

**A CODE OF PRACTICE FOR THE DIAGNOSIS OF BRAIN
STEM DEATH**

**INCLUDING GUIDELINES FOR THE
IDENTIFICATION AND MANAGEMENT
OF POTENTIAL ORGAN AND TISSUE DONORS**

MARCH 1998

PREFACE

Method of Working and Composition of the Working Party

This Code of Practice was prepared by a Working Party established through the Royal College of Physicians on behalf of the Academy of Medical Royal Colleges at the request of the Health Departments. The document produced by the Working Party was submitted in draft to the Colleges and faculties of the Academy of Medical Royal Colleges. Comments received therefrom were used in the preparation of the final document. The membership of the Working Party was:

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CADAVERIC ORGANS FOR TRANSPLANTATION

A CODE OF PRACTICE INCLUDING THE DIAGNOSIS OF BRAIN DEATH

INTRODUCTION

When managing a patient in coma, the first objective for the health care team is to determine the cause and degree of coma, to maintain life by any necessary means, and to attempt to restore function. Such measures are often successful; but when the brain stem has been damaged from whatever cause in such a way and to such a degree that its functions (which include the neural control of cardiac and pulmonary function) are irreversibly destroyed, the heart will inevitably stop beating shortly thereafter. This condition is described as brain stem death. When this has been established by the methods to be described, the patient is dead even though respiration and circulation can be artificially maintained. The humane course of action is then to withdraw mechanical 'life-support', the time for which has passed, and which can impose on the relatives, who should be kept fully informed by the local care team of the diagnosis and likely prognosis, a pointless and distressing vigil. At this stage it becomes proper to consider whether any of the dead patient's organs can be made available for transplant into another patient. In some cases, the organs may themselves have been irreparably damaged during the final illness; but this is not always so, and viable organs are then available for transplantation, subject to specific precautions.

The criteria to be satisfied were set out in a Code of Practice issued from the Health Departments in 1983⁽¹⁾. The emphasis at that time was largely on kidney transplants. Since then, the scope for transplantation has expanded; much experience has been gained, and its lessons codified in national and international publications and guidelines. This enables us now to omit many of the details which were proper in the 1983 Code of Practice, but which are currently available in improved form in other publications to which we later refer.

In the introduction to the 1983 code, the Working Party drew attention to the limited availability of organs which was estimated at that time for kidneys as 'only about half that necessary to meet the demand'. Disparity between need and supply has increased, and now extends to other organs whose failure or dysfunction can be treated by transplanting organs capable of adequate function.

One cause of shortage of organs was identified as 'hesitancy on the part of hospital staff to identify, among their dying patients, those who might be potential donors and to initiate the procedures leading to transplantation'. Similar concern remains, although to a lesser degree, as experience has increased and confidence grown in the criteria for establishing brain stem death. There has been special anxiety about the practice of elective ventilation, which involves the artificial ventilation of the patient before death has been diagnosed, for no purpose other than later to obtain organs. The practice of elective ventilation to obtain organs after death is considered to be unlawful in the United Kingdom⁽²⁾.

Although the principles laid down by the Working Party remain sound, and have been supported by intervening experience, the time has now come for revision of the Code of Practice in the light of that experience. Although the entire text has been reviewed, there are two particular matters which may justify specific reconsideration.

The 1983 Code of Practice carried in its sub-title the phrase 'including the diagnosis of brain death'. The requirement for the removal of organs for transplantation is not death of the whole brain but 'brain stem death' have been satisfied, there is no prospect of survival and cessation of the heart beat will then occur. It is important that this is fully explained to the relatives. The evidence for this approach is given in the review by a Working Group convened by the Royal College of Physicians on behalf of the UK Conference of Medical Royal Colleges and their Faculties, and endorsed by the Conference⁽³⁾. It is because the term 'brain death' has led to real confusion, that we take the view that it should be replaced by 'brain stem death'.

The original Working Party was limited to members of the medical, legal and nursing professions and a representative of the Community Health Councils. For the revision, we have extended our membership to include a member of the Patients' Association, and other representatives of carers and transplant coordinators.

It is our hope that the revised Code, like the original Code, will be of help to those concerned with the care of the dying, by reaffirming the criteria for the diagnosis of brain stem death. In that way, relatives may be spared the ordeal of witnessing treatment which is prolonged but ultimately futile; and when brain stem death is established, it becomes proper to consider the availability of organs for transplant.

CODE OF PRACTICE

1. The Definition of Death

Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person. Thus, it is recommended that the definition of death should be regarded as 'irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe'. The irreversible cessation of brain stem function (brain stem death) whether induced by intra-cranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state and therefore brain stem death equates with the death of the individual.

The current position in law is that there is no statutory definition of death in the United Kingdom. Subsequent to the proposal of the 'brain death criteria' by the Conference of Royal Colleges in 1976 and 1979^(4,5), the courts in England and Northern Ireland have adopted these criteria, as part of the law, for the diagnosis of death^(6,7). There is no reason to believe that courts in other parts of the United Kingdom would not following this approach.

2. Conditions Under Which the Diagnosis of Brain Stem Death Should be Considered

2.1 There should be no doubt that the patient's condition is due to irremediable brain damage of known aetiology. It may be obvious within hours of a primary intracranial event such as a severe head injury, or spontaneous intracranial haemorrhage that the condition is irremediable. However, when a patient has suffered primarily from cardiac arrest, hypoxia or severe circulatory insufficiency with an indefinite period of cerebral hypoxia, or is suspected of having cerebral air or fat embolism 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 may only be reached by continuing clinical observation and investigation.

2.2 The patient is deeply unconscious.

2.2.1 There should be no evidence that this state is due to depressant drugs.

Narcotics, hypnotics and tranquillisers may have prolonged action, particularly when hypothermia coexists or in the context of renal or hepatic failure. The benzodiazepines are markedly cumulative and persistent in their actions and are commonly used as anticonvulsants or to assist synchronisation with mechanical ventilators. It is therefore essential that the drug history should be carefully reviewed and any possibility of intoxication being the cause of, or contributing to, the patient's comatose state should preclude a diagnosis of brain stem death. It is important to recognise that, in some patients, hypoxia may have followed the ingestion of a drug but in this situation the criteria for brain stem death will not be applicable until such a time as the drug effects have been excluded as a continuing cause of the unresponsiveness.

2.2.2 Primary hypothermia as the cause of unconsciousness must have been excluded.

2.2.3 Potentially reversible circulatory, metabolic and endocrine disturbances must have been excluded as the cause of the continuation of unconsciousness.

It is recognised that circulatory, metabolic and endocrine disturbances are a likely accompaniment of brain stem death (eg hypernatraemia, diabetes insipidus) but these are the effect rather than the cause of that condition and do not preclude the diagnosis of brain stem death.

2.3 The patient is being maintained on the ventilator because spontaneous respiration has been inadequate or ceased altogether.

Relaxants (neuromuscular blocking agents) and other drugs must have been excluded as the cause of respiratory inadequacy or failure. Immobility, unresponsiveness, and lack of spontaneous respiration may be due to the use of neuromuscular blocking drugs and the persistence of their effects should be excluded by elicitation of deep tendon reflexes or by the demonstration of adequate neuromuscular conduction with a conventional nerve stimulator. Persistent effects of hypnotics or narcotics must be excluded as the cause of respiratory failure.

3. The Diagnosis of Brain Stem Death

Fulfilment of the clinical criteria for the diagnosis of brain death specified by the Conference of Colleges during the period 1976-1981 is followed by cessation of the heart beat within a short period^(4,5,8,9). This has been confirmed in all published series and has therefore been adequately validated. The following paragraphs recapitulate the criteria in the conference guidelines, with the addition of notes on how they may be elicited, based on intervening experience.

3.1 All brain stem reflexes are absent.

3.1.1 The pupils are fixed and do not respond to sharp changes in the intensity of incident light.

3.1.2 There is no corneal reflect - care should be taken to avoid damage to the cornea.

3.1.3 The vestibulo-ocular reflexes are absent. No eye movements are seen during or following the slow infusion of at least 50mls of ice cold water over one minute into each external auditory meatus in turn. Clear access to the tympanic membrane must be established by direct inspection and the head should be flexed at 30°. The performance of this manoeuvre may be prevented on one or other side by local injury or disease but this does not invalidate the diagnosis of brain stem death.

3.1.4 No motor responses within the cranial nerve distribution can be elicited by adequate stimulation of any somatic area. There is no limb response to supraorbital pressure.

3.1.5 There is no gag reflex or reflex response to bronchial stimulation by suction catheter placed down the trachea.

3.1.6 No respiratory movements occur when the patient is disconnected from the mechanical ventilator. During this test it is necessary for the arterial carbon dioxide to exceed the threshold for respiratory stimulation, that is, the PaCO₂ should reach 6.65kPa. This should be ensured by measurement of the blood gases.

The patient may be moderately hypothermic, flaccid and with a depressed metabolic rate such that the arterial carbon dioxide tension rises slowly during apnoea. Hypoxia during disconnection should be prevented by delivering oxygen at 6 litres per minute through a catheter in the trachea. If the facility for administering 5% CO₂ in oxygen exists, this is the preferred method for performing this test. The patient should first be ventilated with 100% oxygen for 10 minutes, then with 5% CO₂ in oxygen for 5 minutes. The ventilator should then be disconnected for 10 minutes. During this period, oxygen should be delivered through a catheter as above.

Those patients with pre-existing chronic respiratory disease who may be responsive only to supra-normal levels of carbon dioxide and who depend upon hypoxic drive are special cases who should be managed in consultation with an expert in respiratory disease.

3.2 Children. A report of a working party of the British Paediatric Association of 1991 supported by the Council of the Royal College of Physicians suggested that, in children over the age of 2 months, the brain stem death criteria should be the same as those in adults. Between 37 weeks of gestation and 2 months of age, it is rarely possible confidently to diagnose brain stem death and below 37 weeks of gestation, the criteria for brain stem death cannot be applied⁽¹⁰⁾. A Working Party of the Conference of Colleges on Organ Transplantation in Neonates recommended that organs for transplantation may be removed from anencephalic infants when two doctors, who are not members of the transplant team, agree that spontaneous respiration has ceased⁽¹¹⁾. The conclusions of these reports are endorsed by the current Working Party.

3.3 Repetition of testing. The diagnosis of brain stem death should be made by at least two medical practitioners who have been registered for more than five years, are competent in this field and are not members of the transplant team, at least one of the doctors should be a consultant. Two sets of tests should always be performed, these may be carried out by the two practitioners separately or together. The tests are repeated to remove the risk of observer error. The timing of the interval between the tests is a matter for clinical judgement but the time should be adequate for the reassurance of all those directly concerned. The interval between the tests will depend upon the primary pathology, the clinical course of the disease and the progress of the patient. Although death is not pronounced until the second test has been completed the legal time of death is when the first test indicates brain stem death⁽⁶⁾.

3.4 The beating heart in brain stem death. Even if ventilation is continued both adults and children will suffer cessation of heart beat within a few days, very occasionally a few weeks, of the diagnosis of brain stem death.

3.5 Endocrine, metabolic and circulatory abnormalities. Abnormalities, such as diabetes insipidus, hypo or hypernatraemia, hypothermia and disturbance of cardiac rhythm or blood pressure may occur in patients following anoxic, haemorrhagic or traumatic cerebral injury. These abnormalities may be consequences of brain stem failure and must be differentiated from abnormalities of endocrinological, biochemical or autonomic function contributing to failure of brain stem function.

3.6 Limb and trunk movements. Reflex movements of the limbs and torso may occur after brain stem death has been identified. The doctor should be able to explain clearly the significance of these movements to relatives, nurses and other staff who should be given sufficient information to enable them to understand that they are of spinal reflex origin and do not involve the brain at all.

3.7 Investigations. The safety of the clinical criteria for the diagnosis of brain stem death during the past 17 years provides justification for not including the results of neurophysiological or imaging investigations as part of those criteria. At present there is no evidence that imaging, electroencephalography or evoked potentials assist in the determination of brain stem death and, although such techniques will be kept under review, they should not presently form part of the diagnostic requirements.

3.8 Peripheral neurological syndromes of intensive care. There is a range of overlapping neuropathic, neuromuscular and myopathic syndromes which may occur in the context of intensive therapy and may cause problems in weaning a patient from a ventilator. This is not true apnoea (respiratory centre paralysis) and should not be taken as evidence for brain stem death.

3.9 The permanent vegetative state. Problems relating to the diagnosis and management of the permanent vegetative state must not be confused with those relating to brain stem death and the guidelines endorsed by the Conference of the Royal Colleges emphasise the important differences⁽¹²⁾.

4. Management It is essential that relatives, partners and carers be kept fully informed of the clinical condition of the patient and that explanation be given to them regarding the condition and prognosis. Relatives, partners and carers of the patient should be given explanation of the investigations being undertaken and of their interpretation throughout the process of the determination of brain stem death in a sympathetic, timely and appropriate fashion by those concerned with the management of the patient.

4.1 Maintenance of therapy. The maintenance of normal homeostasis by attempting to ensure adequate fluid intake, electrolyte balance, normal blood pressure, the monitoring of urine output by catheter collection and the use of other therapeutic agents, is part of the standard medical care of the patient where brain stem death has not been conclusively established and may be continued after brain stem death is confirmed to maintain the condition of organs to be donated.

4.2 Cessation of Respiration. Sometimes a patient who is not receiving ventilatory assistance is thought to have irreversible brain damage but stops breathing before it has been possible to undertake testing. In cases of this kind brain stem death will not have been diagnosed and it will be possible to say with certainty that it will inevitably occur. In such cases the initiation of artificial ventilation as part of resuscitation is only justified if it is of potential benefit to the patient.

4.3 Elective Ventilation. Very occasionally it may be considered certain that death will inevitably occur shortly, as in the case of gross cerebral trauma or cerebral haemorrhage, but brain stem death has not yet been established. In these cases artificial ventilation of the patient should not be undertaken solely to preserve organ function. The Health Departments have advised that ventilation in these circumstances is unlawful⁽²⁾. It cannot be demonstrated to be for the benefit of the patient (and may indeed run the risk of causing serious harm) and thus is not in the best interest of the patient. The agreement of the relatives to elective ventilation does not alter the legal position.

5. Pre-Donation Issues

5.1 Potential Organ Donation. When doctors recognise that they have in their care a potential organ donor the sooner the local transplant coordinator is contacted the better. If

contact is made before brain stem death has been formally diagnosed this must be made evident to the transplant coordinator.

5.2 Person Lawfully in Possession of Body in Hospital. Under the Human Tissue Acts only the person lawfully in possession of a body or his designate can authorise the removal of organs or tissue from a body^(13,14). This authorisation may be given orally. Where a dead body is in an NHS hospital or other institution, the person with control and management of the hospital or institution (such as an NHS Trust) is the person lawfully in possession of the body until such time as it is claimed by the person who has the right to possession of it for the purposes of disposal (usually the executor, administrator or next of kin of the patient) or, by reason of their statutory obligations, the Coroner or Procurator Fiscal.

The person lawfully in possession of the body has powers and duties in connection with the removal of organs. The Acts empower a health services body (whether Health Authority or NHS Trust) to designate any officer or person to act on its behalf. This Code of Practice will assume that the health services body has delegated its power in this way to an appropriate person (or persons) who will be readily available, for example the consultant clinician in charge of the patient, who will hereafter be referred to as ‘the **designated person**’.

GUIDELINES FOR THE MANAGEMENT OF POTENTIAL ORGAN AND TISSUE DONORS

6. Introduction

The purpose of this section is to explain and provide guidelines on the sequence of events leading to organ or tissue donation by a patient pronounced brain stem dead.

Over the last decade the Transplant Coordinator has played a central role in these events. Transplant Coordinators are usually, but not invariably, based at large transplant centres and fulfil several important functions. A network of Transplant Coordinators now covers all the NHS hospitals in the UK. The local Transplant Coordinator is thus the contact individual to whom all potential organ donors should be referred. Subsequently, the Transplant Coordinator establishes contact, usually in person, with the donor hospital, the relevant doctors and nurses responsible for the care of the potential donor and also the relatives, partners or carers of the donor. At the appropriate time the opinions of the relatives, partners and carers with regard to organ and tissue donation is usually ascertained by the Coordinator following full discussion of the issues. This procedure will be made easier if the Coordinator contacts the United Kingdom Transplant Support Service Authority (UKTSSA) and finds out from the NHS Organ Donor Register whether or not the potential donor was registered as willing to donate all, or some, of his or her organs for transplantation.

UKTSSA is a Special Health Authority responsible, among other things, for the matching, allocation and distribution of organs donated for transplant. As part of this function, UKTSSA maintains the National Transplant Database which contains details of all potential organ transplant recipients in the UK and Republic of Ireland. The UKTSSA is directly linked to transplant centres in the UK and Republic of Ireland through a communications link, and is responsible for liaison directly with Coordinators at transplant centres nationwide to ensure that all potential donor organs are allocated to the patients on the waiting list who can most benefit from them. If organ donation is to proceed, the Transplant Coordinator makes contact with the UKTSSA, and coordinates with the surgical teams responsible for organ removal.

7. Transplant Coordinator

7.1 Contact. The Transplant Coordinator will usually be contacted by medical or nursing staff from the Intensive Therapy Unit or ward on which the patient is being nursed. If there are difficulties in contacting the local Coordinator, contact should be made either directly with the local transplant unit or with the United Kingdom Transplant Support Service Authority (UKTSSA), telephone: 0117 975 7575, who will identify and inform the local transplant unit. The local Transplant Coordinator will usually inform the UKTSSA and the local transplant unit.

7.2 Protocol and Records. The local Transplant Coordinator will provide protocols to be followed when a potential donor is identified. If no local protocols are available, national protocols may be obtained from the United Kingdom Transplant Coordinator's Association (UKTCA), telephone: 0191 213 1674.

7.3 Initial Assessment. If there is any doubt about the suitability of the patient for organ donation this can be discussed by the Transplant Coordinator by telephone. If this initial assessment indicates that the patient is unsuitable for organ donation the relatives will not need to be approached. Otherwise the coordinator will attend the ward on which the patient is being nursed to carry out an initial assessment of the potential donor, collating all clinical details relevant to organ donation.

8. The Relatives

It remains important that relatives, partners and carers be kept fully informed of the clinical state of the patient and decisions regarding management.

8.1 Contact With Relatives, Partners and Carers. The Transplant Coordinator would not normally discuss the possibility of organ donation until the diagnosis, prognosis and concept of brain stem death have been discussed by medical and nursing staff on the ward. Only when relatives indicate, before brain stem death has been formally diagnosed, a willingness that organs be donated would it be reasonable for the coordinator to discuss matters at that stage.

8.2 The Donor Card. If a patient carries a signed donor card or has otherwise recorded his or her wishes, for example by inclusion in the NHS Organ Donor Register, there is no legal

requirement to establish lack of objection on the part of relatives, although it is good practice to take account of the views of close relatives. If a relative or partner objects despite the known request by the patient, staff will need to judge according to the circumstances of the case whether it is wise to proceed with organ removal. Staff need to consider the feelings of relatives, who may be under great stress, so that in practice any objections raised by relatives usually take priority over donor's wishes.

8.3 Authorisation of Removal. If a patient who has died is not known to have requested that organs be removed for transplantation after death, the **designated person** (see paragraph 5.2) may only authorise the removal if, having made such reasonable enquiry as may be practicable, there is no reason to believe;

- that the deceased had expressed an objection to his body being so dealt with after death and had not withdrawn it.
- that the surviving spouse, partner or any surviving relative of the deceased objects to the body being so dealt with.
- there are religious obstacles. Any known religious views should be taken into account and, when a patient adheres to a religious belief whose views on organ donation are not known with certainty, the likely views of the patient should be explored in discussion with the relatives⁽¹⁵⁾.

The designated person need not enquire of the relatives personally but need only satisfy himself or herself that such enquiries have been properly carried out.

8.4 Where a donor has lived closely with someone to whom they are not legally related it is advisable to try to seek the views of the co-habitee or partner as well as those of the relatives.

8.5 It is essential to keep a written record of the enquiries made and their outcome. This should be part of the transplantation check list. If relatives are asked to sign any form, this should be worded in terms of 'lack of objection' rather than 'consent' following the wording of the Human Tissue Acts^(13,14). A form normally used for giving consent to a post mortem examination is not suitable for this purpose. It is recommended practice, but not a legal requirement, that the responsible relative or partner signs a 'lack of objection' form.

8.6 The person who approaches the relatives must be someone with appropriate experience who is aware how much the relatives already know about the patient's condition. It would normally be a hospital doctor with some seniority and experience in carrying out personal interviews of a sensitive nature. There may be occasions when the person best qualified to interview relatives is the Transplant Coordinator, a Senior Nurse, a Chaplain or the Family Doctor. Approaches must be made with proper sensitivity and a feeling for the relatives' distress and staff may value the opportunity to receive relevant training. The views of the relatives and partners should be sought whenever possible in a personal interview and only in quite exceptional circumstances should interviews be conducted by telephone.

8.7 Sometimes a relative approaches the hospital staff and suggests, some time before the diagnosis of brain stem death is made, that the patient's organs might be used for transplantation. If the patient dies some appreciable time after this approach has been made, it may be appropriate to confirm with relatives their lack of objection in case they have changed their minds. Sometimes relatives may offer consent to the removal of organs from a patient who has died when organs would not be suitable for subsequent transplantation. Such offers should be gratefully acknowledged, and the opportunity can often be sensitively used to suggest to relatives other tissues such as corneas, skin or bone, which may be suitable for transplantation.

8.8 In keeping with the view expressed in the Departmental Guidance Circulars on the Human Tissue Acts^(16,17,18,19) the designated person's duty is to make 'such reasonable enquiries as may be practicable'. In most instances it would be sufficient to discuss the matter with any one relative who has been in close contact with the deceased, determining whether there is reason to believe that any other relative or partner would be likely to object. There is no need to establish a lack of objection from all relatives before authorising the removal of organs.

8.9 Authorisation in the Absence of Relatives. If a donor's relatives are unavailable it would be impracticable to ask them and if they were, for example, young children or very seriously ill it would generally be unreasonable to do so. In such circumstances, the **designated person** can proceed to give authorisation if there is no reason to believe that there is a relevant objection but a note of the enquiries made should be entered on the transplantation check list. Cases when a potential donor's views about organ removal cannot be established and the relatives cannot be contacted are exceptional, but it is reasonable to assume in such cases that if a

donor has belonged to a religious group which objects to the removal of organs from the body, he himself would have objected⁽¹⁵⁾.

In those rare occasions where there are no existing relatives, the relatives cannot be traced or the potential donor is unidentified, removal of organs may be authorised by the person lawfully in possession of the body. If the responsible authority has delegated this responsibility to the clinical consultant in charge of the patient's care it is good practice to discuss the issue of organ removal with an appropriate colleague.

8.10 Children. It will be unusual for a child to have requested in advance that his organs or tissue be used for transplantation. In such a case, however, providing the child is of an age when it is reasonable to believe he or she would have understood what that involved, the designated person is entitled to authorise removal in accordance with the request as if the child were an adult. Even where the child has made such a request, enquiry should be made to the parents as a matter of good practice. Where no such request has been made enquiry must be made of the parents whether they, as surviving relatives of the donor, object.

8.11 Involvement of the Coroner. In any case where the cause of brain stem death is not clearly due to natural causes the Coroner, Coroner's Officer, or, in Scotland, the Procurator Fiscal must be consulted. The medical staff involved in the care of the patient ought to be the ones who contact the Coroner or Procurator Fiscal if this is necessary, although the Transplant Coordinator is the person usually responsible for identifying who is in lawful possession of the body and for obtaining the necessary authorisation for organ removal.

8.12 Prohibition on Payment for Organs. The Human Organ Transplants Act 1989 prohibits commercial dealing in organs including non-regenerative tissue. It is a criminal offence to make or receive payment in return for supplying an organ from a dead or living person and intended for transplantation. It is also an offence to broker or negotiate an arrangement involving such payment or to advertise for donors who will be paid. Payment includes money or its equivalent but does not include payment covering the costs of removing, transporting or preserving an organ or reasonable expenses or loss of earnings paid to a donor.

9. Retrieval of Organs and Tissue

When brain stem death is confirmed, the Transplant Coordinator is responsible for obtaining authorisation for organ removal either orally or, preferably, in writing but must in any case ensure that a proper record is kept of the views of relatives.

9.1 The Local Transplant Team. The Coordinator will inform the local transplant team responsible for the retrieval of organs and inform UKTSSA for the provisional allocation of organs.

9.2 Practical Details. The Coordinator arranges the practical procedures involving theatre time, anaesthetic support, the retrieval team and the donor ITU or ward.

9.3 Screening Tests. In accordance with HSG (96) 26 'Guidance on the Microbiological Safety of Human Tissue and Organs used in Transplantation'⁽²⁰⁾, the Transplant Coordinator organises those necessary virological and bacteriological screening tests and arranges tissue screening where relevant. It is also important to exclude, as far as possible, evidence for malignant disease in the donor. There may be differing requirements in this respect for certain tissues e.g. corneas.

9.4 Organ Retrieval and Transplant. Before removing organs or tissue, the surgeon must personally examine the body of the potential donor and on the basis of his examination, and the results of any tests diagnostic of brain stem death made by other doctors, he must be satisfied that the potential donor is dead. Eyes may be removed by an appropriately qualified and trained person who is not a doctor, but not until a doctor who has personally examined the body has stated that the potential donor is dead. When the results of the virological and bacteriological screening are to hand, the Coordinator advises the UKTSSA and the Transplant Units of the results and organ retrieval is undertaken where appropriate. Although it is reasonable to proceed with organ removal expeditiously following certification of brain stem death and receipt of appropriate authorisation for organ removal, organs must not be transplanted until microbiological safety to do so has been established.

10. Transplant Arrangements

The Transplant Coordinator will contact the UKTSSA and the Recipient Transplant Unit to organise organ transplantation.

11. Tissue Banking

The Transplant Coordinator may, with appropriate authorisation from the person lawfully in possession of the body, arrange for tissues such as cornea, bone, skin and heart valves to be retrieved and stored for future clinical use. These tissues can be retrieved from an organ donor up to 48 hours after circulator arrest. When such tissues are to be stored, the Transplant Coordinator must organise liaison with the relevant tissue bank.

**PROCEDURE FOR THE DIAGNOSIS AND MANAGEMENT
OF BRAIN STEM DEATH**

Identification of Coma

↓ Yes

Clinical evidence of cause of coma

(possibly supported by neuroimaging, neurophysiology, CSF, etc.)

↓ Yes

**Exclusion of hypothermia, intoxication,
sedative drugs, neuromuscular blocking agents, severe electrolyte,
acid base or endocrine abnormalities as causative**

↓ Yes

Absent Brain Stem Reflexes

Absent Motor Response

Apnoea $PCO_2 \geq 6.65kPa$

These procedures should be clearly explained to relatives

↓ Yes

**CLINICAL DIAGNOSIS
OF BRAIN STEM DEATH**

↓

Eligible for Organ Donation

↓ Yes

↓ No

**Proceed with Enquiries and
Testing Prior to Organ Donation**

Disconnect from Ventilator

MANAGEMENT OF POTENTIAL ORGAN AND TISSUE DONORS

ITU/Ward Staff identify brain stem death

Relatives are fully informed of the condition and prognosis for the patient



Diagnosis of brain stem death confirmed



Local Transplant Coordinator informed



Lack of objection of relatives, partners, carers confirmed



**Virological and bacteriological testing
Tissue typing**



Suitability confirmed



UKTSSA and User Transplant Units informed



Organ retrieval and transport



Tissue banking

Organ Transplantation

REFERENCES

1. Cadaveric organs for transplantation: A code of practice including the diagnosis of brain death. London 1983 HMSO.
2. Identification of potential donors of organs for transplantation. HSG(94)41 NHS Executive; International ventilation and organ transplantation DGM 94(116) Welsh Office; Elective ventilation NHS MEL (1994) 114 The Scottish Office.
3. Criteria for the diagnosis of brain stem death. J Roy Col Phys 1995 29:381-382.
4. Conference of Medical Royal Colleges and their Faculties in the United Kingdom. Diagnosis of brain death. BMJ 1976 ii:1187-1188.
5. Conference of Medical Royal Colleges and their Faculties in the United Kingdom. Diagnosis of brain stem death. Lancet 1976 ii:1069-1070.
6. Re A (A Minor) [1992] 3 Medical Law Reports 303.
7. Re TC (A Minor) [1994] 2 Medical Law Reviews 376.
8. Robson JG. Brain Death. BMJ 1981; 295:505.
9. Robson JG. Brain Death. Lancet 1981; ii:365.
10. Conference of Medical Royal Colleges and their Faculties in the United Kingdom. Diagnosis of brain stem death in infants and children. London British Paediatric Association 1991.
11. Working party on organ transplantation in neonates: Conference of Medical Colleges and Faculties of the United Kingdom. London DHSS 1988.
12. Conference of Medical Royal Colleges and their Faculties in the United Kingdom. The permanent vegetative state. J Roy Col Phys 1996 30:119-121.
13. Human Tissue Act 1961.
14. Human Tissue Act (Northern Ireland) 1962.
15. Religious and Cultural Issues Educational Leaflet. UK Transplant Coordinators Association 1996.
16. Human Tissue Act 1961. HSC(IS)156 Department of Health and Social Security (1975).
17. Human Tissue Act (Northern Ireland) 1962. HSS(OS3) 7/75 Department of Health and Social Services, Northern Ireland (1976).
18. Human Tissue Act 1961. NHS Circular 1975 (GEN)34. Scottish Home and Health Department (1975).
19. Human Tissue Act 1961). WHSC(IS)155 Welsh Office (1975).

20. Committee on microbiological safety of blood and tissue for transplantation. Guidance on the microbiological safety of human tissues and organs used in transplantation. NHS Exec 1996 HSG(96)26.