

INTENSIVE CARE SOCIETY

Guidelines for Adult Organ and Tissue Donation

Prepared on behalf of the Intensive Care Society by the Society's Working Group on Organ and Tissue Donation

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1. Basic organisation - a synopsis

The purpose of this manual is to assist critical care medical and nursing staff manage the events which take place when a dying adult patient is a potential organ or tissue donor and to provide a template for creating local guidelines. This guidance offers consensus opinion as to how best manage issues surrounding organ donation in adult critical care units. The guidance is not meant to dictate practice but rather offer suggestions as to what might be considered reasonable practice.

1.1 *The Success of Organ Donation and Tissue Transplantation*

Organ and tissue transplantation is one of the major medical success stories of our time. The first reported corneal graft took place in the Czech Republic in 1905. In 1954, Dr Joseph Murray performed the first successful kidney transplant between two identical twins in Boston, USA. Since then, well over a million people worldwide have had their lives saved or their quality of life improved by an organ transplant. Many more will benefit from a tissue transplant. In the UK during 2003-04:

- 2684 solid organs were donated from 772 deceased donors
- 468 living donors donated organs
- 10,000 people donated tissue
- 1644 additional people donated corneas
- 321 people received heart and/or lung transplants
- 686 people received a liver transplant
- 1838 people received a kidney transplant
- 12 people received a pancreas-only transplant
- 2365 people had a corneal graft.

Results of organ transplantation continue to improve every year and in general approximately 90% of transplant recipients will be alive and well after 1 year. This success has led to our current situation where the demand for organs (and in some cases tissues, particularly corneas and bone) currently outstrips supply. This is a particular problem for people from minority ethnic groups as they have a different distribution of blood groups and a wider variety of tissue types but far fewer donors. Certain ethnic groups also have a higher incidence of diseases requiring transplantation (e.g. chronic renal failure in patients of Asian origin). At the end of 2003-04 there were 5673 people in the UK on the national list for an organ transplant; during the year, 401 people died before a new organ became available. The NHS can only meet the need for organs and tissues for transplantation if:

- The public is aware of the possibilities of donating organs and tissues, and are willing to do so.
- Healthcare staff, particularly critical care teams, identify all potential donors.
- Skilled transplant professionals retrieve high quality organs and tissues and use them effectively.

In the UK there are currently 26 adult NHS renal transplant units, 7 liver transplant units and 7 cardiothoracic transplant units. In addition, other surgeons perform well over 10,000 surgical procedures involving tissue transplants.

The Department of Health's policy for the development of transplant services in England is set out in *Saving Lives, Valuing Donors, A Transplant Framework for England*. This aims

to increase organ donation and transplant rates by investing in programmes aimed at maximising both living and cadaveric organ donation. A similar document, *An Organ Donation Strategy for Scotland*, was produced by the Scottish Transplant Group in June 2002².

There is growing evidence of psychological benefit to those close to the deceased if organ or tissue donation has taken place³. If donation is not possible, then it helps to have been given a clear explanation why it was not possible. It is therefore very important to try to ascertain the wishes of both those dying on a critical care unit and/or those close to them about organ and/or tissue donation.

1.2 People who are potential organ donors

1.2.1 Potential Organ Donors

Almost anyone dying in hospital is a potential organ or tissue donor. Corneas can be retrieved and used successfully from patients aged over 80 and kidneys have been successfully transplanted from 80-year-old donors with good renal function. The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) provides national guidance on donor evaluation and testing⁴. This guidance is updated from time to time on their website and the donor transplant co-ordinator will be aware of the latest advice and guidance. The Council of Europe has produced more comprehensive guidance on safety and quality assurance⁵. Essentially, the guidance sets out criteria for screening potential donors so as to identify the risk of transmission of disease from donor to recipient. In the case of tissue donors, the results may rule out the person as a donor. However, this is rarely the case for potential organ donors for whom there are very few absolute contraindications, e.g. certain cancers or a confirmed diagnosis of Human Immunodeficiency Virus (HIV) or known or suspected classical or variant Creutzfeldt-Jacob Disease (CJD). Even patients with known transmissible conditions may be able to donate organs if there is a recipient for whom the risk is worth taking.

1.2.2 Heart beating (HBD) and non-heart beating donors (NHBD)

When transplantation started, all organs were retrieved from patients immediately following cardiorespiratory arrest, i.e. “*non-heart beating*” donors. Following the recognition that death resulted from irreversible damage to the brain stem, and the introduction in 1976⁶ of direct brain stem testing to determine when death has occurred, organ retrieval rapidly switched (except for a very few centres) to patients certified dead following brain stem testing. These “*heart beating*” donors have become the principle source of organs for transplantation for the last 25-30 years. There have been many initiatives aimed at maximising the procurement of organs from HBDs, one of which is the model used in Spain⁷.

Potential HBDs are patients in unresponsive apnoeic coma (Glasgow Coma Score 3) resulting from an identifiable irreversible cause. This may occur under a variety of circumstances but is often associated with traumatic brain injury or intracranial haemorrhage. Before organ/tissue donation can proceed, the patient must have been declared dead following brain stem testing.

A critical care unit in an average sized district general hospital may admit only 5 or 10 patients annually who are potential organ HBDs. The largest critical care units in the UK

with neurosurgical admissions will only look after a maximum of 25-30 potential donors annually. As a result, although the concept of organ donation and transplantation is well recognised, donation and retrieval procedures are not frequent even in large general critical care units.

The number of HBDs is declining and this is likely to continue for two reasons. Fewer younger people are dying as a result of severe injury or catastrophic cerebrovascular events⁸. This together with changes in diagnosis and management of severe brain injuries means that fewer critically ill patients will fulfil the brain stem testing criteria. At present, death is increasingly likely to follow withdrawal of active treatment and so in the future, NHBDs are likely to become critical to the maintenance of organ transplant programmes.

The results from transplantation of kidneys from NHBDs from Leicester, Newcastle, Maastricht and a number of other centres has been reviewed⁹. Although kidneys from NHBDs may be slow to function, the 5-year results from a successful transplant are the same as for kidneys from HBDs. Early results of liver transplants from NHBDs are encouraging and there is growing evidence that lungs can also be transplanted successfully.

Potential NHBDs are principally those patients in critical care units for whom continued treatment is judged to be futile, and it has been agreed that active medical treatment should be withdrawn. The number of such potential donors is uncertain but plans to audit the potential numbers are in place. Organ and/or tissue donation can proceed once death has been certified following cardiorespiratory arrest.

Corneas, bone and skin can be donated up to 24 hours, and in some cases heart valves up to 48 hours, after death and, therefore, may be donated by HBDs or NHBDs.

1.3 The Role of the Donor Transplant Co-ordinator

1.3.1 Education

The donor transplant co-ordinator has an important educational and supportive role for all health care professionals, particularly those working in critical care areas, and for the families of potential organ and tissue donors. The concept of the diagnosis of death by brain stem testing, the criteria for suitability for donation, the management of the donor in critical care, support for staff and the management of bereavement may be dealt with through structured teaching and informal discussion.

1.3.2 Donor referral

It is essential that the donor transplant/tissue co-ordinator is informed of all potential donors as early as possible so that any retrieval can be conducted in a timely fashion. The co-ordinators are best placed to ascertain suitability of potential donors and provide advice to staff on donor identification and clinical management. Notifying the donor transplant co-ordinator will ensure that those closest to the potential donor are informed of the option for organ and/or tissue donation. However the relatives of HBDs should not be formally approached until after the first set of brain stem tests has been performed unless the topic of organ donation has already been raised by the relatives during discussions about the patient's likely outcome. Early referral will also ensure that the donor transplant co-ordinator is able to attend the referring unit at an early stage to facilitate the organ donation process.

1.3.3 The request for donation of organs and/or tissues for transplantation

The request for donation of organs and tissues for transplantation may be made by either medical or nursing staff or by the donor transplant or tissue co-ordinator. However, evidence from the USA and some areas of the UK has demonstrated that when a collaborative approach is made to the family by the patient's clinician and the donor transplant co-ordinator higher consent rates are achieved. In the interests of good communication, it should be decided at an early stage, who will be making the request so that he/she can be involved in the process of discussion and explanation.

1.3.4 Local guidelines

Local guidelines should be developed through discussion between the critical care and laboratory consultant staff and the donor transplant co-ordinator regarding the organisation of haematological and biochemical investigations for potential donors. Some are not carried out on a routine basis, nor out of hours (e.g. liver function tests, serum amylase and possibly drug concentrations if indicated).

1.3.5 The process

The process of donation may be lengthy and requires close liaison between the referring and retrieving hospitals. It is vital that a potential HBD receives comprehensive physiological support so that donated organs remain in optimal condition. An organ that has been retrieved and transplanted in a suboptimal condition is a major cause of graft failure. The donor operation takes place in an operating theatre at the referring hospital and is performed by surgeons from the retrieving hospital. Retrieval teams normally bring all the equipment and staff they need although at present this may not routinely include an anaesthetist. A local anaesthetist/intensivist often provides valuable liaison between visiting teams and operating theatre staff and expert practical assistance during the operation. It is hoped that in the future an anaesthetist/donor care practitioner will routinely accompany the retrieval team.

1.3.6 The provision of follow-up information

The donor transplant co-ordinator will offer the donor's family the opportunity to be informed of the outcome of the transplant operations and give continuing support if required. Staff involved in the donation will also receive information about the outcome of the donation. Confidentiality will be maintained. Critical care staff who have cared for the donor and their family may also make a significant contribution to such after care.

1.4 Critical Care Unit Transplant Link Nurse/Donor Liaison Nurse

Involvement of critical care medical and nursing staff in the organisation of organ donation enhances the relationship between them and the patient's family and friends and is also an important educational exercise. A link nurse (i.e. a local critical care unit nurse who can act as the link with the donor transplant co-ordinator), a donor liaison nurse (who is funded by UK Transplant through the Donor Liaison Schemes) or an in-house donor transplant co-ordinator have an important role through the dissemination of information to medical and nursing staff and revision of local guidelines. They should communicate regularly and update the following hospital departments regarding the management of organ donation:

- intensive care units
- high dependency care units
- Accident and Emergency Departments
- specialist areas such as neurosciences departments

- operating theatres
- laboratory services
- HM Coroner /Coroner's Officers or Procurator Fiscal
- hospital chaplains
- bereavement agencies and patient support services
- staff support services
- hospital porters
- telephone switchboard

1.5 The role of the Coroner/Procurator Fiscal

The Coroner/Procurator Fiscal has a legal responsibility to investigate deaths which appear to be unnatural, due to violence, or to be sudden and of unknown cause. Coroners are judicial officers in England, Wales and Northern Ireland; in Scotland, the nearest equivalent role is carried out by the Procurator Fiscal. Where an inquest is to be held, the principle purpose is to establish “how the deceased came by their death”.

All deaths that cannot be properly certified by a doctor have to be reported to the Coroner (see Appendix 1). The Coroner cannot give consent for organ or tissue donation but can agree to organ or tissue donation proceeding if s/he believes that organ/tissue donation will not interfere with their legal responsibilities to establish the cause of death. For the Coroner, the principle concern will be to establish whether there are any grounds for an inquest. There will, for example, be concern to ensure that the circumstances of the death are understood and that any relevant evidence is preserved. Since only good quality organs can be used for transplantation, any organ implicated in the death would not normally be suitable for donation.

Enquiries about a death are usually made by a Coroner’s Officer on behalf of the Coroner. Coroner’s Officers can be contacted out of normal working hours via the local police station. However, it may be advantageous to develop a formal local 24 hour contact protocol with the Coroner’s Officers so that direct notification is possible. A Coroner may have instructed this officer to raise no objections to the removal of tissues in most cases. If removal of material for donation is refused by the Coroner’s Officer, it may be appropriate to seek confirmation that the decision has been taken personally by the Coroner.

In most circumstances, the Coroner will be able to allow organ or tissue donation to proceed if presented with the relevant information (see Appendix 2 for checklist and information to be collected for the Coroner), and steps are taken to preserve possible evidence. The Coroner/Coroner's Officer may ask the hospital and/or transplant team to take further action to safeguard the judicial process. This may include:

- making notes, or taking photos, of any external injuries
- collecting blood or urine samples for toxicology
- taking samples (e.g. hair, nails or swabs of the genital area)
- supplying a note of the retrieval procedure
- providing reports on the use of any organs or tissues retrieved (e.g. that they functioned well in the recipient).
- having a home office pathologist present during the retrieval procedure.

Further information about the role of the Coroner can be obtained from the Coroners' Society (<http://www.coroner.org.uk/public/>) and for the Procurator Fiscal in Scotland, from the Crown Office (<http://www.procuratorfiscal.gov.uk/>). The future role of the Coroner is currently under review and practices may change in the near future.

1.6 Determination of Death

There are two ways that death can be determined.

For people suffering cardiorespiratory arrest (including failed resuscitation), death can be certified as usual by a registered medical practitioner following cessation of heart and respiratory activity. The doctor has to be certain that, in a normothermic patient, there has been inadequate circulation to the brain for long enough to ensure that there has been irreversible damage to the vital centres in the brain stem.

For potential NHBDs, it is desirable that a medical practitioner with appropriate training and experience certifies death following a minimum of 5 minutes of cardiorespiratory arrest¹⁰.

In the case of determination of death by brain stem testing, medical practitioners must follow the Code of Practice issued by the Department of Health in 1998¹¹ (see *Section 4*).

1.7 The Person Lawfully in Possession of a Body in a Hospital - The Human Tissue Act

The Human Tissue Act (1961) stipulates that the person in lawful possession of the body must authorise the removal of organs or tissue for transplantation. Where a body is in a hospital or other institution, the person with lawful possession is the person "having control or management of the institution" (i.e. the Chief Executive) or "any person designated for that purpose..." until such time that the body is claimed, for the purposes of disposal, by the next of kin, executor or Coroner or Procurator Fiscal. This will normally be the duty manager, or anyone nominated by hospital management who does not have a conflict of interest.

The Human Tissue Bill was introduced into Parliament in December 2003. If passed, it will clarify what is "appropriate consent" to organ and tissue donation and how it may be authorised. It will also establish a Human Tissue Authority which will be required to prepare Codes of Practice covering, among other things, organ and tissue donation. It is hoped that this will clarify many areas of practice.

References

1. Saving Lives, Valuing Donors, A transplant framework for England. London: Department of Health, July 2003 (www.doh.gov.uk/transplantframework).
2. Scottish Transplant Group. An Organ Donation Strategy for Scotland. Edinburgh: Scottish Executive Health Department, June 2002 (www.show.scot.nhs.uk).
3. Sque M, Long T. Organ and tissue donation: Exploring the needs of families. Report to the British Organ Donor Society and National Lottery Community Fund, February 2003.

4. Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used for Transplantation. London: Department of Health, August 2000 (www.doh.gov.uk/msbt).
5. Guide to safety and quality assurance for organ, tissues and cells. Council of Europe, July 2003 (www.coe.int).
6. Conference of Medical Royal Colleges and their Faculties in the United Kingdom. Diagnosis of brain stem death. Lancet 1996 ii: 1069-70.
7. Meeting the Organ Shortage, Transplant Newsletter 2001, published on behalf of the Council of Europe by Fundacion Renal, Madrid.
8. Death rate trends for RTAs and CVAs, WHO European Health for All database – <http://www.euro.who.int/hfadb>.
9. Nicholson M. Kidney Transplantation from Non-heartbeating Donors, The National Kidney Research Fund, Peterborough, 2002. ISBN 1-904227-02-3.
10. Non-heartbeating Organ transplantation: Practice and protocols. Institute of Medicine, National Academy Press, Washington DC, Jan 2000. ISBN 0-309-06641-7 (<http://www.nap.edu/books/0309066417/html/>).
11. A Code of Practice for the Diagnosis of Brain Stem Death, Department of Health, March, 1998.

Appendix 1

REFERRAL TO HM CORONER

Death should be reported to the Coroner if the death cannot be certified as being due to natural causes. Death should also be referred under the following circumstances:

1. Might injury have played a part?

Such injury may have been inflicted by another person, by the deceased himself or herself, or may have arisen as the consequence of an "accident", be it at home, at work, in the street, or in hospital.

"Delayed complications" of injury, such as pneumonia following fractured neck of femur, or pulmonary thrombo-embolism following surgery, should be regarded as a consequence of injury.

It matters not when the injury occurred - for example, septicaemia from urinary tract infection in a paraplegic patient following a spinal injury should be referred to the Coroner even if that original injury occurred decades before death. If the death is a consequence of injury it should be referred to the Coroner.

2. Might any toxic substance be involved?

This includes any death which results from the immediate or delayed actions of any drug or poison, be the drug therapeutic or recreational (including alcohol). The circumstances may include poisoning by another individual, by the deceased himself or herself, by accident or by intention. Fatal "allergic reactions" (e.g. anaphylaxis) to therapeutic drugs should be referred to the Coroner.

3. Might there be something unnatural causing or accelerating the death?

This should be considered carefully where the death is wholly unexpected albeit from natural causes **and** where the possibility exists that someone (or some institution) may be blamed. For example, even if the cause of death is established, if there are allegations of poor or inappropriate treatment or inappropriate delay before treatment or diagnosis, such deaths should be referred to the Coroner. Any death which occurs during surgery or before the recovery from anaesthesia should be referred to the Coroner. Also any death from a disease contracted during the course of employment should be referred to the Coroner; this includes pneumoconiosis.

4. Is there evidence that neglect on the part of any person or any institution has played a part?

Such neglect may be on the part of the individual himself or herself (e.g. a person admitted with hypothermia) or on the part of a "carer" (e.g. where an elderly person is admitted from a nursing home with multiple bed sores and poor nutrition without adequate explanation). Such patients may die in hospital when those conditions have been treated. Therefore there may be a lengthy time interval between admission and death, which supervenes from other causes: it is important to consider the complete history relating to the admission.

5. Was the deceased "in custody" at the time of admission or death?

If a patient has been admitted from prison to hospital the death should be referred to the Coroner. Where death appears to arise from an incident following arrest or pursuit by

police officers, that death should be referred to the Coroner. When a person dies during detention under the Mental Health Act it is wise to refer such a death to the Coroner, if only to allay suspicion.

6. Is there no clinical history or evidence to satisfactorily establish the cause of death?

If there is uncertainty as to the cause of death, the death should be reported to the Coroner. This may be the case in many potential "uncontrolled" NHBDs in Accident and Emergency Departments.

Appendix 2

A checklist for healthcare professionals when the death of a potential organ or tissue donor may need to be referred to the Coroner. In certain circumstances, particularly possible criminal deaths, it may be preferable to contact the Coroner before approaching the relatives. An information summary sheet is given at the end of the appendix.

The referring clinician prior to certifying death could check and document the following:

Action	Date and Time	Details
Hospital staff identify potential donor		<i>Name, age, etc.</i>
Contact donor transplant co-ordinator		
Organ Donor Card?		<i>Yes/No</i>
On the Organ Donor Register?		<i>Yes/No</i>
Is there an advanced directive or other evidence of objection?		<i>Yes/No</i>
Clarify circumstances of death		<i>Complete Coroner Information form (see below). Has an admission blood and/or samples been taken and stored for drug or alcohol levels if clinically indicated?</i>
If a Coroner's case		<i>Complete next sections</i>
Initial donor evaluation		<i>Possible organs/tissues for donation?</i>
Those closest to the deceased that have been identified/contacted		<i>Details name/relationship Contact details</i>
Have deceased's relatives any objections to donation?		<i>Yes/No Do relatives understand need to involve Coroner?</i>

The donor transplant co-ordinator could undertake the following at around the time of death prior to organ retrieval:

Action	Date and Time	Details
Confirm donor information and probable suitability		<i>Which organs? Which tissues? For therapeutic purposes or for research only?</i>
Coroner's requirements for safeguarding the judicial process		<i>List of requirements (e.g. external examination, photos, blood, urine, hair and nail samples)</i>
Compliance with Coroner's requirements		<i>Fully document samples</i>
Destination and use of all organs and tissues		<i>Details sent to Coroner? Yes/No</i>

The transplant surgeon could undertake the following after organ retrieval:

Action	Date and Time	Details
Has transplant surgeon retrieving organs recorded procedure in medical notes?		<i>Yes/No</i>
Transplant surgeon's follow on report sent to Coroner		<i>Yes/No</i>

Information for the Coroner

Information given to the coroner when seeking agreement to organ or tissue donation should be as full as possible and include:

- Full details of the circumstances leading to admission and death.
- Whether the incident leading to admission occurred in another area (i.e. whether the patient was transferred from another hospital); the Coroner may wish to transfer jurisdiction at a later date.
- Whether the police are involved and details of the officer handling the case.
- Whether the dead person's views on organ and tissue donation are known.
- Whether those close to the dead person, and their views on organ and tissue donation, are known.
- Whether this donation will be heart beating or non-heart beating (i.e. whether perfusion is required).
- Which organ(s) and/or tissue(s) are considered suitable for donation and for what purpose.
- What is the maximum permissible interval between death and tissue retrieval (this will be important out of normal working hours to ensure that if retrieval is to be made by the pathologist the post-mortem examination can be organised to take place within that interval).

It will usually be helpful to collect the information systematically by use of a suitable form such as the following example.

NB. This information is collected to help the Coroner make an informed decision about organ/tissue donation, not as evidence for any possible legal proceedings. Information for evidential purposes should be collected in the normal way.

CORONER'S INFORMATION FORM

The following information is helpful when contacting the Coroner at the time of an initial request to retrieve organs or tissue from a potential organ or tissue donor:

Hospital: _____ Transferring Hospital: _____

Donor's name: _____ Age: _____ Sex _____ Ethnic background _____

Hospital/NHS No: _____

Date and time of presenting illness/accident _____

Apparent cause: RTA _____ Other accident _____
 Suicide _____ CVA _____
 Assault _____ Undetermined _____

Brief description of circumstances surrounding the admission:

Police Force involved if known _____ Phone: _____

Name of investigating officer if known _____

Family/friends present _____ or contacted - Phone: _____

Relationship to donor _____ Address: _____

Other witness(es) _____

Coroners Office contacted: _____ Date/Time _____

Organs requested: Heart ___ Intestine ___ Kidneys ___ Liver ___
 Lungs ___ Lymph nodes ___ Pancreas ___ Spleen ___

Tissue requested: Bone ___ Eyes/corneas ___ Heart for valves ___ Menisci ___
 Saphenous veins ___ Skin ___ Tendons ___

Relatives' agreement for organ removal: obtained/ **NOT** obtained

Time and date agreement obtained: Time:_____ Date:_____

If request to Coroner refused, document reason given for refusal:

2. Criteria for organ donation

2.1 General Criteria for Organ Donation

Any patient who meets the following criteria should be considered for organ donation and their family or carers should be offered this option if:

- the patient has suffered major and irreversible neurological damage leading to brain stem death or alternatively whose condition is such that continuing critical care is considered futile and withdrawal of treatment is being considered.
- the patient is HIV negative.
- the patient is not known or suspected to have CJD.

There are no absolute age restrictions although solid organs are rarely retrieved from donors over 80 years of age. Specific criteria may apply in non-heart beating donation; further advice will be available from the donor transplant co-ordinator.

2.2 General Criteria for Tissue Donation

The criteria for tissue donation with respect to both age and medical suitability vary depending on the tissue to be donated. Tissues that can be donated include:

- Eyes for corneal and sclera donation
- Heart for heart valve donation
- Bone
- Tendons
- Menisci
- Skin

Absolute contraindications for tissue donation include patients who have ever:

- tested positive for HIV, hepatitis B, hepatitis C, human T cell lymphotropic virus (HTLV) or syphilis or have high risk behavioural factors for contracting these infections.
- suffered from or have evidence of CJD or a family history of CJD.
- had a progressive neurological disease of unknown pathophysiology, e.g. multiple sclerosis, Alzheimer's Disease, Parkinson's Disease, motor neurone disease.
- suffered from leukaemia, lymphoma or myeloma.
- had a previous transplant requiring immunosuppressive treatment.

Individuals suffering from systemic malignancies are also contraindicated in tissue donation except in the case of eye donation where donation is acceptable. Tissue can be retrieved up to 24 hours after circulatory arrest except for heart valves which can be retrieved up to 48 hours after circulatory arrest.

If there is doubt as to whether a patient is a potential donor, the local donor transplant co-ordinator should be contacted before the patient is declared unsuitable. Further information about the suitability of a potential tissue donor can also be found on the following web sites:

- Royal College of Ophthalmologists - www.rcophth.ac.uk
- National Blood Service - www.blood.co.uk

2.3 Donor Assessment – Documentation and Accountability

The process of offering and allocating organs from potential donors is done through UK Transplant. A potential donor should be registered with UK Transplant when:

- the first set of brain stem tests confirm brain death in potential HBDs.
- the potential donor previously expressed willingness to donate organs.
- the donor transplant co-ordinator has spoken to the family/next-of-kin and gained written 'lack of objection' to NHBD.

Registration is done by the donor transplant/tissue co-ordinator normally once s/he has undertaken a risk assessment in accordance with Microbiological Safety of Blood and Tissues for Transplantation Guidance. In order to fully assess such risks, it is important to obtain as much information as possible about the potential donor. This is obtained from the medical notes, clinicians, family, general practitioner and by examining the potential donor for tattoos, previous surgery or evidence of intravenous drug abuse.

All evidence of possible risk of disease transmission must be reported to the transplant team responsible for the recipient and/or tissue bank. In the case of a tissue bank, the material may be held in quarantine until all the relevant information has been obtained and a decision can be made to accept or reject the material.

2.4 Pathways of care

The non-clinical management of patients prior to organ or tissue donation is shown below as flow diagrams and an expanded checklist.

The process for organ donation in patients certified dead by brain stem testing (BST)

Donor Identification
Up to 85 years of age
Planned for brain stem testing

Absolute contraindications include:

HIV infection, known or suspected CJD

Discuss all potential donors with the donor transplant co-ordinator

Present

Donation is not possible if there are absolute contraindications or no Coroner's consent

No

Permission granted?

Yes

Contact the Coroner or his Officer to obtain permission for donation

Yes

Is the patient to be referred to Coroner?

No

- Legal time of death is at the first set of brain stem tests
- The donor transplant co-ordinators will document lack of objection to donation from the family
- Donor assessment undertaken by donor transplant co-ordinator
- Donor registered at UK Transplant

- The family is supported throughout this process, by the donor transplant co-ordinator and the critical care staff.
- An appointment will be made by the hospital for the family to see the hospital bereavement service.

Organ retrieval takes place in the theatre. The family may see their loved one following donation and are offered follow-up by the donor transplant co-ordinator.

Remember the donor transplant co-ordinator is always available for advice at any time during this process

The process for controlled non-heart beating donation (NHBD) in the ICU

Donor Identification

Discuss possible age restrictions with donor transplant co-ordinator
Planned withdrawal of treatment

Absolute Contraindications include:

HIV infection, known or suspected CJD

Discuss all potential donors with the donor transplant co-ordinator

Present

Absent

Donation is not possible if there are contraindications or no Coroner's consent

No

Telephone your donor transplant co-ordinators

- Discuss the option of non-heart beating organ donation with the family
- Once contacted the donor transplant co-ordinator will attend to discuss the options with the family and critical care staff

Permission granted?

Contact the Coroner or his Officer to obtain permission for donation

Is the patient to be referred to Coroner?

Yes

Yes

No

- The families are informed of the procedure for NHBD, lack of objection documented by the donor transplant co-ordinator
- Donor assessment undertaken by donor transplant co-ordinator
- Arrangements made for the withdrawal of treatment with the family and critical care staff
- Organ retrieval teams on-site and prepared in the operating theatre

- Treatment is withdrawn and the families are supported throughout this process
- After five minutes observation of cessation of cardiorespiratory function, death is certified by the critical care medical staff and documented in the medical notes

Organ retrieval takes place in the theatre. The family may see their loved one following donation and are offered follow-up by the donor transplant co-ordinator

Remember the donor transplant co-ordinator is always available for advice at any time during this process

The process for tissue donation

Donor Identification

Age restrictions do apply
(Discuss with tissue or donor transplant co-ordinator)

Absolute contraindications:
HIV, Hepatitis C or B, Human T cell lymphocytotropic virus, Syphilis,
known or suspected CJD
or at risk of having any of the above.
Have a central nervous disease of unknown aetiology.
Diagnosis of leukaemia, lymphoma or myeloma.
Have Alzheimer's or an unexplained confusional state.

Present

Donation is not possible under these circumstances

Absent

Discuss tissue donation options:
Corneas, Heart Valves, Skin, Bone.
Almost anyone can donate one of the above
Contact your local donor or tissue transplant co-ordinator to ascertain what options are available.

No

It is important to document the relative's lack of objection to donation.
Specify what the families have agreed to donate.
It is preferable to have a relative's signature with the lack of objection statement.
Photocopy lack of objection, which should accompany the body of the deceased to the mortuary

Permission granted?

Yes

Contact the Coroner or his Officer to obtain permission for donation

Yes

Is the patient to be referred to Coroner

No

Contact the donor or tissue transplant co-ordinator
You will need to have the following information ready.

For the deceased: Their name, date of birth, the time and date of death, the cause of death, details of past medical history and any medications taken and GP details.

For the next of kin: Their name, address and a phone number where they can be contacted. The relative should be informed that the donor or tissue transplant co-ordinator will call them before the donation can proceed. They will be asked a few simple questions about past medical and social history. The family will have the opportunity to ask any questions and decide if they would like to know the outcome of the donation.

Remember the donor or tissue transplant co-ordinator is always available for advice at any time during this process.

Checklist for the co-ordination of organ donation

The donor transplant co-ordinator provides liaison between the critical care team and the retrieval team. A checklist may be constructed to ensure that all preparations have been completed. Most of these will be undertaken by the donor transplant co-ordinator who will liaise between the different members of the multidisciplinary team.

1) Donor Transplant Co-ordinator

Inform the donor transplant co-ordinator as early as possible that a patient is a potential organ donor. Ensure that the donor transplant co-ordinator is satisfied that no medical or other contraindications exist.

2) Consultant Responsibility

Ensure that the consultant intensivist and the consultant under whose care the patient was originally admitted are aware of the situation. One of these two people should take part in the discussion with the patient's relatives, regarding the certification of death and the option for organ/tissue donation.

3) Family

Ensure that the family understand the implications of death of the brain stem or the concept of futility of further medical intervention and the reasons for withdrawing treatment.

4) Coroner/Procurator Fiscal

Inform the Coroner or Procurator Fiscal if necessary (see *Section 1 Appendix 1*).

5) Death

Establish and record the certification of death either after brain stem testing or following cardiorespiratory arrest.

6) Donor Management

Read Section 5 of this manual "Clinical management of the potential organ donor".

7) Laboratory Investigations

Obtain and record up-to-date results of the following clinical investigations after the first set of brain stem tests for HBDs or after the decision to withdraw treatment has been made for NHBDs:

- haematology: blood group, full blood count, coagulation screen.
- biochemistry: urea and electrolytes, creatinine, liver function tests, amylase, lipids arterial blood gases, cross match four units blood for HBDs.
- cardiology: 12 lead ECG, if heart or lung transplant is anticipated.
- radiology: portable AP radiograph of the thorax if heart or lung transplantation is anticipated.
- tissue typing and virology screening (e.g. HIV, Hepatitis B and C and cytomegalovirus (CMV)).

Some of the results of the investigations listed above may be available at an earlier stage if they were requested as part of the patient's usual clinical management.

8) Telecommunications

Notify the hospital switchboard so that communication between those involved can be correctly channelled. The availability of a direct-dial phone to the critical care unit with outside access is an advantage.

9) Hospital Representative

Inform the person designated to represent the hospital trust. He/she is legally "in possession" of the donor's body after death. He/she will authorise the organ retrieval when satisfied that all medical and legal issues are resolved.

10) Operating Theatre

Notify the operating theatre that organ donation is planned. Speak to the on-site theatre co-ordinator/manager. Offer an approximate timescale if this is known and request that this information be forwarded to subsequent shifts.

11) Retrieval Teams

The donor transplant co-ordinator will organise the arrival of the team. A doctor from the donor's critical care unit should be available to speak to a member of the retrieval team on the phone regarding the condition of the patient and the arrangements for organ retrieval at a local level.

12) General Practitioner

Notify the donor's general practitioner at the earliest opportunity. Family members may require support from their own general practitioners.

13) Family follow-up

Ensure that the family have information for the usual hospital bereavement processes and have contact details of the donor transplant co-ordinator or medical staff should they have any further questions or concerns.

3. Approaching the family

3.1 Making the Request

Some medical and nursing staff may find it difficult to ask a family whether they would be prepared to consider donating the organs/tissues of a close relative for transplantation when such a request comes after a sudden and unexpected tragedy. It is essential that such a request be made thoughtfully and with compassion. It is not unusual for the family to raise the issue of organ/tissue donation themselves.

As for any patient in a critical care unit, the family should be kept well informed of progress with honest and clear predictions of the probable outcome. The concept and implications of death certification by brain stem testing should be explained clearly using simple language. The family should be informed that the first brain stem tests have shown no activity in the brain stem and that a second set of tests will be performed to confirm death. Once confirmed their relative will be certified dead, the time of death being certified as the time of the completion of the first set of tests.

It is prudent to discuss the suitability of the donor with the donor transplant co-ordinator prior to making the request for donation. Some patients will not be suitable for organ or tissue donation, or the Coroner or Procurator Fiscal may withhold permission. Any patient who has died from unnatural causes must be referred to the Coroner or Procurator Fiscal with whom organ donation must be discussed. However, it is unusual for the legal process to prevent donation (see Section 1 Appendices 1 and 2).

For organ donation, discussions with those closest to the potential donor should be face-to-face, if at all possible; these discussions are usually carried out by the donor transplant co-ordinator. There is evidence that such discussions are best held away from the bedside in a quiet area. It is also important to ascertain if there are any religious or cultural preferences that may need to be taken into account. Initial enquiries should establish the relationship of those present to the dying/deceased and lack of objection to organ or tissue donation. The person closest to the potential donor should be shown or read the list of risk factors. They should be asked to state if, to the best of their knowledge, any of the risks apply to the potential donor. They do not have to give specific details and should be given the opportunity to speak in private. However, the potential risks do have to be identified to decide if it is safe for donation to go ahead. If those close to the donor state that they do not believe it to be safe for organ/tissue donation to take place, or are clearly unwilling for donation to proceed, the donation should not go ahead.

Telephone discussions may sometimes be the only option; they are often more acceptable and appropriate if only tissue donation is being requested. If organ or tissue donation cannot go ahead for any reason, those close to the potential donor should be given a clear and considerate explanation as to why it was not possible. In all cases it is good practice to give those closest, a written copy (either at the time or as soon as possible afterwards) of what donation they have agreed to, or an explanation of why donation was not possible.

It is also important to consult the national Organ Donor Register (ODR) before approaching the family, to see if the potential donor is registered as this may help the family with their decision, particularly if they are not aware of their relative's wishes. If a patient is not registered on the Organ Donor Register it does not mean that the patient did not want to be a donor and the option for donation should still be discussed with the family.

The Organ Donor Register can be accessed via the UK Transplant duty office (Appendix 1)

Senior medical, nursing staff or the donor transplant co-ordinator may make the approach to the family. A collaborative approach by both the patient's clinician and the donor transplant co-ordinator has been shown to achieve higher rates of agreement for donation (Appendix 3). The **formal** approach to the family should not be made until after the first set of brain stem tests have been performed and the family have demonstrated an understanding that their relative is dead. For the families of a non-heart beating donor, the approach should not be made until the family have accepted the futility of continuing treatment, the withdrawal of treatment and the imminent death of their relative. If the family are unsure about the decision to donate the donor transplant co-ordinator may discuss the issue further. Some families will refuse the option of donation, perhaps because of knowledge of the wishes of the deceased. The person making the request should not view a refusal as a failure. The family must feel comfortable with the decision. There should be no question of coercion. Organ donation provides considerable solace for families who have suffered a tragedy.

To ensure that the highest ethical practice is maintained when approaching families for organ donation, the following principles are recommended¹:

- **Respect:** Treating the person who has died and their families with respect.
- **Understanding:** Realising that to many parents and families their love and feelings towards the deceased are as strong as they were in life.
- **Lack of Objection:** Ensuring that lack of objection is sought and given on the basis that a person is exercising fully informed choice.
- **Time and space:** Recognising that family members may need time to consider whether to agree to a donation and will not wish to feel under pressure to agree.
- **Skill and sensitivity:** Staff must be sensitive to the needs of the relatives of someone who has died and sufficient staff skilled in bereavement care must be available.
- **Cultural competence:** Attitudes to organ donation, and particularly to the use of organs and tissues after death, differ between religions and cultural groups; health professionals need to be aware of these factors and respond to them with sensitivity. Leaflets about these issues are available from UK Transplant (www.uktransplant.org.uk)
- **A gift relationship:** The recognition that tissue or organs are given as a gift to help others, and so deserve gratitude.

3.2 Issues to discuss with the family

The following issues should always be discussed with the family:

- The donor transplant co-ordinator must establish whether any medical, social or behavioural risk factors exist.
- Although there is no legal requirement for the family to sign a lack of objection form, this is recommended.
- The family may stipulate which organs/tissues may or may not be removed but conditions relating to the potential recipients are not acceptable.
- Tissues for research may only be taken if this has been discussed with the family. Arrangements for the lawful disposal of material once the research is complete must also be described. It is good practice that information sheets for relatives

regarding any research include the option for them to be informed of findings if they want to. Local documentation should contain these aspects².

The timing of the procedure is discussed. The family may be reassured that they will have the opportunity to visit the deceased after donation has taken place, either at the hospital or the funeral directors.

The family are asked if they have specific requirements for last offices. Some will wish to assist in the final care or may wish items to remain with the donor, such as a special item or piece of jewellery. Locks of hair and handprints can also be taken at this time. The position with regard to gamete donation is outlined in Appendix 2.

The surgical procedure is discussed. The family may be reassured that the wound will be neatly sutured and a dressing applied.

References

1. Department of Health. Human Bodies, Human Choices. The Law on Human Organs and Tissue in England and Wales. A consultation report. London: Department of Health, July 2002.
2. Department of Health Research Governance. Section 2:2:3 A Framework for Health and Social Care. 2nd edn. London: Department of Health, 2003.

Appendix 1

ACCESS TO ORGAN DONOR REGISTER

Background

The NHS Organ Donor Register (ODR) may be accessed by donor transplant coordinators, donor liaison nurses and qualified medical and nursing staff from critical care units and other hospital departments. The Organ Donor Register can be accessed via the duty office at UK Transplant 24 hours a day.

1. PROCEDURE FOR ACCESS

- 1.1 Telephone the duty office on 01179 757575 (switchboard) or 01179 757580 (direct line).
- 1.2 You will be asked for the following information;
 - a) Your name and designation
 - b) Reason for request for access
 - c) Name, address (including postcode) and date of birth of potential donor
 - d) NHS number (if known)
 - e) Location of potential donor including hospital name and critical care unit
 - f) Your contact details via the hospital switchboard telephone number
 - g) Fax number if required

N.B. As information on the Organ Donor Register is covered by the Data Protection Act, the duty office may only return your call via a hospital switchboard number; direct line telephone numbers or mobile phones numbers cannot be used.

- 1.3 Following the search of the Organ Donor Register, which only takes a few minutes, the Duty Office will ring you back with the outcome.
- 1.4 It is possible to provide, by fax, written documentation as proof of Organ Donor Register registration, if required. In order to comply with Caldicott and Data Protection requirements the information can only be faxed to a 'safe haven' fax machine.

Appendix 2

Sperm Donation

Occasionally wives or partners of male potential organ donors ask if it is possible for their partner to donate sperm.

The regulations regarding the donation of gametes (sperm or eggs) are governed by the Human Fertilisation and Embryology Act (1990) and the arrangements regulated by the Human Fertilisation and Embryology Authority (HFEA).

The removal of gametes from a deceased person is governed by the Human Tissue Act (1961) which provides that a person "*lawfully in possession of*" a body may authorise removal of any part from the body for therapeutic purposes or purposes of medical education or research provided that, having made such enquiry as may be practicable, has no reason to believe:

- (a) that the deceased had expressed an objection to his body being so dealt with after death, and had not withdrawn it, or
- (b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.

Once removed, the storage and use of gametes falls within the regulatory remit of the HFEA. The storage of gametes is illegal in the absence of prior written "effective consent" from the donor to storage.

The Human Fertilisation and Embryology Act sets out the requirements for such "effective consent" to storage. In particular, the written consent must:

- (a) specify the maximum period of storage (if less than the statutory storage period) and, importantly,
- (b) state what is to be done with the gametes if the person giving consent dies or is unable because of incapacity to vary or revoke the consent.

Therefore the donation of gametes is legal under the Human Tissue Act (1961); however the storage of gametes is illegal unless there is explicit written consent as above under the Human Fertilisation and Embryology Act (1990).

Appendix 3

COLLABORATIVE REQUESTING

Studies carried out in the UK and other countries¹⁻⁵ in recent years indicate that although the general public expresses overwhelming support for organ donation during their lifetime, similar support is not realised at the time of death when families of potential donors are approached.

Since January 2003, critical care units in the UK have been participating in the national Potential Donor Audit (PDA). Results show that the family refusal rate nationally exceeds 40%.

Practice in the UK has developed whereby the initial approach for organ donation is usually made solely by the critical care unit staff. The donor transplant co-ordinator normally only becomes involved with families who agree to proceed with organ donation or who wish to receive further information from the donor transplant co-ordinator to inform their decision. However, data from studies carried out in other countries suggests that marked increases in consent rates can be realised when the request for donation is made collaboratively by the critical care unit staff and the donor transplant co-ordinator. A study carried out in 1994 by Klieger et al demonstrated a 58% increase in consent rates when the request was made collaboratively⁶. These results suggest that in the UK the number of donors could be increased by a collaborative approach.

References

1. Gortmaker S, Beasley C, *et al*. Improving the request process to increase family consent for organ donation. *Journal Transplant Co-ordination*. 1998; 4: 210-7.
2. Cutler JA, David SD, Kress CJ, *et al*. Increasing the availability of cadaveric organs for transplantation maximizing the consent rates. *Transplantation*. 1993; 56: 225-8.
3. Beasley C, Capossela C, Brigham L, *et al*. The impact of a comprehensive, hospital-focused intervention to increase organ donation. *Journal Transplant Co-ordination*. 1997; 7: 6-13.
4. Fischer-Frohlich C –L, Eichmann E, Kaesler-Heide H, Kulil M, Lauchart W. Consent to Organ Donation: who should make the request? *Organs and Tissues* 2001; 2: 119-23.
5. Ehrle R, Shafer T, Nelson K. Referral, request, and consent for organ donation: best practice –a blueprint for success. *Critical Care Nurse*. 1999; 19: 21-33.
6. Kleiger J, Nelson K, Davis R, *et al*. Analysis of factors influencing organ donation consent rates. *Journal Transplant Co-ordination*. 1994; 4: 132-4.

4. Certification of death by brain stem testing

Brain stem death produces a state of irreversible loss of consciousness associated with the loss of central respiratory drive (apnoea). It was accepted as being equivalent to somatic death by the World Medical Association in 1968 as it represented a state when “the body as an integrated whole has ceased to function”. In the UK this position was accepted in a 1976 memorandum from the Conference of the Medical Royal Colleges and their Faculties^{1,2}. This allowed discontinuation of mechanical ventilation in patients whose brain stem had irreversibly ceased to function and also allowed organ donation from brain stem dead heart beating donors. The criteria for the diagnosis of brain stem death have also been adopted by the courts in England and Northern Ireland for the certification of death. Despite all this, there are some aspects of the performance of brain stem testing that remain ambiguous. In these areas the ICS Working Group has come to a consensus that it is felt represents best practice in the current state of knowledge.

Brain stem death is diagnosed in three stages:

1. It must be established that the patient has suffered an event of known aetiology resulting in irreversible brain damage with apnoeic coma, i.e. the patient is deeply unconscious, mechanically ventilated with no spontaneous respiratory movement.
2. Reversible causes of coma must be excluded.
3. A set of bedside clinical tests of brain stem function are undertaken to confirm the diagnosis of brain stem death.

If the clinicians responsible for the care of the critically ill patient cannot be certain that these three stages can be completed, then brain stem testing should be abandoned and, if appropriate, treatment withdrawn in another manner (see below).

Although cerebral imaging techniques, such as cerebral angiography or transcranial Doppler studies may confirm lack of cerebral blood flow and therefore confirm brain stem death, the Code of Practice in the UK still requires clinical confirmation by brain stem testing at this time³. This requirement will be kept under review.

When brain stem death is suspected, certification of death by brain stem testing should be performed if possible. This often requires stabilisation of the patient. Achieving this diagnosis helps the relatives to understand that the patient had died before the withdrawal of mechanical ventilation and helps to reduce doubt that the patient might have made any recovery. The certification of death by brain stem testing is therefore important in its own right, independent of any subsequent considerations regarding organ donation.

4.1 *Preconditions to brain stem death testing*

There are three important preconditions that must be met prior to testing:

- 1) ***The patient's condition is due to irreversible brain damage of known aetiology.*** This may be obvious such as a severe head injury or spontaneous intracranial haemorrhage. However, when a patient has suffered primarily from cardiac arrest, hypoxia or severe circulatory insufficiency with an indefinite period of cerebral hypoxia, it may take longer to establish the diagnosis and to be confident of the prognosis. In some patients the primary pathology may be a matter of doubt and a confident diagnosis (and hence prognosis) may only be reached by continuing clinical observation and further specialised investigations. It is generally recommended therefore that if brain stem death is secondary to generalised

cerebral hypoxia from cardiac arrest the tests should not be performed until a minimum of 24 hours have elapsed.

- 2) **The patient is in unresponsive coma.** Coma is due to cerebral damage of known aetiology and reversible causes of coma have been excluded.
- 3) **The patient is apnoeic and mechanically ventilated.**

4.2 Reversible Causes of Coma

Potentially reversible causes of coma must be excluded and include:

- 1) **Sedative drugs:** Narcotics, hypnotics and tranquillisers may have prolonged action, particularly when hypothermia coexists or in the context of renal or hepatic failure. It is therefore essential that the drug history should be carefully reviewed. Any possibility of intoxication being the cause of, or contributing to, the patient's comatose state should preclude certification of death by brain stem testing.

Excluding the effects of sedatives may be difficult, particularly after prolonged infusions of long acting cumulative sedatives such as thiopentone. This may involve prediction according to pharmacokinetic principles, the measurement of drug concentrations which may be time consuming or the use of antagonists in the case of opioids or benzodiazepines. If the patient is thought to be brain stem dead, the decision is either to wait to perform the tests when the effect of such sedatives can be excluded, or to withdraw further active treatment on the basis of futility. If sedation cannot be excluded it may be appropriate to consider the use of imaging techniques such as four vessel cerebral angiography or transcranial Doppler to demonstrate the absence of cerebral blood flow, so assisting decision making by confirming futility, even though these do not currently form part of the diagnostic requirements for the diagnosis of brain stem death.

- 2) **Neuromuscular blocking agents:** The effect of neuromuscular relaxant drugs must be excluded as the cause of apparent coma, absent reflexes or respiratory failure by eliciting deep tendon reflexes or by demonstrating adequate neuromuscular conduction with a nerve stimulator.
- 3) **Hypothermia:** the core temperature must be $>34^{\circ}\text{C}$ at the time of testing⁴.
- 4) **Circulatory, metabolic or endocrine disturbances:** Circulatory, metabolic and endocrine disturbances commonly occur as a result of the physiological consequences of brain stem compression and death; these should not preclude certification of death by brain stem testing. Correction of these physiological abnormalities is advisable before brain stem testing if the severity of the disturbance is profound enough to cause depression of consciousness (e.g. severe hypernatraemia or profound hypotension). Routine measurement of hormone levels (e.g. thyroid hormones to exclude myxoedema coma) is only necessary if suggested by clinical circumstances and is not generally a prerequisite before testing.

If these four factors cannot be excluded, then brain stem testing should not be undertaken until a later date when they can be confidently excluded. Unfortunately there may be clinical circumstances where the patient is deteriorating quickly, becoming unstable or where brain stem testing cannot be physically performed. If further intervention is regarded as futile, then active treatment may be withdrawn in accordance with professional

guidelines. Under such circumstances NHBD should be subsequently considered and this option discussed with the relatives.

4.3 Clinical Tests

The following bedside tests, including apnoea testing⁵, confirm the absence of brain stem reflexes. It is recommended that observation for apnoea is undertaken after completion of the other tests.

4.3.1 Brainstem reflexes

No pupillary response to light:

- The pupils do not respond either directly or consensually to sharp changes in the intensity of light.

Absent corneal reflex:

- No response to direct stimulation of the cornea.
- Care should be taken to avoid damage to the cornea by applying gentle pressure to the cornea with either cotton wool or the tip of a gauze swab.

Absent vestibulo-ocular (caloric) reflex:

- Clear access to the tympanic membrane must be confirmed using an auroscope.
- The performance of this test may be prevented by local injury or disease.
- The head should be flexed at 30°. If cervical spine instability is suspected, then the bed may be elevated 30° head up.
- No eye movements are seen following slow injection of at least 50 ml ice cold water over one minute into each external auditory meatus in turn.

No motor response to central stimulation:

- No motor response within the cranial nerve or somatic distribution in response to supraorbital pressure.

Absent gag reflex:

- No contraction of the soft palate when the uvula is stimulated with a throat spatula.

Absent cough reflex:

- No response to bronchial stimulation by a catheter passed at least as far as the carina through the tracheal tube.

Absence of respiratory movement during the apnoea test:

- No respiratory movements seen when the patient is disconnected from the ventilator when the arterial carbon dioxide partial pressure is above the threshold for respiratory stimulation (i.e. greater than >6.65kPa (50mmHg)).
- The UK Code of Practice for the diagnosis of brain stem death also recommends that the total time of observed apnoea is not less than 10 minutes per set of tests.

In order to achieve this in clinical practice the ICS Working Group recommends that:

- The patient should be pre-oxygenated with 100% oxygen for 10 minutes while allowing the PaCO₂ to rise to approximately 5.0 kPa (40mmHg) before the test by decreasing the minute ventilation.

- The patient is disconnected from artificial ventilation and oxygen is insufflated at 6 l.min⁻¹ via an endotracheal suction catheter passed down the tracheal tube to maintain adequate oxygenation during the test. Direct clinical observation is made to confirm apnoea over a 10 minute period during which time the PaCO₂ is allowed to rise to >6.65kPa (50mmHg).
- If the respiratory threshold of 6.65 kPa has not been exceeded after 10 minutes, apnoea should be continued and the PaCO₂ rechecked until this threshold has been exceeded.
- Once the PaCO₂ exceeds 6.65 kPa (50mmHg) and the absence of spontaneous ventilation is confirmed by direct clinical observation, the patient is reconnected to the ventilator.
- If adequate oxygenation of the patient is difficult during the apnoea test, oxygenation may often be maintained by the administration of 100% oxygen, CPAP (possibly at a higher pressure) and a prior recruitment manoeuvre.
- Prior to the test, the addition of extra airway dead space or exogenous CO₂ to the ventilator circuit may be required to elevate PaCO₂ while maintaining a normal minute volume.
- Patient triggered modes of ventilation should not be used as vigorous cardiac contractions may trigger ventilator delivered breaths leading to diagnostic confusion⁶.
- Patients with pre-existing severe chronic respiratory disease may depend upon hypoxic drive and only respond to supra-normal levels of carbon dioxide. A higher threshold for PaCO₂ may be required.

4.4 Performance and Repetition of Testing

4.4.1 *The certification of death by brain stem testing must be performed by at least two medical practitioners:*

- registered with the General Medical Council for more than five years.
- at least one should be a consultant.
- competent in critical care and the certification of death by brain stem testing.
- not members of the transplant team.

4.4.2 The tests must always be carried out twice. Two sets of tests are performed:

- to remove the risk of observer error.
- to re-assure the family.

The Code of Practice is not clear on details of testing with regard the actual number of test performed. The ICS Working Group suggests that tests may be carried out by two doctors together or separately. If two doctors perform the tests together, then one should perform a complete set of tests whilst being observed by their colleague; this would count as one set of tests.

4.4.3 *There is no prescribed time interval between tests:*

- The time interval is a matter for clinical judgement.
- The time interval should be adequate to reassure all those directly involved and should take into account the physiological stability of the patient.
- The diagnosis and implications regarding organ donation will usually be discussed formally with the family after the completion of the first set of tests.

- The second set of tests may closely follow the completion of the first, particularly if the relatives do not want to discuss the clinical situation further.

4.4.4 *Time of death:*

- legal time of death is when the first set of tests indicates brain stem death (i.e. following completion of the first set of tests).
- death is confirmed after completion of the second set of tests, not when ventilation is discontinued.

4.4.5 *Spinal reflexes:*

- A spinal reflex is peripheral muscle movement in response to peripheral stimulation; this represents the neural pathways in the spinal cord with no higher neural input.
- Spinal reflexes are common in brain stem dead patients and may be distressing for relatives to observe.
- Spinal reflexes may occur following peripheral stimulation both during testing and at other times and should be explained to relatives. This is particularly important if they observe the tests being performed.

4.4.6 An example of a documentation for the diagnosis of brain stem death is included in Appendix 1.

References

1. Conference of Medical Royal Colleges and their Faculties in the United Kingdom. Diagnosis of brain death. *British Medical Journal* 1976; *ii*:1187-88.
2. Conference of Medical Royal Colleges and their Faculties in the United Kingdom. Diagnosis of brain stem death. *Lancet* 1976; *ii*:1069-70.
3. A code of Practice for the Diagnosis of Brain Stem Death, Department of Health, March 1998.
4. Planning Committee, Severe Brain Injury to Neurological Determination of Death - A Canadian Forum. *Report on Severe Brain Injury to Neurological Determination of Death - A Canadian Forum*. Edmonton: The Canadian Council for Donation and Transplantation, 2003.
5. Criteria for the diagnosis of brain stem death. *Journal of the Royal College of Physicians* 1995; 29: 381-2.
6. Willatts SM, Drummond G. Brainstem death and ventilator trigger settings. *Anaesthesia*. 2000; 55: 676-7.

Appendix 1

Proforma for documentation of brain stem tests

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. The two doctors may carry out the tests separately or together. Two sets of tests must always be performed.

Name:

Unit No:

Pre-Conditions

Are you satisfied that the patient suffers from a condition that has led to irremediable 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	Dr A		Dr B	
	1st Testing	2nd Testing	1st Testing	2nd Testing
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 there a gag reflex?				
Is there a cough reflex?				
Have the recommendations concerning testing for apnoea been followed?				
Were there any respiratory moments seen?				

Date and time of first testing:

Date and time of second testing:

Dr A Signature: Dr B Signature:

Status: Status:

5. Clinical management of the potential heart beating organ donor

5.1 Pathophysiological Changes after Brain Stem Death

Widespread changes occur after brain stem death, which may jeopardise the function of potentially transplantable organs (Table 1).

Table 1. Approximate incidence of pathophysiological changes after brain stem death (%).

hypotension	80
diabetes insipidus	65
disseminated intravascular coagulation	30
cardiac arrhythmias	30
pulmonary oedema	20
acidosis	10

5.1.1 Cardiovascular changes

There are usually two distinct phases, characterised by sympathetic overactivity and underactivity. The first phase is not seen in all patients.

- i) **Hyperdynamic phase:** Sympathetic overactivity causes a transient catecholamine surge, (particularly adrenaline and noradrenaline) which increases in heart rate, blood pressure, cardiac output and systemic vascular resistance. The catecholamine storm adversely affects the delicate balance between myocardial oxygen supply and demand.
- ii) **Cardiovascular collapse phase (Table 2):** Hypotension results from loss of sympathetic tone, profound vasodilatation and myocardial depression. Hypovolaemia secondary to diabetes insipidus (5.1.2) frequently contributes to hypotension in unsupported patients with brain stem death.

Table 2. Causes of cardiovascular collapse after brain stem death.

Peripheral vasodilation	
Hypovolaemia	diabetes insipidus
	osmotic diuretics (mannitol)
	hyperglycaemia
	therapeutic fluid restriction
Myocardial depression	depletion of high energy phosphate
	mitochondrial inhibition
	possible reduction in T ₃ production
	electrolyte disturbance

Subendocardial myocardial ischaemia and ventricular dysfunction are common even in previously healthy hearts. Blood gas and electrolyte disturbances may also contribute to the ECG abnormalities which include ST segment and T wave changes, arrhythmias and conduction abnormalities. Most changes are usually temporary and reversible.

5.1.2 Endocrine changes

Anterior and posterior pituitary failure causes significant reductions in the circulating levels of tri-iodothyronine (T₃) and thyroxine (T₄). The former may contribute to cardiovascular deterioration. Reduced production of anti-diuretic hormone (ADH) causes diabetes insipidus (DI) which occurs in up to 65% of organ donors. It is characterised by diuresis, hypovolaemia, plasma hyperosmolality and hypernatraemia. Reductions in cortisol production are unrelated to the degree of hypotension but may impair donor stress response.

Insulin secretion is reduced and contributes to the development of hyperglycaemia. This may be aggravated by the administration of large volumes of glucose containing fluids, if used to treat hypernatraemia and increased levels of catecholamines. Untreated hyperglycaemia leads to increased extracellular osmolality, metabolic acidosis, osmotic diuresis and cardiovascular instability.

5.1.3 Pulmonary changes

Pulmonary dysfunction is common in the organ donor and may be due to the development of pneumonia, aspiration of gastric contents, neurogenic pulmonary oedema or pulmonary trauma.

5.1.4 Coagulopathy

Haemostatic disorders may occur secondary to release of tissue thromboplastin by ischaemic or necrotic brain. Disseminated intravascular coagulation is common and its incidence increases with the duration of brain stem death.

5.1.5 Hypothermia

Hypothalamic failure after brain stem death results in impairment of temperature regulation. Heat production is reduced because of a fall in metabolic rate and loss of muscular activity. This is associated with an increase in heat loss because of peripheral vasodilatation. Active measures may be required to prevent hypothermia.

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 brain dead patients.

5.2 Resuscitation and Maintenance of the Organ Donor

Following the certification of death by brain stem testing and the lack of objection to donation, there is a change in the emphasis of care. Therapy previously aimed at preserving brain function is now directed at optimising transplantable organ function. There is no decrease in patient dependency because the need for therapeutic intervention and support of relatives continues. Adequate time must be allowed for confirmation of brain stem death but unnecessary delays should be avoided to minimise the risk of deterioration of the donor. High quality critical care including chest physiotherapy, aseptic precautions and antibiotics may be required. The patient has usually been rendered slightly hypovolaemic by brain protecting therapies. Although hypovolaemia should be corrected, it is important to avoid excessive volume replacement particularly in potential lung and heart donors. The primary goals are maintenance of adequate tissue perfusion and preservation of organ viability.

5.3 Monitoring the Organ Donor

Optimal haemodynamic management requires invasive monitoring. 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 a new central venous or pulmonary artery catheter (PAC) should be inserted into the right internal jugular or subclavian veins.

Intravenous fluid administration must be carefully monitored as organs, particularly the lungs, which may have been damaged during the period of sympathetic hyperactivity, are susceptible to volume overload and capillary leakage.

Echocardiography is useful to exclude major structural abnormalities of the heart and to measure left ventricular ejection fraction. Some transplant units will only request insertion of a PAC in those patients estimated to have a left ventricular ejection fraction below 45%¹.

Transthoracic echocardiography (TTE) may be technically difficult and better images may be obtained with transoesophageal echocardiography (TOE). Transient regional wall motion abnormalities are common and systolic inward motion and thickening may improve with haemodynamic optimisation. Assessment of right ventricular size and function is important and frequently challenging.

5.4 Supporting the Organ Donor

5.4.1 Cardiovascular support

The goals of haemodynamic management are to optimise cardiac output maintaining normal preload and afterload. Where possible, the use of high dose β adrenoreceptor agonists, other inotropes and vasopressors, which increase myocardial oxygen demand and deplete myocardial high energy phosphates should be avoided.

The following haemodynamic goals are generally appropriate in potential adult heart donors (Table 3).

Table 3. 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. These goals can usually be achieved by the standard critical care therapies (Table 4).

Table 4. Principles of critical care management for adult heart donation

Clinical status	Haemodynamic management
↓ Mean Arterial Pressure ↑ Cardiac Output	i) Preload optimisation and ii) vasopressor to ↑ afterload
↓ Mean Arterial Pressure ↓ Cardiac Output	i) Preload optimisation, ii) Vasopressor to ↑ afterload and iii) Inotrope to ↑ contractility
↑ Mean Arterial Pressure ↓ Cardiac Output	i) Preload optimisation and ii) Vasodilator to ↓ afterload ± iii) Inotrope to ↑ contractility

The choice of inotropic support varies between transplant 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 than noradrenaline for the cardiovascular collapse phase.

5.4.2 Endocrine support

Hormone replacement therapy may reduce inotrope requirements and should be considered in all organ donors². The therapies used to correct the common endocrine disturbances are shown in Table 5.

Table 5. The common endocrine problems seen in HBDs.

Clinical problem	Management
Diabetes Insipidus	Maintain $\text{Na}^+ = 155 \text{ mmol.l}^{-1}$ with 5% dextrose ³ Maintain urine output about $1 - 2 \text{ ml.kg}^{-1}.\text{h}^{-1}$ with vasopressin (<i>pitressin</i>) 1 U bolus and $0.5-4.0 \text{ U.h}^{-1}$ infusion ¹ . If vasopressin fails to control diuresis, intermittent desmopressin (<i>DDAVP</i>) may occasionally be required.
Hyperglycaemia	Insulin infusion to maintain plasma glucose $4-9 \text{ mmol.l}^{-1}$ Maintain $\text{K} > 4.0 \text{ mmol.l}^{-1}$
Hypothyroidism	Tri-iodothyronine (T_3) 4 μg bolus then infusion at $3 \mu\text{g.h}^{-1}$

Debate continues over the value of T_3 replacement. Practical difficulties identifying the subgroup of patients with decreased free T_3 have led to most transplant units empirically commencing T_3 infusions in all potential organ donors. High dose methylprednisolone 15 mg.kg^{-1} is commonly given as part of the hormone package to diminish the inflammatory response.

5.4.3 Respiratory support

If the lungs are to be transplanted, the FiO_2 should be kept at or below 0.4 to minimise the risks of oxygen toxicity. A modest level of positive end expiratory pressure (PEEP) (i.e. $<5 \text{ cmH}_2\text{O}$) will prevent alveolar collapse. 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. The transplant team may request an up to date chest X-ray.

Suitable goals for respiratory support are:

- maintenance of normocapnia ($\text{PaCO}_2 \sim 5.0\text{-}5.5 \text{ kPa}$).
- ventilation with the lowest FiO_2 to maintain PaO_2 of $>10.0 \text{ kPa}$.
- PEEP $> 5 \text{ cmH}_2\text{O}$ may reduce cardiac output and is rarely required.
- high inspiratory pressures should be avoided.

The mode of ventilation needs to be carefully selected:

- consider pressure control ventilation.
- modes that allow patient triggered ventilation are not appropriate.
- 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.

5.4.4 Renal support

Hypotension is associated with acute tubular necrosis and failure of transplanted kidneys. Although low dose dopamine is now unfashionable in the general critical care setting, there is some evidence that donor pre-conditioning with dopamine improves initial graft function after kidney transplantation⁴.

5.4.5 Haematological support

The haemoglobin concentration should be maintained over 9 gm.dl^{-1} . Deranged coagulation should be treated with fresh frozen plasma and platelets. Antifibrinolytics such as epsilon aminocaproic acid may cause microvascular thrombi in donor organs and should be avoided.

5.4.6 Temperature support

Hypothermia should be anticipated and heat loss prevented by using:

- warmed intravenous fluids
- warming blankets
- heated and humidified inspired gases
- increased ambient temperature

5.5 Nursing and Psychological Care

Nursing staff working in critical care areas play a key role in caring for potential organ donors and their families. The complex care required by these patients and families has been described as emotionally demanding and stressful⁵⁻⁷. The donor's family, friends and carers will require considerable psychological and pastoral support⁸. The circumstances of the donor's death may engender feelings of remorse guilt or anger. Nurses may have difficulty caring for a patient in whom death has been declared when, previously, care was directed at saving life. Explaining futility of care to families and friends is difficult. The attitudes and actions of nursing staff will significantly affect the family⁵⁻⁷. Therefore it is necessary for critical care units to ensure that nurses caring for these patients have a sound knowledge of:

- Organ/tissue donation, transplantation and ethical issues.
- The diagnosis of death by brain stem testing and its certification.
- The continued clinical management of the potential organ donor.
- Communication skills.
- The ability to support families during a stressful time.
- Awareness of religious and cultural issues with regard to organ/tissue donation.
- The role of donor transplant co-ordinators.

These educational elements should be included in local orientation and on going competency training in critical care. Designating an experienced 'Link Nurse' in the critical care unit, to liaise with the donor liaison nurse and donor transplant co-ordinator will assist in the delivery of such education and updates of any practice changes⁹⁻¹¹. Donor transplant co-ordinators and donor liaison nurses can also support staff in debriefing and reviewing any aspects of individual donations^{6,10}.

Important aspects of medical and nursing care that must be continued are described above; these will require careful explanation to families. As well as continuing to care for the patient, nursing staff will also help families understand the necessity for:

- Continued invasive monitoring.
- Adherence to infection control procedures.
- Mouth and eye care.
- Hygiene needs as required as individual to the patient.
- Regular patient repositioning.

Relatives of potential organ donors report that they derive great comfort in seeing staff maintain care and respect for their dead relative as if they were alive^{8,11,12}.

Effective documentation and communication between medical and nursing staff is vital to ensure the families of organ donors are supported and kept well informed of the progress of events.

Staffing levels and skill mix may need to be reviewed to ensure experienced critical care nurses are available to care for the potential organ donor and their family. All aspects of care will require the full attention of a trained nurse even if the patient's physical needs are minimal, as more nursing time will be required for the family's ongoing support, explanations and discussions.

Further details about managing organ donation will be described in the UK Transplant Donor Management Guidelines which will be available in early 2005, and will be placed on the website www.uktransplant.org.uk.

References

1. Zaroff JG, Rosengard BR, Armstrong WF *et al*. Consensus conference report: maximizing use of organs recovered from the cadaver donor: cardiac recommendations, March 28-29, 2001, Crystal City, Va. *Circulation* 2002; 106: 836-41.

2. Rosendale JD, Kauffman HM, McBride MA *et al.* Hormonal resuscitation yields more transplanted hearts, with improved early function. *Transplantation* 2003; 27: 1336-41.
3. Totsuka E, Dodson F, Urakami A *et al.* Influence of high donor serum sodium levels on early postoperative graft function in human liver transplantation: effect of correction of donor hypernatremia. *Liver Transplantation and Surgery* 1999; 5: 421-8.
4. Schnuelle P, Yard BA, Braun C *et al.* Impact of donor dopamine on immediate graft function after kidney transplantation. *American Journal of Transplantation* 2004; 4: 419-26
5. Hibbert M. Stressors experienced by nurses while caring for organ donors and their families. *Heart and Lung* 1995; 24: 399-407.
6. Pearson A, Robertson-Malt S, Walsh K. Intensive care nurses' experience of caring for brain dead organ donor patients. *Journal of Clinical Nursing* 2001; 10: 132-9.
7. Pelletier-Hibbert M. Coping strategies used by nurses to deal with the care of organ donors and their families. *Heart and Lung* 1998; 27: 230-7.
8. Riley LP, Coolican BM. Needs of families of organ donors: facing death and life. *Critical Care Nurse* 1999; 19: 53-9.
9. Watkinson GE. A study of the perception and experience of critical care nurses in caring for potential and actual donors: implications for nurse education. *Journal of Advanced Nursing* 1995; 22: 929-40.
10. Randhawa G. Specialist nurse training programme: dealing with asking for organ donation. *Journal of Advanced Nursing* 1998; 28: 405-8.
11. Coyle MA. Meeting the needs of the family: the role of the specialist nurse in the management of brain death. *Intensive and Critical Care Nursing* 2000;16: 45-50.
12. Seymour JE. *Critical Moments – Death and Dying in Intensive Care*. Buckingham: Open University Press, 2001.

6 Controlled Non Heart Beating Organ Donation

6.1 The Rationale for Non Heart Beating Donation (NHBD)

NHBD is not new, the first cadaveric organs to be transplanted were retrieved from NHBDs. Initially considered as marginal donors, improved techniques of organ preservation and assessment of function before transplantation have resulted in outcomes (in the case of kidney transplants) to rival those achieved after transplantation of kidneys from heart beating donors¹. This has led to the reintroduction of NHBD schemes.

6.2 Organs suitable for donation

Solid organs suitable for transplantation from NHBDs include kidneys, livers and lungs. The long-term outcome of kidneys transplanted from NHBDs is similar to that from heart beating donors. Preliminary data on liver transplants and small numbers of lung transplants from NHBDs are also promising. Tissue donation (e.g. corneas etc) should also be considered in asystolic cadaveric donors.

6.3 General criteria for donation

Any patient who is having active treatment withdrawn and in whom death is likely to follow shortly could be considered for NHBD. Consideration should be given to discussing all patients in whom treatment is to be withdrawn with a donor transplant co-ordinator. In general exclusions to donation are similar to those for cadaveric heart beating donation. Absolute contraindications to organ donation are:

- Known HIV infection
- Known or suspected CJD
- Known objection by the patient to donation

Age limits may vary from one transplant centre to another.

6.4 Patients suitable for NHBD

An international meeting on NHBD held in Maastricht in 1995 identified four categories of potential non-heart beating organ donors, to which a fifth category has recently been added (Table 1). These may be described as either uncontrolled (Categories I/II and V) or controlled (Categories III/IV) donors.

Table 1. The Modified Maastricht classification of NHBDs.

Category I	Dead on arrival
Category II	Unsuccessful resuscitation
Category III	Awaiting cardiac arrest
Category IV	Cardiac arrest in a brain stem dead donor.
Category V	Unexpected cardiac arrest in a critically ill patient

Controlled NHBD in the critical care unit involves mainly Category III patients, and may increasingly be appropriate for Category IV patients. Both allow organ retrieval to be planned, warm ischaemic time to be minimised and organ outcomes optimised. Category III patients will usually be in a critical care unit, but occasionally in the Accident and Emergency Department. They usually represent patients in whom it has been decided that further active treatment is futile and is subsequently withdrawn. In these patients asystole and cardiac arrest (i.e. death) is predicted and expected. A decision to withdraw or limit active treatment in critical care is common in UK practice where such decisions are made in 12% of all ICU admissions. Fifty percent of all critical care unit deaths are associated with a decision to withdraw treatment^{2, 3}.

In general patients likely to be suitable for NHBD are similar to those who become heart beating organ donors. Typically these are patients who have suffered catastrophic brain injuries (e.g. head injuries, intracranial haemorrhage, hypoxic brain insult) but do not fulfil the criteria for brain stem death and in whom further active treatment is futile. However critically ill patients with other diagnoses who may be suitable for NHBD should be discussed with a donor transplant co-ordinator (1) when a decision to withdraw treatment is made and (2) where it is possible that the patient may die soon afterwards.

6.5 Withdrawal of active treatment

The decision to withdraw treatment should be made in accordance with current guidelines from the ICS, BMA and the GMC. There must be consensus among the critical care consultant, the patient's relatives, the referring consultant and nursing staff that the decision is made in the patient's best interest. However the ultimate responsibility for the decision and its timing rests with the responsible critical care consultant. Further guidance can be obtained from:

<http://www.ics.ac.uk/downloads/LimitTreatGuidelines2003.pdf>

<http://www.bmj.com/withwith/contents.htm>

<http://www.gmc-uk.org/>

General Medical Council. Withholding and Withdrawing Life-prolonging Treatments: Good Practice in Decision-making. London: General Medical Council, 2002.

Intensivists should develop local protocols for treatment withdrawal based on national guidelines. It is important to emphasise that withdrawal of active treatment should be according to the local critical care unit protocol and should not differ when organ donation is being considered. It is mandatory that transplant teams should not be involved in any decision to withdraw treatment. This ensures that the interests of the dying patient remain paramount. The decision should be communicated clearly to the family by the clinician caring for the patient and should be documented in the patient's notes.

6.6 The Donation Process

6.6.1 Communication

Discussion of a patients' suitability for NHBD with the donor transplant co-ordinator should take place before approaching the patient's family to avoid the situation of establishing the family's agreement to organ donation, only to find out later that the patient is not suitable for NHBD. For the same reason, when necessary appropriate patients should be discussed with the Coroner/Procurator Fiscal at this time. It is important to stress that the possibility of NHBD should be discussed with the relatives only after they have understood and accepted the futility of the clinical situation and the reasons for the withdrawal of treatment. The donor transplant co-ordinator should only become involved with the family after this discussion has taken place.

All the procedures involved with NHBD need to be explained sensitively and in detail to the patient's relatives. The logistics of NHBD are different to those from HBDs. The process of cannulation and perfusion that will occur after death should be explained in detail. It is important to explain that:

- Death may occur quickly after treatment withdrawal, and the relatives may have little time with their loved one if organ donation is to be possible.
- Death may **not** occur quickly after treatment withdrawal. Organ donation may not be possible if the dying process is prolonged and results in an unacceptable warm ischaemic time. However tissue donation is still possible in this scenario.
- Organ donation may not be possible if the Coroner/ Procurator Fiscal refuses permission.
- Transplantation may not be possible after organ retrieval if perfusion has failed.
- The family will have an opportunity to see their relative after organ retrieval.
- The relatives can stop the donation process at any stage.

6.6.2 The process of treatment withdrawal

Once a decision to withdraw treatment has been reached by the critical care consultant, the current level of support should continue until the time to withdraw treatment is agreed with the relatives. It is inappropriate to escalate current treatment, add new therapies (e.g. inotropes, heparin, hormone replacement) or to undertake invasive interventions (e.g. vascular cannulation before death for cold perfusion) to improve organ viability. However with the agreement of the relatives it is reasonable for blood samples to be taken from an indwelling line for tissue typing and serology purposes.

The appropriate time to withdraw treatment is influenced by many factors but the wishes and needs of the patients' relatives are the main determinants. Although the donor transplant co-ordinator may be present during withdrawal of treatment if the family find it helpful, it is inappropriate for the retrieval team to meet the family except at the family's request. Communication with the family should remain the responsibility of the critical care team and/or the donor transplant co-ordinator.

Withdrawal of active treatment should proceed in accordance with the usual practice of the critical care unit. This may include stopping artificial ventilation, supplemental oxygen, inotropes, extubating the patient, and commencing the infusion of opioids or sedatives to ensure that the patient is pain free and not distressed. Withdrawal of active treatment should not vary from local practice because organ donation is being considered.

Withdrawal of active treatment should usually take place within the critical care unit. In exceptional circumstances treatment may be withdrawn within the theatre complex (e.g. an anaesthetic room, recovery area). This should be undertaken only as a way of meeting the

patient's and relatives' wish to donate organs and not simply as a means of reducing warm ischaemic time. The same level of critical care nursing skill and expertise in the care of the dying patient should continue to be provided if treatment is withdrawn outside the critical care unit.

6.6.3 Confirmation of death in potential NHBDs

Following withdrawal of active treatment, ECG and intra-arterial blood pressure monitoring facilitates the identification of the onset and persistence of cardiorespiratory arrest. When NHBD is being considered, a member of the critical care unit team should certify death by confirming the absence of cardiac output and respiration, the lack of response to supra-orbital pressure and absence of the pupillary and corneal reflexes. This should be undertaken after a minimum of five minutes after cardiorespiratory arrest as currently recommended by the Institute of Medicine⁴. Any return of cardiac or respiratory activity during this period of observation should prompt a further five minutes observation after this time.

6.6.4 Management following death certification

Following certification of death, a brief respectful period may be valuable for the relatives to have further time with the patient, before transferring the body to the operating theatre. This period of time is usually about 5 minutes; if at this point the relatives still need more time with their loved one, the donation process should be reviewed. Procedures that reduce the warm ischaemic time of organs to be transplanted, but that may inadvertently result in changes to cerebral and /or coronary blood flow are not in the patient's best interests and must not be instituted post-mortem. These include chest compressions and cardiopulmonary bypass. Drugs may not be administered to facilitate organ donation (e.g. heparin) until death has been certified, as this would not be in the patient's best interests.

It is recommended that cannulation and organ perfusion should ideally take place in the operating theatre. However for logistic reasons some critical care units may prefer to cannulate the patient's femoral artery and vein and to infuse cold fluids in the critical care unit after death.

6.6.5 Failure to proceed with donation

Some patients continue to breathe spontaneously or with reduced ventilatory support for some time after treatment is withdrawn. They may become profoundly hypotensive during this time. In these situations the organ donation process may have to be abandoned if organ function has deteriorated so that viable transplantation is not possible. The family will have previously been made aware of this possibility. This decision is usually taken after 2-3 hours. The decision to abandon organ donation is determined by the need to limit the warm ischaemic time and by the availability of an operating theatre and retrieval team. This is a particular problem for hospitals based a long way from regional transplantation centres.

It is central to the principles of organ donation that donation is carried out to meet the wishes of the deceased and also to bring comfort to the relatives. The dignity, well-being and comfort of the dying patient are paramount to this process. The relatives can stop the process of NHBD at any time without reason.

6.7 Implementing a NHBD scheme in the critical care unit

Individual critical care units may choose to develop a protocol that takes into account any local factors influencing the practicalities of NHBD. The critical care medical and nursing staff, theatre staff, the retrieval team, and clinicians that refer patients to the critical care unit all need to be consulted and involved. Local audit of all deaths within the critical care unit provides data on the likely number of suitable NHBD and allows planning and informed discussion with all interested parties. The protocol should be approved by the hospital ethics committee or Trust Board.

The British Transplant Society have published guidelines on all aspects of the transplantation of organs from non-heart beating donors. These are available on www.bts.org.uk.

Unlike the situation in heart beating, brain stem dead patients, the donor transplant co-ordinator needs to be involved before death of the controlled NHBD and has a central role to play in ensuring the smooth-running of organ retrieval from a NHBD. In particular the donor transplant co-ordinator should:

- Confirm the suitability of a patient for NHBD before the family is approached.
- Check whether the patient is registered on the national Organ Donor Register (by calling the UK Transplant duty office on 01179 757575).
- Ensure the potential for NHBD is discussed with Coroner/Procurator Fiscal.
- Discuss all issues (as in 6.6.1) with the family including the requirements for blood tests for virology, blood grouping and tissue typing.
- Ensure that the retrieval team is on site and that an operating theatre is available at the time agreed with the relatives for withdrawal of treatment.

References

1. Weber M, Dindo D, Demartines N, Ambuhl PM, Clavien PA. Kidney transplantation from donors without a heartbeat. *New England Journal of Medicine* 2002; 347: 248-55.
2. Intensive Care National Audit and Research Centre. Evidence for the use of treatment withdrawal from the ICNARC Case Mix Programme. London: Intensive Care National Audit and Research Centre Case Mix Programme Database, 1998; 91-7
3. Manara AR, Pittman JAL, Braddon FEM. Reasons for withdrawing treatment in patients receiving intensive care. *Anaesthesia* 1998; 53: 523-8.
4. Non-heartbeating Organ transplantation: Practice and protocols. Institute of Medicine, National Academy Press, Washington DC, Jan 2000. ISBN 0-309-06641-7 (<http://www.nap.edu/books/0309066417/html/>).

7. Last offices and Follow-up

7.1 Last Offices

The final care of the patient who has donated organs should be the same as any other patient who dies in hospital. The critical care nursing staff will ask the family whether they would like to be involved. Nurses from the theatre or critical care unit perform last offices with the donor transplant co-ordinator. Intravascular cannulae, tracheal tubes and catheters may be removed. However, if a post-mortem examination is to be performed, local policy may dictate that these are left in place.

All documentation should be completed in accordance with local hospital policy. The time of death should be recorded as the time of completion of the first set of brain stem tests or at certification of death following cardiorespiratory arrest.

7.2 Follow-up

Follow-up care of the family is offered in the form of a letter, telephone call or visit. The family or carers are given the opportunity to contact the critical care staff, or the donor transplant co-ordinator, should they wish.

The majority of families do wish to receive information relating to the recipients, so the donor transplant co-ordinator will write to the family within 14 days of the donation to thank them for their generosity and to inform them of the outcome of the transplant operations. It is usual to give specific information regarding the recipients, such as their ages, sex, family background and progress however the identity of the recipients will not be revealed. The same information is sent to the health care professionals at the donating hospital. Families, who at the time of donation say that they do not wish to be informed of any information relating to the recipients should be made aware of how to contact the donor transplant co-ordinator should they wish to do so in the future.

Recipients are given the option to write and thank the family of their donor. Correspondence usually remains anonymous and is sent via the donor transplant co-ordinator. The family of the donor may also wish to write to the recipients, and this can also be arranged through the donor transplant co-ordinator.

Further information can be found in the UK Transplant Donor Family Care Policy which is available on the UK Transplant web site www.uktransplant.org.uk

8. Revision

The whole arena of organ donation is rapidly changing as a result of new legislation, ethical considerations and evolving clinical practices. Therefore these guidelines will be revised in 2007 when intervening developments will be incorporated.

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