Give and take? Human bodies in medicine and research

Consultation summary

Contents

Human bodies: donation for medicine and research – summary of public consultation

A public consultation was held between 20 April and 13 July 2010. A consultation paper entitled *Give and take? Human bodies in medicine and research* was prepared by the Working Party and contained background information and 30 questions for respondents to answer. Respondents were invited to address as many or as few questions as they wished.

The document was disseminated to a variety of individuals and organisations through the use of a targeted mailout, and also through extensive media coverage.[1]

By the end of the consultation, the Working Party had received 179 responses, which informed its report *Human bodies: donation for medicine and research*. Each of these responses was analysed and discussed in meetings of the Working Party. Of these 179 responses, 116 were from individuals and 63 from organisations.

The Working Party and the Council are very grateful to all those who contributed to the consultation, and found the responses to be very insightful, and an invaluable resource when drafting the final report.[2] This document summarises some of the key themes, views, and observations which were raised by the responses received. However, it is not intended to form a quantitative survey; responses were not taken from a representative sample, and should not be treated as such.

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[1] For a detailed list of media coverage received for the Human bodies consultation launch, see: http://nuffieldbioethics.org/human-bodies/human-bodies-media-coverage.

[2] Many of those who responded gave permission for their responses to be made available on the Council’s website. See: http://nuffieldbioethics.org/human-bodies.

Questions

Section one: nature and purpose

1. Are there any additional types of human bodily material that could raise ethical concerns?
2. Should any types of human bodily material be singled out as ‘special’ in some way?
3. Are there significant differences between providing human bodily material during life and after death?
4. What do you consider the costs, risk 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.
5. What do you consider the costs, risk or benefits (to the individual concerned, their relatives or others close to them) of participating in a first-in-human clinical trial?

Section two: purposes of providing bodily material/volunteering in a trial

6. Are there any other additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?
7. Would you be willing to provide bodily material for some purposes but not for others? How would you prioritise purposes?
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?

Section three: ethical values at stake

9. Are there any other values you think should be taken into consideration?
10. How should these values be prioritised, or balanced against each other? Is there one value that should always take precedence over the others?
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?
12. Can there be a moral duty to provide human bodily material, either during life or after death? If so, could you five examples of when such a duty might arise?
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?

Section four: responding to demand

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

Section five: the role of consent

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?
22. How can coercion with the family be distinguished from the voluntary acceptance of some form of duty to help another family member?
23. Are there any circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?
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?
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?

Section 6: ownership and control

26. To whom, if anyone, should a dead body or its parts belong?
27. Should the laws in the UK permit a person to sell their bodily material for all or any purposes?
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?
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.

Section 7: any other issues

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

Chapter one: Nature and purpose

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

Respondents drew attention to several types of bodily material which they felt could raise ethical concerns. Suggestions ranged from hair and nails, to the face and facial tissue. One respondent noted that “the face may raise additional ethical concerns, in particular those relating to personal identity” (The British Transplantation Society).

A handful of respondents focused on reproductively-relevant material such as post-natal cord or placental blood, and also the uterus. In addition, fetal material was also raised as bodily material which could raise ethical concerns. The potential use of fetal material was felt to be ethically relevant as it was “material derived from a controversial or unethical procedure” (The Anscombe Bioethics Centre, Oxford). In addition, autologous ‘donation’ via egg freezing was also raised, and also the practice of surrogacy which, it was suggested, would involve the ‘loan’ of the body.

Several respondents felt that stem cells raise ethical concerns.

In addition to noting additional types of material that could raise ethical concerns, some respondents also felt that there should be no distinction drawn between different types of bodily material.

> “There should not be any distinctions between the tissues in regards to ethical concerns.”
> *Anonymous consultation respondent*

> “Any bodily tissue… raises ethical concerns because a person is giving part of [themselves], not something they own.”
> *Miriam Pryke, consultation respondent*

One respondent felt that the question depended on how ‘tissue’ is understood, noting that “it is not the tissue type that matters so much as the meaning, value and moral salience of the act and context of donation” (Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre).

Other respondents drew attention to ‘genetically significant’ material such as DNA, and raised possible implications for the privacy rights of the person from whom the DNA originated. One respondent noted that material which is used specifically for genetic analysis was particularly sensitive “if genetic information generated from that test is sensitive or predictive, and can be used to diagnose existing disease or predict future ill health” (PHG Foundation).

A further ‘group’ of bodily material that respondents felt might raise ethical concerns were those considered to be ‘waste’ or ‘surplus’ materials. One respondent felt that such material should be considered because it contains the person’s DNA. However, other respondents felt that waste material should specifically be excluded from the Working Party’s deliberations.

In addition, some respondents felt that bodily material removed and used solely for research purposes could raise ethical concerns. The Human Tissues Group noted that these samples are “extremely valuable for research but may raise additional ethical concerns as they would not have been removed otherwise.”

A small number of respondents felt that bodily material used for exhibitions and entertainment warranted consideration for possible ethical concerns. The Anscombe Bioethics Centre, Oxford stated that: “even with consent, are there limits on what kinds of display of human remains are appropriate?”

2. Should any particular type(s) of human bodily material be singled out as ‘special’ in some way?

A number of respondents who answered this question felt that no particular type of bodily material should be singled out as special, and that the every type of human bodily material was ‘special’. This lead Miriam Pryke to conclude that “if human tissue is to be used, it must be used with due respect.” Other respondents, however, took the view that there should be a more fragmented approach to how human bodily material is dealt with, and that any attempt to approach human bodily material as a single entity was an incorrect approach to take. This view was highlighted by Professor Peter Furness who stated that “each different type of ‘bodily material’, however that is defined, deserves different considerations; and the same type of tissue may demand different consideration depending on how it is obtained.” In addition, Lorna Weir, Professor of Sociology and Health at York University, Toronto, stated “there is a need to separate materials to treatment and research, for otherwise research may drive treatment needs…”

The rarity of certain types of material was also considered to be ‘special’ by respondents, precisely because there was a limited amount available.

However, the majority of respondents who answered this question felt that reproductive material should be singled out as ‘special’. Within this group, several reasons singling out reproductive material as ‘special’ were offered. Some respondents, for example, felt that the material was special because the resulting child had a right to know their biological origins. Other respondents also noted the importance of genetic links, noting that “organs and tissue prolong life, but without genetic perpetuation of the donor’s DNA.” (Marcia C. Inhorn)

One respondent also felt that the ‘ten family rule’, where a gamete donation could be used to found up to ten families, was a reason that reproductive tissue should be marked out, especially when compared to organ donation which “may only affect one or two people. The onward potential of gamete and embryo donation will have a significant impact on several families.” (British Fertility Society)

Embryo donation was also singled out by a small number of respondents. One noted that “embryo donation is different from other forms of donation in that donors are not directly donating parts of their own bodies but rather they are donating a separate living entity that has had its origin from their gametes.” (Church of England Mission and Public Affairs Council)

A handful of respondents felt that reproductive tissue was special because of gender implications, thus dividing reproductive tissue into male and female subcategories. For example, Pat Spallone noted that “the removal and use of female reproductive material is a women’s health issue” and that “it is still important to see through the lens of gender in these contexts.”

Others felt that reproductive material was special due to its life-creating purpose. One anonymous respondent noted "choosing to create a new life is an entirely different matter to preserving or enhancing a life." Furthermore, the International Donor Offspring Alliance felt that "the interests of the human being thus created are of paramount importance, and should be considered more highly than those of the donor, recipient, or society in general."

Of those respondents who focused on the special nature of reproductive material, several also drew specific attention to the use of reproductive material for research purposes. The use of fetal tissue was noted as being an area of particular sensitivity. For example CARE took the view that "The use of body tissue from a fetus requires special consideration, due to the material source […] The use of tissues or stem cells from aborted foetuses is highly controversial because of its association with elective abortion."

Stem cells were also focused on. For example, a response from Progress Educational Trust noted how "it is not always possible to obtain stem cells from adults… [which] means that stem cells may pose different challenges and require different considerations from other types of human bodily material." Furthermore, the BMA noted, "as with reproductive material (sperm, eggs and embryos), donated stem cells have at least the theoretical potential to be used to create new life at some future point." A response from the National Research Ethics Advisors' Panel (NREAP) also noted that "human egg and embryo donation for research is another growing area of interest… Particular regard ought to be given to informing donors of the actual and potential uses of their tissue when researchers seek consent."

A handful of respondents also noted that cord blood should be considered to be 'special'.

Other respondents referred to bodily material central to a person's *identity* as requiring special treatment. In the context of reproductive tissue, HEAL (Health Ethics and Law), University of Southampton noted "identities at stakes are not simply those of the donor alone, but also raise potential issues for the wider family and/or kinship construction." More explicitly, Miss E.J. Toogood noted that "aspects of the body that are most directly connected to identity should be classified as being somehow 'special'." Rob Warwick referred to bodily material where there is a "clear emotional thread between the donor and the recipient, for example eyes, the face, limbs…" Amanda Wilson, commenting on face transplants, noted that "people seemed to have problems with this maybe because a face is such a personal thing." In addition, the Royal College of Physicians of Edinburgh felt that "brain tissue would be regarded by the lay public as special because it is the source of thought and consciousness", a point which was also made by Graham Brushett who noted that members of the public "associate the brain and heart as manifesting key aspects of personhood and personality which they believe should be kept intact."

Another distinction drawn by respondents focused on material which regenerates, and that which does not. University Hospitals of Coventry and Warwickshire Clinical Ethics

Committee, on the other hand, observed that “risk analysis does not explain differences in perception between regenerative and non-regenerative materials.”

A small number of respondents felt that kidneys specifically deserved special treatment. For example, Professor Gabriel Danovitch noted that “living kidney donation differs from other forms of donation because of the seriousness of the surgical intervention.” Sally Satel also stated that “kidney transplants save money compared to keeping patients on dialysis, adding a considerable cost-saving dimension to kidney-only systems of exchange.” However, other respondents felt that organ donations that save lives warranted special attention. Graham Brushett, for example, noted that “certain types of donation have an immediate life saving or life transforming impact on the beneficiaries… Therefore in my judgment heart, lung and liver donations do have most ‘special’ significance.”

Despite the fact that very few have been carried out, face transplants received a significant amount of attention from respondents. A variety of reasons were offered as to why the face should be considered to be ‘special’. The Donor Family Network, for example, felt that the face was special because it was visible: “the face can in theory be ‘seen’ by others whereas internal organs cannot.”

A small number of respondents also drew attention to the bodily material which is used for research purposes, and within these responses, some reference was drawn to the events at Alder Hey. Marlene Rose, Imperial College argued that a distinction should be drawn between tissues which have been removed in the course of another procedure, and material taken for specific research purposes.

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

Most respondents answered this question in the affirmative, and offered a range of reasons why they thought this to be the case.

Yes, differences exist for consent and control

Several respondents felt that differences between providing bodily material before and after death were due to issues of consent and control.

Chris Briscoe noted that, in the case of living donation "there can be no doubts about the consent of the donor." The 'nature' of consent needed before and after death was acknowledged in a number of other responses. The party who consents to the providing of bodily material was also noted. For example, Dr Gill Haddow, from the ESRC Innogen Centre noted that "in the case of cadaveric organ donation, the donor's intention to donation is mediated by their family. This brings into play factors about the families' own beliefs about the value of organ donation, death and the dead body." The role of the family in donation after death was raised by a number of respondents, several of whom noted that situations could arise where there the wishes of the deceased person, and those of family members may be contradictory. Attendees of the Ethics Forum at University Hospital Birmingham, organised by Greg Moorlock, therefore took the view that "the autonomy of the deceased is often largely disregarded."

The difference in the process of obtaining consent for living or deceased donation was also raised by respondents. Graham Brushett noted that "the rigour of the living donation consent procedure is exhaustive compared with the simplicity of signing the Organ Donor Register." Moreover, HEAL (Health Ethics and Law), University of Southampton, noted took the view that "during one's life it is possible to change one's mind about consent, whereas following death the consent appears to be 'fixed', either by the deceased or by a proxy decision-maker."

Commenting on the control available to a living person who decides to donate bodily material, Dr Muireann Quigley stated that "[i]t could be argued that an individual has more interests over their body and its tissues whilst living since they still have an immediate and continuing interest in controlling what happens to themselves and their tissues."

Yes, especially in relation to reproductive materials

A number of respondents felt that the donation of gametes differed markedly before and after death. One potential reason for this was offered by The British Psychological Society, which noted that "any resulting child will have to be told that one or both of their genetic parents is/are deceased." Moreover, a small number of respondents noted that obtaining gametes from deceased donors would deprive the child of having a relationship with their biological parent(s). This view was summarised by David Gollancz who stated that "people should if possible be available to their offspring, at least to give an account of themselves."

Yes, because of potential benefits to the living donor

A very small number of respondents referenced an argument that living donation offers benefits to the donor, whereas deceased donation does not. Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre noted that “the possibility of gaining some direct or indirect benefit is open to the live donor and this may be significant to the context in which donation is requested.” Attendees of Ethics Forum at University Hospital Birmingham, organised by Greg Moorlock also noted that “the rewards for organ donation during life… are going to be greater than the rewards for cadaveric donors.”

Yes, because of risks to the donor

Several respondents felt that potential risks to donors were a reason for distinguishing between living and deceased donation. The most common form of risk recognised by respondents was physical risk to living donors. The Human Tissues Group, for example, stated that “post mortem donation cannot physically harm the donor, while donation during life could potentially harm the donor.” Furthermore, Dr David J. Hill felt that “it cannot be ethical to submit a healthy patient to a damaging operation to remove an organ or part of an organ if it is not for his/her benefit.” However, other respondents, such as the National Research Ethics Advisors’ Panel (NREAP) noted the potential effects on deceased donors: “the use of tissue from the dead may raise issues which could be regarded as a form of harm to the deceased (for example, issues related to privacy, confidentiality and reputation.)” The Medical Research Council felt that the risk that should be considered relevant was that to the relatives and friends of the deceased donor.

Yes, for practical reasons

Several respondents focused on practical reasons for recognising significant differences between providing material before and after death. For example, attention was drawn to the fact that living donation offers better clinical outcomes.

Dr Miran Epstein stated that although there were differences between providing material before and after death, “they are universally technical, not ethical.” However, attention was also drawn to the difference in symbolism between living and deceased donation: “…providing human bodily material during life is an anticipatory practice, a gift-giving of hope that some good will come from it from the owner to the potential beneficiary. After death, providing human bodily material is about memorialisation of the deceased through the use of their body in various ways” (HEAL (Health Ethics and Law), University of Southampton).

Living donation was felt to affect donors more onerously than the prospect of deceased donation. Some respondents, for example, referred to the potential for living donors to lose earnings through their decision to donate. Other respondents noted that living donation has the potential to affect the health and wellbeing of the donor. One anonymous respondent noted, for example, that “to use a living donor for organs creates two patients whereas donation after death only has one patient.” The potential impact of living (directed) donation on relationships between the donor and the recipient was also highlighted by respondents.

However, other respondents felt that deceased donation had more potential for harm. For example, the Church of England Mission and Public Affairs Council felt that, in the context of whole body donation, the act of donation could “have an adverse effect on family members who are ‘left with nothing’ during the bereavement process.” Conversely, it was also noted by Graham Brushett that “donation after death does not come with the same emotional baggage for the donor as living donation does.”

Attention was drawn to the need to recognise the burial practices and traditions of certain religions, such as Islam and Judaism – and particularly the fact that burials are required to take place very soon after the person’s death. For this reason, it was noted that Muslims and Jews may be put off from organ donation because of fears that burial may thereby be delayed. More generally, other respondents drew attention to the fact that more cultural and/or religious concerns arise in the context of donation of bodily material after death. It was also noted that “different religious beliefs might entail differences between providing human bodily material during life and after death” (Attendees of Ethics Forum at University Hospital Birmingham, organised by Greg Moorlock).

A number of respondents felt that differences between living and deceased donation arose out of concerns for the definition of death. Almost exclusively, comments received from respondents on this issue raised concerns about the interpretation of brain death criteria. Attention was drawn, for example, to the situation in the United States where criteria for the determination of death is not standardised: “you can be dead in Pennsylvania but still alive in Oklahoma, or dead in the U.S. but still alive in Canada, for that matter” (anonymous consultation respondent). Moreover, CARE stated that, “with the ascertaining and timing of a diagnosis of death […] The kinds of dilemmas raised are whether ‘death’ should reference the brain or other organs.”

No difference between providing human bodily material during life and after death

However, a number of other respondents felt that there were no significant differences between providing material before and after death. For example, Jonathan Lee stated that “there is no additional ethical work done by the contingent fact that the donor is dead.” Chris Briscoe also felt that there was no difference “as long as they [the donors] have made the choices in life and their choice is respected after death.” A similarity between the two types of donation was also raised by the Human Tissue Authority who noted that the “key similarity is that of valid consent being central to both living and deceased donation.”

Other respondents referred to the similarities in the *structures* supporting both living and deceased donation. For example, the European Society for Organ Transplantation Council was of the view that “both live and deceased donation is dependent on [the fact] that the public has confidence in the health care system and in the regulatory framework.” Similarly, Miriam Pryke noted that “there are limits to what people may do, limits to what one person may do in relation to another, and that applies to dead people as well as living people."

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.

Several general comments on the breadth of this question were offered by respondents:

> "the calculation of risks and benefits is often highly subjective and therefore variable dependent on the individual/s involved, the bodily material donated and the context in which it is given."
> *Dr Gill Haddow, ESRC Innogen Centre, consultation respondent*

> "In any medical procedure there are risks of complications and harm to the donor as a result. This varies from procedure to procedure, and thus has to be weighed by the donor."
> *Jonathan Lee, consultation respondent*

> "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."
> *The British Transplantation Society, consultation respondent*

Some respondents chose to focus on the separate issue of costs, risks, and benefits, and applied these concepts to specific types of bodily material.

Costs

Costs: blood donation

Very few respondents highlighted the costs of donating blood. Those who did mention the cost of blood donation drew attention to the normalcy of blood donation, and also the fact that it is quickly replenished by the body. Other than minor inconveniences to the donor, such as time and brief discomfort, very few costs to the donor were recognised by respondents.

Costs: living organ donation

Respondents who focused on the costs of living organ donation distinguished between different parties involved in the donation process.

i. Cost to the donor

Several respondents focused on the potential physical costs to the living donor, including the pain and discomfort experienced as a result of donating. Other respondents drew attention to the potential emotional costs of donating an organ. Karen Dyer, a lecturer in law from the University of Buckingham, for example, noted potential "feelings of guilt if the organ doesn't take." A further point highlighting the emotional impact of donating was raised by Attendees of Ethics Forum at University Hospital Birmingham, organised by Greg Moorlock who stated that "if one placed importance in bodily integrity, one might also feel that one had sacrificed one's 'completeness'.

Practical costs were also highlighted. Some respondents, for example, drew attention to the fact that the donor may be inconvenienced through the need to take time off work, and potentially lose some of their earnings. Moreover, the Human Tissue Authority noted that donors "may also run the risk of losing their job and the HTA has been made aware that this has been the situation in a handful of cases over the past four years."

ii. Cost to the donor's relatives

A handful of respondents noted the cost of living donation to the donor's relatives. Sylwia Maria Olejarz, for example, highlighted the "very high psychological costs both for the donor and his/her family." Highlighting a different aspect, the Human Tissue Authority noted that "friends and family are likely to visit the donor and may incur travel costs… There is no formal mechanism by which friends and relatives can be reimbursed."

iii. Cost to the recipient

Very few respondents highlighted costs to the recipient of the organ from a living donor, although Attendees of Ethics Forum at University Hospital Birmingham, organised by Greg Moorlock felt that "recipients can be significantly emotionally affected if an organ transplant from a living donor fails."

Costs: deceased organ donation

As with perceived costs of living organ donation, respondents who addressed costs to deceased organ donation also focused on the various different parties involved in the process.

i. Cost to the donor's relatives

Most respondents who chose to address the issue of 'costs' of deceased organ donation drew attention to the cost to the donor's relatives, with a particular focus on the emotional costs involved. Many of these respondents felt that the significant cost to relatives lay in situations where they consider the donor's body to be 'incomplete' after donation. Observations included:

> "For some, depending on their worldview, distress at the thought of material being removed from their loved one's body."
> *Christian Medical Fellowship, consultation respondent*
>
> "A sense that their loved one is not 'whole'."
> *Anonymous consultation respondent*
>
> "A family that places value in the completeness of the body after death would be sacrificing something meaningful to them if they agree to donation."
> *Attendees of Ethics Forum at University Hospital Birmingham, organised by Greg Moorlock, consultation respondents*

Other respondents also drew attention to the potential burden families might feel at being approached to allow their relatives' organs to be donated.

ii. Cost to the recipient

Very few respondents referred to the potential costs of deceased organ donation to the person who receives them. However, an anonymous respondent noted that “the recipient can in some cases suffer guilt in that a person (identity unknown) had died to give them life. Patients can in these cases often need support.”

iii. Cost to the donor

Few comments were offered in relation to the potential costs to the donor. However, an anonymous respondent noted that “after death, I could not possibly feel any pain, it won’t cost me anything.”

Costs: donation of reproductive material

A number of respondents to the consultation highlighted the costs of donating reproductive material – specifically gametes and embryos. Again, the analysis of responses may be split into the different parties affected by the donation.

i. Cost to the donor

Several respondents highlighted the costs of donating reproductive material to donors themselves. However, there was a wide range of views on what costs would, or would not, be experienced by donors. For example, one respondent felt that “there are few, if any, financial or physical risks to sperm donors.” Similarly, Haris E. Cazlaris PhD took the view that there is “no cost (the recipient pays the cost).”

Other respondents felt that there were costs to the donor, which had predominantly arisen through the removal of donor anonymity in 2005. This view was taken by Progress Educational Trust, which felt that “since the entitlement to donor anonymity was removed, psychological concerns have also been raised about the donor themselves, specifically about their trepidation at the possible impact upon them and their family, if a child born as a result of their donation should contact them 18 years later.” Similarly, Dr Kevin Johnston noted that “with no rights to anonymity, any person donating eggs or sperm now has to accept the likelihood that their future biological children will make contact with them in the future.” In addition, the Royal College of General Practitioners noted that “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.”

Few respondents referred to costs which may be experienced by egg sharers. However, Progress Educational Trust noted that “studies have indicated that in a scenario where a woman’s fertility treatment is unsuccessful, and that woman has participated in an egg sharing scheme, she may feel anxiety at the thought that her biological child is being raised by others.”

ii. Cost to the donor-conceived child

A significant number of respondents drew attention to the cost of providing gametes to the children conceived as a result of the donation. The British Psychological Society, for example, focused on “the psychological costs of donation” to donor-conceived children. Moreover, CARE noted that “there are significant ethical (and some practical) costs borne by the resulting offspring who will have no biological connection with their social parent(s) and may never know about their complete genetic heritage." The future impact for donor-conceived people was also noted: "the lack of free follow-up professional support for individuals and families affected, including intermediary services for those later wishing to have contact with genetic relatives, is a matter of great concern" (PROGAR (British Association of Social Workers Project Group on Assisted Reproduction)).

iii. Cost to the donor's relatives

Few respondents drew attention to the potential costs to relatives of gamete or embryo donors. However, the International Donor Offspring Alliance noted that "the relatives of the person whose gametes [are] used to create a child may also suffer never knowing this child who will be their grandchild, niece, nephew, cousin, half-sibling etc…"

Risks

Comments about the risk involved in providing bodily material can again be sub-divided into a specific type of bodily material, and the party affected by the donation of bodily material.

Risks: blood donation

Consultation respondents who addressed the issue of the risk of blood donation predominantly took the view that the risk involved was minimal. For example, Professor Peter Furness noted that "a blood sample is less risky" than living organ donation. Sylwia Maria Olejarz commented that the only possible risk might be that of infection. Other respondents, however, took the view that there was no risk involved in blood donation.

Risks: living organ donation

i. Risk to the donor

A general comment was offered by the Royal College of Physicians of Edinburgh, who noted that "risks to health are perceived very differently by individuals, making it difficult to generalise, and between potential donors and their medical team. Often the donors themselves are willing to accept far higher risks than the medical profession."

However, many of the respondents who chose to address the risks involved in living organ donation focused on the physical risks to the donor. Views offered included the observation by the Christian Medical Fellowship that the donation of organs "involves considerable risk including anaesthesia, surgical procedure, pain, morbidity…" Moreover, one respondent noted that "whilst everything possible is done to eliminate risk to the donor it is acknowledged that the risk of donor death is 1:3000." Also included among those who took this view was an anonymous respondent who told the Working Party that "from personal experience, there are considerable risks to live organ donation, my partner experienced a collapsed lung within a day of donating a kidney (to our son) and was unwell for several days, in pain and suffered acute upset stomach due to the antibiotics… However, my son and our entire family has benefited enormously."

In addition to the acknowledged, if rare of death, it was also noted that “a donor will not be able to donate to another friend or relative in future, and if the transplant is not successful they may feel they have let the recipient down.”

Less tangible risks were also noted by respondents. For example, one respondent felt that there would be a “risk of loss of autonomy and control over a piece of your body once the material is stored or in use somewhere else.” In addition, it was noted by the Human Tissue Authority that there was a risk that “living organ donation potentially exposes the donor to duress, coercion and reward. Pressure can be applied on the potential donor by a range of people, including relatives and friends.”

ii. Risk to the recipient

Fewer consultation respondents focused on risks to the recipient of an organ from a live donor. Of those respondents who did draw attention to the risks for recipients, the majority focused on the physical risks. Sylwia Maria Olejarz, for example, noted that there may be a “very high risk of health complications after organ donation” and a response from the University of Leicester Medical School (group 8) drew attention to the harmful side effects of immunosuppressant drugs.

A non-physical risk to recipients was raised by Miss N. Sethi, from the AHRC/SCRIPT Centre at the University of Edinburgh’s School of Law, who took the view that “the potential guilt of the recipient should also be considered in the instance that the transplant is not successful.”

iii. Risk to relatives of the donor

The risk to relatives was noted in a very small number of responses, including that of the Human Tissue Authority which noted that “friends and family must deal with the risk of the death of their relative and also of possible complications. If they also have a relationship with the recipient they must also face these risks with them, making it an exceptionally difficult time emotionally.”

Risks: deceased organ donation

i. Risk to the donor’s relatives

Most respondents who chose to respond to this part of the question drew attention to the risks which need to be faced by the relatives of deceased donors. The Anscombe Bioethics Centre, Oxford, for example, felt that caution needed to be exerted when addressing the issue of deceased organ donation as “taking organs after death with insufficient sensitivity to the feelings of relatives could exacerbate their grief and lead to significant ongoing psychological harm.” Caution was also urged by the Human Tissue Authority, but in relation to the issues which should be considered by the donor’s family: “They (the donor’s family) must consider the risk that, if there are no instructions from the deceased, they could make a decision they would not have made themselves in life.” Further psychological risks were also raised by one respondent, who noted that “there may be psychological risks to relatives who hold cultural or religious views on the disposing or handling of the body.”

Conversely, other respondents took the view that there would be few, if any, significant risks to the relatives.

ii. Risk to the donor

A number of respondents felt that there would be to the deceased organ donor. CARE, for example, stated that "there is a real risk that ventilators may be turned off too early, or not even turned off, until liver, heart and/or lungs are removed, because they need to be perfused with blood." In addition, the UK Donation Ethics Committee noted that "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."

Risks: donation of reproductive material

i. Risk to the donor

Respondents who addressed the issue of risk to donors of reproductive material fell broadly into two categories: physical risk; and emotional and social risk.

Of those respondents who addressed the issue of physical risk, several referred to the risk of donors affecting their future fertility. The British Psychological Society, for example, stated that "medically, there is some evidence that oocyte donation increases the risk of later fertility problems for the donor." Also in relation to egg donation, Progress Educational Trust drew attention to the "side-effects of fertility drugs (which can include hot flushes, irritability and headaches) and the risk of developing ovarian hyperstimulation syndrome while undergoing ovulation induction (this can be a life-threatening complication). Additionally, unlike sperm (which can usually be obtained via ejaculation), eggs must be obtained via a surgical procedure."

Respondents who referred to emotional and social risks to the donor highlighted the possibility of offspring contacting donors in the future as a risk. In addition, Phil Harding noted the "largely psychological [risks] arising from a future sense of guilt, concern, etc from not knowing whether the child created was living a suitable quality of life and a realisation that the donor had not carried out his/her 'parental responsibility' to ensure this was the case."

ii. Risk to the donor-conceived person

Psychological risks to the donor-conceived person featured heavily amongst responses to the question of risk for gamete donation. The Centre for Family Research, University of Cambridge, for example, stated that there were "indications that serious problems may arise if donor children inadvertently discover the manner of their conception as teenagers or adults." However, some respondents felt that the perceived psychological risks of gamete donation for the resulting donor-conceived people needed to be tempered. Progress Educational Trust, for example, noted that "some argue that there are broader psychological risks associated with gamete donation. We believe that these risks have been overstated, as has the emotional significance of gamete donation."

Social risks were also raised. The International Donor Offspring Alliance note that there was a risk that donor-conceived people could be denied "a meaningful relationship with his or her biological mother or father." Moreover, David Gollancz noted that "the primary cost and risk is to the offspring, who will have to manage the complex and compromised relationships created by donation. The ethical position therefore is characterised by the fact that the person who carries the most risk is the only one involved who is not a volunteer."

The medical risk of consanguinity was also raised by a handful of respondents. PROGAR (British Association of Social Workers Project Group on Assisted Reproduction) noted that "the number of families that can be created from any one donor is currently capped at ten. However, even this limit is a matter of concern to many donor-conceived people given that it can lead to multiple genetic half-siblings and to the risk of inadvertent consanguineous relationships."

iii. Risk to egg sharers

A handful of respondents focused on the potential risks attached to egg sharing. Karen Dyer, Lecturer in Law at the University of Buckingham, for example, felt that women who egg share "have to be counselled as to the potential pregnancy in the recipient but the failure for themselves." A similar point was also made by an anonymous respondent, who noted that "there is a serious potential for long term emotional distress if the recipient party or parties become pregnant but the donor party or parties remain childless."

iv. Risk to the donor's relatives

One respondent highlighted the potential risk to the relatives of the donor of the reproductive material, noting that "there is potential for further emotional and relationship complications, particularly with spouses, when they eventually come face to face with these donor conceived people, 18 years or more later."

Risks: tissue donation

A very small of respondents drew attention to the risks involved in tissue donation. Phil Harding, for example, stated that, "for tissue donation, very few risks/costs (virtually nil) to [the] donor, but 'psychological benefits' from helping others." In the context of bone biopsies, it was also noted by Dr J. Reeve that they may be "very occasionally painful if technique is poor."

Risks: material with genetic information attached to it

A small number of respondents drew attention to the risks which may accompany samples of material which have genetic information attached to them. In the context of the storage of cord blood samples, CARE noted the risks attached to "the storage of personal genetic data in the public domain, and the research use of these stem cells and cord blood." In addition, the Church of England Mission and Public Affairs Council felt that risks may arise where there is "unforeseen usage of genome information if used in research."

Benefits

The benefits which might arise through the provision of bodily material were the main focus of a number of responses to this question. Again, these may be subdivided into the type of bodily material, and, where appropriate, the party who might benefit from its provision. However, several general comments about the benefits of providing bodily material were also offered, including:

> "Knowing that another had benefited either by receiving material or that material was helping research from which others would benefit."
> *Anonymous consultation respondent*
>
> "Benefit of feeling pleased with yourself… of knowing you've done your bit and you won't feel guilty if you need help in the future… of repaying a debt… of overcoming a fear."
> *Anonymous consultation respondent*
>
> "There can be emotional benefits."
> *Miss E. J. Toogood, consultation respondent*
>
> "The major benefit… is the hope/medical benefit given to others and the knowledge that this is the case."
> *Anonymous consultation respondent*
>
> "Benefits are to society; explicitly accepting some responsibility for delivering some of the things that individuals are often keen to demand as rights."
> *Professor Peter Furness, consultation respondent*

Benefits: blood donation

Several benefits were highlighted in relation to blood donation. Included among the benefits was a sense of achievement and self-satisfaction from donating. An anonymous consultation respondent, for example, drew attention to the "satisfaction of contributing to the pool." The health benefits to recipients were also highlighted by respondents. However, one respondent felt that there would be no benefit "except a feel-good factor and possibly kudos among a social or work group."

Benefits: living organ donation

i. Benefits to the donor

Several benefits were highlighted in cases where people became living organ donors, most of which focused on the 'feel-good factor' associated with donating. The Church of England – Mission and Public Affairs Council felt that such a feeling could lead to "enhanced self-esteem as a consequence of altruistic behaviour." The Anscombe Bioethics Centre, Oxford also felt that "it allows the donor to express solidarity with others." Other respondents felt that the benefit to the donor would be especially notable where they had donated to a family member.

Aside from the emotional benefits to living organ donation which may be experienced by living organ donors, some respondents also drew attention to the potential health benefits which they may experience. For example, the Human Tissue Authority noted that living donors will "be subject to regular checkups which may lead to the early detection of future health problems."

ii. Benefits to the recipient

A number of respondents highlighted the health benefits to the recipient of a living organ transplant. John Champion, Chair, SCKPA, for example, stated that there would be a longer survival rate of the graft if the transplant came from a living donor. Furthermore, another respondent noted that “for the right patient at the right time a transplant is the best treatment option with a good transplant giving circa 60% of the function of two normal kidneys (compared with only 5% from either form of dialysis). Quality of life improves considerably and graft survival with many [recipients] reaching 10 years plus. A transplant is not however a cure and a stable recipient would still have the kidney function of a patient with Chronic Kidney Disease at stage 3.”

Benefits: deceased organ donation

i. Benefits to the donor’s relatives

Most respondents who chose to focus on this question highlighted the emotional benefits to the donor’s family where their relative becomes an organ donor after their death. One anonymous respondent stated that “families who accept donation in many cases find comfort in the fact [that] their loved one has helped…” This theme of ‘making a difference’ was common to a number of responses. One respondent noted that it engendered “good potentially arising from the tragedy of death.” Other comments along a similar vein included:

> “[knowing] that their cherished one had done their best to be helpful, even in death.”
> *Betty Perry, consultation respondent*

> “Families who accept donation in many cases find comfort in the fact their loved one has helped in some cases to save more than one life.”
> *Anonymous consultation respondent*

> “[It] provide[s] hope and purpose in an otherwise futile situation - ‘death was not in vain’“.
> *Donor Family Network, consultation respondent*

The Donor Family Network also observed that allowing a relative’s organs to be donated gave “control back to the family via the request and consent process at a time when they may feel they have no control of the situation at all”. In addition, R. C. Whiting stated that deceased organ donation brought with it “efficient collection and total disposal (after using anything useful) [which] would relieve kin of any burden.”

Benefits: gamete donation

i. Benefits to the donor

Most of the comments the Working Party received expressing benefits to the donor focused on a sense of achievement and satisfaction that the donor might experience in the knowledge that they have enabled someone else to have a family. The British Psychological Society, for example, noted that there may be “emotional gratification at having helped another couple.”

A different sort of benefit was noted by one respondent in relation to egg sharing: PROGAR (British Association of Social Workers Project Group on Assisted Reproduction) noted that “for women undergoing IVF treatment, sharing their oocytes with other (anonymous) patients may be the only way that they can afford the treatment”. However, the same respondent noted that “there is evidence of the potential for later regret.”

The idea that gamete donation brings about benefits was questioned by a small number of respondents. In terms of benefits bestowed on gamete donors, one anonymous respondent felt that “there are no tangible benefits to sperm donors.” Similarly, the National Gamete Donation Trust took the view that there was “no real benefit to [the] donor unless [they are] helping a relative to conceive or supporting medical research.”

ii. Benefits to the recipient

Few respondents chose to comment on benefits of the provision of reproductive material to recipients, but of those who did, most commented on the benefit of having an opportunity to have a child.

Benefits: material donated for research

A few respondents to the consultation focused on the question of benefits which might arise from bodily material donated for research purposes. Comments received included:

> “There are potential benefits and risks if information of diagnostic or predictive value derived from donated biological material is fed back to donors or their relatives. On one hand, this information might bring direct health benefits (for instance, by allowing early access to treatment or preventive measures). On the other hand such information may not be beneficial if the interpretation is unclear, there is no intervention available.”
> *Medical Research Council, consultation respondent*

> “It is particularly challenging to strike an appropriate balance between realising the potential benefits for society of embryonic stem cell research – which requires human eggs for research – while adequately safeguarding those individuals who choose to donate eggs for research.”
> *Wellcome Trust, consultation respondent*

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?

Respondents offered some general comments to this question aside from the issues of costs, risks, and benefits. Dr J. Reeve, for example, noted that “every new treatment has to be used for the first time… without first-in-human, [there would be] a catastrophic fall in progress in therapeutics.”

Costs

Several respondents noted costs that may arise through participating in first-in-human clinical trials. Some of these respondents considered the costs to be significant, for example by “undergoing monitoring procedures which may be invasive or unpleasant.” Others also referred to the events at Northwick Park as an indication of the costs which may arise through first-in-human research. The Royal College of General Practitioners, for example, stated that there are “significant costs and risks to individuals and their families… as we have seen when things go wrong (e.g. the Northwick Park experience).”

Other respondents chose to focus on the possible financial costs of taking part in a first-in-human clinical trial. For example, the Human Tissue Authority noted that “participants in clinical trials will often be required to take time off work, yet the amount they receive may not equal the loss they incur.”

A handful of respondents took the view that there were no costs in taking part. Graham Brushett, commenting on taking part in two first-in-human trials, recounted that “the risks were explained and deemed to be negligible. No costs of any kind (financial, emotional, physical, and psychological) or inconvenience was incurred as the trial coincided with routine medical checkups.”

Risks

The main focus for respondents regarding ‘risk’ was the unquantifiable and uncertain outcomes of the trials in which volunteers take part. One anonymous respondent, for example, stated that “the main risk is not knowing how the trial will work out, e.g. unknown severe reactions or long term health damage.”

Again, several respondents also referred to the events at Northwick Park in 2006 as an illustration of the risks of first-in-human research. However, some respondents saw Northwick Park as an opportunity as a chance to reduce the risks associated with first-in-human research. The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom, for example, stated that “phase I trials in the UK were already very safe, but the recommendations of the Duff report have made them safer still.”

Lesser concerns about risk were also expressed by other respondents. The Royal College of Pathologists, for example, stated that “these trials have more uncertainties about potential adverse effects but provided these are made clear we don’t feel there are any special issues here." Patricia Stoat, Convenor, Health and Bioethics Committee, National Board of Catholic Women suggested that first-in-human trials brought about a "relatively low risk, and an opportunity for altruistic action (and a chance to pay off student debts)."

Concerns were also expressed for the potential risks associated with first-in-human clinical trials outside the UK. An anonymous respondent, for example, observed that "drug trials, when run by private pharmaceutical industries, have increasingly moved 'offshore' - that is, whereas the market for the drugs themselves may be understood to lie within wealthier countries (especially in North America and Western and Northern Europe), the testing of potential drugs has moved to countries that often lack a basic, working healthcare infrastructure." Similarly, Marcia C. Inhorn felt that the possibility of coercion of trial subjects was of especial concern where first-in-human trials are 'off-shored'.

Some respondents chose to focus on risks which might occur *after* the trial has taken place. Jean-Paul Pirnay, Laboratory for Molecular and Cellular Technology, Military Hospital, Brussels, for example, stated that risks might arise from "helping develop scientifically unsound or non meaningful (from a medical point of view) drugs or techniques." Another respondent also noted that "the issue of 'disappointment', i.e. of the psychological consequences and symptoms related to failure of first-on-humans trials has to be taken seriously."

A different type of risk was also highlighted which focused on financial considerations, namely that "remuneration may be too tempting an inducement for someone who is struggling financially."

Benefits

A handful of respondents took the view that there were no benefits attached to participating in first-in-human research. Pat Spallone, for example, stated that "I would expect no personal benefit from volunteering the loan of my body for such drug trials, and fair risks and costs to body and mind, and maybe 'soul' too."

Other respondents highlighted a number of benefits that they felt might arise from participating, several of which focused on emotional and psychological benefits:

> "[There is a] 'psychological altruistic benefit' from assisting in the development of better medicines."
> *Phil Harding, consultation respondent*

> "Personal satisfaction that that they may have helped the development of medication that may help a lot of other people."
> *Amanda Wilson, consultation respondent*

> "The benefit for healthy volunteers is primarily an altruistic one of helping to develop a new treatment to benefit others."
> *Medical Research Council, consultation respondent*

Financial benefits to volunteers were also noted by a number of consultation respondents, with some considering this type of benefit to be the only one of significance for first-in-human trials. For example, Attendees of Ethics Forum at University Hospitals Birmingham, organised by Greg Moorlock noted that “when there is no expectation of health benefit and the participant is healthy, the potential benefits (beyond monetary) seem less significant.”

Others, such as the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom, however, took the view that benefits were primarily *societal*, with observations such as “there is a potential benefit to society as a whole.” Similarly, Miriam Pryke observed that “a person who is willing to participate in a trial may derive some measure of personal satisfaction from having made a contribution for the ultimate benefit of humanity.”

However, other respondents felt that “benefits to individuals are limited for healthy volunteers.”

Other observations

A number of respondents felt that the consultation document should not have included first-in-human trials. Objections included that offered by The Anscombe Bioethics Centre, Oxford, who felt that “while it is true that the first-in-human volunteer risks and uses his body, the same could be said of many kinds of human activity – from the test pilot to the mountaineer.” A further objection was raised by the National Research Ethics Advisors’ Panel, who took the view that “the issue of ‘whole body’ donation is at stake in many other instances of research and there are often equally serious risks in early-phase clinical trials though we acknowledge that first in man studies are likely to carry a higher risk since less is known about the investigational medicinal product at that stage.” The Wellcome Trust took the view that “a more meaningful parallel for the donation of bodily material for medical research, which might be worth the Working Party considering further, is the use of patient information from medical records for research.”

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

Several additional purposes which might raise ethical concerns for the person providing the material were suggested by respondents to the consultation.

Where the material will be used in a commercial context

A handful of respondents felt that ethical concerns might arise where bodily materials were, or could be, used in a commercial setting. PROGAR (British Association of Social Workers Project Group on Assisted Reproduction) felt that this issue was particularly sensitive in the context of reproductive bodily material. They took the view that "where material such as donated gametes and embryos are provided to an organisation and then sold for profit to a third party, the intermediary's financial gain is an ethical concern."

Where issues of privacy arise

A number of participants highlighted the issue of privacy of information attached to donated bodily material. Comments received by the Working Party included a comment from the PHG Foundation which noted that "the use of human bodily material for the purpose of predictive genetic testing might lead to fears of discrimination or stigmatisation."

Where material is used for cosmetic purposes

Several respondents expressed concerns for instances where human bodily material was used for cosmetic procedures or related research. The Human Tissues Group, referring to their own survey, observed that "one respondent mentioned that they would be uncomfortable about cosmetic uses, except where this was to correct a problem with a serious negative impact on the potential recipient's quality of life." Similarly, Jean-Paul Pirnay of the Laboratory for Molecular and Cellular Technology, Military Hospital, Brussels, felt that the "use of human tissue in purely cosmetic (vanity) procedures" raised ethical concerns. The National Research Ethics Advisors' Panel (NREAP) also felt that "[r]esearchers should alert potential donors to the likelihood that their tissue may be used… [for] non-medical uses… for example in the development of cosmetics thus providing an opportunity for donors to consent to the conditional use of their tissue."

Where the material is used for 'ethically controversial' experiments or procedures

A number of different 'ethically controversial' experiments or procedures were raised by respondents to the consultation.

Where the material concerned is embryonic or fetal

A number of comments were made about the use of embryonic or fetal material. Dr David J. Hill, for example, stated that "embryonic or foetal stem cells require the creation and destruction of human life."

The storage of embryos was also raised in response to this question. Marcia C. Inhorn, for example, stated that "currently, there are millions of embryos in cold storage around the world, because fertility clinics are loath to destroy the embryos, as are the infertile couples who have produced them."

Where the treatment or research uses material from animals

Respondents who highlighted this issue predominantly focused on mixing human and animal reproductive material. For example:

> "There are also concerns for some people who donate gametes that their gametes might be mixed with gametes from other species…"
> *National Gamete Donation Trust, consultation respondent*

A number of other respondents also raised concerns where bodily material might be used for hybrid or chimera research.

Where reproductive material is used to create 'saviour siblings'

The Working Party received a handful of responses from both individuals and organisations about the creation of 'saviour siblings'. The organisation CARE took the view that "children born following pre-implantation tissue-typing need, and should be given, *special and explicit protection*… For example, regulations could specify that they should not be subjected to more than two rounds of bone marrow transplantation…" The British Fertility Society similarly raised the issue of 'saviour siblings' as one which raised ethical concerns, and Miss E.J. Toogood noted that 'saviour siblings' were children "born with useful bodily material."

Where bodily material is used for research on biological warfare

A number of respondents highlighted concerns about the use of bodily material to inform research into biological weapons. As Professor Peter Furness noted, "some uses of tissue would be regarded by most donors as ethically outrageous – for example, developing weapons of biological warfare."

Where the bodily material is used as part of a public exhibition

The work of Günter Von Hagens was cited in a number of responses to this question. Alex Smith, for example, took the view that "[p]roviding, for example, human bodies or body parts for exhibition purposes is wrong." This view was shared by several respondents.

Where the bodily material is used for medical training

Situations where bodily material may be used for medical training was also highlighted by respondents. As the European Society for Organ Transplantation Council noted, "bodily material can also be provided for educational purposes. One possibility is donation of the whole body to a medical university." A comment on such use was raised by Group 14 from the University of Leicester Medical School, who noted that "the use of cadavers in medical schools or during training… may raise concerns about dignity and respect of the donors."

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

* Some respondents (for example organisations) may wish to respond to these questions by commenting on whether they believe any purposes should be singled out for any form of special treatment or priority.

Several respondents took the view that there would be no discrimination between purposes. To this end, the Working Party received a range of views:

> "Personally, if I'm dead I don't care what is used for what…"
> *Aaron Long, consultation respondent*

> "All of the possible uses listed are for the benefit of either an individual or many (i.e. through research) and hence are all equally worthy."
> *Anonymous consultation respondent*

However, other respondents suggested that they would, or would not, be willing to provide bodily material for a range of purposes.

Not where the bodily material would be used for reproduction

Most respondents who stipulated that they would be unwilling to provide bodily material for certain purposes cited that those purposes would be related to reproductive uses of the material. A significant number of these respondents focused on the 'different nature' of reproductive material, and the impact of having a child which is biologically related to the donor, but without the social attachments which normally accompany such a relationship. Comments received by the Working Party included:

> "Because of the importance we place on human relationships, and parental responsibilities in particular, the donation of 'life-creating' material belongs in a special category."
> *Christian Medical Fellowship, consultation respondent*

> "I would not consider providing life creating bodily material for egg donation for an infertile couple as it can be argued that this is something to be treated differently to other purposes..."
> *Miss N. Sethi, AHRC/SCRIPT Centre, School of Law, University of Edinburgh, consultation respondent*

> "I have some ambivalence about donating my own gametes or embryos (or my husband's), in the sense of having a biologically related child 'out there' somewhere, and not knowing its life circumstances. On the other hand, if I were in need, I believe that I could accept a donated embryo or gamete."
> *Marcia C. Inhorn, consultation respondent*

Other respondents referred to the legal ramifications of donating gametes for *treatment*, specifically the fact that donor-conceived individuals are able to access identifying information about the donor once they reach the age of 18.

Another view, which was put forward by Patricia Stoat, Convenor for the Health and Bioethics Committee of the National Board of Catholic Women, highlighted concerns "that fertility treatments are making children into commodities and undermining the key role of loving relationships as the foundation of human family and community."

Not where the bodily material would be used commercially

A number of respondents expressed discomfort at the idea of their bodily material being used for commercial purposes. For example:

> "I would be very resistant to provide material that would provide profit to others either directly (through trade or tissue banks) or indirectly (medical research done for profit)."
> *Chris Briscoe, consultation respondent*

> "My only reservation about providing bodily material is if it was for commercial use or exploitation. So, I would be unlikely to volunteer for a drugs trial or donate bodily material to a commercial organisation, especially if not for a defined purpose."
> *Anonymous consultation respondent*

Other justifications for having reservations about providing bodily material for commercial uses included concerns about the benefit of the donation being restricted by being handled in a commercial environment, and also where the bodily material is used by commercial organisations for undefined purposes.

Dependant on the invasiveness of the procedure

Several respondents highlighted difference in invasiveness between certain types of donation compared with others. Group 13 from the University of Leicester Medical School, for example, felt that "individuals may be more hesitant with regards to invasive procedures that require a longer and perhaps more difficult/uncomfortable period of recovery, where they would be less likely to donate." Similarly, in the context of volunteering for clinical trials, Group 15 from the University of Leicester took the view that "if the trial requires invasive procedures, it would be less likely to attract willing participants." The same respondent noted that "a trial that requires the extraction of eggs from the ovaries would attract fewer volunteers than a trial requiring just a small blood sample."

Similar comments were made in relation to the understanding that donating blood is a relatively non-invasive procedure. Miriam Pryke, for example, took the view that blood is the least problematic form of donation "because it regenerates rapidly and may be procured relatively simply."

If the bodily material is used for 'legitimate' or 'acceptable' research

Some respondents felt it important to state that they would only be willing to donate bodily material for research which was 'legitimate' or 'acceptable'. Comments received by the Working Party included:

> "If it is for research purposes I would evaluate the scientific integrity of the research project being proposed to me. Donation for unspecified purpose is not acceptable to me as there have been so many projects that have been ill-defined and are not properly performed with little value at the end result."
> *Jayne Doran, consultation respondent*

> "Some couples may be happy to use embryos in research designed to improve the culture environment, which in turn may improve IVF success, but may not be happy to donate to stem cell research."
> *British Fertility Society, consultation respondent*

If the provision of bodily material helps family members and friends

Several respondents specified that they would only donate bodily material if it directly benefited their family members or close friends.

This question also invited respondents to specify how they might prioritise the purposes of the provision of bodily material – for example, whether they would prioritise the provision of bodily materials which would enhance life rather than sustain it.

'Life saving' purposes takes priority

Most of the respondents who answered this question stated that life-saving purposes must take priority. For example, the Working Party received the following observation from

> "It is reasonable to prioritise life-saving donations above other forms of donation because of their immediacy and effect. The end-effect of life-prolonging donations, however, is similar to that of life-saving donations although immediacy is not usually a factor… a general approach in which life-saving treatment is prioritised over life-prolonging treatment which in turn is prioritised over life-enhancing treatment is a useful starting point for further discussion."
> *Church of England Mission and Public Affairs Council*

However, the same respondent warned that "trying to prioritise types of donation is fraught with such problems and difficulties. On the whole, apart from life-saving donations it may be better to try to encourage donation across the spectrum rather than to target specific types of donation."

'Life creating' purposes should not take priority

Most of the responses received by the Working Party expressed the view that the provision of bodily material for life creating purposes should not be prioritised. For example, one anonymous respondent stated that he "would be willing to donate to save life, less certain about prolonging or enhancing, and not for creating. I do not view life creation as a right that we should all have."

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?*

* Some respondents (for example organisations) may wish to respond to these questions by commenting on whether they believe any purposes should be singled out for any form of special treatment or priority.

Most respondents who chose to answer this question stated that their willingness to participate in a first-in-human trial would be affected by the purpose of the medicine being tested. A number of such 'purposes' were noted by respondents.

Willingness would be affected if the trial had a life-saving objective

Several respondents took the view that they would participate in trial if it had the potential to bring about a life-saving medicine. Some respondents contrasted life-saving medicines with drugs which could fit into a 'lifestyle' category. For example, Group 14 of the University of Leicester Medical School stated that "within our discussion group, the vast majority would prioritise a life-saving drug over something considered more trivial such as cosmetic medication e.g. anti-wrinkle treatment."

Willingness would be affected by the severity of the disease studied

A handful of respondents stated that their willingness to participate would be affected by the severity of the disease which the trial addressed. The Christian Medical Fellowship, for example, took the view that "people putting themselves potentially at risk have a right to expect a good purpose which is aimed at treating genuine threats to health." However, the Royal College of Physicians of Edinburgh noted that "one might prioritise on the basis of the severity of the disease for which the treatment is designed but, in practice, the choice is more likely to be determined by personal experience." John Champion, Chair of SCKPA felt that "any trial would have to be focused on furthering the reduction of human suffering – there would need to be a clear link." Others highlighted, for example, the growing problem of non-communicable diseases, and felt that they would be more likely to participate if the trial focused on such conditions.

However, some respondents stated that they would be *more* likely to take part in trials which addressed a less serious condition. Haris E. Cazlaris, PhD, for example, stated that "theoretically, I would volunteer more easily for a "benign" medicine (e.g. an oral antiseptic/mouth wash) than for some 'interesting-but-potentially-dangerous' one." The idea of taking part in trials which were used to develop cosmetic products, however, was not one which was given encouragement by respondents.

The *number* of people who might be helped by the trial was also raised by respondents. Betty Perry stated that she would want to know that "there were a considerable number of patients for whom the results of this trial would benefit." This point was echoed by the Royal College of General Practitioners, which suggested that "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.

Willingness would be affected by personal experience

A significant number of respondents noted that willingness to take part in a trial would be influenced by personal experience and, in particular, knowing someone with the condition which the trial focuses on. Comments received by the Working Party to this effect included:

> "I may prioritise participation in a trial for a medicine that cures or improves a condition that I have experienced either first or second hand."
> *Miss E.J. Toogood, consultation respondent*

> "If the medicine being tested would further research in a particular area to which a person has a particular personal link, then her/his willingness to take part may be affected by the purpose of the medicine."
> *Dr Petra Nordqvist, University of Manchester, consultation respondent*

Willingness would be affected if the trial focused on reproductive medicine

A handful of respondents stated that they would not take part in a trial if it focused on reproductive medicine. Phil Harding, for example, stated that he "would not participate in research/trials connected with life creation purposes." Similarly, the Church of England Mission and Public Affairs Council noted that "some individuals will not wish to take part in trials where the medicine or treatment being tested may be used in some forms of infertility treatment, post-coital contraception or abortion."

Willingness would not be affected by the purpose of the trial

Some respondents, however, felt that the purpose of the trial would not affect their willingness to participate. Comments received by the Working Party included:

> "I'd be happy to participate in any trials regardless of the purpose of the trial."
> *Anonymous consultation respondent*

> "The scope of the purpose would not matter to me. That is, participating in a trial to test a medicine intended for use in the context of a very rare condition would be just as worthy of my participation as one that could potentially rid Africa of Aids."
> *Miss E.J. Toogood, consultation respondent*

Chapter two: Ethics

9. Are there any other values you think should be taken into consideration?

A list of ethical values were listed in the consultation document, including altruism, autonomy, dignity, justice, maximising health and welfare, reciprocity, and solidarity. Several respondents used this question as an opportunity to comment on issues raised by these ethical values, before exploring other potential values which might be taken into consideration. Each of the values cited in the consultation will first be explored, before an analysis of other suggested values is undertaken.

Comments on values raised in the consultation document: altruism

Comments received on altruism included several that suggested that its definition should be reconsidered. Several suggestions were made by respondents.

> "We would like to add a concise definition that we have found useful from previous scholarly work that refers to altruistic action as 'an action in the interests of another or the disposition to act in the interests of another."
> *The HeLEX Centre, University of Oxford, consultation respondent*

> "[A] clearer exposition and definition of altruism is needed that delineates it from the concept of obligation or duty and understands the role of reciprocity within the gifting act."
> *Dr Gill Haddow, ESRC Innogen Centre, consultation respondent*

Professor Charis Thompson commented that there is a "false dichotomy between donor and everyone else who works in this field who is assumed not to be altruistic." The British Psychological Society, commenting on the current position, suggested that "there is increasing evidence that donation is often not truly altruistic but rather may be described as an act of benevolence rather than of altruism." Jonathan Lee stated that "as an unfortunate fact of reality, altruism does not produce enough organs."

Comments on values raised in the consultation document: autonomy

Several comments were also received in relation to the concept of autonomy. For example, one anonymous respondent argued that "I don't think that autonomy is always about body ownership. These should be handled separately. I believe autonomy is first and foremost about personal will." Mario Abbud-Filho form the Medical School FAMERP in S.J. Rio Preto observed that "all these principles must be carefully evaluated within the context of specific societies. Autonomy of miserable people that want to donate a kidney is not autonomy." Other comments received include:

> "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."
> *Royal College of General Practitioners, consultation respondent*

> "Autonomy is normally considered a priority, but should not necessarily always take precedence. An example might be when an emerging new infection threatens to become a serious public health issue, in which case testing samples in an existing tissue bank without donor consent could be justified."
> *The Medical Research Council, consultation respondent*

Comments on values raised in the consultation document: dignity

A range of comments were received on the issue of dignity. For some, dignity was seen as a positive concept. Jayne Doran, for example, stated that "dignity and justice should always prevail." However, others were concerned about its potential ambiguity. For example, one anonymous respondent suggested that "dignity is slippery – one imagines there might be a universal understanding of this (nobody should be hacked apart as if it is a piece of meat), but it requires a strong dedication to relativism, too – my sense of dignity may not be the same as yours, yet I ask you to respect it, nevertheless." An anonymous consultation respondent felt that "concepts such as dignity and justice have proven ambiguous in practice and should be minimised."

Some respondents also felt that the definition of dignity offered by the consultation document was too narrow in its focus. Comments included:

> "The definition provided here was a very narrow, very market driven interpretation. This is not the only definition possible for the value of 'dignity'. There are cultural connotations too, and not just commerce-based ones."
> *HEAL (Health Ethics and Law), University of Southampton, consultation respondent*
>
> "The concept of 'dignity' requires a more nuanced consideration than is provided in the consultation document. A useful starting point might be to distinguish between 'dignity as empowerment' and 'dignity as constraint'…"
> *Progress Educational Trust, consultation respondent*

Comments on values raised in the consultation document: justice

The Working Party received just one comment on the notion of 'justice', which was offered by an anonymous respondent who asked "why is justice anchored to recompense?"

Comments on values raised in the consultation document: maximising health and welfare

A number of respondents chose to comment on the value of maximising health and welfare. Marcia C. Inhorn, for example, stated that this "is the value underlying public health. It does not receive enough attention in discussions of life-saving and life-prolonging therapies. Many life-saving techniques, such as organ transplantation, would, in fact, be much less necessary if society placed more emphasis on *prevention* of the kinds of diseases that lead to the need for organs." Another comment was offered by the Royal College of Physicians, which suggested "separating 'maximising health and welfare' into two separate principles - one on maximum welfare and the other on appropriate levels of risk." Other comments received included:

> "Maximising health and welfare should be a major priority."
> *Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom, consultation respondent*

> "There is no doubt in my mind that the altruistic concepts of 'maximising health and welfare', reciprocity and solidarity are sadly missing from discussions in this area." - *Marlene Rose, consultation respondent*

Comments on values raised in the consultation document: reciprocity

A small number of respondents highlighted issues associated with reciprocity. Observations included:

> "Within the realm of organ donation (at least as practice in the U.S.) organs are given willingly (altruistically) without the expectation of reciprocation. Reciprocity nevertheless occurs, *and is widespread*, although this assumes forms that fall outside 'benefits or services': for instance, the surviving kin of deceased donors and organ recipients may locate one another and redefine their relationships as those of kin…"
> *Anonymous consultation respondent*

> "As reciprocity is defined as "providing benefits or services to another as part of a mutual exchange", it raised the query about what the donor receives in exchange for their organ. Since the donor list is anonymous, how does this mutual exchange occur?"
> *University of Leicester Medical School – Group 22, consultation respondent*

> "Reciprocity is an opportunistic 'value' that should be banned: what if I have nothing to 'give' and need to 'take'?"
> *Haris E. Cazlaris PhD, consultation respondent*

> "…reciprocity is a positive concept if it connotes active cooperation among individuals and includes relationships of gratitude and just recompense."
> *The Anscombe Bioethics Centre, consultation respondent*

Comments on values raised in the consultation document: solidarity

Relatively few comments were offered about the concept of solidarity in the consultation document. In a response submitted by HEAL, the view was taken that "the construction of solidarity in the consultation document seemed very narrow." Professor Charis Thompson felt that "the document's use of the notion of solidarity is very depressing: if you agree to give me something then I can get it sooner, and vice versa – a kind of reductionist bartering; should it perhaps be noted that another way to look at solidarity would be to work together, as a nation…?" Other comments received by the Working Party included:

> "Solidarity is very important as 'we are all in it together' in the sense that disease is not chosen and does not strike in a moral way."
> *Anonymous consultation respondent*

> "Solidarity recognises our interconnectedness, the natural compassion that everyone feels (or should feel) toward others in view of the hardships and misfortunes of those others, and it is in compliance with noble values of dignity, respect and mutual help. It emphasises community and mutual obligations."
> *Shawn H. E. Harmon, consultation respondent*

Other values to consider

Several suggestions of other values to consider were made. These included:

- Integrity
- Honesty
- Paternalism
- Trust
- Loyalty
- Respect
- Social justice
- Compassion
- Equality and fairness
- Sanctity of life
- Beneficence and non-maleficence
- Religious and cultural values
- Rationality
- Empowerment
- Responsibility
- Intuition
- Honesty

Of these, extended comments were received in regard to the following values.

Paternalism

Several respondents suggested that paternalism deserved consideration. A variety of reasons were offered for this suggestion, including:

> "The concept of duty of care which emphasises the responsibility of researchers, doctors, regulatory authorities to take measures to protect the safety, welfare and interests of those made vulnerable by the circumstances in which they are approached to be donors. There is therefore something like a justified form of paternalism."
> *Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre, consultation respondents*

> "Other values to be taken into consideration included 'protection and vulnerability', e.g. for incapacitated adults and children, which were not mentioned here."
> *HEAL (Health Ethics and Law), University of Southampton*

Compassion

Some respondents referred to the value of 'compassion'. For example, Graham Brushett felt that "an act of compassion is qualitatively different to an act of altruism. Appealing to human compassion introduces an element of obligation that does not feature in an act of altruism." Similarly, HEAL (Health Ethics and Law), University of Southampton noted that "altruism and solidarity did not quite encapsulate some selfless acts, and therefore 'compassion' was offered as an additional value."

Sanctity of life

Several respondents took the view that sanctity of life should be taken into consideration in the context of reproductive bodily material. Comments received included:

> "life begins at conception, and embryos must be treated as full human beings worthy of respect and legal protection."
> *Christian Medical Fellowship, consultation respondent*

> "Beneficence, non-maleficence, and sanctity of life values… may be derived from personal beliefs and/or religious teaching and must be respected if in conflict with the process of donation of human bodily material."
> *University of Leicester Medical School – Group 21, consultation respondent*

Loyalty and family values

Some respondents highlighted to the values of loyalty, especially in the context of family relationships. Group 3 from the University of Leicester's Medical School noted, for example, that "loyalty is important when considering wider family wishes. An organ donor's family may not want their deceased loved one to donate their organs despite the deceased's wish. This loyalty is more a value to consider than to base practice upon."

Beneficence and non-maleficence

The Working Party received several responses which took the view that beneficence and/or non-maleficence were values which should be taken into consideration. The British Psychological Society, for example, felt that the principle of non-maleficence should be considered. They noted that, "although it may not be possible, in all donation situations, to avoid doing any harm to the donor, we believe that clinicians and others should weigh up any possible harm to the donor against the potential benefits of the donation."

Equity and fairness

A handful of comments were received by the Working Party which focused on equity, including:

> "Equity must be a central component of every aspect of a scheme within which individuals donate any substance, whilst living or after death."
> *Graham Driver, consultation respondent*

> "Formal equality can be beneficial… But always treating people the same may lead to other inequalities through failing to recognise their differences."
> *Dr Rachel Ariss, consultation respondent*

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

Some respondents who chose to address this question felt that prioritising or balancing values should not be attempted. One anonymous respondent stated that "I do not believe in ranking values. They have their own positionality, and do not think they can be pressed in a hierarchical system. Furthermore they relate to each other and cannot be singled out." Similarly, The Anscombe Bioethics Centre, Oxford took the view that "moral principles are not to be weighed up or traded, they are to be combined in a principled way." The Royal College of Physicians went further, stating that "we believe this to be an insoluble dilemma and operationally impossible."

Others took the view that prioritisation depended on who the values were concerned with. For example, the National Gamete Donation Trust stated that "key to the priority in which one orders these considerations is whether one considers the individual first or the society. If one argues for the individual as the most important unit, then autonomy and dignity take precedence over justice and maximising the health and welfare of the community."

However, other respondents felt that a case could be make for arguing that one value should always take precedence over the others. Despite this, no value clearly emerged as dominant.

Altruism

Several respondents felt that altruism should take preference. However, few explained their rationale for this view. Conversely, other respondents explicitly stated why they thought that altruism should *not* take precedence. The most cited reason for this view focused on the idea that an altruistic system does not produce enough organs for transplants. Sally Satel, for example, noted that "while altruism is an admirable virtue, it has not produced nearly enough kidneys to meet demand."

Autonomy

A significant number of respondents thought that autonomy should take precedence over other values. Several reasons were offered by respondents who subscribed to this view:

> "…autonomy is of the utmost importance. To take that away would likely make people unwilling to donate. People should have the ultimate say in what happens to their own body."
> *Amanda Wilson, consultation respondent*

> "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."
> *Royal College of General Practitioners, consultation respondent*

> "Autonomy is the most important of these values - it is central to medical care and so should be central to the use of bodily material and participation in clinical trials."
> *Anonymous consultation respondent*

Concerns were expressed about allowing autonomy to be 'pushed' too far, however. For example, Miss N. Sethi from AHRC/SCRIPT Centre, School of Law, University of Edinburgh, took the view that "one might be tempted to place autonomy at the top of the list of values, due to the human rights based society in which we live, where the individual's right to self-determination is central. However, if this right was to be absolute in nature, we would be unable to stop someone from donating their heart to another, because it would be argued that this was their autonomous wish and right." Similarly, an anonymous respondent felt that "at present, the systems are too strongly in favour of autonomy above all else, without fair consideration to a wider societal context of autonomous decision making."

Justice

Several respondents took the view that justice should take precedence. Some affiliated justice with the notion of equity. Graham Driver, for example, noted that "equity must be a central component of every aspect of a scheme within which individuals donate any substance, whilst living or after death."

Other respondents chose to focus on justice in particular contexts. Graham Brushett, for example, felt that "the patient facing imminent death (if they do not receive a transplant) should have their needs for justice and welfare given greatest priority in the context of deceased donation. Moral values that serve to delay death should have primacy." Similarly, the Medical Research Council stated that "justice and solidarity are important values when considering research in resource poor settings and arrangements for access to new treatments after research is completed."

However, 'justice' as an ethical value caused concern for other respondents. Included among concerns was the argument that justice is an ambiguous concept. More substantive concerns included that offered by Jonathan Lee who argued that "the argument from justice appears to deny that people have different preferences; it is analogous to claiming that allowing people to buy houses punishes the poor because they are forced to rent at higher than mortgage cost."

Reciprocity

Few comments were received which supported the primacy of reciprocity. However, the Working Party did receive one comment from Haris E. Cazlaris PhD, who stated that "reciprocity is an opportunistic "value" that should be banned: what if I have nothing to "give" and need to "take"? For instance, would we ever dare put an infertile woman in a situation where she would trade a kidney for eggs? If no, why do we put her every day in the "egg sharing" situation, where she trades her eggs for a rebate on IVF costs?"

Solidarity

Significant levels of support were offered for the argument that solidarity should take precedence as an ethical value. Many referred to the phrase that 'we are all in it together'. Referring to this one anonymous consultation respondent stated that "we should be particularly wary of activities that diminish solidarity, as they diminish us all and may work to discourage the altruism that fuels donation."

The possibilities which might be opened by emphasising solidarity was also noted by respondents. For example, the University of Leicester Medical School (group 3) stated that "If solidarity held more worth as a value within the population there could be scope for more extensive research and trials in order to maximise health and welfare and to make more medical advances. In this country, there is a general attitude of 'every man for himself'."

However, other respondents felt that in order for solidarity to be given precedence, further consideration needed to be given to it as a concept.

> "Solidarity is very important and all too often given rhetorical recognition without any real practical weight […] Legislators and ethics committees and stakeholders in the public health and organ transplantation setting ought to give much more thought and weight to this value and the creativity that it undergirds when it comes to responding to public needs."
> *Shawn H. E. Harmon, consultation respondent*

Not all respondents, however, were positive about solidarity. For example, Jonathan Lee asked: "Does paying for organs become legitimate if I spread out the payment over a large enough group? Is giving an organ to a foreigner who suffers acute liver failure in Heathrow unethical? Whence then solidarity?"

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?

A handful of respondents took the view that it does not matter whether people take part in trials for free or for some form of compensation. For example, Miss E.J. Toogood stated that “it makes no difference, morally to the undertaking of the volunteer, but it does make a difference, morally to the procurement of volunteers. I.e. some form of compensation may unduly coerce or result in contributions of necessity.” However, Jayne Doran felt that “the motive to take part is more the issue.”

More respondents felt that it is better, morally speaking, to provide bodily material of take part in a first-in-human trial for free. Some respondents chose to make general comments to this effect.

> “The lure of compensation could cloud judgment. I do not think that it is intrinsically “better” to participate for free but I do think that it can be ‘wiser’.”
> *Anonymous consultation respondent*
>
> “It is perhaps less mercenary to participate for free.”
> *Anonymous consultation respondent*
>
> “Our society purports to value altruism very highly so unpaid donation/volunteering has a higher moral value.”
> *David Gollancz, consultation respondent*

However, other respondents chose to respond to differently depending on whether the issue at hand relates to donation or research.

Better, morally speaking, to donate human bodily material for free

Several concerns were expressed in relation to providing some form of compensation for the donation of bodily material. In its response, for example, the British Heart Foundation referred to a survey which it had carried out that found 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 reward.”

Several other respondents referred to the possibility of pressure being applied through the medium of payment, especially to people who are poorer members of society. Furthermore, some took the view that by introducing some sort of compensation – or more specifically payment – affected the nature of the act of donation. The National Gamete Donation Trust, for example, stated that “it is morally speaking better to donate without gain. Only in this circumstance can the act truly be said to be a donation. To be paid makes the person a vendor.”

A concern that by introducing some sort of compensation, ‘worse quality’ donors would be encouraged to donate bodily material. An anonymous respondent noted, there is a "risk that healthier donors might not give because someone else can fill the shortfall or needs the money more than them."

Some respondents focused specifically on gamete donation which generated particular concerns. One anonymous respondent stated, "there should be no inducement because any form of financial compensation which commodifies the creation of human life is morally repugnant and ethically undesirable."

Better, morally speaking, participate in first-in-human research for free

Fewer respondents took the view that volunteers should participate in first-in-human research for free. Views to this effect included:

> "Volunteering for a first in human trial is probably morally best done for free but the current UK system of payment for healthy volunteers is appropriate and recognises compensation for discomfort."
> *Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom, consultation respondent*
>
> "The "right" way to go, morally, is to have all volunteering done by non-paid (non-compensated) volunteers."
> *Haris E. Cazlaris, PhD, consultation respondent*

Some form of compensation is permissible

Some general comments were offered by respondents who felt that some sort of compensation is permissible. For example Brian Dale stated that "nothing is morally wrong with compensation and it does not matter what is being donated or tested."

Some form of compensation is permissible: provision of bodily material for treatment

Several respondents felt that some sort of compensation for the provision of bodily material should be permissible, and made a number of suggestions of the type of compensation which they deemed to be acceptable. For example, the option of giving a donation to charity in return for the provision of bodily material was popular among this group of respondents. Others, such as the National Gamete Donation Trust, felt that donors should be reimbursed for their time, expenses, or loss of earnings. This view was shared by the Human Tissues Group, which stated that "at least the donor should not be out-of-pocket as a result of their donation, so some form of compensation may be appropriate, and there is no doubt that compensation, whatever combination of expenses, time and inconvenience this may encompass, can stimulate donation." Similarly, the MRC Centre for Transplantation, King's College London, NIHR Biomedical Research Centre at Guy's and St. Thomas' NHS Foundation Trust and King's College London (Transplant Theme) supported "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 living donors."

Some form of compensation is permissible: volunteering for research

Most respondents who chose to respond to this aspect of the question felt that it was acceptable for some sort of compensation to be available for research volunteers. A variety of different opinions were offered, however, on how this compensation should be formulated, with some respondents stating that volunteers should be paid, whereas others focused on reimbursement of expenses.

> "I don't see why a pharmaceutical company shouldn't pay participants considering the millions they'd make from the resulting drug(s)."
> *Anonymous consultation respondent*

> "Where payment has always been the norm, as with clinical trials, it would be difficult to withdraw payment without having a detrimental impact upon the numbers of people donating their bodies for this purpose; as a result, demand may not be met."
> *British Medical Association, consultation respondent*

> "I think with caution some categories of reimbursement (with receipts) makes sense: for instance, for travel to and from the research site. But involvement in drug trials should not be a way in which to earn wages."
> *Anonymous consultation respondent*

> "Payment for first-in-human trials is… questionable and if it is to occur at all, it ought to be correlated to potential loss of earnings and not to be promoted as a means of financial gain."
> *Church of England Mission and Public Affairs Council, anonymous consultation respondent*

Only a few respondents commented explicitly on whether the type of bodily material makes a difference. The University of Leicester's Medical School's Group 21, for example, stated that "we do not think that there should be [an] intrinsic difference in the compensation of different material donated." Conversely, Jonathan Lepper stated that "individuals may well differentiate between 'life saving' and 'life prolonging' donation and 'life creating' donation… 'life-creating' donation may be viewed as less of a necessity by potential donors, and hence mean they are more likely to accept compensation."

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?

Several general comments were made by respondents who took the view that there can be a moral duty to provide bodily material. However, most of these responses stated that this moral duty only arose after death. Examples included:

- “after death when we no longer have need for our organs we have a moral duty to allow someone else to. During life the needs of the living for what they have is paramount.” (Anonymous respondent)
- “it is difficult to avoid the sense that there is a moral duty to make bodily material available after death, given the difference they can make to survivors.” (David Gollancz, consultation respondent)

Other respondents were of the view that a moral duty only arose in regard to certain types of bodily material, or in certain circumstances.

A moral duty arises if the risk or cost is not too high

A number of respondents were of the opinion that a moral duty arises if the risk or cost of providing bodily material is not too high. The Church of England Mission and Public Affairs Council, for example, stated that “it may be argued that everyone has a moral duty to act to save or to protect life if in so doing no unreasonable risk is incurred.” The Royal College of Practitioners similarly stated that a duty arose “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.” The correlation between risk and duty was also made by the organisationLiberal Judaism: “the greater the risk, the less it is a duty to provide material and if there is a significant risk to the donor, then donation would be discouraged.”

A moral duty arises if a person is a recipient of donated bodily material

Several respondents felt that, where a person had been the recipient of donated bodily material, a moral duty to donate would arise. Aaron Long, for example, stated that “if a person received donor material, especially organs, they should be obligated to become a donor at their own death… People may argue that they have the right to live and the right to take organs without reciprocating; do these same people assume that they have the right to take money from a bank without repaying it?”

However, other respondents took a less individualistic approach, instead suggesting that a duty arose as a result of community collective responsibility. For example, the European Society for Organ Transplantation Council stated that “in a democratic country, the decision to have donation/organ transplantation could be seen as a decision made by the citizens and thus it could be argued that there is a moral obligation to contribute by donating your organs. On the individual level, however, the individual should have a choice both regarding donation during life and after death.” Similarly, Group 3 from the University of Leicester’s Medical School, took the view that “a moral duty can arise [as] it can be thought of as mutual exchange and support within a community.”

A moral duty arises if a relative needs the bodily material

Several respondents took the view that should a situation occur whereby a relative needed a transplantation, then a moral duty would arise. Most responses which answered in this respect, however, did not explore the issue of familial donation beyond recognising the assertion that a duty would occur. One observation, however, was noted by the UK Donation Ethics Committee: "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."

Other respondents firmly took the view that no moral duty arose. View offered included:

> "It would be dangerous to say there is a moral duty as this represents moral blackmail."
> *Phil Harding, consultation respondent*
>
> "No. Why should there be, my body is my body it's up to me what I do with it. I am not compelled to donate and resent any person or organisation enforcing the harvesting of my body parts."
> *Grant Mackie, consultation respondent*

The view that the existence of a moral duty undermines a person's individual autonomy was frequently referred to by respondents who responded to this question in the negative. Similarly, several respondents felt that any recognition of a moral duty would lead towards a system where donation became forced rather than voluntary. Such a view was offered by one anonymous respondent who stated that "donating should be based on a free will basis, and if there is a connotation to duty, even if it is moral, to me it means that the individual is not free but bound by such obligations, which I find is questionable on ethical grounds." Similarly, a response submitted by the Christian Medical Fellowship stated that "the concept of freewill offering transcends all concepts of moral 'duty', or obligation. Any obligation at all diminishes the worth of the act, which is then no longer a donation, a gift."

A different perspective was offered by Miriam Pryke, who felt that a moral duty would "never [arise] under any circumstances […] You get one life. When your body packs up, that's it. You can't take other people's. If they freely give, that is quite another matter. A world in which we take, we demand, from people what they do not freely give, is not a world worth living in."

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?

Very few respondents felt that there was an unequivocal moral duty to participate in first-in-human trials. Most responses which answered this question in the affirmative took the view that a moral duty could occur, but only if certain conditions were invoked. For example, the Church of England Mission and Public Affairs Council stated that a moral duty "may reasonably be thought to exist where all the following conditions are met: an individual hopes to benefit directly from the development of a particular drug; he or she is considered to be an acceptable candidate; he or she is able to take part in the trial given family, work and other commitments; there are no unreasonable risks involved in the trial." The Royal College of Physicians, referring to its own research ethics guidelines, noted that "all other things being equal one should participate if it were possible to do so… Participation should be part of the social contract and being part of society is more than obeying the law."

Several respondents felt that a moral duty might arise in the context of certain groups of people. For example, Sylvia Maria Olejarz took the view that such a duty "may arise arise in the case of parents/family/relatives of a child (or other family member), who is suffering from a certain disease and such participation in the trials can contribute to invention of an effective medicine, which can save his/her life." Group 3 from the University of Leicester's Medical School, however, noted that "some would argue that those who have inflicted bad things on individuals perhaps have a higher level of moral duty than others to redeem themselves."

However, there was no overriding consensus on the group of people a moral duty might be bestowed upon. A theme which was recognised by a number of respondents, however, concerned participation in clinical trials where an epidemic or pandemic disease emerges. Marcia C. Inhorn, for example, stated that "if there was a global, life-threatening pandemic, I would hope that many global citizens would participate in vaccine trials to prevent the wipeout of the human population." Conversely, another respondent, Miriam Pryke, stated that there cannot be a moral duty: "never. Not to save the world from a pandemic. Not if the whole world is faced with certain death if you don't coerce people. There is no such moral duty. Moral duties cannot be created. What can be created are coercive laws."

The majority of respondents took the view that no moral duty could arise in the context of first-in-human clinical trials. Comments received by the Working Party included:

> "We should have the right to say yes/no. I believe this is a universal right, and it is the moral duty of the state to protect this right (to say yes or no)."
> *Anonymous consultation respondent*

> "There is a history here of medical experimentation on disempowered people - concentration camp inmates, black prisoners in the US - which is uniformly ugly. I think that both donation and participation in [first-in-human] trials must always be voluntary and based on impulse and perhaps a private, rather than municipal, moral sense."
> *David Gollancz, consultation respondent*

> "If participation in first-in-human trials becomes an obligation or moral duty, solidarity will be taken to an extreme. This could have a number of impacts - it could involve members of the population coming together and supporting each other, or could create clear divisions in society with those that do participate and those that do not."
> *University of Leicester Medical School, Group 2, consultation respondent*

Chapter three: Supply and demand

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

Is it always right to try to meet demand?

No

A significant number of respondents took the view that it is not always right to try to meet demand. For example:

> “We teach our children from their earliest days that ‘I want...’ is no basis on which to proceed. A demand-driven service will always be running hard to try and catch up with its own shadow.”
> *Anonymous consultation respondent*

> “Trying to meet demand is an ideal to strive towards, but raising expectations that demand can/will be met is unethical, it raises false hopes and can create unnecessary hardship/suffering.”
> *HEAL (Health Ethics and Law), University of Southampton, consultation respondent*

Respondents also suggested several reasons for taking the view that it is not always right to try to meet demand. For example, Shawn H. E. Harmon stated that “given scarce resources, rising populations, and increasing environmental degradation, it is probably not morally necessary to meet every demand.” The effect of trying to meet demand on developing countries was also noted by several respondents. Miss N. Sethi from the AHRC/SCRIPT Centre at the University of Edinburgh’s School of Law, for example, took the view that the question of meeting demand “depends on how the demand is met, and by whom. For example, in developing countries such as India, the black market in kidney trade is rife, such organs are often sold for minimal amounts of cash… Thus attempts to meet demand here are clearly not without their dangers… not trying to meet domestic demands may result in propelling travel tourism, driving patients to other countries.” Similarly, Dr Petra Nordqvist from the University of Manchester stated that “If meeting demands mean to compromise other ethical dilemmas such as reproductive tourism to poorer countries where bodily material is perhaps more readily available, then I do not think it is right to meet that demand.”

A pragmatic point of view was also offered by some respondents, such as that submitted by C. A. Growney RN, who noted that “death is an inevitable part of life and there is a time for each person to go through this.”

Yes

A significant number of responses stated that it is right to try to meet demand. Several general observations were made to support this view. For example, one anonymous respondent, focusing on demand for donor organs, felt that “an unharvested healthy organ is a wasted organ, a wasted opportunity to help a living person and a wasted opportunity to restore a family’s way of life.” Other respondents felt that attempts should be made to meet demand, providing that the attempt is undertaken by ‘ethical’ means, or if the demand is for a 'medically appropriate' purpose, or, indeed, if it is *affordable* to try to meet demand.

Respondents also suggested that there may be a number of justifications for endorsing the view that there should be an aim to meet demand. One anonymous respondent, for example, felt that "if demand is met within the UK, there would be far less, if any, 'tourism' for organs." Similarly, Progress Educational Trust stated that "failure to do so makes it more likely that unregulated and potentially unsafe practices will prosper." In a response submitted by Dr Lindsay Stirton and Jurgen De Wispelaere, it was stated that "any argument against a proposal to meet the demand for organs for transplant in a particular manner must weigh the following costs in the balance: … loss of life; impaired quality of life; economic and productivity losses; additional moral costs… failure to meet demand to the maximum morally permissible extent may lead desperate patients to engage in even more exploitative practices, for example the purchase of organs on unregulated or black markets."

Are some demands more pressing than others?

Demand for life-saving bodily material is more pressing

A significant proportion of respondents who answered this question were of the opinion that demand for life-saving bodily material is the need which could be deemed 'most pressing'. However, comments were limited in terms of further explanation of this view.

Several comments were submitted in relation to blood donation, which focused on the relative ease of donating, and the fact that blood is a renewable bodily material. In a response submitted by HEAL (Health Ethics and Law), University of Southampton, it was suggested that "whilst it might be right to try to meet 'demand' for renewable materials such as blood, the 'demand' for female egg donation is potentially limitless." In addition, Miss E. J. Toogood stated that "blood is certainly a more pressing demand than the demand for organs, since blood can be procured and used at reasonably low cost, with little inconvenience and appears not to adversely affect the donor. Its use can be life saving." Similarly, Professor Dr Jayapaul Azariah took the view that it was right to meet the demand for blood as it is renewable. In addition, an anonymous consultation respondent stated that "we should have a system where supply for daily essentials (blood for instance) is greater than demand."

A comment from the Royal Brompton & Harefield NHS Foundation Trust also offered an example from experience, noting the supply of donor organs: "whilst we continue to run both a successful heart and lung transplantation programme, the rate-limiting step for both clinical services is the supply of viable organs, with the demand for organs exceeding, as it has done for many years, the number available. Supply is further compromised in that a high proportion of donor organs are currently not suitable for transplant..."

Demand for reproductive bodily material is less pressing

The view that the demand for reproductive bodily material is less pressing was prevalent in consultation respondents' answers to this question. Submissions received by the Working Party included:

> "IVF is less important than a kidney transplant… No one has ever died not being able to have kids."
> *Grant Mackie, consultation respondent*

> ""It is not right to meet any medically sought demand that has no basis in medical need and involuntary childlessness is not a disease requiring a medical cure…"
> *Anonymous consultation respondent*

> "One can live childless, but not blood-less..., and existing life is more precious than life-to-be."
> *Haris E. Cazlaris, PhD, consultation respondent*

One counter-argument to this view was offered by Progress Educational Trust who noted that "there have always been those who seek to disparage or deprioritise gamete (sperm, egg and embryo) donation on the grounds that the absence of pregnancy is not a disease. However, this reasoning is fallacious. Infertility is classified by the World Health Organization not as a misfortune, but as 'a disease of the reproductive system."

Focusing on egg donation for research, Celia Roberts and Karen Throsby stated that "there is no evidence of a demand from women to be 'allowed' to donate eggs for research. We suggest that this absence of demand has to be taken seriously."

Other observations

Several respondents used this question as an opportunity to make several other helpful observations about supply and demand, several of which focused on the *concepts* of supply and demand.

> "'Needs' and 'demands' are socially engineered concepts."
> *Human Tissue Authority, consultation respondent*

> "The commercial language of supply and demand is inappropriate and morally wrong in this context."
> *Miriam Pryke, consultation respondent*

> "This is again an economic approach to issues that are not just economic from the outset, or ought not be thought of in economical terms."
> *Anonymous consultation respondent*

> "Clearly, uses of tissues for diagnosis and treatment and organs for transplant must take precedence over the needs of researchers."
> *Human Tissues Group, consultation respondent*

> "The question of what constitutes a 'want' or 'demand', as opposed to a 'need', and what makes a 'need' reasonable, are matters of interpretation, and perceptions will inevitably differ."
> *British Medical Association, consultation respondent*

> "It is an exaggeration that the perceived shortage or organs is „critical", since there is no 'right' to organs … Judgment should not be clouded by the impression that the demand for organs is critical and that people will die if organs are not donated."
> *Miss E. J. Toogood, consultation respondent*

Other respondents also suggested that the question of whether demand should be met could depend on the *reasonableness* of the demand in question. Others called for better understanding of the demands in question. Susan Bewley, Consultant Obstetrician, noted, for example, that “some ‘needs’ and ‘demands’ need to be more fully understood to be ameliorated. The infertility ‘epidemic’ (doubling in last 20 years) is largely caused by avoidable risk factors: use of contraception and abortion through the fertile years, rising age of couples before attempting pregnancy, smoking, obesity, tubal damage from sexually transmitted diseases.”

In addition, comments were made on the issue of opportunity for some people to donate, for example: “there is always a sense that not only is there an unmet demand, but there is also an unmet population of potential donors for whom there are practical difficulties providing the opportunity to donate.”

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?

Responses to this question fit broadly into ‘yes’ or ‘no’ categories.

Yes

Respondents offered some general comments in support of the idea that different forms of incentive, compensation or recognition should be used to encourage people to donate. However, most chose to focus on the acceptability of certain types of incentive.

Financial incentives

Several respondents felt that ‘straight cash’ should be used to encourage people to donate. Jonathan Lee, for example, felt that “it is better to pay donors for tissue than it is to have patients dying on the waiting lists.” Graham Brushett argued that “somehow it is viewed as tacky or morally debased to pay cash to a person who has spent 14 hours in an operating theatre to give part of their liver to save another person’s life. Why? The recipient benefits and society saves considerable resources in the care of the formerly dying patient. Surely the living donor presents a ‘win-win’ situation to society that is worthy of reward.”

Mr Brushett also provided the Working Party with a range of other financial incentives that might be offered, including “providing tax credits or increased personal tax allowances for people who register as donors – even higher credits for actual donors” or [paying] “the tuition fees for students [who] have registered and/or have donated.”

Compensation, reimbursement, and paying expenses

The idea of reimbursing donors for expenses they incur during the process of donation was an idea which was welcomed by a number of consultation respondents. Comments received by the Working Party included:

> “People who provide materials or participate in first-in-human trials should not suffer any financial hardship, so I would be in favour of paying any reasonable expense including any loss of earnings.”
> *Betty Perry, consultation respondent*
>
> “The minimum a donor should receive is generous compensation for their inconvenience and the potential risks they have incurred.”
> *Graham Brushett, consultation respondent*
>
> “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… 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.”
> *The British Transplantation Society, consultation respondent*

Indirect compensation

Some respondents felt that indirect compensation should be offered to donors. Perhaps the most notable example of this provided by respondents was that of payment of funeral expenses. One anonymous consultation respondent stated that “on funeral expenses: perhaps a token amount only, but not paying for the full funeral. Perhaps, for instance, the cost for cremation or embalmment might be offered because the body is inevitably marred by procurement procedures.”

Recognition of the donation

A significant number of respondents took the view that recognition should be used to encourage people to donate bodily material. A range of suggestions of forms of such recognition were suggested, including simple thank you letters, physical or online memorials to deceased donors, memorial services, and a book of remembrance. Dr Maryon McDonald, for example, stated that “a more acceptable way of recognising donation that avoids fears of commodification, exploitation and bioavailability, might be collectively to memorialise the act of donation. This is already practised in anatomy schools in the UK.”

Substantive comments which supported the recognition of donation through such methods included an observation from the Donor Family Network, which noted that “bereaved families want recognition not compensation. Money cannot replace a loved one.”

Offering donors priority on transplantation waiting lists

Some respondents took the view that, in the context of organ donation, priority should be given to those people who have themselves donated, or promise to donate (i.e. by signing the Organ Donor Register). Comments received included:

> “One’s priority on a waiting list… seems only fair—you endangered your life when healthy to help someone else who was ill.”
> *Anonymous consultation respondent*

Sending a donation to charity on the donor’s behalf

A number of respondents supported the idea that a donation should be made to charity on the behalf of a donor. Included in justifications for why this was an acceptable approach included the observation that such a donation might be a reward, but that no ‘profit’ comes from it being bestowed.

No

Conversely, a significant amount of respondents took the view that no incentives, compensation or recognition should be used as an encouragement to donate. Some general comments were offered in support of this view.

> “A donor is only a donor when they *donate*, that is when their motive is one of altruism and not of personal gain. Once we are start discussing incentives or rewards we are talking of vending.”
> *National Gamete Donation Trust, consultation respondent*

> "I believe this [donation] should be about altruism and solidarity."
> *Anonymous consultation respondent*

> "Distinctions should be drawn between the provision of incentives and the removal of barriers. Making people aware of options to donate and making it easy (removing the costs of donating) differ greatly from incentives that accrue material benefits to the person donating."
> *Lorna Weir, Professor of Sociology and Health, York University, Toronto, Canada*

Comments on financial incentives

Some of our consultation respondents felt that all 'incentives' were ethically dubious because they altered individuals' perceptions of the relative risks and benefits of donation, and could also be exploitative. Others highlighted that financial incentives might encourage people to donate solely to acquire money, and expressed concerns that they were potentially coercive. There were also concerns that financial incentives could lead to a 'black market' in bodily material, for example: "If tissue donation of any kind [is] subject to significant financial reimbursement, there is an increased risk of creating a black market in human tissues/organs."

Comments on egg sharing agreements

A number of respondents commented on egg sharing, taking the view that this sort of agreement should not be used to encourage egg donation. Views received by the Working Party included:

> "I oppose the offering of free fertility treatment (generally worth several thousand pounds) to those who are prepared to donate eggs lest this introduce an element of coercion."
> *Dr Ian Jessiman, consultation respondent*

> "offering a significant amount of money off IVF fees *will* compromise a woman's decision on whether to donate eggs or not, especially if she is economically disadvantaged in any way."
> *CARE, consultation respondent*

Using media, education, and discussion to encourage donation

Several respondents felt that, instead of considering incentives and compensation, encouragement to donate should be through media and education. Shawn H. E. Harmon, for example, stated that multimedia public educational and promotional campaigns could encourage young people "so that health solidarity and transplantation/donation become a part of the national social fabric." Haris E. Cazlaris PhD was also of the opinion that "we (as an organised society) should spend time, energy and money educating our people to donate bodily material for the common good, without expecting any compensation."

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?

If your answers to any of questions 16-19 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

Incentives are not unethical

A few respondents felt that incentives could not, of themselves, be considered unethical. The Royal College of Physicians, for example, commenting specifically on payment for first-in-human trials, stated that "payment is never coercive and participants can say no, or walk out." Similarly, Miss E. J. Toogood noted that incentives are not unethical in themselves "providing the interests of the donor are put first. Incentives should be offered on an 'official' basis and should be standardised." A further argument was put forward by Jonathan Lee:

> "If an incentive were to be unethical in and of itself, then this would imply that the nature of the procedure utilising the tissues was immaterial. It seems implausible that death or shortening the lives of patients is preferable to offering an incentive… if an incentive is unethical it must be so as a result of both the incentive and the procedure."

A larger proportion of respondents, however, felt that some incentives were unethical in themselves, and offered a number of examples where this was the case.

Incentives in general are unethical

The view that incentives in general are unethical was offered by several respondents. Professor Peter Furness, for example, noted that "pointing a loaded gun at the head springs to mind. That example is at the extreme end of a spectrum of potential coercion and society has to decide with great care what level of persuasion is acceptable, probably on a case-by-case basis." Other respondents came to the general conclusion that *all* incentives are unacceptable.

Direct financial rewards are unethical

A significant proportion of respondents who addressed this question took the view that direct financial incentives to potential donors constituted an unethical incentive. Reasons included the perception that financial incentives could potentially cloud the judgment of those who might be inclined to donate, or that financial incentives "would be unethical in encouraging a commercial value to the organs being offered for donation" (Allan King, consultation respondent). Similarly, the Christian Medical Fellowship stated that "excessive financial incentives lead society towards the buying and selling of human material, which from respect for human dignity we resist." Moreover, CARE felt that "donation means a gift, without compensation, with no strings attached."

Specifically, some respondents raised concerns about the donation of reproductive material, and the potential for the commoditisation of children. Another concern raised – by the International Donor Offspring Alliance – was that "it is unethical to provide a financial incentive to encourage people to create children of theirs that they have no intention of having a meaningful relationship with."

Indirect financial compensation is unethical

Some respondents were of the opinion that indirect financial compensation was unethical. Examples of such compensation included funeral expenses. One anonymous respondent stated that "providing funeral expenses would be a *huge* risk to consent, some people really worry about funeral costs." A scheme where Londoners were offered free taxi rides in exchange for signing the Organ Donor Register was also cited in a response from Attendees of Ethics Forum at University Hospital Birmingham, organised by Greg Moorlock. This response noted that "whilst not exactly payment for organs, some concerns were raised about the principles behind this. In cases such as this, it seems that although the incentive might encourage people to sign up to the ODR, this might not be a well-considered action and that big decisions such as this are not the sort of thing that should be influenced by taxi-fares."

Giving priority for transplantation for organ donors is unethical

A handful of respondents stated that giving priority for transplantation to those who have pledged to become organ donors themselves (i.e. by signing the ODR) was unethical form of incentive, despite it being "potentially highly effective" (anonymous consultation respondent). Similarly, a response from the National Research Ethics Advisors' Panel stated that "it is likely that instances of research where participants are explicitly rewarded with priority access to health care and treatment will be unethical either because of the potential for the undue influence of patients or because of the injustice to patients not participating in the research."

Egg sharing arrangements are unethical

Comments were received which argued that egg sharing arrangements were an unethical form of incentive. Views received by the Working Party which argued this point included:

> "[Egg sharing is] highly immoral and effectively flouts the current guidelines on payments to gamete donors."
> *Anonymous consultation respondent*
>
> "Egg sharing schemes are likely to be taken up by those who are more disadvantaged financially and who have less favourable access to NHS funded IVF treatment."
> *Celia Roberts and Karen Throsby, consultation respondents*
>
> "Offering a reduction in IVF fees will certainly compromise a woman's decision on whether to donate eggs for treatment and/or research."
> *CARE, consultation respondent*

Incentives that coerce or compromise consent are unethical

A number of respondents, rather than highlight specific examples of unethical incentives, focused on a more general category of 'incentives which coerce and compromise consent'. This view was highlighted in a response from the British Medical Association, which noted that "where an incentive is deliberately designed or intended to make someone act contrary to their better judgment, or where payment is intended as compensation for taking a particular risk, the BMA would consider this to be unethical." Similar views were expressed by other respondents, including the Church of

England Mission and Public Affairs Council, which expressed concerns about "emotional or psychological incentives or disincentives that may result in individuals donating out of guilt or fear." Other responses specifically highlighted the fear that consent could be compromised. Dr Petra Nordqvist from the University of Manchester, for example, noted that "this is a question of informed consent and what might compromise such consent. I believe that case incentives can compromise a person's informed consent and his/her ability to say no to participation."

Does it make a difference if the incentive is offered by family/friends?

The Working Party received several comments from respondents who chose to comment on the question of whether it makes a difference if the incentive is offered by family or friends.

Incentives offered by family/ friends do make a difference

Several respondents raised concerns about situations where incentives might be offered by family or friends, most of which referred to personal or vested interests that friends or family might have in the donation process. This, it was argued by some respondents, paved the way for emotional coercion and unfair pressure on the potential donor, such that they feel that they are unable to refuse a request to donate. Group 14 from the University of Leicester Medical School, for example, felt that "there is already familial pressure on an individual to donate and that monetary gain in exchange for bodily material may be another form of persuasion."

Incentives offered by family/friends do not make a difference

Some respondents felt the source of the incentive was irrelevant. Comments submitted which subscribed to this view included:

> "The source, I believe, does not make any difference, at stake is the question about the incentive in itself, not who launches it."
> *Anonymous consultation respondent*

> "It makes no ethical difference who offers an incentive to donate."
> *Progress Educational Trust, consultation respondent*

> "Significant financial reward would seem inappropriate, even if offered by family or friends."
> *Royal College of General Practitioners, consultation respondent*

A further observation on this issue was raised by the Human Tissue Authority, which noted that "in many of the 1,100 plus reports we receive each year from our IAs [independent assessors] we are told how the donor and recipient share a joke about how they may 'buy each other a pint' or 'go out for dinner' following the donation, and for the vast majority of families and friends this is a normal facet of their lives."

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

** Some respondents (for example organisations) may wish to respond to this question by commenting on whether they believe any forms of incentives can be counter-productive.*

If your answers to any of questions 16-19 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

A significant proportion of respondents drew attention to incentives which would make them less likely to agree to provide material. Each of these will be addressed in turn.

Incentives in general

A handful of respondents used this question as an opportunity to set out their misgivings about incentives in a general sense. Comments received by the Working Party included:

> "I suspect that I would refuse to participate in donation if I were incentivised. I was proud of the awards I received for donating blood but they were not the reason I was a donor and i did not stop donating after receiving my badges."
> *Alex Smith, consultation respondent*
>
> "An incentive is a bribe. To accept that incentive is to succumb to a bribe… An incentive is a temptation. It causes people to question moral boundaries and tempts them to move them for other than moral reasons."
> *Miriam Pryke, consultation respondent*

Financial incentives

Several respondents expressed the view that financial incentives would make them less likely to donate material or participate in a trial. The Human Tissues Group, for example, stated that "it may be that providing very high levels of incentive for participation in human tissue donation might also make people wary of taking part." Commenting on the perspective of those close to potential donors, the Donor Family Network stated that "many families may be discouraged by the idea of benefiting financially from the death of a loved one."

Preferential treatment for donors

A small number of respondents felt that offering preferential treatment for donors would discourage them from donating themselves. Betty Perry, for example, drew attention to "preferential medical treatment which might mean a patient with more pressing needs than mine would have their treatment delayed." Similarly, another respondent noted that "priority in case I needed treatment in the future… to me, is totally immoral"

There is no kind of incentive that would make respondents less likely to agree to provide or participate

Some respondents, however, stated that they would not be discouraged from donating or participating in a trial just because a particular type of incentive is offered. For example, a respondent who themselves had benefited from donation commented: "Having benefited from an organ donation, without which I would now be dead, there are no incentives that would make it less likely that I would agree to provide organ donation myself" (Jonathan Lepper). In the context of clinical trials, Group 14 from the University of Leicester's Medical School stated that they "do not believe that there is any kind of incentive that could make a person less likely to provide material or participate in a trial. This is because the definition of an incentive is a positive motivation to encourage action.”

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

If your answers to any of questions 16-19 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

Responses to this question can be broadly split between those respondents who did, and those who did not, perceive there to be a difference between indirect compensation and direct financial compensation.

There is a difference

Most respondents who addressed this question took the view that there was a difference between the two types of compensation. Several of these responses focused on how indirect compensation and financial compensation are perceived. An anonymous respondent stated, for example, that "indirect compensation is seen as 'cleaner' and less 'tainted'." Similarly, Grant Mackie noted that "indirect compensation appeals to my sense of philanthropy and makes me more likely to donate." Differences were also highlighted in terms of *who* the two different types of compensation would appeal to. A response from the European Society for Organ Transplantation Council, for example, took the view that the "risk for influencing the decision making and to attract poor and vulnerable groups seems far greater with direct financial compensation." A similar view was taken by Marcia C. Inhorn who stated that "direct financial compensation may be sought by the poor, by those with an addiction, or by those in some kind of desperate situation. Indirect compensation is more likely among the actual community "in need" of the treatment."

The perception of the opportunities offered by 'straight cash' payments as opposed to indirect compensation was also recognised by Graham Brushett: "Straight cash payments are seen as devaluing the worth of the human body… However, indirect compensation ultimately has a transferable monetary value. But I can recognise the argument that funeral vouchers are harder to convert into cocaine or alcohol than cash."

In a response submitted by Jonathan Lee, however, the *efficiency* of direct financial compensation was noted: "Direct financial compensation is more efficient for the simple reason that the incentive offered translates into a greater utility for the recipient, and hence less need to be offered. This lets you save lives."

One anonymous respondent highlighted the 'linkage' of the compensation to the donation, stating that: "In the case of free treatment or funeral expenses the compensation is connected directly to *an event* e.g. a deceased donation being acknowledged by funeral expenses being paid. Direct financial compensation is not connected to the event in the same way."

No difference/difference irrelevant

Fewer respondents stated that there was no difference between the two types of compensation. However, as with those who felt that there was a difference, *how* compensation is perceived was raised by respondents. For example, the Christian Medical Fellowship felt that there was no difference "in an ultimate philosophical sense… However, we recognise that they may be perceived differently, and this may affect acceptability.” The British Fertility Society also stated that there was “no moral difference in the type of benefit.” Jonathan Lee noted that “whilst some people may find it comforting to categorise “indirect” and “direct” compensation differently, what this is revealing is that they are uncomfortable with the brute fact that these activities value life, and that furthermore they can avoid cognisance of this if the compensation is made indirect.” Anthony Rimmer felt that “both provide a financial reward for something that should be an altruistic action motivated by generosity and solidarity rather than personal gain.”

A lack of practical difference between the two types of compensation was suggested by an anonymous respondent: “Apart from non-cash incentives such as mugs etc. for blood donation, all other direct and non-direct incentives are completely equal. Paying for someone’s funeral is only saving someone from paying it themselves, so indirectly giving them cash.” In addition, although not overtly stating that there are differences between the two forms of compensation, the National Research Ethics Advisors’ Panel response noted that “although there may well be a difference between these forms of compensation in terms of their likely influence on participants, any form of compensation has the potential to be unethical and should therefore be carefully weighed by the REC.”

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?

If your answers to any of questions 16-19 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

There is a difference

Several respondents were of the view that there was a difference between compensation for economic losses, and compensation or payment for time, discomfort and inconvenience. A variety of reasons were given for taking this approach.

Compensation for economic loss is easier to quantify

This view was popular among respondents who addressed this question, and included the following submissions:

> "The former are easy to measure – ask for receipts. The second are not, so the value of the compensation is hard to decide and will inevitably arouse suspicion of 'payment for donation'."
> *Professor Peter Furness, consultation respondent*

> "The text of the Declaration of Istanbul (10) avoids the use of the word 'compensation' and prefers the term 'reimbursement' precisely because the latter only considers economic losses, which can be accurately assessed, while the former includes forms of frank payment."
> *Professor Gabriel Danovitch, consultation respondent*

> "Economic losses are more objective, and therefore more easily measurable, than subjective factors such as time, discomfort or inconvenience."
> *Progress Educational Trust, consultation respondent*

Compensation for economic loss ensure participants aren't out-of-pocket

A small number of respondents explicitly commented that compensation for economic losses ensure that participants are not left in a financially worse situation than before they provided the bodily material. Graham Brushett, for example, stated that "compensation for economic loss should be automatically guaranteed – there is no way a person should experience a loss of any kind by contributing to a donor programme."

Compensation for economic loss maintains altruism

Again, a small number of respondents argued that compensation for economic loss does not undermine altruism. Comments received included:

> "By compensating loss but no more, the sacrificial 'gift' element remains, and altruism is an important concept that should be encouraged."
> *Christian Medical Fellowship, consultation respondent*

> "Compensation in the form of reimbursement is consistent with participation driven primarily by altruism. Anything else smacks of a fee."
> *David Gollancz, consultation respondent*

Compensation for time, discomfort, or inconvenience is open to abuse

A handful of respondents took the view that compensation for economic losses would be more open to abuse than other compensation for time, discomfort or inconvenience. In a response submitted by The Anscombe Bioethics Centre, Oxford, for example, it was suggested that "compensation for expenses is less open to exploitation and corruption than compensation for inconvenience… It is essential that compensation should be modest in scale and should not represent a covert incentive scheme."

There is no difference

A number of respondents stated that there is no difference between the two sorts of compensation. Several different reasons were given for taking this view, including:

> "Most people will value their free or non-working time. Therefore compensation or payment for time or inconvenience is really no different than compensation for economic loss."
> *Anonymous consultation respondent*
>
> "All are valid in my eyes. [A]t the end of the day someone wants what I have so I think I am entitled to at least some recompense for time and trouble."
> *Grant Mackie, consultation respondent*

However, most respondents who took this view simply stated that there was no 'moral difference' between the two sorts of compensation. The MRC Centre for Transplantation, King's College London, NIHR Biomedical Research Centre at Guy's and St. Thomas' NHS Foundation Trust and King's College London - Transplant Theme, for example, stated: "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…"

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?

A large number of respondents chose to address this question.

Scientific developments

A wide range of scientific developments were raised by respondents. Included in these suggestions were:

New surgical/medical procedures and equipment

- Artificial organs and devices, such as left ventricular assist devices.
- Ex-vivo perfusion (of lungs) "which 'reconditions' donor lungs prior to transplantation." (Royal Brompton & Harefield NHS Trust).
- Earlier detection of diseases associated with organ failure, such as chronic kidney disease.
- Developments in translational research, particularly in the field of protein therapeutics, which "has considerable potential to improve the quality and suitability of organs for transplants." (MRC Centre for Transplantation, King's College London, NIHR Biomedical Research Centre at Guy's and St. Thomas' NHS Foundation Trust and King's College London - Transplant Theme)

The use of stem cells and regenerative medicine

- "Advances in the development of stem cell-derived human cells that fully demonstrate a native cell phenotype will inevitably impact the need for fresh human tissues in some areas in the future." (Anonymous consultation respondent). Similarly, the British Medical Association noted that "developments in stem cell technology, which enable tissue to be grown from stem cells in order to repair damaged organs, suggest that it may eventually be possible to use an individual's own cells and tissue, rather than that of a donor."
- "the development of a highly porous scaffold for orthopaedic applications." (Wellcome Trust, consultation respondent).
- "The development of 'living bandages' using stem cells for the treatment of burns and chronic wounds." (Wellcome Trust, consultation respondent).

'Artificial' bodily material and tissue engineering

- Developments in artificial replacements for human organs and tissue: "'off the shelf' organs are just about a reality. However, they won't be truly viable and exceptional for another 20-50 years."
- Progress in attempting to create synthetic blood.

Xenotransplantation

- "The transplantation of tissues or organs from genetically engineered animals producing desired gene products, either constitutively or under regulation, would be uniquely possible for xenotransplants… [However] concerns over infectious risks have precluded translation of this work into the clinical domain." (MRC Centre for Transplantation, King's College London, NIHR Biomedical Research Centre at Guy's and St. Thomas' NHS Foundation Trust and King's College London - Transplant Theme, consultation respondent).

Reproductive techniques

- The use of intra-cytoplasmic sperm injection (ICSI) to reduce the need for donor sperm.
- The emergence of artificially created gametes.
- The possibility of 'social' egg freezing.

Progress in techniques used in first-in-human research

- "Work designed to reduce animal testing by the use of computer modeling and cell cultures that may make first-in-human testing safer." (Patricia Stoat, Convenor, Health and Bioethics Committee, National Board of Catholic Women)
- Streamlining and further efficiency in research

Policy developments

Respondents also drew attention to a number of policy developments, including:

- The introduction of paired and pooled donor schemes
- Discussions about moving to an 'opt-out' system for organ donation, for example that suggested by the Welsh Assembly Government.
- Recommendations made by the Organ Donation Taskforce, and subsequent implementation of these recommendations.
- Cross-border collaborations.
- Requested allocation for deceased organ donation.
- Public health schemes which raise the profile of preventative methods of avoiding organ failure and the need for transplants, for example, prevention of diabetes in order to maintain kidney function.

There are no developments which will reduce demand

However, a small number of respondents stated that there were no developments which might significantly reduce demand. One anonymous response, for example, noted that "we still need humans to provide… material." Highlighting technological advances specifically, The Anscombe Bioethics Centre, Oxford stated: "there may well be novel uses for human tissue, that increase demand. Furthermore, progress in the success of organ transplantation will itself lead to a widening of patients, who could benefit and hence to greater demand. Hence there is little reason to think that technology of itself will lead to a reduction of demand."

Chapter four: Consent and control

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?

If your answers to questions 21 or 22 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

Our consultation responses showed considerable polarisation around the issue of the invalidation of consent. Responses can therefore be subdivided into two categories: those who felt that there are forms of encouragement or incentive which do invalidate consent, and those which took the view that there were no incentives or encouragements which would have this effect. For those who answered in the affirmative, a number of forms of encouragement or incentive were provided which might be seen to invalidate consent.

Yes

Any incentive

A small number of respondents took the view that any incentive would invalidate consent. Jeff McILwain MD FRCS, for example, stated that "any incentive of any nature is a bribe, irrespective of the end outcome ethical advantage." Similarly, the University Hospitals of Coventry and Warwickshire Clinical Ethics Committee noted that "some Committee members wondered whether incentives were by definition coercive." Miriam Pryke commented: "Anything that is an incentive invalidates consent automatically because it commodifies that which is not part of an economy, but belongs to a human being not as property but constitutively."

Significantly high financial incentives

Respondents also noted that where financial incentives are high, consent might be invalidated. One anonymous respondent stated that "the potential reimbursement or incentive must be reasonable and not, of itself, provide an economic reason to donate that outstrips the other more altruistic reasons to donate."

Where the incentive targets someone in financial hardship

A greater number of respondents felt that incentives which target someone who is in financial hardship could invalidate consent. This was felt to be especially so "where a person or family's financial hardship was such that it was the primary reason for making the donation of bodily material" (Phil Harding, consultation respondent). Moreover, the UK Donation Ethics Committee stated that "there is an ethical and moral duty to avoid preying on essentially vulnerable people with 'offers they can't refuse'." Other respondents, however, took the view that, where people were in dire financial straits, then even the offer small amounts of financial incentives – namely money – could invalidate consent.

Where the incentive is too great or important for the recipient to resist

A similar strand of reasoning was offered by another group of respondents, who took the view that consent could be invalidated by incentives that were too excessive or important. Some stated that financial incentives could fit into this group. For example, the Human Tissues Group stated that “any financial or other form of reward, or one which is sufficiently excessive, may induce a potential donor to take substantial risks they would not otherwise consider.” A response from the British Fertility Service couched this in terms of “the offer of a benefit of high value to the donor that cannot be obtained through any other route.” Commenting on *money* offered, the Human Tissue Authority stated that “those participating in first-in-human trials are often rewarded financially and this is accepted in this field. It should not be the case, however, that participants are offered such a significant amount of money they would find it difficult to say no, whatever the risk.”

Moral and other forms of coercion

A number of respondents felt that forms of coercion, especially ‘moral coercion’ might invalidate consent. Views ranged from respondents highlighting situations where donors might feel it is their moral *duty* to donation, to situations where pressures arise through the input of family members or friends. Sylwia Maria Olejarz, for example, noted that “if a donor and recipient are the members of one family the encouragement or rather the pressure from the family can invalidate the consent (causing the feeling of guilt, feeling of anxiety, shame, threaten of physical abandoning, emotional abandoning, betraying, blackmailing and similar).”

Egg sharing

A number of respondents stated that offering cheaper IVF treatment for women who donated their eggs for other women’s use could amount to an invalidation of consent. Comments received include:

> “No doubt the women who undergo so-called “egg sharing” feel they are consenting and might even be outraged to be called non-autonomous, but infertility itself can be so overwhelming and distressing that voluntariness goes out of the window.”
> *Susan Bewley, Consultant Obstetrician, consultation respondent*

> “Offering the option of “egg sharing” for free or cut-price treatment is an obvious case where such encouragement is presented as giving of a choice but in reality it is nothing more than a coercive inducement.”
> *Anonymous consultation respondent*

> “Receiving payment of free IVF treatment in return for ‘donating’ gametes strongly distorts the ability of the ‘donor’ to think clearly and truly understand the significance of what they are participating in.”
> *International Donor Offspring Alliance, consultation respondent*

No

A relatively small group of respondents who chose to answer this question took the view that there were no types of encouragement or incentives which would invalidate consent. Comments received which made this point include:

"Unless the encouragement or incentives concealed the risks of the donation, they would not infringe on consent."
Jonathan Lee, consultation respondent

"There are still choices to be made irrespective of the incentives offered, although concern was expressed over possible exploitation."
HEAL (Health Ethics and Law), University of Southampton, consultation respondent

"When does an incentive become a bribe? We think that in general, provided that full and clear information is given and that the person making the decision and giving consent has the relevant capacity, the answer is no."
Patricia Stoat, Convenor, Health and Bioethics Committee, National Board of Catholic Women, consultation respondent

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

If your answers to questions 21 or 22 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

Impossible/difficult to distinguish

The overarching conclusion reached by respondents who focused on this question was that it was impossible or extremely difficult to distinguish coercion from voluntary acceptance of a duty in a familial context. Comments received by the Working Party included:

> "It would be very difficult to distinguish, particularly in the case of a child being asked to help a sibling."
> *Anonymous consultation respondent*

> "It is impossible unless language suggests otherwise; e.g. the use of the term "we the family" suggests a collective tribal approach by and for the tribe rather than for the person."
> *Jeff McILwain MD FRCS, consultation respondent*

> "I don't believe it can. We are all simple creatures at heart. Guilt is the undoing of most of us and there is nothing like a family to allow guilt to kick in, making us feel (rightly or wrongly) that it is our moral duty to look after family members."
> *Karen Dyer, Lecturer in Law, University of Buckingham, consultation respondent*

> "Mental pressure can have many forms making it difficult to pack them into two different boxes."
> *Anonymous consultation respondent*

> "No system of assessing donor suitability will ever totally eliminate the risk of coercion. Family politics and power relationships within social groupings do not readily lend themselves to checklist assessment criteria."
> *Graham Brushett, consultation respondent*

Suggestions for how a distinction can be made

A number of suggestions were, however, made as to how distinctions between coercion and voluntary acceptance might be made. Included among suggestions were:

- Undertaking interviews assessing, for example, the reason the potential donor cites for choosing to donate, in closed session with potential donors and trained counsellors;
- Carrying out psychological assessments;
- Encouraging further research into family dynamics and relationships;
- Recognising that "One mark of voluntary acceptance will be evidence of a genuinely personal contribution to family discussion about the propriety of provision or participation" (University Hospitals of Coventry and Warwickshire Clinical Ethics Committee, consultation respondent);
- Using staffed trained in recognising cultural differences;
- Undertaking observational activities with families and potential donors;

Other observations

Other observations included: “I have a colleague whose mother needs a kidney transplant, is on dialysis, but is adamant that she won’t accept a kidney from her son, because of the risks involved - so family pressure works the other way too!” (Anonymous consultation respondent)

Others felt that coercion itself was a difficult concept to understand and quantify, especially in the context of family relationships. For example, Progress Educational Trust stated that “‘coercion within the family’ is not a meaningful or useful concept. Family members exercise and elicit dutiful actions in relation to one another as a matter of course. There is nothing wrong with this – indeed, in many respects it is a positive thing… There is no need to be specifically concerned about coercion within the family, and certainly not in relation to human bodily material.”

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?

Yes

Several respondents felt that circumstances did exist in which it would be ethically acceptable to use human bodily material for additional purposes for which explicit consent had not been given. Some general comments were made supporting this view:

> "Yes, there are some circumstances where it is appropriate to do so, but not all possible examples would stand up to scrutiny."
> *HEAL (Health Care Ethics and Law), University of Southampton, consultation respondent*

> "We do not know what the future development of medicine holds. Thus restricting the future research use of bodily material based on our current knowledge could compromise this research."
> *Royal College of Pathologists Lay Advisory Committee, consultation respondent*

Other respondents explored a number of circumstances where the use of bodily material might be appropriate, despite the fact that explicit consent for that use had not been given.

If the aim is to cure a disease

A small number of respondents felt that, where the aim of using bodily material is to cure a disease, then it may be used without explicit consent.

If the aim is to make scientific advances

Similarly, a small number of respondents highlighted the value which bodily material could offer scientific research. Asterand, for example, stated that "incredible scientific research value is locked up in archive tissue/biofluid collections and the scientific community should be able to realise the latent value as scientific breakthroughs emerge and technology rapidly advances." A similarly course of argument was taken by the MRC Centre for Transplantation, King's College London, NIHR Biomedical Research Centre at Guy's and St. Thomas' NHS Foundation Trust and King's College London - Transplant Theme which stated that "we are even aware of specific instances where, possibly as a result of this ambiguity, principal research investigators have 'missed out' on the opportunity to contribute to important collaborative research that has already been in receipt of local research ethics approval. This is at best disappointing."

A general comment on surplus surgical tissue was also noted by an anonymous respondent: "consent rates for surplus surgical tissues remain very high for all such research purposes, so long as the perceived goal involves the development of new diagnostics, prognostics or treatments for disease."

If the donor's generic consent is adhered to

A further group of respondents felt that there could be ethically acceptable uses of bodily material on the proviso that the donor had previously given *generic* or *broad* consent.

If the donor is deceased

A very small number of respondents stated that a circumstance where it would be ethically acceptable for bodily material to be used for additional purposes was in cases where the donor is deceased.

If it is impractical to seek further consent

Several comments were received by the Working Party which illustrated the view that, in circumstances where it is impractical to seek explicit consent, then it might be ethically acceptable to use bodily material for other purposes. For example:

> "Provided clear and simple information is given as to why that explicit consent cannot be sought at that moment in time, it is likely that the majority of people who are willing to donate would be happy for this secondary purpose for their tissue."
> *The British Psychological Society, consultation respondent*
>
> "It may be impossible, unduly difficult, impractical or uneconomic to return to donors to seek additional consent. In addition, it may even be unethical and cause concern or distress to do so."
> *Anonymous consultation respondent*
>
> "Tracing stem cell donors to obtain explicit consent for new research stages may be disproportionally onerous."
> *Progress Educational Trust, consultation respondent*

If the material will not be used for controversial purposes

Some respondents thought that the key to ethical acceptability lay in the *purposes* for which the material might be used. The Anscombe Bioethics Centre, Oxford, for example, stated that it would be ethically acceptable "[on] the condition that the additional purpose is non-controversial... If eggs were given for research into fertility, it cannot be assumed that the consent would cover the cloning of embryos for stem cell research... Some kinds of research should always require explicit consent...." The PHG Foundation stated that "we support the use of human bodily material for purposes such as public health monitoring, clinical audit and certain types of epidemiological research, the results of which guide the development of more effective health services, particularly public health interventions."

If the material will save a life

The possibility of a circumstance arising whereby a life might be saved was also highlighted by respondents. Commenting from the perspective of Judaism, Liberal Judaism stated that "[It is] ethically acceptable to use human bodily material to directly save a life or for research that is likely to lead to life-saving treatment even if explicit consent has not been given, on the basis that Judaism values the saving of life and does not consider a person to have ultimate 'ownership' of their body." A similar argument was made by Haris E. Cazlaris PhD: "One may imagine any other scenario in extreme situations (battlefield, shipwreck...), where the emergency use of bodily material from one dying human may save another human."

If the bodily material is anonymised

A significant number of respondents took the view that ethically acceptable circumstances would be ones in which the bodily material had been anonymised. Coupling this with other requirement, the BMA noted that “if the bodily material is ‘left over’, following diagnostic procedures, surgery or use for other research purposes, anonymised and its use has received research ethics committee approval, it is generally ethically acceptable to use it for additional purposes for which explicit consent has not been obtained.”

If the use of the material is subject to ethical review

Similarly, several respondents stated that ethically acceptable circumstances would be those in which the further use of the bodily material had been subject to ethical review. The Human Tissues Group, for example, stated that “unless the original consent specifically excluded additional uses, we believe that it would be appropriate to use donated material for additional non-consented uses, as long as these uses were given appropriate ethical approval.”

No

A significant number of respondents, however, unequivocally stated that there were no circumstances in which it is ethically acceptable to use human bodily material for purposes for which explicit consent had not been given. Some thought that such a proposal would undermine trust and have an impact on people’s willingness to donate bodily material for both treatment and research. Dr Miran Epstein, for example, took the view that “blank/abstract/vague consent is a mock. Either you respect the person’s autonomy or you don’t.” Similarly, Graham Brushett stated: “Explicit and informed consent has been designed over decades to safeguard the best interests of patients/donors and health care professionals. Situations that undermine these prerequisites based on trust and consent have the potential to alienate public support for the donor/transplant process…”

Other respondents specifically commented that material should not be used for additional purposes even if it had been anonymised. In such circumstances, one anonymous respondent stated that “I would argue that it remains the patient’s property and should not be used for any purpose for which they have not explicitly consented.”

Some respondents also felt that special protection should be urged where the material in question was reproductive. One respondent stated: “reproductive material, by its nature of potentially producing life should not be used without prior consent of the donor. If consent is sought it should be explicit and consent sought for every act and experiment proposed.” Similarly, PROGAR (British Association of Social Workers Project Group on Assisted Reproduction) was of the opinion that “it would never be ethical to use human embryos and gametes for the treatment of others without the proper consent of the donor given that the intention is the creation of another person.”

Other observations and suggestions

A number of other suggestions were made in response to the issues raised by this question. David Thewlis and Stuart Taylor, for example, suggested “that there could be some form of tick-box' system as there would be some material we would not wish to be used in medical research as outlined previously, for example, in reproductive areas." Other suggestions for 'systems' changes included that offered by the Human Tissues Group: "It would be helpful if the Department of Health provided all Trusts with guidance and templates for incorporating a simple level of generic consent for research storage of tissue into surgical/biopsy consent processes, and for managing "surplus" tissue as a research resource for the public good. Aim for an "NHS Tissue Bank" with uniform standards and procedures. Realistically defined levels of compliance with this should be made a target for NHS Trusts." Another suggestion made by the Human Tissues Group was that GPs or nurses should be encouraged to ask patients when they attend a GP's surgery whether they would be willing to consent for residual tissues to be used in research, should the need for them to have surgery arise in the future.

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?

Responses to this question can be broadly sectioned into those who felt that there is a difference between making a decision for yourself and others, and those who felt that no such difference existed.

There is a difference

The vast majority of respondents who chose to answer this question took the view that there is a difference between making a decision for oneself and making a decision for somebody else. Comments received by the Working Party included:

> "Making a decision for oneself, one is bound to give different weight to factors such as pain, fear, inconvenience; one may also engage in a degree of self-deception, consciously or unconsciously, about what the other person 'would want'."
> *Anonymous consultation respondent*
>
> "When taking a decision for oneself one may take into account all relevant aspects and weigh any possible harms (to oneself, generally) against foreseen good to oneself and others. When deciding on behalf of a child or incapable adult the decision must consider only good or harm to them (and not to others)."
> *Dr Ian Jessiman, consultation respondent*
>
> "I believe it is generally easier to make these sorts of decisions for oneself. Also, when deciding for others, one generally does not (and can't) do this alone—there are always other parties involved who disrupt a smooth transition to making a clear decision."
> *Anonymous consultation respondent*
>
> "The problems parents face when deciding whether one child should go through an invasive procedure, to save, potentially, a sibling's life, are significant. Making a decision for someone else is often a difficult thing to do, without the added pressure of that decision affecting the health of another relative… When acting as an intermediary you must try to make a decision that is the best one for that child."
> *Human Tissue Authority, consultation respondent*
>
> "Making a decision for oneself may involve acting against self-interest in favour of another person(s) or in deference to a principle. Particular care ought to be taken not to impose a 'moral duty' on another person or to assume that he or she would wish to act altruistically, if able to give consent."
> *Church of England Mission and Public Affairs Council, consultation respondent*

There is no difference

A significantly smaller number of respondents took the view that there was no notable difference. Dr Miran Epstein, for example, stated that "both a decision one makes for oneself as well as a decision one makes for someone else reflect one's own interests." The Human Tissues Group also felt that "as long as the individual is in an appropriate position as representative/ decision taker in other life aspects, then there is no difference between making a decision for self and for others."

Another distinction was made by David Gollancz, who noted that “it is likely to be more intellectually and emotionally burdensome; not necessarily morally different.” In addition, Haris E. Cazlaris PhD stated: “Theoretically yes, because each individual is an individual. But in a practical situation where a decision must be made, and provided that the risk to the donor-to-be is minimal, I think there is no difference.”

25. What part should family members place 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?

General points

Respondents used the issues raised by this question to highlight a number of general points about the role family members should play when considering donating the bodily material of deceased relatives. These included:

> "We should seek as far as possible to avoid asking the recently bereaved to make difficult decisions. It can add considerably to their distress. But that does not mean that we should allow an opportunity to help the living go to waste."
> *Professor Peter Furness, consultation respondent*

> "… a minority of cases (less that 10%) will find carrying out these wishes [of their deceased family member] to donate, simply too arduous, at a time of intense grief when faced with an unexpected loss. *We need to know more about these relatives; who they are and why they veto the wishes of the deceased in order to provide more support to them and to the health professionals who are expected to mediate in the situation.*"
> *Dr Gill Haddow, ESRC Innogen Centre, consultation respondent*

> "The cultural context is… important. Further, other legal systems would, for example, recognise a closer connection between the family and the body, vesting ownership of the body to family members."
> *HEAL (Health Ethics and Law), University of Southampton, consultation respondent*

> "Ideally the deceased will have discussed their wishes with family members before death so that they understand and respect the expressed wishes."
> *Medical Research Council, consultation respondent*

Where wishes are known

Pro-veto

A number of respondents stated that family members should have a veto where their relative's wishes are known. Several reasons were offered for taking this viewpoint. For example, a small number of respondents questioned the validity of the consent potential donors give when they sign the Organ Donor Register. Others drew attention to the possibility that "some surviving kin might well be haunted by images of the partitioning of the body for research or organ donation and, thus, it is important to honour their needs and desires." Similarly, some respondents drew attention to pain and suffering which might be experienced by relatives. Other views included concerns about undermining the UK's current donation system through breaking down relationships between the medical profession and relatives. For example:

> "relatives have a *prima facie* moral duty to respect the person's wishes. Nevertheless, the wishes of the deceased person are not the only consideration and where it would add to the grief of relatives (for example if traditional rites of death could not be observed), then this may be a reason not to force the issue… it is important to consider not only what is done, but how it is done, and how the grief of the relatives be treated with sensitivity."
> *The Anscombe Bioethics Centre, Oxford, consultation respondent*

Anti-veto

A significantly higher proportion of respondents who addressed this question were of the opinion that, where a relative's wishes are known, family members should not be able to overrule those wishes. Comments received by the Working Party included:

> "Family members should not have the right to veto, ever. The idea is absurd, how does defying someone's final wishes show any sign of respect for the deceased?"
> *Aaron Long, consultation respondent*
>
> "To be asked to make a decision so soon after the death of a family member is an onerous task… However, having been through the process, my view is that, once a person is on the donor register, the family should not have the right of veto. They should instead be counselled to help them understand that they are carrying out the final wishes of their loved one."
> *Anonymous consultation respondent*
>
> "It is as important to respect a Yes to donation as a No."
> *European Society for Organ Transplantation Council, consultation respondent*
>
> "The family and friends of the deceased are those who will have to experience the repercussions of that decision and that this may cause upset. We do not, however, feel that this is a good enough reason to allow the family power of veto."
> *University of Leicester Medical School - group 1, consultation respondent*

Where wishes are unknown

Pro-veto

A greater proportion of respondents felt that, where the wishes of a deceased person are not known, families should be able to state whether or not their organs are donated. Furthermore, several respondents stated that families should be consulted before any bodily material is donated. Other views offered by respondents included:

> "…families should be persuaded as much as possible, including hearing testimony from `other families who have agreed to donation in these circumstances, but I think that they should be allowed to veto ultimately."
> *Anonymous consultation respondent*
>
> "There is no reasonable alternative to allowing their nominated person, if there is one, or family members in a qualifying relationship to decide in lieu of the individual."
> *Anonymous consultation respondent*
>
> "Consent should rest with the family, and the person in the family who knew that person best, following detailed discussions with an appropriately trained healthcare professional."
> *Donor Family Network, consultation respondent*

Anti-veto

A small number of those who chose to answer this question felt that family members should not have a veto where the wishes of the deceased person were unknown. Most of these responses felt that, instead of family's input, policy initiatives such as presumed consent, or mandated choice should be used to determine what should happen to the deceased person's organs. For example, Marcia C. Inhorn stated that "these kinds of difficult situations can be avoided by policy measures, such as the one in the US involving donation decisions on the back of drivers' licenses. Fewer cases of "unknown wishes" will then occur."

Other observations

Several respondents used this question as an opportunity to highlight other observations.

> "In all circumstances where a person has indicated a wish to be a donor he or she ought to be encouraged to communicate this to family members."
> *Church of England Mission and Public Affairs Council, consultation respondent*

> "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."
> *UK Donation Ethics Committee, consultation respondent*

> "Many individuals on [the] organ donor register are surprised that their families could potentially stop their organ donation if they want to."
> *Anonymous consultation respondent*

Chapter five: Ownership and commercial benefit

26. To whom, if anyone, should a dead body or its parts belong?

No one

A significant number of respondents stated that a dead body or its parts should belong to no one. Some respondents, for example, felt that the body remains part of the deceased, and that notions of 'belonging' to a third party were unfounded. Similarly, other respondents took the view that bodies and their parts were "things of themselves" and the University of Leicester Medical School (group 13) stated: "[It should] belong to no one. They should be passed into the care of the next of kin, in terms of the planning of a funeral or any other arrangements that where expressed in life." The Human Tissue Authority also noted that "a body is without legal ownership. Over the past four years we have encountered situations where confusion about who was responsible for a body at a given time has risked, or on occasion caused, regulatory non-compliance. The potential for confusion between different legal and regulatory regimes is significant."

The family of the deceased

Several respondents took the view that a dead body should belong to the family of the deceased, although the term 'belong' was not always seen as helpful. Graham Brushett, for example, commented that "family members remain the custodians of the dead person, but I am not sure whether in a legal sense that means the body 'belongs' to the family in property terms. Donated bodily materials belong to the recipients or end users in a commercial context. The law needs clarification on these issues."

To institutions which carry out medical research

A small number of respondents stated that the body and its parts should belong to institutions it had been 'bequeathed to' in life. Comments received included:

> "If someone has donated their body to science then the body should belong to the institution that has accepted it."
> *Anonymous consultation respondent*

> "If the wishes of the deceased person is known then if consent is given those body parts belong to 'medical science' otherwise they belong to the family. If no wishes are known then the body should belong to 'medical science'."
> *Anonymous consultation respondent*

> "Medical research, unless the deceased has explicitly stated otherwise."
> *Aaron Long, consultation respondent*

> "There is no reason to assign property rights automatically, unless the individual has bequeathed their body to an academic institution, say."
> *Miss E. J. Toogood, consultation respondent*

To society or the state

A small number of respondents stated that bodies and their parts should belong to society or the state. Shawn H. E. Harmon, for example, stated that “there is some justification for adopting the position that the dead body [is a] public good and part of the person’s ‘giving back’ to society and comporting to solidarity.” Similarly, other respondents felt that bodies should be available ‘for the common good’. Marcia C. Inhorn commented that “if a person dies without any known close relatives, then I suppose that the body belongs to the state. In the US, many cadavers used in medical research have been of dead indigent persons, with no known relatives.”

Other observations

Respondents also used the issues raised by this question as an opportunity to raise a number of related points, predominantly focused on the idea of ownership of the body. Some, for example, felt that the notion of ‘ownership’ did not fit such situations.” Similarly, The Anscombe Bioethics Centre, Oxford stated: “To regard the body as property, which is owned and might be bought, sold, or traded, is to disregard the dignity of the human body.” This objection to the concept of body ‘ownership’ was one raised by a significant number of respondents. The Human Tissues Group suggested that “the concept of ownership may be better replaced with the concept of stewardship… a steward should only pass material to a third party if that party agrees to act in accordance with the requirements of the steward.”

Grant Mackie made comparisons with other kinds of ‘ownership’, stating: “just because I am dead doesn’t make it ownerless like if you buy a car it becomes my property and after use just because it doesn’t work doesn’t mean it doesn’t belong to me.”

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

If your answers to questions 27 or 28 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

Responses to this question broadly fit into those who felt that laws *should* permit the sale of bodily material, and those who thought it should *not*. However, some respondents felt that there was a ‘third way’, where selling might be acceptable should certain conditions or circumstances apply.

UK law should permit a person to sell their bodily material

The Working Party received a handful general comments which expressed support for the proposition that UK law should permit a person to sell their bodily material.

> “Yes, and why not it’s my body.”
> *Grant Mackie, consultation respondent*

> “Yes; my mind is my own in the same contingent fashion as that of my body, yet I may sell the fruits of my mind. I may sell the right to direct my future thought or action, subject to some mild restrictions. Why then would mere tissues be considered so fundamentally different?”
> *Jonathan Lee, consultation respondent*

> “… autonomy is paramount, and a logical corollary of this is that there should be scope for commercial transactions involving human bodily material, concerns about dignity and commodification notwithstanding.”
> *Progress Educational Trust, consultation respondent*

Selling should only be permitted in certain circumstances

A higher number of respondents felt that selling might be permitted in certain circumstances, or for certain types of bodily material. For example, several respondents felt that selling should be permitted where the bodily material can be separated from the body of the donor without high risks being initiated (examples provided by respondents included hair, blood, bone marrow, and gametes). This point is illustrated by a response from Marcia C. Inhorn: “selling organs is more ethically egregious than selling blood or gametes (such as sperm), based on potential abuses that have been documented in ethnographic research.” Similarly, Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre stated that “both the social meaning and the practical consequences of selling blood are different from selling reproductive tissues, and different again from being paid for taking part in research trials.”

Other respondents stated that selling should only be permitted if safeguards in the form of regulations are in place, although few comments were received which described how these regulations might operate.

UK law should not permit a person to sell their bodily material

A number of respondents felt, unequivocally, that bodily material should not be sold, although some commented that it was hard to explain why: “this is [a] matter of a good taste, gut feeling and something which cannot be perfectly verbalised/ explained." (Sylwia Maria Olejarz, consultation respondent)

However, other respondents set out more specifically *why* the selling of bodily material should not be permitted. Some respondents, for example, felt that selling bodily material would impact on the quality of the material provided. This view was one offered by one respondent who stated that "shortage of organs has already led to them being accepted from donors older than might be ideal, and introducing financial incentives would risk opening the floodgates to donation by substance abusers and others at the margin of society who are more likely to be exposed to infectious disease and to have damaged immune systems."

Another group of respondents felt that selling bodily material was exploitative, in particular for vulnerable people. Such a view was put forward by the University of Leicester Medical School (group 13): "Monetary gain can be an overwhelming lure for people to sell tissues/organs, even when doing so can put their own life at risk. This is especially evident in the most vulnerable members of society […] This idea could be made even worse by the possibility of wealthy people picking and choosing an organ – almost auditioning potential donors." Similarly, University of Leicester Medical School (group 11) argued that "there is a strong possibility that the poorer members of society may be tempted to offer body parts as a method of easing financial difficulties."

Other respondents focused on potential risks which might befall the sellers of organs. As John Miller from Glasgow vehemently stated: "No, no, no, no! Sell body parts, next you will have poor students trying to get rid of a kidney here and a lung there to pay student loans." Other concerns include those raised by an anonymous respondent, who noted that "free market principles should not be extended to donation or "any purpose" as there is a danger that people could jeopardise their health and wellbeing by donating or volunteering for money." Similarly, The Human Tissue Authority felt that "payment for organs brings with it a set of risks we do not currently have to mitigate against in this country. Those from the most disadvantaged communities would be the most likely to be motivated by payment and arguably need greater protection by the State."

The commodification of the body was also a concern raised by respondents who felt that selling should not be permitted. Church of England - Mission and Public Affairs Council, for example, stated that selling bodily material risked "the commodification of the human body or its parts, to risk undermining human dignity, to risk compromising personal and social relationships and to risk compromising free and informed consent." Arguments about damage to the dignity of and respect for the body were also raised by a number of respondents. Patricia Stoat, Convenor, Health and Bioethics Committee, National Board of Catholic Women, argued that "the body is intimately linked to the person, to identity and the sense of self, and is not property."

The potential for undermining the 'gift' concept was also raised by several respondents:

> "Part of the opposition to creating a market for bodily material is that the gift status central to all altruistic donation, whether of blood, organs or other tissue, would be lost."
> *Royal College of Physicians of Edinburgh, consultation respondent*

> "If they provide bodily material the primary reason should be altruism followed then by fair and reasonable incentives and rewards. Selling simply for monetary or material gain should not be allowed."
> *Anonymous consultation respondent*

> "We think that the 'gift relationship' is of the essence when bodies and donations are under consideration."
> *Patricia Stoat, Convenor, Health and Bioethics Committee, National Board of Catholic Women, consultation respondent*

Other comments

A number of comments which, although related to the question, did not answer it directly, were also received by the Working Party.

> "If you have a right to sell do you therefore have a right to buy?"
> *Donor Family Network, consultation respondent*

> "Commodification and the buying and selling of bodies/body parts also need to be understood as social and economic relations."
> *Lorna Weir, Professor of Sociology and Health, York University, Toronto, Canada, consultation respondent*

> "The question also arises as to who would pay. Would the State pay those that came forward to donate, or would it be down to the recipient to meet the cost?"
> *Human Tissue Authority, consultation respondent*

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?

If your answers to questions 27 or 28 would depend on the nature or purpose of the bodily material or medicine being tested in the trial, please say so and explain why.

Responses to this question fit broadly into 'yes' and 'no' categories.

Yes

The Working Party received some general comments supporting the proposal that proceeds should be shared.

> "For too long these companies have wanted something for nothing and it's neither right nor ethical to reap rewards from a free donated bio material gene pool."
> *Grant Mackie, consultation respondent*

> "Currently the commercial companies give too little back and the donors take all the risk, therefore a fairer share is required."
> *Graham Brushett, consultation respondent*

By sharing proceeds with donors, or others affected by the research

Some respondents ascribed to the view that profits made by companies should be shared with the donors who supply the material which is used for research. For example, Marcia C. Inhorn stated: "those who donate their body materials could be given "royalties," just as authors and artists are given royalties by their publishers/companies." Other respondents argued that companies "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" (Royal College of General Practitioners).

By making a donation to charity on behalf of donors

A number of respondents took the view that companies should make a donation to charity in recognition of the contribution of donors. The Anscombe Bioethics Centre, Oxford suggested that "it may be that this show of gratitude is directed at support to the specific community, from which the donors come, whether this is defined by location, by health characteristics, or in some other way." It was also suggested that companies might donate a percentage of the drugs or treatments developed to countries too poor to buy them.

By sharing proceeds with the NHS

The idea of companies sharing proceeds with the NHS was also a popular idea among a number of respondents. Lorna Weir, Professor of Sociology and Health, York University, Toronto, Canada took such a view, arguing that "a percentage of profits should be transferred to publicly funded health care for reimbursement of the hospital costs and other care required by those with immediate or long term adverse reactions to living donations and clinical trial research."

By contributing to or funding further research

Respondents also suggested that companies should contribute to other research projects, either in terms of information sharing, or by financing further studies. The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom, for example, stated that "companies who benefit commercially from tissue donation or clinical trial outcomes should not be required to share the proceeds but they should publish the results of their research whether positive or negative for society as a whole to have access to the data." Similarly, one respondent argued that gains should be fed "back into the health innovation cycle" and the Church of England Mission and Public Affairs Council that "any medical or scientific knowledge gained from the donation of bodily material or from first-in-human trials ought to be made available to the medical and scientific communities."

By establishing a philanthropic community fund or social enterprises

The idea of establishing philanthropic enterprise schemes was also raised by several respondents. For example, Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre suggested: "One alternative here would be a more generalised repayment, e.g. through a community fund, which would acknowledge the donation in a way that places it within a framework of social solidarity rather than the individual market." Similarly, Miss E. J. Toogood stated: "Any gains should be offered to charitable causes or a great cultural venture such as a new music hall or a beautiful garden."

Through further taxation

The suggestion of requiring companies who benefit commercially through donations of bodily material to 'pay back' through the tax system was also made by respondents. The National Gamete Donation Trust, for example, suggested the introduction of a 'tissue tax' "which could be ploughed back into the hospitals and clinics who see donors and prepare them." A similar suggestion was made by Dr Petra Nordqvist from the University of Manchester: "One suggestion could be, for example, that companies who gained commercially from bodily material pay back to a nation state or a particular community through higher taxes or investments in local/regional communities within a nation state, and in such a way make companies responsible not towards a singular person but towards a group."

No

The Working Party received several general comments which took the view that companies who benefit from volunteers for research or the donation of bodily material should not share the proceeds of gains arising through those donations. Comments included:

> "Why should an entity be forced into sharing the proceeds of things given to them freely by third parties?"
> *Jonathan Lee, consultation respondent*

> "These organisations bear the full cost of research failures in addition to the successes."
> *Anonymous consultation respondent*

In addition, other respondents cited specific reasons why companies should not share gains:

It would be practically difficult to implement

The practical ramifications of the suggestion that companies should share their gains were highlighted by a number of respondents. For example, an anonymous respondent stated that "the idea is fraught with legal difficulties that would probably only benefit lawyers and accountants rather than the donors. It would be very difficult to assess what should be made payable and how such payments would be equitably distributed between a variety of stakeholders." A further point was made by the Human Tissues Group: "In most cases, it would be very difficult to try to trace back whose tissue contribution, if any, made a defining contribution to a commercially successful venture, and how to fairly apportion proceeds in that case."

Potential gains could be potentially coercive

Some respondents took the view that, if commercial enterprises were to share proceeds with those who donate their bodily material, this could lead to undesirable consequences. Such comments included:

> "Sharing proceeds would inevitably introduce a bargaining component to the donation process, which would exponentially increase the already steep costs associated with the tissue donation and collection processes."
> *Anonymous consultation respondent*

> "We would be reluctant to see direct payment to individual donors here, since that would seem to reinforce the idea of a straightforward 'ownership' of body parts."
> *Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre, consultation respondents*

> "If those proceeds are distributed in the form of payments to individuals, care is needed to avoid the charge that they are potentially coercive."
> *University of Leicester Medical School, group 13, consultation respondents*

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.

Answers submitted in response to the first part of this question ranged from absolute control, to some control, to no control. However, responses made it clear that, for many respondents, the future use of their bodily material is something of fundamental personal concern.

Absolute control

Several respondents took the view that a person should have absolute control over the future use of their bodily material. A range of arguments were made to support this view, including:

> "Whatever degree they want - it's theirs! It is not for us to be judgemental."
> *Dr John Fitton, consultation respondent*

> "Complete control… If someone wishes his/her material given only to particular racial group or similar I think these wishes have to be accepted, no matter how disgusting I find those people to be."
> *Alex Smith, consultation respondent*

> "If it is going to be used for other or future purposes the donor should be notified and asked. That should apply to all bodily materials used for treatment and research."
> *Anonymous consultation respondent*

Some control

Other respondents felt that donors should have some control over the future use of their bodily material. For example, CARE felt that "most people will wish to prioritise and retain some element of control over the purpose to which their bodily material is put in the present and future." Several limiting factors were incorporated into the responses of those respondents who took this view. An anonymous respondent stated that donors "should consent to specific uses of the material, but it would be inappropriate for the donor to specify preconditions. This would open up the possibility for racist donors to specify an ethnic group to receive their tissue, or for a donor to deny their liver to a patient with alcoholic liver disease." This view was shared by the Christian Medical Fellowship: "there should be societal and governmental agreement about the limits individuals can set on use of their material. For example, a blanket refusal to donate to any member of another race would not be acceptable."

Focusing on potential consequences arising from genetic testing, the University of Leicester Medical School (group 13) felt that "it is not always appropriate for a living individual to retain an absolute veto over the use of their tissue, if the analysis of genetic material in that tissue might be used to avoid serious illness or death in a family member, for example for mutation analysis."

Rob Warwick focused on control according to different stages of the donation or research process: “For all material, the donor or their family should have full control over the material up until the point it has been “clinically committed” to another. At this point there can be no control, even if mistakes in consent etc have been made during the process.”

Limited or no control

The practicalities of a donor having absolute control were raised by The British Transplantation Society, which noted that “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… in our view consent should be generic and apply to all conceivable types of clinical and research applications.” This view was shared by a number of respondents, including the MRC Centre for Transplantation, King’s College London, NIHR Biomedical Research Centre at Guy’s and St. Thomas’ NHS Foundation Trust and King’s College London - Transplant Theme

A smaller number of respondents were of the opinion that donor should have no control over their bodily material’s future uses, and that rights are relinquished once donations have been made. Building on this argument, and referring to the fast pace of scientific developments, David H. Howard, Associate Professor, Department of Health Policy and Management, Emory University stated that “it will be difficult to write contracts/consent forms in a way that anticipates the potential future uses of the tissue. Therefore, donors ought to have limited or no control unless granting some degree of control is necessary to elicit donations.”

A different perspective was offered by The Anscombe Bioethics Centre, Oxford: “to give something is to give away control of that thing. There are sometimes problems with attaching conditions to a gift… Restrictions would limit the usefulness of the gift, but more fundamentally it would adversely affect the ethos of caring for the sick according to need. It is for this reason that conditional organ donation is not to be encouraged.”

However, other respondents felt that the amount of control depended on the nature, purposes, and consequences of a particular type of donation.

Where the material is life-creating

The overwhelming view expressed by respondents in relation to the control of life-creating bodily material was that donors *should* be able to exercise control over its future use. Several arguments were made in support of this view, including:

> “Gamete donors should always have complete control over the use of any bodily material they have donated, but the reality is that they have *no control whatsoever once it has left their body*… Both egg and sperm donors should have the right to refuse their gametes being used by women well past the age of natural menopause.”
> *Anonymous consultation respondent*

> "Reproductive material constitutes its own category. The person providing the material must be aware of the intended use, and must have the right to specify the possible use, or uses, whether fresh or cryopreserved tissues and cells are concerned."
> *Haris E. Cazlaris, PhD, consultation respondent*

> "Gamete donation for reproductive purposes is seen as lifestyle rather than lifesaving, and in many cases strongly connected with personal or cultural identity, and here there seems more tolerance for the idea that donors can exert some constraints over who receives their gametes."
> *Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre, consultation respondents*

> "As gametes have potential to create life, they should have a greater level of control."
> *University of Leicester Medical School, group 13, consultation respondent*

However, the view that gamete donors should be able to control their donation was not one which was universally accepted by respondents. On a pragmatic note, the British Fertility Society highlighted that "once donors have given their gametes and embryos for donation and they have been used they have no rights whatsoever over the material." Commenting on the fact that gamete donors' may choose not to donate, for example, to lesbian couples, the Progress Educational Trust stated that "such conditions pose a moral problem, because they introduce an element of bad faith into a system which is largely predicated upon good faith."

Deceased organ donation

A handful of comments were received by the Working Party in the context of control for deceased organ donation, the majority of which argued that control in terms of preferences for who receives a donor organ should not be sanctioned.

> "Donation after death should never be conditional, but where a preference can be accommodated, for example by meeting the requirements of Department of Health policy on requested allocation of a deceased donor organ, it should be."
> *British Medical Association, consultation respondent*

> "Historically, the presumption behind donation of e.g. blood or organs for clinical purposes has been that of an unrestricted gift: they are seen as lifesaving and so any restriction *by the donor* on who can receive them as effectively allowing the donor's presumptions/prejudices to determine who lives."
> *Simon Woods, Jackie Leach Scully, Pauline McCormack, and Ilke Turkmendag of the Policy Ethics and Life Sciences Research Centre, consultation respondents*

Donation for research

The Working Party received a small number of responses which focused on control where bodily material is donated for research.

> "During life, they should be offered the opportunity to determine whether their body parts could be transferred e.g. from one not for profit to another or to a commercial organisation. It is not reasonable to expect that in research the re-use of a body part (e.g. frozen plasma) should be queried when the outcome of the first and foreseen research suggests follow on unforeseen use would answer new and related research questions."
> *Dr J. Reeve, consultation respondent*

> "In the case of material to be used for research, donors should be free to state that the material can be used for *any* purpose, without having to give explicit consent for every use to which it may be put."
> *British Medical Association, consultation respondent*

Depends on who the donation will go to

Some respondents felt that the party who received the donated bodily material was key to the question of control. Two views in particular are noted:

> "There is an important distinction to be made between if a person donates to a family member/friend or to a 'stranger'. If the purpose of the donation is to help a friend or someone in a person's family, then it is probably very important to secure control over the donation. However, if it is a 'stranger' donation, then I believe that it is important that people cannot choose who the donation should go to."
> *Dr Petra Nordqvist, University of Manchester, consultation respondent*

> "The kind of control a person should have over their bodily material depends crucially on the purpose and context of their providing it to a third party."
> *Heather Widdows and Sean Cordell, consultation respondents*

Other observations

Respondents also took the opportunity to raise other observations on the issue of control of future use. Comments received included:

> "Personhood is strongly connected to control over one's body, what can be done with one's body and body parts, before and after death."
> *Dr Rachel Ariss, consultation respondent*

> "The legitimacy of a person's control over the usage of their bodily material should not entail or depend on the claim that the material is their 'property'."
> *Heather Widdows and Sean Cordell, consultation respondents*

> "If the human person were principally conceptualized as a 'choosing' being, then there is an intelligible corresponding emphasis on the principle of personal autonomy. The right to choose would embrace a right to be 'selfish' and to achieve one's own self-interest. However, if the human person is conceptualized as an 'integrated totality' of body, mind and spirit, then the notion of there being some limits to what one can properly do with human bodily material becomes rationally defensible."
> *University Hospitals of Coventry and Warwickshire Clinical Ethics Committee, consultation respondent*

Other issues arising

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

A wide range of issues were raised by respondents, including:

- The question as to whether donation itself is unethical.
- The need for uniformity across regulatory bodies.
- The issue of opt-out (where respondents noted the issue without reference to a specific question in the consultation document), including comments such as:

> "What cannot be accepted and should be resisted at all cost is the attempt to introduce Presumed Consent. The State cannot assume ownership of the human body."
> *David Thewlis and Stuart Taylor, consultation respondents*

> "I would like to see the United Kingdom government make it automatic for consent to donation of any and all bodily parts to be taken as automatic once dead, save should an individual express the contrary in a witnessed document."
> *Michael Fulton, consultation respondent*

> "I find the notion of presumed consent abhorrent."
> *Mr G. Smith, consultation respondent*

> "We draw attention to the potential impact that the introduction of an 'opt-out' model of consent for organ donation may have on consent models in other areas of medical treatment and research, including effect on public confidence."
> *Wellcome Trust, consultation respondent*

- The idea of conscripting donors.
- Payment for funeral expenses for those who donate.
- Incorporating the question of joining the Organ Donor Register into a will.
- Having places located in local communities where people can call in to discuss donation.
- Examining how education can be used to encourage donation.
- Concerns about the definition and diagnosis of death in the context of organ donation.
- The need for open conversations about death within families.
- The issue of secrecy in gamete donation.
- Concerns about cross-border transplants and reproductive treatments using donor gametes.
- The potential use of sub-optimal organs.
- Practical difficulties in increasing supply, for example with the number of beds, operating theatres, specialist members of staff.
- Shortages in BME donations.
- Difficulties in obtaining tissue for research:

> "Lack of interest and motivation among custodians of tissue collections, coupled with disorganisation and fear of privacy laws is driving me to work with US collaborators instead."
>
> "Due to the increasing pressure to save money in University and Hospital departments alike - support staff in all areas will be cut, and I am afraid tissue banking is likely to slip further down everyone's agenda, despite its importance for the academic and pharmaceutical research sectors."
>
> "Lack of understanding amongst frontline staff of the importance of biopsy samples in medical research, as well as lack of time, hampers potential donor recruitment."
>
> "Routine access to non-transplantable tissues from transplant donors (both heartbeating and non-heartbeating) for research purposes is essential if human bodily material is to continue to make a significant contribution to the advance in human healthcare."
> *Human Tissues Group, consultation respondent (all quotes listed above)*

In addition, several general observations were made by respondents. Professor Arthur Matas from the Department of Surgery at the University of Minnesota stated: "All the rhetoric (and the debate about principles and ethical values) boils down to a single question - do we want to maintain the status quo in which the waiting list and waiting times (for a kidney transplant) are getting longer (and candidates are suffering and dying while waiting) or do we want to see if trials will increase donation (while protecting the donor) and improve and prolong the lives of our patients?" Professor Peter Furness noted that "human biological samples can ultimately be provided only by individuals, not by organisations. If individuals do not accept that responsibility in sufficient numbers, the current system will fail."

Terminology

The Working Party also received a number of comments which focused on the use of terminology in the context of the donation of bodily material. Comments received included:

> "The word encouragement should not be used in the context of medical research as it suggests inducement, which would not meet criteria for ethical acceptance."
> *British Fertility Society, consultation respondent*
>
> "The usage of the word 'material' leads to the idea of 'commodities'."
> *Professor Dr Jayapaul Azariah, consultation respondent*
>
> "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?"
> *The British Transplantation Society, consultation respondent*

Omissions

A number of respondents felt that the consultation document had omitted to address certain issues and topics. Comments included:

> "It is a pity that the terms of reference only cover recent advances in biological and medical research as there are many ethical questions about donor conception which need to be identified and addressed."
> *Anonymous consultation respondent*

> "We note that there is nothing in the document about confidentiality/anonymity."
> *Royal College of Pathologists Lay Advisory Committee, consultation respondent*

> "No consideration is given in this consultation document to what happens to the related information that is provided alongside human bodily materials for the various purposes stated in this document."
> *The HeLEX Centre, University of Oxford, consultation respondent*

> "With respect, we are not convinced that those who have constructed this questionnaire have fully taken on board the significance of the many different worldviews at play."
> *Christian Medical Fellowship, consultation respondent*

Comments on Terms of Reference and scope of the project

Several comments were also received in relation to the scope of the project and its terms of reference.

> "The terms of reference ought explicitly to cover information gained from donation as well [as] covering the purposes for which bodily material may be donated. This has particularly relevance for genomic information."
> *Church of England - Mission and Public Affairs Council, consultation respondent*

> "The terms of reference of this consultation are too broad to cover all the issues adequately. [The Nuffield Council should] narrow its focus upon a more limited set of questions that emerges from the consultation."
> *The Anscombe Bioethics Centre, consultation respondent*

> "The use of donated gametes (sperm and eggs) has consequences so different from the use of donated somatic tissue (non sperm and eggs) that a consultation which considers them together cannot possibly produce clear conclusions about the ethical validity of the use of gametes."
> *International Donor Offspring Alliance, consultation respondent*

> "[There is] nothing there about educating scientists, medical and other professionals."
> *Professor Charis Thompson, consultation respondent*

In addition, Professor Charis Thompson also felt that the Working Party should have included a representative from a patient group or a member of the public.