



Blood on Board

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Disclosures

No conflicts to disclose

Objectives

1. Describe the key features of the Blood on Board Program
2. Describe the cooler validation process
3. Describe the program implementation process
4. Discuss progress post-launch



Where it began

1. Need

Pre-hospital transfusion by Ornge air medical transport.

2. Collaboration

Ornge and Sunnybrook's Division of Transfusion Medicine & Tissue Bank (TMTB).

3. Initiative

TMTB to supply blood in coolers for Ornge air medical transport.



The Collaboration



Sunnybrook
HEALTH SCIENCES CENTRE

BLOOD ON BOARD OPERATIONAL INDEX

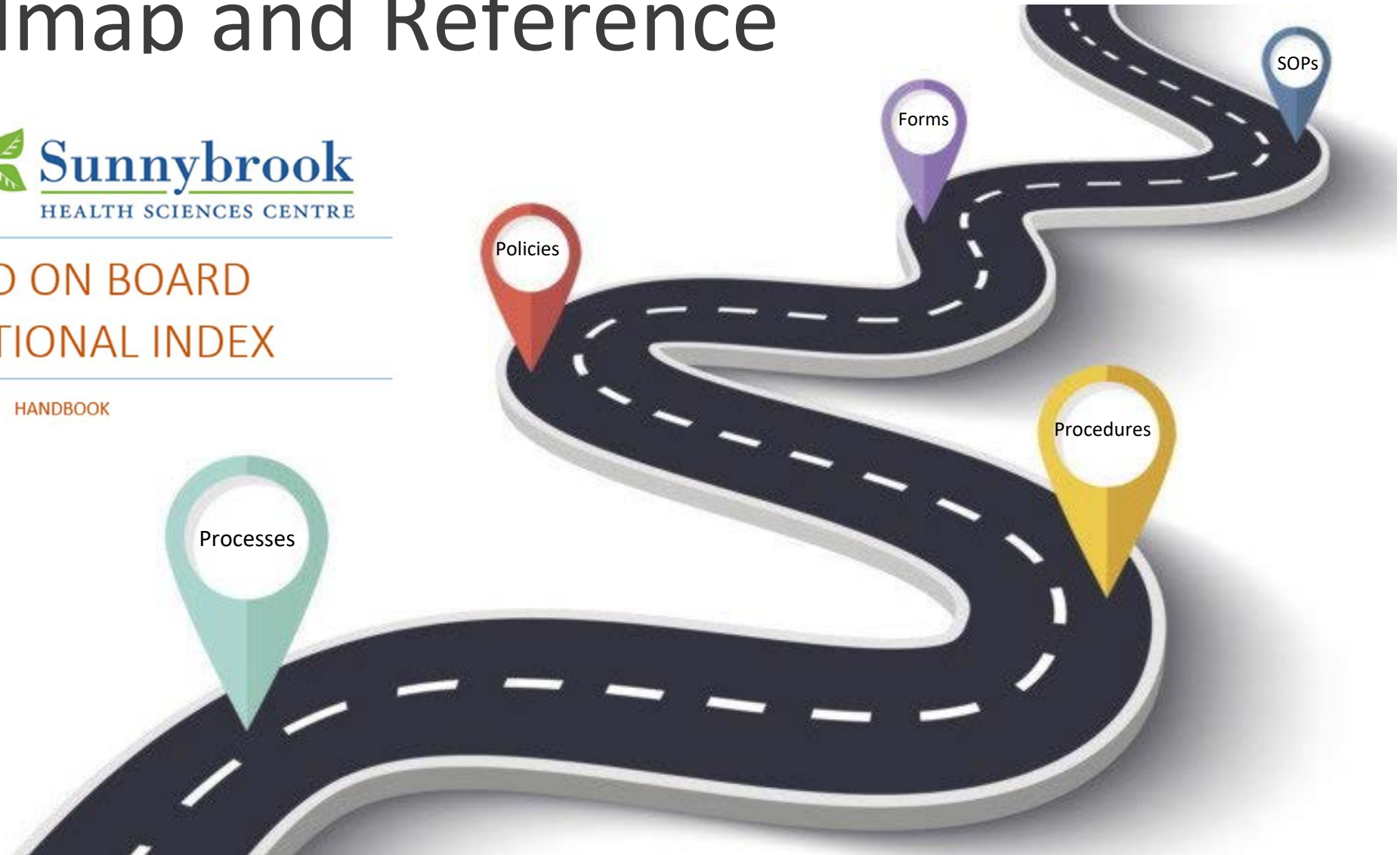
HANDBOOK

Roadmap and Reference



BLOOD ON BOARD OPERATIONAL INDEX

HANDBOOK



The Challenge

Standards

Rules

Policies

Regulations

Compliance

Law

The Challenge

Develop a prehospital transfusion program that meets:

- Blood Regulations under the Food and Drugs Act
- Canadian Standards Association (CSA) Standard for Blood and Blood Components CSA-Z902 (“CSA Standard”)
- Institute for Quality Management in Healthcare (IQMH)/Accreditation Canada standards
- Sunnybrook Transfusion Policies



The Challenge

Policies include the following as per the CSA Standard 1.4 and 4.1.2

- Storage, packing and transportation
- Physical facilities and equipment
- Requests, acceptance criteria
- Transfusion
- Qualification and training of personnel
- Adverse event reporting (transfusion reactions and errors) and surveillance and corrective action
- Recipient notification and informed consent
- Record management
- Traceability (CSA 9.1.2)
- Emergency plan in response to incidents that could endanger, safety, quality or efficacy of blood (CSA 4.2.1.6)
- Periodic Audits (CSA 4.6.3.1)



The Goal:

A temperature monitored cooler used to store RBCs for transfusion by air medical transport

Validate a temperature recorder that:

1. Continuously records the internal cooler temperature
2. Has a programmable alarm for out of range temperatures
3. Is equipped with visual temperature alerts
 - For paramedics to verify that storage temperature is OK at time of transfusion

Validate a cooler that:

1. Maintains RBC storage temperature of 1-6°C
2. Maintains storage temperature for a considerable duration of time
 - Ideally can hold temperature for 3-5 days
 - Goal is to reduce the frequency of cooler switchovers required

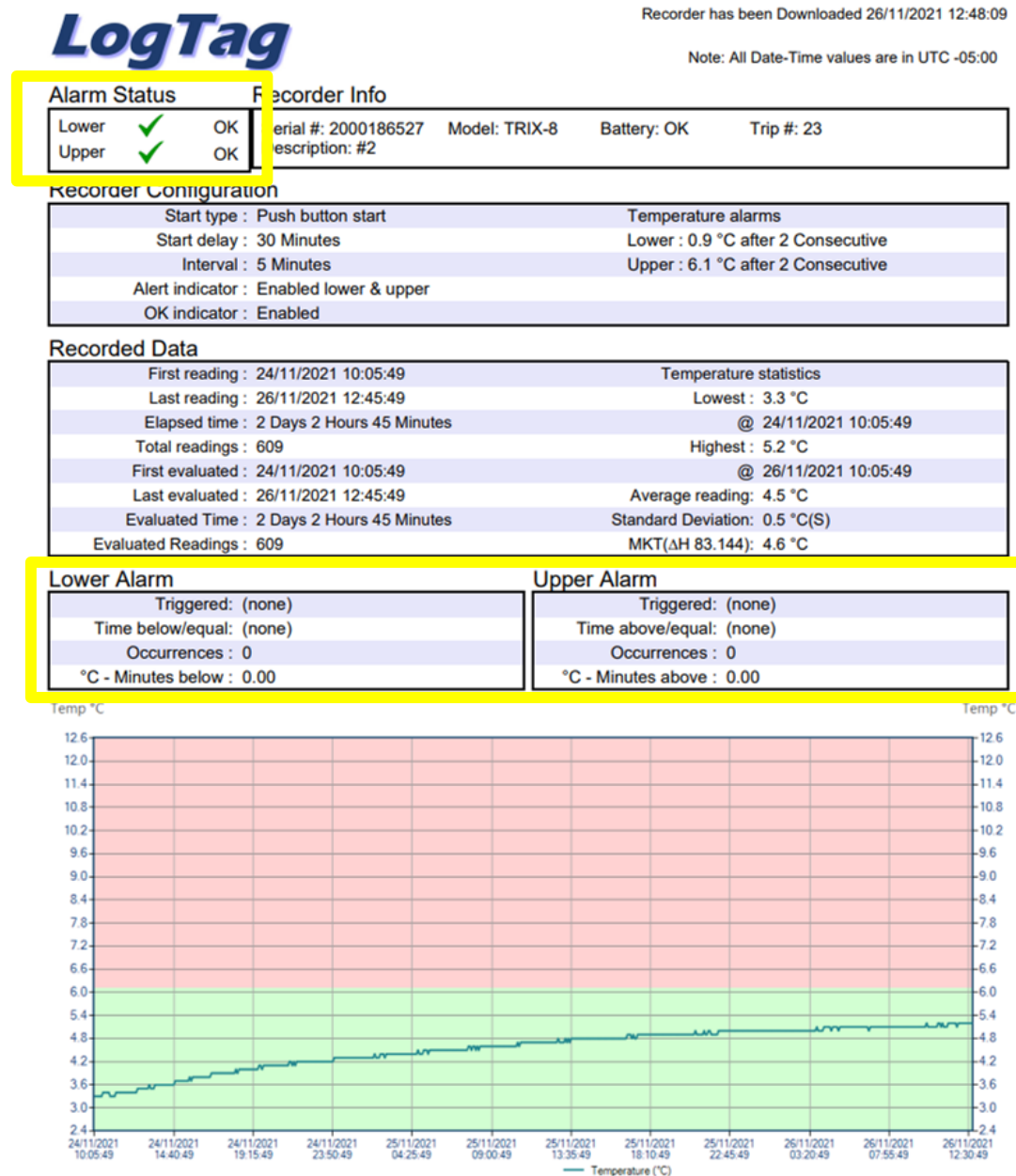
Temperature Monitoring



LogTag TRIX-8 Temperature Recorder:

- Records temperature at customizable time intervals (every 5 minutes, 10 minutes, etc)
- High and low customizable alarms
 - 1-6°C range
- Green 'OK' & red 'ALERT' indicators

Temperature Monitoring



Source: TRIX-8- 2000186527 Started 24_11_2021 10_05_49, Finished 26_11_2021 12_45_49.ltd

File Location: C:\Users\labsntest\Documents\My LogTag Data

Created : 26/11/2021 15:54:34

Page: 1 of 10

Cooler Validation Journey

The Beginning



In-lab validation of initial cooler showed duration of max **47 hours**



Payload Size

6 × 5 × 4 in
152 × 127 × 108 mm



Outer Dimensions

12 × 10 × 8 in
300 × 249 × 196 mm

Product Specifications

Temperature Range	2°C-8°C	Payload Volume	2.00 litres
Duration	120 hours	Coolant Type	PCM Coolant
Payload Size Imperial	6 × 5 × 4 in	Payload Size Metric	152 × 127 × 108 mm
Outer Dimensions Imperial	12 × 10 × 8 in	Outer Dimensions Metric	300 × 249 × 196 mm
Tare Weight Imperial	10 lb	Tare Weight Metric	4 kg
Product Type	Reusable Parcel	Product Series	Series 4

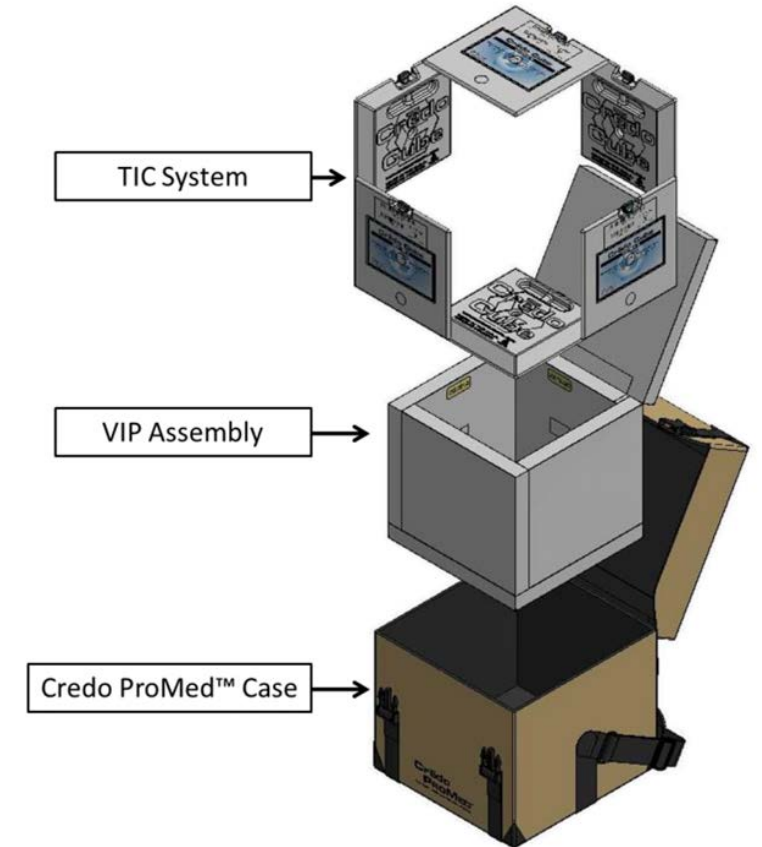
Validation Journey

- Different coolers and bags
- TIC (Thermal Isolation Chamber) panel conditioning time
- Temperature recorder management
- Placement of temperature recorder in cooler
- Vertical/Horizontal RBC unit positioning
- No gel pack vs with gel pack

A	B	C	D	E
Date	Cooler type	Cooler Testing	Method	
22/04/2021	Duracube	1 TIC Conditioning Time/Temp	IR thermometer	
26/04/2021		LogTag acclimation to lower temps	LogTag in walk in fridge	
27/04/2021 - 29/04/2021	Duracube	1 TIC conditioning + cooler validation	TIC conditioned in walk in fridge, RBC from walk in fridge, LogTag at RT on top	
29/04/2021 - 03/05/2021	Duracube	1 TIC conditioning + cooler validation	TIC conditioned at RT, RBC and LogTag from available fridge, LogTag on top	
29/04/2021 - 30/04/2021		Temp stability of Specials Fridge for TIC storage	Logtag in specials fridge	
29/04/2021 - 30/04/2021		Temp stability of Available Fridge for TIC storage	LogTag in available fridge	
03/04/2021 - 06/05/2021	Duracube	1 TIC conditioning + Cooler validation	LogTag from available fridge, on side	
06/05/2021 - 10/05/2021	Duracube	1 TIC conditioning + Cooler validation, validate IR thermometer and LogTag	LogTag from available fridge, on side, Fluke vs LogTag vs IR thermometer when TIC thawing	
13/05/2021 - 17/05/2021	Duracube	2 TIC Conditioning + Cooler validation	LogTag on top	
13/05/2021 - 17/05/2021	Duracube	3 TIC Conditioning + Cooler validation	LogTag on top	
17/05/2021	Duracube	1 Ambient temperature of SB-Base-Heil	LogTag attached to cooler brought to site visit	
19/05/2021 - 25/05/2021	Credo Cube	4 TIC conditioning + cooler validation	TIC conditioned in -28C LogTag on side	
19/05/2021 - 25/05/2021	Credo Cube	5 TIC conditioning + cooler validation	TIC conditioned in -78C for <24hr (frozen), LogTag on side	
20/05/2021 - 25/05/2021	Credo Cube	6 TIC conditioning + cooler validation	TIC conditioned in -78C for 24hr, LogTag on side	
25/05/2021 - 04/06/2021	Credo Cube	4 TIC conditioning + cooler validation - parallel run	TIC conditioned in -78C for >24 hours, top of cart, LogTag on side	
27/05/2021 - 04/06/2021	Credo Cube	5 TIC conditioning + cooler validation - parallel run	TIC conditioned in -78C for >24 hours, middle of cart, LogTag on side	
28/05/2021 - 04/06/2021	Credo Cube	6 TIC conditioning + cooler validation - parallel run	TIC conditioned in -78C for >24 hours, bottom of cart, LogTag on side	
04/06/2021 - 11/06/2021	Credo Cube + Bag	4 TIC conditioning + cooler validation	TIC pre-conditioned in -78C for 30 min, conditioned in -28 for min 24 hr, LogTag on side, TIC wiped	
09/06/2021 - 14/06/2021	Credo Cube + Bag	5 TIC conditioning + cooler validation	TIC pre-conditioned in -78C for 30 min, conditioned in -28 for min 24 hr, LogTag on side	
10/06/2021 - 15/06/2021	Credo Cube + Bag	6 TIC conditioning + cooler validation	TIC pre-conditioned in -78C for 30 min, conditioned in -28 for min 24 hr, LogTag on side	
11/06/2021 - 18/06/2021	Credo Cube + Bag	4 TIC conditioning + cooler validation	TIC pre-conditioned in -78C for 30 min, conditioned in -28 for min 24 hr, LogTag on side, TIC wiped	
14/06/2021 - 21/06/2021	Credo Cube + Bag	5 TIC conditioning + cooler validation + LogTag placement (sandwich)	TIC pre-conditioned in -78C for 30 min, conditioned in -28 for min 24 hr, thawed on shelf, LogTag in middle, TIC wiped	
17/06/2021 - 22/06/2021	Credo Cube + Bag	6 TIC conditioning + cooler validation + LogTag placement (sandwich)	TIC pre-conditioned in -78C for 30 min, conditioned in -28 for min 24 hr, thawed on shelf, LogTag in middle, TIC wiped	
18/06/2021 - 23/06/2021	Credo Cube + Bag	4 TIC conditioning + cooler validation + LogTag placement (sandwich)	TIC pre-conditioned in -78C for 30 min, conditioned in -28 for min 24 hr, thawed on shelf, LogTag in middle, TIC wiped	
21/06/2021 - 28/06/2021	Credo Cube + Bag	4 TIC conditioning + cooler validation + LogTag placement (sandwich)	25 min thaw, no plastic bag, logtag on side and sandwiched	
22/06/2021 - 24/06/2021	Credo Cube + Bag	6 TIC conditioning + cooler validation + LogTag placement (sandwich)	25 min thaw, no plastic bag, logtag on side and sandwiched	
23/06/2021 - 30/06/2021	Credo Cube + Bag	4 Trial run	25 min thaw, no plastic bag, logtag on side and sandwiched, logtag on exterior	
28/06/2021 - 03/07/2021	Credo Cube + Bag + New pan	5 TIC conditioning + cooler validation	25 min thaw, no plastic bag, logtag on side	
28/06/2021 - 03/07/2021	Credo Cube + Bag + New pan	6 TIC conditioning + cooler validation	25 min thaw, no plastic bag, logtag on side	
03/07/2021 - 09/07/2021	Credo Cube + Bag	4 80H validation, logtag alert	delay 15 min recording + 2 consecutive alerts, open after 80H	
03/07/2021 - 10/07/2021	Credo Cube + Bag + New pan	6 80H validation, logtag alert	delay 15 min recording + 2 consecutive alerts, open after 80H	
30/06/2021 - 03/07/2021	Credo Cube + Bag + New pan	5 Open+Close, 80H, logtag alert	delay 15 min recording + 2 consecutive alerts, open after 80H, open 5 min @ 24H and open 5 min @ 48H	
12/07/2021 - 15/07/2021	Credo Cube + Bag	4 Closed Cooler Trial run	delay 15 min recording + 2 consecutive alerts, closed on multiple flights (3), 72 hours	
12/07/2021 - 15/07/2021	Credo Cube + Bag + New pan	5 Closed Cooler Trial run	delay 15 min recording + 2 consecutive alerts, closed on multiple flights (6), 72 hours	
12/07/2021 - 15/07/2021	Credo Cube + Bag + New pan	6 Closed Cooler Trial run	delay 15 min recording + 2 consecutive alerts, closed in crew room, 72 hours	
16/07/2021 - 19/07/2021	Credo Cube + Bag	4 Opened Cooler Trial Run	delay 15 min recording + 2 consecutive alerts, open twice 20 mins apart, (72 hours, opened 29 hours apart)	
16/07/2021 - 19/07/2021	Credo Cube + Bag + New pan	6 Opened Cooler Trial Run	delay 15 min recording + 2 consecutive alerts, open twice 20 mins apart, (72 hours, not taken on any flights or opened)	
16/07/2021 - 20/07/2021	Credo Cube + Bag + New pan	5 80H validation, logtag alert	delay 15 min recording + 2 consecutive alerts, open after 80H	
23/07/2021 - 26/07/2021	Credo Cube + Bag	4 Opened Cooler Trial Run	taken on flights, open twice (15s) 20 minutes apart, check for LogTag alert. Cooler taken to SIM, opened 3rd time, 1RBC n	
23/07/2021 - 26/07/2021	Credo Cube + Bag + New pan	6 Opened Cooler Trial Run	taken on flights, open twice (15s) 20 minutes apart, check for LogTag alert	
27/07/2021 - 31/07/2021	Credo Cube + Bag + New pan	5 RBC packing configuration	RBC vertical, 1 gel pack sandwiched in middle, LogTag on side	
30/07/2021 - 30/07/2021		Time for TIC Refrigerator conditioning	TICs placed in refrigerator after removing from freezer	
30/07/2021 - 05/08/2021		Time for TIC Refrigerator conditioning	TICs placed in refrigerator after Room Temp conditioning (refrigerated hold) for 5 days	
05/08/2021 - 09/08/2021	Pro-Med Coolers	1 Cooler validation, RBC configuration validation, LogTag Placement	96H, RBC vertical, 1 gel pack in middle, LogTag on top, side, middle	
05/08/2021 - 09/08/2021	Pro-Med Coolers	2 Cooler validation, RBC configuration validation, LogTag Placement	96H, RBC vertical, 1 gel pack in middle, LogTag on top, side, middle	
05/08/2021 - 09/08/2021	Pro-Med Coolers	3 Cooler validation (refrigerated TICs), RBC configuration validation, LogTag Placement	96H, TIC from refrigerator, RBC vertical, 1 gel pack in middle, LogTag on top, side, middle	
10/08/2021 - 14/08/2021	Pro-Med Coolers	7 Cooler validation, RBC configuration validation	96H, RBC vertical, 1 gel pack in middle, LogTag on side	
10/08/2021 - 14/08/2021	Pro-Med Coolers	8 Cooler validation, RBC configuration validation	96H, RBC vertical, 1 gel pack in middle, LogTag on side	
10/08/2021 - 14/08/2021	Pro-Med Coolers	1 Cooler validation, RBC configuration validation	96H RBC flat, no gel, LogTag on side	
10/08/2021 - 14/08/2021	Pro-Med Coolers	2 Cooler validation, RBC configuration validation	96H RBC flat, no gel, LogTag on side	
10/08/2021 - 14/08/2021	Pro-Med Coolers	3 Cooler validation, RBC configuration validation	96H RBC flat, no gel, LogTag on side	
16/08/2021 - 20/08/2021	Pro-Med Coolers	1 Closed Cooler Trial run	96H, gel pack, LogTag on side, closed in crew room	
16/08/2021 - 20/08/2021	Pro-Med Coolers	2 Opened Cooler Trial Run	96H, gel pack, LogTag on side, opened twice on first flight (open 15s, 20 min apart)	
16/08/2021 - 20/08/2021	Pro-Med Coolers	3 Opened Cooler Trial Run	96H, gel pack, LogTag on side, opened twice on two flights, one day apart (aug 16th & aug 17th) (open 15s, 30 and 20 m	
17/08/2021 - 21/08/2021	Pro-Med Coolers	7 Cooler validation, RBC configuration validation	96H, gel pack, LogTag on side	
17/08/2021 - 21/08/2021	Pro-Med Coolers	8 Cooler validation, RBC configuration validation	96H, gel pack, LogTag on side	
03/08/2021 - 06/09/2021	Pro-Med Coolers	4 Cooler validation	96H, gel pack, LogTag on side	
03/08/2021 - 06/09/2021	Pro-Med Coolers	5 Cooler validation	96H, gel pack, LogTag on side	
03/08/2021 - 06/09/2021	Pro-Med Coolers	6 Cooler validation	96H, gel pack, LogTag on side	

The Final Cooler

Crêdo ProMed™ Series 4 4L

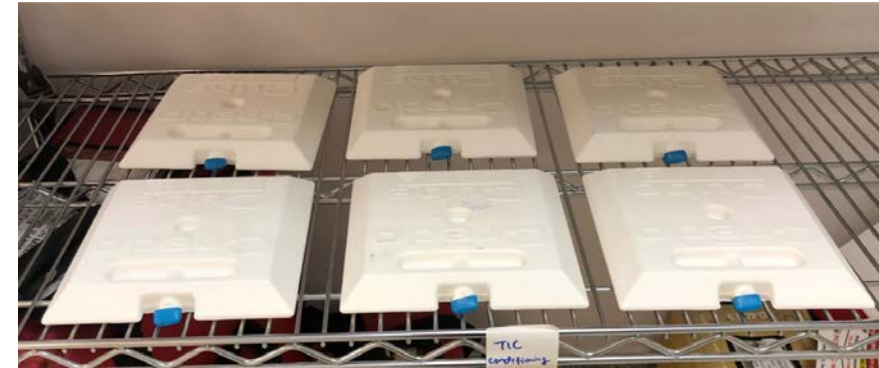


Validation

Series of in-lab and in-flight validations (coolers closed and opened) performed

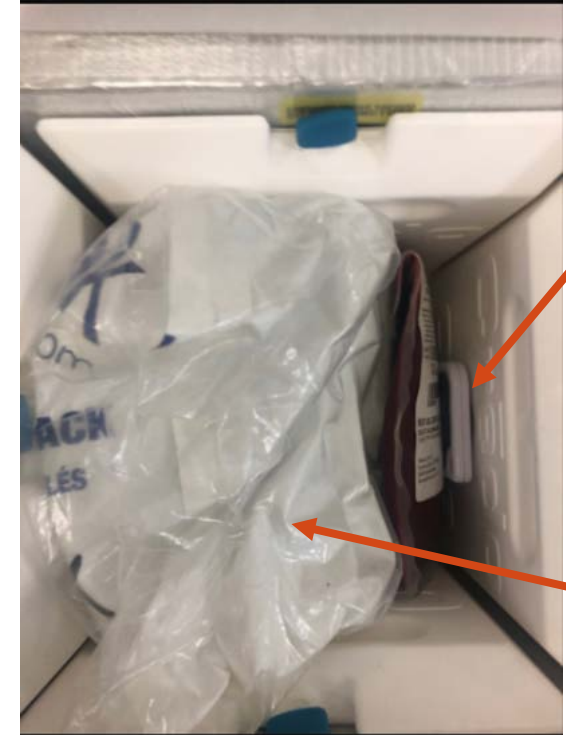
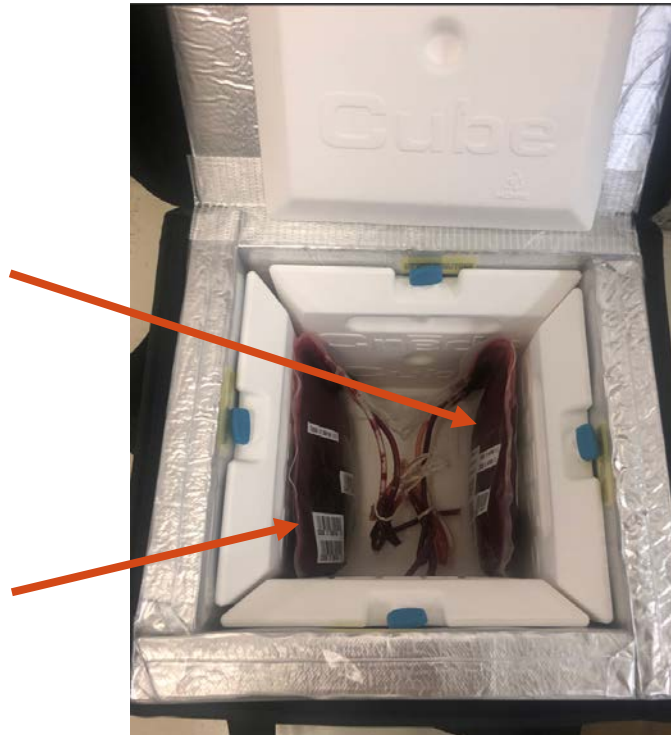
Findings:

- Cooler's TIC panels must be freezer conditioned at $<-18^{\circ}\text{C}$ for minimum of 24 hours, then room temperature conditioned on ventilated rack for 25 minutes before use.
- Vertical upright placement of RBC's provided longer duration vs flat in cooler.
- Temperature recorder most accurate when placed between RBC and TIC panels in cooler.
- 1 fridge temperature gel pack helps achieve our goal of 96 hour storage.



Final Cooler Configuration

- Stores 2 units of RBC at 1-6°C for up to 96 hours
- Inside:
 - 2 x RBCs (O Negative, tagged K Neg)
 - 1 x fridge temperature gel pack
 - 1 x LogTag temperature recorder



In-Flight Simulation

Test coolers sent to Ornge Toronto Base for use validation

Paramedics were instructed to open the cooler twice, 20 minutes apart

- To simulate taking one unit out at a time for transfusion in-flight

LogTags were attached to the outside of the cooler

- To help us understand the extremity of temperatures the coolers would be exposed to in summer (August) temperatures.

Findings:

- LogTag within cooler was flashing “OK” at each opening, indicating that the cooler was able to maintain a temperature of 1-6°C at/after each opening.
- Highest temperature the cooler was exposed to was 34.8°C

Blood on Board

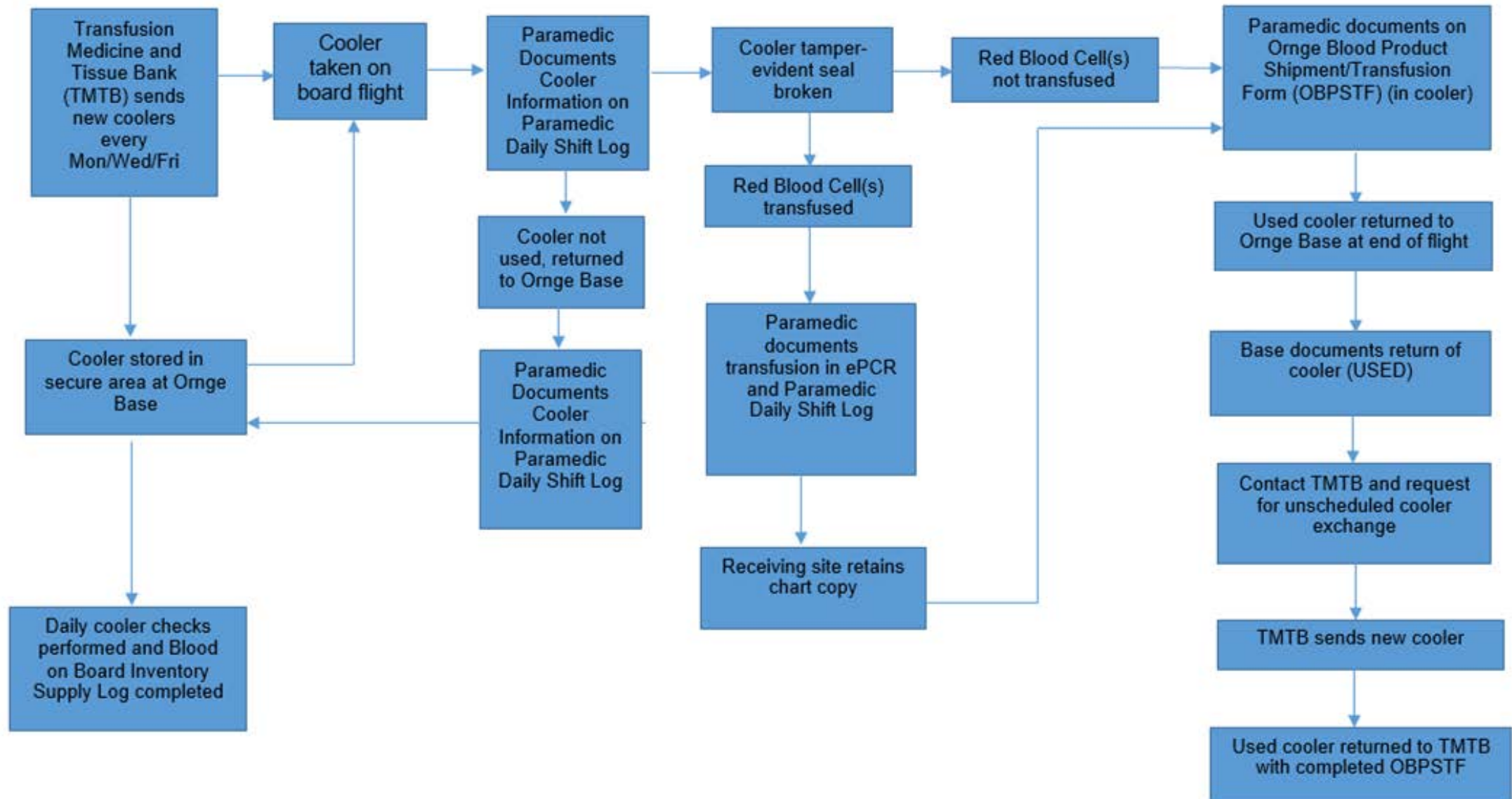
From lab to scene and back again



Designing “Blood on Board”

- LIS tracking of RBC shipments, returns, and transfusions
- Blood and cooler preparation within the lab
 - Fridge, freezers, RT shelf space for conditioning
- Cooler use and storage at Ornge base
 - How many coolers should they have on hand?
 - Is there a temperature controlled room?
 - Is the room only accessible by paramedics?
- Cooler exchange logistics
 - Exchange schedule?
 - What happens when they use a cooler?
 - Will the courier take the ferry to the island?
- Draft and prepare SOPs, flow charts, documents and forms
- Train lab and Ornge staff

Blood on Board Overview Process



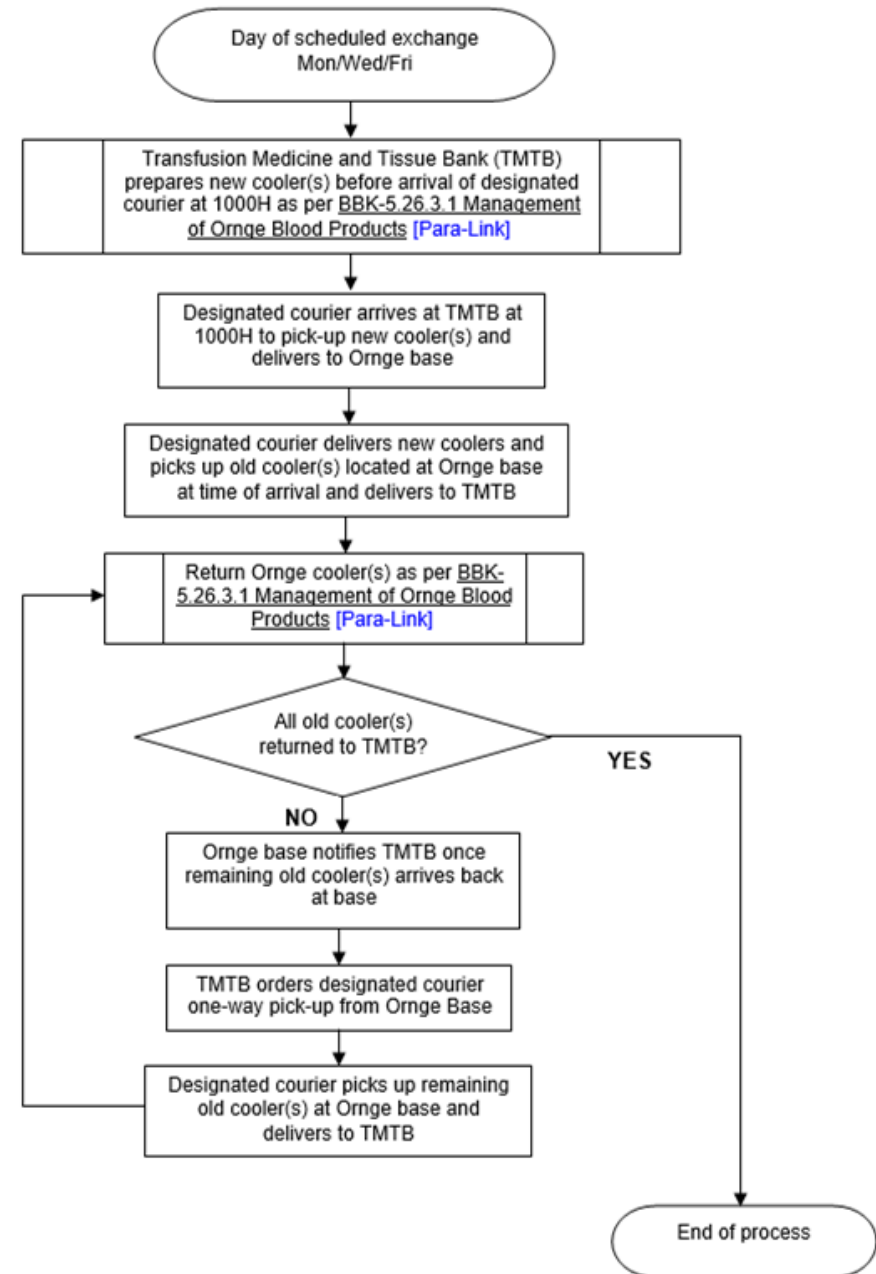
Scheduled Cooler Exchange

TMTB Process

3 coolers exchanged 3x a week

Longest time between exchange being 3 days, giving 1 day buffer

Scheduled Cooler Exchange Process

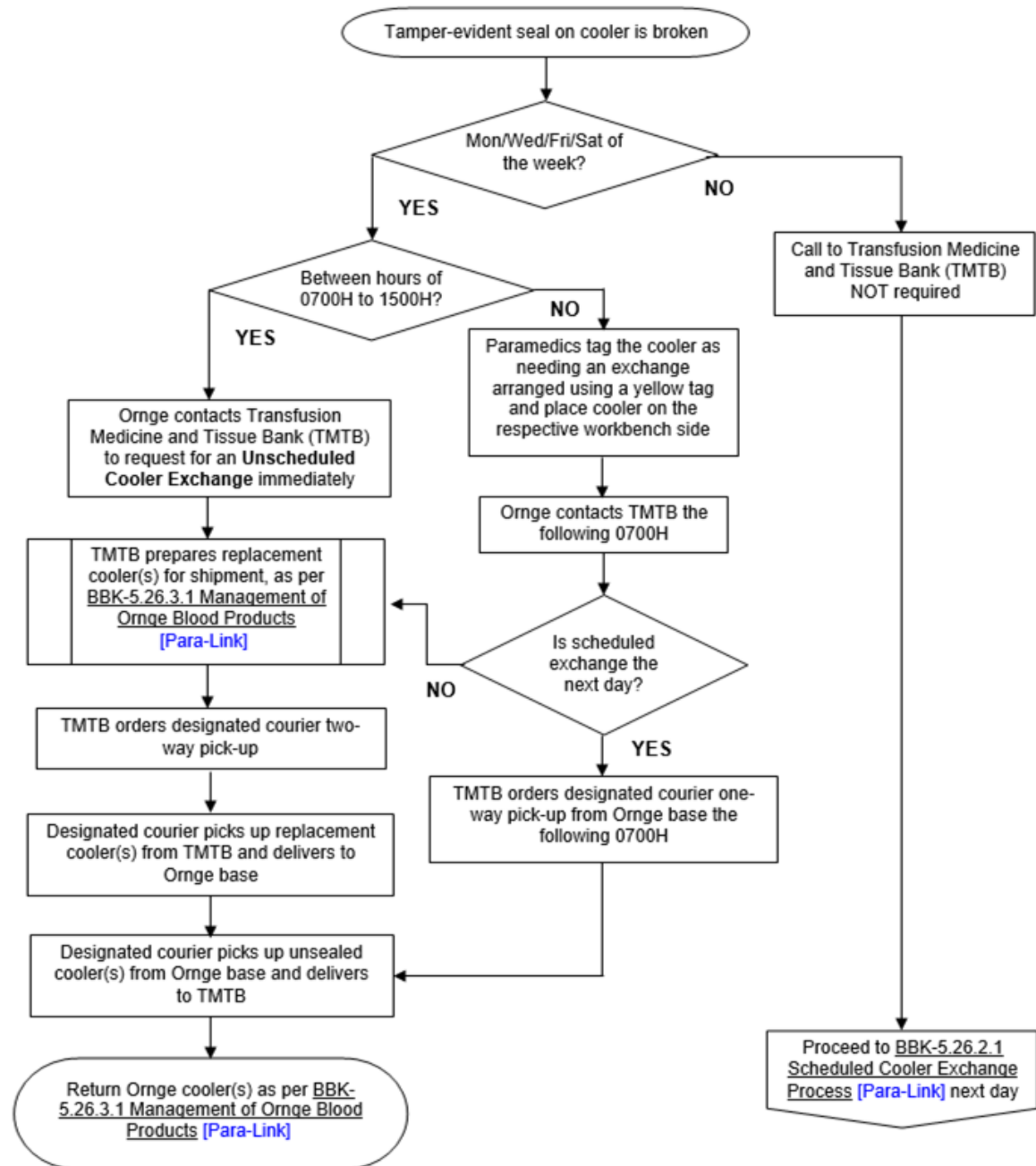


Unscheduled Cooler Exchange

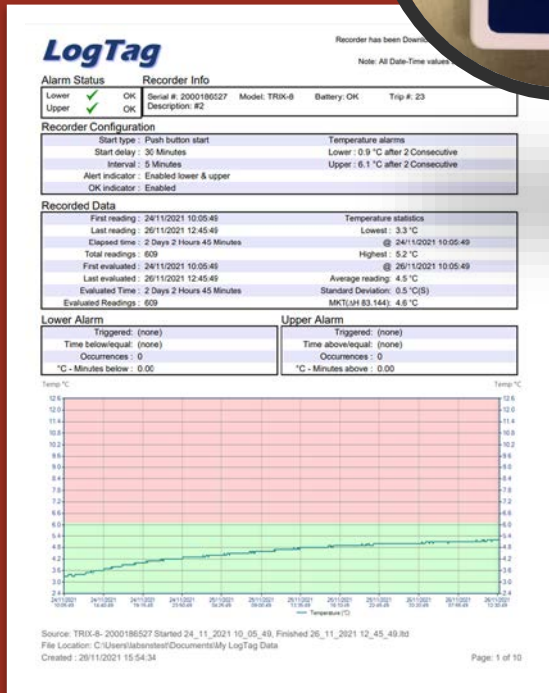
TMTB Process

Occurs when the tamper evident seal on a cooler is broken and/or blood was transfused

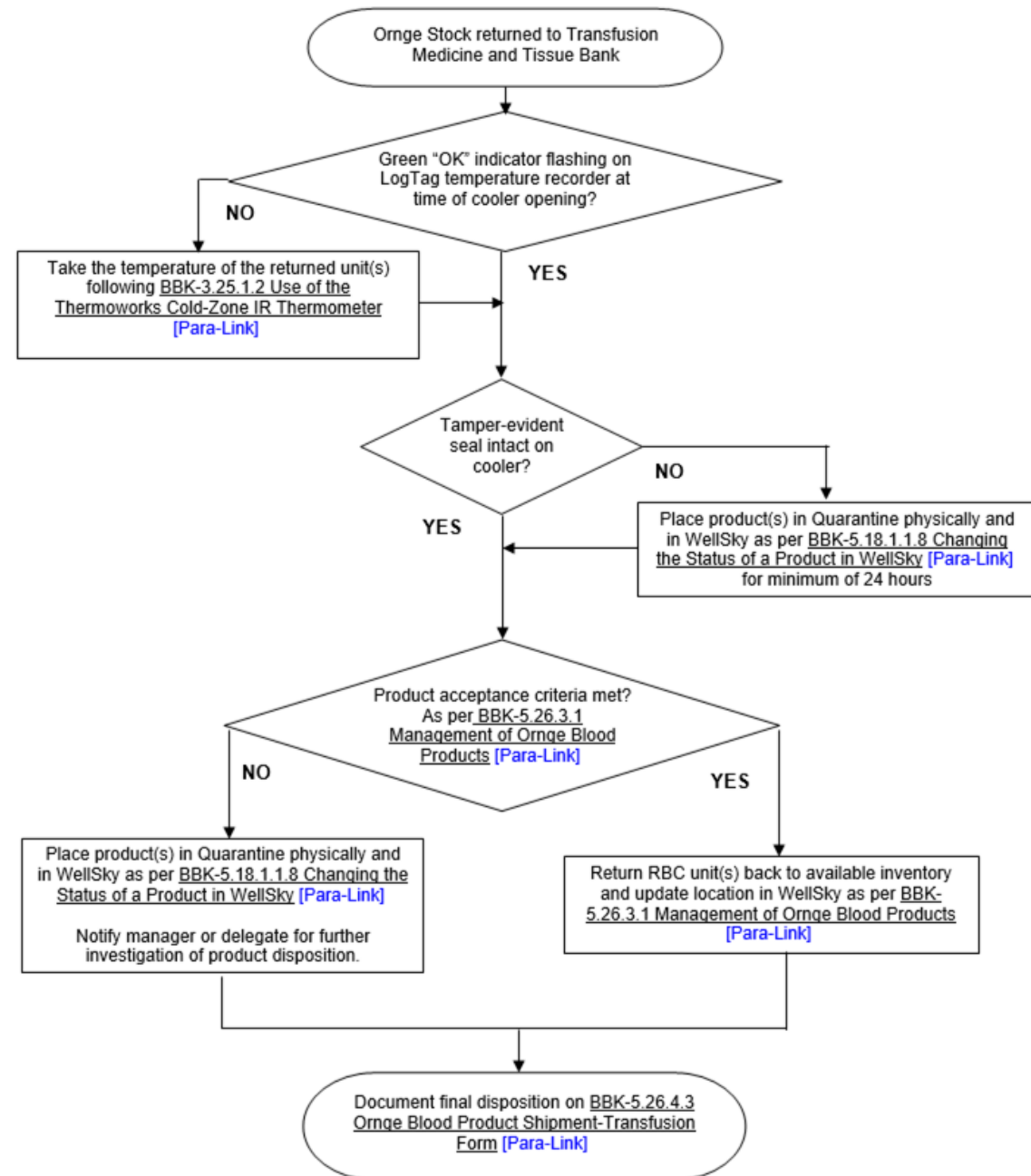
Unscheduled Cooler Exchange Process



Cooler Return Process



Return of Ornge Stock Process



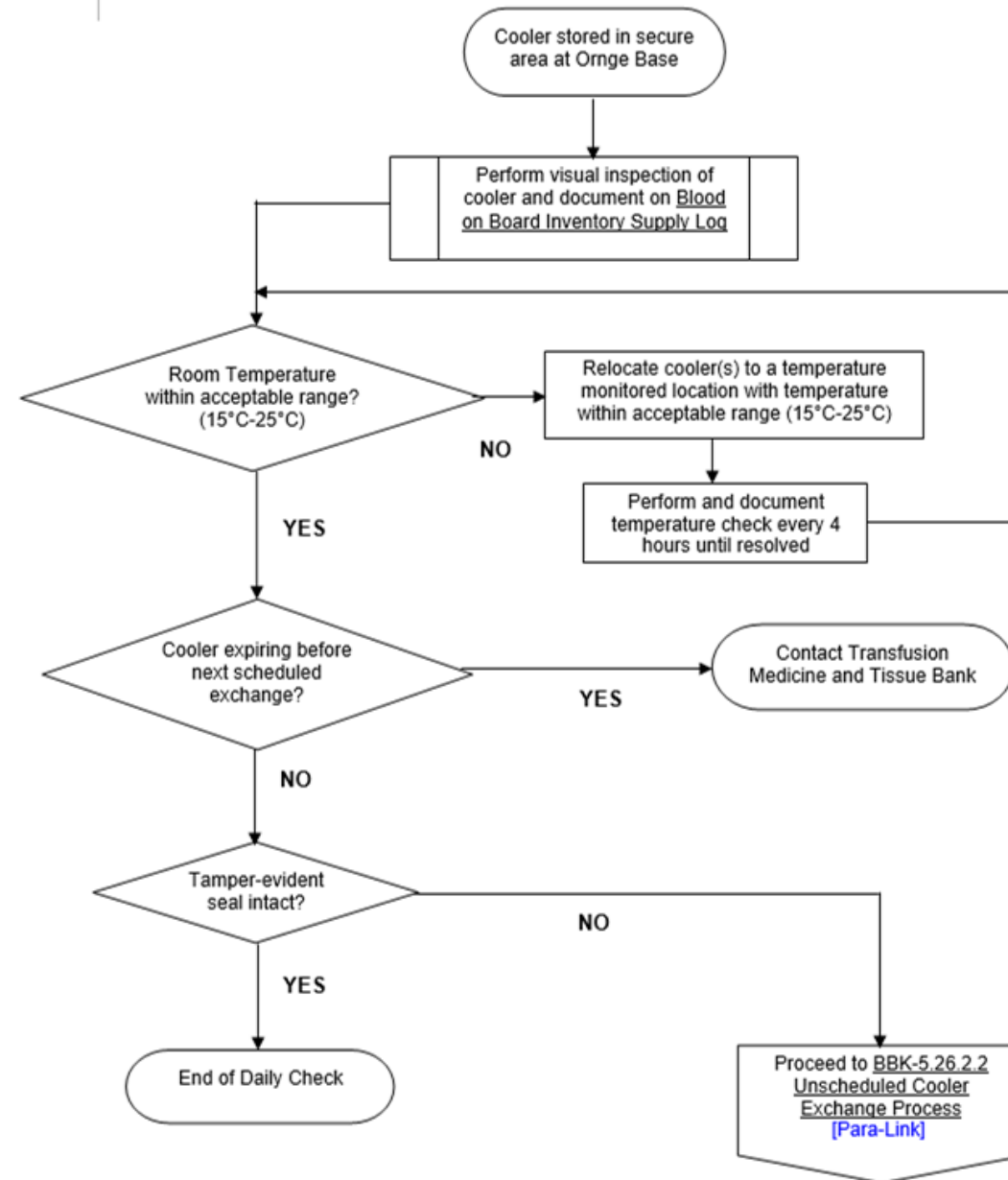
Base Daily Check

Ornge process

Coolers stored in a secured temperature controlled room at base

Prarmedics to take one cooler with them on on flight on a call-to-call basis

Ornge Daily Cooler Check Process



Transfusion Process



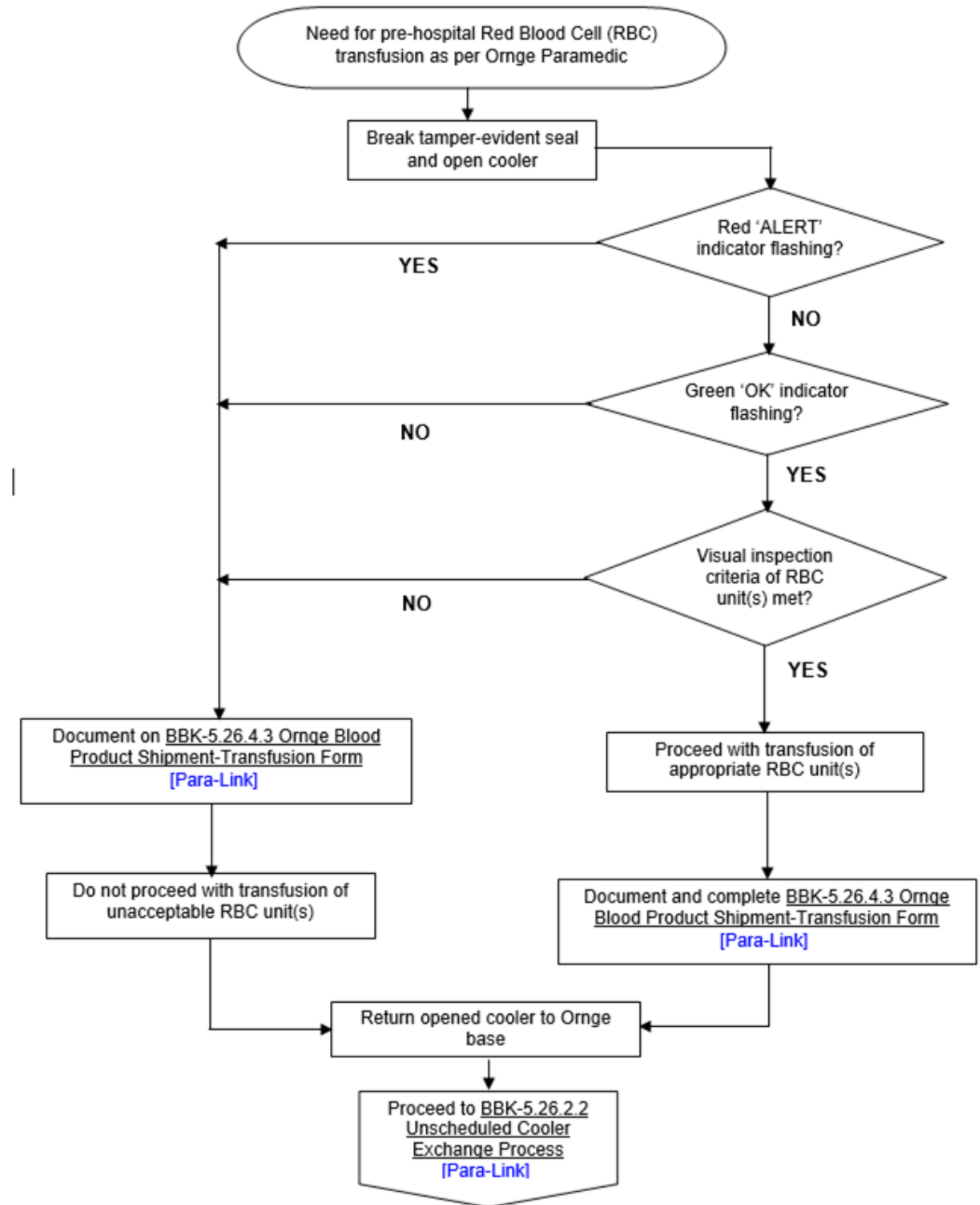
Clinical Affairs

Ornge Blood Product Transfusion Policy

Title:	Ornge Blood Product Transfusion Policy
Policy #:	CA-POL-001 R0 (Ornge Blood Product Transfusion Policy)
Applies to:	Transport Medicine Physicians and Ornge Certified Paramedics
Issue Date:	[insert date]
Issued By:	Director, Clinical Affairs
	Associate Medical Officer – Operations, Education, OCC

Patient Care

Ornge Transfusion Process



Ornge Blood Product Shipment/Transfusion Form

 2075 Bayview Avenue Toronto, ON M4N 3M5	Department of LMMD Division of Transfusion Medicine and Tissue Bank Transfusion Medicine	BBK-5.26.4.3 Version: 1 Page 1 of 2 Effective: 2022/02/28 E-Authorized by: Medical Director
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Ornge Blood Product Shipment-Transfusion Form

Shipment Details				Voucher#:202X-MM-DD-Cooler#				
Date Products Shipped (dd/mm/yyyy)	Time Products Shipped	Cooler ID#	Temperature Recorder#	Packaged by				
Cooler Expiry Date (dd/mm/yyyy)	Cooler Expiry Time	Receiving Ornge Base Toronto						
Product Details								
Product Type and ABO/Rh	Unit Number	Completed by Ornge		Completed by TMTB				
		Transfused	Reason Not Transfused	Date/Time Cooler Returned to TMTB	Log Tag Indicator "OK" Upon Unpacking	Unit Returned	Disposition	Date/Tech
		<input type="checkbox"/> *Yes *Time of Transfusion: <input type="checkbox"/> No	<input type="checkbox"/> Not required <input type="checkbox"/> Temperature unacceptable <input type="checkbox"/> Other (specify):		<input type="checkbox"/> Yes <input type="checkbox"/> No Date/Time:	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Inventory <input type="checkbox"/> *Discarded <input type="checkbox"/> *Quarantine (*specify reason): <input type="checkbox"/> Shipped in WellSky	
		<input type="checkbox"/> *Yes *Time of Transfusion: <input type="checkbox"/> No	<input type="checkbox"/> Not required <input type="checkbox"/> Temperature unacceptable <input type="checkbox"/> Other (specify):			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Inventory <input type="checkbox"/> *Discarded <input type="checkbox"/> *Quarantine (*specify reason): <input type="checkbox"/> Shipped in WellSky	
Transfusion Documentation								
Both units transfused to the same patient? <input type="checkbox"/> Yes <input type="checkbox"/> No (Complete reverse side if 2 nd unit was transfused to a different patient)								
Date of Transfusion (dd/mm/yyyy)		Name of Paramedic			OASIS#			
Flight#	Patient Pickup Location			Patient Receiving Location				
Name of Patient (LAST NAME, First Name)				Date of Birth (dd/mm/yyyy)		Ornge TC#		
Transfusion Reaction								
<input type="checkbox"/> Yes <input type="checkbox"/> No		Reaction Description:						

Ornge and Sunnybrook Health Sciences Centre launch 'Blood on Board'



Ornge and Sunnybrook Health Sciences Centre launch 'Blood on Board'

Program to lead to improved outcomes for remote trauma patients and others

August 31, 2021 | Mississauga | By: Ornge Media



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Temperature Monitoring Troubleshooting

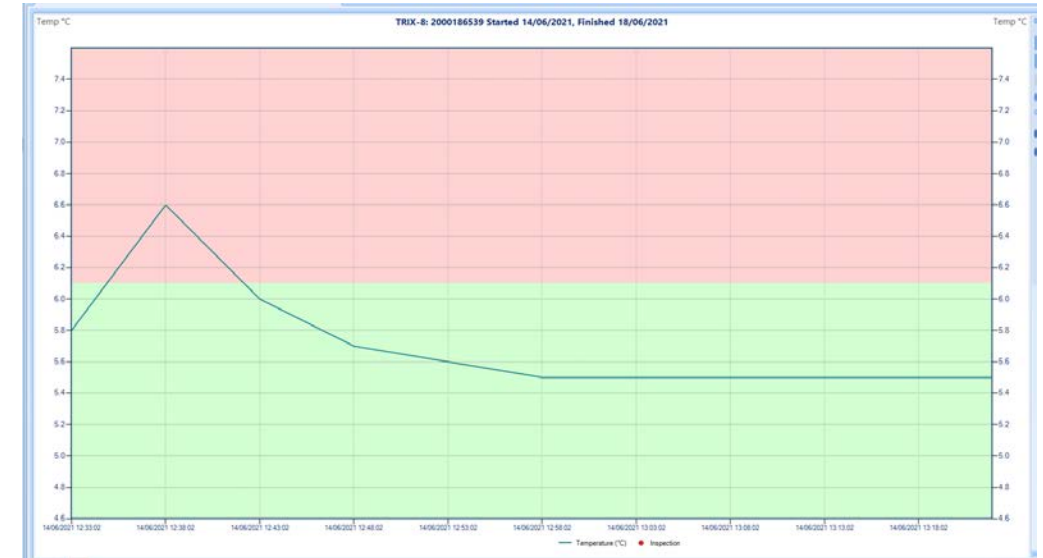
PROBLEM:

HIGH temperature alarm triggered during validation.

Triggered during/shortly after cooler packaging, and recorded data indicated that the recorder and internal of the cooler require some time to cool down.

SOLUTION:

Temperature recorders stored in fridge and adjusted to begin recording after 15 minute delay.



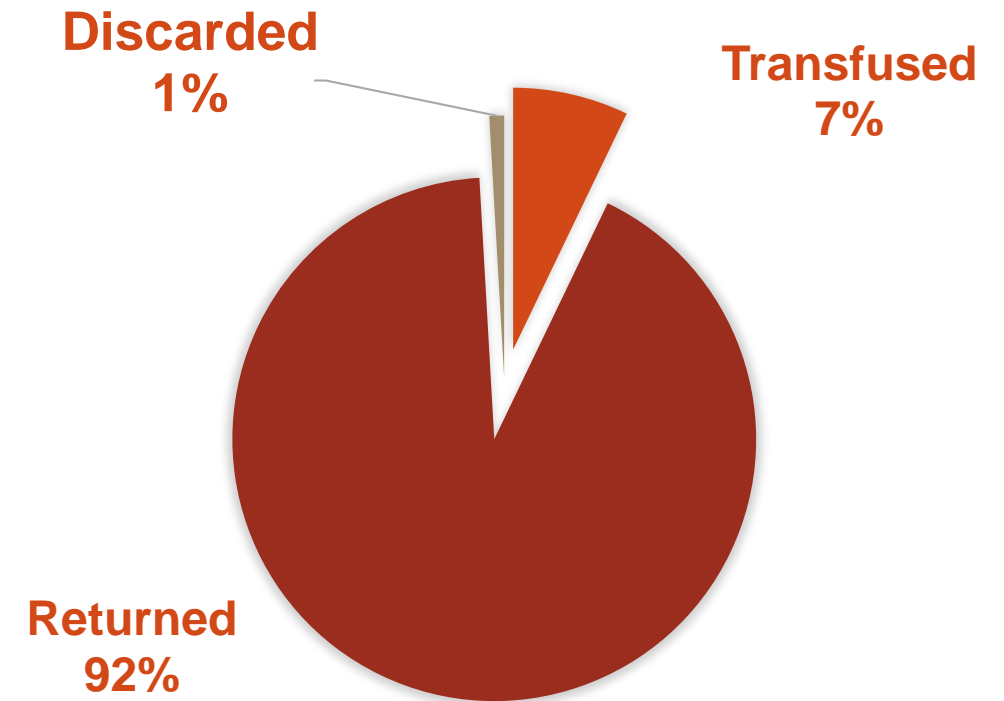
PROBLEM: After program launch, still had some temperature alarms triggered after the 15 minute delay.

SOLUTION:

Increased recording delay to 30 minutes.

Data – Since Program Launch

Metric	Launch To date (August 31, 2021 to July 22, 2022)	Monthly Average
# of Units Transfused	63	5.7
# of Units Discarded	10	0.9
# of Deviations	23	2.1
# of Transfusion Reactions	0	0



Data

Reporting and audit process

- Daily report on utilization
- 100% clinical audit for 3 months
- Monthly Blood transfusion notification

Monthly reconciliation process

- 100% reconciliation of Sunnybrook TMTB unit numbers with Ornge Charts

Monthly recipient notification process

Data reporting and metrics (Sept-Dec 2021)

- 14 cases
 - 2 Interfacility – Medical
 - Transfusion delay minutes saved* 20 minutes
 - 12 Trauma
 - 4 Direct from scene
 - Time to transfusion 11-36 minutes
 - Transport Time 53-77 minutes
 - 8 modified
 - Transfusion delay minutes saved* 25 - 55 minutes
- Final Status
 - 5 better
 - 7 no change
 - 2 worse

* Time from unit administration to Ornge Transfer of Care

Expansion to other sites



Thank you to the Teams!



Thank you to the members of the Prehospital Transport Programs in Vancouver (BCEHS), Edmonton/Calgary/Saskatoon/Winnipeg (STARS) for their support.



Questions?