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Identification errors in the blood transfusion laboratory: A still relevant issue for patient safety

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ABSTRACT

Remarkable technological advances and increased awareness have both contributed to decrease substantially the uncertainty of the analytical phase, so that the manually intensive preanalytical activities currently represent the leading sources of errors in laboratory and transfusion medicine. Among preanalytical errors, misidentification and mistransfusion are still regarded as a considerable problem, posing serious risks for patient health and carrying huge expenses for the healthcare system. As such, a reliable policy of risk management should be readily implemented, developing through a multifaceted approach to prevent or limit the adverse outcomes related to transfusion reactions from blood incompatibility. This strategy encompasses root cause analysis, compliance with accreditation requirements, strict adherence to standard operating procedures, guidelines and recommendations for specimen collection, use of positive identification devices, rejection of potentially misidentified specimens, informatics data entry, query host communication, automated systems for patient identification and sample labeling and an adequate and safe environment.

Laboratory diagnostics is pivotal to the clinical decision making. Laboratory data contribute up to 80% to clinical decision making, assisting diagnostic reasoning, providing valuable information for the follow-up of several pathologies and – last but not least – representing a crucial tool in therapeutic drug monitoring (TDM). The blood transfusion laboratory plays a crucial role in the provision of safe and compatible blood to meet patients' needs. There is reliable evidence from 'haemovigilance' schemes and scientific publications that diagnostic (laboratory) errors continue to be one of the leading causes of incompatible or inappropriate blood transfusions, jeopardizing patient safety and resulting in adverse outcomes such as severe morbidity and even mortality [1–3]. As such, the implementation of a quality system in the blood transfusion laboratory would definitely help to reduce errors and ensure that the right test is performed on the right sample, the right results obtained and the right blood product and provided to the right patient at the right time.

The total testing process is typically represented as a cycle (the classical Lundberg's "brain to brain loop"), which begins from and also ends in the head of the requesting physician [4]. Throughout this "loop", the diagnostic activities are typically clustered in analytical and extra-analytical process. The former group comprises all those activities being performed in the clinical laboratory (i.e., the "analysis" of the specimens). The latter group, which develops mainly outside the laboratory environment, is further divided into preanalytical and postanalytical phases. Several studies have already established that most diagnostic errors are typically extra-analytical, the vast majority of them (up to 60–70%) arising from the manually-intensive and less standardized activities of the preanalytical phase [5,6].

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Despite quality control systems and electronic data processing [1], mistransfusion is still regarded as a considerable problem in transfusion medicine, posing serious risks for patient health and carrying a huge expense for the healthcare system (e.g., lack of reimbursement for added patient care, increased insurance premiums, legal action taken against the facility) [2,3]. The vast majority of mistransfusions results from avoidable errors at various points in the transfusion chain. As for other diagnostic areas, blood grouping errors can be due to technical (analytical) failures, especially in serological testing; inadequate or inappropriate (preanalytical) procedures leading to misidentification of patient or donor samples; or to inappropriate (postanalytical) reasoning which might cause misinterpretation of test results. While there is a widespread perception that even in the blood transfusion laboratory the errors are often a combination of factors, with the original mistake being compounded by a lack of adequate checking procedures within the laboratory, there is now growing evidence that sample mislabeling and patient misidentification are both frequent.

In a recent article published in this journal, Tondon et al. carried out a prospective study on the prevalence and type of errors reported in a cross match lab, the potential contributing factors, the underlying system problems, and their association with adverse clinical outcomes [7]. While most of the errors detected (87.1%) were considered as "clerical", it is noteworthy that the vast majority of them were "preanalytical" and occurred outside the blood bank (86.5%), with labeling errors being the most frequent (76% of all errors detected, 4.85/1000 patients). A further sub-analysis revealed that this high frequency was attributable to the wrong blood in the tube (8.5% of all errors detected, 0.65/1000 patients), no labeling on the sample vial (4.4%, 0.34/1000 patients), the sample vial containing the patient's full name only (8.5%, 0.65/1000 patients), the sample vial containing the CR number only (6.9%, 0.52/1000 patients), a mismatch of one patient identifier between the sample vial and the reaction form (11.8%, 0.09/1000 patients), no phlebotomist name and date of collection on the sample vial (20.8%, 1.5/1000 patients) and overwritten specimen labels (15.1%, 1.1/1000 patients). Remarkably, the frequency of technical (analytical) errors was much lower (8.9%, 0.67/1000 patients), in large agreement with the data on the prevalence of analytical errors in traditional laboratory diagnostics [8,9]. Further support comes from a previous study published in this journal, which showed that out of a total of 343,432 red blood cell (RBC) units transfused at the Charité University Hospital in Berlin (Germany), 8 patients erroneously received ABO-incompatible RBC concentrates and the most frequent cause was preanalytical (i.e., incorrect bedside testing) [10]. Moreover, data gathered from the Serious Hazards of Transfusion scheme (SHOT) in the UK, also show that only 30% of errors occur in the laboratory, while the remaining are prevalently extra-analytical [1]. Overall, the identification errors in blood grouping have similar causes as those observed in the clinical chemistry testing, where the leading sources of errors are the physician ordering laboratory tests on the wrong patient, incorrect or incomplete entry of the patient's data in the Laboratory Information System, collection of specimens from the wrong patient, inappropriate labeling of the specimens, lost identification (label) on the specimens, and incorrect entry of patient's results in the database of the Laboratory Information System. In clinical terms, it is not always possible to establish a strict causal link between blood grouping errors and patient outcomes due to under reporting or concomitant morbidities. Nevertheless, the College of American Pathologists (CAP) Q-Probes study has reported that approximately 1 in every 18 identification errors can produce an adverse event for the patient, although more than 70% of the adverse events typically result in significant patient inconvenience with unknown change in treatment or outcome [11]. In other studies, mistransfusions resulting from specimen mislabeling were consistently prevailing among all causes of errors, with a rate of a few per thousand specimens and ranging from 0.7% to 3.2% [12–14].

Although the risk of transfusion reactions from blood incompatibility is much higher than the risk of viral infections, modest media attention and healthcare effort have been spent to prevent identification errors. The National Patient Safety Goals issued by the Joint Commission has stated the issue of improving the accuracy of patient identification as a primary goal from 2004 through 2011 [15]. As such, considering that identification errors are still a major concern in the blood transfusion laboratory, as well as in the traditional clinical laboratory [16], some urgent actions might be undertaken (Table 1). Typically, healthcare workers tend to work around problems, meeting immediate needs (e.g., the dramatic clinical consequences of an incorrect blood transfusion), but the root cause of the error is often overlooked. It is instead advisable to re-

Table 1
Potential solutions to prevent identification errors.

1. Root Cause Analysis
2. Compliance with accreditation requirements (e.g., ISO 15189: 2007)
3. Strict adherence to standard operating procedures (SOPs), guidelines and recommendations for specimen collection
4. Positive identification devices
   - Bracelets with an alphanumeric code
   - Machine-readable bracelets with barcodes or radiofrequency identifier devices (RFID)
   - Machine-readable anthropometric data
5. Reject potentially mislabeled or misidentified specimens
6. Informatics data entry and query host communication
7. Automated systems for patient identification and sample labeling
8. Adequate and safe environment

assess all the vulnerable activities and redesign the entire process accordingly (i.e., performing a Root Cause Analysis (RCA)). RCA is, in fact, aimed to describe in detail and chronological order what has happened during an adverse event, to identify the root cause of that specific event and, most importantly, to recommend and implement corrective actions. This is in agreement with the conventional concept of haemovigilance, which requires an organized system for observing, recording, analyzing, reporting when something goes wrong and using the lessons learned to take action to avoid it going wrong again.

Most obviously, strict adherence to quality system requirements (ISO 15189: 2007), standard operating procedures (SOPs) as well as guidelines and recommendations for specimen collection should be followed to prevent misidentification and other types of preanalytical errors. Then, the Joint Commission clearly recommends using at least two patient identifiers when providing every type of care, treatment or services, and conduct a final verification process to confirm the correct patient, procedure and site using active communication techniques prior to any procedure (National Patient Safety Goals 2011: Goal 1.1) [15]. Accordingly, new technologies implementing safety systems, such as positive identification devices (e.g., bracelets with an alphanumeric code that opens a mechanical barrier system, machine-readable bracelets with barcodes or radiofrequency identifier devices (RFID) and machine-readable anthropometric data), request forms, test tubes and labels with a unique identity code for each patient would ease and make much safer the process of patient identification. It is noteworthy that microchip RFIDs have larger memory capacities, wider reading ranges, and faster processing than traditional barcodes. A barcode identification system involving handheld computers that check if the patient details on the wristband barcode match those on the barcode on the blood bag has already been implemented, and a pilot study in the UK demonstrated positive identification in 100% of patients wearing a barcode identification wristband [17]. As already suggested in the article of Tondon et al. [7], rigorous "tolerance zero" policies of rejecting each potentially mislabeled or misidentified specimen should be established. The large use of innovative technologies is also advisable in other preanalytical areas, such as informatics data entry (to identify variance of results from historical values and avoid manual transcription of data) as well as automated systems for patient identification and specimen labeling (hospital research suggests that return on investment (ROI) in automation systems is extremely high, generating positive returns in less than 1 year) and, last but not least, an adequate and safe environment might be advisable to prevent any type of preanalytical error while collecting blood. Whenever automatic data entry and query host communication is not available, a double check of manual transcripted data is essential.

Misidentification of patients is an important cause of avoidable harm in all areas of clinical practice, not only blood transfusion [16]. Expert consensus and scientific studies describe significant error reduction in individual facilities after implementing revised patient identification processes. Safety and quality practice should therefore be urgently put into practice to prevent this unfavorable event and monitor compliance with the protocol for both patient safety and quality control purposes.

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