

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Give and take? Human bodies in medicine and research between April 2010 and July 2010. The views expressed are solely those of the respondent(s) and not those of the Council.

Sue Rabbitt Roff

Two years ago a BMJ editorial (BMJ 2008:336 14 June 2008) asked "In the spirit of evidence based policy making, is it time to pilot payment of donors by the state within a strictly regulated and geographically limited system?" Now the Nuffield Council on Bioethics is conducting a public consultation around what sort of incentives are ethically acceptable to increase live kidney or liver transplants at a time when donation rates are at best plateaued while the waiting lists in the UK continue to increase. The terms of reference of the Nuffield Working Party revolve around issues of payment, consent and ownership. We would have to resolve these issues both ethically and legally in order to create the framework or 'moral economy' for an 'official market' in body tissues, fluids and organs in a country such as the UK.

This new moral economy will come from two sources – a refinement of the principles that already exist, and the social construction through consultations such as the Nuffield initiative that are incorporated into law. But it will also involve some 'thinking beyond the present paradigms' as both medical science and public opinion evolve in the 21st century.

The present submission considers some of the issues to be addressed in both living donation and deceased donation.

1. *Whose Kidney is it Anyway? – developing the legal basis for ownership of body parts in order for them to be fungible by living donors*

We now permit 'stranger' donations of live kidneys to recipients who are unknown to the donor and have no emotional connection to them. Kidney transplants are increasingly 'pre-emptive' to improve the quality of life of the recipient *before* the onset of end stage renal disease. One patient may need two or three such transplants which of course increases the demand. There are recurring calls for 'presumed consent' – the weakest form of consent - in an 'opt out' system for deceased or dying donors. But the long term outcome for poorly matched living kidney donation is still better than that for highly favourable matching cadaveric donation.

As one of my undergraduate medical students commented in a course on transplant ethics for the 21st century, "The leading argument for this is that a market already exists." And that was before it was reported that the organs of 50 NHS donors have been transplanted into foreign patients in a two year period in operations in private hospitals costing about £75,000 each. I have outlined ¹ the several types

¹ BMJ 2006:331:51

of regulated, legally sanctioned market models that are being practised for the sale of blood and gametes or the compensation tariffs for limb, eye or organ injuries which draw on long-standing trading practices².

But there are curious inconsistencies in these models and practices around the notions of *ownership* and *consent* that have constrained us from extending market practices such as payment to live kidney or liver slice provision.

It is commonly said that in common law Britons do not own their bodies. However in a recent judgment in the Court of Appeal (Yearworth and Ors v. North Bristol NHS Trust [2009] EWCA Civ 37 Lord Judge, the lord chief justice, concluded that “developments in medical science now require a re-analysis of the common law’s treatment of and approach to the issue of ownership of parts or products of a living human body...” He found that sperm that had perished in the care of the Trust was property owned by the men who had sought to store it for future procreation after chemotherapy.

Lord Judge notes that he could have relied on the longstanding principle that the application of skill and work to human materials creates a property which can be owned (for instance in the creation of anatomy specimens for teaching such that anyone who steals them can be prosecuted for theft). But he chose to develop the connection between the *consent* the men gave for the storage of their sperm, which included their capacity to withdraw consent from the holding of the material, and their *ownership* of the sperm as *property*. The Human Fertilisation and Embryology Act 1990 “recognizes in the men a fundamental feature of ownership, namely that at any time they can require the destruction of the sperm.”

Two interesting possibilities arise from this reasoning for the provision of kidneys and liver slices by live vendors. On the one hand could not the notion of ownership in ‘worked with skill’ material be applicable to these organs since their viability depends on a great deal of skill in maintaining perfusion etc until the time of transplantation? As Pattinson has commented³, at present the law in the UK “seems to be more willing to recognize the property rights of those who manipulate and derive products from human tissue, than of the source of that tissue..”

Secondly, if the lord chief justice considers that ownership rests in the capacity to consent and withdraw consent do we not need to look very closely at the notions of *autonomy* that allow us to not only encourage but positively solicit donation from healthy individuals? We consider that donors are exercising their autonomy to consent to invasive non-therapeutic treatment. Such a donation is supererogatory to the tenets of every major religion. As Matas⁴ has pointed out:

² *Discourse* 2008:7;2: 187-206

³ Medical Law and Ethics Second Edition 2009 Sweet and Maxwell Thomas Reuters (Legal) Limited p.492

⁴ *BMJ* 2008 p.1342

“We accept living donation: thus, to be successful, arguments [against vending] must differentiate compensated from conventional living donation, which many fail to do.” What in fact happens is that the discourse of *autonomy* turns into one of *exploitation* – whereas autonomy is celebrated in the donor, the vendor is viewed as highly likely to be exploited.

The medico-legal ethicist Shaun D. Pattinson argues that “all five groups of moral theories are *potentially* compatible with acceptance of a *regulated, voluntary system* of commercial dealing in human tissues and organs.” [emphases in original] (p488) We need to explore this in order to construct a new moral economy of transplant ethics for the twenty first century.

As Aldous Huxley wrote in Antic Hay 90 years ago:

The kidneys are so beautifully organized; they do their work of regulation with such a miraculous – it’s hard to find another word – such a positively divine precision, such knowledge and wisdom, that there’s no reason why your archetypal man, whoever he is, or anyone else, for that matter, should be ashamed of owning a pair.”

2. Strengthening and clarifying the ‘opt-in pathway’ for deceased organ and tissue donation

Although donations after brain death remain the ‘gold standard’ for organ donation because they are the only source of viable hearts for transplantation and provide better livers, donors after cardiac/respiratory death are an increasingly important source for kidneys in particular.⁵ Cardiac/respiratory deaths now account for 10% of deceased organ donors in the US, up from 1% a decade ago. Donors after cardiac/respiratory death in the UK have doubled in the last three years and now constitute a third of deceased donors. Brain death donors have declined in recent years in the UK.

The USA, the UK, Spain, the Netherlands, Switzerland and Japan are among the countries that have begun to turn back to what used to be known as ‘non-heart beating donors’ to help redress the shortage. It is estimated that they could be central to eliminating the waiting list in Canada within five to ten years. UK Transplant reported a 20% increase in kidney transplants from NHB donors in the year to March 2005, within an overall decline of cadaveric donations.⁶

⁵ *Working Together to save lives* The Organ Donation Taskforce Implementation Programmes’ Annual Report 2008/09. Department of Health. P.19

⁶ UK Transplant Statistics at <http://www.uktransplant.org.uk/ukt/statistics/statistics/jsp>

But donors are an infinitesimal percentage - 0.17% in the UK and 0.33% in the USA - of the half million people who die in the UK each year or the two and a half million who die in the USA annually. According to the US Scientific Registry of Transplant Recipients in 2005 when there were about 90,000 people on the organ transplant waiting list, there were 13,091 individuals who died under the age of 70 using cardiac and brain death criteria and who were eligible to become organ donors. Of these, only 58% or 7,593 were actual donors who provided just over 23,000 organs.⁷

Less than a decade ago two UK live transplant surgeons distinguished between retrieval of organs from patients who had died from cardiac arrest and those who had been declared 'brain dead' by explaining:⁸

"The fundamental distinction between non-heart-beating donors and conventional heart beating donors is the diagnosis of death. In a non-heart beating donor diagnosis is by cardiac criteria, whereas in a heart beating donor diagnosis is by brain stem criteria. The beating heart donor is always ventilated before death and the heart remains beating at the time of retrieval, thus virtually eliminating any warm ischaemic injury to donor organs. With a non-heart beating donor (in controlled circumstances) the organs are retrieved after a 'stand off' period of five minutes during which death is certified. The organs are therefore subjected to a variable period of warm ischaemia, which is detrimental to outcome and predisposes to delayed graft function or at worst to complete non-functioning of the graft."

But this distinction has been overtaken by new techniques in the preparation of organs for transplantation prior to either form of death.

The Academy of Medical Royal Colleges issued a Code of Practice on the diagnosis of death in October 2008. This describes the manner in which death may be diagnosed on the basis of neurological criteria (often shortened to "brain stem death" or "brain death") or on the basis of irreversible cardio-respiratory arrest (sometimes called cardiac or circulatory death). These terms define the manner in which death is diagnosed. If organ donation follows death it will be different depending on the manner by which death has been diagnosed. Death by neurological criteria is diagnosed whilst the heart is still beating - hence the (old) term "heartbeating donation". Death after cardio-respiratory arrest occurs, by definition, after the heart stops beating - hence the (old) term "non-heartbeating donation". Increasingly the terms "Donation after Brain Death" and "Donation after Cardiac (or Circulatory) Death" are being used internationally."

⁷ Prefatory Note to the Revised Uniform Anatomical Gift Act (2006) USA www.optn.org

⁸ *British Medical Journal* in 2006 (332.p377)

But in recent years it has been realised that the time limits on the viability of material from NHB donors can be greatly extended by delaying the process of dying “with manoeuvres which are of no utility for the patient but which greatly help others.”⁹ These interventions as death approaches increasingly blur the distinction between brain and cardiac/respiratory causes of death. There is also now a very active debate¹⁰ about the nature of the dying process, the point at which dying becomes irreversible, and some considerable disquiet about the ‘bringing forward’ of the retrieval processes into earlier stages of the dying process.

There needs to be a full public debate and education programme about these issues so that we can make informed choices for ourselves and our loved ones *before* if possible a decision to donate has to be made *in extremis*. It has to be a very honest discussion about the actual procedures that take place, and when. Many people will be able to accept them; many people won’t. But one major reason for relative refusal is probably the shock of having to understand and commit to such procedures at highly stressful points in a loved one’s illness.

It should be noted that the new guidance on *Legal issues relevant to non-heartbeating organ donation* issued by the Department of Health in November 2009 seems very confused on the nature of NHBD. For instance at 1.3 it states “In the UK, NHBD takes place most commonly when death, established following the irreversible cessation of the heart, follows the withdrawal of life-sustaining cardiorespiratory support...” yet at 1.4 “People who are potential non-heartbeating donors will almost always lack the capacity to make their own treatment decisions because they will have had a catastrophic brain injury and are likely to be unconscious” (also at 3.2)

The public debate might begin with examination of the actual ‘opt in pathway’, going beyond the narrow ‘opt out/opt in’ construction into a fully transparent education about the process. It might well be centred on a consideration of the ‘presumption of donation intent’ as mandated in the USA.

In the USA the Uniform Anatomical Gift Act (2006) (UAGA) was revised in 2009 (Revised UAGA) to permit the use of life support systems at or near death for the purpose of maximizing procurement opportunities of organs for transplantation even though the procedures to maintain perfusion of transplantable organs is held by some to challenge the Patient Self Determination Act (PSDA) which provides for advance care directives including the refusal to accept life support systems at end-of-life. “The challenges are predicated on the UAGA revising the default choice to *presumption of donation intent* and the use of life support systems to ensure medical suitability of organs for transplantation. The default choice trumps the

⁹ Zamperetti N, Bellomo R and Como (2003) Defining death in non-heart beating organ donors. *Journal of Medical Ethics* 29:182-185.

¹⁰ See for example the writings of Kerridge, Zamperetti, Truog, Veatch and Bernat over the past decade.

expressed intent in an individual's advanced care directive to withhold and/or withdraw life support systems at the end-of-life".¹¹

Since January 2007 federal regulations require Medicare-approved hospitals to design policies and procedures for donation after cardiac death from patients or at near death. "In effect, a patient on life support systems at the end-of-life (and without signed refusal [to donate]) is defaulted to the presumption of intent to donate organs, and therefore life support systems cannot be withdrawn until the OPO's (Organ Procurement Organisation) evaluation for organ donation is complete. The OPO can then determine that the patient *is* a prospective donor."¹² Then "measures necessary to ensure the medical suitability of an organ for transplantation may not be withheld or withdrawn. The initiation and/or continuation of life support systems is the default rule and overrides a prospective donor's expression in an advance health care directive not to have life prolonged by life support systems."¹³

The Revised UAGA (2006) requires a prospective donor to expressly provide *contrary intent* to prevent the use of life support systems for organ donation purposes. Even its critics accept that this is not presumed consent. As the National Conference of Commissioners on Uniform State Laws point out in their preamble to their recommendation to states to approve the Revised UAGA (2006) "This revision retains the basic policy of the 1968 and 1987 anatomical gift acts by retaining and *strengthening* the 'opt-in' system that honors the free choice of an individual to donate the individual's organ (a process known in the organ transplant community as 'first person consent' or 'donor designation')."¹⁴

In essence, the Revised UAGA (2006) recognises that at a certain point the medical team will "subordinate care of the patient to care of the organ"¹⁵ but only until intention to donate is confirmed or ruled out.

The UK Organ Donation Taskforce Programme Delivery Board has instituted clinical leads in hospital trusts, together with more Donor Transplant Coordinators and enhanced financial provisions for transplant operation costs.¹⁶ In order to achieve their vision of making donation "a usual and integral part of our health service culture" and "a usual rather than unusual event as part of end-of-life care across

¹¹ Verheidje JL, Tady MY and McGregor JL. (2007) The United States Revised Uniform Anatomical Gift Act (2006): New challenges to balancing patient rights and physician responsibilities. *Philosophy, Ethics, and Humanities in Medicine*. 2:19 doi:10.1186/1747-5341-2-19) emphasis in original.

¹² Op cit

¹³ ibid

¹⁴ At <http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63> Emphasis added.

¹⁵ DeVita MA and Caplan AL (2007) Caring for Organs or for Patients? Ethical Concerns about the Uniform Anatomical Gift Act (2006). *Ann Intern Med* 147:876-9, p.878

¹⁶ *Working Together to save lives* The Organ Donation Taskforce Implementation Programmes' Annual Report 2008/09. Department of Health.

the NHS" should we not look to strengthen what we might call our "opt-in pathway" by

- Instituting 'mandated choice' which as advocated by the Royal College of Physicians of Edinburgh would *require* 'all adults to express their wishes regarding use of their organs, for example through the electoral roll or when registering with a general practice. This choice would be to consent to, or refuse, use of organs after death for transplantation, or to refuse to be registered, or to leave the choice to the family'.¹⁷
- Establishing willingness to donate in tandem with Do Not Attempt Resuscitation Orders which are now routine in UK hospitals.
- Extending the Human Tissues Acts to clarify and give substance to the Department of Health guidance on 'Legal issues relevant to non-heartbeating organ donation' (November 2009) in ways similar to the US Revised UAGA (2006).
- Publicising the new capacity to direct allocation of one's organs or tissues to family members or close friends that was mandated in March, 2010.¹⁸

There would of course need to be a major education campaign to help Britain's adults to make their decisions but we need to extend, clarify and co-ordinate the 'opt-in pathway' far beyond a donor register to help individuals, their loved ones - AND NHS staff - maximise the possibilities of fully informed consent to organ and tissue donation.

¹⁷ RCP Edinburgh Response to Organ Donation taskforce 'Opt-out system of consent for organ donation'. 31 July 2008. <http://www.rcpe.ac.uk/2008/opt-out.php>

¹⁸ Department of Health. Requested allocation of a deceased organ donor. 29 March 2010. <http://www.dh.gov.uk/en/Publications> and statistics/Publications