

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.

British Transplantation Society

Response to Nuffield Council on Bioethics Consultation Paper

Give and Take?

Human Bodies in Medicine and Research

The key aim of the British Transplantation Society (BTS) is to advance the study of the biological and clinical problems of tissue and organ transplantation, to facilitate contact between persons interested in transplantation, and to make new knowledge available to any person for the general good of the community. The Society may also concern itself with the social implications of transplantation. The Society's membership is multi-disciplinary. It includes clinicians from a wide range of specialties, basic scientists, scientists working in Histocompatibility and Immunogenetics, nurses, donor coordinators, professions allied to medicine and ethicists.

The overall vision of the BTS is to be the national professional voice of transplantation, representing all the disciplines of the transplantation community and developing scientific, clinical and ethical practice for the benefit of patients. This vision is supported by four strategic objectives:

1. To influence personal and political opinion and operational strategy regarding transplantation issues;
2. To promote professional standards and ethics across the multi-disciplinary transplantation community;
3. To contribute to the development of transplantation, and integral associated services;
4. To support scientific and clinical research relevant to the practice of transplantation.

The BTS welcomes the opportunity to respond to this consultation paper on human bodies in medicine and research. Advances in science, medicine and biotechnology mean that human bodies and parts thereof may be used in an ever increasing range of clinical and research applications and that, as a result, demand for the donation of such material has increased considerably. In some instances demand has outstripped supply. The shortage of organs available for clinical transplantation is one example. We understand that the intention of this consultation paper is to explore the ways in which society might appropriately respond to this demand and in particular to consider what limits there should be, if any, on the promotion of donation or volunteering, including examination of whether the use of inducements

are, or can ever be, legitimate; the role of consent; ownership and control of donated materials; the role of those acting as intermediaries between donors and recipients; and cultural and international perspectives.

The remit of this consultation paper is broad and encompasses issues related to the uses of donated human material that are currently regulated by three different authorities. We realise that these authorities appear to have adopted different approaches to the matter of donation and volunteering, perhaps in response to different demands and governing statutes, and appreciate that the intention of the working party is to consider whether the existing regulatory differences can be justified. We have chosen to respond primarily with reference to issues that affect the donation of organs and tissue for clinical transplantation and we would be happy to expand upon any of the points made in this response. However we would also like to acknowledge that to date, medical research in the field of transplantation has yielded significant advances in our understanding of transplant biology. Moreover, ongoing basic scientific and clinical research in the field hold much promise for refining current immunosuppression (anti-rejection treatment) protocols and improving transplant outcomes. We would like to emphasise the need to continue research in this evolving field.

General Comments and Response to Selected Consultation Questions

Section 1: Nature of human bodily material and first-in-human trials

Question 1: Are there any additional types of human bodily material that could raise ethical concerns?

The face has now been designated as an organ. To date only one full face transplant and very few partial face transplants have taken place worldwide. While whole and partial organs are included in the different types of human bodily material set out in the consultation document we consider that the face may raise additional ethical concerns, in particular those relating to personal identity. Other additional material includes composite transplants (eg. hand, limb) and transplant biopsy specimens. As a matter of routine, and for important clinical purposes, 'time zero' biopsy specimens are obtained from donated organs at the time of donation. Who, if anyone, is entitled to agree or refuse to such a procedure taking place? And to whom does this biopsy specimen correctly belong?

Question 2: Should any particular type(s) of human bodily material be singled out as 'special' in some way?

While we fully appreciate that certain types of body parts, perhaps most obviously the heart, invoke emotional responses, and may be viewed in different lights by some communities, we consider that it is unhelpful to consider that any type(s) of human bodily material be singled out as 'special' in some way. One possible

exception to this is the (as yet theoretical) transplantation of germ cells, from say an ovary transplant. However we would like to acknowledge that tissues/organs donated for transplantation do differ and require different treatment pre-, peri-, and post- transplant. These differences need not mean (or require) the ascription of 'special' status, but they do emphasise that tissues/organs for transplant may have features that are unique (or peculiar) to them that may mean (or require) that they are treated differently.

Question 3: Are there significant differences between providing human bodily material during life and after death

The BTS consider that there are significant, morally relevant, differences between *providing* human bodily material during life and after death. These differences relate most obviously to obtaining valid consent. Living donation entails risk, including, in specific instances, the risk of death. In contrast to the deceased, living donors may be harmed and incur potential loss of earnings by providing bodily material. In making this distinction it is not our intention to suggest that an individual is not entitled to decide, during life, whether or not to become an organ donor in the event of their death, nor yet to imply that an individual's wishes during life regarding an event in death are not morally relevant. On the contrary, we would wish to guard against a failure to honour and respect an individual's wishes regarding donation, further we consider that a potential deceased donor may, during life, be harmed if there were for instance a lack of information relevant to decision-making and a system incapable of capturing their individual wishes.

Question 4: What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them) of providing bodily material? Please distinguish between different kinds of bodily material if appropriate.

The costs, risks or benefits to an individual in providing bodily material are likely to vary enormously depending on which body part they are providing and to whom they are providing it. Living donor kidney donation for example is associated with a mortality risk of 1 in 3000.¹ Living donor liver donation carries a far greater mortality risk of 1 in 200.² Beyond empirical differences, the current models and evolving landscape of living donor transplantation highlight the good deal of variety in the sorts of values and importance that individuals place on costs, risks and benefits associated with providing bodily material.

In the context of deceased donation where an individual has chosen to become a deceased organ donor in the event of their death, and this is clearly documented, we consider that it is wrong to allow family members to invoke a veto to organ transplantation and where possible this should be discouraged. In our view the

¹ E. M. Johnson, M. J. Remucal, K. J. Gillingham, *et al* 'Complications and risks of living donor nephrectomy' *Transplantation* 64(8) (1997), 1124-8.

² Estimates vary. See for example R. M. Ghobrial, C. E. Freise, J. F. Trotter, *et al* 'Donor morbidity after living donation for liver transplantation' *Gastroenterology* 135(2) (2008), 468-76.

wishes of the individual providing bodily material should be respected and, in all but exceptional circumstances, outweigh possible costs and risks to their relatives or others close to them.

Section 2: Purposes of providing bodily material/volunteering in a trial

Classifying treatments using donated material may be helpful. Often though donations for transplantation overlap in the categories, for instance a kidney transplant may be life-saving and life-enhancing. Further, these classifications are not really about the *purposes* of the donations but rather about their results.

It is not clear how the issue of 'directing' or 'not directing' organs for transplants provides guidance on their purposefulness *per se* other than to perhaps frame the legitimacy of the purpose in the context of societal responsibility and the interest of the common good, or some relationship or another. The recent Department of Health Public Policy framework document *Requested Allocation of a Deceased Donor Organ*³ takes account of and to some extent addresses this issue. Whether organs for transplants may be directed or not might usefully be considered in conjunction with section 5: the role of consent, and/or section 6: ownership and control.

We agree with the assertion 'material provided for a specified use may also turn out later to have a value for research purposes that could not be predicted at the time the material was provided'. However, it does not follow that this will be true in all instances, not all future uses are, or need be, 'hence unspecified'. Further, future purposes may have clinical as well as research value, for instance, in the context of transplantation future testing for donor specific antibodies. A category which captures 'future specified clinical and research' purposes may be useful.

Donated tissues and organs for transplants are used in their 'existing form' insofar as the material transplanted is the same material that was donated. However, donated tissues/organs are often the subject of a good range of procedures, which may or may not be part of a clinical research project, prior to transplantation including, but not limited to, preservation techniques and bench preparation. The purpose of these interventions is to optimise the donor tissue/organ for transplantation. While we do not consider that this amounts to 'transforming' the donated material in any way it may, for some individuals, raise ethical concerns which relate to the timing/purpose of such interventions. This has particular import in the context of deceased donation.

Referring to 'whole organs donated after death' as being 'used non-commercially within the health system' usefully reinforces the position that organs for transplants are donated voluntarily and freely in the NHS. However, it is a little

³ *Requested allocation of a deceased donor organ*

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_114800

ambiguous and suggests that whole organs donated after death may quite legitimately be used commercially elsewhere! Further, hospitals are in receipt of 'payment' from a Department of Health/ NHS funding source (usually a Primary Care Trust) when a deceased or living donor organ is transplanted.

Section 3: Ethical Values at Stake

The ethical values stated appeal to the virtue of saving life through organ transplantation. The NHS exists for the common good. Identifying ways in which we might maximise health and welfare is a legitimate and worthy goal.

Question 9: Are there any other values that you think should be taken into consideration?

The BTS is a professional society and a significant proportion of our membership has professional responsibilities, an integral part of which is a duty of care. We think it would be useful for professional's values, including for example the principle of 'do no harm', and responsibility, to be taken into consideration. These responsibilities become particularly relevant in the setting of living donor transplantation where greater risks are incurred.

Question 10: How should these values be prioritised, or balanced against each other? Is there one value that should always take precedence over the others?

It is not clear that there could ever be a straight forward way in which the competing values set out in this section can be prioritised. Different people hold different values and beliefs about organ transplantation. Individual circumstances differ and it is clear that, in many cases, one person's set of values will not be relevant for another. However, we do support the view that rights and comparable interests should be considered on equal terms. We also take the view that since the value of life is, in most circumstances, accorded the highest value that morality recognises there should be just reasons for limiting or curtailing the ways in which we might appropriately save life.

While not wanting to detract from the virtue of the ethical values listed it is not clear that they only compete with each other in isolation. As we have highlighted above professional responsibilities require consideration. Further, while not ethical values *per se*, other factors, for instance coercion and exploitation, may impact on the donation process and the effective delivery of transplant services. Deciphering whether an act (a donation for transplantation in this case) is the result of coercion or altruistic voluntariness is not always straightforward and may be notoriously difficult in the clinical setting.

Question 11: Do you think that it is in any way better, morally speaking, to provide human bodily material or volunteer for a first-in-human trial for free, rather than for

some form of compensation? Does the type or purpose of bodily material or medicine being tested make a difference?

The BTS supports the view that organs and tissues for transplantation should be freely given without exploitative commercial consideration or financial profit. The Society does support the reimbursement of costs incurred and losses attributable to the transplant donation process. We take the view that such reimbursement should be the responsibility of the health services and that information regarding reimbursement should be made available and accessible to all potential donors. Any system set up to provide such reimbursement should be open and transparent and have appropriate safeguards in place that as far as is possible exclude the possibility of inducement, exploitation of donors, or profit to intermediaries. In our view the type of bodily material or the purpose for which it is donated makes no difference in this regard.

Section 4: Responding to Demand

Question 14: Is it right always to try and meet demand? Are some 'needs' or 'demands' more pressing than others?

There are good reasons to support the view that it is right always to try and meet the demands of a clinical service, particularly when the moral imperative is to save life. It is straight-forward to agree on aiming to achieve this end goal. Matters are made more complicated when we take account of the means by which we might legitimately achieve this goal. At the present time in the UK the system of tissue/organ donation is based upon altruism and the good will of others. The BTS supports the view that decisions regarding tissue/organ donation for transplantation should remain a matter of individual choice.

The clinical needs of some individuals waiting on the transplant list are more urgent and pressing than others. The BTS supports the view that deceased donor organ allocation schemes must give priority to patients in desperately urgent clinical need. Patients registered on the NHS Blood and Transplant (NHSBT) 'Urgent Heart Scheme' or 'Super Urgent Liver List' should always take priority.

Question 15: Should different forms of incentive, compensation or recognition be used to encourage people to provide different forms of bodily material or to participate in a first-in-human trial?

As seen in our response to question 11, the BTS supports the reimbursement of costs incurred and losses attributable to the transplant donation process/procedure and this includes loss of earnings due to time off work. We do not consider that donating different forms of bodily material for transplantation requires different forms of reimbursement. However, we acknowledge that claims for expenses incurred and compensation for lost earnings may differ in amount and that this may depend in part on which tissue/organ is donated. For example a living kidney donor

may require less/more time off work following the donation procedure than say a bone marrow donor.

Question 16: Are there forms of incentives that are unethical in themselves, even if they are effective? Does it make any difference if the incentive is offered by family or friends, rather than on an 'official' basis?

We believe there are forms of incentives that, regardless of whether one takes the view that such incentives are 'unethical in themselves', may have the resultant effect of coercing or exploiting an individual's good-will to donate bodily material for transplantation. In our view coercing or exploiting an individual's good-will in this context, no matter whether the good effect of organ donation is achieved, is unethical. We believe this is so regardless of whether such a state of affairs came about through family or friends or an 'official' basis, however we acknowledge that in the context of family/friends such a state of affairs may come about covertly. As we acknowledged in our response to question 10, deciphering whether an act (a donation for transplantation in this case) is the result of coercion or altruistic voluntariness is not always straightforward and may be notoriously difficult in the clinical setting.

Question 18: Is there a difference between indirect compensation (such as free treatment or funeral expenses) and direct financial compensation?

The BTS does recognise a difference between indirect compensation and direct financial compensation. The BTS supports the view that organs and tissues for transplantation should be freely given without exploitative commercial consideration or financial profit. However, the BTS does support the reimbursement of costs incurred and losses attributable to the transplant donation process. We do not consider that 'funeral expenses' amount to a cost incurred by the transplant donation process.

Question 19: Is there a difference between compensation for economic losses (such as travelling expenses and actual lost earnings) and compensation/payment for other factors such as time, discomfort or inconvenience?

As seen in our responses to questions 11 and 18, the BTS supports the reimbursement of costs incurred and losses attributable to the transplant donation process. We do not consider that there is a morally relevant difference between *compensation* for economic losses (such as travelling expenses and actual loss of earnings) and other factors such as time, discomfort or inconvenience which are consistent with losses attributable to the transplant donation process. In our view such compensation does not amount to 'payment' for the donated organ.

Section 5: The Role of Consent

The BTS fully supports the view that as far as is possible models of individual informed consent should form the basis upon which donor organs become available for transplantation.

Question 21: In your opinion are there any forms of encouragement or incentive to provide bodily material or participate in first-in-human research that could invalidate a person's consent?

As seen in our response to question 16 we believe there are forms of incentives that, regardless of whether one takes the view that such incentives are 'unethical in themselves', may have the resultant effect of coercing or exploiting an individual's good will to donate bodily material for transplantation. In this event we believe that an individual's consent to donation will be invalidated.

Question 22: How can coercion within the family be distinguished from the voluntary acceptance of some form of duty to help another family member?

We fully support living related transplantation and consider that autonomous individuals are perfectly entitled to undertake to help another family member. Just because an individual may feel compelled to honour a moral duty to help another family member does not necessarily mean that they have been coerced into doing so. However, as we acknowledged in our responses to questions 10 and 16, deciphering whether an act (a donation for transplantation in this case) is the result of coercion or altruistic voluntariness is not always straightforward and may be notoriously difficult in the clinical setting.

Question 23: Are there circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?

There are almost certainly additional purposes for which using the human bodily material donated for transplantation may be of considerable value for both clinical and research purposes. For the scheduled purpose of transplantation, the practical experience of BTS members suggests that it is not always clear to those involved in organ donation and transplantation whether an individual's 'appropriate consent', set out in sections 2 and 3 of the Human Tissue Act 2004, to deceased organ donation extends to consent to any 'additional purposes'. There is much ambiguity surrounding who should seek consent for the use of human bodily material for additional purposes, when it should be sought, and, in particular, the implications if consent obtained by a 3rd party and accepted by a clinician/pathologist/researcher in good faith turns out to have been obtained inappropriately.

It would be useful to clarify the meaning and application of the term 'appropriate consent' in this context and in particular whether it extends to consent to the use of donor tissue/organs for all clinical and research applications which may include future unknown ('secondary') purposes. In our view unless consent is generic and applies to all conceivable types of clinical and research applications (that have been approved by an appropriate ethics committee) that could be carried out on donated organs and tissues, then any consent will be meaningless and researchers will need

to re-visit patients' relatives to acquire consent for procedures that were not previously envisaged. This may prove practicably impossible.

Question 24: Is there a difference between making a decision on behalf of yourself and making a decision on behalf of somebody else: for example your child, or for an adult who lacks the capacity to make the decision for themselves?

There are clear legal and morally relevant differences between making a decision on behalf of yourself and making a decision on behalf of somebody else. We support the view that any decision made on behalf of those who, for whatever reason, lack capacity should be in their 'best interests'.

Question 25: What part should family members play in deciding whether bodily material may be used after death (a) where the deceased person's wishes are known and (b) where they are unknown? Should family members have any right of veto?

As seen in our response to question 4, in the context of deceased donation where an individual has chosen to become a deceased organ donor in the event of their death, and this is clearly documented, we consider that it is undesirable for family members to invoke a veto to organ transplantation and where possible this should be discouraged. In our view the wishes of the individual providing bodily material should be respected and, in all but exceptional circumstances, outweigh possible costs and risks to their relatives or others close to them.

Matters differ when the deceased's wishes are unknown and in this event we accept that there may be circumstances in which family members have a legitimate right of veto.

Section 6: Ownership and Control

Question 27: Should the laws in the UK permit a person to sell their bodily material for all or any purposes?

The BTS considers the laws in the UK should not permit a person to sell their bodily material for the purposes of transplantation. The BTS supports the view that organs and tissues for transplantation should be freely given without exploitative commercial consideration or financial profit. However, as previously stated, the BTS does support the reimbursement of costs incurred and losses attributable to the transplant donation process. We take the view that such reimbursement should be the responsibility of the health services and that information regarding reimbursement should be made available and accessible to all potential donors. Any system set up to provide such reimbursement should be open and transparent and have appropriate safeguards in place that as far as is possible exclude the possibility of inducement, exploitation of donors, or profit to intermediaries.

Question 29: What degree of control should a person providing bodily material (either during life or after death) have over its future use? If your answer would depend on the nature and purpose of the bodily material, please say so and explain why.

It is not clear that a person's 'degree of control' over future uses of their bodily material (either during life or after death) necessarily requires that material to be the subject of property or ownership. A model of consent may, quite legitimately, provide the basis upon which an individual may exert a degree of control over contemporaneous and future uses of 'their' bodily material and this may, for the individuals concerned, depend on the nature of the material provided and the intended purpose(s) of its use. For example at the present time an individual is entitled to withhold, and a good number do withhold, certain body material from donation for transplantation, their eyes say.

However, from a purely practical point of view it may prove difficult to uphold an individual's every wish in this regard, and it is unlikely that the process of informed consent, however detailed, is ever likely to capture all possible future clinical and research uses of donated bodily material. For this reason, as we set out in our response to question 23, in our view consent should be generic and apply to all conceivable types of clinical and research applications (provided that any research applications have been approved by an appropriate ethics committee) that could be carried out on donated organs and tissues to advance the study of the biological and clinical problems of tissue and organ transplantation.

Question 30: Are there any other issues, connected with our Terms of Reference that you would like to draw to our attention?

At the outset the consultation document language is framed in terms of 'give and take' and 'transactions'. While we do not oppose these terms *per se* we would like to highlight that they may be seen, by some, as pre-empting a conclusion. Is for instance the phrase 'give and take' endorsing or making an appeal to some sort of justice or solidarity? In like vein, although the glossary makes clear that the term 'transactions' used in this document is intended as an 'umbrella concept', considering the ethical, legal and social implications framed in these terms to some extent assumes first, that 'contractual arrangements' are possible or even desirable in such a setting and second, that the discussion inherently rests upon the legitimacy of considering the human body and bodily material as 'property' to be 'exchanged' under the terms of such a 'contract' or 'transaction'. Mindful that (rightly or wrongly) use of the term 'the gift of life' is commonplace in the setting of organ donation and transplantation, it is not entirely clear that the term 'transactions' provides a useful starting point for discussion.

Consultation response prepared by Dr. Antonia J Cronin on behalf of the BTS Ethics Committee and approved by BTS Council July 2010.

