Title:	**RECEIPT AND RETURN OF BLOOD PRODUCTS IN COMMUNITY HOSPITALS**	Ref No: 2008 Version 2
		Classification: Policy
Directorate:	Community	
		Due for Review: 21-04-2020
Responsible for review:	Blood Bank Section Leader Transfusion Practitioner	Document Control
Ratified by:	Patient Blood Management Group	
Applicability:	All community sites receiving blood and blood components	

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1 Purpose

1.1 This policy aims to: ensure that blood and blood components that are transferred to community sites meet the requirements of the Blood Safety and Quality Regulations 2005 (amended).

1.2 Blood is often required to be transferred between Hospitals either with a patient or because the patient is located in a Community Hospital.

1.3 It is essential for legal reasons (Blood Safety and Quality Regulations 2005 (as amended)) to ensure the audit trail is maintained when blood is transferred and to ensure patient records are updated accordingly. The temperature control of blood components are strictly regulated and must be stored at precise temperatures. The Medicines and Healthcare Products Regulatory Agency (MHRA) have specific requirements which must be compiled with by blood transfusion laboratories. The quality assurance processes for ensuring correct temperature control/storage during transfer of blood between Hospitals must be maintained. The European Union Directive 2002/98/EC and the Blood Safety and Quality Regulation 2005 (BSQR) require adequate systems are in place to ensure traceability of blood and blood components. It is essential for laboratories to ensure that cold chain and traceability audit trails are maintained and records updated accordingly when blood is transferred between Hospitals. Transport boxes are validated to maintain cold storage for up to 4 hours, thus maintaining Cold Chain during transit.

2 Introduction

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

2.2 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

2.3 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

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

2.5 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 unambiguous evidence of the fate of all blood components issued by the Transfusion Department. To ensure that blood products are stored, transported and distributed in the correct manner and that the correct storage temperature is maintained at all times. The correct storage of blood components is essential to ensure patient safety. Adhere to requirements for full traceability of every blood product received onto the premises.

3 Roles and Responsibilities

3.1 The Matron/Ward Manager within the ward/hospital has responsibility for ensuring this procedure is carried out, in authorizing, reporting and monitoring reports.

3.2 The procedure can be performed by those members of staff that have up to date training in the procedures associated with blood component/product transport and storage. Members of staff are allocated responsibility, and given training by the appropriate Community Hospital Blood Champion or Transfusion Practitioner.

3.3 Courier drivers training will be provided by the Transport department.

4 Main body of the document

4.1 To ensure that blood and blood components that are transferred to community sites meet the requirements of the Blood Safety and Quality Regulations 2005 Clear detail of the content and scope of the document.

4.2 Blood Component Issue

The blood components or products are packed by the Blood Transfusion staff at Torbay Hospital and delivered by Hospital courier, or by a Taxi that has a contract with the Torbay and South Devon NHS Foundation Trust. Only transport boxes that have been validated by the Transfusion laboratory may be used for this process. These are referred to as ‘Blood Porter Boxes’’

- The Blood Porter Box is packed at Torbay Hospital Transfusion Department.
- The blood box will be packed by a member of laboratory staff, who will complete the 1st section of the transport log sheet – and place this in the front pocket of the Blood Porter box. The box will not be packed more than 15 minutes before collection.
- The courier will collect the BloodPorter box from the laboratory and will complete the 2nd section of the transport log sheet. The box will be collected no more than 15 minutes before the courier departure time from Torbay hospital. Boxes must be collected by the courier who will be transporting the blood. If boxes are then handed over to a different courier the handover must be logged on the transport log sheet.
- On arrival at the community hospital the courier will hand the Blood Porter box to a responsible person. This person will vary between the community hospitals; main reception, ward, porters or MIU. It is the responsibility of the individual courier to ensure that the relevant person receives the Blood Porter box. On arrival at the receiving Hospital, the member of staff receiving the Blood Porter box should ensure that the seal on the box is unbroken.

- Check to ensure that the transit time is less than four hours by checking the time the box was packed (on the transport log sheet in the front pocket of the Blood Porter box). If the time exceeds four hours immediately contact the Transfusion Medicine Department at Torbay Hospital who will arrange collection of the units and replacement if required.
- Complete the transfer documentation, entering time and date received and signing in the relevant places. Replace the transfer document in the clear pocket on the front of the box The person receiving the blood will either personally ensure that the box is unpacked immediately and the blood placed into the blood fridge, or hand it to a designated member of trained staff to action. For community hospitals with no blood fridge the blood components must remain in the Blood Porter box until transfusion commences.
- Before placing the units in the fridge, check each unit to ensure it is correctly labeled and that this correlates with the register slip.
- Check the unit integrity
- If Blood Storage fridges available scan each unit into the fridge using Blood Hound, then place in fridge.
- If no Blood Storage fridge available the transfusion can commence using Blood Hound, after these checks have been performed.
- Retain the register slip in a secure location
- Leave the Blood Porter box, with the coolpacks still inside , in a suitable area ready for the Hospital courier to pick up to return to Torbay.
- Do not retain the coolpacks. These must be returned with the Blood Porter box.

4.3 Blood Component Recall Internal Recall

4.3.1 **Quarantine.** On occasion, the laboratory may request that the units are placed into quarantine. At this point, these units must not be used for transfusion. They must be clearly labeled as 'Quarantined unit – for return to Torbay' and kept in the blood fridge until the laboratory arranges for a Blood Porter box to be delivered for the return of the units.

4.3.2 **Suspected Transfusion Reaction**. In the event of a suspected transfusion reaction, the blood transfusion laboratory must be contacted immediately. Complete the 'Investigation of a Transfusion Reaction form' and return this with the units, 1x 6ml pinked topped EDTA sample and 1x FBC sample to the blood transfusion laboratory. The laboratory will arrange for a Blood Porter box to be delivered in a timely manner for the return of ALL units; transfused or waiting to be transfused

4.3.3 **Failure of Cold Chain**. If it has been decided that the issued components have been subjected to unacceptable conditions during storage (i.e. fridge failure or transportation error) they should be returned to the blood transfusion laboratory. The blood transfusion laboratory must be contacted immediately to arrange transport for the return of the units. The blood should remain in the fridge with the door shut to preserve the temperature. Ensure that the units are labelled 'Quarantined unit – for return to Torbay' so that they are not used until investigated. If the units are proved to have been kept between 2oCand 6oC it may be possible to still use them.

4.4 Blood Component Recall External Recall

4.4.1 These will be instigated by the NHSBT via the blood transfusion laboratory. These could be due to

- The donation is considered to be a microbiological risk.
- The donation no longer meets the standard acceptance criteria
- Problems identified with donation testing
- Problems identified associated with manufacturing defects

4.4.2 The blood transfusion laboratory will initially be contacted by NHSBT; the laboratory will then contact the community Hospital by telephone.

4.4.3 If the unit(s) has not been transfused, the ward will be requested to quarantine the implicated unit(s)

4.4.4 An approved Taxi will be used for the timely return of the unit.

4.4.5 Complete the recall notice and send this back with the unit (Appendix 1)

4.5 Non urgent return of unused units

4.5.1 Blood that has not been transfused must be returned to the blood transfusion department at Torbay after 72 hours.

4.5.2 It is the responsibility of the ward based staff to inform the laboratory of the status of unused units.

4.5.3 Contact the blood transfusion laboratory to arrange the delivery of a blood porter box from Torbay. This has been validated to transport blood components for up four hours.

4.5.4 The blood should remain in the fridge until the fresh Blood Porter box arrives.

4.5.5 For those using Bloodhound, track the blood electronically into the Blood Porter box to return to Transfusion department. This process is identical to the standard fridge out process on the handheld device. On the final screen the drop down menu should be used to select 4 hour coolbox.

4.5.6 Place the unit(s) in the porter box and complete the relevant section of the transport log sheet

4.5.7 It is the responsibility of the Community Hospital to correctly package the returned units and then to arrange a taxi to return the blood back to the Transfusion Department.

4.5.8 The use of the dedicated couriers is not advisable due to ensuring the units will be returned within the stipulated four hours.

5 Training and Supervision

5.1 All those members of staff who handle blood products, who partake in any transfusion related task or have been allocated responsibility in this process, must maintain compliance with mandatory blood transfusion education requirements and be assessed and trained by the appropriate Community Hospital Blood Champion or Transfusion Practitioner.

5.2 Courier drivers employed by Torbay and South Devon NHS Foundation Trust and authorised taxi drivers must ensure that they have read and signed that they understand the relevant sections of the current handout

6. Monitoring and Auditing

The transport log sheets will be returned to the Blood Transfusion Laboratory, where they will be reviewed by the Blood Bank Section Leader. Clinical incidents will be generated on any non-conformancies.

7. References

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

8. Equality and Diversity

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

9. Further Information

9.1 0219 Blood Transfusion Policy

10. Appendices

Appendix 1 – Recall Notice Pro-forma

11. Document Control Information
12. Mental Capacity Act and Infection Control Statement
13. Rapid (E)quality Impact Assessment

Appendix 1

RECALL NOTICE PROFORMA

Hospital ……..

REASON FOR RECALL

TRANSFUSION REACTION INVESTIGATION ☐
NHS-BT RECALL ☐
FAILURE OF COLD CHAIN ☐

TRANSFUSION REACTION

Date and Time of phone call …… Name of requestor ……
Implicated Product type …… Implicated Unit Number ……..
Implicated Unit Expiry Date …… Crossmatch Date and Time ……
Implicated Unit Blood Group ……Patient Blood Group ……
Patient Hospital Number …… Patient Name ……
Date and Time unit/samples received ……..
Investigation form filled in correctly YES / NO Sample labelled correctly YES / NO
Recall all units from implicated crossmatch YES / NO Recall performed by ……

NHS-BT RECALL

Date and Time ward contacted …… Name of person contacted ……
Unit Number(s) Recalled ……
Unit Fate(s) ……
Reason for Recall ……
Untransfused units Quarantined YES / NO Cold Chain maintained YES / NO
Consultant Haematologist Informed YES / NO Head of Department informed YES / NO

FAILURE OF COLD CHAIN

Implicated Product(s) ……
Batch / Unit Number(s) ……
Date and Time of Recall …… Recall initiated by ……
Fate of implicated Products USED/TRANSFUSED ISSUED/FREE
Consultant Haematologist informed YES / NO Head of Department informed YES/NO
Reason for Cold Chain Failure
……
……

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:	2008		
Document title:	Receipt and Return of Blood Products in Community Hospitals		
Purpose of document:	This policy aims to: ensure that blood and blood components that are transferred to community sites meet the requirements of the Blood Safety and Quality Regulations 2005 (amended).		
Date of issue:	21 April 2017	**Next review date:**	21 April 2020
Version:	2	**Last review date:**	February 2017
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:	Patient Blood Management Group		
Date approved:	18 April 2017		
Links or overlaps with other policies:	All TSDFT Trust Strategies, policies and procedure documents 0219 – Blood Transfusion Policy		

	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:
4 February 2016	1	New	Hospital Transfusion Team
21 April 2017	2	Revised	Patient Blood Transfusion Group
12 February 2018	2	Review date extended from 2 years to 3 years	

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.

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)	*2008 Receipt and Return of Blood Products in Community Hospitals*	**Version and Date**	*Version 2 March 2017*
Policy Author	Transfusion Practitioner		

An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.

Who may be affected by this document?

Patients/ Service Users ☐	Staff ☒	Other, please state… ☐

Could the policy treat people from protected groups less favorably than the general population?
PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below

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

Is it likely that the policy 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'.	

VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion

Is inclusive language[5] used throughout?	Yes ☒ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?	Yes ☐ No☐ NA ☒
Does the policy encourage individualised and person-centered care?	Yes ☐ No☐ NA ☒
Could there be an adverse impact on an individual's independence or autonomy[7]?	Yes ☐ No☐ NA ☒

EXTERNAL FACTORS

Is the policy a result of national legislation which cannot be modified in any way?	Yes ☒ No☐

What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)

Who was consulted when drafting this policy?

Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups) ☐
Staff ☐	General Public ☐	Other, please state… ☐

What were the recommendations/suggestions?

Does this document require a service redesign or substantial amendments to an existing process? ***PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below***	Yes ☐ No☒

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)	Transfusion Practitioner	**Signature**	