Improvement in transfusion safety using a new blood unit and patient identification system as part of safe transfusion practice

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A new patient and blood unit identification system designed to confirm the identity of crossmatched blood products and that of the intended recipient was evaluated. Six hundred seventy-two red cell concentrates were transfused to 312 patients. Participating hospital personnel and patients were interviewed regarding the use and benefit of this unique system, which incorporates a "lock-box" approach to the identification process. The product and procedure were accepted unanimously and enthusiastically, and three potential mistransfusions were avoided by use of the system during the limited period of observation. This type of approach to the identification process affords greater security than conventional practices and minimally burdens staff. **TRANSFUSION** 1991;31:401–403.

THERE IS WIDESPREAD concern about the transmission of infectious agents by blood transfusion. This problem is being addressed through a number of actions. Donor exclusion criteria have been broadened, individuals at high risk are encouraged to refrain from donating, and all donated blood is tested for a variety of serologic markers of infectivity. It is generally acknowledged that the blood supply has never been safer. Unfortunately, the safety of transfusion itself is not influenced by these measures. The administration of compatible blood products is the linchpin of transfusion safety, but the acute hemolytic reaction remains a leading cause of transfusion-associated death.[1,2] The majority of these reactions are the result of human error.[3,4] The elimination of such errors depends on fail-safe identification of both the patient and the unit of blood prior to transfusion.

Hospitals and transfusion services have practices and controls designed for the proper administration of medications and blood. A unit of blood is routinely identified by a unique number, an ABO/Rh label, and (once it is crossmatched) a tag that associates the unit with the intended recipient. The patient is identified by name, location, and patient identification number, which are inscribed on his or her wristband. Unfortunately, these identification procedures frequently prove to be less than fail-safe.[1,2] They are easily circumvented and prone to erroneous use.[5,6] A system that incorporates a physical barrier to transfusion—one that can be removed only by proper identification of the unit *and* recipient—provides a greater likelihood of consistent and proper use. We describe our experience with such a system (Blood-Loc, Novatek Medical Inc., Greenwich, CT).

Materials and Methods

The Blood-Loc system is intended for use in conjunction with the hospital's standard identification protocols. It consists of four elements (Fig. 1): a unique three-letter code printed on a colored adhesive sticker, a single-use plastic combination lock designed to seal the opening of a plastic bag, a back plate that works in conjunction with the lock, and a 5 × 13-inch clear plastic bag. When a patient is admitted, one of the coded stickers is applied to his or her wristband insert in a manner that does not obscure the information customarily noted there. The sticker is chosen at random from a peel-off sheet, and the letter combinations provide for 12,167 individual, nonrepetitive codes. The code is purposely not recorded in the hospital information system, on the patient's chart, or anywhere other than on the wristband. The unique code remains with the patient throughout the clinic visit or hospital stay, and a new code is assigned on each subsequent admission. When a blood specimen is drawn for a type-and-screen or crossmatch, the phlebotomist copies the code onto the specimen label. The code is circled to distinguish it from the phlebotomist's initials that also appear on the label. Because the code can be obtained from only one source, the phlebotomist must complete this transcription at the patient's bedside using the wristband identification. Subsequent labeling at a remote location using the patient's chart or Addressograph plate is not possible. Upon receipt of the specimen in the blood bank, this code is recorded in a limited-access file. This file is maintained in a manner that denies access to all personnel other than the laboratory staff. In addition to the laboratory's routine, the codes on all subsequent specimens are verified against the recorded code.

When the blood bank receives a request for the issue of a crossmatched product, a technician retrieves the patient's recorded code, selects a disposable lock, and permanently sets the combination to the proper sequence. The technician easily

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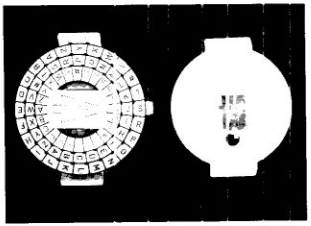

FIG. 1. The Blood-Loc identification system. The system consists of four elements: a unique three-letter code printed on a colored adhesive sticker and attached to the patient's wristband, a single-use plastic combination lock (left), a back plate (right), and a plastic bag (see Fig. 2).

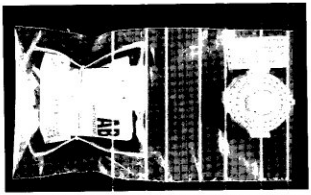

FIG. 2. The 5 × 13-inch plastic bag of the identification system, with the combination lock inserted through holes in the bag's opposing sides.

accomplishes this by dialing the code and pressing on the face of the lock. Once set, the lock cannot be reprogrammed and will open only with the use of the proper code. The blood product is placed into the plastic bag, which is then sealed with the lock by insertion of the lock mechanism through holes in the bag's opposing sides (Fig. 2), placement of a back plate on the lock, and scrambling of the dials. When the blood product is received by the clinical service, the combination lock must be opened before it is removed from the bag. The clinical staff must again consult the patient's wristband to retrieve the code, thereby completing the identification cycle.

The following errors can cause a discrepancy between the code in the combination lock and the patient code: submission of an erroneous primary code as a result of faulty transcription, submission of another patient's code as a result of improper specimen procurement or specimen labeling, incorrect encoding of the lock due to an error made in the blood bank, or an attempt to transfuse the wrong patient. If the lock does not open, the clinical staff is instructed to confirm all identification procedures. If that does not resolve the problem, the product is returned to the blood bank. The blood bank cannot reissue the product unless the error is corrected. This requires recognition of their own error and the use of a new, properly encoded lock and/or correction of the clinical service's error by a request for a new specimen and initiation of another crossmatch.

Our hospital served as the primary test facility for this new patient and blood unit identification system. Over a period of 5 months, 672 units of red cells were issued to 312 recipients in accord with the described protocol. The system was initially used in the outpatient transfusion facility to allow a small number of individuals to gain familiarity with it. After a successful 2-month observation, the system was introduced in the inpatient oncology unit as well. Quality control checks were performed in the blood bank on a daily basis. These procedures involved encoding of a lock by one technologist and attempts by a second technologist to open it without knowledge of the code, attempts to open the lock by purposeful dialing of a sequence with a single error, and finally, opening the lock by use of the proper code. No malfunctions were encountered in more than 200 quality control checks. A total of 56 individuals were involved in the evaluation of the system (32 nurses, 12 blood bank technologists, 10 house officers, and 2 clerks). These people were interviewed on a daily basis by supervisory personnel involved in the project. A standardized evaluation form was completed after each meeting. The evaluation addressed all aspects of the use of the system, the time requirements imposed by its use, noted deficiencies in the product or protocol, problems encountered with the system that would not have occurred with traditional practices, and, most important, the benefit(s) derived from its use. At the end of the evaluation period, an extensive debriefing conference was held for all the participants. Patients also were informed of the purpose and function of the product, so that their reactions and comments could be solicited. These ongoing critiques led to several product modifications.

Results

Acceptance of and enthusiasm for the Blood-Loc system were expressed by all survey participants. Blood bank personnel found that use of the system added no more than 30 seconds to the routine used to issue units of blood. They also noted that no unsigned specimen tube labels were received from clinical areas where the system was in use. Failure by phlebotomists to confirm specimen identities by signing tube labels had been a chronic problem; therefore, the need to read the wristband identification to determine the code is believed to have resulted in confirmation of the patient information as well. The products from one lot failed to lock after proper initialization. The problem was caused by an improper assembly, was corrected onsite, and did not recur. It was quickly discovered that several letters in the code transcribed to the tube label, such as V and U and G and Q, could be mistaken for one another. The manufacturer eliminated this problem by removing two of the letters and adding a symbol.

Nursing and house staffs were quick to point out that staffing patterns and their other responsibilities frequently made it difficult to conform to the hospital's policy that two individuals must confirm the identities of the patient and of the unit of blood prior to transfusion. The second signature was often obtained in a manner that they believed did not add to the safety practice. They were of the opinion that an additional identification process, particularly one whose use cannot be circumvented, such as the Blood-Loc system, provides a sounder and more practical approach to the process. The admission clerks had no difficulty with the system, as wristband identification is an existing requirement and the random selection of a printed code sticker from a peel-off sheet imposes little extra

burden. Patients, particularly those anticipating the receipt of autologous or directed blood donations, were reassured by the procedure and frequently reminded the phlebotomist of the presence of the code on their wristband. It is of greatest importance that, during this limited period of use and in a relatively small number of transfusions, the system was successful in preventing three potential mistransfusions. In two of these instances, attempts were made to transfuse a patient other than the intended recipient, and in the third, the specimen submitted for crossmatch had been obtained from a patient other than the intended recipient.

Discussion

Review of the literature with regard to adverse transfusion reactions yields a surprisingly small number of articles that address human error. It is even more frustrating to attempt to derive statistical data on the topic. Nevertheless, there is documentation that clerical error is a frequent cause of hemolytic transfusion reactions[2-4,7] and the single most important cause of transfusion associated fatalities.[1,8] The incidence of mistaken transfusion is unknown. In 1975, the Bureau of Biologics made it mandatory to report all fatal complications of transfusion. During the first 3 years of reporting, there were 37 clerical errors that resulted in patients' deaths. It is acknowledged that these reports represent a fraction of the total number of mistransfusions. Recently, several states have required the reporting of all incidents involving mistaken transfusions, but these numbers have not yet been published.

Binder et al.[2] performed a retrospective study involving more than 80,000 transfusions given at their hospital in 6 years. The authors documented a total of 30 incompatible transfusions during this period: 18 clearly were caused by clerical error, for an incidence of approximately one error in every 4500 red cell transfusions. This ratio extrapolates to more than 2600 mistransfusions per annum in the United States alone. Furthermore, the finding is not unique to the United States. Binder's ratio is in close agreement with that from a report from the United Kingdom, in which an incidence of one error for every 6000 red cell transfusions has been confirmed.[9] The impact of these statistics is heightened by a recognition that they represent a best-case scenario, as they do not account for serologically compatible transfusion errors or the underreporting of adverse incidents. Of equal concern is the observation that the institution of a variety of paper-based check mechanisms fails to decrease the error rate.[2]

The percentage of transfusion errors increases with the transfusion activity in a given area.[2] This suggests that such errors are caused by inadvertent circumstances related to workload and are not likely to be prevented by the prospect of punitive measures or extensive in-service training sessions. Clerical errors are the result of a number of omissions and/or failures. They can occur during specimen collection (mislabled specimen, wrong patient's blood), the issue of blood (inappropriate labeling, wrong unit), or the transfusion process itself (wrong recipient). The described system has been designed to eliminate all of these possibilities. Unlike other identification systems, Blood-Loc serves as a physical barrier to transfusion and must be used effectively and appropriately. A mistake in specimen collection will cause the phlebotomist to inscribe on the blood tube a code that will not open the lock—that is, will not coincide with the recipient's code. The codes will also disagree if the issue of a unit of blood is in error or if an attempt is made to transfuse the wrong patient. These problems must be resolved prior to transfusion. But it is more likely that such workload-related problems will continue. It is therefore appropriate to incorporate into the operation the use of fail-safe devices to ensure the highest possible degree of patient safety. Measures such as unit dosage systems have proved to be of great value in dispensing drugs. Systems such as the Blood-Loc can be expected to provide similar benefits in the transfusion of red cells.

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