

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Give and take? Human bodies in medicine and research between April 2010 and July 2010. The views expressed are solely those of the respondent(s) and not those of the Council.

The Human Tissue Authority

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to this consultation.
2. The HTA regulates the storage and use of dead bodies; the removal, storage and use of material from a dead body; and the storage and use of material from the living. Established by the Human Tissue Act 2004 (the Act), we began regulating in 2006. Created against the backdrop of the Alder Hey and Bristol Royal Infirmary Inquiries we have been determined to learn from these tragedies and address the failings they highlighted.
3. The HTA is also one of two Competent Authorities under the EU Tissues and Cells Directive, under which we regulate the human application sector. Under the Act we regulate:
 - Anatomy
 - Post mortem
 - Public display
 - Research
 - Living organ donation
4. The thread which links each of these sectors, and the overriding principle of our regulation, is the requirement of consent. With very limited exceptions, the Act requires consent to be in place prior to bodily material being removed, stored or used.
5. For the first four sectors listed we are responsible for licensing and inspecting establishments carrying out that activity. Our Regulation Managers are trained to assess licensing applications, inspect premises, apply conditions where necessary and offer advice and guidance.
6. Our role in living organ donation is central, ensuring that the donor is consenting freely. No living organ transplant can go ahead lawfully without HTA approval. We check for any evidence of duress or coercion, or offer of a reward, and that the donor understands the procedure and the risks involved. We assess cases of

living kidney and part liver donation, as well as paired, pooled and altruistic (stranger) donations.

7. Across the organisation we provide advice and guidance on an ad-hoc and more formal basis. We also, when necessary, comment from a regulatory perspective to facilitate improvements across a whole sector.
8. Our aim is at all times to work with the sectors to be compliant with legislation and to adhere to recognised good practice, keeping focused on the important personal and wider public benefits that all of the sectors provide.

Overview

9. In the introduction to the consultation paper the question is posed whether or not regulatory differences in this field can be justified? Differences are highlighted between the donation of eggs or sperm, other forms of bodily material, and participation in first-in-human trials.
10. The HTA has responsibilities in relation only to some of these fields, and in what follows we will not comment directly on areas outside our specific remit. We do not believe, however, that seeming variations in practice are to be regarded necessarily as inconsistencies and as problematic. On the contrary, we approach our work on the assumption that differences of practice are likely to reflect perceptions of differences in the nature, meaning and significance of the material being given, obtained, preserved or in other ways handled. The challenge when confronted by these various practices is to seek to discern the particular concerns and principles which have led to these variations, rather than to impose a false simplicity and consistency upon them.
11. The Act sets out to preserve, protect and support respect for the body and body parts in the context of what had seemed to be neglect of such respect. In our work in applying the Act, and in exercising our discretion in guiding conduct in the various spheres which we regulate, the HTA is conscious of a responsibility to gain knowledge and understanding of well established practices and procedures, and of course of any problems there may be with them. We believe that it is on the basis of such expertise that sound and reliable regulation can be developed, and not on the basis of the application of general principles alone.

Consent

12. For consent to be valid it must be freely given, by an appropriately informed person who has the capacity to consent.
13. As the law stands, consent is fundamental to any consideration of donation of bodily material and participation in first-in-human trials. In the case of the living, knowing that the person who donated material, or participated in a trial, freely agreed to do so gives comfort to all involved. The donor knows they are in receipt of all the necessary information to make that decision; the recipient or beneficiary knows that the material was given willingly; and those using the material know they are working within the law.
14. When considering donation after death, or a hospital post-mortem examination, it is the decision (if known) of the deceased in life which establishes whether or not there is valid consent for the activity, or the consent of a relative after death.¹ A recipient can be confident that, in accordance with the requirements of the Act, valid consent has been given by the donor or a relative for the use of organs or tissue after death.
15. In the research sector it is necessary that consent is obtained from either the donor in life, or their relatives after death, to use their bodily material. The only exception to this is for tissue from the living, if the research project has REC approval, and the samples are anonymised, the tissue can be used without consent.
16. The freely given and appropriately informed strands of the valid consent test may be affected by other factors, such as the provision of detailed information or the offer of recompense for loss, for inconvenience, as an incentive or in recognition of risk.

Role of payment and other forms of remuneration

17. The HTA believes that the practice of non-payment for body parts is fundamental to the success of both living and deceased organ donation in this country. The Act makes it illegal for the living to buy or sell body parts. This definitive expression of the unacceptability of such action provides society with clear and precise direction.

¹ s.74 of the Act sets out a hierarchy of qualifying relationships – people who can consent if the deceased's wishes in life are not known. This includes, at the end, a friend of long standing. See page 27, paragraph 105.

18. The HTA is charged with protecting living donors from any undue pressure, and from the offer of a reward for donating an organ. Our experience attests to the value of this, as the opportunity for a prospective donor to speak to someone outside their family group, and away from the clinical team, gives them the freedom to raise difficult issues during an open conversation.
19. A system for reimbursement of living donors exists, which aims to put them back in the position they would have been in had they not donated. This system can work well, but there needs to be more widespread promotion to ensure all donors are able to claim the funds available to them. We are aware of different practices in different transplant centres, both in terms of the total amount available to a donor and the method by which this is paid. Implementing a nationally consistent scheme would move to prevent financial hardship being a consequence of donating.
20. The number of living organ donations goes up every year without the offer of payment. The motivation of friends and family to help their relatives meant the HTA approved 1,140 donations in 2009/10, an 8% increase on the previous year. There is little or no substantive evidence to suggest that allowing payment would lead to an increase in the number of donors coming forward, and there is a risk it would lead to a reduction.
21. Altruistic (stranger) donation also increases year on year, with 23 people choosing to donate to improve someone else's life, with no knowledge of their identity, in 2009/10. One recent news story told of an altruistic donor who chose to come forward after he had read about the increase in this type of donation the year before,² showing that motivation can be non-financial. By publicising the success of living transplantation, organisations such as the HTA can play a role in raising awareness.
22. When considering deceased donation, direct payment to the donor in life, or to their family following their death, has rarely been discussed. The practice that deceased donation must be unconditional and without payment has created the framework for organ donation following death in this country. However, while over 90% of people say they wish to be considered for organ donation when they die, only 27% of us have signed up to the Organ Donor Register (ODR).³ With 1,000 people dying each year before an organ becomes available, NHS Blood and Transplant have recently launched a hard-hitting campaign to increase this figure

²Gift of life: the UK's living organ donors, The Guardian, 22 June 2010

<http://www.guardian.co.uk/lifeandstyle/2010/jun/22/uk-living-organ-donors>

³About Campaigns, NHSBT <http://www.organdonation.nhs.uk/ukt/campaigns/index.jsp>

and work with strategic partners (Boots Advantage Card, DVLA) to promote the ODR.

23. The HTA notes that Israel offers those on the register priority if they ever need an organ, and in Sweden there is money available to cover the funeral costs of donors. While not amounting to payment, these incentives may be an ethically acceptable way of increasing the number of people registered. These incentives are being monitored to understand what affect they have on donation.
24. Donation of bodily material may be a one-off activity by its very nature (living kidney donation), or a donor may give a number of times (blood and sperm donation, for example). Consideration should be given as to whether this distinction: one-off vs. regular giving, could be helpfully employed to decide when, or if, payment or incentivisation is ethical.
25. When a person can donate only once, the risks are often significant, both in terms of the procedure and also the possible affect on them in the future. However, when there is the possibility of making multiple donations, because the material is replaced or there is an abundance of it, it is in the main part less uncertain.
26. Payment for taking a significant risk does not sit comfortably within the existing principles of donation, nor does it fit with the ethos of medical practice. Conversely, taking very little risk, but on a regular basis, does not pose the same ethical questions. If someone is going out of their way to be helpful, and not putting themselves at risk, payment is less ethically questionable. If such a system were to be established it would require a significant framework, the cost of which may make it untenable.

Questions of subsequent use, ownership and control

27. The HTA believes that consent must remain fundamental to the use of body parts after death.
28. With research using bodily material from the deceased, there is significant debate as to whether consent is vital. We remain of the view that it is, but would highlight that in the research sector obtaining generic consent is adequate. Generic consent allows the material to be used for any research project, and by taking this more material may be available to researchers.

29. When consent is limited to just one research project, or research with a particular aim, then this must be respected. Even when only a very small amount of material is required for a research project (a block or slide), if there is not consent for that project, it cannot and should not be used.
30. In our codes of practice, we make it clear that those seeking consent must be well trained and aware of the conditions for valid consent. This allows all involved to be confident in the consent obtained.
31. 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.
32. A coroner may be responsible for a body for a period of time, and may release it back to the relatives complete, or retain some material as necessary. The police may have an interest in a body, or part of it, and again may have responsibility for a period. The wishes of the deceased and/or their family should be observed, and full information shared with them, when the body is no longer the responsibility of any other authority.
33. This system is complicated and confused and the HTA believes that this must be addressed to prevent families suffering significant distress, and to build public confidence.

The role of intermediaries

34. Most of us have family, friends and acquaintances who have views on the issues raised by this consultation. For many people these relationships may inform their decision making, but ultimately, their decision will be one they come to on their own. Whilst it is always preferable to have the support of relatives, in our experience, it is not uncommon for people to act against the wishes of friends and family when becoming living organ donors.
35. For children without capacity the situation is different, someone else (most likely a parent) will be consenting on their behalf. The HTA is responsible for assessing bone marrow donations where the donor is a child (or an adult lacking capacity). 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.

36. Most people are able to assess the level of risk they are willing to take and make decisions using that as a guide. When acting as an intermediary you must try to make a decision that is the best one for that child, while attempting not to allow your judgment to be clouded by other factors.
37. The HTA continues to promote and advocate child bone marrow donors receiving age appropriate information about the procedure they may be undertaking, and to be asked what they feel and think about it. While it will be the parent consenting, knowing the child has understood what is planned gives a much greater insight into the family dynamics and the basis for that adult's decision.

Cultural and international perspectives

38. We note that there is a disproportionate shortage of deceased organs available to the black and South Asian communities in the UK. NHSBT launched a campaign to increase the number of people from these communities signing up to the ODR in February 2010. It is vital that the specialist nurses who work with the potential donor's family are aware of the different cultural and religious beliefs surrounding donation and are sensitive to these.
39. Our regulatory experience in living donation has informed our understanding of the differing approach taken by different communities. Our Independent Assessors (IAs), the people who interview donors and recipients on our behalf, work with us to ensure that we act in a way which is sensitive to an individual's beliefs, while ensuring the conditions for donation are met. For some female donors this has meant having another person in the room when been interviewed by a male IA. For others it has been ensuring that the IA is not a Chaplain, and that they have no outward indicators of faith.
40. When enquiring about the donor's understanding of risks, we are regularly told that 'it is in God's hands', and implicitly that no other information is required by that individual. However, in order to approve a case we must be sure the donor has a full understanding. Our trained IAs are well placed to understand and empathise with the individual's religious, moral and cultural beliefs, while carrying out their duty to explain the role of the HTA and elicit information on the possible risks. The HTA strikes a balance between respecting beliefs and ensuring the donor understands the procedure they are about to undertake.

41. In July 1999 a family stipulated that they would only consent to the donation of their relative's organs if they went to a white person.⁴ The hospital ultimately decided to accept these organs with the condition attached. This was a major departure from the unconditionality which had defined donation up until this point, and the debate following this information entering the public domain placed unconditionality firmly back at the centre of donation.
42. A case in 2008 prompted investigation into the possibility for deceased directed allocation (DDA), in very limited circumstances. The HTA contributed to the Department of Health's policy on DDA. We remain supportive of the decision to retain unconditionality as the underpinning principle, while allowing for reasonable discretion if the deceased planned to donate in life to a friend or relative – or if their family believe that is what they would have wanted.
43. The HTA hopes that a wide range of community groups will respond to this consultation to provide greater insight into this particular question.

⁴ Head to head: Donor Ethics, BBC News Website, 7 July 1999
<http://news.bbc.co.uk/1/hi/health/388281.stm>

Annex A

Response to questions

1. Only questions relevant to the role and remit of the HTA have been answered. Most responses are based on our experience of regulating living organ donation and the research sector; however there are exceptions to this and these are made clear.

Question 2

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

2. All human bodily material has significance. In our response to the questions posed we refer to a range of bodily material from whole organs, to blocks and slides. Popularly, life giving/prolonging organs are likely to be seen as ‘special’ in a way that blocks and slides used for research may not be. However blocks and slides can have the same significance due to their use in research. It is difficult to imagine a system that could make one of these ‘special’, and the other ‘ordinary’.
3. The Act specifically refers to ‘relevant material’,⁵ this is material, apart from gametes, which consists of, or includes, human cells. It does not include embryos from outside the human body, or hair and nail from the body of a living person. The HTA publish a list of relevant material to ensure it is clear whether the use of that material is regulated by us.
4. Relevant material could be viewed as ‘special’ as it is defined in the Act and a list is produced by the HTA. It is also the material which Parliament instructed the HTA to regulate and as such has ‘special’ standing.

Question 3

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

5. In the field of organ donation there are significant differences between donating in life and after death.

⁵ s.53 the Act

6. The key similarity is that of valid consent being central to both living and deceased donation.

Living organ donation

7. A person donating an organ or part organ in life faces a wide range of clinical risks. They must understand that there is a risk of death (1:3000 for kidney donors, 1:200 for adult to adult liver donors) and myriad post operative risks in order for the donation to be approved by the HTA. They risk serious and minor complications during and post surgery, including infection, thrombosis, bleeding and pain.
8. 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.
9. It is an offence under the Act⁶ to remove an organ from a living person for the purpose of transplantation if the conditions specified in the Regulations⁷ are not met. These are:
 - that there is no evidence of a reward;
 - that there is no evidence of duress and coercion;
 - that the donor understands the nature of the procedure and the risks associated with it;
 - that consent is valid and the donor knows they can withdraw it at any time.
10. If convicted, a person is liable to up to 51 weeks in prison, a fine of not more than £5,000, or both.

Deceased organ donation

11. Deceased organ donors are not exposed to any clinical risks, nor can they be duressed, coerced or rewarded once dead. Media stories supporting donation may encourage readers/viewers to register to donate their organs. There is the possibility that a person might feel coerced or pressured in life to consent as a result. This highlights the importance of informed consent.

⁶ s.33(1) the Act

⁷ The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

12. Only in the most narrow circumstances can an organ be directed after death⁸ and there is therefore little potential for a recipient to apply pressure to the donor or offer them a reward.

Research

13. In the context of the Act, 'research' means the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'.⁹
14. The Act facilitates this type of research by providing a number of consent and licensing exemptions. Tissues or cells removed from a living person may be stored and used for research without consent providing that the researcher cannot identify the person and the research has project-specific ethical approval from a 'recognised' Research Ethics Committee (REC), which is typically an NHS REC.¹⁰ Human material 'surplus to requirements' for example, following a surgical procedure or a diagnostic test,¹¹ can be a valuable resource for research, so prior valid consent can be sought or the aforementioned consent exemption could be applied.
15. One concern the HTA has heard expressed is that a reluctance, or failure, by healthcare professionals to seek consent for research during routine clinical interactions results in missed opportunities to increase the material available for research.
16. The consent requirements of the Act in relation to storage and use of human material removed from the deceased are stricter. However, it is increasingly common for people to register to donate material after their death, often to one of the HTA licensed brain banks in the Medical Research Council's (MRC) network.
17. Clinical trials are a form of research in its broadest sense. However, the use of human tissues or cells on, or in, a human recipient is not a research purpose under the Act. Establishments using tissues or cells for treatment as part of a clinical trial must be licensed by the HTA under different legislation: the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

⁸Requested Allocation of a Deceased Donor Organ, Department of Health, March 2010
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_114803.pdf

⁹ Schedule 1, Part 1, 6

¹⁰ s.1(9)

¹¹ s.44

Question 4

What do you consider to be 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.

Living organ donation and the individual donating

Costs

18. An individual who is donating an organ in life is likely to experience loss of earnings. They 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. Donors also need to attend hospital appointments both pre and post operatively, as well as annual checkups in the future, and this will have a cost in terms of travel and lost earnings. Donors can currently claim reimbursement of reasonable expenses.¹²

Risks

19. A living donor risks losing their life. 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.

Benefits

20. Most living donors choose to concentrate on the benefits of donating. Those most frequently referenced are seeing a friend or relative regain health, gaining a sense

¹² Reimbursement of living donor expenses by the NHS, Department of Health, 3 July 2009
http://www.dh.gov.uk/en/Healthcare/Longtermconditions/Vascular/Renal/RenalInformation/DH_4069293

of purpose and the feeling of having done a good thing. They will also be subject to regular checkups which may lead to the early detection of future health problems, which can be seen as a benefit.

Relatives and those close to the living organ donor

Costs

21. Friends and family are likely to visit the donor and may incur travel costs. They often provide care following the transplant and this can lead to a loss of earnings, the build up of travel costs, and also costs for food as they may be doing the shopping and cooking for the donor. There is no formal mechanism by which friends and relatives can be reimbursed.

Risks

22. 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.

Benefits

23. If they also have a relationship with the recipient, friends and relatives will potentially see someone they love regain their health following the gift from the donor. If they only have a relationship with the donor, they may feel that there is no benefit.
24. It is worth noting here that in our experience of altruistic donation, which has been covered in some depth in the media, the families of the donor are often not supportive. A range of reasons have been given for this including the fact that the donor will not be able to donate to a relative in future, that they are putting their health at risk for a stranger and that the donor wants to feel 'saintly' and have the moral high ground.¹³

Deceased donors and their relatives

¹³ Why do people choose to become live organ donors?, The Sunday Times, 11 October 2009
http://www.timesonline.co.uk/tol/life_and_style/health/article6867112.ece

25. There are no costs incurred, or risks posed, to a deceased donor. The HTA believes that a more helpful way of approaching deceased donation is to consider the meaning and significance of the donated material.
26. If the deceased has made the decision in life to donate following their death, they will often have had the benefit of knowing that when they die, their organs may be of benefit to someone else.¹⁴
27. If the donor's family are making the decision to donate they must consider the benefit those organ(s) will bring another, and the benefit of knowing their relative has helped others. They must also 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.
28. If we turn to the meaning and significance of the donated organs we are confronted with a range of issues. Is it possible for the family to establish from the actions of the deceased in life whether or not they would wish to donate (if no instructions have been left)? Should the views and beliefs of the family be a factor when they are deciding whether or not to donate, is it in fact impossible to separate out one's own views when making a decision for someone else? Are there reasons why the family would want their relative to be buried or cremated 'whole'? Do they have the information, both clinical and spiritual, they need to be able to make a decision?
29. The questions above display that although there are different considerations in deceased donation, this does not make the decision less charged. The way we, collectively, think about death is highly charged and we must recognise the differences between living and deceased donation and support them, rather than seeking to find a consistent approach to both forms of donation.

Research

Costs

30. At the moment there should be no costs incurred by donors, relatives or relevant others. The HTA believes that this is the correct approach and should be maintained. It should be noted, however, that participants in clinical trials will often

¹⁴Parents' pride as Matthew's dying wish saves lives, Coventry Telegraph, 5 July 2010
<http://www.coventrytelegraph.net/news/coventry-news/2010/07/05/parents-pride-as-matthew-s-dying-wish-saves-lives-92746-26787640/>

be required to take time off work, yet the amount they receive may not equal the loss they incur.

Risks

31. Risks, other than physical ones, can occur in living and deceased donation, particularly where research leads to the discovery of a disease susceptibility for which there is no cure. This may have a serious negative impact on relatives in the case of heritable disorders.

Benefits

32. Research can lead to advances in diagnosis, treatment and management of diseases, which has obvious benefits to wider society.
33. There may also be a benefit to the individual who is donating the material. If they have a tumour which needs to be removed, and their health will benefit from this, they may choose to consent for it to be used for research. This would mean the benefit of improved health, and also improved understanding.

Question 14

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

34. 'Needs' and 'demands' are socially engineered concepts. In organ donation we currently accept in this country that the need is formed of people waiting on the list and the demand is for that number of organs to be made available within a timeframe which will save their life.
35. That is not to say that we should not strive to meet these needs and demands. The critical point here is that this cannot be at any cost; most notably, this cannot be at the cost of consent.
36. The removal of valid consent from the donation process would undermine the entire system of donation. The fact that a donor, or person consenting on their behalf, must be appropriately informed, give their consent freely and have the

capacity to do so,¹⁵ gives certainty to all those involved; from surgeons to donors, and family to recipients.

37. The HTA has seen, at close proximity, the significant increase in all forms of living organ donation over the past four years. Since we started regulating living donations in 2006 the increase in cases submitted has been marked:

	Directed	Non directed altruistic	Paired and pooled
2006/07*	343	0	0
2007/08	984	10	6
2008/09	1,022	15	22
2009/10	1,091	23	29

* September 2006-March 2007

38. With proportionate regulation new forms of donation can be safely introduced and allow more people the opportunity of a successful transplant.

Question 15

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

and

Question 19

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

¹⁵ Para 30, HTA code of practice 1 - Consent

39. The HTA has addressed questions 15 and 19 together.

Incentive

40. The current system for living organ donation and reward is clear and straightforward to communicate. No reward can be offered by the recipient in order to secure the donation. If this was discovered to exist, the HTA would not be able to approve the donation and would refer the matter to the Crown Prosecution Service (CPS).¹⁶

41. Clarity and certainty are very important. Donor/recipient pairs need to know where they stand and the message must be a straightforward one for Transplant Units to deliver.

Compensation

42. In living organ donation, commonality of approach to compensation of the donor's loss of income is important.

43. In our experience some Trusts are more forthcoming with information on the help available than others. A standard leaflet to be issued to anyone enquiring about becoming a living donor would be a cost effective approach to take.

44. This question of adequate compensation which does not become reward is more difficult to address when the donor is not a UK citizen. There are a number of donations each year, c. 5% of the total, where the recipient is a UK citizen but the friend or relative who is donating to them is not. The issue of visa conditions for overseas donors is currently being addressed by the Department of Health and the Home Office. However, the issue of compensation for such donors is far from straightforward. They are often required to spend significant sums of money on flights to get to the UK and are concerned how their family back home will survive without their income.

Case Study

45. The HTA received a report from an IA in which the recipient was a UK citizen and the donor, a relative, had come from overseas to donate a kidney. Initial testing in

¹⁶ s.32 the Act

the home country had shown this person to be a match. The potential donor paid for flights to the UK (c. £600) and their partner and children had been trying to make ends meet without the household's primary income. The donor, a skilled worker, would have been earning the equivalent of £250 a month. The recipient's partner had been transferring amounts to the donor's partner which just reimbursed the loss of income and covered the cost of the flight.

46. With this level of detail we were in a position to approve this case as it could be established that the money which had been transferred only put the donor and their family back in the position they would have been in. This was a pragmatic approach as generally there should only be reimbursement by the State, not by the recipient or their relatives. However, as official payment was not an option in this case, we believed this was entirely reasonable and in keeping with the spirit of living donation.
47. We would welcome further debate on the issue of compensation for economic loss.

Recognition

48. Our IAs interview every living donor and the range of opinions expressed about recognition are vast. Some donors do not enjoy the attention from the family group which focuses on them and 'just want everything to go back to normal', while other donors are keen to speak to the media about their experience.
49. Beyond a small, discrete token it is unlikely any other mark of recognition would suit every donor.
50. We are aware that there are plans to introduce a consistent approach to the tokens of recognition which are given to donors, likely to be a small pin badge. A pin seems an appropriate token that can be worn, or not, as the donor desires.
51. We note that recognition could be in the form of a future promise rather than a token or gift. In Israel a scheme has been introduced which gives those who carry donor cards a 'slight priority'¹⁷ if they subsequently require an organ. In the UK a living kidney donor, whose second kidney failed as a result of the transplant operation was given priority in receiving a deceased kidney.

¹⁷ Altruism + incentive = more organ donation, The Times, 11 June 2010

http://www.timesonline.co.uk/tol/comment/columnists/guest_contributors/article7148469.ece

52. A recommendation of the inquiry chaired by Elisabeth Buggins, was that foreign resident living liver donors, who donate in the UK and subsequently require a deceased liver, should not immediately be listed as 'super urgent', but remain in Group 2.¹⁸ This is an example of a live donor not receiving recognition for coming forward to donate.

Economic loss vs. payment for time, discomfort and inconvenience

53. Putting someone back in the position they would have been in had they not come forward to help someone else is neither an incentive nor a disadvantage, and in the vast majority of cases is easy to work out with supporting evidence (pay slips, bank statements, train tickets, etc.).
54. Time, discomfort and inconvenience are not open to any form of standard measurement. Pain thresholds vary from person to person, and while some people may spend all their spare time out and about, others may prefer to read or sew. If there was a move to compensate for lost time, then it would seem unreasonable that the donor's lifestyle should be taken into account while those with more sedate hobbies receive less. It would be much harder to work out what this figure should be for each donor and would place excessive administrative burden on the NHS while also being open to abuse.

Research

55. It is a matter for sponsors and study participants to agree on the type and level of reimbursement. Many factors need to be considered when setting the suitable reimbursement amount and it is unlikely that any external body would be better placed to do so than the sponsors.

Question 16

¹⁸ Allocation of organs to non UK EU residents, 31 July 2009

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_1035

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?

56. The HTA believes that the principle that organs cannot be paid for, but must be offered freely, is sound and should not be lost in any debate on increasing the number of organs available for transplantation.
57. It is illegal to buy an organ for transplantation; it is also illegal to offer a potential donor a reward to secure their organ.¹⁹
58. The HTA not only applies the letter of the law, but seeks to promote the spirit of it. We stress to our IAs, during their training, the need for open and honest conversations with both the donor and recipient, as well as to the point questioning.
59. Our IAs have the skills required to establish whether there is any unease or inconsistency between a donor and recipient. This is key in assessing whether there has been any offer of a reward over and above what the person-on-the-street would view as reasonable. They ask direct questions about reward, duress and coercion and give the donor opportunity to raise any concerns they may have.
60. This open and honest approach has in the past given donors the chance to let our IAs know they no longer wish to proceed with the donation and acts as a safeguard.
61. From the way we train our IAs, to the ethos of our office staff, the HTA is committed to the principles which underpin our founding legislation; that a donor is consenting freely and is not being placed under any undue pressure, or being paid, to donate.
62. In other types of donation incentives are morally and socially accepted; such as women who agree to share their eggs having their own treatment subsidised.²⁰ This further supports the HTA's belief that we should not be seeking a consistent approach for all forms of donation, but rather separate, but fitting, approaches.

¹⁹ s.32(1)(a) and (b), the Act

²⁰ Egg Donation and Egg Sharing, Human Fertilisation & Embryology Authority
<http://www.hfea.gov.uk/egg-donation-and-egg-sharing.html#1>

63. The HTA has significant experience of considering cases where there are complex family dynamics.
64. In our experience of regulating living organ donation we have found that incentives offered by family and friends are much more difficult to separate from a reward than anything offered officially.
65. While often well meaning, incentives offered by a family or friends to a potential donor are always likely to be motivated by a desire to see the recipient's health improve. However, as the donor will be undergoing a procedure, which by its nature carries a risk, which will not benefit their health, it is vital they are protected. A simple and effective way of offering this protection is to ban any meaningful reward being offered by friends and family.
66. In many of the 1,100 plus reports we receive each year from our IAs 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. Proportionate regulation allows for this low key kind of 'thank you' to be offered while protecting the donor from being unduly pressured by offers of money, or perhaps being accepted back into the family following a period of ostracism.
67. Any official incentive must be offered equally, easy to apply for, well publicised and paid in a timely manner.

Question 18

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

68. Valid consent under the Act comprises three elements. It must be:
 - given freely
 - by an appropriately informed person
 - who has the capacity to consent

69. The question is whether any indirect compensation would prevent or compromise consent being given freely. Direct financial compensation is clearly more likely to prevent consent being given freely, especially by those in more limited financial circumstances.²¹
70. Free medical treatment (which is not provided on the NHS) for living organ donors, such as the subsidy for treatment which those sharing their eggs are eligible for, may well be an incentive, but there would be no guarantee they would need to use it.
71. Funeral expenses are something families and friends will have to pay on death. Many people choose to make provision for these in life so they do not prove a burden. There is a certainty which exists in the payment of funeral expenses which is not true of other forms of indirect compensation. However, it is debatable whether this would prove enough of an incentive to encourage people to sign up to become deceased donors, and therefore remove the freely given aspect of their consent.
72. Other countries have deemed making an offer of indirect compensation suitable. In Sweden there is an incentive scheme for deceased donors of €5000 which can be used towards funeral expenses, payment to charity or some form of public recognition.²² We understand there is some research underway to assess how effective this is in increasing the number of donors and this may help inform the debate in this country.

Question 21

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

73. Any form of encouragement or incentive which means consent is no longer freely given invalidates their consent.
74. There is, however, a spectrum of encouragement and incentives, some of which would seem reasonable to the person-on-the-street, while some would not.
75. In bone marrow and peripheral blood stem cell (PBSC) donation parents often promise the donor child sweets if they are good in hospital. Most people would see this as reasonable

²¹ Comparison of some socioeconomic characteristics of donors and recipients in a controlled living unrelated donor renal transplantation program, A.J Ghods, S Ossareh, P Khosravani, Transplantation Proceedings, August 2001 (Vol. 33, Issue 5, Pages 2626-2627)

²² Faisal Omar, Department of Medicine and Health, Linöping University, Sweden – 18.04.2010

and the HTA would not turn a case down if this information had been shared during the interview with our Accredited Assessor (AA).

76. In the field of living organ donation we are very clear that a one-off ‘pint’ or ‘nice dinner’ will not be considered as an incentive which could invalidate consent, however the promise of a high value item or cash would instigate further investigation.
77. The HTA believes that cases of living organ donation, and bone marrow donation by children, should continue to be assessed independently and by people trained to recognise what level of incentive gives rise to concern.
78. 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.
79. It should be noted that bodily material is not a commodity in the same way our time or effort are. It is important to remember that bodily material is of particular significance and any incentive or encouragement to donate should be considered carefully.

Research

80. It is a matter for sponsors and study participants to agree on the type and level of reimbursement. It is likely that only unusually high payment could possibly invalidate consent. If the payment was so high that it was not congruous with a research project of that nature, this may cause the participant to volunteer with little or no thought to the risk. Payment far above the standard rate may impact on the participants’ ability to give their consent freely.

Question 22

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

81. This is an exceptionally difficult distinction to draw. The current requirement that all living organ donors must be interviewed by one of our IAs, both separately and (generally)²³ with

²³ Recipients who are very young children are not interviewed, nor are those that are too ill to take part in an interview. In paired and pooled donations it is the donor and their partner who are interviewed together, and in non directed altruistic donation only the donor is interviewed.

the recipient, has allowed us a great insight into the range of issues that can exist within family units.

82. There is a subtle but distinct difference between the duty many people feel as part of a family, and coercion. Putting pressure on yourself is very different from being placed under pressure by others. We have found that by interviewing both parties separately our IAs are able to identify any differences in the reasons given for that particular person coming forward as a donor. Our IAs have been able to identify reticent donors and give them an opportunity to speak to someone outside the clinical team about their concerns. Sometimes this has been to alleviate the pressure they are placing on themselves and occasionally this has been to raise issues of family pressure.
83. We believe that the current system of clinical teams getting to know the families and exploring the options with them, combined with an independent assessment where the donor feels free to speak their mind, works well and allows this distinction to be drawn. It is unlikely that a rigid framework document will ever be able to do this as effectively as a well trained individual meeting the donor and recipient face to face.
84. Cases which are paired, pooled or altruistic and those which concern adult to adult liver donation are considered by a panel of three Authority Members. This is to provide a further check to ensure that any coercion (or other issue(s)) is identified. If the executive believes there is evidence of coercion then they are able to refer the case to a panel for consideration, even if it falls outside of the group of cases listed above.
85. The HTA is mindful of differences which may exist between different cultures when it comes to living donation. While donors from some faiths believe their fate is 'in the hands of God' we are still required to assess whether they understand the risks associated with the procedure. We entrust our well trained and qualified IAs to ensure that we have the necessary amount of information, without causing the donor any offence or upset.

View from Gill Nelson, HTA Independent Assessor

“I have had occasions when the donor will tell me that they have been informed of the risks associated with donation but they do not choose to consider them. They tell me it is God’s wish that they offer a kidney and it will be his decision as to the outcome. It is essential that at this time I show respect of these beliefs. I always explain at the beginning of the interview that my role is to protect the donor by ensuring that they are making an informed decision to donate and that they have had the opportunity to explore the implications of that decision. The donors have always been grateful that this protection is offered to them and we have always been able to proceed with discussions of the risks.

“Often individuals from overseas or from ethnic minorities come from large and extended families and the discussions that help the donor make their decisions come from that support within their family. Spending time talking to the couple about their family and the support they provide often gives the IA insight into the way that the donor has considered the risks associated with donation. This is particularly relevant when we are considering the implication of the donor not being able to donate to any siblings or children in the future.”

Question 23

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

Research

86. Both the Act and the HTA’s codes of practice are clear that separate consent must be given for distinct purposes. These consents can be taken at the same time, as long as the individual consenting has appropriate information about each purpose.
87. The only exception to this is if research is to be carried out in a situation where the person carrying it out will not know the identity of the person from whose body it came **and** the research has REC approval, then consent is not required.²⁴
88. It is also acceptable to seek generic consent when the tissue is been retained for research purposes. If conducting [research](#) on samples of tissue, it is good practice to request generic consent because this avoids the need to obtain further consent in the future. It is still important however that the consent is valid.
89. There must be consent in place for the purpose of research in order for any material to be used in this way; the amount of material is of no significance. This is seen by some in the research sector as unhelpful.
90. Tissue that is taken from the living for diagnosis and subsequently stored in a diagnostic archive can be a valuable research resource. Purely diagnostic archives do not need to be stored on HTA licensed premises.

²⁴ s.1(9) the Act

91. Working with the National Research Ethics Service (NRES), the HTA have provided and publicised a mechanism by which archives of diagnostic material can apply to become research tissue banks with the arrangements for generic ethical approval, the generic ethical approval can transfer to researchers receiving non-identifiable tissue from a REC approved bank. This means they do not need to gain additional project specific approval or store the tissue under the authority of a HTA storage licence, subject to certain requirements; this gives researchers wider access to high quality samples.
92. If motivated parties wish to lobby parliament with the purpose of amending the Act to treat specified types and quantities of relevant material differently, for example, a blood sample versus a brain, then this is a matter for public and parliamentary debate and not for the HTA. We support informed consent in the spirit of the Act's intention to make consent the fundamental principle in ensuring the proper use of human material.
93. We are aware that there is some frustration in the research sector that 'residue' bodily material which was legitimately procured for one purpose, but not required for that purpose, cannot be used for a linked, if different activity.
94. A good example of this is additional material taken for transplantation (usually deceased) which is stored for testing in case there are any problems with the graft. Past a certain point in time this tissue may no longer be an effective alternative to taking a biopsy of the graft, however it would be of value for research. If consent for research was not taken at the time of the donation it may be difficult to go back and seek consent later.
95. At present, this material cannot be used for research and there is an argument that doing so anonymously and with the end of improving the efficacy of transplantation, would be a legitimate activity and should be allowed. This would require a change in the law, and there would need to be consideration of how an individual's wishes could remain paramount.
96. Another option would be to more widely promote the benefits of research and the value of donated material for this in an effort to increase the number of people consenting to this purpose. This is something the HTA sought to do when issuing our code of practice on research in September 2009.
97. There have been successful advertising campaigns to increase the number of people on the ODR and this is something that could be considered by other sectors. There are also considerations around the information provided to the specialist nurses who also take consent for bodily material being used for research purposes.

98. It will, on occasion, be clinicians who seek consent for transplantation and working further with them to ensure they also address the issue of research could increase the amount of material available.

Question 24

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

99. In the four years since we started regulating living organ donation we have not been required to consider a case where the donor is a child or an adult who lacks capacity to consent. We have provided clear guidance that we would only accept such a case following court approval being granted. Such a case would require consideration by a panel of Authority Members in order for a decision to be made.²⁵
100. The HTA is also responsible for considering bone marrow and PBSC donations where the donor is a child. Our experience of assessing these cases has given us an insight into the differences between making a decision for yourself and making a decision on behalf of your child.
101. In the case of bone marrow and PBSC donations the parent consenting on behalf of their child is normally doing so in order that another of their children receives a transplant, which could be lifesaving. Parents in this position are placed under a significant amount of pressure, especially when the donating child is old enough to understand and is concerned about the process. Here they must balance the needs of their sick child against the fears of a sibling who has been found to be a good match to donate.
102. We have seen how the support of a range of professionals within Bone Marrow Transplant (BMT) Units have helped parents make this decision and overcome any concerns of the donor. The work done by play therapists, child psychologists, specialist nurses, consultants and other members of BMT teams has allowed even very young children to gain an age appropriate understanding of the procedure they are to undertake. This support allows the

²⁵ s.12(2) The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

parent(s) to consent with the knowledge that the donor child has a suitable amount of information and any fears have been addressed.

103. The information above displays how different support is needed for those consenting on the behalf of others. It also shows that even when an individual cannot consent themselves, it is important they have as much information as possible and play a full role in the process.
104. A question posed recently to the HTA by a clinician working in a BMT team was: how should we weigh up the possible benefits of a treatment, for example a bone marrow transplant, against its likely efficacy, cost and detriment to the donor? The National Institute for Health and Clinical Excellence (NICE) provides guidelines on which drugs can be used, but does not provide similar information on treatments. This point is particularly relevant when a person is consenting on someone else's behalf, as will often be the case with bone marrow, when parents are usually consenting on behalf of a child to help another child. The clinician who raised this question pointed out that although we may be able to make a decision to halt any future treatment for ourselves, making that decision for someone else is much more difficult and likely to be less objective.

Question 25

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

105. The Act is very clear. The wishes of an individual are paramount.²⁶ If their wishes are known, whether to donate or not, these cannot be overridden by anyone else. In the case of deceased donation, when a person's wishes are not known, then a nominated representative²⁷ (if one exists) or, if none, a person in a qualifying relationship can make the decision. The Act provides a hierarchy of those people in a qualifying relationship:²⁸

- spouse or partner
- parent or child
- brother or sister
- grandparent or grandchild
- niece or nephew
- stepfather or stepmother

²⁶ s.2 and 3 the Act

²⁷ s.4 the Act

²⁸ s.27(4) the Act

- half-brother or half-sister
- friend of long standing

106. This hierarchy has caused some debate, as it is the decision of the person highest up the list that will prevail. When there is more than one person at the same level in the hierarchy, for example, three adult children of the deceased, only one of them needs to consent in order for the activity to go ahead. In practice, if there is disagreement between people at the same level, then the clinical team would be unlikely to go ahead with the removal of organs for transplantation, although the law does allow for this.²⁹
107. Although the law is clear, there may be practical difficulties. If a person in life has given consent for organ donation following death, this decision should not be overridden by relatives. However, in practice, it is difficult to imagine circumstances where, following the death of a relative, a transplant surgeon would be willing to remove organs for transplantation in the face of strong opposition from the family.
108. In order to move to a position in this country where the family could not, in practice, veto a positive decision to donate after death, it is vital that the register recording these decisions is robust. The register needs to allow an individual to update their wishes at anytime and full information should be available through a range of channels – online, leaflets and telephone help lines.
109. It is important here to note that high refusal rates which exist in the UK. Forty per cent of families approached by transplant coordination teams in 2009 did not consent for their relative's organs to be donated.³⁰
110. It would not only require a change to the ODR to see a reduction in the 40% figure, but also a societal change. Custom and practice in this country dictates that a family has the choice whether to donate their relative's organs after death. To move to a position where they did not have a veto would require a broad acceptance of this by the general public and considerable engagement.
111. Although Spain is viewed as having the most successful deceased donation programme in Europe, they still allow families the opportunity to veto the deceased's decision to donate.³¹

²⁹ s.3(6) the Act

³⁰ NHSBT statistics

http://www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/2008_09/tx_activity_report_2009_uk_pp69-87.pdf

Research

112. Relatives or friends can also decide whether to donate the deceased's bodily material for research following their death, and the same hierarchy is used. If a person has said in life that they wish to donate their brain for research for example, then this should be paramount, however it is unlikely it would be taken against the family's wishes.

Question 26

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

113. In this country (generally, see paragraph 119) an individual does not own their body or its parts in life, and their family do not own it after death.³² A body is without legal ownership.
114. Our experience has given us an insight into the problems which can arise under the current system. As detailed at the beginning of our response, there is opportunity for confusion and misunderstanding as things stand, and attention must be turned to this as a matter of urgency. Clear guidance, suitably enforced, will bring comfort to all involved.
115. As the HTA has no role in the regulation of sperm or gametes, we were not directly affected by the Court of Appeal's decision that sperm is capable of being the property of the man who produced it. However, we note the significance of this decision and the possible shift away from human skill (for example, the creation of demineralised bone products) having to be applied to bodily material for it to become property.
116. We are aware that others may have strong views in relation to this and will be interested to read the responses received by the Nuffield Council on Bioethics on this subject.

Question 27

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

³¹ Opt in or Opt out, NHSBT

http://www.uktransplant.org.uk/ukt/newsroom/statements_and_stances/statements/opt_in_or_out.jsp

³² *Doodewood v Spence* (1908) 6 CLR 406

117. The Act prohibits commercial dealings in human material for transplantation but does not make it an offence for any of the other scheduled purposes.

Living Organ Donation

118. 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. It would also mean that the most affluent would have more ready access to organs and have an advantage in securing them over others with more limited means. This may free up altruistically donated organs and increase the total number available but it is likely that the regulatory framework would need to be more detailed and require additional resources to administer.

119. 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 costs? Whether or not payment would impact on the validity of consent would very much depend on the individual and their circumstances at that time. There is a difference between an incentive which may impact consent and the commercialisation and commodification of bodies and body parts. While the first may be considered acceptable as it will, on occasion, impact consent but this could be regulated for, the second would be a step too far.

120. It is also possible that payment for organs would stigmatise the act of donation and lead to a reduction in the number of non directed altruistic donors coming forward.

121. There is also evidence that, when payment is permitted for organs, the quality of organs donated diminishes.³³

122. Questions such as how any payment would be facilitated, what factors it would be contingent on and whether a regulated price would be set, would also need to be addressed.

Question 29

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

³³ Kidney transplantation in patients travelling from the UK to India or Pakistan; Rob Higgins, Nick West, Simon Fletcher, Andy Stein, For Lam and Habib Kashi - 2003

123. If a person has made a decision to allow their bodily material to be used for a specific purpose, or made a decision **not** to allow its use for a specific purpose, then this should be observed. Without such certainty it is likely there would be a fall in the number of people coming forward as donors due to the perception that their bodily material could be used against their wishes.
124. Any action which would have a detrimental impact on the number of donors would be a significant step backwards.
125. However, as noted in our response to question 23, there are grey areas. The willingness of the donor to consent to one activity and their silence regarding another activity, could be construed as an indicator of their general wish to help. If, for example, the tissue had been taken for transplantation and was no longer required, but could usefully be used for research purposes, would the general public think it unreasonable for it to be used without specific consent?
126. In the circumstance outlined above, the tissue could be used if consent was in place, or the tissue was not identifiable and was to be used in a study with project specific ethical approval from a recognised REC.
127. On the other hand, it could also be questioned whether silence should ever be inferred to mean consent. An example of this is the ODR. When an individual registers they tick which organs/tissue they wish to donate (if not all) and the other tick boxes remain empty. There is not a 'no' option. In this case, the act of omitting to positively choose to donate a certain organ is most likely to be a conscious decision not to donate it. Silence would therefore mean 'no'. We are aware of cases where not ticking the box is treated as no decision being made by the deceased and the family then being asked whether those organs can be donated.
128. Donors of material have the right to withdraw their consent to an activity at any time. However, practically, this is not always possible. In living donation the point at which it is possible for the donor to withdraw their consent is immediately before anaesthetic is administered. In research, withdrawal of consent depends whether the material has been used.
129. A wider discussion on this point, to gain an understanding of the public's view, would undoubtedly move the debate forward.

Overview of HTA donation and approval process

