Whittington Health NHS

Organ Donation Guideline

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Version Control Sheet

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1.0	May 13	Dr M Cepkova, C Murdoch, Dr C Shaw	Approved by CGC	Version 1 for intranet

➢ Criteria for use

In those patients:

- who meet the criteria for neurological brain stem testing **or**
- where treatment is to be withdrawn for reasons related to best interests and where imminent death is expected

➢ Summary

The guideline aims to ensure that organ donation becomes a routine part of end of life care planning and that all families, where appropriate, are given the opportunity to consider organ and tissue donation.

This guideline covers donation from both brainstem dead patients and those where the decision has been made for withdrawal of treatment. Many steps in the donation process are the same for both Donation after Brain Death (DBD) and Donation after Cardiac Death (DCD). *Explanation is offered throughout this document where differences occur.*

➢ Background/ introduction

Our primary role is to fully support families prior to, during and after death of a loved one. In this context, where appropriate, we must discuss organ and tissue donation, choosing the right time and best-skilled person to do so.

The 2004 Human Tissue Act, enacted in 2006 requires formal consent for organ and tissue donation to proceed, and emphasises the requirement to carry out the patient's wishes. A patient is deemed to have given sufficient consent if they are on the organ donor register, carry a donor card, made their wishes known or documented their wish within a written will, but the wishes of the family are always taken into account. It also recommends that any approach for donation should be undertaken by a suitably-trained healthcare professional, comfortable with discussing the option of donation in collaboration with the Specialist Nurse for Organ Donation.

➢ Collaborative approach

Best practice in approaching families for donation is the 'collaborative approach'- *and this is the agreed process at the Whittington Hospital*. Here, families are fully supported by the clinical team (such as the Intensive Care Consultant, bedside nurse or someone familiar with the family such as the ward sister) and an embedded Specialist Nurse for Organ Donation (SNOD). This helps to produce an environment in which the relatives:

- are approached in a timely manner by a professional trained in asking for organ donation
- can receive information regarding organ and tissue donation, and other end of life care issues, and
- can ask questions and/or discuss relevant concerns

Where brainstem death is an issue, they also:

- have access to a specialist during and following the diagnosis of brain stem death.
- fully understand the clinical implications of a brain stem death diagnosis.

➢ Inclusion/ exclusion criteria

Inclusion criteria

- Defined clinical trigger in patients who have had a catastrophic brain injury, namely:
    - the absence of one or more cranial nerve reflexes **and**
    - Glasgow Coma Scale (GCS) score ≤4 unexplained by sedation
- The intention to withdraw life-sustaining treatment with likely consequent circulatory death

Patients who die in a manner where organ donation is not an option should be considered for tissue donation.

Exclusion Criteria

Absolute contraindications

- Patients who have an HIV related illness (HIV infection alone is not a contraindication)
- Patients with CJD/ a family history of CJD

Relative contraindications *(these patients should still be discussed with SNOD)*

- Active invasive cancer in the last 3 years excluding non-melanoma skin cancer and primary brain tumor
- Heamatological malignancy – myeloma, lymphoma, leaukaemia

➢ The referral

Trigger for referral:
All patients who

- meet the inclusion criteria, or
- whose family have enquired about the possibility of organ donation

Referral Process
A discussion will take place on the daily ward round determining whether or not each patient meets the requirement for referral to the SNOD.
The responsibility for ensuring the referral has been made rests with the Consultant on call and the nurse in charge. The task of making the referral, whether it be directly to the embedded SNOD or to the on call team via pager system, may be delegated to another team member (FY1 or FY2 for example). A referral can be made by anyone outside the daily ward round as long as the Consultant on call has been informed.

Discuss the case with the **SNOD on call (pager 07659 100 103)**. If no response after 20 minutes, call the Bristol Duty Office 01179757580, who will continue to page on your behalf. The referral should be made within a timeframe which allows the SNOD to be present when the medical team discuss diagnosis, prognosis and end of life care with the family. (See Appendix 1 for algorithm for approach for donation after brain stem death)

Continue to fully support the potential donor: **all patients who meet the referral criteria should be admitted to critical care** where possible. If a bed is not immediately available, critical care staff will support the patient with the SNOD until alternative arrangements can be made.

If possible, do not initiate discussion of organ donation with the family at this time.

When the SNOD arrives, the first priority is to review case history and clinical condition to confirm donor potential prior to planning the approach with staff involved in the care of the patient.

➢ Approach for donation

The main emphasis regarding the timing of the approach for donation is that the relatives must have demonstrated an **understanding that the patient has died, or that treatment is futile and not in the patients best interests**. The time taken for the relatives to accept this can vary considerably.

If the family do not understand the diagnosis of brain stem death/inevitable death, every attempt should be made to assist them to do so. **Allowing the family to watch the brain stem death tests/apnoea test**, offering written information in leaflets, and showing all relevant CT scans (or using drawings and alternative explanations can all help.

The SNOD should initially be introduced to the family as a specialist nurse (*not* a specialist in organ donation: the SNOD needs to assess the family's understanding and readiness to have the donation conversation before this is mentioned).

If the patient is on the Organ Donor Register, the SNOD will inform the relatives of the patient's wishes regarding donation. As patient consent has already been lawfully given, the SNOD will discuss the donation procedure, answer questions, and complete consent documentation. If the family disagree with the patient's wishes, this requires further exploration. There are clearly some circumstances when this may mean that donation does not occur.

If the patient has not made their wishes known, the SNOD will try to determine if the patient has nominated a representative to act on their behalf after their death. If none is identified, the relative nearest the top of the hierarchy (as per Human Tissue Act 2004) will be approached to discuss the possibility of organ donation.

If the family happen to raise the possibility of organ donation with local staff without being formally asked, the consultant should be informed and a referral to the SNOD made. The SNOD will advise staff on suitability and how to proceed.

During the donation conversation, the SNOD will provide relevant information, discuss the process involved and answer the family's questions **before** seeking an informed, confidential and definite 'yes or no' decision.

If donation is declined, the SNOD will ensure that this is not due to misunderstanding. Regardless of whether or not donation is to proceed; the family *will be offered hand prints and hair locks of their loved one as keepsakes.* Treatment/support will be withdrawn by the hospital staff and care of the deceased patient's body will be performed.

➢ Consent

If the next of kin gives consent for organ donation, the SNOD will discuss donation with the family and obtain formal documented consent. Donation should then be discussed with HM Coroner, who may place some restrictions on the donation due to the circumstances of death.

With HM Coroner permission to proceed, the SNOD will collect clinical information so that a suitable recipient can be found. The help of medical and nursing staff may be required.

➢ Donor Management – Donation After Brain Death (DBD)

1. Diagnosing brainstem death

Brain stem death is the irreversible loss of consciousness associated with the irreversible loss of the central respiratory drive (apnoea).

Brainstem death-testing (BSDT) should be performed as soon as possible to spare the family further intervention not in the patient's best interest. This is professionally and legally acceptable (Code of Practice for the Diagnosis and Confirmation of Death 2008).

The Intensive Care doctor, bedside nurse and SNOD will explain the process of the BSDT to the patient's family. They will be given ample time to ask questions. The family should be made aware at this point that once the first set of tests have been completed the patient is legally dead, and that this will be confirmed with a second set of tests.

Brain Stem Death is diagnosed in 3 stages:

1. **Preconditions must be met:**
   - Diagnosis compatible with brainstem death and evidence of irreversible structural brain damage (which might include hypoxic injury)
   - Apnoea dependent on mechanical ventilation
   - GCS = E1V1M1, fixed and dilated pupils and no other cranial nerve function
2. **All reversible causes of coma must be treated and excluded:**
   - Absence of effects of sedative, hypnotic, analgesic and muscle relaxant drugs must be confirmed. The drugs should be discontinued > 6hours prior to testing. If benzodiazepines and thiopentone have been used, the time period might be longer, depending on total dose and elimination times.
   - Absence of primary hypothermia
   - Metabolic disorders (esp sodium, glucose and pH) must be corrected. While Na+ levels> 160mmol/l can be associated with unresponsiveness, hypernatraemia is often caused by brainstem death. If the latter is clear, brainstem tests can be completed.
3. **Two sets of brain stem death tests (Appendix 2) are performed.**
   - The tests are performed by at least two appropriately trained medical practitioners, each registered for > 5 years. At least one must be a consultant.
   - The legal time of the diagnosis of brain death is after the first set of tests.
   - Results of testing must be recorded on the form in Appendix 3, which must be clearly attached to the medical notes along with all confirmatory blood gas analyses.

If brainstem death is not declared, then the medical team should decide, with the family, what is in the best interests of the patient i.e. continuing treatment, retest at a later point or withdraw treatment.

If brainstem death *is* declared, the family are informed by the doctor, bedside nurse and SNOD. If the patient is a potential organ donor, the process is then explained in detail by the SNOD.

If brain stem death is declared and the patient is not to be an organ donor, when appropriate time has been given to relatives, the ventilator should be switched off and all infusions discontinued. There should be no "weaning process" since the patient has been certified dead.

2. Pathophysiological Changes after Brain Stem Death

Widespread changes occur after brain stem death, which may jeopardise the function of potentially transplantable organs.

2.1 Cardiovascular changes

There are usually two distinct phases:

i) Hyperdynamic phase: Not seen in all patients, sympathetic overactivity increases heart rate, blood pressure, systemic vascular resistance, and myocardial oxygen demand.

ii) Cardiovascular collapse phase results from loss of sympathetic tone (vasodilatation, and reduced cardiac output), hypovolaemia (from the diabetes insipidus seen in <60%, or osmotic diuresis secondary to hyperglycaemia/ mannitol administration). Subendocardial myocardial ischaemia may also occur even in previously healthy hearts.

2.2 Endocrine changes

Anterior and posterior pituitary failure reduces circulating tri-iodothyronine (T_3) and thyroxine (T_4), contributing to cardiovascular deterioration. Reduced production of anti-diuretic hormone (ADH) causes diabetes insipidus (DI): resulting diuresis may cause hypovolaemia, hyperosmolality and hypernatraemia unless managed. Reductions in cortisol production are unrelated to the degree of hypotension but may impair the donor stress response.

Insulin secretion is reduced and contributes to the development of hyperglycaemia

2.3 Pulmonary changes

Pulmonary dysfunction is common (pneumonia, aspiration, pulmonary trauma. or neurogenic or cardiogenic pulmonary oedema)

2.4 Disseminated intravascular coagulation

This **is** common and its incidence increases with the duration of brain stem death.

2.5 Hypothermia

Hypothermia may result from reduced heat production (fall in metabolic rate and loss of muscular activity), increased loss (vasodilatation) and hypothalamic failure (impaired temperature regulation).

The clinical course of a ventilated but otherwise unsupported brain stem dead patient is short with asystolic cardiac arrest generally occurring within 72 hours. However cardiac and other body functions have been maintained for many days in fully supported patients.

3 Monitoring the Organ Donor

Invasive monitoring is required to maintain appropriate intravascular volume, stroke volume and peripheral vascular resistance. Because of the order in which the great vessels are ligated during the donor operation, any newly placed arterial cannula

should be inserted into the **left radial or brachial artery**. Equally any new central venous or pulmonary artery catheter (PAC) should be inserted into the **right internal jugular or subclavian veins**.

Echocardiography or PA catheter insertion is not necessary unless clinically indicated, or requested by the transplant service.

4 Clinical management - Supporting the Organ Donor after brain stem death (summary in Appendix 4 and bedside form in Appendix 5)

Resuscitation and Maintenance of the Organ Donor

Following confirmation of a plan for organ donation, the goals of care shift from preserving brain function to maintaining tissue perfusion and optimising transplantable organ function. Adequate time must be allowed for confirmation of brain stem death but unnecessary delays should be avoided to minimise the risk of donor deterioration.

4.1 Cardiovascular support

The goals of haemodynamic management are to optimise cardiac output, maintaining normal preload and afterload. Where possible, the use of pressors which increase myocardial oxygen demand and deplete myocardial high energy phosphates should be minimised. Hypovolaemia should be corrected, but excessive volume replacement avoided, particularly in potential lung and heart donors.

The following haemodynamic goals are generally appropriate in potential adult heart donors (Table 1).

Table 1. Appropriate haemodynamic goals for potential adult heart donors.

Mean Arterial Pressure	60-80 mmHg
Preload	Central venous pressure ~ 4-10 mmHg
	Pulmonary artery occlusion pressure ~ 10-15 mmHg
Heart Rate	60 – 100 beats.min^{-1}
Rhythm	Sinus rhythm is desirable
Cardiac Output	Cardiac Index > 2.1 l.min^{-1}.m^{-2}

Patients who do not achieve these goals may still be considered for donation of other organs.

The choice of inotropic/vasopressor support varies between units and may be guided by data from pulmonary artery catheterisation but:

- High dose adrenaline may result in detrimental vasoconstriction in donor organs.
- The vasodilator effects of dobutamine may lead to undesirable hypotension and tachycardia.
- Vasopressin is less likely to cause metabolic acidosis or pulmonary hypertension and may be a more appropriate vasoconstrictor than noradrenaline.

4.2 Endocrine support

The therapies used to correct the common endocrine disturbances are shown in Table 2 (See Appendix 5 for details)

Table 2. The common endocrine problems seen in DBDs.

Clinical Problem	Management
Diabetes Insipidus	Maintain Na+ <= 150 mmol.l^{-1} with 5% glucose[3] Maintain urine output of approx1ml/kg/h with vasopressin (pitressin) 1U bolus and 0.5 - 4.0 Units/h infusion If vasopressin fails to control diuresis, intermittent desmopressin (DDAVP) may occasionally be required
Hyperglycemia	Insulin to maintain plasma glucose 4 - 10 mmol/l Maintain K >4.0 mmol/l
Hypothyroidism	Tri-iodothyronine (T3) 4 microgram bolus then infusion at 3 micrograms/h

4.3 Respiratory support

If the lungs are to be transplanted, the lowest FiO2 commensurate with PaO_2 of >10.0 kPa should be used, in order to prevent lung toxicity. Strict asepsis should be continued during physiotherapy and tracheal toilet. Physiotherapy should include hourly gentle inflation of the lungs and two hourly side-to-side turning. Suitable goals for respiratory support are:

- maintenance of normocapnia
- ventilation with the lowest FiO_2 to maintain paO2 > 10kPa
- PEEP applied as needed with minimum of 5 cmH_2O
- Tidal volumes at 4-8 mls per kg and plateau pressure < 30cmH2O.
- Very sensitive ventilatory triggers may allow cardiac cycle-induced pressure changes to trigger the ventilator. This may cause diagnostic confusion by giving the appearance of a spontaneous breath.

4.5 Haematological support

The haemoglobin concentration should be maintained over 90 $gm.l^{-1}$. Deranged coagulation should be corrected. Antifibrinolytics such as epsilon aminocaproic acid may cause microvascular thrombi in donor organs and should be avoided.

➢ Donor Management – Donation After Cardiac Death (DCD)

1 Decision to Withdraw Life-Sustaining Treatment

Any withdrawal decision must be completely, and demonstrably independent or uninfluenced by any consideration regarding organ donation.

In accordance with best practice at The Whittington Hospital, this would usually be a joint decision involving ≥2 senior doctors, one ideally from the patient's admitting team.

2 Clinical Management of the Donor

There is often an intermediate time period where the treating clinicians may identify the patient as a potential DCD donor, but the patient's wishes, and family agreement to possible donation, are yet to be confirmed. In this situation:

1. Taking and testing blood for donation purposes is inappropriate No patient should be moved from their current location for the purposes of facilitating potential organ donation.
2. Maintenance of current treatment (maintenance fluids, inotrope infusions, ventilator settings) is acceptable, but escalation or introduction of new therapies would be **inappropriate**.

Where the family have given written agreement for DCD, it is appropriate to:

1. Take and test blood.
2. Move the patient to other areas of the hospital to facilitate donation provided this location can provide adequate end of life care for the patient, and support for their family.
3. Treat to maintain physiological stability (maintenance fluids, current inotrope infusions, current ventilator settings). Escalation of treatments to a physiological endpoint (eg fluid boluses, titration of existing pressor infusions, or transfer from a spontaneous mode of ventilation to a mandatory mode) or new interventions are only acceptable if it is the view of the treating clinician from their discussions with the patient's family and reference to the patient's previously expressed wishes that this represents the best interest of the patient. Escalation should not cause the patient (or risk them experiencing) harm or distress (and, for such reasons, heparinisation for the purposes of organ donation is usually unacceptable). **Cardiopulmonary resuscitation is not acceptable.**

3 The Withdrawal Process

Any withdrawal of life-sustaining treatment should be carried out in accordance to national guidelines (ref General Medical Council and the Intensive Care Society.)

Specifically, in patients where donation after cardiac death is intended, the following should be confirmed BEFORE the withdrawal of life-sustaining treatment:

1. Clear documentation of decisions regarding futility and withdrawal of treatment exists.
2. A 'Do Not Resuscitate' order is in place.
3. A full explanation of the withdrawal process, the certification of death, the time constraints for successful donation and the reasons why donation may not proceed, has been given to the family and time allowed for their discussion and questions.
4. Written agreement to proceed with DCD has been obtained from the patient's next of kin.
5. All family, who wish to be present, are in attendance.
6. Approval has been sought from H.M. Coroner for organ donation to proceed following death.
7. The Anaesthetic Consultant and the Theatre Coordinator have been informed about an imminent DCD donor. The required theatre staff and facilities have been discussed and there is confirmation that these are to be available in the predicted time period of death and subsequent donation. The Anaesthetic Consultant and the Theatre Coordinator will balance this request against the other emergencies awaiting an allocated theatre time. The Theatre Coordinator should be kept updated during the planned withdrawal by a member of the Donor Team. The final decision on theatre availability will rest with the Theatre Coordinator and the Anaesthetic Consultant.
8. The Surgical Retrieval team are in readiness in theatre.
9. The patient's bed and bed area is prepared for rapid transfer to theatre following the certification of death.

No member of the surgical retrieval team will attend the patient or advise on the withdrawal process. The method of life sustaining treatment withdrawal is up to discretion of the treating clinician.

Upon withdrawal of life-sustaining treatment, the patient should continue to be monitored. The bedside monitoring screen may be turned off to minimise family distress.

The continuation of good end of life care, including measures to maintain the comfort and dignity of the patient should never be compromised for the purposes of facilitating donation.

A member of the Donor Team will make observations from the time of withdrawal.

The following will be documented by the SNOD:

- The time of life sustaining treatment withdrawal
- The time at which systolic BP $\leq$ 50mmHg

- The time at which spO2 ≤ 80%
- **The time at which asystole commences**

At the onset of asystole the clinician and the patient's family, if desired, should be notified. Monitoring should continue following the onset of asystole as outlined in Section 10) It is acceptable that the surgical and theatre team be informed of the above events.

If, after the withdrawal of life sustaining treatment, death does not seem imminent or if organ viability appears to have been compromised, donation may no longer be possible. The family should be informed within the timeframe previously agreed with the SNOD.

4 Determination of Death

Death is a process and can only reliably be judged retrospectively after a period of confirmatory time has elapsed in which there has been no sign of a return of heart (brain stem death excluded) or brain activity.

Following the onset of monitored asystole the patient should continue to be monitored for 5 minutes. If during this time there is any return of cardiac or respiratory activity a further five minutes of observation should recommence.

For the purposes of this guideline, asystole is defined as 'absent or near absent electrical activity of the heart associated with no evidence of cardiac output (ie absent peripheral pulsation / arterial line trace).'

At the conclusion of five minutes of monitored asystole, death can be certified as per the Code of Practice for the diagnosis and confirmation of death (Academy of Medical Royal Colleges, 2008), once an examining medical practitioner can ascertain / has ascertained that:

- The patient is: pulseless (an absent arterial waveform trace would satisfy this requirement)
- apnoeic
- fixed pupils
- absent corneal reflexes
- no response to supra-orbital pressure

The medical practitioner must record their certification of death in the patient's medical notes.

The family may stay with the patient prior to and during the withdrawal of treatment and until death has occurred. The family will have been informed as part of the consenting process that they may withdraw consent for donation up until surgical retrieval commences in the operating theatre. Upon certification the family will be given the opportunity for farewells following which the patient should be moved rapidly to theatre. The family will also be given the opportunity to see their relative once the operation has been completed.

5 Opportunity for Family Farewells and Transfer to Theatre

It is important that families have been made aware during the consenting process that following asystole and the subsequent five minutes confirmatory time it will be necessary to rapidly transfer their relative to theatre for donation after cardiac death to be successful. After death has been certified, any extended farewell for longer than a few minutes is likely to jeopardise organ viability.

If however after certification of death the family wish to have an extended period of farewell with their relative, then the fact that donation will not occur should be explained to them so they are fully aware, then their wish to stay with their loved one should be respected.

Following the certification of death and with the agreement of the family the patient is disconnected from monitoring and moved immediately to the waiting theatre.

There is no time to await theatre porters and therefore staff, both medical and nursing, should assist in the transfer to theatre.

➢ Theatre procedure

The theatre staff should be informed at an early stage of potential organ retrieval, ideally following verbal consent from the family. The SNOD should book onto the theatre list. It is unusual to be able to estimate a theatre time before late evening, as the retrieval team cannot be mobilised until all the organs have been offered and placed.

The Theatre Coordinator and SNOD will organize a theatre time and staff. A theatre assistant is required to help with transfer onto the theatre table during donation after cardiac death, and also during cross clamp of the aorta during donation after brain death (in both cases to shorten the warm ischaemic time).

Booked lists and emergency operations usually take priority over organ retrieval. However, organ transplantation is also classed as an emergency. Donor instability may lead to reprioritisation.

The Theatre Coordinator will be regularly updated by the SNOD. The final decision on theatre availability will rest with the Theatre Coordinator (bleep 2707) and the Anaesthetic's on call (bleep 3005) that is responsible for this.

The theatre staff member who will be assisting should make themselves known to the SNOD. The theatre staff act as circulating assistants and advise visiting staff on theatre layout and local policies. If the circulating theatre nurse or healthcare assistant is unable to stay in theatre throughout the procedure, then a bleep number for contact and immediate response should be left behind with the SNOD.

The retrieval teams aim to be self-sufficient and bring their own operating sets, sutures, ties, swabs, blades, etc. The Whittington Hospital supplies an anaesthetic machine, the diathermy, two or three large instrument trolleys, several drip stands and two bowl-stands, and adequate suction capacity (2x4 suction units).

The retrieval team brings their own scrub nurses with them. If local staff wish to assist as a learning experience, this can be arranged.

Retrieval surgery lasts approximately 3-5 hours.

The dignity and respect of the body must be maintained at all times.

Laminated **'QUIET PLEASE – NO ENTRY**' signs should be adhered to the anaesthetic room doors in cases of donation after cardiac death when family may be present and treatment is being withdrawn.

During the retrieval procedure, expect the arrival of registered personnel responsible for the safe transport of donated organs to the recipient hospitals. Theatre staff should communicate with SNOD regarding estimated pick-up time. If there is going to be a delay, they should communicate this to the transport personnel. Transport personnel should be shown to the staff room, asked to wait, reminded that access in the theatre clinical area is restricted, and requested to refrain from wandering unsupervised.

Following the retrieval procedure, the retrieval surgeons will leave the hospital site with the donated tissue/organs, leaving the SNOD and theatre staff to complete last offices.

The SNOD and the circulating nurse or healthcare assistant perform the last offices.. There is a 'last offices' box in theatre. It is the responsibility of those who last used it to ensure that it is restocked according to the agreed checklist. The critical care staff and next of kin may wish to be involved and this should be facilitated.

The family can view the body after the operation. Ideally this should occur in the mortuary but in special circumstances a restricted number of people may be accommodated in theatre for a limited time period.

➢ Documentation and follow-up

A clear and precise record of all events should be recorded in the hospital medical notes by all those involved in the donor's care including the medical staff, the nursing staff, the SNOD and the retrieving surgeons. This should include brainstem test forms, consent and patient assessment forms.

If required, a post-donation debrief/follow up session with the SNOD can be arranged.

➢ Contacts (inside and outside the Trust including out-of-hours contacts)

- **Specialist Nurse for Organ Donation (SNOD) on call via pager 07659 100 103**
- Bristol Duty Office 01179757580
- Clinical Lead for Organ Donation (CLOD) Dr. Magda Cepkova can be reached via switchboard

➢ Glossary

DBD	Donation after Brain Death
DCD	Donation after Cardiac Death
SNOD	Specialist Nurse for Organ Donation
CLOD	Clinical Lead for Organ Donation
HIV	Human immunodeficiency virus
CJD	Creutzfeld-Jacobs Disease
BSD	Brain Stem Death
BSDT	Brain Stem Death Testing
GCS	Glasgow Coma Scale
ADH	Antidiuretic Hormone
DI	Diabetes Insipidus
PAC	Pulmonary Artery Catheter
ICU	Intensive Care Unit
SIMV	Synchronized Intermittent Mechanical Ventilation
PEEP	Positive End Expiratory Pressure
NATCO	North American Transplant Co-ordinators Organization

➢ References (evidence upon which the guideline is based)

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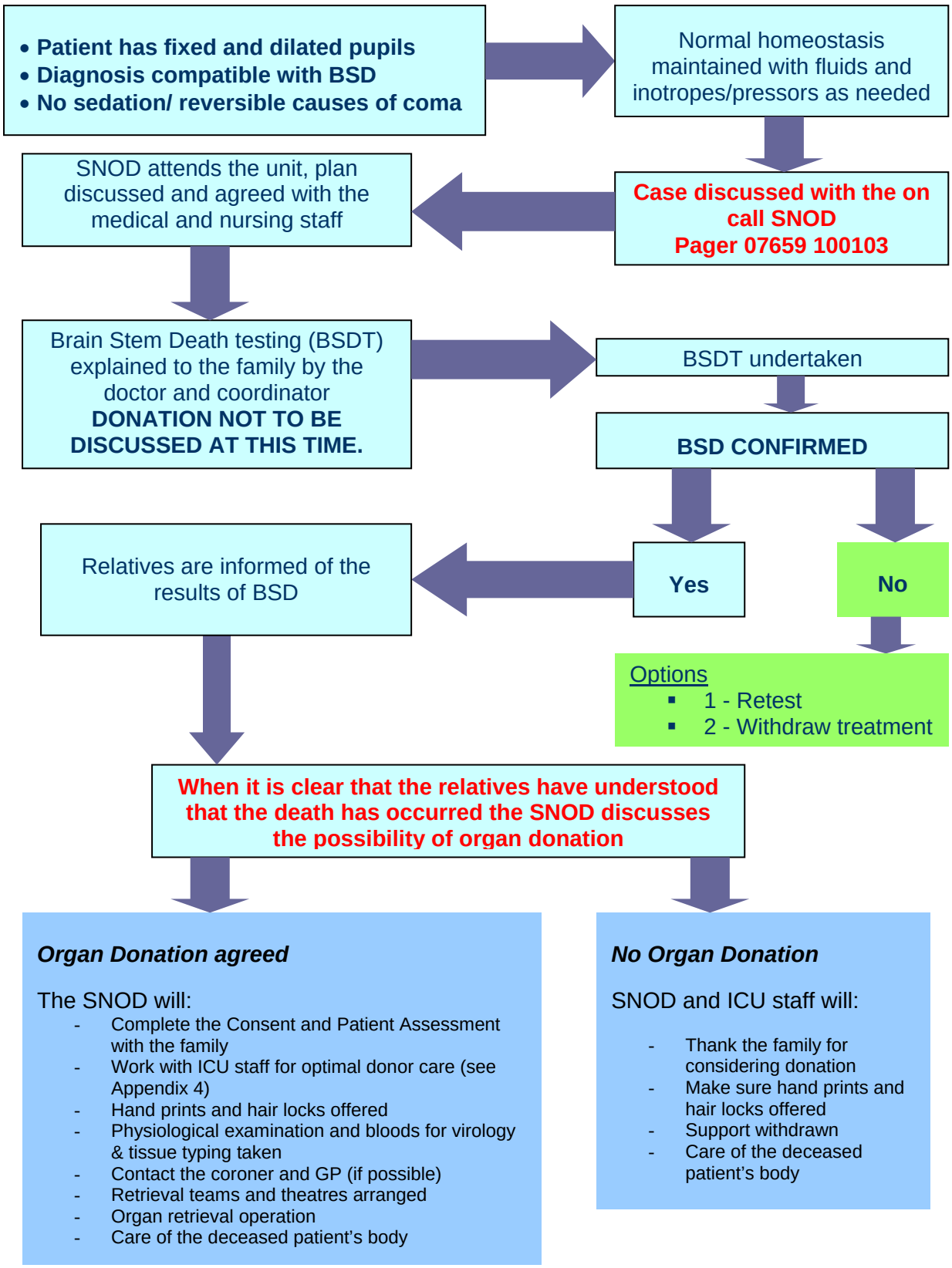
APPENDIX 1

Approach for Organ Donation after Brain stem Death (DBD)



APPENDIX 2

Test for absence of Brain stem function

Equipment needed (to be prepared by the bed-side nurse):

- Torch
- Sterile gauze
- Otoscope
- 200ml of ice cold water
- 50 ml syringe
- Kidney dish
- Water's circuit
- Suction catheter

Diagnostic Test	Cranial nerve	Area of brain-stem tested
Absent pupilary reflex- fixed diameter pupil, unreactive either directly or indirectly to sharp changes in light	Optic (II) Oculomotor (III)	Midbrain
Absent corneal reflex – no blink occurs when cornea brushed with gauze	Trigeminal (V) Facial (VII)	Midbrain
Absent vestibule-ocular reflex – no eye movement occurs in response to slow injection of at least 50ml of ice cold water over 1 min into each external auditory meatus . *Clear access to tympanic membrane must be established by direct inspection*	Acoustic (VIII) Abducens (VI)	Pons
No motor response with cranial nerve distribution in response to stimuli No limb response to supraorbital pressure Absent grimacing to pain No head movement	Facial (VII) Accessory (XI)	Midbrain Medulla
No gag reflex in response to suction catheter passed down the trachea, no slowing of heart rate	Glossopharyngeal (IX) Vagus (X)	Medulla
No respiratory movements occur when disconnection from ventilator allows PaCO2 to rise above the threshold for respiratory stimulation (6.65kPa)		Respiratory centre in medulla

Testing for apnoea:

- Pre-oxygenate with 100% oxygen for 10 minutes
- Reduce SIMV rate to allow rise of ETCO2 >6.0 kPa, check ABG to confirm that PaCO2 is at least >6.0 KPa and pH is less than 7.4
- Disconnect the patient from the ventilator and deliver O2 at 5l/min via an ET catheter. Observe for 5 min.If maintenance of adequate oxygenation is difficult then CPAP maybe used
- After 5min of apnoea repate ABG to confirm a minimum of a further 0.5kPa rise in PaCO2 to confirm loss of respiratory drive

APPENDIX 3

PROCEDURE FOR THE DIAGNOSIS AND CONFIRMATION OF CESSATION OF BRAIN-STEM FUNCTION BY NEUROLOGICAL TESTING OF BRAIN-STEM REFLEXES

Diagnosis is to be made by two doctors who have been registered for more than five years and are competent in the procedure. At least one should be a consultant. Testing should be undertaken by the doctors together and must always be performed completely and successfully on two occasions in total.

Patient Name: **Unit No:**

Pre-conditions

Are you satisfied that the patient suffers from a condition that has led to irreversible brain damage?

Specify the condition:
Dr A: **Dr B:**

Time of onset of unresponsive coma:

Dr A: **Dr B:**

Are you satisfied that potentially reversible causes for the patient's condition have been adequately excluded, in particular:

	DR A:	DR B:
DEPRESSANT DRUGS		
NEUROMUSCULAR BLOCKING DRUGS		
HYPOTHERMIA		
METABOLIC OR ENDOCRINE DISTURBANCES		

TESTS FOR ABSENCE OF BRAIN-STEM FUNCTION	1ST SET OF TESTS	2ND SET OF TESTS	1ST SET OF TESTS	2ND SET OF TESTS
DO THE PUPILS REACT TO LIGHT?				
ARE THERE CORNEAL REFLEXES?				
IS THERE EYE MOVEMENT ON CALORIC TESTING?				
ARE THERE MOTOR RESPONSES IN THE CRANIAL NERVE DISTRIBUTION IN RESPONSE TO STIMULATION OF FACE, LIMBS OR TRUNK?				
IS THE GAG REFLEX PRESENT?				
IS THERE A COUGH REFLEX?				
HAVE THE RECOMMENDATIONS CONCERNING TESTING FOR APNOEA BEEN FOLLOWED?				
WERE THERE ANY RESPIRATORY MOVEMENTS SEEN?				

Date and time of first set of tests: **Date and time of second set of tests:**

Dr A Signature: **Dr B Signature:**

Status: **Status:**

APPENDIX 4

Management of the patients for Donation after Brain Death

Once family has decided that their relative should be an organ donor the aim of management is to support the patient's organs for transplantation

Brain death affects nearly every organ system and there are many complications that can make donor management difficult

These complications include hypotension, diabetes insipidus, hypothermia, electrolyte abnormalities, coagulopathy, hypoxia and cardiac arrythmias

RESPIRATORY SUPPORT	• PaO2 >10kPa with the lowest possible FiO2 • PaCO2 within normal limits • pH > 7.25 • PEEP > 5 mmH2O • Tidal volulme 4-8 ml/kg • Inspiratory pressure <30cmH2O
CARDIOVASCULAR SUPPORT	• Maintain intravascular volume (CVP 4-10mmHg) • Systolic BP > 100mmHg, MAP 60 – 80 mmHg • HR 60 – 100 bpm • Vasopressors if required • Sinus rhythm is desirable • If PA catheter present aim cardiac index >2.1l/min/m2 and PAOC 10-15 mmHg
ENDOCRINE SUPPORT	• Maintain urine output >1ml/kg/h (DDAVP for diabetes insipidus) • Maintain serum sodium <150mmol/l • Mainain serum potassium > 4mmol/l • Hormonal replacement with ADH (Pitressin-Argipressin), Tri-iodthyronine T3, Methylprednisolone and Insulin
HEAMATOLOGICAL SUPPORT	• Fresh frozen plasma (FFP) to correct coagulopathies • Platelets to correct low platelet count
TEMPERATURE SUPPORT	• Core temperature > 35 C • Utilise warming blankets and warmed IV fluids and heated and humidified inspired gases as needed

APPENDIX 5

Donation after Brainstem Death (DBD)

Donor Optimisation Extended Care Bundle

NHS Blood and Transplant

Whittington Health NHS

Patient Name_____Date of Birth_____

Unit Number_____ Date and Time_____

Priorities to address are **Y N/A**

1. Assess fluid status and correct hypovolaemia with fluid boluses
2. Introduce vasopressin infusion where required introduce flow monitoring
3. Perform lung recruitment manoeuvres (e.g. following apnoea tests, disconnections, deterioration in oxygenation or suctioning)
4. Identify, arrest and reverse effects of *diabetes insipidus*
5. Administer methylprednisolone (all donors)

Cardiovascular (primary target MAP 60 – 80 mm Hg)

		Y	N/A
1.	**Review intravascular fluid status and correct hypovolaemia with fluid boluses**	☐	☐
2.	Commence cardiac output / flow monitoring	☐	☐
3.	**Commence vasopressin (0.5 – 4 units/hour) where vasopressor required, wean or stop catecholamine pressors as able**	☐	☐
4.	Introduce additional vasopressor or inotrope if required	☐	☐
5.	Commence Liothyronine at 3 units/hour (+/- 4 unit bolus) (in cases of high vaso-active drug requirements or as directed by the cardiothoracic retrieval team)	☐	☐

Respiratory (primary target $PaO_2 \geq 10$ kPa, pH > 7.25)

1.	Perform lung recruitment manoeuvres	☐	■
2.	Review ventilation, ensure lung protective strategy (Tidal volumes 4 – 8ml/kg ideal body weight and optimum PEEP (5 – 10 cm H_2O)	☐	■
3.	Maintain regular chest physio incl. suctioning as per unit protocol	☐	■
4.	Maintain 30 – 45 degrees head of bed elevation	☐	■
5.	Ensure cuff of endotracheal tube is appropriately inflated	☐	■
6.	Patient positioning (side, back, side) as per unit protocol	☐	■
7.	Where available, and in the context of lung donation, perform bronchoscopy, bronchial lavage and - toilet for therapeutic purposes	☐	☐

Signature _____**Print Name** _____

Fluids and metabolic management

1.	**Administer methylprednisolone ?(dose 15 mg/kg, max 1 g)**	☐	■
2.	Review fluid administration. IV crystalloid maintenance fluid (or NG water where appropriate) to maintain $Na^+ < 150$ mmol/l	☐	☐
3.	**Maintain urine output between 0.5 – 2.0 ml/kg/hour** (If > 4ml/kg/hr, consider *Diabetes insipidus* and treat promptly with vasopressin and/or DDAVP. Dose of DDAVP 1 – 4 mcg ivi titrated to effect)	☐	■
4.	Start insulin infusion to keep blood sugar at 4 –10 mmol/l (minimum 1 unit/h; add a glucose containing fluid if required to maintain blood sugar)	☐	■
5.	Continue NG feeding (unless SN-OD advises otherwise)	☐	☐

Thrombo-embolic prevention

1.	Ensure anti-embolic stockings are in place (as applicable)	☐	☐
2.	Ensure sequential compression devices are in place (as applicable)	☐	☐
3.	Continue, or prescribe low molecular weight heparin	☐	☐

Lines, Monitoring and Investigations (if not already done)

1.	Insert arterial line: left side preferable (radial or brachial)	☐	■
2.	Insert CVC: right side preferable (int jugular or subclavian)	☐	■
3.	Continue hourly observations as per critical care policy	☐	■
4.	Maintain normothermia using active warming where required	☐	■
5.	Perform a 12-lead ECG (to exclude Q-waves)	☐	■
6.	Perform CXR (post recruitment procedure where possible)	☐	■
7.	Send Troponin level in all cardiac arrest cases (and follow-up sample where patient in ICU > 24 hours)	☐	☐
8.	Where available, perform an Echocardiogram	☐	☐
9.	Review and stop all unnecessary medications	☐	■

Date _____ **Time** _____

NHS Blood and Transplant

Donation after Brainstem Death (DBD)

Donor Optimisation Extended Care Bundle

Patient Name_____ Date of Birth_____

Unit Number_____ Date and Time_____

Cardiac output / flow monitor used: .....

Physiological Parameters / Goals **Tick ✓ = achieved, x = not achieved**

	O/A	+1hr	+2hrs	+4hrs	+6hrs	+8hrs	+10hrs	+12hrs	+14hrs	+16hrs	+18hrs
$PaO_2 \geq 10.0$ kPa ($FiO_2 < 0.4$ as able)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
$PaCO_2$ 5 – 6.5 kPa (or higher as long as pH > 7.25)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
MAP 60 – 80 mmHg	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
CVP 4 – 10 mmHg (secondary goal)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cardiac index > 2.1 l/min/m^2	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
$ScvO_2$ > 60 %	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
SVRI (secondary goal) 1800 – 2400 dynes*sec/cm^5/m^2	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Temperature 36 – 37.5 °C	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Blood glucose 4.0 – 10.0 mmol/l	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Urine output 0.5 – 2.0 ml/kg/hour	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Signature											
Print name											
Date											
Time											

APPENDIX 6

GUIDELINES FOR DONOR MANAGEMENT
HORMONE REPLACEMENT PROTOCOL
for potential Cardiac donors

THE FOLLOWING INFUSIONS SHOULD BE PRESCRIBED AND COMMENCED AS SOON AS POSSIBLE

T3 – Liothyronine (Triiodothyronine ®)
20 microgram vials, Make up with water for injection to 1mcg/ml solution. Give an initial bolus of 4mcg followed by an infusion of **3mcg/hr** N.B. A supply of liothyronine is kept in the emergency drug cupboard on Nightingale ward for out of hours use

Argipressin – Synthetic Vasopressin (Pitressin ®)
Ampoules 20 units in 1ml Make up with 40mls of 5% glucose to 0.5unit/ml solution. Give initial bolus of 1 unit followed by infusion at 0.5units/hr N.B There may be an increase in blood pressure when argipressin is commenced, if so wean inotropes. Therefore **prescribe 0.5- 4 units/ hr to maintain MAP > 70** N.B. A supply of argipressin (vasopressin) is kept on Intensive Care

Steroids
Methylprednisolone (Solu-Medrone®) 15mg/kg bolus (Discuss with Cardiothoracic centre)

Insulin sliding scale **Please speak to coordinator before commencing this**
Sliding scale to maintain blood sugar between 4-9 mmol/L

These doses are suitable for patients weighing between 40-100kgs. For patients below 40kg refer to North America Transplant Co-ordinators Orginasation (NATCO) sheet for guidance. Discuss with the on call Cardiac Centre if in any doubt.

APPENDIX 7

ADVICE FOR ANAESTHETISTS

There are four probable scenarios:

(1)Donation After Brain Death (DBD excluding cardiothoracic donation

(2)Donation After Brain Death (DBD)) including cardiothoracic donation

(3)Donation After Cardiac Death (DCD) excluding lung donation

(4)Donation After Cardiac Death (DCD) including lung donation

1. Donation After Brain Death excluding cardiothoracic retrieval:

The retrieval team will not bring a cardiothoracic physiologist or anaesthetist.

The Whittington anaesthetist will be required to support ventilation and circulation up to the point of cross clamping. Case must be discussed with the consultant on call to make sensible clinical and manpower planning decisions.

Summary of the responsibilities of the Whittington anaesthetist:

1) Take over care from the ICU team and transfer the donor to theatre
2) Continue invasive monitoring which is in most cases already in place (arterial line, CVC)
3) Continue mechanical ventilation
4) Provide circulatory support until cross clamp – fluid management and vasoactive drugs. Be prepared for cardiovascular instability.
5) Administer muscle relaxation to prevent spinal reflexes
6) Administer heparin
7) Administer antibiotic therapy and steroids if required
8) Provide blood sampling

Intra-operative donor management – general principles:

The Whittington anaesthetist will be providing critical care support to the donor during the multi-organ retrieval procedure. Maintaining stability during this procedure allows for unhurried removal of organs in optimal condition. Reliable large bore intravenous access and intra-arterial monitoring is required. Maintaining an ‘anaesthesia’ record may help monitor trends during the procedure. Essentially this is a laparotomy and blood loss is usually minimal.

- **Position and Access** The patient is supine, with arms by the side to facilitate surgical access. Ensure large bore access is patent and reliable. A large bore extension set and three-way tap is often useful.
- **Anaesthesia** There is no need for ‘anaesthesia’ as such as patients are brain stem dead. But spinal reflexes will still be present and can be marked, and it is important to ensure full paralysis. Rocuronium 100 mg will usually suffice for the entire procedure, but any relaxant is suitable to obtund autonomic reflexes. Opiates and sedatives are generally not used in patient after brains stem death, but opiates mabe used.

- **Ventilation** should continue as started on ICU with the following goals:
    - Use the lowest inspired oxygen to maintain PaO2 >10kPa
    - Maintain normocapnia (PaCO2 ~ 4.5 – 5.5 KPa)
    - Tidal volumes are chosen to limit peak inspiratory pressure yet ensure no atelectasis. Keep tidal volumes at 6-8 mls per kg and plateau pressure < 30cmH2O.
    - Keep PEEP at 5 cmH2O, higher levels of PEEP may reduce cardiac output and are rarely necessary
- **Hemodynamic management** Following brain stem death there can be a variable intensity and duration of "sympathetic storm" with tachycardia vasoconstriction and blood pressure instability. Treatment of these rapid changes may be difficult and short-acting agents should be used. Following this phase more consistent syndrome of marked vasodilation and relative hypovolemia develops. Donors are likely to be in this phase when taken to theatres for retrieval.
    - Aim to keep sinus rhythm at 60-100 bpm. MAP 60-80 mmHg, CVC <12 mmHg and cardiac index (if measured) of > 2.4 l/min/m2
    - Hypotension:
        - Ensure euvolemia, use colloid or crystalloid boluses 3-5ml/kg
        - Vasopressin (0.5- 4.0 U/h infusion) is used preferentially for pressor/inotropic support in donors; less likely to cause metabolic acidosis or pulmonary hypertension
        - High dose adrenaline should be avoided as it may result in detrimental vasoconstriction in donor organs
    - Hypertension is generally well managed by the introduction of low concentrations of isoflurane which may also have some beneficial pre-conditioning effects on organs or short-acting peripheral vasodilatators.
- **Steroid and antibiotics** The patient will almost certainly have received methylprednisolone in the intensive care unit but if this is not the case 1g of methylprednisolone can be given intravenously following discussion with retrieval surgeons. Antibiotics may be needed and would be drawn up by retrieval team and usually consist of a cephalosporin, penicillin, and gentamicin in patients who are not allergic. Alternative antibiotics will be given if the patient is penicillin allergic – please check.
- **Heparin** The retrieval team may also at this stage prepare a syringe of heparin (usually 20,000). This should not be given until later in the procedure, the exact timing of heparin administration will be discussed between the cardiothoracic and abdominal retrieval surgeons, and the Whittington anaesthetist will be required to give it intravenously.
- **Blood Sampling** The retrieval team will ask for blood samples (up to 100mls, sometimes more) which can be taken from arterial line or central venous catheters.

Approximately 1-2 hours after knife to skin, the cross clamp is applied to the ascending aorta. Cross clamp of the aorta is a critical point during the retrieval process, and the expertise and support of everyone involved is required to ensure the warm ischaemic time is kept to a minimum. Cardioplegia is delivered, asystole induced and ventilation discontinued.

The Whittington anaesthetist is no longer required by the retrieval team but may choose to observe the rest of the procedure for education/experience.

2. Donation After Brain Death including cardiothoracic retrieval:

The retrieval team will bring their own anaesthetist or cardiothoracic physiologist.

The visiting cardiothoracic team will need to spend about one hour assessing and optimising the donor before retrieval begins.

Cardiothoracic team will assess the donor:
- Identification, examination, data collection
- Cardiac output studies & TOE
- Bronchoscopy, BAL
- Possible research studies if consented

The cardiothoracic team will then manage the donor:
- Hormone therapy T3, vasopressin, insulin, methylprednisolone
- Cardiac output optimisation with fluids +/- inotropic support
- Respiratory / ventilatory optimisation

Retrieval surgery will start after initial assessment. In principal the Whittington anaesthetist is responsible for routine care of the multiorgan donor during the operation until the cross clamp of the aorta, while the visiting anaesthetist performs the special investigations and functions in collaboration and co-operation with the home anaesthetist.

Summary of the responsibilities of the Whittington anaesthetist:

1) Take over care from the ICU team and transfer the donor to theatre
2) Continue invasive monitoring (arterial line) and assist the visiting anaesthetist with line placement – CVC (if not present) and PA catheter
3) Continue mechanical ventilation and work with the visiting anaesthetist to optimize respiration
4) Assist with transfer of monitoring to retrieval team setup if considered necessary
5) Assist the visiting anaesthetist with optimal haemodynamic management
6) Administer muscle relaxation to prevent spinal reflexes
7) Assist with heparin administration
8) Assist with administration of antibiotic therapy and steroids if required
9) Provide blood sampling

Intra-operative donor management – general principles:

The same general donor management principles apply as with DBD without full cardiothoracic retrieval (See above).

3. Donation After Cardiac Death excluding lung donation:

The Whittington anaesthetist will need to transfer the patient to the anaesthetic room and withdraw support . The method of treatment withdrawal will have already been discussed with the Consultant Intensivist (it usually involves discontinuing inotropes and extubating the patient). The patient should already be on the end of life care pathway (and will have an opiod infusion running). The role of the anaesthetist is to withdraw support and prescribe/administer any interventions required to ensure a comfortable and dignified death. For example, this may involve palliation drugs or suction therapy. The patients nurse will be in attendance to support the anaesthetist and help provide end of life care.The role of the

SNOD at this point in time is to monitor the patient and support the family (along with the patients nurse).

Death can be confirmed by cardiopulmonary criteria after 5 minutes of asystole. During this five minute ‘stand off’ time, the family can remain with the patient. There should be no electrical activity on the ECG, and if sporadic QRS complexes are observed, the five minute ‘stand off’ time is repeated (this is to ensure public confidence and eliminate the theoretical risk of autoresucitation). If death does not appear to be imminent, after discussion with the SNOD, the anaesthetist may leave the anaesthetic room as long as a contact bleep number is given and a plan to return at once should the patient suddenly deteriorate should be made.

Once death is certified, the SNOD will ask the family to leave the anaesthetic room and the patients nurse will go with the family (to offer support and help show the way back to the relatives room).

Following the confirmation of death the donor will then be moved into the theatre, transferred onto the table, skin prepared and knife to skin incision made **with a degree of haste** in an effort to shorten the warm ischaemic time. Once the donor is safely transferred onto the operating table, the Whittington anaesthetist is no longer required but may choose to remain to observe the process for education/experience.

4. Donation After Cardiac Death including lung donation:

Same procedure as above. However, successful lung donation requires reintubation after the diagnosis of death and before the start of abdominal retrieval to protect the lungs from aspiration. Intubation and re-inflation of the lungs is always performed once the donor has been transferred onto the operating table, by using the application of a recruitment manoeuvre that does not involve mechanical ventilation – for example, by applying a high level of CPAP (such as 40cmH2O) for 40 seconds followed by the maintenance of 5 cmH2O. Cardiothoracic surgeons will guide the anaesthetist with the specifics - as long as there is no cyclical reinstitution of mechanical ventilation exclusion of the cerebral circulation is not necessary.

Summary of Advice for Whittington Anaesthetists

NB these cases must always be discussed with the consultant on call

Donors	Whittington Anaesthetic Team	Retrieval cardiothoracic Team
DBD **With heart/lung donation**	Transfer patient to theatre. IPPV and circulatory support until cross clamp. Consider positioning, ventilation, anaesthesia, steroid/antibiotics, heparin, blood sampling.	Assessment and management Includes PAC, TOE, Bronchoscopy, inotrope & hormone therapy
DBD **No heart/lung donation**	Transfer patient to theatre. IPPV and circulatory support until cross clamp. Consider positioning, ventilation, anaesthesia, steroid/antibiotics, heparin, blood sampling.	Not present
DCD **With lung donation**	Transfer patient to theatre. Withdraw support in anaesthetic room. Prescribe/administer PRN. Confirm death. Re-intubate and re-inflate lungs. Transfer to theatre.	Not present
DCD **Without lung donation**	Transfer patient to theatre. Withdraw support in anaesthetic room. Prescribe/administer PRN. Confirm death. Transfer to theatre.	Not present

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval

		Yes/No	Comments
1.	**Does the procedural document affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the procedural document likely to be negative?**	No	
5.	**If so can the impact be avoided?**	N/A	
6.	**What alternatives are there to achieving the procedural document without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Director of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact the Director of Human Resources.

Checklist for the Review and Approval of Procedural Document

To be completed and attached to any procedural document when submitted to the relevant committee for consideration and approval.

	Title of document being reviewed:	Yes/No	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is it clear that the relevant people/groups have been involved in the development of the document?	Yes	
	Are people involved in the development?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
5.	**Evidence Base**		
	Are key references cited in full?	N/A	
	Are supporting documents referenced?	N/A	
6.	**Approval**		
	Does the document identify which committee/ group will approve it?	Yes	
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to	Yes	

	Title of document being reviewed:	Yes/No	Comments
	support the monitoring of compliance with and effectiveness of the document?		
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Executive Sponsor Approval			
If you approve the document, please sign and date it and forward to the author. Procedural documents will not be forwarded for ratification without Executive Sponsor Approval			
Name		Date	
Signature			
Relevant Committee Approval			
The Director of Nursing and Patient Experience's signature below confirms that this procedural document was ratified by the appropriate Governance Committee.			
Name		Date	
Signature			
Responsible Committee Approval – only applies to reviewed procedural documents with minor changes			
The Committee Chair's signature below confirms that this procedural document was ratified by the responsible Committee			
Name		Date	
Name of Committee		Name & role of Committee Chair	
Signature			

Tool to Develop Monitoring Arrangements for Policies and guidelines

What key element(s) need(s) monitoring as per local approved policy or guidance?	Who will lead on this aspect of monitoring? Name the lead and what is the role of the multidisciplinary team or others if any.	What tool will be used to monitor/check/observe/Assess/inspect/ authenticate that everything is working according to this key element from the approved policy?	How often is the need to monitor each element? How often is the need complete a report ? How often is the need to share the report?	What committee will the completed report go to?
Element to be monitored	**Lead**	**Tool**	**Frequency**	**Reporting arrangements**
Monitoring all potential and actual organ donors	**James Van Der Walt**	**Audit of all potential donors (DBD's and DCD's)**	**Monthly** **Written reports every 6 months**	**Organ donation committee meetings every 3 months** **QI/clinical audit committee**