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Review article

The British Transplantation Society guidelines on ethics, law and consent in relation to deceased donors after circulatory death

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ABSTRACT

The British Transplantation Society (BTS) 'Guideline on transplantation from deceased donors after circulatory death' has recently been updated and this manuscript summarises the relevant recommendations from chapters specifically related to law, ethics, donor consent and informing the recipient.

1. Introduction

The British Transplantation Society (BTS) 'Guideline on transplantation from deceased donors after circulatory death' has recently been updated [1] and this manuscript summarises the relevant recommendations from chapters specifically related to law, ethics, donor consent and informing the recipient.

2. Methods

The BTS 'Guideline on transplantation from deceased donors after circulatory death' was written in line with the BTS guideline development policy, and the recommendations of NICE Evidence [2]. Contributors performed their own literature search using PubMed® to identify relevant evidence. Virtual progress meetings between the guideline development group and contributors were held. A face-to-face meeting was then held for review and discussion of the final grading of the recommendations. Comments on the preliminary draft were invited from patient representatives. The Guidelines were further edited and opened for public consultation through the website of the BTS. In the Guidelines

the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system has been used to rate the strength of evidence and the strength of recommendations [3].

3. Overall benefit and organ donation

We recommend that:

- 'Overall benefit' should be the guiding principle when making decisions about end-of-life care in relation to organ donation. (1D)

The UK Donation Ethics Committee (UKDEC) endorsed two guiding principles in their work [4], and these are used in this guidance to underpin the ethical aspects of DCD:

Principle 1: Where donation is likely to be a possibility, full consideration should be given to the matter when caring for a dying patient.

Principle 2: If it has been established that further life-sustaining treatment is not of overall benefit to the patient, and it has been further established that donation would be consistent with the patient's wishes, values and

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

These principles highlight the importance of establishing a patient's wishes, in relation to their end-of-life care in general, and specifically how organ donation might form a part of this.

The ethically distinctive aspect of DCD is that the patient is alive, albeit in most cases lacking capacity, when decisions about, and preparations for, organ donation are made. The usual ethical and legal framework for making treatment decisions in the absence of capacity therefore applies which means decisions regarding treatment and end-of-life care should be made on the basis of overall benefit to the patient, in line with GMC guidance on end-of-life care [5]. We use 'overall benefit' rather than 'best interests' to refer to the ethical basis and guiding principle on which decisions are made about treatment/care for adult patients who lack capacity to make decisions for themselves. This ensures consistency with relevant legislation across all devolved nations.

There are different perspectives to consider when determining overall benefit. There is a medicalised perspective that weighs the medical harms and benefits that different treatment options may offer. This perspective weighs heavily in decisions about withdrawal of life sustaining treatment (WLST). The medicalised perspective is, however, incomplete. Determining what is, on balance, best for somebody also requires consideration of a person's wishes, values and beliefs.

Something might be beneficial to a person if it helps them to achieve their goals, or harmful if it prevents them from achieving their goals. Accordingly, what counts as a benefit/harm can vary from person to person. The ethical principle of respect for autonomy makes the wishes of a patient a central consideration in determining what is best for that patient, and this principle is reflected implicitly in mental capacity legislation. Respecting the autonomous wishes of a patient with respect to legitimate goals can be considered to provide them with benefits and frustrating these, to harm the patient. The benefits and harms of respecting a patient's wishes need to be weighed against other benefits and harms (such as 'medical' benefits and harms), so it is not the case that always respecting a patient's wishes necessarily provides overall benefit. Where respecting a patient's wishes will provide some significant benefit to a patient, and the harms of respecting those wishes are low, however, respecting those wishes can provide *overall* benefit.

The benefits to a deceased donor of donating their organs may be abstract or symbolic, as they cannot experience them, but they are nonetheless considered important. Being remembered positively for undertaking a final generous, altruistic act or giving one's loved ones something positive to take from a difficult situation are examples of the types of benefits that may accrue to donors beyond just the benefit of having their wishes respected. Additionally, knowing during life that one may help others after one's death may be considered a benefit.

Given these benefits to donation, if a dying patient wishes to become an organ donor, then taking action to facilitate organ donation may be considered to provide some overall benefit. Any interventions, though, must be balanced against the harms they may cause, as well as the potential harm of frustrating the patient's wishes to be a donor.

4. Establishing and considering patients' wishes

We recommend that:

- The strength of a patient's wishes and decisions regarding organ donation should be included in any consideration of overall benefit. (1D)
- It should not be assumed that someone opting-in to organ donation necessarily has a stronger wish to donate their organs than someone who did not record a preference. (1D)

4.1. Capacity legislation

Relevant legislation for making decisions for adult patients who lack capacity differs according to country. Mental Capacity Act 2005 applies in England and Wales [6], the Adults with Incapacity (Scotland) Act 2000 applies in Scotland [7], and the Mental Capacity Act (Northern Ireland) 2016 applies in Northern Ireland [8]. Although there are differences in precise terminology, the guiding principle of each is the promotion of 'overall benefit'. Each piece of legislation also makes clear that decisions should take into account the wishes and feelings of the patient when determining overall benefit.

4.2. Organ donation legislation

England [9], Scotland [10], Wales [11] and Northern Ireland [12] have all adopted systems of deemed consent for organ donation. Consent for organ donation is defined within the legislation applicable to each devolved nation, and although each has minor differences, they all provide a way of establishing a patient's wishes in relation to organ donation. In summary, under deemed consent systems people can do different things to record their organ donation wishes. First, even though these are known as opt-out systems, it remains possible to opt-in and record a positive wish and 'express consent' to become an organ donor (and to state specific organs one would be willing to donate). Second, if one does not wish to become an organ donor, one can opt-out. Third, one can do nothing: in this final scenario it is presumed that a lack of action implies consent/authorisation for donation, provided certain conditions are met.

When it has been determined that life-sustaining treatment is not offering overall benefit, and it has been determined that organ donation is consistent with the patient's wishes, consideration of organ donation should become an integral part of the patient's care. The difficult ethical question is how the pursuit of organ donation should be weighed against other important considerations at the end-of-life.

Views about becoming an organ donor can vary. Some people may feel very strongly about donating and helping others may be at the core of their identity. Others may not hold strong views about donating, but nonetheless see few downsides and therefore be marginally overall in favour. When someone has a strong wish to become a donor (or in other words, when becoming an organ donor is particularly important to someone) becoming a donor can be considered to offer them significant benefit. If someone was known to be largely indifferent to donation but nonetheless had not opted out, it is likely that they had a much weaker wish to become a donor, then donation is less important to them and consequently is likely to offer less significant benefit.

4.3. 'Strength of evidence' versus 'evidence of strength'

It may be tempting to assume that someone opting-in to organ donation has a stronger wish to donate than someone who has not opted out, since they have taken positive action to record their wish. It is important to draw a distinction, however, between 'strength of evidence' of a wish to donate, and 'evidence of strength' of a wish to donate [13]. A positive action to express consent and opt-in may provide the clearest evidence of a wish to become a donor, but it does not provide definitive proof of a strong wish to donate. Similarly, in a situation where express consent may be absent and consent is deemed, this does not necessarily imply a weaker wish to donate. 'Evidence of strength' of a wish to donate may be best determined through sensitive conversation with those who know the donor best to gain a fuller understanding of a patient's values and beliefs with respect to donation.

The strength of the wish to donate, or the importance of donation to a particular patient, is a vital consideration when determining what is of overall benefit to that patient. Because the benefits and harms of particular courses of action to facilitate donation have to be weighed against the benefits and harms of donation proceeding or not, more

intrusive actions to facilitate donation may be more permissible for patients with strong wishes to become donors than those with weak wishes.

5. Resolving conflicting duties

DCD organ donation can give rise to multiple potential conflicts, which require careful consideration. The first significant potential conflict arises with the decision to WLST. This initial decision must never be made in conjunction with decisions about organ donation, or decisions about organ donation made prior to this decision. It must remain clear to patient's families and the wider public that the potential for organ donation never leads to treatment being withdrawn.

5.1. Potential for harm

A potential conflict arises if actions that might make it possible or increase the likelihood of organ donation proceeding, run the risk of causing harm to the patient. For example, organ donation may require delaying the WLST, even though it has been determined previously that life-sustaining treatment is not providing an overall benefit to the patient. Healthcare professionals have a duty to not harm their patients and continuing with interventions that are not resulting in benefit – given that there may be some burden associated with them – could be construed as harmful. Patients can be harmed in different ways, however, and these potentially different harms need to be balanced.

Some procedures run the risk of harming a patient if, for example, they are likely to cause pain and suffering or actively hasten a patient's death. Patients may also be considered harmed if their wishes are unnecessarily frustrated. Herein arises the key tension: continuing with interventions that are no longer providing benefits, may run the risk of causing harm to a patient but may be necessary to avoid frustrating the patient's wish to become an organ donor. It is unlikely that any intervention posing a risk of distress or serious harm to the patient would be considered to provide overall benefit regardless of the impact on organ donation, but other interventions may fall into a category of permissibility. Each action to facilitate donation should be considered in terms of its harms and benefits, and in light of the strength of the patient's wish to donate, to determine whether it is likely to contribute to overall benefit. This extends to interventions necessary to maximise the prospects of successful donation and/or transplantation.

5.2. Maximising prospects of successful transplantation

It is reasonable to assume that individuals who wish to donate organs, or who are presumed not to object to organ donation, wish for donation to bring benefit to others. Accordingly, the wish to be a donor is not wholly fulfilled by the removal of organs, nor by transplantation of those organs into another's body: the wish is that those donated and transplanted organs will extend, or improve the quality of the life of the recipient. Equally, recipients agree to be transplanted not to fulfil the donor's wishes but because transplantation offers them the best prospects for a longer and/or better quality of life. In this respect the wishes of recipients and donors are aligned; both wish for a successful transplantation where success is measured in terms of the survival and effective functioning of the transplanted organ.

Successful transplantation can never be guaranteed, but measures that will make this more likely include interventions undertaken before death is declared and whilst the organs are still in situ in the donor. Such measures could be perceived as generating another conflict of interest since they are interventions done to one patient to benefit another. The resolution here also turns on the strength of the donor's wishes to donate. There is a risk that if measures to improve the prospects of successful transplantation are not taken, donation will not proceed because the condition of the organs will be too poor. On the one hand, it is wrong to assume that a willingness to be a donor encompasses

anything and everything necessary for the donation to be successful. Decisions made for a patient's overall benefit, taking into account information provided by those who knew the donor best, have to be made on an intervention-by-intervention basis. A potential DCD donor remains under the protection of mental capacity legislation, and this protection is not weakened by considerations of the overall benefit to potential recipients save insofar as these are harmonious with the interests of the donor.

Potential recipients and their surgeons must make their own decisions about whether to proceed based on the quality of organs offered for donation. The potential donor is not wronged if transplantation does not proceed provided reasonable efforts have been made to facilitate their wishes compatible with the overarching duty to act for their overall benefit. Similarly, they are not wronged if there are contraindications to donation [14].

Potential organ recipients will understandably hope to secure good quality organs. For many, the quality of the organ will be a secondary consideration to the primary concern of being offered any organ while they are still well enough to benefit from transplantation. Most deceased donor organs are allocated nationally [15] and therefore the ethical implications of allocation models are the domain of the national bodies charged with keeping them under review. Recently, deceased donor kidney allocation models have, where possible, attempted to align organ quality with recipient risks. Recipients do not have to accept an organ just because it has been offered, however. Some recipients who do not require immediate transplantation may choose to balance the risks of accepting a 'higher risk' organ against the risk of waiting for a better alternative, which may or may not materialise. Permitting recipients to make these choices may come at a cost to others on the transplant waiting list in part because delays in allocating a deceased organ can increase its risk rating, and also because when potentially transplantable organs are not allocated, the waiting list, and therefore waiting time, is not reduced. Moreover, further progress in overall transplantation depends on pushing the boundaries with riskier organs and learning how to reduce and mitigate the risks.

5.3. Duties to relatives

There may also be conflict between duties to the patient and perceived duties to the patient's relatives. Although there is much ethical literature arguing against the so-called 'family veto', it has historically been the case that organ donation will not generally proceed unless family members agree. The NHSBT website makes it clear that clinicians will never proceed with organ donation if a patient's family objects [16], which potentially puts patient wishes in conflict with the wishes of their family. In some instances, this conflict may also be resolved by giving more holistic consideration to overall benefit: potentially willing donors may not wish to proceed with donation that it was going to cause distress to their relatives, in which case not going ahead with the donation better respects their wishes. This is unlikely to be universally true, however, so each case will require careful consideration of the benefits and burdens to the potential donor and their family, and the available evidence of the strength of wishes to donate.

5.4. Donation actions framework

We recommend that:

- Appropriate frameworks/guidance ('Donation Actions Framework' in England, Wales and Northern Ireland; 'Guidance on the authorisation and undertaking of pre-death procedures' in Scotland) should be used to guide decision-making regarding what actions are ethically and legally permissible in the context of DCD. (1D)

A framework has been developed to support consideration of which 'donation actions' are likely to be permissible in England, Wales and

Northern Ireland [17]. This framework defines ‘donation actions’ as “activities or interventions carried out in relation to a potential organ donor, either before or after death, for the purpose of exploring donation eligibility, facilitating deceased organ donation, increasing organ utilisation, and/or optimising transplant outcomes”. We recommend that this guidance be used to provide a systematic and structured approach to supporting decisions about what may or may be permissible in the context of DCD. Scotland has its own guidance, and we recommend that this is used in Scotland [18].

6. Use of organs for research

We recommend that:

- Further consideration is given to ethical considerations related to undertaking organ donation research, particularly in relation to consent for such activities. (1D)

Research related to organ donation can be split into two broad categories: i) research involving donated organs and ii) research involving the organ donor. The latter arguably raises more complex ethical issues than the former, particularly in cases of DCD where the donor may still be alive at the time research participation is being considered. Ethical aspects of organ donation research remain the subject of debate and are more complex than some other types of research. For example, there are multiple stakeholders to consider, including the donor, their relatives, and potential recipients. Recent literature has highlighted the need for specific guidance for research related to organ donation [19], as well as the need for further empirical work exploring appropriately context-sensitive consent models [20]. NHS Blood and Transplant provide a detailed Research Process Handbook which covers the practical aspects of undertaking research, including detailed guidance on consent requirements [21].

7. Informing the recipient

Valid consent requires that the potential transplant recipient be informed of the risks and benefits of an intervention, namely transplantation using a DCD donor organ. The NHSBT and BTS have jointly produced a Guideline for Consent for Solid Organ Transplantation [22]. This provides specific recommendations about the provision of information during patient consent and reflects the challenges that are unique to transplantation such as the diversity of risk versus benefit depending upon organ type, recipient and donor co-morbidity, timeframes for decision making, and limited organ supply. The guideline highlights key areas for consideration to facilitate consent:

- Information to be given prior to joining the transplant waiting list
- Maintaining consent while on the waiting list
- Informing patients about risk
- Patient choice and the donor organ
- Discussions at the time of an organ offer
- Information which the recipient is entitled to know about the donor
- Information which the donor family is entitled to know about the recipient

We recommend that:

- Providing information, both orally and in writing, for the potential transplant recipient is a requirement for consent and is the responsibility of the multi-disciplinary transplant team. This must be updated and reviewed annually and the outcome of discussions clearly documented in the patient's medical record. (1B)
- Information should be tailored to the requirements of the potential recipient, recognising that not all patients wish to receive detailed

information. However, this must not preclude engagement with the transplant process. (1B)

- The final risk:benefit analysis presented to the potential transplant recipient following an organ offer must explain the relative risk for that recipient of remaining on the transplant waiting list compared to that of receiving a DCD organ. (1B)

7.1. Providing information

Informing the recipient is a complex process and individual patients have different requirements for information. The method of delivery must be flexible to reflect this and is best achieved through a multi-disciplinary approach. Specialist nurses/recipient coordinators often take a lead role in providing education and support for potential recipients, but engagement across the multi-disciplinary team is vital. To augment verbal and written communication the use of visual and infographic materials may further aid consent discussions.

7.2. Consent

A two-stage consent process is advocated.

Stage one involves patient registration on the national deceased donor transplant waiting list, accompanied by oral and written information from the multidisciplinary team on the risks and benefits of transplantation. Peer support also provides a valuable opportunity to involve patients who have previously experienced transplantation in the support of those who are embarking upon the process. This complements the approach of healthcare professionals, encourages acceptance of chronic illness, and supports decision-making [22]. Best practice recommends that consent and accompanying information are updated annually for recipients who remain on the list [23].

Stage two involves confirmation of consent on admission for transplantation by the transplanting surgeon. From a legal perspective, the surgeon is held accountable for consent and there are a number of issues arising from the judgment in *Montgomery v Lanarkshire* that apply [24].

The surgeon is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments.

The test of materiality is whether in the circumstances of the particular case a reasonable person in the patient's position would be likely to attach significance to the risk or the surgeon is or should reasonably be aware that the particular patient would be likely to attach significance to it.

We suggest that:

- Final consent for transplantation of a DCD organ, where the donor type has a significant impact on expected organ outcomes, should not normally be delegated, particularly given the complexities around the discussion of alternative strategies, like waiting for another organ offer. (2D)
- Units generate consent addenda that adhere to NHSBT/BTS guidance covering risks and benefits specific to transplantation of different organ types that should include information regarding transplantation of organs from DCD donors, where the donor type has a significant impact on expected organ outcomes. (2D)

7.3. Specific considerations for the recipient of a DCD organ

The key issue for any potential transplant recipient is to understand the risks and benefits of remaining on the transplant waiting list versus those of accepting the organ on offer (as per a discussion of reasonable alternative or variant treatments).

In the context of DCD, there are organ-specific considerations relating to the type of organ that is required and the characteristics of the individual organ, and recipient considerations such as the likely

length of time to wait for an alternative organ and the risk of death while waiting (as per a discussion of material risks).

Where the donor type has a significant impact on expected organ outcomes, the risks involved from DCD organs, and the risks involved in waiting for a non-DCD organ, need to be individualised wherever possible, with data from the transplant unit being supplemented by national data where available. NHSBT offers a useful online risk assessment tool which can help both the patient and transplant clinician quantify many of the risks involved aiming to be an adjunct to decision-making [25]. It is pertinent to note that, while the risk of receiving an organ transplant is correctly highlighted in the consent process, the risk of remaining on the transplant waiting list is often significantly underestimated.

It is the responsibility of the treating clinician to obtain consent (although this may be delegated to an appropriately experienced health care professional or team) [20]. Final consent for transplantation of a DCD organ, where the donor type has a significant impact on expected organ outcomes, should not normally be delegated, particularly given the complexities around the discussion of alternative strategies, like waiting for another organ offer.

8. Discussion

Legislative changes to introduce systems of deemed consent for organ donation have made it easier to record one's wish to become an organ donor or not: doing nothing can now be presumed to indicate willingness. A patient's overall wish to become a donor needs to be considered carefully alongside a patient's wishes regarding the treatment and interventions necessary to become a donor. Since the patient will be unconscious, decisions need to be made for the patient, weighing in what is known about their wishes in relation to donation. In this updated guideline we have explained the role of 'overall benefit' in determining the right course of action for a potential organ donor and situated this in the context of the most recent UK legislative changes. Of particular importance we draw a key distinction between 'strength of evidence' and 'evidence of strength'. It is hoped that these Guidelines will harmonise practice and set the direction for further expansion of DCD organ donation and transplantation in the UK and beyond.

Declaration of Competing Interest

None.

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