government Hospitals: a comparative study. *BMC Health Serv Res* 2014;14:88.
14. Valenstein PN, Raab SS, Walsh MK. Identification errors involving clinical laboratories: a College of American Pathologists Q probes study of patient and specimen identification errors at 120 institutions. *Arch Pathol Lab Med* 2006;130:1106–13.
15. Lippi G, Becan-McBride K, Behúlová D, Bowen RA, Church S, Delanghe J, et al. Preanalytical quality improvement: in quality we trust. *Clin Chem Lab Med* 2013;51:229–41.
16. Henneman PL, Fisher DL, Henneman EA, Pham TA, Mei YY, Talati R, et al. Providers do not verify patient identity during computer order entry. *Acad Emerg Med* 2008;15:641–8.
17. Schulmeister L. Patient misidentification in oncology care. *Clin J Oncol Nurs* 2008;12:495–8.
18. Joint Commission International. Joint Commission International Accreditation Standards for Hospitals, Joint Commission International: Oakbrook Terrace, Illinois, 5th ed. 2013:22.
19. Clinical Laboratory Standards Institute. Accuracy in patient and sample identification; approved guideline. CLSI document GP33-A. CLSI: Wayne, PA, 2010.
20. Hawkins RC. Specimen labelling: before or after collection? *Clin Chem Lab Med* 2011;49:2119–20.
21. Lippi G, Sonntag O, Plebani M. Appropriate labelling of blood collection tubes: a step ahead towards patient's safety. *Clin Chem Lab Med* 2011;49:1921–3.
22. Morrison AP, Tanasijevic MJ, Goonan EM, Lobo MM, Bates MM, Lipsitz SR, et al. Reduction in specimen labeling errors after implementation of a positive patient identification system in phlebotomy. *Am J Clin Pathol* 2010;133:870–7.
23. Bölenius K, Söderberg J, Hultdin J, Lindkvist M, Brulin C, Grankvist K. Minor improvement of venous blood specimen collection practices in primary health care after a large-scale educational intervention. *Clin Chem Lab Med* 2013;51:303–10.

24. Lima-Oliveira G, Lippi G, Salvagno GL, Montagnana M, Picheth G, Guidi GC. The effective reduction of tourniquet application time after minor modification of the CLSI H03-A6 blood collection procedure. *Biochem Med* 2013;23:308–15.
25. Lima-Oliveira G, Lippi G, Salvagno GL, Montagnana M, Picheth G, Guidi GC. Impact of the phlebotomy training based on CLSI/NCCLS H03-a6-procedures for the collection of diagnostic blood specimens by venipuncture. *Biochem Med* 2012;22:342–51.
26. Plebani M, Sciacovelli L, Aita A, Chiozza ML. Harmonization of pre-analytical quality indicators. *Biochem Med* 2014;24:105–13.
27. Plebani M, Astion ML, Barth JH, Chen W, de Oliveira Galoro CA, Escuer MI et al. Harmonization of quality indicators in laboratory medicine. A preliminary consensus. *Clin Chem Lab Med* 2014;52:951–8.
28. Plebani M, Sciacovelli L, Aita A, Pelloso M, Chiozza ML. Performance criteria and quality indicators for the pre-analytical phase. *Clin Chem Lab Med* 2015;53:943–8.