A multicentre observational study evaluating the effectiveness of a phlebotomy check-list in reducing preanalytical errors

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ABSTRACT

Several preanalytical errors are attributable to inappropriate or poorly standardized activities during the venous blood collection. We designed a multicenter observational study to establish whether the implementation of a phlebotomy check-list in 7 phlebotomy centers and 4 emergency departments is effective in reducing the rate of preanalytical errors related to the blood drawing. The investigation was divided in two 3-month periods during which 5 common preanalytical errors were systematically recorded. After the introduction of the phlebotomy check-list, the rate of preanalytical errors was significantly decreased in phlebotomy centers (0.04% vs. 0.05%, P=0.001), but remained unchanged in emergency departments (0.83% vs. 0.82%, P=0.84). A significant decrease was achieved for sample identification errors and clotted specimens in phlebotomy centers and emergency departments, whereas a significant reduction in hemolysis was noticed only in phlebotomy centers. The rate of inappropriate filling and wrong containers remained unchanged. The results obtained in this study show that the introduction of a phlebotomy check-list may help in reducing preanalytical errors related to misidentification and undue clotting.

INTRODUCTION

The implementation and continuous monitoring of a quality system throughout the total examination process are essential for producing reliable results of laboratory testing (1). According to the classical model proposed by George Lundberg more than 40 years ago, the total testing process is typically divided in 3 to 5 separate parts, which entail the (pre-)preanalytical, analytical and (post-)post-analytical phases (2). There is now convincing evidence that the vast majority of laboratory mistakes emerges from the manually intensive activities of the preanalytical phase and is mostly attributable to inappropriate actions performed during collection of blood specimens (3, 4). This is mainly due to the fact that the health care personnel with blood collection responsibility is not adequately trained or does not follow best practice recommendations while drawing blood (5, 6). Another remarkable source of problems is the lack of universal agreement on the best phlebotomy practices, which has led to development of a number of international and national guidelines for venous blood collection, including those issued by the Clinical and Laboratory Standards Institute (7), WHO (8) and SIBioC (9).

Standardization and/or harmonization of practices across the different steps of the testing process is a cornerstone for improving global quality in laboratory diagnostics (10). This rather obvious and appealing concept has persuaded SIBioC to embark in a strategy aimed to develop guidelines and produce scientific

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Table 1
The phlebotomy check-list employed in the study

Item no.	Question
1	Are you wearing personal protective equipment?
2	Has the patient remained seated for not less than 5 min?
3	Did you check the identity of the patient?
4	Did you check that the patient identity matches that on labels of blood tubes?
5	Did you label blood tubes before venipuncture?
6	Did you prepare all the necessary material before blood drawing?
7	Did you assemble the blood collection device?
8	Did you apply the tourniquet for less than 2 min?
9	Did you avoid to insist in case of a difficult venipuncture?
10	Did you fill blood tubes at their nominal volume?
11	Did you gently mix blood tubes after collection for at least 4-6 times?
12	Did you safely discard potentially infectious materials?

evidence that should ultimately improve harmonization throughout the testing process, reduce the chance of diagnostic errors and, ultimately, improve patient safety (11). In line with this valuable purpose, the SIBioC-SIMeL working group on extra-analytical variability (WG-EV) first released recommendations for venous blood collection and management of unsuitable specimens (9, 12), and then developed a 12-item check-list consisting of a concise list of activities that should be completed or verified during venous blood drawing (13). The aim was to support phlebotomists to standardize practice and reduce the potential burden of preventable errors. This multicentre observational study was planned to verify whether the implementation of the phlebotomy check-list in different phlebotomy centers (i.e., outpatient clinics) and emergency departments (ED) may be effective in reducing the burden of some preanalytical errors during venous blood collection.

MATERIALS AND METHODS

A total of 7 phlebotomy centers and 4 ED agreed to participate to the study. The multicentre study was divided in two observational 3-month periods, before (June-August 2014) and after (September-November 2014) implementation of the phlebotomy check-list. The sequential periods were chosen in order to reduce the impact of excessive turnover of personnel.

The phlebotomy check-list is shown in Table 1 (13). Before the second phase, the personnel in duty of venous blood collection was appropriately trained about the content of the check-list and asked to follow the items before each venipuncture. In agreement with recent recommendations (14), the following preanalytical quality indicators were monitored throughout the two study periods: a) total identification errors, b) sample received in inappropriate container (wrong blood tube), c) blood tubes inappropriately filled (for sodium citrate blood tubes), d) hemolysed samples (for clinical chemistry tests) and e) clotted samples (for EDTA and sodium citrate blood tubes). The total number of non conformances was registered according to local practices and means of recording did not vary between the two study periods. In all centers, the same type of blood collection device was used before and after the implementation of the check-list. The error rates for each preanalytical quality indicator between the two periods were compared by the chi-square test, performed with the Analyse-it software. The relative risk of preanalytical error before and after implementation of the check-list was estimated and reported in terms of odds ratio (OR) and 95% confidence interval (CI), using MedCalc software v. 12.3.

RESULTS

The cumulative number of blood tubes and preanalytical errors recorded in the different facilities before and after implementation of the phlebotomy check-list are shown in Table 2. After introduction of the phlebotomy check-list the rate of preanalytical errors was significantly decreased in phlebotomy centers [(0.04% vs. 0.05%, P=0.001; OR, 0.77 (0.66-0.90)], but remained unchanged in ED [(0.83% vs. 0.82%, P=0.84; OR, 1.01 (CI, 0.95-1.07)]. In agreement with previous evidence, the rate of hemolysis was found to be up to 24-fold higher in ED compared to outpatient clinics, whereas that of inappropriate filling and clotted specimens was 6 to 10-fold higher in ED. When different preanalytical quality indicators were analysed separately, a significant decrease of errors was achieved for identification errors and clotted specimens in phlebotomy centers and ED, whereas a significant reduction of hemolysis was noticed only in phlebotomy centers. Overall, the risk of identification errors was reduced by ~70% (OR, 0.31 to 0.34), whereas that of clotted specimens decreased by more than 30% in ED and by 45% in phlebotomy centers.

Table 2
Rates of preanalytical errors before and after implementation of the phlebotomy check-list in 7 phlebotomy centers (PC) and 4 emergency departments (ED)

Error type	Before implementation		After implementation		P	OR (95% CI)
	Total number of blood samples	Errors	Total number of blood samples	Errors		
Identification errors						
PC	256,705	22 (0.009%)	304,763	8 (0.003%)	0.002	0.31 (0.14-0.69)
ED	77,092	26 (0.034%)	77,990	9 (0.012%)	0.003	0.34 (0.16-0.73)
Inappropriate container						
PC	256,705	18 (0.007%)	304,763	23 (0.008%)	0.815	1.08 (0.58-1.99)
ED	77,092	17 (0.022%)	78,577	15 (0.019%)	0.409	0.87 (0.43-1.73)
Inappropriate filling						
PC	15,302	15 (0.098%)	16,291	17 (0.104%)	0.430	1.06 (0.53-2.13)
ED	17,772	110 (0.619%)	17,821	107 (0.6%)	0.438	0.97 (0.74-1.27)
Hemolysed specimens						
PC	71,473	238 (0.333%)	83,326	230 (0.276%)	0.024	0.83 (0.69-0.99)
ED	26,664	1651 (6.19%)	26,622	1759 (6.61%)	0.066	1.06 (0.99-1.14)
Clotted specimens						
PC	76,204	41 (0.054%)	87,813	26 (0.030%)	0.011	0.55 (0.34-0.90)
ED	42,728	177 (0.414%)	42,560	122 (0.287%)	0.001	0.69 (0.55-0.87)
Total errors						
PC	676,389	334 (0.049%)	796956	304 (0.038%)	0.001	0.77 (0.66-0.90)
ED	241,348	1981 (0.821%)	243570	2012 (0.826%)	0.841	1.01 (0.95-1.07)

OR, odds ratio; CI, confidence interval.

DISCUSSION

Preanalytical variability plays a substantial role in decreasing the quality of the total examination process. Therefore, major efforts should be undertaken to improve and harmonize preanalytical activities in order to enhance the quality of laboratory diagnostics (3, 10, 11). With the awareness that blood collection represents the leading source of unsuitable specimens (3), the SIBioC-SIMeL WG-EV has placed great focus on this unavoidable step of the testing process, by publishing consensus recommendations aimed to disseminate best practices among society members (9, 12) and culminating in the development of a phlebotomy check-list that should help health care operators to optimize blood collection. As an obvious next step, a multicentre observational investigation was designed to verify the effectiveness of this approach. Taken together, the results obtained in this study show that the introduction of the phlebotomy check-list in outpatient clinic and ED produces a remarkable reduction of some preanalytical errors, especially those related to misidentification and undue clotting.

These favorable findings are probably attributable to two different aspects. A recent survey of education and training on phlebotomy in 28 European countries has emphasized that the education of health care personnel in duty of drawing blood is largely inadequate (5). More specifically, the majority of participating countries reported that no specific training is available as continuous educational resource for phlebotomists (64%) and the schooling for venous blood collection is not part of the education required to become qualified (79%). Moreover, the average time of phlebotomy training (i.e., 5 h) was largely inadequate in those countries where training was provided.

The Italian situation is not different from that reported in the continental survey. It is hence not surprising that the introduction of a simple phlebotomy check-list, such as that developed by the SIBioC-SIMeL WG-EV, was effective to decrease the rate of preanalytical errors, since this valuable result could be, at least partially, obtained by filling an educational gap during the formation of phlebotomists.

The widespread lack of compliance to existing recommendations should be regarded as a second important aspect that contributes to increase the vulnerability to errors in blood collection (6). It is hence conceivable that the availability of a simple and standardized consensus list of essential

recommendations might help to achieve a major degree of harmonization of blood collecting practices among different facilities, with the elimination of inaccurate or inappropriate steps and introduction of crucial activities, previously overlooked or underestimated. This is supported by the observation that a remarkable decrease (~70%) occurred in the rate of identification errors in both phlebotomy centers and ED, a result that could be obtained by instructing health care personnels to use a systematical approach for checking patient identity before drawing blood samples. Similarly, the notable decrease of clotted samples (from 31% to 45%) is probably attributable to increased attention to mixing blood specimens immediately after collection, as clearly advocated by the check-list. The decreased rate of hemolysed specimens globally recorded in outpatient clinics is surprising and somehow unexpected, although this trend was not observed in two out of the 7 outpatient clinics. The origin of spurious hemolysis is complex and potentially multifactorial in nature (15), but we cannot rule out that some indications contained in the check-list (especially those aimed to reduce the length of tourniquet time and restrain from difficult attempts to locate the vein) may have contributed to decrease the chance of *in vitro* hemolysis. On the other hand, it is not surprising that these two recommendations have been ineffective for reducing hemolysis in ED, since blood samples are typically collected from intravenous routes in this health care setting (16), a practice that causes high shear stress (17), thus contributing by itself to enhance the risk of red blood cell injury (18, 19).

In conclusion, the results of this multicentre study demonstrate that the introduction of a phlebotomy check-list may be effective in reducing the rate of some preanalytical errors both in phlebotomy centers and in ED.

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CONFLICTS OF INTEREST

None.

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