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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)

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Abstract

Background: An observational study was conducted in 12 European countries by the European Federation of Clinical Chemistry and Laboratory Medicine Working Group for the Preanalytical Phase (EFLM WG-PRE) to assess the level of compliance with the CLSI H3-A6 guidelines.

Methods: A structured checklist including 29 items was created to assess the compliance of European phlebotomy procedures with the CLSI H3-A6 guideline. A risk occurrence chart of individual phlebotomy steps was created from the observed error frequency and severity of harm of each guideline key issue. The severity of errors occurring during phlebotomy was graded using the risk occurrence chart.

Results: Twelve European countries participated with a median of 33 (18–36) audits per country, and a total of 336 audits. The median error rate for the total phlebotomy procedure was 26.9 % (10.6–43.8), indicating a low overall

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compliance with the recommended CLSI guideline. Patient identification and test tube labelling were identified as the key guideline issues with the highest combination of probability and potential risk of harm. Administrative staff did not adhere to patient identification procedures during phlebotomy, whereas physicians did not adhere to test tube labelling policy.

Conclusions: The level of compliance of phlebotomy procedures with the CLSI H3-A6 guidelines in 12 European countries was found to be unacceptably low. The most critical steps in need of immediate attention in the investigated countries are patient identification and tube labelling.

Keywords: guidelines; observational study; phlebotomy; preanalytical phase; risk analysis.

Introduction

Venous blood sampling (phlebotomy) is the most common invasive procedure performed in health care. It consists of several discrete steps, all of which can be subject to errors [1, 2] which potentially impact patient safety. Amongst the errors are patient/sample misidentification so that analytical results are not associated with the correct patient [3]; alteration of the concentration of some analytes by prolonged use of a tourniquet [4, 5] or by contamination of the sample with intravenous fluids [6] and contrast media [7]; inadequate patient preparation, i.e., fasting [8–10] or increased physical activity [11]; not achieving the specified blood collection volume, which may lead to the incorrect additive to blood ratio and thus affect the test results [12] and many others. In addition to factors that can affect sample quality, some practices can also have an impact on patient or healthcare worker safety [13]. For example, if the collection site is not correctly disinfected, or is touched post disinfection, then the site will not be sterile. Also, if the healthcare worker does not wear gloves or dispose the collection device correctly, there is the potential for the worker to come into contact with blood-borne pathogens.

Whilst guidelines on correct practice are available, including the H3-A6 guideline issued by the Clinical Laboratory Standards Institute (CLSI) in 2007 [14], recommendations issued by national societies [15], or the guidelines on drawing blood published by the World Health Organization in 2010 [16], the complexity and large number of blood collections, in conjunction with their locations, make assessments of adherence to guidelines challenging. There are many reasons for which blood collections do not conform to published guidelines, including the lack of understanding the impact of using incorrect procedures, not being familiar with the relevant guidelines, an unwillingness to follow the guidelines, workload or insufficient time [17]. External factors such as a lack of support from others in the hospital environment can also have an impact [18]. Changes in laboratory methods can lead to a need to adapt phlebotomy procedures, and training can help to improve practices [19, 20]. Currently, there is a wide range of different professions with varying level of experience and education who are involved in blood sample collection procedures at the European level. Due to such heterogeneity, there is obviously a need for continuous education and training of healthcare personnel involved in phlebotomy procedures [21]. It has been demonstrated that education leads to improved adherence to guideline recommendations for patient identification, tourniquet release and test tube labelling [22].

Unfortunately, the quality of practices and procedures related to blood sample collection in European countries is currently not known. Therefore, the aim of our study was: 1) to assess the level of compliance of phlebotomy procedures with CLSI H3-A6 guideline; and 2) to identify the most critical steps which need immediate attention and improvement in EFLM member countries by creating a risk occurrence chart based on the observed error frequency and severity scoring.

Materials and methods

Survey design

This survey was conducted by the EFLM Working Group on the Preanalytical Phase in the period of June 2013–March 2014. Important key issues were chosen from the CLSI guideline by all members of the working group and addressed in such a manner that an observational study was possible with simple yes/no answers for the majority of the questions. As shown in Figure 1 the study checklist consisted of 29 specific questions for the observer, addressing different issues of the venous blood sampling process from the preparation phase (Did the collector assemble all necessary supplies prior to collection?) through the sampling process (Did the collector clean the venipuncture site?) to the post sampling phase (Did the collector check potential complications of venipuncture?).

The investigation was conducted as an observational study. Staff members performing blood collection (i.e., *collector*) were observed three times in three different settings: 1) an outpatient phlebotomy unit; 2) a hospital clinical ward; and 3) an emergency department. Since, due to the practical or legal issues, it was not possible to perform collections in all settings, the final number of collections per location differed among participating countries.

Data analysis

Possible replies were: 1) yes; 2) no; and 3) not applicable (NA). The favourable answer (compliance) for most of the study checklist

PHLEBOTOMY COLLECTOR OBSERVATION FORM												
Observer name												
Ward												
Hospital												
Country												
Phlebotomist name/ID												
Phlebotomist profession												
Collection number	Collection 1				Collection 2				Collection 3			
Date of collection												
Question 1 Did the collector assemble all necessary supplies prior to collection?	Yes		No		Yes		No		Yes		No	
Question 2 Does the collector have an identified request form?	Yes		No		Yes		No		Yes		No	
Question 3 Did the collector check the expiry dates of devices in use?	Yes		No		Yes		No		Yes		No	
Question 4 Did the collector identify the patient according to CLSI or local guidelines	Yes		No		Yes		No		Yes		No	
Question 5 Did the collector appropriately sanitize hands?	Yes		No		Yes		No		Yes		No	
Question 6 Has the collector verified that the patient is properly prepared for phlebotomy?	Yes		No		Yes		No		Yes		No	
Question 7 Was the chair used for venipunture specific to the task?	Yes		No		N/A	Yes		No		N/A	Yes		No		N/A
Question 8 If lying, did the collector ensure the arm was appropriately positioned?	Yes		No		Yes		No		Yes		No	
Question 9 Did the collector place the tourniquet 4 finger widths (10cm) above the venipuncture site?	Yes		No		Yes		No		Yes		No	
Question 10 Did the collector select a suitable venipuncture site according to standard	Yes		No		Yes		No		Yes		No	
Question 11 Did the collector put on a new, fresh clean pair of gloves?	Yes		No		Yes		No		Yes		No	
Question 12 Did the collector clean the venipuncture site?	Yes		No		Yes		No		Yes		No	
Question 13 Did the collector leave the venipuncture site to dry (30secs)?	Yes		No		Yes		No		Yes		No	
Question 14 Did the collector leave the venipuncture site untouched post cleaning?	Yes		No		Yes		No		Yes		No	
Question 15 Did the collector ensure a fist was released when blood flow commenced?	Yes		No		Yes		No		Yes		No	
Question 16 Did the collector release the tourniquet when blood flow commenced?	Yes		No		Yes		No		Yes		No	
Question 17 Was the collector using a closed system for venipuncture?	Yes		No		Yes		No		Yes		No	
Question 18 Did the collector follow the correct order of draw according to the guidelines?	Yes		No		Yes		No		Yes		No	
Question 19 Were any of the sample tubes clearly under or over filled?	Yes		No		Yes		No		Yes		No	
Question 20 Were all sample tubes immediately and appropriately mixed according to manufacturers specifications?	Yes		No		Yes		No		Yes		No	
Question 21 Did the collector place a clean gauze or cotton ball over the venipuncture site?	Yes		No		Yes		No		Yes		No	
Question 22 Was the safety feature in the blood collection system activated immediately?	Yes		No		Yes		No		Yes		No	
Question 23 Was the needle/collection system safely and immediately disposed?	Yes		No		Yes		No		Yes		No	
Question 24 Has the patient been warned not to bend his arm?	Yes		No		Yes		No		Yes		No	
Question 25 When were the sample tubes labelled?	Pre		Post		Pre		Post		Pre		Post	
Question 26 Were the tubes labelled in the presence of the patient?	Yes		No		Yes		No		Yes		No	
Question 27 Was the collection successful i.e. all required tubes collected from a single venipuncture?	Yes		No		Yes		No		Yes		No	
Question 28 Did the collector check potential complications of venipuncture?	Yes		No		Yes		No		Yes		No	
Question 29 Did the collector recorded his/her ID?	Yes		No		Yes		No		Yes		No	

Figure 1 Study checklist use to assess the level of compliance of phlebotomy procedure with CLSI H3-A6 guideline.

questions was *yes*. If the reply was *no*, it was considered as evidence for non-compliance with the procedure.

Q6 was analysed only in phlebotomies performed in outpatients.

Q13 and 14 were analysed only in those who responded positively to question 12 (Did the collector clean the venipuncture site?).

For Q19 (Were any of the sample tubes clearly under- or over-filled?), *no* was considered as the favourable answer. Therefore, for this question *yes* was considered as non-compliance and presented in the study results as deviation from the correct procedure (i.e., error).

For Q25 (When were the sample tubes labelled?), the favourable answer was if samples were labelled after phlebotomy.

Q26 was analysed only for those who have labelled the tubes after phlebotomy.

Results are presented as counts and percentages. Differences between groups were analysed with χ^2-test. Data were analysed in MedCalc statistical software 11.5.1.0 (Frank Schoonjans, Mariakerke, Belgium). A p-value <0.05 was considered as statistically significant.

Risk analysis

Risk occurrence analysis was done using the semi-quantitative methodology developed for medical device manufacturers in the internationally agreed standard ISO 14971 Annex D [23]. This analysis defines processes and tools to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. In our study, rather than hazards associated with a medical device, we have used the risk occurrence analysis to assess potential hazards associated with the phlebotomy procedure. Severity was assessed individually by all members of the working group (n=11) and the median score was used for further analysis. Probability was equal to the frequency of the error observed during the survey. Possible occurrence and severity scores were as follows (Tables 1 and 2).

Severity and probability were used to construct the risk occurrence chart (Table 4). Phlebotomy steps located in the 'green' region are considered as generally acceptable and for those steps no further risk reduction is required. 'Yellow' region is the region of ALARP (as low as reasonably practicable), where probable risk should be as low as reasonably practicable. Steps in that region are pointing to the need for an action to lower the probability of risk. 'Red' zone is the intolerable region. Steps located in the red zone are those for which the estimated risk is unacceptable. For those steps, immediate action is required to lower the probability of an error.

Results

Twelve European countries participated in this study: Croatia, Czech Republic, Denmark, Italy, Kazakhstan, The Netherlands, Norway, Russia, Serbia, Sweden, Turkey and the UK.

The median number of audits per country was 33 (18–36). The total number of audits was 336. Their distribution across three categories of patient healthcare setting [emergency department (EMG), outpatient department (OUT) and clinical wards (WARD)] is presented in Figure 2.

Phlebotomies observed during the study were performed by five different healthcare personnel categories: medical doctors (DR), nurses (NURSE), laboratory staff (LAB), phlebotomists (PHLB) and administrative staff (ADMIN). The majority of phlebotomies were done by nurses and laboratory personnel. The distribution of phlebotomies performed by different professions is presented in Figure 3.

Administrative staff was involved in phlebotomies only in the outpatient setting, whereas all other professions were equally distributed across patient settings (emergency department, outpatient department and clinical wards).

Summary results for all 29 questions are presented in Figure 4.

Table 1 Probability of occurrence scoring system.

Probability of occurrence			
Probability of harm	**Abbreviation**	**Textual definition**	**Probability**
Incredible	O1	Harm almost certainly will not happen	<0.01
Improbable	O2	Harm is very unlikely	>0.01–0.1
Remote	O3	Harm is not a strong likelihood	>0.1–0.2
Occasional	O4	Harm is sporadic	>0.2–0.5
Probable	O5	Harm is almost certain	>0.5–0.75
Frequent	O6	Harm is virtually assured	>0.75

Table 2 Severity scoring system.

Severity		
Ranking	**Abbreviation**	**Textual definition**
None	S1	No impact
Limited	S2	Additional (unnecessary) sample collection
Moderate	S3	Delayed diagnosis
Severe	S4	Inappropriate therapy based on inaccurate lab results
Life threatening	S5	Potential fatal outcome

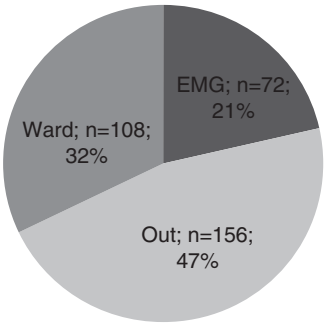

Figure 2 The distribution of audits performed across three categories of patient healthcare setting.
EMG, emergency department; OUT, outpatient department; WARD, clinical wards.

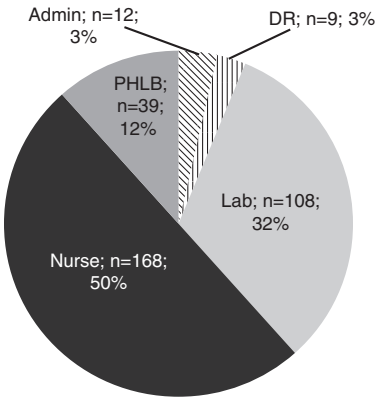

Figure 3 The distribution of audits performed by different healthcare professions.
ADMIN, administrative staff; DR, medical doctors; LAB, laboratory staff; NURSE, nurses; PHLB, phlebotomists.

Frequency of errors occurring during the phlebotomy and their respective severity scores are presented in Table 3. Q2, 3, 7, 17 and 25 relate to the policy of the institution and show collective behaviour and systematic deviations from the correct procedure, rather than individual non-compliance. For Q10, we have observed only one non-compliant sampling occasion probably reflecting difficulty of the auditor to assess whether the phlebotomy site was suitable, rather than the actual compliance. For this reason, this question was excluded from further analysis and interpretation. Median error rate for the total phlebotomy procedure (complete checklist, without Q10) was 26.9 (10.6–43.8), pointing to the low overall compliance with recommended CLSI procedure.

The risk occurrence chart (Table 4) provides an overview of the priority that was estimated by WG members for each phlebotomy step. In our survey, the steps in the 'red zone' which had the highest combination of impact and probability were Q3, Q4, Q25 and Q26. Those steps were assessed as being of critical importance and a top priority for laboratory professionals. A critical error within the phlebotomy procedure was the identification procedure (Q4).

For Q4 (Identification procedure), the level of compliance of a collector with a recommended identification procedure differed significantly between different patient settings (p=0.011). The overall frequency of identification errors was rather low, but identification errors were still assessed as causing the major patient safety risk, due to potential high degree of severity of harm to the patient. Identification errors were more frequent in emergency and outpatient departments, as compared with clinical wards (Figure 5).

The level of compliance (for Q4) with recommended identification procedure also differed significantly between different type of professions (p<0.001). Administrative staff was most likely to be non-compliant with the recommended identification procedure (Figure 6).

Q25 and 26 were also in the 'red zone' due to their substantially high degree of potential harm to the patient

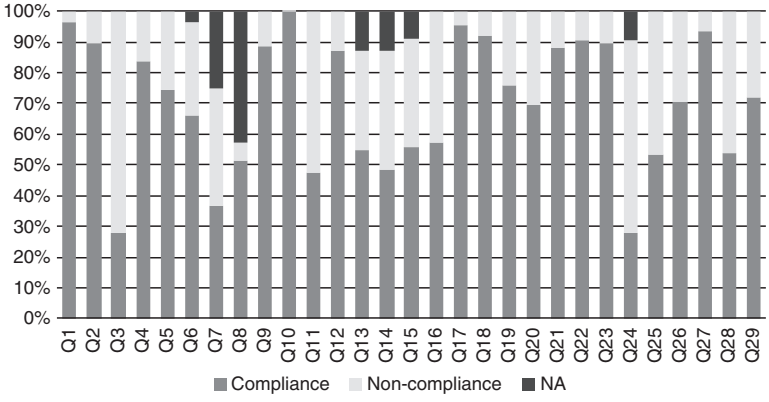

Figure 4 Summary of results.
Frequencies for all 29 questions observed during each phlebotomy.

Table 3 Audit results. Frequency of errors observed during phlebotomies (n=336) and their assessed respective severity scores, along with the calculated differences between different patient settings and various professions.

Q	Question	Severity score	Rationale	Error frequency, %	Probability of error occurrence	Overall risk rating	Difference between settings p[a]	Difference between professions p[b]
1	Did the collector assemble all necessary supplies prior to collection?	S1	No real harm	3.6	O2	S1O2	<0.001	0.015
2	Did the collector have an identified request form?	S4	Incorrect patient identification, therefore incorrect treatment or transfusion	10.5	O3	S4O3	<0.001	<0.001
3	Did the collector check the expiry dates of devices in use?	S3	Expire stock may result in underfilled tubes or reduced potency of additives	71.9	O5	S3O5	0.657	<0.001
4	Did the collector identify the patient according to CLSI or local guidelines	S5	Incorrect patient identification, therefore incorrect treatment or transfusion	16.1	O3	S5O3	0.011	<0.001
5	Did the collector appropriately sanitize hands?	S2	Potential patient infection	25.8	O4	S2O4	0.118	0.002
6	Did the collector verify that the patient was properly prepared for phlebotomy?	S3	May impact sample results	31.3	O4	S3O4	0.003	0.009
7	Was the chair used for venipuncture specific to the task?	S2	Risk of injury to patient, e.g., falling from chair	51.2	O5	S2O5	<0.001	<0.001
8	If lying, did the collector ensure the arm was appropriately positioned?	S2	Potential for back flow with poor technique	10.6	O3	S2O3	<0.001	<0.001
9	Did the collector place the tourniquet 4 finger widths (10 cm) above the venipuncture site?	S2	Elevate or suppressed analytical results	11.3	O3	S2O3	0.008	0.510
10	Did the collector select a suitable venipuncture site according to standard practice?	S3	Poor sample quality or collection site complications	0.3	O1	S3O1	0.157	0.910
11	Did the collector put on a new, fresh clean pair of gloves?	S2	Potential patient infection	52.5	O5	S2O5	0.005	<0.001
12	Did the collector clean the venipuncture site?	S3	Potential patient infection	13.0	O3	S3O3	0.373	<0.001
13	Did the collector leave the venipuncture site to dry (30 s)?	S2	Potential patient infection	37.0	O4	S2O4	<0.001	0.053
14	Did the collector leave the venipuncture site untouched post cleaning?	S3	Potential patient infection	44.5	O4	S3O4	0.090	<0.001
15	Did the collector ensure a fist was released when blood flow commenced?	S3	May impact sample results	38.7	O4	S3O4	0.004	<0.001
16	Did the collector release the tourniquet when blood flow commenced?	S3	May impact sample results	43.0	O4	S3O4	0.144	<0.001
17	Was the collector using a closed system for venipuncture?	S3	Infection, poor sample quality etc.	4.8	O2	S3O2	<0.001	0.663
18	Did the collector follow the correct order of draw according to the guidelines?	S2	May impact sample results	8.1	O2	S2O2	0.004	0.067
19	Were any of the sample tubes clearly under- or overfilled?	S3	May impact sample results	24.2	O4	S3O4	0.009	<0.001
20	Were all sample tubes immediately and appropriately mixed according to manufacturer's specifications?	S3	May impact sample results	30.4	O4	S3O4	0.001	<0.001
21	Did the collector place a clean gauze or cotton ball over the venipuncture site?	S2	Potential patient infection/collection site complications	11.9	O3	S2O3	0.370	0.041

(Table 3 Continued)

Q	Question	Severity score	Rationale	Error frequency, %	Probability of error occurrence	Overall risk rating	Difference between settings p[a]	Difference between professions p[b]
22	Was the safety feature in the blood collection system activated immediately?	S4	Health care worker safety	9.3	O2	S4O2	<0.001	<0.001
23	Was the needle/collection system safely and immediately disposed?	S4	Health care worker safety	10.4	O3	S4O3	0.001	<0.001
24	Was the patient warned not to bend his arm?	S2	Collection site complications	69.3	O5	S2O5	0.001	<0.001
25	When were the sample tubes labelled?	S5	Incorrect patient identification, therefore incorrect treatment or transfusion	46.6	O4	S5O4	0.005	<0.001
26	Were the tubes labelled in the presence of the patient?	S5	Incorrect patient identification, therefore incorrect treatment or transfusion	29.6	O4	S5O4	<0.001	<0.001
27	Was the collection successful, i.e., all required tubes collected from a single venipuncture?	S2	Additional needle stick will be required	6.6	O2	S2O2	0.158	0.007
28	Did the collector check potential complications of venipuncture?	S2	Patient discomfort	46.4	O4	S2O4	0.003	<0.001
29	Did the collector record his/her ID?	S2	Traceability to avoid recurrence	28.0	O4	S2O4	<0.001	<0.001

[a]p, difference between different patient settings; [b]p, difference between various professions.

Table 4 Risk occurrence chart for various phlebotomy steps.

Occurrence probability	Severity of harm				
	None	Limited	Moderate	Severe	Life threatening
	S1	S2	S3	S4	S5
Frequent O6					
Probable O5		Q7, Q11, Q24	Q3		
Occasional O4		Q5, Q13, Q28, Q29	Q6, Q14, Q15, Q16, Q19, Q20, Q23		Q25, Q26
Remote O3		Q8, Q9, Q21	Q12	Q2	Q4
Improbable O2	Q1	Q27, Q18	Q17	Q22	
Rare O1					

Figure 5 Level of compliance of staff performing blood collection with CLSI identification procedure across different patient settings. EMG, emergency department; OUT, outpatient department; WARD, clinical wards.

Figure 6 The level of compliance (for Q4) with recommended identification procedure between different types of professions. ADMIN, administrative staff; DR, medical doctors; LAB, laboratory staff; NURSE, nurses; PHLB, phlebotomists.

and frequency. Whereas Q25 probably reflects the importance of institutional policy, Q26 provides information about whether the tubes were labelled in the presence of the patient (this question was applicable only for those

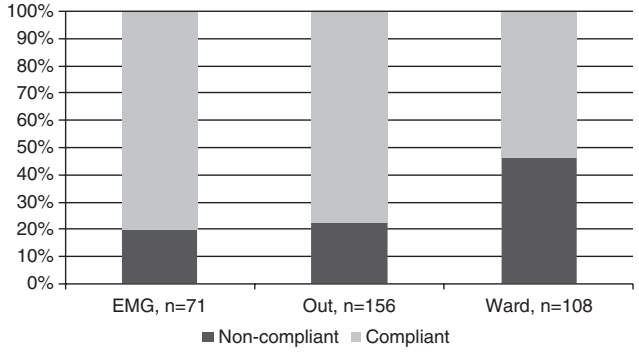

Figure 7 The level of compliance (for Q26) with recommended tube labelling procedure between different types of patient settings. EMG, emergency department; OUT, outpatient department; WARD, clinical wards.

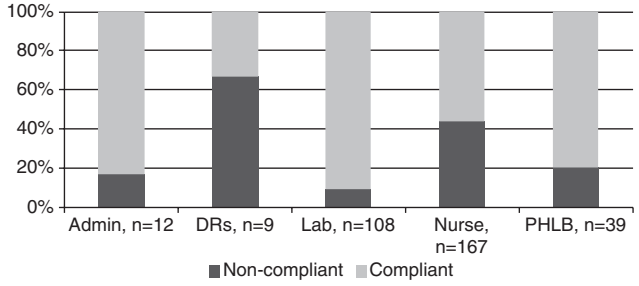

Figure 8 The level of compliance (for Q26) with recommended tube labelling procedure between different types of professions. ADMIN, administrative staff; DR, medical doctors; LAB, laboratory staff; NURSE, nurses; PHLB, phlebotomists.

phlebotomies during which tubes were labelled after the phlebotomy). The frequency of errors related to Q26 differed relative to the different patient settings and were more prevalent on clinical wards than in emergency departments and outpatient settings ($p<0.001$) (Figure 7). Furthermore, the error frequency was highest in medical doctors and nurses than in other types of professions involved in phlebotomy ($p<0.001$) (Figure 8).

Discussion

The level of compliance of phlebotomy procedure with the CLSI H3-A6 guideline in 12 European countries was found to be unacceptably low and patient identification and tube labelling were found to be the most critical steps.

Preanalytical phase has been recognised as the significant source of errors and variability in laboratory testing since the early 1970s of the last century and the terms 'influence' and 'interference factors' became a part of standard terminology in laboratory sciences ever since [24]. In fact the preanalytical phase is now acknowledged as the main contributor to diagnostic errors in the total testing process [1]. Venous blood specimen haemolysis or clotting, incompletely filled test tubes, patient misidentification and mislabelling of test tubes are some of the most frequent errors in the preanalytical phase. Most of the errors are detected and corrected for, but a substantial proportion of unsuitable specimens and test requests unfortunately goes undetected and may in the end affect the clinical management of the patients. Potential consequences of preanalytical errors for the patient are: the need for test repetition and repeated blood sampling causing the patient discomfort and risk of delayed diagnosis or therapy, additional diagnostic procedures, increased healthcare costs, inappropriate diagnosis or therapy as well as hospitalisation and even death.

Laboratories and laboratory personnel have traditionally been putting most of their efforts into the improvement of the analytical phase with focus on sample processing and reducing analytical bias and variation. Since phlebotomy is most often done outside the laboratory and not under the direct supervision of the laboratory staff, errors which occur during phlebotomy are not easy to address and correct. In addition, analytical laboratories often monitor, register and address the seemingly randomly distributed preanalytical errors that arise throughout the healthcare organisation. These errors are often not effectively managed and still pose a challenge to laboratory professionals and constantly jeopardise patient safety [25].

Clinical practice guidelines aim to guide healthcare staff in decision making and are an indispensable part of professional quality systems [26]. Adherence to guidelines aims to standardise medical care; raises care quality and reduce patient risks by reducing inappropriate variations in practice [27, 28]. Clinical practice guidelines are usually consensus statements on best available practice in a particular area, and are increasingly embraced by international healthcare organisations, such as the World Health Organization (WHO) [29].

Guidelines on venous blood specimen collection practice, such as the commonly used CLSI H3-A6 guideline (CLSI 2007) or the guideline published by the WHO, are comprehensive and extensive and describe many discrete chronological practice steps, all of which can be subject to error. The drawback of the standards is that numerous practice steps are quite often difficult to remember for the phlebotomist. Thus, the most important steps may be forgotten or unintentionally missed. The standards are limited to the collection procedure and therefore to a large

extent focused on patient and collectors safety and not on the overall effects of a bad sample collection or sample handling on the patient safety. The guidelines in addition do not contain risk evaluation of the different steps and also lack advice on how to best implement and sustain practices recommended by the guideline. As such, these standards are less suited for daily healthcare practice or for risk management to minimise the risk for compromised patient safety.

In our study, the observed phlebotomy error frequency and a severity scoring yielded a risk occurrence chart where the key issues in the critical 'red region' which had the highest combination of impact and probability were Q3 (expiry dates of collection devices), Q4 (patient identification), Q25 and Q26 (specimen labelling). The identification and labelling steps are important safety barriers and are intended to prevent patient identity mix-up as the last defense. Q3 was left aside as expiry dates of devices by the collecting staff were seldom performed directly by the phlebotomist as demanded by the guidelines, but performed by other staff in the logistic chain and therefore judged as an overall moderate risk. A critical error within the phlebotomy procedure was the identification procedure (Q4) because of the high severity scoring combined with a remote frequency of observed errors. Identification errors were more frequent in emergency and outpatient departments, as compared with clinical wards. Misidentification errors are not easily detectable in daily work [3]. However, they have been reported with unacceptable frequency in everyday routine work by several authors [30–32]. Identification errors along with the proper diet restriction assessment and failure to allow patients to rest prior to phlebotomy were the most frequent errors observed in one recent cross-sectional comparative study performed in three government hospitals in South Ethiopia from February 2012 to September 2012 [33]. Improving patient identification by reducing the frequency of errors is therefore an ongoing challenge in all types of blood collection procedures and also a critical issue in other healthcare areas [34].

The specimen labelling questions (Q25 and 26) were also in the 'red zone' due to their substantially high degree of potential harm to the patient and frequency. Labelling the specimen after blood sampling and not in the presence of the patient was a moderately frequent error in our study but was assessed as being possibly life threatening. This issue is therefore of critical importance, highly relevant and obviously shows room for improvement.

Individual [17] as well as organisational external factors [18] impact guideline non-conformity. Our data indicate corrective action flaws at both the organisational and individual levels. Recent studies on clinical practice guideline adherence have mainly focused on the organisational aspect. Studies to identify reasons for individual hazard behaviour that might explain habitual choices to ignore important safety rules are few and empirical research on the relationship between workplace affiliation and healthcare staff adherence to venous blood specimen collection practice guidelines is currently lacking. It is remarkable that administrative staff were non-adherent to patient identification and doctors to tube labelling procedures. This could reflect serious flaws in their phlebotomy education and should be addressed with great attention. The association of various occupations with adherence to guideline practices was shown to differ significantly in a study of hand hygiene [35]. However, in a study of guideline adherence in cardiopulmonary resuscitation, no such association was found [36]. Further research is warranted on both organisational and individual factors contributing to higher levels of clinical practice guideline adherence and increased patient safety. Patient safety programmes that minimise risk of harm to patients and providers through system effectiveness as well as individual practice are needed [37, 38].

Guideline adherence may be improved by education and training [22] but accreditation of venous blood specimen collection only has marginal effects [39]. The ISO 15189:2012 standard [40] regulates that the laboratory is responsible for producing adequate instructions and possibility for training and that it is responsible for the conditions of the samples at arrival too. This means that the preanalytical conditions are regularly reviewed by the laboratory and the national accreditation bodies in turn regularly assess the laboratory's adherence to good practice [41]. National societies of clinical chemistry and laboratory medicine carry a substantial responsibility to ensure, preserve and improve patient safety. With existing contradictory or insufficient guidelines and regulations, errors may occur in the lower levels of the organisation [42–44]. Modifying guidelines to become more focused, easy to understand and applicable should be prioritised in future research and health care [18].

Modifying staff behavior to conform more closely to practice guidelines and other recommended practices has proved to be a difficult task [45]. One reason is that efficient and accurate methods of measuring adherence are missing as they are essential for policies and programmes aiming to improve adherence. Questionnaires are the most widely used instrument to assess clinical guideline adherence [46–48] and questionnaires have successfully been used also to monitor venous blood specimen collection guideline adherence [49]. Observational studies are seldom used, but have the advantage of direct observation

of specimen collection errors and when performed in a larger scale, such as this study, also allow an error frequency determination for each key issue. In this observational study we added a severity grading to the observed error frequency to get an overall risk assessment and indication on the most critical practice steps when to implement corrections.

Adoption of clinical practice guidelines is affected by several issues, among them the way they are implemented [50]. High evidence that the context is accessible to change, appropriate monitoring and feedback mechanisms [26], and available time for personnel to discuss research findings [51, 52] are mentioned as important factors for improving adherence to guidelines.

Conclusions

Observation of venous blood specimen collection practices using a template checklist and risk analysis is an efficient method to assess critical steps in phlebotomy. Moreover, feedback, discussions and reflection amongst phlebotomy personnel promises to be an efficient tool to implement and sustain adherence to phlebotomy guideline practice [53–55] and lead to long-term improvements in patient safety.

Our study shows that the overall level of compliance of phlebotomy procedures with CLSI H3-A6 guideline in 12 European countries is unacceptably low, especially regarding patient identification and tube labelling. These issues call for immediate attention and improvement.

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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. 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.
4. Lima-Oliveira G, Lippi G, Salvagno GL, Montagnana M, Manguera CL, Sumita NM, et al. New ways to deal with known preanalytical issues: use of transilluminator instead of tourniquet for easing vein access and eliminating stasis on clinical biochemistry. Biochem Med 2011;21:152–9.
5. Lippi G, Salvagno GL, Solero GP, Guidi GC. The influence of the tourniquet time on hematological testing for antidoping purposes. Int J Sports Med 2006;27:359–62.
6. Lippi G, Avanzini R, Sandei F, Aloe R, Cervellin G. Blood sample contamination by glucose-containing solutions: effects and identification. Br J Biomed Sci 2013;70:180–3.
7. Lippi G, Daves M, Mattiuzzi C. Interference of medical contrast media on laboratory testing. Biochem Med 2014;24:80–8.
8. Simundic AM, Cornes M, Grankvist K, Lippi G, Nybo M. Standardization of collection requirements for fasting samples: for the Working Group on Preanalytical Phase (WG-PA) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). Clin Chim Acta 2014;432:33–7.
9. Kackov S, Simundic AM, Gatti-Drnic A. Are patients well informed about the fasting requirements for laboratory blood testing? Biochem Med 2013;23:326–31.
10. Lima-Oliveira G, Salvagno GL, Lippi G, Danese E, Gelati M, Montagnana M, et al. Could light meal jeopardize laboratory coagulation tests? Biochem Med 2014;24:343–9.
11. Sanchis-Gomar F, Lippi G. Physical activity – an important preanalytical variable. Biochem Med 2014;24:68–79.
12. Favaloro EJ, Funk DM, Lippi G. Pre-analytical variables in coagulation testing associated with diagnostic errors in hemostasis. Lab Med 2012;43:1–10.
13. De Carli G, Abiteboul D, Puro V. The importance of implementing safe sharps practices in the laboratory setting in Europe. Biochem Med 2014;24:45–56.
14. 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.
15. Nikolac N, Supak-Smolcic V, Simundic AM, Celap I. Croatian Society of Medical Biochemistry and Laboratory Medicine: national recommendations for venous blood sampling. Croatian Society of Medical Biochemistry and Laboratory Medicine. Biochem Med 2013;23:242–54.
16. World Health Organization. WHO guidelines on drawing blood. Available from: http://whqlibdoc.who.int/publications/2010/9789241599221_eng.pdf. Accessed 11 January, 2013.
17. Amon E. Communication strategies for reducing hospital error and professional liability. Obstet Gynecol Surv 2002;57:713–4.
18. Francke AL, Smit MC, de Veer AJ, Mistiaen P. Factors influencing the implementation of clinical guidelines for health care professionals: a systematic meta-review. BMC Med Inform Decis Mak 2008;8:38.
19. 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.

20. 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.
21. Simundic AM, Cornes M, Grankvist K, Lippi G, Nybo M, Kovalevskaya S, et al. Survey of national guidelines, education and training on phlebotomy in 28 European countries: an original report by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PA). Clin Chem Lab Med 2013;51:1585–93.
22. Bolenius K, Soderberg 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.
23. ISO14971:2012 Medical devices: application of risk management to medical devices. International Organization for Standardization: Geneva, 2012.
24. Guder W. History of the preanalytical phase: a personal view. Biochem Med 2014;24:25–30.
25. Simundic AM, Lippi G. Preanalytical phase – a continuous challenge for laboratory professionals. Biochem Med 2012;22:145–9.
26. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003;362:1225–30.
27. Grol R. Successes and failures in the implementation of evidence-based guidelines for clinical practice. Med Care 2001;39(8 Suppl 2):II46–54.
28. Eccles M, Grimshaw J. Selecting, presenting and delivering clinical guidelines: are there any 'magic bullets'? Med J Austr 2004;180:S52–54.
29. Schunemann HJ, Fretheim A, Oxman AD. Improving the use of research evidence in guideline development: 1. Guidelines for guidelines. Health Res Policy Syst 2006;4:13.
30. Grecu DS, Vlad DC, Dumitrascu V. Quality indicators in the preanalytical phase of testing in a stat laboratory. Lab Med 2014;45:74–81.
31. 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.
32. 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.
33. 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.
34. 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.
35. Sahay S, Panja S, Ray S, Rao BK. Diurnal variation in hand hygiene compliance in a tertiary level multidisciplinary intensive care unit. Am J Infect Control 2010;38:535–9.
36. Kallestedt ML, Berglund A, Thoren AB, Herlitz J, Enlund M. Occupational affiliation does not influence practical skills in cardiopulmonary resuscitation for in-hospital healthcare professionals. Scand J Trauma Resus Emerg Med 2011;19:3.
37. Thornlow DK, McGuinn K. A necessary sea change for nurse faculty development: spotlight on quality and safety. J Prof Nurs 2010;26:71–81.
38. Lillo R, Salinas M, López Garrigós M, Naranjo Santana Y, Gutiérrez M, Marín MD, et al. Reducing preanalytical laboratory sample errors through educational and technological interventions. Clin Lab 2012;58:911–7.
39. Ho B, Ho E. The most common nonconformities encountered during the assessments of medical laboratories in Hong Kong using ISO 15189 as accreditation criteria. Biochem Med 2012;22:247–57.
40. Jansen RT, Kenny D, Blaton V, Burnett D, Huisman W, Plebani M, et al. Usefulness of EC4 essential criteria for quality systems of medical laboratories as guideline to the ISO 15189 and ISO 17025 documents. European Community Confederation of Clinical Chemistry (EC4) working group on harmonisation of quality systems and accreditation. Clin Chem Lab Med 2000;38:1057–64.
41. Huisman W. European Communities Confederation of Clinical Chemistry Working Group on Accreditation: past, present and future. Clin Chim Acta 2001;309:111–4.
42. Norris B. Human factors and safe patient care. J Nurs Manage 2009;17:203–11.
43. Sandström B, Borglin G, Nilsson R, Willman A. Promoting the implementation of evidence-based practice: a literature review focusing on the role of nursing leadership. Worldviews Evid Based Nurs 2011;8:212–23.
44. Makitalo O, Liikanen E. Improving quality at the preanalytical phase of blood sampling: literature review. Int J Biomed Lab Sci 2013;2:7–16.
45. Mittman BS, Tonesk X, Jacobson PD. Implementing clinical practice guidelines: social influence strategies and practitioner behavior change. Qual Rev Bull 1992;18:413.
46. Williams AB. Adherence to highly active antiretroviral therapy. Nurs Clin North Am 1999;34:113–29.
47. Lenicek KJ. Nationwide survey of policies and practices related to capillary blood sampling in medical laboratories in Croatia. Biochem Med 2014;24:350–8.
48. Dukic L, Simundic 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.
49. Bolenius K, Brulin C, Grankvist K, Lindkvist M, Söderberg J. A content validated questionnaire for self-reported venous blood sampling practices. BMC Res Notes 2012;5:39.
50. Gagliardi AR, Brouwers MC, Palda VA, Lemieux-Charles L, Grimshaw JM. How can we improve guideline use? A conceptual framework of implementability. Implement Sci 2011;6:26.
51. Fink R, Thompson CJ, Bonnes D. Overcoming barriers and promoting the use of research in practice. J Nurs Adm 2005;35:121–9.
52. Ploeg J, Davies B, Edwards N, Gifford W, Miller PE. Factors influencing best-practice guideline implementation: lessons learned from administrators, nursing staff, and project leaders. Worldviews Evid Based Nurs 2007;4:210–9.
53. Grol RP, Bosch MC, Hulscher ME, Eccles MP, Wensing M. Planning and studying improvement in patient care: the use of theoretical perspectives. Milbank Q 2007;85:93–138.
54. Foy R, Ovretveit J, Shekelle PG, Pronovost PJ, Taylor SL, Dy S, et al. The role of theory in research to develop and evaluate the implementation of patient safety practices. Br Med J Qual Saf 2011;20:453–9.
55. Allegranzi B, Gayet-Ageron A, Damani N, Bengaly L, McLaws ML, Moro ML, et al. Global implementation of WHO's multimodal strategy for improvement of hand hygiene: a quasi-experimental study. Lancet Infect Dis 2013;13:843–51.