Use of indicators to verify maintenance of appropriate temperature for returned red cell units.

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Background

All blood products must be stored within a specified temperature range in order to preserve their integrity and maximize storage time. Strict storage requirements are met by designating qualified refrigerators for the storage of blood products only. These refrigerators must meet the Canadian Society for Transfusion Medicine (CSTM), American Association of Blood Banks (AABB) and Health Canada/Canadian Standards Association (CSA) standards for storage devices containing thawed plasma and packed red blood cells. They must maintain a temperature of 1 to 6°C throughout their interior space and each have a continuous temperature monitoring and recording system.[1] As well, they must have audible alarms to alert staff, enabling them to take appropriate action before any blood products reach unacceptable temperatures.[1]

Our concern is with blood products that are issued from the blood bank to remote refrigerators but **not** transfused. In order to determine if these products can be returned to inventory and re-issued safely, we must have absolute confidence that no product has been outside a monitored refrigerator environment for greater than 30 minutes. Products

that remain at Room Temperature (RT) for 30 minutes or longer are discarded because the temperatures of the units may have risen above 10°C, after which they are deemed unsafe for use.[1]

Current policy and standard practice dictate that once blood products have been issued out of the laboratory's inventory, they are to be transported directly to the receiving area's remote refrigerator. The products are to be removed only at such time as they are required for transfusion.[2] However, once blood products leave the lab we cannot track the length of time they have actually spent outside of a monitored refrigerator. It is possible that a blood product was sent at some point to the site intended for transfusion, left at the patient's bedside for an undetermined length of time, and then returned to the refrigerator. Unused blood products are periodically retrieved from remote refrigerators and returned to the laboratory's inventory for re-issue. Currently, this occurs without confirmed knowledge that the blood products have spent no longer than 30 minutes outside of a monitored refrigerator.

Our limited blood supply makes it imperative that blood products are not discarded needlessly; hence there is a need to ensure that products issued to remote refrigerators can safely be returned to the laboratory's inventory for re-issue to other patients.

Objectives

The AABB uses temperature, not time, as the standard to allow blood products to be returned to inventory.[1] Safe-T-Vue (Williams Laboratories, Inc., CT)is a non-reversible temperature indicator that signals, by permanent colour change, if the temperature of a

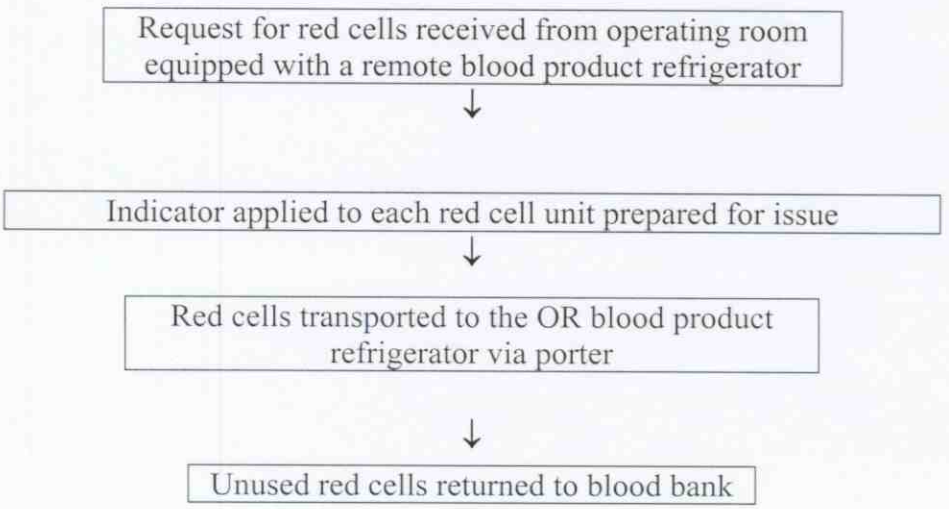
blood bag reaches 10°C.[3]

The purpose of our study was to use these temperature indicators to determine the percentage of returned packed red blood cells that had reached a temperature greater than 10°C during storage outside the blood bank.

Secondarily, the indicator was used as a tool to evaluate compliance with the existing policy related to blood storage in remote refrigerator sites and return to blood bank following removal from the monitored environment.

Design overview

- A regional evaluation was conducted in two hospitals.
- Packed red blood cells (rbc) only, were evaluated.
- The operating room staff, and others handling the blood products after issue,were blinded to the study (they were not advised as to the presence or purpose of the attached indicators).
- Each request for rbc would be processed as follows:



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Indicators inspected for evidence of a colour change from white to red, which would indicate the internal temperature of the red cell unit had risen above 10°C

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Red cells passing Indicator inspection as well general visual inspection for any evidence of clots, hemolysis, or physical damage, were returned to the blood bank inventory

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Red cells not passing inspection were quarantined for review by a pathologist and then discarded.

Methods

Initial Validation: To ensure that the indicator would indeed change colour when the internal temperature of the red blood cell unit reached 10°C an initial, internal validation was undertaken as follows:

Before use, the safe-t-vue indicators were allowed to equilibrate at 4°C for 24 hours. A thermocoupler probe was inserted into the midpoint of an expired rbc unit, which had also been stored at 4°C. An indicator was then attached to the back of the lower portion of the unit. The temperature of the probe was monitored every 5 minutes to see at what temperature the indicator would change colour. It should also be noted that the manufacturer includes QA documentation with every shipment of indicators.[4]

Controls: **False negative**: The initial validation procedure was repeated 5 times, and each time, the safe-t-vue turned red once the thermocoupler probe showed that the internal temperature of the rbc unit had reached 10°C. Combining these findings with the manufacturer's QA documentation, we concluded there should be no incidences of false negatives.

False positive: Safe-T-Vue indicators (Williams Laboratories, Inc., CT) were placed on a designated portion of the blood bank stock of rbc at the time the units were received into inventory. The unit numbers were recorded on an Indicator Study "QC" form before they were placed in their regular spot in the blood bank refrigerator. Once per day, the colour of the indicators was checked and recorded on the QC form. Since all refrigerators approved for the storage of blood product have continuous temperature monitoring, we could ensure that the temperature of our "control" rbc was maintained between 1 and 10°C. Therefore, any colour change that occurred indicated a false positive result. We tracked the percentage of false positive results that occurred, and compared that value to the actual number of rbc returned with indicators that had changed colour.

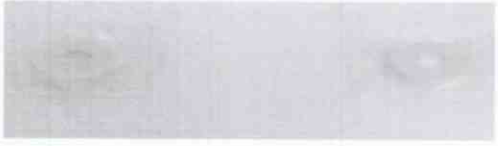
Note: the rbc acting as quality control units for this study continued to be issued to patients as they would under normal circumstances. Replacement stock became replacement quality control units.

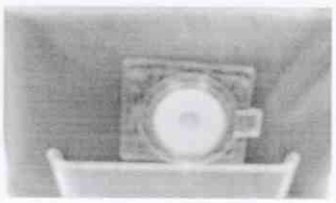
Pre and Post issue prodedures:

The study process was followed in conjunction with the routine issuing process. The appropriate number of units were selected and prepared as usual, adding on the Indicator application step. The required study information was recorded on the Indicator Study "Issue form" before proceeding to allocate and issue the units. This included the unit number, the time, date, and location/site of issue, and the colour of the Safe-T-Vue (Williams Laboratories, Inc., CT) temperature indicator. The issued rbc were transported as per standard practice at each hospital.

Any rbc returned from remote refrigerators were evaluated to determine if they could be returned to blood bank inventory or if they were required to be entered into quarantine status. This decision was based on the colour of the indicator affixed to each unit as well as standard inspection criteria including review for colour, hemolysis and clots. (A true positive indicator was kept as a colour comparison for the indicators on returned units.) The return date and time of each unit was recorded on the study worksheet along with the colour of its indicator and its new status (ie: "Inventory" or "Quarantine"). Upon being put into quarantine, a pathologist evaluated each unit to determine whether or not it should be discarded. The percentage of failed units was calculated.

Results



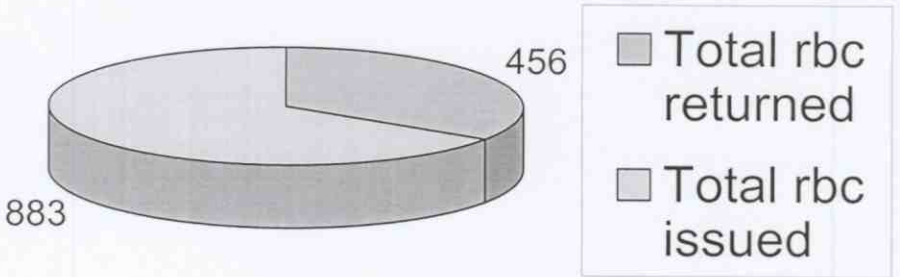


a) Positive vs. negative indicator results.

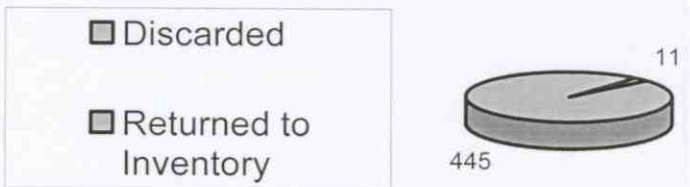
b) Indictor showing colour change on an rbc unit.

c) Rbc unit ready for issue.

I. Proportion of units returned



II. Disposition of units returned



Discussion

The false positive rate reflected early difficulties in determining positive vs. negative results as colour change was sometimes ambiguous. A positive control was

developed and used as a comparison for all returned units and the false positive rate decreased. Only a very small population of the returned red cells measured greater than 10°C and were discarded. This indicates that OR staff are generally compliant with the policies regarding storage of blood products. 10 units returned were missing indicators. Since OR staff were blinded to the study, an explanation was not sought as to why they were removed. No inquiries regarding the indicators were received.

The number of units returned far exceeded our expectations. This indicates that the transfusion rate is lower than anticipated. The current process for stocking remote refrigerators is initiated by OR staff with a request for blood when the patient is en route. All requested units are tagged and issued for storage in the remote refrigerator. Our study findings precipitated a process review for blood orders from the OR. Limiting blood storage outside of the blood bank or new technology such as "blood vending machines" may also allow for better inventory control.

Conclusions

Although the number of units discarded was low, Safe-T-Vue indicators do provide a simple and relatively inexpensive method to ensure safe return to inventory. The number of units issued for remote storage should be limited.

References

1. Brecher ME, editor. Technical manual. 14th ed. American Association of Blood Banks; 2002. p.180-5.

2. Capital Health Hospital Transfusion Services: Guide to Blood Transfusion, Section 5 Transfusion of Blood and Blood Products. *5.1.1 Handling of blood products prior to transfusion*. 2002.

3. Williams Laboratories, Inc. *Safe-T-Vue for blood, Procedure for using*. 2000. (product insert)

4. William Laboratories, Inc. *Quality Assurance: Safe-T-Vue non-reversible blood bag temperature indicator*. 2002.