Continuous quality control of the blood sampling procedure using a structured observation scheme

Tine Lindberg Seemann[1], Mads Nybo*[1]

[1]Department of Clinical Biochemistry and Pharmacology, Odense University Hospital, Odense, Denmark

* Corresponding author: mads.nybo@rsyd.dk

Abstract

Introduction: An observational study was conducted using a structured observation scheme to assess compliance with the local phlebotomy guideline, to identify necessary focus items, and to investigate whether adherence to the phlebotomy guideline improved.

Materials and methods: The questionnaire from the EFLM Working Group for the Preanalytical Phase was adapted to local procedures. A pilot study of three months duration was conducted. Based on this, corrective actions were implemented and a follow-up study was conducted. All phlebotomists at the Department of Clinical Biochemistry and Pharmacology were observed. Three blood collections by each phlebotomist were observed at each session conducted at the phlebotomy ward and the hospital wards, respectively. Error frequencies were calculated for the phlebotomy ward and the hospital wards and for the two study phases.

Results: A total of 126 blood drawings by 39 phlebotomists were observed in the pilot study, while 84 blood drawings by 34 phlebotomists were observed in the follow-up study. In the pilot study, the three major error items were hand hygiene (42% error), mixing of samples (22%), and order of draw (21%). Minor significant differences were found between the two settings. After focus on the major aspects, the follow-up study showed significant improvement for all three items at both settings ($P < 0.01$, $P < 0.01$, and $P = 0.01$, respectively).

Conclusion: Continuous quality control of the phlebotomy procedure revealed a number of items not conducted in compliance with the local phlebotomy guideline. It supported significant improvements in the adherence to the recommended phlebotomy procedures and facilitated documentation of the phlebotomy quality.

Key words: observation; phlebotomy; preanalytical phase; quality control

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Introduction

It was recently reported that if medical error was a disease, it would be ranked as the third leading cause of death in the United States of America (1). As the commonly used statistic is that 70% of medical decisions rely on laboratory results, reduction of errors related to the laboratory are crucial. The ongoing vast automation of the laboratories certainly helps in this matter, but preanalytical errors remain a challenge, and studies have reported that up to 75% of laboratory errors occur in the preanalytical phase, where the blood sampling procedure is a pivotal area (2-4). It is well-known that errors in phlebotomy can influence diagnosis and also affect patient care in a harmful way (3,4). Recent reports on the un-harmonised training in European countries of the personnel performing phlebotomy and the lack of adherence to guidelines by the Clinical and Laboratory Standards Institute (CLSI) and the International Organization for Standardization (ISO) is therefore alarming (5-8). Efforts are made to improve this, e.g. an expansion of the pre-examination procedures section in the revised international standard ISO 15189:2012, where laboratories are required to include a number of activities, e.g. collection and pre-collection activities, specific instructions for patient preparation, and sample transportation (7). Furthermore, the European Federation of Clini-

cal Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE) has recommended monitoring phlebotomy quality regularly in order to ensure the quality of the blood collection procedure (8). Quality control of phlebotomy is however challenging because errors associated with phlebotomy cover a variety of aspects such as patient/sample misidentification, prolonged use of tourniquet, inadequate patient preparation, low blood collection volume, and impeded healthcare worker safety (4). It is difficult to collect information on all these aspects, but this diversity of errors is what makes striving for an objective assessment even more necessary.

A number of quality indicators have been proposed, but the phlebotomy procedure itself is not sufficiently covered by those. In order to assure the quality of blood samples drawn by trained as well as untrained personnel a continuous, structured quality control assessment of the blood sampling procedure is needed (9). This will not only assure blood sampling quality, but also enable documentation of sampling quality, and last but not least assessment of untrained personnel will make it possible for the laboratory organization to ensure the blood sample quality for all samples arriving at the laboratory as requested in the ISO 15189:2012.

A continuous quality control of the blood sampling procedure was introduced at our university hospital using a structured observation scheme as suggested by the EFLM WG-PRE (10). The hypotheses were that i) an observational quality control would enable identification of some critical issues in the blood sampling procedure, and ii) implementation of corrective actions (education of the staff) would result in better adherence to the guidelines. The aim of our study was to assess the level of compliance with the local phlebotomy guideline, to investigate if the tool could help identifying necessary focus items, and finally to study whether continuous quality control of the phlebotomy procedure over time would improve adherence to the phlebotomy guideline.

Materials and methods

Study design

The investigation was conducted at Odense University Hospital, Denmark, as an observational study in two phases: a pilot study and a follow-up study.

Pilot study

All staff members performing phlebotomy at Department of Clinical Biochemistry and Pharmacology, Odense University Hospital, Denmark, were observed. At Odense University Hospital the vast majority of blood samples are drawn by professionally trained laboratory technicians, an education that includes specialised training in phlebotomy. Blood samplings take place at either the outpatient phlebotomy ward or at the hospital wards, but are carried out by the same circulating phlebotomist staff. Due to work rotation all phlebotomists were not observed the exact same number of times.

During a three-month period (September to November 2014) blood sampling was observed at the outpatient phlebotomy unit and at the hospital wards, respectively. Three blood collections by the same phlebotomist were observed at each session, and all observations were performed by the same trained staff specialist (TLS, first author of this paper and responsible for the phlebotomy procedure at the hospital) using a structured checklist.

The observation checklist for quality control of phlebotomy was constructed based on the scheme designed by the EFLM WG-PRE and adjusted to local procedures (10). The adjustments were decided by the team responsible for blood sampling consisting of the physician in charge of phlebotomy, the quality control manager and the person responsible for education of phlebotomist students. As an example, use of gloves is nationally not recommended, and locally, checking utensils for expiry dates are performed centrally. Therefore, these two points were removed. In observation item #7 (Figure 1), the observation was used to ensure that the phlebotomist used standard

Quality control on blood sampling Dept. of Clinical Biochemistry and Pharmacology Odense University Hospital		
Observer		
Date		
Phlebotomist		
Sample No	YES	NO
Item # 1 Is the requisition correctly filled out?		
Item # 2 Was the patient identified according to the CLSI guideline?		
Item # 3 Was the instruction for correct hand hygiene followed?		
Item # 4 Did the phlebotomist assure that the patient was properly prepared (e.g. fasting)?		
Item # 5 Was the tourniquet placed correctly?		
Item # 6 Did the phlebotomist select a suitable venipuncture site?		
Item # 7 Was an appropriate venipuncture device used (not a Safety-Lok™ Blood Collection Set)?		
Item # 8 Was the venipuncture site disinfected properly?		
Item # 9 Was the alcohol allowed to evaporate before the venipuncture?		
Item # 10 Did the venipuncture site remain untouched after disinfection?		
Item # 11 Did the phlebotomist assure that the fist was not clinched when blood flow began?		
Item # 12 Was the tourniquet released immediately after blood flow began?		
Item # 13 Was the correct order of draw followed?		
Item # 14 Were the blood tubes filled properly?		
Item # 15 Were all blood tubes mixed immediately after sampling?		
Item # 16 Was a cotton ball or gauze placed over the venipuncture site after sampling?		
Item # 17 Were syringes etc. disposed correctly immediately after sampling?		
Item # 18 Was the patient advised not to bend the arm?		
Item # 19 Were the tubes labelled in presence of the patient?		

Figure 1. The questionnaire used in the pilot study.

blood sampling devices and not a Vacutainer® Safety-Lok™ Blood Collection Set, which primarily is for paediatric use or for the difficult obtainable sample. Altogether, this resulted in an observation scheme containing 19 observation items (Figure 1). Observation item #2 concerning patient identification was mandatory to be correct, as it was assessed as potentially severely harmful. If patient identification was performed incorrectly, the observer intervened immediately and assured correct identification. Otherwise, this was strictly an observational study without interruption by the observer. Results were recorded as yes/no for all phlebotomists in each setting and later calculated for the two settings, respectively.

Interventions

Issues identified by the pilot study (e.g. hand hygiene) were submitted to educational intervention, including formal lectures, discussion at staff meetings and supervised exercises. Based on the pilot study the observation scheme was optimised by removing four items that had all been correctly performed in the pilot study and altering one item. Removed items were observations regarding the test request, suitable venipuncture site, fist clenching, and bending of the arm. The altered item was to check that bleeding has actually ceased (according to the CLSI guideline) before sending the patient off, not just place adhesive or gauze bandage at the venipuncture site. This resulted in a new observation scheme containing 15 items (Figure 2).

Follow-up study

The follow-up study was performed during a three-month period (January to March 2016) by the same procedure as described for the pilot study except for the alteration that only two blood samplings were observed at each session (for logistic reasons).

Statistical analysis

The results of the observational study are reported as percentage incorrect phlebotomies per item out of the total number of observations, reported for the phlebotomy ward and the hospital wards, respectively.

Differences between results at the two settings (the phlebotomy ward and the hospital wards) were analysed with Fisher's exact test. Also, changes in observations between the pilot study and the follow-up study was analysed using Pearson's Chi-Square test. A P-value < 0.05 was considered significant; analysis was performed using GraphPad Prism 6 (La Jolla, California, USA).

Results

Pilot study

A total of 126 phlebotomies, 59 at the phlebotomy ward and 67 at the hospital wards, were performed by 39 different phlebotomists. The errors revealed are shown in Figure 3. At the phlebotomy ward, the most frequent error was performing hand hygiene contrary to the described procedure (item #3, 42%). Second-most frequent was that 24% did not follow the correct order of draw (item #13), followed by improper mixing of samples by 19% (item #15).

At the hospital wards, the most frequent error was also 42% performing hand hygiene erroneously (item #3), while the second-most frequent was the 25% that did not mix the samples properly after drawing blood (item #15). Finally, 18% did not follow the correct order of draw (item #13). An infrequent, but crucial error is the patient identification process, which was performed incorrectly in two instances at the hospital wards.

Altogether, the three most frequent errors were identical at the two settings. Two of them did however differ significantly between the two phlebotomy settings, as incorrect order of draw were more frequent at the phlebotomy ward ($P = 0.04$), while mixing of tubes were more frequent at the hospital wards ($P = 0.04$). No other errors differed significantly between settings.

Follow-up study

In the follow-up study, a total of 84 phlebotomies, 30 at the phlebotomy ward and 54 at the hospital ward, were performed by 34 different phlebotomists. The errors revealed are shown in Figure 4.

Quality control on blood sampling Dept. of Clinical Biochemistry and Pharmacology Odense University Hospital		
Observer		
Date		
Phlebotomist		
Sample No	YES	NO
Item # 1 Was the patient identified according to the CLSI guideline?		
Item # 2 Was the instruction for correct hand hygiene followed?		
Item # 3 Did the phlebotomist assure that the patient was properly prepared (e.g. fasting)?		
Item # 4 Was the tourniquet placed correctly?		
Item # 5 Was an appropriate venipuncture device used (not a Safety-Lok™ Blood Collection Set)?		
Item # 6 Was the venipuncture site disinfected properly?		
Item # 7 Was the alcohol allowed to evaporate before the venipuncture?		
Item # 8 Did the venipuncture site remain untouched after disinfection?		
Item # 9 Was the tourniquet released immediately after blood flow began?		
Item # 10 Was the correct order of draw followed?		
Item # 11 Were the blood tubes filled properly?		
Item # 12 Were all blood tubes mixed immediately after sampling?		
Item # 13 Was the venipuncture site inspected for bleeding before the patient left?		
Item # 14 Were syringes etc. disposed correctly immediately after sampling?		
Item # 15 Were the tubes labelled in presence of the patient?		

Figure 2. The questionnaire used in the follow-up study.

At the phlebotomy ward, the by far most frequent error was the new item #13, where only one out of thirty inspected the venipuncture site for bleeding before sending the patient off (Figure 4). The second-most frequent error was that 20% did not use the appropriate venipuncture device (item #5), followed by item #10, where 13% did not use the correct order of draw. At one phlebotomy session, the patient identification process was not performed correct.

At the hospital wards, the most frequent error was also the new item #13 with 69% not inspecting the venipuncture site correctly. The second-most frequent was item #12, where 13% did not mix the

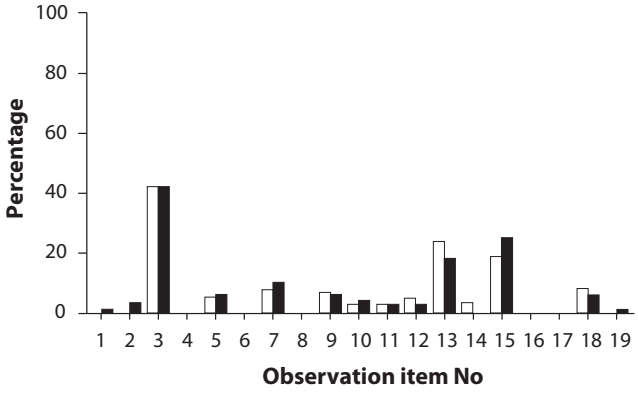

Figure 3. Results from the pilot study.
The numbers on the x-axis refer to the observation items in Figure 1. White bars: Blood sampling item conducted erroneously at the phlebotomy ward. Black bars: Blood sampling item conducted erroneously at hospital wards.

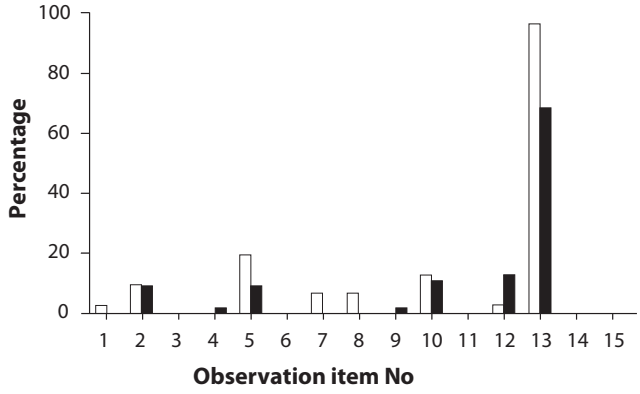

Figure 4. Results from the follow-up study.
The numbers on the x-axis refer to the observation items in Figure 2. White bars: Blood sampling item conducted erroneously at the phlebotomy ward. Black bars: Blood sampling item conducted erroneously at hospital wards.

samples properly after drawing, followed by 11% that did not use the correct order of draw (item #10).

The error frequencies that differed significantly between the two phlebotomy settings (phlebotomy ward and hospital ward) were items #13 (Was the venipuncture site inspected for bleeding before the patient left, P = 0.01), #12 (Were all blood tubes mixed immediately after sampling, P = 0.02), and #5 (Was an appropriate venipuncture device used, P = 0.03).

Differences between the pilot study and the follow-up study

The number of phlebotomies with improper hand hygiene was significantly lower in the follow-up study, namely 10% *vs*. 42% (both settings) in the pilot study (P < 0.01). Also, lack of tube mixing improved from 19% at the phlebotomy ward to 3% (P < 0.01) and from 25% at the hospital wards to 13% (P = 0.01). Finally, the number of erroneous order of draw declined significantly from 21% (mean for both settings) to 12% (P = 0.01). Unfortunately, the number of samplings using the improper venipuncture device (according to the standard operating procedure) increased significantly from 8% to 20% at the phlebotomy ward (P = 0.01), while remaining unaltered at the hospital wards.

Discussion

This observational study describes a continuously used phlebotomy quality control system based on the EFLM WG-PRE guideline (10), first in an implementation phase and later in a follow-up phase. The pilot study reveals a number of items in need of focused attention and increased staff teaching, while the follow-up study shows significant improvement for the three major issues found in the pilot study, namely hand hygiene, order of draw and mixing of samples. The quality control therefore seems to enable the laboratory to facilitate focus on critical issues, improve sampling quality, and also to ensure documentation of the sampling QC. We will here address the specific quality issues and the possible future use of a phlebotomy quality control.

In the pilot study, hand hygiene was performed erroneously in 42% of the phlebotomies performed at the phlebotomy ward as well as at the hospital wards, while the follow-up study showed that the error rate had declined significantly to 10%. In comparison, the EFLM WG-PRE study revealed that 25.8% of the observed phlebotomies deviated from the procedure recommended by CLSI regarding hand hygiene (10). As the error frequency was the same at the phlebotomy ward and at the

hospitals ward, the major problem does not seem to have been availability of hand sanitizer, which one could have suspected, but rather missing alertness on the issue. Hand hygiene is traditionally regarded as the single most important infection prevention, and all control measures available must therefore be instituted to improve adherence to the guidelines on this issue. Routine hand hygiene audit by direct observation has been recommended in order to identify local problems and improve practice (10). This is however not specifically related to blood sampling, but rather to health care personnel in general and nurses in particular, where implementation of automated group monitoring has been shown to improve hand hygiene (11). Compatible with this we found a significant improvement using the continuous observational QC described here along with a dedicated focus on the issue.

Another frequent error was the order of draw, where 21% did not follow the correct procedure in the pilot study (24% at the phlebotomy ward and 18% at the hospital ward). There are no good explanation for the significantly higher proportion of incorrect draw-order at the phlebotomy clinic compared to the hospital wards ($P = 0.03$) as one would expect it to be the opposite due to working conditions etc. However, the actual difference in numbers are quite low (14 *vs.* 12 phlebotomies), so it could be a coincidental finding. After the issue was addressed specifically at staff meetings, the frequency of incorrect order of draw fell to 13% at the phlebotomy ward and 11% at the hospital ward. This is a little higher than the error frequency found in the EFLM study (10), where 8.1% did not follow the correct order of draw, and a new procedure has therefore recently been introduced, where the order of draw is shown at the labels following the requisition, which makes the correct order more evident. The importance of a specific order of draw as recommended in the CLSI guideline H3-A6 (8) has often been questioned, and some studies has indicated that incorrect order of draw under ideal phlebotomy conditions does not cause contamination if a closed blood collection system is used (12,13). It is however evident that a significant frequency of sample contamination does occur (14,15), and as this study shows ideal phlebotomy conditions are not always present. It is therefore generally recommended to follow the order of draw as stated in the CLSI guideline H3-A6, which is also the procedure at our laboratory.

The third-most frequent error was improper mixing of the samples: 19% did not perform this appropriately at the phlebotomy ward, while the number was 25% at the hospital ward. In comparison, the error frequency in the EFLM study for this item was 30.4% (10). The significant difference between the phlebotomy settings could indicate that the working conditions at the phlebotomy ward are more aligned with proper laboratory standards, whereas sampling at the hospital wards often are performed under more tumultuous conditions. The blood sampling quality control offers a possibility to document a possible critical impact on the sampling procedure and the following analysis result. Therefore, the fact that blood sampling conditions are challenging at the hospital wards can be presented to the right authorities using the blood sampling quality control results in order to obtain optimal working conditions for the phlebotomists. Studies have shown that specially for coagulation testing mixing of the sample is crucial (16), and a recent study showed that 24% of the rejected tests during a year was due to a clotted specimen (17). As results of coagulation testing often are needed fast, improper mixing must be corrected and e.g. the use of an automated roller mixer, which can be transported to the hospital wards, seems to improve the reliability of coagulation testing (18). In the follow-up study, the error frequency had declined to 3% at the phlebotomy ward and to 13% at the hospital wards. Again, a clear focus on a specific procedure needing improvement appears to have been prosperous, but still there is room for improvement at the hospital wards.

None of these three most frequent errors were in the red zone described in the EFLM study as having the highest combination of impact and probability (10). An error in the red zone is however the patient identification process, which according to the CLSI H3-A6 is crucial, and it relies entirely on the phlebotomist to ensure that the phlebotomy is

actually performed on the individual designated on the request form (8). Patient identification was performed incorrectly in two instances in the pilot study and once in the follow-up study. In comparison, the frequency of patient identification error was as high as 16.1% in the EFLM study (10), being more frequent among outpatients than at the hospital wards. Regardless, this type of error is unacceptable and must be avoided at all cost. Despite being a crucial procedure, it is not custom to examine how patient identification is actually performed on a daily basis (19). However, with a continuous blood sampling quality control, misidentification errors should be eliminated by constantly increasing the awareness on the issue. Recently, a harmonisation of the patient identification procedure was suggested by the EFLM WG-PRE in order to prevent patient identity mix-up (20), so hopefully such harmonized procedures can improve patient safety in the future.

A new item was introduced in the follow-up study, namely proper inspection of the venipuncture site to assure that bleeding indeed had stopped. The study showed that this was an important issue to include as it was almost neglected at the phlebotomy ward (only correctly performed in one out of 30 phlebotomies), and also very critical at the hospital wards (an error frequency of 69%). This strongly emphasizes that the observation scheme must evolve continuously to exploit new areas, where focus is needed. With renewed focus on this small item, it will hopefully be possible to show improvement in the error frequency for this issue also.

As stated the follow-up study showed that a continued focus on critical key issues indeed did result in a significant improvement for the three major issues found in the pilot study. It is however not enough to identify and deal with such issues, it is also necessary to maintain focus on the phlebotomy process and the alterations to come in this pivotal procedure. This study was not designed to demonstrate the possibility of such "maintenance value" using a quality control system, but it is our strong believe that it is capable of maintaining the focus on the phlebotomy procedure as it is seen for other QC systems the laboratory use every day.

More importantly, the quality control system will also be an important asset outside the laboratory: In the health care system, increasing fiscal demands and a wish for faster turn-around times are inevitable, and this has increased the interest in having other professionals than trained phlebotomists to perform blood sampling. A likely future scenario is therefore an increased number of decentralised blood samplings (e.g. by doctors or nurses at the hospital wards). From a laboratory point-of-view it will be essential to ascertain the phlebotomy quality, which will be possible through a blood sampling quality control.

Our study has potential strengths and limitations. All observations in this study were performed by the same person. This could be strength in the study, but also could be a potential bias as future observations probably will involve several persons. However, a larger staff will on the contrary potentially introduce an inter-observer bias. In order to avoid this, future observers will be thoroughly trained to assure as uniform an observation practice as possible. The questionnaire was adapted to local procedures and do therefore not fully reflect the CLSI recommendations. The purpose of the study was however not to elucidate the adherence to the CLSI guidelines (as in the EFLM study), but to see if an observational quality control would enable identification of some critical issues in the blood sampling procedure, and also to disclose if implementation of corrective actions would result in better adherence to the guidelines; as stated we found that both these hypotheses were supported by the study.

In conclusion, continuous quality control of the blood sampling procedure using a structured observation scheme was feasible and useful. It revealed a number of items that were not conducted compliant with the phlebotomy guideline. Also, it supported significant improvements in the adherence to the recommended phlebotomy procedures and facilitated documentation of the phlebotomy quality.

Potential conflict of interest

None declared.

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