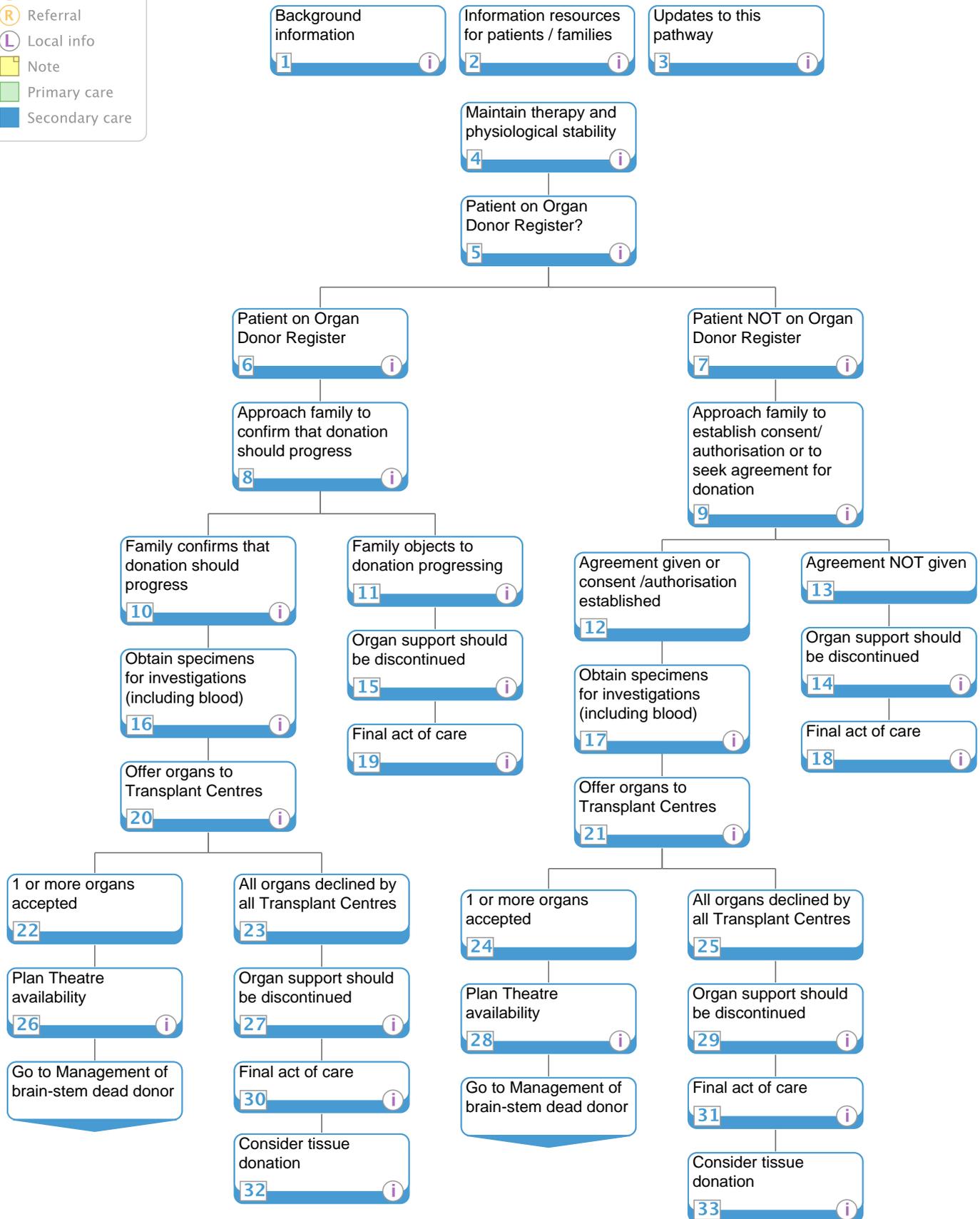


Consent / Authorisation for Donation after Brain-stem Death

Medicine > Organ donation > Donation after Brain-stem Death, Adult

- i Information
- R Referral
- L Local info
- Note
- Primary care
- Secondary care



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Medicine > Organ donation > Donation after Brain-stem Death, Adult

1 Background information

Quick info:

Donation after Brain-stem Death, Adult Pathway

Scope:

- Donation after Brain-stem Death (DBD), also known as Heartbeating Donation (HBD), refers to the retrieval of organs and eye tissue for the purposes of transplantation after death that is confirmed using neurological criteria (brain-stem death).
- In the UK, DBD programmes currently support the retrieval and transplantation of the following solid organs:
 - Heart
 - Lung
 - Kidney
 - Liver
 - Pancreas
 - Small bowel (stomach, ileum, jejunum, colon, abdominal wall, spleen)
 - Facial tissue (in some parts of England)
- Tissue donation from potential DBD donor, including when solid organ donation does not progress
- Donation from all care settings, most commonly but not exclusively ICUs and Emergency Medicine Departments

Out of scope:

- Donation from paediatric patients
- Tissue donation from tissue only donors
- However information is provided on tissue only donation for patients who start on the clinical pathway

Incidence and prevalence:

- The incidence of diagnosed brainstem death on ICUs in the UK has declined considerably over recent years, with the Potential Donor Audit recording 1147 cases in 2008/9 compared to 1339 in 2004/5. There has been a corresponding fall in the number of heartbeating brain-stem donors, from 664 to 611 respectively. DBD donors donate an average of 4 organs per donation
- The most up to date statistical information can be found in the NHS Blood and Transplant Annual Transplant Activity Report http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/transplant_activity_report.jsp

2 Information resources for patients / families

Quick info:

An information leaflet for families is available here: [Organ and Tissue Donation Information for Families](#)

3 Updates to this pathway

Quick info:

This is the first version of this pathway.

4 Maintain therapy and physiological stability

Quick info:

Detailed information on management of brain-stem dead patients can be found at: [Management of brain-stem dead donor](#)

5 Patient on Organ Donor Register?

Quick info:

The legislative framework for donation in the UK is that of an 'opting-in' system of consent. The primary legislation that cover this framework are the Human Tissue Act (2004) and the Human Tissue (Scotland) Act 2006. Although it may not equate with the standard of informed consent as it is used elsewhere in medical practice, the Human Tissue Act 2004, which governs practice in England and Wales, specifically uses the term 'consent' in its wording. The Human Tissue (Scotland) Act 2006 differs in this respect,

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and uses the term 'authorisation'. Practice in Northern Ireland is governed principally by common law, although in general terms it follows the legal principles that are applied elsewhere in the United Kingdom.

Both the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 give primacy to the wishes of the individual however they have been stated. The Acts recognise that a wish to donate may have been recorded or stated in various ways – by having a Donor Card, verbally, in writing or via the various means of accessing the NHS Organ Donor Register (ODR). Before approaching a family, clinicians should confirm whether their patient is on the ODR (approximately a quarter of the UK population is currently registered on it), since this has a direct influence on the subsequent approach to the individual's next of kin. This can be done on behalf of clinicians by the local Specialist Nurse for Organ Donation or directly by contacting the Duty Office at the Directorate of Organ Donation and Transplantation in Bristol on 0117 9757580 or 0117 9757581. When making an enquiry, clinical staff will be asked to provide the following information:

- Patient name
- Patient date of birth
- Patient address including postcode
- Their own contact details, including the name of the hospital and specific clinical area.

The Duty Officer will return the call within a few minutes via the hospital switchboard, and can provide a facsimile copy of a patient's registration if required to help with subsequent conversations with family members.

6 Patient on Organ Donor Register

Quick info:

The NHS Organ Donor Register (ODR) was established in 1981, and provides residents of the UK with a formal means of recording their desire to donate organs and / or tissue after death. By July 2010 the ODR had accumulated more than 17 million registrations. Registration occurs

- when individuals apply for a driving licence
- when individuals register with a new general practitioner
- through applications for the Boots Advantage customer loyalty card.
- online at <http://www.organdonation.nhs.uk/ukt/default.jsp>
- by telephone on 0300 1232323
- by texting SAVE to 84118

Registration on the Organ Donor Register (ODR) is considered to represent consent for donation by both the Human Tissue Act 2004 and authorisation for donation by the Human Tissue (Scotland) Act 2006. If an individual has recorded a desire to donate organs and / or tissue this wish, at law, has primacy over the views of that individual's next of kin, and the approach to the individual's family in such circumstances should reflect this. Thus the family should be asked to confirm that donation can proceed in accordance with their loved one's wishes. When confirming with a family that donation can proceed, the input of a Specialist Nurse Organ Donation is advised as they are trained in the inherent complexities of this process. In summary, a family should be aware:

- of the need for additional blood sampling to allow for microbiological screening, blood grouping and tissue typing
- that donation may not be possible
- if the Coroner or Procurator Fiscal refuses permission
- if cardiovascular instability leads to asystole before the retrieval team have arrived
- if there is no suitable recipient
- of the various interventions associated with donor management: [Management of brain-stem dead donor](#)

In law, families have no authority to overrule the wishes of an individual to donate in the event of their death. However, it seems unlikely that clinicians would ever ignore the objections of close family members, although in Scotland families are required to sign a written declaration that indicating the legal authorisation of their loved one have been overruled. Families should be advised that donation will not be halted once the retrieval laparotomy has begun.

7 Patient NOT on Organ Donor Register

Quick info:

The NHS Organ Donor Register (ODR) was established in 1981, and provides residents of the UK with a formal means of recording their desire to donate organs and / or tissue after death. By July 2010 the ODR had accumulated more than 17 million registrations. Registration occurs

- when individuals apply for a driving licence

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- when individuals register with a new general practitioner
- through applications for the Boots Advantage customer loyalty card.
- online at <http://www.organdonation.nhs.uk/ukt/default.jsp>
- by telephone on 0300 1232323
- by texting SAVE to 84118

Although 28% of the UK population are now registered on the ODR, the majority of actual deceased organ donors are not on the ODR when they die. If an individual is not on the ODR it is incorrect to conclude that they would not wish to donate, since it is possible that they, like the majority of the population, were supportive of donation but had missed or overlooked the opportunities to register this wish formally. It is also possible that an individual had recorded their wishes in a different way – in conversation with family and friends for instance. In circumstances when an individual is not on the ODR therefore, the initial responsibility for clinical staff is to determine whether the views of the individual regarding donation were known to his / her close family and friends, since these views – however they might have been recorded or expressed - take priority, at law, over whatever a family's own views or wishes might be. If the family provide evidence of an individual's stated wish, then they should be asked to confirm that donation can proceed in accordance their loved one's wishes.

There will be circumstances however when wishes of the potential DBD donor cannot be determined. In these circumstances the law allows for an individual's next of kin to decide on their behalf. Both the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2004 provide a hierarchical list of qualifying relatives who might assist with such decision making, although in practice it is sensible to be sensitive to the specific dynamics within a given assembly of family and close friends. Whereas the Human Tissue Act 2004 describes such a decision as 'consent', the Human Tissue (Scotland) Act 2006 refers to this as 'authorisation'. When seeking agreement for donation, the input of a Specialist Nurse Organ Donation is advised as they are trained in the inherent complexities of this process. In summary, a family should be aware:

- of the need for additional blood sampling to allow for microbiological screening, blood grouping and tissue typing
- that donation may not be possible
- if the Coroner or Procurator Fiscal refuses permission
- if cardiovascular instability leads to asystole before the retrieval team have arrived
- if there is no suitable recipient
- of the various interventions associated with donor management, see [Management of brain-stem dead donor](#)

Families will occasionally seek to withdraw their agreement for donation, although it should be noted that families have no authority to overrule the wishes of an individual to donate in the event of their death. Furthermore, in Scotland it is unlawful to withdraw authorisation once it has been given, and in this jurisdiction families are required to sign a written declaration that they have chosen to reverse their initial decision. Families should be advised that donation will not be halted once the retrieval laparotomy has begun.

8 Approach family to confirm that donation should progress

Quick info:

The approach regarding organ donation should only be made when the family has accepted that the patient is dead, and should only be made by staff who are fully competent to do so. The recent ACRE study into collaborative requesting did not demonstrate any benefit of collaborative requesting. However, many clinicians value the input of a SN-OD when approaching a family for consent / authorisation, all SN-ODs having received substantial training for this role.

In the consent / authorisation process, families should be aware:

- of the need for additional blood sampling to allow microbiological screening, blood grouping and HLA tissue typing. Consent / authorisation must be obtained for microbiological screening if the results may have health implications for family or partners.
- that donation may not be proceed if:
 - the Coroner / Procurator Fiscal refuses permission
 - cardiovascular instability leads to asystole before retrieval is underway
 - there is no suitable recipient
- they can withdraw consent at any time up until the beginning of the retrieval procedure (in England, Wales and Northern Ireland)
- under Scottish law, it is unlawful to allow authorisation to be withdrawn once it has been given. However, clinicians sometimes take the pragmatic view that donation cannot proceed without the support of the family

Consent / authorisation for virology, blood grouping and HLA typing is also part of the consent / authorisation process.

9 Approach family to establish consent/authorisation or to seek agreement for donation

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Quick info:

Aspects of law relevant to consent / authorisation include the Human Tissue Act (2004) and the Human Tissue (Scotland) Act 2006. Both acts give primacy to the wishes of the individual, however they might have been recorded, as well as indicating how decision-making should proceed when these are not known. The Human Tissue Act (2004) governs actions in England and Wales and specifically uses the term 'consent'. The Human Tissue (Scotland) Act 2006 differs in this respect, and uses the term 'authorisation'. Practice in Northern Ireland is governed principally by common law, although in general terms follows the principles enacted elsewhere in the United Kingdom.

At law, registration with the Organ Donor Register is considered to represent consent / authorisation for organ donation, even though this may not meet the standards set for 'informed consent' in other areas of medical practice.

The approach regarding organ donation should only be made when the family has accepted that the patient is dead, and should only be made by staff who are fully competent to do so. The recent ACRE study into collaborative requesting did not demonstrate any benefit. However, many clinicians value the input of a SN-OD when approaching a family for consent / authorisation, all SN-ODs having received substantial training for this role.. Registration with the Organ Donor Register should not be viewed as consent / authorisation, but rather as an indication of the wishes of an individual that can be used to inform an assessment of best interests. In the consent / authorisation process, families should be aware:

- of the need for additional blood sampling to allow virological screening, blood grouping and HLA tissue typing. Consent / authorisation for virology, should be obtained.
- that donation may not be proceed if:
 - the Coroner / Procurator Fiscal refuses permission
 - cardiovascular instability leads to asystole before retrieval is underway
 - there is no suitable recipient
- they can withdraw consent at any time up until the beginning of the retrieval procedure (in England, Wales and Northern Ireland)
- under Scottish law, it is unlawful to allow authorisation to be withdrawn once it has been given. However, clinicians sometimes take the pragmatic view that donation cannot proceed without the support of the family

10 Family confirms that donation should progress

Quick info:

Families are advised that if any microbiology results are found to be positive, and if there may be implications for their own health, that they will be informed.

11 Family objects to donation progressing

Quick info:

If families object to donation proceeding:

- this should be explored in a sensitive way with families to understand that donation was their loved one's wish in life
- families should be thanked for their consideration and time

14 Organ support should be discontinued

Quick info:

If donation is not proceeding organ support should be discontinued.

Reference:

Academy of Medical Royal Colleges. A Code of Practice for the Diagnosis and Confirmation of Death, October 2008. <http://www.aomrc.org.uk/aomrc/admin/reports/docs/DofD-final.pdf>

15 Organ support should be discontinued

Quick info:

If donation is not proceeding organ support should be discontinued.

Reference:

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Academy of Medical Royal Colleges. A Code of Practice for the Diagnosis and Confirmation of Death, October 2008. <http://www.aomrc.org.uk/aomrc/admin/reports/docs/DofD-final.pdf>

16 Obtain specimens for investigations (including blood)

Quick info:

2 specimens of blood will be taken, 1 for microbiology and 1 for tissue typing. These will be sent to a regional laboratory and this would be organised by the Specialist Nurse Organ Donation.

1 microbiology sample will be tested for:

- Human immunodeficiency virus (HIV)
- Hepatitis B
- Hepatitis C
- Cytomegalovirus (CMV)
- Toxoplasmosis
- Syphilis
- Human T-lymphotropic virus (HTLV) (some laboratories)

If there is a possibility that a female patient may be pregnant, the unit should undertake a pregnancy test. Detailed guidance is available from: http://www.nhsbt.nhs.uk/downloads/board_papers/mar10/guidelines_for_testing.pdf

Reference:

'Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation', Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation MSBT

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4079053.pdf

17 Obtain specimens for investigations (including blood)

Quick info:

2 specimens of blood will be taken, 1 for microbiology and 1 for tissue typing. These will be sent to a regional laboratory and this would be organised by the Specialist Nurse in Organ Donation.

1 microbiology sample will be tested for:

- Human immunodeficiency virus (HIV)
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- Cytomegalovirus (CMV)
- Toxoplasmosis
- Syphilis
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Reference:

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http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4079053.pdf

18 Final act of care

Quick info:

The Final Act of Care will be carried out as per hospital policy.

19 Final act of care

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Quick info:

The Final Act of Care will be carried out as per hospital policy.

20 Offer organs to Transplant Centres

Quick info:

The SN-OD offers each consented / authorised organ to each Transplant Centre in sequence until either the organ is accepted or has been declined by each centre.

This process typically takes between 1 and 5 hours. Each Transplant Centre is allowed 45 minutes to decide whether or not to accept an organ. Only those organs that have been accepted by a Transplant Centre with the intention to transplant will be retrieved.

The decision whether or not to accept an organ is made by the transplanting surgeon and is based on multiple factors, including:

- Clinical condition of recipient
- Logistics of potential recipients' arrival at the Transplant Centre within the required timeframe
- Individual Transplant Centre's acceptance criteria

21 Offer organs to Transplant Centres

Quick info:

The SN-OD offers each consented / authorised organ to each Transplant Centre in sequence until either the organ is accepted or has been declined by each centre.

This process typically takes between 1 and 5 hours. Each Transplant Centre is allowed 45 minutes to decide whether or not to accept an organ. Only those organs that have been accepted by a Transplant Centre with the intention to transplant will be retrieved.

The decision whether or not to accept an organ is made by the transplanting surgeon and is based on multiple factors, including:

- Clinical condition of recipient
- Logistics of potential recipients' arrival at the Transplant Centre within the required timeframe
- Individual Transplant Centre's acceptance criteria

26 Plan Theatre availability

Quick info:

The SN-OD will negotiate a time for the availability of Theatre, based on:

- Family wishes
- Availability of Theatre
- Other pressures on donating Unit
- Availability and arrival time of retrieval team(s) - there are usually separate abdominal and cardiothoracic retrieval teams
- Availability of an Anaesthetist from the donating hospital:
 - Required for abdominal only donors
 - May be required as backup for cardiothoracic donors

27 Organ support should be discontinued

Quick info:

If no suitable recipient can be found for any organ, organ support should be discontinued.

Reference:

Academy of Medical Royal Colleges. A Code of Practice for the Diagnosis and Confirmation of Death, October 2008. <http://www.aomrc.org.uk/aomrc/admin/reports/docs/DofD-final.pdf>

28 Plan Theatre availability

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Quick info:

The SN-OD will negotiate a time for the availability of Theatre, based on:

- Family wishes
- Availability of Theatre
- Other pressures on donating Unit
- Availability and arrival time of retrieval team(s)
 - There are usually separate abdominal and cardiothoracic retrieval teams.
- Availability of an Anaesthetist from the donating hospital.
 - Required for abdominal only donors
 - May be required as backup for cardiothoracic donors.

29 Organ support should be discontinued

Quick info:

If no suitable recipient can be found for any organ, organ support should be discontinued.

Reference:

Academy of Medical Royal Colleges. A Code of Practice for the Diagnosis and Confirmation of Death, October 2008. <http://www.aomrc.org.uk/aomrc/admin/reports/docs/DofD-final.pdf>

30 Final act of care

Quick info:

The Final Act of Care will be carried out as per hospital policy.

31 Final act of care

Quick info:

The Final Act of Care will be carried out as per hospital policy.

32 Consider tissue donation

Quick info:

See attachment for detailed information on tissue (including eye) donation: [Tissue and Eye Donation Information](#)

33 Consider tissue donation

Quick info:

See attachment for detailed information on tissue (including eye) donation: [Tissue and Eye Donation Information](#)

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Key Dates

Due for review: 02-Sep-2012

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