NHS Blood and Transplant
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National Standards for Organ Retrieval from Deceased Donors

Index

Summary of changes

Changes to Version 9

- Clarification of vessel retrieval if the liver is to be split
- Actions if the heart is to be donated for tissue
- Updated guidance should there be a return of effective, sustained cardiac output in DCD after death
- Guidance on kidney biopsy for NORS surgeons
- Updated abdominal perfusion protocol in Appendix 3
- Addition in Appendix 9; Guidance for the Surgical Count.
- Addition in Appendix 10; NRP National Protocol

All changes are highlighted in purple

Useful Information

1. ***Associated Documents***
2. ***Incident Reporting***
3. ***Other Useful Links***
4. ***National Operating Procedures***

1. Associated Documents

- Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation - POL188 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents)
- Establishing Pregnancy Status and Pregnancy in Donation - MPD891 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/)
- Theatre Manual for Deceased Organ Donors - SOP5499 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/)
- Physical Assessment - MPD873 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/)
- Responsibilities of Clinicians for the Acceptance of Organs from Deceased Donors - POL192 (https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/)
- Logistics & NORS Mobilisation Manual - Hub Operations – SOP4574 *
- Completion Guidelines for Retrieval Team Information Form FRM4125 - INF1365*
- Retrieval Team Information – FRM4125*
- Organ Donation and Transplantation Peak Activity Policy – POL224*
- NHSBT Surgical Safety Checklist - FRM4135*
- Guidance and Principles - Donor Organ Photographs - MPD1100 (https://www.odt.nhs.uk/retrieval/policies-and-nors-reports/)
- Findings During Retrieval Requiring Histopathology Assessment - SOP5352 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/)
- Heart Retrieval on Behalf of NHSBT Tissue Services for Valves from a Deceased Donor - INF195*
- Medical Records Entries for Proceeding and Non- Proceeding Organ and/or Tissue Donation - MPD910 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/)
- Organ Handover Form - FRM4217*
- Minimum Operating Standards – Patient Identifiable Data – Hub Operations - MPD1086*
- Reporting an Organ Donation or Transplantation Incident to NHSBT – SOP3888 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/)
- Basic Guidelines for Theatre Staff at Donor Hospital – INF1424 (https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/)
- Guidelines for use of organ boxes (https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4382/organ_boxes_instructions_for_use.pdf)
- Guidance on Assessment of Organs During Deceased Donation Retrieval – DAT4034*
- Vessels Form - FRM6199*

* Associated documents without active links apply only to NHSBT staff and are therefore only accessible via NHSBT controlled documents library.

2. Incident Reporting

An incident may occur within the chain of organ donation and transplantation for which there is a legal requirement to report under the Regulations. An incident may also occur from which organisations may benefit from shared learning. Additionally, feedback to the retrieval team on the quality of organ retrieval is recognised as being essential for patient safety, training, competence, and continuing education of retrieval staff. Constructive feedback helps increase retrieval surgeons' knowledge to maximise the quality of donated organs.

All incidents should be reported to the OTDT Directorate of NHSBT using the following link:

https://safe.nhsbt.nhs.uk/IncidentSubmission.

All UK establishments licensed under the Regulations - The requirement to report serious adverse events (SAEs) and serious adverse reactions (SARs) applies to all UK establishments licensed under the Regulations, regardless of geographical location or whether they are a private or an NHS organisation.

SAEARs Definitions
Serious Adverse Event
A serious adverse event (SAE) is defined in the Regulations as 'any 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.

SAEs that may influence the quality and safety of an organ, and that may be attributed to the testing, characterisation, procurement, preservation, and transport of organs, must be reported, and investigated.

Serious Adverse Reaction
A Serious Adverse Reaction (SAR) is defined in the Regulations as 'an 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'.

SARs observed during or after transplantation, which may be connected to the testing, characterisation, procurement, preservation, and transport of organs, must be reported, and investigated.

In accordance with The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (https://www.legislation.gov.uk/uksi/2007/1523/contents/made) serious adverse events and reactions relating to whole organs retrieved with the intention of being transplanted as tissues (whole heart for valves, pancreas for islets and liver for hepatocytes) must be reported. To this aim, incidents involving such tissues must also be reported via the OTDT Directorate of NHSBT (https://safe.nhsbt.nhs.uk/IncidentSubmission).

3. Other Useful Links
Human Tissue Authority - https://www.hta.gov.uk/
British Transplantation Society - https://bts.org.uk/
NHS Blood and Transplant - http://www.nhsbt.nhs.uk/
ODT Clinical Website - http://www.odt.nhs.uk/
SaBTO - https://www.gov.uk/government/groups/advisory-committee-on-the-safety-of-blood-tissues-and-organs
ESOT - http://www.esot.org/
Academy of Medical Royal Colleges - http://www.aomrc.org.uk/
NORS Review 2015 - https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1411/nors_review_report_2015.pdf
Organ Donation and Transplantation 2030: Meeting the Need - https://www.odt.nhs.uk/odt-structures-and-standards/key-strategies/meeting-the-need-2030/
Faculty of Intensive Care Medicine - https://www.ficm.ac.uk/standards-and-guidelines/access-standards-and-guidelines

Code of Practice for the Diagnosis of Death (Academy of Medical Royal Colleges 2008.
https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1338/aomrc-death-2008.pdf
The diagnosis of death by neurological criteria in infants less than two months old.
https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1354/neurological-death-dnc-guide-final.pdf

4. National Operating Procedures
Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation – NOP001 (POL278)
https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

Verification of Donor Identity Consent and Authorisation Organ and Donor Characterisation in deceased and Living Donation and Transplantation - NOP002 (POL279)
https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

Packaging Labelling and Transport of Organs in Deceased and Living Donation and Transplantation - NOP003 (POL280)
https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

National Operating Procedure NOP004 Management of Procurement Material and Equipment in Deceased and Living Donation and Transplantation – NOP004 (POL281)
https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

Activities to be Performed Under the Guidance of a Registered Medical Practitioner - NOP005 (POL282)
https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data - NOP006 (POL283)
https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

Glossary

Advisory Groups
NHSBT ODT has established solid organ Advisory Groups (AGs) (shown below) that are the key fora for clinicians and scientists to meet with representatives from NHS Blood and Transplant (NHSBT), commissioners and Departments of Health and others to review and develop policies, assess outcomes, and work with partners and stakeholders to improve outcomes for patients. ODT has also established the National Organ Donation Committee (NODC) and the Retrieval Advisory Group (RAG; formerly National Retrieval Group). These advisory and operational bodies within ODT include operational ODT staff as well as advisory clinician-stakeholders necessary to prepare, review and carry out the policies and tasks of organ donation, donor management and organ retrieval.

In addition, ODT has established the Advisory Group Chairs Committee including the Chairs of the respective AGs and Chairs of NODC and RAG to advise ODT SMT.
The Advisory Groups advise and NODC and RAG report to the Organ Donation and Transplantation (ODT) Senior Management Team (SMT):

- **CTAG – Cardiothoracic Advisory Group**
- **KAG – Kidney Advisory Group**
- **LAG – Liver Advisory Group**
- **MCTAG – Multi-visceral & Composite Tissue Advisory Group**
- **NODC – National Organ Donation Committee**
- **PAG – Pancreas Advisory Group**
- **RAG – Retrieval Advisory Group**
- **RINTAG – Research, Innovation & Novel Technologies Advisory Group**

CLODs
Clinical Leads for Organ Donation

Contract Review Meeting
An annual meeting between NHSBT Commissioners and the NORS Centre key contacts, as well as any key members of the NORS Team, to discuss finance, activity, clinical governance, and any ad hoc agenda items.

DBD
Donation after brainstem death

DCD
Donation after circulatory death

EOS
Electronic Offering System

HTA
Human Tissue Authority

Incident
Any event in the organ donation and/or transplantation process which can or does affect the donor, recipient safety or the quality of the organs for transplantation.

Retrieval Advisory Group (RAG)
The Retrieval Advisory Group (RAG) is a structural body within ODT which supersedes the National Retrieval Group. It came into being on the 1st of October 2019. It advises SMT on policies as regards organ retrieval and carries out operational tasks and activities that are part of the commissioned National Organ Retrieval Service (NORS). RAG membership includes each of the sixteen NORS Clinical Leads, along with a broad representation from all steps in the donation and retrieval pathway. The Retrieval Advisory Group, together

with the National Organ Retrieval Service, plays a vital role within organ donation and transplantation, retrieving the organs which are at the core of transplantation as a realistic option for people on the transplant waiting list.

National Organ Donation Committee (NODC)
The National Organ Donation Committee is an advisory committee to NHSBT and acts as the national representative body for the twelve UK Regional Organ Donation Collaboratives. The membership of the Committee includes the Regional Managers for Organ Donation and their respective Regional Clinical Leads. NODC meetings are attended by representatives of relevant professional bodies as well as senior staff from the Directorate of Organ and Tissue Donation and Transplantation (OTDT) at NHSBT.

NHSBT
NHS Blood and Transplant organisation

NORS
National Organ Retrieval Service.
NHSBT commissions the service on behalf of the four UK Health Departments, who contribute funding for the provision of an integrated UK-wide retrieval service. NORS consists of 16 highly specialised organ retrieval teams across the UK based in transplant centres. Together, these teams retrieve organs and tissues which enable thousands of lives to be transformed across the UK every year.

NORS Centre
The NHS Trust or Board at which the NORS Team is based. Key contacts at the NORS Centre include:

- NORS Team Clinical Lead – a surgeon, usually a senior consultant, who is responsible for overseeing and managing the clinical performance of the NORS Team.
- NORS Management Lead – a named individual who is responsible for the operational management of the NORS Team.
- NORS Finance Lead – a named individual who is responsible for completion and submission of quarterly finance returns.

NORS Team
A surgical team from a commissioned group led by a NORS Surgeon (as defined by the NORS Training and Registration guidelines) that performs organ retrievals. The team includes the following roles:

- NORS Surgeon – a surgeon who is competent in retrieval, as established by the NORS Team Clinical Lead and who has completed required clinical and theoretical training.
- Surgical Assistant – a healthcare professional who provides support to the Lead Surgeon.
- Organ Preservation Practitioner – a practitioner who is capable of performing preservation, perfusion and packing of organs.
- Scrub Practitioner – a theatre practitioner who provides expert assistance to the surgical team in theatre.

National Transport Contract
This is the contract between NHSBT (the Commissioner) and a transport provider (identified by a procurement tender), to provide transport for NORS Teams, SNODs and unaccompanied organs.

ODT Hub Information Services
ODT Hub Information Services retrieves and provides information from and to those in the wider donation and transplantation community to make transplants happen, ensure patient safety, and fulfil statutory obligations.

ODT Hub Operations
Hub Operations provides a link in the transplant process between the Organ Donation Services Teams, the National Organ Retrieval Service, and transplant centres. Hub Operations supports the organ donation and transplantation community by matching organ donors to potential recipients. The Hub coordinates the deployment of NORS teams, and so organises and manages the safe retrieval and delivery of organs for transplant or research, 24 hours a day, 365 days per year to the UK, Republic of Ireland and European organ exchange organisations.

Perioperative Staff
The Organ Preservation Practitioners and Scrub Practitioners.

RCPOC
Retrieval/Recipient Centre Point of Contact

Regulations
The Human Tissue Act 2004
The Human Tissue (Scotland) Act 2006

The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.
http://www.legislation.gov.uk/uksi/2014/1459/contents/made

https://content.hta.gov.uk/sites/default/files/2021-06/HTA%20The%20Quality%20and%20Safety%20of%20Organs%20Intended%20for%20Transplantation%20Documentary%20Framework%20April%202021.pdf

The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (As Amended).
https://content.hta.gov.uk/sites/default/files/2021-06/HTA%20guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Human%20Tissue%20and%20Cells%20for%20Patient%20Treatment%20-%20Jan%202021.pdf

SACs
Specialty Advisory Committees

SNOD
Specialist Nurse - Organ Donation

Workforce Tariff
Also known as “the Tariff”, this is a sum of money paid to part-time NORS Centre for mobilising a NORS Team when not on-call, or in the two-hour period prior to the end of their week on call. The tariff is also paid when any NORS Centre mobilises two teams at the same time. This payment is made to cover the cost of the workforce; transport and consumables are reimbursed separately.

Rationale and Policy Statement

The Rationale for National Standards
Standards are required to ensure that:

1. The best possible transplant outcomes are achieved for all organs offered by donors and their families.
2. Organs are retrieved in a timely and co-ordinated fashion.
3. All donors are managed by competent personnel whose objective is to optimise subsequent function of all organs retrieved for transplantation.
4. The retrieval operation is performed by competent surgical teams to ensure that the quality of transplantable organs is not compromised during the retrieval process and thereafter.
5. Members of the NORS Team act as ambassadors for transplantation and behave in a professional manner throughout the retrieval process.
6. Donor hospitals throughout the UK receive a rapid and efficient service, minimising disruption to their other services whilst ensuring that organ retrieval can proceed as soon as possible.
7. Respect for the donor and donor family is given the highest consideration throughout the retrieval process.
8. The coordination and timing of retrieval, the quality of retrieval surgery and of the organs that are retrieved must reflect the principle that safety of transplant recipients is paramount.

This document specifies the Standards which all health care professionals involved in solid organ retrieval should follow in order to provide a high-quality service in the UK.

The National Standards provide guidance for retrieval from adult, paediatric and neonatal donors, and cover the retrieval of deceased donor organs currently routinely transplanted in the UK. They include retrieval of heart, lung, liver, pancreas, kidney, and intestine (or combinations of those organs) from donors after brain death (DBD) and donors after circulatory death (DCD). They also cover retrieval of the heart for aortic/pulmonary valves, pancreas for islets, liver for hepatocytes, and removal of tissue required to facilitate transplantation i.e. spleen, lymph nodes, blood, blood vessels and fascia.

The National Standards do not cover retrieval of organs from uncontrolled DCD donors or from living donors, nor do they cover retrieval of tissue such as corneas, bone, and skin. Emerging opportunities, including the retrieval and subsequent transplantation of vascularised composite allografts (VCA), i.e. abdominal wall, limbs, and uterus, are not yet included.

Retrieval of organs intended to be transplanted as tissue/cells (whole heart for valves, pancreas for islets and liver for hepatocytes) are covered by these Standards. Tissue procurement is in accordance with The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as Amended) (https://www.legislation.gov.uk/uksi/2007/1523/contents/made) and covered by a Third-Party Agreement (Schedule 9 of the NORS contract) between individual NORS teams and NHSBT (Human Application HTA licence number 11018).

On rare occasions when a NORS team attends a donor resident in a non-EU third party country, for example Jersey, Guernsey or Isle of Man (which are not part of the UK or EU), retrieval of whole heart for valves, pancreas for islets and/or liver for hepatocytes is carried out to the same standards as in the UK – ensuring equivalence as required by the *Implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells*, Annex IV.(https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1428582345653&uri=OJ:JOL_2015_093_R_0007).

As NHSBT facilitates research, the National Standards already provide guidance in relation to the support of research for transplantation/healthcare.

Use of this document
All associated links within this document should be read in conjunction with these National Standards and should not be saved locally in order to ensure that the most up-to-date version is accessed.

1. *Donor Assessment and Offering*

1.1. NHSBT has a Memorandum of Understanding in place with all donor hospitals in the UK to adhere to the core standards underpinned by the four key outcomes from the TOT2020 strategy and in Scotland the National Strategy to 2020 for Organ Donation as published by the Scottish Government Health Directorate.

1.2. Every potential donor hospital in the UK will have access to a SNOD who, in collaboration with the consultant intensivist, will be responsible for assessing the patient, approaching the family and ensuring that appropriate consent/authorisation has been ascertained, and for organising and co-ordinating organ retrieval at that hospital in collaboration with ODT Hub Operations.

1.3. The donor hospital will ensure that the diagnosis and confirmation of death in potential organ donors will be:

a) Conducted by appropriately trained and experienced clinical staff in compliance with accepted national professional standards; and

b) Recorded clearly and accurately in the patient's medical records.

These requirements apply to both the diagnosis of death using neurological criteria in potential DBD donors and the diagnosis of death using circulatory criteria in potential DCD donors.

Coordinating the process of WLST and confirmation of death in DCD donors is a complex matter. To avoid confusion, the NORS team should not contact or communicate with the intensive care team unless the SNOD is directly involved, for example, at the brief.

The SNOD must be the person to confirm with the intensive care team that the NORS team is ready for WLST. The NORS team will take no direct part in such communications, aside from informing the SNOD when they are ready.

Any contact between the NORS team and donor prior to declaration of death is inappropriate and is strongly discouraged. There may be rare cases where, for example, the position of devices such as external fixators or vascular cannulas has a bearing on DCD retrieval surgery. In such cases, every effort should be made to convey such information by drawings or scans, in discussion with the intensive care team and SNOD. Only with the agreement of the SNOD and the intensive care team, and in the presence of the SNOD at a minimum, can the lead surgeon assess such devices in the donor prior to surgery.

1.4. The SNOD should ensure the guidance has been followed and the form has been accurately and fully completed following neurological death testing, whilst the clinicians are available to discuss should any queries arise.

a) For DBD donation death is diagnosed using neurological criteria. SNODs should examine the documentation relating to this diagnosis as soon as possible and always before the patient is transferred to theatre. Any apparent errors or uncertainties should be resolved with the senior medical staff caring for the donor as quickly as possible and in a fashion that does not delay or jeopardise organ retrieval. Should the SNOD become aware that the patient is exhibiting spontaneous or spinal reflex activity on the ICU, he/she will highlight this to the caring team. The SNOD will make relevant staff aware of NHSBTs Safety Alert on the subject if required (Appendix 1).

b) For DCD donation, death is confirmed after five minutes of continuous absence of cardio-respiratory function. SNODs must ensure that the clinician who confirms death using circulatory criteria makes an entry to this effect in clinical records and that this is signed, timed, and dated.

In Scotland, a registered medical practitioner must pronounce death. However, elsewhere in the UK, appropriately trained nurse practitioners may now pronounce death. The governance remains with the ITU medical team as to the medical diagnosis of death.

1.5. The SNOD will seek confirmation from the caring consultant that they have liaised where necessary with the Coroner/Procurator Fiscal to ensure that there is no objection to organ retrieval going ahead.

1.6. If a donor has reproductive capacity, the possibility of pregnancy should be explored by the SNOD in accordance with the schedule laid out in MPD891 and any associated deviations. If the donor is known or confirmed to be pregnant then the SNOD must contact the Regional Manager on Call to escalate decision making. In the first instance, a specialist Obstetric opinion as to fetal age should be sought from the donor hospital obstetric service. Retrieval teams must not be engaged until a final decision that donation can proceed, as directed by senior members of NHSBT medical team. MPD891 provides detailed guidance.

If a potential donor is found to be pregnant during SNOD assessment, and it is decided that donation can proceed, the SNOD must discuss this with the consultant on call who is responsible for the NORS team prior to engagement of the retrieval team.

If a donor is found to be pregnant during the retrieval operation, the retrieval team must stand down immediately. The ITU medical team must be called immediately for further management. The lead retrieval surgeon must contact the on-call consultant at the NORS team base hospital to discuss the situation. Whilst retrieval surgery can only take place when the fetus has been delivered or pronounced dead by an appropriate specialist, it is recognised that the retrieval team may be unable to perform further surgery. In this regard, the opinion of the lead surgeon, in discussion with the Consultant on call at the NORS base, will be final.

1.7. The SNOD will ensure that appropriate investigations (blood group, microbiology, ECG, pregnancy test in females between 12 and 55 years) are performed before the retrieval operation and that the results of these investigations are available for the surgeons to review in theatre.

1.8. The SNOD should record details of any blood or blood products the donor received during their hospital stay and request a pre-transfusion sample where appropriate.

1.9. ODT Hub Operations will ensure that all potential donor organs are offered to transplant centres subject to any absolute contra-indications specified by relevant organ Advisory Groups (e.g. disseminated malignancy). Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation (POL188): https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/procedural-documents/

1.10. Organ offers will be made in accordance with the ODT Patient Selection and Allocation Policies (https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/). Organ offers will be moved onto the next centre in the offering sequence if the offering time has expired. In exceptional circumstances extensions to offer response times can be granted by ODT Hub Operations Shift Manager either on site or on-call, the on-call Regional Manager and the SNOD as long as this does not result in unacceptable delays to donation.

1.11. For organs offered to countries outside the UK, ODT Hub Operations must inform the respective transplant centre(s) that the retrieval will be carried out by a NORS Team. The transplanting centre may send representation (i.e. a surgeon with/without assistance) to participate in or observe the retrieval procedure pending agreement of the responsible NORS Lead Surgeon. Participation must not delay the retrieval process or prejudice the chance of donation occurring.

1.12. In the event that a potential DCD donor is subsequently diagnosed with brainstem death during preparations for retrieval and consent/authorisation for DBD donation is given, donation may be delayed whilst the SNOD or ODT Hub Operations offers the heart and any other organs that have been turned down because DCD donation was initially anticipated, provided that the donor family/hospital agrees to such a delay. If recipients for DCD organs from that donor have already been identified and notified, then their transplant centres may retain those organs for use in those identified recipients.

1.13. A potential DBD or DCD donor kidney will only be deemed unsuitable for transplantation if the organ has been offered and declined by all transplant centres through the Fast Track Scheme.

1.14. A potential DBD cardiothoracic organ donor will only be deemed unsuitable for transplantation if the organs are declined because of grossly subnormal organ function by at least four transplant centres in the cardiothoracic offering sequence.

1.15. For potential liver, pancreas and intestinal organ donors, a DBD or DCD donor organ will only be deemed unsuitable for transplantation if all potential transplant centres decline the organ except where the Liver, Pancreas and Bowel Advisory Groups have notified NHSBT of absolute contra-indications to donation.

1.16. Well-functioning organs declined for other reasons (e.g. hepatitis C positive donor, Hep B surface antigen positive donor, HIV positive donor/HCV positive donor, HTLV positive donor) will be automatically simultaneously offered to those centres which have agreed to participate.

1.17. A nominated RCPOC at the transplant centre e.g. recipient co-ordinator, transplant nurse or clinician, must be available at all times to liaise with the SNOD and the NORS Team.

1.18. Transplant centres must provide NHSBT with a robust method of communication for the receipt of organ offers, which must be available 24 hours a day. Transplant centres must also have access to EOS to view the documented donor data.

1.19. If there is no response from that telephone or pager after 45 minutes of trying to make contact, then the on-call NHSBT Regional Manager or ODT Hub Operations may move on to offer the organ to another transplant centre.

1.20. Whilst transthoracic and/or transoesophageal echocardiography and short clinical films of function in situ are considered desirable by some cardiothoracic transplant centres, they are not mandatory investigations for cardiothoracic NORS Teams. Transplant centres may be required to make a judgement on whether or not to accept a heart based upon the information available without these investigations.

1.21. A consultant transplant surgeon must be available at all times to receive donor organ specific information from ODT Hub Operations and/or SNODs and to relay recipient specific information to the NORS Team.

1.22. The names and contact numbers of both the recipient co-ordinator and the accepting and transplanting consultant surgeons must be supplied to the SNOD when an offer of a donor organ is accepted.

1.23. Transplant surgeons accepting an organ offer should be mindful of the guidance given by The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) regarding the risks of disease transmission from donors with specific infections or tumours.

1.24. It is the responsibility of all transplant surgeons to review the full Donor Characterisation data and the Medical and Social History (MaSH) Questionnaire (FRM4211) on EOS prior to implantation in order to have a clear understanding of the relevant donor information. The NORS Lead surgeon and RCPoC must also review both forms prior to the team leaving their base to ensure the NORS team are aware of any additional requirements for retrieval.

1.25. Transplant centres must adhere to the 45-minute timeframe for named, centre, group and fast track offers and 60 minutes for a cardiothoracic block offer.

If the offering time has expired and all efforts have been made to contact a transplant centre in accordance to the withdrawing offers protocol outlined in the Hub Operations manual(s), ODT Hub Operations will move to the next transplant centre in the offering sequence.
If unsuccessful, organ offers will then be moved on to the next transplant centre in the offering sequence. Transplant centres may contact ODT Hub Operations to request an extension to the offer response time, although this will only be granted in exceptional circumstances and must be approved by the on-call ODT Hub Operations Shift Manager who will escalate, if appropriate, to the on-call Regional Manager.

2. NORS Co-ordination and Mobilisation

2.1. Organ retrievals in the UK will be carried out by a commissioned NORS Team, which includes at least one competent abdominal and one competent cardiothoracic surgeon as appropriate. When organs are accepted by non-UK transplant centres, they may send representation (i.e. a surgeon with/without assistance) to participate in or observe the retrieval procedure pending agreement of the responsible NORS Lead Surgeon. Participation must not delay the retrieval process or prejudice the chance of donation occurring. The RTI and HTA-A forms will be completed by the UK NORS Team and payment for consumables will be made accordingly.

2.2. Once consent/authorisation (SOP5818/SOP5878) for donation is ascertained the SNOD will arrange organ retrieval in accordance with SOP5499.

2.3. ODT Hub Operations will hold a record of all NORS Team movements and will mobilise the NORS Team in accordance with the current mobilisation guidance and advise the SNOD in line with SOP4574. The SNOD must ensure that all communication about mobilisation should be directed via ODT Hub Operations.

2.4. The designated NORS Team will always be required to attend a retrieval, however, where specialist and/or additional expertise is required (for example in paediatric liver and/or kidney donors equal to or younger than 2 years of age), a surgeon from the transplanting centre may offer, or be asked, to attend and participate in the retrieval operation performed by the NORS Team providing this does not delay the retrieval process and prejudice the chance of donation and successful transplant occurring. The RTI and HTA-A form will be completed by the designated NORS team and payment for consumables will be made accordingly.

2.5. Should specialist retrieval expertise be required for certain recipients, these patients must be identified and agreed with the relevant solid organ Advisory Group at the time of listing of the recipient by his/her transplant centre.

2.6. The only exceptions to 2.4 and 2.5 are:

a) Small cardiothoracic donors (height <145cm OR weight <40kg) where the specialist team will attend (Newcastle or Papworth) and be paid for transport/consumables.
b) Complex congenital recipients (listed as such with NHSBT) – the NORS Team of the accepting transplant centre may attend instead of the closest available on-call NORS Team and be paid for transport/consumables.
c) Donors outside the UK – if the local organ retrieval team is unable to attend, one of the on-call NORS Teams will be asked to travel and retrieve the respective organ(s). In general, the NORS team selected will be the team accepting the donor liver. If this team is not available, the first available team with the lowest retrieval activity (retrievals per annum) will attend. In paediatric cardiothoracic donors, one of the specialist NORS Team (Newcastle or Papworth) will retrieve abroad. In special cases where additional retrieval expertise is required, i.e. paediatric liver and/or kidney donor <2 years, a dedicated surgeon from the accepting paediatric UK transplant centre may join the abdominal NORS Team to attend and be paid for transport/consumables.
d) Intestinal/multi-visceral donors: These will be attended by the NORS team of the accepting intestinal transplant centre which will retrieve all abdominal organs, not just the intestine. If the intestinal retrieval is cancelled prior to the retrieval team leaving base, the on-call NORS Team will retrieve as normal. If the accepting intestinal centre is not on call for NORS, the appropriate on call NORS team will attend the donor, and the accepting intestinal centre will send appropriate surgical staff to support the retrieval of the intestine.
e) Certain donors may require specialist input and senior surgeons from either the NORS or recipient centre may attend to support the NORS team at retrieval.

2.7. When a part-time NORS Centre mobilises when not on-call or in the two-hour period prior to the end of their week on call, they will be reimbursed for workforce ("Workforce Tariff"). This tariff is also paid when any NORS Centre mobilises two teams at the same time. This payment is made to cover the cost of the workforce; transport and consumables are reimbursed separately. The current Workforce Tariff payment is detailed in the NORS contract.

2.8. The NORS Teams are not expected to attend uncontrolled DCD donors.

2.9. It is standard practice for NORS Teams to travel by road. Air transport may, however, be used if:

- Road travel is not possible (e.g. for Northern Ireland or for Gibraltar).
- Estimated road travel time is over four hours (unless there are exceptional circumstances).
- Organ viability might be compromised by any delay.

If travel time is estimated to be between three and four hours, ODT Hub Operations will decide whether a flight can be booked, taking into account the flight cost, likely mobilisation time of flight, efficiency and time saving, and distance by road between airport and hospital. Traversing city road networks at busy times (0800-0900 and 1530-1800) will adversely affect travel times by road and may not necessarily be reflected in computer mapping predictions. Road transport in adverse weather conditions may also be fraught, more so than air travel (cold weather in particular). All such aspects, and especially team safety, must play into the decision for road or air travel. RCPOCs are welcome to discuss transport decisions with the Hub if local conditions suggest an alternate means of transport is more appropriate.

2.10. The timing of the retrieval operation will be arranged between the SNOD, the respective NORS Team Lead/RCPOC (when assigned by the Hub Operations) and the recipient centre(s), in good collaboration. Timings will be based on the proximity/availability of the NORS Team to the donor hospital, stability of the donor, urgency of any recipient, wishes of the family, availability of resources at the donor hospital, and time required to prepare recipients for surgery. ODT Hub Operations will keep the NORS Team and the transplanting centre informed of any delays. Any changes to agreed retrieval times must be escalated to Hub Operations as any delays will impact on other attending retrieval teams or the mobilisation sequence for donors planned for by Hub Operations.

VAD or other complex (re-do) patients may require a delay of cross clamp after the heart has been assessed as suitable for transplant. It is disruptive to the conduct of multiple other transplants when this delay is excessive or where there are multiple additive delays. Protracted delays also result in excessive work periods for retrieval staff.

To minimise retrieval delay, VAD explant or other complex (re-do) patients should be ready for anaesthesia at the time when knife goes to skin in the donor operation. Once the heart is judged to be suitable for transplant, the donor cardiothoracic surgeon should discuss with the recipient cardiothoracic surgeon as to the timing of recipient surgery and donor cross clamp.

Cross clamp delays in such circumstances, and the management of delays in general, are described in Section 6.

A theatre time can be set, and the NORS Teams mobilised once one cardiothoracic AND one abdominal organ has been accepted or, where no cardiothoracic organs are to be retrieved, once one abdominal organ has been accepted. The cardiothoracic team will arrive one hour before the abdominal team so that the necessary screening can be carried out in DBD donors.

For standard DCD donors, CT or Abdo teams require 1 hour to set-up before planned WLST, and may arrive at the same time as each other.

For DCD/OCS heart, the CT team will arrive 2 hours prior to WLST. Please see Appendix 8 for detailed guidance.

For aNRP, the Abdo team will arrive 2 hours prior to WLST.

The NORS Team will not be mobilised or booked to attend a donor over five hours in advance of the theatre time. ODT Hub Operations may deviate from this rule (for example, if the donor is in Northern Ireland or Cornwall) but the reason must be documented.

2.11. If the closest available NORS team is more than three hours away, ODT Hub Operations will predict when a closer team will become available and advise the specialist nurse to await and adjust the start time of the retrieval operation if this is clinically appropriate.

2.12. Concerns or conflicts relating to NORS Team co-ordination will be escalated and reported to Clinical Governance, and to the Retrieval Advisory Group (RAG).

2.13. In cases where HLA typing is not yet available, and a kidney matching run has not been performed and the SNOD considers it highly likely that the kidneys will be placed for transplantation, it is acceptable for the SNOD to request that the NORS Team is mobilised prior to an organ being accepted for transplantation. The final decision to mobilise will be with the NORS Team. Such a decision to mobilise must also take into account the effect on other transplants arising from the donor. If the donor is also a potential cardiac donor, the conventional pathway must apply.

2.14. NORS Teams must be able to leave the NORS Centre within 60 minutes (these timings have recently increased to a 90-minute mobilisation time on a trial basis) of call out by ODT Hub Operations; however, the mobilisation time must take into consideration travel time, family wishes, complex recipients, and planned theatre time. In general, there will be more than one hour's notice prior to mobilisation.

2.15. Trusts/Hospitals which participate as a NORS Centre must provide fully staffed NORS Teams which are available 24 hours per day, 7 days per week when on call. NORS Teams must be on call for organ retrieval without any interfering elective or other (transplantation) commitments.

2.16. If requested, each NORS Centre must be prepared to provide a team (fully staffed at the time of mobilisation) for more than one donor per 24-hour period, although they will not be required to attend simultaneous donations.

2.17. If required, teams are permitted a total of 2 hours between "back-to-back" retrievals (1 hour to rest, 1 hour to restock/mobilise) before leaving for a further retrieval, although this rest period is not mandatory.

2.18. NORS Teams will be asked to attend "back-to-back" retrievals only by the Hub Operations if this team is the only team left or if it is the most efficient use of NORS Teams in a particular donor situation and the shift patterns of the team members allow it. If the team does not have sufficient equipment, the transport provider can be asked to return to base to collect additional kit.

2.19. On occasions, if an additional NORS Team is required, NORS Centres may be asked to mobilise a team when they are not on-call, or to mobilise a second team if the first team is out retrieving. NORS Centres are not obliged to mobilise a team in these cases but will be paid a one-off sum to cover their workforce costs if they are willing and able to do this (Workforce Tariff). Transport and consumables will be paid in addition to the workforce.

2.20. A NORS Centre Point of Contact from each NORS Centre must be available 24 hours to receive calls from ODT Hub Operations and to mobilise the NORS Team when called upon to do so.

2.21. The NORS Centre is responsible for making cost-effective and timely transport arrangements for its NORS Team.

2.22. Perioperative staff (both abdominal and cardiothoracic) are responsible for taking all necessary equipment, preservation/perfusion fluids, drugs, ice, organ transfer boxes and documentation (organ specific HTA forms) for the retrieval process.

2.23. Every cardiothoracic NORS Team should bring the equipment needed for cardiac output and pressure measurements within the central circulation, DC cardioversion, and to perform bronchoscopy.

2.24. Robust, published duty rotas must be in place for all NORS team members including, when available, anaesthetic and donor care support, and for on-call Consultants and the NORS Centre Point of Contact.

2.25. Rotas must conform to European Working Time Directives and be made available to NHSBT upon reasonable request.

2.26. To enable the effective dispatch of NORS Teams, ODT Hub Operations will hold information regarding the availability of all NORS Teams. It is, therefore, the responsibility of a designated member of the NORS Team to ensure that ODT Hub Operations is notified when the NORS Team has returned to base following any mobilisation.

2.27. If a part-time team is approaching the end of their week on call, they are required to mobilise up to two hours before the end of the shift – failure to do so will be investigated as a contractual breach.

In the two hours before the end of their on-call shift, the NORS team can decide whether to mobilise, and if they attend, they will be paid the workforce tariff for doing so. If a team does not mobilise in that two-hour period, this will not be considered a failure to mobilise and will not be investigated as a breach.

3. Retrieval Operations and Preservation

The following is intended as an overview of roles and responsibilities during DBD and DCD organ retrieval. Specific DCD guidance is below.

DCD Organ Retrieval Guidance

3.1. Stand down rules for NORS Teams during a DCD procedure: Following withdrawal of treatment from a potential controlled DCD donor, NORS Teams must wait as follows:

- Cardiothoracic NORS Teams must wait at least two hours for the onset of functional warm ischaemia (defined as systolic BP <50mmHg).
- Abdominal NORS Teams must wait at least three hours for the onset of functional warm ischaemia (defined as systolic BP <50mmHg).
- If the systolic blood pressure has not fallen <50mmHg after the times stated above, then teams may stand down at that stage.
- If, despite fast-tracking, transplant centres have declined all the offered-out organs prior to the moment of stand down, teams may stand down earlier.

3.2. Abdominal NORS Teams may wait longer than three hours from treatment withdrawal if progressive cardiovascular instability suggests that asystole is likely to occur.

3.3. Once the systolic BP has fallen below 50mmHg (i.e. onset of Functional Warm Ischaemia) the NORS Teams will wait 30 minutes before abandoning the liver and pancreas, one hour before abandoning the lungs, and three hours before abandoning the kidneys as deemed untransplantable due to excessive warm ischaemia. If transplant centres have declined all the offered-out organs prior to the moment of scheduled abandoning, teams may abandon earlier.

3.4. If an abdominal NORS Team wishes to use normothermic regional perfusion in a DCD donor who is also a potential lung donor, the abdominal RCPOC must inform the Hub Operations as early as possible. At the donor hospital the abdominal NORS Team Lead must first discuss the details with the cardiothoracic NORS Team Lead before commencing surgery. Both teams should refer to current documentation which describes DCD retrieval with novel technologies. Links are provided in Appendix 8.

The abdominal NORS Team will cannulate the abdominal aorta and IVC or the groin vessels and the cardiothoracic NORS Team will then clamp the lower thoracic aorta and the IVC within the pericardium, and will then vent the aortic arch, after which NRP can commence. The cardiothoracic team will then immediately proceed to perfuse the lungs, after which a 30-minute hiatus is observed, during which the abdominal team establishes stable NRP. The cardiothoracic NORS Team may then commence lung retrieval, but must maintain excellent haemostasis throughout and must not stand down until both teams are satisfied that there is no significant bleeding into the chest.

When NRP is in use, DCD lung retrieval should commence in the usual way with cold perfusion and venting. However, the Cardiothoracic team must allow 30 minutes to pass from cross clamp before commencing lung explant, so that NRP can be safely established. The Cardiothoracic NORS Team Lead must be capable of meticulous retrieval surgery when NRP is in use, as if in a living patient. Cardiothoracic teams must be aware that the procedure to remove the lungs in this situation requires a substantially higher degree of haemostasis and surgical care than for conventional DCD lung retrieval.

If more than 4 units of red cells are required to be added to the NRP circuit, or NRP is terminated prematurely, or organs are lost as a consequence of bleeding in the chest after lung retrieval, such events will be reported to clinical governance and considered as SAEAR.

3.5. Although exceptionally rare, it is possible that effective and sustained cardiac activity could emerge after death during DCD retrieval. Cardiac activity after death does not by itself constitute the serious adverse event; consider DCD heart donation. It is re-perfusion of the brain which is inappropriate in DCD donors (AoMRC 2008) and which must be prevented.

The only exception to this is when the donor has already been pronounced dead by neurological criteria (Maastricht Category IV DCD). In this case, re-perfusion has no clinical effect, as the donor is equivalent to DBD in terms of arch vessel perfusion.

Note that these directions apply to the SNOD and retrieval team. Other specialists involved will follow their own protocols and apply their own clinical judgements.

It should be borne in mind that DCD retrieval proceeds at the fastest possible speed; what seems logical and ordered in the text below may be challenging to deliver.

Situation 1. Maastricht Category III DCD.

- The donor is pronounced deceased by circulatory criteria as usual.
- The retrieval surgeon notes that the heart is beating in an effective and sustained fashion and/or there is a pulse in the aorta. This could be at the very start of the DCD procedure, or perhaps subsequently.
- If the retrieval surgeon considers that there is effective, sustained cardiac activity which could perfuse the brain, the retrieval team(s) should abandon all retrieval-related interventions immediately, including any form of ventilation, and stand away from the donor. The NORS Lead Surgeon should inform the on-call consultant at the NORS base.
- The SNOD should summon support from the donor hospital anaesthetic / critical care team as a matter of urgency.
- The donor hospital anaesthetic / critical care team should re-instate ECG and arterial pressure monitoring if practicable and consider the administration of analgesic and sedative agents to prevent the possibility of the patient suffering prior to the return of cardio-respiratory arrest (*Excerpt from NODC guidance)*
- Cardiac activity is unlikely to be sustained for long and circulatory arrest will occur.
- If all team members agree, it is permissible for organ retrieval to resume once directed to by the donor hospital anaesthetic/critical care team. However, the NORS surgeon, in discussion with the on-call consultant, may consider that the team are not able to complete surgery.
- In the situation where donation proceeds, any lung reinflation prior to lung retrieval must be delayed until at least 15 minutes after the final asystole (*Excerpt from NODC guidance).*
- The on-call Regional Manager should be called as soon as practicable and the incident should be reported through both the donor hospital and NHSBT incident reporting systems. The lead personnel involved in the incident should complete a comprehensive account of the incident in the patient's medical records.

Situation 2. NRP in Maastricht Category III DCD (TANRP; see Appendix 10).

- The donor is pronounced deceased by circulatory criteria as usual.
- At the commencement of the operative procedure, the ascending aorta is vented prior to starting the pump.

- If the myocardium contracts, blood will be vented, limiting any further myocardial activity with immediate effect. To ensure the arch is empty, a larger vent should be fashioned and suction applied to the lumen of the aortic arch.

- Any subsequent myocardial activity is likely to be ineffectual and un-sustained, as the coronary artery perfusion pressure is atmospheric when the aortic arch is vented.

- If the retrieval surgeon considers that there is effective, sustained cardiac activity which could perfuse the brain, **prior to the arch being vented**, the retrieval team(s) should abandon all retrieval-related interventions immediately, and follow the directions as for Situation 1.

AoMRC 2008; A code of Practice for the Diagnosis and Confirmation of Death. Academy of Medical Royal Colleges, 2008)

NB: For guidance on lung retrieval from DCD donors see Appendix 2

Organ Retrieval Operation

Donor Hospital

3.6. The donor hospital will provide a fully equipped operating theatre for the retrieval procedure, including appropriate anaesthetic equipment and drugs to support the donor (as per Basic Guidelines for Theatre Staff at Donor Hospital – INF1424).

3.7. Donor hospitals should allow the retrieval procedure to start as soon as possible after the NORS Team has arrived.

3.8. The donor hospital will provide an anaesthetist to support DBD donors in the operating theatre during the retrieval procedure.

3.9. The donor hospital will provide a suitable member of staff, such as a qualified theatre practitioner and/or operating department assistant, who is familiar with the theatre facilities and the whereabouts of the surgical and anaesthetic equipment, instruments and drugs which may be needed by the NORS surgeons and anaesthetist.

3.10. This/these individual(s) will remain in theatres during the retrieval procedure to aid the Scrub Practitioner (provided by the NORS Team) the anaesthetist and the Organ Preservation Practitioner (OPP) and assist the SNOD with the final act of care.

SNOD responsibilities

3.11. In conjunction with staff at the donor hospital the SNOD will ensure that operating facilities for the retrieval operation and for the safe transfer of the donor to theatre have been arranged.

3.12. The SNOD will maintain a presence in theatre to ensure continued co-ordination of the retrieval process.

3.13. The SNOD should adhere to SOP5499 – Theatre Manual for Deceased Organ Donors ensuring that it is agreed prior to surgery commencing who will take responsibility for sample collection, for the correct packaging and labelling of organs and samples retrieved for transplant. Organ boxes must be clearly labelled with the full hospital address including postcode (no abbreviations) and agreed drop off point.

3.14. The SNOD will ensure that appropriate consent/authorisation has been ascertained and recorded for the removal of individual organs prior to organ retrieval and that the retrieving surgeons have completed the peri-op section of the Retrieval Check List on DonorPath (or FRM4135 NHSBT Surgical Safety Checklist if DonorPath is unavailable), checked the identification of the donor, the consent/authorisation form and all other relevant documentation before commencing the retrieval operation.

3.15. The SNOD must ensure that the pre-theatre section of the Retrieval Check List on DonorPath (or FRM4135 NHSBT Surgical Safety Checklist if DonorPath is unavailable) is completed before the start of the retrieval operation.

3.16. The SNOD must confirm there are dedicated personnel to communicate the cross-clamp time with the transplant centre receiving the organs at the earliest opportunity after cross-clamp has occurred.

3.17. The SNOD will record all the necessary key time points required for each of the organ specific donor record forms, including the time that each organ was removed from the operative field and placed in cold solution.

3.18. The SNOD will ensure that the donor information has been fully completed on Donor Path. It is the SNOD's responsibility to legibly record the donor demographics on the HTA Organ Specific forms.

3.19. The SNOD will liaise with recipient centres to keep them informed about the progress of the retrieval process including cross-clamp times and alert them when the organs are dispatched from the donor hospital.

3.20. The SNOD must document in the patient's medical records a note for the pathologist stating:

IMPORTANT NOTE FOR PATHOLOGIST REGARDS A POST MORTEM EXAMINATION:

If a post-mortem (PM) examination is performed, the Pathologist must immediately contact NHS Blood and Transplant ODT Hub Operations on telephone number 0117975 7580 if the PM identifies pathology that is, or may be, relevant for the health or future health of the transplant recipient(s) and/or the patient's family. In particular, evidence suggesting a transmissible infection or neoplasm should be communicated as soon as possible.

The clinical notes of the donor must contain the above information, along with the details of the SNOD. (SNOD Name) Specialist Nurse – Organ Donation; (ODST Team Name) Organ Donation Services Team

3.21. The SNOD will take responsibility for ensuring the correct organs are dispatched to the transplant centres and complete the Organ Handover Form FRM4217.

Organ Preservation Practitioner (OPP) Responsibilities

3.22. The OPP of the abdominal NORS Team is responsible for abdominal organ preservation, liver, kidneys, and pancreas during organ retrieval. The OPP of the cardio-thoracic NORS Team is responsible for cardio-thoracic organ preservation; heart and lungs during organ retrieval.

3.23. The Abdominal and Cardiothoracic Perfusion and Preservation Protocols for NORS Teams in the UK (Appendix 3), should be adhered to.

3.24. Packing and labelling of all specimens, particularly spleen and lymph nodes, as well as blood vessels is the responsibility of the Organ Preservation Practitioner. The individual taking responsibility for packing the organ and sealing the box must ensure that each sample and any vessels (including ad hoc requests for vessels) accompanying the organ has three points of donor identification and FRM6199 Vessels Form is completed

3.25. It is the responsibility of the OPP to ensure that the HTA Organ Specific forms and any necessary vessel forms (FRM6199) have been fully completed. Nonetheless, the lead surgeon remains legally responsible for the content and accuracy of these forms, regardless of who completes them. The lead surgeon's name and contact details must appear on the HTA forms. The OPP must ensure forms are dispatched with the retrieved organs and tissue to transplant centres.

The lead surgeon may direct another team member to sign the HTA A forms. This may happen when, for reasons of cold ischaemic time, the surgeon is otherwise engaged in organ packing. **In all cases, the**

lead surgeon remains legally responsible for the content and accuracy of these forms.

3.26. Ad-hoc vessel requests
Ad-hoc vessels and rectus facia are those retrieved in addition to those commonly required for transplantation of the organs retrieved from that donor according to SOP5685. They may be requested to support a complex transplant with bespoke vascular reconstruction, or an additional transplant (e.g. Living donor transplant). Such vessels must be packaged as detailed above and documented on the Kidney HTA A form and a copy of this form sent with the ad hoc vessels.

NORS Team Responsibilities

3.27. Members of the NORS Cardiothoracic and Abdominal Team should be aware that they are ambassadors for organ donation, retrieval and transplantation and must behave in a professional and respectful manner throughout the retrieval process.

3.28. The NORS Team should keep a presence in theatre throughout the procedure, including any agreed or planned delays/breaks.

3.29. Before commencing the retrieval operation, the competent NORS Cardiothoracic and Abdominal Team Lead Surgeon(s) must review the patient's medical notes. Cardiothoracic and Abdominal Lead Surgeons must participate in the NHSBT Surgical Safety Checklist and the pre-theatre briefing before knife-to-skin begins. In particular, they must:

a) Have a clear understanding of the donor information prior to the start of the retrieval.

b) Check the identity, hardcopy blood group and virology of the donor and cross reference against entry on DonorPath. The SNOD will ensure that the appropriate hard copy paperwork is immediately available so that the surgeon may review hard copies and DonorPath at the same time. Nonetheless, the SNOD, not the surgeon, remains responsible for the correct completion of DonorPath.

c) Identify that death has been diagnosed and confirmed using either neurological or circulatory criteria by appropriately trained and qualified clinical personnel in the local donor hospital, and that it has been documented correctly in the patient's clinical records.

On the rare occasions where there are concerns over the correctness of documentation confirming death using neurological criteria, these concerns should be raised with the SNOD. The SNOD will liaise with the critical care team and escalate to on-call staff as necessary to address any errors or omissions. Detailed help and exemplar forms are available in the "Code of Practice for the Diagnosis of Death (Academy of Medical Royal Colleges 2008)" https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1338/aomrc-death-2008.pdf and the corresponding document for infants "The diagnosis of death by neurological criteria in infants less than two months old". https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1354/neurological-death-dnc-guide-final.pdf

d) Retrieval team members have a right to be confident in the diagnosis of death. If the Lead Surgeon has concerns which are not addressed, the surgeon should discuss with the on—call Consultant at the NORS centre and/or the appropriate ITU Consultant. Although it should be recognised that the application and interpretation of the criteria used to diagnose death using neurological criteria falls out with their own area of expertise, surgeons can expect the form to be completed correctly. In doing so, NORS Team members must act in a way that does not jeopardise organ retrieval or the confidence of other staff members in the integrity of the process.

e) Check that appropriate consent/authorisation has been documented for the organs and tissue to be retrieved.

f) Any restrictions placed on the retrieval of organs by the Coroner/Procurator Fiscal have been discussed and reviewed between the SNOD and Lead Surgeons in accordance with MPD865

g) If the donor's height is to be measured, this should be done in accordance with the NHSBT Physical Assessment Management Process Description (MPD873).

h) If after having reviewed the patients' medical notes the NORS Team Lead Surgeon(s).

- is concerned about the clinical information in the medical notes and/or EOS.
- and/or finds information of concern in the medical notes not documented on EOS preoperatively.

The NORS Team Lead Surgeon should urgently communicate the information to the SNOD. The SNOD should urgently inform the Hub Operations of the new information and update EOS.

If the Lead Surgeon feels that this information could significantly affect the suitability of the organs for transplantation, the SNOD should inform the Hub to contact recipient centres with the new information.

3.30. Cardiothoracic and Abdominal Lead Surgeons must participate in the NHSBT Surgical Safety Checklist and the pre-theatre briefing before knife-to-skin.

3.31. Any novel or uncommon procedure or deviation from accepted protocols which might have an adverse impact on other organs retrieved from that donor can only be carried out after discussion and agreement of all parties involved in the retrieval.

3.32. If, for any reason, there is an unusual aspect which is not clear in previously agreed retrieval protocols, and agreement cannot be reached by the attending competent NORS Team Lead Surgeon(s), then these NORS surgeons should contact the Consultant Surgeons on call in their centres and/or the relevant NORS Clinical Leads to resolve the matter. This should be organised with the SNOD and on-call NHSBT Regional Manager.

3.33. In some instances, review of anonymised photographs of the patient (e.g. unusual skin rash or mole) or organ(s) taken before, during or after retrieval will help the transplant surgeon in making the most appropriate decision as to whether to accept a retrieved organ for transplantation. NORS Teams are encouraged to record and send photographs of organs or tissues to the transplant surgeon where it is clinically appropriate, provided donor anonymity is protected (donor ID only - no patient identifiable information). If sending images via ODT Hub Operations, three points of ID must be sent (donor ID, donor hospital and donor's date of birth). See MPD1100.

3.34. If the transplant surgeon wishes that an organ is placed on machine perfusion immediately after retrieval, then it is his/her responsibility to liaise with the retrieval surgeon to ensure that they are willing and competent to do this. Otherwise, the transplant surgeon should arrange for a competent member of his/her team to attend and place the organ on the machine. The travel and consumables are not part of the commissioned NORS service and will not be reimbursed by NHSBT. Attendance of the recipient centre staff in such cases is supported only if it does not involve additional delay.

If the team attending is a NORS Team that is not on-call and is ONLY attending at their own request (i.e. not at the request of ODT Hub Operations) then the workforce tariff will not be paid. If machine perfusion is not possible then the retrieval surgeon must package the organ in static cold storage in accordance with standard protocols.

3.35. All aspects of the retrieval operation should be conducted in accordance with appropriate infection control procedures.

3.36. In the case of donors with systemic infection, universal infection control measures must be taken. Refer to SaBTO guidance: https://www.gov.uk/government/collections/sabto-reports-and-guidance-documents

3.37. After a laparotomy and/or thoracotomy have been undertaken, a thorough inspection of the organs should be performed both to exclude pathology such as malignancy or any other condition which might preclude organ transplantation or impact upon a recipient. Any pre-existing injury or abnormalities found

at organ retrieval should be clearly documented in the donor's medical notes. The same information should be documented on the Witness 12 statements, if applicable.

3.38. Retrieval surgeons must take all reasonable steps to exclude malignancy in the donor. The entire gastro-intestinal tract, pancreas, liver, and pelvic organs must be examined, ideally at the start of the procedure. The kidneys should be inspected directly after retrieval by incising Gerota's fascia and clearing the fat adequately not only to confirm satisfactory organ perfusion but also to exclude renal tumours. Unless specifically excluded, a median sternotomy as well as a laparotomy should be performed, and the lungs, hilar nodes and thoracic oesophagus examined. On the rare occasions where only cardiothoracic organs are to be retrieved, it is expected that the cardiothoracic NORS team would be able to examine the GI tract and retrieve spleen and lymph nodes without the need to mobilise the abdominal team.

DCD donors require exactly the same scrutiny as DBD donors. It may only be possible to examine the viscera in the donor once the organs have been retrieved in the DCD setting. Nonetheless, the same detailed scrutiny must be applied.

Surgeons must consider that failure to identify transmissible disease in the donor places the recipients at grave risk. Such events, although rare, may cause mortality, and the donor surgeon will naturally be asked for an account of the donor findings.

Keep recipients safe and keep yourself safe. Examine the donor carefully and document findings. Pass on any concerns to recipient centres.

3.39. It is important that malignancy in a retrieved organ is identified before any other organ from that donor is transplanted

3.40. Care must be taken to avoid surgical injury to organs and their vasculature. In particular:

a) Ventilation (DBD) or lung inflation (DCD) should be interrupted during median sternotomy to prevent injury to the lungs.
b) The liver should be protected with a swab during median sternotomy and, during mobilisation; it should be retracted gently to prevent avulsion of its peritoneal attachments.
c) Handling of the pancreas should be kept to a minimum; during mobilisation the spleen should be used to act as a handle.
d) During kidney retrieval the ureters should be kept as long as possible together with sufficient soft tissue to preserve ureteric blood supply. Care must be taken not to exert undue traction on the renal pedicle.
e) In paediatric kidney retrieval (<20kg), a cuff of bladder should be provided with each ureter to facilitate implantation.
f) The iliac arteries and veins should not be "pulled" during removal. Unsuspected arterial dissection as a consequence may have grave implications for a liver or pancreas recipient.

3.41. Biliary tract: prior to retrieval, the gall bladder should be opened and gently sucked out. Repeated room temperature saline washes should be performed to clear the gall bladder of bile before the onset of cold ischaemia.

3.42. In DBD retrieval, the common bile duct must be carefully but thoroughly flushed with UW solution using approximately 250 ml (Abdominal Perfusion and Preservations Protocol for NORS Teams in the UK (Appendix 3). This can be done according to preference of the NORS Team: either in situ before retrieval of the liver and ex situ on the back-table or just ex situ on the back-table. UW solution is used because it has a neutral pH; saline is not used since it has an acidic pH.

Flushing the bile duct in DCD retrieval must be done as soon as the aortic perfusion is running. It must be copious. UW is strongly preferred and is the most commonly used flush in NORS practice.

3.43. Ice slush should be used in the abdomen and chest around the organs to be retrieved.

3.44. NORS Teams are required to remove all allocated abdominal organs. Additional perfusion/packing should take place on the back table to prevent warm ischaemia time within the donor body.

3.45. Where the pancreas has been offered out, either for solid organ or for islet transplantation, and the NORS Team has concerns at time of retrieval about the quality of the organ, it has been agreed that the pancreas is to be removed in all instances to be properly inspected on the back-table by the Lead Surgeon to assess whether it appears suitable for transplantation or islet isolation. The Lead Surgeon's assessment will be conveyed to the Hub Operations that will inform the allocated centre and fast-track when appropriate. Additional photos may be of help to be sent to the receiving Transplant Team.

3.46. If there is an accessory right hepatic artery which cannot be safely preserved in its entirety either because it travels through the pancreas or gives a major branch to the pancreas then, as agreed by the Pancreas Advisory Group and the Liver Advisory Group, it can be divided at the duodenum. Before transecting it, the following applies:

a) The liver transplant centre should be informed by the SNOD.
b) If the liver transplant centre agrees then divide the RHA at the duodenum.
c) If the liver transplant centre feels that there is a valid exception to this, then discussion needs to take place between the consultant liver and pancreas surgeons to agree the course of action.
d) The SNOD should be informed of their decision within 30 minutes.

3.47. Prior to insertion of the abdominal arterial perfusion cannula in DBD donors 300units/kg of heparin should be given intravenously at least 2 minutes before cannulation.

3.48. Please refer to the Abdominal Perfusion and Preservations Protocol for NORS Teams in the UK – revised September 2014 (Appendix 3) for guidance on organ flushing, preservation and packing. Abdominal organ perfusion is carried out by the OPP in attendance as outlined above.

3.49. All organs must be accompanied by appropriate specimens (blood samples, lymph node, and spleen) (see para 3.58 below) and by completed organ specific NHSBT and blood group forms. Liver and pancreas must always be accompanied by the blood vessels needed for reconstruction in the recipient. NORS Teams need to be aware that a pancreas declined for an islets recipient would still be offered as a whole organ for transplant.

3.50. If the liver is split in situ at the donor hospital, the **recipient consultant surgeons who will receive the two liver grafts must discuss in advance** which graft will be retrieved with the native arteries in continuity, and which graft will be allocated the donor iliac artery and vein.

Only in exceptional circumstances, such as for re-transplantation and the creation of an arterial conduit, should additional vessels be requested at the time of retrieval (Carotid arteries or superior mesenteric artery). In this situation, consultant (liver) to consultant (pancreas) discussion must take place to determine which vessels will travel with which organs.

Vessels to accompany the liver and pancreas should either be packed in a sterile small plastic container (or sterile inner first bag) submerged in preservation solution (not saline), that is then double bagged, with the second and third bag de-aired and remaining dry. It is important all bags are firmly tied. The vessels should not be placed in the bag/bowl with the organ but should be packaged separately by the OPP. It is essential to label these vessels using the appropriate labels and identifiers. It is similarly essential to pack the artery and vein separately.

3.51. In cases of cardiothoracic retrieval, once the heart and/or lungs have been removed abdominal surgeons should interrupt their cold phase dissection to supply lymph node and spleen samples (see para 3.58 below) to the cardiothoracic NORS Team so that the heart and lungs can be shipped to transplant centres without delay.

3.52. NORS Teams intending to drain through the inferior cava into the dedicated 'reservoir' are asked to announce such intention and explain to the theatre team and to the SNOD why they are doing this.

3.53. Standard practice under NORS is to retrieve abdominal organs separately unless indicated otherwise. En-bloc retrieval of liver and pancreas is accepted, but undue delay whilst splitting organs on the backtable is a risk in this case and must be avoided. Nonetheless, the speed of en-bloc retrieval in DCD donors reduces time to place organs on ice, a desirable outcome.

3.54. If there is an unintended breach of the gastro-intestinal tract during retrieval, this should be managed using a standard surgical approach of reducing contamination and decontaminating the cut edge of that part of the intestinal tract. This breach should be documented on the HTA-A Form and urgently communicated to ODT Hub Operations so that they can pass this information on to all the relevant transplant centres.

3.55. All abdominal organs (including liver, pancreas and both kidneys) that have been accepted or are still on offer should be retrieved by the NORS team and inspected on the back-table.

3.56. If there are late declines such that a SNOD must re-offer organs after withdrawal of life-sustaining treatment (WLST) in DCD, or during surgery in DBD donors, the operation will proceed including cross clamp and cold preservation/retrieval until it is clear that all organs have been finally declined for clinical transplant. If such late declines occur before the DBD donor is in theatre, or before WLST has occurred in DCD donors, the SNOD should complete re-offering prior to WLST or surgical start. Such events should be the subject of clinical governance reports to NHSBT.

3.57. NORS Teams will remove pancreas for islet transplant and liver for hepatocyte transplant but are not expected to retrieve tissue such as corneas, bone, and skin. However, they should be aware that these may, on occasion, be retrieved in theatre by local staff. NORS Teams may be asked to remove the heart for aortic/pulmonary valves, if consent/ authorisation has been given, following standard guidance on retrieval (INF195).

3.58. Care must be taken to identify and report abnormal anatomy such as aberrant or accessory renal and hepatic arteries.

3.59. The abdominal team will retrieve at least 2 palpable lymph nodes per allocated organ, blood vessels, and spleen samples to accompany the organs and any additional samples as required. The SNOD will arrange for the blood samples to accompany each organ.

3.60. Kidneys from donors aged under 5 years will be retrieved and offered en-bloc while kidneys from donors aged 5 years and over will be retrieved and transplanted singly wherever possible. En-bloc kidney retrieval relates to the removal of both kidneys in continuity with the aorta and inferior vena cava. En-bloc kidneys will be offered on a centre, rather than patient basis, to any centre wishing to receive offers of such kidneys. If the recipient centre wishes to implant both kidneys separately, then they will divide the two kidneys on receipt at the recipient centre - splitting a paediatric bloc is NOT a requirement of the NORS Team.

3.61. Livers may be split in-situ if both recipient liver transplant centres agree and provided that the attending cardiothoracic NORS Team does not object, but must be abandoned if, in the opinion of either the abdominal or the cardiothoracic NORS Team, the donor becomes unstable. Where agreement cannot be reached on liver splitting in-situ, the paediatric recipient centre is the index centre where the whole liver will be sent to be split unless both recipient liver transplant centres agree otherwise.

3.62. In the case of any liver retrieval the competent NORS Team Lead Surgeon(s) will contact the recipient centre to communicate about the quality of the respective organ as, frequently in these cases, the recipient operation will start before the arrival of the organ. For all other organs it is sufficient that the competent NORS Team Lead Surgeon(s) notifies the recipient centre immediately if any organ appears sub-optimal or if any unexpected damage or abnormality is encountered which might compromise the function or safe use of that organ. The NORS Team Lead Surgeon is responsible for documenting the conversation in the medical notes as well as for documenting any unusual findings that cause concern.

3.63. On completion of the operation, the NORS Team Lead Surgeon is responsible for producing an accurate operation record in the donor patient notes. This note should include clear documentation of all organs

and tissue removed from the body, including which organs have been removed and which have been accepted for transplantation. Documentation of any abnormalities/injuries noted during laparotomy or thoracotomy, the start time of the retrieval operation, and any communication with members of the transplant team(s) is required.

3.64. The NORS Lead Surgeon should also document any conversations with accepting transplant centres and their response to that conversation.

3.65. After signing the notes, the surgeons must clearly write their names and the names of their NORS Centre together with a contact number in case ODT Hub Information Services or Coroner/Procurator Fiscal wishes to contact them.

3.66. Where required, it is the competent NORS Team Lead Surgeon's responsibility to complete MG11 forms (Witness Statements), if requested by the Coroner.

3.67. HTA A form: The SNOD will legibly record the donor demographics on the HTA Organ Specific forms. Documenting and recording fluid type and batch number is the responsibility of the Organ Preservation Practitioner. The NORS Team Lead Surgeon(s) must ensure that all surgical and anatomical details are legibly recorded and then signed and returned to the SNOD prior to leaving the premises. If the form is not returned to the SNOD then ODT Hub Information Services will contact the NORS Team Lead Surgeon(s) for a copy of the form. Regardless of the individual who completed the A forms, the Lead surgeon remains legally responsible for their content and accuracy.

3.68. The retrieval team must not be delayed in its departure from the donor hospital. This is particularly the case when the team is transporting an organ with a short cold ischaemic tolerance. If organ(s) have not been placed with a transplant centre at the end of a retrieval, it is the NORS Abdominal Team's responsibility to take the organ(s) back to their base. The SNOD will inform ODT Hub as to which organ(s) are going to the NORS base. The organ(s) should be held in a well-defined and secured environment at their base until ODT Hub Operations informs them that they have been placed. The recipient centre will arrange transport as usual, collecting the organ(s) from the NORS centre.

Should such organs being held in a NORS centre not be used for transplantation or research, nor be returned to the donor, the NORS Team will be responsible for arranging disposal of the organ according to NORS Centre policy and recording on the HTA-B form.

If an organ is removed at retrieval which is not accepted for transplant or research or for example if the Cardiothoracic surgeon removes the heart to aid lung retrieval and the heart is not being sent for heart valves, the organ must be returned to the body and such then be clearly documented in the donor patients medical notes.

In addition to donation of organs for transplantation, deceased donors often donate tissue as well ('Heart for Valves'). Should an organ donor be found unsuitable for organ donation as a result of pathology revealed during donor surgery, the question arises as to whether tissue donation is still feasible.

3.69. In this situation, the SNOD should be consulted to determine whether tissue donation can proceed. The SNOD, having referred to the appropriate exclusion criteria, and mindful of the pathological findings noted by the surgeon, will direct the surgeon to retrieve the heart for valve donation if appropriate. Alternatively, the SNOD will direct the surgeon to close the patient if no tissue donation is possible.

If the heart is to be retrieved for valve donation in a DCD donor, the heart is retrieved and prepared as usual. In DBD donation, the surgeon should exsanguinate the donor in the usual fashion and retrieve the heart. The heart is then prepared for placing in the heart pot as usual

3.70. If, in a donor attended by a NORS Team, a specific organ is found to be unsuitable for transplantation and is declined by the relevant transplant centres, then the NORS Team may retrieve it for research purposes provided that appropriate consent/authorisation has been obtained. NB: Under HTA rules, if material is being removed from the deceased for the primary purpose of research, then a specific HTA licence for the premises where the material is removed must be in place unless the respective Trust is covered by the extended NHSBT Research Licence for specifically NHSBT approved research studies.

The Human Tissue Act only applies to England, Wales, and Northern Ireland. There is no requirement for an HTA licence to procure organs and tissue for research for hospitals in Scotland.

3.71. NHSBT facilitates research and NORS Teams are required to obtain samples during retrieval for QUOD or projects agreed by RINTAG, where appropriate consent/authorisation has been obtained. There is a potential conflict when a research biopsy (e.g. QUOD) is considered in a donor where an organ may have undergone a biopsy for clinical assessment purposes. Kidney biopsies in particular have led to governance incidents. Therefore, the SNOD and the lead surgeon must consider the following priorities specifically for **kidney biopsies.**

Priority 1. Organ Safety Assessment.
These biopsies are obtained if there is concern relating to malignancy or other serious disease. Adequate material should be taken to secure a pathological diagnosis, excluding or confirming the diagnosis definitively. Biopsies may be wedge, punch or other as appropriate. The NORS surgeon **must discuss with recipient centres.**

Priority 2. Organ Quality Assessment.
Such biopsies are taken on the clinical request of the implanting centre for their allocated kidney to determine quality. A punch biopsy is recommended. Only one quality assessment biopsy should be taken from a kidney. A quality assessment biopsy may be taken in addition to an organ safety assessment biopsy (Priority 1), if deemed necessary and **requested** by the recipient centre.

Priority 3. QUOD Biopsies.
QUOD (research) biopsies should only be taken if **no other biopsies are requested or taken**. Only one attempt should be made to take a QUOD biopsy, and only one QUOD biopsy should be taken from a kidney. For the avoidance of doubt, if a biopsy has been taken for organ safety and/or organ quality, **a further research biopsy must not be taken.**

3.72. Retrieval surgeons using banked blood, for example as part of a machine perfusion technique, must capture the DIN number of each unit on the HTA form for the organ. The DIN number(s) must also be recorded in the operation notes for the donor. Refer to Appendix 7 (Blood utilisation for donor organ retrieval, ex situ machine perfusion and preservation technologies).

3.73. In recognition of the gift of donation, NORS Team leads may wish to acknowledge the donor. Some feel that the task of organ retrieval surgery is made more stressful and emotionally challenging by adding such a personal element to the process before the operation begins.

Accordingly, when all aspects of the retrieval process are completed, for example when the donor is undergoing last offices, a gesture may be made by team members who feel able to do so. Examples could be a moment's reflection in silence, or a brief message of thanks given by the Lead Surgeon. Participation in such a gesture is voluntary and could be done individually or as a group. Team members should make their own decision, and there will be no coercion to participate.

3.74. The SNOD and members of the NORS Team will report any significant adverse occurrence during retrieval within 48 hours (SOP3888) by accessing the NHSBT Incident reporting form via https://safe.nhsbt.nhs.uk/IncidentSubmission or via the ODT Clinical website: https://www.odt.nhs.uk/.

3.75. All SAEARs should be reported within **24 hours** of discovery by the license holder. In cases where an urgent notification is required, the establishment must telephone the NHSBT Hub Operations on 01179 757575 immediately upon discovery. The telephone call must be followed up by an online submission of a report form detailing any immediate actions taken. Such urgent notification would be required in cases where there are potential implications for other recipients.

3.76. A Retrieval Team Information (RTI) form (FRM4125) must be completed by the NORS Team and submitted by the NORS Centre for every donor attendance.

Communication of Intra-Operative Findings

Table 1 (overleaf) is not intended to be an exhaustive list of findings but serves as a guide for effective communication before, during and after organ retrieval.

If the Lead Abdominal and/or Cardiothoracic Lead Surgeon is concerned about any element of the donor's medical history, findings during theatre and anything else that may impact on the health and safety of the intended recipient then they must discuss with the accepting consultant transplant surgeon.

** It is recommended that best practice is for the Lead Retrieval Surgeon to discuss any concerns directly with the Consultant Transplant Surgeon at accepting Transplant Centres. This conversation may be facilitated by Hub Operations e.g. the SNOD/the Lead Surgeon may request the Hub Operations to contact the Transplant Centre recipient points of contact and request that the Consultant Surgeon calls the Lead NORS Team Lead Surgeon.

Table 1

Finding	**Who informs Who?**	**Documentation**
Lead Surgeon(s) review medical notes and EOS at the donor hospital, any new information or information of concern should be communicated to accepting transplant centres	Lead NORS Surgeon(s) informs Hub Operations who must inform Recipient points of contact at accepting transplant centres Lead surgeon(s) should also inform the SNOD of his/her concerns	Conversation documented in the medical notes SNOD should document on DonorPath and inform HUB Operations
Findings in theatre requiring urgent biopsy: suspicious nodule/possible tumour Intended specimens taken and processed in the donor hospital	SNOD informs Hub Operations that an urgent biopsy is being processed and results will be communicated when available Hub Operations inform all accepting recipient points of contact at accepting transplant centre	SNOD documents on DonorPath
When biopsy results are available, recipient points of contact at accepting centres informed	Benign results – SNOD informs Hub Operations who communicate the result to accepting recipient points of contact Possible malignancy/ confirmed malignancy- Lead Surgeon informs Hub Operations. Hub Operations inform accepting recipient points of contact *Recommendation- it is advised that best practice is for the accepting Consultant Transplant Surgeon and the Lead Surgeon to liaise directly upon receipt of the information.* **This conversation may be arranged by Hub Operations	SNOD documents result on DonorPath Lead Surgeon documents conversation in the medical notes e.g. who was told what information, and the centre's response

Suspicious area/ nodule identified on an organ/ in the donor hospital at the back-table and a decision is made for the biopsy to be done at the Transplant Centre	Lead surgeon informs the accepting Transplant Consultant at the Transplant Centre. **This conversation may be arranged by Hub Operations If the Cardiothoracic NORS Team has left the OT with organs for transplant the abdominal Lead Surgeon informs the accepting Consultant Transplant Surgeon at the CT Centre The Lead Surgeon informs Hub Operations of this and requests that the accepting transplant units are urgently informed	Lead surgeon documents on the HTA form Lead Surgeon documents conversation in the medical notes e.g. who was told what information and the centre's response Hub Operations will document on NTxD SNOD should document in DonorPath
Poor or inadequate kidney/pancreas/liver perfusion	Lead surgeon informs the SNOD SNOD informs Hub operations Hub Operations inform recipient points of contact	Lead surgeon documents on the HTA form SNOD documents on DonorPath
Unusual or extra ordinary anatomy or injury that might compromise any recipient of an organ from that donor must be reported immediately to ODT Hub Operations	Lead Surgeon informs the SNOD during the procedure, SNOD informs Hub Operations, who should then inform recipient point of contact at accepting Transplant Centres After the procedure the Lead Surgeon contacts the recipient surgeon(s) **This conversation may be arranged by Hub Operations	Lead Surgeon documents in the medical notes and on the HTA A form Conversation documented including the response from the accepting transplant surgeons
Organ damage requiring possible repair at the accepting centre	Lead surgeon informs the accepting Recipient Surgeon **This conversation may be arranged by Hub operations	Lead surgeon documents on the HTA form Lead Surgeon documents conversation in the medical notes e.g. who was told what information and the centre's response
If there is an unintended breach of the digestive tract during retrieval, this should be documented on the HTA Form	Lead Surgeon informs Hub Operations to convey information to all relevant Transplant Centres **This conversation may be arranged by Hub Operations	Lead Surgeon documents in the medical notes Lead Surgeon documents on the HTA A Form Hub Operations document on NTxD

4. NORS Centre Requirements

4.1. Each NORS Centre must ensure they have the appropriate workforce in place for the NORS Team:

a) Lead Surgeon – a surgeon who is competent in retrieval
b) Surgical Assistance – a healthcare professional who provides support to the Lead Surgeon.
c) Organ Preservation Practitioner – a practitioner who is capable of performing preservation, perfusion and packing of organs.
d) Scrub Practitioner – a theatre practitioner who provides expert assistance to the surgical team in theatre.

4.2. Each NORS Centre must have a named NORS Team Clinical Lead; a named NORS Management Lead; and a named NORS Finance Lead. These individuals' contact details must be provided to NHSBT.

4.3. Each NORS Centre must have clear, written, regularly reviewed, version controlled and circulated protocols for the retrieval procedures that they will undertake, including for both DBD and DCD operations.

4.4. There should be effective and sustainable workforce planning covering all professional disciplines included in the multidisciplinary NORS Team. All staff should have regular appraisals and agreed professional development plans.

4.5. NORS Centres must provide opportunities for training for all members of the NORS Team to maintain competency levels. There should be explicit consultant involvement in the educational aspects of the retrieval programme, on the job training, and the assessment of competency of trainees by NORS Team Clinical Leads.

4.6. All NORS Centres must hold monthly meetings to audit their own activity and performance, and to identify and rectify deficiencies in donor care, organ integrity, inefficient processes, and poor communications.

4.7. Audit meetings should include clinical governance incidents and outcome of retrieved organs, organ damage and dysfunction, punctuality and delays, difficulties encountered in donor hospitals, transport problems and feedback from donor hospitals and SNODs.

4.8. Audit meetings should be chaired by the named NORS Team Clinical Lead and attended by as many members of the NORS Team as possible. Members of the local SNOD teams and CLODs should be invited to attend these meetings.

4.9. Minutes of audit meetings should be recorded, distributed to all members of the NORS team, and made available to NHSBT on request.

4.10. All NORS Centres should, when requested, contribute data to national audits and registries. Such data should be accurate, complete, and transmitted on time.

4.11. There should be provision of appropriate staff for the collection, storage and transmission of audit and registry data.

4.12. All NORS Centres are expected to participate in national clinical research projects aimed at improving the quality of retrieved organs when called upon to participate.

4.13. There should be clear accounting for all income to the Trust/NHS Board that is designated for the delivery of retrieval services in accordance with financial governance procedures. This will include finance directly managed by the transplant service and finance that is managed by the financial infrastructure within the Trust/NHS Board.

4.14. The NORS Centre will submit a quarterly financial return of actual and forecasted costs. For those centres that are not under the National Transport Contract, this must include all costs and transport journey details, including donor numbers, journey type and organ type.

4.15. There should be annual Contract Review Meetings to address issues specific to NORS, including but not limited to, financial, activity, audit, clinical governance. The annual meetings are held at the NORS Centre.

4.16. Robust arrangements should be in place for timely and accurate collection of data. Data should be made available to NHSBT under agreed reporting mechanisms.

4.17. There should be clear and accountable leadership of the NORS service at each centre with a NORS Team Clinical Lead notified to NHSBT.

4.18. The NORS Team Clinical Lead is responsible for ensuring that all members of the NORS Team possess the appropriate qualifications, experience, and skills to perform the roles and duties assigned to them. The team must include a competent and certified NORS Team Lead Surgeon, competent Organ Preservation Practitioner, and Scrub Practitioner.

4.19. All NORS Team surgeons who were already trained and in post as at 1st April 2014 were automatically deemed to be certified and competent under the 'Grandfather clause'*.
*(*Practising members of a NORS team as at 1st April 2014 are automatically deemed to be 'fully registered and competent.').*

4.20. All Surgeons or Surgeons-in-Training aspiring to competency in organ retrieval to participate eventually in a NORS Team as independent and competent Lead Surgeons need to register with NHSBT ODT. The NORS Team Clinical Lead will be responsible for ensuring the NORS surgeon is of an appropriate standard before that surgeon operates as a Lead Surgeon in a NORS team. To gain full registration, the surgeon must complete all requirements as documented in the current 'Training and Registration Document' This includes completion of e-learning (as provided by NHSBT for NORS); attendance at the annual NHSBT Organ Retrieval Masterclass, and any other current requirements.

If the NORS Clinical Lead feels that a surgeon is competent to work as a team Lead Surgeon (NORS surgeon), and that the only outstanding aspect is attendance at the annual Masterclass, the NORS clinical lead may permit the surgeon to operate as an independent NORS surgeon. This decision, as for all other decisions as to who may lead a NORS team, rests with the NORS Clinical Lead.

4.21. The NORS Team Clinical Lead is responsible for ensuring that the 'trainee' retrieval surgeon is assessed when undertaking a retrieval independently. If the 'trainee' is deemed competent the NORS Team Clinical Lead must complete the necessary documentation to sign off the 'trainee' retrieval surgeon as competent informing NHSBT that will then enter the name of the trainee in the Register of Competent NORS Lead Surgeons.

4.22. The NORS Team Clinical Lead is responsible for providing a list of all Lead Surgeons, within each NORS Centre, to NHSBT together with a declaration that each has been assessed as competent to lead their NORS Team during a retrieval procedure.

4.23. NORS Team Clinical Leads must check, validate, and return a prefilled list of NORS Team surgeons (competent and in-training) to NHSBT on a quarterly basis. This should include details of all new surgical members entering the competency training facilitated by NHSBT.

4.24. Once registered as competent, NORS Team surgeons are required to have actively participated in retrieval rotas to maintain competence. The NORS Clinical Lead will decide whether a surgeon remains competent if there is a break in practice.

4.25. Competent NORS Lead Abdominal Surgeons must be capable of accurately assessing and retrieving liver, pancreas, and kidneys. Competent NORS Lead Cardiothoracic Surgeons must be capable of accurately assessing and retrieving heart and lungs.

4.26. All members of the NORS Team are expected to participate in continuing professional development by attending appropriate courses and meetings.

4.27. Trainees in higher surgical training programmes should be instructed in all aspects of organ retrieval and maintain a logbook of surgical procedures in accordance with SAC guidelines.

5. *Post Retrieval and Receipt at Transplant Centre*

5.1. On receipt of a retrieved organ, the transplant surgeon is responsible for checking the integrity and suitability of the retrieved organ, including donor details on the organ specific HTA-A form, the blood group, and microbiology results before implanting it into the recipient.

5.2. In cases where an organ is deemed unsuitable for the allocated recipient the transplant surgeon is advised to discuss the reason with a surgical colleague. If the organ is still deemed to be transplantable the surgeon/recipient co-ordinator should immediately inform ODT Hub Operations to reallocate the organ as per national allocation policies. In cases where the transplant surgeon and their surgical colleague decide the organ is not transplantable ODT Hub Operations should be informed. ODT Hub Operations will then advise on the appropriate course of action as set out in the national allocation policies in relation to further offering for transplantation, offering for research or if the organ should be disposed of.

Whether an organ is accepted for clinical transplantation, or for research, organs will be packed in the same fashion, with the same degree of care and attention, and with the same fluids and sterile bags, as for clinical transplantation.

5.3. Transplant centres have an obligation to urgently report any abnormality such as a suspected or proven malignant tumour which might impact adversely on recipients of other organs. Any such abnormality must be reported immediately to ODT Hub Operations who will then immediately notify other transplant centres.

5.4. Transplant centres must notify NORS Teams of any organ damage or abnormality that was not recognised or recorded on the organ specific HTA-A form during the retrieval process.

5.5. If, post-transplant, positive results from cultures of the transport perfusion fluid are identified, this must be reported to ODT Hub Operations. Results that require reporting to ODT Hub Operations include:

- Candida
- Staphylococcus aureus
- Pseudomonas
- Enterobacter
- Multi-drug resistant organisms

5.6. If the transplant centre, at back table assessment, note any suspicious nodes/etc. and take a sample for histopathology prior to implant then this must be communicated to ODT Hub Operations immediately (see Table 1 under Section 4).

5.7. Transplant centres must participate in organ retrieval audits when called upon to do so.

5.8. Centres should have a clear policy on the storage and disposal of any unused organs, tissues, or surplus tissue in compliance with the Human Tissue Act (2004), the Human Tissue (Scotland) Act, 2006 and Human Transplantation (Wales) Act 2013.

5.9. Transplant centres should maintain a record and summary of all offers of donor organs assessed and accepted or declined for transplantation. Transplant centres will undertake a rolling audit of donor offers and notify NHSBT of their reasons for declining individual organs.

5.10. The transplant centre is responsible for arranging transport of retrieved organs from the donor hospital to the transplant centre with the exception of pancreas and kidneys. NHSBT will continue to make transport arrangements for retrieved pancreas and kidneys.

5.11. The transplant centre should record the time that the organ arrived at the centre and the time that the organ was transferred from cold solution into the operative field (i.e. end of cold ischaemia time).

5.12. The transplant centre must ensure completion of an HTA-B form for each organ intended for transplant in accordance with the Human Tissue Act (2004) and the Human Tissue (Scotland) Act, 2006.

5.13. Transplant centres must record on the HTA-B form any abnormality or damage to organs that they receive. Retrieval damage should be classified as indicated on the form.

5.14. The transplant centre must return the HTA-B forms to ODT Hub Information Services within seven days of receipt of the organ.

5.15. If, due to retrieval damage, the organ fails to function following transplantation, then the transplant centre must notify NHSBT by accessing the NHSBT Incident reporting form via https://safe.nhsbt.nhs.uk/IncidentSubmission or via the ODT Clinical website https://www.odt.nhs.uk/.

6. Management of Delays during the Retrieval Process

These changes formalise retrieval and cross clamp delays. There should be essentially no change for the great majority of retrievals. If there is difficulty, there should be rapid escalation.

Communication between regional managers, recipient centres' consultants and/or NORS Leads should occur in order to avoid loss of organs or jeopardising the safety of recipients or NORS teams.

Scenarios Leading to Delay

6.1. **Delays of Team Mobilisation** (request by recipient or retrieval team/SNOD/logistics). In this scenario, retrieval teams will leave later than originally requested.

6.1.1. **Delay to facilitate normal working**
This is a common situation generally involving small delays with no adverse effects. The SNOD, **in negotiation with all parties involved**, arranges the finalised departure/arrival times of the retrieval team(s) by mutual agreement. Providing there is unanimity amongst all those involved, there are no grounds for change, as this kind of 'delay' is part of the normal running of the service.

If the SNOD feels that any such informal request to delay is excessive or unjustifiable, or there is disagreement amongst the parties involved, the SNOD may discuss with the Regional Manager on call to plan a way forward. A governance report may be submitted as appropriate.

If one of the potential recipients is super-urgently listed, delay of this kind may not be supported. The SNOD will arrange for the earliest possible arrival of teams.

6.1.2. **Organ acceptance and intentional delay**
The question of intentional retrieval delay to facilitate sequential transplants in one centre has been raised. It was decided that delaying retrieval (and multiple other recipient operations) so as to allow one centre to perform sequential rather than parallel transplants was **not supported.**

Exceptions
Super Urgent Recipient
If a super-urgent recipient is allocated a graft in a centre which is already transplanting, **retrieval delay may allow the super-urgent transplant to proceed**, which otherwise may not be possible. **Operative delay must be managed to safeguard super-urgent recipients.**

Paediatric Recipient
If a centre is offered a graft for a paediatric recipient whilst already transplanting, **retrieval delay may permit the paediatric transplant to proceed.** Providing no other recipients allocated organs from that donor are super-urgently listed, **a maximum delay of mobilisation of 3 hours is supported in this situation.** If another recipient from the same donor is super-urgently listed, the paediatric recipient consultant surgeon and the super-urgent recipient consultant surgeon must discuss. They will determine the approach with minimum mortality and maximum utilisation and inform the Hub of their decision.

6.2. **Planned Cross Clamp Delay.**
In this situation, it is known ahead of time that a delay will be required during the retrieval operation. This is needed when the recipient team must undertake irreversible preparatory surgery to the recipient before the onset of cold ischaemic time.

6.2.1. **Common scenarios**

For example, a cardiac recipient team knows that their patient will require a planned delay of cross clamp because they need to remove the VAD from the recipient first. They can only commit to this if the heart is suitable for transplant, which is unknown until inspection.
At the time of organ acceptance, Hub staff are informed by the recipient centre of the need for cross clamp delay, and the reason. Retrieval teams will then be informed by the Hub that a cross clamp delay is planned and the reason for this.

Requested cross clamp delays will have a maximum of 3 hours.

Given the potential for significant added expense and logistical challenge, excessive delays will be monitored and investigated as appropriate through the governance process.

Unnecessary delays, such as the recipient not being immediately ready for anaesthetic when the organ is deemed suitable, are clearly a matter for governance.

Planned delays are supported, even if one of the recipients is super-urgently listed. Further delays, greater than 3 hours, are not supported and will be investigated as appropriate through the governance process. If the super-urgent recipient may be harmed by delay, recipient consultant surgeons must discuss delay and attendant risks to the recipients between them, then inform the Hub of their decision.

6.2.2. **Multi-visceral donors.**
Multi-visceral donors are a special case. There are less than 20 such transplants a year in the UK. In approximately half of these cases, there may need to be a delay of cross clamp.

It may not be possible to estimate the need for delay until the small bowel is inspected by the multi-visceral retrieval team.

Given the uncertainty, the abdominal team must be permitted the opportunity to inspect the abdominal organs as the first step in the operation. At retrieval, the cardiothoracic NORS team will await the completion of this multi-visceral assessment phase before performing cardiothoracic assessment, as agreed by CTAG. It is imperative that cardiac and abdominal teams collaborate in such cases, as virtually all such donors will donate both cardiothoracic and abdominal organs.

If the bowel is unsuitable, the earliest possible intimation of this will expedite the remainder of the retrieval operation.

If a multi-visceral graft is accepted for a recipient, the multi-visceral team must inform the Hub of the cross clamp delay they may require, and the Hub must inform teams and recipient centres about the potential delay.

On commencement of the donor operation, the abdominal team must be permitted to assess the abdominal organs as the first step in the retrieval operation.

If the donor is to donate a multi-visceral graft, and the liver or the heart is allocated to a super-urgent recipient, the recipient consultant surgeons must discuss delay and attendant risks to the recipients between them, then inform the Hub of their decision. Delay must be minimised to safeguard super-urgent recipients. Mortality must be avoided at all costs.

6.3. **Unplanned Delay**
In this situation, new information comes to light and time is urgently required to maximise the safety and utility of donation and transplantation.

6.3.1. **Unforeseen circumstances.**
This could happen at any stage of the process. Individuals who require an unplanned delay must contact the Hub as soon as possible. The requested duration and reason must be provided.

If an unplanned delay occurs in the pathway at any time from NORS mustering onwards (1 hour prior to team departure), this will be investigated as appropriate through the governance process.

If one of the potential recipients is super-urgently listed, an unplanned delay will not be supported. The SNOD will arrange for the earliest possible arrival of teams and should discuss with the Regional Manager.

Exception
If a patient safety issue comes to light, for example potential malignancy in the donor, delay is supported whilst clarification is sought.

6.3.2. **Late decline of the heart/lungs.**
Inspection of the Heart and Lungs by the cardiothoracic team should take place as early as possible in the donor operation. This is because a decline on inspection, which usually triggers re-offering, is considered to be a potential cause of late, unplanned, excessive, cross clamp delay.

Many late declines arise as a result of new information gathered on inspection, which is unfortunate but cannot be foreseen. Given that the donor is approximately 90 minutes from cross clamp at the time of organ decline on inspection, heart/lungs will be therefore be fast-tracked according to current offering rules.

If the heart/lungs are declined after inspection, fast-track offering will commence, and abdominal surgery should continue, but teams should not cross clamp until the result of fast-track offering is known.

If a super-urgent recipient awaits the liver, it may be necessary to cross clamp as soon as possible. The SNOD/Hub must emphasise to teams considering the fast track cardiothoracic offer that the liver is placed with a super-urgent recipient.

If the donor is to donate a cardiothoracic organ, and the liver is allocated to a super-urgent recipient, the recipient consultant surgeons must discuss delay and attendant risks to the recipients between them, then inform the Hub of their decision. Delay must be minimised to safeguard all potential recipients.

Cardiothoracic fast-track offering will be concluded about 60 minutes after commencement. Generally, this will be prior to the time abdominal team are ready for cross-clamp, providing the cardiac team have assessed the organs early in the procedure.

The SNOD will inform the retrieval teams whether or not the cardiothoracic organs have been accepted at the conclusion of fast-track offering.

If cardiothoracic organs have been declined, the abdominal team should proceed to cross clamp as normal.

If the cardiothoracic organs have been accepted after fast-track, cross clamp is very likely to be delayed whilst a new recipient is brought to the transplant centre.

The maximum supported delay from the time of fast-track organ acceptance will be 3 hours.

The structured approach to delays as described above will hopefully bring some predictability and understanding to retrieval delays. Above all, there will be better opportunities to manage expectation and for good governance.

Appendix One

Organ Donation and Transplantation Safety Alert

Interpretation and management of spinal movements in potential brain-stem dead donors
May 2014

Unexpected movements in patients who are brain-stem dead can be distressing for both family members and clinical staff and may generate uncertainty over the validity of a diagnosis of brain-stem death. Misinterpretation of spinal movements in a brain-stem dead donor by a member of an organ retrieval team has resulted in the loss of cardio-thoracic organs and unnecessarily added to the distress of a grieving family.

Clinical features of spinal movements in brain-stem death

Brain-stem death relieves the spinal cord from descending central control, allowing the emergence of spontaneous and reflex movements from neuronal networks within the spinal cord – so called spinal movements.

Spinal movements are seen in circumstances where brain-stem death has been confirmed by four-vessel cerebral angiography. For this reason, clinicians can be confident that **spinal movements in no way invalidate the diagnosis of brain-stem death.**

Spinal movements often appear after an initial period of complete flaccid paralysis. For this reason, they may be seen for the first time after brain-stem death has been confirmed, for instance during donor optimisation, transfer to theatre or organ retrieval.

Spinal movements may be triggered or exaggerated by hypotension or acid-base disturbances and are often reported during apnoea testing or following the withdrawal of mechanical ventilation in patients not proceeding with organ donation.

Spinal movements can be abolished with anaesthetic muscle relaxants.

Spectrum of spinal movements seen in brain-stem death

- Flexor / extensor plantar responses
- Triple flexion response
- Abdominal reflex
- Cremasteric reflex
- Tonic-neck reflexes
- Isolated jerks of the upper extremities
- Unilateral extension-pronation movements
- Asymmetric ophisthotonic posturing of trunk
- Undulating toe flexion sign
- Myoclonus
- “Lazarus sign”
- Head rotation
- Respiratory-like movements
- Quadriceps contraction
- Eye opening response
- Leg movements mimicking periodic leg movement
- Facial myokymia

Spinal movements are reported to occur in as many as 50% of brain-stem dead patients. Whilst some movements are clearly 'abnormal', others can appear alarmingly purposeful. To view an example of spinal movements go to http://ccforum.com/content/17/4/440/suppl/S1 (head rotation).

Actions

Who: Clinical Leads for Organ Donation
Organ Donation Team Managers
Specialist Nurses - Organ Donation
National Organ Retrieval Service Clinical Leads

What:

Please ensure that

- all staff who care for potential brain-stem dead donors are aware of this safety alert
- all staff have an adequate knowledge of the aetiology, nature and implications of the spinal movements associated with brain-stem death, and that they clearly understand that such movements do not invalidate its diagnosis
- members of retrieval teams are aware that inexperienced staff may be alarmed by spinal movements, and they have a duty to avoid misleading statements that will add to this uncertainty.
- members of retrieval teams recognise that brain-stem death is diagnosed by senior medical staff on ICU, and that if they wish to seek clarification on points of detail this should be done respectfully, discretely, and without causing alarm to other team members.
- muscle relaxants are given prior to organ retrieval and are continued until the aorta is cross clamped. Suitable drugs and their doses (based upon a 70kg adult) are as follows:
    - rocuronium, 100mg at start of procedure
    - atracrium, 50 mg with 10 mg boluses repeated every 30 minutes
    - vecuronium 10 mg, with 2 mg boluses repeated every 30 minutes

  remembering that neuromuscular blockade should be monitored using a nerve stimulator and that volatile agents may also be used to blunt spinal movements.

References

1. Saposnik G, Basile VS, Young GB. Movements in Brain Death: A Systematic Review. Can. J. Neurol. Sci. 2009; 36: 154-160.
2. Wu Y, Balaguer PO: Spontaneous and reflex head turning in brain death. Critical Care 2013, 17:440.

Appendix Two

LUNG RETRIEVAL FROM DCD DONORS

Preparation for DCD lung retrieval

1. Lung DCD retrieval requires careful planning and close collaboration between all of those involved in the care of the patient.
2. Prior to treatment withdrawal, the Specialist Nurse – Organ Donation (SNOD) and the lead surgeons from the abdominal and thoracic NORS Teams should meet with a senior member of the ICU / anaesthetic team in order to
    a. Establish whether treatment withdrawal will include extubation
    b. Identify who will be responsible for re-intubation (where relevant), re-inflation and re-ventilation to facilitate lung retrieval
        i. Ideally this will be a member of the donor hospital ICU / anaesthetic team, who should be available
        ii. If the donor hospital ICU / anaesthetic team are not able to support the various airways interventions, the retrieval team must ensure they are appropriately staffed and equipped to support lung retrieval.
    c. Ensure that all involved have agreed the respective timings of the various airway interventions as defined below.
    d. Ensure that all the necessary equipment to support the various airway interventions is available in the retrieval theatre.
3. **Any uncertainties or disputes with regards to airway interventions must be resolved prior to withdrawal of life sustaining treatments.**

Pathway for DCD lung retrieval

1. The abdominal and cardiothoracic NORS Teams should be ready and prepared in theatre prior to treatment withdrawal
    a. The equipment required to re-intubate the donor and to re-inflate / re-ventilate the lungs should be available in the theatre prior to treatment withdrawal.

2. Life -sustaining treatments are withdrawn by the donor hospital team.
    a. Lung retrieval should be stood down if asystole does not occur within 2 hours of treatment withdrawal

3. Death is diagnosed and confirmed by the donor hospital team after 5 minutes of continuous absence of cardio-respiratory function in accordance with national professional guidance.

4. Upon the arrival of the donor in theatre, the priority of the cardiothoracic NORS Team is the airway and lungs whilst the priority of the abdominal team is perfusion of the abdominal organs as quickly as possible. **The cardiothoracic team should facilitate and support the abdominal team during cannulation and abdominal perfusion.**

5. Re-intubation
    a. If the patient has been extubated as part of treatment withdrawal, the airway should be re-intubated with a cuffed endotracheal tube as soon as possible after death has been confirmed in order to prevent contamination of the airways with gastric contents (the likelihood of which increases considerably during the retrieval laparotomy).
        i. The cuff of the endotracheal tube should be firmly inflated to ensure that airway soiling is prevented.
    b. **The lungs must not be inflated until ten minutes has elapsed since the onset of irreversible asystole.**

6. Inflation of the lungs
    a. **At a point no earlier than 10 minutes after the onset of irreversible asystole**, the lungs should be re-inflated with single vital capacity breath of oxygen enriched air.

i. If lung re-inflation is performed by a member of the anaesthetic / ICU team, this should be done using an anaesthetic machine and circuit to deliver a single vital capacity breath of 50% oxygen. Initially, the APL valve should be adjusted to maintain airway pressures of 30-40 cm H_2O for 30 seconds to aid lung recruitment. Thereafter, gas flows and the APL valve should be adjusted to maintain steady lung inflation at 5–10 cm H_2O CPAP
ii. If lung re-inflation is performed by a member of the retrieval team, a self-inflating manual device such as an Ambu Bag® should be used to re-inflate the lungs with a single breath of oxygen-enriched air. Thereafter, the endotracheal tube should be clamped to maintain lung inflation.

b. Over-inflation should be avoided.
c. **Cyclical lung ventilation must not be instituted automatically at this stage and can only begin once lung perfusion has commenced (see below).**

7. Cyclical ventilation, either with an anaesthetic machine or by hand-bagging, should start during lung perfusion to aid distribution of perfusate. Cyclical ventilation of the lungs is not allowed **until the retrieval team has started to flush the lungs and vented the left atrium.**
   a. If initiated by a member of the anaesthetic / ICU team, the lungs should be ventilated with 60% oxygen using an anaesthetic ventilator. If possible, a protective ventilatory strategy (pressure-controlled ventilation, 5 – 10 cmH_2O PEEP) should be employed.
   b. If initiated by a member of the retrieval team, the lungs should be ventilated manually with oxygen-enriched air using an Ambu Bag® or similar device.
   c. Over-inflation should be avoided.

8. If the arch vessels are to be divided, for instance to support normothermic regional perfusion, then lung recruitment and ventilation can begin as soon as the cerebral circulation has been so isolated.

9. Bronchoscopy should be performed as soon practicable and include thorough bronchial toilet.

10. On explantation, the trachea should be clamped with the lungs ¾ inflated. Over inflation must be avoided, particularly if the lungs are being transported by air to the implanting centre

Appendix Three

Abdominal Perfusion and Preservation Protocol for NORS Teams in the UK

Please refer to Appendix 4 below for Perfusion protocol for abdominal organ retrieval from infant and neonatal donors (DBD and DCD)

Background

Following a meeting of representatives from all of the NORS abdominal centres on 9th October 2012, a national protocol for the use of preservation solutions was agreed. This protocol was reviewed on 17 September 2014. The protocol covers the following:

1. Donor type: DBD or DCD
2. Organ specific: Liver, pancreas, and kidney retrieval
3. In-situ portal flush of the liver
4. Back table perfusion of liver, pancreas kidney
5. Packing for static cold storage and transport
6. Specific issues were also highlighted: use of streptokinase in DCD, pressurised aortic in-situ perfusion, minimum volumes of solution.
7. Where the document refers to University of Wisconsin (UW) solution, this should be read as "UW or equivalent". "Equivalent" means the fluid used must have the same chemical composition as University of Wisconsin fluid for cold storage solution.

In situ perfusion

1. The aim of in situ perfusion should be to ensure the effluent runs clear.
2. Teams should record the volume of fluid used per donor.

DBD	**Aorta (type/volume)**	**Portal vein (type/volume)**
Liver, pancreas, and kidney	UW solution 50 – 70 ml/kg	Nil or UW 1 litre
Liver and kidney	UW or Soltran solution 50 – 70 ml/kg	UW 1 litre when Soltran is used
Kidney	UW or Soltran solution 50 – 70 ml/kg	N/A
DCD III		
Liver, pancreas, and kidney	UW solution alone (heparinised) 50 – 70 ml/kg or 1 litre flush with heparinised low viscosity solution followed by UW solution 50 - 70 ml/kg	UW 1 litre
Liver and Kidney	UW solution alone (heparinised) 50 – 70 ml/kg or 1 litre flush with heparinised low viscosity solution followed by UW solution 50 – 70 ml/kg	UW 1 litre
Kidney	UW solution alone (heparinised)	N/A

	50 – 70 ml/kg or 1 litre flush with heparinised low viscosity solution followed by UW solution or Soltran solution alone (heparinised) 50 – 70 ml/kg	

Important: the use of Soltran solution only for aortic in-situ perfusion was agreed for liver and kidney DBD retrievals, with the proviso that portal vein perfusion with UW solution is also undertaken (either in-situ or during the back table).

There was discussion around the merits of flushing the aorta and the organs in the context of DCD with 1 litre of low viscosity solution, such as Soltran solution. It was noted that while there is currently no clear evidence for a benefit, teams who prefer this regimen can continue to do so.

Back table perfusion

Back table perfusion may not be required if in situ examination demonstrates that the organs are well-perfused. However, portal perfusion must take place, either in situ or on the back table.

DBD	**HA (type/vol)**	**Portal (type/vol)**	**CBD (type/vol)**	**Pancreas (type/vol)**	**Kidney (type/vol)**
Liver	UW 200-500 ml	UW 500-1000 ml	UW 250 ml		
Pancreas				Nil unless indicated (UW)	
Kidney					UW or Soltran 200-300 ml or until clear
DCD III					
Liver	UW 200-500 ml	UW 500-1000 ml	UW 250 ml		
Pancreas				Nil unless indicated (UW)	
Kidney					UW or Soltran 200-300 ml or until clear

Packing for static cold storage and transport

Packing	**Liver (type/vol)**	**Kidney (type/vol)**	**Pancreas (type/vol)**
DBD	UW until submerged (approx. 2 L)	UW or Soltran (approx. 250 ml)	UW (approx. 500 ml)

DCD	UW until submerged (approx. 2 L)	UW or Soltran (approx. 250 ml)	UW (approx. 500 ml)

Other discussion points and specific issues:

1. The administration of streptokinase in an initial flush is not acceptable in the retrieval of liver or pancreas, as it must be delivered at normal body temperature, and concern was expressed about the delay in cold perfusion. The evidence base for its use in liver and pancreas retrievals is non-existent.
2. The group supported the administration of heparin in the aortic flush.
3. The use of pressurisation of fluids was debated, with the recommendation that a pressure of max 200 mmHg be exerted, which has previously been shown to correspond to an intra-aortic pressure of around 40 mmHg.
4. The addition of additives, such as benzyl penicillin, insulin, and dexamethasone, to the preservation solution UW is not recommended any more. The addition of fresh glutathione is optional, although no clinical evidence is available for a benefit.
5. When UW solution is obtained from Bridge to Life (Belzer UW Solution) or from ORS (SPS-1) no filter is needed.
6. Auxiliary blood vessels retrieved for use as conduits should be stored in UW solution in separate pots plus two bags to ensure sterile conditions where possible to facilitate transport to the transplanting centres. If the vessels are to be stored after the transplant, then antibiotics may be added to the pots at the recipient centre according to current centre practice.
7. It was agreed that all organs should be stored in **THREE** bags except for the liver that will be stored in a bowl as well.
8. All organs should be stored as follows:
    a. Each organ is submerged in sufficient cold preservation solution in the first bag.
    b. The second bag is filled with at least 250 ml cold saline (without any ice).
    c. A small amount of fluid (sufficient to ensure there is no air in the bag) shall be placed between the second and third bags.
    d. Important: each bag is firmly tied after adequate de-airing.
    e. The bagged organs are then placed in the transport box and covered with non-sterile melting ice.
9. The liver should be placed in a sterile bowl (if the liver is too large to fit in the bowl, the bowl should not be used) and submerged in preservation solution. The bowl with the liver is then packed as described above.
10. For all livers which are to be split, and in all paediatric donors, all perfusion must be with UW solution, and must include in situ portal vein perfusion.
11. It was noted that following the initial in-situ flush first liver and then pancreas should be retrieved followed by immediate additional back table flush and packing. Ideally, another team member could retrieve the kidneys at the same time to reduce 'warm ischaemic' time.

In the tables the 'generic' names for the preservation solution are used as according to tender processes brand names may vary.

Appendix Four

Perfusion protocol for abdominal organ retrieval from infant donors (DBD and DCD)

Donor Criteria

- All paediatric donors weighing 15 kilograms or less
- DBD and DCD
- Abdominal Organ Retrieval

Heparin / Perfusion Fluids

DBD donors: administer Heparin at 100IU/Kg 5 minutes prior to cross - clamp

DCD donors: add Heparin to the flush solution (Hartmann's or Ringers Lactate) and preservation solution (University of Wisconsin) at a concentration of 10,000 IU /L

Ideal perfusion temperature for University of Wisconsin cold storage solution should be between 2-4^{0}C.

Perfusion

- Cannulate through the right or left common iliac artery. Be mindful of the ureter.
- Initial flush through aorta with Hartmann's solution (Maximum 500mls) at **room temperature** under gravity holding the infusion bag at 100 cm above the donor. **Do not apply additional external pressure.**
- Vent in the chest whenever possible, otherwise in the pelvis.
- After infusion of Hartmann's solution continue with the aortic flush using cold UW cold storage solution. Perfuse 50-70 ml/Kg until organs are flushed, sufficiently cold and ready to be removed.
- In DCD: in view of the constraints with warm ischaemia time, **in-situ portal vein perfusion is not recommended**. This can often cause injury to major vasculature in such small donors. Proceed with in-situ portal flush if it is felt safe to do so, portal flush can be done more effectively on the back table before packing the organs.
- In DBD: in-situ portal flush can be done if it's safe to do so, or if the consultant transplant surgeon request in situ portal flush after previously considering the experience of the retrieving surgeon

Back Table

- Flush liver through portal vein, hepatic artery and common bile duct using UW solution.
- Kidneys can prove difficult to flush on the back table, avoid injury whilst attempting to perform back table flushing. If necessary, they can be re-flushed after completion of back table dissection.
- Pack all organs submerged in UW solution.

Note

Paediatric kidneys do not flush well with cold UW solution, hence the initial use of Hartmann's solution at room temperature.

Appendix Five

Donor Heart Perfusion & Preservation Protocol for NORS Teams in the UK

1. Systemically anticoagulate donors with 30,000 units of IV heparin
2. Venting of the IVC (chest or abdomen) as agreed between the NORS teams present
3. Donor heart preservation solution:
    a. Sterile Concentrate for Cardioplegia Infusion (SCfCI, Martindale Pharma®) should be used for all national shared donor hearts
    b. This will be diluted by adding 20ml of SCfCI to 1 litre of Ringers solution
4. Volume:
    a. Donor weight 30-70 Kg: administer 1 litre of reconstituted SCfCI solution
    b. Donor weight >70 Kg: administer 1.5 L of reconstituted SCfCI solution
    c. At the request of the **recipient** transplant surgeon, it is permissible to change the above doses dependent on logistics and/or donor physiology
5. Delivery pressure: 60-90 mmHg
6. Storage of donor heart for transport:
    a. Inner bag: cold Saline 2 L
    b. 2nd bag: cold Saline 2 L
    c. Outer bag: cold Saline 2 L

Appendix Six

Donor Lung Perfusion & Preservation Protocol for NORS Teams in the UK

1. Systemically anticoagulate donors with 30,000 units of IV heparin
2. Donor lung preservation solution: Perfadex® Plus
3. Volume: 50 - 75ml/Kg (see table below)

Donor Wt (Kg)	Antegrade Vol (L)	Retrograde Vol (L)	Total Vol (L)	Number of 1L bags required
21-40	1.0	1.0	2.0 (50-95 ml/kg)	2
41-60	2.0	1.0	3.0 (50-73 ml/kg)	3
61-80	3.0	1.0	4.0 (50-67 ml/kg)	4
81-100	4.0	1.0	5.0 (50-62 ml/kg)	5
101-120	5.0	1.0	6.0 (50-59 ml/kg)	6
121-140	6.0	1.0	7.0 (50-58 ml/kg)	7

4. Temperature for both DBD and DCD donor lungs:
    a. first 1L at room temperature
    b. the rest of fluids cold

5. Prostacycline (Flolan):
    a. For DBD donors, systemic heparinisation by the anaesthetists and then 10ml of Flolan injected slowly into pulmonary artery prior to cross clamping.
    b. For DCD donors, heparin injected into the pulmonary artery by retrieval surgeon directly followed by 10ml of Flolan.

6. Technique:
    a. Insert a straight 24F cannula in pulmonary artery
    b. Place lung perfusion fluid bags 25cm above the donor or use delivery pressure of 25 mmHg
    c. Preservation solution is delivered in two phases:
        i. Antegrade for all bags except for the final 1L
        ii. The final 1L bag is administered retrograde - the antegrade cannula is removed from the PA and placed into each pulmonary vein in turn
        iii. Prior to the retrograde flush, the heart is excised and the pulmonary trunk transected just proximal to its bifurcation
        iv. The retrograde phase consists of delivering 250 mls of Perfadex® Plus into each pulmonary vein in turn. This is done by pinching the cannula between the fingers so as to prevent the fluid from leaking back into the left atrium.

7. Lung inflation:
    a. FiO_2 = 0.5
    b. Airway pressure = 15–20 cmH2O

8. Storage of donor lungs for transportation:
    a. Inner bag: cold Saline 2 L
    b. 2nd bag: cold Saline 2 L
    c. Outer bag: cold Saline 2 L

PREPARATION OF PERFADEX

1. Store at 2-25° C

2. DO NOT add any drugs or buffering agents to the Perfadex bags until it is finally confirmed that lungs are being retrieved

3. Once the Perfadex® Plus container is opened and additives have been added the solution must be kept cold and used within 24 hours.

4. **No THAM or Calcium is required (Perfadex® Plus is pre-supplemented with THAM and calcium)**

5. The first 1.0L Perfadex® Plus bag should contain:
    a. Prostacyclin 500 mcg
    b. GTN 25 mg diluted in 50 mL of supplied diluent

6. Drugs should be added to the bags individually, giving each bag a good shake to mix

7. Once additives are used or the container is opened the contents should be chilled and used within 24 hours.

8. Ensure that the Perfadex® Plus bag is not in direct contact with ice.

	Bag 1	Bag 2	Bag 3	Bag 4	Bag 5	Bag 6	Bag 7
Temperature	**Room**	**Cold**	**Cold**	**Cold**	**Cold**	**Cold**	**Cold**
Prostacyclin	**Yes**	-	-	-	-	-	-
GTN	**Yes**	-	-	-	-	-	-

Appendix Seven

Blood utilisation for donor organ retrieval, *ex situ* machine perfusion and preservation technologies

Definitions:

1. **Direct procurement and machine perfusion (DPMP) 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 cross-matched 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 utilised, donor blood should not be taken for *ex situ* technologies until completion of NRP).
- *Ex situ* perfusion should utilise bank 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* machine 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
DPMP heart/lung with abdominal NRP	4 (for DPMP) + 4 (for NRP) = 8 units RBC	Donor typed
DPMP 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 *ex situ* perfusion	Donor blood taken immediately prior to cross clamp or 4 units RBC*	Donor typed
Heart	DCD TANRP with *ex situ* perfusion	Donor blood taken at end of NRP phase immediately prior to cold perfusion; or 4 units RBC*	Donor typed
Heart	DCD DPMP with *ex situ* perfusion	Donor blood taken immediately prior to cold perfusion or 4 units RBC*	Donor typed
Heart	DCD DPMP of heart with *ex situ* perfusion and abdominal NRP	8 units RBC*	Donor typed
Lung	DBD with *ex situ* perfusion	Donor blood taken immediately prior to cross clamp or 4 units RBC*	Donor typed
Lung	DCD TANRP with *ex situ* 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 DPMP *ex situ* perfusion	Donor blood taken immediately prior to cold perfusion or 4 units RBC*	Donor typed
Lung	DPMP lung with abdominal NRP	4 + 4 = 8 units RBC*	Donor typed
Liver	DBD 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 bank blood should comply with all current regulations for testing and safety and the Donor Identifier Number (DIN) for each unit of blood should be clearly recorded in the paperwork accompanying the organ (HTA A form) as well as the donor notes (where appropriate).
- Bank blood used for *ex situ* machine perfusion should be Rhesus matched to the donor. This is to avoid Rhesus positive blood perfusing a Rhesus negative organ that gets transplanted into a Rhesus negative female recipient and so sensitises the recipient to Rhesus antigens with consequences with respect to future pregnancies.
- 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 likely 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, bank blood will be administered to the donor. Bank 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.

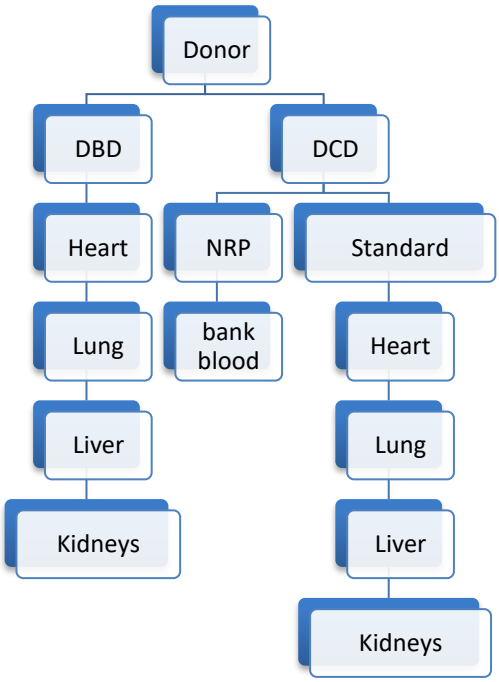

Figure 1. Suggested organ priority for allocation of donor blood when the type and technique of organ retrieval allows it and several technologies are to be used.

Appendix Eight

UK National Protocol for direct retrieval and perfusion (DRP) of DCD Hearts and Lungs with or without abdominal NRP (A-NRP) to Ex-situ Normothermic perfusion

Version number 2
Date: 1 November 2021

Responsible author; Marius Berman, co-chair of the Novel Technologies Implementation Group

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Preface

This protocol was produced by a combination of clinicians covering donation, organ retrieval and transplantation, NHSBT and acquired experience for the past years. It is acknowledged that some of the details might have local variation, but, this is the overall framework we recommend to adhere to.

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Protocol amendments

1. Version 1.0, date 24/03/2021 Final version approved
2. Version 1.1, date 01/04/2021 Updated clarification re DCD Heart Assessment, Section 2; minor typos
3. Version 2. Date 1/11/2021;
    - Delete NRP priming and refer to updated relevant protocol
    - Open OCS AFTER assessment for coronary artery disease p 8
    - Reference to Papworth OCS and Cell Saver training manuals p21
    - OCS perfusion parameters and final acceptance criteria. p21
    - Diagram of OCS management - deleted

1. DCD HEART DONOR SELECTION

Donor Inclusion Criteria

- Controlled DCD (Maastricht Category 3 and 4)
- Age ≤ 50 years
- Weight ≥ 50 Kg.
- Weight ≥30 kg – if suitable paediatric recipient at GOSH or Newcastle, discuss directly with Papworth on call retrieval consultant. Refer to DCD paediatric protocol. Protocol will be updated in future once perfusion technology available for < 30kg donors.
- Consent/authorisation obtained from next of kin/ organ donor register

Donor Exclusion Criteria

- Previous cardiac surgery
- Previous midline sternotomy
- Valvular heart disease
- Congenital heart disease
- Significant coronary artery disease
- Chronic atrial fibrillation
- Insulin dependent diabetes
- Virology: HIV+
- Current IV drug abuse.
- Tumour with high risk of transmission according to SABTO guidelines

NORS team Mobilisation

- Cardiac NORS team to arrive up to 2 hours before the planned withdrawal of treatment time
- Abdominal team to arrive 1 hour before withdrawal of treatment time.
- If NRP being used, both teams must arrive at the same time as the Cardiac team (2 hours before planned withdrawal time)

2. DCD HEART ASSESSMENT

- A transthoracic Echocardiogram (TTE) will be performed for all donors and be available at the time of the offer. All efforts should be made to transfer the images for review by the implanting team prior to mobilization of the NORS DCD Heart team. If that is not possible, the retrieval team will review the images (only if they are available on arrival at the donor hospital) and communicate with the implanting team prior to withdrawal of life sustaining treatment (WLST).
- If there are no images available but a full detailed TTE report is available, the retrieval should proceed if the recipient centre is happy with the findings.
- If an echocardiogram has not been performed prior to offering, there should be no more than 3h delay in performing and conveying the results.
- If no formal echo available, explore if the ICU team will be willing to perform a Focused Cardiac Ultrasound (FCU – previously known as FICE) though this is not mandatory for the ICU. This will serve as a screening step.
- Formal TTE will be performed by donor hospital, or, trained member of the retrieval team. NO TOE (transoesophageal) echocardiography will be performed at any stage!
- If no FCU or TTE is available, heart should still be offered for transplantation. It is the responsibility of the lead transplanting surgeon to discuss with the lead retrieval surgeon regarding the offer without an ECHO. The decision to accept or decline must be made within the standard offering timeframe.
- Echo main criteria: EF > 50%, no valvular pathology, PW and/ or IVS < 15mm

DCD HEART Withdrawal of life sustaining treatments

- Withdrawal of life sustaining treatments should ideally be undertaken in the anaesthetic room / theatre complex by the local hospital intensive care team.
- If it is not local practice to withdraw in the anaesthetic room / theatre complex then it may need further discussion between retrieval and donor hospital teams, aiming to withdraw support as close to theatre as possible, in order to minimize the ischaemic time during transfer to theatre. The place of withdrawal should be agreed before the NORS team is mobilised to avoid disagreement at retrieval.
- Height of donor table should be as the same as theatre table. This is done simply by marking the height of the donor bed by tape of the SNOD trousers and match this with the theatre table height.

- SNOD – If Heart is not suitable for transplantation, please explore pathway for research approved project or valves.
- **It is recommended that the donor is transfused to Hb of >= 100 g/L.** Timing of transfusion - once CT NORS team is mobile.
- ***Heparin in the donor before circulatory arrest***

Maastricht 3 donors: No pre-mortem interventions are currently allowed in the UK
Maastricht 4 donors (donor is already certified dead by brain stem criteria): heparin can be given. A suggested dose is 300units/kg (around 25000 units for a 80kg person) given just prior to withdrawal of treatment

- **SNOD – prepare units of packed red blood cells (cross matched to donor) :**
  - **4 units – no NRP**
  - **8 units - abdominal NRP**

DCD HEART Functional Warm ischaemia and Stand Down Criteria

- After withdrawal of treatment, regular contact will be maintained with the SNOD regarding blood pressure and arterial saturations on the donor.
  - When Harefield is implanting team and the ICU team in the donor hospital are agreeable; once arterial saturation is <80% an arterial blood gas should be taken to confirm donor

hypoxia, according with local hospital policy.

- Functional warm ischaemia begins when systolic blood pressure falls below 50mmHg.
- 30 minutes from beginning of functional warm ischaemia until cold cardioplegia is delivered will be tolerated before standing down.
- Essential for the team diagnosing death to be familiar with the Academy of Medical Royal Colleges 2008 Code of Practice for the Diagnosis and Confirmation of Death.
- If cardiac arrest does not occur within 120 minutes from withdrawal of treatment, consider standing down DCD heart retrieval at this stage, unless death is likely to be imminent
- We recommend having a discussion between retrieval and recipient centres after 60 min from withdrawal.

If the donor meets criteria the OCS module should be opened at that point and the priming process started

Transfer to operating theatre

- When the donor is brought into the operating room, the SNOD shows the patient name band to confirm donor identity. If withdraw adjacent to operating theatre, if SNOD and both NORS teams are in agreement, consider confirming demographics and name band prior to withdrawal.
- **ONLY IF LUNG RETRIEVAL IS TAKING PLACE AS WELL.** Once the donor is transferred to the operating table, an endotracheal tube size above 8 is inserted. At a point no earlier than 10 minutes after the onset of mechanical asystole, the lungs are re-inflated with a single breath of oxygen-enriched air. Lung ventilation will commence once ascending aorta is clamped, as per described in the National Standards for Organ Retrieval.
- The thoracic and abdominal surgeons will prepare the skin with an alcohol-based skin preparation solution and apply 4 drapes.
- A midline sternotomy is performed with a retractor to spread the sternal tables placed upside down. The abdominal surgeon will open the abdomen simultaneously.

Composition of the DCD CT Retrieval Team

- A theatre practitioner scrubbing for organ retrieval
- Organ preservation practitioner (OPP)
- Advanced Perfusion and Organ Preservation Specialist (APOPS)
- Two surgeons, at least one has been accredited as competent DCD cardiothoracic organ retrieval
- If aNRP, it is recommended to seek additional surgeon from Harefield or Papworth

For all retrievals, first do assessment for coronary disease and only afterwards, give clear instruction to open and prime the OCS. The assessment can take place while draining blood to prime the OCS.

3. Surgical protocol – NO ABDOMINAL NRP

Preparation

- Prepare St Thomas cardioplegia - Add the following medication to 500ml bag of Ringers:
  - 2,500iu of Epoetin Alfa
  - 50mgs GTN
  - 3mls Sodium bicarbonate 8.4% (840mgs in 10ml amp)
  - 10mls cardioplegia concentrate
  - Add heparin 300u/kg
  - *(Solution to be put back into the ice box but easily accessible for use when donor arrives in theatre)*
- Prepare St Thomas cardioplegia for back at implant site – Add the following medication to 1L bag of Ringers:
  - 5000iu of Epoetin Alfa
  - 100mgs GTN
  - 6mls Sodium bicarbonate 8.4% (840mgs in 10ml amp)
  - 20mls cardioplegia concentrate

  (Solution to be put back into the ice box for use when heart is at implant site))

- Blood collection – see also Appendix 2: Minimum of 1.2-1.5L to be collected with a raised table in head down position. It is crucial to ensure that no preservation solution is given until donor blood is drained, and no vasoconstrictor bolus is given at this stage. This should take no more than 60secs.
  - There are several variations across units;
  - Insertion of a 2-stage venous cannula connected to a blood collection bag with Heparin 25,000 IU. If this is the case, 25,000 IU of heparin are injected into the right atrium and 25,000 IU of heparin into the pulmonary trunk prior to blood drainage.
  - Insertion of a drainage cannula connected to a sucking device or sterile reservoir. Blood is drained under suction and simultaneously mixed with the OCS priming solution containing 60000 IU of heparin
- During donor blood collection the cardiothoracic surgeon will clamp the descending aorta above the diaphragm, as low as possible. The cardiothoracic surgeon will announce this clamp is in place and the time will be recorded on the National DCD Heart Passport.
- A clamp is placed across the ascending aorta and a DLP cannula inserted into the ascending aorta for cardioplegia delivery and the heart excised in the standard fashion for heart retrieval.
- If the lungs are to be retrieved, the local hospital anaesthetist or the NORS team donor care practitioner will reintubate the donor during sternotomy as per DCD Lung retrieval.

- Care must be taken to leave the posterior wall of PA carina when removing the heart. As soon as the heart is removed, ante-grade pneumo-plegia is delivered through these cannulae followed by retrograde pneumo-plegia via the pulmonary veins. Fibre optic bronchoscopy is performed and lungs are retrieved in standard fashion for DCD lung retrieval.

Preparation of the DRP-DCD heart prior to Ex-Situ perfusion

- The heart is immediately placed into a basin of ice cold sterile saline solution.
- Dissection made to free the aorta from the pulmonary artery placing and securing the appropriately sized perfusion connector for the Organ Care System (OCS) with the supplied cable tie. Teflon pledgeted aortic stitches are used to further secure the aorta to the OCS so reducing the risk of disconnection during travel to the recipient hospital.
- The heart is placed and de-aired onto the primed OCS.
- Insert and secure LV vent through the left atrium into organ chamber.

Place ventricular pacing wires in case pacing is required at a later stage.

PA cannula (Protocol difference)

Harefield implanting or retrieval – PA cannula secured and connected. (SVC and IVC - sutured) and connect blue flow probe – follow Transmedics protocol.
Manchester/Papworth retrieval – PA cannula NOT connected, allowing free drainage.

Three teams agreed cross over protocol at JiF DCD meeting on 28/1/2020

OCS perfusion parameters during transport:

Commence OCS perfusion of donor heart aiming for:

- Mean AOP 55-70 mmHg
- Aortic flow of 900-1100 mL/min-
- Coronary flow 650-750 ml/min
- Heart rate 70-90 BPM with V-pacing
- Once heart rhythm and perfusion are stable consider to synchronise perfusion depending on discussion with implanting team.

Acquire simultaneous AV blood samples. Perfusate targets are:

- Hct >15%
- Calcium 1.0-1.3 mmol/l
- Bicarbonate 22-29 mmol/l

- Ph – 7.3-7.45

Video clip to be transferred to implanting center at 30min reperfusion on the rig

Transport

Ensure to travel with a safety ice box and roadside bag which will include;

- Ice, cardioplegia, giving set + pressure bag, 8 litres of cold saline

Roadside bag – sterile instruments, sterile gloves different size, sterile gowns, 3 packing bags for heart.

Cardioplegia at recipient site (agreed telecom 2.9.20)

Once implanting team are happy to receive the heart,

- The retrieval team have set up to administer cardioplegia.
- All 3 teams will administer St. Thomas at retrieval and implant site when retrieving for any 6/7 UK centers.
- Harefield will carry both Custadiol and St. Thomas and will have a choice of Custadiol or St. Thomas when retrieving for Harefield.

(Refer to St. Thomas preparation on page 7)

Trouble shooting;

- Check placement heart on the rig (twist, impaired drainage..)
- Syringe drives
- Flow probes and sensors
- Module position within the rig
- Redo medication preparation

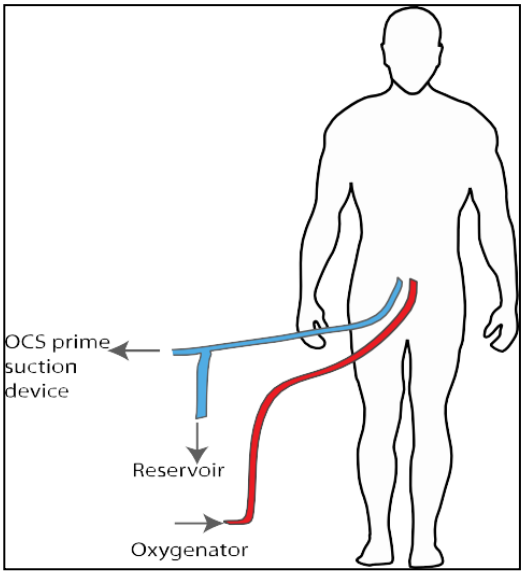
4 **Surgical protocol – WITH ABDOMINAL NRP**

For the most up to date version, please refer to;

https://www.odt.nhs.uk/retrieval/policies-and-nors-reports/

Circuit

The NRP circuit needs to have a Y attachment on the venous return limb just above the reservoir, and needs to be fitted prior to arrest. This needs to be connected to the cell saver to allow for donor blood drainage needed for *ex situ* heart perfusion, but clamped initially.



The NRP circuit is primed with 1.5 litres of Hartmann's, to which are added 4 units of red cells. The circuit needs to be set up before withdrawal of treatment, and warmed to 37°C by circulating through the oxygenator/heat exchanger.

A pump sucker will be connected to the reservoir for blood loss recovery. (This is the preferred standard with teams working towards this, until then existing practice will prevail). This will only be used to recover blood from the pericardium if heart retrieval only, or to recover blood from pericardium and pleural space if combined heart-lung retrieval. Blood should not be recovered from the pleural space in the presence of chest sepsis. Additional care must be taken to avoid any perfusion fluid/saline being recovered using this sucker.

THIS ADDITIONAL SUCKER WILL NOT BE USED IN CASES OF PERICARDIAL, MEDIASTINAL OR SYSTEMIC INTECTION. CAREFUL HAEMOSTASIS SHOULD BE PERFORMED IN THE CHEST EVEN IN THE EVENT OF HAVING A PUMP SUCKER AVAILABLE.

Two long DeBakey vascular clamps will be ready to use by the cardiothoracic team prior to WLST to clamp descending aorta and IVC. Two Roberts clamps will also be ready to clamp SVC and ascending aorta. It has been agreed that clamps will be provided by the abdominal team as they need to stay in place once the CTh team has left the operating theatre.

Due to the complexity of the technique all cardiothoracic organs will be perfused and retrieved only for transplantation or valve donation purposes.

Operative procedure

Following verification of death 5 minutes after circulatory arrest, the patient is transferred to the operating table.

IT IS MANDATORY TO FOLLOW THIS STEP SEQUENCE

Abdominal procedure

1 The circulating pump is stopped, and the sash is clamped and divided; the arterial cannula may be attached and primed at this point.

2 Once the donor is in theatre, the abdomen is opened through a midline incision.

3 The venous cannula is placed in the right common femoral vein (or iliac vein or IVC) and connected to the venous limb of the sash, with care to exclude air. Care should be taken not to insert too much length of cannula to prevent it going into the right atrium.

IF there is problem with achieving venous cannulation the thoracic team may choose to cannulate the right atrial appendage; this cannula should be removed and the appendage ligated before starting NRP or else air will be entrained in the circuit and NRP fail. For this reason atrial cannulation is a last resort.

4 Clamps are removed and 1.5L venous blood drained out and diverted into the collecting receptacle for the heart Organ Care System (OCS) (such as the cell saver system used by Harefield).

5 The Y-connector is then clamped and venous return blood now diverted to drain back into the reservoir (see figure 1). Please ensure having the correct connectors – 3/8, and ½.

6 The arterial cannula is placed in the right femoral artery, common iliac artery or aorta while the venous drainage occurs.

7 Once the cardiac team have clamped the descending thoracic aorta and stated that clearly for both teams to hear, and the 1.5L venous OCS prime has drained, the NRP pump is started aiming for flows over 2.5L/min. The time that the descending thoracic aorta is clamped will be recorded on the National DCD Heart Passport.

Abdominal NRP must not start until both teams have confirmed for all to hear that the descending aorta is clamped and aortic arch is vented via a DLP cannula.

8 Once the heart is removed it is important to check the security of the supra-hepatic IVC clamp – this may need to be sutured in place to avoid inadvertent unclamping or slipping from the cut IVC. The cut ends of the pulmonary vessels and SVC may be oversewn with 3/0 Prolene at this stage also. While the cardiac surgeons should ensure haemostasis in the chest, in reality it is the abdominal surgeons who are usually free at this stage and can stop large vessel bleeding.

There should be no major bleeding.

Heart Retrieval

The chest is opened in the midline and sternum split while the abdomen is being opened.
Pericardiotomy

Heart retrieval only

The left pleural space is opened and DESCENDING THORACIC AORTA IS CLAMPED above the diaphragm to isolate abdominal NRP. Priority will be given to ensure absence of brain reperfusion via NRP system. The act of clamping the descending aorta should be announced loud enough for all to hear and the time will be recorded on the National DCD Heart Passport.

PLACEMENT OF DOUBLE LUMEN DLP CANNULA IN THE ASCENDING AORTA, as high as possible. Initially, used to drain the ascending aorta blood. Later in the sequence, it can be used for cardioplegia delivery.

Once the DLP cannula is in place and open to air, the cardiothoracic surgeon announces that the aortic arch is vented. The time will be recorded on the National DCD Heart Passport. If there is copious arterial bleeding from the DLP cannula, the NRP pump must stop and the clamp on the descending aorta must be re-positioned to occlude the aorta. Only then can the NRP pump re-start.

1. The SVC and azygous vein are dissected to ensure enough length.

2. The IVC is dissected around. If the tip of the cannula is inside the right atrium, the abdominal team should be asked to pull the cannula back below diaphragm to allow for IVC clamping at a later stage. Check to ensure the venous cannula does not encroach into the right atrium.

The heart is assessed for any visible anomalies, palpable coronary artery disease, left ventricular hypertrophy, trauma, congenital disease etc.

3. Once 1.3-1.5L of donor blood has been received into the receptacle / cell saver for the OCS prime, CLAMPS ARE PLACED ACROSS THE IVC ABOVE THE DIAPHRAGM, AND THE SVC *CAUDAL* TO THE AZYGOS. The SVC is transected caudal to clamp, placed below azygos vein.

4. The ascending aorta is clamped, in addition to the descending thoracic aortic clamp.

5. IVC is opened just cranial to the clamp for venting and left atrium is opened at level of

pulmonary veins for pulmonary return.

6. Cardioplegia supplemented with 25000 IU heparin, EPO and 50 mg of GTN is administered via a large bore needle PROXIMAL to the cross clamp. The previously placed DLP cannula, distal to the cross clamp, at the level of the arch will remain in situ and open to air.

7. **Once cardioplegia is finished, the large bore cannula is removed.**

8. The heart is then excised leaving all previously placed clamps in situ to minimize blood loss.

9. Establish with the abdominal team and identify team member who is going to secure potential bleeding points. – stich 3/0 stump IVC (with or without the clamp), SVC, azygos and pulmonary veins.

10. The heart graft is prepared at the back table and re-perfused with ex situ normothermic perfusion technology in the usual manner.

Heart and Lung retrieval

Once the donor is transferred to the operating table, an endotracheal tube size above 8 is inserted. At a point no earlier than 10 minutes after the onset of irreversible asystole, the lungs are re-inflated with a single breath of oxygen-enriched air. Lung ventilation will commence once ascending aorta is clamped, as per described in the National Standards for Organ Retrieval.

Bronchoscopy performed usually at this point if an additional surgeon is available, or later after pneumoplegia completion.

1. The left pleural space is opened and DESCENDING THORACIC AORTA IS CLAMPED. The act of clamping the descending aorta should be announced loud enough for all to hear and the time will be recorded on the National DCD Heart Passport.

2. Placement of double lumen DLP cannula in the ascending aorta, and cannula opened to air; This cannula is used initially to ensure absence of brain perfusion and later used for cardioplegia delivery.
Once the DLP cannula is in place and open to air, the cardiothoracic surgeon announces that the aortic arch is vented. The time will be recorded on the National DCD Heart Passport. If there is copious arterial bleeding from the DLP cannula, the NRP pump must stop and the clamp on the descending aorta must be re-positioned to occlude the aorta. Only then can the NRP pump re-start.

3. SVC, IVC dissection and donor blood drainage, as per heart only retrieval technique, is performed.

4. Clamps are placed across the IVC above the diaphragm and the SVC caudal to the Azygos. The IVC is opened just proximal to the clamp for venting and the left atrial appendage is vented widely.

5. The ascending aorta is clamped, proximal to DLP cannula, only during cardioplegia delivery. Cardioplegia supplemented with 25000 IU heparin, EPO and 50 mg of GTN is administered via a large bore needle PROXIMAL to the cross clamp. The previously placed DLP cannula, distal to the cross clamp, at the level of the arch will remain in situ and open to air.

6. **Once cardioplegia is finished, the large bore cannula is removed.**

7. After cardiectomy, antegrade pneumoplegia is completed according to National protocol. Simultaneously, the pleurae are opened widely and lungs inspected and palpated, ensuring adequate delivery of flush and topical cooling with copious volumes of 4°C saline.

8. If significant collateral flow from pulmonary veins, consider delivering retrograde pneumoplegia into the pulmonary veins

9. **After completion of antegrade pneumoplegia, wait for aNRP to reach 30 min, prior to starting dissection.**

10. After 30 min, inform everyone in theatre that CT surgeons start lung dissection.

11. If the lungs are suitable and accepted for transplantation a competent lung retrieval surgeon will complete rest of dissection while abdominal NRP continues, by dividing the descending thoracic aorta and taking this along with the lung bloc. This would involve ligaclipping all the intercostal arteries (L and R) up to the arch, being careful to avoid bleeding.

The care and detail required to retrieve lungs whilst NRP is running is the same as would be required in a living patient. The abdominal organs may be lost if the lung retrieval is performed in haste. If we are to build a future with novel technologies, both teams need to support maximal organ retrieval and utilization.

Consider applying a second clamp on the descending thoracic aorta, just distal to left subclavian artery, in order to minimize bleeding. We recommend removing the lung block with the thoracic aorta, however, some might feel more comfortable dissecting in front of the aorta, in particular if there is no prospect of using EVLP. Need to bear in mind the left pulmonary artery when dissecting in this plane.

12. **The azygos vein must be ligated twice and cut in between**. This can be done easily in the right pleural space.
The rest of the lung dissection can be completed with diathermy and by using surgical Liga-clips aiming to minimize blood loss.

13. The trachea is stapled and cut leaving a clamp or staple line on the top end.

14. Retrograde pulmonary venous flush of the lungs is performed on the back-table at the donor site and lungs are packed as per National protocol.

Lung retrieval only

Once the donor is transferred to the operating table, an endotracheal tube size above 8 is inserted. At a point no earlier than 10 minutes after the onset of irreversible asystole, the lungs are re-inflated with a single breath of oxygen-enriched air. Lung ventilation will commence once ascending aorta is clamped, following all steps as per the National Standards for Organ Retrieval.

Bronchoscopy performed usually at this point if an additional surgeon is available, or later after pneumoplegia completion.

1. The left pleural space is opened and DESCENDING THORACIC AORTA IS CLAMPED. The act of clamping the descending aorta should be announced loud enough for all to hear and the time will be recorded on the National DCD Heart Passport.

2. Placement of double lumen DLP cannula in the ascending aorta to ensure absence of brain perfusion
   Once the DLP cannula is in place and open to air, the cardiothoracic surgeon announces that the aortic arch is vented. The time will be recorded on the National DCD Heart Passport. If there is copious arterial bleeding from the DLP cannula, the NRP pump must stop and the clamp on the descending aorta must be re-positioned to occlude the aorta. Only then can the NRP pump re-start.

   Place pnemoplegia cannula into the PA.

   Clamp proximal PA .

   Cut LA appendage.

3. Antegrade pneumoplegia as per UK National guidelines is administered. Simultaneously, the pleurae are opened widely and lungs inspected and palpated, ensuring adequate delivery of flush and topical cooling with copious volumes of 4°C saline.

   CT WILL WAIT after delivering antegrade pneumoplegia to complete 30min aNRP perfusion prior to carry on any further dissection. CT NORS might choose to use this time to repeat FOB or assess in more detail the lungs.

   THIS WILL ALLOW ESTABLISH OF aNRP flows for at least 30min, period crucial to liver recovery. Risk of bleeding is minimal at this stage.

4. Ascending aorta is clamped proximal to DLP cannula, and cannula should be open to air to ensure absence of brain perfusion.

5. SVC, IVC dissection is performed. Clamps are placed across the IVC above the diaphragm and the SVC caudal to the Azygos. The IVC is opened just proximal to the clamp for venting and the left atrial appendage is vented widely.

6. Heart -lung retrieval will be carried en-bloc. This is to minimize potential catastrophic blood loss.

7. Cardiectomy performed leaving **a long IVC cuff above previously placed IVC clamp**. Ascending aorta and SVC are both cut caudal to clamps, which stay in place to avoid bleeding.

8. If the lungs are suitable and accepted for transplantation the rest of dissection will be completed while abdominal NRP continues, being careful to avoid bleeding.

   The care and detail required to retrieve lungs whilst NRP is running is the same as would be required in a living patient. The abdominal organs may be lost if the lung retrieval is performed in haste. If we are to build a future with novel technologies, both teams need to support maximal organ retrieval and utilization.

9. **The azygos vein must be ligated twice and cut in between.** This can be done easily in the right pleural space.

10. The rest of the heart-lung bloc dissection can be completed with diathermy and by using surgical Liga-clips aiming to minimize blood loss.

11. The trachea is stapled and cut leaving a clamp or staple line on the top end

12. Secure major remaining stumps – IVC, SVC, arch vessels and any other source of bleeding.

13. Retrograde pulmonary venous flush of the lungs is performed on the back-table at the donor site and Lungs are packed as per National protocol.

14. Heart to be returned into the chest and document this action.

The cardio-thoracic surgeon should ensure haemostasis in the chest during and at the end of retrieval, before leaving the donor hospital. Excess bleeding may result in an unusable liver, pancreas and kidneys.

Requirements to undertake DRP and NRP

The following are required for the successful removal of the heart during NRP

From the cardiac team

- Senior surgeon who is experienced in DRP retrieval
- The *ex situ* normothermic heart perfusion machine. Technician to operate the *ex situ* perfusion machine and the cell saver
- The necessary sterile tubing and adapters to connect to the NRP circuit (3/8 and ½ inch tubing). An appropriately staffed and equipped lung retrieval team if the lungs are also being retrieved

Set up of Transmedics OCS and use of Cell Saver

Papworth have developed an OCS training manual for DCD hearts and an OCS blood collection with cell saver manual. These are available for reference on the NHSBT ODT microsite here Policies and NORS reports - ODT Clinical - NHS Blood and Transplant

OCS perfusion parameters during transport:

In general, it is recommended to maintain the OCS in manual rather than automatic mode.

Changes to flow and pacing have an immediate effect whereas changing the infusions of epinephrine or maintenance fluid may take minutes to take effect.

Commence OCS perfusion of donor heart aiming for:
• AOP: 55-70 mmHg
• Aortic flow: 800-1100 mL/min
• Heart rate: 70-90 BPM with V-pacing
• Aim CF: 650-750 ml/min
• Once heart rhythm and perfusion are stable consider synchronising perfusion depending on discussion with implanting team.

Acquire simultaneous AV blood samples. Perfusate targets are:
• Hct: >15%
• Calcium: 1.0-1.3 mmol/l
• Bicarbonate:22-29 mmol/l
• pH: 7.30-7.45

Parameters to consider prior to final decision

- **AOP 55-75 mmHg with Maintenance fluid <30 ml/Hr**
- **Aortic flow 800-1100 ml/min**
- **HR**
- **Total lactate trend decreasing over time**
- **Lactate consumption profile i.e. Lac_{Art} > Lac_{Ven}**
- **Contractility**
- **Prescence of superficial petechia and/or oedema**
- **FWIT < 30min i.e. Time from SBP<50mmHg to start of OCS perfusion**
- **OCS perfusion time + all the above + predicted preparation of implant (for example; if OCS > 4hours and redo surgery with predicted additional 2-2.30 hours OCS perfusion) need to asses all the above real time**
- **If in doubt, call on-call retrieval consultant surgeon at Royal Papworth Hospital for advice**

SAFETY CHECKLIST FOR DIRECT RETRIEVAL OF THE HEART/ HEART AND LUNGS AND *IN SITU* NORMOTHERMIC REGIONAL PERFUSION OF THE ABDOMINAL ORGANS

TO BE COMPLETED AT HANDOVER	***CTH SURGEON***	***ABDO SURGEON***
1 Protocol reviewed prior to WLST	œ	œ
2 Debrief completed prior to WLST	œ	œ
3 CTh team equipment ready ***(Cell saver, Clamps, OCS, Fluids for perfusion)***	œ	
4 Abdominal team equipment ready		œ

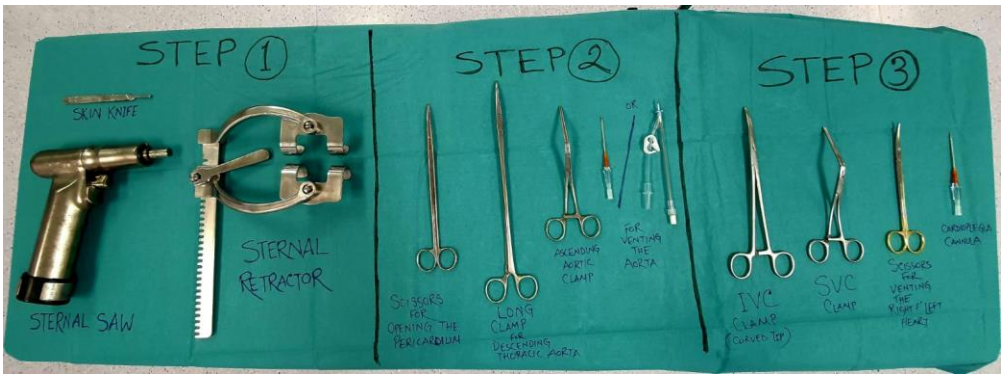
Leading surgeon; Full name and signature

TO BE COMPLETED PRIOR TO START ABDOMINAL NRP

(Time to be noted and signed by Abdominal team Perfusionist)

1 Descending Aorta x clamp time

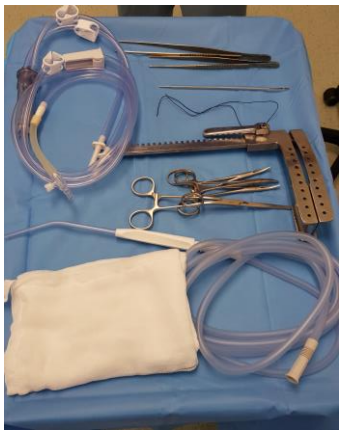
Scrub trolley discipline:



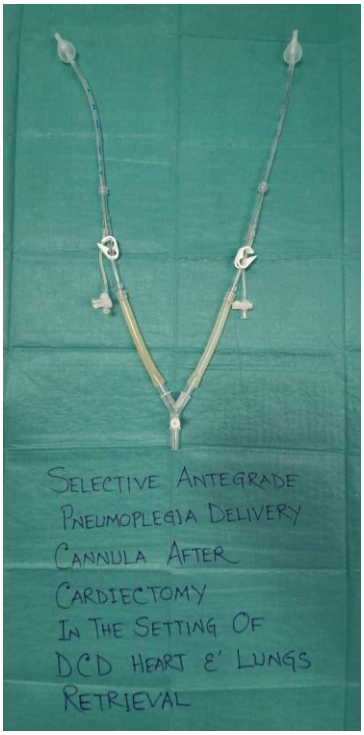
The above figure demonstrates the scrub trolley discipline, which correlates with the surgical steps, and this can be very helpful in the DCD with A-NRP retrieval specially at the very beginning of the process till the start of the antegrade cardio and pneumoplegia. This is not only helpful but also comfortable for the surgeons and the scrub to work in harmony and to prevent unwanted events as well as to maintain sterility in a hasty procedure.

Some teams would prefer a second trolley is prepared for the assistant and will be on the left of the donor The trolley contains: SEE PHOTO

- Two suckers (Cell saver and wall sucker (Cell saver marked by a black tie to distinguish from wall sucker and not be used once cardioplegia started)
- Clamp for the SVC
- Two Dunhill clips.
- One Abdo pack
- Heparin syringe
- Two forceps
- Chest retractor
- Cardioplegia and pneumoplegia lines.



In the setting of DCD heart and lungs retrieval cardioplegia delivery finishes before pneumoplegia. But, if one has to wait for the pneumoplegia to finish before starting procurement of the heart, several precious minutes will be lost. To avoid that as soon as cardioplegia delivery finishes, antegrade pneumoplegia delivery can be paused for procurement of the heart. After that through the cut end of main pulmonary artery the selective antegrade pneumoplegia delivery cannula (shown in the figure) can be used to complete the rest of the pneumoplegia.



Cardiothoracic Synchrony between the Surgeons

SURGEON 1	SURGEON 2
• Skin Incision • Sternotomy	Handle the suckers and the plegia lines
	• Placing the Sternal retractor (Not fully opened in order not to stretch the pericardium
• Opening of the pericardium • Opening of the Left pleura • Retracting the Left lung to expose the descending thoracic aorta	
• Inject heparin in right atrium	Inject heparin in PA
	• Clamping the Descending Thoracic Aorta with a long clamp
• Incising right atrial appendage and collection blood for OCS	
• Ascending Aortic clamp • Insertion of venting needle distal to the clamp	
	• Securing the venting needle/cannula
• ~~Rule out CAD~~	
• Venting the Right (Clamping the IVC in the pericardium and Flush cutting) and Left Heart (through LAA or LSPV) • Inserting with wide bore cannula (medicut) **and holding it in place** proximal to the ascending aortic clamp to deliver antegrade cardioplegia	• SVC clamp caudal to Azygos away from SA node
	• Connecting the cardioplegia line to the cannula • Surface cooling with cold saline
• At the completion of the cardioplegia, careful procurement of the heart (after securing the Azygos and ensuring adequate SVC length)	• Helping the Surgeon 1
• Heart out and preparing it for OCS in the back table	
	• Securing bleeding points and ensuring haemostasis for a smooth A-NRP run

Appendix Nine

NATIONAL ORGAN RETRIEVAL SERVICE

Guidance for Surgical Count

PURPOSE:

This guidance aims to standardise safe practice and the operative environment for organ donors, NORS teams and donor hospital staff. This statement is in response to several incidents associated with missing Raytec swabs. Although our patients are deceased, families have a right to expect the same high standards of surgical care in organ donation as for any other patient. A retained item can bring untold donor family distress, and we must strive to minimise this possibility.

AIM:

To ensure safe practice it is essential that each team attending a multi organ retrieval undertakes an independent two-person surgical count of instruments, sharps, swabs and packs prior to knife to skin. **All Raytec swabs and packs should be recorded and collected in a central location in theatre.**

RATIONALE:

The nature of the retrieval procedure means the cardiothoracic team leaves the donor theatre prior to the end of the operation, therefore the abdominal scrub practitioner is responsible for the full final check of remaining accountable Raytec items.

SAFETY BRIEF:

At the team safety brief the procedure for the surgical count must be discussed and agreed.

PRACTICE:

As the cardiothoracic team prepare to leave the table, the CT scrub practitioner must undertake an accountable item check. The CT scrub practitioner will take responsibility for their instruments and safe disposal of their sharps and will advise the abdominal scrub practitioner of the outcome.

All swabs and packs will be collected in a central location in theatre.

The Abdominal team will proceed with the retrieval of the abdominal organs and complete the retrieval process. Prior to closure, a full check of remaining accountable items inclusive of **all** swabs and packs must be undertaken and documented.

ACTIONS:

In the event of a miscount, local policy must be followed, acknowledging that the donor thoracic and abdominal cavity is easily inspected for retained Raytec items. Any untoward incidents must be reported via the incident reporting tool.

https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/

The surgical count should not distract the scrub practitioners from the principal of safe removal and timely despatch of organs to recipient centres.

Thank you for your continuing effort ensuring we maintain high standards of practice, respect for the donor whilst minimising risk of family distress, a safe surgical environment and standardisation of practice for all involved in the organ retrieval process.

Appendix Ten

UK Protocol for Normothermic Regional Perfusion (NRP) in controlled Donation after Circulatory determination of Death

NRP NATIONAL PROTOCOL

Version number: 1.4.2
Date: 29th June 2021

Responsible author: Chris Watson, co-chair of the Novel Technologies Implementation Group

Preface

This protocol was produced by the NHSBT NRP implementation group (see section 11).
The protocol reflects the combined experience of UK experts over many years developing NRP in the UK. It is acknowledged that it reflects practices that have evolved locally and which may be superseded as more evidence and experience accrues. It also reflects the equipment available to clinicians at the time of writing and is not meant to endorse any particular piece of equipment.

Table of contents

Amendments

Version 1.0 Dated 18th March 2021

Final protocol agreed 18/3/21.

Version 1.1. Dated 19th March 2021

Removal of reference to previous antibiotic protocol and correction of typographical errors.

Version 1.2, dated 8th April 2021.

Introduction of clamping the SVC and IVC in the chest to prevent cardiac filling and reanimation.

Version 1.3, dated 10th April 2021

Additional note to make it clear that venting the ascending aorta is mandatory in all cases of A-NRP (including Maastricht 4) where no cardiothoracic team is attending.

Version 1.4, dated 26th June 2021

Change in requirement when an Endoclamp is used to require formal venting of the ascending aorta with a separate cannula.

Removal of requirement to clamp the IVC and SVC (amendment 3.3)

Revert to adding antimicrobials to the prime.

Recommendation to cannulate artery first.

Recommendation for someone to call out times at 10, 15, 20 minutes following knife to skin to guide surgeon on when to abandon and go cold.

Guidance on amount of red cells to be added to prime if donor is anaemic.

Suggestion to ligate the artery supplying the contralateral leg if femoral or iliac artery cannulation has taken place.

Alteration in requirement for liver function tests from every 30 minutes to every 30-60 minutes.

Further notes on Maastricht category 4 donors:

- Addition of 5 minute stand-off in 4 donors
- Possibility of delivery of UW down aortic root if heart fibrillates.
- No need to ligate neck vessels for TA-NRP

Version 1.4.2, dated 29th June

Addition of section 9 regarding documentation of NRP on organ passport.

Introduction

Abdominal in situ normothermic regional perfusion (A-NRP) is a technique to restore the circulation to the abdominal organs following circulatory arrest for the purpose of transplantation. This involves establishing a localised, abdominal perfusion Extracorporeal Membrane Oxygenation (ECMO) circuit, perfusing the organs with oxygenated blood at 37°C for a period of typically 2 hours.

This will allow:

1. Recovery from warm ischaemia and replenishment of ATP reserves
2. Assessment of organ function and quality
3. A less hasty retrieval.

NRP has been shown to increase the utilisation of all abdominal organs, and significantly improve the outcomes of liver and kidneys, with no adverse effects on the pancreas. For the liver it is associated with better transplant survival and a very low incidence of cholangiopathy when compared to conventional DCD donor livers; for the kidney it is associated with better renal function at 12 months.

This protocol details the technical aspects of the procedure. It is written with regard to the current legislation and observes the Academy of Royal Medical Colleges (AoRMC) code of practice for the diagnosis and confirmation of death that forms the basis of organ donation from deceased donors.

Composition of Organ Retrieval Team for A-NRP

With the addition of NRP to clinical practice, the core membership of the abdominal retrieval team should consist of:

- A theatre practitioner scrubbing for organ retrieval
- Organ preservation practitioner: A theatre practitioner competent in organ perfusion/preservation techniques:
- Advanced Perfusion and Organ Preservation Specialist (APOPS): A senior theatre practitioner competent in operating the NRP machine and monitoring the perfusion
- Two surgeons, at least one of whom has been accredited as competent to perform A-NRP

Thoracic and/or cardiac surgeons may attend for retrieval of thoracic organs; separate protocols exist for recovery of those organs and adaptations of this protocol in those circumstances are discussed at the end of this document.

Mobilisation

Mobilisation for A-NRP is the same as for any DCD retrieval, arriving 1 to 2 hours or more before the proposed withdrawal time. For combined procedures with cardiothoracic teams the scheduled arrival should be 2 hours ahead of proposed withdrawal time to enable full communication and rehearsal of the steps involved in retrieval to ensure a successful outcome for both teams. It should be noted that the abdominal team will need at least 2 additional vascular clamps or equivalent when a combined retrieval is planned with the cardiothoracic team. These clamps, applied to large vessels to permit heart, and/or lung retrieval, will remain in place one the cardiac team have gone and must therefore be carried by the abdominal NRP team.

Setting up the equipment for A-NRP

Ordering blood

The SNOD should order packed red cells cross-matched to the organ donor so they are available prior to the abdominal retrieval team arriving. The blood should be in the theatre suite *before* withdrawal of treatment. The amount ordered depends on circumstances:

- Standard abdominal NRP: 4 units
- Abdominal NRP with heart or lungs are being recovered by direct retrieval and cold perfusion: 8 units
- Thoraco-abdominal NRP: 6 units

Donor hospital handover

Once at the donor hospital the abdominal retrieval team should inform local theatre staff of the planned procedure. They should also discuss the relevant protocols for removal of heart or lungs with the respective retrieval team. Protocols are clearly defined for combined procedures and must be followed (see odt.nhs.uk microsite).

Someone should be identified who can perform blood gas analyses if a point of care device is not available in the donor theatre. Similarly, someone should be identified to run samples to the biochemistry laboratory if a point of care device is not available. However, each team should have the necessary equipment, fully maintained and quality assured, and be independent of laboratories for such assays.

The standard pre-retrieval handover should be undertaken, including verification of information in the core donor data form by reviewing the case notes, and checking the blood group and virology results.

Timing and Place of Withdrawal of Life Supportive Therapy (WOLST)

The normal practice at the donor hospital regarding the place of treatment withdrawal may be observed. The time of withdrawal, the time systolic BP falls under 50mmHg, and the time of circulatory arrest are recorded according to current practice. In addition, the time NRP is commenced and stopped will also need to be recorded.

As soon as death is verified, the patient is transferred to the operating theatre.

The acceptable duration between WOLST and death for retrieval of specific organs should be discussed with the implanting team, but these are likely to be longer than considered with DCD donors in whom NRP is not performed. As per NORS guidance the retrieval team is expected to stay for 3 hours. There should be no need for premature stand down since viability will be tested during NRP.

Pre-retrieval preparation

This involves several steps:

a) The scrub practitioner will setup the operating environment in a similar fashion to the current practice for DBD retrieval. This includes setting up the diathermy machine (as available in the host theatre) and the power saw for thoracotomy (where available).
b) Two 60 ml catheter tip syringes filled with heparinised saline should be prepared. They will be used to flush the aortic and IVC lines prior to connecting to the NRP circuit.
c) The aortic and IVC cannulas should be identified.
d) The connections between the proposed cannulae and the sash are checked to make sure they are compatible and no additional connectors are required.

e) Once the potential donor's systolic pressure has fallen below 50mHg or after circulatory arrest, the sterile part of the NRP circuit (the "sash") should be handed to the scrub practitioner.
f) Both limbs of the sash should be clamped approximately 10cm from the ends of the red and blue line tubes and divided.
g) The arterial and venous cannulae should be opened at this stage; opening them earlier may result in wastage if the donor does not die.
h) If a heart team is planning to recover the heart by direct recovery and perfusion in the cold, they will need 1.5L of donor blood to prime the OCS heart machine. This must be recovered before NRP commences. This is best facilitated by having a Y-connector on the blue venous return pipe above the reservoir that can be connected to their blood receptacle. This is best placed before priming if one is not already built into the circuit (figure 1).

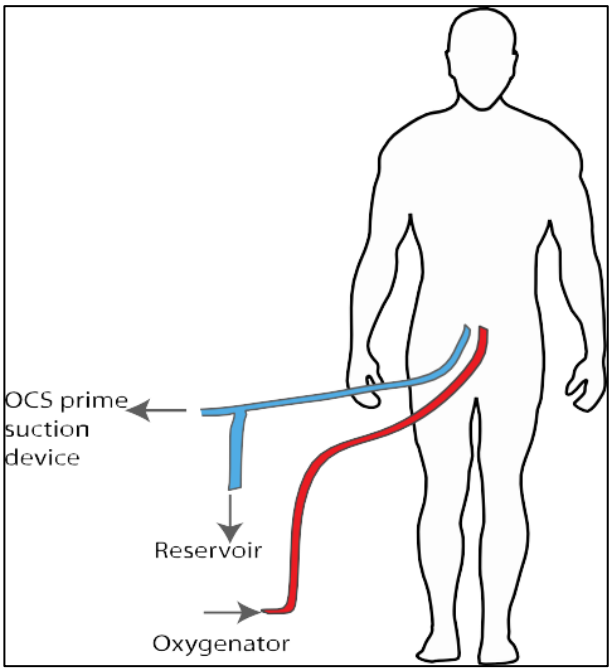


Figure 1 Y-connector to facilitate blood being removed to prime the OCS device.

NRP setup

The NRP setup depends on the machine used.

The heater

Maquet's Cardiohelp: The heater is separate and should be topped up with water and switched on with the temperature set at 37°C.

Organ Assist's Donor Assist: switching on the heater is part of the automated setup.

Heparin in the donor before circulatory arrest

Maastricht 3 donors: No pre-mortem interventions are currently allowed in the UK.

Maastricht 4 donors (donor is already certified dead by brain stem criteria): heparin can be given. A suggested dose is 300units/kg (around 25000 units for a 80kg person) given just prior to withdrawal of treatment

Preparation of cold perfusion fluids

Two one-litre bags of cold University of Wisconsin solution should be prepared with 300u/kg (around 25000 units for an 80kg man) of heparin added to *each*, as for a standard DCD, and run through a large bore 'Y' giving set so they can be used immediately should NRP fail to be established or problems are encountered during perfusion and rapid conversion to a standard technique is required. The giving set may be pre-connected to the NRP circuit and once primed the UW bags should be replaced in ice until needed. When cold perfusion starts it is imperative a clamp is placed on the arterial line proximally to prevent back flow into the pump/reservoir.

Composition of circuit priming fluid

Standard prime

- Bicarbonate 8.4%, 1ml/kg
- Hartmann's 2000 mls
- Heparin 50,000 u
- Methylprednisolone: 1 gram
- Phentolamine 5mg
- Pancuronium 12 mg – to prevent abrupt diaphragmatic contraction when phrenic nerve is divided which can cause distress to attending teams and host staff.
- Fluconazole: 400 mg
- Antibiotics to be added into the prime:
  - 200mg teicoplanin
  - 120mg gentamicin
  - 500mg metronidazole

Anaemic donor (Hb<70gm/L)

If the donor is anaemic a unit or more of packed red cells may be added to the reservoir in place of some of the Hartmann's solution. Typically if less then 6gm/L, add 2 units packed red cells; if between 6 and 8gm/L, add 1 unit packed red cells.

Small donor or paediatric donor

If the donor is small the dilution effect of the prime solution will be large. Therefore:

- *For donors >30kg but <50kg,* add 2 units of blood to the prime and only 1000ml of Hartmann's.
- *For donors ≤30kg*, use 3 units of blood in the prime with 500mls Hartmann's.

Flow rates will be proportionately lower in smaller donors.

Additional fluids during retrieval

During perfusion it is usually necessary to add more volume, in which case Gelofusine or blood are appropriate. *DO NOT ADD Hartmann's* once perfusion has started as it contains lactate and makes the lactate result impossible to interpret.

Additional heparin during retrieval

During perfusion an ACT *may* be checked or, in the absence of this, additional heparin *may* be given at 90 min using a dose of 150 u/kg.

Heparin should also be added if severe haemorrhage occurs, e.g. during cardiac retrieval, and is replaced by a lot of bank blood, since this will dilute out any existing heparin with the risk of clotting. This is not usually required in A-NRP only.

Surgical Protocol for DCD NRP

Before withdrawal of treatment the operating surgeon and pump operator should check how the chosen cannulae are connected to the circuit, and whether any additional connectors are necessary (see above).

Cannulation

Cannulation can either be in the groin using the femoral vessels, or in the abdomen with direct or indirect access to the aorta and IVC. Surgeons need to be familiar with all techniques. It is helpful to have the perfusion practitioner call out the time taken at 10, 15, and 20 minutes following knife to skin to inform the surgeon. Cannulation should not take longer than 20 minutes, and will typically take around 10 to 15 minutes.

Femoral cannulation

This is a simple and rapid technique, and is most appropriate in the following circumstances:

- for younger donors with little chance of occlusive ilio-femoral arterial disease
- when thoracic surgeons wish rapid access to the chest
- where access to the abdominal vessels may be delayed (e.g. previous surgery; ankylosing spondylitis where the patient may not be flat on the operating table)
- for known vascular anomalies seen on available cross-sectional imaging (e.g. known lower polar vessels coming off distal abdominal aorta/iliacs; retro-aortic left renal vein originating at confluence of iliac veins; left sided IVC, horseshoe or pelvic kidney).

A transverse or oblique incision is made immediately below the inguinal ligament. When the heart is being retrieved, the vein must be cannulated first to allow rapid blood drainage to prime the OCS machine; otherwise it may be easier to cannulate the artery first.

The femoral vein is isolated, the distal end either clamped or ligated. A venous cannula is passed up the femoral vein and secured either with a ligature or snugger. The cannula is then connected to the venous limb of the sash, and the sash's venous clamp removed to allow drainage into the reservoir.

The femoral artery is isolated, distal end ligated, and cannulated. The cannula is secured with a ligature or snugger, and connected to the arterial limb of the sash with care taken to exclude air.

The choice of cannulae for the femoral vessels varies according to the patient's size:

- *Femoral artery:* typically a 19F French cannula (e.g. Medtronic Biomedicus 19F), although alternative 15Fr, 16Fr or 18Fr cannulas may be required in small patients or for diseased arteries.
- *Femoral vein*: a 25 French (e.g. Medtronic Biomedicus 25F/38cm) cannula

It is possible that difficulties arise during femoral vein or arterial cannulation and the surgeon needs to be prepared to switch to abdominal cannulation in such eventualities. Typically the extra time taken is compensated by being able to restore a circulation to the abdominal organs before cold storage.

Aorto-iliac cannulation

A midline incision from xiphoid to pubis is made. The right colon and small bowel mesentery are mobilised and retracted to the left by the assistant. The aorta or right common iliac artery may be cannulated first in preference to the IVC, since any venous bleeding will make subsequent identification of the artery difficult.

The distal infrarenal aorta or right common iliac artery is identified and slung using a vascular snugger. The distal aorta is cross clamped or ligated. The aortic cannula is inserted, checking the proximal position of the tip is approximately 2 to 5cm above the cannulation point. The cannula is secured in place with the vascular snugger or ligature. The arterial limb of the circuit (the tube with the red line) is then connected to the cannula, with care taken to eliminate all air bubbles (alternatively, this can be pre-connected and the perfusion practitioner can forward flush slowly during cannulation).

The infrarenal IVC (or right common iliac vein) is dissected and encircled using a ligature or vascular snugger. The distal end is clamped or ligated. The venous cannula is inserted into the IVC. The cannula should be adjusted so its tip sits just below the diaphragm to allow the clamping of the suprahepatic IVC without compromising the venous return in the circuit. The venous limb of the circuit (the tube with the blue line) is then connected to the cannula and the clamp released. Blood should flow back into the reservoir.

The choice of cannulae for the intra-abdominal vessels varies less with the patient's size than when cannulating in the groin. The same cannulas as used for a femoral approach may be used, or alternative larger cannulas may be used:

- *Aorta or common iliac artery:* a 20 or 24Fr cannula (e.g. DLP Medtronic cannula).
- *IVC or common iliac vein*: a multistage cannula of 25 French or more (e.g. 36/46 Fr 40 cm Edwards Lifesciences Q3 Trim-Flex two or three Stage).

The contralateral external iliac artery

If the cannulation has been into a femoral artery or common iliac artery, the contralateral common external iliac artery may be ligated or clamped to optimise abdominal organ perfusion. Care should be taken not to reduce the length available for subsequent vascular reconstructions.

Controlling the thoracic aorta

A rapid sternotomy is carried out using either a power saw or Gigli saw. If cannulation was in the groin the abdomen does not need to be opened first. The thoracic aorta is clamped below the level of the left subclavian artery close to the diaphragm. A stab incision is made in the ascending thoracic aorta with a number 11 blade and a 24G cannula (the hole left by an 11 blade inserted to its hilt is the same size as the 24G cannula) or a Medtronic DLP Aortic Root Cannula (avoiding the need for a prior stab) is inserted and left open to atmosphere to allow monitoring of pressure and flow in the aorta and intracranial arterial supply. Typically, there is a small column of dark deoxygenated blood 1 to 5cm. This aortic vent should have no flow within it; if there is flow the pump should be stopped and the thoracic aortic clamp repositioned. The aortic vent can be connected to the reservoir if the column of blood reaches the top of the cannula, so long as it does not represent oxygenated blood from the NRP circuit.

An alternative approach is to insert an aortic endo-clamp (e.g. Cook 32/37mm, 120cm Coda LP balloon catheter) in the descending thoracic aorta. It is critical to check the length prior to insertion to ensure that

the balloon is positioned in the descending aorta, and not in the left subclavian or anomalous right subclavian artery. An ascending aortic vent cannula still needs to be inserted, after which the NRP circuit can be started. This approach would allow the cardiothoracic team to undertake the sternotomy and mobilise the lung and clamp the descending aorta (if simultaneous lung retrieval).

NOTE: The ascending thoracic aorta **MUST** always be vented before starting NRP including in Maastricht 4 donors, and the vent kept open for the duration of NRP.

Maastricht 4 controlled DCD donors

Maastricht 4 donors, which are brain stem dead donors going through the DCD pathway usually at the request of the next of kin, pose a number of issues worth noting.

i. The donor can be heparinised before ventilation is discontinued
ii. The National Organ Donation Committee have agreed that a no touch period of 5 minutes following circulatory arrest be respected before the donor is transferred to the operating room and surgery commenced.
iii. An aortic vent should always be placed in a category 4 donor
iv. Since the next of kin have concerns about the beating heart, the donor team should consider infusing UW solution (or cardioplegia) into the aortic root via the vent cannula, with a temporary clamp distal to this, to cause a cardioplegic arrest and suppress fibrillation if this occurs.
v. In cases of thoraco-abdominal NRP in category 4 donors, there is no need to ligate or separately vent the neck vessels.

Establishing NRP

- The pump must only be started once the circuit is completely connected, the thoracic aorta is cross-clamped/occluded and the aorta above the clamp is vented.
- The heater temperature should be 37°C.
- The air/O_2 mixer should be set to deliver gas flow at 2 litres/minute with a starting FiO_2 of 21% (air). High FiO_2 should be avoided. Changes to the oxygen/air mixture may be required subsequently depending on the blood gas analysis. High oxygen concentrations may generate reactive oxygen species and can exacerbate reperfusion injury to the organs.
- The preferred NRP duration is two hours.

Haemodynamic and biochemical goals

The following parameters are suggested:

- Pump flow 2-3 litres/minute
- Temperature 35.5°C - 37.5°C
- Air / O_2 to maintain a venous O_2 saturation (SvO_2) 60-80%
- Arterial pH 7.35-7.45
- Haematocrit > 20%
- Gas flow to maintain arterial pCO_2 4.5 to 6.0 kPa.

During NRP

Haemostasis

Once the NRP is established, meticulous haemostasis must be ensured from the abdominal wound edges, sternotomy and retroperitoneal tissues disrupted during aortic and IVC cannulation. Bleeding is not usually troublesome for the first 60 minutes or so.

As there is a potential for significant blood loss, volume replacement (blood or colloid) should be readily available. If volume is lost from the circuit, the two most common sites are in the chest where the thoracic aorta is clamped, and where an intercostal or vertebral branch may have been avulsed, and around the aortic and caval cannulae. Volume loss is also observed routinely with vasodilation consequent on loss of sympathetic tone, without overt blood loss, and volume replacement will be required during the NRP procedure.

Direct retrieval and perfusion of lung or heart

There is potential for significant bleeding when lungs / or heart are retrieved and therefore there is a separate protocol for combined A-NRP with cold thoracic retrieval (see odt.nhs.uk microsite). The supra-hepatic IVC is clamped at the cavo-atrial junction in the chest and therefore it is important to ensure that the tip of the venous cannula is below the level of the diaphragm to avoid compromising the venous return. The thoracic surgeon must ligate the azygous vein, the SVC, and leave a clamp across the descending thoracic aorta.

Additives to the perfusion fluid

- Heparin may be added every 90 minutes (150 u/kg). More frequent heparin boluses will be required if a large quantity of bank blood (or cell saved blood) are added as may happen in cardiac retrievals.
- Bicarbonate should be added according to the initial blood gas results: if the pH<7.0 after starting NRP give 25ml of 8.4% immediately. Correction is seldom necessary once NRP is established, since functioning liver and kidneys correct the acidosis quickly, and gas flow across the oxygenator can also be used to regulate pH.
- Subsequent volume replacement should either be red cells or gelofusine

Surgical dissection

Once NRP is established, the surgeon should perform a full laparotomy and a macroscopic evaluation of the abdominal organs, in particular the liver, pancreas and kidneys. At the start of NRP the liver will appear congested and feel stiff. As time passes the liver should feel less firm and a normal colour return. The bile duct should be divided early and the gallbladder incised, emptied and flushed with normal saline (0.9%), care being taken not to flush thick gallbladder bile into the common duct. A careful examination of small bowel, the blood supply to the cut end of the bile duct and the appearance of the gallbladder mucosa should be undertaken (indicative of ischaemia). If the lungs are not being retrieved the contents of the thoracic cavity should be inspected thoroughly looking for lung and oesophageal neoplasms and other pathology.

After these initial procedures it is often sensible to scrub out for 60 minutes to avoid unnecessary blood loss, leaving one person scrubbed in case of emergencies. In addition, dissection around the liver causes haemodynamic instability at a time when you are trying to allow the organs to recover from warm ischaemia.

In the face of excessive blood loss, it is preferable to stop NRP early, rather than to persist with transfusions for the full 2 hours.

Cold perfusion

The cold phase dissection is carried out as for DBD retrieval. The abdomen may be filled with ice slush just before cold perfusion commences. The cold inflow may be attached to a suitable port or Y-connector on the arterial side of the circuit distal to the oxygenator if not already attached – do not run the cold perfusate through the oxygenator as this will warm it up. Alternatively, the arterial line can be clamped and the cold UW giving set connected to tubing just proximal to the arterial cannula. The standard quantity of UW is infused into the aorta as for any normal retrieval.

The cannulation of the portal vein in the cold phase is at the discretion of the retrieving surgeon. The portal vein ***must*** be extensively flushed with UW on the back table if it is not cannulated and perfused *in situ*.

The venous cannula may be pulled back to aid drainage of the kidneys, as the cava will collapse on the cannula potentially impairing venous drainage. The venous effluent may be collected into the circuit's reservoir or separate drainage bag (depending on the NRP machine and circuit used), or it may be allowed to collect in the chest from where it can be sucked out.

1.1 Biochemical Evaluation

Serial samples (gases and ALT/AST every 30 to 60 minutes) are taken to assess the organs and to stay within the parameters described above; more frequent testing is appropriate where shortened periods of perfusion may occur, such as when cardiothoracic teams are involved. Blood cultures should be taken as soon as NRP starts and at the end of NRP (0 and 2 hours). Volume replacement to support flows, whether blood or colloid, will dilute the biochemical markers of damage and function; this should be borne in mind when interpreting them.

Biochemical assessment should be done on machines that are quality assured (Human Tissue Authority requirement). This may be by the retrieval centre's own biochemistry department.

Liver

The following biochemical parameters are important:

- *Transaminases as liver damage markers.* There is no international consensus on the degree of rise in ALT/AST which represents a usable liver. Current UK practice is to accept livers with a rise in ALT ≤ 500iu/L over 2 hours. Cases have been described in Italy where PNF occurred with the terminal ALT>1000iu/L.
- *Lactate as a function marker.* The lactate should fall over the course of two hours, but may not reach normal values due to venous return from the upper body and non-perfused limbs. Clamping the intrathoracic IVC may be associated with a greater fall in lactate measured in the circuit.

A routine **liver biopsy** before or after NRP (or both) is supported for quality assurance purposes where the NRP team feel it is appropriate. Biopsy sites in the liver should be sutured and noted on the A form

Pancreas

Amylase measured on the near patient analyser may indicate pancreatitis, but visual appearance is more useful.

Kidneys

Urine output falls off and may stop completely during NRP. There is no useful biochemical marker.

Post NRP

The appropriate paperwork should be filled in and a copy sent with each organ.

Failure to establish NRP

If NRP cannot be established, initial cold perfusion should follow the standard DCD protocol. If NRP is successful, cold perfusion should follow the DBD protocol. Back-table preparation should follow the current protocols.

Documentation

It is important that the perfusion characteristics during NRP, the blood gases, the fluids used and the timings, are all captured on the approved NHSBT NRP organ passport, and a copy sent with each organ for the recipient surgeons. A copy should also be retained by the NOORS team and a further copy sent to NHSBT.

Troubleshooting NRP

Communication

Many of the issues occurring during NRP can be avoided by a good team brief and handover before the procedure so that everyone knows what is expected of them. This is particularly important when a cardiothoracic team is present.

Volume loss

Volume losses occur for the following reasons:

- Relaxation of alpha-adrenergic vasoconstriction occurring prior to death and loss of sympathetic tone;
- Bleeding, typically in the chest near the thoracic aortic clamp, or in the pericardium if lung and/or heart have been removed. In the abdomen it is often around the venous/arterial cannulae;
- Occlusion of the venous cannula, usually due to pressure or manipulation on the liver or bowel;
- Increasing the flow rate may reduce the reservoir volume.

Sudden loss of venous return can rapidly exhaust the circuit reservoir resulting in failure of the circuit: a one litre volume in the reservoir will disappear in 20 seconds at a flow rate of 3L/min. The perfusion practitioner should keep careful watch on the reservoir level, caution the surgeon and replenish the reservoir as the volume falls.

If volume is lost suddenly it may be because the wall of the cava has been sucked onto the cannula and occludes the holes due to manipulation of the organs; temporarily stopping organ manipulation, and manoeuvres such as reducing the height difference between donor and pump, or partial occlusion of the venous return tubing may also be effective. Alternatively, this is remedied by stopping the pump, waiting a couple of seconds, then restarting at a lower flow rate.

Air in the circuit

Air in the arterial limb can embolise and impair perfusion of organs. It is important to de-air the cannula and circuit when establishing the circuit at the beginning to prevent air entry. Small amounts of air in the venous

side will run off into the open reservoirs of currently used circuits and cause no harm. Large volumes of air, as may occur if the cannula becomes dislodged, will cause an airlock which will block blood returning to the reservoir. This airlock needs to be walked along the tube by holding the tube distal to the airlock upwards to allow the tube to fill from below, and displace the air.

Clots in the circuit

A clot in the circuit can embolise into the organs. Fresh clot is most likely to occur first on large surface areas such as the oxygenator and leucocyte filter, and will impede flow. Clots in the circuit occurs for the following reasons:

- Failure to add any or sufficient heparin to the prime solution
- Failure to circulate heparin around the circuit before starting perfusion
- A long delay between connecting the venous cannula and draining blood into the reservoir, and starting NRP. Non-heparinised blood in the venous line will clot; that in the reservoir should not as it mixes with heparinised prime solution.
- Excessive bleeding requiring replacement with large volumes of non-heparinised fluids
- Pre-existing venous clots associated with lines

Troubleshooting Cs for poor flows

The following Cs are worth remembering when trouble-shooting (courtesy of James Richards):

- **C**annulas: check position, check vein not collapsing on cannula (if so increase volume)
- **C**lamps: check cross-clamp on thoracic aorta is on aorta, and all clamps on circuit released? Check position of supra-hepatic caval clamp
- **C**ava: are you compressing on it in your dissection or is it collapsing?
- **C**ircuit: anyone or anything compressing the circuit
- **C**hest: a common site for bleeding
- **C**lots: venous or atrial clots preventing venous return; clots on leucocyte filter or oxygenator
- **C**OLD: if you can't resolve issue in timely fashion then go cold and salvage the organs

Appendix 1 Protocol for direct recovery and perfusion of the heart and A-NRP

Due to the complexity of the procedure and the risk to the abdominal organs this combined technique is only appropriate for use where the heart is being retrieved for transplant purposes.

Cardiac team requirements for successful cardiac recovery

The following are required:

- Senior surgeon who is experienced in DCD heart retrieval
- A cell saver, to enable blood to be washed plus disposables
- The *ex situ* normothermic heart perfusion machine.
- Technician to operate the *ex situ* perfusion machine and the cell saver
- The necessary sterile tubing and adapters to connect to the NRP circuit ($^3/_8$ and ½ inch tubing).
- An appropriately staffed and equipped lung retrieval team if the lungs are also being retrieved

Abdominal team requirement for successful cardiac recovery during A-NRP

- Senior surgeon who is experienced in NRP
- The NRP disposable circuit
- NRP heater/cooler and pump (e.g. Cardiohelp)
- Experienced NRP perfusion practitioner
- 2 x long vascular clamps for descending aorta and IVC clamping (e.g. long straight and curved DeBakey)
- 2 Roberts clamps, one for the SVC and one for the ascending aorta

SNOD requirements

8 units of bank blood, 4 to be added to prime

Circuit

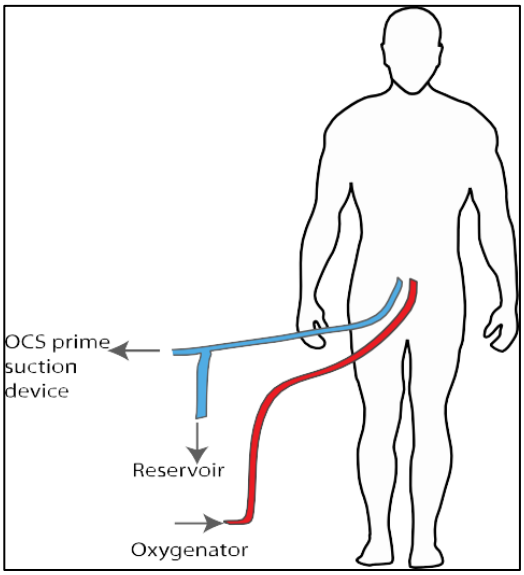
Preparation

The NRP circuit needs to have a Y attachment on the venous return limb just above the reservoir, and needs to be fitted prior to arrest if it is not already present on the circuit. This needs to be connected to the cell saver to allow for donor blood drainage needed for *ex situ* heart perfusion, but clamped initially.

Prime solution

- 4 units packed red cells (approx. 1200mls)
- 1.5 litre Hartmann's solution
- 50000 units heparin
- Phentolamine 5mg
- Pancuronium 12 mg – to prevent abrupt diaphragmatic contraction when phrenic nerve is divided which can cause distress to attending teams and host hospital staff.
- 1ml/kg 8.4% sodium bicarbonate (=1mmol/kg)
- 1gm Methyl prednisolone
- Fluconazole: 400 mg
- Antibiotics to be added once perfusion begins:
  - 200mg teicoplanin
  - 120mg gentamicin
  - 500mg metronidazole

Figure 1. Drainage of blood for priming the OCS device



The NRP circuit is primed with 1.5 litres of Hartmann's, to which are added 4 units of red cells. The circuit needs to be set up before withdrawal of treatment, and warmed to 37°C by circulating through the oxygenator/heat exchanger.

Ideally, a pump sucker is connected to the reservoir for blood loss recovery during NRP, and the reservoir placed under negative suction. This is the preferred standard with teams working towards this, until then existing practice will prevail. This will only be used to recover blood from the pericardium if heart retrieval only, or to recover blood from pericardium and pleural space if combined heart-lung retrieval. Blood should not be recovered from the pleural space in the presence of chest sepsis. Additional care must be taken to avoid any perfusion fluid/saline being recovered using this sucker.

This additional sucker will not be used in cases of pericardial, mediastinal or systemic infection. Careful haemostasis should be performed in the chest even in the event of having a sucker available.

Two long DeBakey vascular clamps will be ready to use by the cardiothoracic team prior to WLST to clamp descending aorta and IVC. Two Roberts clamps will also be ready to clamp SVC and ascending aorta. It has been agreed that clamps will be provided by the abdominal team as they need to stay in place once the Thoracic team has left the operating theatre.

Due to the complexity of the technique, cardiothoracic organs will be retrieved only for transplantation purposes whilst the donor undergoes NRP. The heart for valves may be retrieved after NRP is concluded.

Operative procedure

Following verification of death 5 minutes after circulatory arrest, the patient is transferred to the operating table.

IT IS MANDATORY TO FOLLOW THIS STEP SEQUENCE

Abdominal team procedure

1. The circulating pump is stopped, and the sash is clamped and divided; the arterial cannula may be attached and primed at this point.
2. Once the donor is in theatre, the abdomen and right groin are prepared and draped.
3. The venous cannula is placed in the right common femoral vein common (or iliac vein or IVC) and connected to the venous limb of the sash, with care to exclude air. Care should be taken not to insert too much length of cannula to prevent it going into the right atrium.

   IF there is problem with achieving venous cannulation the thoracic team may choose to cannulate the let atrial appendage; this cannula should be removed and the appendage ligated before starting NRP or else air will be entrained in the circuit and NRP fail. For this reason atrial cannulation is a last resort.
4. Clamps are removed and 1.5L venous blood drained out and diverted into the collecting receptacle for the heart Organ Care System (OCS) (such as the cell saver system used by Harefield).
5. The Y-connector is then clamped and venous return blood now diverted to drain back into the reservoir (see figure 1)
6. The arterial cannula is placed in the right femoral artery, common iliac artery or aorta while the venous drainage occurs.
7. Once the cardiac team have clamped the descending thoracic aorta and stated that clearly for both teams to hear, and the 1.5L venous OCS prime has drained, the NRP pump is started aiming for flows over 2.5L/min. The time that the descending thoracic aorta is clamped will be recorded on the National DCD Heart Passport.

Abdominal NRP must not start until both teams have confirmed for all to hear that the descending aorta is clamped.

Once the heart is removed it is important to check the security of the supra-hepatic IVC clamp – this may need to be sutured in place to avoid inadvertent unclamping or slipping from the cut IVC. The cut ends of the pulmonary vessels and SVC may be oversewn with 3/0 Prolene at this stage also. While the cardiac surgeons should ensure haemostasis in the chest, in reality it is the abdominal surgeons who are usually free at this stage and can stop large vessel bleeding.

There should be no major bleeding.

Cardiac procedure

The chest is opened in the midline and sternum split while the abdomen or groin is opened for cannulation. The cardiothoracic team will apply a clamp across the descending thoracic aorta, and announce to theatre when this has been done. They will then place a DLP cannula, open to air, as vent in the ascending aorta to monitor for possible brain perfusion

Once the DLP cannula is in place and open to air, the cardiothoracic surgeon announces that the aortic arch is vented, at which point the NRP pump may begin. The time will be recorded on the National DCD Heart Passport. If there is copious arterial bleeding from the DLP cannula, the NRP pump must stop and

the clamp on the descending aorta must be re-positioned to occlude the aorta. Only then can the NRP pump re-start.

Figure 2. DLP cannula

The details of heart and lung retrieval are in the separate cardiothoracic protocol for DCD donors "*Direct retrieval and perfusion (DPP) of DCD heart and lungs with or without A-NRP to ex situ normothermic perfusion*" at odt.nhs.uk microsite

Procedure for lung retrieval alone without heart while on A-NRP

See separate protocol for "*Direct retrieval and perfusion (DPP) of DCD heart and lungs with or without A-NRP to ex situ normothermic perfusion*" at odt.nhs.uk microsite.

The thoracic team will stand back for 30 minutes after cold in-situ perfusion of the lungs. Dissection of the lungs will then begin, which can be assisted by the abdominal surgeons as appropriate. This should be carried out with care and detail, to enable stability to be established on A-NRP, and to maintain stability during and after the lungs have been removed.

Appendix: UK NRP implementation group members involved in drafting the protocol

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