

NHS BLOOD AND TRANSPLANT ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

Traceability of allogeneic blood when used in novel technologies to support organ donation and transplantation

Purpose

The purpose of this paper is to provide a proposal to the MHRA about how traceability of allogeneic blood can be maintained when used in novel technologies during organ retrieval.

Background

The approach to organ retrieval is evolving, especially in donors after cardiac death (DCD)

There is increased utilisation of normothermic regional perfusion (NRP) and ex situ preservation of organs donated for transplantation.

Some of these approaches require access to allogeneic blood to prime the circuit and perfuse the organ/s, during retrieval at the donor centre or during transport of the organ to the recipient centre.

To avoid any potential competing interests for donor blood when more than one of these technologies is used, a paper has recently been agreed by the National Organ Retrieval Service teams (NORS) detailing which technologies should use donor blood (autologous) and which should use allogeneic blood, based on organ priority (see appendix 1).

It is therefore important to have clear processes in place to ensure that any allogeneic blood products used in new perfusion technologies are appropriately traced to the donor, the organ, or the recipient.

This paper outlines a proposal for traceability of allogeneic blood that has been reviewed and agreed by NORS surgeons as being the most appropriate operational means of maintaining traceability.

Use of allogeneic blood – scenarios

Any allogeneic blood used in NRP of the donor during organ retrieval, or in any medical devices used during transport of individual organs (e.g. OCS or OrganOx Metra) will be issued to the donor in accordance with any relevant SaBTO recommendations for organ recipients.

Each unit of blood has a unique Donation Identification Number (DIN) which is utilised by a Hospital Blood Bank to ensure compliance with Blood Safety and Quality Regulations (BSQR) as it is used to provide the required traceability from the point of receipt from NHSBT to the recipient. When the hospital transfusion laboratory issues a unit of blood to a patient, they often also issue the unit with a set of labels bearing

the DIN number that can be applied to the patient's medical notes generated by the hospital LIMS system. This will link the unit of blood to the organ donor

When blood is requested for use in novel technologies, or for transfusion in a potential organ donor themselves, the requestor must make clear that the blood is intended for an organ donor. This information must be held in the transfusion laboratory records and, if required at the point of a look back, act as a prompt to follow up final recipients who may have been exposed to the blood. In the absence of this, there is a risk that the transfusion laboratory may consider the organ donor – being deceased – to be the end point for any traceability.

For the purposes of traceability, the DIN should be used throughout the chain as this is unique and can be used to trace back to the blood donor if required.

The three potential scenarios where technologies may use allogenic blood are detailed in the table below with proposals to ensure traceability.

Use of allogeneic blood	Location of use	Blood issued to:	Traceability - Donation Identification Number (DIN) on blood product/s to be written in:	Traceability Record of blood product for NHSBT ODT
1) Normothermic regional perfusion of organs in situ	At the donor hospital	The organ donor The requestor will add a specific reference that it is for use in an organ donor	Captured in the organ donor medical notes as part of written instruction Hospital transfusion laboratory will hold record of unit transfused for 30 years in accordance with trust policy Documented in organ donor's operation notes	Captured on HTA A form in DIN field SNOD* will copy donor's operation notes and keep an electronic copy in the donor's file held by NHSBT in the donor records department.
2) Ex situ perfusion of individual organ	At the donor hospital and in transport	The organ donor The requestor will add a specific reference that it is for use in an organ donor.	Captured in donor medical notes as part of prescription Hospital transfusion laboratory will hold record of unit transfused for 30 years in accordance with trust policy Documented in organ donor's operation notes	Captured on HTA A form in DIN field SNOD will scan a copy of the operation notes to be kept in donor's file

3) Pre transplantation	At the recipient hospital	Compatible with both donor and recipient	Recipient's medical notes	Recipient notes, if required

* Specialist Nurse Organ Donation

Table 1 – Proposal for traceability of allogeneic blood used in novel therapies to support organ donation.

1) Extracorporeal perfusion of the donor with allogeneic blood prior to organ retrieval will result in more than one potentially transplantable organ being exposed to the blood product/s and so may involve exposure to multiple recipients. For this reason, traceability of these blood products should be captured against the donor by recording the use of the product in the donor's medical notes. These notes must be kept for 30 years as part of the minimum retention period for health records, outlined by the Department of Health and the requirements of the Quality and Safety of Organs Intended for Transplantation Regulations (2012). Laboratory traceability records will also be kept for 30 years.

2) Ex situ perfusion of an individual organ may take place at the hospital and continue during transport. Blood will be issued to the organ donor by the transfusion laboratory. In these circumstances it is important to capture the traceability of the blood product for the individual organ by recording the DIN on the organ specific HTA form. This paper form is the responsibility of the lead surgeon to complete at the time of retrieval and a copy travels with the organ to the transplant destination. The information would then be available to the recipient's medical team. The DIN of the blood product will be recorded in the donor's operation notes with a note to say which specific organ it has perfused and would also be captured in the recipient's medical notes.

3) If blood was ever used to perfuse an organ at the recipient centre prior to implantation, the blood would be issued as compatible for both donor and recipient, rather than matched to the recipient – to avoid any issues if the recipient was changed prior to transplantation. In reality, it is seen as very unlikely that an organ which had been perfused with normothermic allogeneic blood at the recipient centre would ever be reperfused and packaged in order to be sent to a different transplant centre for a different recipient. Traceability would be captured in the recipient's medical notes.

Traceability of blood from transfusion laboratory to organ recipient/s.

Traceability information linking an organ donor to any organ recipients is held in the National Transplant Database (NTxD) owned and managed by NHS Blood and Transplant. Traceability for recipients of tissue taken from organ donors may be either captured in NTxD or managed by the National Retrieval Centre (NRC). When new information is received about an organ donor, the NRC are notified to identify any tissue recipients of the same donor that may be impacted.

In accordance with the Blood Quality and Safety Regulations (BQSR) all transfusion laboratories must have systems in place to trace blood to recipients. As such, the laboratories will have processes in place to do this from blood donor to organ donor (in accordance with the original request and issue of the allogeneic blood).

Transfusion laboratories should update their processes to include details that in the event that new information was received about a possible transmissible infection in a blood donor and the blood had been requested for use in an organ donor, the transfusion laboratory should contact NHSBT ODT Duty Office (+44 (0) 1179 757 575) who will be able to manage traceability beyond the Hospital LIMS system and provide details of which organ / tissue recipients have been exposed to the unit/s of blood, in accordance with the three scenarios captured in the table above.

This paper will be discussed at NRG and comments collated ahead of being presented at the Blood Consultative Committee in May. This paper has been requested by the MHRA who have requested assurance around traceability of blood used in novel technologies to support organ donation.

This paper has been written / reviewed by;

- NHSBT QA for ODT and Blood
- Clinical lead for NRP
- Patient Blood Management Practitioner
- Transfusion laboratories

Appendix 1

Proposal for blood utilisation for donor organ retrieval, *ex situ* perfusion and preservation technologies

Gabriel Oniscu, Steven Tsui, Chris Watson, John Dark

Definitions:

1. **Direct procurement and perfusion (DPP) of heart/lung** – DCD heart/lung retrieval is undertaken rapidly and the organs placed on portable perfusion technology(ies) using donor blood. Abdominal procurement is undertaken as standard with cold perfusion.
2. **Thoraco-abdominal NRP (TANRP)** – NRP of thoracic and abdominal compartments, restarting the heart *in situ* prior to procurement. This is similar to a DBD donor procurement.
3. **NRP** – abdominal normothermic regional perfusion
4. **Donor blood** – this refers to the donor's own circulating blood.
5. **Bank blood** – blood that is crossmatched to the donor (for technologies used at the donor centre) or recipient (for technologies used at the recipient centre).

Background

- The approach to DCD retrieval is evolving, with an increased utilisation of abdominal normothermic regional perfusion (NRP), or extended thoraco-abdominal NRP to include heart and lung retrieval. NRP recirculates the donor blood to establish the extra-corporeal circuit and throughout the duration of perfusion, prior to cross-clamping and cold perfusion.
- At the same time there has been an increased utilisation of novel *ex situ* preservation and perfusion technologies for heart, lung, liver and kidneys donated for transplantation in the UK.
- Some of these approaches utilise a normothermic approach and therefore require access to blood to prime the circuit and perfuse the organ, immediately after retrieval at the donor centre.

It is, therefore, important to avoid any potential competing interests for access to donor blood and establish the need for banked blood products availability at the donor hospital for all new perfusion technologies.

Working principles

- The retrieval process and technique should not be compromised by the use of the *ex situ* technologies (for example if abdominal NRP is utilized, donor blood should not be taken for *ex situ* technologies until completion of NRP).
- *Ex situ* perfusion should utilise allogeneic blood, or use donor blood only after circulatory arrest and NRP have finished.
- This document should be used by the SNOD and retrieval teams to ensure a smooth process at the donor hospital

The indicative amount of blood required during **donor surgery (table 1)** and **organ specific *ex situ* perfusion/preservation technology (table 2)** is illustrated below.

Donor and retrieval technique	Blood requirement	ABO and Rh type
DBD	None	
DCD with abdominal NRP (no CT component)	4 units RBC	Donor typed
TANRP DCD	4 units RBC	Donor typed
DPP heart/lung with abdominal NRP	4 (for DPP) + 4 (for NRP) = 8 units RBC	Donor typed
DPP DCD	none	

Table 1. Indicative amount of blood required, source and ABO/Rh type for the donor procedure according to the type of planned organ procurement technique.

Organ	Retrieval type	Blood requirement	ABO and Rh type
Heart	DBD With <i>ex situ</i> perfusion	Donor blood taken immediately prior to cross clamp or 4 units RBC*	Donor typed
Heart	DCD TANRP with <i>ex situ</i> perfusion	Donor blood taken at end of NRP phase immediately prior to cold perfusion; or 4 units RBC*	Donor typed
Heart	DCD DPP with <i>ex situ</i> perfusion	Donor blood taken immediately prior to cold perfusion or 4 units RBC*	Donor typed
Heart	DCD DPP of heart with <i>ex situ</i> perfusion and abdominal NRP	8 units RBC*	Donor typed
Lung	DBD with <i>ex situ</i> perfusion	Donor blood taken immediately prior to cross clamp or 4 units RBC*	Donor typed
Lung	DCD TANRP with <i>ex situ</i> perfusion	Donor blood taken immediately prior to cold perfusion for the heart, (end of NRP phase) 4 units RBC for the lungs* (4 units for lung +4 units for heart if donor blood not used)	Donor typed
Lung	DCD DPP <i>ex situ</i> perfusion	Donor blood taken immediately prior to cold perfusion or 4 units RBC*	Donor typed
Lung	DPP lung with abdominal NRP	4 + 4 = 8 units RBC*	Donor typed

Liver	DB All DCDs	4-6 units RBC [#]	Donor typed (if liver placed on machine at donor hospital) Donor and recipient compatible (if liver placed on machine at recipient hospital)
Kidney	DBD All DCDs	1 unit RBC	Donor and recipient compatible

* Organ priorities may apply if more than one ex-situ technology is to be used for organs from the same donor / # - depending on the ex-situ machine used

Table 2. Indicative amount of blood required, source and type for *ex situ* perfusion and preservation technologies.

- The use of allogeneic blood should comply with all current regulations for testing and safety and its use should be clearly recorded in the paperwork accompanying the organ as well as the donor notes (where appropriate).
- If the type of the retrieval procedure allows for the use of donor blood and if several *ex situ* technologies are to be used for different organs, it is unlikely that the donor blood volume will be insufficient to accommodate the use of all these devices. In these cases, a suggested organ priority strategy is proposed below.
- It is likely that during NRP DCD retrieval, allogeneic blood will be administered to the Donor. Allogeneic blood should be used for all *ex situ* perfusion of organs retrieved before completion of NRP. At the completion of NRP, donor blood use will be prioritised according to Figure 1.

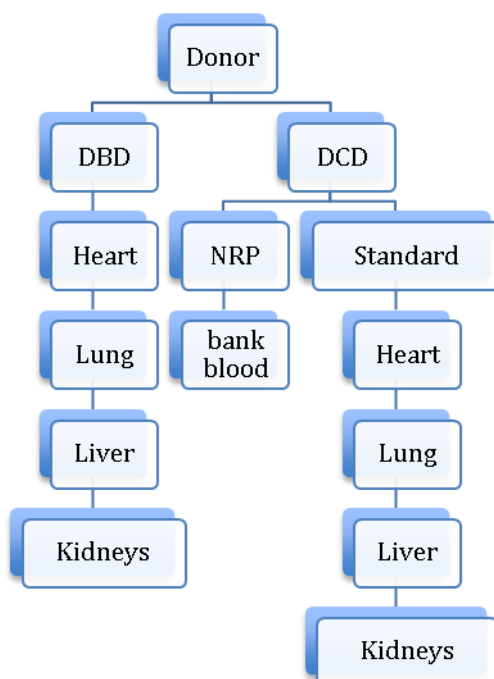


Figure 1. Suggested organ priority for allocation of donor blood when the type and technique of organ retrieval allows it and several technologies are to be used.