

This National Operating Procedure replaces: NOP006

Effective: 6th December 2016

Summary of Significant Changes

Document updated to reflect minor changes in legislation and terminology.

Policy

The data needed to ensure traceability at all stages of the chain from donation to transplantation, or disposal, must be stored for 30 years after donation.

The transfer and storage of donor and organ characterisation information must ensure that the security and confidentiality of personal data is maintained.

Purpose

The purpose of the procedure is to give guidance on

- The transfer of donor and organ characterisation information
- The storage of donor and organ characterisation information
- The storage of traceability data

The procedure applies to **deceased** and **living** donation and transplantation.

Text in this document which is underlined is a mandatory requirement under the Quality and safety of organs for transplantation regulations 2012, (Updated July 2014).

Responsibilities

Implanting Surgeon (living and deceased donation and transplantation) – to ensure perfusion solution name and batch number(s) are recorded if organ is re-perfused following retrieval. To ensure HTA B Form is completed and returned to NHSBT within 7 days following transplantation of an organ, or if received organ is used for research or is disposed of.

Retrieval Surgeon (deceased donor) – To ensure relevant NHSBT organ specific forms (HTA A Forms) are completed. To sign relevant NHSBT organ specific forms (HTA A Forms).

Retrieval Surgeon (living donor) – To ensure relevant NHSBT living donor assessment pre and post-operative form is completed. To sign relevant NHSBT living donor assessment pre and post-operative form.

Transplant Unit Personnel – To ensure procedures are in place to record transportation details (to include date and time).

Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

Definitions

Complementary Data Set – Information required for the characterisation of organs and donors. To be collected in addition to the **minimum data set**, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

Disposal - Final placement of an organ if it is not used for transplantation or research.

Donor characterisation - Collection of relevant information on the characteristics of the donor needed to evaluate his/her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation.

HTA - Human Tissue Authority.

Implanting surgeon – Surgeon who makes the final decision to use an organ for transplantation, also responsible for performing the transplant operation.

Living Donor Co-ordinator (LCD) – Specialist Nurse with the relevant knowledge, skills and training in living donation and transplantation.

Minimum Data Set – Information for the characterisation of organ and donors, which must be collected for each donation.

NHSBT – NHS Blood and Transplant.

NOPs – National Operating Procedures.

Organ - Differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation. For the purposes of this procedure, an organ is considered to be intended for transplantation, and includes those tissues and cells retrieved to directly support organ transplantation e.g. accessory vessels, spleen, lymph nodes.

Organ characterisation - Collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation.

Retrieving Surgeon – Lead retrieval surgeon.

Serious Adverse Event (SAE) - Undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

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Serious Adverse Reaction (SAR) - Unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Specialist Nurse – Organ Donation (SN-OD) – Specialist Nurse with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST).

Traceability - Ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to

- Identify the donor
- Identify the retrieving and implanting surgeons
- Identify the recipient and the recipient centre where the organ is implanted
- Locate and identify records of the perfusion solution which comes into contact with the organ, the record must include the name of the perfusion solution and the batch number. **N.B** The details relating to the manufacturer of the perfusion fluid can be traced, if required, via the name and batch number.

Transplantation – Process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient.

Applicable Documents

FRM4121 - Kidney Donor Information (KP4)

FRM4122 - Deceased Donor Pancreas Information (P-DEC-DI-INTERIM)

FRM4147 - Liver Donor Information (L4)

FRM4194 - Cardiothoracic Donor Information (C-DI)

FRM4190 - Kidney Living Donor Assessment Pre and Post-Operative Form

FRM4150 - Living Liver Donor Pre and Post-Operative Assessment Form

FRM4195 - Human Tissue Authority – Form B

NOP001v2 - Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation

NOP002v2 - Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation

NOP003v2 - Packaging, Labelling and Transport of Organs for Transplantation in Deceased and Living Donation

The Quality and Safety of Human Organs Intended for Transplantation - a documentary framework, 2012, (Updated July 2014) Human Tissue Authority, www.hta.gov.uk

Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

1. INTRODUCTION

- 1.1. To ensure the quality and safety of organs for transplantation from deceased and living donors, information must be available to ensure traceability and to permit characterisation of organ donors and donated organs.
- 1.2. Information on donor and organ characterisation must be received by the implanting surgeon within a time period that will not compromise the quality and safety of the organ.
- 1.3. The transmission of donor and organ characterisation information must ensure that the security and confidentiality of personal data is maintained.
- 1.4. Data to ensure the quality and safety of organs must be kept for 30 years after donation. This will include:
 - Donor and organ characterisation information (to include records of any risk-benefit analyses undertaken if a donated organ is used in the absence of complete data, as defined in the minimum data set)
 - The traceability data from HTA A and B forms
 - Information on the disposal of an organ, if it is not used for transplantation
 - Records of the transportation of organs arriving at, and leaving, an establishment, including the consignment record documentation, if available
 - Records associated with a Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)
 - Records of perfusion fluid coming into contact with an organ. At a minimum, this will include the product name and batch number.

2. TRANSFER AND STORAGE OF TRACEABILITY AND ORGAN AND DONOR CHARACTERISATION DATA

2.1. DECEASED DONATION – TRACEABILITY DATA

- 2.1.1. The retrieval surgeon is responsible for ensuring the completion of the relevant organ specific form(s) and signing the completed form (FRM4194/4147/4121/4122). (N.B. These forms are referred to as the HTA A forms in the Quality and Safety of Organs Intended for Transplantation – a documentary framework, 2012 (Updated 2014), HTA)
- 2.1.2. A copy of the organ specific form(s) (FRM4194/4147/4121/4122) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

2.2. DECEASED DONATION – DONOR AND ORGAN CHARACTERISATION DATA

2.2.1. NHSBT is responsible for the storage, for 30 years, of the following organ and donor characterisation data:

- Confirmation of donor identity (**see NOP002v2 Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation**).
- Confirmation of consent/authorisation (**see NOP002v2 Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation**).
- Minimum mandatory data set (**see NOP001v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation**).
- Patient Assessment Form
- Complementary data set (**see NOP001v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation**). This must be stored for 30 years when it is considered necessary to permit adequate characterisation of a particular donor or donated organ.

2.3. LIVING DONATION – TRACEABILITY DATA

2.3.1. The retrieval surgeon is responsible for ensuring the completion of the Kidney Living Donor Assessment Pre and Post-Operative Form or the Living Liver Donor Pre and Post-Operative Assessment Form and signing the completed form (FRM4190/4150). (These forms are referred to as the HTA A forms in the Quality and Safety of Organs Intended for Transplantation – a documentary framework, 2012, HTA (updated 2014))

2.3.2. A copy of page 1 of the HTA A form (FRM4190/4150) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

2.4. LIVING DONATION – DONOR AND ORGAN CHARACTERISATION DATA

2.4.1. The donation and/or transplant unit are responsible for the storage, for 30 years, of the following data which must be recorded in the donor and/or recipient's medical records, ensuring that confidentiality and data security measures are in place:

- confirmation of donor identity
- confirmation of consent/authorisation
- Minimum mandatory data set (see NOP001v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation).
- Complementary data set (see NOP001v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation). This must be stored for 30 years when it is considered necessary to permit adequate characterisation of a particular donor or donated organ

3. TRANSFER AND STORAGE OF PERFUSION FLUID DATA

3.1. DECEASED DONATION

3.1.1. The retrieval surgeon is responsible for ensuring that the name of the perfusion solution and batch number(s) is recorded on the relevant organ specific form(s) (FRM4194/4147/4121/4122). (N.B. These forms are referred to as the HTA A forms in the Quality and Safety of Organs Intended for Transplantation – a documentary framework, 2012 HTA) (updated 2014),

3.1.2. A copy of the organ specific form(s) (FRM4194/4147/4121/4122) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

3.1.3. In cases where an implanting surgeon inspects an organ prior to transplantation and as part of the inspection the organ is re-perfused, the name and batch number of the perfusion fluid must be recorded.

3.1.3.1. In circumstances where the organ is subsequently transplanted at that transplant unit, the name of the perfusion fluid and batch number recorded on the HTA B Form (FRM4195). The completed HTA B form must be returned to NHSBT within 7 days.

3.1.3.2. In circumstances where the organ is re-packaged for transportation to another transplant unit for transplantation, a record of the name of the perfusion solution and batch number must be noted on the organ specific form which accompanies the organ in the transport box. A copy of this form with the extra information must be returned to NHSBT by the receiving transplant centre within 7 days.

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- 3.1.4. In cases where a liver is split for transplantation into two recipients the name and batch number of the perfusion fluid used must be recorded. If part of the liver is retained for transplantation at the 'splitting centre' the name and batch number of the perfusion fluid must be recorded on the HTA B Form (FRM4195).
- 3.1.5. In cases where part of a split liver is packaged and transported to another transplant centre for transplantation a record of the name of the perfusion solution and batch number must be noted on the organ specific form which accompanies the organ in the transport box. A copy of this form with the extra information must be returned to NHSBT by the receiving transplant centre within 7 days.
- 3.1.6. In circumstances where a record of the name and batch number(s) of perfusion fluids used are recorded on an HTA B Form (FRM4195) returned to NHSBT, the data will be stored for 30 years by NHSBT. Perfusion fluid data not recorded on an HTA B Form (FRM4195) and returned to NHSBT must be recorded by the transplant unit to enable traceability to a transplant recipient and stored for 30 years.

3.2. LIVING DONATION

- 3.2.1. The retrieval surgeon is responsible for ensuring that the name of the perfusion fluid and batch number(s) is recorded on the Kidney Living Donor Assessment Pre and Post-Operative Form or the Living Liver Donor Pre and Post-Operative Assessment Form (FRM4190/4150).
- 3.2.2. A copy of page 1 of the Kidney Living Donor Assessment Pre and Post-Operative Form or the Living Liver Donor Pre and Post-Operative Assessment Form (FRM4190/4150) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

4. STORAGE OF ORGAN TRANSPORTATION RECORDS

4.1 DECEASED DONATION

- 4.1.1 Transplant units must ensure that a record of the transportation of organs (to include date and time) being released for transportation or received for transplantation are stored for 30 years after donation (see **NOP003v2 Packaging, Labelling and Transportation in Deceased and Living Donation and Transplantation**)
- 4.1.2 The SN-OD at the donating hospital will complete an NHSBT Organ Handover Form to ensure that transport release data (date and time) is recorded. The receiving transplant unit(s) will be required to record transport data (date and time) on receipt of the organ.

4.2 LIVING DONATION

- 4.2.1 Transplant units must ensure that a record of the transportation of organs (to include date and time) being released for transportation or received for transplantation are stored for 30 years after donation.

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4.2 On delivery of the organ(s) the transplant centre must ensure that procedures are in place to record the delivery details (date and time) and for the form to be retained and stored in the transplant unit for 30 years. Transplant centres may also wish to keep local records at the retrieval/transplant centre as an alternative to using the NHSBT form.

5. RETRIEVED ORGAN TRACEABILITY

5.1 Transplant units must ensure that data required to ensure the traceability of organs received by their transplant unit is recorded and stored for 30 years.

5.2 Transplant units must ensure that on receipt of an organ, a HTA B Form (FRM4195) is completed and returned to NHSBT within 7 days who will store the data for 30 years. This form must be completed if the received organ is transplanted, the organ is used for research or the organ is disposed of in accordance with hospital policy.

6. IMPLEMENTATION AND AUDIT

6.1. The National Operating Procedures (NOPs) are available to download from the NHSBT ODT Clinical website at www.odt.nhs.uk

6.2. Transplant Units may

6.2.1. Adopt the NOPs fully

6.2.2. Adopt the NOPs with local adaptation

6.2.3. Write their own procedural documents

6.3. If the NOPs are not fully adopted, Transplant Units must ensure that local procedures are compliant with the requirements of the EU Directive and in accordance with the regulatory framework of the HTA: *The Quality and Safety of Human Organs Intended for Transplantation - a documentary framework*.

6.4. Accountability for the NOPs and their implementation will lie with each individual Transplant Unit

6.5. Transplant Units will be responsible for

- Implementation of the NOPs according to local Trust/Board policy
- Document review according to local Trust/Board policy, and in response to developments in organ donation and transplantation practice, or changes in national policy or guidance
- Document control
- Staff training

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