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Review

Blood venous sample collection: Recommendations overview and a checklist to improve quality

Daide Giavarina^{a,*}, Giuseppe Lippi^b

^a Clinical Laboratory, St. Bortolo Hospital, Vicenza, Italy

^b Section of Clinical Biochemistry, University of Verona, Verona, Italy

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ABSTRACT

The extra-analytical phases of the total testing process have substantial impact on managed care, as well as an inherent high risk of vulnerability to errors which is often greater than that of the analytical phase. The collection of biological samples is a crucial preanalytical activity. Problems or errors occurring shortly before, or soon after, this preanalytical step may impair sample quality and characteristics, or else modify the final results of testing. The standardization of fasting requirements, rest, patient position and psychological state of the patient are therefore crucial for mitigating the impact of preanalytical variability. Moreover, the quality of materials used for collecting specimens, along with their compatibility, can guarantee sample quality and persistence of chemical and physical characteristics of the analytes over time, so safeguarding the reliability of testing. Appropriate techniques and sampling procedures are effective to prevent problems such as hemolysis, undue clotting in the blood tube, draw of insufficient sample volume and modification of analyte concentration. An accurate identification of both patient and blood samples is a key priority as for other healthcare activities. Good laboratory practice and appropriate training of operators, by specifically targeting collection of biological samples, blood in particular, may greatly improve this issue, thus lowering the risk of errors and their adverse clinical consequences.

The implementation of a simple and rapid check-list, including verification of blood collection devices, patient preparation and sampling techniques, was found to be effective for enhancing sample quality and reducing some preanalytical errors associated with these procedures. The use of this tool, along with implementation of objective and standardized systems for detecting non-conformities related to unsuitable samples, can be helpful for standardizing preanalytical activities and improving the quality of laboratory diagnostics, ultimately helping to reaffirm a "preanalytical" culture founded on knowledge and real risk perception.

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* Corresponding author: Clinical Laboratory, St. Bortolo Hospital, AULSS n. 8 Berica, Viale Rodolfi 37, 36100 Vicenza, Italy.

E-mail address: daide.giavarina@aulss8.veneto.it (D. Giavarina).

1. Introduction

Laboratory medicine is a science aiming to generate useful information for the diagnosis, prognostication and therapeutic monitoring of many human conditions. This science develops through the analysis of biological samples and uses physical, chemical and biological methods. The quality of the information is inherently dependent on the quality of all the activities contributing to the total testing process, i.e., from selection of right tests at the right time for the right patient, up to appropriate interpretation of test results and establishment of suitable medical decisions according to laboratory data. Several lines of evidence accumulated in the past decades attest that preanalytical activities are crucial for quality of testing, and should be seen as the greatest source of medical errors attributable to laboratory diagnostics. According to this definition, the quality of biological samples represents an essential aspect for obtaining accurate and reliable diagnostic information. The procedures needed for obtaining suitable biological samples should therefore be designed for preserving their integrity according to original chemical and physical conditions, which should be as representative as possible of the biological status *in vivo*.

Laboratory tests are performed using many biological fluids, which can be normally present in the body (e.g., cerebrospinal fluid, amniotic fluid, semen, etc.) or resulting from a variety of pathological states (cavitary and cystic fluids, etc.). Although each single biological fluid and tissue may be a representative sample for generating useful diagnostic and prognostic information in health and disease, blood specimens are those most widely used due to simplicity of collection and the stability over time of analytes concentration. Each sample has specific needs for collection and requirements for preanalytical treatment and handling. However, some general principles characterizing blood specimens can be extended to all other biological materials.

2. Biological samples variables

When limiting the analysis to preanalytical activities strictly related to collection of biological samples, the many variables can be distinguished according to their allocation before, during and after collection (Table 1). Each of these events can substantially impact the quality of the specimen, so potentially jeopardizing accurate diagnosis or appropriate patient management.

2.1. Issues related to sample collection

2.1.1. Patient and sample identification errors

There are many opportunities to incur patient and sample identification errors, which can be realistically considered the worst among all mistakes in healthcare industry. Patient misidentification may occur for homonymy, when patients share similar names and neighbor beds in the hospital. Wrong identification documents may also be presented by the patient, or else a wrong label may be used for labeling a blood

tube. Then, results of testing may be attributed to the wrong patient. According to a recent report of the ECRI Institute (formerly the “Emergency Care Research Institute”), a nonprofit foundation aimed to improve healthcare in the United States, as many as 72% identification errors occur during patient encounter, and up to 36.5% are associated with diagnostic procedures [1].

The correct patient identification is a key element for a safe care, and is a primary goal of any healthcare organization. Despite the major focus placed on this issue, identification errors remain a major problem in healthcare [2]. Notably, a number of recommendations for preventing misidentification in healthcare have been released by international organizations and societies, including those of the Clinical and Laboratory Standards Institute CLSI (H3-A6 document; Procedures for the Collection of Diagnostic Blood Specimens by venipuncture) [3], the World Health Organization (WHO; Guidelines on Drawing Blood: Best Practices in Phlebotomy) [4], the Joint Commission [5], the Working Group on laboratory errors and patient safety of the International Federation of Clinical Chemistry and Laboratory Medicine (WG-LEPS) [6], and the International Organization for Standardization (ISO; standard 15189:2012) [7]. Prevention of identification errors has also been the target of additional recommendations from many working groups of European scientific societies (e.g., in Ireland, UK, Spain, Slovenia, Sweden, Italy and Croatia) [8]. The implementation of these guidelines and recommendations are effective for reducing the burden of this highly harmful preanalytical error. Table 2 summarizes the major activities at risk of generating identification errors, as well as the best practices for their prevention. The issue of labeling blood tubes, reported in Table 1 within the group of “after sampling” activities as for the CLSI H3A-6 guidelines, are herein discussed together, since there is an ongoing debated at national and international level as to whether blood tubes should be labeled before or after collection [8,9].

2.2. Problems occurring during blood sample draw

2.2.1. Container errors (materials used for collecting blood and blood tubes)

The devices and materials used for drawing blood play a key role for ensuring the integrity of the specimen and its appropriate use in the analytical phase. The containers are designed for containing, allowing transportation and permitting analysis of the blood and its derivatives (e.g., plasma and serum), while preserving the main chemical, physical and biological properties of the different analytes. In theory, they are designed to preserve composition and concentration of the various blood constituents such as molecules and corpuscular elements of blood, but should also grant a high degree of sterility of biological materials used for testing. Preservatives and additives are often used for preventing clotting and inhibiting other catabolic activities, for preventing breakdown of molecules (e.g., protein, carbohydrates, and nucleic acids) due to the biological activity of microorganisms or endogenous proteinases. Notably, some tests have been developed and validated using specific biological matrices, so they cannot be performed on other types of samples (e.g., serum, different types of plasma, etc.). A general consensus has been reached that the materials used for drawing venous blood should be characterized by full integration of single-use needles, support systems (e.g., holders) and primary evacuated blood tubes [10, 11]. The use of syringes still represents a possible alternative in emergency conditions, especially when integrated devices for drawing blood are unavailable or blood needs to be collected from particular anatomical and/or physical sites (e.g., elbows or wrist), where the use of conventional devices may be impossible or inadvisable. However, closed systems for blood sampling are preferable, because they were proven to be safer than open systems [12].

Labels on primary blood tubes shall contain a minimal useful information for the phlebotomist, including the type of additive, the drawing volume and the expiration date. The selection and purchasing of evacuated blood collection systems should be considered a critical issue for assuring quality, safety and efficiency of preanalytical phase. The

Table 1
Preanalytical errors classified according to sample collection event.

| Timing | Error |
|--------------------------|--|
| Before sample collection | Patient identification errors Sample identification errors |
| During sample collection | Wrong container or sample matrix Wrong additive Inappropriate blood to additive ratio Insufficient volume Undue clotting Spurious hemolysis Sample contamination |
| After sample collection | Labeling error Inappropriate sample management (e.g., mixing) Inappropriate transportation Inappropriate storage (time and temperature) |

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