Blood Transfusion Events—Lessons Learned from a Complex Process

INTRODUCTION

The American Red Cross reports that more than 30 million transfusions of blood components are performed each year in the United States. Blood transfusions are safer today than in the past because of advances in donor screening; improved testing of the blood supply; use of emerging technology, such as barcoding; and improvements in transfusion medicine practices. However, transfusion is not without risk. Complications can range from mild reactions to life-threatening conditions, such as transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO), and hemolytic transfusion reactions (HTR). Administering a blood transfusion is a complex process, involving multiple steps and staff from multiple locations from the time of donation through administration. Studies have shown that mislabeling the blood sample and patient misidentification continue to occur, resulting in the wrong blood getting to the wrong patient. Mistransfusion, giving the wrong blood to the wrong patient, remains a major cause of transfusion-related illnesses and fatalities. The final check of the patient’s identity and the product label are critical steps in preventing mistransfusion.

The US Food and Drug Administration (FDA) is responsible for the regulatory oversight of the US blood supply. Since the 1950s, the American Association of Blood Banks (AABB) has published standards to improve the quality and safety of blood banks and transfusion services. Additionally, the College of American Pathologists (CAP) has established standards for laboratories, and both organizations provide accreditation programs for blood banks, laboratories, and transfusion services. Hemovigilance programs began in France in the early 1990s. The goal of the program primarily was to improve safety of blood transfusions, but also quiet the public’s fear after incidents of HIV-tainted blood were reported in France. In 2010 the Centers for Disease Control and Prevention (CDC), with support from the AABB, launched the National Healthcare Safety Network biovigilance component hemovigilance module surveillance protocol (NHSN HVM). This voluntary program implements national surveillance protocols for the entire transfusion process, from donor to product administration. CDC also analyzes adverse events and makes evidence-based public health recommendations for the transfusion community.

Pennsylvania health care facilities reported transfusion-related events to the Pennsylvania Patient Safety Authority. The Pennsylvania Patient Safety Reporting System, PA-PSRS, is unique among state reporting systems and collects reports of unsafe conditions and events without harm, as well as events with harm. The literature supports that, besides reviewing serious and fatal events, studying transfusion incidents that don’t harm the patient can help improve safety in transfusion medicine.

METHODS

Analysts queried the Authority’s PA-PSRS database for event reports submitted from January 1, 2010, through December 31, 2014. The search to identify events included events coded as “transfusion” event type or containing “transfus” in the narrative details. Events were excluded if the transfusion was unrelated to use of blood or a blood product or if information about the transfusion was incidental. The remaining events were analyzed by calendar year, gender, harm score, age, event type, and subcategories of transfusion events.

RESULTS

The initial query found 21,884 reports of events involving transfusions; 2,197 were excluded, leaving 19,687 events for further review. The majority of transfusion events (99.01%, n = 19,492 of 19,687) were reported as Incidents and did not result in harm to the patient. Only 0.99% (n = 195) were reported as Serious Events, resulting in patient harm. Of the 10 events associated with severe harm or death, only 1 event was attributed to the patient receiving the wrong blood (see Figure 1). Transfusion events occurred most frequently in patients age 70 to 79 years (18.96%, n = 3,732) followed by age 60 to 69 (18.57%, n = 3,655) and age 80 to 89 (17.55%, n = 3,456; see Figure 2). The most frequently reported event type was transfusion event (83.88%, n = 16,513) followed by an error related to procedure/treatment/test (6.66%, n = 1,312) and complication related to a procedure/treatment/test (4.36%, n = 858; see Figure 3).

For those events entered as transfusion (G) events, the most common subcategories were:

- Events related to sample collection (29%)
- Events related to blood product administration (20%)
- Apparent transfusion reactions (16%)
- Events related to blood product dispensing/distribution (9%)

The following are samples of events reported to the Authority, beginning with examples of events related to sample collection:

Two tubes of blood drawn by phlebotomy for type/screen on ER [emergency room] patient. The tubes arrived in blood bank with only the patient's last name. Medical record

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.
number, encounter number, date, and initials were missing. Tubes rejected by blood bank and phlebotomy notified to recollect patient. Standard operating procedures for drawing blood bank specimens were not followed. Specimen received for type and cross that had no encounter number on it. When I spoke to the OR [operating room] staff they stated that the patient didn’t even have an armband on. I alerted them that they need to armband the patient, collect, and properly label a new specimen.

The following reports are examples of events related to blood product administration:

Patient received an incorrect unit of blood during emergency transfusion. Blood was sent for another patient. Both patients had the same blood type.

Patient received 2 units of packed red blood cells, each unit over 4 hours. Patient received 2 units within 4 hours due to misread of the order. Patient experienced shortness of breath and oxygenation desaturation.

The following reports are examples of events of an apparent transfusion reaction:

Patient with sickle cell anemia developed chest pain and chills after transfusion of 1 unit red blood cells. The patient was transferred to the emergency department. Cardiac markers were negative. Patient was given Benadryl and steroids intravenously. Patient improved and was discharged.

Patient developed fever, hypotension, and oxygen saturation of 77% following blood product transfusion. Patient was transferred to the intensive care unit and required a higher level of care. Physicians believe the patient developed transfusion related acute lung injury (TRALI), which is a risk of transfusion.

The following reports are examples of events related to blood product dispensing/distribution:

Blood dispensed by blood bank was for the next case scheduled in the OR. Staff retrieving blood did not have a patient sticker to verify whether the blood is for the correct patient. The error was discovered before the patient received the transfusion.

While checking 4 units of FFP [fresh frozen plasma], found 2 units that had expiration dates that did not match what was recorded on the paperwork. Units returned to the blood bank resulting in delay of stat FFP order by a few minutes. Per the lab, the blood bank has inventory of FFP received pre-International Society for Blood Transfusion (ISBT) barcode conversion and also post ISBT where all new received FFP product has a specific ISBT product barcode. Two of the units prepped for this patient had pre-conversion labels where the lab staff must manually change the date/time on the unit. The cross-match paperwork sent with the units was correct. Product returned to blood bank and expiration date on product corrected. Two other units had ISBT labels where the updated date and time automatically print on the label.

**DISCUSSION**

The American Red Cross reports that in the United States, blood transfusions occur in more than 10% of all hospital admissions that include a procedure. 1,18 Although media coverage frequently focuses on transfusion infection risks, the risk of receiving infected blood is now much lower than the risk of receiving incompatible blood. 15,16

FDA has published updated rules, effective May 23, 2016, which mandate
changes to donor screening tests, including changing the infectious disease language from “communicable disease” to “transfusion-transmitted infection.” The rules also updated donor clinical parameters for minimal hemoglobin levels (minimum hemoglobin levels for males from 12.5 g/dL to 13.0 g/dL; for women, remains the same), specification of blood pressure levels (minimum and maximum blood pressure levels of 90 to 180 mm Hg systolic and 50 to 100 mm Hg diastolic), and heart rate (50 to 100 beats per minute) and removes the requirement that donor specimens must be tested on the day of donation, thus allowing flexibility in test timing. The new rules address decisions that must be made by the “responsible physician” and cannot be delegated and dictate when the responsible physician must be physically present.\(^6,7\)

Healthcare organizations and blood centers are required to report to FDA fatalities related to blood transfusions.\(^1\) In fiscal year 2014, FDA received reports of 68 patient fatalities. Of these, 59 occurred after receiving a transfusion; 9 deaths occurred after a patient had donated blood. Of these post-donation fatalities, upon further review, 2 deaths were not directly related to blood donation and in one case the patient became lightheaded after donating, fell, and sustained fatal brain injury. For the remaining 6 deaths, donation as a contributing factor could not be ruled out, because the cause of death was unclear.\(^3\)

**The Cost of Errors**

Besides causing patient harm and distress, blood-transfusion errors also impose a considerable expense for healthcare systems.\(^9\) Since 2007, the Centers for Medicare and Medicaid Services has identified and denied additional costs related to preventable hospital errors. Mistransfusion is considered a preventable error and no costs can be passed along to the patient or reimbursed by Medicare.\(^9\) Additionally, increases in professional liability insurance premiums and the cost of litigating or settling a lawsuit can be significant.\(^9,10\) Other indirect costs associated with transfusion errors include discarding the blood, repeating sample collection, doing additional testing, correcting the patient record, and relabeling blood components. Additional calls and communication among staff may result in transfusion delays.\(^17\)

Masken et al. performed a prospective study of transfusion errors at a large teaching hospital in Canada from 2005 to 2010, which showed that the cost of blood-product waste due to errors was C$593,337. The estimated cost of collecting improperly labeled specimens was C$80,766.\(^21\)

**Mistransfusion**

In a seminal study of blood transfusion events, in which the focus was shifted from infectious complications to identifying the rate of transfusion errors, Linden et al. performed a 10-year study, from 1990 to 1999, which reviewed the incidences of giving a blood transfusion to the wrong patient or issuing an incorrect ABO or Rh group for transfusion. The authors showed that there was 1 incorrect administration for every 19,000 red blood cell (RBC) units given. Approximately 56% of these events were caused by a single error in a patient care area. Blood bank errors accounted for 29% of the events. The remaining 15% were compound errors that involved multiple clinical areas and staff. The identification process, whether of the patient, the specimen, or of the blood product to be transfused was the most frequently found error.\(^22\)

In 2014, Dehnavich et al. performed a cross-sectional study of the blood transfusion process using failure mode effects and analysis, which identified 77 potential failure modes for 24 sub-processes in 8 processes of blood transfusion. Of these, 13 were identified as unacceptable risk, with the majority of failure modes in the pre-analysis stage of blood transfusion (i.e., collecting, identifying, and processing the specimen) and the majority of errors in care-processes stages (i.e., clinical judgment and task errors).\(^23\) Irreducible risks remain, even though healthcare facilities may have appropriate policies and procedures in place to mitigate errors.\(^5,7\)

Many errors go undetected or unreported because staff might not realize that events that are caught and corrected before they reach the patient are still errors. Some staff might decide that the incident failed to meet the criteria for submitting an event report because of a lack of harm.\(^7\) Li et al. performed a retrospective study of pediatric patients receiving platelet transfusions from 2010 to 2011 and showed that 116 cases out of 805 transfusions met the definition of an acute transfusion reaction; 4 of the 116 cases were reported to the hospital transfusion committee.\(^24\)

**Severe Transfusion Events**

The FDA reports that TRALI caused the highest number of transfusion-related deaths (41%) in the 2010 to 2014 period, followed by TACO (22%) and HTR (21%).\(^3\) TRALI has been a known risk of blood transfusions for nearly 60 years but was not named until 1983. It is defined as a new onset of hypoxemia within 4 to 6 hours after transfusion, accompanied by new pulmonary infiltrates on chest x-ray study.\(^5,25-27\) Treatment is supportive, with oxygen administration and, possibly, mechanical ventilation.\(^5,28\) The majority of cases are caused by passive infusion of human leukocyte antigen (HLA) and human neutrophil antigen (HNA) in donor blood.\(^27\) HLA and HNA are mostly found in blood from multiparous women who became sensitized during pregnancy.\(^26,27,28\) Eliminating female donors who have been pregnant significantly reduces the risk of TRALI for FFP and platelets.\(^5,26,28,29\) Recipient risk factors for TRALI include end-stage liver disease, sepsis, mechanical ventilation, and blood malignancies; risks are increased in patients receiving platelets or FFP.
risk of TRALI increases in relation to the number of units being transfused. Patients with TACO develop pulmonary edema within 6 hours of receiving a blood transfusion and exhibit dyspnea, orthopnea, cyanosis, tachycardia, jugular venous distention, and widening pulse pressure. Management includes treatment of the underlying condition, fluid restriction, diuretics, and ventilator support. Patients most susceptible include the elderly, infants, and patients with a history of renal failure, anemia, heart failure, hypalbuminemia, or plasma transfusion.

HTR occurs when the transfused RBCs are destroyed by the patient’s immune system. This type of reaction can be related to an ABO incompatible transfusion. Reactions can range from mild to severe and patients can experience back and flank pain, hematuria, chills, and fever. Symptomatic treatment, including intravenous fluids and antipyretics, may be appropriate for mild reactions. For patients with severe HTR, treatment is focused on preventing kidney failure and shock.

IMPROVING TRANSFUSION PRACTICES

Blood Management Programs

Reducing the use of blood and using blood-conservation techniques during surgery help reduce the risk of adverse reactions by reducing the need for transfusions. Endorsed by AABB, a blood-management program is defined as “an evidence-based multidisciplinary approach to optimizing the care of patients who need a transfusion.” The multidisciplinary goals of a blood-management program recognize that managing blood use through monitoring operative blood use and curtailing inappropriate orders for blood products may result in better patient outcomes, such as reduced complications and infections and shorter lengths of stay.

The Joint Commission published patient blood management (PBM) performance measures in 2011. The seven performance measures are as follows:

- Transfusion consent
- RBC transfusion indication
- Plasma transfusion indication
- Platelet transfusion indication
- Blood administration documentation
- Preoperative anemia screening
- Preoperative blood type screening and antibody testing

These measures, although not nationally endorsed, can serve as a guideline for healthcare organizations when reviewing their internal practices.

In 2011, De Leon et al. used the Joint Commission’s PBM-02, RBC transfusion indications, because RBC orders represented more than 70% of all blood components at the study facility. Before the study, the health care organization had implemented transfusion guidelines, which included a blood component order form that contained all the data points in the Joint Commission’s PBM-02. An earlier study found only that 13% of orders contained a clinical indication for RBC transfusion. The study found that 96% of the orders contained the appropriate clinical indications and hemoglobin and hematocrit levels before the transfusion, representing a significant improvement.

Goodnough et al. performed a retrospective study from 2008 to 2013 in which RBC transfusions were reviewed before and after implementing a clinical decision support (CDS) system. The CDS triggered at the time of computerized physician order entry (CPOE) and contained the consensus guidelines for ordering, a link to current literature, and a section for the provider to document the reason for continuing with the order if it didn’t fall within ordering guidelines. The study included all inpatients whose hemoglobin was greater than 7 g/dL at discharge. The study revealed that the use of real-time CDS at the time of CPOE resulted in a decrease in RBC transfusions. They also noted that quality indications for clinical patient outcomes improved, leading them to associate decreased blood use with improved quality of care, evidenced by decreased patient exposure to RBC transfusion, fewer blood transfusions, and decreased blood-transfusion costs.

In a telephone interview, Carmelita Moultrie-Savage, BSN, RN, MT, BB (ASCP), the blood bank quality manager at The Children’s Hospital of Philadelphia (CHOP), shared quality issues and initiatives she is working on at her organization. Moultrie-Savage is responsible for ensuring that CHOP meets all laws and regulatory guidelines related to blood transfusion set forth by AABB, CAP, TJC, FDA, and Department of Health of both New Jersey and Pennsylvania. The hospital also follows National Security Association guidelines for security against terrorist acts, because of special type of equipment in the blood bank. CHOP is reviewing a quality initiative addressing the use of platelets, because platelets have a short half-life and inappropriate orders may result in product waste.

Jennifer Hill, BSN, RN, CPN, and clinical nurse peak II on the apheresis unit at CHOP discussed in a telephone interview the highlights of risk-reduction strategies performed on her unit.

The apheresis unit is busy, and Hill reports that in 2015, staff performed 1,771 procedures and infused 6,417 units of RBCs. Hill reports that ensuring the patient gets the right blood is a top priority on the unit. Staff is trained to allow no distractions as they check seven patient and blood identifiers on all units of blood prior to administration. Before a procedure, two RNs check the identifiers on all of the units of blood. She believes that this commitment to following the protocol reduces the risk of errors.

Hemovigilence Systems

Hemovigilence programs are in place worldwide, with the first programs...
implemented in France in 1993 and in the United Kingdom in 1996. A hemovigilance program can be described as the collection and analysis of information on the complications of blood transfusion.13 In 2010 CDC, in partnership with AABB, launched the National Healthcare Safety Network biovigilance component, hemovigilance module surveillance protocol.12,34 The NHSN HVM is voluntary program that healthcare facilities and blood centers can join. This program’s goal is implementing national surveillance protocols of the transfusion process, from donor to product administration, and analyzing its associated adverse events to improve patient safety, minimize fatalities, and develop evidence-based public health recommendations for the transfusion community.33,34 Because the surveillance definitions are designed to capture data in a consistent fashion, national benchmarks will be produced that can be used for quality-improvement processes. Additionally, NHSN HVM allows comparison of US data with data from other countries.35 This system allows facilities to better identify incidents without harm.12 In 2011, 100 hospitals were enrolled and about 2,500 adverse reactions and incidents had been reported.9 The program published findings for the first three years of the program. By 2012, 164 facilities were enrolled in NHSN HVM and 5,136 adverse events and incidents where included for analysis.6 During the years 2010 to 2012, 239.5 adverse reactions were reported per 100,000 transfused blood components, with 8% being identified as severe, life-threatening, or fatal.4 As of 2016, 247 organizations were participating in the program, but this still represents a small percentage of healthcare organizations that could participate; compare that to the United Kingdom’s Serious Hazards of Transfusion (SHOT) program, which as of 2013 had 99.5% voluntary participation.4,36 Because the NHSN HVM is new, the program has been evaluated to determine whether improvements are needed. In 2013, AuBuchon et al. performed an AABB validation study to review how healthcare facilities were assigning the HVM definitions to transfusion events. Twenty-two facilities participated, of which 11 were actively participating and another 11 were not participating but had access to the HVM definitions and training materials. The study revealed that two-thirds of the time, the group had a matching diagnosis with the HVM criteria and expert review. The authors also found that individual medical judgment allowed participants to follow the HVM criteria loosely and inconsistently, which may result in difficult data analysis.37 It was also noted that hemovigilance systems with active surveillance had more adverse reactions reported than did passive systems.36 Heddle et al. performed a study from May 2008 to March 2010. Nurses and physicians from five countries, including the United States, were interviewed. Five major areas of interest emerged: pre-transfusion checking process, organizational policies, staff training, opportunities for errors, and transfusion monitoring.6 In the pre-transfusion checking process the authors found opportunities for errors that included:

- Staff being unfamiliar with organizational policy or having difficulty accessing policies
- Inadequate training, resulting in staff’s unfamiliarity with the process
- Patient-identification issues, including whether the correct wristband was on the patient and whether staff was familiar with the patient
- Location where the checks were done (i.e., at the patient’s bedside)
- Number of persons performing the check
- A busy environment and other distractions that caused the staff to fail to follow the process6

Additionally, use of technology, such as the BloodLoc™ system, increased transfusion safety because correct patient identification information must be entered before the transfusion product is released. These systems are not used consistently because they increase the cost of transfusion.6 Advances in technology can help prevent transfusion errors. The use of BloodLoc and wristband bar-coding technology has been found effective in preventing human-error identification errors associated with transfusions.12,38 Nuttall et al. performed a retrospective study to determine the effect of a bar-code system for blood identification over four years before implementation and four years after implementation from 2002 to 2005 and 2007 to 2010 (2006 was excluded). The study results showed that before the bar-code system was implemented, the manual process caught only three errors. After bar coding was implemented, 113 incidents were found.38

CONCLUSION

Slightly less than 1% of transfusion-related event reports received by PA-PSRS involve patient harm, and nationally, the fatality rate attributed to blood transfusion is small. The relatively uncommon serious risks associated with blood transfusions can cause patient mortality and morbidity. Non-life-threatening errors can result in patient discomfort and increased cost to an organization from product waste and additional efforts by staff to correct the errors. Transfusion medicine has expanded its scope of review from studying only severe reactions to valuing opportunities for practice improvement, including the study of incidents that did not result in harm. Nationally, the safety of transfusions has been attributed to advances in transfusion medicine, including improved donor screening and testing; advances in technology, such as barcoding; increased hemovigilance surveillance protocols; and blood management programs.
NOTES


An Independent Agency of the Commonwealth of Pennsylvania

The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (Mcare) Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents.

For more information about the Pennsylvania Patient Safety Authority, see the Authority’s website at http://www.patientsafetyauthority.org.

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The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a nonpunitive approach and systems-based solutions.