Transfusion recipient identification

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Recent reports from different haemovigilance systems indicate that errors in the whole-blood transfusion chain – from initial recipient identification to final blood administration – occur with a frequency of approximately 1 in 1000 events. Although mistakes occur also within the blood transfusion service, about two-thirds of errors are associated with incorrect blood recipient identification at the patient’s bedside. To prevent the potentially fatal consequences of such mistakes, specific tools have been developed, including patient identification bracelets with barcodes and/or radio frequency identification devices, mechanical or electronic locks preventing access to bags assigned to other patients, and palm computers suitable for transferring blood request and administration data from the patient’s bedside to the blood transfusion service information system in real time. The effectiveness of these systems in preventing mistransfusion has been demonstrated in a number of studies.

Key words: blood transfusion, identification, safety.

Introduction

Mutual personal recognition is a common element in many human activities. Specific examples of procedures developed to ensure correct subject identification and increase the safety and reliability of activities can be drawn from the technical, legal, financial and medical worlds. Consolidated methodologies include many variants of the so-called ‘biometric’ technologies, such as automated fingerprint identification, facial and vocal recognition, iris scanning, etc. [1,2]. Although actually or potentially interesting for a number of procedures, some of the above technologies are not readily applicable to the fields of medicine and surgery, particularly if they depend on the active participation of conscious subjects to be identified or if pathological alterations affect the anatomical elements used for identification [3].

Despite the existing difficulties with the above technologies, the implementation of practical, inexpensive and simple methods for correct patient identification remains an issue of paramount importance for increasing the safety of transfusion medicine. In fact, although the current risks of acquiring viral infection through blood transfusion are very small [4–6], the administration of incompatible components to non-designated recipients can cause severe acute reactions – most notably haemolysis – leading to death of the recipient [7,8]. Traditionally, attention to increased transfusion safety has focused mainly on the prevention of transmission of known infectious agents of major clinical relevance, such as hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Very appropriately, this important component of safety is still the object of great attention [9]. However, more recently, a broader concern encompassing the whole transfusion chain – ‘from vein to vein’ – has become popular among blood providers and clinical blood users [10]. This development has been prompted by studies showing that blood component transfusion to non-designated recipients occurs in about 1 of 10 000 transfused units [11].

The evidence that the risk of mistransfusion is not negligible is confirmed by the annual reports of the Severe Hazards of Transfusion (SHOT) program developed in the UK. These and other reports contain detailed information about failures in the transfusion chain, which mostly occur at the patient’s bedside [12–14]. As in a previous series [7], mistransfusion followed by acute haemolysis has been consistently identified as the leading cause of death. Although multiple errors may contribute to ‘wrong blood’ events, about two-thirds of errors occur in clinical areas. The commonest error is failure of the pretransfusion checking procedure to be carried out at
the patient’s bedside. The current data probably underestimate the magnitude of failures, because only one-third of ABO errors are followed by clinically significant consequences. Insufficient nurse staffing, which can result in unsafe conditions among hospitalized patients, has been mentioned as an important causative factor [15]. The above evidence and concerns prompted the development of simple and effective methodologies to ensure correct identification of transfusion candidates, to be carried out as an adjunct to existing policies and procedures for blood administration [16,17].

The main strategies developed to date for preventing identification errors are shown in Table 1. Of paramount importance is the implementation of adequate quality systems, including validated standard operating procedures and the regular monitoring of their efficacy [18]. Moreover, lack of formal training on blood transfusion is an important obstacle to safety improvement [19]. It is also important to assign clear responsibilities to qualified personnel. This approach is quite common in countries where transfusion procedures must comply with laws, decrees and guidelines developed to locate the person to be charged with the possible adverse event [20]. The above policy which aims at drawing the attention of the personnel to error prevention, has been recently adopted in France, in the UK and in Canada, through the implementation of a novel position, named the transfusion safety officer [21]. The latter professionals engage in a broad range of quality assurance activities, thus helping the safety officer [21]. The latter professionals engage in a broad range of quality assurance activities, thus helping the safety officer [21].

Besides the above organizational strategies, technology derived from industry and commerce has been incorporated into the blood transfusion chain. The ultimate purpose of these systems is to make right and wrong actions easy and difficult, respectively [22]. In this regard, it has been suggested that error is the price we pay for having a creative mind. For this reason, it is wise to use ‘stupid’ technical devices to check repetitive and boring pretransfusion procedures [23].

Identification technologies

Correct labelling procedures were defined many years ago within the broad field of clinical pathology and specifically in transfusion medicine. The use of barcoded labels, not only for blood units but also for tubes containing the donor’s and the patient’s samples, is a well accepted standard. The latter represents a consolidated – albeit partial – element of safety. In fact, the transfer of patient’s blood into a tube which carries a ‘correct’ barcoded label from another patient [the so-called ‘wrong blood in tube’ (WBIT)], or blood administration to a non-designated recipient, can occur with tubes and units which are, or appear to be, correctly labelled. For this reason, positive donor–recipient identification at blood collection and administration is the cornerstone of safety.

To our knowledge, the first positive donor–recipient identification system was described in 1973 [24]. At present, it is possible to use active identification systems linked to mechanical devices or palm computers able to read bracelets carrying barcodes, microchips or radio frequency identification devices (RFIDs). Moreover, patient fingerprint readers have been proposed (Table 2).
The currently available systems can be grouped into three types: bracelets with alphanumeric codes that open a mechanical barrier system; machine-readable bracelets with barcodes or RFIDs (smart tags); and devices able to read anthropometric data. The background philosophy of the existing methodologies is to force operators towards self-correction during the procedure. Whenever an error is detected, its occurrence is recorded, thus favouring process monitoring and action traceability.

In 1977, Sherer et al. described studies performed with prototype systems that were aimed at obtaining a hand-held bedside automated donor–recipient identification, but none of the systems tested proved fully acceptable under clinical conditions [25]. Since then, a small number of experiences have been reported in the scientific literature, which limits the possibility of comparing the effectiveness of the different technical approaches. The published reports are discussed below.

In 1991, the Albert Einstein College of Medicine in New York evaluated the BloodLoc system, which consists of a disposable plastic lock sealing a plastic bag overwrapping the blood unit. In this system, an alphabetic code taken from the patient’s bracelet must be used to access the assigned blood unit [26]. The same system was implemented at the Dartmouth-Hitchcock Medical Center in New Hampshire (USA) [27] and at the Gaetano Pini Orthopedic Institute in Milan, Italy, on autologous units [28].

The Hollister transfusion identification system provides a single barcode for the four key elements of the transfusion process: the transfusion request; the specimen tube label; the recipient’s wristband; and each compatible blood unit. The check is performed by a handheld bedside laser scanner. A pilot study was performed at the Hennepin County Medical Center in Minneapolis [29].

The I-TRAC system, and its modified versions Safe Track and I-TRAC Plus, consist of an identification bracelet, namely a barcoded wristband, and a handheld portable data terminal that identifies patients and blood units through a scanner and downloads information through a portable printer. This system was implemented at the Department of Hematology of the Oxford Radcliffe Hospital in 1996. A pilot study demonstrated that 100% of patients wearing a barcoded identification wristband achieved positive identification [30]. The same system was implemented in pilot studies at the Georgetown University Medical Center in Washington DC and at the Ospedale Maggiore of Milan in Italy [31]. The Hospital Carlo Poma in Mantua, Italy, has a 2-year experience with I-TRAC applied to all transfusions performed in 36 clinical wards.

The CARU system consists of a wristband with an electronic chip, an electronic lock for a plastic bag overwrapping the blood unit, and a handheld portable data terminal: it resumes barrier systems and electronic devices. A pilot study with this system was performed at the Ospedale Maggiore in Bologna, Italy [32].

Encouraging studies with barcoded bracelets, including RFID, have been recently reported by Dzik et al. [33] and by Sandler et al. [34]. In the former study, a method was devised to prepare 13.56 MHz radiofrequency blood bag tags integrated with computerized blood bank systems. The tags were used in combination with radiofrequency patient wristbands and a device in which the operating room table contains built-in radiofrequency readers. The authors of this novel approach reported an encouraging 233 correct scans performed during major orthopedic surgery. Furthermore, the radiofrequency pretransfusion check required < 0.5 s per unit. In the latter study, Sandler et al. compared conventional visual methods vs. barcoded labels vs. RFID tags (13.56 MHz, 2 kR transponders) for transfusion of 50 blood components. Although nurses matched patients and components more quickly, initially, by using the visual method (1–2 min), compared with barcode scans (5–7 min) or radiofrequency scans (4–6 min), the latter methodology prevented the need for a second person for a conventional visual double-check verification, thus increasing scanning efficiency.

Outcomes of different approaches

A summary of the effectiveness of the different systems in detecting errors and in preventing mistransfusion is reported in Table 3. The errors were identified thanks to the specific technical system used in each study. These studies show that errors continue to occur, despite diligent implementation of modern quality control systems, thus confirming the value of specific systems for positive transfusion recipient identification. Moreover, the effectiveness in preventing mistransfusion needs to be monitored through efficient national haemovigilance systems, such as those developed in the UK, in Canada and in France. In France, where haemovigilance was started by law in 1993 through a national agency [35], the 2003 report shows the occurrence of 21–28 ABO errors per year during 2000/2003 – defined as ‘immunological ABO incompatibility reported on the blood transfusion incident form’ – out of approximately 2.5 million blood components transfused, with an estimated incidence of one event in 106 680 blood components transfused [36].

With regard to the economic aspects, an earlier study by AuBuchon & Littenberg [27] concluded that the application of a barrier system for preventing mistransfusion and related morbidity and mortality could be cost-effective. Other systems, not using expensive disposable devices, would probably be even cheaper and more cost-effective. Moreover, sharing of costs with the hospital pharmacy might be a useful means of lowering the bar coding system cost for transfusion alone.
Although improvements are necessary at different levels – for example to trace all blood units to all their recipients [37] – the data discussed in this review indicate that important advances in blood transfusion safety have been obtained through the implementation of positive recipient identification systems and of national haemovigilance programmes.

**Conclusions**

The use of positive blood recipient identification systems, despite their demonstrated effectiveness in preventing potentially fatal untoward effects of blood transfusion, have not been widely adopted. There could be a number of practical reasons for this lack of consensus, including a lack of economic resources. Although this could be a good reason in many settings, it is interesting to note that even measures commonly considered unequivocally not cost effective [38], such as nucleic acid amplification technology (NAT) testing, are currently in place as a mandatory requirement in many countries.

Where economic resources are available, a possible additional step to improve blood transfusion safety could be to develop more specific programmes, for example the adoption of computer-controlled ‘intelligent blood refrigerators’ managed using software integrated within the blood transfusion information system and placed at critical locations for remote blood storage, in particular, in operating rooms, emergency departments or special wards with frequent blood use, such as leukaemia or thalassemia clinics.

Additional considerations apply to haemovigilance systems, where a non-blaming culture, as opposed to a punitive perspective, should be promoted [39], together with due attention to the monitoring not only of actual errors but also of those situations in which an error almost occurred (‘near misses’). The latter represent a free lesson in causing no harm to patients, which can be very instructive for procedure review. Continuing education and active involvement of clinical nurses are of the utmost importance in this regard [40,41].

Necessarily, methods of encoding patient identification must be integrated in the blood transfusion service information system. Wherever possible and economically compatible, the use of automation in all laboratory procedures should be encouraged. All the above greatly facilitate error detection and prevention, increase documentation of the transfusion process and improve haemovigilance [42]. Moreover, barcode identification of all patients improves the electronic cross-match process [43–45].

In conclusion, we believe that after a long period of analysis the solutions to achieve total accuracy in blood sample, donor and recipient identification have reached a mature stage of development and there should therefore be no excuse to avoid their routine use in settings where economic resources are available.

**References**

26 Wenz B, Burns ER: Improvement in transfusion safety using a new blood unit and patient identification system as part of safe transfusion practice. Transfusion 1991; 31:401–403
27 AuBuChon J, Littenberg B: A cost-effectiveness analysis of the use of a mechanical barrier system to reduce the risk of mistransfusion. Transfusion 1996; 36:222–226
30 Turner CL, Casbard AC, Murphy MF: Barcode technology: its role in increasing the safety of blood transfusion. Transfusion 2003; 43:1200–1209
32 Luppi D: L’errore trasfusionale ABO. La Trasf del Sangue 2000; 45:311
34 Sandler G, Langeberg A, Feldman CF, Arnett B: Radio-frequency identification complements barcodes for positive identifications for transfusions. Transfusion 2005; 45(suppl):86A
38 Busch MP, Dodd RY: NAT and blood safety: what is the paradigm? Transfusion 2000; 40:1147
39 Kaplan HS, Callum JL, Fastman BR, Merkley LL: Medical event reporting system for transfusion medicine: will it help get the right blood to the right patient? Transfus Med Rev 2002; 16:86–102
41 Foss ML, Moore SB: Evolution of quality management: integration of quality assurance function into operations, or ‘quality is everyone’s responsibility’. Transfusion 2003; 43:1330–1336