

Interventions before death to optimise donor organ quality and improve transplant outcomes: guidance from the UK Donation Ethics Committee

Preface

The Departments of Health in England and Wales¹ and Northern Ireland² have issued general guidance on legal issues relevant to organ donation after circulatory death. This guidance from the UK Donation Ethics Committee (UKDEC), published by agreement with these Health Departments, is designed to assist clinicians in applying that guidance on legal issues by providing a more detailed account of the generic balancing process that clinicians may need to follow.

To further assist clinicians in applying this guidance, we will also publish separate applications of the detailed balancing process in relation to individual interventions. The first two such applications of our generic guidance cover heparin and extubation, with further applications to individual interventions planned.

1. In *An Ethical Framework for Controlled Organ Donation After Circulatory Death* (2011), the UKDEC established two guiding principles:³

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,⁴ and it has been further established that donation would be consistent with the patient's wishes, values and*

¹ Department of Health. *Legal issues relevant to non-heartbeating organ donation* 2009.

² Department of Health, Social Services and Public Safety. *Legal issues relevant to donation after circulatory death (non-heart-beating organ donation) in Northern Ireland* 2011.

³ UK Donation Ethics Committee *An Ethical Framework for Controlled Organ Donation After Circulatory Death* 2011, v.

⁴ In *An Ethical Framework for Controlled Organ Donation After Circulatory Death*, 'we ... used the term 'overall benefit' when describing the course of action most appropriate to a particular patient at a particular time. This followed the approach taken in recent GMC guidance on end of life care, and was intended to ensure that the points discussed are applicable to the legal frameworks throughout the UK.' Ibid. xi. As this document is not intended to apply to Scotland, we have reverted here to the use of the term 'best interests' as this is currently the legal test for decision-making on behalf of adults lacking capacity in both England and Wales (Mental Capacity Act 2005) and Northern Ireland (*Re F* [1990] 2 AC 1, *Airedale NHS Trust v Bland* [1993] AC 789).

beliefs, consideration of donation should become an integral part of that patient's care in their last days and hours.

2. In this document the UKDEC also set out the legal framework and ethical considerations relevant to deciding whether organ donation would be in the best interests of a patient for whom it has already been decided that continuation of life-sustaining treatment is no longer in their best interests:

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

1.4. 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.

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.***

3. This document applies at the third of three decision-making stages, after

(1) it has been decided that the continuation of life-sustaining treatment is no longer in the best interests of the patient, and

(2) it has been decided that organ donation would be in the best interests of the patient.

We seek here to provide a more detailed account of the balancing process for deciding:

- (3) whether particular interventions to optimise donor organ quality and improve transplant outcomes would be in the best interests of the patient, in a manner that is both ethical, and lawful under the terms of the relevant legislation applying the legal guidance issued by the Departments of Health.⁵ It is possible that one of these precursor decisions ((1) or (2)) may need to be revisited, for example if the patient's condition improves so that continuation of life-sustaining treatment would now be in their best interests or is no longer needed, or if evidence emerges that the patient would not have wanted to be an organ donor.
4. Before the balancing process is undertaken in relation to a particular intervention, a clear justification for the intervention in terms of its potential to optimise donor organ quality and improve transplant outcomes from the patient's donation(s) should be identified. The absolute minimum level of intervention should be used consistent with facilitating the success of the transplant. If an intervention is routinely undertaken but the evidence for its potential to optimise donor organ quality and improve transplant outcomes is weak, then the potential for the patient to benefit from the intervention will be proportionately reduced. Where, however, the evidence for an intervention's potential to optimise donor organ quality and improve transplant outcomes is strong, then the potential for the patient to benefit from the intervention will be proportionately increased. Where there is genuine uncertainty about whether an intervention has the potential to optimise donor organ quality and improve transplant outcomes, clinical research should, where possible, be undertaken.
 5. In order to assess whether an intervention would be in the best interests of the patient, the potential benefits to the patient must be balanced against the potential harm or distress (or risk of harm or distress) which may be caused by the intervention.

⁵ Which indicates that an intervention may be lawful if having 'weighed up' all of the relevant factors, it is decided that the intervention is in the patient's best interests, or for their benefit. Department of Health. *Legal issues relevant to non-heartbeating organ donation* 2009, [5.4]; Department of Health, Social Services and Public Safety. *Legal issues relevant to donation after circulatory death (non-heart-beating organ donation) in Northern Ireland* 2011, [5.4].

6. In the assessment of the balance of benefits and harms for any such intervention, considered in the wider sense including social, emotional, cultural and religious interests,⁶ the strength of the patient's decision or wish to donate will play an important role. Further information from the patient's family and friends about their wishes, feelings, beliefs and values about organ donation and (if available) any procedures designed to optimise donor organ quality and improve transplant outcomes may also be valuable in building up a picture of the patient's wishes.⁷

Potential benefits

7. The legal guidance published by the Departments of Health recognises that there are potential benefits which may accrue to the patient by facilitating their wish to be an organ donor, including actions aimed at optimising the successful use of retrieved organs.⁸
8. The potential benefits encompass both the prospective benefit of knowing their wishes will be facilitated, as well as the future benefit attaching to their legacy. In most cases the patient will have an interest in the well-being of their family and friends and so may also be benefitted indirectly if the donation helps family and friends come to terms with their loss and promotes the prospects of positive memories of the patient after death.

Potential harm

⁶ Department of Health. *Legal issues relevant to non-heartbeating organ donation* 2009, [4.2]; Department of Health, Social Services and Public Safety. *Legal issues relevant to donation after circulatory death (non-heart-beating organ donation) in Northern Ireland* 2011, [1.11], [4.2]; UKDEC. *An Ethical Framework for Controlled Organ Donation After Circulatory Death* 2011, [1.4.10].

⁷ Mental Capacity Act 2005, ss.4(6)-(7); Department of Health. *Legal issues relevant to non-heartbeating organ donation* 2009, [4.3]-[4.6], [5.3]; Department of Health, Social Services and Public Safety. *Legal issues relevant to donation after circulatory death (non-heart-beating organ donation) in Northern Ireland* 2011, [4.3]-[4.7]; UKDEC. *An Ethical Framework for Controlled Organ Donation After Circulatory Death* 2011, [1.4.8].

⁸ Department of Health. *Legal issues relevant to non-heartbeating organ donation* 2009, [5.1]; Department of Health, Social Services and Public Safety. *Legal issues relevant to donation after circulatory death (non-heart-beating organ donation) in Northern Ireland* 2011, [5.1]. Both use the same wording: 'maximising the chance of fulfilling the donor's wishes about what happens to them after death; enhancing the donor's chances of performing an altruistic act of donation; and promoting the prospects of positive memories of the donor after death'. Similarly, in *An Ethical Framework for Controlled Organ Donation After Circulatory Death* 2011, [1.4.3]-[1.4.4], we described the potential harm of frustrating the patient's wish to be an organ donor.

9. An intervention may potentially cause harm or distress (or risk causing harm or distress) to the patient. Examples of potential harm include pain, discomfort, shortening the patient's life and worsening the patient's medical condition. Examples of potential distress include feelings of suffocation, choking, gasping, panic, weakness, isolation, loneliness and invasion of privacy.⁹
10. Every effort should be made to minimise potential harm or distress to the patient consistent with facilitating the success of the transplant. This may include, where relevant, delaying an intervention if such delay would decrease the risk of causing such harm or distress.
11. Account should be taken of the extent to which symptoms of pain, discomfort or distress which might be so caused could be alleviated.
12. Assessments of the risk of shortening the patient's life or worsening the patient's medical condition should be made in the knowledge that there is a possibility of improvement in the condition of a patient, for whom it has been decided that life-sustaining treatment is no longer in their best interests, either before, or indeed after, the withdrawal of that treatment.
13. The risk of causing distress to the patient's family should also be considered a potential risk of harm to the patient. Ways of minimising this should be explored through careful explanation of both the need for particular interventions in order to facilitate the patient's wish to be a donor and what is involved in those interventions.
14. Those caring for the patient must also ensure that interventions are carried out in a way which is as respectful as possible of the patient and their family and friends.

Balancing potential benefits and harm

15. The stronger the evidence of the patient's desire to become an organ donor, the greater the weight this should be given in assessing whether a particular intervention would be in the patient's best interests. If, for

⁹ Department of Health. *Legal issues relevant to non-heartbeating organ donation* 2009, [5.1]; Department of Health, Social Services and Public Safety. *Legal issues relevant to donation after circulatory death (non-heart-beating organ donation) in Northern Ireland* 2011, [5.1].

example, the patient has provided consent to a particular intervention in advance of the loss of capacity, this should be regarded as compelling evidence that the intervention would be in their best interests unless it would cause the patient harm or distress (or a significant risk of harm or distress).

16. For each patient and each proposed intervention, the clinical team will need to assess whether the potential benefits of the intervention outweigh any potential harms which cannot be prevented or alleviated. If so, the proposed intervention would be in the patient's best interests. A wide range of relatively minor interventions are likely to meet this threshold for all patients who wanted to become organ donors. A few interventions carry such serious risks of harm that very strong evidence of potential benefits would be needed in order for them to be in the best interests of the patient.
17. The evidence relating to the risks of harm or distress associated with particular interventions and their potential to optimise donor organ quality and improve transplant outcomes is likely to change over time. This evidence should be regularly revisited by another suitable body, and reviewed by UKDEC, in order to ensure that clinicians are able to make evidence-based assessments of those risks and benefits.
18. Pre-mortem interventions can usefully be divided into two categories:
 - a) those which are integral to the withdrawal of life-sustaining treatment ('WLST-integral'), for example extubation or sedation; and
 - b) those which are independent of the withdrawal of life-sustaining treatment ('WLST-independent'), for example femoral cannulation or heparin.

As is evident from the examples given, within each category there will be both mechanical interventions and pharmacological interventions. Guidance on specific interventions will be published by UKDEC separately.