

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 Heart Foundation

'Give and take? Human bodies in medicine and research'

Introduction

The British Heart Foundation (BHF) is the nation's heart charity. We're fighting to eradicate premature death from heart and circulatory disease, the UK's biggest killer and provide support and voice for heart patients around the UK.

We welcome the opportunity to respond to this consultation. Heart transplants offer the best chance of long term survival for critically ill heart failure patients. Unfortunately there is a shortage of donor hearts for use in transplantations across the UK.

The BHF supports measures to improve the UK's rate of organ donation. These measures include consistent national promotion coupled with a strong infrastructure of organ retrieval and professional training. Whilst such measures will go a long way to improving donor organ availability, we believe that an opt out system (presumed consent) where close relatives retain the power of veto should underpin organ transplantation in the UK.

In medical research the use of human tissue is extremely important in order to increase the understanding of disease and to help develop new and improved treatments. At the BHF, many projects within basic science rely on human tissue that has been donated. First-in-human clinical trials are also an essential part of the pathway enabling new treatments to be rigorously tested for safety prior to being widely used by patients.

Our response focuses on those areas that are of most relevance to our vision of a world in which no-one dies prematurely of heart disease. We recently conducted a survey of around 60 heart patients, medical researchers and campaigners on the issues raised within this consultation, and their views are reflected throughout our response below.

Q4: What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them) of providing bodily material?

Heart transplants can make an enormous difference to the lives of those with severe heart failure. Between 2008 and 2009 130 heart or heart and lung transplant operations were carried out, of which 34 were undertaken on young people under the age of 16.¹ Tissue donation is similarly important in the development of new treatments that can benefit heart patients.

The majority of respondents to our survey (87 per cent) had made their intentions clear in wanting to donate their organs after death. 91 per cent of these chose to do so because they saw a clear benefit in their actions helping to save the lives of others. This mirrored the reasoning behind a willingness to donate tissue (92 per cent). Over half of those that had donated tissue also did so because they wanted to contribute to important medical research.

A small number of respondents to our survey (around 10 per cent) indicated that they had not signed up to the Organ Donor Register. Around half of these said they distrusted the system. Two respondents felt concerned about who their organs would be donated to. Other

concerns listed included the uncertainty of the effects on themselves and their families.

Q5: 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?

Nearly three quarters of respondents to our survey (71 per cent) would consider taking part in a first-in-human trial through a desire to save lives, lower than the responses for both organ and tissue donation. Similarly, 64 per cent were willing to do so to benefit medical research, less than the response on the same issue for tissue donation.

However, 82 per cent were concerned by the risk to their own health that may result from taking in part in such a trial. 63 per cent were concerned with the level of safety. 15 per cent also felt that members of their family would not be happy with the prospect of them taking part.

Q6: Are there any additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?

The BHF estimates that every week three young people die from a rare heart condition that they were unaware that they had. These conditions are genetic in origin, and can go unnoticed for many years. Though there is no national data currently collected on inherited cardiac conditions, these are estimated to result in between around 140-540 deaths in England every year for those aged under 65.^{2,3}

¹ Transplant Activity in the UK 2008 – 2009, NHS Blood and Transplant, 2009

² Bowker T.J. et al. (2003) Sudden unexpected cardiac or unexplained death in England: a national survey. *Q J Med* 96:269–279

³ Behr E.R. et al. (2007) Sudden arrhythmic death syndrome: a national survey of sudden unexplained death. *Heart* 93:601–605

Post-mortems can identify whether a death has been caused by an underlying inherited cardiac condition. Tissue samples can then be genetically tested in order to discover the genetic markers for this condition. As a result, close family members that may be at risk can be screened to establish whether they have the same condition, and take steps to ensure that the risk of future cardiac death is reduced.

The Human Tissue Act allows for the retention of tissue from autopsy only until a coroner's authority has ended and the post-mortem has been completed. At that point, the tissue samples are then either returned to the family or destroyed, unless the family consents to their retention for research or other purposes as listed within the Human Tissue Act.

Consent in these cases raises some ethical considerations. Respondents to our survey indicated that in cases of a death from a suspected inherited cardiac condition, pathologists should not, need to explicitly seek permission from family members to send tissue samples away for genetic testing. This is contrary to current law.

Q9: Are there any other values you think should be taken into consideration?

Treatment should be available on the NHS on the basis of clinical need, and this value should remain central to organ donation.

Q11: 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?

Our survey reinforced our view that financial benefits should not be provided for organ donors, with only 22 per cent believing this should happen. In contrast, only 18 per cent disagreed with the notion that volunteers for first-in-human trials should receive financial rewards. This indicates that people do view the two differently, with organ donation viewed more as an altruistic act.

Q12: Can there be a moral duty to provide human bodily material, either during life or death? If so, could you give examples of when such a duty might arise?

59 per cent of respondents to our survey suggested that they would donate organs on a moral basis. We do not believe that people have a moral duty to be an organ donor. We respect that people hold different views on organ donation, and these views should always be made clear. That is why in our support for a soft opt out system for organ donation, we make it clear that people should be given opportunities to make any wish not to donate clear, and why close family members should be given final say on a decision to retrieve organs after death.

Q14: Is it right always to try to meet demand? Are some 'needs' or 'demands' more pressing than others?

There is a serious shortage of donor organs in the UK. In 2008-09 20 people on the heart transplant list died before the transplant could be arranged. The transplant waiting list would be larger if there were more donor organs available as a lot of people don't get put on the waiting list by their doctor as their chances of receiving a transplant in time are slim.⁴ Doctors don't want to add to the anxiety of a terminal illness.

All UK Governments should take steps to meet this demand for organs. The current system of organ donation does not adequately capture public support – 90 per cent of the UK public support organ donation, yet only 27% of the UK population are on the NHS Organ Donor Register.⁵ The recommendations of the 2008 report by the Organ Donation Taskforce may go a long way to improving donor organ availability. But we believe that an opt out system should underpin organ donation in the UK. This would help to meet the demand for organs, and save lives as a result.

It is right to try to meet demand, however there are inevitably some needs and demands that are more pressing than others. There is therefore a need to prioritise, and this should seek to balance the issues of available resources and clinical need of patients.

Q16: 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?

Offering payments to organ donors may encourage some people to donate who may not have chosen to do so otherwise. However, we believe this would raise significant ethical problems. Those from lower socioeconomic groups may be the most likely to seek to donate organs for monetary gain, and there is a serious danger that under a payment system these

groups could be taken advantage of. We believe payment for organs, whether offered by family or friends or on an official basis, should remain out of the equation.

In our survey, only a quarter of respondents were in favour of the idea that organ donors should receive financial incentives for donating, such as contribution to funeral costs. 71 per cent opposed the idea that people should be paid for donating organs or tissue. Two thirds of respondents felt that organ donation should be altruistic, with no rewards given to those that donate.

Other incentives mentioned in the consultation included 'non-cash incentives' such as mugs or t-shirts. Only 19 per cent of respondents to our survey, when presented with this option, supported it.

⁴ Organ Donation Taskforce (2008): The potential impact of an opt out system for organ donation in the UK.

⁵ NHS Blood & Transplant website, February 2010.

Q20: 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 trials? How effective do you think they will be?

As mentioned in our answer to question 14, we believe a change to an opt out system for organ donation would significantly improve the number of donor organs available, and as a result alleviate the pressures on the current transplant lists. We are encouraged by the developments within Wales, where the National Assembly has expressed its intention to move towards an opt out system for organ donation.

In terms of reducing the need for transplants in the future, we believe that regenerative medicine may in the future be used to treat those with severe heart failure. The majority of people in need of a heart transplant have severe heart failure. The body is not able to repair this damage. With further development of the basic science of stem cells, we may in the future be able to use these cells to help hearts repair themselves. This could bring long-term benefits to people who have chronic heart failure, and reduce the need for heart transplantation.

Q23: Are there circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?

As highlighted in question 6, in cases where someone has died of a suspected inherited cardiac condition, tissue samples can be genetically tested in order to discover the genetic markers for this condition. Close family members can then be screened to establish whether they have the same condition. In this instance, ensuring that tissue from a post-mortem is sent for genetic testing is essential.

Respondents to our survey indicated that in cases of a death from a suspected inherited cardiac condition, pathologists should not need to explicitly seek permission from family members to send tissue samples away for genetic testing.

67 per cent of respondents also indicated that they would be prepared to donate their organs and tissue to be used in medical research projects that they had not explicitly consented for. This suggests that a more flexible means of consenting for such a purpose may be appropriate.

Q25: 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 BHF supports the introduction of an opt out system for organ donation for the UK. We believe that family members, under such a system, should retain the right of veto when asked whether organs can be retrieved after death. This would help to ensure that no organs are retrieved where the person concerned may have been unable to suitably register his or her desire to opt out. Regardless of any future change to the organ donation system, we believe it is vitally important that people talk to their families about organ donation so that their intentions are made clear.

We recommend that in cases of suspected deaths from inherited cardiac conditions, where the deceased is unable to consent for genetic testing of tissue samples, that families are contacted at the earliest opportunity to seek consent.

Q29: What degree of control should a person providing bodily material (either during life or after death) have over its future use?

People should be able to fully state their intentions during life on whether they consent to organ or tissue donation after death. Unfortunately, the current organ donation system does not capture the extent of public support for organ donation, and as such many people who would be happy to donate their organs do not do so. This is a key reason why a move to an opt out system of organ donation is necessary.

Conclusion

- There is a shortage of donor hearts for use in transplantations across the UK, which are vital to improve long term survival for critically ill heart failure patients
- Donation of tissue and participation in first-in-human clinical trials are important for researching new treatments
- An opt out system should underpin organ donation in the UK. This would help to meet the demand for organs, and save lives as a result
- Treatment should be available on the NHS on the basis of clinical need, and this value should remain central to organ donation
- If you would like further information about this response, please contact Joseph Clift, Policy Officer, on cliftj@bhf.org.uk or 0207 554 0156.

**Kind regards,
Betty McBride**

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