Vox Sanguinis

Original Paper

Vox Sang 1996;70:16–20

F. Mercuriali
G. Inghilleri
M. T. Colotti
M. Farè
E. Bitti
A. Vinci
M. Podico
R. Scalamogna

Centro Trasfusionale e di Immunoematologia, Instituto Ortopedico G. Pini, Milano, Italy

Bedside Transfusion Errors: Analysis of 2 Years' Use of a System to Monitor and Prevent Transfusion Errors

Abstract

Clerical errors occurring during specimen collection, issue and transfusion of blood are the most common cause of AB0 incompatible transfusions. 40–50% of the transfusion fatalities result from errors in properly identifying the patient or the blood components. The frequency and type of errors observed, despite the implementation of measures to prevent them, suggests that errors are inevitable unless major changes in procedures are adopted. A fail-safe system, which physically prevents the possibility of error, was adopted in January 1993 and concurrently a quality improvement program was implemented to monitor any transfusion errors. Up to December 1994, 10,995 blood units (5,057 autologous and 5,938 allogeneic) were transfused to 3,231 patients. Seventy-one methodological errors (1/155 units) were observed, half of which were concentrated during the first 4 months of introducing the system. However the system detected and avoided four potentially fatal errors (1/2,748 units). Two cases involved the interchanging of recipient sample tubes, 1 case was due to patient misidentification and the other involved misidentification of blood units. In conclusion the system is effective in detecting otherwise undiscovered errors in transfusion practice and can prevent potential transfusion-associated fatalities caused by misidentification of blood units or recipients.

Introduction

In the last decade the infectious risks of blood transfusion led to the adoption of a number of measures such as stricter criteria for blood donor selection and the introduction of sophisticated tests for screening donor blood. This allowed a remarkable decrease in the incidence of transmission of infectious diseases by blood and blood components. Moreover a further increase in the safety of transfusion has been achieved through the development of autologous transfusion [1–6]. However, in spite of the improvements in these areas of transfusion practice, the occurrence of errors, leading to transfusion of AB0 incompatible blood, has not significantly changed through the years. Clerical errors may occur during collection of samples for compatibility testing, at the issuing of blood, or at transfusion of recipients [7–12].

From the analysis of the literature reporting the incidence of AB0-incompatible transfusions it can be observed that this has remained practically the same during the last 40 years (ranging from 1 in 10,000 to 1 in 40,000 blood units transfused) although a number of measures have been adopted in recent years with the aim of preventing the oc-

Francesco Mercuriali, MD, Director
Centro trasfusionale e Immunoematologia
Istituto Ortopedico G. Pini
piazza C. Cerruti 1
I-20122 Milano (Italy)

Received
April 3, 1995
Accepted
June 23, 1995

currence of such potentially fatal human errors [11–15]. Moreover it must be considered that the real incidence of errors is underestimated as these studies are retrospective and rely on reporting of clinically relevant events.

A recent study [16] on the frequency and nature of bedside transfusion errors in prospectively selected patients, carried out in three major teaching hospital in Belgium, observed a total of 15 major errors (including misidentification of patients or blood units and the transfusion of a patient with allogeneic blood when autologous units were still available) in a total of 3,000 blood units transfused, giving an incidence of major transfusion errors of 1 in every 185 units transfused.

The majority of clerical errors in transfusion are due to a lack of adherence to blood component administration policy and procedures. This observation supports the role of extensive quality assessment/quality improvement (QA/QI) programs in transfusion practice as an effective means to reduce the incidence of transfusion errors [17].

To reduce phlebotomy and bedside identification errors, a device, based on the forcing function concept, was proposed by Wenz et al. [18]. The system (Bloodloc Safety System, Novatek Medical Inc., Greenwich, Conn., USA) consists of a coded locking system so that a blood unit cannot be accessed without matching a three-letter code that can be found only on the patient's wristband. Any error in patient or blood unit identification would make it impossible to open the lock, and consequently to transfuse the patient, and all the errors are automatically referred to the transfusion

Materials

The Bloodloc Safety System was intended for use in conjunction with the hospital's standard identification protocol and consisted of a colored wristband with a prepriated random three-letter code, a clear plastic bag in which the assigned blood units were placed and a single use plastic combination lock with a three-letter dial sealing the opening of the plastic bag; in order to better characterize autologous donors and autologous blood products a special series of wristbands and outer plastic bags were used, which were distinguished by green color and by the presence of a pound sign (#) in the three-letter code.

Methods

For Allogeneic Blood Transfusion. Each patient admitted to the hospital, received a wristband with a unique three-letter code randomly chosen from a peel-off sheet. The code was unique to each patient and was deliberately not recorded in the hospital information system, the patient's chart or anywhere other than on the wristband. In the case of blood samples submitted to the blood bank for pretransfusion tests the phlebotomist had to transcribe, in addition to the standard identification, the patient code on the specimen tube label. As the code could *only be obtained from the patient's wristband, the phlebotomist had* to complete this transcription at the patient's bedside. Upon receipt of the specimen in the blood bank the code was recorded in a limited access file only available to the laboratory staff. No samples were accepted by the blood bank without the patient's three-letter code.

When the blood bank assigned a blood unit to the patient, the unit was placed into a plastic bag which was sealed with the lock set permanently with the patient's code, then the dials were scrambled. When the blood product was received by the clinical service the usual clerical checks were performed identifying the patient and the unit of blood. In addition, to access the blood unit the combination lock was opened, by setting the dial according to the code obtained only from the wristband worn by that patient. If the lock did not open at the patient's bedside, the unit was returned to the blood bank. The blood bank could not reissue the blood until the error was identified and co[illegible]

Table 1. Number and type of errors observed during the study period

	January-June 1993	July-December 1993	January-June 1994	July-December 1994
Absence of the code on blood sample	31	–	6	–
Wrong transcription of patient code on blood sample	2	2	8	7
Wrong setup of the Bloodloc	2	4	7	2
Attempt to transfused the wrong patient		1		–
Attempt to transfuse the wrong unit		–	–	1
Misidentification of blood sample		2	–	–

bedside transfusion. An error was considered to have occurred each time a sample was received without a code and each time a Bloodloc failed to open. Each error was rated on a specific log where the accession number, date, time, type of error and the name of the person notifying the error were reported. In addition, a worksheet was completed giving detailed information about circumstances of the error and the action taken. Periodically these were analyzed, counted and recorded on a Performance Indicator Report according to the type of error: absence of the code on the blood sample, wrong setting of the Bloodloc by blood bank personnel (methodological errors), misidentification of blood sample, attempt to transfuse the intended patient with the wrong unit, attempt to transfuse a blood component to a patient other than the intended patient (potentially fatal errors).

Implementation of Bloodloc System

The Bloodloc system was implemented in January 1993 after the approval of the transfusion committee with the setting up of protocols for clinical service and blood bank followed by meetings involving clinicians, nurses, medical technologists and blood bank staff to describe the method in detail. The system was initially used only for patients predepositing autologous blood units. After 3 months of utilization a preliminary evaluation was carried out taking into consideration the time requirement imposed by the system, deficiencies in the product or protocol and problems encountered with the system that would not have occurred with traditional practices. As acceptance of the system was expressed by all survey participants in April 1993 the system was extended to all transfused patients, and concurrently, the QI programme was implemented.

Results

During the first 2 years of the use of the Bloodloc system, 10,995 blood units (5,057 predeposited autologous blood units and 5,938 allogeneic units) were transfused to 3,231 patients (2,219 patients predeposited an average of 3.1±2.0 units). Seventy-one methodological errors (absence of the three-letter code on the patient's specimen n = 37, phlebotomist error in transcribing patient's code on the tubes n = 19 and improper encoding of the lock by the blood bank n = 15,) were detected (table 1) giving an incidence of 1 in every 155 units transfused. Nearly half of the total number of methodological errors (n = 35, 48%) were concentrated in the first 4 months of implementation of the system.

In the study period, 4 potentially fatal errors (1 in every 2,748 units transfused) were detected and prevented by the use of Bloodloc. Two cases involved the interchange of recipient sample tubes resulting in misgrouping of blood, 1 case arose from patient misidentification and 1 case from blood unit misidentification. The first 3 cases occurred 9 months after the implementation of the system and the 4th after 21 months.

The reason for the first two accidents was the phlebotomist drawing the blood of patient A into a tube labelled with the name of patient B. Having filled the tube, the phlebotomist transcribed the code from the wristband of the patient bled (A). The inverse error occurred for patient B. Consequently the blood bank performed pretransfusion tests on blood samples identified with the code corresponding to the patient from which the blood was collected but identified with the name of the other patient. The blood units were assigned to the patient reported on the tube label but were sealed with the lock set with the code corresponding to the other patient. When the anesthesiologist in the operating room attempted to transfuse the patient to which the blood units were assigned, the mismatching of the Bloodloc code denied access to the unit. One of these patients was group 0+ and was assigned 2 AB+ blood units. The third accident involved an attempt to transfuse the wrong unit (an autologous unit donated by another patient) to the intended patient. Again the Bloodloc code was different from that reported on the patient's wristband and access to the wrong unit of blood was physically prevented.

Discussion

Errors are inevitable when humans are required to perform large numbers of repetitive tasks [13]. Human error is a significant cause of transfusion-associated fatalities [9]. The majority of incompatible transfusions are the result of clerical errors (in 40–50% of blood transfusion fatalities blood was given to the wrong patient) [10]. During the transfusion processes the following errors occasionally occur: (1) submission of the wrong patient's blood, (2) misgrouping of blood, (3) interchange of recipient sample tubes, (4) transcription errors in writing or interpreting the requisition of blood, (5) errors in processing blood in the blood bank and (6) clerical errors in blood administration. A clerical error can result in the wrong blood being given to a patient and in about 1/3 of these cases the blood is AB0-incompatible (estimated mortality is 1/422,000 and the wrong patient transfusion rate 1/12,700) [14]. An AB0-incompatible transfusion may occur when the blood is administered without identifying the recipient when the transfusion is started or at the time the blood sample is drawn. Data from New York State [7] proves that 1 of every 33,000 units transfused is AB0-incompatible with the recipient. The majority of these errors result from failure to properly identify the patient or the blood component. Moreover, the true incidence of human errors in transfusion practice is underestimated because the majority of the published figures rely on the reporting of clinically relevant events or on indirect methods. A recently published study [16] conducted in a 'descending' method, i.e. tracing all units down to their end point, disclosed an incidence of major bedside errors (including misidentification and administration of allogeneic blood when autologous blood was still available) of 1 of every 185 units transfused. A number of measures were tried out to prevent transfusion accidents: (1) use of trained and experienced personnel, (2) carefully designed request forms, (3) adequate time for performing tests in blood banks, (4) proper identification of blood samples (double sampling) and units (AB0 grouping on blood bag), (5) proper identification of the intended recipient, (6) special wristband, (7) alphanumeric and color-coded systems, (8) use of patients' photographs, (9) patient's signature, (10) bedside AB0 typing and (11) bedside mixing of patient and donor blood. None of these measures favorably influenced the incidence of hemolytic transfusion reactions [15]. The opportunity for human error grows as the volume and complexity of blood transfusion increase [13]. Most hospital systems, if adhered to, would prevent transfusion accidents but Bloodloc is the only system which defeats human error because it provides a physical barrier that stops a transfusion when an error is about to occur and ensures that properly crossmatched blood is transfused to the recipient. Linden et al. [7] stated that the Bloodloc system if fully used could be expected to prevent 75% of the erroneous transfusions, and would have prevented all 3 deaths reported in the New York State from January 1, 1990 to October 31, 1991. Moreover 7 of the 15 major errors described by Baele et al. [16] could have been prevented (7 units transfused to unintended patients) and it could have been prevented that 5 allogeneic units were given when autologous blood was still available as the presence of the # sign in the code of autologous donors would have made the technician check whether autologous blood was still in store before releasing allogeneic blood and the ward personnel receiving an allogeneic unit for a patient wearing a green wristband check in the transfusion center on the presence of autologous blood.

The system dissociates error recognition from patient symptoms: errors will always happen, but they should be spotted before harm is done to the patient (proactive), not afterwards (retroactive). Moreover, the introduction of the Bloodloc helps to implement a QI program which monitors performance. The introduction of QI makes possible the documentation of the type of errors, including the most common errors, such as wristband omission and erroneous transcription of the patient's code on the specimen tube. Error detection is important as stated by Shulman et al. [17] because a QA/QI process improves transfusion safety, reduces the percentage of transfusions associated with errors and contributes to the involvement of the transfusion service with bedside transfusion practice, areas so far beyond the control of the blood bank. In our experience many samples were received without the three-letter codes in the first 4 months of implementing the system. After this initial period these errors occurred at a rate of 2 errors per month and this may reflect an increasing attention to patient identification due to a more proper use of the system. This type of error can be attributed to a lack of attention of hospital personnel and to protocol violation. The two errors caused by the interchange of the recipient sample tubes and assignment of wrong units, as well as the cases of patient or blood unit misidentification were detected by the Bloodloc system and inappropriate transfusions were prevented. The system fits in with the usual protocol for allogeneic and autologous blood transfusion. In allogeneic blood transfusion there is a concern of transfusing AB0-compatible blood; when transfusing autologous blood there is the additional concern of transfusing a specific unit donated by a specific patient. There are legal and ethical risks involved in transfusing a patient with allogeneic blood when autologous blood is available. There is a further risk that an autologous blood unit may be transfused to a patient other than the donor.

In our setting, Bloodloc was easily accepted by all hospital staff and the compliance with the program increased following the presentation of the errors prevented in this period. The data obtained through the implemented QA are distributed to all participants and discussed every 3 months. Awareness that errors may happen at each step of the transfusion process (including in the Blood Transfusion Centre) stresses the importance of the system and reinforces the message that the system should not be forced or bypassed. Except in only one case, which occurred 2 months after the implementation of the system, no case of bypassing the locks (cutting the bag or rupture of the locks) was recorded. In our experience the Bloodloc system is effective in detecting errors in transfusion practice and preventing potential fatalities due to transfusion of the wrong blood units.

References

1 Perioperative blood cell transfusion. Consensus conference. JAMA 1988;260:2700–2703.
2 The use of autologous blood. The National Blood Resource Education Program Expert Panel. JAMA 1990;263:414–417.
3 Toy PTCY, Strauss RG, Stehling LC, et al: Predeposited autologous blood for elective surgery. N Engl J Med 1987;316:517–520.
4 Dzik WH, Sherburne B: Intraoperative blood salvage: Medical controversies. Transfus Med Rev 1990;4:208–235.
5 Stehling L, Zauder HL: Acute normovolemic hemodilution. Transfus 1991;31:857–868.
6 Martin E, Hansen E, Peter K: Acute limited normovolemic hemodilution: A method for avoiding homologous transfusion. World J Surg 1987; 11:53–59.
7 Linden JV, Paul B, Dressler KP: A report of 104 transfusion errors in New York State. Transfusion 1992;32:601–606.
8 Taswell HF, Sonnenberg CL: Error analysis: Types of errors in the blood bank; in Smit Sibinga CT, Taswell HF, Das PC (eds): Quality Assurance in Blood Banking and Its Clinical Impact. Boston, Nijhoff, 1982, pp 227–237.
9 Editorial: Blood transfusion accidents. Br Med J 1953;2:390–391.
10 Sazama K: Reports of 355 transfusion-associated deaths: 1976 through 1985. Transfusion 1990;30:583–590.
11 Binder LS, Ginsberg V, Harmel MH: A six year study of incompatible blood transfusions. Surg Gynecol Obstet 1959;108:19–34.
12 Linden JV, Kaplan HS: Transfusion errors causes and effect. Transfus Med Rev 1994;3:169–183.
13 Taswell HF: It's in the bag! (or is it?). Transfusion 1991;31:386–387.
14 Murphy WG, McClelland DBL: Deceptively low morbidity from failure practice safe blood transfusion: An analysis of serious blood transfusion errors. Vox Sang 1989;57:59–62.
15 Sharp DE, Cook SS, Gerv in AS: Transfusion related mortalities – Prior lesson unlearned. Transfusion 1984;24:433.
16 Baele PL, De Bruyere M, Deneys V, et al: Bedside transfusion errors. A prospective survey by the Belgium SANGUIS Group. Vox Sang 1994; 66:117–121.
17 Shulman LA, Lohr K, Derdarian AK, Piculkaric JM: Monitoring transfusionist practices: A strategy for improving transfusion safety. Transfusion 1994;34:11–15.
18 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.