

Legal issues relevant to non-heartbeating organ donation



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Contact details	Triona Norman Head of Policy, Organ and Tissue Transplantation Department of Health Wellington House London SE1 8UG 020 7972 4921 triona.norman@dh.gsi.gov.uk www.dh.gov.uk/publications
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1. Introduction and summary

- 1.1 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 and unambiguous framework of good practice”*.¹ This in part reflects concerns about non-heartbeating donation (referred to in this document as NHBD), and recognises that a possible conflict of interest may be felt between the responsibilities of the doctor to the dying patient, who is a potential donor after death, and uncertainty as to whether the steps taken to facilitate donation are lawful.
- 1.2 This document sets out the Department of Health’s view of the legal position in relation to interventions taken prior to death to facilitate NHBD. 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.
- 1.3 In the UK, NHBD takes place most commonly when death, established following the irreversible cessation of the heart, follows the withdrawal of life-sustaining cardiorespiratory support that has been judged to be no longer in a patient’s best clinical 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.
- 1.4 People who are potential non-heartbeating donors will almost always lack the capacity to make their own treatment decisions because they will have had a catastrophic brain injury and are likely to be unconscious. The Mental Capacity Act 2005 (MCA) allows health professionals to treat someone who lacks capacity, provided that they reasonably believe their actions to be in the person’s best interests.
- 1.5 A person’s best interests depend on their individual circumstances – it is therefore 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 their family to take full account of the person’s previously expressed wishes, general preferences and beliefs.
- 1.6 This document sets out the general principles governing decision-making for people who lack capacity when their potential for non-heartbeating organ donation is being considered. In general terms, decision-making will be guided by the person’s wishes and beliefs concerning donation. It is therefore important

¹ Organ Donation Taskforce (2008) *Organs for Transplants: A report from the Organ Donation Taskforce* (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082122).

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 them). 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.

- 1.7 As with any decision concerning medical treatment, the details of individual cases may vary. As a result, trusts and health professionals must always be able to satisfy themselves that individual decisions are made in that person's best interests and are therefore in compliance with the law.

In many cases, actions that can facilitate NHBD 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 NHBD. Further practical guidance is given below under paragraph 6: "Specific steps before death to facilitate NHBD."

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 decisions regarding withdrawal of treatment is available in chapter 5 of the MCA Code of Practice;² paragraphs 5.29–36 deal with life-sustaining treatment.
- 2.3 NHBD takes place when death has been established following irreversible cessation of the heart (ie following cardiorespiratory arrest). In 2008 the Academy of Medical Royal Colleges issued guidance on the diagnosis and confirmation of death.³
- 2.4 There are a number of steps that can be considered before a person has died, which can 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 coordinate its withdrawal with the availability of an organ retrieval team; and
 - c) introducing new treatment or activities, the sole intention of which is to enhance the prospects of a successful organ transplant.

² www.publicguardian.gov.uk/mca/code-of-practice.htm

³ Academy of Medical Royal Colleges (2008) *A code of practice for the diagnosis and confirmation of death* (www.aomrc.org.uk/aomrc/admin/reports/docs/DofD-final.pdf).

Although there has been a substantial increase in the rate of non-heartbeating organ donation 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. The Organ Donation Taskforce acknowledged these concerns and gave a commitment to seek clarification on the law in this area.

3. The law

- 3.1 The MCA and the Human Tissue Act 2004 (HTA) are relevant in this context, as is professional guidance issued by the General Medical Council.
- 3.2 Potential non-heartbeating donors are usually people who have had a catastrophic brain injury and who 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 of functional recovery. As required by the MCA and best clinical practice, a clinician must make treatment decisions that are based on 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.
- 3.3 In circumstances where:
 - a) a 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 non-heartbeating organ donation after death;it is permissible to consider care and treatment relating to donation provided that decision-making continues to be consistent with the MCA and is made in the person's best interests.
- 3.4 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.
- 3.5 The HTA is also relevant. Decisions about NHBD once the person has died will be governed by the HTA. 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.
- 3.6 Guidance is provided below on the Department of Health's view of how these legal principles can be applied in the context of NHBD, including how the MCA 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 the MCA Code of Practice emphasises the importance of considering all of these aspects, including past behaviours and habits, 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 therefore 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. While registration on the ODR provides consent for donation after death for the purposes of the HTA, the Department of Health does not consider that registration can be viewed as advance consent to steps to facilitate NHBD. It would, however, be important evidence of a person's wish to donate.
- 4.5 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 rely solely, for instance, on one assertion by one person.
- 4.6 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. In such cases, a clinician would need a compelling reason to consider actions to facilitate NHBD 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, 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; and
 - d) distress to family and friends.

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 or should 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 as required by the MCA, it is decided that a particular action or actions that will facilitate NHBD are in that person's best interests, then they may be carried out. Equally, if it is decided that an action is not in the person's best interests, then it cannot be carried out.
- 5.5 The key steps are set out below, along with the Department of Health's view on some of the issues that may be relevant to each of these steps.

6. Specific steps before death to facilitate non-heartbeating donation

- 6.1 Some of the actions that are needed to initiate the process of donation fall outside the scope of the MCA and should be carried out as a matter of good practice, while others are important to ascertain what other steps may be in that person's best interests:
- a) alerting the donor transplant coordinator and transplant team of a potential donor and speaking to the relatives about donation prior to the person's death; and
 - b) 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 that do fall within the scope of the MCA and/or 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) the timing and location of withdrawal of treatments.

a) Taking and analysis of blood samples

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

6.6 Taking blood from a person who lacks capacity must be carried out in line with the MCA and 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 in line with the MCA.

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 regulations⁴ allow deemed consent to the use of tissue for the purpose of transplantation. Similar considerations to those made under the MCA will apply when assessing best interests.

6.9 Clinicians will therefore 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.

Taking blood and testing blood or serum samples may therefore 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.

⁴ The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006.

b) Maintenance of life-sustaining treatment

- 6.10 There are occasions when haemodynamic or ventilatory instability ahead of readiness of the surgical retrieval team jeopardises the prospects of successful donation. Some interventions are designed to temporarily reverse such instability and 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 Decisions to carry out such interventions must be made in line with the MCA. If a person wanted to be an organ donor and such steps facilitate donation, then this will mean that these steps may be considered to be in that person's best interests. However, these considerations must be weighed against any significant risk of harm in maintaining each treatment and any distress that may be caused to the family by certain procedures, before determining if such steps would be in their best interests.
- 6.12 This guidance cannot cover in detail all possible interventions but in each case the general principles (as set out in this document) will apply. Therefore, if a person has been identified as a person who would have wanted to be a donor, then certain interventions which facilitate donation can be viewed as being in their best interests on the basis that the interventions promote what the person would have wanted and 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. If there is a significant risk of the intervention causing harm or distress it will not be in the person's best interests.

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

- 6.13 Other more invasive steps could include:
- a) systemic heparinisation;
 - b) resuscitation; and
 - c) femoral cannulation.

6.14 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.

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

6.15 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 person has an interest in the manner in which they die and in how they are remembered.

6.16 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. Because it commonly takes some hours for arrangements for retrieval to be completed, this requires withdrawal of cardiorespiratory support to be delayed if NHBD 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.

6.17 Again, it will be necessary for clinicians to assess whether such actions are in the best interests of the potential donor. If the person wanted to donate, then in many cases, because these steps facilitate donation, they may be considered to be in that person's best interests. The decision-maker must therefore consider whether this is something the person wanted to happen, whether the actions would cause any harm or distress to the person, or whether there was any significant risk of such an occurrence when determining if such steps would be in their best interests.

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.

6.18 For all the interventions mentioned above, individual best interests decisions will depend on the specific situation of the person concerned.



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