

Misguided presumptions: British Medical Association (BMA) and National Institute for Health and Clinical Excellence (NICE) guidance on organ retrieval and ‘opt out’ or ‘presumed consent’

Fiona Randall and Robin Downie

ABSTRACT – Three documents have been produced in an attempt to increase the number of organs available for transplant: a National Institute for Health and Clinical Excellence (NICE) clinical guideline, a British Medical Association (BMA) report and a Welsh Government white paper. All three are ethically flawed: NICE and the BMA recommend that whenever there is intention to withdraw life-sustaining treatment and death is expected, patients should instead be stabilised to assess for donation. This is contrary to patients’ best interests, the principles of mental capacity legislation and current criteria for accessing intensive care units. Regarding consent, the BMA and Welsh Government recommend an ‘opt-out’ policy, but consent in law requires information and cannot be ‘presumed’ or ‘deemed’ on the basis of failure to express or register ‘opting out’. The language of all three proposals is manipulative, and patient trust may be undermined because the doctor’s attention must move from the interests of the patient to those of the unknown organ recipients.

KEY WORDS: end-of-life care, opt out, organ donation, presumed consent, deemed consent

In an attempt to reduce the shortfall between the number of solid organs available for transplant and the number of potential recipients, the National Institute for Health and Clinical Excellence (NICE) recently issued a clinical guideline¹ (based on the Organ Donation Taskforce’s report²) with the aim of increasing the number of organs available. This guideline and the recent British Medical Association (BMA) report on organ donation policy³ give recommendations regarding the management of patients who are expected to undergo cardiorespiratory arrest following planned withdrawal of life-sustaining treatment, with the aim of enabling potential retrieval of their organs after death. Furthermore, the guideline aims to make organ donation a ‘usual part of end of life care’. Contemporaneously, the Welsh Government, via a white paper,⁴ and the BMA report have both proposed a change to an ‘opt-out’ policy, whereby the patient’s consent to organ retrieval is ‘presumed’ unless there is evidence to the contrary.

It is our contention that the NICE guideline¹ and the proposed ‘opt-out’ policy^{3,4} together constitute significant changes

in medical ethics. The World Medical Association, expressed in the Declaration of Geneva,⁵ states: ‘The health of my patient will be my first consideration’, hence the imperative to act in the best interests of our patients. However, the new proposals encourage the doctor to focus instead on the wider population of those who might benefit from an organ retrieved from the doctor’s patient. The guideline and proposed policy retain the traditional terminology of serving ‘the best interests of the patient’ while focusing on the interests of potential organ recipients. We point out the several inconsistencies involved in this, including its incompatibility with the principles of the Mental Capacity Act, with the criteria for accessing intensive care units and with current recommendations for good care in the last days of life. Furthermore, we note that the guideline is written in manipulative language, when we might expect a balanced presentation.

Care of the dying

The NICE guideline promotes organ retrieval from patients after cardiac death following the planned withdrawal of life-sustaining treatment.¹ The BMA in its report on organ donation policy describes ‘donation after cardiac death’ or ‘DCD donors’ as ‘patients in whom treatment has been withdrawn following a clinical decision that attempts to prolong life are no longer able to achieve any therapeutic goal and are not, therefore, in the patient’s best interests.’³ The BMA notes that such donations constitute 37% of all deceased donations.

In this context, many patients will lack mental capacity for decisions around treatment withdrawal and end-of-life care, so the basis of decisions made on their behalf must be their own best interests.⁶ Contrary to this ethical and legal imperative, the NICE guideline’s flowchart advises that:¹

Whenever there is intention to withdraw life-sustaining treatment and death is expected to follow such withdrawal, discussions should be initiated with the specialist nurse for organ donation; doctors should ‘clinically stabilise the patient in an appropriate critical care setting’ to enable ‘assessment for donation’ [and then] ‘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.’

In this situation, the patient’s wishes around organ donation are a critical element of best interests judgements pertaining to

Fiona Randall, consultant in palliative medicine; Robin Downie, emeritus professor of moral philosophy and professorial research fellow

¹Isle of Wight NHS Trust; ²Glasgow University

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.

The BMA's report states that mental capacity legislation 'provides the legal justification for taking some steps before death to facilitate donation, where it is known the individual wished to donate organs'.³ However, the BMA report³ and NICE guideline¹ both promote the taking of 'minimum steps' before the patient's wishes are known. They do not provide ethical or legal justification for this practice.

Furthermore, transfer to a critical care unit followed by deliberate delay in withdrawing treatment judged to be no longer in the patient's interests do not constitute 'minimum steps'. In an editorial in the *BMJ*, consultants in intensive care note that 'stabilisation' would probably involve 'the insertion of multiple cannulae for drug and fluid infusions to maintain circulation, tracheal intubation for mechanical ventilation, and sedation to allow the patient to tolerate these interventions'.⁷ These are not 'minimum steps'. The BMA wants to open debate on such elective ventilation, but the position has already been made clear by the intensivists, who note that patients with untreatable or rapidly lethal conditions are currently not admitted to, or treated on, intensive care units because such management prolongs dying and may result in harm. Moreover, Fullerton and Perkins have also argued that the use of scarce intensive care unit resources for speculative organ retrieval is ethically problematic, as it conflicts with the prioritisation of patients according to likelihood of recovery.⁸

The BMA, referring to the Organ Donation Taskforce's report,² makes it clear that all clinical areas that provide end-of-life care should be included in these measures, specifically naming emergency departments, acute stroke units, medical assessment units and general medical wards.³ In contrast, national policy on end-of-life care,⁹ including some pertinent NICE guidance from 2004,¹⁰ recommends following a care-of-the-dying pathway and that death (where possible) should occur in the patient's preferred location. Now, however, NICE and the BMA stipulate that when there may be potential for organ retrieval, patients should be treated in certain ways in critical care,^{1,3} heavily influencing the timing and location of their death before their wishes around donation or potential to donate are known. These steps are to be taken despite the BMA's acknowledgement that organ usage for transplant will probably be impossible in about 43% of potential DCD donors because of an extended period between withdrawal of treatment and death. It is not clear how NICE can promote the Liverpool Care Pathway for the dying¹¹ and preferred location of death while its guideline promotes organ retrieval via intensive treatment unit care and clinical practice that deliberately 'prolongs dying'.¹

Consent

When patients retain capacity to make their own decisions, the NICE guideline instructs doctors to 'obtain their views on, and consent to, organ donation'.¹ Although views and consent may be sought, the peremptory language from NICE that both must be 'obtained' sounds coercive towards patients in a very vulnerable situation. Moreover, it is disappointing to note that nowhere in the NICE guideline¹ or BMA report³ is there mention of informing patients and the public about the change to their own pre-death care that organ retrieval following cardiac death would make. Writers of the *BMJ*'s editorial noted the paucity of publicly available information on the processes involved in facilitating organ retrieval after cardiac death.⁷

'Opt-out' policies

The BMA and Welsh Government support 'opt out with safeguards' or 'soft opt-out' policies, respectively.^{3,4} It follows from opt-out policies that consent to organ retrieval will be 'presumed' unless the patient signs an opt-out register or the family provides evidence of the patient's prior expression of opposition to organ donation. Patient consent is a central tenet of medical law and ethics; to be valid it requires adequate detailed information to be provided contemporaneously to and understood by the individual. However, these conditions are not met by an opt-out system. Not signing an opt-out register is hardly a valid ground for any kind of presumption, especially in the absence of a widespread and effective public information initiative describing the actual processes involved in organ retrieval. The failure of proponents of the 'opt-out' system to call for such a public information initiative suggests reluctance to inform potential donors of the effects on both their own care and the experience of their families.

Manipulative language

It is not surprising that the Welsh Government's white paper⁴ is presented with the enthusiasm of a political initiative, but it is surprising to note the all-pervasive manipulative language of the NICE guideline,¹ in which it would be reasonable to expect a more balanced presentation. For example, organ retrieval is consistently referred to as 'donation', even where there is no explicit knowledge of the patient's wishes. If you sign the organ donor register or carry the donor card you are certainly to be praised as a donor, but you are not a 'donor' if the state indicates it will harvest your organs without your explicit informed agreement or manipulates you (or your relatives) into agreeing to the procedure. Indeed, the attitudes displayed by NICE,¹ the BMA,³ and the Welsh Government⁴ may, in fact, discourage genuine donation.

Furthermore, NICE actually recommends the use of manipulative language in trying to gain consent from the relatives, advising clinicians to 'Use positive ways to describe donation'.¹ Surely the doctor seeking 'consent' from relatives should be

giving unbiased and balanced information. If the matter was, for example, palliative chemotherapy, it would not be ethically acceptable to use only 'positive ways' to describe it. Screening mammography services have been criticised recently as having 'let women down, simply by not providing them with the well argued evidence based information they have every right to expect'.¹²

More seriously, NICE actually recommends that relatives are told things that are manifestly untrue: 'Explain that donation is a usual part of end-of-life care',¹ when it just isn't! Moreover, for the majority of dying patients it can never be, since, as the BMA acknowledges, 'people who die at home or at the scene of an accident, or even on a general ward in hospital, are most unlikely to be able to donate solid organs'.³ It would not be considered ethically acceptable to provide patients with false information for their own benefit (perhaps to 'give them hope'), yet NICE is recommending giving false information for the benefit of potential organ recipients.

In addition, NICE instructs doctors to provide relatives 'assurance that the primary focus is on the care and dignity of the patient (whether donation occurs or not)'.¹ However, this is false assurance, as this guideline explicitly directs the doctor's focus away from the patient and instead to the retrieval of organs for potential recipients.

A striking but different example of tendentious language occurs in the summary of the NICE guideline published in the *BMJ*.¹³ The opening paragraph states: 'Currently about 500 people in the United Kingdom die each year because of a shortage of donated organs'. This implies an ethical imperative to increase the donation rate, but if the cause (that is, sufficient condition) of death in 500 people is a shortage of donated organs, their death certificates should list as cause of death 'shortage of donated organ'. This is patently absurd. The same paragraph claims that the shortage is partly 'the result of inefficiencies in the donor identification and consent process'. There may well be inefficiencies in donor identification, but to speak of 'inefficiency' in the 'consent process' is a distortion of the ethical significance of consent.

Consent to organ donation should be freely given on the basis of adequate, truthful and balanced information and not extracted by language designed to manipulate both doctor and patient. Respect for patients' or their relatives' autonomy and dignity are now fundamental to medical ethics; both are undermined by manipulative language.

Culture and social attitudes to the body

A widespread attitude that crosses geographical areas and historical periods is that the body is neither garbage requiring disposal nor a commodity – and neither is it just a source of organs for transplant. This attitude is fundamental to the human psyche and does not depend on religious belief. It is standard in medical ethics to maintain that autonomy must be respected, but the human body must also be treated with respect. This attitude was evidenced by the outrage felt by the parents of children whose

organs were retained after autopsy at the Royal Liverpool Children's Hospital.¹⁴ Quite apart from inadequacies in the consent process, the parents expressed a desire to have their children's organs returned and buried with them. Respect for the body is also seen in the desire for repatriation of the bodies of soldiers killed in conflict. This deeply held attitude is universal and may partly explain the discrepancy between public professions of support for the donation of organs for transplant and the reluctance of many people to join the organ donor register and of their relatives to authorise organ retrieval. In scenarios involving cardiac death, relatives refused organ retrieval in 49% of cases. In view of these cultural attitudes, guidelines designed to improve organ retrieval rates must be honest and sensitive.

Conclusions

Future implementation of the NICE guideline and BMA report,^{1,3} possibly including a change to an opt-out policy, would have radical implications for patient care. Currently, if life-sustaining treatment is withdrawn following a best interests judgement, a patient would normally be expected to die peacefully in the ward or at home (with family in attendance). However, according to the NICE and BMA recommendations,^{1,3} the patient should be moved to the intensive care unit to have (unlimited) treatment continued until such time as suitability for organ retrieval and willingness to 'donate' (including searching an opt-out register) had been determined. This scenario would radically alter the way a significant number of people die.

Our main criticism of the NICE and BMA recommendations^{1,3} is that they conflict with central principles of ethics: that the interests of the patient should be the doctor's first consideration and that adequate and honest information should be provided. The recommendations also seem to conflict with legislation governing decision making for patients who lack capacity, with criteria for access to intensive care units and with other guidance on end-of-life care. In different ways they shift the focus of the doctor's attention from the overall benefit of their identifiable patient to the interests of possible recipients of that patient's organs. No doubt the hope of these organisations is to benefit organ recipients, but implementation of their recommendations may undermine the trust that patients have in their doctors, and undermining trust ultimately is not conducive to increasing organ donation and retrieval.

References

- 1 National Institute for Health and Clinical Excellence. *Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation*. Manchester: NICE, 2011. www.nice.org.uk/guidance/CG135 [Accessed 6 October 2012].
- 2 Organ Donation Taskforce. *Organs for transplants: a report from the Organ Donation Taskforce*. London: Department of Health, 2008.
- 3 British Medical Association. *Building on progress: where next for organ donation policy in the UK?* London: BMA, 2012.
- 4 Welsh Government. *Proposals for legislation on organ and tissue donation: a Welsh Government white paper*. Cardiff: Welsh Government, 2011.

- 5 World Medical Association. WMA declaration of Geneva. www.wma.net/en/30publications/10policies/g1/ [Accessed 6 October 2012].
- 6 UK Government. *Mental Capacity Act 2005*. London: Stationery Office, 2005.
- 7 Watkinson P, McKechnie S, Wilkinson D *et al*. Actively delaying death to increase organ donation. *BMJ* 2012;344:e1179.
- 8 Fullerton JN, Perkins GD. Who to admit to intensive care? *Clin Med* 2011;11:601–4.
- 9 Department of Health. *End of life care strategy*. London: Department of Health, 2008: 53–54, 64–66.
- 10 National Institute for Health and Clinical Excellence. *Improving supportive and palliative care for adults with cancer*. London: NICE, 2004:118–119.
- 11 Marie Curie Palliative Care Institute. *Liverpool care pathway for the dying patient (LCP)*. Liverpool: Marie Curie Palliative Care Institute, 2012.
- 12 McPherson K. How we got it wrong with breast cancer screening. *BMJ* 2012;344:e3450.
- 13 Chamberlain K, Baker MR, Kandaswamy P *et al*. Donor identification and consent for deceased organ donation: summary of NICE guidance. *BMJ* 2012;344:e341.
- 14 Royal Liverpool Children's Hospital Inquiry Committee. *Royal Liverpool Children's Hospital inquiry report*. London: Stationery Office, 2001.

**Address for correspondence: Dr F Randall, Earl Mountbatten Hospice, Halberry Lane, Newport, Isle of Wight, PO30 2ER.
Email: fiona.randall@iow.nhs.uk**

Books

RCP history and heritage series

Founded in 1518, the Royal College of Physicians is the oldest medical college in England, and has built up its collection of books, manuscripts and portraits over almost five centuries. The history and heritage series of monographs are written by doctors and others interested in the history of medicine, and serve to illustrate significant aspects of the RCP's past and its collections.

Sir Clifford Allbutt: scholar and physician by Alexander G Bearn

Sir Clifford Allbutt was an immensely influential physician and scholar. As well as playing a prominent role within the RCP he was a founding member of the Medical Research Council and became president of the BMA.

Allbutt was not only the inventor of the short clinical thermometer, he was also responsible for the introduction of the ophthalmoscope, weighing machine and microscope to the wards. His investigations led to improved treatment of arterial disease.

This monograph is a celebration of a man who, more than 80 years after his death, remains an example of an outstanding professor of medicine and an advocate for science. ■

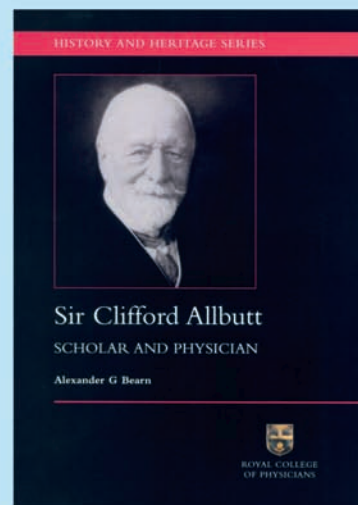
Published: March 2007 ISBN: 978 186016 302 9

Price: £10 UK, £12 overseas (inc post and packing)

To order: Tel: +44 (0)20 3075 1358 (8.30am – 4.30pm)

Online: <http://bookshop.rcplondon.ac.uk>

Email: publications@rcplondon.ac.uk



**Royal College
of Physicians**

10% discount for fellows and members

Quote the reference *Clinical Medicine* when making your order