Title: **COMMUNITY BLOOD STORAGE REFRIGERATORS**

Ref No: 1982
Version 3
Classification: Standard Operating Procedure

Directorate: Community

Due for Review: 15-06-2021
Document Control

Responsible for review: Blood Bank Section Leader
Transfusion Practitioner

Ratified by: Patient Blood Management Group

Applicability: As indicated below

## Contents



## 1 Purpose

This policy aims to standardise the procedures across the community hospital sites ensuring that the blood storage refrigerators are monitored and maintained in accordance with The Blood Safety and Quality Regulations that became effective in the United Kingdom in November 2005.

## 2 Introduction

The Blood Safety and Quality Regulations became effective in the United Kingdom in November 2005.

These regulations implement 2 European Directives;

- 2002/98/C standards for quality and safety for collection, testing, processing, storage and distribution of blood and blood components
- 2004/33/EC technical requirements for blood and blood components

Later, 2 further directives were added and adopted by the European Commission

- 2005/61/EC traceability and notification of serious adverse events and reactions
- 2005/62/EC community standards and specifications leading to a quality system for blood establishments

These were then transposed into UK legislation 31 August 2006 and compliance is regulated by the MHRA.

The Blood Safety and Quality Regulations also apply to all Blood Facilities, i.e.; hospitals that receive blood from a hospital blood bank for transfusion purposes, but do not do any of the compatibility testing on site. All Blood Facilities must be able to demonstrate compliance with

regard to Cold Chain and controlled monitoring, maintenance and calibration of any controlled temperature storage equipment, e.g.: Blood Refrigerator.
Red cell components must at all times be stored in a refrigerator capable of maintaining component core temperature 4ºC +/- 2ºC. Storage temperatures must be monitored continuously and a permanent record produced. An alarm system giving warning of temperature deviations and mains failure and must provide a signal at a continuously staffed site. The alarm for mains failure and temperature deviation should be tested at least once a week during routine working hours and recorded. All staff must be trained in the procedure of testing the alarms and dealing with alarms, should an alarm occur. Daily checks must be performed and documented. All temperature records must be kept for at least 30 years. The temperature monitoring system utilises one sensor to measure the air temperature surrounding the red cell units, and a second that is connected to a temperature chart recorder give a continuous paper record.

## 3 Roles & Responsibilities

The Matron/Ward Manager within the ward/hospital has responsibility for ensuring this procedure is carried out, in authorizing, reporting and monitoring reports.
The procedure can be performed by those members of staff that have up to date training in the procedures associated with Blood Storage Refrigerator Temperature monitoring. Members of staff are allocated responsibility, and given training by the appropriate Community Hospital Blood Champion, Transfusion Practitioner or Blood Bank Section Leader

## 4 Main body of the document

**Required Reagents** (including storage/stability and preparation)

- Detergent - Store at room temperature. Used in dilution as per manufacture recommendations
- Alcohol Wipes.
- Disinfectant Wipes

**Required Equipment**

- Blood Storage Refrigerator
- Keys to Temperature Recorder Charts
- Temperature Recorder Charts
- Temperature Recorder Chart File
- Temperature Monitoring Record Folder

**Calibration Procedure** (Metrological traceability)
Calibration performed annually by ABB/Arena/LabCold. All equipment and probes must have a valid UKAS traceable calibration and be marked accordingly. The overall uncertainty of a temperature measurement point should be <+/-0.5C

**Daily Inspection and Cleaning**
Ensure that the correct and current version of the Temperature Monitoring Log is used each month.
Complete each log with the relevant Blood Fridge details;

- Hospital Location
- Month/Year
- Blood Fridge Model Code
- Blood Fridge Serial Number

1. Examine recorder chart to ensure that the temperature has not exceeded the limits 2°C – 6°C. Tick on the appropriate day if the reading falls within range.

2. If the chart is recording temperature out of range then inform the Biomedical Scientist (BMS) in charge of Transfusion Medicine; 01803 655241 immediately.
3. Confirm that the digital reading is between the limits 2°C – 6°C and record this value on the record sheet. Record both Load and Air temperatures if appropriate. If the Blood Fridge does not display Load temperature then place N/A in Load temperature column.
4. If either temperature is recorded out of this range, then inform the BMS in charge of Transfusion Medicine; 01803 655241 immediately.
5. Confirm that the reading on the recording chart agrees with that of the displayed digital reading.
6. Report any difference of more than 1°C between the chart and the display to the BMS in charge of Transfusion Medicine; 01803 655241 immediately.
7. Check the fridge for unused red cells. If crossmatched blood is found in the fridge and is no longer required, contact the Transfusion Department as soon as possible so that collection using an audited Coolbox can be arranged.
8. Perform an exterior fridge clean. Using disinfectant wipes or alcohol wipes, wipe the outside of the fridge. Sign the log to confirm the process.
9. Ensure that the log is complete every day.
10. Notify a senior member of staff if there are concerns over the temperature or check list cannot be signed off. A Trust Incident form must also be completed if any of the tasks cannot be signed as valid or complete

**Weekly Inspection and Cleaning**

1. Select the correct replacement temperature chart
2. Carefully change the 7-day temperature recorder chart and record the change on the record sheet. Ensure that the pen touches the chart at the correct position for time and date.
3. Label each new chart with hospital, serial number of fridge, date and initials of person changing the chart.
4. Check the existing chart and inform a senior member of staff or the Transfusion Department of any discrepancies with the chart.
5. Sign the log to confirm chart change.
6. The alarm must also be tested on a weekly basis.
7. The alarm test procedure may differ slightly dependent on the age of the blood fridge.
8. Press the test button on the panel where the temperature is displayed. The fridge will run through a series of self-alarm checks. If there is a failure, the fridge will alarm at the end.
9. Some fridges will have ‘Test’ button. Some fridges will have ‘Alarm test’ button. Some fridges will have an LCD display, place finger on the telephone icon and hold, all alarm icons will appear and alarm will sound. Release finger after alarm testing complete.
10. The mains failure alarm must also be tested. Switch the fridge off at the mains. The fridge should alarm within 2 minutes locally, and dependent on each hospital remotely also. The remote alarm is generally set to alert after a further 8 minutes. Do not mute local alarm; allow alarm to continue until remote alarm is heard.
11. Confirm that these alarms are heard at the remote site also, if the fridge is located somewhere which is not manned 24 hours a day, 7 days a week.
12. All alarm testing should then be recorded on the log and signed.
13. Switch the fridge back on. This should allow the alert status on the fridge to cease and alarm stop sounding. At this point the remote alarm may need resetting, if it already hasn’t, dependent on the type of alarm system each hospital has. Most will require pressing the reset button to turn alarm off and reset the status. If there is an issue with resetting the remote alarm, press the telephone icon again on the fridge (or Test button) which will allow complete reset of all the alarm relays, then depress the remote alarm button again to reset.
14. Sign the weekly maintenance log to confirm alarm checks have been performed.
15. Any alarm problems then bring to the attention of a staff member at the Transfusion Department.

16. A thorough clean of the door seals is also required on a weekly basis. Using disinfectant wipes or alcohol wipes, clean the door seal of the blood fridge. Check to see if there are any faults or rips and report to a senior member of staff. Once clean, sign the maintenance log to confirm

**Monthly Cleaning**

1. The blood fridge should be cleaned every month.
2. Should the fridge appear dirty on daily inspection, then decontaminate at that point. Do not wait for the next for the scheduled clean.
3. Alcohol wipes or detergent wipes maybe used on the interior of the fridge, ensuring any residue left is also wiped with dry tissue.
4. This process should also be documented on the log sheet.

**Variations**

**Biological reference intervals or Clinical decision values**

- On inspection of the digital display and the recording chart, there may be a deviation of +/-1$^{o}$C
- Any greater deviation, inform the Transfusion Department and complete a Trust Incident form

**Potential sources of variation**

- Ambient temperature at each hospital, where the fridges are sited will affect the running of the fridge
- Fridge age

**Reporting**

**Reportable interval of examination results**

- Temperature recording charts and log must be returned to the Transfusion Manager on a monthly basis.
- It is vitally important that the log is complete and all tasks are performed when due.

**Alert / Critical values (where appropriate)**

Contact the Transfusion Department immediately when;

- Chart is not within limits
- Digital display is out of range
- Temperature deviation between chart and recorder is more than 1$^{o}$C
- An alarm is sounded. All alarm triggers require logging and corrective action documenting

**In the event of an alarm sounding, take immediate action**

1. Try to ascertain what is causing the alarm trigger and correct if possible (this maybe door left open or loss of power for instance)
2. Contact duty engineer if resolution not possible.
3. Contact BMS staff at the Torbay Transfusion Department on 01803 655241 (internal 55241) or ask switchboard to bleep duty BMS (219) if out of hours.
4. Check to see if Red Cells are in storage and inform BMS.
5. Both the BMS in the Transfusion Department and the staff member informing of the alert should log the incident and any corrective action taken.

## 5 Training and Supervision

Members of staff are allocated responsibility, and given training by the appropriate Community Hospital Blood Champion, Transfusion Practitioner or Blood Bank Section Leader

Local records of training must be maintained as per the individual hospital's policies
Records of training must also be communicated to the Blood Bank Section Leader and Transfusion Practitioner; these will be recorded along with all other transfusion education and competency assessments by the Hospital Transfusion Team.
The training database will be made available to Community Matrons and Associate Director of Nursing on a regular basis and on request

## 6 Monitoring, Auditing, Reviewing & Evaluation

On a monthly basis, a horizontal audit based on all returned Cold Chain documentation is performed by the Blood Transfusion Section Leader. The purpose of this is to monitor and record Cold Chain compliance.
Every two years, a vertical audit will also be performed by the Blood Transfusion Section Leader. The purpose of which is to confirm all relevant documentation with regard to refrigerator maintenance and training records are being maintained in accordance with the Blood Quality and Safety Regulations. Reports are distributed to key members of staff on regular occasions.

## 7. References

7.1 The Blood Safety and Quality Regulations 2005
7.2 http://www.transfusionguidelines.org.uk/regulations
7.3 http://www.mhra.gov.uk/Howweregulate/Blood/
7.4 HSC 2007/001 Better Blood Transfusion – Safe and Appropriate Use of Blood

## 8. Equality and Diversity Exceptions

8.1 This document complies with Torbay and South Devon NHS Foundation Trust Equality and Diversity Statements

**Equality and Diversity Exeptions**

Refer to the submitted EIA form

## 9. Distribution

All community hospitals with blood refrigerators via the Trust intranet

## 10 Further Information

Links to policies 0219 Blood Transfusion Policy

Best practice information

Forms/Recording Documentation – Appendix 2

## 11 Appendices

Appendix 1 - Hazards associated with this policy
Appendix 2 - Temperature Monitoring Chart

**Appendix 1**

Hazards associated with this policy

| **PROCEDURE: Community Blood Storage Refrigerators** | | | | | |
|---|---|---|---|---|---|
| **HAZARD** | **Severity (A) 1 - 5** | **Likelihood (B) 1-5** | **Risk Rating AxB** | **PRECAUTIONS** | **DISPOSAL** |
| **Biological Hazards**<br>**Blood** | **4** | **1** | **4** | **Good distribution practice** | **Wasted or fated blood units must be discarded as per hospital policy** |
| **Physical Hazards** | | | | | |
| **Chemical Hazards**<br>**Disinfectant**<br><br>**Alcohol Wipes**<br>**Disinfectant Wipes** | **1**<br><br>**2**<br>**2** | **2**<br><br>**2**<br>**1** | **2**<br><br>**4**<br>**2** | **Care not to splash. Wear gloves and goggles.**<br>**Wear gloves and goggles.**<br>**Not classified as harmful by ingestions, skin contact or inhalation** | **Dispose as per local procedure** |
| **Severity rating:**<br>1. Insignificant<br>2. Low<br>3. Moderate<br>4. High<br>5. Fatal | | **Likelihood rating:**<br>1. Rare<br>2. Unlikely<br>3. Likely<br>4. Probable<br>5. Everyday occurrence | | Risk rating score:<br>13 - 25 High<br>6 - 12 Medium<br>1- 5 Low risk | |

**Appendix 2** **Community Blood Bank Temperature Monitoring**

| Date | Temperature | | | | Check for unused blood | Exterior Fridge Clean / Initials |
|---|---|---|---|---|---|---|
| | Chart within Limits 2°C-6°C | Digital Display | | Initials | | |
| | | Temperature Range (Air) 2.5°C – 7.5°C | Temperature Range (Load) 2.5°C – 5.5°C | | | |
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| 31 | | | | | | |

**Hospital**

**Month/Year**

**Blood Fridge Model Code**

**Blood Fridge Serial Number**

**Blood Transfusion**

**Ext 55241**

**Bleep 219**

| Monthly Interior Fridge Clean | |
|---|---|
| Date | Performed by |
| | |

| Date | Weekly Maintenance | | Alarm Testing | | Performed by / Initials |
|---|---|---|---|---|---|
| | Clean Door Seals | Chart Change | Confirm Local Alarm | Confirm Remote Alarm | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**ACTION TRIGGERS:** Digital Displays out of temperature range
Chart not within limits
Temperature deviation between chart and load temperature more than 1°C

All action triggers have taking into account the measurement of uncertainty. These trigger ranges to be reviewed annually after calibration

## 11. Document Control Information

*This is a controlled document and should not be altered in any way without the express permission of the author or their representative.*

*Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.*

*If printed, this document is only valid for the day of printing.*

| | | | |
|---|---|---|---|
| **Ref No:** | 1982 | | |
| **Document title:** | Community Blood Storage Refrigerators | | |
| **Purpose of document:** | This policy aims to standardise the procedures across the community hospital sites ensuring that the blood storage refrigerators are monitored and maintained in accordance with The Blood Safety and Quality Regulations that became effective in the United Kingdom in November 2005 | | |
| **Date of issue:** | 15 June 2018 | **Next review date:** | 15 June 2021 |
| **Version:** | 3 | **Last review date:** | June 2018 |
| **Author:** | Blood Bank Section Leader & Transfusion Practitioner | | |
| **Directorate:** | Community | | |
| **Equality Impact:** | The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief | | |
| **Committee(s) approving the document:** | Care and Clinical Policies Group<br>Hospital Transfusion Team | | |
| **Date approved:** | 5 February 2016 | | |
| **Links or overlaps with other policies:** | All TSDFT Trust Strategies, policies and procedure documents | | |

| | *Please select* | |
|---|---|---|
| | *Yes* | *No* |
| **Have you considered using Equality Impact Assessment?** | ☒ | ☐ |
| **Does this document have implications regarding the Care Act?** *If yes please state:* | ☐ | ☒ |
| | | |
| **Does this document have training implications?** *If yes please state:* | ☒ | ☐ |
| | | |
| **Does this document have financial implications?** *If yes please state:* | ☐ | ☒ |
| | | |
| **Is this document a direct replacement for another?** *If yes please state which documents are being replaced:* | ☒ | ☐ |
| | | |

**Document Amendment History**

| Date | Version no. | Amendment summary | Ratified by: |
|---|---|---|---|
| 6 May 2016 | 1 | Uploaded to ICON | Care and Clinical Policies Group<br>Hospital Transfusion Team |
| 17 February 2017 | 2 | Amended layout | Transfusion Practitioner |
| 12 February 2018 | 2 | Review date extended | |
| 15 June 2018 | 3 | Amended | Patient Blood Management Group |

**12.**

## The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

**"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)**

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

## Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

**13.**

NHS South Devon and Torbay Clinical Commissioning Group  Torbay and South Devon NHS NHS Foundation Trust

## Rapid Equality Impact Assessment *(for use when writing policies and procedures)*

| | | | |
|---|---|---|---|
| **Policy Title** (and number) | ***Community Blood Storage Refrigerators*** | **Version and Date** | |
| **Policy Author** | Blood Bank Section Leader & Transfusion Practitioner | | |
| **Associated documents** (if applicable) | n/a | | |

| RELEVANCE: Does the aim/purpose of this policy relate to each of the aims of the Public Sector Equality Duty? | |
|---|---|
| · Eliminate unlawful discrimination or other conduct prohibited by the Equality Act 2010 | Yes ☐ No☒ |
| · Advance equalty of opportunity between people from different groups | Yes ☐ No☒ |
| · Foster good relations between people from different groups | Yes ☐ No☒ |

| **SIGNIFICANCE AND IMPACT:** Consider the nature and extent of the impact, not the number of people affected. | |
|---|---|
| Does the policy affect service users, employees or the wider community? (if no, proceed with sign off) | Yes ☒ No☐ |
| Does the policy affect service delivery or business processes? | Yes ☐ No☒ |
| Does the policy relate to an area with known inequalities (deprivation/unemployed/homeless)? | Yes ☐ No☒ |

**EQUALITY ANALYSIS:** How well do people from protected groups fare in relation to the general population?
***PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below***

**Is it likely that the policy/procedure could treat people from protected groups less favorably than the general population? (see below)**

| | | | | | |
|---|---|---|---|---|---|
| Age | Yes ☐ No☒ | Disability | Yes ☒ No☐ | Sexual Orientation | Yes ☐ No☒ |
| Race | Yes ☐ No☒ | Gender | Yes ☐ No☒ | Religion/Belief (non) | Yes ☐ No☒ |
| Gender Reassignment | Yes ☐ No☒ | Pregnancy/ Maternity | Yes ☐ No☒ | Marriage/ Civil Partnership | Yes ☐ No☒ |

| | |
|---|---|
| **Is it likely that the policy/procedure could affect particular 'Inclusion Health' groups less favorably than the general population?** (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees) | Yes ☐ No☒ |

**Please provide details for each protected group where you have indicated 'Yes'.**
Due to the nature of the tasks detailed in this policy persons with certain disabilities will not be a ble to perform the task. This task cannot be redesigned to enable these persons to be able to perform the task according to the policy.

**What if any, is the potential for interference with individual human rights?**
(consider the FREDA principles of Fairness/Respect/Equality/Dignity/Autonomy)

None

**RESEARCH AND CONSULTATION**

**What is the reason for writing this policy?** (What evidence/leglisation is there?)

It is a legal responsibility under the Blood Safety and Quality Regulations 2005 to ensure that all blood refrigerators are monitored and maintained as detailed in this policy

**Who was consulted when drafting this policy/procedure? What were the recommendations/suggestions?**

**ACTION PLAN:** Please list all actions identified to address any impacts

| Action | Person responsible | Completion date |
|---|---|---|
| | | |
| | | |

**AUTHORISATION:**
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them

| | | | |
|---|---|---|---|
| **Name of person completing the form** | Transfusion Practitioner | **Signature** | |
| **Validated by (line manager)** | Blood Bank Manager | **Signature** | |

**Clinical and Non-Clinical Policies – New Data Protection Regulation (NDPR)**

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU New Data Protection Regulation (NDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

NDPR intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy.

Furthermore, NDPR requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data. The most effective way of being open is through data mapping. Data mapping for NDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the NDPR.

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our GDPR page on ICON.