

AN ETHICAL FRAMEWORK FOR CONTROLLED DONATION AFTER CIRCULATORY DEATH

UK DONATION ETHICS COMMITTEE

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INTRODUCTION

i. This paper, developed by the UK Donation Ethics Committee, discusses the key ethical issues that arise in considering controlled donation after circulatory death. This document has been developed from a draft published for consultation in January 2011¹.

ii. This ethical framework is presented in three parts:

Part One discusses the principal ethical issues that are relevant to donation after circulatory death, including determination of the potential donor's best interests and issues relating to the diagnosis and confirmation of death.

Part Two sets the principal ethical issues in the context of the patient pathway, and sets out recommendations for current practice in more detail. We discuss how, at each stage in the end of life care pathway, decisions can be made and care provided in accordance with the ethical framework.

Part Three outlines some areas where UKDEC believes that further consideration and development would be helpful, either by UKDEC or other relevant organisations

iii. This ethical guidance is a working document, aimed primarily at doctors and other healthcare workers who are responsible for the various aspects of organ donation and transplantation, rather than the lay public. As a result, it has been structured along the patient pathway in such a way as to provide logical and sequential advice to those involved in the clinical care of donors and recipients. Nevertheless UKDEC acknowledges that it will be more widely read and has therefore tried to write the document in a readable and understandable form for those less familiar with some of the clinical concepts discussed.

The role of UK Donation Ethics Committee

iv. 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.² 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 Annex one.

Guiding Principles

- v. 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 in their last days and hours.

- vi. 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 where there are no medical contra-indications, and that, 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 be offered the same opportunity to donate 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.

Definitions, terminology and scope

Donation after circulatory death

- vii. 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.³ 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).
- viii. Donation after circulatory death may be controlled or uncontrolled. The term '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). There are significant differences between the two forms of DCD, and uncontrolled DCD happens very rarely in the UK at present.
- ix. **This guidance has been developed for controlled DCD***, although many of the principles described will apply equally well to other forms of deceased donation. This paper seeks to determine the ethical status of DCD in itself, and to recommend ethically sound procedures for its implementation.

Donation after brain stem death

- x. Donation after brain stem death (BSD) is organ donation that takes place following diagnosis of death by neurological criteria, as laid down in the Code of Practice for Diagnosis and Confirmation of Death.³ It is also sometimes known as heartbeating donation. Issues specific to this form of donation do not form part of this guidance, although some of the recommendations and issues discussed may be relevant.

Overall benefit

- xi. 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 care⁴, and is intended to ensure that the points discussed are applicable to the legal frameworks throughout the UK. Other terms, such as 'best interests', are only used in the context of specific legislation.

* Controlled DCD includes categories III and IV in the Maastricht classification of DCD.

Controlled Donation after Circulatory Death (DCD)

- xii. The rise in controlled donation after circulatory death in recent years has been well documented in the UK and in some other countries.⁵ At the same time, changes in neurocritical care have led to a fall in the proportion of potential donors after brain stem death in the UK. The number of donors after cardiorespiratory death in the UK increased from 200 in 2007-08 to 336 in 2009-10, while the number of heartbeating (brain stem dead) donors rose only slightly from 609 to 623 in the same period.⁶
- xiii. The introduction of DCD has increased the number of organs available for transplant, as kidney, liver, lung and pancreas may all be donated in this way, with acceptable outcomes for recipients. Hearts are not yet donated as a matter of routine, but this procedure has been carried out in infants in the US⁷ and interest is growing in the UK.
- xiv. DCD does not depend upon a new definition of death. It has long been routine for death to be confirmed by the absence of respiration and pulse (circulation). This means of confirming death is impossible when patients are artificially ventilated and so, since the second half of the twentieth century, neurological criteria have been applied to establish brain stem death (BSD) in ventilated patients. Artificial ventilation may continue after death has been diagnosed in this way to maintain the organs in good condition for transplant, and the majority of post mortem donations occur after a diagnosis of brain stem death. But not all those who wish to donate their organs after death die whilst being artificially ventilated, and developments in transplant techniques have made possible the use of organs from deceased donors whose circulatory systems are not mechanically supported. Current professional standards endorse the view that both sets of criteria reliably identify the state of death and thereby define the point at which organ retrieval can begin.

The clinical, legal and ethical frameworks for donation after circulatory death

- xv. In the absence of artificial ventilation, organs must be retrieved swiftly if they are to be transplanted successfully, as they quickly become damaged in the donor without the flow of oxygenated blood. This time pressure brings the need for clear legal, ethical and clinical guidance into sharp relief. A comprehensive framework is needed that can be supported by clinicians and patients alike. Over the last 18 months, a number of guidance documents on the legal and clinical aspects of donation after circulatory death have been published, building on existing guidance for organ donation more generally (see list below). In this document the UK Donation Ethics Committee has sought to provide an ethical commentary to complement these recommendations and answer the fundamental ethical questions that arise in donation after circulatory death.
- xvi. This document needs to be read in conjunction with other relevant legislation and guidance documents, including:
- 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, and supported by NHS Blood and Transplant (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 2010,⁸ and is referred to throughout the remainder of this document as ‘the Consensus Statement’.
 - Department of Health legal guidance on non-heartbeating donation (also known as donation after circulatory death), published in 2009⁹, and equivalent guidance published in Scotland¹⁰ and Northern Ireland¹¹.
 - Code of Practice on the Diagnosis and Confirmation of Death, published by the Academy of Medical Royal Colleges in 2008. This sets out clinical guidance on diagnosis and confirmation of death using both brain stem death criteria and cardio-respiratory criteria. It is referred to throughout the remainder of this document as ‘the Code of Practice’³.
 - Human Tissue Act 2004, which applies to England, Wales and Northern Ireland and the associated Codes of Practice. In Scotland, the Human Tissue (Scotland) Act 2006 applies.¹²
 - Mental Capacity Act 2005, which applies in England and Wales, and the associated Code of Practice.¹³ In Scotland, the Adults with Incapacity (Scotland) 2000 Act applies.¹⁴



PART ONE: ETHICAL FRAMEWORK

Donation after circulatory death gives rise to a number of significant ethical questions, relating to how death is diagnosed; how decisions are made about end of life care and donation; and conflicts of interest. In this section we explore these in some depth.

- **Definition, diagnosis and confirmation of death**
- **Exploring a competent individual's views about organ donation.**
- **Deciding that continuation of life-sustaining treatment is no longer of overall benefit.**
- **Determining whether organ donation is of overall benefit to an incompetent patient**
- **The Organ Donor Register**
- **Conflicts of interest**

1.1. DEFINITION, DIAGNOSIS AND CONFIRMATION OF DEATH IN THE CONTEXT OF ORGAN DONATION

- 1.1.1. A clear and common understanding of the definition, diagnosis and confirmation of death is essential if clinicians, patients and the public are to have confidence in donation and transplantation programmes. This is true for both donation after brain stem death (DBD) and donation after circulatory death (DCD)
- 1.1.2. A robust professional Code of Practice for the diagnosis and confirmation of death in the UK was published in 2008 by the Academy of Medical Royal Colleges³. The document provides detailed technical guidance that underpins the diagnosis of death in the UK, and is referred to throughout the remainder of this document as 'the Code of Practice'.
- 1.1.3. DCD follows death that is confirmed using cardio-respiratory criteria as defined in the Code of Practice. Although donation after circulatory death does not, and should not, require a special definition of death, it is nevertheless essential that everyone involved is confident that diagnosis of death is no less certain for DCD donors than for any other patient.
- 1.1.4. Death is regarded as the irreversible loss of the capacity for consciousness combined with the irreversible loss of the capacity to breathe, both of which are functions of the brain-stem and which are lost rapidly after cardiac arrest. The cardio-respiratory criteria for the diagnosis and confirmation of death therefore define the circumstances in which respiration and consciousness are irreversibly lost following circulatory arrest. The purpose of this is to identify both the irreversible loss of circulatory function and also, crucially, the loss of neurological function (including both consciousness and respiration) that inevitably follows.
- 1.1.5. Cardiac arrest may occur in many circumstances, some of which merit a prolonged period of cardio-pulmonary resuscitation before the irreversible loss of cardiac function can be identified. Within the context of planned treatment withdrawal however cardio-pulmonary resuscitation

is clearly inappropriate. It is the absence of the possibility of spontaneous return of cardiac function that determines when the circulation has been irreversibly lost. Published evidence¹⁵ indicates that this point is reached **after five minutes of continuous cardio-respiratory arrest**, with one very recent publication suggesting that two minutes may be sufficient¹⁶.

- 1.1.6. The Code of Practice requires that, after five minutes of continuous cardio-respiratory arrest, a neurological examination confirms the absence of brain-stem function, including respiration, consciousness and brain-stem reflexes. It is at this point that death using cardio-respiratory criteria can be confirmed, **since cardio-respiratory function has been irreversibly lost and so too therefore have the neurological functions dependent upon it**. The criteria are valid providing:
- there is no intention to attempt cardio-pulmonary resuscitation
 - the possibility of spontaneous resumption of cardiac function has passed
 - when reperfusion of organs with oxygenated blood is performed as part of the retrieval process, it should, as far as it practical, be restricted to the relevant organs.
- 1.1.7. As emphasised in the Code of Practice, the diagnosis and confirmation of death after five minutes of cardio-respiratory arrest is critically dependent upon close adherence to the schedule laid out in the Code and the principles defined above. Only in this way will confidence in the criteria be established.
- 1.1.8. Although DCD transplantation techniques may involve interventions which preserve individual organs for the benefit of the recipient, the apparent health or potential vitality of those organs does not in any way imply that the donor is still alive, because the core requirements for the diagnosis of death (the irreversible loss of the capacity to breathe together with the irreversible loss of the capacity for consciousness, both of which rely on the integrative function of the brain stem), are met.
- 1.1.9. For instance, the fact that the filtration activity of the kidney or the metabolic activity of the liver can be restored by the provision of a supply of oxygenated blood (for instance after transplantation or following artificial machine reperfusion) is not an indication that the donor was alive at the time of retrieval because neither organ is responsible for consciousness or the capacity to breathe.
- 1.1.10. Similarly, restoration of mechanical activity of the heart once it has been removed from the body does not indicate that the donor was alive or preclude its use for transplantation. Death (i.e. the irreversible loss of the capacity to breathe and the capacity for consciousness) has followed irreversible loss of integrated cardio-respiratory function, not the capacity of the heart to contract after reperfusion in vitro or transplantation into another individual.

- 1.1.11. The Consensus Statement refers to the possibility that the mechanical function of the heart may inadvertently be stimulated after death has been confirmed by re-inflation of the lungs to facilitate lung retrieval, although there is no documentary evidence to support this. It would be inappropriate to attempt resuscitation in such circumstances, because the neurological requirements to sustain heartbeat, respiration and consciousness are no longer present. Rather, the process for confirmation of irreversible cardio-respiratory arrest as described above should be repeated, preferably by a member of the critical care team. It would be inappropriate for a member of the retrieval team to undertake this.
- 1.1.12. Dying is a process, as opposed to actual death which is an event timed when the relevant tests have been conducted and subsequently confirmed. The irreversible loss of the circulation allows death to be confirmed when the absence of meaningful and integrated neurological function has been verified. It also indicates that progression to total brain death is inevitable providing the criteria set out in paragraph 1.1.6 are adhered to. Any procedure that risks restoring circulation throughout the whole body has the potential merely to prolong the final stages of the dying process, and is therefore unethical and not of overall benefit to the patient. Furthermore, recent evidence suggests that cerebral re-perfusion may also have a detrimental effect on the organs to be donated.¹⁷ The fact that the Code of Practice clearly states at the end of Section 3 “it is obviously inappropriate to initiate any intervention that has the potential to restore cerebral perfusion after death has been confirmed” provides professional support for such a view.
- 1.1.13. Resolution of many of the ethical questions that arise in the process of donation after circulatory death depends on a clear understanding of the time of death. The Code of Practice provides this clarity, and the legal time of death as diagnosed by cardiorespiratory criteria is at end of the five minute observation period, when death is confirmed. At this point the duty of care is transferred from the donor team to the retrieval team. In section 1.6 (Conflicts of interest), we illustrate how this definitive point can be used to determine who can and cannot care for the donor at any given stage.

Recommendations

- **Death should be confirmed through strict adherence to the schedule laid out in Code of Practice. When reperfusion of organs with oxygenated blood is performed as part of the retrieval process, it should, as far as it practical, be restricted to the relevant organs.**
- **Some actions carried out after death to facilitate donation carry a very small risk of re-starting the heart. An appropriately trained member of staff, preferably from the critical care team, and not part of the retrieval team, should resume the process for confirmation of cardio-respiratory arrest as laid out in the Code of Practice.**

1.2. EXPLORING A COMPETENT INDIVIDUAL'S VIEWS ABOUT ORGAN DONATION

1.2.1. An individual may decide at any time and for a variety of reasons that they wish to donate their organs or other tissues after their death. Ideally, they will have considered the issues, made a decision, and if that decision is to donate, put their name on the Organ Donor Register, and discussed this with their family. In many cases this consideration and discussion does not happen, and a family, having just learned a loved one is close to death, is confronted with the difficulty of trying to work out whether donation is something their loved one would have wanted. This difficulty is compounded by the fact that most deaths leading to organ donation are the result of sudden catastrophic injury or illness (a road traffic accident or a massive stroke). Later in this document we discuss the legal frameworks for decision making in these circumstances, and the factors that need to be taken into account in deciding the course of action for any particular patient.

1.2.2. There are other circumstances, for example where a patient has received a diagnosis of terminal illness, where end of life care planning can take place with the full involvement of the patient. GMC guidance Treatment and care towards the end of life addresses the issue of advance care planning in some detail in paragraphs 50 to 62.⁴ Specific reference to organ donation is made:

54. *Depending on the patient's circumstances, it may also be appropriate to create opportunities for the patient to talk about what they want to happen after they die. Some patients will want to discuss their wishes in relation to the handling of their body, and their beliefs or values about organ or tissue donation.*

1.2.3. The UKDEC recognises that organ or tissue donation will not always be possible, depending on the nature of the patient's condition and other factors, but where it is a possibility, UKDEC, like the GMC, believes that clinicians should create opportunities for patients to receive information and express their wishes. Not every patient will want to discuss donation, but those who do may raise the issue at any point in their course of treatment. Whenever this happens, clinical teams have a very important role to play in discussing the issues, answering any questions the patient or their family might have, and making a clear record to assist in planning the final stages of end of life care. Where donation will not be appropriate, patients and their families should similarly be given an opportunity to discuss this if they wish. It is equally important to ensure patients and their relatives do not have cause to regret having missed an opportunity at a later date.

1.2.4. Early discussion and knowledge of an individual's wishes with regard to donation are therefore desirable, but cannot and should not be forced. UKDEC and the GMC are planning to undertake some joint work to develop learning materials to support the guidance set out in Treatment and care towards the end of life.

1.3. DECIDING THAT CONTINUATION OF LIFE-SUSTAINING TREATMENT IS NO LONGER OF OVERALL BENEFIT.

1.3.1. 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 of overall benefit to them. This decision point is pivotal, and needs to be demonstrably independent of consideration of organ donation. In the typical case the patient will be unconscious and receiving care in an intensive care unit, and unable to decide this for themselves. The clinician responsible for making the decision will need to consult with those close to the patient in order to come to an appropriate view. The relevant 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.^{13,14} Further professional guidance is set out in the GMC guidance document 'Treatment and care towards the end of life'.⁴

1.3.2. A comparison can be made with confirmation of brain stem death, where two senior doctors are required to confirm the diagnosis.³ 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, such as being the Clinical Lead for Organ Donation for the Trust, since with regard to this decision they are both solely concerned with discharging their duty of care to the patient.

Recommendation

- **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).**

1.4. DETERMINING WHETHER ORGAN DONATION IS OF OVERALL BENEFIT FOR A PATIENT WHO LACKS CAPACITY

- 1.4.1. Once it has been agreed that further active treatment is no longer of overall benefit, the potential for organ donation should be explored, in accordance with Principle 1 and Principle 2 set out at the beginning of this ethical framework.

The concept of harm

- 1.4.2. Determining the course of action appropriate for a patient who lacks capacity requires an assessment to be made of whether the options available may cause, or risk causing harm to the patient. The Mental Capacity Act does not provide a definition of harm, as it will vary according to the situation. Some consideration is therefore needed as to what constitutes harm in the context of a potential organ donor.
- 1.4.3. In this context, harm may encompass two elements. One is the undesirable physical effect that may be caused by an intervention, such as the risk of unpleasant side-effects of a medication, pain or discomfort, and distress. The other is the harm that may be caused by doing wrong to the patient, such as by ignoring their expressed wishes for end of life care. In considering whether a particular intervention or course of action may cause harm to a patient, both of these elements need to be considered and a judgement made.
- 1.4.4. If the patient is known to have wanted to be an organ donor, then adjustments may be needed to their end of life care to enable this to happen. Some such interventions may cause or carry a risk of undesirable physical effects. These sorts of harms have to be weighed against the harm of frustrating the patient's wish to be an organ donor. Small harms such as the puncture wounds caused by taking blood samples for tissue typing purposes are normally thought to be outweighed by the harm of not acting in accordance with an expressed wish to become a donor. In other cases, the undesirable effects of interventions or risks they pose weigh more heavily and may be thought so considerable that they outweigh the wish to become a donor. For example, if the patient needs

a particular test to determine their suitability to be a donor that can only be carried out at a different location, but there is a significant risk that the patient will die during the transfer.

Recommendation

- **Clinicians should take a balanced view of the risk of harm when considering particular interventions or course of action, encompassing both the risk of physical harm, and the risk of doing wrong by not acting in accordance with the patient's wishes.**

Determining whether organ donation is of overall benefit

- 1.4.5. The legal framework for donation after circulatory death incorporates requirements of the Mental Capacity Act 2005¹³ (Adults with Incapacity (Scotland) Act 2000 in Scotland)¹⁴, which applies while the potential donor is still alive, and the Human Tissue Act 2004 (Human Tissue (Scotland) Act 2006 in Scotland)¹², which applies after death. The UK Departments of Health have provided legal guidance^{9,10,11} which describe the requirements applicable to donation after circulatory death.
- 1.4.6. We seek here to provide a more detailed exploration of how the appropriate course of action can be determined for each potential donor, in a manner that is both ethically sound and lawful under the terms of the relevant legislation.

Organ donation under the Human Tissue Act 2004

- 1.4.7. Organ donation can only proceed if consent to that donation is available under the Human Tissue Act. Consent can be provided either:
- a. by the donor, or
 - b. by a third party, either someone nominated by the donor (a 'nominated representative'), or more likely, by the family (someone in a 'qualifying relationship' to the donor)
- 1.4.8. Both categories will include a spectrum of possibilities which will overlap. The first category will include: (i) donors who have both consented to donation and agreed to undergo any procedures which would increase the probability of a successful transplant; (ii) donors who have simply consented to donation by joining the Organ Donor Register, signing a donor card or advance directive; and (iii) donors who have consented to donation (communicated by their family) without performing one of the formalities in (ii). Even though consent is available from the donor in this last example, consent may also be sought from a third party. In addition,

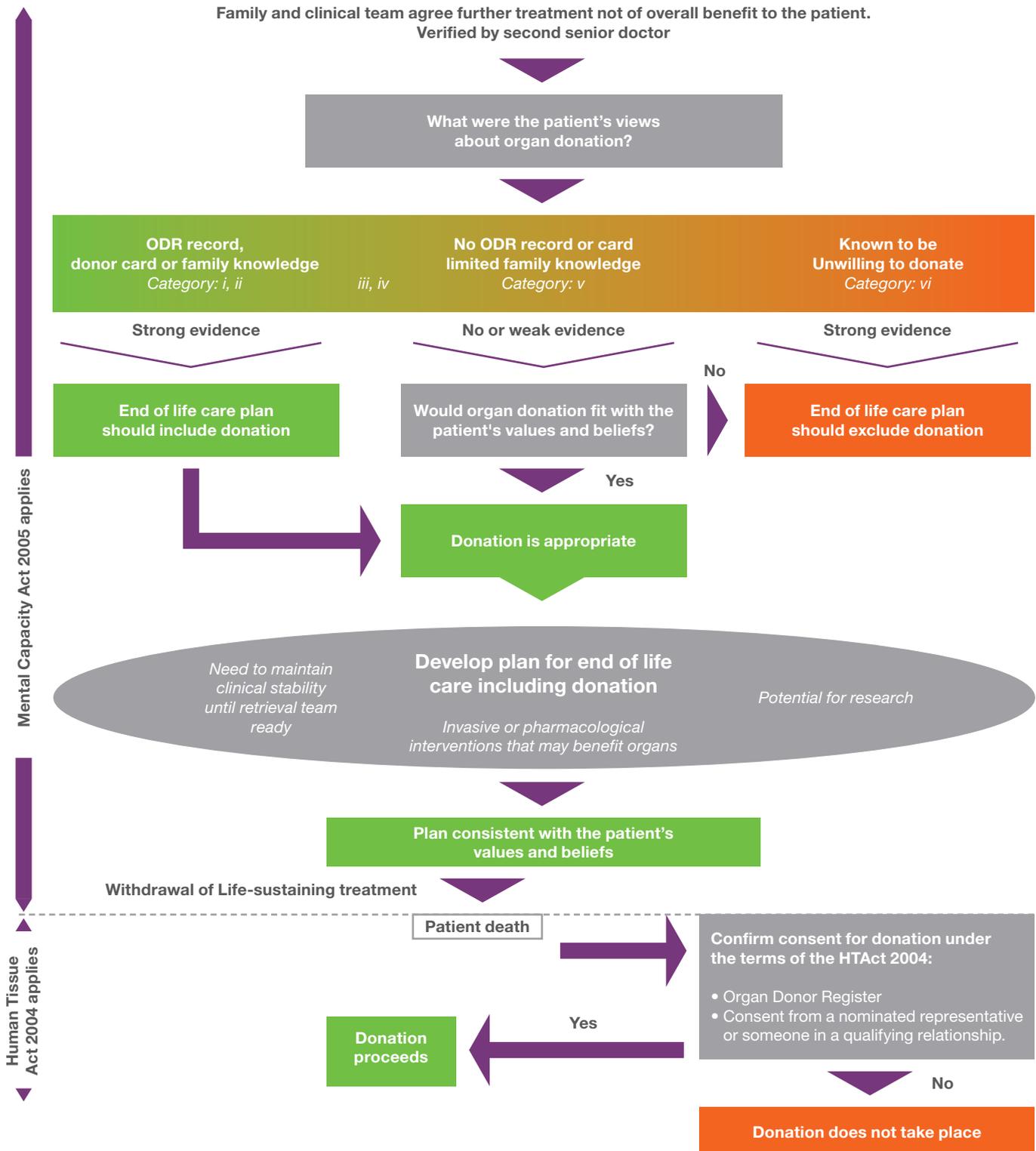
the ‘third party’ category will also include (iv) donors for whom consent is provided on the basis of their wishes and feelings; (v) donors for whom consent is provided on the basis of the beliefs and values that would be likely to influence their decision; and (vi) donors for whom consent is provided although there is little or no evidence of their wishes and feelings on donation, or that donation would be consistent with their beliefs and values.

- 1.4.9. Within the ‘third party’ category, although most consent providers will be influenced by the donor’s wishes, there is no requirement in the Human Tissue Act for the consent, or lack of it, to reflect the donor’s wishes.

End of life care under the Mental Capacity Act 2005

- 1.4.10. Prior to death, the incompetent patient must be treated in accordance with their best interests under the Mental Capacity Act. When assessing best interests, the patient’s wishes and feelings, beliefs and values must all be considered. The courts have established that a person’s best interests are wider than simply their clinical interests. The Mental Capacity Act Code of Practice 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).
- 1.4.11. UKDEC recommends that, once a decision has been made by the treating team that continuing life-sustaining treatment is no longer in the incompetent patient’s best interests, the end of life care plan should incorporate the patient’s views on organ donation, if known. Unlike the decision to donate taken after the patient’s death, which may not reflect the patient’s wishes or be in accordance with their interests (category vi above), decisions about the patient’s end of life care must be for the overall benefit of the patient. Where organ donation is a clinical possibility, the end of life care plan should include donation for patients who fall within categories i to v above.
- 1.4.12. Once a decision has been made to include organ donation within the patient’s end of life care plan, the plan will need to be developed. Facilitating DCD may involve continuing or adjusting or commencing treatments, instituting procedures, changing the place of care or other decisions that may have no direct medical benefit to the patient. Every decision taken must nonetheless be for the overall benefit of the incompetent patient. There can be no standard test of ‘overall benefit’. Individual feelings, beliefs and values must all be taken into account alongside medical needs and consideration of the risks and burdens (if any) to the patient.
- 1.4.13. Diagram 1 shows schematically how the decision making process can work. It is possible that, although a family initially consider donation is appropriate, they change their view once they understand more about

DIAGRAM ONE: DETERMINING WHETHER ORGAN DONATION IS OF OVERALL BENEFIT



the process and decide that donation should not proceed. It is also acknowledged that organ donation is only one of a number of factors that may have an impact on the end of life care pathway. It may, for example, be appropriate to delay the withdrawal of life-sustaining treatment to enable relatives to travel to the hospital.

1.5. ORGAN DONOR REGISTER

- 1.5.1. The Organ Donor Register (ODR) is one of a number of sources of evidence as to a patient's wishes regarding donation, but the process of checking the ODR occasionally causes concern. Checking the 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 will be of overall benefit to them). 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. UKDEC believes these fears to be misplaced. Our recommendation, that two doctors must confirm when further life-saving treatment is not in the patient's best interest is intended to allay such fears. It should also be remembered that families retain the ability to say no to donation, which is the ultimate safeguard where families feel they have been placed under undue pressure or they are otherwise concerned about what is happening to their loved one.
- 1.5.2. UKDEC does not consider that knowledge of ODR status at an early stage of a patient's care has any ethical consequences beyond normal patient confidentiality. Local trust policies should determine when the ODR is consulted and by whom. The ODR record is a vital part of the evidence that the clinical team needs to have in order to determine the end of life care path once a decision has been made that life-sustaining treatment is no longer of overall benefit to the patient. The ODR must therefore be checked before approaching the family about organ donation and end of life care.

ODR and children

- 1.5.3. 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. Parents can register their children if they are under the age of 12. Although nearly half a million children in the UK are registered on the ODR, most UK children who donate organs are not.
- 1.5.4. The points regarding accessing ODR data discussed above apply equally to children, in that the clinical team should have the ODR record before approaching the family about organ donation.

Recommendations

- **The patients views on organ donation, including whether they have signed the organ donor register, should be sought after the decision to withdraw life-sustaining treatment has been agreed by the clinical team, verified by a second senior doctor, and accepted by the family.**
- **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, and before the family are approached about organ donation.**

1.6. CONFLICTS OF INTEREST

Donors and recipients

- 1.6.1. 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 of overall benefit to the patient, the reasons to continue active treatment appear to fall away, with the emphasis shifting to appropriate palliative measures.
- 1.6.2. 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 donation 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 for the overall benefit of the patient, but rather for the overall benefit of the potential recipients.
- 1.6.3. This is a narrow interpretation of ‘overall benefit’. The courts have established that a person’s ‘best interests’ (the term used to mean overall benefit in the Mental Capacity Act) are wider than simply their medical interests. The Mental Capacity Act Code of Practice¹³ 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, and the clinician is legally obliged to take this wider view. Similar principles apply in the legislative framework for Scotland. 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 (or to be of overall benefit to them).

- 1.6.4. 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. Clinicians caring for patients who are potential donors thus continue to act for the overall benefit of their patient at all times. Consideration of the recipient (which would result in a conflict of interest) does not play any part.

Recommendation

- **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.**

Staff roles and responsibilities

- 1.6.5. Any member of staff may feel they have a conflict of interest if they appear to have responsibilities both to the donor and to the recipient, or have other responsibilities that might influence their judgement in some way. The fundamental concern is that this may lead them to make an inappropriate decision about the care of one of the patients. Recommended staffing structures, which totally separate donor and recipient clinical teams, are designed to avoid such conflicts. This protects both staff and patients, and seeks to build confidence in donation programmes among clinicians and the wider public.
- 1.6.6. In a busy clinical unit the ideal staffing arrangement may not be readily available at the time a donation becomes a possibility. The lead clinician or nurse in charge is then faced with considering whether donation can still be offered, or whether the circumstances are too difficult and it would be unethical to proceed with donation at that time. In developing local protocols for donation, organisations need to consider what options should be available in the event of staffing shortages in order to achieve the potential donor's wish. This might include calling in agency staff or cross-cover arrangements. The impact on other patients is a major factor, as all patients need to have appropriate care from staff with the right skills.
- 1.6.7. In the following paragraphs we discuss the issues relating to particular key staff, discussing the ideal situation, and setting out recommendations for the limits of their practice.

Recommendations

- **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.**
- **The lead clinician 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.**

Clinical Leads for Organ Donation

- 1.6.8. Clinical Leads for Organ Donation (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. Thus the role (which is typically undertaken by a senior clinician, often an intensive care physician who has direct experience of organ donation), is a managerial rather than a clinical responsibility. Another subject of debate has been 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.
- 1.6.9. 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 incorporating organ donation into the patient's end of life care plan would be of overall benefit to them, and working with the family and the SN-OD to facilitate donation if appropriate for that patient. This is enshrined in recent GMC guidance on end of life care⁴:
81. *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.*
 82. *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.*

- 1.6.10. Our recommendation proposing that the decision to withdraw life-sustaining treatment should be verified by a second senior doctor provides a clear safeguard. In addition, potential donors and their families can be reassured that, although the doctor in the intensive care unit may open the discussion about organ donation, they do not make the final decision as to whether the organs can be used. Their duty is to ensure that the patient's end of life care will be of overall benefit to them and consistent with their expressed wishes.

Specialist Nurses for Organ Donation

- 1.6.11. 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.
- 1.6.12. UKDEC recommends that SN-ODs should not provide medical care for 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.
- 1.6.13. After death the SN-OD continues to perform a number of duties supporting the organ donation process, 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.

Recommendation

- **Specialist Nurses-Organ Donation should not provide medical care for the potential donor whilst they are still alive.**

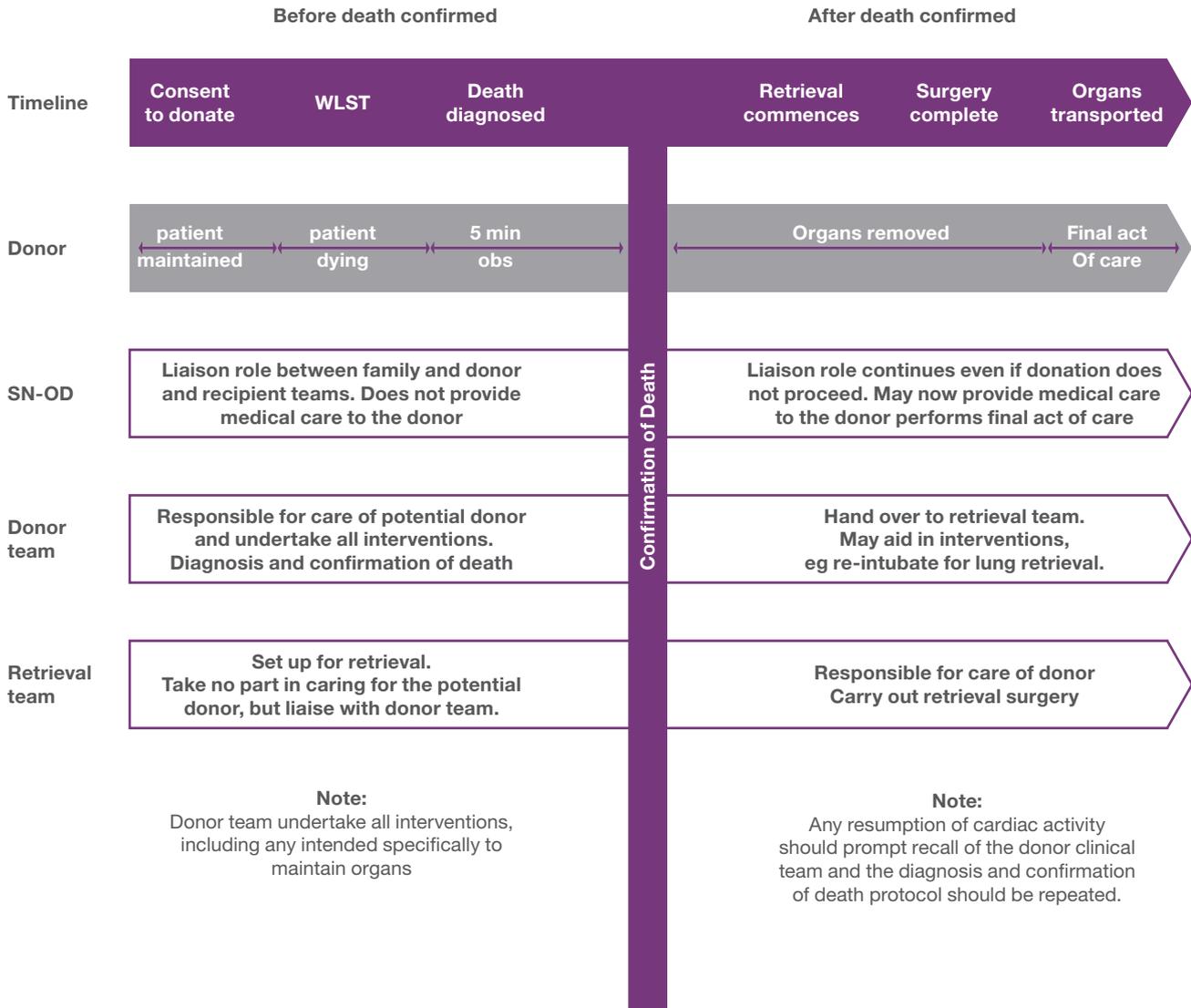
Retrieval team and recipient's team.

- 1.6.14. Members of the retrieval team and the recipient's clinical team should not be involved in the care of the potential donor prior to the confirmation of death. There are a number of specific situations in which questions relating to this principle may arise, and UKDEC gives an opinion below. However, it is for organisations to agree local protocols, consistent with this principle, that meet the needs of local circumstances.
- a) **Interventions that are performed to secure the best outcome to the donation rather than to be of direct medical benefit to the patient.** In this situation, the retrieval or transplant team may wish to advise on appropriate interventions, but it is for the donor team to undertake the intervention, if they are content it is of overall benefit to the potential donor.
 - b) **Who can diagnose and confirm death if the ITU consultant is not immediately available?** This situation may arise when the donor has been moved from the ITU for withdrawal of treatment. In these circumstances, if the ITU consultant has returned to the ITU, the on-call anaesthetist may be asked to diagnose and confirm death. The question arises as to whether it is appropriate for the same anaesthetist to be involved in the care of the recipient later in their shift? At the time at which death is diagnosed and confirmed, the individual practitioner should not already have an established duty of care to the recipient.
 - c) **Who can undertake re-intubation of a patient after death to facilitate lung retrieval?** It is of overall benefit to both the donor and the recipient for this procedure to be carried out 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 once death has been confirmed.

Recommendation

- **Any clinician involved in the care of the donor should not have a duty of care to the recipient at that time. In particular, members of the retrieval team and the recipient's clinical team should not be involved in the care of the potential donor prior to death being confirmed. 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**
- **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 an organ donor has been taken, it is for the overall benefit of both the deceased patient and the 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.**

DIAGRAM TWO: TIMELINES AND RESPONSIBILITIES





PART TWO: THE POTENTIAL DONOR PATHWAY

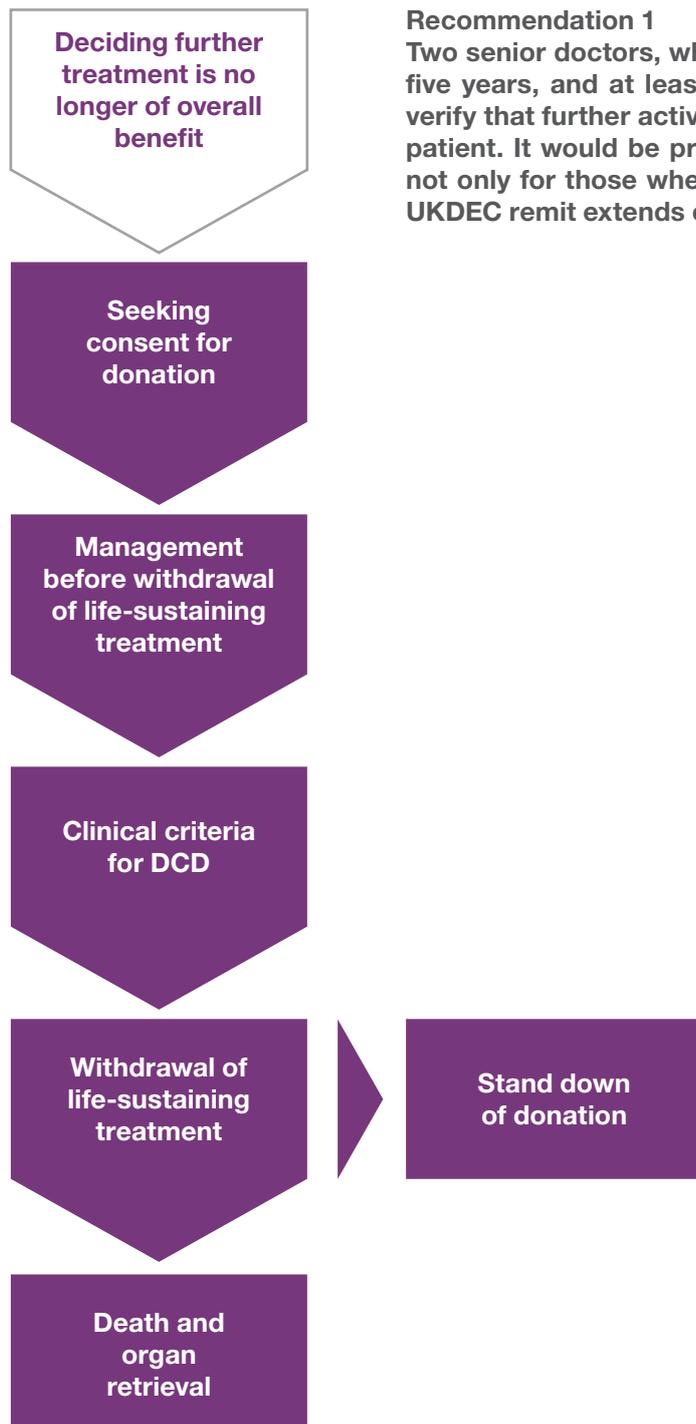
2. INTRODUCTION

Part Two provides a detailed explanation of how the ethical framework discussed in part one can be applied in practice. It is written in the context of the potential donor being an unconscious patient, typically being cared for in an intensive care unit.

2.1. DECIDING FURTHER TREATMENT IS NO LONGER OF OVERALL BENEFIT

- 2.1.1. Deciding that further life-sustaining treatment is no longer of overall benefit is a critical point in the care pathway of a severely ill patient. In Part One, paragraphs 1.3.1 – 1.3.2 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, 18 which suggests that a second opinion should be sought where there is any doubt.
- 2.1.2. 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 within the clinical professions about organ donation in recent years, and an explicit policy of seeking a second opinion is one way of allaying those concerns.
- 2.1.3. 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.

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)

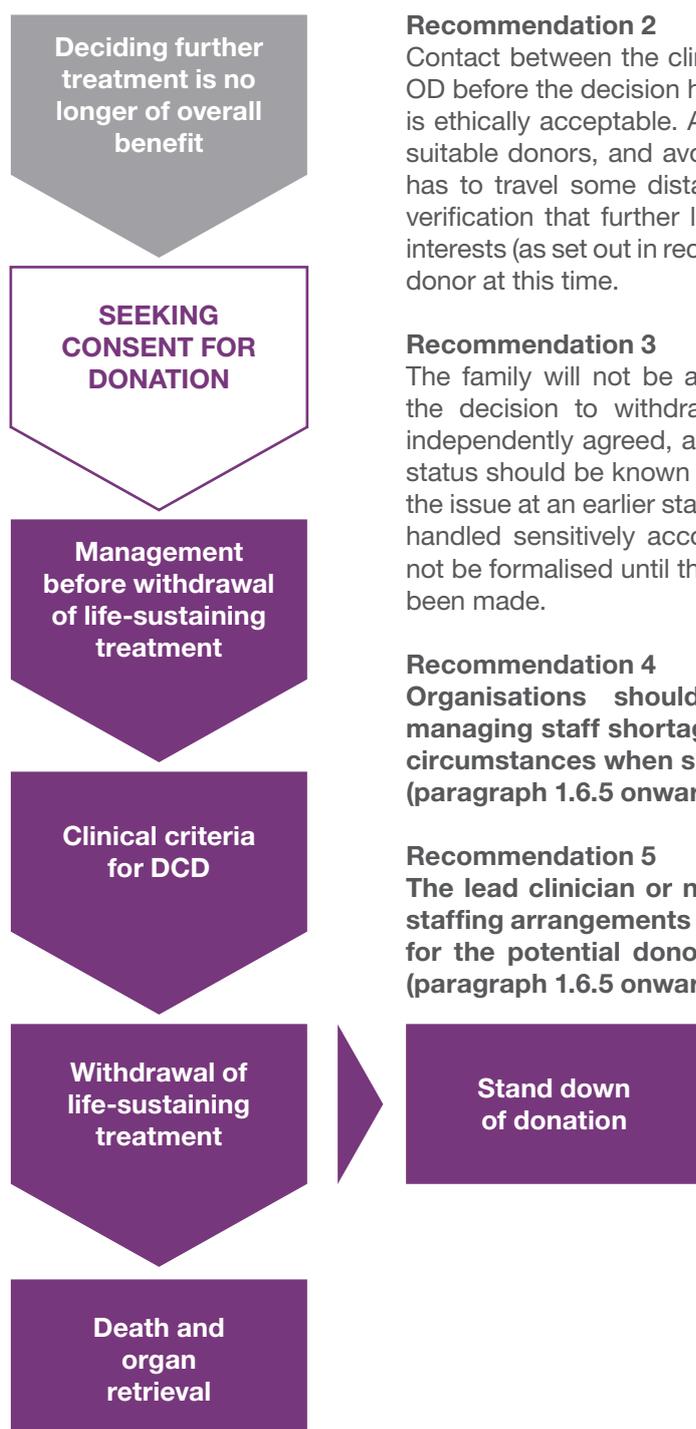
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

2.2 SEEKING CONSENT FOR ORGAN DONATION

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

- 2.2.1. The Specialist Nurse for Organ Donation (SN-OD) ensures 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.
- 2.2.2. 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 organ donation, in which case the issue of donation either does not need to be raised with the family at all, or if the family raise the issue it can be explained why organ donation is not appropriate. 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.
- 2.2.3. 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 Organ Donor Register 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.
- 2.2.4. UKDEC is in agreement with the Organ Donation Taskforce recommendations. Flexibility is needed, and 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.

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)

Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

Early involvement of the SN-OD with the family

- 2.2.5. Early involvement of the SN-OD with the family (sometimes known as the 'long contact model') 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. It has been the subject of some debate within the transplant community, with some arguing that it leads to higher consent rates for donation as the SN-OD is already part of the team supporting the family before the approach is made. Others argue that there is a risk of coercion, and fragmentation of support to the family as, if the family decide donation is not appropriate, the SN-OD may leave.
- 2.2.6. There are many different ways of putting a long contact model into practice. The example described in the box shows how it has been put into effect at St George's Hospital NHS Trust in London. It is important to note that the specialist nurse's role is to support the family through the end of their relative's life, whether or not organ donation is part of the end of life care plan. Thus the specific duties of the SN-OD are incorporated into a wider role in end of life care.
- 2.2.7. UKDEC does not endorse exclusively either the long contact model generally, or the St George's model in particular, over other ways of working with families. Rather, clinical teams need to work with potential donors and families in a way which is ethically sound and gives the best chance of enabling families to make fully informed decisions about organ donation at a difficult and stressful time. The most effective model will vary between institutions depending on local circumstances, but the need to support the family in giving effect to their relative's wishes, whether or not this includes organ donation, remains paramount. UKDEC supports the General Medical Council position that all patients in their last days and hours should be offered the end of life choice to be a donor when no medical contra-indications to donation exist.¹⁹

Long Contact Model: An example from St George's Hospital NHS Trust

At the Neurological Intensive Care Unit (NICU) at St George's the specific duties of the Specialist Nurse for Organ Donation are incorporated into a wider job role to work with and support families as they face the prospect of their loved one reaching the end of life. This embedded role offers a support system for potential donor families, meeting their personal, cultural and spiritual needs, and ensures that the families make a properly informed decision about whether or not organ donation is appropriate.

Following the decision, by the multidisciplinary team (MDT), that life-sustaining treatment is no longer considered in the patient's best interests the specialist nurse is involved. The presence of the specialist nurse in the room while the consultant explains the clinical reasons for the withdrawal of support allows for continuity of information and avoids any misunderstandings. They are introduced as 'specialist nurse' as they have the expertise to discuss all aspects of end of life care with families, not only organ donation.

Accepting the change in focus from treatment to end of life care may take time for the family and it is important the family are in agreement with the decisions made by the MDT.

This time frame is focused on the families understanding and needs. The consultant may choose to leave the room after all the family's questions have been answered and the specialist nurse remains with the family. If the family expresses any concerns regarding withdrawal of treatment, the specialist nurse alerts the consultant for further discussion with the family.

The specialist nurse usually raises the option of donation unless the family raises the subject first. Offering the choice of donation is not simply asking the question. The specialist nurse broaches the issue of donation only if:

- d) The family fully accept that further treatment is not in the patient's best interests
- e) All family's needs are met

Follow up care, regardless of donation, is maintained by the embedded specialist nurse, including support with bereavement services, social services, and identifying any specialist funeral arrangements including repatriation. If donation does proceed, the specialist nurse facilitates the donation and remains in telephone, email or letter-writing contact with all families as laid out in the 'donor family care policy'.

This model has been in place for the last three years, and there has been positive feedback from all the families (even the ones that did not choose donation as an option) as they feel very supported through a difficult time.

Role of Coroner

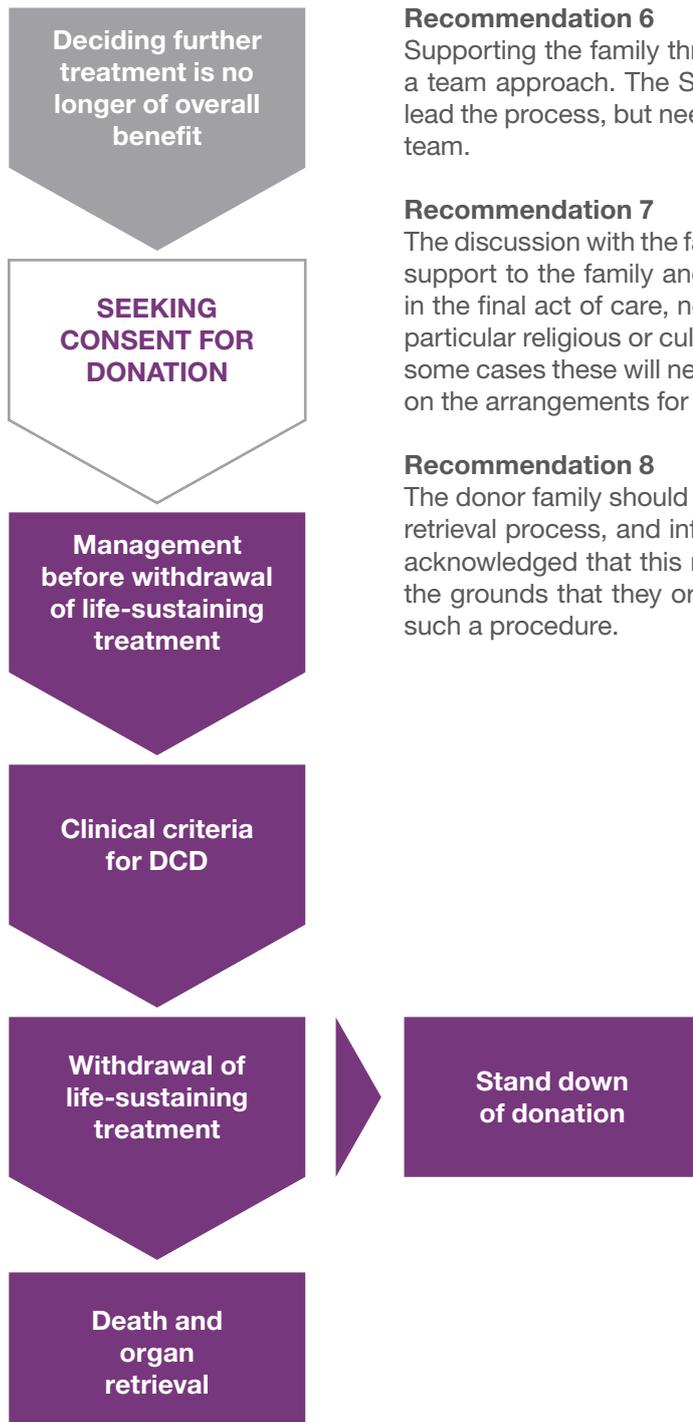
- 2.2.8. The Coroner (or Procurator Fiscal in Scotland and Northern Ireland) has a legal duty to enquire into deaths in his or her jurisdiction where the cause is unknown, where the death is violent or unnatural, or where the death occurs in custody. Nearly all Coroners will expect deaths within 24 hours of admission to hospital to be referred to them, unless known to be for palliative care. In all these cases, even in suspicious cases where the police are involved, the Coroner is responsible for the final decision as to whether a donation can go ahead, if the family decide that donation is of overall benefit to their relative. The Coroner must be satisfied that donation will not interfere with his or her duty to investigate the death.
- 2.2.9. For donation after circulatory death, the Coroner must be consulted before the patient has died, and this may well be out of normal office hours. There is no statutory duty on Coroners to be available out of hours for this purpose before death has occurred, so it is essential that protocols are developed and agreed with the local Coroner's office so that appropriate consideration can be given in a timely manner. Guidance for SN-ODs on referrals to the Coroner for England and Wales can be found on the Department of Health website.²⁰ Separate arrangements have been agreed between the Scottish Transplant Group and the Procurator Fiscal Service in Scotland and in Northern Ireland.

Process for Seeking Consent

- 2.2.10. 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 whether donation is appropriate can commence. In Part One, we discuss the different kinds of evidence of the patient's wishes that may be available (see page 17). The treating clinician will need to weigh up the evidence, and determine whether or not donation would be of overall benefit. If donation is agreed to be an appropriate goal, then detailed planning needs to be undertaken with the family to ensure that the steps necessary to facilitate donation in the end of life care are appropriate. This may include, for example, delaying the withdrawal of life-sustaining treatment until the retrieval team has been assembled.
- 2.2.11. Some clinicians want to lead the initial discussion about whether organ donation is appropriate, 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 of overall benefit to the patient.
- 2.2.12. For incapacitated patients under the age of eighteen it is the parents, or those with parental responsibility, who are able to consent to organ donation, as with other therapies. Their decision making can be informed by any prior discussions with the child, and indeed the child may have signed the ODR.

- 2.2.13. 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.
- 2.2.14. The process will need to be flexible to take account of different circumstances. In particular, donation programmes from the Emergency Department need to reflect that the family may be faced with a sudden death and a situation that is moving at a faster pace than for patients and their families in intensive care. In these circumstances, it may be more appropriate for a member of the healthcare team caring for the patient to make the the initial approach, rather than to expect a family to wait if the SN-OD is not immediately available.
- 2.2.15. 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 care after death, 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
- 2.2.16. There will be times when the family raises the issue of organ donation at an earlier stage in the process, before the decision has been made that further treatment is no longer of overall benefit. In such circumstances the clinical team need to deal with this sensitively, noting their wishes and answering any immediate questions but helping the family to understand that it is not yet time to make these decisions.

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.

Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

Information for donor families

- 2.2.17. 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.
- 2.2.18. UKDEC received responses to our preceding consultation document calling for a legal minimum level of information that should always be offered. UKDEC is of the view that the team working with the family are best placed to make that judgement in the light of all the circumstances of a particular case. The principle followed by SN-ODs and others working with donor families is that information should be available and offered to those who want it.
- 2.2.19. 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 of this approach on the organ donation programme is likely to be positive, even if it might occasionally result in reversal of a decision to donate.
- 2.2.20. 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.

Staffing and logistical considerations

- 2.2.21. Caring for a potential donor is resource intensive, and there will be times when staffing or other logistical issues may make it difficult to offer organ donation. 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. Organisations need to have policies in place to support staff in these circumstances, setting out both when additional resources (such as agency staff) can be sought, and when offering organ donation would not be appropriate. These issues, and the ethical limitations on particular staff groups, are discussed in more detail in Section 1.6, page 21.

2.3. MANAGEMENT BEFORE WITHDRAWAL OF LIFE SUSTAINING TREATMENT

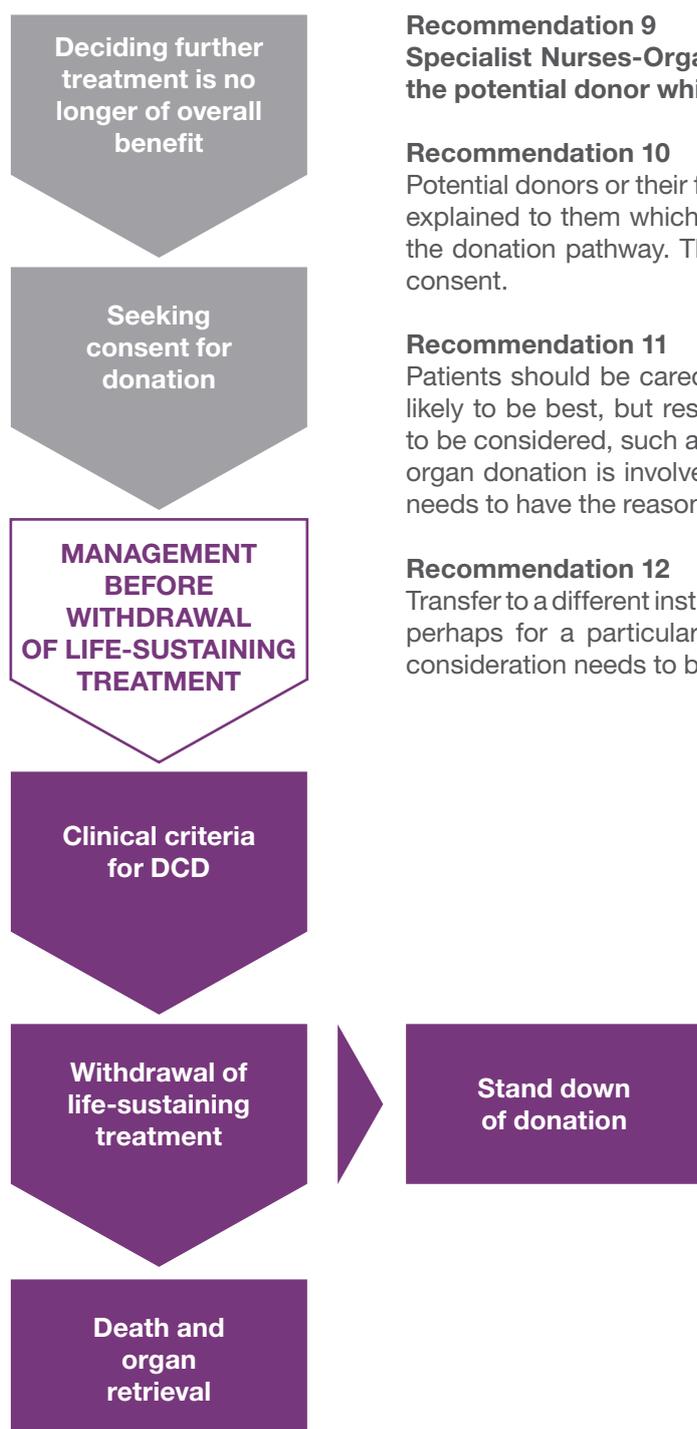
Planning and communication

- 2.3.1. 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.
- 2.3.2. Donation after circulatory death 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.
- 2.3.3. 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 later section)

Location

- 2.3.4. 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 that donation to happen.

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.

Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

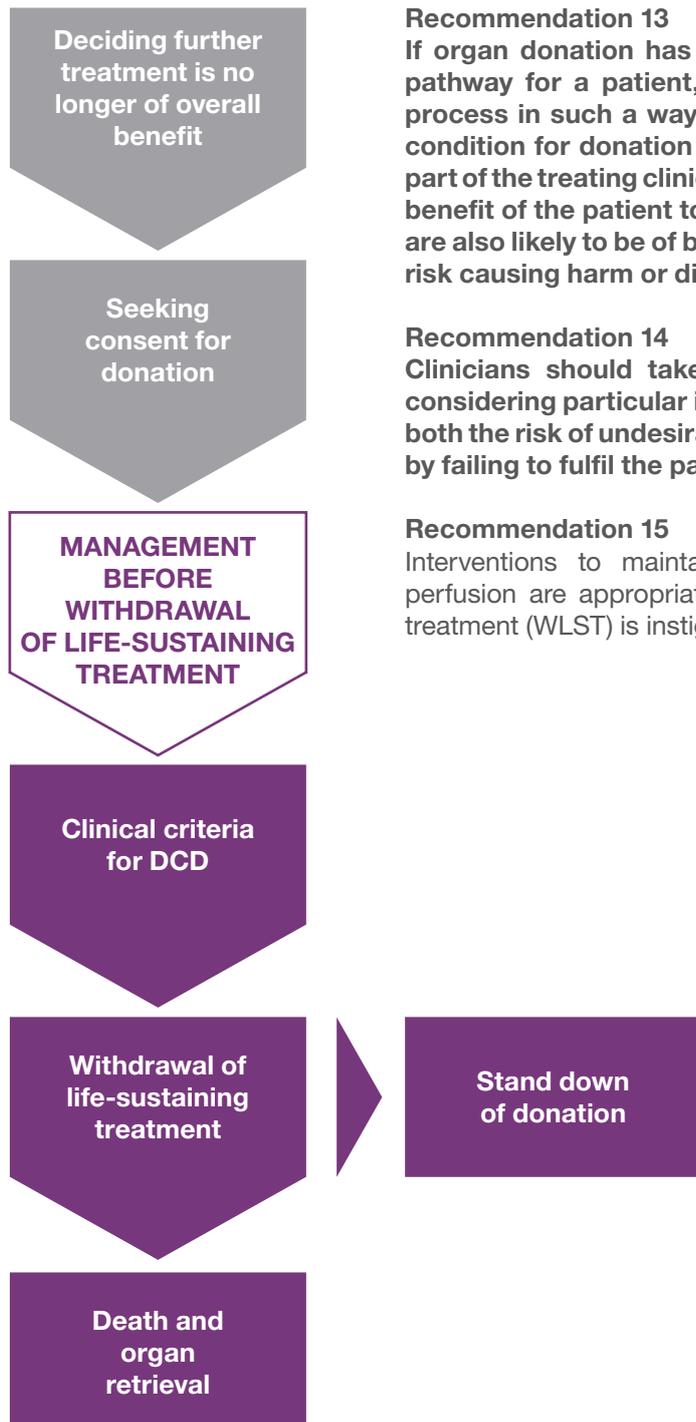
- 2.3.5. A decision as to the most appropriate environment for end-of-life care needs to be taken in an unhurried way and at a senior level. It can be difficult to offer a compassionate and peaceful end of life in the Emergency Department, so a different location may need to be considered. Transfer to 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.
- 2.3.6. 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

- 2.3.7. UKDEC is of the view that, where it is agreed that organ donation would be of overall benefit to the patient, it is ethically appropriate to enable that donation to take place as successfully as possible. In planning and managing the end of life care with the aim of donation as an outcome, the clinician is therefore acting for the overall benefit of the patient and does not have a conflict of interest. The issues of conflict of interest in this context are discussed in more detail in Part One (paragraph 1.6.1 – 1.6.4)
- 2.3.8. 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. Further consideration of what constitutes 'harm' is set out in Part One (paragraph 1.4.2 – 1.4.4)
- 2.3.9. The Department of Health document 'Legal issues relevant to non-heartbeating donation', which applies in England and Wales⁹ gives similar advice about the management of the patient prior to the withdrawal of treatment. The core principle is set out as:

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.

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.

Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

- 2.3.10. 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. It suggests that 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.
- 2.3.11. The Scottish Government and Northern Ireland Assembly Health Departments have issued similar guidance to clarify the legal position on issues relevant to donation after circulatory death.^{10,11} Although the legal framework in Scotland is slightly different, the principles as they relate to donation after circulatory death are very similar.
- 2.3.12. UKDEC is aware of the view that certain pre-mortem invasive interventions (such as cannulation) and pharmacological interventions (such as systemic heparinisation) would be beneficial to the quality of the organs. This area should be the subject of further work, which is outlined in Part Three (section 3.2).

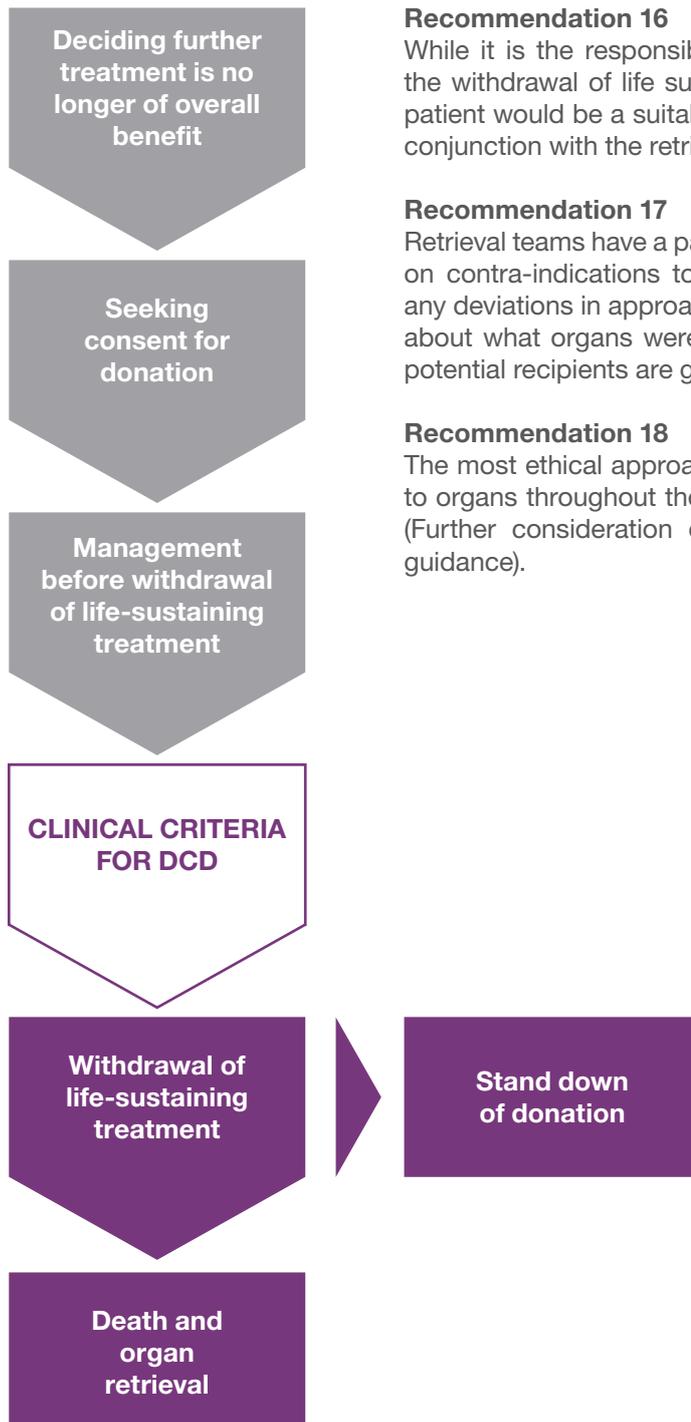
Management of cardio-respiratory instability

- 2.3.13. 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 stabilising, 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.
- 2.3.14. In donation after circulatory death, 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 a level appropriate for satisfactory organ perfusion 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.

2.4. CLINICAL CRITERIA FOR DCD

- 2.4.1. The Consensus Statement provides detailed information on suitable criteria for DCD. From the ethical perspective, the relevant issues are ensuring that donation takes place if it is of overall benefit to the patient, and that decisions are made about suitability for DCD by the appropriate person at the appropriate time.
- 2.4.2. As discussed in section 1.4 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 of overall benefit to the patient. 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.
- 2.4.3. While there are very few absolute contra-indications for suitability as a donor, which means that many patients may begin the path to organ donation, there is significant variability in the criteria for acceptance by retrieval and transplant teams, leading to different outcomes for donors with similar profiles. In turn this means the opportunities for potential recipient to get an organ will vary.
- 2.4.4. UKDEC is of the view that retrieval teams have a particular responsibility to abide by national guidelines in this area, and to justify any deviations in approach. This will enable families, if they wish, to have proper information about what organs were used; and potential recipients are given consistent opportunities to receive a viable organ. Further work is recommended on contra-indications (see Part Three, paragraph 3.3).
- 2.4.5. 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.

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).

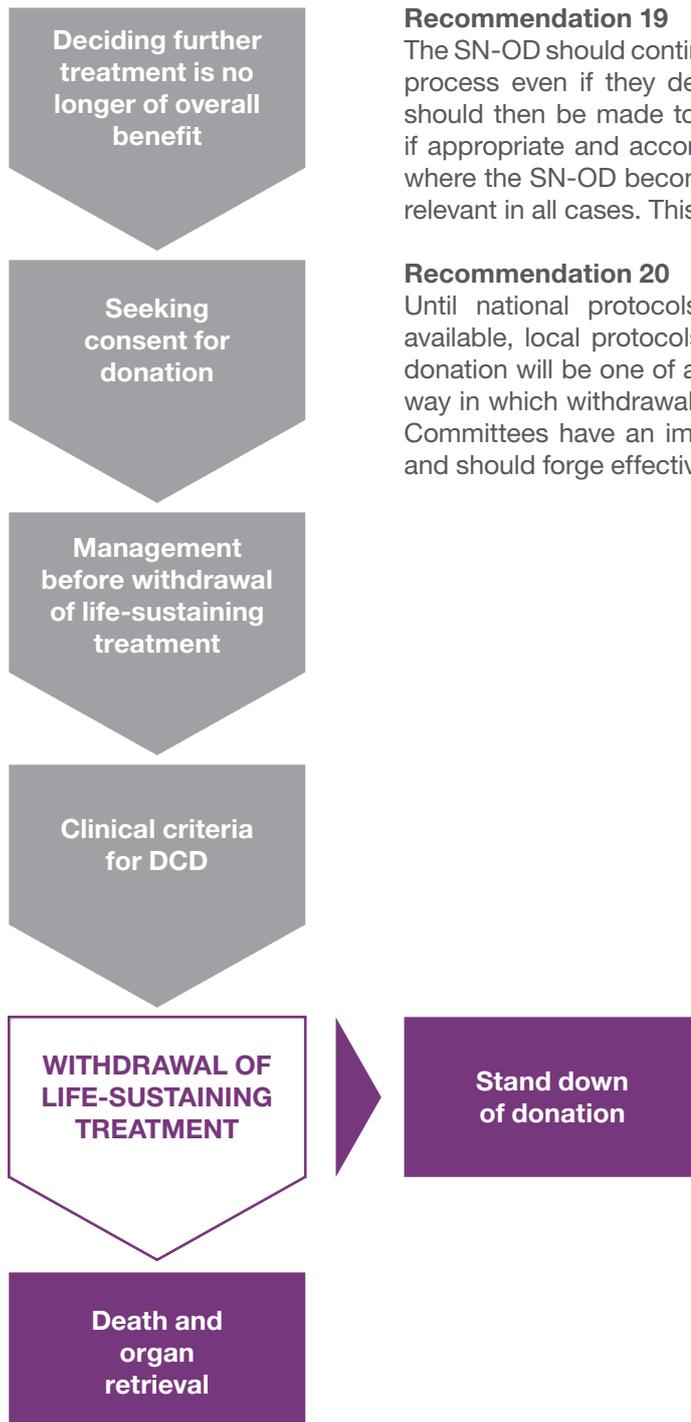
Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

2.5. WITHDRAWAL OF LIFE-SUSTAINING TREATMENT

Protocols for withdrawal of treatment

- 2.5.1. 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.²¹ The British Transplantation Society/Intensive Care Society 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.⁸ This has a bearing on DCD as the method of airway management in terminal care may be an important factor in the time it takes from withdrawal of life-sustaining treatment to death, with successful DCD requiring a relatively short time.
- 2.5.2. Many of the concerns expressed by physicians and other staff in regard to donation after circulatory death surround changes to the usual process of caring for dying patients (although 'usual' means different things to different practitioners, as noted above). In the context of organ donation, the prime aim 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, or on behalf of, the dying patient carry great moral weight, especially if made with full information about the process.
- 2.5.3. UKDEC considers that development of a nationally agreed protocol for withdrawal of life-sustaining treatment would be very beneficial. This is discussed further in Part Three (paragraph 3.4).
- 2.5.4. 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
- 2.5.5. 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 also to produce and implement local protocols that are based upon existing national policies and guidance.

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.

Managing the patient

2.5.6. 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. 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.

2.5.7. The importance of planning care as a team is recognised in Australian guidelines:²²

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.*

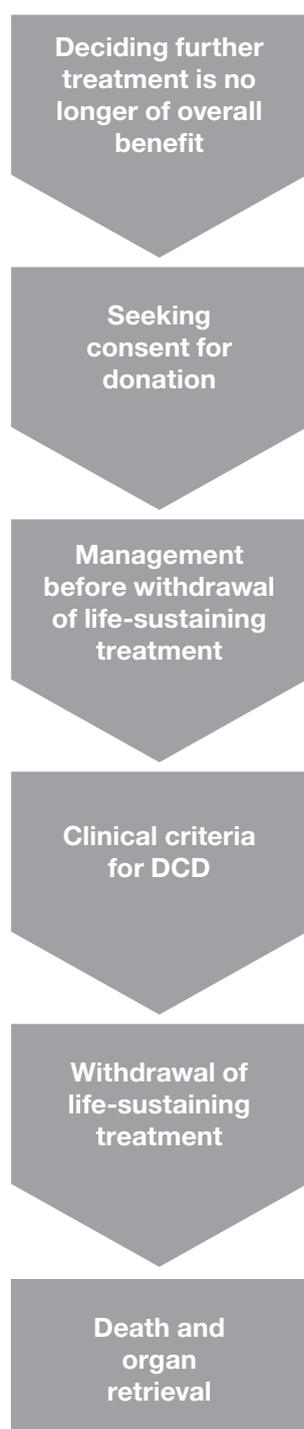
2.5.8. In developing local protocols for the management of potential donors, a variety of options should be considered so there is sufficient flexibility to avoid the situation where a donation is not possible, simply due to resource and staffing issues. Flexible staffing arrangements involving the SN-OD are discussed further in Part One of this document (conflicts of interest, page 21). 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 families.

2.6. STAND DOWN OF DONATION

Time factors affecting suitability of organs for donation.

- 2.6.1. 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.
- 2.6.2. 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.
- 2.6.3. 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 either retrieved and cooled (or reperfused with oxygenated blood) as soon as possible after the confirmation of death to reduce the adverse impact of the lack of oxygen.
- 2.6.4. 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 (ie at least 2 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.*
- 2.6.5. 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.

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.

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.

Recommendations in bold are discussed in depth in Part One (paragraph references in brackets).

- 2.6.6. 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.

When donation cannot go ahead

- 2.6.7. 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 to move the patient if there were a risk of death during the transfer.
- 2.6.8. Families need to be fully informed and supported when it becomes clear that organ donation for transplantation will not be possible, so the SN-OD role in relation to the family continues to be essential. 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.
- 2.6.9. 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 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.
- 2.6.10. Donation after circulatory death 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.

2.7. DEATH AND ORGAN RETRIEVAL

Dying and death

- 2.7.1. A detailed discussion of the diagnosis of death in the context of organ donation is set out in Part One (see section 1.1). In summary, death should be confirmed through strict adherence to the schedule laid out in the Academy Code of Practice.

Interventions after death

- 2.7.2. 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.
- 2.7.3. 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 that the donor receives appropriate care, and that no conflicts of interest arise. This is discussed in more detail in section 1.6. In summary two areas are particularly relevant:
- Re-intubation to facilitate lung retrieval needs to be undertaken by an appropriately trained member of staff. After death, there is no conflict of interest preventing a member of the donor's critical care team performing this procedure.
 - Some actions carried out after death to facilitate donation carry a very small risk of re-starting the heart after the diagnosis of death has been confirmed, as discussed in (as discussed in paragraph 1.1.11). There have been no documented cases of this occurring to date, but if this should be observed, an appropriately trained member of staff, preferably from the critical care team, and not part of the retrieval team, should repeat the process for confirmation of cardio-respiratory arrest as laid out in the Academy Code of Practice
- 2.7.4. 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 donors and their families as it keeps the organs in optimal condition for successful transplantation, which is the goal of donation.
- 2.7.5. 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 in this document 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.

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 blood is performed as part of the retrieval process, it should, as far as it is practical, be restricted to the relevant organs. (paras 1.1.1 – 1.1.7)

Recommendation 27

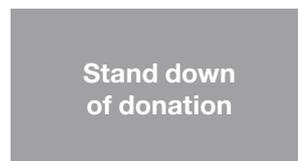
After death, the potential conflict of interest between saving the life of the patient and respecting their interest to be an organ donor disappears. Once the decision for the patient to become a donor has been taken, it is of overall benefit to the donor and recipient for procedures such as re-intubation to facilitate lung retrieval to be carried out by a 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



Re-establishing cardiac function

- 2.7.6. Re-establishing cardiac function is an important area for consideration as it could lead to heart retrieval and transplantation, and indeed heart transplants from DCD donors have been performed successfully.⁷ UKDEC is undertaking further work in this area, as outlined in Part three (section 3.6).

When the process is complete

- 2.7.7. 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.
- 2.7.8. 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.

PART THREE: ISSUES FOR FUTURE CONSIDERATION

3. INTRODUCTION

This section outlines a number of areas where UKDEC is of the view that further work would be beneficial in order that more patients are given the opportunity to donate when appropriate, and that their wishes are fulfilled as effectively and sensitively as possible.

3.1 ORGAN DONOR REGISTER

Recommendation 30

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

- 3.1.1. Putting a name on the Organ Donor Register does not require the same level of informed consent as for other medical procedures, when a health professional will describe what is going to happen and why, and answer any questions the patient may have before they sign the consent form. While this is a matter of concern for some, there is also the fact that many people who put their names on the register take the view that what happens to their body after death is not something they wish to think about in any detail. The challenge for NHSBT, as the custodian of the register, is to ensure that people who put their name forward are offered information and opportunities to discuss any questions, while at the same time not putting off people who wish to go no further than a simple yes or no. UKDEC recognises the complexity of this challenge but urges NHSBT to continue exploring further options. This should include undertaking research to better understand whether, and under what circumstances, the public would want to express more detailed views about what happens after their death.

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.

- 3.1.2. During the time that UKDEC has been considering the issues laid out in this report, and other aspects of donation, the potential for the Organ Donor Register (ODR) to be a far richer resource of information than it is at present has been a recurring theme. Families and clinicians might have greater confidence in, and clearer evidence of, the wishes of the donor if the ODR contained more detail.
- 3.1.3. In our consultation document we referred to the approach taken in Israel, where a person can direct that diagnosis of death by brain stem death criteria should not be applied to them.²³ UKDEC proposed that this should also be considered in the UK, particularly since some faith and cultural groups find brain stem death a difficult concept and may refuse to put their name on the ODR as a result, although they are not necessarily unwilling to donate.
- 3.1.4. This recommendation prompted some concern, with a number of responses simply stating that it was inappropriate. As a society in the UK we do not generally feel comfortable discussing issues relating to death, and UKDEC accepts it is premature to consider altering the ODR in this way. However faith communities in particular are becoming more engaged in organ donation and death diagnosis debates. Clinicians may see increasing numbers of families wanting to discuss how the diagnosis of death will be made, and need to be prepared to engage in these discussions.
- 3.1.5. As with the previous recommendation, developing the ODR is an ongoing challenge, and one which needs to be in tune with the changing views of society. UKDEC supports the need for a wider debate in society.
- 3.1.6. Plans in Wales to move to a ‘presumed consent’ system may change the nature of this debate, as it moves the discussion from offering an opportunity to make an altruistic donation, to one of a duty or responsibility to donate. UKDEC will study the detailed proposals, due for publication in 2012, with interest.

3.2. 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.

- 3.2.1. The UK Health Departments published legal guidance on non-heartbeating donation,^{9,10,11} which clarified a number of issues relating to the legal status of the processes required for donation after circulatory death. There remains a concern that the legal status of some pharmacological or mechanical interventions to support and protect the organs, remains problematic. The difficulty arises as these could be undertaken after the withdrawal of life sustaining treatment, but before death has been confirmed. The document states:

Anything that places the person at risk of serious harm (such as systemic heparinisation) or distress (such as resuscitation) is unlikely ever to be in the person's best interests in this situation. A clinician would need strong and compelling reasons to consider these types of actions and would be recommended to seek a declaration from the Court of Protection in relation to the person's best interests before doing so. (paragraph 6.14)

- 3.2.2. UKDEC understands there is a growing view that this stance on heparin in particular needs to be revisited, as heparin or equivalent medication is considered a beneficial (and in some cases an essential) element of some transplantation protocols, while the risk of harm to the donor varies substantially and would be better assessed on a case-by-case basis.
- 3.2.3. UKDEC is clear that there is no ethical barrier to such interventions, providing that the treating clinician is satisfied that there is sufficient evidence that this accords with the patient's wishes and values. (See Part One for discussion of determining overall benefit). UKDEC has further outlined an approach to the assessment of harm that balances the risk of undesirable physical effects of an intervention with the risk of doing wrong by ignoring a patient's wish to donate their organs (see paragraph 1.4.2 – 1.4.4).

3.3. 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 for acceptance by retrieval and transplant teams. This risks additional distress to donor families.

UKDEC recommends that the professional bodies concerned reach agreement in these areas.

- 3.3.1. 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 FiO₂ with poor oxygenation and other clinical criteria. UKDEC supports further work in this area. Closely related is the issue of acceptance criteria by retrieval teams and transplant surgeons.
- 3.3.2. UKDEC calls on the relevant professional bodies to reach agreement in both these areas and develop evidence-based guidelines that are consistently applied.

3.4. 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.

- 3.4.1. 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 to embed organ donation as a consideration in that process.
- 3.4.2. 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.
- 3.4.3. 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.

3.5. 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 identifying patients who would not be suitable for donation after circulatory death.

- 3.5.1. As discussed in Part Two (see paragraph 2.6.1 – 2.6.6), there are time-related factors that affect whether or not organs will be suitable for transplant after the donor has been confirmed dead. 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.
- 3.5.2. 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 (eg 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. 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.

- 3.6.1. Interest in cardiac donation after circulatory death is growing in the UK, particularly for paediatric donors. Some people feel uneasy about re-establishing cardiac function in a heart from a DCD donor, given that irreversible cessation of cardiac function is a key component of the diagnosis of death. In physiological terms, cardiac function cannot be restored within the original biological system (ie 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 transplanted to a recipient and re-started.
- 3.6.2. UKDEC recognises that this is a difficult area for many people, and although there is no fundamental ethical barrier, this procedure raises a number of issues that need to be properly addressed. UKDEC is in discussion with clinical teams interested in developing a programme of cardiac donation after circulatory death in the UK.

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ANNEX ONE

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
Paul Murphy	National Clinical Lead for Organ Donation (observer)
James Neuberger	NHSBT (observer)
Vicky Marshment	Human Tissue Authority (observer)

Pete Nightingale	Academy of Medical Royal Colleges (observer)
Chris Rudge	National Clinical Director for Transplantation (observer)

Terms of reference

The UKDEC will:

- consider ethical issues, both general and specific, relating to the field of organ donation and transplantation and provide independent advice to clinicians, policy leads and others as appropriate and/ or relevant issues referred to the group by local donation committees.
- 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.

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