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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 (bank) 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 for use in these technologies a paper has recently been agreed by the National Organ Retrieval Service teams (NORS) detailing which technologies should use donor blood and which should use allogeneic (bank) [OG1]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~~machines~~) will be crossmatched to the donor and issued in accordance with SaBTO recommendations.

Each unit of blood will have a Donation Identification Number (DIN) which is issued at the point of blood donation and is used to trace the unit of blood from donor to patient. This number is unique to the unit of blood. When the hospital transfusion laboratory issues a unit of blood to a patient, they often issue the unit wi~~th~~th~~l~~ a set of labels ~~with~~ that can be applied to the patient's medical notes generated by the

hospital LIMS system after cross match (actual or virtual). This will link the unit of blood to the patient (organ donor).

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	Matched and released to:	Traceability - Donation Identification Number (DIN) on blood product/s to be written in:	Traceability Record of blood product for NHSBT ODT
1) Extracorporeal perfusion of organs in situ	At the donor hospital	The donor	Captured in patient medical notes as part of prescription Hospital transfusion bank will hold record of unit used Note made in operation notes Field to capture DIN on the organ specific HTA A form and written in the donor operation notes.	Captured on HTA A form in DIN field SNOD* will copy medical operation notes and keep an electronic copy in the donor's file
2) Ex situ perfusion of individual organ	At the donor hospital ~~or~~ and in ~~in~~ transport[OG2]	The donor	Captured in patient medical notes as part of prescription Hospital transfusion bank will hold record of unit used Note made in operation notes Field to capture DIN on the organ specific HTA A form and written in the donor 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	The recipient	Recipient's medical notes	Recipient notes, if required

* Specialist Nurse Organ Donation

1) Extracorporeal perfusion of the donor with ~~allergenic~~ 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.

2) Ex situ perfusion of an individual organ may take place at the hospital ~~or~~ and continue during transport. Blood will be crossmatched and released for use in the 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 operation notes with a note to say which specific organ it has perfused and would be present in the patient's medical notes.

3) If blood was ever used to perfuse an organ at the recipient centre prior to implantation, this blood would be matched to the recipient [A3]and captured in the recipient medical [OG4]notes. [OG5]