Irreversible Temperature Indicators as an Audit Tool for Assuring Blood Product Temperature Control

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ABSTRACT

Background. AABB Standards for Blood Banks and Transfusion Services mandates that blood products shall be maintained within appropriate temperature ranges during transport/storage outside the Blood Bank. A problem is how to determine if units returned to the Blood Bank are acceptable for reissue. During a recent Failure Mode and Effects Analysis (FMEA) of the blood transfusion process at our hospitals, this problem was highlighted. Of particular concern were blood products issued in coolers or to remote refrigerators for use in the operating rooms (ORs), where non-used products frequently are not returned to the Blood Bank for 8-16 h.

Project. A pilot study targeted units of packed red blood cells (PRBC) issued to ORs at two different hospitals. One is a 587-bed university hospital (A), the other, a 553-bed community-based, tertiary care hospital (B), transfusing ~ 24,000 and 15,000 PRBC units/year, respectively. Temperature indicators (Safe-T-VueR, Williams Laboratories, Inc., CT) were attached to the outside of PRBC-units dispensed to ORs. These indicators irreversibly turn color from white to red if the surface temperature of the blood bag reaches 10°C. The PRBC were distributed to remote refrigerators close to the ORs (hospital A), or in validated, portable coolers going directly to ORs (hospital B). Blood Bank technicians inspected the temperature indicators on returned units: an unchanged indicator was necessary for reentry to inventory.

The Table and graphs illustrate the results of the first eleven months of audit, indicating improved temperature control over time.

The number and proportion of deviation incidents and discarded units was initially significantly higher for hospital A, which distributed blood for ORs to remote refrigerators. The audit information was shared with the clinicians who use the blood products at both hospitals, as a routine monthly deviation report, and by occasional targeted communications, contributing to increased user awareness during the course of the audit.

Conclusion. Irreversible temperature indicators are useful for monitoring temperature control of blood products when outside the Blood Bank. Validated, portable coolers appear superior to remote refrigerators in assuring temperature control. Increased user awareness of temperature control failure leads to improved processes, but additional measures may also be needed (hospital A).

BACKGROUND

AABB Standards for Blood Banks and Transfusion Services (22nd Ed.):

5.18.3 Reissue of Blood and Components

Blood and components that have been returned to the blood bank or transfusion service shall be reissued only if the following conditions have been observed:

2) All components have been maintained at the appropriate temperature.

PRBCs dispensed for possible use at surgery are frequently outside blood bank/transfusion service (BB/TS) control for extended times. The units returned to BB/TS are stored in remote refrigerators or transport/storage coolers, but may also have spent significant time bedside at room temperature. To assess whether this creates regulatory problems concerning return to inventory, a pilot audit project was performed using irreversible temperature indicators attached to units.

Auditing red cell units returned to transfusion service from ORs using irreversible temperature indicators

1. Back to inventory

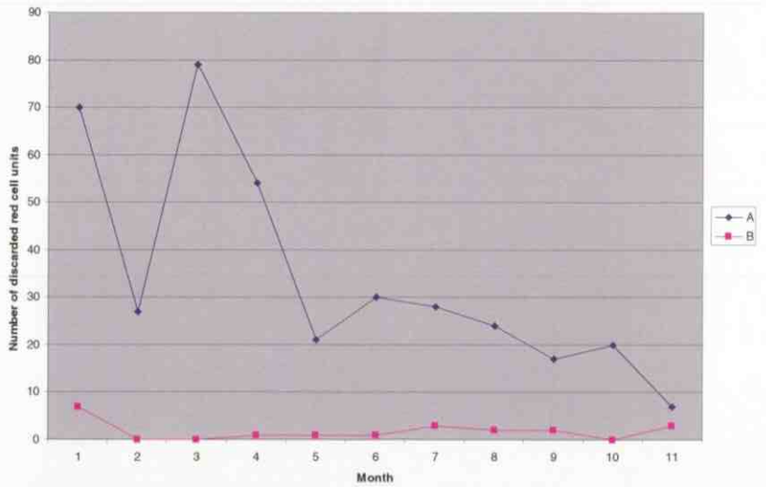
2. Discard

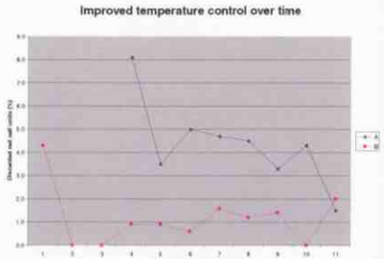
PROJECT

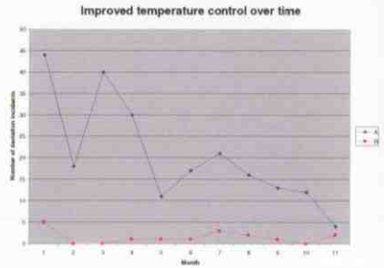
During the audit, the following measures were recorded monthly at both hospitals: Number of PRBC units dispensed to and returned from OR, number of return sendings containing units with triggered temperature indicator or, sometimes, missing temperature indicator (deviation incidents), as well as absolute number of units thus discarded. The results are compiled in the Table and graphs.

		Month										
Hospital	PRBC Units	1	2	3	4	5	6	7	8	9	10	11
A	# Dispensed				974	1,012	959	948	880	883	771	877
A	% Returned				69	60	63	60	58	56	60	52
A	# Deviations	44	18	40	30	11	17	21	16	13	12	4
A	# Discarded	70	27	79	54	21	30	28	24	17	20	7
A	% Discarded				8.1	3.5	5.0	4.9	4.5	3.4	4.3	1.5
B	# Dispensed	292	365	260	303	235	418	376	321	298	339	344
B	% Returned	56	48	44	39	48	41	49	51	48	46	45
B	# Deviations	5	0	0	1	1	1	3	2	1	0	2
B	# Discarded	7	0	0	1	1	1	3	2	2	0	3
B	% Discarded	4.3	0	0	0.9	0.9	0.6	1.6	1.2	1.4	0	2.0

Improved temperature control over time







CONCLUSION

1. The pilot project demonstrated an existing problem of temperature control of PRBC units sent to ORs, particularly at hospital A.
2. Increased awareness of the problem, as emphasized by deviation reports sent to nursing, and other directed communication BB/TS-staff-to-OR-staff, sufficed to improve temperature control.
3. In addition, hospital A invested in validated coolers for transport/storage of PBRC units taken from remote refrigerators to ORs (implemented from Month 4 to the present), which further enhanced temperature control.