

Editorial

Appropriate labelling of blood collection tubes: a step ahead towards patient's safety

Giuseppe Lippi, Oswald Sonntag and Mario Plebani

Laboratory diagnostics is a complex and multifaceted enterprise, developing throughout a multiple series of activities traditionally clustered within five main phases, i.e., the pre-preanalytical, preanalytical, analytical, post-analytical and post-post-analytical. Although remarkable technological advancements, internal quality control, external quality assessment and/or proficiency testing have enabled to consistently decrease the burden of errors in the central, analytical phase (1–3), several problems still plague other activities of the total testing process (4). Reliable evidence attests that the vast majority of errors in the modern laboratory diagnostics occurs in the preanalytical phase, whereby a series of manually intensive procedures, not appropriately automated or non automatable, make blood collection inherently vulnerable to ambiguity and human faults (5, 6). Results of several studies and surveys attest that most preanalytical errors are attributable to collection of samples of inappropriate quality (i.e., haemolysed, clotted, contaminated) or quantity (i.e., insufficient volume, incorrect blood to anticoagulant ratio). Although these preanalytical mistakes still jeopardise patient's safety when the samples are processed with generation of unreliable data, they are however straightforwardly detectable before test results are being released to the clinicians by either visual inspection of the sample or through technological aids such as the use of serum indices (7). Misidentification is an additional source of errors in the preanalytical phase, which is reportedly less frequent, but potentially much more hazardous. Identification errors virtually afflict each medical activity, whenever there is a direct interaction between the patient and a healthcare professional, either for diagnostic, clinical or therapeutic purposes.

Identification errors might occur with a significant frequency in nearly almost diagnostic disciplines, including laboratory medicine (from approx. 1% to 9% of cases) (8), transfusion medicine (from 0.7% to 3.2%) (9, 10), anatomic pathology (approx. 1%) (11) as well as radiology, where the frequency of incorrect patient data and side markers in a recent survey was found to be unpredictably higher (i.e., 18% and 5% of cases, respectively) than in other diagnostic disciplines (12). At variance with other types of mistakes, the definitive frequency of labelling errors is however hardly outlined due to the objective difficulty to intercept them, because there is typically no direct interaction between the patient and the healthcare professional who perform or interpret test results, so that the published

figures might represent the tip of the iceberg rather than a real estimate. As previously mentioned, the latent risk for the patient health of diagnostic errors due to misidentification is dramatically high, since the patients might be diagnosed with someone else's pathology and subjected to a wrong clinical decision making which might finally lead to the administration of inappropriate or unjustified therapy (13). Although the overall prevalence of adverse outcomes due to misidentification errors can be as high as 6%, more than two-thirds of them cause significant patient inconvenience with unknown change in treatment or outcome (14).

Owing to this serious hazard, the Joint Commission, National Patient Safety Goals (NPSGs, Effective July 1, 2011) still include appropriate patient identification at the first place of the Elements of Performance (i.e., NPSG.01.01.01), whereby it is clearly stated that (a) at least two patient identifiers should be used when collecting blood samples and other specimens for clinical testing, and (b) containers used for blood and other specimens should be labelled in the presence of the patient (15).

As specifically regards laboratory diagnostics, several specific efforts have been devised over the past decade to prevent identification errors, strongly supported and propelled by a multitude of worldwide societies and organisations, including the Working Group "Laboratory Errors and Patient Safety (WG-LEPS)" instituted by the division of Education and Management (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) (16), the College of American Pathologists (17), the Italian Society of Clinical Biochemistry and Molecular Biology (SIBioC) (18), and the German Society for Clinical Chemistry and the German Society for Laboratory Medicine (19). The common denominator of all these guidelines and recommendations is that primary blood tubes should be labelled (a) in the presence of the patient, (b) by using at least two identifiers, and (c) before venipuncture is performed.

In a letter that we publish in this issue of *Clinical Chemistry and Laboratory Medicine*, Hawkins highlights that the Clinical and Laboratory Standards Institute (CLSI) guidelines on procedures for the collection of diagnostic blood specimens (H3-A6, 2007) places labelling of blood collection tubes as step 15, after sample collection (step 9) (20). Even more surprisingly, the CLSI document clearly affirms, "tubes must be positively identified after filling, not before, with a firmly attached label..." (item 8.15). Hawkins concluded the letter by acknowledging "labelling specimens immediately after collection should not be considered unacceptable practice

and is the standard and preferred approach". We strongly agree with, and support, this conclusion, which is also in complete agreement with other national and international guidelines, as well as with the recent article of Söderberg et al. who deemed post-collection labelling of the tubes "a substantial risk of identification errors" (21). As the standard operating procedures for blood drawing may vary according to local preferences and technological opportunities, it should also be mandatory to recommend that a double check is made of the identity of the patient and samples, before and after tubes are collected, as clearly mandated by the Joint Commission.

Besides these general and speculative considerations, there are however three major issues that should be targeted. First, it would be very important to plan further investigations to assess the practice of blood collection either locally, or universally. This would pave the way to the second foremost action, i.e., standardisation or harmonisation of operating procedures among phlebotomists according to the best practice (22). Finally, solutions to facilitate and improve positive patient identification should be urgently devised. Although the use of barcoded wristbands still represents the most used means for patient identification (e.g., the phlebotomist should carry a scanner, check the patient's ID against a bar coded specimen label or collection list, and draw blood only in the event of a correct match), barcode technology in healthcare is not as widespread as in other industries (e.g., all commercial products in a market are now labelled with barcode and read with a scanner at the cash desk). Interestingly, the widespread use of barcodes would definitively solve the issue as to whether blood tubes should be labelled before or after venipuncture, since the latter circumstance would be virtually abolished while matching the barcode on the tube with that on the wristband. Novel and even more effective technologies are also emerging, such as radiofrequency identification (RFID)-encoded wristbands and cross-match labels (23), as well as "active" tubes containing a microchip that allow a rapid, safe and more effective match of patient and tube identity, avoiding to rely on patients to correctly identify themselves, and thereby eliminating the need of labelling of the tube (Figure 1). Additional advantages of RFID is that the scan eliminated

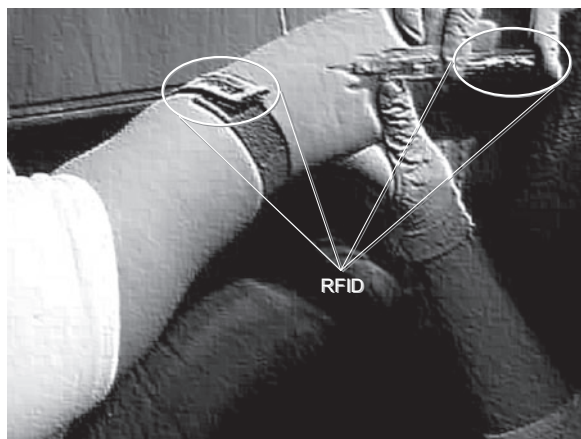


Figure 1 Positive identification by radiofrequency (RFID) of a patient and a blood collection tube.

failures or delays caused by worn or crinkled barcoded wristbands, the potential to read multiple tags simultaneously, higher data storage capacity, faster data transmission rate, capacity to perform multiple read-writes of data to the tag, add-in capacities for temperature and time monitoring from collection to processing of the blood tube (24), which also enable reliable retrospective calculation of the turnaround time (TAT) (25). There is only one debated issue as yet with RFID technology, i.e., the potential interference with patient safety or medical devices.

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