

Changes in this version

New Document

Policy

This policy has been created by the Liver Advisory Group on behalf of NHSBT.

This policy previously received approval from the Transplant Policy Review Committee (TPRC). This committee was disbanded in 2020 and the current governance for approval of policies is now from Organ and Tissue Donation and Transplantation Clinical Audit Risk and Effectiveness Group (OTDT CARE), which will be responsible for annual review of the guidance herein.

Last Updated: February 2024

Approved at OTDT CARE: April 2024

To be reviewed July 2025

Purpose

The aim of this document is to provide a policy for the offering and acceptance of liver lobe/s from living or domino donors to adult and paediatric recipients in the United Kingdom (UK). These criteria apply to all proposed recipients of organs from living donors.

In the interests of equity and justice all centres will work to the same offering criteria.

Non-compliance with these guidelines will be handled directly by NHSBT, in accordance with the Non-Compliance with Selection and Allocation Policies (POL198).

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, mechanisms are in place for the offering of organs in exceptional cases.

Applicable Documents

- POL191 Guidelines for consent for solid organ transplantation in adults
- POL195 Liver Transplantation: Selection Criteria and Recipient Registration
- POL196 Deceased Donor Liver Distribution and Allocation
- POL198 Non-compliance with Selection and Allocation Policies
- POL200 Introduction to Patient selection and Organ Allocation Policies
- POL274 Living Donor Kidney Transplantation
- POL322 Exceptional Donation requests Policy
- The NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005

(Template Version 03/02/2020)

Effective date: 21/05/2024

1. Introduction

This policy describes all aspects of living donor liver transplantation including:

- Non-directed altruistic donation (NDAD)
- Directed altruistic donation (DAD)
- Direct living donation
- Domino donation

This policy applies to both adult and paediatric recipients and was formed from existing living donor transplantation policies and the living donor liver transplantation (LDLT) initiative, endorsed through stakeholder engagement (including Liver Advisory Group (LAG)) and the LDLT project board. Matching criteria are consistent with the deceased donor liver allocation policy (**POL196**), unless otherwise stated.

Under HTA approval requirements, all donors are consented prior to surgery to specify their preferred destination of the donated liver lobe/s if it cannot be implanted into the intended recipient after the hepatectomy. These include offering to another recipient, re-implantation into the donor or research.

Within the Human Tissue Acts, the Human Tissue Authority (HTA) can give legal approval for any living donation (including DAD cases) to proceed if the Authority is satisfied that two requirements are met:

- a) there is no evidence of coercion of the donor
- b) there is no evidence of reward for the donor

For potential serious adverse events and serious adverse reactions, incidents must be reported via ODT on-line incident reporting so that these can be investigated and learning shared (see https://www.odt.nhs.uk/living-donation/critical-incident-reporting/ for latest reporting criteria).

For questions related to the policy or advice, please contact the Associate Medical Director for Living Donation and Transplantation at NHSBT or Statistical Lead for Liver Transplantation directly or via the following teams:

Core Hours (09:00-17:00) <u>livingdonorlivertransplants@nhsbt.nhs.uk copying the Associate</u> Medical Director for Living Donation and Transplantation

Out of Hours odthub.operations@nhsbt.nhs.uk

odthuboperations.shiftmanagers@nhsbt.nhs.uk



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2. Non-directed altruistic donation

2.1 Donation to the UK transplant list

Non-directed altruistic donation (NDAD) is when a person donates an organ to a recipient on the UK transplant list with whom they have no genetic or emotional relationship. NDADs need to contact their local transplant centre/centre of their choice to discuss potential donation via https://www.organdonation.nhs.uk/become-a-living-donor/donating-part-of-your-liver/donate-part-of-your-liver-to-someone-you-dont-know/. NDADs will be assessed in the donating centre but, if their preferred centre does not accept NDAD referrals and/or is not performing LDLT, they will be referred to a centre that accepts NDADs for assessment.

Liver lobe/s from a NDAD will be offered to the local transplant centre. If they do not wish to use the liver lobe/s locally, options to reoffer the liver lobe/s will be considered in line with an agreed referral pathway approved by the LDLT project board. Centres can accept the offer for any of their patients on their transplant list and NHS Group 1 patients will take precedence over NHS Group 2 patients. Any NDAD offer being considered for a Group 2 patient must have approval from Chair/Deputy Chair of Liver Advisory Group.

If a NDAD liver lobe/s cannot be transplanted into the intended recipient, either on the day of surgery or after explant and an alternative transplant for an identified local recipient cannot be performed 'on-site', consideration could be given to performing the transplant in another nearby centre (e.g., within a transplant collaborative or adjacent regional centre).

Anonymity between donor and recipient is required before surgery but may be broken afterwards, if all parties agree, via the living donor coordinators.

2.2 Coordinating Transplants for suitable NDAD-recipient pairs

Dates of surgery are scheduled within or between centres (if more than one is involved) by the living donor coordinators. Suitable storage and transport of liver lobe/s is arranged by the named living donor coordinator contacts at transplant centres.

3 Directed altruistic donation

Directed altruistic donation (DAD) is when a person donates to an intended recipient with whom they have:

- A genetic relationship but no established emotional relationship or
- No pre-existing relationship prior to the identification of the recipient's need for a transplant

Advice and guidance about how to manage offers of DAD from social media/media appeals is available here https://www.odt.nhs.uk/living-donation/tools-and-resources/

4 Directed living donation

Directed living donation is when a person donates liver lobe/s to a specific recipient with whom they have

- A genetic relationship where the potential donor is a blood relative of the potential recipient
- An emotional relationship where the potential donor has a relationship with the potential recipient; for example, spouse, partner, or close friend.



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If a recipient within a directed living donor pair cannot be transplanted from their intended donor, the donated liver lobe/s is redirected to an alternative recipient on the transplant list. Re-direction of the donated liver lobe/s in **directed living donor cases** will be offered as described in Section 2.1:

If a directed liver cannot be transplanted into the intended recipient and a local recipient cannot be identified, consideration could be given to offering the liver to a nearby centre (see section 2.1) provided that complete donor information can be provided to inform the local offering process in a new recipient centre.

If a directed liver retrieved in the private sector cannot be transplanted into the intended recipient, the following options could be considered:

- a) If the private sector organisation is associated with a NHS centre, a local recipient could be identified within this NHS centre, provided that complete donor information can be provided to inform the local offering process in the recipient centre.
- b) If the private sector organisation does not have an associated NHS centre, the liver could be offered to a nearby NHS centre (as above) with the same requirements for the accompanying information to inform the offering process in the recipient centre.

Non-NHS entitled living donors must be aware that there is no cost recovery arrangement in place if either of the above options is actioned.

5 Domino Liver

5.1. Overview

The transplantation of domino livers is currently in development and is therefore outside of the formal liver allocation process described in **POL196**. Centres may use domino livers for patients outside the current selection criteria for liver transplantation (see section 3 Selection criteria in POL195 – Liver Transplantation: Selection Criteria and Recipient Registration). Priority should be given to Group 1 patients over Group 2 patients. A non-directed domino donor liver that is registered with Hub Operations for offering will be offered according to the DCD donor offering sequence (detailed in Section 1.5.3 in **POL196**).

The donor must be recorded as a 'Domino Donor' with NHSBT to ensure that these donors are not included in the UK Living Donor Registry for the purposes of outcome monitoring and follow-up. If there are any queries about domino donation, please contact the Associate Medical Director for Living Donation and Transplantation at NHSBT.

Donor assessment and preparation for donation initiated as per UK Guidelines and local transplant centre protocol.

5.2. Protocol

Date of surgery scheduled according to clinical/patient need but with advance planning time if possible.

Once a recipient has been identified, special considerations relating to the donor, donor surgery and donated liver that are relevant to the acceptance of liver by the recipient are discussed. This includes the possibility that the transplant may not proceed if the liver is not considered viable at retrieval.

Anonymity between donor and recipient is required before surgery but may be broken afterwards, if all parties agree, via the living donor coordinators.

6 Previous living donors requiring a liver transplant6.1 Eligibility

Any NHS entitled living liver donor (directed/non-directed) who develops acute liver failure as a consequence of donation within 28 days of the donor operation will be eligible for listing on the super-urgent liver transplant list. Living donors who develop acute liver failure 29 days or more weeks after the donor operation will not automatically be eligible for super-urgent listing and the current clinical eligibility criteria (specified in **POL195**) for recipients of a transplant will apply and they will be placed on the UK transplant list by a designated transplant centre.

In the case of a non-NHS entitled living donor, should the same clinical scenario occur, listing on the super-urgent liver transplant list is subject to appeal to all transplant centres (as per the existing process specified for super-urgent listing in POL195). See point d below.

Non-NHS entitled living donors who have donated, regardless of the status of the recipient, are not eligible for listing (super urgent or routine) on the UK transplant list, unless:

- a. The acute liver failure is a direct consequence of the donation
- b. The donor has not been discharged following the donation procedure
- c. The donor has been transferred to continue their care in an NHS facility
- d. As a humanitarian gesture all centres agree that transplantation should be considered as the only treatment option (as above)

This policy applies to first and subsequent transplants and any other organ required following living organ donation. For example, a living liver donor who requires an emergency liver transplant due to vascular thrombosis of the liver remnant and subsequently develops kidney failure as a consequence of immunosuppressive treatment would be eligible for priority for a kidney graft.

Transplant centres are responsible for reporting all cases of end-stage liver disease in previous living donors to the UK Living Donor Registry via NHSBT hub information services.

7 Death of an intended living donor

In the event the intended living liver donor dies before donation, please see POL322.

8 Proctor team

Transplant centres wishing to undertake adult to adult living donor transplants will collaborate with the LDLT Proctor Team using the standardised documentation (clinical pathway, checklist and NHSBT sign-off) that have been developed specifically within the LDLT Project to support this activity across UK centres. Relevant documents can be accessed in the LDLT Proctor Team folder at this link https://www.odt.nhs.uk/living-donation/living-donor-liver-transplantation/

All participating centres will be required to record monthly activity to NHSBT using a bespoke monitoring form. The Proctor Team will be responsible for signing centres off as self-sufficient in performing LDLT, according to criteria agreed with NHSBT. The form will be accessed in the LDLT Proctor Team folder at this link https://www.odt.nhs.uk/living-donation/living-donor-liver-transplantation/

9 Donor Follow-up



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The Living Liver Donor Pre and Post-operative Assessment form (FRM4150) must be completed for all livers retrieved from all living donors alongside the elective liver recipient registration form (FRM4332) (if the patient is not already registered prior to transplant) and the first week transplant record form (FRM4123).

Annual follow-up must be completed alongside the Donor Reported Outcome measures (DROMs) and Donor Reported experience measures (DREMs).

Other useful resources for living organ donation:

Further information:

www.odt.nhs.uk

https://www.organdonation.nhs.uk/about-donation/living-donation/

Standards and Guidelines:

https://bts.org.uk/guidelines-standards/

Legal framework for living organ donation:

www.hta.gov.uk