Transportation Cooler Interventions Reduce Plasma and RBC Product Wastage

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ABSTRACT

Objectives: The rate of plasma product wastage for the United States in 2011 was approximately 1.8%. The plasma wastage rate at our institution was higher, mainly due to products returned out of temperature range from procedural areas. A process review and intervention to reduce plasma wastage was undertaken, which included modifications to our transport cooler.

Methods: A new cooler system was designed, and this device was implemented alongside an updated protocol for delivering plasma while also enhancing the previous RBC cooler validation time. We audited plasma and RBC product wastage prior to these interventions, from January 2013 to February 2014, vs after the intervention from April 2014 to March 2015.

Results: After the intervention, the monthly plasma wastage rate declined 60% (12.6 units/100 units transfused preintervention vs 5.0 units/100 units transfused postintervention; P < .0001). The monthly RBC wastage rate also decreased 28% (3.2 units/100 units transfused preintervention vs 2.3 units/100 units transfused postintervention; P < .01).

Conclusions: Our intervention resulted in significantly decreased plasma and RBC wastage and is broadly applicable, since out-of-temperature product wastage in procedural areas is likely a significant problem at many institutions.

The most recent data collected by the US Department of Health and Human Services in 2011 indicate that the percentage of plasma product wasted nationally was 1.8%.1 Data were not published for RBC unit wastage, but prior studies suggest RBC wastage rates may be similar but variable.2 A significant challenge in wastage is that products go out of temperature (OOT) when they are held in procedural areas to help meet the clinical need of instant blood access. Through our quarterly Transfusion Service Committee meetings, we became aware that product wastage at Stanford Healthcare (SHC) was noticeably higher than the national average. The primary driver of the increased wastage was products returned OOT from operating rooms (OOT for transport coolers: >10°C). While SHC has employed a number of strategies to provide blood emergently to procedural areas, including emergency blood order sets, close physical proximity, and a dedicated pneumatic tube system channel, there is added comfort for operating room (OR) personnel to have instant access within a room to cross-matched blood products for elective, complex surgical cases.

Here we review our experience and results from process improvement initiatives to lengthen cooler validation time intervals for blood products, reduce repacking during surgical cases, validate cooler temperature range within the stricter 1°C to 6°C range instead of 1°C to 10°C, and overcome challenges with chemical temperature-sensitive adherent monitors.
Materials and Methods

The study was approved by the appropriate institutional review board, and the requirement for written informed consent was waived by the institutional review board.

Process Analysis

As part of our quarterly Transfusion Service Committee meeting, we identified that plasma product wastage was significantly higher than RBC wastage and higher than the national average for plasma products. A process analysis was performed by surveying staff within the transfusion service and the OR to identify potential causes for OOT wastage. A lead team was designated to directly question the transfusion service staff about potential causes of plasma waste. The same team also made trips to the SHC OR to directly observe blood product transport, use, and return procedures. During these trips, team members discussed plasma wastage with OR staff aiming to understand the root causes of plasma waste so that we could identify potential areas of improvement.

Cooler Design

The Igloo Legend Cooler Series 24 (Igloo, Toronto, Canada) was modified by placing additional coolant material within a pouch attached to the cooler lid that was designed to extend the cooler valid time. As part of this design, the placement of the foam brick was tested to ensure closure of the lid by gravity alone. Cooling material consisted of frozen foam gel refrigerants (ThermoSafe Polar Pack, Sonoco ThermoSafe, Arlington Heights, IL; 15 oz each), stored at –20°C for a minimum of 24 hours, and refrigerated gel packs (ThermoSafe Polar Pack; 48 oz each), stored at 1°C to 6°C for a minimum of 24 hours. Green wrapping cloth supplied by the hospital laundry service department was also used for packing. Adherent gauges (Safe-T-Vue 10; William Laboratories, Enfield, CT) were eliminated and replaced by measurement with the VWR Traceable Infrared Thermometer with Type-K Probe (cat 36934-178; VWR International, Radnor, PA) to collect temperature data upon blood product return.

Validation Plan

A validation plan was created to assess whether previously refrigerated thawed plasma and RBC products would remain at a temperature range of 1°C to 6°C in the modified Igloo Legend Cooler Series 24. Temperature readings were recorded from continuous monitoring at 30-minute intervals at two ambient temperature ranges: 20°C to 25°C and 30°C to 35°C. This procedure was carried out until units reached a threshold of more than 6°C or until a predetermined period had passed (6, 8, or 10 hours). Measuring devices included a Temp-Check (Model TC-3; Hampshire Control, Dover, NH), VWR Traceable Infrared Thermometer with Type-K Probe, and calibrated timers.

Responsibilities

The performance qualification, maintenance/calibration, required support services, and validation performance were provided by the transfusion service staff. The transfusion service manager, the quality assurance coordinator, and the medical director performed review of the validation. Implementation of the validation plan was authorized by the transfusion service medical director. Installation qualification was not applicable for this validation plan.

Operational Qualification

The operational qualification was performed in accordance with the following pertinent standard operating procedures for the Stanford transfusion service: cooler inspection and validation, temperature monitor (Temp-Check) validation, cooler packing, and returning and reissuing blood components and products. In addition to the Igloo Legend Cooler Series 24, several additional materials were required. RBCs were stored in a monitored refrigerator at 1°C to 6°C, while plasma frozen within 24 hours (FP24) was stored in a monitored freezer at –20°C. Products used for calibration included expired plasma and RBC products.

The following testing cooler scenarios were interrogated: (1) two units of expired thawed plasma at 20°C to 25°C for 6, 8, and 10 hours; (2) six units of expired thawed plasma at 20°C to 25°C for 6, 8, and 10 hours; (3) two units of expired thawed plasma at 30°C to 35°C for 6, 8, and 10 hours; and (4) six units of expired thawed plasma at 30°C to 35°C for 6, 8, and 10 hours. Similarly, expired RBC units were tested at the same temperatures (20°C-25°C and 30°C-35°C) and the same hour intervals (6, 8, and 10 hours). Coolers were packed with two, six, and eight RBC units for this part of the validation. Finally, a mixture of plasma and RBC units (two of each) was tested for validation of our initial trauma response cooler. The plasma starting temperature was between 2°C and 4.5°C.

Coolers were packed as follows: (1) wrap the frozen foam bricks with a green cloth, (2) place the wrapped frozen foam brick on the bottom of the cooler, (3) place the calibrated digital thermometer in temperature bag in the cooler with the thawed plasma, (4) place a refrigerated 48-oz gel pack directly on top of the thawed plasma, and (5) place another 48-oz refrigerated gel pack in the pouch attached to the cooler lid to ensure the lid remains closed. Next the cooler ID, the initial temperature of the frozen and refrigerated coolants using Temp-Check, and the ambient temperatures for each testing scenario were recorded. The temperature of the products using a temperature bag was recorded every 30 minutes for up to 10 hours. The acceptance criteria for the performance qualification included...
maintaining temperature within 1°C to 6°C. The acceptable maximum time was the time for the cooler to exceed 6°C, up to a maximum of 10 hours.

Audits

The newly validated coolers were implemented at Stanford Hospital, the adult hospital for which the transfusion service provides blood products. Plasma and RBC product wastage rates were audited at Stanford Hospital before (January 2013 to February 2014) and after (April 2014 to March 2015) implementation of the new coolers. The transition period occurred during March 2014, and although audit data were collected for this time period, these data were excluded from analysis.

Statistical Analysis

The total number of wasted units (either plasma or RBCs) from the 14 months prior to and 12 months after the intervention was compared for OR and non-OR units independently using a two-tailed Wilcoxon rank sum test with R statistical software (version 3.0.2; R Foundation for Statistical Computing, Vienna, Austria). We considered that differences between these two periods could have been due to variability in the total demand for blood products. To control for this possibility, we conducted a separate analysis to normalize the total number of wasted units each month by taking the number of wasted units per 100 units transfused. To generate these values, for either plasma or RBCs, wasted units issued to either the OR or non-OR locations were combined and divided by the total number of transfused units for the SHC transfusion service and multiplied by 100. A two-tailed Wilcoxon rank sum test was then used to compare these values from the 14 months prior to and 12 months after the intervention. A threshold for rejecting the null hypothesis of $P < .05$ was used for all statistical tests.

Results

We began our study by conducting a process analysis that included frontline users in both the transfusion service and the procedural areas. This analysis identified three critical flaws within our cooler blood transport system that could lead to increased wastage. First, coolers were validated to store products for only 3 hours and required OR personnel to repack coolers for many surgical cases. Second, we recognized that coolers provided to ORs were only validated for RBCs and that OR staff routinely stored unused plasma at room temperature, causing wastage of any unused units. Third, the cooler lids were often left ajar or completely open for prolonged periods, potentially reducing the cooler’s effectiveness. Furthermore, an additional weakness of the system was the use of color-coded temperature sticker monitors adherent to the issued blood product (green = within temperature; red = OOT). These were found to be operationally unreliable since they often partially changed color during the initial issuing process, were at times difficult to interpret, and represented only a binary view of a continuous product temperature spectrum.

To reduce waste, our first goal was to lengthen the cooler validation time beyond 3 hours to alleviate the repacking burden on the OR staff. A new cooler packing procedure allowed for the placement of either plasma or RBC units within the cooler directly on top of the green hospital cloth-wrapped frozen packs. Based on validation recordings, the procedure used postintervention allows for cooler configurations for up to eight RBC or six FP24 units in a cooler or two FP24 and two RBC units in the same cooler, which represents the ratio often requested for our minor/moderate trauma cases.

Overall, 11,295 units of plasma were transfused during the 14-month control period (January 2013 to February 2014) and 10,482 units of plasma transfused during the 12-month period (April 2014 to March 2015) after implementation of the new coolers. This corresponds to a mean of 807 and 874 units of plasma transfused per month, respectively. Overall plasma wastage was 101 units per month prior to our intervention compared with 43 units per month after the new coolers were in place. The number of wasted units decreased significantly after the cooler intervention, and the most pronounced reduction was for units issued to ORs ($P < .0001$ for OR and $P < .01$ for non-OR) and plasma wastage was decreased from 12.6 units per 100 units transfused to 5.0 ($P < .0001$). Seventy-six percent of wasted products were issued to the OR, which dropped slightly to 67% with the new coolers, indicating that OR-issued products still account for the bulk of wasted products. The estimated overall annual savings based on cost per unit alone was $52,200.

Although our intervention was initially focused on reducing plasma wastage, we considered that our new cooler and product issuing protocol would have a beneficial effect on RBC waste as well. Over the same audit period, 26,523 RBC units were transfused (1,895 per month) during the 14 months prior to our intervention (again January 2013 to February 2014), while 24,160 units were transfused (2,013 per month) during the 12-month period after new coolers were implemented (Table 1). The total numbers of units wasted during these periods were 853 and 553, respectively. Units wasted per month decreased from 61 to 46. The overall RBC unit wastage
dropped from 3.2 units per 100 units transfused to 2.3 (P < .01) (Figure 2B). The overall wastage of RBC units decreased, and the wastage of units that had been sent to the OR showed a highly significant reduction (P < .0001) (Figure 2A,B). Non–OR-issued unit wastage showed no difference after the intervention (Figure 2A). The overall estimated annual savings based on RBC unit cost amounted to $36,000. Therefore, the combined annual savings due to the new cooler implementation when taking both RBC and plasma units into account was $88,200. Additional savings of $6,400 per year were achieved by eliminating the need to purchase adherent temperature gauges for use per blood product. Instead, already available temperature scanners to measure temperature of a blood product at time of return were used.

Discussion

Wastage of blood products issued to operating rooms at SHC was significantly higher than the national published rate of wastage. Through a process analysis, new cooler
design, and implementation of an updated protocol, a significant reduction in unit wastage was effected with the added benefit of reduced cost. Although they can be difficult to quantify, these updates have also resulted in other positive outcomes. Decreased wastage has improved global inventory management for the transfusion service. In addition, OR personnel have appreciated the greatly decreased repacking requirement since most procedures are complete within 8 hours.

The energy and time dedicated to keeping products within the AABB-defined temperature range raised two important questions: (1) how to distinguish transport vs storage conditions for cooler use and (2) whether there was convincing evidence that product safety and/or efficacy was compromised when products go beyond the acceptable temperature range. AABB standards require the temperature of stored blood products to be between 1°C and 6°C for plasma and RBC units. Transport cooler temperature is between 1°C and 10°C. The issue of whether coolers in the OR are considered storage or transport has caused confusion and has been addressed in the past, although it remains controversial.

In this study, the additional step of validating coolers to maintain the tighter temperature range of 1°C to 6°C was taken to accommodate longer surgical procedures. The robustness of the redesigned coolers was exemplified by maintaining this more stringent temperature range while achieving a significantly longer validation time. Even though, from a temperature range standpoint, the criteria for storage were met, a recent change in the language of the AABB standards also requires concomitant temperature monitoring at least every 4 hours to be considered storage. This additional requirement to meet the definition of storage may be unnecessary given the cooler’s validation process, which regularly monitored temperatures through opening the cooler at 30-minute intervals. The next iteration of our validation process used a new electronic system of temperature monitoring that continuously monitored temperature, providing an even more complete view of product temperature over time.

AABB standards state that units returned to the transfusion service can be reissued if the appropriate temperature has been maintained. Another question arises: what is the practical significance of maintaining temperature within these confines? A previous study demonstrated that when RBC units (in either plastic bags or bottles) are removed from the 1°C to 6°C storage temperature range and incubated at room temperature, the units tend to be out of temperature range within 45 to 60 minutes. The “30-minute rule” was likely borne from this study, which is not an AABB standard. Regardless, the concern with warming arises primarily from possible bacterial contamination risk as well as product quality. Studies with a wide range of methods have not convincingly demonstrated significant differences in the rate of bacterial contamination or RBC unit quality with warming beyond 10°C for varying periods, even with careful monitoring for hemolysis, adenosine triphosphate concentration, and in vivo recovery.

One study did show that growth of Gram-negative Serratia species was enhanced slightly after RBC units were contaminated and incubated at room temperature compared with contaminated units at storage temperatures. While the numbers of colony-forming units (CFUs) increased compared with storage temperature controls for both experiments, the number of CFUs did not reach clinically significant levels. Studies to date have not conclusively shown evidence of a decline in physiologic quality or increased risk of clinical bacterial sepsis from blood products exceeding defined temperature ranges, and additional well-designed studies are needed.

Although the interventions in this study are broadly applicable, they may have particular importance in the setting of large academic hospitals with busy surgical services and complex cases requiring high-volume blood product support. For patients with significant hemorrhage, several products may be ordered (eg, in instances requiring a massive transfusion protocol), many of which may not be used depending on the circumstances of the case. When unused...
units are returned to the transfusion service, there is an opportunity to place them back in the inventory. Lean Sigma methods have been shown to be effective for optimizing operations, leading to significant reductions in RBC wastage.9,10 Our simple strategy of working with frontline users to quickly establish root causes (gemba rounding) and to test our hypothesis through action (iterating to improvement) had profound impacts. The ideal quality strategies for transfusion services may need to include a comprehensive mix of practices identified in the literature with a tincture of common sense and local organizational culture.

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Figure 2: New cooler implementation reduced plasma and RBC waste. A, The total number of units wasted each month during the study period prior to the intervention and following the intervention is plotted. Wasted units are separated based on whether they were issued to the operating room (OR) or other locations within the hospital (non-OR). B, The aggregate units wasted each month (summing OR and non-OR together), which were normalized per 100 units transfused each month prior to and following the intervention, are plotted. Data for plasma units are shown on the left and data for RBC units are shown on the right. Wastage pre- and postintervention was compared using a Wilcoxon rank sum test. NS, not significant. For both plasma and RBC units, n = 14 months preintervention and n = 12 months postintervention.
References


