

Legal and ethical implications of NICE guidance aimed at optimising organ transplantation after circulatory death

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ABSTRACT – Increasing the number of organ transplants is a priority for most governments. While potential new legislation for donor registration, such as the Welsh Government white paper on establishing an opt-out system for Welsh residents, is the focus of most ethical and legal scrutiny, there are also other approaches to increase the number of patients receiving organ transplants. The then National Institute for Health and Care Excellence (NICE) published guidance on this issue in 2011, but subsequent debate in this journal has suggested that the guidance was presumptuous and might encourage unethical practice. This paper addresses these concerns and concludes that the NICE guidance provides a legal, ethical and clinically relevant way forward in a complex and developing public health issue.

KEY WORDS: Organ donation, consent, best interests, family, ethics, NICE, decision-making, guidance, law, Mental Capacity Act 2005, Mental Health Act 2005

Introduction

Transplantation is one of the success stories of modern medicine. In 2011–12, 3,960 lives were transformed in the UK by patients receiving an organ transplant, while at the same time, over 10,000 people were still waiting for a transplant.¹ Successive governments have been committed to increasing donor numbers and to reducing the variation in practice between hospitals. In 2009, NICE was commissioned to produce guidance aimed at implementing the recommendations of the Organ Donation Taskforce² by improving donor identification and increasing consent rates. In December 2011, NICE published clinical guideline 135, *Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation*.^{3,4} In such a controversial area, there were bound to be ethical and legal questions, so in addition to the normal NICE processes of synthesis of evidence reviews and establishing an independent multidisciplinary guideline development group, including

patient involvement and public consultation on draft documents, an extra stage was added when guideline developers met legal representatives and academic legal advice was sought. Despite this comprehensive approach and general support for the guidance, serious objections to some of the recommendations and the general tenor of the guidance have been raised.⁵ This paper addresses these objections and concludes that the NICE guidance provides a legal, ethical and clinically relevant way forward in a complex and developing public and personal health area.

What are the criticisms of NICE's recommendations?

The NICE guidance consists of 13 recommendations structured around five core themes: identifying potential donors; assessing best interests; seeking consent to donation; approaching those close to the patient; and organising identification, referral, and consent processes.^{3,4} A range of concerns have been expressed about the guidance. Some have been concerned that the language of the guidance is 'manipulative',⁵ placing undue emphasis on the acquisition of the organ and having insufficient regard to the interests of the potential donor. A further concern has been that the recommendations on stabilising patients with a view to transplantation conflict with a central principle of medical ethics, that the doctor must only act in the best interests of the patient. Finally, there has been a suggestion that parts of the recommendations are 'manifestly untrue', by suggesting that relatives should be told that donation is a usual part of the end of life.

Stabilisation

At the heart of the current debate is the issue of whether it can be appropriate to stabilise the patient in order to ascertain the patient's or their legal representative's views on transplantation. Randall and Downie⁵ argue that:

(Where a patient lacks capacity) the patient's wishes around organ donation are a critical element of best interests judgements pertaining to end-of-life care, yet before those wishes are explored or known, the guideline recommends that the patient's management is significantly altered by stabilisation in a critical care unit and continuation of unlimited life-sustaining treatment that itself has been judged as no longer in the patient's best interests. The guideline's priority has become the facilitation of organ retrieval for the interests of others.

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When the patient's views are unknown at the point the patient falls unconscious, it might well be possible to determine them if the patient's life is preserved (in the unconscious state) while more information is gathered. (For instance, by gathering more information on the factors that guide a 'best interests' calculation, which are laid down in Mental Health Act 2005, s4.) This is when the question becomes whether it can be in the patient's best interests to intervene to preserve life in order to determine whether organ donation is in the best interests of the patient.

At this point, there are a range of different decisions that might have to be made. They will be different for each patient, but often include whether to stabilise the patient to determine their views (and the views of those close to them) around donation; whether to stabilise for diagnostic tests; whether to delay withdrawal of life-prolonging treatment; and whether to take preparatory steps for organ retrieval while the patient is still alive. Each must be taken in the best interests of the patient.

The NICE guidance states the following:

1.1.5. If a patient lacks capacity to make decisions about their end-of-life-care, seek to establish whether taking steps, before death, to facilitate organ donation would be in the best interests of the patient.

1.1.6. While assessing the patient's best interests clinically stabilise the patient in an appropriate critical care setting while the assessment for donation is performed – for example, an adult intensive care unit or in discussion with a regional paediatric intensive care unit (see recommendation 1.1.8).

1.1.7. Provided that delay is in the patient's overall best interests, life-sustaining treatments should not be withdrawn or limited until the patient's wishes around organ donation have been explored and the clinical potential for the patient to donate has been assessed in accordance with legal and professional guidance.

Section 1 of the Mental Capacity Act (MCA) 2005 requires that:

An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.

The law is therefore clear that any act or decision taken while the patient is alive must be in the patient's best interests.

The guidance reflects the law by making clear that a patient's best interests are paramount. Any delay in withdrawing life-sustaining treatments must be in the patient's best interests (contrary to the criticism quoted above). Any positive action to facilitate organ donation must be in the best interests of the patient.

Randall and Downie correctly state that the patient's wishes are a critical element of best-interest judgements pertaining to end-of-life care. They appear to argue that stabilisation carried out before the patient's wishes are known cannot be in that patient's best interests.

This is not the case. The Mental Capacity Act sets out various factors to be taken into account when assessing best interests. These are also listed in the guidance itself. The patient's wishes are one (extremely important) factor, but not the only factor.

The other factors to be considered are set out in section 4 of the Mental Capacity Act. They include:

(6)

- (b) *the beliefs and values that would be likely to influence his decision if he had capacity, and*
- (c) *the other factors that he would be likely to consider if he were able to do so.*

And,

(7) *..., if it is practicable and appropriate to consult them, the views of –*

- (a) *anyone named by the person as someone to be consulted on the matter in question or on matters of that kind,*
- (b) *anyone engaged in caring for the person or interested in his welfare,*
- (c) *...*
- (d) *...,*
as to what would be in the person's best interests and, in particular, as to the matters mentioned in subsection (6).

Medical professionals must consider whether it is in a patient's best interests to stabilise him or her, while assessing whether any further delay or steps to facilitate organ donation would be in the patient's best interests.

Since the purpose of any stabilisation is to allow time for ascertaining the patient's views and, if practicable, the views of those close to the patient, it is highly unlikely that medical professionals will be able to consider those factors when assessing whether the stabilisation itself is in the patient's best interests.

Whether or not such stabilisation is in the patient's best interests will depend on the particular circumstances of each case. The MCA emphasises the importance of ascertaining the patient's views, and if practicable, the views of those close to the patient when assessing a patient's best interests. This weighs in favour of stabilisation being in the patient's best interests where that stabilisation is for the purpose of ascertaining those views. This is reinforced by Department of Health guidance published in 2009, which states:

4.2 When considering decisions about treatment, the courts have established that a person's best interests are wider than simply treating their medical condition. Best interests include a person's social, emotional, cultural and religious interests...

4.3 In deciding whether actions to enhance the chance of a successful donation are in a person's best interests, it will be important to assess what their wishes and preferences would have been in relation to organ donation.

As the purpose of any stabilisation would be to enable the medical professional to obtain those views, it follows that it may be in the patient's best interests for some stabilisation to take place. It is important to remember that those who do not wish to donate are not necessarily those who do not wish to be stabilised. There may be patients who would prefer to have their views ascertained before any definitive decision on donation is made, even if that decision would be negative. Any move to encourage stabilisation is therefore not automatically unjust to those who do not wish to donate.

There will be some harm done to those who wish neither to donate nor to be stabilised. Given the legal and ethical requirements solely to consider the perspective of the individual, this is

a harm that we acknowledge but must accept. There would be a mirrored harm both to patients who would prefer their views on donation to be ascertained and to those who wish to donate if no intervention was made.

It may be that only once there has been some initial stabilisation can the factors for determining the best interests of the patient, as regards donation, be explored and properly determined. This ensures that the final decision made on donation while the patient is still alive is fully compliant with the legal and ethical frameworks, and their basis of individual autonomy.

This does involve a presumption that it is in the best interests of the patient to stabilise in the first place. It only does so to allow doctors to take advantage of the new capabilities medical technology has given, so we can now be certain that the best interests of the patient are respected as regards the more significant, invasive choice about donation and steps before death to facilitate donation. We already accept such a principle of presuming that individuals want their best interests determined in a range of situations. Blood transfusions are given to the unconscious without determining if they are Jehovah's Witnesses, so they can be stabilised and assessed for further treatment. Likewise, paramedics regularly have physical contact with unresponsive casualties without consent, on the presumption that further decisions can only be made later if the patient survives.

We therefore believe that the objective of determining the best interests of the patient can justify the intervention.

The governing law places a premium on determining, and acting upon, the desires of the patient when making a decision. The legislation and the Department of Health guidance places great importance on the wishes of the patient, although this is not conclusive. The NICE guidance therefore considers that, dependent on the wider circumstances, it can be in the best interests of the patient to take some measures to stabilise them temporarily while further information is sought. This is contrary to the opinion of Randall and Downie. It is intended precisely to explore and know the best interests of the patient, as Randall and Downie are rightly anxious to achieve. Once the patient's wishes have been established, the care team and family might then consider it in the patient's best interests to continue stabilisation for further diagnostic testing.

Communication with the patient's family

If the patient has previously made their consent to organ donation clear, and the family or representative of the patient is in agreement, then it is likely that some steps before death to facilitate organ donation will be in the patient's best interests. However, even where a patient has previously made his wishes known, his family may still oppose donation. Currently, even when the patient is entered on the register, donations do not go ahead on 45% of occasions because of relatives' opposition.⁶ While the patient's own consent is sufficient legal authority for donation, current practice generally is not to proceed if relatives do not also consent. The issue is, therefore, how to inform and discuss this sensitively with relatives, which the NICE guidance seeks to do in a balanced way.⁷

The patient's best interests – the wider ethical debate

Outside of the individualist approach taken by the legislation, there are three further ethical arguments that support NICE's approach (although the authors emphasise that the following ethical arguments are not consistent with the governing legislation, and were not factors taken into account by NICE in producing the guidance). The first is that stabilisation will often be necessary to ascertain the wishes of the patient. Surveys suggest that a majority of people (even those not on the register) wish to be a donor after death.² This indicates that, in the absence of other information, it is likely that the patient would want to donate. This further suggests that the interests of the patient will be better served by seeking further information from their loved ones. Second, the NHS is a valued institution and since its inception has been based on, and become popular due to, a concept of solidarity. It is therefore feasible that a patient would wish to donate in the collective interest and to save a life. To satisfy that collective interest might well require stabilisation. Third, (despite the current law's focus on the patient's best interests only), on a balance of the interests of the potential donor and the potential recipient, the harm to the patient is minimal compared to the potential benefits of the recipient.

Where Randall and Downie suggest that the current guidance is a breach of medical ethics, it should be remembered that public health ethics often strive for broader good at the risk of not meeting the best needs of the individual, for instance in any rationing decision. These supporting propositions, particularly the latter two, are drawing more on public health ethics than on the classical bioethical model.⁸ We concur with Randall and Downie that if you take the traditional bioethical model in its narrowest interpretation, then on those occasions when stabilisation is deemed to be in the best interests of the patient and subsequently transplantation does not proceed (for whatever reason) then some 'wrong' could be considered to have been suffered by those patients. However, the actions of the doctors would still be in line with the legislation because at the time the doctors made their decision, they were acting in the best interests of the patient.

Conclusions

It is clear that in an area as sensitive and controversial as this there is space for a range of reasonable and validly held opinions. It is therefore important to have a considered debate drawing on a variety of sources, including medical specialists, ethicists and the wider public. The present law is absolutely focused on the best interests of the patient while he or she is alive. Both the wider law and medical ethics place great value on the principle of self-determination; without the focus on the patient, an argument could be made that those who are incapacitated are valued less than others. Such an argument would need strong public approval to become policy. However, there are also a number of ethical considerations that need to be taken into account. It is clear that there is a wide gap between public support for organ donation and the level of registration as a potential donor; this is one of the main arguments for an 'opt-out' system.⁹ Furthermore, we propose that the balance between the potential harm to the patient and their family

(who may not wish to see their loved one undergoing further medical procedures when death is inevitable) and the potential benefits to someone who requires a donated organ to continue living is weighted in favour of the recipient.

It is inevitable that commentators coming from differing perspectives, such as palliative care doctors, transplant surgeons, relatives of donors, and recipients of successful transplants and their relatives, will have legitimately differing views of the situation, and perhaps differing concerns over any potential for over- (and under-) emphasis of legal permissions. By giving the referral to NICE to issue guidance to improve donor identification and consent rates for deceased organ donation, it was the Department of Health (and not NICE) that deemed this activity to be a priority for the NHS. NICE's role was to set out an ethical application of the legal position. Medical professionals must take decisions about organ donation as quickly and as sympathetically as possible, for the sake of the patient, the family of the patient and the lives which may be saved. It is reassuring that on 11 April this year, the NHS Blood and Transplant announced that 3,100 lives were transformed by deceased donors in the past 12 months, which means that the NHS achieved the 50% increase in deceased organ donation that was set by the Organ Donation Taskforce in 2008.²

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References

- 1 NHS Blood and transplant. Transplants save lives, 2013. www.organdonation.nhs.uk/newsroom/fact_sheets/transplants_save_lives.asp [Accessed 5 June 2013].
- 2 Department of Health. Organs for transplants: a report from the organ donation taskforce. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf [Accessed 5 June 2013].
- 3 National Institute for Health and Care Excellence. Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation. NICE Guideline 135, December 2011. www.nice.org.uk/nicemedia/live/13628/57502/57502.pdf [Accessed 5 June 2013].
- 4 Chamberlain K, Baker MR, Kandaswamy P, *et al.*; Guideline Development Group. Donor identification and consent for deceased organ donation: summary of NICE guidance. *BMJ* 2012;344:e341.
- 5 Randall F, Downie R. Misguided presumption; British Medical Association (BMA) and National Institute for Health and Care Excellence (NICE) guidance on organ retrieval and 'opt out' or 'presumed consent'. *Clin Med* 2012;12:513–6.
- 6 Hodgson H. A difficult dilemma. *Clin Med* 2012;12:499–500.
- 7 Neuberger J. BMA and NICE guidance on organ retrieval: neither misguided nor presumptuous. *Clin Med* 2012;12: 517–9.
- 8 Roberts MJ, Reich MR. Ethical analysis in public health. *Lancet* 2002;359:1055–9.
- 9 Welsh Government. *Proposals for legislation on organ and tissue donation: A Welsh Government white paper*. Cardiff: Welsh Government, 2011. <http://wales.gov.uk/docs/dhss/consultation/111107orgdonwpn.pdf> [Accessed 5 June 2013].

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