

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

Nicole Walker, Wilma Haughton\*, Kathy Fryia, Gwen Clarke Royal Alexandra Hospital, Misericordia Community Hospital\*, Dynacare Kasper Medical Laboratories.

### 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.<sup>1</sup> As well, they must have audible alarms to alert staff, enabling them to take appropriate action before any blood products reach unacceptable temperatures.<sup>1</sup>

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.<sup>1</sup>

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.<sup>2</sup> 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.<sup>1</sup> Safe-T-Vue (Williams Laboratories, Inc., CT) is a non-reversible temperature indicator that signals, by permanent colour change, if the temperature of a

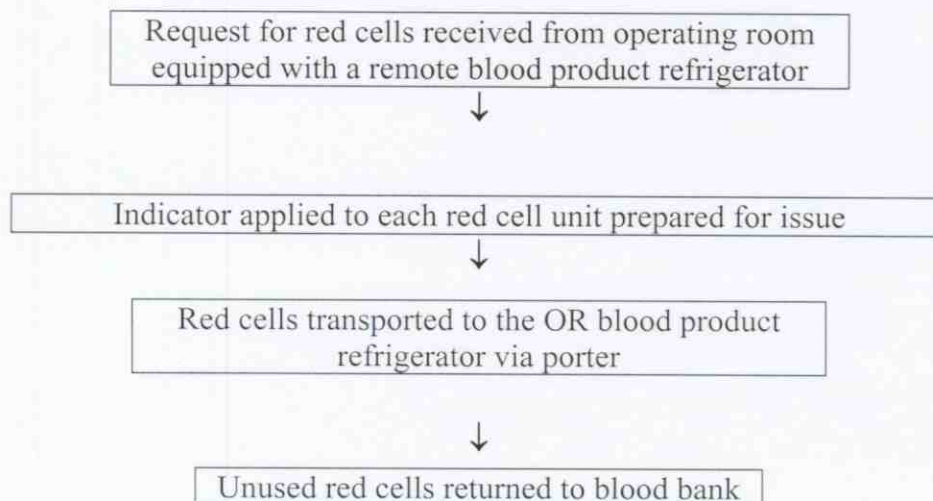
blood bag reaches 10°C.<sup>3</sup>

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:





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



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



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.<sup>4</sup>

