Mini Review

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Blood sampling guidelines with focus on patient safety and identification – a review

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Abstract: It has been well documented over recent years that the preanalytical phase is a leading contributor to errors in the total testing process (TTP). There has however been great progress made in recent years due to the exponential growth of working groups specialising in the field. Patient safety is clearly at the forefront of any healthcare system and any reduction in errors at any stage will improve patient safety. Venous blood collection is a key step in the TTP, and here we review the key errors that occur in venous phlebotomy process and summarise the evidence around their significance to patient safety. Recent studies have identified that patient identification and tube labelling are the steps that carry the highest risk with regard to patient safety. Other studies have shown that in 16.1% of cases, patient identification is incorrectly performed and that 56% of patient identification errors are due to poor labelling practice. We recommend that patient identification must be done using open questions and ideally three separate pieces of information. Labelling of the tube or linking the identity of the patient to the tube label electronically must be done in the presence of the patient whether it is before or after sampling. Combined this will minimise any chance of patient misidentification.

Keywords: blood sampling; patient identification; patient safety; phlebotomy; tube labelling.

Introduction

The preanalytical phase has been highlighted over the last couple of decades as a leading contributor to diagnostic error rates [1–3]. Initially, the preanalytical phase lagged behind the analytical phase with regard to improving quality in this area, but in recent times the rate of advice and guidelines in this important area are rapidly improving in quality and numbers. This has largely been driven by the existence of working groups such as the European Federation for Laboratory Medicine Working Group for the Preanalytical Phase (EFLM WG-PRE), International Federation of Clinical Chemistry and Laboratory Medicine Working Group for Laboratory Errors and Patient Safety (IFCC WG-LEPS) and national societies. Patient safety is clearly one of the forefront goals of any healthcare system, so any drive to reduce errors in the diagnostic process will have a consequence of improving patient safety [4]. In the total testing process (TTP), the preanalytical phase makes up a significant number of steps as highlighted by George Lundberg in his brain-to-brain loop model [5]. One of the key steps in the TTP is the collection of blood samples. This is done via venous blood sampling (phlebotomy) which is the most common invasive procedure that occurs in the healthcare setting. Phlebotomy itself consists of a significant number of steps, all of which can result in an error in the analysis and therefore a risk of patient harm [6, 7]. There are various guidelines available to promote standardisation of the phlebotomy process such as the Clinical Laboratories Standards Institute (CLSI) GP41 guideline [8]. However, an observational study conducted in 12 European countries has shown that compliance with the guidelines is unacceptably variable [9]. As well as looking at compliance with phlebotomy guidelines, this survey looked at the risks associated with each stage of the phlebotomy process and, by looking at how often deviations from best practice occurred in the observational survey, the probability of it happening again. Once the severity and risk of occurrence were combined, the steps in the phlebotomy process that carried the highest risk-occurrence were identified as:

- Patient identification
- Tube labelling

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There were several other areas of the phlebotomy process that were identified as carrying intermediate risk which will be discussed later.

Current guidelines and practice

The GP41 guideline states that identification of the patient is crucial and that the phlebotomist must not rely on bed labels or records in the vicinity of the patient. It suggests asking the patient to provide/spell their full name, date of birth and identification number (for those patients without ID bands). In the case of an unconscious patient, an individual who knows the patient such as a relative or nurse should identify the patient, and this should be documented. GP41 also states that any discrepancies as well as the identity of the phlebotomist must be noted [8]. Clearly, a failure to identify the patient adequately carries a huge risk, but despite this there is a failure to do so in 16.1% of venous blood collections [9]. If a sample is taken from the wrong patient, there is the possibility of a diagnosis and/or treatment being made or initiated based on results that relate to another patient entirely. This could then lead to direct harm, not just to the patient being falsely treated, but also to the patient whose diagnosis has been delayed.

Whilst sample mix-ups can happen at various stages, it has been shown that 56% of patient identification errors are due to a problem with the specimen labelling [10]. Once the patient has been positively identified, it is important to make sure that the tube is labelled accurately to ensure order-patient-sample traceability. The CLSI document mandates that all tubes must be labelled only once filled and whilst still in the presence of the patient [8]. In the EFLM WG-PRE survey, however, it was found that 46% of phlebotomists labelled the samples after blood draw, and 54% before. Of greater concern, in 30% of venous blood collections where labelling occurred after phlebotomy, they were not labelled in the presence of the patient [9]. There has been much debate over whether samples should be labelled before or after venous blood collection, and there is a roughly 50:50 split in practice across Europe. This could be due to differences in local operating procedures or due to differences between individuals. What is clear however is that labelling the blood tubes or electronically linking the pre-barcoded tubes to the patient identification in the presence of the patient reduces the risk of having multiple unlabelled or unidentified pre-barcoded tubes lying around, a situation that would greatly increase the chances of a tube mix-up.

What should we be doing for patient identification

As already stated above, patient identification and tube labelling are critical steps in the venous blood collection process and there are some obvious differences in how this is performed across Europe. The questions that needed clarifying were how should the phlebotomist identify the patient and how and when should the phlebotomist label the tubes. To address this, the EFLM WG-PRE published a call for harmonisation in 2016 which included advice on how it should be done [11]. They stated several recommendations to answer the above questions. The patient identification process should use open-ended questions wherever possible and should require at least two but preferably three patient identifiers, one of which must be the full name. Other identifiers could be date of birth, address, unique identification number [e.g. National Health Service (NHS) number in the UK]. They also recommended that if it is someone other than the patient making the identification then this person should be recorded as in GP41 above.

To further improve patient identification, hospitals should aim to employ the most up-to-date process and look to use technology wherever possible. At a basic level, this would be the use of patient ID wrist bands, but also processing from this to employ barcoded wrist bands and radiofrequency identification (RFID) tagging on samples, wrist bands and blood products. In addition to the advantages already discussed, by making the patient identification something attached and not easily removable from the patient, it ensures that once the barcode is on the correct patient they can be positively identified regardless of where they may be, their level of consciousness and their age. This can be of particular importance for patients who are difficult to identify.

In addition to using technology to identify patients, it should also ensure samples are labelled correctly. This could take the form of sample label printing being triggered only by the correct patient's barcode (or other identification). Or it could go one step further and use a device that delivers pre-printed tubes following positive patient identification in the presence of the patient, [12, 13].

For the issue of tube labelling, it was felt that if it stated it must be done before or after blood sampling, this would not lead to adoption given the 50:50 split across institutions and that the evidence to support one or the other does not exist [14]. The EFLM WG-PRE therefore recommended that a local risk assessment was performed to consider whether to label before or after collection, but

that labelling should occur in the presence of the patient to avoid the risk of mislabelling [15]. Cross referencing pre-barcoded tubes to patient identification electronically is also considered labelling and should be done at the patient bedside.

In addition, the EFLM WG-PRE also stated that there must be a local policy on venous blood collection which should include processes to maintain quality. There should be a zero-tolerance policy for samples with patient identification errors and there must be a system of monitoring the frequency of the errors. Phlebotomists should have basic training stressing in particular the importance of correct patient identity and correct tube labelling. Phlebotomists passing an individual venous blood specimen collection program should have a certificate issued and valid for a specified period of time. E-learning programmes on venous blood specimen collection have been shown to be a time-effective and efficient educational form [16].

Other risks

Of the intermediate risks, the first to be considered was the verification of whether the patient had been properly prepared for the blood tests. What constitutes correct preparation depends on the blood test, but as a general principle, even if there are no specific preparatory steps for the tests required, it would be advisable for the patient to avoid any significant differences from their normal day, i.e. diet and exercise. Both of these can significantly affect blood test results and it would be desirable for the laboratory to be made aware of any lifestyle changes or herbal supplements the patient is taking [15, 17–21]. The preparation of the phlebotomist themselves is also critical and they must ensure that they not only have their own supplies ready, and have checked that they are all in date, but that they have the correct equipment for the patient, i.e. the correct chair. Ideally the patient would have been settled for at least 15 min before sampling in either a supine or seated position as position changes can affect test results [22] and reference intervals are based on patient being seated for 15 min prior to blood collection. One other aspect of equipment and preparation include sterilisation of the phlebotomist and patient. For the phlebotomist, this should include wearing gloves or sterilising hands, but gloves were only found to be worn in 52.5% of cases. Upon investigation this is likely due to differing infection prevention policies across nations and institutions. Worryingly, only 13% of observations showed the phlebotomist cleaned the venepuncture site, a clear infection risk. Other

steps in the venous blood collection process covered areas of when to release the tourniquet, appropriate tube filling and use of safety devices. From a sample quality perspective, safety devices have no bearing, but clearly, we should be endeavouring to ensure the safety of all laboratory and hospital professionals. Tourniquets must be released as soon as possible to avoid venous stasis. In fact, if their use can be avoided entirely it should be [22]. If used, disposable tourniquets are recommended to minimise the risk of infection. There is evidence that reusable tourniquets may act as transmissions of various pathogens [23, 24]. Finally, the appropriate filling and mixing of tubes is essential to ensure that any additives are adequately mixed to ensure they perform their desired function [25–27].

How should adherence be assessed?

In order to assess how well a particular institution is performing with regard to compliance with guidelines and therefore the provision of a safe evidence-based phlebotomy procedure, there must be a mechanism to monitor compliance. There are numerous ways to collect key performance indicators (KPIs) in the preanalytical phase and these have been reviewed elsewhere [28], but essentially the ideal solution is to set up automated processes where data on performance can easily be extracted from. There also needs to be a mechanism to address any deteriorations in performance. In addition to routine collection of KPIs, another approach to assessing patient safety would be to perform an observational audit or to survey the patients themselves.

European phlebotomy guidelines

What can be clearly seen from the above and the referenced surveys is that although several guidelines exist for venous blood collection, there is still a great deal of variation in how blood collections are actually performed in the real world. In order to try and achieve standardisation in the preanalytical phase, a series of recommendations have already been produced covering fasting [17], patient identification [11] and order of draw [29–31]. However, this is not enough alone, and therefore, a European phlebotomy guideline has been developed. This guideline has been developed in conjunction with representatives from many European nations and by

consulting specialist phlebotomists wherever possible. The guideline is designed to not be a series of mandatory steps, but to look at the phlebotomy process step by step and analyse the risk to the patient of not following the guideline together with how well evidenced each step is. This has allowed each step to be graded taking the risk and evidence into account and will therefore allow individual nations and institutions to use it in a way that fits with their own requirements. The new guidelines will be launched in 2018 and will be accompanied by training materials including training presentations and certificates and also audit pro formas. This should allow all institutions to implement the guideline in a standardised manner with a target of standardised phlebotomy across Europe.

In summary

It has become clear that the preanalytical phase is a key area in the TTP and that there remains huge scope for improvement. Phlebotomy is one of the biggest parts of the preanalytical phase and as such standardising this will vastly improve the TTP. A European guideline is being developed to do just this. One of the highest risk steps in the phlebotomy process is patient identification and subsequent tube labelling. Patient identification must be done via open-ended questions and labelling must be done whilst at the patient side to avoid any risk of misidentification.

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