How I minimize mistransfusion risk in my hospital

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"Every system is perfectly designed to get the results it gets."

—Paul Batalden, MD, Center for the Evaluative Clinical Sciences, Dartmouth Medical School

Some of the aphorisms of quality management and process improvement are imbued with much common sense. I believe that the truism above can help us understand how to reduce the risk of mistransfusion.

IT'S ALL ABOUT PROCESS

Increased attention to patient safety in hospitals has highlighted the importance of the "Five Rights" in medication administration: right patient, right time, right drug, right dose, and right route.[1] These issues—particularly "right patient" and "right drug" (i.e., "right unit")—pertain to transfusion recipient safety, but the transfusion process has an added twist: For the "right patient" to get the "right unit" we must make sure that the pretransfusion testing sample was collected from the right (i.e., same) patient. To my eye, the process is a loop that starts at the patient's arm, goes through the transfusion service, and ends at—hopefully—the same patient's arm (Fig. 1).

This process, however, does not loop back correctly to far too many patients. We should take no comfort that many more patients are harmed by errors in medication administration each year than transfusion.[2] We should be energized by the recognition that more than 1000 units of red blood cells (RBCs; 1 of every 12,000) are transfused to the wrong patient each year in the United States![3] In this era where we put donors under a bright light of inquisition before accepting their gift and then test it almost until the cows come home, we kill between one and two dozen patients *every year* in the United States because of errors that lead to acute hemolytic transfusion reactions. That's not a track record of which we should be proud. We should recognize the implication that our hospitals are working with faulty systems and improve those systems.

The sophisticated medical delivery systems in developed countries have created routines—procedures—that help staff "get it right." When a process does not yield the intended result, there is always one and often more than one spot in a procedure where an error was made. This error was made by a human, but categorizing the event as being caused by "human error" does little to protect the next transfusion recipient. As the gurus of risk reduction have told us time and again, we need to look at *why* and *how* the error came to occur and how it resulted in patient harm or the potential for that.[4,5] We need to look at the *system* in which the patient was being managed to identify its flaws and weaknesses; then, we should redesign that system to remove the opportunity for the humans in it to make that error again. Better yet, we should proactively review all critical procedures to probe them for points of weakness so that we are not left explaining to the decedent's family or the media what we'll do to prevent a recurrence of a fatal mistransfusion.

A RESPONSE TO DANGER

Shortly after I arrived at Dartmouth-Hitchcock Medical Center, we began planning for our move to a new facility, a move that would change a variety of steps in our operation that, unfortunately, would increase the risk of mistransfusion.[3,6] Among them:

- Pretransfusion samples would now be collected by a phlebotomy team rather than by transfusion service techs.
- Requests for issuance of components would be received by phone rather than by written order.
- Units would be delivered by pneumatic tube rather than by a transporter.
- Only the lab staff issuing the unit would be checking unit, label, and patient identities for congruence rather than working as a team with the transporter.

ABBREVIATION: RFID = radiofrequency identification.

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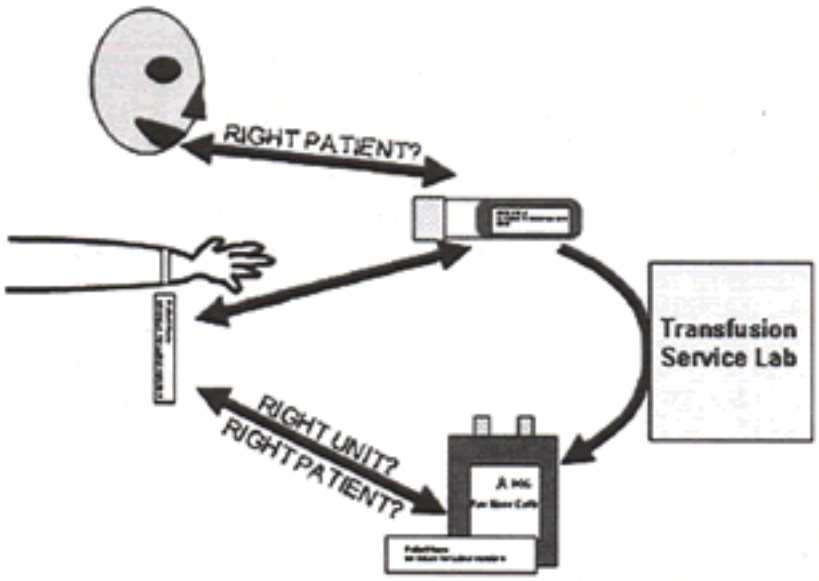

Fig. 1. Key elements in a common approach to preventing mistransfusion. Identification of the patient at the time of collection of the pretransfusion testing sample is best based on both the patient's wristband and the patient's statement of his or her name with bedside labeling of the tube with this information. Similar verifications of identity are performed (often by two staff persons) at the time of transfusion of a labeled unit. These steps are adequate, but the system may fail if the humans involved do not perform each verification as intended.

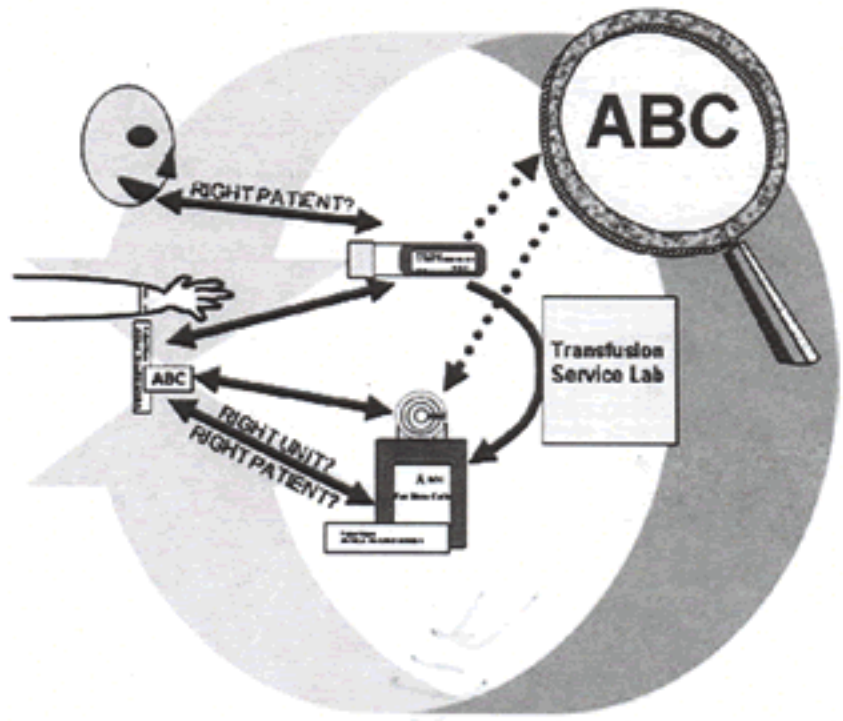

Fig. 2. Impact of the inclusion of a mechanical barrier system into the transfusion process. The additional coded identifier (ABC) is critical in that it requires verification of closure of the "identification loop" before transfusion can occur. Successful opening of the mechanical barrier at the bedside provides a "process control" step that verifies the successful completion of the patient identification steps at both ends of the transfusion process.

I was excited about the move, but I was certainly also nervous about its implications.

The first publication regarding a mechanical barrier system (Bloodloc, Novatek, Greenwich, CT) appeared about that time,[7] and it opened the door to a new approach to preventing mistransfusion. Now I could see a way to "close the loop" by including a process control in the system, a step that, when completed, verified that all previous steps in the system had been accomplished successfully. (A time-honored process control is practiced in every transfusion service multiple times daily: The addition of check cells to a negative test that employed antihuman globulin to ensure that unbound and potentially neutralizing IgG had been washed away successfully. A critical step in an important process deserves a process control!) The mechanical barrier system utilizes a randomly assigned code affixed to the patient's identification band (and not present on the patient's chart). The phlebotomist transcribes the code onto the tube of blood collected for pretransfusion testing along with all other usual identifiers. When issuing a unit of RBCs for transfusion, the laboratory encodes the patient's code into a lock and closes it to prevent access to the outlet ports of the unit. In addition to comparing the label information on the unit with patient identification, the transfusionist uses the code on the patient's wrist band to gain physical access to the unit (Fig. 2). Access to the unit is prevented unless the unit were about to be transfused to the patient from whom the pretransfusion testing sample had been collected. (This system goes beyond those that assign a separate, unique identifier to a patient and the patient's pretransfusion sample [and then the unit for transfusion] by requiring that this code *actually be matched and verified* prior to the transfusion.) Importantly, a mechanical barrier system does not require a reduction in "human error" to reduce mistransfusion. Instead, it modifies the system by enforcing the requirements for key identification steps in the process.

Implementation of this system required about 6 months of concerted work among nursing unit supervisors, admissions staff, and transfusion service management staff. Surprisingly, the most time-consuming step was identifying all the different ways patients could be admitted to our hospital. I had no idea there were so many "doors" to the building! We also had to devise ways to deal with patients being transfused as outpatients and to deal with samples collected preoperatively where the patient would not be admitted until the day of surgery. Patients transfused in the hematology and oncology outpatient clinic generally have their pretransfusion specimens collected the day of transfusion and thus keep their code for the day. In the case of collection the day before transfusion, the wristband with the code attached is given to the patient to bring back the following day. A slightly different approach is used for preadmission testing of patients

coming to surgery. Their wristbands and codes are assigned at the time of testing and kept in the folder containing all a patient's preoperative paperwork. On the day of surgery, when identity is confirmed, this same wristband and code are then put on the patient's wrist. These systems have worked consistently and dependably, in large measure because of the support of nurses who have been convinced that they play an active part in reducing patient risk.

Diligent application of the system by nurse transfusionists has been observed through interactions surrounding problems that occasionally arise and through periodic audits. Blatant disregard of the system is seen only occasionally and then only among physicians who transfuse (e.g., anesthesiologists). The offending physician is usually a resident who has not gone through a 2-week orientation in clinical pathology that we offer (and that most take) and who has waited until the moment that transfusion is needed to open the lock. At that point, the anesthesiologist may feel too pressured to "take the time" to open the lock and instead removes it forcibly. Support from the chair of the department of anesthesiology and periodic reeducation sessions (e.g., grand rounds) have kept such incidents to a minimum.

In setting up this system, we did have to ensure that both the lab's procedures and those elsewhere in the hospital were ready to handle problematic situations. These situations require defined courses of action to preserve the system's protections while addressing the need for timely transfusion. What if the lock won't open? (In this case, we ask the caller for the code. If it's correct, we ask that the unit be sent back so that we can reapply a lock and resend the unit. If the transfusionist is trying to open the lock with a different code than we have seen on the tube, we assume that there had been incorrect sample labeling, and ask the caller to submit a repeat type and screen sample.) What if the transfusion is urgent? (Call the lab; tell us the code; if correct, cut the lock off; if incorrect, Group O RBCs are sent.) What if uncrossmatched Group O units are issued for an emergent transfusion? (The mechanical barrier system is not used in this situation because of the reduced potential for acute hemolysis.)

The system we have been using for more than a dozen years has paid dividends. It has been responsible—in itself—for detecting more than 50 samples that were collected from the wrong patient and played a part in preventing three mistransfusions. Before we implemented this system, our hospital was not one that had an unusually frequent problem with patient misidentification, and it enjoys a stable, motivated workforce. Although our apparent mislabeling rate of samples (1/5000) and mistranfusion rate (1/40,000 RBC units transfused) are below those reported from similar institutions,[3,8,9] we are pleased to be able to offer the additional assurance that a mechanical barrier system provides.

We recognize that the system we use is not a perfect one. For example, it cannot prevent inadvertent switching of samples in the laboratory, leading to a misassignment of ABO and Rh on a first-time recipient. (As part of our electronic crossmatching system, two techs test each first-timer's sample independently, but mislabeling of pour-off tubes or calling up the wrong patient's record in the laboratory computer system could still lead to an erroneous typing. Our current primary method of performing types and screens via an automated instrument that identifies samples by their bar-coded label and transmits the results directly to the laboratory information system provides an additional step in the security chain by removing the possibility of tube misidentification and clerical misentry.) Deliberate actions to ignore the mechanical barrier system's warnings also will sabotage its effectiveness. The chance of a mistransfusion between two patients with the same code is extremely low (approx. 1/100,000) and is further reduced by cycling batches of the code stickers in active use. We have not removed all potential for human error to wreak havoc on a patient, just reduced it, and we are continually assessing our system to see how we can improve it, especially through the introduction of process controls.

The preceding paragraphs have outlined the steps in the processes we use to "human-proof" our transfusion system with the intent of preventing the inevitable human error from causing a catastrophe. Of course, implementation and continued use of this system would not be possible without a dedicated, committed transfusion service staff and the support—or at least acquiescence—of physicians, nurses, and other hospital staff across multiple departments. Getting their attention, convincing them of the importance of the issue, and achieving their buy-in of the solution were predicated on strong relationships. These were built over time and over multiple opportunities to engage them in a productive and supportive manner so that they had confidence in the transfusion service's commitment to patient safety and the correctness of its focus on the issue of mistransfusion as an item of prime importance.

ALTERNATIVE APPROACHES

Some might accept that mislabeling of specimens or mistransfusion occurs, note that the frequency appears to be low (in their estimation), and hope that various human-based double checks along the path from bedside to lab and back to bedside will detect any mistakes that occur. Acceptance of the demonstrated inadequacies of the systems commonly used in hospitals for the delivery of transfusion is, to me, illogical. With all the time, effort and money put into making the contents of a unit as virologically safe as possible, shouldn't a similar amount of attention be paid to getting it to the right patient so that the

component does not harm the recipient? The cost of the potential interventions—whether in direct costs or time to implement them—pale in comparison to the enormous expenditure on testing units with genomic amplification techniques when those virologic risks are already lower than the immunologic ones! I know of no other potentially life-threatening medical intervention that is practiced today the same way it was 50 years ago. Focusing on transfusion *systems* can help address the largest risk of mortality in transfusing RBCs.[10]

Although we are very happy to be using the current mechanical system, we would also like to move forward to combine the physical security it offers with the electronic tracking available through multiple manufacturers' bedside medication systems (see Dzik[11] for a listing of companies marketing or developing devices and systems to improve transfusion safety). Many of these systems offer the possibility of reading a bar-coded wristband and printing the tube label right at the bedside.[12,13] This should help reduce the frequency of mistransfusion attributable to tube mislabeling (currently approx. 10%[3,6]). The same systems can read bar-coded information on the unit and the unit's transfusion label to compare with the recipient's wristband to ensure that this misidentification step (currently the cause of almost half of mistransfusions[3,6]) is handled correctly.

The "perfect" system is still being developed, however. Identifying patients and units with radiofrequency identification (RFID) tags would simplify the bedside steps,[14] and coupling such a system with a mechanical lock on the unit would ensure that the system was actually used when it was intended. Prototype systems utilizing these features have been created and are under trial or are available outside the United States (M. Rubertelli, MD, Tiomed, January 5, 2006, personal communication). As an interim measure, we have considered incorporating the code for the mechanical barrier system into the bar-coded information on the wristband generated at the time of admission so that it appears correctly on the pretransfusion tube label when captured by a digital handheld system. Manual entry of the code by the transfusionist can be verified by the electronic system when it reads the recipient wristband, verifying that the unit is about to be transfused to the intended patient. We would prefer a hybrid system such as this when the hospital implements electronic bedside medication tracking since we are uncomfortable abandoning the mechanical barrier system's high level of protection.

One could also envision an automated dispensing system that would be useful for blood availability in remote locations, such as the operating room when the transfusion service is distant from it. A specially designed monitored refrigerator would be filled periodically with units of various blood types or specially selected and crossmatched units for alloimmunized patients scheduled for surgery. The units would be bar-coded into the refrigerator's tracking system or their presence might be detected through imbedding an RFID tag in their label. The refrigerator would be interfaced with the transfusion service laboratory's computer system so that a request for a unit for a specific patient by an operating room staff person would lead to the dispensing of a compatible unit (possibly with the printing of a transfusion tag). The unit would still need to be carried to the correct room and the intended recipient verified, but reading information again imbedded in the RFID tag of the dispensed unit and reading the patient's identity also by RFID could facilitate the final match-up. Several such systems are also under development and are available outside the United States (M. Murphy, MD, October 19, 2005, personal communication).

Another approach that eschews additional contraptions focuses on the patient identification step: Issuing only group O RBCs until a second, independently collected sample has been verified as having the same ABO group as the patient's first submission. This approach places additional burden on group O RBC inventories and on phlebotomy teams, but it does emphasize the importance of getting the patient's identification onto the tube correctly. Since 1 of every 1000 samples arriving at transfusion services in developed countries contain the blood of a patient other than the one whose name is on the label,[9] there is something to be said for this approach. Unfortunately, however, it only addresses the "front end" of the system and does not ensure that the unit issued for Patient X actually is transfused to that patient.

HOW'S YOUR SYSTEM?

No system involving human participants is perfect or without the potential for a significant error to occur. Understanding how one's system works and acknowledging its potential for allowing a human-created error to slip through are the first steps toward reducing this possibility. The next step is to modify the system so that error(s) cannot be continued, missed, ignored, or multiplied to the point that a patient is harmed. This is the "reengineering" process that is critical to reduction of error. Different institutions may use different means to accomplish the same ends, but depending on humans for critical steps will, some day, lead to an error with catastrophic outcome. Both the AABB and the CAP have received recommendations to require that accredited facilities move beyond the systems that have proved inadequate for the last half-century and implement one or more process changes that would reduce the risk of mistransfusion (Table 1). Hopefully, transfusion services will seize the opportunity to participate in the national effort toward improved patient safety by redesigning their transfusion processes to reduce the risk of mistransfusion before being told they have to—

TABLE 1. Some system improvements to reduce mistransfusion

- Require ABO confirmation on two independently collected samples before releasing RBCs other than group O
- Use a handheld electronic system to generate pretransfusion sample labels from data on the patient's wristband at the bedside
- Use a handheld electronic system to verify from the patient's wristband and unit label that the patient is the intended recipient
- Employ a mechanical barrier system

and, more importantly, before one of their patients falls victim to a "human error."

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