

Document Control

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1. Background

- 1.1. Red blood cell components must be stored at 4 °C +/- 2 °C in a certified blood bank refrigerator which is compliant with BS4367: Part 1:1991. Northern Devon Healthcare Trust has employed the use of Labcold Blood Bank refrigerators which are UK manufactured and are compliant with ISO quality management specifications. Labcold devices are all registered in accordance with Directive 93/42/EEC and BS4367: Part 1:1991 compliant.
- 1.2. Every blood bank refrigerator is fitted with a temperature recorder and an audible alarm. Northern Devon Healthcare Trust has 4 monitored refrigerators distributed at community hospitals for transfusion purposes. Community blood bank refrigerators are suitably positioned and should be manned 24/7 to ensure that alarms are heard and acted upon. The community hospitals which do not operate overnight or at weekends must have an external alarm system in place to allow 24/7 monitoring.
- 1.3. Each community hospitals should employ a system which allows full blood traceability of blood components whilst maintaining the integrity of the cold chain which is a requirement set by the BSQR 2005 Part 4.

2. Purpose

- 2.1. Management of the community blood banks is the responsibility of Northern Devon Healthcare (NDHT) NHS Trust. This document sets out the Trust's procedures for management of these blood banks and safe storage of blood products in accordance with requirements detailed below.
- 2.2. The storage conditions for blood and blood products are defined by NHS Blood and Transplant (NHSBT) to ensure the safety of all blood products for transfusion. They are laid out in the Guidelines for the Blood Transfusion Services in the UK (2013 red book) and have been adopted by the NDHT.
- 2.3. The Blood Safety and Quality Regulations (BSQR) (2005) is the legislation which governs adherence to NHSBT guidelines on blood product storage. The Medicines and Healthcare Regulatory Agency (MHRA) is the body which checks and enforces the requirements of these regulations across any site used for blood/product storage and ultimate transfusion. They require evidence that the "cold chain" has been maintained i.e. that we can prove that blood and products have been stored correctly.
- 2.4. The cold chain involves vein to vein traceability i.e. we have to be able to account for every minute of a blood product's 'life' from donor to recipient or disposal.

- 2.5. Any red blood cell component out of temperature control for >30 minutes should be reported to the transfusion laboratory immediately and not transfused. The laboratory will provide further actions to be taken by the community hospitals.
- 2.6. Failure to comply with this Policy, findings found at audit, or non-return of documentation to NDHT transfusion will result in suspension of blood supply to the community hospital. Suspension will remain until appropriate remedial action has been carried out which will be established by the transfusion laboratory. The laboratory will notify the hospital of this and also when supplies will be resumed, by telephone and confirmation by email. A form will also be issued (T-FORM-14) to the hospital showing the necessary information for the hospital's blood bank records.

3. Scope

- 3.1. The recording and documentation of community blood fridges should be carried out by designated community personnel whom have read and understood Management of Community Blood Banks policy, and completed the competency assessment on BOB; [Management of Blood Fridge \(Community Based\)](#). The community hospitals being supplied with blood components must ensure that all documents stated in section 6 are sent back to the transfusion Department promptly.
- 3.2. The Transfusion laboratory is responsible for ensuring all paper work and charts are received back from the community hospitals and that any discrepancies have been investigated and rectified. All documentation is stored on the G: DRIVE for a minimum of 15 years for traceability.
- 3.3. Red blood cell components are to be kept at 4°C (+/- 2°C) as stated by the BSQR 2005 requirements Part4. Any donation not within a controlled temperature state exceeding 30 minutes will be discarded by Transfusion laboratory staff. The use of the documents stated in Section 6 help to provide safety measures for blood components by ensuring full traceability of components sent to community sites.
- 3.4. Labcold refrigerators are calibrated annually or after major repair or prolonged outage; certification is uploaded onto the Q-Pulse quality management system.
- 3.5. All Labcold refrigerators are annually temperature mapped by ARENA, mapping will also be carried out follow major repair or prolonged outage, certification is uploaded onto the Q-Pulse management system.

4. Location

- 4.1. This Policy can be implemented in all Community Blood Bank areas where competent staffs are available to undertake this role.
- 4.2. Transfusion Champions have been identified for each community hospital. They will be responsible for cascading the training to staff for each community site.
- 4.3. Completed competencies/Sign Off sheets ([T-RECORD SHEET-33](#)) should be copied, 1 should be forwarded onto the blood transfusion manager at NDHT with another copy kept with the Community blood bank folder.
- 4.4. Please contact the laboratory on 01271 322327 for further information.

5. Equipment

- 5.1. Shipment container: Helpet Clinimed container with ≤ 3 hour validation for storage of blood components/ Small Grey NHSBT for short journeys ≤ 7 hour validation.

5.2. LABCOLD REFRIGERATORS

Holsworthy community hospital: T-ASSET-8 Serial number: 8C0247

South Molton community hospital: T-ASSET-7 Serial number 8C0248

Tyrrell community hospital: T-ASSET-6 Serial number: 8C0249

Torrington community hospital: T-ASSET-50 Serial number: G022567

NOTE: NDHT only provide blood for and are only responsible for the blood fridges stated above.

5.3. EQUIPMENT REQUIRED BY COMMUNITY HOSPITALS

4 spare charts (order code WGB817LC)

2 pen nibs (order code FDI282LC)

4 Maintenance checklist (available on BOB)

4 Blood Fridge Fault/Error Log (available on BOB)

4 Blood fridge alarm log (available on BOB)

4 blood movement log (available on BOB)

2 spare batteries (size AA) for the chart recorder

6. Procedure

6.1. RECEIPT OF BLOOD FROM NDHT

6.1.1 In order to receipt blood dispatched from NDHT ensure that the relevant paper work (T-FORM-1) has been correctly completed by laboratory staff, and that the plastic zip tie has remained intact during delivery.

6.1.2 Deliveries of red blood cell components are restricted to a 3 hour limitation from time packaged to time stored. If the time from package has exceeded the time limitation contact the transfusion laboratory immediately for guidance and further instructions.

6.1.3 Complete [T-RECORD SHEET-74](#) Blood movement log; ensure all relevant sections are completed to prevent breach of the “cold chain”.

6.2. RETURN OF BLOOD FROM COMMUNITY HOSPITALS

6.2.1 If blood is to be returned to NDHT it must be packed back into the validated Helpet clinimed/Small grey NHSBT box in which it was delivered in.

6.2.2 The blood must be packed into the validated Helpet clinimed box using pre-cooled cool packs (stored at 4 degrees for a minimum of 24 hours). All dead air space must be filled before sealing the box with a plastic zip tie. Holsworthy must pack blood in the provided grey NHSBT container.

6.2.3 The relevant paper work (T-FORM-1) must accompany the components being sent back so the transfusion laboratory can complete the cold chain.

NOTE: Failure to follow these set procedures in their entirety can result in immediate and indefinite suspension of blood supply to the hospital.

6.3. INTERNAL AND EXTERNAL MAINTENANCE OF COMMUNITY BLOOD REFRIGERATORS

INTERNAL DAILY MAINTENANCE

6.3.1 Each community hospital is provided with a daily maintenance checklist ([T- RECORD SHEET-24](#)) which must be completed on a daily basis.

- 6.3.2** The air temperature is digitally displayed on the front of the refrigerator and runs between 2-8 degrees. Deviations may occur if the door is left open for a prolonged period of time. Ensure refrigerator door is closed promptly after use.
- 6.3.3** The load temperature is also digitally displayed and should reflect the same reading obtained from the chart (+/-1 degree). The load temperature mimics the expected temperature of blood components this again should run a 4 degrees (+/-2).
- 6.3.4** The temperature trace recorded on the chart must also be documented and it should reflect real time readings. Document the day/time and temperature of the trace.
- NOTE: If there are any deviations noticed on the trace, digital load temperature or air temperature then please report to the transfusion department and complete the anomaly record [I-RECORD SHEET-42](#). Give detail on the anomaly if known.**
- 6.3.5** Check that the trace pen is working on the chart recorder. Replace nib if the trace is not present or faint. Clear trace records are an essential requirement for cold chain compliance. Spare nibs should be available on site, for replacements please contact the transfusion department if unable to obtain one.
- 6.3.6** Expiration dates on all stored blood components must be checked daily. Any components exceeding expiry or due to expiry before transfusion, then the transfusion team must be immediately informed. Also check the fridge has not been used for the storage of other non-blood components other than cool packs. Any non-blood products must be immediately removed and reported to the transfusion laboratory.
- 6.3.7** For more information regarding maintenance procedures please refer to Labcold Medical device Instruction manual for additional advice on alarms.

INTERNAL WEEKLY MAINTENANCE

- 6.3.8** Perform weekly fridge alarm by gently holding the touchscreen telephone alarm icon on the fridge which is demonstrated below.



NOTE: Please note that the screens on the fridges are fragile and work by detecting the temperature of your finger. To operate these screens touch them gently and await a response.

6.3.9 Once the alarm sounds an independent alarm company is informed: EMCS service for Challenge alarms Barnstaple. Alarm activation sends an automatic report to the alarm receiving centre, detailing time, location and type of alarm activated. EMCS phone NDHT switch board who then alert the Transfusion laboratory

6.3.10 South Molton community hospital is manned 24/7 meaning an external source is not required for alarm testing purposes.

NOTE: If the fridge is in an unknown alarm state (not testing) indicating fridge failure, then the blood within must be set up within a 30 minute time frame. If this is not possible please inform the transfusion laboratory immediately and await instructions. Complete [T-RECORD SHEET-42](#).

6.3.11 The fridge chart runs over a 7 day period and needs to be replaced weekly. When replacing ensure that the current date and corresponding hospital is detailed appropriately and eligibly onto the chart. [\\Nds.internal\public\PATHOLOGY\Transfusion Team\HTT\2020\May 2020\T-RECORD SHEET-24 v 9 CBB \(1\).doc](#) Ensure that the chart being removed also has the appropriate date and hospital transcribed onto it; the chart should also be signed and dated upon removal to show that it has been checked for discrepancies. Ensure signature and date does not cover the trace. The chart should then be attached to [T-RECORD SHEET-24](#) which is sent back to the laboratory to allow complete traceability of the cold chain.

NOTE: If, for any reason, the check sheet didn't get filled in or there are problems with the chart recorder or trace, ensure the reasons for this are clearly marked on the fault sheet ([T-RECORD SHEET-42](#)) and ensure that NDHT Transfusion is notified immediately. A copy of the fault sheet must be returned with the chart/checklist to NDHT.

6.3.12 Check fridge interior is clean and dry. Ensure nothing has leaked in the fridge and there is no condensation or water in the fridge. If there is, dry it up and report to the responsible person at the community site. Check the overall condition of the fridge including the fit of the door seal and the state of cleanliness. If necessary, clean the fridge with warm soapy water.

6.3.13 For more information regarding maintenance procedures please refer to Labcold Medical device Instruction manual for additional advice on alarms.

6.4 EXTERNAL MAINTENANCE

SERVICING

6.4.1 All NDHT blood fridges are under maintenance contracts with Labcold which is performed annually. The transfusion laboratory will inform the community hospitals when inspections are due.

CALIBRATION

6.4.2 All NDHT blood fridges require annual calibration which is part of the Labcold maintenance contract. Which again is arranged by NDHT, and community hospitals will be informed about the proposed date of calibration.

NOTE: Please ensure that you send copies of ALL engineer reports, calibrations etc. to NDHT Transfusion using the address labels provided.

TEMPERATURE MAPPING

6.4.3 Temperature mapping is a procedure used to check that the blood fridges are being maintained at the correct temperature through-out the whole unit. The load temperature that is being constantly measured only corresponds to one set point in the unit. Mapping measures 3-5 points evenly distributed through-out the unit for a period of 24-48 hours. This procedure is carried out by an external company ARENA who will provide evidence of mapping to NDHT.

6.5 HOW TO ACTION AN ALARM EVENT

- 6.5.1** If the alarm sounds, check the equipment for obvious faults e.g. the door has been left open or the unit has been disconnected. If there is no obvious cause for the alarm then inform a senior member of staff who will contact the Transfusion Laboratory to arrange for an engineer to visit.
- 6.5.2** When the alarm sounds you must complete the log to record the event ([T-RECORD SHEET-41](#)) and send a copy of the sheet to NDHT Transfusion Laboratory immediately.
- 6.5.3** Before and following repair of the equipment the laboratory must be informed, and any paperwork copied to it. The transfusion manager will then arrange to have the equipment mapped where relevant.
- 6.5.4** Please refer to Labcold Medical device Instruction manual for additional advice on alarms.

6.6 NDHT RECEIPT OF PAPERWORK

- 6.6.1** The Transfusion laboratory staff at NDHT are required to check and file the paperwork returned from the community hospitals.
- 6.6.2** Upon receipt of check lists and recorder charts, Laboratory staff should check that the sheets are fully completed and that the charts match the information given. Each Sheet has a sign off section for laboratory staff to complete or investigate if sections are not completed. Any sections that have not been fulfilled may require a non-conformance and blood suspension may be enforced
- 6.6.3** It is a BSQR requirement to retain documentation of the cold chain for Blood components. Traceability must be available for a minimum of 15 years as stated by Guidelines for the Blood Transfusion Serviced in the United Kingdom (2013 red book). The transfusion laboratory scans all returned documentation from community hospitals and retains them for a minimum of 15 years on the internal G: DRIVE.

7. References

BSQR 2005 Requirements

ISO 15189:2012 section 5.3

JPAC: Understanding the “Cold Chain” requirements

UKBTS/NIBSC Professional Advisory Committee- Deviations from .4C temperature storage for red cells: effect on viability and bacterial growth, February 2005

CC/5434 – Temperature evaluation of short journey transport containers/extended journey times using additional phase change material.

8. Associated Documentation

[T-RECORD SHEET-24](#): Community Blood Bank Daily Checklist

T-RECORD SHEET-32: Community Blood Bank File Front Cover

[T-RECORD SHEET-33](#): Community Blood Bank Policy sign off

[T-RECORD SHEET-41](#): Blood fridge alarm log

[T-RECORD SHEET-74](#): Blood movement log

[T-RECORD SHEET-42](#): Blood Fridge Fault/Error Log

T-FORM-1: Community Blood Transfer

T-FORM-14: Suspension of blood supply form.

[Assessment of Competency: Management of Blood fridge](#)

Labcold Medical Device Instruction manual: Located and kept with corresponding unit.

Appendix 1 T-RECORD SHEET-33

SOP Sign-Off Sheet

The undersigned staff confirm that they have read and are conversant with the contents of the Policy '**Management of Community Blood Banks**' and the rationale behind it.

Name of Hospital.....

Name	Position	Sign and Date

Please forward a copy of this sheet to NDDH Transfusion when completed.

Appendix 2 T-RECORD SHEET-74

Blood Movement log

Name of Hospital:

BLOOD INTO FRIDGE						BLOOD OUT OF FRIDGE				ADMINISTRATION		
DATE	TIME	PATIENT'S NAME	NHS/HOSPITAL NUMBER	UNIT NUMBER	SIGNED	DATE	TIME	SIGNED	FATE OF UNIT ¹	START TIME	STOP TIME	PINK SLIP COMPLETED ²

1. Fate of unit: Transfused / Returned to Transfusion Lab (give reason).
2. Pink slip completed applies to hospitals supplied by NDDH only.

****PLEASE PHOTOCOPY THIS SHEET AND RETURN TO RELEVANT TRANSFUSION LABORATORY AFTER EACH TRANSFUSION EPISODE****

Laboratory BMS/MLA check of blood movement log
 Sign: _____ Date: _____

Appendix 3 T-RECORD 24

Name of Hospital:		Equipment Name:					
Daily tasks (performed by day staff please)	Date						
	Time						
Record Air Temperature							
Record Load Temperature							
Record actual day and time chart is set to (do not tick box)							
Record chart temperature							
Check pen is working, if not replace nib							
If blood components are in the storage unit, check it's within expiry date							
Check there are no non blood products in storage unit							
Check Agitator is working (If applicable)							
Signature							

WEEKLY TASK	Yes/No	DATE/TIME	SIGNATURE
Check the alarm (and remote alarm where applicable) use the appropriate procedure for storage unit, ensure alarm sounds			
Write date and name of hospital on new circular record chart			
Replace chart (sign and date old chart) taking care to set correctly. Ensure the chart is placed squarely over the shaft before replacing the screw.			
Check the door seals and check to see if the interior is clean and dry; if not clean with warm soapy water, report any excess water			
Attach the previous circular record chart to this record sheet			
MONTHLY TASK: Clean internal/external surfaces using alcohol wipes and/or neutral detergent			

Blood Fridge: Air temperature range is 2-8°C. Load temperature should be 4°C +/- 2°C

IN ORDER TO COMPLY WITH MHRA REQUIREMENTS AND E.U. LAW YOU MUST, PLEASE:

Report any problems and faults to NDDH Transfusion laboratory on 01271 322327 immediately
Send copies of any service/repair/calibration paperwork to the NDDH Transfusion laboratory as soon as possible.
Return this sheet, fully completed, and the previous week's chart immediately each week.

Laboratory manager check of maintenance log:

Appendix 4 T-RECORD SHEET- 42

Location of blood fridge:

Please return a copy of this sheet to NDDH Transfusion Laboratory with the chart/check sheet in question

DATE	TIME	PROBLEM / ISSUE e.g. gap in chart graph	REASON e.g. chart reset following battery change	NDDH LAB INFORMED Write name of person you spoke to and date/time	SIGNED Please sign legibly

Laboratory BMS/MLA check of blood movement log Sign:

Date:

Appendix 5 T-RECORD SHEET-41

Fridge Location.....

DATE / TIME	REMOTE ALARM TRIGGERED Y/N	CAUSE IF KNOWN <small>e.g. door left open</small>	ACTION TAKEN <small>e.g. engineer visit requested</small>	NDDH LAB INFORMED <small>Write name of person you spoke to, date and time</small>	SIGNED <small>Please sign legibly</small>

Appendix 6 Assessment of Competency

Competency: Management of Blood Fridge (Community Based)

Competency Statement:

The member of staff has been observed as competent in the task of managing a blood fridge on the date(s) recorded below.

Underpinning Knowledge:

The staff member must be able to demonstrate supporting knowledge and understanding of the maintenance and management of a blood bank fridge and the relevant legislation and procedures associated.

Underpinning knowledge and relevant legislation	Date and Assessor's signature
Understands the relevance of the Blood Safety and Quality Regulation (2005)	
Can demonstrate knowledge of MHRA requirements for the blood components	
Understands the importance of maintaining the Cold chain with regards to red cell storage for transfusion purposes.	
Understands the need to complete the blood Movement log for each unit of red cells.	

Policies and Procedures:

All staff members must have read the relevant SOP provided by the blood transfusion department and watched the training videos supplied on BOB before carrying out any tasks involved with using the blood bank fridges for transfusion purposes.

Policies and Procedures	Date and Assessor's signature
Has read and understood T-SOP-68 "Management of Community Blood Banks"	
Has watched the training Video on BOB "How to change a chart"	
Has watched the training Video on BOB "How to change the battery of the chart recorder"	