UKDEC
UK Donation Ethics Committee

ACADEMY OF MEDICAL ROYAL COLLEGES

Involving the family in deceased organ donation

A discussion paper
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Contents

Note: This document was originally intended to offer ethical guidance on involving the families of potential organ donors in the conversation about donation. However, following the English Department of Health's decision to withdraw UKDEC's funding, it became apparent that the committee would not have time to conduct a consultation on the draft guidelines. As a result, this document is published as a discussion paper.

Executive Summary

The aim of this discussion paper is to describe and analyse the role played by the family in organ donation, identify ethical issues, and suggest how processes involving the family could be improved in order to minimise the stress placed on families in this context, while also respecting any wishes of patients regarding donation.

As well as providing a recent social and medical history for the patient, the family can play one of two major roles in the donation process. First, if there is no evidence regarding whether a patient wanted to donate, a family member must make the decision regarding whether to donate (except in Wales, where consent can be deemed). Which family member should do this is dictated by a legal hierarchy. If there is evidence of a wish to donate on the part of the donor, for example from the organ donor register or of oral consent, the family's role should be limited to informing the assessment of whether donation would be of overall benefit to the patient.

We suggest six potential strategies that could improve the deceased organ donation process for families. See pages 16-18 for the full recommendations.

1. Families should be placed at the centre of the donation decision-making process in ways that minimise their distress.

2. Those who wish to donate their organs should be encouraged not only to sign up to the register, but also to communicate their intentions to family members and friends.

3. The family hierarchies set out in law should only be used for their intended purpose of determining which relative is highest in the ranking of family members and friends where there is no evidence of a patient's wishes regarding donation. The family hierarchies should never be used to "rank" evidence from family members of a patient's wishes regarding donation.

4. Many of the reasons given for declining donation are not genuine overrules, but are actually new evidence regarding a patient's refusal to donate, or reasons for reassessment of overall benefit. Distinguishing between these categories could bring greater clarity to interactions with families and help to identify when attempts to overrule should be challenged. Furthermore, more information on the "other" category of reasons for refusal could be recorded by healthcare professionals.

5. Attempting to discuss reasons for declining donation is almost always appropriate when a family attempts to overrule a known wish to donate.

6. The organ donor register could be amended in several ways to help donors, professionals and families. For example, more information could be provided to those signing up to the register, and they could be given more freedom to indicate specific preferences when registering as donors. Strengthening the ODR in this way would provide better evidence regarding consent to / authorisation of donation.

1 Introduction

1.1 Aim

The family plays a key role in the process of organ donation from deceased patients in the United Kingdom. The aim of this paper is to describe the role played by the family, identify ethical issues, and suggest how processes involving the family could be improved in order to minimise the stress placed on families in this context, while also respecting any wishes of patients regarding donation. It is hoped that the descriptive elements of this paper will provide useful context for families and healthcare professionals, and that our suggested future strategies will also further improve the organ donation process for families.

It should be noted from the outset that "family" is often used as more practical shorthand for both "family members" and "family and friends" in the clinical context. However, it is important to remember that the family is not a singular unit, but is rather composed of various individuals whose knowledge of the deceased and opinions concerning donation may differ. Furthermore, patients' friends may also be highly relevant to the consent process in deceased organ donation.

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 (both before and after death). This follows the approach taken in recent GMC guidance on end of life care,[1] 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 on decision-making prior to death.

1.2 Specific Objectives

With regard to the legislation, codes of practice and guidelines applicable in the four UK jurisdictions, this paper aims to consider and discuss several aspects of the family's role in donation. These include the following topics and sub-topics.

What is the role of the family where there is no indication of the patient's wishes?

Relevant issues here include consent (authorisation in Scotland), the impact of families' values/beliefs/culture on decision-making and the implications for the donation process; and family conflicts, including a consideration of the current "hierarchy" of family members and friends set out in the applicable legislation.

What is the role of the family where the patient has expressed a wish to be a donor either through registration on the organ donor register or by otherwise indicating his or her intentions?

Issues here include: clarifying the role of the family in these circumstances; taking evidence from family members into account (regarding both the patient's wishes

[1] Treatment and care towards the end of life: good practice and decision making, GMC, 2010, which came into effect on 1 July 2010.
[2] Walker W1, Sque M2. Balancing hope and despair at the end of life: The contribution of organ and tissue donation. J Crit Care. 2016; 32:73-8.

and the family members' own views); the extent to which family members are able to "overrule" the wishes of the deceased, and why they do so; how to strike an appropriate balance between meeting family members' needs/expectations and fulfilling the deceased's wish to be a donor, including the various potential harms and benefits to be considered (including those to potential recipients); and family members' role in contributing to decisions about what course of action would be of overall benefit to the patient (e.g. on interventions to optimise organ quality/successful donation before or after death).

2 Legal summary

What does the law say about the family's role in donation?

The relevant legislation differs in the different countries of the United Kingdom, but broadly speaking, there are two scenarios. If the patient has not recorded donation intentions on the organ donor register and the family and friends present no evidence regarding an intention to donate, a family member will be asked to make a decision because the patient is either unconscious and dying or deceased already and thus cannot express his or her donation decision directly. Which family member has the authority to make the decision is dictated by a hierarchy of different relatives (see Appendix on legal context for details.) Alternatively (but very rarely), the patient will have nominated a representative to make a legally effective decision about donation. This option does not exist in Scotland.

Since December 2015, deemed consent legislation applies in Wales (see below). This has altered the legal role of the family in Wales in cases where a donation wish has not been recorded. Some of the guidance in this paper is not directly applicable to the Welsh legislation but we hope it still offers helpful generic guidance.

The second scenario involves cases where the patient had recorded his or her wish to donate or family members present evidence of such a wish. This constitutes consent (or authorisation in Scotland) to donation and should normally be respected. In cases where the patient is a child who had registered a wish to donate, their consent has the same legal status as that of a registered adult donor. Appendix A provides details of the applicable legislation.

3 Involving the family where there is no indication of the patient's wishes

How should the family be approached when there is no indication of the patient's wishes?

Families are already in a potentially distressing situation even before donation is raised as a possibility, and all efforts should be made to provide appropriate bereavement support. Where a potential organ donor has not recorded his or her intentions on the organ donor register, families will normally be approached sensitively by a specialist nurse for organ donation (SNOD) or other clinical professional to establish whether the patient had orally communicated any wishes regarding donation, in line with NHS Blood and Transplant, Human Tissue Authority and National Institute for Health and Care Excellence guidelines. In cases where there is no registered intent and the family is unaware of any wishes in this regard, the SNOD will use the relevant hierarchy of relationships to determine which family member or friend will make the decision regarding donation. The discussion with the family will include a description of what is involved in the donation process, and particularly withdrawal of treatment, and what is involved in donation after brainstem death (DBD) or donation after circulatory death (DCD), including discussion of any relevant pre-mortem or post-mortem interventions (see section 5 of this paper). This decision-maker can then decide whether or not to proceed with donation. Discussion with family members and friends in these circumstances should be designed to support informed decision-making, regardless of whether the ultimate result is agreement to donation or a decision to decline to donate.

Which family member has legal authority to make the decision regarding donation, in cases where there is no evidence of the patient's intentions?

The hierarchies of relationships set out in the Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006 (see Table 1, below) provide guidance regarding who should be approached to give consent or authorisation to donation in cases where the patient was not a registered organ donor, and no other evidence regarding their wishes exists.

Table 1: Hierarchies of relationships in UK legislation

Human Tissue Act 2004	Human Tissue (Scotland) Act 2006
1. spouse or partner; 2. parent or child; 3. brother or sister; 4. grandparent or grandchild; 5. child of a person falling within 3 (brother or sister) 6. stepfather or stepmother; 7. half-brother or half-sister; 8. friend of longstanding.	1. spouse or civil partner 2. a person living as husband or wife for a period of not less than 6 months; 3. child; 4. parent; 5. brother or sister; 6. grandparent; 7. grandchild; 8. uncle or aunt; 9. cousin; 10. niece or nephew; 11. a friend of longstanding.

These hierarchies provide a legal framework for staff who must approach families for consent or authorisation. However, it is important to note that Tthese hierarchies should not, however, be applied outside the context for which they were designed (see section 4.1).

What happens if family members disagree about donation in cases where the patient's wishes are not known?

In some cases, other family members might want to prevent donation going ahead even if the one who is highest in the hierarchy agrees to donation; alternatively, some family members might want donation to proceed where the highest-ranked relative does not want to give consent/authorisation. Where there is disagreement about donation, the family member who ranks highest in the applicable hierarchy has the legal authority to make the decision. However, it might be difficult not to accede to the wishes of other family members. SNODs and other staff should try to help families achieve a consensus, with a view to supporting the family member who ranks highest in the hierarchy to make a decision. The role of the SNOD should be to support the family as a whole, whatever the decision about donation. The default position should not be that the views of family members who feel uncomfortable about donation should be given greatest weight.

Are families asked to consent to / authorise anything else, apart from organ donation itself?

Yes. Consent / authorisation is also sought for tissue donation (eg corneas and heart valves), for blood tests from the potential donor (including virology for transmissible diseases) and occasionally for removal of additional tissues such as blood vessels. Where appropriate, consent / authorisation to research intended to improve transplantation outcomes using donated organs is also sought.

Could the results of blood tests have any implications for family members?

In some cases the results of blood tests could be relevant for family members, as they could reveal information about exposure to viruses or about paternity. Family members may refuse to give consent to these tests for related reasons. However, in most cases the results will not have any such implications.

What other questions are the family asked?

As well as being asked about the patient's wishes (if any) regarding donation, the family will also be asked about his or her recent medical and social history which will inform the decision whether donation can take place.

Should families be informed about the potential benefits of donation to recipients or to family members?

Yes. While some family members may already have considered the potential benefits of donation to recipients (and in turn to their families), many may be unaware that donation can save more than one life and benefit several people. Furthermore, many family members benefit from knowing that their relative's organs saved or improved the lives of others, and this knowledge can ease the bereavement process.[2] Information about benefits to recipients and family members is relevant to making a decision about donation, and withholding it would do a disservice to families.

What should be done if the family requires religious guidance?

Faith leaders play an important role in the community, and may be asked to advise families regarding the permissibility of donation within particular belief systems. For example, some persons of faith may assume that their faith is fully supportive of organ donation and will want to ensure appropriate end of life rituals are followed whilst organ donation takes place; whereas other people of faith might assume that donation is regarded as unholy, or forbidden by a sacred text. A faith leader could counsel them regarding these matters, and clarify any misunderstandings (both where there is no registered intention to donate and where there is).

What if no family members or friends can be contacted?

If family or friends cannot be contacted then donation will not proceed, as consent / authorisation must come from someone on the relevant hierarchy. In Wales, consent can be deemed in the absence of family members but any organs donated would be treated as higher-risk due to the lack of information about the patient's medical and social history.

[2] Walker W1, Sque M2. Balancing hope and despair at the end of life: The contribution of organ and tissue donation. J Crit Care. 2016; 32:73-8.

4 Involving the family when the patient has expressed a wish to be a donor

What is the role of the family when the patient was a registered organ donor or had communicated their intention to donate to a family member?

As in cases where there is no evidence of donation intentions, the family is usually approached by the clinical team and a SNOD. When informing family members of a patient's prior decision to consent to or authorise organ donation, the SNOD should assume the family will support this decision. Whoever is speaking to the family is advised to "obtain a hard copy of the ODR registration where possible, to use as a guide for the patient's family, when confirming the first person consent of specific organs and/or tissues."[3]

What happens if the family states that the patient had changed his or her mind about donation since registering an intention to donate?

If the patient registered consent/authorisation to donation on the ODR but the family state that the patient has since changed his or her mind, the family is asked to provide 'relevant information' to support this. The family will be asked why they thought that to be the case, why the person would have objected and what evidence they have to show this is the case. Normally no documentary evidence will be available and the evidence will be based on the family recollecting significant or otherwise relevant conversations with the patient. The evidence should be of the views of the potential donor him or herself (see section below on new evidence of refusal), and should appear to be credible.

Are families asked to consent to / authorise some procedures even if the patient was on the register?

Yes. Legally, the patient's first-person consent / authorisation as indicated by the register is sufficient for any procedures necessary to support donation. However, SNODs will normally also ask families for written consent (evidenced by a signature) to taking specific blood vessels and virology testing (the results of which could have implications for family members) and where appropriate to consent to research intended to improve transplantation outcomes using the donated organs. In such situations, the HTA hierarchy will be used to establish which family member should provide consent.[4]

What if no family members or friends can be contacted?

If family or friends cannot be contacted but the patient had registered an intention to donate (and in Wales where consent can be deemed), then donation may not proceed unless a recent medical and social history can be obtained from another

3. NHS Blood and Transplant form MPD902/2.
4. NHS Blood and Transplant. Consent – Solid Organ and Tissue Donation (Form FRM4281/3.2).

source such as the patient's GP.. If donation does go ahead the patient will be treated by default as a "higher-risk" donor, which might mean that donation will not go ahead in some circumstances.

What if family members do not wish to take part in any donation discussion?

In some cases the relatives of someone who is known to have consented may not oppose donation, but do not want to answer social and health questions about the patient. It is not ethically acceptable to put pressure on them to become part of the donation process in such cases, but they should be informed that the patient will be regarded as a "higher-risk" donor because family members do not wish to answer these questions.

4.1 "Overruling" the wishes of a patient who wanted to donate

What happens if family members object to donation in cases where the patient was a registered donor?

Families can object to donation for a variety of reasons. The appropriate response to an objection to donation depends on the reason given for objection. Frequently, any reason given by a family for objecting to donation from a registered donor is described as an "overrule" or "veto" of donation. UKDEC suggests that many objections which are classified as "overrules" are not overrules at all (see Appendix B for a detailed analysis). In many cases the family is actually presenting new **evidence of refusal** to donate. In others, the family might claim that the context of organ donation has changed or is different from what the donor probably anticipated, meaning that it may be necessary to **reassess the overall benefit to the patient**. Some attempts to prevent donation are indeed **genuine overrules** which reflect the wishes of the family members rather than those of the patient**.** In the following discussion we suggest how to involve families in each of these three different contexts; discussions with families may be made easier if distinctions between these three categories are borne in mind.

What should happen if a family attempts to stop donation because they say the patient no longer wanted to donate?

In some cases, rather than overruling a wish to donate, families are presenting new **evidence of refusal** by the patient. Where family members state that the patient did not want to donate, or there is disagreement between family members regarding the patient's wishes, the issue to be decided is not whether to let the family overrule the wishes of a registered donor, but whether their evidence outweighs the recorded intentions of the patient. Where family members agree that the patient had expressed a refusal to donate since registering his/her donation intentions, donation should normally not proceed because there is strong evidence that the patient's wishes had changed. This is not an overrule; at most, it is a revision of the evidence for consent/authorisation. If family members present evidence of a wish not to donate which predates a subsequent recorded decision to donate, the family's evidence should not be determinative in the light of the patient's subsequently stated wishes. In cases like this, care should be taken to inform families sensitively

that their evidence does not seem to reflect the most recently expressed wishes of the patient and that donation should therefore proceed.

What should be done if there is disagreement within a family about whether a patient wanted to donate?

Cases where family members disagree on the evidence about the wishes of the patient are more challenging. The temptation in situations of disagreement might be to abandon donation in order to avoid upsetting those who object to it. But family members who want to donation proceed may also experience distress if it does not. Where the donor had formally registered an intention to donate, the presumption should be in favour of donation rather than against it. Cases where there are competing claims of oral evidence are even more difficult. Normally the most recent evidence should be treated as the most persuasive, but in some cases older evidence may appear to be stronger. In such cases healthcare professionals will have to weigh carefully the competing claims before making a decision regarding which evidence should be regarded as more persuasive.

Is it appropriate to use the family hierarchy in situations where someone wants to overrule donation?

Where family members disagree about the patient's wishes, the hierarchy of family members and friends should *not* be applied to 'rank' evidence. The hierarchies are intended to determine who should make the decision regarding donation in cases *where it has already been established that there is no record of consent or refusal from the patient and no nominated representative*. Using the hierarchy to determine whose evidence about donation decisions should be treated as paramount is inappropriate, as this is not its intended purpose. The strength of evidence given by different family members should be considered on its own merits.

What should happen if a family claims that a patient would not have wanted to donate in these circumstances?

Family members may agree that the patient wanted to donate, but state that they do not want to proceed with donation in this specific context or that they believe the patient would not have wanted to proceed with donation in this specific context. In such cases, there may be a case for **reassessing what course of action would be of overall benefit to the patient** in the particular circumstances**.** Obtaining an initial consent from the donor or the family is not the end of the consent process, as time and circumstances can change. There is a range of tests and interventions that might need to be conducted, which involve a varying degree of invasiveness for the patient and sacrifice for the family. For example, measuring a patient or conducting on-going monitoring of the heartbeat are unlikely to change the assessment of overall benefit. But in situations where the donation process will take a prolonged amount of time, invasive procedures are required to facilitate donation, or the family will be unable to stay with the patient after death, whether continuing with donation would still be of overall benefit to the potential donor might need to be reconsidered.

Another important factor is whether the donation pathway is DBD or DCD. In the case of the latter it might be some time before treatment is withdrawn and the

patient might not die in a time frame that allows for donation, creating genuine uncertainty. The family can experience several misfortunes; first the unexpected loss of a relative, then the protracted process of saying goodbye, and then also potentially finding that the chance for some comfort from donation proceeding cannot be realised. In such cases, especially where the chance of donation proceeding is low, clinicians might decide not to proceed with donation. This is not an overrule, but a re-evaluation of what would be of overall benefit to the patient, all things considered: although he or she had expressed a wish to donate, the specific circumstances mean that donation would no longer be of overall benefit. In this context, it is worth noting that even well-informed potential organ donors might be unaware that donation can take a very long time, or of the different pathways involved in DBD and DCD. A patient who would otherwise wish to be a donor, might not wish to be one in circumstances that were very burdensome or additionally distressing for his or her family. For example, a patient might have assumed that s/he would be declared brain-stem dead before any approach was made to the family. As such, although the patient wanted to donate, he or she might not have realised just how distressing the process could be for their family. These factors make re-evaluation of overall benefit an important aspect of deciding whether to proceed with donation. (For more detailed discussion of assessing overall benefit, see other UKDEC guidance.[5,6])

How can it be determined whether donation is of overall benefit to the patient?

Whether it is no longer of overall benefit to the patient to proceed with donation will often be difficult to determine. The most important factor in these circumstances is likely to be the strength of the patient's wish to donate. If the patient had told all family members and friends that he or she wanted to donate "no matter what", then there should be a strong presumption in favour of donation. In cases where the only evidence is an entry on the organ donor register, it can be more difficult to assess the strength of the patient's wishes. However, an entry on the register still constitutes consent / authorisation and health care professionals must be careful not to abandon the donation process only because family members raise objections or are very upset.

If a family member were to say something like "yes, he wanted to donate, but not to the extent that he'd want us to wait for so long", this might seem to be new evidence of refusal to donate. However, concerns like this should rather be balanced in a reassessment of overall benefit. This will avoid "second-guessing" the donor's intentions at the evidence assessment phase, and allow for a more holistic assessment of overall benefit in cooperation with family members should the need arise because of DCD or a particular technical intervention.

How can healthcare staff balance protecting the family from distress with respecting the patient's wish to be a donor?

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[5] AOMRC. Interventions before death to optimise donor organ quality and improve transplant outcomes: guidance from the UK Donation Ethics Committee.
[6] AOMRC. An Ethical Framework For Controlled Donation After Circulatory Death. Guidance from the UK Donation Ethics Committee.

Familial distress should not automatically prompt the conclusion that donation is no longer of overall benefit to the patient for at least two reasons. Families can be expected to be upset at the loss of a relative, and allowing distress alone to determine overall benefit decisions may not honour the dying patient's expressed decision. Patients who intended to donate may also have anticipated that their families will be upset at their deaths, and potentially also at the thought of donation. Objections should be explored so that any misconceptions are clarified to ensure the family is properly informed about the donation process. Some distressed relatives may attempt to overrule donation (see genuine overrules, below).

Isn't going ahead with donation always of overall benefit to a patient?

It seems reasonable to suppose that people would want to, or even perhaps ought to, save lives or improve the quality of the lives of others if they can do so at relatively little cost to themselves. However, this attitude fails to take into account that people may not care so much about those who are 'morally distant' from them, such as potential recipients of organs whom the patient has never met. While a case could certainly be made that the needs of such potential recipients are morally significant, an assessment of overall benefit must be patient-centred and based solely on consideration of the patient's wishes, feelings, beliefs and values.

Is it permissible to let families overrule donation even when doing so would not be of overall benefit to the patient?

Only in very rare cases will a "**genuine overrule**" be appropriate, that is one which is based on the family's own wishes rather than those of the patient. In cases where a family member or members themselves object to donation proceeding, they should be encouraged to accept the patient's wishes and focus not on their own wishes/values/beliefs but on those of the patient. If a family has discussed options and been provided with information but still wants to overrule despite having been challenged, an overrule may have to be permitted. However, some of the reasons given in this category (see Appendix B) appear to be based on misunderstandings or biases, and could perhaps be addressed given careful conversation with families.[7]

In some cases, it will be unclear whether a given reason calls for an assessment of overall benefit or is really an attempt to overrule. For example, it might be objected that "family did not want surgery to the body" should be considered as an argument for reconsidering the overall benefit to the patient. However, if a patient wanted to donate, that clearly requires surgery, and it would seem disrespectful to the patient to let the family overrule donation on those grounds alone. However, there are other aspects of the donation process which the donor could not necessarily have anticipated – such as some of the interventions or understanding how long a family is able to stay with a donor's body after death. If a family wishes to stay with the patient after death, that is normally possible in the case of donation after brain death but not in the case of donation after circulatory death (because of the need to retrieve organs quickly). These factors are contingent upon the specific circumstances of donation, and they are not factors that the typical donor could

7. Shaw D and Elger B. Persuading Bereaved Families to Permit Organ Donation. Intensive Care Medicine, 2013, doi: 10.1007/s00134-013-3096-4.

have anticipated in the same way as surgery to facilitate donation. In cases where the family cites a religious motivation for wanting to overrule donation, it may be important to emphasise that it is the beliefs of the deceased, not of themselves, that should be decisive. Faith leaders and chaplains could play an important role in such cases (see next section.)

(Some of the reasons given in an attempt to overrule might in a specific case be good grounds for reassessing overall benefit – for example, if the family argue (based on their knowledge of the patient's wishes, feelings, beliefs or values) that s/he would not have wanted to carry on with donation if the family disagreed about going ahead with it. However, in most cases these reasons will constitute an attempt at a genuine overrule because they appeal to family member's wishes rather than those of the patient (see Appendix B). It might also be argued that "family was divided over the decision" might suggest that this reason should be placed in category 1, but it is not obvious that this reason refers to contradictory accounts of the evidence for or against donation).

Should a strong initial refusal from a family be respected, if no reasons for wanting to overrule donation are provided?

One reason that is sometimes given for permitting an overrule is "strong refusal – probing not appropriate". This is problematic because even a strong refusal may be based on a misunderstanding. We suggest that sensitive discussion with families is almost always appropriate, regardless of how strongly initial refusal is expressed. Indeed, NHSBT guidance states that 'It is perfectly reasonable (and is in fact good practice) to probe initial family negative responses, as these may be based on misunderstanding, poor information or on remarks taken out of context."[8] However strong an initial refusal, experience suggests that a strong initial refusal may change once more information is provided to the family.

It is also possible that families might initially acquiesce to donation without really thinking about what it means because they are too upset or are trying to do what they think the clinical team wishes them to do. Equally, therefore, an initial acceptance should not be taken as signifying that family members do not need to be provided with full and comprehensive information about what donation involves. All decision-making about organ donation should be adequately informed, whether or not the provision of information will result in donation.

While families may find the initial suggestion of donation too distressing given the context of the sudden death of a relative, there is evidence that some families who refuse to permit or who overrule donation come to regret the decision.[9] In some circumstances, it may be appropriate to advise families sensitively that there is a possibility that they might come to regret overruling donation. Similarly, many families who permit donation have testified to the good that comes from their relative's gift as something of a "silver lining" to the loss of their relative.[10]

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8. NHS Blood and Transplant. Approaching the families of potential organ donors. Best practice guidance. www.odt.nhs.uk/pdf/family_approach_best_practice_guide.pdf
9. Morais M, da Silva RC, Duca WJ (2012) Families who previously refused organ donation would agree to donate in a new situation: a cross-sectional study. Transp Proc 44(8):2268–2271.
10. Evidence from UKDEC member in contact with families of deceased donors (DC).

What happens if the family want donation to take place but there is evidence that the patient did not?

If the patient had communicated a refusal to donate, his or her family would not normally be able to overrule this refusal. However, if the family provided persuasive evidence of consent to donation which was more recent than the earlier refusal (whether registered or not), donation could be considered. It should be noted, though, that this would not be an overrule, but new evidence of consent to donation. In such cases the patient's most recently expressed wishes should be respected. In contrast, if the patient has made a decision not to consent to donation but the family wants donation to go ahead, the donation cannot proceed as the patient's decision is legally effective. In summary, new evidence of consent can supersede a refusal, but families cannot overrule refusal.

5 Pre- and post-mortem interventions

Several pre- and post-mortem interventions may be necessary to increase the probability that donated organs will be effectively transplanted. UKDEC has issued guidance on the ethical and legal issues raised by such interventions, so we do not explore them in depth here. Generally, the family should, if they wish, be involved in discussion about pre- and post-mortem measures in order to inform assessments of the overall benefit to the patient. The stronger the patient's desire to become an organ donor, the greater the weight this evidence should be given in assessing whether a particular intervention would be of overall benefit to the patient.

Is it necessary to obtain the family's consent to each and every intervention required to optimise organ quality and improve transplant outcomes?

No. Nonetheless, even where the patient is a registered donor or the family provides consent, all interventions or procedures should be subject to an assessment of overall benefit to the patient (see discussion in section 4.1).

Which interventions might be necessary before death?

Potential pre-mortem interventions in cases of DCD can be divided into two main categories, as described in the UKDEC generic guidance on interventions:

> 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.[11]

The acceptability of particular interventions to the patient can form part of the assessment of overall benefit to the patient, and the family will play an important role in this process. If a patient had expressed a strong wish to be a donor, this should affect the assessment of particular interventions that are required to facilitate or to optimise donation. For more details on the balancing of interests, benefits and harms, see the UKDEC generic guidance on interventions.

Which interventions might be necessary after death?

There are also several post-mortem interventions (in the context of both DBD and DCD) which ensure that organs are not damaged by warm ischaemic injury, which occurs when insufficient blood reaches the organs. For example, if a patient is declared brain dead, but his heart then stops, cardiopulmonary resuscitation (CPR) could be used to keep the heart beating and avoid ischaemic injury. However, if the family were still present, it could be distressing for them to witness what looks like an attempt to bring the patient back to life soon after they have been told he or she is dead. Most registered donors will not have anticipated this possibility. However,

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

CPR is less invasive than donation itself and in some cases will be essential to ensuring that donation occurs. Therefore, in line with UKDEC guidance on DBD,[12] "clinicians should discuss the potential difficulties that may arise and the limits of interventions after death with the patient's family." This also applies to other post-mortem interventions such as extracorporeal membrane oxygenation (ECMO), which uses an external device linked to the patient to restore or maintain circulation following determination of death in order to prevent ischaemic injury. Other interventions similar to ECMO include full cardiopulmonary bypass and mechanical ventilation with oxygen to facilitate lung donation after DCD.[13]

12. AOMRC. An Ethical Framework For Donation After Brainstem Death. Guidance from the UK Donation Ethics Committee. ADD LINK
13. Manara AR, Murphy PG, Callaghan GO. Donation after circulatory death. Br. J. Anaesth. (2012) 108 (suppl 1): i108 i121. http://bja.oxfordjournals.org/content/108/suppl_1/i108.full (table 6)

6 Potential strategies for improving the donation process for families

In this section we suggest several strategies which, if implemented, might improve the donation process for families of patients. These are based on our analysis in the preceding text; some concern potential changes in the way healthcare staff interact with families, while others are further-reaching. We hope that these suggestions will provoke discussion amongst healthcare professionals and ultimately lead to refinement of the processes that involve families in donation decision-making.

1. Families should be placed at the centre of the donation decision-making process in ways that minimise their distress. However, their level of involvement in decision-making will vary according to their particular circumstances. Where there is evidence of a wish to donate, their role should be limited to updating that evidence, and contributing to any assessment of overall benefit to the patient. Where there is no evidence of a wish to donate, and there is no nominated representative, the family hierarchy should be used to determine who should make a decision regarding donation (except in Wales, where consent will be deemed in such cases). The aim in such cases should always be to help a family towards an informed 'yes' or an informed 'no'. Faith leaders may play an important role in advising the family during this difficult period.

2. Those who wish to donate their organs should be encouraged not only to sign up to the register, but also to communicate their intentions to family members and friends to strengthen further the evidence-base supporting their consent to donation. Similarly, those who do not wish to donate should also share their wishes with family members. This will minimise the risk of disputes about what patients would want and consequent attempts to overrule donation, and reduce distress among family members.

3. The family hierarchies set out in law should only be used for their intended purpose of determining which relative is highest in the ranking of family members and friends. They should never be used to "rank" evidence from family members of a patient's wishes regarding donation.

4. Our re-categorisation of 'overrules' could be adopted by clinicians, SNODs, and organisations such as NHSBT. Many of the reasons given for declining donation may not be genuine overrules, but rather new evidence regarding consent or refusal, or reasons for reassessment of overall benefit. Distinguishing between these categories could bring greater clarity to interactions with families and help to identify when attempts to overrule should be challenged. Only in rare cases will a genuine overrule be appropriate. Furthermore, when recording the reason that donation did not go ahead because of an objection from family members, more information on the "other" category for overrule could be provided by healthcare professionals. Staff could be encouraged not to use this category provided a match can be found

with another category, and/or an option could be added to enable those using this category to enter a brief textual description of why donation did not occur. Implementation of this suggestion could provide better evidence to improve further the donation process for families and avoid future ethical dilemmas.

5. We agree with current NHSBT guidance[8] that attempting to discuss reasons for declining donation is almost always appropriate when a family attempts to overrule a patient's wish to donate his or her organs. An initial strong refusal to consider donation could mask a misunderstanding.[8] While probing should sometimes be abandoned at an early point (and SNODS are highly skilled at identifying this point) attempting to ascertain the reasons behind a refusal is very important as it may lead to a more informed decision. Similarly, families might agree to donation without reflection and should be properly informed. Any overrule of donation should be informed, just as any consent to donation should be informed, and every opportunity should be offered to the family to make as informed a decision as possible.

6. Going further, NHS Blood and Transplant could reassess the advantages and disadvantages of the current organ donor register system. Potentially, the ODR could be amended in several ways to help donors, professionals and families in realising a wish to donate. For example, more information could be provided to those signing up to the register, and they could be asked to indicate whether they want to donate "no matter what" or whether they want to donate unless their family objects. Having a "free text" option on the register might be the best way to enable people to indicate their donation preferences. Strengthening the ODR in this way would provide better evidence in two ways: (a) it would allow "strong donors" to say they are happy with any measures and want to donate regardless of what their family wants (avoiding the need for reassessment of overall benefit); and (b) in cases where potential donors are more ambivalent, it will provide better evidence for the assessment of overall benefit. Another possibility would be for the organ donor register system to remind registered donors on a yearly basis that they can change their registered wishes if they wish (via text message or email). This would help remove doubts about whether the patient's consent has become out-of-date and/or superseded by discussions with family members. While complicating the registration process might have some disadvantages in terms of making the process lengthier or deterring people altogether, improving the quality and reliability of data on the register would be likely to result in fewer difficulties in dealing with families and friends. One way to avoid deterring people who are happy to consent without learning too much about the process would be to have both a detailed and a simple consent option. People who want to know more could click a link to detailed information, but those who are happy to consent need not read it. However, this simple option would not address the issues addressed in this paper to the same extent.

Appendix A: Legal context

Understanding the legal context is essential to any analysis of the role of the family in organ donation. Various pieces of legislation in the United Kingdom's component nations govern organ donation from deceased patients. The following summary of issues relating to consent and to the family is intended to provide sufficient background for consideration of the relevant ethical issues.

1. Organ donation under the Human Tissue Act 2004

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 (s.3(6)(a)), or
b. by a third party, either someone nominated by the donor (a 'nominated representative' (s.3(6)(b), 4)), or more likely, by the family (someone in a 'qualifying relationship' to the donor (ss.3(7), (8))).

The distinction between these two categories is a very important one in terms of the role of the family in the donation process. Both category a. (consent from donor) and category b. (consent from a third party) 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, agreement 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. 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.

In relation to (iii), the Human Tissue Authority's 2014 Code of Practice on Donation provides ([101]): 'If no records are held, an approach should be made to the deceased person's partner, relatives or close friends by a transplant coordinator or a member of the team who cared for the person, or both together, to establish any known decision of the deceased person to consent (or not) to donation.'

Under the Act, it is lawful to take an organ if appropriate consent has been given, but it is not obligatory. A previous version of the Human Tissue Authority's Code of Practice on Donation from 2006 set this out clearly ([56]) but this statement is no longer found in the more recent Codes of Practice. Instead, the 2014 Code of Practice on Donation states ([102]):

“Once it is known that the deceased person consented to donation, the matter should be discussed sensitively with those close to the deceased. They should be encouraged to recognise the wishes of the deceased and it should be made clear, if necessary, that they do not have the legal right to veto or overrule their wishes. There may nevertheless be cases in which donation is considered inappropriate and each case should be assessed individually.”

Furthermore, the 2014 Code of Practice on Consent states:

> 84. If those close to the deceased person object to the donation, for whatever purpose, when the deceased person (or their nominated representative …) has explicitly consented, the healthcare professional should seek to discuss the matter sensitively with them. They should be encouraged to accept the deceased person's wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes…
>
> 85. The emphasis in these difficult situations should be placed on having an open and sensitive discussion with those close to the deceased where the process is explained fully to them. Healthcare professionals should also consider the impact of going ahead with a procedure in light of strong opposition from the family, despite the legal basis for doing so. For example, healthcare professionals may consider that carrying out an anatomical examination would leave relatives or family members traumatised (or lead to their objections), despite the deceased person having consented to this whilst alive.

In cases where *consent is sought from the family*, the qualifying relationships are ranked in the following order (we discuss this hierarchy in detail in section 3 of this paper, but also describe it here as it is an important feature of the legal context):

1. spouse or partner;
2. parent or child;
3. brother or sister;
4. grandparent or grandchild;
5. child of a person falling within 3 (brother or sister);
6. stepfather or stepmother;
7. half-brother or half-sister;
8. friend of longstanding.

With regard to qualifying relationships, the HTA’s 2014 Code of Practice on Consent states the following:

> 96. Where there is a conflict between those accorded equal ranking [by virtue of their qualifying relationships], then this needs to be discussed sensitively with all parties …, whilst explaining clearly that so far as the HT Act is concerned, the consent of one of those ranked equally in the hierarchy is sufficient for the procedure to go ahead.
>
> 97. ‘a person's relationship shall be left out of account if: 1. they do not wish to deal with the issue of consent; 2. they are not able to deal with the issue; 3. in relation to the activity for which consent is sought, it is not practical to communicate with that person within the time available if consent in relation to the activity is to be acted on’.

2. End of life care under the Mental Capacity Act 2005

Prior to death, the patient lacking capacity 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.

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) to the patient which may be caused by the intervention. 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, 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.

In most cases, the best interests decision-maker for clinical matters will be the relevant clinician (s.5), unless (a) the patient has appointed a donee of a lasting power of attorney for health and welfare (s.6(6)(a)) (who may or may not have been given (by the patient) authority to make decisions about life-sustaining treatment (s.11(8)), or (b) the Court of Protection has appointed a deputy (s.17(1)) (who will not have authority to make decisions about life-sustaining treatment (s.20(5)).

3. Organ donation under the Human Tissue (Scotland) Act 2006

The 2006 Act is regarded as a strengthening of the system of 'opting in'. It is based on the principle of 'authorisation', an expression intended to convey that people have the right, during their lifetime, to express their wishes about what should happen to their bodies after death, in the expectation that those wishes will be respected. The main aim of the legislation is that a person's own wishes should be acted upon. The validity of authorisation does not depend on the giving or receiving of information about organ donation or transplantation.

Section 6 of the 2006 Act provides that adults can authorise the removal and use of a part of their own body after death for the purpose of transplantation, as well as for the purposes of research, education or training, and audit (section 3(1) of the Act). This is usually referred to as 'self-authorisation'. Expressions of authorisation are valid whether given in writing (including electronically) or verbally. An adult can withdraw authorisation for transplantation at any time, but must do so in writing so that there is complete clarity about which wishes should prevail at the time of the adult's death. There are specific provisions for adults who are blind or unable to write.

Where the wishes of the adult in favour of donation for the purpose of transplantation are clear, it would be technically unnecessary under the terms of the 2006 Act (section 7(2)) to seek authorisation for that purpose from the adult's nearest relative (see below), as the deceased's wishes in these cases are all that are needed to allow the removal of body parts for transplantation to proceed lawfully, though seeking assent might be reasonable.

Where the deceased adult left no formal wishes regarding the donation of body parts for transplantation (ie. Category (b) as described above, where consent must be sought from a third party), the nearest relative will be asked to consider giving authorisation for that purpose, on the basis of what they believe the deceased's wishes would have been (section 7(1) of the 2006 Act). The nearest relative may not give such authorisation if they have actual knowledge that the adult was unwilling for any part of their body, or the part in question, to be used for transplantation (section 7(4)). Such authorisation by the nearest relative of the use of body parts for transplantation can be written and signed, or given verbally. Once given, it cannot be withdrawn (section 7(7)), because of the potential risks a last-minute withdrawal would pose to potential recipients of body parts.

The 'nearest relative' hierarchy is set out in section 50 of the 2006 Act. It aims to identify the person closest in life to the deceased adult and therefore most likely to be able to reflect the deceased's wishes. The ranking of the hierarchy is as follows (we discuss this hierarchy in detail in section 3 of this paper, but also describe it here as it is an important feature of the legal context):

1. spouse or civil partner (unless permanently separated from or deserted by the adult;
2. a person living as husband or wife for a period of not less than 6 months;
3. child;
4. parent;
5. brother or sister;
6. grandparent;
7. grandchild;
8. uncle or aunt;
9. cousin;
10. niece or nephew;
11. a friend of longstanding.

Where there is more than one person in each category, it is sufficient to obtain authorisation from one of them (section 50(5)). The relationship with the adult is to be left out of account if the person was, immediately before the adult's death, under the age of 16, or if the person does not wish or is unable to make a decision on the issue of authorisation (section 50(6)).

4. End of life care under the Adults with Incapacity (Scotland) Act 2000

The system of authorisation set out in the 2006 Act applies only after the point at which death has been pronounced. Up until that point, the provisions of the 2000 Act are those that apply. The terms of section 47 of the 2000 Act would probably not regard interventions intended solely to preserve organs for transplantation as a permitted form of medical treatment, since the interventions are intended to benefit others, not the patient.

Guidance on the subject was issued as CMO (Chief Medical Officer) Letter SGHD/CMO(2010)11 on 3 May 2010, with some clarification provided in SGHD/CMO(2012)8, issued on 23 July 2012. The CMO Letter explains (paragraph 19) that the concept of 'benefit' is likely to be wider than the person's immediate medical situation. It can be interpreted as permitting something that the adult could reasonably be expected to have chosen to do if capable, even though of a gratuitous or unselfish nature. It is therefore important to take account of whether such actions would benefit the adult with incapacity by:

- maximising the chance of fulfilling the potential donor's wishes about what happens to them after death;
- enhancing the potential donor's chances of performing an altruistic act of donation; and
- promoting the prospect of positive memories of the donor after death.

Other aspects must also be considered, such as the risk of harm to the adult with incapacity by worsening their medical condition or shortening their life, or any distress an action may cause the person or their family or friends.

In the interval between reaching agreement on the withdrawal of treatment and the actual moment at which treatment is withdrawn, maintenance of the patient would be considered reasonable, so as not to cause distress to the relatives. That maintenance would cover adjustment of cardio-respiratory support, including maintaining the patient's blood pressure and generally making sure the patient's condition remains stable. The CMO Letter took the view that any further interventions, which it characterised as more 'invasive', would not be permissible under the terms of the 2000 Act. These would include steps such as full CPR, heparinisation or the insertion of venous or arterial cannulae, if intended purely to optimise the donation of organs for the purpose of transplantation. A change to the current legislation would be needed in order to provide a lawful basis on which such procedures could be undertaken.

5. Differences between the 2004 Act and the 2006 Act

While the 2004 Act is couched in terms of consent, the 2006 Act uses the language of authorisation. As the Human Tissue Authority's Code of Practice on Consent recognises, however, these are essentially both expressions of the same principle (paragraph 19). In its Code on the Donation of solid organs for transplantation, the HTA notes (paragraph 97) that the guidance in the section of that Code dealing with deceased organ donation does not apply to Scotland but points instead to the guidance on the requirements of the 2006 Act set out in Health Department Letter (2006)46 of 20 July 2006.

For practical purposes, including the nature of the approach to families, the detailed provisions of the 2006 Act relating to authorisation of the use of body parts for transplantation and other purposes are reflected in the authorisation form developed by NHS Blood & Transplant, as well as in the detailed operating procedures used by Specialist Nurses for Organ Donation (SNODs) working in Scotland.

6. Organ donation under the Human Transplantation (Wales) Act 2013

New legislation came into force in Wales in 2015, introducing a system of "deemed consent" where it is assumed that patients want to donate unless they have registered an objection (commonly known as an "opt-out" or "presumed consent" system). This applies to all adult patients who have been resident in Wales for at least 12 months. As well as registering an objection, prospective donors can also continue to register intent to donate or appoint a nominated representative to make the decision on their behalf. In cases where a representative was nominated but is unavailable, the hierarchy of qualifying relationships described above (in the Human Tissue Act 2004) will be used to determine from whom consent may be obtained. It should be noted that this is the only context in which the hierarchy will ever be applicable in Wales under the new legislation, as any patients for whom there is no evidence regarding consent or objection will be deemed to have consented. In all cases where consent is obtained from the patient's entry on the donor register or via evidence regarding their wishes from family members, from a nominated representative or a person in a qualifying relationship, the consent is described as "express" rather than "deemed".

The move to a system of deemed consent has some important ramifications for the role of the family. The publicity surrounding the change in the consent system in Wales may have encouraged people to sign up to the register or nominate a representative; however, because it will no longer be necessary to register one's intention to donate, many people may not bother to do so. This means that when it comes to raising the issue with their family, there may be little or no evidence regarding their intentions. Clinical staff can of course point to the fact that a deemed consent system operates in Wales, but this is unlikely to have the same impact on the family as showing them a copy of the patient's entry in the organ donor register. This is particularly problematic in the case of overrules (see below). Welsh residents who wish to donate their organs may wish to register their intention to donate to ensure that their wishes are respected in the event of any family dispute regarding whether donation should proceed.

Appendix B: Categorisation of reasons for refusing donation from registered donor

The data given here is derived from Table 7 of the NHSBT document "Investigating family declines to Organ Donation", which covers the two-year period from 1 April 2013 to 31 March 2015. The numbers after each reason give the percentage of all recorded 'overrules' where this reason was given; the numbers after the headings give the added total for each category.

Here, we provide a framework for dealing with families who attempt to 'overrule' organ donation in cases where the patient was on the organ donor register or where other evidence exists regarding his or her intentions. We suggest a reclassification of these reasons into three new categories: new evidence of refusal, reassessment of overall benefit to the patient, and genuine overrule.
While there may be disagreement over which category some reasons should be placed in, we believe that this re-categorisation provides a useful framework for considering how to deal with families in some situations.

1. New evidence of refusal (9.6%)
Patient had stated in the past that they did not wish to be a donor (6.7% ODR)
Family were not sure whether the patient would have agreed to donation. (2.9%)

2. Reassessment of overall benefit (31.6%)
Family felt the length of time for donation process was too long. (28.2%)
Family wanted to stay with the patient after death (2.9%)
Family had difficulty understanding/accepting neurological testing (0.5%)

3. Genuine overrule (46.5%)
Family did not want surgery to the body (8.1%).
Family felt the patient had suffered enough (7.7%)
Strong refusal - probing not appropriate (6.2%)
Family were divided over the decision (6.7%)
Family concerned that organs may not be transplanted (6.2%)
Family did not believe in donation (5.3%)
Family felt the body needs to be buried whole (unrelated to religious or cultural reasons) (2.4%)
Family felt it was against their religious/cultural beliefs (1.9%)
Families concerned about organ allocation (1%)
Family concerned that other people may disapprove/be offended (0.5%)
Family concerned donation may delay the funeral (0.5%)

4. Other – 12.4%