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AN ROINN

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

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## **LEGAL ISSUES RELEVANT TO DONATION AFTER CIRCULATORY DEATH (NON-HEART-BEATING ORGAN DONATION) IN NORTHERN IRELAND**

**March 2011**

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## Legal issues relevant to Donation after Circulatory Death (Non-heart-beating Organ Donation)

**This guidance is only applicable in Northern Ireland.**

### 1. Introduction and Summary

- 1.1 While there has been a substantial increase in the rate of Donation after Circulatory Death (referred to in this document as DCD) in the UK over the last ten years, many clinical teams remain concerned about the lawfulness of the actions that are taken to facilitate this. This document sets out the Department of Health, Social Services and Public Safety's (DHSSPS') view of the current legal position in Northern Ireland in relation to interventions taken prior to death to facilitate DCD. It is hoped that all those working in this area will be able to build on this information when drawing up more detailed clinical advice and guidance.
- 1.2 Until recently, this type of donation has been referred to as 'Non-heart-beating Organ Donation' or 'Donation after Cardiac Death'. However, there now appears to be a move towards the terminology of 'Donation after Circulatory Death' (DCD). In considering the issues relating to terminology, the UK Donation Ethics Committee set out in its 2011 consultation document, *An Ethical Framework for Controlled Donation After Circulatory Death*, that "there is an inherent inconsistency in the term 'donation after cardiac death'. This implies the heart has died, which is incorrect, since although the patient has died following cardio-respiratory arrest the heart is, in many cases, still capable of beating [...] UKDEC therefore recommends that the term 'donation after circulatory death' should be used. This is also in accordance with developing thinking internationally."
- 1.3 The criteria for diagnosing death are the subject of *A Code of Practice for the Diagnosis and Confirmation of Death*, issued by the Academy of Medical Royal Colleges<sup>1</sup>. For all DCD donors, cessation of cardiorespiratory function is used to determine the time of death. Any reference in this guidance to circulatory death refers to death following cessation of cardiorespiratory function meeting the criteria for the confirmation of death identified in the Code.
- 1.4 The Organ Donation Taskforce report of January 2008, setting out ways to increase donation rates, included a recommendation that "urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear

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<sup>1</sup> *A Code of Practice for the Diagnosis and Confirmation of Death*, Academy of Medical Royal Colleges, 2008.

and unambiguous framework of good practice”.<sup>2</sup> This refers not only to ethical concerns about DCD, but also to the need to avoid possible conflicts of interest between doctors’ responsibilities to dying potential donor patients and towards patients in need of donated organs, and to the uncertainty about the extent to which steps taken to facilitate donation are lawful.

- 1.5 At the time of publishing this legal guidance, the UK Donation Ethics Committee is developing a guideline setting out the key ethical issues that arise in considering controlled DCD and recommendations for current practice. The formal consultation on this guidance, *An Ethical Framework for Controlled Donation After Circulatory Death*, was commenced in January 2011, and the finalised guidance is due for publication in Summer 2011.

## Legal Context

- 1.6 Organ donation is governed in Northern Ireland by the provisions of the Human Tissue Act 2004, which also extends to England and Wales, with specified provisions for Scotland. However, it is important to note that England, Wales, and Scotland also have mental capacity legislation which does not apply in Northern Ireland; the Mental Capacity Act 2005 which extends to England and Wales, and the Adults with Incapacity (Scotland) Act 2000.
- 1.7 One of the key recommendations of the Bamford Review is that there should be a single, “principles-based” legislative framework for Northern Ireland which would incorporate new mental capacity provisions, and existing and amended mental health provisions. Consequently, DHSSPS is currently developing a single Bill encompassing mental capacity and mental health provisions in Northern Ireland.
- 1.8 The proposed Northern Ireland legislation may have similar mental capacity provisions to the Mental Capacity Act 2005 in respect to the ‘Autonomy’ and ‘Best Interests’ principles, the test of capacity, and substitute decision-making arrangements. However, this is still to be determined. Due to the size and complexity of the Bill resulting from combining mental capacity and mental health provisions, it is expected to be introduced to the Northern Ireland Assembly in 2011, with enactment in 2013 at the earliest. In the interim, case law is largely relied upon to inform mental capacity issues in Northern Ireland.

## Main Issues

- 1.9 In the UK, DCD takes place most commonly when death, established following irreversible cessation of cardiorespiratory function, follows the withdrawal of life-sustaining cardiorespiratory support that has been judged

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<sup>2</sup> Organ Donation Taskforce (2008) *Organs for Transplants: A report from the Organ Donation Taskforce* ([www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_082122](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082122))

to be no longer in a patient's best interests. It is recognised that the care and treatment that a patient receives around the time of death may need to be adjusted if the patient's potential to donate is to be maintained or optimised. Such adjustments may include the timing and place of death, and also blood sampling for purposes such as tissue-typing and virological screening.

- 1.10 Patients who have the potential for DCD will almost always lack the capacity to make their own treatment decisions because they are likely to have had a catastrophic brain injury and be unconscious. However, the effect of the common law position in Northern Ireland appears to be that the invasive treatment, to facilitate the patient's potential to donate, of a person unable to consent to it through lack of capacity, may be deemed lawful if it can be established that such a process is in the patient's best interests.
- 1.11 A person's best interests depend on their individual circumstances. Therefore, it is not possible to say categorically whether a specific action or decision will always be in every patient's best interests. However, the courts have established that best interests are wider than simply treating a person's medical condition, and include a person's social, emotional, cultural, and religious interests. Therefore, a clinician will need to consider not only all the factors relevant to the person's medical condition, but also consult the patient's family to take full account of the person's previously expressed wishes, general preferences, and beliefs.
- 1.12 This document sets out the general principles governing decision-making for patients who lack capacity when their potential for DCD is being considered. In general terms, decision-making will be guided by the person's wishes and beliefs concerning donation. Therefore, it is important to establish these either through knowledge of the individual's wishes (for example, by registration on the NHS Organ Donor Register [ODR]), or through an assessment of what the individual would have wanted (for example, through the person's family and their knowledge of the patient).
- 1.13 If a person's wishes were to be a donor, then certain actions which facilitate donation may be considered to be in their best interests if they do not cause the person harm or distress, or place them at a material risk of experiencing harm or distress.
- 1.14 Given that the lawfulness of an intervention in any particular case is bound to be highly fact-specific, this guidance can not prospectively advise that any particular step will be accepted as lawful by the courts. In reality, it can only give guidance from which the risks of adverse findings can be better assessed.
- 1.15 As with any decision concerning medical treatment, the details of individual cases may vary. As a result, Health Trusts and health professionals must

always be able to satisfy themselves that individual decisions are made in that person's best interests and thereby comply with the law.

**In many cases, actions that can facilitate DCD most successfully will be in the person's best interests. Equally, there will be some occasions when this will not be the case, and it will not be possible to take such actions to facilitate DCD. Further practical guidance is given below under section 6, "Specific Steps Before Death to Facilitate DCD."**

## 2. Background and Clinical Context

- 2.1 It is clear that any decision about the futility of further treatment, and whether or not such treatment should be withdrawn, must be made purely in the interests of the person and independently of any consideration of possible organ donation.
- 2.2 Guidance on best interests when making decisions about life-sustaining treatment is available in the General Medical Council guidance *Treatment and care towards the end of life: good practice in decision making*<sup>3</sup>. While the provisions of the Mental Capacity Act 2005 do not extend to Northern Ireland, the guidance available in chapter 5 of the Mental Capacity Act Code of Practice<sup>4</sup>, paragraphs 5.29-36, may also be of some informative use.
- 2.3 In the UK, DCD takes place when death has been established following irreversible cessation of cardiorespiratory function. The Academy of Medical Royal Colleges issued a Code of Practice for the diagnosis and confirmation of death in 2008<sup>5</sup>.
- 2.4 There are a number of steps that can be considered before a person has died which may optimise the chances of a successful donation and transplant. These steps fall into the broad categories of:
  - a) actions to check the person's wishes about donation and their suitability to be a donor
  - b) temporary continuance of cardiorespiratory support that has been judged to be clinically futile so as to co-ordinate its withdrawal with the availability of an organ retrieval team, and
  - c) introduction of new treatment or activities, the sole intention of which is to enhance the prospects of a successful organ transplant.

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<sup>3</sup> [www.gmc-uk.org/guidance/ethical\\_guidance/6858.asp](http://www.gmc-uk.org/guidance/ethical_guidance/6858.asp)

<sup>4</sup> [www.publicguardian.gov.uk/mca/code-of-practice.htm](http://www.publicguardian.gov.uk/mca/code-of-practice.htm)

<sup>5</sup> [www.aomrc.org.uk/publications/reports-guidance.html](http://www.aomrc.org.uk/publications/reports-guidance.html)

### 3. The Law

- 3.1 If a person lacks the mental capacity to consent at common law, physical contact will be unlawful unless justified by some overarching legal principle. The most apposite principle in this context is the application of the principle of necessity as identified by the House of Lords in *Re F* (Mental patient: sterilisation) [1990]<sup>6</sup>. In England and Wales, the Mental Capacity Act 2005 has now supplemented the common law structure which followed on from that case in two ways:
- firstly, by giving statutory force to the principle that treatment and care provided to a person lacking capacity does not attract liability, criminal or civil, merely because of a lack of consent, so long as various conditions are fulfilled, and
  - secondly, a system for obtaining court authorisation in difficult cases has been set up.
- 3.2 In the absence of the Mental Capacity Act 2005 or equivalent, Northern Ireland still depends on the common law as analysed in *Re F* and subsequent cases, mainly decided in English courts (at common law, English cases have persuasive rather than binding authority in Northern Ireland). The result is that invasive treatment of a person unable to consent to it through lack of capacity will often be lawful if it is in the person's best interests.
- 3.3 The Human Tissue Act 2004 is also relevant in this context, as is professional guidance issued by the General Medical Council.
- 3.4 Patients with the potential for DCD usually have had a catastrophic brain injury, and will therefore be unconscious and lack capacity. They will usually be in Intensive Care Units or Departments of Emergency Medicine, with relatives and loved ones close by. At some stage, the clinical team may reach the view that further active treatment is clinically futile, either because death is inevitable or because there is no prospect for functional recovery. A clinician must make treatment decisions that are based upon an assessment of the person's best interests. This requires consideration and evaluation of all aspects of the person's condition, consultation with their family and loved ones, and an exploration of the person's previously expressed wishes.
- 3.5 It is permissible to consider care and treatment relating to donation provided that decision-making continues to be made in the person's best interests in circumstances where:

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<sup>6</sup> [1990] 2 AC 1

- a) a lawful decision has been made to withdraw life-sustaining therapies that have been judged to be clinically futile,
- b) it has become clear that death will follow the withdrawal of such therapies, **and**
- c) there exists a potential for DCD.

- 3.6 Clinicians would also need to be satisfied that any exchange of information relating to the potential donor complies with the law relating to confidentiality and data protection.
- 3.7 Once the person has died, the removal, storage and use of organs or part organs for transplantation is governed by the Human Tissue Act 2004 (HTA) as for all organ donation. The HTA also governs the testing of existing whole blood samples and, in the case of a person who lacks capacity, such decisions also have to be made in the person's best interests. More information is given in the HTA Codes of Practice.
- 3.8 Guidance is provided below on DHSSPS' view of how these legal principles can be applied in the context of DCD, including how the current legal position should be interpreted to establish best interests when considering organ donation.

#### **4. How to Assess Best Interests in Relation to a Potential Organ Donor**

- 4.1 There are a number of factors to consider when assessing a person's best interests, including:
- a) the person's known wishes and feelings, in particular any relevant written statements
  - b) the beliefs or values that would be likely to influence the person's decision if they had the capacity to make it
  - c) any other factors they would be likely to consider if they were able to do so
  - d) the views of the person's family, friends, and anyone involved in their care as appropriate as to what would be in the person's best interests, and
  - e) anyone named by the person to be consulted about such decisions.
- 4.2 When considering decisions about treatment, the courts have established that a person's best interests are wider than simply treating their medical condition. Best interests include a person's social, emotional, cultural, and religious interests, and all of these aspects, including past behaviours and habits, should be considered in assessing a person's best interests.
- 4.3 In deciding whether actions to enhance the chances of a successful donation are in a person's best interests, it will be important to assess what their wishes and preferences would have been in relation to organ donation. There are a number of ways that such wishes and preferences can be established.
- 4.4 Some people will have indicated their desire to be an organ donor by joining the ODR, or by carrying an organ donor card. Others might have discussed their wishes with family or friends, or by indicating this in some other way. Clinicians should consult the ODR and talk to the person's family and friends to find out if the person had expressed any wishes about donation to them.
- 4.5 While registration on the ODR provides consent for donation after death for the purposes of the Human Tissue Act 2004, DHSSPS does not consider that registration can be viewed as advance consent to steps to facilitate DCD. It would, however, be important evidence of a person's wish to donate.
- 4.6 If the person has not expressed views about organ donation directly, clinicians should attempt to determine what the person would have wanted had they been able to make the decision themselves. This should be based on what is known about their values and other matters which would have been

important to them. The person's family may be able to give a view on what the person would have wanted based on their knowledge and experience of them as a person. In such situations, a prudent decision-maker will, whenever possible, look for a combination of factors which point to one conclusion or the other, rather than relying solely, for instance, on one assertion by one person.

- 4.7 There may be times when it is not possible to obtain information about the person's values and preferences (for example, if the person's family or friends are not able to give any advice on this aspect). Alternatively, there may be a dispute between close family members about the person's views, which is impossible to resolve. In such cases, a clinician would need a compelling reason to consider actions to facilitate DCD to be in that person's best interests.

## **5. The Role of Wishes and Preferences in Assessing Best Interests**

5.1 Once it has been established that a person wanted to donate, either through direct knowledge of their wishes or as a result of discussions about what the person would have wanted, improving the prospects of successful donation may be seen to be in the person's wider best interests in a number of ways:

- a) by maximising the chance of fulfilling the donor's wishes about what happens to them after death
- b) by enhancing the donor's chances of performing an altruistic act of donation, and
- c) by promoting the prospects of positive memories of the donor after death.

5.2 Clinicians must consider whether any of the actions taken to facilitate or optimise donation carry with them any risk of harm or distress to the patient. They will need also to have regard to a person's best interests in personal dignity, especially when close to death. Examples of potential harm include:

- a) worsening of the patient's medical condition
- b) shortening of the patient's life
- c) pain from an invasive procedure
- d) distress to family and friends
- e) prejudice to the person's dignity while dying and the memories of family and friends, and
- f) interference with the process of dying.

Clinical teams will need to balance these risks against the knowledge that they have regarding a patient's wish to donate.

5.3 Clearly, if the person has indicated that they do not want to be an organ donor after their death, then no further action to facilitate organ donation can be taken.

5.4 If, having considered and weighed up all of the factors relevant to the person's situation and consulted their family, friends and carers, etc, it is decided that a particular action or actions that will facilitate DCD are in that person's best interests, then it/they may be carried out. Equally, if it is

decided that an action is not in the person's best interests, then it can not be carried out.

- 5.5 It is important in each case that the decision-maker takes into account all the available information, having made all reasonably practicable and appropriate inquiries of relatives and carers, and then balances the advantages and disadvantages to the person of either undertaking the preparatory intervention steps, or of not doing so. There can be no uniform answer applicable to all cases.
- 5.6 A number of the key steps to facilitate DCD are set out below, along with DHSSPS' view on some of the issues that may be relevant to each of these steps.

## **6. Specific Steps Before Death to Facilitate DCD**

6.1 Some actions to pass on and obtain information required to initiate the process of donation are not part of the treatment and care of a patient, giving rise to issues of lawfulness (other than in the context of those obligations attached to the processing of confidential information). Such actions should be carried out as a matter of good practice, and are important to ascertain what other steps may be in that person's best interests:

- a) alerting the donor transplant co-ordinator and transplant team of a potential donor
- b) speaking to the relatives about donation prior to the person's death, and
- c) seeking details from family members of the person's medical history relevant to donation.

6.2 Looking at the person's medical history and speaking to their relatives will be important in order to ascertain whether other steps relating to donation will be in that person's best interests.

6.3 The usual rules of confidentiality apply to obtaining this sort of information, and the Data Protection Act 1998 will apply to the processing of that information.

6.4 Actions which are part of the treatment and care of a patient giving rise to issues of lawfulness and/or falling within the scope of the HTA include:

- a) the taking and analysis of blood samples
- b) the maintenance of life-sustaining treatment
- c) specific and more invasive treatments and interventions, and
- d) withdrawal of treatments and the timing and location thereof.

### **a) Taking and analysis of blood samples**

6.5 Tests may include virology screening and blood group and tissue-typing analyses needed to facilitate the donation process.

6.6 Taking blood from a person who lacks capacity will only be lawful if it would be in that person's best interests.

6.7 Stored whole blood (cellular material) or serum (non-cellular material) samples are property over which the patient is entitled to exercise control.

Therefore, before testing existing samples from a person who lacks capacity, clinicians will need to determine if this would be in the patient's best interests.

- 6.8 Testing existing whole blood samples is also covered by the consent requirements of the HTA. If it is reasonably believed that the patient lacks capacity and that storage and use would be in their best interests, then Regulations<sup>7</sup> allow deemed consent to the use of tissue for the purpose of transplantation.
- 6.9 Therefore, clinicians will need to decide if taking blood and testing blood or serum samples are in the person's best interests. This will include considering if the person wanted to be a donor and whether these steps contribute to fulfilling that wish. Clinicians will also need to consider the risk of any harm or distress that may be caused to the person, including consideration of the information the tests may generate in the context of confidentiality, privacy, and property obligations.

**Taking blood and testing blood or serum samples may be considered to be in the best interests of someone who wanted to be a donor if they facilitate donation and do not cause the person distress or harm, or prejudice the person's dignity.**

**b) Maintenance of life-sustaining treatment**

- 6.10 There are occasions when haemodynamic or ventilatory instability before the surgical retrieval team is ready jeopardises the prospects of successful donation. Some interventions are designed to temporarily reverse such instability. This guidance can not cover in detail all possible interventions, but in each case the general principles (as set out in this document) will apply. These interventions may include:
- a) the adjustment of existing treatments (for example, increases in inspired oxygen concentration, adjustments to the ventilator settings, or alteration of the rates of administration of existing fluid and drug therapies)
  - b) the introduction of new therapies, such as inotropic support, and the siting of venous cannulae.
- 6.11 If it is established that a person wanted to be an organ donor and such interventions facilitate donation, then, these steps may be considered to be in that person's best interests. However, before determining if such steps

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<sup>7</sup> The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations, 2006

would be in their best interests, they must be weighed against any significant risk of harm or prejudice to dignity in maintaining each treatment, and any distress that may be caused to family by certain procedures.

- 6.12 Therefore, if a patient has been identified as a person who would have wanted to be a donor, then certain interventions which facilitate donation may be in their best interests on the basis that the interventions promote what the person would have wanted and their interest in how they are remembered. Before reaching a decision, consideration must be given to the risk of harm or distress the patient or their family may experience.
- 6.13 If there is a significant risk of the intervention causing harm or distress, it will not be in the person's best interests. It would also be unwise to take this course if the close family and/or other significant individuals expressed concern about this, even after careful explanation of the benefits.

**Maintenance of life-sustaining treatment may be considered to be 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.**

### **c) Specific and more invasive treatments and interventions**

- 6.14 Other more invasive steps could include:
- a) systemic heparinisation
  - b) resuscitation, and
  - c) femoral cannulation.
- 6.15 Before any such step is taken, careful consideration should be undertaken of the medical effects and risks, and also of the concerns its use may have for relatives and others who become aware of this either at the time or later. Anything that places the person at risk of serious harm or distress (such as systemic heparinisation or resuscitation) is unlikely ever to be in the person's best interests in this situation.
- 6.16 A clinician would need strong and compelling reasons to consider these types of actions, and would be recommended to seek a declaration from the Family Division of the High Court in relation to the person's best interests before so doing.

**Anything that places the person at risk of serious harm or distress is unlikely ever to be in the person's best interests.**

**d) Timing and location of withdrawal of treatments**

- 6.17 Decisions about the timing of withdrawal of treatment must be made in the person's best interests. It is generally understood and accepted that there is some flexibility in timing (for example, to allow family members to be present or to make sure the relevant health professionals are available to oversee the donation process). In practice, the timing of withdrawal of treatment is a matter for discussion and agreement between the person's family and clinicians. An important aspect may be allowing time for absent family members and friends to be present. This recognises that a patient has an interest in the manner in which they die, and in how they are remembered.
- 6.18 It is necessary to begin organ retrieval very soon after death has been declared. In practice, this means that the surgical retrieval team must be ready and an operating theatre available before cardiorespiratory support is withdrawn. As it commonly takes some hours for retrieval arrangements to be completed, this requires withdrawal of cardiorespiratory support to be delayed if DCD is to be possible. For similar reasons, local circumstances may necessitate moving the patient to a different location within the hospital, close to or within the operating theatre complex, ahead of withdrawal of treatment.
- 6.19 Again, it will be necessary for clinicians to assess whether or not such actions are in the best interests of the potential donor. If the person has been identified as a person who would have wanted to be a donor, then in many cases, because these steps facilitate donation, they may be considered to be in that person's best interests. Therefore, when determining if such steps would be in the person's best interests, the decision-maker must consider whether or not this is something the person wanted to happen, whether or not the actions would cause any harm or distress to the person, or whether or not there is any significant risk of harm or distress.
- 6.20 For example, in relation to the location of the patient, it might be difficult to justify a move if it carried any appreciable risk of shortening the patient's life. On the other hand, if there was no such risk, and particularly if there was a dual purpose in moving the patient to a location where, for example, there was a greater degree of privacy for the patient and family, it is difficult to see what objection could be raised.

**Delaying the withdrawal of treatment and changing a patient's location may be considered to be in the best interests of someone who wanted to be a donor if this facilitates donation and does not cause the person harm or distress, or place them at significant risk of experiencing harm or distress.**

- 6.21 For all the interventions mentioned above, individual best interests decisions will depend on the specific situation of the person concerned.
- 6.22 Furthermore, it appears to be a constant theme throughout literature on the actual practice of organ transplants that the decisions about the care, treatment, and best interests of the patient should be separated from those connected with retrieving organs for transplant. At all times up to the death of the patient, the treating clinicians have the sole charge of the patient. This is to avoid any actual or perceived conflict in priorities. It would be important that decisions about whether or not to offer or propose preparatory interventions in respect of a dying patient should remain in the hands of the treating clinicians, who must always act solely in the best interests of their patient.