

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.

UK Donation Ethics Committee (UKDEC)

Nuffield Council on Bioethics Consultation Paper: Give and Take? Human bodies in medicine and research

Response of the UK Donation Ethics Committee (UKDEC)

UKDEC considered this document and offered comments as individuals, then discussed their responses at their meeting on 16 July 2010. Members did not disagree with any of the individual views in this response, unless otherwise stated. Professor Farsides is a member of the UKDEC and a member of the Nuffield Working Party, and as such did not take part in this discussion.

These responses are limited to organ donation and transplantation, in line with the remit of the UKDEC.

Nature of human bodily material and first-in-human trials.

The consultation refers to all types of bodily material – blood, organs, tissues, reproductive material, from both living and dead donors.

Questions:

- 3. Are there significant differences between providing human bodily material during life and after death?*

Responses:

- The main differences between donation before and after death are the implications for the individual concerned. Before death there are the considerations of how donation will affect the individual. This could either be medically, in terms of a healthy person donating one kidney and therefore diminishing their potential or real reserve with their one remaining organ, emotionally in terms of altruistic living donation to either a relative or an unknown recipient or legally in terms of on-going responsibility. In the case of donated tissues such as eggs or sperm, there is consideration of the potential responsibilities of creating life in the future.
- After death, although some of these issues go away, others are simply transferred to the relatives. Post-mortem donation is often difficult for relatives to come to terms with and successful donation is often a way of helping them to see some good coming out of a tragedy. But if the donation is handled badly this can be very difficult for the family.
- The risk of harming the donor is lessened by his/her death. The concept of harming the dead is difficult to formulate, relying on a sense of harming the person who was but now isn't, who cannot experience harm and require us to be thinking of the person who has died as somehow still alive to harm.

- During life the donor is not only able to formulate and express his/her own wishes (where able to do so) but he/she is also able to defend his/her decisions against conflicting views expressed by e.g. family members. The dead may have left clear instructions and thoughts about e.g. donation, but these cannot be challenged or defended.
 - During life consent can be fully informed, given, modified at any stage, and ultimately withdrawn. With the imminent introduction of mandated choice in Wales, the implications of this, in terms of informed consent, will need further consideration.
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 types of bodily material if appropriate.*
- The costs, risks and benefits are similar to the above and relate to the risk of subsequent medical disease and on-going responsibility as a result of the ways in which one's organs or tissues have been used.
 - Risks to living donors (and to some extent their relatives) depend upon what is being donated. Donation of non-regenerative material from living donors leaves them with the possibility that subsequent health problems may be more serious (eg disease or damage to the remaining kidney will leave them with no kidney function). In such circumstances, perhaps the patient should be prioritized for transplantation, given their history as a living donor.
 - In the case of donation after death, the kind of death experienced may be altered: this could potentially impact on the dying person but also on his/her relatives. Also experiences immediately post-mortem e.g. sitting with the body for sometime after death, preparing the body for burial.

Purposes of providing bodily material/volunteering in a trial.

Questions:

- 6 *Are there any additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?*
- While many donors have registered in the expectation that their organs or tissues will be used in the ways described, once processing, transformation and other forms of modification are concerned, then other issues related to consent may become important. For example, while various faiths and doctrines may well support conventional donation and transplantation, they may not support processing, modification, genetic manipulation, etc. If such developments were planned, it would be essential to discuss the implications with the leaders of the various faiths in advance.
 - Further purposes may include education/archiving, display/art.
- 7 *Would you be willing to provide bodily material for some purposes but not for others? How would you prioritise purposes?*

- (Note: this requires a personal response given the nature of the question – one member offered this) I believe that most people who register for organ donation do so in the belief that their organs will be transplanted to enhance the life of another individual. I, and I suspect others, would feel disappointed and to a certain extent let down if my organs were used solely for research, unless they were first deemed unsuitable for transplantation. Although, as a donor, I have already died and am not therefore affected by donation, the stress on relatives can be enormous and successful transplantation is one way of helping them overcome this. I would certainly not want my organs or donated tissues to be used for financial gain in any way. We all have altruistic feelings and organ donation is a wonderful way of fulfilling these.

Ethical values at stake

Questions:

- 12 *Can there be a moral duty to provide human bodily material, either during life or after death? If so, could you give examples of when such a duty might arise?*
- We have a duty to help others if we can, provided the burden of doing so is in proportion to the aid being offered and taking into account competing duties. This is a difficult balance that arguably requires us to be more generous than we are currently inclined to be. There may be particular duties on family members to help each other, especially parents in relation to children. Duties do not have to be enforceable to be recognised as such.

Responding to demand

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

Response:

- Demands and needs will always expand – as provision increases, expectations will increase more. The question of whether it is always right to meet demands is always going to turn on how reasonable those demands are.
- In the case of demand for solid organs, at present we are far off meeting the demand for any organ. Nevertheless, it is preferable to build confidence in the registration process and in the conversion of registered donors to organs retrieved and transplanted rather than any form of coercion. This is particularly important in cases where an individual has expressed a wish to be a donor, but only to donate a limited number of organs. Provided one can be confident that this has been a properly thought out decision, then this should be respected. Further coercion to try and persuade the individual to donate additional organs should not be used, despite the fact that shortages exist. It is all about ensuring that, at the time of registration as a donor, all the information is given and the decisions are taken in an informed way.
- It is also true to say there is a difference between persuasion and coercion and offering incentives/removing obstacles and coercion.

Increasing supply

Questions

- 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?*
- 16 *Are there forms of incentive 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?*
- 17 *Is there any kind of incentive that would make you less likely to agree to provide material or participate in a trial? Why?*
- 18 *Is there a difference between indirect compensation (such as free treatment or funeral expenses) and direct financial compensation?*
- 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?*
- 20 *Are you aware of any developments (scientific or policy) which may replace or significantly reduce the current demand for any particular form of bodily material or for first-in-human volunteers? How effective do you think they will be?*

Response:

- The reimbursement of directly incurred expenses such as travel, accommodation and loss of earnings to allow donation is reasonable but nothing more is appropriate or desirable. As soon as payments start to become involved, then those in greatest need of financial or other incentive, will inevitably tend to be those who come forward. This will in turn result in donation occurring which is not in the best interest of either the donor or the recipient and there are plenty of examples of the problems that this can create. It does not matter whether this is a direct or an indirect payment and offering incentives such as funeral expense reimbursement is again something that will inevitably affect the less fortunate and less well off in society. The key factor in all this, is to increase the confidence of the healthcare profession and the public in the whole question of donation, so that the conversion rate of donor consent to actual donation is significantly increased.
- New developments – in cardiac surgery increasingly sophisticated left ventricular assist devices are being developed. Some patients with these are asking to be taken off the transplant waiting list. Total artificial hearts are about to undergo clinical trials.

The role of consent

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

- As soon as incentives are involved, particularly financial ones, there is always the risk that extraneous factors could influence an individual's decision to donate, take part in a trial or participate in first-in-human research. There are already well known examples of this. While it could be argued that the participant was given all the information available at the time and therefore gave fully informed consent, we believe there is an ethical and moral duty to avoid preying on essentially vulnerable people with "offers they can't refuse". UKDEC members expressed a range of views about when an incentive becomes coercive, with the accompanying risk of commercialization of body parts.

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

- It is very difficult to understand or be privy to the decisions made within a family, particularly a close one. The obtaining of consistent views from individual family members at private and confidential individual interviews may help, if not to actually clarify the issue, then at least to suggest discrepancies and thus an element of coercion. The views of those involved in an individual's medical care in the longer term may well throw some light on coercion, since decisions which are truly the choice of an individual are seldom made on the spur of the moment and without any discussion of the implications. It is vital however, not to pressurise someone who has genuine altruistic feelings towards one of their relatives, when life saving donation should be celebrated.

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?*

- This depends upon whether the donor, or their relatives, have actually been subsequently asked about the additional purposes. Since initial consent was obtained, surely it is possible to approach the individual concerned or their relatives, in the case of post-mortem donation, with an additional request? If this was done, the additional request will either be granted or refused. In cases where it is impossible to make a request for consent to further purposes, I do not believe it is acceptable to proceed.
- It is not obvious how explicit consent needs to be. We may all have different views about this that range from 'tell me everything in minute detail and I will decide, and don't deviate from my decision under any circumstances' to 'do anything with my body that you think will do some good in the world'.
- It is possible for consent to be general and explicit – such as giving consent to use of material for future research, although that research is not yet defined.

Roles of families

Questions

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

- Living donation of solid organs may or may not subject the donor to risk or more permanent disability. Living donation of solid organs by a competent adult such as a kidney should never be undertaken without the expressed wish of the donor.
- There is obviously difference between the two in the sense that in one case one decides for oneself and in the other one decides for someone else. There is something suspect about expecting (and therefore 'consenting' for) others to do something that one would not oneself be willing to do (all things considered). Equally, it is odd that we do not assume that everyone would, if they were able to do so, decide to act well. Deciding what it means to act well probably depends upon the extent to which one believes that there is an all things equal decision to help others. That said, it may be the case that e.g. parents have a greater obligation to help their children, than those same children do to help their parents or each other. Such special obligations might not transfer well onto others in different relationships and need to be part of the 'all things considered' view.

25 *Donation after death: 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?*

- The first consideration must be whether the individual who lacks capacity at the time of death actually clearly expressed a wish to donate prior to losing capacity. Wherever possible, ensuring that a person's best interests are respected, if these are known, should be paramount and this is made clear in the DoH's legal interpretation of the MCA. Some minors of course are perfectly able to have an opinion and to have expressed it to those close to them. If so and there is good reason to believe that this was expressed in an informed way, then this should be respected. In the case of a child or someone who has not expressed or is unable to express a wish, then consultation should follow the accepted hierarchical structures. In this situation, provided adequate discussion has taken place, one should respect the wishes of the family, whatever they may be.
- Where a deceased potential donor has expressed clear wishes (either for or against donation) the family should have no right to contradict those wishes. I also think it should be possible for a person who explicitly states their consent to donation after their death (or their opposition to it) to include in that expression of consent a stipulation that their relatives should not have any role in determining the future of their organs after death. If the law deems the involvement of relatives indispensable, then it should be possible in life to nominate the relative who will make the decision after one's death.
- One important question is what should happen in the case of a deceased child with two parents who disagree on whether the child's organs may be donated. Is the consent of one parent enough? Does the consent of one trump the refusal of the other (or vice versa)? In legal terms the Human Tissue Act requires only one parent to consent, but is this enough from an ethical perspective?

Any other issues

30 Are there any other issues, connected with our terms of reference, that you would like to draw to our attention?

The right of a transplant recipient to accept or decline an organ chosen for them by their surgical team.