

G A T E S H E A D H E A L T H N H S T R U S T

**PROCEDURE FOR PROVISION OF DONOR ORGANS FOR
TRANSPLANTATION**

This policy is effective from March 2002

Approved by the Trust Policy Forum in September 2001

and the Critical Care Steering Group in October 2001

Policy will be reviewed April 2003

POLICY STATEMENT

INTRODUCTION

There is always a need for human organs and tissues for transplantation. Most publicity in this area revolves around solid organs, i.e. heart, lungs, liver and kidneys. Tissues suitable for donation are heart valves, corneas, skin and bone and also on occasions tendons and cartilage.

This policy aims to provide information regarding the legal requirements and some of the practical aspects, which need to be observed.

Most patients who die in hospital are potential tissue donors. The majority of solid tissue donors will be referred from either the Accident & Emergency Department (A&E) or the Intensive Care Unit (ICU). Staff are ideally placed to approach relatives to offer the option of donation. We would very much place the emphasis on **offering the family the option**, as families can gain a great deal of comfort from the knowledge they have helped someone else.

The Regional Transplant Co-Ordinator can be contacted 24hrs a day via:

- **Freeman Road Hospital Switchboard 0191 2843111**
- **Directly via pager 07693415493 when calling via the pager you can either enter a number directly, or wait for the operator and leave a message.**

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.

- Age 0 - 80yrs
- Has suffered complete and irreversible brain-stem damage resulting in brain-stem death
- Is maintained on a ventilator, WITH THE EXCEPTION OF THE NON-HEART BEATING DONORS
- No prolonged hypotension or shock
- No severe untreated hypertension
- Has NO malignancy (except certain primary brain tumours)
- Has NO major systemic sepsis (bacterial meningitis/septicaemia which has been treated with appropriate antibiotics for \geq 24hrs is ok)
- Has No known social or medical high risk factors for HIV

SPECIFIC CRITERIA

Kidneys

1 - 80 yr.

Acceptable renal function,

Liver

2 months - 75 yr.

NO known liver disease, Absence of alcohol or drug abuse, NO known history of Hepatitis B/C

Heart

2months - 65 yr.

NO known cardiac disease

Low dose inotropic support

Lungs

2months - 65 yr.

Acceptable blood gases on less than 50% oxygen

Corneas

1 yr. - 100 yr.

Retrieved within 24hrs of asystole

Heart Valves

Birth - 60 yr.

Retrieval within 72 hrs of asystole

Skin

17 yr. - 60 yr. Female 16 yr. - 75 yr. Male

Retrieval within 24 hrs of asystole

Bone

17 yr. - 60 yr. Female 17 yr. - 75 yr. Male

Retrieval within 24 hrs of asystole

NON - HEART BEATING DONORS

At present the majority of kidneys come from those patients diagnosed as brain stem dead, who are maintained on a ventilator in ICU. Organs are removed at the time of cessation of ventilatory support thus preventing ischaemic damage. The kidneys, unlike other major organs can tolerate a short period of ischaemia from which they suffer reversible tubular injury. Therefore, in certain circumstances kidneys can be retrieved and transplanted following cardio-respiratory death. This form of kidney retrieval is known as non-heart beating donation (NHBD). This type of donor is classified into 4 categories (Maastricht 1995).

- Category 1 " Dead on Arrival "

These potential donors are rarely used in the UK, due to out of hospital cardio-respiratory arrest and may not have had any resuscitation attempt.

- Category 2 " Unsuccessful Resuscitation "

This group are those who have commenced cardio-pulmonary resuscitation following collapse usually due to a myocardial infarct, intracerebral catastrophe, head injury or hypoxic event. The decision to discontinue resuscitation is made by the caring teams when it has proved unsuccessful. Most of these potential donors are in the A&E department. The Regional transplant team MAY NOT be able to support this group of patients

- **Category 3 " Awaiting Cardiac Arrest "**
Patients who are being managed in the ICU, coronary care unit and medical wards may fulfil this category. The patient's medical condition is incompatible with life and death is imminent. Most have suffered neurological problems.
- **Category 4 " Cardiac Arrest in a Brain Stem Donor "**
A patient who is confirmed brain stem dead who has a cardiac arrest whilst awaiting the organ retrieval surgical team.

IDENTIFICATION OF A POTENTIAL NHB DONOR

The following criteria apply to a potential NHB:

Age	18yrs - 60 yr.
Cardiac Arrest	Less than 30minutes(this does not include period of effective resuscitation but does include time between initial cardiac arrest and start of resuscitation.
Resuscitation Time	No more than 2 hours resuscitation in total
NO	long standing untreated hypertension Renal impairment Malignancy (other than certain brain malignancies which have not metastasised) Systemic infection or Viraemia
Social	Not a high risk for HIV or Hepatitis B/C (the following are excluded from donation-Iv drug users, homosexuals, + others classified by the Department of Health as high risk)

If unsure please refer or seek advice from the transplant co-ordinator

CONTRAINDICATIONS TO ORGAN DONATION

In order to prevent the transmission of viral infections or cancers to patients, who receive organ grafts, the following patients are prohibited from donating organs or tissues.

Those who have ever:

- Tested positive for HIV / Hepatitis B / C
- Been treated for haemophilia or other blood clotting disorders
- Injected themselves with drugs (IV Drug Abuse)
- Worked as prostitutes
- Received human growth hormone before 1985
- (Men) had sex with another man
- Had sex in the last two years with anyone who lives or who has lived in Africa (except Morocco, Algeria, Libya and Egypt) in the last two years
- Had sex with anyone in the complete above list
- Suffered from CJD or have a family history of CJD
- Had a previous cancer diagnosed
- Had malaria, possible confirmed rabies or tuberculosis
- Had a neurological disease of unknown cause, e.g. multiple sclerosis, Alzheimer's Disease.

THE DIAGNOSIS OF BRAIN STEM DEATH.

When death is determined on the basis of brain stem death, it should be diagnosed by the combination of two doctors who have been fully registered with the General Medical Council for at least 5 years. It is recommended that at least one of these should be a consultant who has been trained in the administration of the tests necessary to make the diagnosis. Neither doctor should be a member of the transplant team and the results of the examination and the diagnosis should be recorded in the patients case notes. (Appendix A - Checklist for Criteria for Diagnosis of Brain Death).

Two sets of test must be performed. The two doctors may perform the tests together or separately. There is ongoing debate regarding the value of the second set and the duration of the interval between the sets. There is no stipulated interval between the two sets. Death is only conclusively established when the criteria have been satisfied on two successive occasions, but the legal time of death is when the first test indicates brain stem death.

The Human Tissue Acts stipulate that the person in lawful possession of the body must authorise the removal of organs or tissue for transplantation after certain enquiries have been completed. Where a body is in hospital or other institution, the person with lawful possession is the person with control and management of the hospital or institution until such time that it is claimed, for the purposes of disposal, by the next of kin, executor or Coroner. The Act empowers a health service body (e.g. NHS Trust) to designate any officer or person to act on its behalf. In the context of organ donation, the Lead Clinician of the ICU or designated deputy may be designated, provided there is no conflict of interests. The code of practice for the diagnosis of brainstem death (DOH 1998) assumes that the person will be readily available.

PROCESS OF REFERRAL

The responsibility for the identification of potential donors lies with the Consultant in Charge of the patient and/or the Consultant in Charge of the ICU if the patient is on the ICU at the time of death.

On identification of a potential donor, either the Clinical Nurse Manager ICU/SHDU (bleep 2218) or deputy is to be informed whose responsibility it is to ensure that all documentation is completed correctly and inserted in the patients case file. This person together with the Consultant who has identified the potential donor should decide who will contact the nearest relatives.

In the event of a potential donor being identified, it is the responsibility of the Consultant in Charge of the patient and/or the Consultant in Charge of the ICU if the patient is on the ICU at the time of death to ensure that the Regional Transplant Co-Ordinator on-call is informed.

To contact the duty Transplant Co-Ordinator, telephone 07693415493 and leave your name, location and telephone number. The Co=Ordinator will reply immediately. The Transplant Co-Ordinator will require the details from the completed Potential Donor Checklist (Appendix B Potential Donor Checklist).

ESTABLISHING LACK OF OBJECTION OF RELATIVES.

Definition of the term 'relative'

Husband or Wife

Common - Law Spouse / Partner

Son or Daughter

Mother or Father

Brother or Sister

Grandparent

Grandchild

Uncle or Aunt

Niece or Nephew

The nearest relative is the person described in the list above who is alive. If there are relatives of equal standing the eldest is preferred (e.g. Father or Mother). The nearest relative is not determined by gender. If the patient normally resides with or is cared for by one or more of their relatives before admission, those relatives are given preference over all others.

Medical or Nursing staff should ensure that permission is sought from the Consultant in charge of the potential donor before approaching the relatives for organ donation. Staff will need to decide in the light of the individual circumstances who is best qualified to approach the relatives. Relatives should not normally be approached before death has occurred; it would normally be after the first diagnosis of brain stem death.

Permission from the potential donor's next of kin must be sought even if the patient carries a donor card or is registered on the National Organ Donor Register and should confirm the relatives will not go against the donors expressed wish to proceed to organ donation.

If there is any dispute between the relatives then before proceeding advice ought to be sought from the Legal Services Department as to the wisdom or otherwise of an application being made to the Court to resolve any potential conflicts between relatives.

Written consent must be obtained from the relative (Appendix C Permission for the Removal of Organs). As part of the consent procedure, the family must be advised that it is a requirement for all donors to be tested for HIV/Hepatitis B&C and Syphilis. They should be asked if they have any reason to suspect that their relative may be positive, or in any of the high risk groups, for these viruses. A "Keeping Transplants Safe " card should be shown to the relatives and any comments noted.

In some circumstances and always with Consultant involvement, it may be necessary to obtain permission from HM Coroner prior to donation. In practice, the Coroner would rarely object to organ donation, but his permission must be sought. The Coroners are always helpful in making quick decisions in order that the donation may proceed. Even in murder or manslaughter cases, organ donation could go ahead, but in these circumstances the Home Office Pathologist for the Region would be involved. The Coroner can be contacted by ringing Northumbria Police on #6246 and ask for Gateshead Coroners Officer. If the Coroners Officer is not available the Consultant Histopathologist or Transplant Co-Ordinator will be able to offer advice. In these cases until consent has been given by the Coroner the designated person for the Trust may not authorise the removal of any organs.

If the coroner is not involved the death certificate may be completed before the completion of the second set of brain death tests.

The time of death should be recorded as the time when the death was conclusively established (usually after the first test which confirms brain stem death) and under normal circumstances this would be the most suitable time to complete the death certificate.

DONOR MAINTAINANCE

Any tests or treatment carried out on a patient before they die must be for their benefit and not solely to preserve their organs for transplantation. Following diagnosis of brain stem death, maintenance of the donor will be advised by the Transplant Team and is contained in the yellow folder kept on ICU.

COUNSELLING OF RELATIVES

Arrangements for counselling bereaved relatives will be assessed on the needs of the individual case and the relatives involved. There are no set rules about who can ask the responsibility may lie with either: -

- Consultant in Charge of the Potential Donor

- Consultant responsible for ICU
- Senior Nursing Staff ICU
- Transplant Co-Ordinator
- Hospital Chaplain

Immediate and longer-term bereavement support is offered by the Transplant Co-Ordinators.

If required the British Organ Donor Society 01223-893636, members of the society are families of Donors and exist to give support to other Donor families.

CORNEAL AND TISSUE DONATION (SKIN, BONE, TENDONS, HEART VALVES)

Separate guidelines are available for tissue donors. The Code of Practice CADAVERIC ORGANS FOR TRANSPLANTATION is broadly applicable to the removal of eyes or corneas although the following additional points need to be made. All adult patients are suitable as donors provided they have no known history of eye disease and have not undergone intraocular surgery. Those suffering from syphilis or infective hepatitis would also be unsuitable and it would be prudent to exclude as donors those patients with infective polyneuritis, corneas from patients with neurological disease, suspected of having either a viral or immune pathogenesis should not be used for transplantation. Children too, are generally less suitable as donors because their corneal thickness is inadequate.

Useful eyes can be obtained up to 24hours following cessation of respiration and circulation. To preserve the corneas please ensure the eyes are moistened with normal saline or artificial tears and then taped closed prior to the removal of the body to the hospital mortuary. Operating theatre conditions are not required to remove eyes. The Regional Transplant Co-Ordinator must be notified as soon as possible after death in order to make arrangements with the mortuary staff for the removal of the corneas to take place within the mortuary.

Before the corneas can be removed there must be:

- Consent from the deceased's next of kin or prior written consent from the deceased. (Appendix C. Permission for the Removal of Donor Organs).
- Consent from the Coroner should the death be of interest to him.
- Negative screen for HbsAG, HIV and syphilis. This will be performed by the Transplant Team.

DOCUMENTATION TO BE FILED IN PATIENTS' HEALTH RECORDS

- Checklist of Criteria for Diagnosis of Brain Stem Death – Appendix A
- Potential Donor Checklist – Appendix B
- Permission For the Removal of Organs for Donation – Appendix C

ORGANISING THE REREVAL OF DONOR ORGANS

Donor organs for transplantation **MUST** removed within the theatre environment, with the exception of corneal donation, see above guidance. The nurse in charge of the ICU will liaise with the transplant co-ordinator and the nurse in charge of the theatre to make the necessary arrangements

CONTACT TELEPHONE NUMBERS

Transplant Co-Ordinator 24hour cover

Freeman Rd Hospital Switchboard 0191 2843111 or 01893415493 and leave message with the operator.

Gateshead Coroners Office 24hour cover

#6246 or via Northumbria Police Switchboard and ask for Gateshead Coroners Officer.

Gateshead NHS Trust Organ Donor Link Nurse

Contact ICU at Queen Elizabeth Hospital on extension 2131 or 2007

REFERENCES

Cadaveric Organs for Transplantation, A Code of Practice for the Diagnosis of Brain Stem Death- including Guidelines for the Identification and Management of Potential Organ and Tissue Donors (DOH 1998).

Corneal Tissue Act (DOH 1986)

Donation of Organs for Transplantation the Management of the Potential Organ Donor (ICS 1999).

Freeman Hospital, Newcastle upon Tyne, UK, Non-Heart Beating Donation, Information for Health Professionals (Buckley P. Balupuri S. Talbot D 2000)

Human Tissues Acts (DOH 1998)

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