## National Standards for Organ Retrieval from Deceased Donors

This Management Process Description replaces MPD1043/6	Copy Number			
	Effective	03/10/16		
Summary of Significant Changes				

- Removal of references to retrieval zones
- Points 2.2 and 5.9: Clarification of responsibilities re diagnosis of death
- Revised Section 5: Protocol for lung retrieval from DCD donors
- Addition of references to en-bloc abdominal organs at points 3.19, 5.11 and 5.21
- Amendment to small cardiothoracic donor criteria at 1.8
- Addition at 5.22 of procedure to follow if there is an unintended breach of the gut during retrieval
- Update to offering times at 6.12
- Addition of MPD1234 ODT Flight Authorisation Process for Flights over £10,000

#### Policy

Transplantation is well established as the best and often the only treatment for many patients with end-stage kidney, liver, intestinal, cardiac and pulmonary failure. Whilst some types of transplant can be achieved with organs from living donors, most patients are reliant upon organs from deceased donors.

The Organ Donation Task Force (ODTF), which was published in 2006, set out a series of recommendations for increasing organ donation rates in the UK. These recommendations contributed to a 50% increase in donation, and a 30.5% increase in transplantations, achieved by 2013.

To build on the progress achieved following the ODTF recommendations, a new strategy has been established, Taking Organ Transplantation to 2020 (TOT2020), which sets out four key outcomes:

- Outcome One action by society and individuals will mean that the UK's organ donation record is amongst the best in the world, and people donate when and if they can.
- Outcome Two action by NHS hospitals and staff will mean that the NHS routinely provides excellent care in support of organ donation, and every effort is made to ensure that each donor can give as many organs as possible.
- Outcome Three action by NHS hospitals and staff means that more organs are usable and surgeons are better supported to transplant organs safely into the most appropriate recipient
- Outcome Four action by NHSBT and Commissioners means that better support systems and processes will be in place to enable more donations and transplant operations to happen.

This document outlines the core standards, underpinned by the four key outcomes, for all stakeholders involved with the retrieval process, from the donor hospital to the transplanting team.

#### Purpose

To provide national standards for the retrieval of organs from deceased donors across the UK.

# National Standards for Organ Retrieval from Deceased Donors

#### Responsibilities

Donor Hospitals Specialist Nurses – Organ Donation Retrieval Centres NORS Teams Recipient Centres

#### Applicable Documents

MPD910 – Medical Records Entries for Proceeding and Non Proceeding Organ and/or Tissue Donation MPD886 - Collection, Labelling and Transport (Organs and Samples) MPD884 – Organise Solid Organ Retrieval MPD891 - Pregnancy in donation MPD873 Physical Assessment FRM4135 – NHSBT Surgical Safety Checklist MPD889 – Abdominal Perfusion MPD1100 - Guidance and Principles -**Donor Organ Photographs** MPD902Consent Conversation for Organ and/or Tissue Donation MPD1119 - NHSBT Duty Office Organ Offering Protocol MPD1234 – ODT Flight Authorisation Process for Flights over £10,000

FRM4217 – Transport Handover Form POL188 -Contraindications to organ donation– A guide for SNODs

<u>POL192</u> -Responsibilities of clinicians for the acceptance of organs from deceased donors

<u>SOP4574</u> - National Organ Retrieval (NORs) Mobilisation Process

<u>INF195</u> – Heart retrieval on behalf of NHSBT Tissue Services for valves from a deceased donor

(Template Version 07/10/08)

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# National Standards for Organ Retrieval from Deceased Donors

#### 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 processand 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 high consideration throughout the retrieval process.
- 8. Finally, the Standards are based on the overriding principle, with respect to the quality of the organs that they receive, that the safety of transplant recipients is paramount.

This document specifies the Standards which all health care professionals involved in solid organ retrieval should fulfil in order to provide a high quality national organ retrieval service (NORS) in the UK.

The standards cover cardiothoracic, renal, pancreatic, liver and retrieval from deceased donation after brain death (DBD) and donation after circulatory death (DCD) donors. They do not cover retrieval of organs from uncontrolled DCD donors or from living donors, nor do they cover retrieval of tissue such as eye tissue, bone and skin.

#### National Standards for Organ Retrieval from Deceased Donors

# SECTION ONE

#### 1. Topic 1 Retrieval Arrangements

- 1.1. As a result of the NORS Review the national system of multi-organ retrieval zones centred upon national multi-organ NORS teams appointed by NHSBT was changed from 4<sup>th</sup> April 2016 to an arrangement whereby the closest available team to the donor hospital will be mobilised to retrieve organs. (Refer to INF1321).
- 1.2. The NORS teams are responsible for retrieving from DBD donors and from controlled DCD donors.
- 1.3. In order to mobilise a team, SN-ODs will contact the NHSBT Duty Office which will hold a record of all NORS Team movements and will advise SN-ODs of the closest available team.
- 1.4. Organ retrieval at each donor hospital will be provided primarily by the closest available abdominal and cardiothoracic NORS teams, with back-up from the closest next available NORS team if that 1<sup>st</sup> on-call NORS team is already committed to retrieval elsewhere.
- 1.5. The appropriate NORS team will always be required to attend a retrieval, however, where specialist and/or additional expertise is required (for example paediatric abdominal donors, organs retrieved for non-UK recipients), a surgeon from the transplanting centre may 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 occurring. The HTA-A form will be completed by the UK NORS team lead surgeon, and payment (transport and consumables) will be made to the attending NORS team.
- 1.6. 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.

The only exceptions to 1.5, 1.6 and 1.7 are:

- a) small cardiothoracic donors (height <145cm) where the specialist team will attend (Newcastle or Papworth) and be paid for transport/consumables
- b) complex congenital recipients the NORS team of the accepting transplant centre will attend and be paid for transport/consumables
- c) donors outside the UK if the local organ retrieval team is unable to attend, the NORS team from the accepting UK transplant centre will attend and be paid for transport/consumables
- d) multi-visceral donors these will be attended by the accepting intestinal transplant centre which must retrieve all abdominal organs, not just the small bowel, as a second abdominal NORS team will not be mobilised. If the planned multi-visceral retrieval is cancelled prior to the accepting intestinal retrieval team leaving base then the SNOD, in collaboration with the NHSBT Duty Office, should arrange for a NORS team to attend to retrieve. If the accepting intestinal retrieval team has either arrived or is near the donor hospital then they must attend to retrieve all abdominal organs.
- 1.7. Kidneys from donors aged 4 years and under (before their 5<sup>th</sup> birthday)will be retrieved and offered en bloc (but may be split if appropriate) 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 together with the aorta and cava remaining attached. En bloc kidneys will be offered on a centre, rather than patient basis, to any centre wishing to receive offers of such kidneys. Clinical leads from NORS and transplanting teams must communicate so that the NORS Team Lead is clear of the requirements of the transplant surgeon(s) on whether and how the kidneys en-bloc have to be split. If they are to be split this should not take place at the donor hospital.

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- 1.8. In the event that, 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 in order to procure organs and tissue for research for hospitals in Scotland.
- 1.9. Stand down rules for DCD: 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 recipient centres have declined all the offered out organs prior to the moment of stand down, teams may stand down earlier.

- 1.10 Abdominal NORS teams may wait longer than three hours from treatment withdrawal if progressive cardiovascular instability suggests that asystole is likely to occur.
- 1.11 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 two hours before abandoning the kidneys as deemed untransplantable due to excessive warm ischaemia.
- 1.12 The NORS teams are not expected to attend uncontrolled DCD donors.
- 1.13 When possible, NORS teams will travel by road. However, if this is not possible (e.g. for Northern Ireland), or if estimated road travel time for one leg of the journey is 3 hours or more than the estimated travel time by air, or if organ viability might be compromised by any delay, then air transport may be used.

#### 2. Topic 2 Donor Hospitals

- 2.1. All hospitals in the UK should comply with the NHSBT Memorandum of Understanding and 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.
- 2.2 The donor hospital will ensure that the diagnosis and confirmation of death in potential organ donors will be conducted by appropriately trained and experienced medical practitioners in compliance with accepted national professional standards. This applies to the diagnosis of death using neurological criteria in potential DBD donors and the diagnosis of death using circulatory criteria in potential DCD donors.

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- 2.3. The donor hospital will provide a fully equipped operating theatre for the retrieval procedure, including appropriate anaesthetic equipment and drugs to support the donor.
- 2.4. The donor hospital is responsible for the safe transfer of the donor to the operating theatre.
- 2.5. The donor hospital will provide an anaesthetist to support DBD donors in the operating theatre during the retrieval procedure.
- 2.6. The donor hospital will provide a suitable member of staff, such as a qualified theatre nurse 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 retrieval surgeons and anaesthetist.
- 2.7. This/these individual(s) will remain in theatres during the retrieval procedure to provide assistance to the theatre practitioner (provided by the NORS team) and the anaesthetist, and assist the SN-OD with the final act of care.
- 2.8. Donor hospitals should allow the retrieval procedure to start as soon as possible after the NORS team has arrived.

#### 3. Topic 3 The Specialist Nurse – Organ Donation (SN-OD)

- 3.1. Every potential donor hospital in the UK will have access to a SN-OD 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 the NHSBT Duty Office.
- 3.2. The SN-OD will ensure that the consultant intensivist caring for the potential donor liaises, when necessary, with the Coroner/Procurator Fiscal to obtain permission to proceed with organ retrieval.
- 3.3. The SN-OD will refer to and work in accordance with <u>MPD891</u> when pregnancy in the donor is suspected and/or when pregnancy is confirmed.
- 3.4. Once consent/authorisation (MPD902) for donation is ascertained the SN-OD will arrange organ retrieval in accordance with MPD884.
- 3.5. Whilst organs can be offered pending Coroner/Procurator Fiscal (PF) consent, under normal circumstances NORS Teams should not be mobilised until consent is gained. If there are exceptional circumstances such as concerns regarding a donor's stability that may require the NORS Team to mobilise prior to Coroner/PF consent, then senior advice must be sought.
- 3.6. The timing of the retrieval operation will be arranged based on the proximity /availability of the NORS team to the donor hospital, stability of the donor, wishes of the family, availability of resources at the donor hospital, and time required to prepare recipients for surgery. The SN-OD will keep the NORS team and the transplanting centre informed of any delays.

- 3.7. In the case of DBD a theatre time can be set and the NORS teams mobilised once one cardiothoracic organ has been accepted or, where no cardiothoracic organs are to be retrieved, once one abdominal organ has been accepted. In the case of DCD, a theatre time can be set if both of the lungs are unsuitable and one abdominal organ is placed or once the lungs are placed, if they are suitable.
- 3.8. In cases where HLA matching is not yet available, and the SN-OD considers it highly likely that the kidneys will be placed for transplantation, it is acceptable for the SN-OD 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 in accordance with paragraph 3.6 above.
- 3.9. NORS teams must be able to leave the retrieval centre within one hour of call out by the SN-OD, however the mobilisation time must be discussed and mutually agreed with the NORS team taking into consideration travel time, family wishes, complex recipients, and planned theatre time.
- 3.10. The SN-OD 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). NHSBT Contraindications to Organ Donation (http://www.odt.nhs.uk/pdf/contraindications\_to\_organ\_donation\_a\_guide\_for\_snods.pdf)
- 3.11. Organ offers will be made in accordance with the ODT Patient Selection and Allocation Policies (<u>http://www.odt.nhs.uk/transplantation/guidance-policies/</u>) and the NHSBT Organ Offering Protocol (<u>MPD1119</u>). 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 the NHSBT Duty Office Team Manager either on site or on-call, the on-call Regional Manager and the SN-OD as long as this does not result in delays to donation.
- 3.12. 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 ascertained, donation may be delayed whilst the SN-OD 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 recipient centres may retain those organs for use in those identified recipients.
- 3.13. 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 either the National Kidney Allocation Scheme or the Fast Track Scheme.
- 3.14. 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 centres in the cardiothoracic offering sequence. Well functioning organs declined for other reasons (e.g. hepatitis C positive donor) must be offered to all cardiothoracic transplant centres, except where the Cardiothoracic Advisory Group have notified NHSBT of absolute contra-indications to donation.
- 3.15. For potential liver, pancreas and intestinal organ donors, a DCD or DBD donor organ will only be deemed medically unsuitable for transplantation if all potential recipient centres decline the organ except where the Liver, Pancreas and Bowel Advisory Groups have notified NHSBT of absolute contra-indications to donation.

- 3.16. In conjunction with staff at the donor hospital the SN-OD will ensure that operating facilities for the retrieval operation and for the safe transfer of the donor to theatre have been arranged.
- 3.17. For DBD and DCD donors, the SN-OD will ensure that the necessary tests for either the diagnosis of death using neurological criteria or death after circulatory arrest have been completed and documented correctly by the appropriate medical staff at the donor hospital. This should be done:
  - For DBD on SN-OD arrival in the unit
  - For DCD following asystole
- 3.18. The SN-OD will ensure that appropriate investigations (e.g. blood group, microbiology, ECG) are performed before the retrieval operation and that the results of these investigations are available for the surgeons to review in theatre.
- 3.19. The SN-OD should record details of any blood or blood products the donor received during their hospital stay and request a pre-transfusion sample where appropriate.
- 3.20. The SN-OD 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 <u>FRM4135</u> NHSBT Surgical Safety Checklist, checked the identification of the donor, the consent/authorisation form and all other relevant documentation before commencing the retrieval operation.
- 3.21. The SN-OD must ensure that the pre theatre section of the <u>FRM4135</u> NHSBT Surgical Safety Checklist is completed before the start of the retrieval operation.
- 3.22. The SN-OD will maintain a presence in theatre to ensure continued co-ordination of the retrieval process.
- 3.23. If required to do so (i.e. no theatre practitioner present) the SN-OD will undertake the perfusion of the abdominal organs in line with responsibilities set out in NHSBT <u>MPD889</u> Abdominal Perfusion.
- 3.24. In some instances, review of anonymised photographs of the patient (eg unusual skin rash or mole) or organ(s) taken before, during or after retrieval will help the recipient surgeon make the most appropriate decision as to whether to accept a retrieved organ for transplantation. Recording and sharing photographs of organs or tissue is encouraged, where it is clinically appropriate, provided donor anonymity is protected. See <u>MPD1100</u>.
- 3.25. The SN-OD/Theatre Practitioner (if in attendance) 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.
- 3.26. The SN-OD should adhere to <u>MPD886</u> Collection, Labelling and Transport (organs and samples) and <u>MPD885</u> In-Theatre Support ensuring that it is agreed prior to surgery commencing who will take responsibility for sample collection (2 palpable lymph nodes per allocated organ; one 2 x 2 x 2 cm cube of spleen per allocated organ; vessels required by the recipient centre) for the correct packaging and labelling of organs and samples retrieved for transplant.

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3.27. The SN-OD will ensure that the core donor information has been fully completed on EOS and that the Organ Specific donor forms and any necessary vessel forms have been fully completed by the surgeons and are dispatched with the retrieved organs and tissue to recipient centres.

3.28. It is the SN-ODs responsibility to legibly record the donor demographics on the HTA Organ Specific forms. Documenting and recording fluid type and batch number is the responsibility of the individual undertaking perfusion. It is the lead surgeon's responsibility that all surgical and anatomical details are legibly recorded and then signed and returned to the SN-OD prior to leaving the premises. If the signature placement will invoke delay of transportation of any already retrieved organ as the surgeon is still operating, the HTA has allowed that another Health Care Professional can sign on the surgeon's behalf provided he/she is authorised by the surgeon to do so. If the form is not returned to the SN-OD then NHSBT Information Services will contact the lead surgeon for a copy of the form.

- 3.29. The SN-OD is responsible for ensuring that the relevant copy of the HTA organ specific form A is returned to NHSBT within 7 days in accordance with the Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006.
- 3.30. The SN-OD will ensure that a copy of the HTA organ specific form and donor's blood group form accompanies each organ.
- 3.31. The SN-OD will liaise with recipient centres via the nominated Recipient Centre Point of Contact, to keep them informed about the progress of the retrieval process, and alert them when the organs are dispatched from the donor hospital.
- 3.32. The SN-OD will report any significant adverse occurrence during retrieval within 48 hours (SOP3888) by accessing the NHSBT Incident reporting form via <u>https://www.organdonation.nhs.uk//IncidentSubmission/</u> or via the Organ Donation website <u>www.organdonation.nhs.uk</u>.
- 3.33. The SN-OD must document in the patient's medical records a note for the pathologist stating:

#### **IMPORTANT NOTE FOR PATHOLOGIST RE: POST MORTEM EXAMINATION:**

If a post-mortem (PM) examination is performed the Pathologist must immediately contact NHS Blood and Transplant (NHSBT) Duty Office on telephone number 0117 975 7580 should the PM identify pathology that is, or may be, relevant for the health or future health of the transplant recipient(s) and/or the patient's family.

xxxxxxxxx Specialist Nurse – Organ Donation xxxxxxxxx Organ Donation Services Team

The SN-OD will take responsibility for ensuring the correct organs are packaged and dispatched to the recipient centres and complete the OrganHandover Form <u>FRM4217</u>.

#### 4 Topic 4 Retrieval Centres

4.1. Trusts/Hospitals which participate as a retrieval (NORS) centre must provide fully staffed NORS teams which are available 24 hours per day, 7 days per week for organ retrieval when on call.

- 4.2. The retrieval centre must make arrangements so that NORS teams are able to leave the retrieval centre within one hour of call out by the SN-OD. The mobilisation time must be negotiated taking into consideration travel time, family wishes, complex recipients, and planned theatre time.
- 4.3. If requested, each retrieval centre must be prepared to provide a NORS team (fully staffed at the time of mobilisation) for more than one donor per day (although they will not be required to attend simultaneous donations). If required, teams are permitted a total of 2 hours to rest between retrievals (1 hour to rest, 1 hour to restock/ mobilise) before leaving for a further retrieval.
- 4.4. A Retrieval Centre Point of Contact from each NORS centre must be available 24 hours to receive calls from SN-ODs and to mobilise the NORS team when called upon to do so.
- 4.5. Each NORS team must provide NHSBT with at least one contact telephone number which must be available 24 hours to enable SN-ODs to access the Retrieval Centre Point of Contact.
- 4.6. The retrieval centre is responsible for making cost effective and timely transport arrangements for their NORS team.
- 4.7. 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 Retrieval Centre Point of Contact.
- 4.8. Rotas must conform to European Working Time Directives and be made available to NHSBT upon reasonable request.
- 4.9. There should be clear and accountable leadership of the retrieval service at each centre with a named consultant notified to NHSBT.
- 4.10. The NORS Team Lead is responsible for ensuring that all members of the NORS team are competent and possess the appropriate qualifications, experience and skills to perform the roles and duties assigned to them.
- 4.11. The NORS Team Lead will provide a list of all lead abdominal and cardiothoracic surgeons together with a declaration that each has been assessed as competent to lead the NORS team.
- 4.12. The NORS retrieval centre should support the NORS Team Lead with a named manager who is notified to NHSBT.
- 4.13. Each NORS retrieval centre must have clear, written, regularly reviewed, version controlled and circulated protocols for the retrieval procedures that they will undertake, including for both DCD and DBD operations.
- 4.14. 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.
- 4.15. NORS retrieval 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 lead surgeons.

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- 4.16. All NORS retrieval 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.
- 4.17. 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 SN-ODs.
- 4.18. Audit meetings should be chaired by the named NORS Team Lead and attended by as many members of the NORS team as possible. Members of the relevant SN-OD teams and Clinical Leads for Organ Donation (CLODs) in the primary (1<sup>st</sup> on-call) catchment area should be invited to attend these meetings.
- 4.19. Minutes of audit meetings should be recorded, distributed to all members of the NORS team and made available to NHSBT on request.
- 4.20. All centres should, when requested, contribute data to national audits and registries. Such data should be accurate, complete and transmitted on time.
- 4.21. There should be provision of appropriate staff for the collection, storage and transmission of audit and registry data.
- 4.22. All centres are expected to participate in national clinical research projects aimed at improving the quality of retrieved organs when called upon to participate.
- 4.23. 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.
- 4.24. The NORS retrieval centre will submit a quarterly financial return of actual and forecasted costs. This will include detail of all costs and transport journey details, including donor numbers, journey type and organ type.
- 4.25. There should be regular business meetings to address issues specific to the transplant service including financial reports, activity reports, education, audit, clinical governance and research.
- 4.26. Robust arrangements should be in place for timely and accurate collection of data. Data should be made available to NHSBT under agreed reporting mechanisms.

#### 5. Topic 5 NORS Teams

- 5.1. All NORS team members must be qualified and competent to perform the roles to which they are assigned.
- 5.2. Each NORS team must have a competent NORS Team Lead surgeon and certified (via training or grandfather clause) assistant surgeon, plus scrub nurse and theatre practitioner (optional). A combined team must include a practitioner competent to support cardiothoracic perfusion and retrieval.
- 5.3. Certified lead abdominal surgeons must be capable of accurately assessing and retrieving liver, kidneys and pancreas; certified lead cardiothoracic surgeons must be capable of accurately assessing and retrieving heart and lungs.

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- 5.4. The theatre practitioners and scrub nurses (both abdominal and cardiothoracic) are responsible for taking all necessary equipment, perfusion fluids, drugs, ice, organ transfer boxes and documentation (organ specific HTA forms) for the retrieval process.
- 5.5. Every cardiothoracic NORS team should bring the equipment needed for cardiac output and pressure measurements within the central circulation and to perform bronchoscopy.
- 5.6. All members of the NORS team must be available 24 hours a day, without elective or other transplantation commitments, whenever they are on-call for retrieval. They must be prepared to attend more than one donor per day with a fully staffed NORS team available at the time of mobilisation.
- 5.7. The NORS team members must be able to leave the retrieval centre within one hour of call out by the SN-OD. The mobilisation time must be negotiated taking into consideration travel time, family wishes, complex recipients, and planned theatre time.
- 5.8. In the case of donors with H1N1, universal infection control measures must be taken. H1N1 is not a contra-indication to donation and all organs, with the exception of bowel and lung, can be retrieved.
- 5.9. Before embarking on the retrieval operation, the competent NORS Team lead retrieval surgeons must review the patient's medical notes. In particular they must:
  - Have a clear understanding of the donor information prior to the start of the retrieval
  - Check the identity, blood group and microbiology of the donor;
  - Identify that death has been diagnosed and confirmed using either neurological or circulatory criteria by appropriately trained and qualified medical personnel in the local donor hospital, and documented in the patient's clinical records.
  - Check that appropriate consent/authorisation has been documented for the organs and tissue to be retrieved;
  - If there is a requirement to re-measure the donor's height this should be done in accordance with the NHSBT Physical Assessment Management Process Description (MPD873);
  - Complete the peri op section of <u>FRM4135</u> Surgical safety checklist.

It is the NORS Team Lead retrieval surgeon's responsibility to:

- a) Document and communicate any new donor information not identified on EOS preoperatively to both the SN-OD and recipient teams;
- b) Inform the SN-OD of their findings; and
- c) Urgently advise recipient centres of new findings not documented on EOS.
- 5.10. Cardiothoracic and abdominal lead surgeons must discuss and agree details of the procedure, including knife-to-skin/cross-clamp times and requirements of the recipient, before retrieving the organs. The SN-OD/Theatre Practitioner must confirm the cross clamp time with the transplant centre receiving the organs.
- 5.11. 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 SN-OD why they are doing this.
- 5.12. 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.

- 5.13. Clarity on any procedure requiring an en-bloc technique should be agreed to ensure that all parties have a clear understanding of which organs and tissues there is an intention to remove. En-bloc kidney retrieval relates to the removal of both kidneys together with the aorta and cava remaining attached. En-bloc abdominal or multivisceral retrieval refers to removal of all abdominal organs as a cluster attached to the aorta. Separation may take place on the back table or at the recipient centre under optimal conditions. This technique is predominantly used in very small donors. This may be used to facilitate donation of specific organs without the intention or possibility to transplant all removed organs.
- 5.14 If an abdominal NORS team wishes to use normothermic regional perfusion in a DCD donor who is also a potential lung donor, they must first discuss the details with the cardiothoracic NORS team. The abdominal NORS team will cannulate the abdominal aorta and IVC and the cardiothoracic NORS team will then clamp the lower thoracic aorta and then immediately proceed to remove the lungs. The cardiothoracic NORS team must then secure good haemostasis and must not stand down until both teams are satisfied that there is no significant bleeding into the chest.
- 5.15 If a recipient team wishes that an organ is placed on machine perfusion immediately after retrieval then it is their responsibility to liaise with the retrieval surgeon to ensure that he/she is willing and competent to do this. Otherwise, the recipient 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. If machine perfusion is not possible then the retrieval surgeon must package the organ in static cold storage in accordance with standard protocols. It is the responsibility of the retrieval surgeon to ensure that the organs are either perfused or packed before leaving the theatre.
- 5.16. Livers may be split *in situ* 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.
- 5.17. All aspects of the retrieval operation should be conducted in accordance with appropriate infection control procedures.
- 5.18. Members of the NORS team should be aware that they are ambassadors for organ donation and transplantation and must behave in a professional manner throughout the retrieval process.
- 5.19. The NORS team should keep a presence in theatre throughout the procedure, including any agreed or planned delays/breaks.
- 5.20. NORS teams must work to agreed retrieval protocols during the procedure.
- 5.21. 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 retrieval surgeons, then a member of the NHSBT ODT Medical Team should be asked to arbitrate. This should be organised via the SNOD and on call NHSBT Regional Manager.
- 5.22. If there is an unintended breach of the gut during retrieval, this should be documented on the HTA-A Form and communicated to the NHSBT Duty Office so that they can pass this information on to all of the relevant recipient teams.

- 5.23. Retrieval surgeons must take all reasonable steps to exclude malignancy in the donor. The entire gastro-intestinal tract, pancreas and liver must be examined 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. Whenever possible, a median sternotomy as well as a laparotomy should be performed and the lungs examined.
- 5.24. It is important that malignancy in a retrieved organ is identified before any other organ from that donor is transplanted. If an unexpected tumour is discovered in a retrieved organ then the NHSBT Duty Office must be informed immediately so that they can pass this information on to all of the relevant recipient teams.
- 5.25. On completion of the operation, the competent lead surgeon from each NORS team 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 the use of the en-bloc technique describing which organs have been removed and which have been accepted for transplantation. Documentation of any abnormalities/injuries noted during laparotomy or thoracotomy, and the time of respiratory and/or cardiac arrest is required.
- 5.26. On completion of the operation, the competent lead retrieving surgeon from each NORS team is responsible for completing/checking and signing the HTA-A form.
- 5.27. After signing the notes the surgeons must clearly write their names and the names of their NORS retrieval centre together with a contact number in case NHSBT Information Services or Coroner/Procurator Fiscal wishes to contact them.
- 5.28. In conjunction with the SN-ODs and in line with <u>MPD886</u> Collection, Labelling, & Transport (organs & samples) the competent NORS Team lead retrieval surgeons must ensure that organs are appropriately packaged and labelled and that any specimens required by recipient centres to support transplantation are also appropriately packaged and labelled and accompany the organs.
- 5.29. In the case of heart, lung and liver retrieval the competent NORS Team lead retrieving surgeon(s) and recipient transplant surgeon(s) should communicate about the quality of the respective organ as, frequently, in these cases, the recipient operation will start before the arrival of the organ. In the case of pancreas and kidney retrieval it is sufficient that the competent NORS Team lead retrieving surgeon(s) notifies the Recipient Centre Point of Contact and NHSBT Duty Office 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.
- 5.30. It is the competent NORS Team lead retrieval surgeon's responsibility to complete the organ specific HTA forms including a legible record of all surgical and anatomical details, including any biopsies with closing sutures where appropriate, and a legible name and contact telephone number of the competent NORS Team lead retrieving surgeon. The lead surgeon must ensure that the appropriate documents accompany each retrieved organ and tissue, including specific forms for blood vessels that have been introduced to satisfy HTA requirements for vessel storage.
- 5.31. Where required, it is the competent NORS Team lead retrieval surgeon's responsibility to complete MG11 forms (Witness Statements), if requested by the Coroner.

- 5.32. All abnormalities/anomalies, organ damage (severe if organ untransplantable; moderate if organ can be repaired surgically to render it transplantable; or mild if of no consequence), sub-optimal perfusion or donor instability during the procedure must be documented in the HTA-A organ specific forms and discussed with the recipient surgeon.
- 5.33. Any abnormality (e.g. unexpected cancer) that might compromise any recipient of an organ or tissue retrieved from that donor must be reported immediately to the NHSBT Duty Office and should be communicated directly to the consultant surgeon(s) at all the recipient centre(s).
- 5.34. Members of the NORS team will report any significant adverse occurrence during retrieval within 48 hours by accessing the NHSBT Incident reporting form via <u>https://www.organdonation.nhs.uk//IncidentSubmission/</u> or via the Organ Donation website <u>www.organdonation.nhs.uk</u>.
- 5.35. In some instances, review of photographs of the organ taken before, during or after retrieval will help the recipient surgeon make the most appropriate decision as to whether to accept a retrieved organ for transplantation. Recording photographs of organs or tissue is encouraged, where it is clinically appropriate, provided donor anonymity is protected. See <u>MPD1100</u>.
- 5.36. NORS teams are not expected to retrieve tissue such as corneas, bone and skin but 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 (<u>INF195</u>). Note: alternative arrangements for Scotland regarding labelling/documentation and sending the heart to SNBTS Tissue Services are detailed in Section 8.
- 5.37. All members of the NORS team are expected to participate in continuing professional development by attending appropriate courses and meetings.
- 5.38. Trainees in higher surgical training programmes should be instructed in all aspects of organ retrieval and maintain a log book of surgical procedures in accordance with SAC guidelines.
- 5.39. Those seeking certification for organ retrieval to eventually participate in a NORS team are required to maintain a log book of surgical procedures.
- 5.40. If organ(s) have not been placed with a recipient 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 organ(s) should be held in a well defined and secured environment at their base until the NHSBT Duty Office informs them that they have been placed. It is then the responsibility of the NORS team to liaise with the Recipient Centre Point of Contact, who will arrange for transport of the organs. Unplaced organs should be disposed of according to local hospital policy.
- 5.41. To enable the effective dispatch of NORS teams, the NHSBT Duty Office will hold information regarding the availability of all NORS teams. Therefore it is the responsibility of a designated member of the NORS team to ensure that the NHSBT Duty Office is notified when the NORS Team has returned to base following any mobilisation.

## National Standards for Organ Retrieval from Deceased Donors

#### 6. Topic 6 Recipient Centres

- 6.1. A nominated Recipient Centre Point of Contact e.g. recipient co-ordinator, transplant nurse or clinician, must be available at all times to take calls on donor offers and to liaise with the SN-OD and the transplant team.
- 6.2. Recipient centres must provide NHSBT with a single contact telephone number which must be available 24 hours for notification of organ offers.
- 6.3. Recipient centres must provide NHSBT with a primary and secondary method for the receipt of organ offers in line with the NHSBT Organ Offering protocol, and must have access to EOS or EOS mobile to view the documented donor data.
- 6.4. If there is no response from that telephone or pager after 15 minutes of trying to make contact, then the on-call NHSBT Regional Manager, SN-OD or NHSBT Duty Office may move on to offer the organ to another centre.
- 6.5. 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. Recipient centres may be required to make a judgement on whether or not to accept a heart based upon the information available without these investigations.
- 6.6. The recipient centre is responsible for arranging transport of retrieved organs from the donor hospital to the recipient transplant centre with the exception of pancreas and kidneys. NHSBT will continue to make transport arrangements for retrieved pancreas and kidneys.
- 6.7. A consultant transplant surgeon must be available at all times to receive information from SN-ODs and give advice to NORS teams.
- 6.8. The names and contact numbers of both the recipient co-ordinator and the accepting and transplanting consultant surgeons must be supplied to the SN-OD when an offer of a donor organ is accepted.
- 6.9. Surgeons accepting an organ offer should be mindful of the guidance given by The Advisory Committee on the Safety of Blood, Tissues and Organs regarding the risks of disease transmission from donors with specific infections or tumours.
- 6.10. It is the responsibility of all transplant / implanting surgeons to review the full Core Donor Data Sheet on either EOS or EOS mobile prior to implantation in order to have a clear understanding of the relevant donor information.
- 6.11. In some instances, review of anonymised photographs of the patient (eg skin rash or mole) or organ(s) taken before, during or after retrieval will assist in making the most appropriate decision as to whether to accept a retrieved organ for transplantation. Requesting or sending photographs of organs or tissue is encouraged, where it is clinically appropriate, provided donor/recipient anonymity is protected.

# National Standards for Organ Retrieval from Deceased Donors

6.12. Recipient centres must adhere to the offering timeframes for responding to an organ offer as outlined in the Offer Time Monitoring Procedure (2010).

**Cardiothoracic** – 45 minutes for full offer, then 30 minutes if provisional offer has already been received or for urgent offers following receipt of HLA

**Liver** - 60 minutes for full offer, then 45 minutes if provisional offer has already been received

Kidney - 60 minutes for a kidney offer, then 30 minutes following receipt of anatomy

Small Bowel/Intestine - 60 minutes for a small bowel/intestine offer

Pancreas - 60 minutes for a pancreas offer.

Organ offers will be moved on to the next centre in the offering sequence if the offering time has expired. Extensions to offer response times will only be granted in exceptional circumstances and must be approved by the on-call NHSBT Regional Manager, on-call NHSBT Duty Officer and SN-OD.

- 6.13. Recipient centres should maintain a record and summary of all offers of donor organs assessed and accepted or declined for transplantation. Recipient centres will undertake a rolling audit of donor offers, and notify NHSBT of their reasons for declining individual organs.
- 6.14. On receipt of a retrieved organ, the consultant transplant surgeon is responsible for checking the integrity and suitability of the retrieved organ, including donor details on the organ specific HTA-A form and the blood group, microbiology results before implanting it into the recipient. In cases where an organ is declined for a particular recipient the consultant 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 the NHSBT Duty Office to reallocate the organ. In cases where the transplant surgeon and his/her surgical colleague decide the organ is not transplantable the NHSBT Duty Office should be informed. The NHSBT Duty Office 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.
- 6.15. The recipient 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).
- 6.16. The transplant surgeon must complete a HTA B form for each organ intended for transplant in accordance with the Human Tissue Act (2004) and the Human Tissue (Scotland) Act, 2006.
- 6.17. Recipient centres must record on the HTA B form any abnormality or damage to organs that they receive. Retrieval damage should be classified as severe if organ untransplantable; moderate if organ can be repaired surgically to render it transplantable; or mild if of no consequence.
- 6.18. The recipient centre must return the HTA B forms to NHSBT within seven days of receipt of the organ.

- 6.19. If, due to retrieval damage, the organ fails to function following transplantation, and after the HTA B form has been returned, then the recipient centre must notify NHSBT by accessing the NHSBT Incident reporting form via <u>https://www.organdonation.nhs.uk//IncidentSubmission/</u> or via the Organ Donation website <u>www.organdonation.nhs.uk</u>.
- 6.20. Recipient centres have an obligation to report immediately 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 the NHSBT Duty Office who will then immediately notify other recipient centres.
- 6.21. Recipient 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.
- 6.22. Recipient centres must participate in organ retrieval audits when called upon to do so.
- 6.23. Centres should have a clear policy on the storage and disposal of any unused organs or surplus tissue in compliance with the Human Tissue Act (2004), the Human Tissue (Scotland) Act, 2006and Human Transplantation (Wales) Act 2013.

# National Standards for Organ Retrieval from Deceased Donors

# **SECTION 2**

# **GLOSSARY OF ABBREVIATIONS**

CLODs Clinical Leads for Organ Donation

DBD Donation after brain death

DCD Donation after circulatory death

SN-OD Specialist Nurse - Organ Donation

EOS Electronic Offering System

HTA Human Tissue Authority

NHSBT NHS Blood and Transplant organisation

NORS National Organ Retrieval Service

NORS Team

Commissioned group of healthcare professionals involved in national organ retrieval. This will include a surgeon who is the Clinical Lead of the NORS team and who is competent in retrieval, either certified following accredited training or by the grandfather clause

ODT Organ Donation and Transplantation: A Directorate of NHSBT

# National Standards for Organ Retrieval from Deceased Donors

# **SECTION 3**

## AUDIT AND MONITORING OF RETRIEVALS

## A. Times to be Recorded:

- Time that each retrieval centre (abdominal & cardiac) is first notified of the donor
- Time of telephone call from a SN-OD asking retrieval centre to mobilise a NORS team
- Time agreed with the SN-OD that the NORS team should leave base hospital
- Time that the main NORS team leaves base hospital
- Time that the main NORS team arrives at donor hospital
- Time that donor arrives in theatres
- Time that cardiac assessment in theatres starts and ends (if applicable)
- Abdominal surgical start time ("knife to skin")
- Cardiothoracic surgical start time

The following times are collected as part of the HTA-A forms which are signed by the surgical lead:

- Time of aortic cross clamp, cessation of ventilation and start of in situ perfusion
- Time that each organ is removed from the body and placed in cool solution for ex situ perfusion
- Time that each organ is placed under ice in the transport box
- Time donor operation ends (completion of skin closure)

The following times are reported by the transplanting centre on the Transplant return form:

- Time each organ is removed from cool solution for implantation into a recipient
- Time each organ is re-perfused with blood

#### In addition For DCD Donors:

- Time treatment withdrawn
- Time systolic BP< 50 mmHg
- Time Oxygen Saturation < 80%
- Time of asystole
- Stand-down time for DCD donors that do not progress to donation

# National Standards for Organ Retrieval from Deceased Donors

#### B. Constituent Personnel of NORS Team Identity, Role and Status

e.g. Mr Smith, Lead abdominal surgeon, Consultant Ms White, Assistant surgeon, SpR Mr Green, Theatre practitioner

## C. Record of Organ Damage

- Details of damage to be recorded by both retrieving and implanting surgeon at the time of retrieval/transplantation:
  - No damage
  - Mild if it is of no consequence
  - Moderate if the organ requires surgical repair to render it transplantable
  - Severe if the organ is untransplantable

[NB: If initially graded as Moderate, but subsequently the damage had a significant impact on the recipient's health, then the recipient centre should formally report this as a SAEAR.]

- Indicate whether the organ was physically injured or whether damage was inferred because the organ perfused badly during cold perfusion.
- Indicate whether the organ suffered physical injury:
  - o prior to retrieval (e.g. during a RTA)
  - o or due to surgical injury during the retrieval
  - o or during transport between centres
  - o or during back table preparation at the recipient centre
  - o or during implantation at the recipient centre
- If the organ was physically damaged or poorly perfused before it was sent to the recipient centre, was this recognised and reported by the retrieving surgeon?

#### D. Reasons for Non-Use of an Organ

- Declined without attempt at retrieval due to:
  - Unsuitable donor Poor quality graft Other
- Declined following surgical exploration due to: Poor quality graft Graft damaged during the retrieval process Poor perfusion
- Unable to Place the graft due to: No suitable recipients in the UK or abroad Prolonged ischaemia Other specified
- Failure to retrieve
  - Retrieval centre unable to mobilise a NORS team Donor becomes too unstable before the NORS team can reach donor hospital.

# National Standards for Organ Retrieval from Deceased Donors

#### E. Outcome Measures

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Liver and Heart N	lo evidence that the organ ever functioned leading to death or e-transplantation.
Kidney N d	lo evidence that the organ ever functioned with need for permanent lialysis post transplant.
Pancreas N	lo reduction in insulin requirements post transplant.
"Primary dysfunction"	

- Liver:Peak AST/ALT > 2000iu/lKidney:Need for temporary post-operative dialysis within the first<br/>seven days.Cardiothoracic:Need for device support
- 30 day Patient and Graft Survival using risk-adjusted funnel plots for each organ type.

#### National Standards for Organ Retrieval from Deceased Donors

# **SECTION 4**

#### EXTRACTS FROM DOCUMENTS OF PARTICULAR RELEVANCE TO NORS TEAMS

#### DCD DONORS

In June 2010 The British Transplantation Society held a collaborative meeting with the Intensive Care Society, supported by the Department of Health, the Devolved Administrations and NHS Blood and Transplant. The two societies subsequently issued a Consensus Document on Organ Donation after Circulatory Death.

In January 2011 the UK Donation Ethics Committee of the Academy of Medical Royal Colleges issued a Consultation Document entitled *An Ethical Framework For Controlled Donation After Circulatory Death.* 

A selected summary of recommendations from these documents pertinent to the National Organ Retrieval Service are outlined below. *Readers are reminded that this is an evolving topic and they should refer to current documents if and when these quoted documents are superseded.* 

- 1. No treatment specifically aimed at organ donation should be instituted before the decision to withdraw treatment has been made.
- 2. Following the decision to withdraw treatment, maintenance of life-sustaining treatment and interventions to facilitate donation may be considered to be in the best interests of someone who wanted to become a donor if it facilitates donation and does not risk causing them harm or distress.
- 3. Invasive procedures such as the insertion of perfusion cannulae which may cause distress to the patient, or administration of drugs to facilitate donation such as heparin which might cause complications in the patient before the diagnosis of death is established are not appropriate.
- 4. Bronchoscopy to assess the potential for lung donation may be appropriate provided it does not cause the patient distress and is agreed by the patient's family.
- 5. The Specialist Nurse for Organ Donation should not care for the potential donor whilst they are still alive.
- 6. Members of the NORS team and the recipient's clinical team should not be involved in the care of the potential donor, nor in the diagnosis of death.
- 7. If the NORS team has any doubts about whether the correct process has taken place to establish the diagnosis of death then they should contact the clinician who was managing the patient.
- 8. Death can be confirmed for DCD after five minutes of continuous absence of cardio-respiratory function. There must be no attempt at cardiopulmonary resuscitation or any measure that might restore blood flow to the brain.
- 9. Should the heart temporarily restart (theoretically possible when moving the donor e.g. during transfer to the operating table) then a further period of five minutes asystole must elapse and be confirmed by donor hospital medical staff before organ retrieval can begin.

# National Standards for Organ Retrieval from Deceased Donors

- 10. No intervention that can potentially restore cerebral circulation is allowed. This has particular relevance for lung retrieval. The accepted method to isolate cerebral circulation is a cross clamp of the relevant cerebral vessels or aortic arch. Balloon occlusion of the thoracic aorta is only acceptable if non-blood perfusion is used.
- 11. Tracheal re-intubation to facilitate lung donation, may be performed after the declaration of death but under no circumstances should cyclical mechanical ventilation be re-instituted before exclusion of the cerebral circulation. However, reinflation of the lungs using a single recruitment manoeuvre is appropriate after 10 minutes of circulatory arrest. Further single recruitment manoeuvres may be performed during the lung retrieval process, as deemed necessary by the NORS team.
- 12. The management of a patient who does not die within an appropriate time period remains the responsibility of the clinical team under which they were receiving care prior to treatment withdrawal. The family should be warned beforehand that this may happen. It is essential that the patient and family have an identified member of donor hospital staff with them able to provide necessary care. A suitable place for the patient to be cared for in this eventuality must be identified before treatment withdrawal especially if withdrawal does not take place on the critical care unit.

13. Definition of terms used following treatment withdrawal:

- The Withdrawal Period (or agonal period). Time from treatment withdrawal to asystole.
- Asystolic warm period. Time from asystole to the onset of cold perfusion.
- Functional Warm Ischaemic Period. Starts when systolic blood pressure falls below 50mm Hg and extends to the onset of cold in situ perfusion.

# National Standards for Organ Retrieval from Deceased Donors

# SECTION 5

## LUNG RETRIEVAL FROM DCD DONORS

# Preparation for DCD lung retrieval

- Lung DCD retrieval requires careful planning and close collaboration between all of those involved in the care of the patient.
- Prior to treatment withdrawal, the Specialist Nurse Organ Donation (SN-OD) 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 reventilation 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 are 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<sub>2</sub>O 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<sub>2</sub>O CPAP
    - ii. If lung re-inflation is performed by a member of the retrieval team, a selfinflating manual device such as an Ambu Bag® should be used to to reinflate 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,  $5 10 \text{ cmH}_2\text{O}$  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 clamped, 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 as possible and include thorough bronchial toilet.
- 10. On explantation, the trachea should be clamped with the lungs <sup>3</sup>/<sub>4</sub> inflated. Over inflation must be avoided, particularly if the lungs are being transported by air to the implanting centre.

## National Standards for Organ Retrieval from Deceased Donors

# SECTION 6

#### PROTOCOLS FOR ORGAN RETRIEVAL

- 1. Each centre must have clear, written protocols for the retrieval procedures that they will undertake, including for both DCD and DBD operations. These protocols should be sent to NHSBT for approval by the relevant advisory groups to NHSBT.
- 2. When separate cardiothoracic and abdominal NORS teams attend a donor the surgeons must discuss and agree details of the procedure before retrieving the organs.
- 3. Any novel or uncommon procedure, or modification of a recognised procedure which might impact on other donated organs (e.g. use of cardio-pulmonary bypass or of ECMO, *in-situ* liver split, multi-visceral retrieval, DCD lung retrieval protocol which differs from that in Section 5) may not be performed unless it has been discussed and agreed by both abdominal and cardiothoracic NORS teams.
- 4. A thorough laparotomy and, if the chest is opened, a thorough inspection of thoracic organs should be performed both to exclude pathology such as malignancy which might preclude organ transplantation and to inform the Coroner/Procurator Fiscal in case he/she subsequently requires a report on the condition of the body. Pre-existing injury, (e.g. damage to organs sustained during a road traffic collision) should be recorded.
- 5. Care must be taken to identify and report abnormal anatomy such as aberrant or accessory renal and hepatic arteries.
- 6. 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.
- 7. Biliary tract: prior to retrieval, the gall bladder should be opened and gently aspirated. Repeated saline washes should be performed to clear the gall bladder of bile before the onset of cold ischaemia. Following wash-out, the hole in the gallbladder can be closed with a tie to prevent bile contamination of the preservation fluid during cold storage. After flush-out through the aorta and before bagging the liver in the bowl, the common bile duct has to be carefully but thoroughly flushed with UW solution using approximately 250 ml (Abdominal Perfusion and Preservations Protocol for NORS Teams in the UK – revised September 2014 (see Section 7 below). 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.

- 8. If there is a replaced 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, before transecting it, the retrieving surgeon must contact the liver implanting surgeon to discuss whether he/she is happy to accept a liver with a short hepatic artery. If not then the artery is preserved with the liver. In this situation the pancreas cannot be used as an intact organ but should be offered for islet purification.
- 9. 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.
- 10. Ice slush should be packed around the kidneys, pancreas and liver.
- Please refer to the Abdominal Perfusion and Preservations Protocol for NORS Teams in the UK – revised September 2014 (Section 7 below) for guidance on organ flushing, preservation and packing.
- 12. All organs must be accompanied by appropriate specimens (blood samples, lymph node, and spleen) (see para 3.26 above) and by completed organ-specific NHSBT and blood group forms. Liver and pancreas must be accompanied by the blood vessels needed for reconstruction in the recipient.
- 13. Vessels to accompany the liver and pancreas should either be packed in a small plastic container or 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.
- 14. 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 3.26 above) to the cardiothoracic NORS team so that the heart and lungs can be shipped to recipient centres without delay.

# National Standards for Organ Retrieval from Deceased Donors

# SECTION 7

# Abdominal Perfusion and Preservation Protocol for NORS Teams in the UK

#### Background

Following a meeting of representatives from all of the NORS abdominal centres on 9<sup>th</sup> 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 mls/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	

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Kidney	UW solution alone (heparinised)	N/A
	50 – 70 ml/kg	
	or	
	1 litre flush with heparinised low viscos	sity
	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	НА	Portal	CBD	Pancreas	Kidney
	(type/vol)	(type/vol)	(type/vol)	(type/vol)	(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 mls	UW 500-1000 mls	UW 250 mls		
Pancreas				Nil unless indicated (UW)	
Kidney					UW or Soltran 200-300 mls 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)

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#### 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 pots 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, in line with European practice, all organs should be stored in **THREE** bags.
- 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.
- 12. In the tables the 'generic' names for the preservation solution are used as, according to tender processes, brand names may vary.

# National Standards for Organ Retrieval from Deceased Donors

# SECTION 8

# <u>Heart retrieval on behalf of NHSBT Tissue Services for valves from a deceased donor</u>

NORS teams may be asked to remove the heart for aortic/pulmonary valves, if consent/authorisation has been given, following standard guidance on retrieval (<u>INF195</u>)

Below are the alternative arrangements applicable to Scotland re labelling/documentation and sending the heart to Scottish National Blood Transfusion Service (SNBTS)

# Labelling / Documentation

- The outer surface of the heart container must be labelled with 3 points of ID either name, DoB& CHI or ODT no, DoB & CHI / hospital no
- Complete LIBF TSD 062 Heart for Valves Retrieval Checklist (including date / time of withdrawal of blood sample)
- Heart must be packaged according to the instructions on LIBF TSD 062, placed into the transport box with ice and secured
- Place LIBF TSD 062 in an envelope along with copy of <u>FRM1538</u> (Authorisation) &<u>FRM4211</u> (Patient Assessment), and place underneath the lid of the organ transport box before sealing with numbered security tag

# Sending the Heart to SNBTS

• Ordinarily, the heart should be brought back to the Royal Infirmary of Edinburgh (RIE) with SORT, and taken to SNBTS Blood Issue Reception. If SORT not present or not returning to RIE, contact The Tissues & Cells Nurse on Call (07659107029) who will arrange a courier.

#### National Standards for Organ Retrieval from Deceased Donors

# SECTION 9

Additional reference documents:

- NHSBT <u>POL188</u> Contraindications to organ donation (<u>http://www.odt.nhs.uk/pdf/contraindications\_to\_organ\_donation\_a\_guide\_for\_snods.pdf</u>)
- NHSBT/BTS <u>POL192</u> Responsibilities of clinicians for the acceptance of organs from deceased donors (<u>http://www.odt.nhs.uk/pdf/nhsbt\_responsibilities\_acceptance\_organs\_deceased\_donors.pdf</u>)
- NHSBT MPD891 Pregnancy in donation (http://www.odt.nhs.uk/pdf/pregnancy\_in\_donation.pdf)
- NHSBT <u>MPD1100</u> Guidance and Principles Donor Organ Photographs (<u>http://www.odt.nhs.uk/pdf/guidance\_and\_principles\_donor\_organ\_photographs.pdf</u>)