Royal College of General Practitioners

Nuffield Council on Bioethics consultation – Give and Take? Human bodies in medicine and research

1. I write with regard to the Nuffield Council on Bioethics consultation – Give and Take? Human Bodies in medicine and research.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the 'voice' of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 39,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

3. The College welcomes the opportunity to respond to this consultation. Please find below our detailed answers to the specific questions:

1. ***Are there any additional types of human bodily material that could raise ethical concerns?***
Yes - stem cells (and by implication umbilical cord blood) in particular because of their ability to be grown and developed into different tissues.

2. ***Should any particular type(s) of human bodily material be singled out as 'special' in some way?***
Yes. Reproductive tissue including sperm, eggs, and embryos - this should be treated differently because of the fact that the material will not only affect the recipient but will potentially be passed on to future generations. Also, as genetic technology advances, embryonic analysis will become more commonplace and is likely to remain an area of controversy

3. ***Are there significant differences between providing human bodily material during life and after death?***
There are significant differences in consent.
There may be concerns with live donors that the consent is not freely given. Donation may not necessarily be what they want to do but they feel obliged to do it as there may be significant family expectation and pressure.
After death there can be issues of consent when no indication has been given by the individual whether or not they wish to donate and families are left to decide. There may also be issues when at some time the individual has indicated that they wish to donate but next of kin/relatives object to this decision.

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.

*Reproductive material. There are issues here that extend far beyond the donor and recipient. For instance, there can be a significant effect on a future or current family, with the knowledge that there is another child with a parent's or partner's DNA. This may make a significant difference to family relationships. Some may see this as a benefit to the family, others may see this as a real threat.

*Live donation has costs for the individual in terms of risk, including risks of associated surgery, infection and morbidity, as well as loss of income, and may have a cost to the country in terms of sickness benefit, although this would be outweighed if a recipient could return to work.

*There are potential issues for a family if disease or genetic testing showed that the donor had a disease or increased risk of developing a disease he did not know about.

*Donation after death can bring some benefit and comfort to grieving family in the knowledge that some good will come from their loss and others will be helped by the death of their loved one.

5. What do you consider the costs, risks or benefits (to the individual concerned, their relatives, or others close to them) of participating in a first-in-human clinical trial?

There are potentially significant costs and risks to individuals and their families in participating in first in human clinical trials as we have seen when things go wrong (e.g. the Northwick Park experience). The only real benefit to individuals is the knowledge that they may help others, potentially including their own relations. There is an issue about payment, which should normally just recompense the expenses and loss of earnings, but for those unemployed or on low incomes may be a significant factor in their consent - they may take risks for themselves and their families that others financially better off individuals may not take.

6. Are there any additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?

DNA banks – samples taken by the police.

In the future, with the development of predictive genetic testing, one can envisage pressure from insurance companies for material to be provided.

Particularly in circumstances such as above there may be concern about the use to which this material may be put in the future without explicit consent. There must be safety mechanisms in place to ensure that material is not used for a purpose other than that for which it was given, and that no third party exchange of material is acceptable without consent.

7. Would you be willing to provide bodily material for some purposes but not for others? How would you prioritise purposes?*

It would seem more likely that people will provide material when doing so has minimal risk to themselves eg blood donation and also when giving bodily material may be potentially life saving to another individual.

We believe that the moral and ethical issues around the donation of reproductive tissue may mean many people will be less willing to provide this type of tissue.

8. Would your willingness to participate in a first-in-human trial be affected by the purpose of the medicine being tested? How would you prioritise purposes?*
If the medication was one that could benefit a large number of people and it was to treat a serious or life threatening condition then we believe this would have significant weight when making a decision whether or not to take part in a first – in human trial. An individual's decision may also be influenced by whether they have personal experience of illness or have seen a close relative suffer.

9. Are there any other values you think should be taken into consideration?
Religious values should be taken into consideration.
Also, the idea of clinical utility, where it is explicitly stated that a particular donation may lead to a positive outcome that results in change.

10. How should these values be prioritised, or balanced against each other? Is there one value that should always take precedence over the others?
Autonomy and the ability of an individual to give or decline consent should be paramount. Values should therefore be prioritised relating first to the individual and then society. However there are values of responsibility, citizenship and being part of the community to be considered.

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?
There is an issue about financial reward and inequality in that those less well of could be financially motivated to take greater risk than those who are financially better off. However if someone does volunteer for first in human trials for the benefit of society and things go wrong, then we consider that society should ensure that the individual is appropriately compensated and cared for.

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 believe it could be argued that there is a moral duty where donation of tissue such as blood causes little risk or inconvenience to the potential donor and where it is known that failure to donate in a particular instance could lead to death of a particular individual – for example where there are complicated tissue matching issues and the pool of possible donors is limited. However we consider autonomy is still overriding.

13. Can there be a moral duty to participate in first-in-human trials? If so, could you give examples of when such a duty might arise?
We do not believe there can be a moral duty to participate in first in human trials. One is unable to give clear indications of the risks and benefits. If one is considering the benefit to society then for a moral duty it should be for a condition which affects many and has

serious consequences. If it affects many then there are many people who could volunteer to take part in first –in –human trials.

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

It might be agued that needs that preserve life are more pressing than those that simply improve the quality of life. It might be also argued that needs in relation to treating a young child are more pressing than those of an infertile woman or an elderly person with Parkinson's, but it is extremely difficult to make objective comparisons (other than economically) between the needs of different groups.

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?

Those detailed in the report would appear ethically sound, particularly the notion that payment should not be related to risk. If harm arises from an act undertaken for the good of society then there should be appropriate compensation and caring provided by society.

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?

Significant financial reward would seem inappropriate, even if offered by family or friends, as this could sway the decision making away from altruism to that of short term financial gain.

17. Is there any kind of incentive that would make you less likely to agree to provide material or participate in a trial? Why?*

Anything with racial or religious overtones that would be discriminatory against some individuals.

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

Yes in that free treatment should benefit the individual whereas financial compensation may be used by others or used for matters that are not necessarily of benefit to the individuals wellbeing (such as the purchase of alcohol and cigarettes.). The payment of funeral expenses, in particular, might be seen as an extension of the altruistic motive, in that family are the likely beneficiaries.

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?

Yes. Payment for discomfort and inconvenience could be difficult to quantify and lead to more ambiguity.

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?
Stem cell technology and cloning. They are in their infancy but are potentially very powerful therapies. That could significantly reduce demand for donations.

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?
Consent should be freely given without undue coercion - if there is too much external pressure or the material rewards offered are very high, then this may not be true voluntary consent. In addition consent should be informed so the risks and benefits as known must be presented in a balanced manner - if not the consent may be invalid as it may not be informed.

22. How can coercion within the family be distinguished from the voluntary acceptance of some form of duty to help another family member?
We feel that this is very difficult. However where there is significant risk to an individual as a result of donating, the individual should be interviewed and assessed by a psychologist without family present. There needs to be a full, independent process to test the willingness of the individual and their understanding of the potential risks – this would be to the benefit both of the individual and of the family, in allaying any potential guilt or recrimination should the procedure result in harm to the donor.

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?
The College does not believe that there are any circumstances. We consider that consent should be explicit and it should always be an opt in, not an opt out process.

24. 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?
Yes. The difference is between patient autonomy and acting in the best interest of an individual who does not have capacity.

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?
We believe that the person who has lawful possession of the body should have a veto, (except in issues where the coroner is involved). However with this should come responsibility and the overriding duty should be to act in the best interest of the deceased individual and wherever possible to carry out what he believes that individual would have wished, It may be however that although some years earlier the individual had expressed a view to donate there may be knowledge that this view had changed - eg he had changed his religious belief.

26. To whom, if anyone, should a dead body or its parts belong?
They should belong to the person '*lawfully in possession of the body' – usually the family, and if not then to a guardian elected by the state.*

27. Should the laws in the UK permit a person to sell their bodily material for all or any purposes?
We believe that it should remain illegal to sell organs. Financial reward as opposed to recompense of expenses and loss of earnings could lead to pressure from family/acquaintances and individually to donate for financial rather than altruistic reasons. This may lead to those less well off taking significant risks that they would not have taken if they were financially better off.

28. Should companies who benefit commercially from others' willingness to donate human bodily material or volunteer in a trial share the proceeds of those gains in any way? If so, how?
They could reasonably be expected to reinvest a proportion of the profits into further research and education in the subject for which the tissue was donated or the trial entered.

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 or purpose of the bodily material, please say so and explain why.
If the person has capacity they should have full control. It should only be used for the purpose for which express consent was given. (The exception of course being after death where the coroner has jurisdiction of the body and for instance toxicology or staining for histology is carried out to aid investigation of the cause of death)

30. Are there any other issues, connected with our Terms of Reference, that you would like to draw to our attention?
No

4. We gratefully acknowledge the contributions of our Ethics Committee and Clinical Innovation and Research Centre (CIRC) in formulating this response.

Yours sincerely

Professor Amanda Howe
Honorary Secretary of Council