UKDEC
UK Donation Ethics Committee

ACADEMY OF MEDICAL ROYAL COLLEGES

AN ETHICAL FRAMEWORK FOR CONTROLLED DONATION AFTER CIRCULATORY DEATH

EXECUTIVE SUMMARY

DECEMBER 2011

INTRODUCTION

This summary paper sets out the recommendations made by the UK Donation Ethics Committee for ethical practice in controlled donation after circulatory death. A full discussion of the ethical considerations and background to the recommendations is in the full Ethical Framework.

Definitions and Terminology

i. Donation after circulatory death (DCD) is organ donation that takes place following diagnosis of death by cardio-respiratory criteria, as laid down in the Code of Practice for Diagnosis and Confirmation of Death.[1] This form of donation has been known as non-heartbeating donation (NHBD), and donation after cardiac death (also shortened to DCD) in recent times. In accordance with developing international practice, UKDEC recommends using the term 'donation after circulatory death' (DCD).

ii. There are a number of different forms of DCD. This guidance is concerned with controlled DCD, which occurs when donation follows the planned withdrawal of treatment. Patients who become donors in this way are normally being cared for in an intensive care unit, deeply unconscious and supported by artificial ventilation.

iii. In this guidance we have used the term 'overall benefit' when describing the course of action most appropriate to a particular patient at a particular time. This follows the approach taken in recent GMC guidance on end of life care[2], and is intended to ensure that the points discussed are applicable to the different legal frameworks throughout the UK. Other terms, such as 'best interests', are only used in the context of specific legislation.

Guiding Principles

There are two guiding principles behind the work of the UK Donation Ethics Committee:

Principle 1: where donation is likely to be a possibility, full consideration should be given to the matter when caring for a dying patient; and

Principle 2: if it has been established that further life-sustaining treatment is not of overall benefit to the patient, and it has been further established that donation would be consistent with the patient's wishes, values and beliefs, consideration of donation should become an integral part of that patient's care plan in their last days and hours.

The full document 'An Ethical Framework for Donation After Circulatory Death' can be downloaded from www.aomrc.org.uk/donation-ethics-committee.html

The recommendations presented here have been developed in accordance with these principles. Actions to implement many of these recommendations depend upon their being used as guidance for the preparation of local policies and protocols, which in turn can take account of local circumstances.

Part One: Ethical Framework

Definition, diagnosis and confirmation of death

Diagnosis of death in a potential DCD donor should be in accordance with current guidance as set out in the Code of Practice for Diagnosis and Confirmation of Death.[1] The process is the same regardless of whether donation is a clinical possibility. UKDEC believes that the Code is robust and evidence based, with one key requirement being *"a minimum observation period of 5 minutes between diagnosis and confirmation of death*". As such it provides a firm foundation for organ donation.

Exploring a competent individual's views about organ donation

When a fully competent patient has been diagnosed with a terminal condition, it is incumbent on the treating clinicians to make opportunities for them to express their wishes about organ donation and discuss any questions or concerns that they might have. This is in line with recent GMC guidance.[2] This does not apply if organ donation is not possible in their circumstances, although the patient or their family may still raise the issue. If this happens they should be given the opportunity to discuss and understand why donation is not possible for them.

Deciding that life-sustaining treatment is no longer of overall benefit

Making the decision that continuation of life-sustaining treatment is of no overall benefit to the patient is the critical point in the care pathway. This decision needs to be wholly independent of the decision as to whether organ donation is appropriate. As the patient will typically be unconscious in an intensive care unit,

1 A Code of Practice for the Diagnosis and Confirmation of Death, Academy of Medical Royal Colleges, 2008

2 Treatment and care towards the end of life: good practice and decision making, GMC, 2010

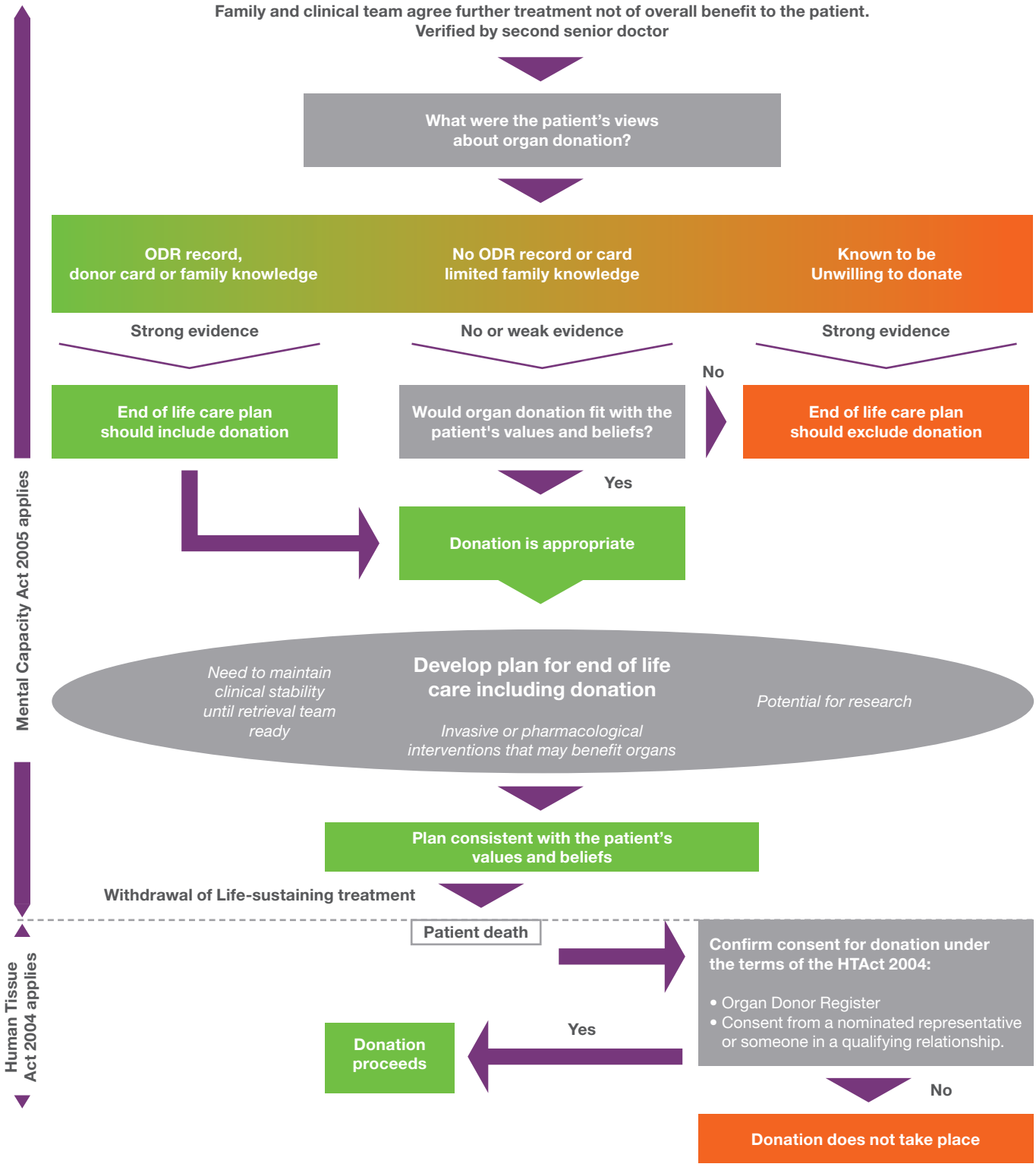
3 The Human Tissue Authority website gives full details of human tissue legislation for the UK http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm; for the Mental Capacity Act 2005 and associated Code of Practice see: http://www.justice.gov.uk/guidance/protecting-the-vulnerable/mental-capacity-act/index.htm; for the Adults with Incapacity (Scotland) Act 2006 see http://www.scotland.gov.uk/Publications/2006/03/07090322/0]

the clinician responsible will need to consult with the patient's family and come to an appropriate view. Legal requirements are set out in the Mental Capacity Act 2005 and the Adults with Incapacity (Scotland) Act 2000 and their associated Codes of Practice. UKDEC recommends that this decision should be verified by a second senior doctor.

Determining whether organ donation is of overall benefit to an incompetent patient

The clinical team need to determine, with those close to the patient family, whether organ donation is appropriate. Where a patient has made their wishes known by joining the Organ Donor Register, carrying an organ donor card or through previous discussions with family members, this is straightforward. Where there is little or no evidence, then the clinical team need to work with the family to decide whether organ donation would accord with their values, wishes and beliefs. An end of life care plan should be developed that includes organ donation, if appropriate, and that addresses any other factors such as spiritual or cultural requirements. A detailed discussion of the factors involved and the associated legal framework is in the full Ethical Framework.

DIAGRAM ONE: DETERMINING WHETHER ORGAN DONATION IS OF OVERALL BENEFIT



Conflicts of Interest.

Conflicts of interest arise if a person involved in treating a potential donor has a vested interest in them becoming a donor, thus leading to the risk of a (subconscious) tendency to focus on securing a successful donation rather than to facilitate a comfortable and peaceful end to their life. Further conflicts may arise as a result of staffing or other logistical issues.

UKDEC recommends that organisations should have protocols setting out options for managing staff shortages in order to achieve a potential donor's wish, and the circumstances when such difficulties render donation inappropriate.

UKDEC recommends that the lead clinician or nurse in charge is responsible for ensuring that staffing arrangements are such as to provide appropriately skilled care for the potential donor that meets the necessary ethical standards.

UKDEC has considered the position of three professional groups:

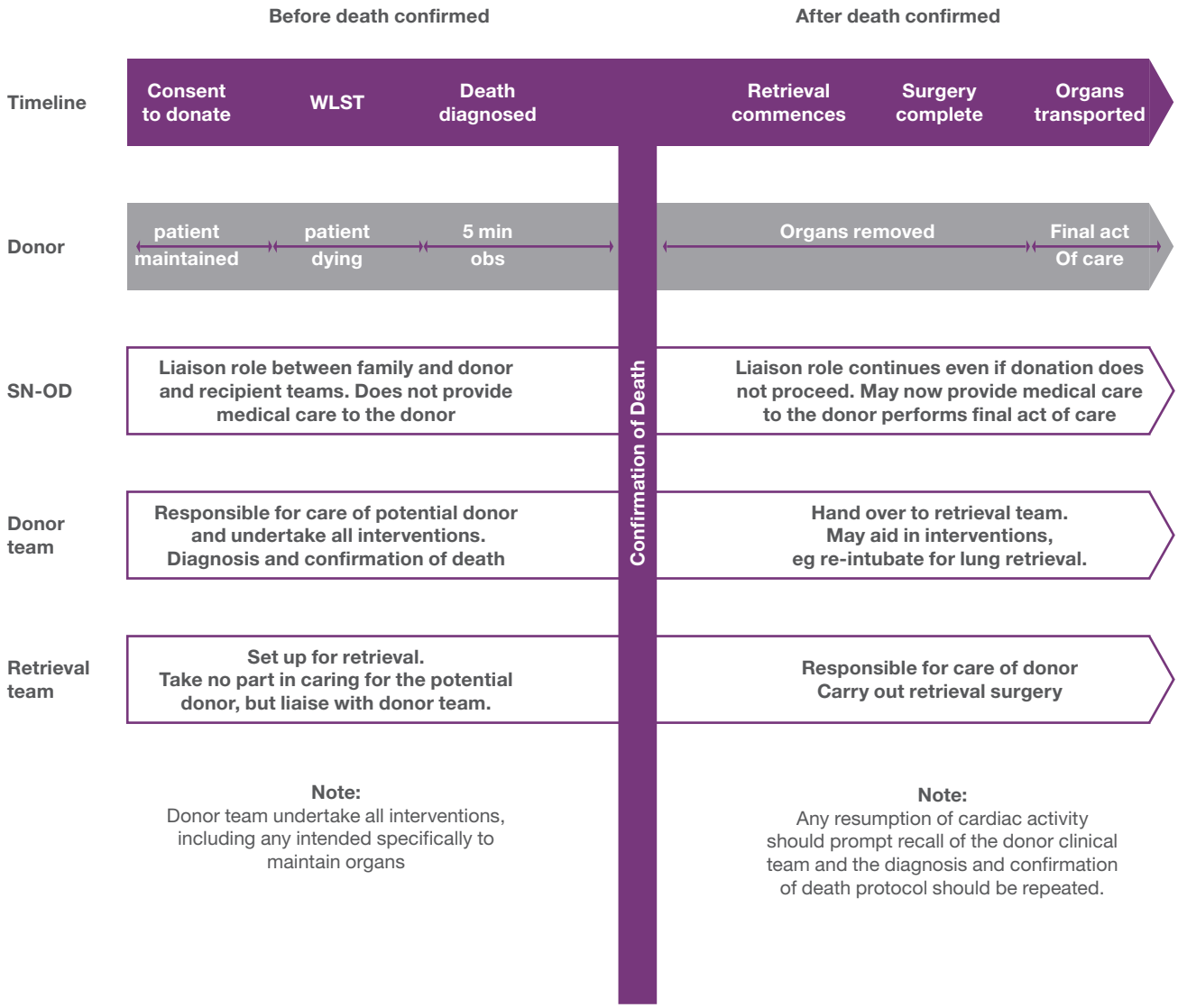
- Clinical Lead for Organ Donation (CLOD) – typically an intensive care consultant who has additional responsibilities to ensure that organisational and managerial requirements are in place to facilitate donation. **UKDEC does not consider there to be a conflict of interest if the clinician treating a potential donor is also a CLOD.**

- Specialist Nurse-Organ Donation (SN-OD) – the SN-OD is employed by NHS Blood and Transplant (NHSBT) to work with the potential donor's family, and if consent for donation is given, to co-ordinate the donation process, liaising between the donor team, the retrieval team and with NHSBT. SN-ODs are typically intensive care nurses by training, and if staffing is tight they may be asked to help nurse the potential donor. **UKDEC considers there would be a conflict of interest if the SN-ODs were to provide medical care to potential donors whilst they are still alive.**

- Retrieval team – the retrieval team is the surgical team who carry out the operation to retrieve organs. The potential donor is handed over into the care of the retrieval team after death has been confirmed. **UKDEC considers there is a conflict of interest if the retrieval team play any part in the care of the patient before death.**

After death, the SN-OD and members of the intensive care team may assist in caring for the donor if their particular skills are required. For example, re-intubation to facilitate lung retrieval may be carried out by a member of the donor team if necessary.

DIAGRAM TWO: TIMELINES AND RESPONSIBILITIES

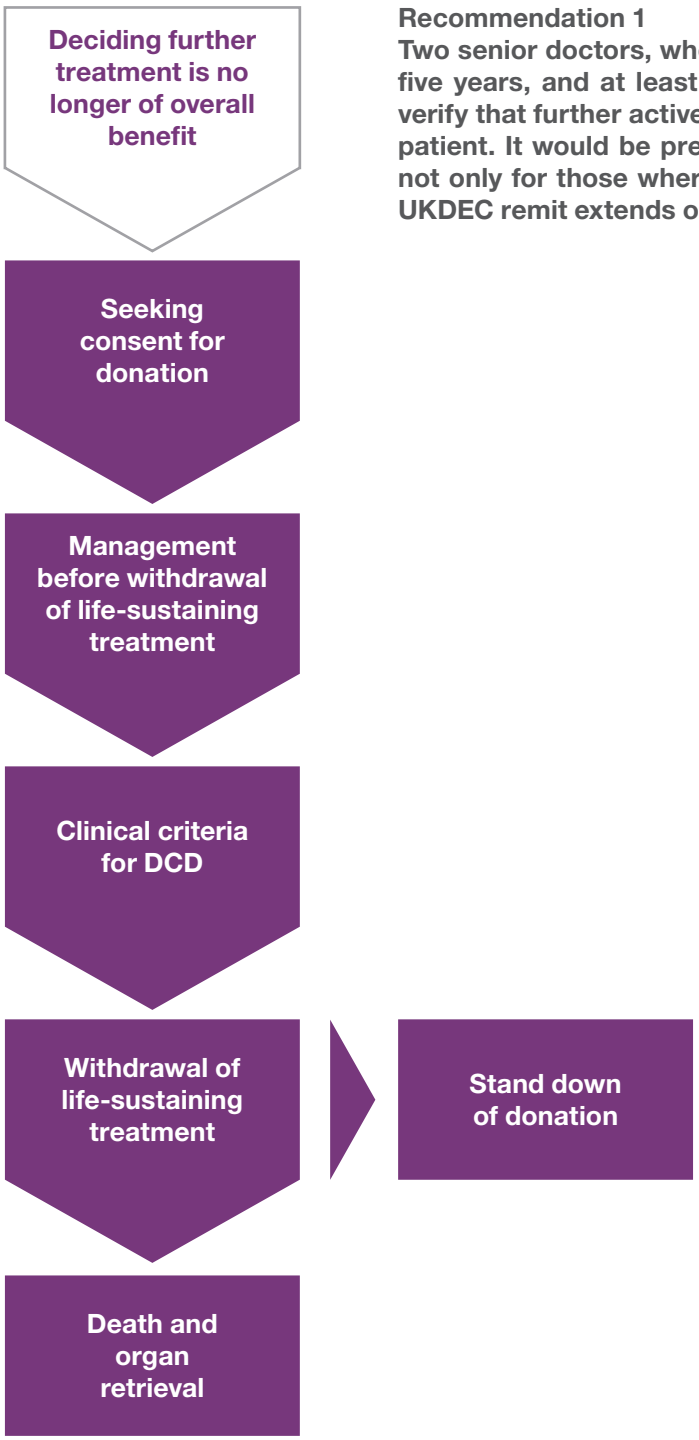


PART TWO: THE POTENTIAL DONOR PATHWAY

This section sets out recommendations for ethical practice along the patient pathway from the point of deciding that further life-sustaining treatment is no longer of overall benefit to the patient. Recommendations only are set out here. For detailed explanation and discussion, see the full Ethical Framework.

PATIENT PATHWAY

DECIDING FURTHER TREATMENT IS NO LONGER OF OVERALL BENEFIT

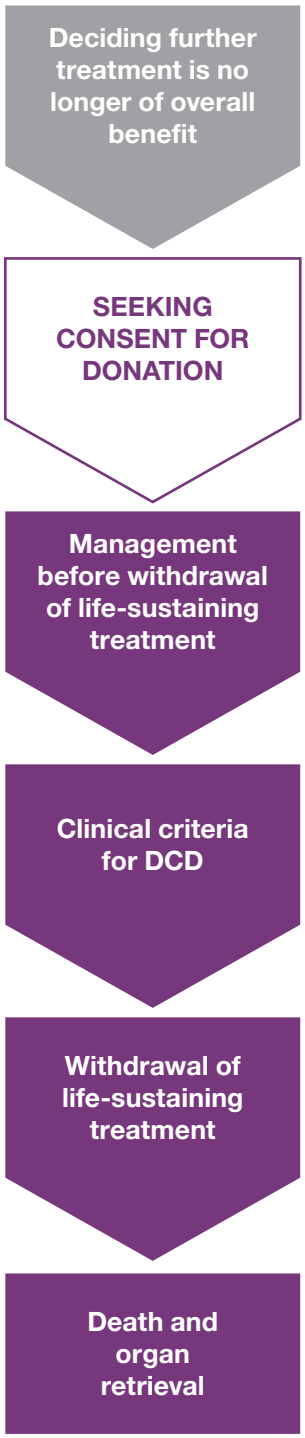


Recommendation 1
Two senior doctors, who should both have been registered for at least five years, and at least one of whom should be a consultant, should verify that further active treatment is no longer of overall benefit to the patient. It would be preferable for this to be the case for all patients, not only for those where organ donation is a possibility (although the UKDEC remit extends only to organ donation). (see paragraph 1.3)

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY

SEEKING CONSENT FOR DONATION (1)



Recommendation 2
Contact between the clinical team treating the potential donor and the SN-OD before the decision has been made to withdraw life-sustaining treatment is ethically acceptable. Advantages include identifying patients who are not suitable donors, and avoiding distressing delays to the family if the SN-OD has to travel some distance to get to the unit. The need for independent verification that further life-sustaining treatment is not in the patient's best interests (as set out in recommendation 1) acts as a safeguard for the potential donor at this time.

Recommendation 3
The family will not be approached about organ donation unless and until the decision to withdraw life-sustaining treatment has been made and independently agreed, and the family has accepted this. The patient's ODR status should be known before the family are approached. If the family raise the issue at an earlier stage any information should be noted and discussions handled sensitively according to the family's needs, but decisions should not be formalised until the decision to withdraw life-sustaining treatment has been made.

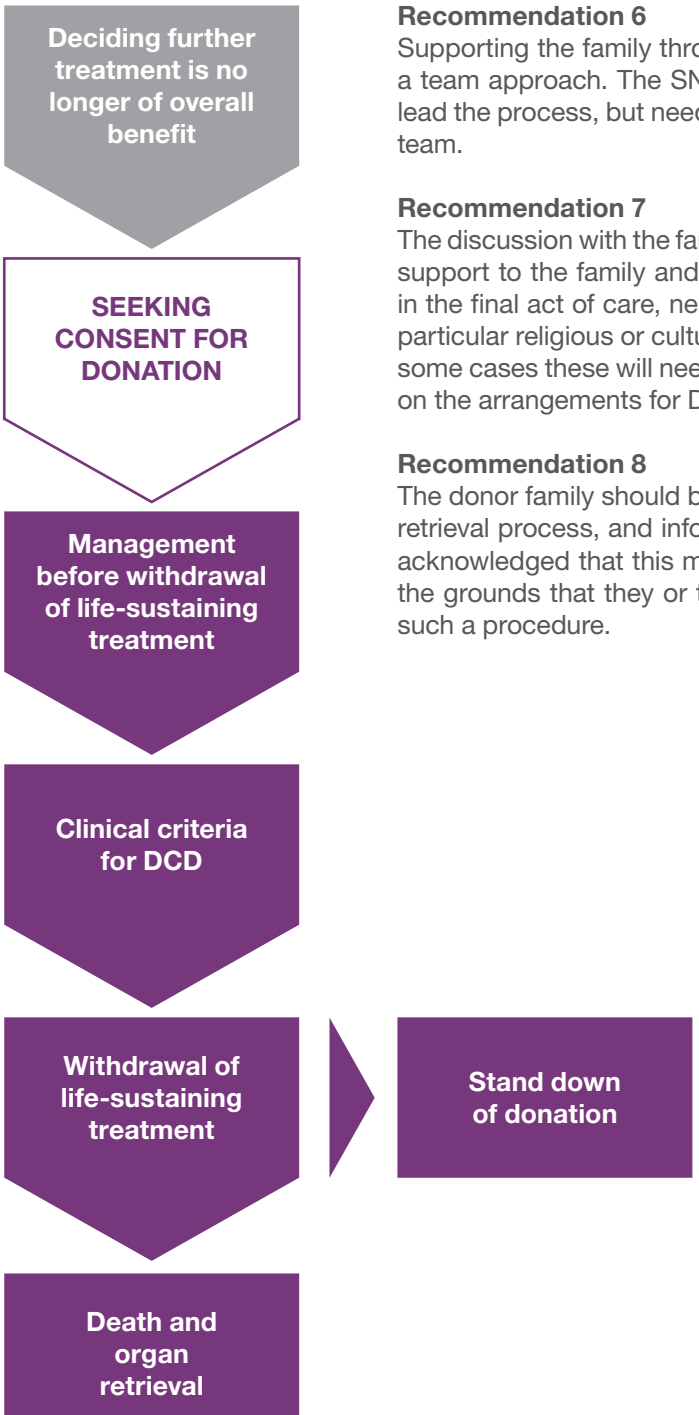
Recommendation 4
Organisations should have protocols setting out options for managing staff shortages in order to achieve a patient's wish, and the circumstances when such difficulties render a donation inappropriate. (paragraph 1.6.5 onwards)

Recommendation 5
The lead clinician or nurse in charge is responsible for ensuring that staffing arrangements are such as to provide appropriately skilled care for the potential donor that meets the necessary ethical standards. (paragraph 1.6.5 onwards)

Stand down of donation

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY



SEEKING CONSENT FOR DONATION (2)

Recommendation 6
Supporting the family through the discussion about organ donation requires a team approach. The SN-OD has the detailed knowledge and expertise to lead the process, but needs to be supported by other members of the clinical team.

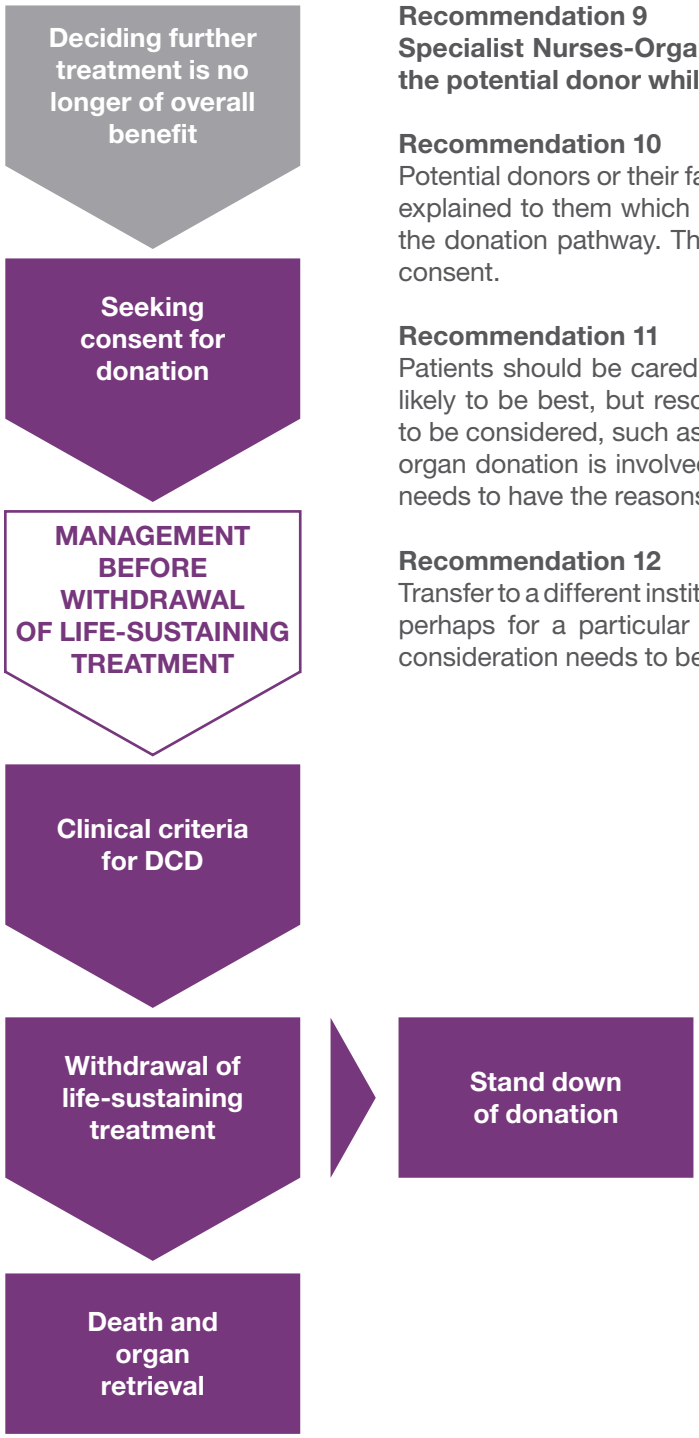
Recommendation 7
The discussion with the family, which may include offering religious or spiritual support to the family and a discussion of the family's wishes to be involved in the final act of care, needs to address at an early stage whether there are particular religious or cultural traditions that need to be taken into account. In some cases these will need to be undertaken quickly, and can have a bearing on the arrangements for DCD.

Recommendation 8
The donor family should be asked whether they would like to know about the retrieval process, and information given at an appropriate level of detail. It is acknowledged that this may result in some families withdrawing consent on the grounds that they or their loved one would not have wished to undergo such a procedure.

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY

MANAGEMENT BEFORE WITHDRAWAL OF LIFE-SUSTAINING TREATMENT (1)



Recommendation 9
Specialist Nurses-Organ Donation should not provide medical care to the potential donor whilst they are still alive. (paras 1.6.11 – 1.6.13)

Recommendation 10
Potential donors or their families should have a clear action plan for treatment explained to them which outlines various eventualities that may arise during the donation pathway. The action plan should only be carried out with their consent.

Recommendation 11
Patients should be cared for in an appropriate location. The ICU or HDU is likely to be best, but resource constraints may mean that alternatives need to be considered, such as recovery rooms and theatre suites, whether or not organ donation is involved. Local policies need to be flexible and the family needs to have the reasons for the chosen location explained to them.

Recommendation 12
Transfer to a different institution may, very exceptionally, need to be considered perhaps for a particular test to determine suitability for donation. Careful consideration needs to be given to the risk of death during transfer.

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY

MANAGEMENT BEFORE WITHDRAWAL OF LIFE-SUSTAINING TREATMENT (2)

Recommendation 13
If organ donation has been identified as part of the end of life care pathway for a patient, then caring for that patient during the dying process in such a way as to maintain the organs in the best possible condition for donation does not represent a conflict of interest on the part of the treating clinician. Because it is considered to be for the overall benefit of the patient to become a donor, interventions to facilitate this are also likely to be of benefit unless they may cause harm or distress or risk causing harm or distress (paras 1.4.2 – 1.4.4 and 1.6.2 – 1.6.4)

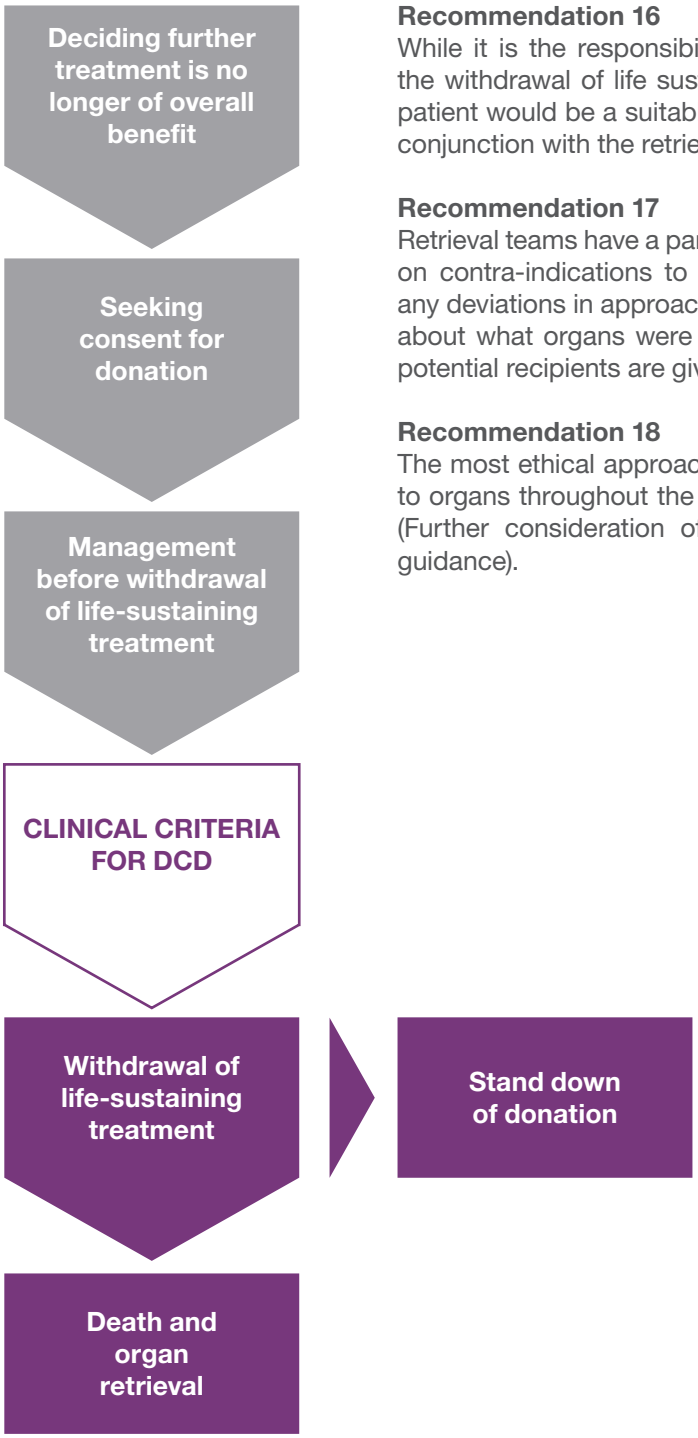
Recommendation 14
Clinicians should take a balanced view of the risk of harm when considering particular interventions or course of action, encompassing both the risk of undesirable physical effects, and the risk of doing wrong by failing to fulfil the patient's wishes (para 1.4.2-1.4.4).

Recommendation 15
Interventions to maintain cardiorespiratory stability and critical organ perfusion are appropriate, until such time as withdrawal of life-sustaining treatment (WLST) is instigated.

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY

CLINICAL CRITERIA FOR DONATION AFTER CIRCULATORY DEATH



Recommendation 16
While it is the responsibility of the team caring for the patient to instigate the withdrawal of life sustaining treatment, any decision about whether the patient would be a suitable candidate for donation is made by the SN-OD in conjunction with the retrieval team.

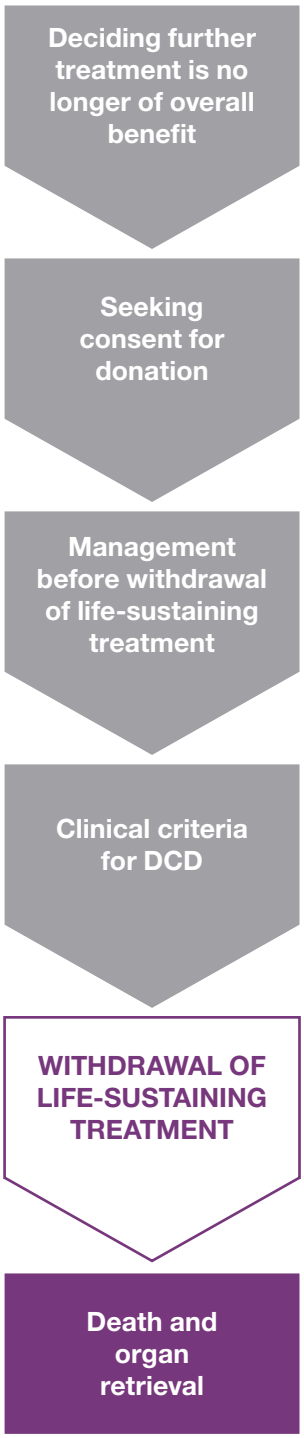
Recommendation 17
Retrieval teams have a particular responsibility to abide by national guidelines on contra-indications to donation and stand-down periods, and to justify any deviations in approach in order that families can have proper information about what organs were used and why, if they wish to receive it; and that potential recipients are given every opportunity to receive a viable organ.

Recommendation 18
The most ethical approach to organ allocation is to ensure equity of access to organs throughout the country on the basis of agreed allocation policies. (Further consideration of allocation issues is outside the scope of this guidance).

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY

WITHDRAWAL OF LIFE-SUSTAINING TREATMENT



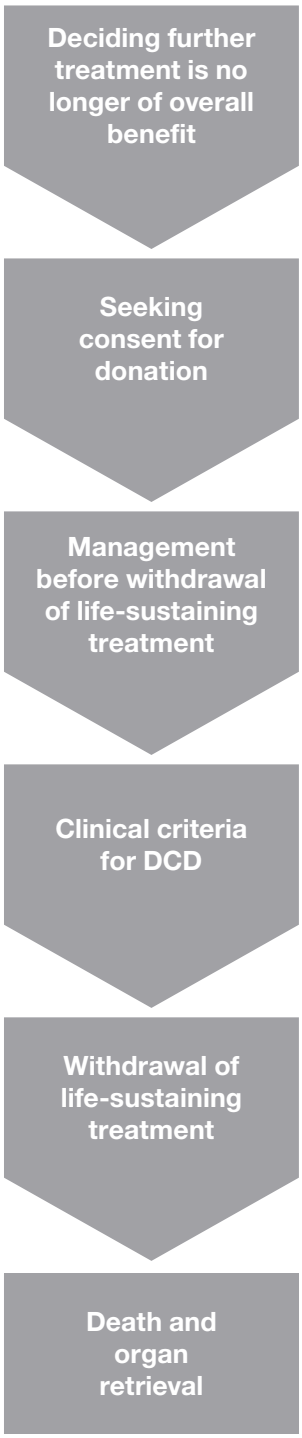
Recommendation 19
The SN-OD should continue to provide support to the family through the dying process even if they decide not to proceed with donation. Arrangements should then be made to involve further bereavement and support services if appropriate and according to local policies. This is particularly important where the SN-OD becomes involved in the case at a very early stage, but is relevant in all cases. This duty should be clear in the SN-OD job description.

Recommendation 20
Until national protocols for withdrawal of life-sustaining treatment are available, local protocols need to be agreed within each institution. Organ donation will be one of a number of factors which will have a bearing on the way in which withdrawal of life-sustaining treatment is carried out. Donation Committees have an important role in facilitating their development locally and should forge effective links with End of Life Care strategy teams.

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY

STAND DOWN OF DONATION



Recommendation 21
Retrieval teams should, as a minimum, adhere to the nationally agreed time limits for functional warm ischaemia and donation stand down time. The final decision about organ suitability should lie with the retrieval team and the transplant centre that has opted to receive the organ(s), since they are best placed to know the requirements of their potential recipients.

Recommendation 22
The end of life care plan for a patient on the DCD pathway should include a plan for how to proceed if the time to death following treatment withdrawal is incompatible with successful transplantation, and families and all staff (donor and retrieval teams) should be fully informed. The patient remains the responsibility of the clinical team from which they are receiving care. Consideration should be given to the possibility of tissue donation.

Recommendation 23
Good communication between all the teams involved is essential. This includes the potential donor's clinical team, the retrieval team and other staff involved such as the operating theatre team. All staff should be fully informed at the outset and understand their roles and responsibilities, and the range of possible outcomes.

Recommendation 24
Where donation does not take place, staff should be given an opportunity to discuss what has happened, and offered help and support to understand the outcome where necessary.

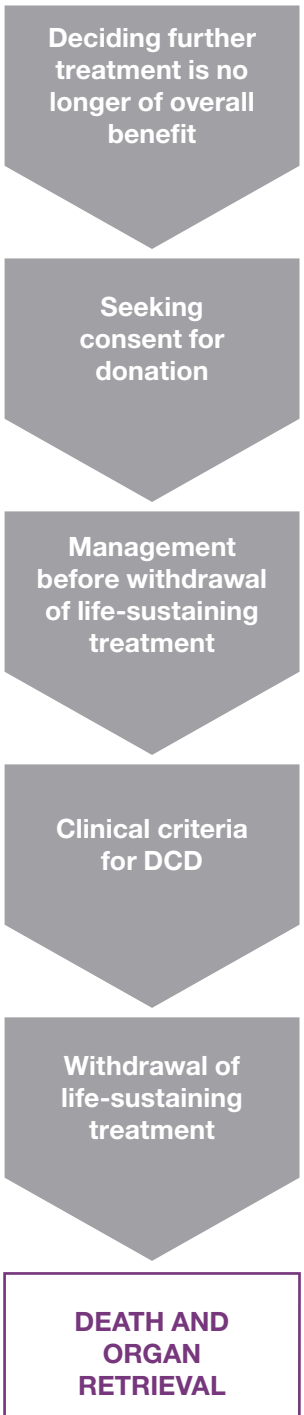
STAND DOWN OF DONATION

Recommendation 25
The family needs to be supported throughout, and helped to understand the outcome when donation is not possible. This is a key role for the SN-OD, and others involved in the process need to recognise their responsibility to keep the SN-OD informed of any changes.

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PATIENT PATHWAY

DEATH AND ORGAN RETRIEVAL



Recommendation 26
Death should be confirmed through strict adherence to the schedule laid out in Academy Code of Practice. When reperfusion of organs with oxygenated bloodis performed as part of the retrieval process, it should, as far as it practical, be restricted to the relevant organs. (paras 1.1.1 – 1.1.7)

Recommendation 27
After death, the potential conflict of interest between saving the life of the patient and respecting their interest to be an organ donor disappears. Once the decision for the patient to become a donor has been taken, it is of overall benefit to the donor and recipient for procedures such as re-intubation to facilitate lung retrieval to be carried out by suitably trained individual. Thus, although this professional may have been a member of the donor's clinical team prior to death, this no longer represents a conflict of interest. (paras 1.6.1 – 1.6.4 and 1.6.14)

Recommendation 28
Some actions carried out after death to facilitate donation carry a very small risk of re-starting the heart. If this should be observed, an appropriately trained member of staff, preferably from the critical care team, and certainly not part of the retrieval team, should repeat the process for confirmation of cardio-respiratory arrest as laid out in the Code of Practice. (paras 1.1.8 – 1.1.11)

Recommendation 29
The interests of the deceased patient, including one who is a potential DCD donor, extend beyond the confirmation of death. Following death the deceased patient must be treated with dignity and respect, in line with their cultural and religious views in life

Stand down of donation

See Part Two of main guidance document for further explanation of the patient pathway.
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

PART THREE: ISSUES FOR FUTURE CONSIDERATION

In considering issues relating to current practice in donation after circulatory death, the primary concern has been to ensure that patients are given the opportunity to donate where appropriate, and that their wishes are fulfilled as effectively and sensitively as possible. UKDEC has identified a number of areas where further work would be beneficial in pursuit of this aim.

Organ Donor Register

Recommendation 30
Further work is needed to consider how registration should reflect an informed decision to donate.

Recommendation 31
Further work is needed to explore the potential of the ODR to hold more detailed and up to date information, which could include comments about reasons for donation, and views about interventions during the dying moments to support donation, research and other issues.

Interventions before death to maintain organs

Recommendation 32
UKDEC is of the view that further work should be undertaken to reconsider whether some interventions that may be helpful for preservation of organs (pharmacological or mechanical) should be permissible within the current legal framework in the UK, as is the case elsewhere in the world. At present, for an intervention to be considered, it has to be shown not to cause or risk causing harm or distress to the patient, but the degree of risk versus benefit is undefined.[4]

4 Legal issues relevant to non-heartbeating donation, Department of Health, 2009 (England and Wales); Guidance on legal issues relevant to donation following cardiac death, Scottish Government Health Directorates, May 2010;
Legal Issues Relevant to Donation After Circulatory Death (Non-Heartbeating Donation) in Northern Ireland, Department of Health, Social Services and Public Safety (Northern Ireland), March 2011

Suitability to be a donor: contra-indications and acceptance criteria

Recommendation 33
Further work on contra-indications to donation would be helpful to minimise inappropriate referral of patients and to avoid unnecessary distress to families.

Recommendation 34
While there are very few absolute contra-indications for suitability as a donor, there is significant inconsistency in the criteria applied by retrieval and transplant teams. This risks additional distress to donor families.

UKDEC recommends that the professional bodies concerned reach agreement in these areas and ensure that guidance is applied consistently.

Withdrawal of life-sustaining treatment

Recommendation 35
UKDEC recommends that the professions should develop a nationally agreed protocol that defines how life-sustaining treatments should be withdrawn. At a minimum it should be appropriate for organ donors, but ideally would address the majority of cases. Once available, it is incumbent on clinicians to follow such a nationally agreed protocol.

Time between WLST and death, and impact on organ donation

Recommendation 36
Development of scoring systems to help predict the likelihood of death within a given time period would be a welcome development, saving families considerable distress by helping to identify patients who would not be suitable for donation after circulatory death.

Cardiac donation after circulatory death

Recommendation 37
There is no fundamental ethical barrier to re-establishing cardiac function in a heart from a DCD donor after it has been removed from the donor. Further work is needed to determine the ethical parameters for this type of procedure, and UKDEC is in ongoing discussion with clinical teams interested in developing such protocols.

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