

This National Operating Procedure replaces: NOP001

Effective: 6th December 2016

Summary of Significant Changes

Document updated to reflect minor changes to terminology and to accommodate the changes to the manner in which information is collected and shared within the transplant community.

Policy

To ensure the quality and safety of organs for transplantation from deceased and living donors, information must be available to permit characterisation of organ donors and donated organs.

Characterisation will enable the recipient centre to identify and document any risks associated with the use of an organ, in order to allocate it to a suitable recipient.

The decision to use an organ for transplant is the responsibility of the implanting surgeon based on the information available.

Purpose

The purpose of this document is to detail the information required to permit the characterisation of organ donors and donated organs before an organ is used for 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 - To review all information obtained during donor and organ assessment. To ensure that the information is sufficient to permit characterisation of the donor and donated organ before the organ is used for transplantation.

Living Donor Coordinator (LDC) - To undertake a thorough assessment of the potential donor to ensure an accurate medical, family and social history, in conjunction with Registered Medical Practitioners (RMPs) within the transplant medical team.

NHSBT Duty Office - To communicate donor information provided by the Specialist Nurse – Organ Donation (SN-OD) to the Recipient Centre Point of Contact (RPoC).

Recipient Centre Point of Contact (RPoC) - To communicate the information provided by the SN-OD to the implanting surgeon. To communicate requests for further information from the implanting surgeon to the SN-OD or retrieving surgeons.

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Retrieving Surgeon - To review the information collated during donor assessment and to ensure relevant investigations have been performed. To undertake peri-operative assessment of the donor and donated organ/s. To ensure the RPoC and implanting surgeon are notified if an organ appears sub-optimal, or if any damage or unexpected abnormality is encountered which might compromise the function or safe use of an organ.

Specialist Nurse – Organ Donation (SN-OD) - To obtain and document information required for donor and organ characterisation. To seek advice and guidance from the retrieving or implanting surgeon, if required. To communicate all information to the RPoC, the NHSBT Duty Office or the implanting surgeon.

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.

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.

Donor Path Application – Electronic application used by SNODs to capture donor data.

EOS – Electronic Operating System.

EOS Mobile – Electronic Operating System mobile version.

The EU Directive/European Union Directive - The Directive (2010/53/EU) of the European Parliament and of the Council of 7th July 2010 on standards of quality and safety of human organs intended for transplantation.

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

Living Donor Coordinator (LDC) - Specialist Nurse with the relevant knowledge, skills and training in living donation and transplantation.

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

UK Living Kidney Sharing Scheme (UKLKSS) - Includes paired/pooled donation, altruistic donation and altruistic donor chains.

NHSBT – NHS Blood and Transplant.

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NOPs – National Operating Procedures.

NORS Standard - The National Standard for Organ Retrieval from Deceased Donors.

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.

Recipient Centre Point of Contact (RPoC) - Healthcare professional responsible for relaying information to the implanting surgeon for a final decision to be made on accepting an organ for transplant.

Registered Medical Practitioner (RMP) - Medical practitioner who is registered and with a licence to practice by the General Medical Council.

Retrieving surgeon - The lead retrieval surgeon.

SaBTO - means the Advisory Committee on the Safety of Blood, Tissues and Organs:
www.dh.gov.uk/ab/SaBTO

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).

Transplant medical team - Members of the transplant team who are medical practitioners, licensed to practice by the General Medical Council, one of whom will be the implanting surgeon.

Applicable Documents

The British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation (current edition)

Directive 2010/53/EU of the European Parliament and of the Council 7 July 2010 on standards of quality and safety of human organs intended for transplantation

POL188 - Clinical contraindications to approaching families for possible organ donation

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)

MPD1043 - National Organ Retrieval (NORS) Mobilisation

NOP006 - Transfer And Storage Of Donor And Organ Characterisation Information and Storage Of Traceability Data

NHSBT Patient Selection and Allocation Policies, www.odt.nhs.uk

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

1. INTRODUCTION

1.1. Information from a potential donor's medical, family and social history, physical examination and complementary tests should be collected for the adequate characterisation of the organ and the donor. To obtain an accurate, reliable and objective history, interviews must be performed with the living donor or, where appropriate, with the relatives of the deceased donor, during which the potential risks and consequences of donation and transplantation are explained.

2. INFORMATION REQUIRED FOR THE CHARACTERISATION OF ORGANS AND DONORS

2.1. Before the decision is made to use an organ for transplantation, information must be available to permit characterisation of the organ donor and donated organ. Characterisation enables the implanting surgeon to make an assessment of the suitability of the donor and organ, in order to minimise the risk of harm to the transplant recipient.

2.2. The minimum mandatory information required for donor and organ characterisation is defined as the **Minimum Data Set** and **must be collected for all donors**.

2.2.1. The **Minimum Data Set** is specified in Part A of the Annex to the EU Directive (see Appendix 1 of this Procedure).

2.2.2. In circumstances where this information is not available, the transplant medical team may still consider using an organ for transplantation. The decision to do so must take into account the benefit to the intended recipient of the donated organ, versus the risks posed by the lack of information available. The implanting surgeon must document in the recipient's medical records:

- the decision and
- the risk-benefit analysis undertaken.

2.3. Other information that may be required for donor and organ characterisation is defined as the **Complementary Data Set**.

2.3.1. The **Complementary Data Set** is specified in Part B of the Annex to the EU Directive (see Appendix 1 of this Procedure)

2.4. Information in the Complementary Data Set **must be collected when it is considered necessary to permit adequate characterisation of a particular donor and donated organ.**

2.4.1. The transplant medical team is responsible for deciding if this information is required.

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2.4.2. The decision to collect this information will take into account the availability of the information, and the individual circumstances of the donor and the potential recipient of the donated organ.

2.5. The decision to use an organ for transplantation should take into account

- The absolute contraindications to organ donation specified in **POL188** Clinical contraindications to approaching families for possible organ donation for deceased donation, and other relevant UK guidelines and standards documents (e.g. British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation).
- The guidance issued by SaBTO on the use of organs from donors with infections or tumours
- NHSBT Patient Selection and Allocation Policies.

2.6. To ensure quality, safety and reliability, all tests used for donor and organ characterisation must be carried out by appropriately accredited laboratories.

3. SOURCES OF INFORMATION FOR DONOR AND ORGAN CHARACTERISATION

3.1. Information required for the characterisation of donors and donated organs will be collected by the SN-OD in deceased donation and by the LDC in living donation.

3.2. In **deceased** donation, the SN-OD will:

3.2.1. Undertake a thorough assessment of the potential donor to ensure an accurate medical, behavioural and travel history is available. Sources of information may include

- Medical records from the current admission
- Medical records from previous admissions where available
- Information from the General Practitioner
- Information from other specialists e.g. oncologists
- Information from the potential donor's family including information regarding medical, behavioural, travel history.

3.2.2. Collate the results of relevant diagnostic tests including

- Blood tests
- Blood group
- Microbiology
- Imaging/cardiology
- Screening for infections

3.2.3. Undertake a physical examination of the potential donor, and facilitate any further examination or assessments required, to identify factors that could have an impact on the quality and safety of organs for transplant

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3.3. In **living donation**, the LDC, in conjunction with Registered Medical Practitioners (RMPs) within the transplant medical team, will undertake a thorough assessment of the potential donor, including a physical and psychological evaluation, to ensure an accurate medical, family and social history. This assessment must be consistent with principles of best practice as specified in national and local standards, guidelines and policies (e.g. the British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation).

3.4. In **deceased and living donation**, the retrieving surgeon must review the information collated during the assessment of the potential donor, before retrieval, and ensure that factors that could affect the quality and safety of organs for transplantation have been identified and appropriately investigated.

3.5. The retrieving surgeon may discuss directly with the implanting surgeon any implications for the intended recipient of the donated organ.

4. PERI-OPERATIVE ASSESSMENT OF DONOR AND ORGAN CHARACTERISATION

4.1. Principles of best practice, as specified in national and local standards, guidelines and policies, should be applied to the peri-operative assessment of donor and organ characterisation (e.g. the NORS standard, the British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation).

4.2. The retrieving surgeon is responsible for:

- Peri-operative assessment of the donor and donated organ/s.
- Taking all reasonable steps to assess for evidence of previously unidentified co-morbid disease in the donor (in particular malignancy) that could affect the quality and safety of the donated organ/s.
- Identifying any disease process that could affect the suitability of an organ for transplant, and ensuring that it is discussed immediately with the implanting surgeon.
- Ensuring the NHSBT Duty Office is informed immediately if malignancy, or other relevant finding, is identified in an organ from a deceased donor, so that the information can be relayed to all relevant recipient teams.
- Ensuring the RPoC and implanting surgeon are notified immediately if an organ appears sub-optimal, or if any damage or unexpected abnormality is encountered which might compromise the function or safe use of that organ
- Signing the completed organ specific forms (FRM4194/4147/4121/4122), recording which organs have been removed from the body, all abnormalities/anomalies, organ damage, sub-optimal perfusion or donor instability during retrieval.
- Documenting full details of the donor operation in the donor's medical record, including:
 - Which organs and tissues have been removed from the body
 - Any abnormalities/injuries noted

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4.3. The retrieving surgeon must sign the medical records entry and print their name and the name of the retrieval centre with a contact telephone number.

5. TRANSMISSION OF INFORMATION

5.1. DECEASED DONATION

5.1.1. The SN-OD will record donor characterisation information on DonorPath which in turn will populate the Core Donor Data Form and the Patient Assessment Form (PA1). EOS and EOS Mobile display two links to PDF documents; the Core Donor Data Form (CDDF) and the Patient Assessment Form (PA1). It is vital that both documents are reviewed in their entirety by the recipient transplant teams, particularly when accepting an organ offer.

5.1.2. Hard copies of all results will be collated where possible.

5.1.3. The SN-OD will communicate information to the RPoC, or implanting surgeon, verbally, via EOS, EOS Mobile or via the NHSBT Duty Office.

5.1.4. Once an organ has been offered to a recipient centre, any further changes made to DonorPath must be communicated verbally as well as electronically to the RPoC.

5.1.5. Information that cannot be entered onto EOS will be faxed/emailed to recipient centres via secure fax/ secure email where possible. The recipient centres will be notified that information that cannot be entered onto EOS will be forwarded where possible by either the SN-OD or Duty Office.

5.2. LIVING DONATION

5.2.1. For directed donations, information on donor and organ characterisation will be held within the donating and/or recipient centres and transmitted to NHSBT Data Executive within one month of the date of donation.

5.2.2. In the UKLDSS, information on donor and organ characterisation is transmitted to NHSBT at the time of recipient and donor registration. Subsequent to matching, LDCs in donating and recipient hospitals will exchange relevant donor and recipient information to inform the preparation and scheduling of the donation and implantation surgery.

6. ASSESSMENT OF DONOR AND ORGAN CHARACTERISATION AT THE RECIPIENT CENTRE

6.1. Principles of best practice as specified in national and local standards, guidelines and policies should be applied to the assessment of donor and organ characterisation at the recipient centre (e.g. NORS Standard, British Transplantation Society/Renal Association UK Guidelines for Living Donor Kidney Transplantation, SaBTO).

6.2. The implanting surgeon is responsible for:

- Checking the integrity of the organ and the suitability of the organ for the recipient.
- Ensuring that they have received all relevant information about the donor and donated organ to enable a decision to be made on its suitability for implantation. In deceased donation the surgeon should review the Core Donor Data Form and the Patient Assessment Form (PA1) prior to implant via EOS.
- Ensuring that identity details on all documentation and tissue samples (where relevant) accompanying the organ are checked and correlate with those given to the RPoC. As a minimum, this will include 3 unique identifiers:
 - In deceased donation: donor ODT number, date of birth and hospital number/CHI number.
 - In living donation: donor name, date of birth and hospital number/CHI number.
- Checking that the organ has been transported appropriately to maintain quality and safety, and within an acceptable ischaemic time.
- Ensuring that the Organ Specific Form (FRM4194/4147/4121/4122) and, in deceased donation, the witnessed blood group form accompanying the organ in the transport box, are reviewed.

6.3. Recipient centres must immediately report to the Duty Office at NHSBT any abnormality found which contributes directly to donor and organ characterisation.

7. STORING DATA ON ORGAN/DONOR CHARACTERISATION

7.1. Information on donor and organ characterisation, including any risk-benefit analyses undertaken, must be stored for 30 years (see ***NOP006v2 Transfer And Storage Of Donor And Organ Characterisation Information and Storage Of Traceability Data***)

8. IMPLEMENTATION AND AUDIT

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

8.2. Transplant Units may

- Adopt the NOPs fully
- Adopt the NOPs with local adaptation
- Write their own procedural documents

8.3. 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*.

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

8.5. 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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**PART A
MINIMUM DATA SET**

This information **must** be collected for **all** donors:

The establishment where the procurement takes place and other general data

Type of donor

Blood group

Gender

Cause of death (in deceased donation)

Date of death (in deceased donation)

Date of birth or estimated age

Weight

Height

Past or present history of IV drug abuse

Past or present history of malignant neoplasia

Present history of other transmissible disease

HIV; HCV; HBV tests

Basic information to evaluate the function of the donated organ. This has been defined by the Chairpersons of the UK Organ Advisory Groups as follows:

Heart echocardiogram (ECG)

Lungs chest x ray

Kidney serum creatinine

Liver INR and/or prothrombin time

Pancreas information on the history or absence of diabetes

Bowel information on the history or absence of intestinal or peritoneal disease

**PART B
COMPLEMENTARY DATA SET**

This information **must** be collected **when it is considered necessary** to assess the suitability of a **particular** donor and donor organ:

GENERAL DATA

Contact details of the procurement organisation/the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

DONOR DATA

Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor/organ and the recipient.

DONOR MEDICAL HISTORY

Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

PHYSICAL AND CLINICAL DATA

Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.

LABORATORY PARAMETERS

Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

IMAGE TESTS

Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

THERAPY

Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.