

## One-year use of the Bloodloc system in an Orthopedic Institute

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### Summary

Human error in patient or specimen identification due to fatigue, stress and lack of attention by technologists, nurses, interns, and physicians, can cause routinely safety procedures to be circumvented. Clerical errors may occur during the specimen collection, the issue of blood unit and the transfusion of blood. The introduction in an increasing number of hospital of preoperative autologous blood donation programs further increases the chance of error, because a single patient can predeposit multiple units of blood. In this cases there is a greater commitment not only to transfuse any blood unit that is ABO compatible but to transfuse the specific units the patient previously donated for his own use. Human error has been recognized as a significant cause of transfusion-associated fatalities. The persistence of the frequency and type of errors observed in spite of extensive efforts to eradicate them, suggests that errors are inevitable as long as large number of repetitive procedures are performed unless major system changes are adopted. A system (Bloodloc System) that physically prevents the possibility of error was adopted since January 1993 and concurrently a quality improvement program (QI) was implemented specifically designed to monitor: 1. the absence of the code on the blood samples, 2. the blood bank error in setting the Bloodloc, 3. the misidentification of blood samples, 4. any attempt to transfuse the wrong blood unit, 5. any attempt to transfuse, the wrong patients.

Results: 4895 blood units (2469 autologous and 2426 allogeneic units) were transfused to 1478 patients (849 predeposited an average of  $3.3 \pm 2.0$  units). The methodological errors (absence of three-letter code on the patient's specimen tube, wrong transcription of the code on the blood sample, wrong setting of the Bloodloc in the blood bank) - 41 cases - were limited at the first four months of implementation of the system. In the same period however have been reported 3 potentially fatal errors which have been avoided by the Bloodloc. Two cases of misidentification of blood samples at the moment of the specimen collection, and one attempt to transfuse the wrong units to the wrong patients.

Conclusions: The Bloodloc system is effective in preventing potential transfusion-associated fatalities caused by units or recipients misidentification.

## Introduction

It has been shown that the most common cause of fatal acute hemolytic transfusion reaction is the transfusion of ABO-incompatible blood units. The actual incidence of such potentially fatal events has been estimated to be in the range from 1 in 10,000 to 1 in 100,000 blood units [1]. This evaluation has been confirmed by data from New York State [2] showing that in 1991 1 of every 33,000 unit was ABO-incompatible with the recipient.

While blood bank laboratory errors in pre-transfusion tests may cause some ABO incompatible transfusions the greatest number are the result of clerical error occurring during the specimen collection, the issue of blood units and principally the transfusion of blood [3]. It has been demonstrated that 40%-50% of blood transfusions fatalities result from failure of transfusionist to identify properly either the patient or the blood component that patient receive [4].

In recent years intense concern over this mortality and morbidity has led to proposals and implementation of many additional measures aimed at prevention of transfusion accidents as, for example the administration of blood transfusions only by specially trained personnel or other more sophisticated measures such as the use of patient photograph on blood transfusion forms.

Unfortunately these procedures have been proved to be less than fail-safe, they are easily circumvented and prone to erroneous use. Moreover, it has been proven that the incidence of these clerical errors is not affected by the implementation of reform aimed at preventing their recurrence [5]. Sharp and colleagues [6] compared the incidence of transfusion fatalities between two periods (the first from 1976 to 1979 and the second from 1980 to 1983). Although during the latter period some prevention measures were adopted the incidence of human errors in causing blood transfusion related fatalities did not change.

The persistence of the same human errors in the same order of frequency in spite of extensive efforts to eradicate them, suggests their inherent irreducible quality. As long as humans perform large numbers of repetitive procedures, errors are inevitable unless major system changes are adopted [7].

Recently, a system (Bloodloc Safety System, Novatek Medical Inc., USA) has been developed to physically prevent the administration of the wrong unit of blood to a patient. In a subsequent publication Linden [8], analyzing 104 transfusion errors,

3 of which resulted in the death of the patient, concluded that based on the type of the errors observed, the use of the Bloodloc System could have prevented 75% of the errors and would have prevented all 3 deaths.

The experience of 1 year use of the Bloodloc System in the Orthopedic Institute of the University of Milan is reported.

## Methods

### Setting

Our Institute is composed of 24 surgical wards with a total of 477 beds. More than 7000 operations are performed per year. The hospital has an autogeneic blood transfusion program which provides 69% of the patients to receive their own blood during surgery; an average of 2.9 autologous blood unit per patient are collected.

### Materials

The Bloodloc system consists of: 1) a pre-coded coloured wristband preprinted with a three-letter code (a total of 12,167 individual non-repetitive three-letter codes separated into three colors - blue, red, yellow - are available); 2) a single use plastic combination lock with three letter dial designed to seal the opening of a bag; 3) the outer clear plastic bag.

A special series is reserved for autologous blood transfusion that is characterized by the green color of both the wristband and the plastic bag and by the presence of the pound sign (#) somewhere in the code.

When a patient is admitted to the hospital or on the occasion of the first donation for a patient enrolled in an autologous blood program, he receives a wristband with a unique three-letter code randomly chosen from a peel-off sheet. The code, that is unique to each patient for the length of the hospital stay, is purposely not recorded in the hospital information system, on the patient's chart or anywhere other than on the wristband. For any blood sample drawn for the blood bank, the phlebotomist transcribes, in addition of standard identification, the patient code on the specimen tube. As the code can be obtained only from the patient wristband, the phlebotomist must complete this transcription at the patient's bedside. Upon receipt of the specimen in the blood bank the code is recorded in a limited

access file whose access is denied to all personnel other than the laboratory staff.

When typed and matched blood unit is issued from the blood bank, the blood unit is placed into a transparent plastic bag and the bag is closed with the lock permanently set with the patient's code. When the blood product is received by the clinical service for transfusion the usual clerical checks are performed to identify the patient and match that patient with the unit of blood. Moreover, to have physical access to the blood unit the combination lock must be opened dialing the right code that can be obtained only consulting the patient's wristband. If the lock doesn't open at patient's bedside the blood unit must be returned for checking to the blood bank. The blood bank cannot reissue the blood unit unless the error is identified and corrected.

### Implementation of Bloodloc System

In our hospital, the Gaetano Pini Orthopedic Institute, the Blood Loc System has been used since January 1993.

Concurrently with the use of the Bloodloc system a quality improvement (QI) program has been implemented that is based on the ability of the Bloodloc System to detect and highlight any variances, both serious and silent, that may happen during the transfusion process.

This QI program is specifically designed to help detect and count variances in the transfusion process, aid in their analysis, document what improvement are made in response to the variance and moreover it provides a "performance indicator" that measures the improvement achieved. The variances monitored by the QI are the following: absence of the code on the blood samples; blood bank error in setting the Bloodloc; misidentification of blood samples; attempts to transfuse the wrong blood unit; attempts to transfuse the wrong patient.

### Results

Up to december 1993, 4895 blood units (2469 autologous and 2426 allogeneic) were transfused to 1478 patients (849 patients predeposited an average of  $3.3 \pm 2.0$  units).

A total of 41 methodological errors were observed (35 cases of the absence of the three-letter code on the patient's specimen tube and 6 cases in which Bloodloc was wrongly set in the blood bank) but

they were limited to the first four months of implementation of the system. After this initial period the errors did not occur any more. This type of error can be attributed to lack of attention by hospital personnel and to protocol violation.

In this period, 3 potentially fatal errors have been avoided by the use of Bloodloc:

Two cases of interchange of recipient pilot tubes which resulted in a misgrouping of blood and consequently assignment of the wrong blood units to both patients and 1 case of misidentification the patient at moment of the transfusion. The first accident involved two patients of the same department; at the moment of blood sampling the phlebotomist put the blood of the patient A in the tube labeled with the name of the patient B, but after the phlebotomy transcribed on the tube label the code of patient A. The same error occurred for patient B. The blood units for recipients A and B were issued at the same time from the Blood Bank with the Bloodloc System. At the time of transfusion in the operating room, lack of correspondence of the unit codes with those of the patients' wristbands alerted the anesthesiologists in both cases, the errors were discovered and the transfusion of the wrong units prevented (one of the patients was group O+ but was assigned 2 AB- blood units). The second accident involved recipient misidentification in the ward. In this case the transfusionist tried to get access to the unit intended for another patient. Also in this case the code set on the Bloodloc was different from that reported on patients' wristband and the access to the wrong unit was denied.

### Conclusions

Bloodloc is a system which defeats human error because it provides a physical barrier that stops a transfusion when an error in patient or blood identification is made and insures that the property cross-matched unit of blood is transfused to the correct recipient. Errors become evident before a transfusion takes place, not after. Moreover, the introduction of the Bloodloc was helpful to implement a QI program to monitor performance, to avoid accidents and to identify any links in the system. The introduction of QI allows to document all types of errors, including the most common, such as wristband omission or erroneous transcription of patient's code on the specimen tube, which might go undetected. Error detection is very important not only because it allows necessary correction to be undertaken.

ken but also, as stated by Shulman *et al.* [2], because a Quality Assessment/Quality Improvement process could improve transfusion safety, can reduce significantly the percentage of transfusion with associated variances and contribute to an increase involvement by transfusion service director in the oversight of transfusion practice. In our experience the number of samples received without the three-letter code was concentrated in the first four months after the implementation of the system. After this initial period this error did not occur any more. This type of error can be attributed to lack of attention by hospital personnel and to protocol violation. The two errors of interchange of recipient pilot tubes which led to the assignment of wrong units and the case of patient misidentification at the time of transfusion were all detected by the Bloodloc and the transfusion of the wrong units prevented. The system fits in the usual protocol for allogeneic and autologous blood transfusion. In allogeneic blood transfusion there is a concern to transfuse ABO compatible blood. When transfusing autologous blood there is the additional concern to transfuse 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. Moreover, there is a risk that an autologous blood unit may be transfused to a patient other than the donor. In the case of autolo-

gous transfusion Bloodloc allows to avoid all such risks.

In our setting Bloodloc system was easily accepted by all hospital staff and the compliance to the program increased following the presentation of the errors occurred in this period by the transfusion Committee. In our experience the Bloodloc system was effective in detecting errors in transfusion practice and preventing a potential fatality due to the transfusion of the wrong blood units.

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