UKDEC

UK Donation Ethics Committee

AN ETHICAL FRAMEWORK FOR CONTROLLED DONATION AFTER CIRCULATORY DEATH

CONSULTATION

UK DONATION ETHICS COMMITTEE

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ACADEMY OF MEDICAL ROYAL COLLEGES

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CONTENTS

EXECUTIVE SUMMARY

Introduction

This consultation paper, developed by the UK Donation Ethics Committee, discusses the key ethical issues that arise in considering controlled donation after circulatory death (also known as controlled donation after cardiac death, or non-heartbeating organ donation, NHBD). It sets out recommendations for current practice, and identifies some areas for further work. A final version will be published once consultation responses have been taken into account. Details of how to respond to the consultation are given in Section 4.

Terminology

In considering the issues relating to terminology, UKDEC felt that there is an inherent inconsistency in the term 'donation after cardiac death'. This implies the heart has died, which is incorrect, since although the patient has died following cardio-respiratory arrest the heart is, in many cases, still capable of beating. Indeed successful heart transplants from neonatal DCD donors have been reported.[i] UKDEC therefore recommends that the term 'donation after circulatory death' should be used. This is also in accordance with developing thinking internationally.

Guiding Principles

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

Principle 1: The offer of organ donation should be a routine part of planning end of life care

Principle 2: That once it has been agreed that organ donation is in the patient's interests, (defined in the Mental Capacity Act as 'best interests') the ethical imperative is to enable the most successful outcome to that donation.

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.

[i] Ref Boucek MM, Mashburn C, Dunn SM, Frizell R, Edwards L, Pietra B *et al*. Pediatric heart transplantation after declaration of cardiocirculatory death. *N.Engl.J.Med.* 2008;359:709-14

Recommendations

General Considerations

Conflicts of interest

Issues relating to conflicts of interest, particularly for Clinical Leads for Organ Donation, have been the subject of much discussion in the transplantation community since the publication of 'Organs for Transplants', the report of the Organ Donation Taskforce.[ii] UKDEC has spent some time considering the issues and offers the following recommendations for comment: See section 2.1 (page 4) for more detailed discussion.

Recommendation 1:
Two doctors, one of whom should be a consultant, should independently verify that further active treatment is no longer in the patient's best interests. It would be preferable for this to be the case for all patients, not only those where organ donation is a possibility (although the UKDEC remit extends only to organ donation). This matches the process adopted for diagnosis and confirmation of brain stem death.

Recommendation 2:
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 in the patient's best interests to become a donor, interventions to facilitate this are likely to reflect those interests unless they may cause harm or distress or risk causing harm or distress.

Recommendation 3:
The Specialist Nurse for Organ Donation should not care for the potential donor whilst they are still alive.

Recommendation 4:
Members of the retrieval team and the recipient's clinical team should not be involved in the care of the potential donor. There should, however, be effective liaison and communication between the retrieval team and those caring for the potential donor in order to ensure that the interests of the patient as a potential donor are maintained at all times.

[ii] Organs for Transplants: A report from the Organ Donation Taskforce, Department of Health, January 2008. Download at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082122

Recommendation 5:
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 to accept the organs has been taken, it is in the best interests of the deceased patient 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.

Recommendation 6:
Some actions carried out after death to facilitate donation (such as moving the deceased patient to theatre) carry a theoretical risk of re-starting the heart. An appropriately trained member of staff, not part of the retrieval team , should re-confirm cardiac standstill if necessary before the retrieval operation commences.

Organ Donor Register

The Organ Donor Register (ODR) is often cited as having great potential for offering a far richer picture of the views and wishes of potential donors in life. UKDEC is likely to consider issues relating to the ODR in more detail in the future. Two areas for further work are outlined in recommendations 9 and 10 below. UKDEC would welcome comment on these or other aspects of ODR. See section 2.2 (page 8) for more detailed discussion.

Recommendation 7:
Rigid policies on who can or should check the Organ Donor Register and when are unhelpful. The patient's ODR status must be known before beginning to plan for their end of life care.

Recommendation 8:
Specific paediatric guidelines in terms of suitability of potential DCD donation would be useful, however, in all children with traumatic or hypoxic-ischaemic brain injury or other cases in which DCD may be possible referral to the SN-OD together with checking of the ODR is recommended.

Recommendation 9:
Further work is needed to consider how registration should reflect a informed decision to donate.

Recommendation 10:
Further work is needed to explore the potential of the ODR to hold more detailed and up to date information, which could include whether the person has any preference as to whether their death should be diagnosed on the basis of cardiorespiratory criteria or brain stem testing; their views about interventions to support donation, research and other issues should also ideally be recorded.

The Donor Pathway

These recommendations are presented following a 'patient pathway' approach. For completeness there is some repetition between this and the previous section.

Deciding that further life-saving treatment is no longer in the patient's best interests, and seeking consent for donation.

The process of deciding that it is no longer in the patient's best interests to maintain life-sustaining treatment, and determining whether organ donation would be in accordance with their wishes or values will be a unique journey for each patient and their family. UKDEC believes that organ donation should be offered to all dying patients (and/or their relatives) as a routine end of life choice. Clinical teams, including SN-ODs, need to have great skill when working with families at this stressful time. See section 3.1 (page 10) for more detailed discussion).

UKDEC considers that the following ethical considerations should apply:

Recommendation 1:
Two doctors, one of whom should be a consultant, should independently verify that further active treatment is no longer in the patient's best interests. It would be preferable for this to be the case for all patients, not only those where organ donation is a possibility (although the UKDEC remit extends only to organ donation). This matches the process adopted for diagnosis and confirmation of brain stem death.

Recommendation 11:
Early contact between the clinical team treating the potential donor and the SN-OD 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 12:
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, and is discussed in greater detail in paragraphs 43-46 (pages 11- 12).

Recommendation 13:
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.

Recommendation 14:
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 15:
The discussion with the family, which may include offering religious support to the family and a discussion of the family's wishes to be involved in the Last Offices, 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 16:
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.

Management before Withdrawal of Life Sustaining Treatment

The time between deciding that further life sustaining treatment is not in the patient's best interests, and the withdrawal of that treatment may be quite considerable, although all practical steps should be taken to minimise delays and ensure that potential donors are informed at all times. See section 3.2 (page 14) for more detailed discussion.

Recommendation 17:
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 18:
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. Local policies need to be flexible and the family needs to have this explained to them.

Recommendation 19:
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.

Recommendation 20:
The ethical imperative is to act in the best interests of the patient. Interventions aimed solely at maintaining or improving the viability of the organs, which do not cause harm or distress, or risk causing harm or distress are acceptable in ethical terms.

Recommendation 21:
UKDEC is of the view that further work should be undertaken to reconsider whether some interventions that may be helpful for preservation of organs (such as systemic heparinisation) should be permissible within the current legal framework. 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.

Recommendation 22:
Interventions to maintain cardiorespiratory stability and critical organ perfusion are appropriate, until such time as withdrawal of life-sustaining treatment (WLST) is instigated.

Suitable criteria for DCD

From the ethical perspective, decisions about suitability for DCD need to be made by the appropriate person at the appropriate time, using criteria that are commonly agreed and consistently applied. See section 3.3 (page 17) for more detailed discussion.

Recommendation 23:
While there are very few absolute contra-indications for suitability as a donor, there is significant variability in the criteria for acceptance by retrieval and transplant teams. This risks additional distress to donor families. UKDEC recommends that the professional bodies concerned reach agreement and ensure that retrieval teams apply this consistently.

Recommendation 24:
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. (See also recommendation 29).

Recommendation 25:
Further work on contra-indications to donation would be helpful to minimise inappropriate referral of patients and to avoid unnecessary distress to families. Retrieval teams have a particular responsibility to abide by national guidelines in this area, 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 26:
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).

Process of withdrawal of life-sustaining treatment (WLST)

The process of withdrawal of life-sustaining treatment is a subject of significant debate at present within the intensive care community, and this was reflected in the Consensus Statement published by the British Transplant Society and Intensive Care Society in December 2010.[iii] UKDEC intends to return to this topic in more detail in the near future, and would particularly welcome further comments through this consultation. See section 3.4 (page 18) for more detailed discussion.

Recommendation 27:
UKDEC strongly recommends that in cases in which organ donation is in the patient's best interests, it is incumbent on clinicians to follow a nationally agreed protocol that defines how end of life decisions should be arrived at and how life-sustaining treatments should be withdrawn. UKDEC further recommends that the professions should develop such a protocol. At a minimum it should be appropriate for organ donors, but ideally would address the majority of cases.

Recommendation 28:
Until national protocols for WLST 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 WLST 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.

If death does not occur within a time appropriate for donation

One of the most difficult aspects of donation after circulatory death is the inevitable uncertainty that arises when life-sustaining treatment is withdrawn. Unless death occurs in timely fashion, donation will not be possible. Families and clinical teams need to be prepared if donation cannot take place. See section 3.5 (page 21) for more detailed discussion.

[iii] Organ Donation after Circulatory Death. Report of a Consensus Meeting held on 7 June 2010, between representatives of the Intensive Care Society (ICS) and British Transplantation Society (BTS), NHS Blood and Transplant and others on 'controlled' organ donation after circulatory death (DCD), held by the Department of Health in association with the devolved administrations. It has been endorsed by the ICS and BTS, see http://bts.org.uk/transplantation/standards-and-guidelines

Recommendation 29:
The time frames within which organs can be transplanted with a good outcome for the recipient vary, need to be based on robust evidence, and consistently applied. The British Transplant Society/Intensive Care Society Consensus Statement is helpful in this regard. 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 30:
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 were receiving care. Consideration should be given to the possibility of tissue donation.

Recommendation 31:
Good communication between the potential donor's clinical team, the retrieval team and other staff involved such as the operating theatre team is essential. All staff should be fully informed at the outset and understand their roles and responsibilities, and the range of possible outcomes.

Recommendation 32:
Where donation does not take place, staff should be given an opportunity to debrief and to understand the outcome.

Recommendation 33:
The family needs to be supported throughout. 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.

Recommendation 34:
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 identifying patients who would not be suitable for donation after circulatory death.

Death and subsequent interventions

Death is a process rather than an event, with resuscitation a technical possibility after the heart has stopped beating in some circumstances. This means that the moment of death is the subject of on-going philosophical debate internationally. UKDEC has not sought to engage with this debate, but rather to develop a practical ethical framework for actions to facilitate donation based on current UK clinical guidelines for diagnosis of death.[iv] See section 3.6 (page 25) for more detailed discussion.

Recommendation 35:
In the context of DCD, death can be confirmed after five minutes of continuous absence of cardio-respiratory function. The diagnosis of death in these circumstances depends upon there being no intention to attempt cardiopulmonary resuscitation or institute any measure that might result in restoration of blood flow to the brain.

Recommendation 36:
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.

Recommendation 37:
Some procedures carried out after death to facilitate organ donation carry a theoretical risk of re-starting the heart. As it has already been decided that continuing life-sustaining treatment is no longer in the patient's best interests, interventions carried out after death should include additional measures where necessary to counter any risk of resuscitation or restoration of circulation to the brain. If the heart does temporarily re-start, a further period of five minutes must elapse after it again stops before organ retrieval can begin.

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

Part Three: Consultation

In this document UKDEC has sought to set out the ethical considerations regarding controlled donation after circulatory death. In some cases there are areas where UKDEC believes that further work would be beneficial. This might be undertaken by UKDEC directly, or working in a facilitative role with others, or it may be for others to take forward. Following the consultation period, UKDEC will publish a final set of recommendations with an action plan for future work.

UKDEC welcomes views from anyone with an interest in organ donation.

Details of how to respond to the consultation are given on page 28.

The consultation will close on **18 March 2011.**

UK Donation Ethics Committee

January 2011

1 INTRODUCTION

1. This consultation paper, developed by the UK Donation Ethics Committee, discusses the key ethical issues that arise in considering controlled donation after circulatory death (DCD, also known as controlled donation after cardiac death). It sets out recommendations for current practice, and identifies some areas for further work. A final version will be published once consultation responses have been taken into account.

The role of UK Donation Ethics Committee

2. The Organ Donation Taskforce, in its report 'Organs for Transplants' described the ethical and legal complexity surrounding various aspects of donation and transplantation, particularly (but not exclusively) DCD.[1] It recommended that a UK-wide Donation Ethics Committee should be established. The UK Donation Ethics Committee (UKDEC) was established in January 2010, with a brief to provide advice and resolution on ethical aspects of organ donation and transplantation (but not to increase organ donation per se). Details of the membership and terms of reference can be found in the Appendices. This report and recommendations on DCD is its first publication.

Scope of this guidance

3. Donation after circulatory death may be controlled or uncontrolled. Controlled DCD describes organ retrieval that follows the planned limitation or withdrawal of cardio-respiratory treatments at the end of a critical illness from which a person will not recover. This contrasts with uncontrolled DCD, which occurs following a sudden, unexpected and irreversible cardiac arrest (such as following acute myocardial infarction). This guidance has been developed for controlled DCD, although many of the principles described will apply equally well to other forms of deceased donation. There are significant differences between the two forms of DCD, and uncontrolled DCD happens very rarely in the UK at present. It may be the subject of further consideration by UKDEC in the future if clinical practice develops.

4. In considering the issues relating to terminology, UKDEC felt that there is an inherent inconsistency in the term 'donation after cardiac death'. This implies the heart has died, which is incorrect, since although the patient has died following cardio-respiratory arrest the heart is, in many cases, still capable of beating. Indeed successful heart transplants from neonatal DCD donors have been reported.[2] UKDEC therefore recommends that the term 'donation after circulatory death' should be

used. This is also in accordance with developing practice internationally.

Structure and recommendations

5. This document first identifies two guiding principles that the UKDEC has used to develop its recommendations. It then addresses conflicts of interest, which has been an area of growing concern in recent months. The remainder of the document is structured following a patient pathway approach, discussing the ethical issues that arise at each stage, and offering recommendations where appropriate. There are recommendations for local implementation, and some areas where further work is needed. Subject to consultation, these will form part of the work programme for the UKDEC in the next year. Details of how to respond to the consultation can be found in Section 4.

6. In developing this document, UKDEC has had regard to the report of the DCD consensus meeting held on 7 June 2010, which was organised by the Department of Health (in association with the Devolved Administrations) on behalf of the Intensive Care Society and the British Transplantation Society, supported by NHSBT. The meeting brought together interested parties to consider DCD, developing a consensus where possible, and identifying how to move forward when more divergent views were expressed. The resulting report was published in December 2010,[3] and is referred to throughout the remainder of this document as 'the Consensus Statement'. This document from UKDEC has been developed independently, offering a commentary on the clinical practices recommended in the Consensus Statement and elsewhere. It is hoped that these recommendations will complement those in the Consensus Statement, giving a clear framework for ethical practice in donation after circulatory death.

Ethical issues in donation after circulatory death

7. The rise in donation after circulatory death in recent years has been well documented, both in the UK and internationally.[1] As rates of donation after brain stem death have fallen, donation after circulatory death has risen substantially in the UK, with DCD donors now comprising a third of all deceased donors in the UK.[4]

8. A clear and common understanding of the diagnosis of death in the context of organ donation is essential if clinicians, patients and the public are to have confidence in DCD programmes. Death is a process rather than an event, with resuscitation a technical possibility after the

heart has stopped beating in some circumstances. This means that the nature of death is the subject of on-going philosophical debate internationally. UKDEC has not sought to engage in this, but rather to develop a practical ethical framework for actions to facilitate donation based on current UK clinical guidelines for diagnosis of death.[5] Further information about the different criteria used for diagnosing and confirming death is given in section 3.6 (pages 25-27).

Guiding Principles

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

   Principle 1: The offer of organ donation should be a routine part of planning end of life care

   Principle 2: That once it has been agreed that organ donation is in the patient's best interests, the ethical imperative is to enable the most successful outcome of that donation.

10. There are many other ethical, legal and practical considerations that come into play in determining the right course of action for any particular patient at any particular time. This is true for all patients with life threatening conditions who are receiving critical care, and not just for potential donors. The UKDEC supports as fundamental the principle that all patients entering end of life care should be offered the opportunity to donate. This duty is set out in recent GMC guidance on end of life care.[7] Within the hospital setting, this should happen irrespective of where that end of life care takes place. For example, patients in the Emergency Department should have their potential recognised in the same fashion as those in an Intensive Care or High Dependency Unit. In developing local policies and protocols for organ donation, institutions should consider how to ensure that these principles can be followed, particularly across specialty boundaries. This will require flexible policies and protocols, implemented with the commitment and leadership necessary to maximise opportunities for organ donation. Both donor families and recipients will benefit.

2 GENERAL CONSIDERATIONS

2.1 CONFLICTS OF INTEREST

Donors and recipients

11. A major ethical obstacle to DCD is the perceived conflict of interest that arises for clinicians caring for potential donors in acute hospital settings – usually critical care or emergency departments. Clinicians will ordinarily prioritise treatments and interventions designed to secure the survival of their patient. When survival is no longer likely, or no longer in the patient's best interests, the reasons to continue active treatment appear to fall away, with the emphasis shifting to appropriate palliative measures.

12. However, if the patient is known to have wanted to be a donor, or to have values and beliefs compatible with being a donor, the possibility of facilitating DCD provides a reason to continue treatments, which may have no direct medical benefit to the patient, rather the benefit accrues to the potentially donatable organs and thereby ultimately to the recipients. This concept can leave some clinicians feeling conflicted, concerned that they are no longer acting in their patient's best interests, but rather in the best interests of the potential recipients.

13. This is to misunderstand the interpretation of 'best interests'. The courts have established that a person's best interests are wider than simply their medical interests. The Mental Capacity Act Code of Practice[6] emphasises the importance of considering a person's social, emotional, cultural and religious interests in determining what course of action may be in their best interests (similar provisions apply in Scotland as set out in the Adults with Incapacity (Scotland) Act 2000 and associated codes of practice). When planning end of life care for a patient for whom life-sustaining treatment is no longer appropriate, if the patient wished to become an organ donor, then care that facilitates successful donation is likely to be highly compatible with their best interests.

14. As with any patient, every decision about the potential donor's care needs to be a balance of factors. Some interventions may cause harm or distress or risk causing harm or distress and should not be undertaken, even if this means that donation does not go ahead. (This is discussed in more detail in section 3.2). Clinicians caring for patients who are potential donors thus continue to act in their patient's best interests at all times. Consideration of the recipient (which would result in a conflict of interest) does not play any part.

Clinical Leads for Organ Donation

15. Specific concerns have been raised as to whether a Clinical Lead for Organ Donation (CLOD) can also be involved in the treatment of patients who may become potential donors. CLODs are responsible for giving leadership to a Trust's organ donation programme, ensuring that the organisational and managerial requirements are in place for organ donation to proceed smoothly and appropriately. The role is typically undertaken by a senior clinician, often an intensive care physician who has direct experience of organ donation. This raises the question of whether there is a conflict of interest if an intensive care physician, who is also the Trust CLOD, cares for a patient who becomes a potential organ donor.

16. The clinician treating the donor has well defined responsibilities. They do not take any part in deciding whether an individual patient is a suitable donor, nor do they have any role in the allocation of organs. Their role is restricted to determining whether organ donation is in the patient's best interests as part of their end of life care, and working with the family and the SNOD to facilitate donation if appropriate for that patient. This is enshrined in recent GMC guidance on end of life care:[7]

> *"If a patient is close to death and their views cannot be determined, you should be prepared to explore with those close to them whether they had expressed any views about organ or tissue donation, if donation is likely to be a possibility.*
>
> *You should follow any national procedures for identifying potential organ donors and, in appropriate cases, for notifying the local transplant coordinator. You must take account of the requirements in relevant legislation and in any supporting codes of practice, in any discussions that you have with the patient or those close to them. You should make clear that any decision about whether the patient would be a suitable candidate for donation would be made by the transplant coordinator team, and not by you and the team providing treatment."*

17. The challenge facing UKDEC in this area is to consider whether current arrangements provide sufficient safeguards against the risk of a conflict of interest when an intensivist also performs the duties of a CLOD. The success of organ and tissue donation relies on the confidence that the public can invest in the donation, retrieval and transplant process.

18. The critical point in the care pathway of a patient who may go on to become a DCD organ donor is the decision about whether further life-sustaining treatment is in their best interests, or whether their condition is non-survivable and active treatment should cease. This decision point needs to be completely independent of consideration of organ donation.

19. A comparison can be made with confirmation of brain stem death, where two senior doctors are required to confirm the diagnosis.[5] UKDEC considers that the decision to withdraw life-sustaining treatment should be approached with the same safeguards, given that the expected consequence will be the imminent death of the patient. This applies whether or not one of the doctors has additional duties relating to organ donation.

20. Two doctors, one of whom should be a consultant, should verify that further active treatment is no longer in the patient's best interests. 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).

Specialist Nurses for Organ Donation

21. Specialist Nurses for Organ Donation (SN-ODs) have a well-defined role to play in the organ donation process. They work with donor families to seek consent for donation and continue to support them throughout a difficult time. They are also responsible for liaison with NHSBT and the retrieval team. SN-ODs are often intensive care nurses by training. Caring for a potential donor is resource intensive and when staffing is limited clinical teams may seek clinical help from the SN-OD in addition to their liaison role.

22. SN-ODs should not nurse a potential DCD donor whilst they are still alive. The SN-OD role in relation to donation means that there is a clear conflict of interest. After the potential donor has died this conflict of interest no longer exists, and the SN-OD can take care of the patient if necessary. This commonly happens in patients who have been declared dead following brain stem death.

23. A DCD process always requires meticulous planning of the care of the patient and their family, with all members of the clinical team understanding their individual roles and responsibilities. This is particularly true when staffing is tight. Teams need to operate flexibly to facilitate donation in an ethically appropriate manner. For example, a SN-OD may not be able to nurse a potential donor – but they could

nurse a different patient on the ward, freeing up another appropriately skilled staff member to care for the potential donor.

24. After death the SN-OD continues to perform a number of duties supporting the organ donation, whilst providing ongoing support to the family. If a family that has supported consent for donation is becoming increasingly anxious because of delays which are preventing the commencement of funeral rituals which their tradition requires are undertaken quickly, then a conflict may arise for the SN-OD. This underlines the importance of discussing any cultural requirements the family may have during the consent process. This will allow a realistic assessment to be made as to whether donation can be consistent with the cultural requirements, and the effect of delays can be built into the planning process.

Retrieval team.

25. Members of the retrieval team and the recipient's clinical team should not be involved in the care of the potential donor. After death any potential conflict of interest disappears and it is in the best interests of the former patient for procedures such as re-intubation to facilitate lung retrieval, to be carried out expeditiously by an appropriately trained individual. For that individual to have been a member of the donor's clinical team prior to death does not constitute a conflict of interest.

26. The Consensus Statement noted that some actions that are necessary to facilitate retrieval carry a theoretical risk of re-starting the heart, such as patient movement during transfer to the operating theatre. While the likelihood of this is low, UKDEC is of the view that in such circumstances it is in the patient's best interests for an appropriately trained individual who is not a member of the retrieval team to re-confirm cardiac standstill.

2.2 ORGAN DONOR REGISTER

Checking the Organ Donor Register

27. Checking the Organ Donor Register (ODR) is an action which is sometimes viewed as somehow compromising the physician's primary duty, which is to save or prolong their patient's life (so long as this is in their best interests). There is a similar perception of fear on the part of patients that they will be disadvantaged if their status is known, and less will be done to keep them alive. These misconceptions need to be challenged. Our recommendation, that the decision that further life-sustaining treatment is not in the patient's best interests be confirmed by two senior doctors, provides a tangible safeguard.

28. Knowledge of ODR status at an early stage of a patient's care makes no difference in ethical terms. Rigid policies about who can check the ODR and when are unhelpful. It is, however, a vital part of the evidence that the clinical team needs to have in order to determine the patient's best interests with regard to end of life care, once a decision has been made that life-sustaining treatment is no longer in the patient's best interests. The ODR must therefore be checked before approaching the family about organ donation and end of life care.

ODR and Children

29. Anyone who is legally competent can join the Organ Donor Register. Children can register but their parents or those with parental responsibility must provide consent. If a child who is under 12 years of age registers, a letter will be sent to their parent or those with parental responsibility to acknowledge registration. Parents can register their children if they are under the age of 12. Although 464,354 children in the UK are registered on the ODR, most UK children who donate organs are not.

30. Currently paediatric intensive care unit staff do not check the ODR as part of routine end-of-life care, this is only checked by the SN-OD on attending a potential donor to help guide the approach to families. The majority of younger children that die in intensive care are not currently suitable organ donors, due to the high proportion of severe congenital malformations, genetic disease, disseminated malignancy and results of extreme prematurity in this group. In older children the increased proportion of traumatic or hypoxic-ischaemic brain injury means a greater proportion of those who die are potential donors.

Potential enhancements to the Organ Donor Register

31. The ODR is potentially a powerful tool for recording the wishes of people in more depth than is the case at present. Under current arrangements, people typically put their name on the register in response to a simple prompt on a driving licence renewal or Boots Advantage card application form, or a form picked up in their GP surgery. This is a very valuable, positive expression of their views about organ donation. However, it is not informed consent in the way that is typically expected for other medical procedures, and this has led to some debate.

32. Organ donation generally, and donation after cardiac death in particular, is a process which brings both technical and ethical complexities and one which, inevitably, the public understands relatively poorly. At present the potential donor's clinical team, working with the patient's family, have to resolve these issues to the best of their ability, with little direct evidence of the patient's wishes beyond their general consent to donation.

33. An organ donor register which people join only after receiving more comprehensive information, and which includes more detailed information about their wishes, could potentially simplify matters. For example, people could express wishes about the method of testing to be used to confirm their death. There is an international precedent for this in Israel. Orthodox Jews can direct that the diagnosis of death using brain-stem death criteria cannot be applied to them, irrespective of medical eventuality. Whereas others can agree that either brain-stem death or traditional cardiorespiratory criteria may be applied to them.[8]

34. This type of system could be adapted to include information about therapeutic interventions to facilitate organ donation, and limitations the patient may wish to place on them. Further information about use of organs and tissues for research purposes could also be included. Information about all these areas could greatly reduce the burden on families at a distressing time, and offer a much clearer picture of what course of action is in the potential donor's best interests.

35. The points in paragraphs 31-34 above are areas that UKDEC is likely to return to in the future. As part of this consultation we would welcome views about these or any other issues relating to the ODR, and how the UKDEC might most usefully take this work forward.

3 THE POTENTIAL DONOR PATHWAY

3.1 DECIDING FURTHER TREATMENT IS NO LONGER IN A PATIENT'S BEST INTERESTS AND SEEKING CONSENT FOR ORGAN DONATION

Determining best interests in end of life care

36. Deciding that further life-sustaining treatment is no longer in their best interests is a critical point in the care pathway of a severely ill patient. In paragraphs 18-20 we have argued that this should be viewed in a similar manner to brain stem death testing, and should be confirmed by a second senior doctor. This recommendation goes further than GMC guidance,[7] which suggests that a second opinion should be sought where there is any doubt.

37. It is essential that patients, the public and clinical staff have confidence in the decision-making process around the withdrawal of life-sustaining treatment and subsequent organ donation. Concerns about conflicts of interest have been a strong feature of discussion and debate about organ donation in recent years, and an explicit policy of seeking a second opinion is one way of allaying those concerns.

38. Putting this recommendation into practice requires the development of locally agreed protocols, appropriate to the individual hospital concerned and agreed by all relevant staff. CLODs and Donation Committees have an important role to play in taking this work forward locally and facilitating discussion so that protocols are implemented effectively.

Working with the Specialist Nurse for Organ Donation (SN-OD)

39. The Specialist Nurse for Organ Donation (SN-OD) has a major role to play in ensuring the process runs smoothly from identification of a potential donor through to their death and retrieval of the organs, with an ongoing responsibility to the donor family. They combine duties to act as advocates for the donor and their family with co-ordinating the donation process, and are highly skilled in working with families at what is a very difficult time.

40. There is no ethical dilemma if the treating clinician wishes to make contact with the SN-OD at an early stage, while the patient is seriously ill and death is likely, but before a formal decision has been made to withdraw life-sustaining treatment. Such early discussions might be valuable for a variety of reasons. These include establishing whether

there are contra-indications for donation, in which case the issue of donation does not need to be raised with the family at all.[9] Other practical and organisational factors might be relevant – if the SN-OD is based at a distant location then early contact can help to minimise distressing delays for the family.

41. The Organ Donation Taskforce recommended that, as a minimum, the SN-OD should be notified when the decision to withdraw treatment had been agreed, and that the ODR should be checked at this point if this had not already been done. However, it encouraged units to consider developing earlier referral criteria based on clinical condition alone.

42. UKDEC is in agreement with the Organ Donation Taskforce recommendations. Rigid policies on when the SN-OD should be contacted formally are unhelpful. There are a variety of circumstances when earlier contact (whether informal discussion or formal referral) is appropriate. In many cases it will be a matter of clinical judgement, supported by local protocols where appropriate, as to when the SN-OD should be made aware of the case.

Early involvement of the SN-OD

43. Early involvement of the SN-OD (sometimes known as the 'long contact model') has been the subject of some debate within the transplant community, with some arguing that it leads to higher consent rates for donation. This means the SN-OD joins the clinical team when they begin to talk through with the family that further life-sustaining treatment is no longer in their relative's best interests. Once the family has accepted this, then the SN-OD is already part of the team supporting the family and therefore well placed to make the approach about organ donation.

44. This model means that the SN-OD has to be introduced to the family as a 'Specialist Nurse', with no reference to organ donation, and have their role explained as being there to support the family at a difficult time as their relative is seriously ill. They can take no part in nursing the patient. Where the family give consent to donation, the SN-OD goes on to support the family and undertake their other duties through the donation process.

45. The need to avoid disclosing the full nature of the SN-OD's role in these circumstances is something which some people find challenging. It is UKDEC's view that it is not unethical for the SN-OD to become involved at an early stage in a support capacity as part of their role, and to delay discussion about organ donation until an appropriate time. UKDEC would welcome views on this point, and information about how this early contact model has been implemented locally.

46. If it is decided it is not in the patient's best interests to become a donor, the continuing role of the SN-OD needs some consideration. As far as the family is concerned at this point, the SN-OD is someone who is supporting them through a very difficult time. It would be wrong for the SN-OD to leave as soon as donation is ruled out, and indeed most would not wish to do so. However, the job description and role and responsibilities of the SN-OD are entirely geared towards supporting donor families and the donation process. No mention is made of support for families when donation is not in the patient's best interests, which could lead to a conflict for the SN-OD. This is most significant where the 'long contact model' is being used, but applies to all potential donors.

Seeking Consent

47. When the clinical team has agreed that there is no overall benefit for treatment to continue and when the family has understood and accepted the implications of this, then dialogue about donation can commence. Some clinicians want to lead this process, whilst others want the SN-OD to lead the process from the earliest opportunity. Information from the ODR should be brought to the discussion, as it will be an important element in determining whether organ donation is in the patient's best interests.

48. For those under the age of eighteen and incapacitated, it is the parents, or those with parental responsibility, that are able to consent to organ donation, as with other therapies. Their decision making can been informed by any prior discussions with the child, and indeed the child may have signed the ODR.

49. The conversation with families about bereavement support and organ donation requires a team approach bringing together the knowledge and expertise of various healthcare professionals. Given the sensitive nature of the process, the clinical staff who have established the strongest rapport with the family ought to be involved in this collaborative approach, and it is the consultant in charge of the patient's care and the SN-OD who should bring the greatest depth of expertise to this dialogue given that this is their professional remit.

Information for donor families

50. Donor families will vary considerably in their wish to know the details of the retrieval process. Some may wish to know simply what organs were successfully donated. Others will be content with the principles of the retrieval process such as the need to use additional medication and fluids to keep the organs in a good condition before they are removed, while others may want the full details. The SN-OD should ascertain what information the family would like to receive. If there are web-based resources or information available, these could be given for the family to access when and if they are ready.

51. There is a possibility that once families are aware of the details of the organ donation process they may feel differently and be concerned that their loved one would not have wanted a particular type of procedure. However, it is ethically necessary that information should be offered and, in addition, this is required to ensure the public's confidence in organ donation is maintained. (Equally, details of medical procedures should not be forced on patients or relatives who would rather not know them). The overall effect on the organ donation programme can only be positive, even if it might occasionally result in reversal of a decision to donate.

52. In most, if not all, cases, the family have unexpectedly found themselves in the most difficult and distressing of circumstances. Management of discussion with the family throughout the process of consent and donation needs to reflect this, enabling them to feel they are being offered support that is tailored to and matches their unique circumstances, rather than being taken through a standard protocol.

3.2 MANAGEMENT BEFORE WITHDRAWAL OF LIFE SUSTAINING TREATMENT

Planning care for the potential donor

53. Managing a potential DCD donor through the donation pathway is a complex process. Robust planning at the outset gives a firm basis for discussion of the pathway with families, ensuring that they are comfortable with the process and have raised any concerns they may have about end of life care, including cultural or faith requirements. This plan should include likely timescales, decision points, whether the donor may need to be moved to a different location, and other matters.

Location

54. A patient for whom the decision has been made to withdraw life-sustaining treatment should be cared for in an appropriate environment by staff with the appropriate skills and experience to deliver their end of life care plan. If it has been agreed that organ donation should form part of that plan because this reflects the interests, values or wishes of the patient, then there is an ethical justification for enabling is to enable that donation to happen.

55. A decision as to the most appropriate environment for end-of-life care needs to be taken in an unhurried way and at a senior level. It can be difficult to offer a compassionate and peaceful end of life in the Emergency Department, so a different location may need to be considered. Transfer to the Intensive Care or High Dependency Unit may be difficult if others require the same resources, but other possibilities include a side ward, the theatre recovery room, or an anaesthetic room. Careful consideration needs to be given to the risk of death during transfer. It is important that families are fully aware of and understand the reasons for the move.

56. There may be very rare cases where, having established the patient's wish to become a donor, it is necessary to transfer them to a different institution to enable donation to take place. UKDEC is aware of one such case to date in the UK, which was to undertake specialised testing to determine suitability for donation. In this situation the patient should be assessed carefully to determine whether they are fit for transfer, and commencement of withdrawal of life-sustaining treatment should not take place until after the transfer has been completed. Proper liaison, organised by the SN-OD, should ensure that an appropriate environment and arrangements for withdrawal of life-sustaining treatment are in place in the receiving institution.

Interventions prior to the withdrawal of life-sustaining treatment

57. UKDEC is of the view that, where it is agreed that organ donation is in a patient's best interests (as defined by the Mental Capacity Act), it is ethically appropriate to enable that donation to take place as successfully as possible. End of life care should be planned and managed accordingly. Interventions aimed solely at maintaining or optimising organ function are ethically acceptable, providing any such interventions do not cause harm or distress or place the patient at significant risk of harm or distress.

58. The Department of Health document *'Legal issues relevant to non-heartbeating donation'*, which applies in England and Wales gives similar advice about the management of the patient prior to the withdrawal of treatment. The core principle is set out as:[10]
"Maintenance of life-sustaining treatment may be considered in the best interests of someone who wanted to be a donor if it facilitates donation and does not cause them harm or distress, or place them at significant risk of experiencing harm or distress."

59. The Department of Health document gives further guidance on some specific interventions including taking and analysis of blood samples, and maintenance of life-sustaining treatments to treat haemodynamic or ventilatory instability. Some interventions, including systemic heparinisation are classified as unlikely ever to be in the patient's best interests due to the risk of harm or distress.

60. The Scottish Government Health Departments have issued similar guidance to clarify the legal position on issues relevant to donation after cardiac death. Although the legal framework in Scotland is slightly different, the principles as they relate to donation after circulatory death are very similar.[11]

61. UKDEC is aware of a commonly held view that systemic heparinisation in particular would be beneficial to the quality of the organs, and that risks to the patient are minimal providing it is not administered to high risk patients. UKDEC is of the opinion that this area should be the subject of further work, which would include:

    - Reviewing the evidence for improving the quality of the organs
    - Reviewing the evidence of causing, or risking causing harm or distress to the patient.

62. UKDEC would welcome views on this through the consultation process, including what other interventions should be given further consideration.

Management of cardiorespiratory instability

63. Management of the patient if their blood pressure falls after the decision to withdraw treatment has been made, but before arrangements for organ retrieval are in place, has also been the subject of some debate. Instigating inotropic support may facilitate organ donation, but it could be argued that it may theoretically result in an improvement in the patient's condition or in their level of consciousness. Given the extremely serious nature of the patient's illness, a more likely outcome is the short term use of inotropes stablising but not improving the patient's condition while arrangements for retrieval are put in place. Inotropes can then be withdrawn and death allowed to occur naturally.

64. In DCD, a gradual reduction in blood pressure is frequently part of the dying process. UKDEC is of the view that instigating the use of inotropes is ethically justified after the decision to withdraw treatment has been made, if this is necessary to maintain blood pressure at an appropriate level while arrangements for retrieval are put in place. If organ donation is in the patient's best interests, this approach accords with the ethical imperative to facilitate this without causing or risking harm or distress.

3.3 SUITABLE CRITERIA FOR DCD

65. The Consensus Statement provides detailed information on suitable criteria for DCD. From the ethical perspective, the relevant issues are ensuring that donation takes place where it is in the patient's best interests, and that decisions are made about suitability for DCD by the appropriate person at the appropriate time.

66. As discussed in section 1 the treating clinician has a duty to explore the option of donation with the patient, if competent, or their relatives, and to facilitate this if it is decided that donation is in the patient's best interests.[7] Early contact with the SN-OD may help to establish whether the patient has a medical condition that would prevent them from donating after their death.

67. The Consensus Statement proposes that further work is needed to define additional absolute contra-indications in order to avoid unnecessary and inappropriate referral of patients who are unsuitable DCD donors. These should include upper age limit, the presence or degree of multi-organ failure, the need for high dose inotropic support and/or high FiO_2 with poor oxygenation and other clinical criteria. UKDEC supports further work in this area.

68. If donation is a possibility then a formal referral is made to the SN-OD and the family are approached for consent, as discussed earlier. The SN-OD will take a detailed medical history and is then responsible for the decision as to suitability for the donation pathway.

69. While there are very few absolute contra-indications for suitability as a donor, there is significant variability in the criteria for acceptance by retrieval and transplant teams. This risks additional distress to donor families. UKDEC recommends that the professional bodies concerned reach agreement and ensure that retrieval teams apply this consistently.

70. 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. The transplanting surgeon makes the final decision as to suitability of a particular organ, having consulted widely within the multidisciplinary team.

3.4. PROCESS OF WITHDRAWAL OF LIFE-SUSTAINING TREATMENT

Protocols for withdrawal of treatment

71. There is significant variation across the UK in how treatment withdrawal is managed in adult intensive care units. This contrasts with paediatric intensive care medicine, where there is much greater consistency.[12] The British Transplant Society/Intensive Care Consensus Meeting in June 2010 discussed this in some depth and at the present time, there continue to be strongly held and apparently conflicting views with regard to airway management during terminal care within the adult intensive care profession.[3]

72. Many of the concerns expressed by physicians and other staff in regards to DCD surround changes to the usual process of caring for dying patients (although 'usual' means different things to different practitioners). In the context of organ donation, the prime aim at this time remains the care and support of the dying patient and their loved ones. However, alterations to the end of life care pathway to facilitate the process of organ donation at the explicit request of the dying patient carry great moral weight, especially if made with full information about the process.

73. A well designed and adhered to protocol should have as one of its goals minimal disruption to families and their loved one. This would encompass being sensitive to cultural and religious requirements. Standard nationally agreed protocols, openly available to potential donors, with this emphasis would be of great help to all involved in the process of human dying and death, and would help rightly to embed organ donation as a consideration in that process.

74. Modern medicine is widely supported by protocol and we believe that developing a consensus around the appropriate management of potential donors in this situation would benefit all parties and facilitate an exploration and sharing of the ethical issues which are currently most acutely felt by the clinicians.

75. UKDEC strongly recommends that in cases in which organ donation is in the patient's best interests, it is incumbent on clinicians to agree to follow a nationally agreed protocol. UKDEC further recommends that the professional bodies should develop such a protocol. At a minimum it should be appropriate for organ donors, but ideally would address all cases.

76. Until a national protocol becomes available, local protocols, agreed and adhered to by all relevant staff, need to be in place. At a minimum these should be specific to cases where the intention is for organ donation to take place. Organ donation is only one of a number of factors that may be relevant to the process of withdrawal of life-sustaining treatment. Others include:

- The individual's comfort, dignity, cultural and religious requirements and privacy
- Continuity of care by the clinical team
- Unlimited close access for the family
- A manner of death with which those involved in the care of the patient are comfortable.

77. Donation Committees may be well placed both to identify the need for robust and consistent practice in this element of end of life care and to also to produce and implement local protocols that are based upon existing national policies and guidance.

Managing the patient

78. While the patient is still alive, the duty of care remains the same as for any other patient. They should be cared for by staff who have the appropriate skills and experience to take them through their end of life care plan to organ donation. Both the wider clinical team and the family need to be fully informed and to understand the roles of the team members caring for the potential donor.

79. The importance of planning care as a team is recognised in Australian guidelines:[9]

"It is considered important that both the ICU team and operating room team meet to plan care during the Donation after Cardiac Death process.

- *The ICU meeting should include the intensivist and bedside nurse, other members of the ICU team, organ donor co-ordinator and allied health professionals, and serves to assign roles and responsibilities during the withdrawal of cardio-respiratory support and later the Donation after Cardiac Death process.*
- *In the operating room the organ donor co-ordinator, the operating room staff and the organ retrieval team meet to assign roles and responsibilities for the retrieval surgery. This operating room meeting should occur following the consent for organ and tissue donation but prior to the withdrawal of cardio-respiratory support."*

80. In developing local protocols for the management of potential donors, a variety of options should be considered so there is sufficient flexibility to avoid the situation where a donation is not possible, simply due to resource and staffing issues. Flexible staffing arrangements involving the SN-OD are discussed further in Section 2.1 of this document, paragraphs 21-24 (pages 6-7). Pragmatic steps such as the team meetings suggested above are a useful mechanism for ensuring that the complex process of organ donation runs smoothly, tailoring the process for each potential donor and their family.

3.5 IF DEATH DOES NOT OCCUR WITHIN A TIME APPROPRIATE FOR DONATION

Time factors affecting suitability of organs for donation.

81. Once life-sustaining treatment has been withdrawn, there are time constraints – both practical and physiological - that affect the suitability of organs for donation. At present protocols vary, but a stand-down time for the retrieval team of two hours from time of withdrawal of treatment to death is common. Work in this area is developing rapidly, as more is understood about the physiological processes involved and the specific responses of individual organs to these changes.

82. Death that follows the withdrawal of cardio-respiratory support is ultimately the result of failure of all circulatory and respiratory function. When organs are deprived of blood and nutrients at body temperature, they become damaged, a process known as warm ischaemia. This begins before death when blood pressure and oxygen saturation fall below a critical point, and is at its most damaging after cardiac arrest.

83. Warm ischaemic injury has two crucial implications for DCD:

- Successful transplantation may not be possible if the circulation to the organs is below the minimum acceptable threshold for too long
- Organs must be retrieved and cooled as soon as possible after the confirmation of death to reduce the adverse impact of the lack of oxygen.

84. DCD protocols variously describe a number of different time intervals that may have a bearing on the extent of warm ischaemic injury and the possibility therefore of organ donation. These time intervals are described in detail in the Consensus Statement, and can be summarised as:

- The withdrawal period (sometimes called the agonal period): the time from treatment withdrawal to asystole
- The functional (or true) warm ischaemic period: commences when the systolic blood pressure has a sustained (i.e. at least two minutes) fall below 50 mm Hg (or haemoglobin oxygen saturation below 70%) and extends up to the onset of cold in situ perfusion
- The asystolic warm period (also known as the primary warm ischaemic time): the time from loss of circulation (asystole) to the perfusion of the organs with cold preservation solution in situ.

85. Knowledge and thinking in this field is developing rapidly, with the functional warm ischaemic period a relatively new concept, but one which gives a more accurate indication of the likely damage to the organs.

86. UKDEC does not have a role in commenting on the technical aspects of time limits. Rather, it supports the development of robust and evidence-based clinical guidelines and their consistent application by retrieval teams to make best use of the organs available. The recommendations in the Consensus Statement in this area are very helpful, and need to be consistently applied. We expect that work in this area will continue to develop with further updating of guidelines over time.

Communication

87. DCD is relatively unfamiliar to many clinicians, and junior medical and nursing staff may feel particularly uneasy and vulnerable. This, together with the rapid developments in this area of practice means that it is essential that the donor and retrieval teams communicate effectively and agree at the outset their respective roles and responsibilities. This should lead to the formulation of a clear plan for end of life care for the patient that anticipates all possible outcomes – when donation goes ahead, when it becomes restricted to certain organs, or when organ donation is no longer viable. As ever, the primary responsibility of all staff is to the comfort and dignity of their dying patient and the support that their family and friends need at this time.

88. There are certain aspects of the DCD pathway that require specific attention and it is recommended that these are covered during a team briefing. These include:

- Location of treatment withdrawal
- Mode of treatment withdrawal, including airway management and pharmacological comfort measures
- Who will diagnose death, and what monitoring modalities are to be used to confirm it
- Transfer arrangements
- Responsibility for re-intubation and lung insufflation should lung retrieval be considered
- Further care arrangements should donation not be possible (see below).

89. If the patient has been moved to an anaesthetic room for withdrawal of life-sustaining treatment, but it then becomes clear donation cannot go ahead, a judgement needs to be made about whether it is appropriate to move the patient back to the intensive care unit or an alternative place of care. Although they have not died within the timeframe to allow for organ donation, death is still expected and it would be uncaring if the patient were to die during a transfer.

90. Families need to be fully informed and supported when it becomes clear that organ donation for transplantation will not be possible. If they have already left they should be given the opportunity to return if they wish. Organ donation for research, and tissue donation, which will have been part of the initial consent discussion with families, may still be successful.

91. Members of the clinical teams involved also need to be fully informed. This includes not only donor and recipient teams, but also the operating theatre staff who will have been on standby to perform the retrieval surgery. Staff may need an opportunity to debrief and to discuss and understand why organ donation did not go ahead for this potential donor. It needs to be recognised that a successful DCD programme is one which plans and manages the end of life care for potential donors equally well, whether or not they are ultimately able to donate organs.

92. DCD places a heavy burden on the resources of organ retrieval teams – they may have had to travel some distance to get to the hospital, wait some time before treatment is withdrawn, and in approximately 40% of attendances leave the donor hospital without donation having been possible. Retrieval teams are therefore resource intensive but vital to the success of organ donation programmes. Their contribution needs to be recognised.

Predicting time from withdrawal of life-sustaining treatment to death

93. Management of the situation where a patient does not die within an appropriate timescale or where the maximum functional warm ischaemic time for successful transplantation is exceeded, is difficult for all those involved, so identifying whether patients are likely to meet the time criteria would be helpful. Various scoring systems designed to estimate the likely time interval from withdrawal of treatments to asystole have been developed (e.g. in Wisconsin and by the United Network for Organ Sharing in North America), but none have been fully validated. Once further progress has been made on development and adoption of a common protocol for withdrawal of life-sustaining treatment, a scoring system for the UK context would be a useful development.

3.6. DEATH AND SUBSEQUENT INTERVENTIONS

Dying and death

94. The interests of a deceased patient extend beyond the confirmation of death. Interventions that are applied after death to improve the potential for successful transplantation from a DCD donor must at all times respect and be consistent with these interests. The deceased patient must be treated with dignity and respect at all times, and in a manner consistent with their cultural and religious views in life.

95. Death is a process rather than an event. The key elements of a biological standard for death are considered to be the simultaneous and irreversible loss of both the capacity for consciousness and the capacity to breathe. In order to allow proper confirmation of death in a timely manner A Code of Practice for the Diagnosis and Confirmation of Death[5] sets out the necessary diagnostic criteria in all situations. For some people, death is diagnosed after the brain stem has irreversibly ceased to function, by means of a series of neurological tests. In this situation, which is commonly referred to as brain-stem death, death is diagnosed even though the person continues to have cardiorespiratory function through artificial life support. This will cease once life support is removed.

96. For most people, and for all DCD donors, cessation of cardiorespiratory function is used to determine the time of death. Death is diagnosed after five minutes of continuous and complete loss of cardiorespiratory function, as set out in the Code of Practice. It is critical to note, however, that a period of five minutes is not sufficient to guarantee that residual brain function has been irreversibly lost, and that, were the circulation to be restored, there might be some limited restoration of cerebral function. It follows that within the context of DCD, the diagnosis and confirmation of death is critically dependent upon all of the following:

- A clear intention not to attempt to resuscitate the patient in order to restore circulatory, and therefore cerebral, function
- The likelihood of spontaneous resumption of cardiac function to have passed.
- The prohibition at any time of any intervention that might restore the flow of oxygenated blood to the brain, either directly or by provoking a resumption of cardiac function.

97. If a decision has been made that further life-sustaining interventions are not in the patient's best interests, then resuscitation – being one such intervention – is inappropriate. This is the case for potential DCD donors. Any actions which could resuscitate the brain, whether deliberate or incidental to the retrieval process, would conflict with the earlier decision to withdraw life-sustaining treatment in the patient's best interests.

98. As discussed in the previous section the retrieval operation needs to commence as soon as possible after death has been diagnosed (in accordance with the Code of Practice), and families have had their final minutes with their loved one. Given this short timescale, there is a possibility that the brain tissue of the donor may still be sensitive to stimulation if circulation of oxygenated blood is restored.

99. As it has already been decided that continuing life-sustaining treatment is no longer in the patient's best interests, interventions carried out after death should include additional measures where necessary to counter any risk of resuscitation and restoration of circulation to the brain.

Interventions after death

100. After death the donor is in the care of the retrieval team, but the clinical team treating them during life may still have a role to play to ensure no conflicts of interest arise. This is discussed in more detail in section 2.1 (paragraphs 25-26), but in summary it is recommended that a suitably trained individual, who may also be a member of the clinical team responsible for the donor's care during life, should be responsible for:

- Re-intubation to facilitate lung retrieval
- Re-confirmation of cardiac standstill (if necessary after moving the body or other necessary actions that could risk re-starting the heart).

101. The challenge for the retrieval team is to halt, and if possible reverse, the warm ischaemic damage that will have occurred since cessation of cardiorespiratory function. This ensures the best possible outcome for the donor and their family as it keeps the organs in optimal condition for successful transplantation, which is the goal of donation.

102. UKDEC does not have a view on the technical details of retrieval procedures, but they must be in accordance with the ethical principles set out above and carried out in such a way as to not risk conflict with the decision to withdraw or the process of withdrawal of life-sustaining treatment from the donor.

Restoring cardiac function

103. Restoring cardiac function is an area of interest as it could lead to heart retrieval and transplantation, and indeed heart transplants from DCD donors have been performed successfully.[2]

104. Some people feel uneasy about restoring cardiac function, given that irreversible cessation of cardiac function is a key component of the diagnosis of death in the donor. In physiological terms, cardiac function cannot be restored within the original biological system (i.e. the donor) without artificial support. The diagnosis of death applies to that person as a whole, not to their individual organs. There is therefore no ethical inconsistency if the heart is re-started and transplanted to a recipient. Furthermore the use of the term "circulatory" rather than cardiac death removes any appearance of inconsistency.

Dignity and respect

105. After death the donor must be treated with the same dignity and respect as any other deceased person. Cultural and religious views are important and should be respected.

When the process is complete

106. Organ donation is only an occasional event, but when it happens many different teams throughout the donor hospital will have had an important part to play, often at short notice. This contribution is best acknowledged by ensuring that everyone involved hears the outcome and has their role recognised. Retrieval teams should similarly be given information about the final outcome, and support where necessary.

107. Where donation for transplantation was not possible, staff need to understand the reasons why and be reassured that the time and effort they gave were an essential part of the end of life care for the patient. Where organs were transplanted successfully, everyone involved should know that they were able not only to fulfil the wishes of the donor and their family, but that the recipients have also benefited as a result.

4 CONSULTATION

108. In this document UKDEC has sought to set out the ethical considerations regarding controlled donation after circulatory death. In some cases there are areas where UKDEC believes that further work would be beneficial. This might be undertaken by UKDEC directly, or working in a facilitative role with others, or it may be for others to take forward. We would particularly welcome comments on these aspects of the recommendations – both in terms of the scope of future work areas, and suggestions for further issues that need to be addressed.

109. This guidance is open to consultation until **18 March 2011**, and comments are invited from anyone with an interest in organ donation.

110. Consultation responses may be published, unless respondents specify they are to be kept confidential. Responses should include name, affiliation and contact details of the author.

Electronic responses should be sent to:
donationethics@aomrc.org.uk

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Following the consultation period, UKDEC will publish a final set of recommendations with an action plan for future work.

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3 Organ Donation after Circulatory Death. Report of a Consensus Meeting held on 7 June 2010, between representatives of the Intensive Care Society (ICS) and British Transplantation Society (BTS), NHS Blood and Transplant and others on 'controlled' organ donation after circulatory death (DCD), held by the Department of Health in association with the devolved administrations. It has been endorsed by the ICS and BTS, and can be accessed at www.ics.ac.uk or www.bts.org.uk .

4 For current donor numbers see NHS Blood and Transplant statistics at http://www.organdonation.nhs.uk/ukt/statistics/calendar_year_statistics/donor/donor.jsp

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

6 Mental Capacity Act Code of Practice, Chapter 5 'What does the Act mean when it talks about 'best interests'?, *Department for Constitutional Affairs*, April 2007. For equivalent provisions in Scotland see http://www.sehd.sct.nhs.uk/mels/CEL2008_11.pdf

7 Treatment and care towards the end of life: good practice and decision making, *GMC*, 2010, which came into effect on 1 July 2010.

8 Cerebro-Respiratory Death Act, 2008, Israel http://www.hods.org/English/h-issues/documents/law51Braindead.pdf

9 National Protocol for Donation After Cardiac Death (Draft for consultation 2009), Australian Organ and Tissue Donation and Transplantation Authority

10 Legal issues relevant to non-heartbeating donation, Department of Health, 2009

11 Guidance on legal issues relevant to donation following cardiac death, *Scottish Government Health Directorates*, May 2010

12 Withholding or Withdrawing Life Sustaining Treatment in Children: A Framework for Practice, *Royal College of Paediatrics and Child Health*, London, 2004.

APPENDIX 1
UKDEC Membership 2010 - 2011

Sir Peter Simpson (Chair)	Past President, Royal College of Anaesthetists
Paula Aubrey	Regional Manager, NHS Blood and Transplant
Keshwar Baboolal	Consultant Physician and Nephrologist, University Hospital of Wales, Cardiff
Joe Brierley	Consultant Paediatrician, Paediatric and Neonatal Intensive Care Unit, Great Ormond St Hospital, London
Graham Brushett	Lay member, heart and kidney transplant recipient
Stephen Cole	Consultant in Anaesthesia and Intensive Care Medicine, Ninewells Hospital, Dundee
Heather Draper	Professor of Biomedical Ethics and Director of the Centre for Biomedical Ethics, Department of Primary Care Clinical Sciences, University of Birmingham
Bobbie Farsides	Professor of Clinical and Biomedical Ethics, Brighton and Sussex Medical School
Leslie Hamilton	Consultant Cardiac Surgeon, Freeman Hospital, Newcastle Upon Tyne
Penney Lewis	Professor of Law, School of Law and Centre of Medical Law and Ethics
Gurch Randhawa	Professor of Diversity in Public Health and Director, Institute for Health Research, University of Bedfordshire
Anthony Warrens	Honorary Consultant Physician and Dean for Education, Barts and The London School of Medicine & Dentistry
Eleanor Updale	Writer
Helen Lovell	Secretary

Observers may attend from the Department of Health and Devolved Administrations. NHS Blood and Transplant, the Human Tissue Authority and the Academy of Medical Royal Colleges.

APPENDIX 2
TERMS OF REFERENCE

The UKDEC will:

- Consider ethical issues, both general and specific, relating to the field of organ donation and transplantation. This includes considering relevant issues referred to the group by local Donation Committees, and providing independent advice to clinicians, policy leads and others as appropriate.

- Develop and maintain links with relevant professional and ethical associations/ societies.

- Ensure that advice given is independent and not unduly influenced by the views of any other organisation or individual.

- Produce, maintain and promulgate guidelines relating to ethical issues on organ donation and transplantation.

- Support Local Clinical and Research Ethics Committees, and Donation Committees in their provision of out of hours advice at a local level, based on DEC frameworks.

- Assist in the development of training content for those involved in organ donation and transplantation.

- Receive and collate any advice given locally, based on DEC frameworks, to harmonise advice where appropriate, determine whether any issues have any regional/ national implications and take action as appropriate.

- Be accountable to the Academy of Medical Royal Colleges:
    a. Setting out an annual work programme
    b. Providing an annual report summarising work undertaken and accounting for the use of funds
    c. Liaising with the Academy before publications are put in the public domain.