

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.

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Introduction

The Anscombe Bioethics Centre is the oldest national bioethics centre in the United Kingdom, established in 1977 by the Roman Catholic Archbishops of England and Wales. It was originally known as The Linacre Centre for Healthcare Ethics and was situated in London before moving to Oxford. The Centre engages with the moral questions arising in clinical practice and biomedical research. It brings to bear on those questions principles of natural law, virtue ethics, and the teaching of the Catholic Church, and seeks to develop the implications of that teaching for emerging fields of practice. The Centre engages in scholarly dialogue with academics and practitioners of other traditions. It contributes to public policy debates as well as to debates and consultations within the Church.

The Centre welcomes the opportunity to respond to the Nuffield Council Consultation Report *Give and take?: Human bodies in medicine and research*, recognizing that this covers important ethical issues of wide concern. This response generally does not rely on premises held by Catholics only, except where this is explicitly stated. On the contrary, for the most part, the arguments presented are potentially acceptable to those of other faiths, and of no faith. Furthermore, much of this response goes beyond the current teaching of the Church, both because it concerns scientific questions outside the Church's competence (for example, the diagnosis, as opposed to the definition of death), and because this is an area in which Church teaching is still in the process of formation.

Before addressing the consultation questions in detail it is helpful to set out the key orientation of Roman Catholic teaching in relation to the use of human tissue after death.

The use of the human body after death

The Catholic Church does not oppose, and has never opposed, the ethical use of the human body for medical or research purposes. On the contrary, when the possibility of solid organ transplantation was first explored this was welcomed by Pope Pius XII. "It also follows from this that a person may will to dispose of his body and destine it to ends that are useful, morally irreproachable and even

noble (among them the desire to aid the sick and suffering).”¹ The value of donation was forcefully reiterated by Pope John Paul II; “We should rejoice that medicine, in its service to life, has found in organ transplantation a new way of serving the human family, precisely by safeguarding that fundamental good of the person.”²

The Catholic Church is thus of one mind with men and women of good will, who see in organ donation the possibility of great human benefit. Much of the remainder of this submission concerns the essential ethical prerequisites for the donation and use of human tissue. Nevertheless, these ethical considerations should not be seen as a rejection, or even a discouragement of organ and tissue donation in principle. Rather, the Catholic Church emphasizes the importance of ethical safeguards, precisely because donation can be a beneficial human activity, which the Church wishes to encourage: “Organ donation after death is a noble and meritorious act and *is to be encouraged* as an expression of generous solidarity.”³

Ethical prerequisites

For organ donation to be pursued in an ethical manner, it is essential that no one is unjustly harmed by the procedure. In donation from living donors the welfare of the donor must take precedence over the welfare of people who might be helped by the donation. People can and do take risks with their lives but medical professionals should never deliberately harm one patient for the sake of another. This means, for example, that whole unpaired vital organs must never be removed from a living donor. In relation to donation after death, organs such as the heart and liver can be donated, but in this case it is essential to establish that death has occurred and to do so by the use of clear, agreed, objective criteria. In both live and post mortem donation the informed consent of the donor is another important ethical requirement. This is clearly the case in live donation where there is risk to health, but it is also true for donation after death. For the foundation of the idea of ‘organ donation’ is of a gift, i.e. something provided voluntarily.

In addition to avoiding harm and obtaining consent there are other considerations in relation to specific kinds or uses of tissue. One specific area that should be distinguished from others is that of human procreation. Parenthood is not reducible to human biology. Nevertheless, the biological aspect of parenthood involves the fusion of cells – sperm and egg cells – and people trace their

¹ Pius XII, ‘Address to the delegates of the Italian Association for Cornea Donors and the Italian Union for the Blind’, May 14 1956. For further references see D.A. Jones (2001) *Organ Transplants* London: Catholic Truth Society.

² John Paul II ‘Address to the participants at the First International Congress on the Transplant of Organs’, June 20, 1991.

³ *Catechism of the Catholic Church* Paragraph 2296, emphasis added.

ancestry through their genetic inheritance which is passed on by these cells. Interventions that affect the process of human reproduction therefore raise a different kind of concern.⁴

This is shown, for example, by the right of information, that is now given to people, who were conceived using donated gametes. The ethical considerations also relate to the donor, as the use of sperm or eggs to conceive a child clearly requires the consent of those who will become genetic parents. It is noteworthy that in the United Kingdom the Human Tissue Authority (HTA) is not regarded as a suitable body to oversee these practices but they require their own specialized regulator, the Human Fertilisation and Embryology Authority (HFEA). While the Catholic Church does not endorse the decisions of the HFEA, many of which it regards as excessively libertarian and unduly influenced by the fertility industry, the Church endorses the need for a separate and specialised oversight of fertility treatment. Use of reproductive tissue raises issues not raised by other somatic tissue transplantation.

These and other ethical considerations are address below in more detail through addressing the questions provided by the Nuffield Councils.

⁴ These are spelled out in more detail in the Vatican document of 1987 *Donum Vitae* and in the document of 2008 *Dignitas Personae*. From this perspective, assisted reproductive technologies are only ethical where they are used in the context of marriage and where they facilitate and utilise acts which express the reciprocal love between husband and wife, and where they respect the inviolability of human life from fertilisation. Notwithstanding these wider concerns, the present submission focuses specifically on the ethics of using human tissue, and hence on issues such as specific and explicit consent.

Questions

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

The consultation is wide in scope but has not considered the donation, storage and use of human tissues in non-medical contexts – for example in criminal investigations, in the storage and display of anthropological specimens, or the use of bodies for education or for entertainment (which are not always easily distinguished).

Such uses raise a different set of questions about, for example, the storage of human tissue for the purposes of DNA identification, especially in those not convicted of any offence. This is related to the wider question of consent for storage of material in tissue banks, but has the added dimension of potential use of this tissue in criminal proceedings. The samples may well have been taken under duress or in circumstances where the ‘donor’ had little choice. It is a very specific area and clearly requires its own consideration.

Very different arguments concern the return of human remains in museums to the people who claim common ancestry. This raises the significance not only of individual consent but also of the consent of a wider group to which the person belongs – an issue in population genetics. Retention of specimens for anthropological reasons also raises the issue of reverent disposal of human remains and whether human remains should be used for display or public entertainment (when this is deemed educational). A variant on this issue was evident in the use of human remains in the *Body Worlds* exhibition. Had these bodies all been obtained with prior consent of the donors? Even with consent, are there limits on what kinds of display of human remains are appropriate?

A further type of human bodily material which raises problems is material derived from a controversial or unethical procedure, such as donation or foetal tissue after termination of pregnancy, organ donation (whether voluntary or involuntary) after state execution and, as recently reported in Belgium, organ donation after euthanasia. In all cases the request for consent seems to make the recipient complicit in the original procedure. The issue is less whether subsequent donation might encourage such procedures (abortion, state execution or euthanasia), but more whether it implicitly condones the practice, by agreeing to benefit from an ongoing pattern of behaviour.

Some of these issues were considered in the 2002 Department of Health consultation *Human Bodies Human Choices*. The present consultation might consider examining not only that report, but also the submissions made to that consultation, including the submission of the Linacre Centre of Healthcare Ethics.

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

As argued above, the use of reproductive tissue is a different category from other somatic tissue taken for research purposes. A greater degree of informed consent is necessary, if tissue is used for reproductive purposes. Whereas some secondary use of human tissue may be ethically acceptable without explicit consent, it can never be ethical to generate new human life without the consent of both parents. This should be evident in cases where a child is born and will wish to know about his or her ancestry. It is, furthermore, already the case that the generation of a human embryo is an action that absolutely requires the consent of both parents.

It is not only the Catholic Church that recognizes that human gametes and human embryos must be distinguished in ethics, law and public policy from other types of human tissue. The Joint report on the draft Human Tissues and Embryos Bill took evidence from a wide variety of interested parties and there was strong and near universal opposition to the government's proposal to amalgamate the Human Tissue Authority with the Human Fertilization and Embryology Authority. These kinds of human bodily material...

The Nuffield Council should give explicit consideration to somatic cell nuclear transfer, by which a human embryo or human admixed embryo might be generated. This is not a major area of current research, but is significant, as it could lead to non-reproductive somatic tissue (blood or skin cells) being used in a reproductive way (i.e. to generate an embryo).

Another area that is controversial is that of the transplantation of neurological material. While it seems pure science fiction to affect personality, or transfer mental traits by transplanting brain tissue, experiments in animals have shown the transfer of behavioural traits in this way.⁵ Such psychological side-effects would not necessarily rule out this kind of procedure absolutely, but they would mark this kind of tissue out as a special category for the purposes of consent and justification.

The association with identity and personality also relates to very recognizable human features, such as the face or the eyes. It is not unusual for people to consent to organ donation after death with respect to their internal organs, but to make an exception of the eyes. This public human significance of certain body parts does not rule out donation, but emphasizes the need for explicit specific consent.

⁵ Balaban, E. (1997) "Changes in multiple brain regions underlie species differences in a complex, congenital behavior". *Proc. Natl. Acad. Sci. U.S.A.* 94 (5): 2001-2006.

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

In relation to live donation there may be a serious question of risk to life or health, for example in giving a kidney. This is an unnecessary medical procedure not for the benefit of the patient but for the benefit of another. It can be justified as an expression of altruism but only then if the harm is not inevitable and the risks are not excessive. People may wish to sacrifice themselves, by donating an unpaired vital organ, but it is not the proper role of medicine to harm the patient, even at the patient's request.

In relation to donation after death there is an important issue of establishing the death of the donor. The Roman Catholic Church has accepted neurological criteria for death in principle, but not necessarily as they are applied in practice.⁶ There is an ongoing controversy among Catholic scholars, as to whether the criteria for 'brain death' fulfill the Catholic understanding of death, as the loss of integration of the organism as a living whole.⁷ The Church has not spoken definitively on the criteria for diagnosing death.⁸

Similar concerns emerge from the re-introduction of donation after cardiac death, with some people anxious that this is less secure than brain death and the suspicion that new criteria for death have been introduced only to increase the supply of organs. The diagnosis of death is an issue that the Council certainly should consider. It is a key ethical issue. If the patient were not dead when his or her heart was donated then the 'organ harvesting' operation would amount to killing one patient for the sake of another.

4. What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them) of providing bodily

⁶ "Here it can be said that the criterion adopted in more recent times for ascertaining the fact of death, namely the complete and irreversible cessation of all brain activity, if rigorously applied, does not seem to conflict with the essential elements of a sound anthropology. Therefore a health-worker professionally responsible for ascertaining death can use these criteria in each individual case as the basis for arriving at that degree of assurance in ethical judgement which moral teaching describes as 'moral certainty'." John Paul II, 'Address to the participants at the First International Congress on the Transplant of Organs', June 20, 1991.

⁷ This internal controversy is evident, for example, in the contrast between the paper by Alan Shewmon *Why the Concept of Brain Death is Valid as a Definition of Death* published by the Pontifical Academy for Sciences, Rome in 2008 and the collection of papers of De Mattei Roberto (ed.), (2006), *Finis Vitae: Is Brain Death Still Life*, Consiglio Nazionale delle Ricerche, Rome. It is also evident in the different views taken by Alan Shewmon and Edmund Pellegrino in the US President's Council on Bioethics report of 2009, *Controversies in the Determination of Death: A White Paper by the President's Council on Bioethics*, Washington DC.

⁸ It should be noticed that conference papers or publications of the Pontifical Academy of Sciences not necessarily represent the view of the Pontifical Academy and, furthermore, the Pontifical Academy does not define or promulgate official Church teaching – this is done by Popes, Councils, national conferences of bishops (in communion with Rome) and by the Congregation for the Doctrine of the Faith.

material? Please distinguish between different kinds of bodily material if appropriate.

There are many costs and risks of donating human tissue, if this is done badly. In live donors it may bring excessive risk, or be due to coercion. Financial inducements could easily lead to exploitation of the poor, especially in combination with healthcare tourism. Taking organs after death with insufficient sensitivity to the feelings of relatives could exacerbate their grief and lead to significant ongoing psychological harm. It could also be a violation of the person if organs were taken against someone's will, even after death. In such circumstances organ transplantation "would no longer correspond to an act of donation but would amount to the dispossession or plundering of the body."⁹

If done well, organ donation could benefit not only the recipient, but also the donor and the relatives. It allows the donor to express solidarity with others. It may help assuage the grief of relatives if they can think some good has come out of the human tragedy, especially if this is seen as an expression of the person's own generosity.

For foetal and embryonic tissue the providing of material is typically the concomitant of the destruction of their lives. There are circumstances where material might be obtained from a spontaneous miscarriage, but the more obvious context is termination of pregnancy. The use of this material is ethically problematic, as it involves cooperation with, and perhaps complicity with the deliberate destruction of a human embryo or a foetus.¹⁰ This is incompatible with the ethical principle of the inviolability of all human lives, from conception and is not justified by benefits it might bring to the parents, or to the born siblings of the unborn child.

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?

The issues of first-in-human trials are somewhat analogical to donation by living patients, but in other ways they are dissimilar and more similar to the much wider question of experimentation on human subjects. 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. The question of remuneration in human trials should not be limited to first-in-human and would be better treated in a separate inquiry, where justice could be done to the issues.

⁹ John Paul II, 'Address to the participants at the First International Congress on the Transplant of Organs', June 20, 1991.

¹⁰ "[T]here is a duty to refuse to use such 'biological material' even when there is no close connection between the researcher and the actions of those who performed the artificial fertilization or the abortion" *Dignitas Personae* paragraph 35.

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

Yes, see 1 above.

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

As discussed above, donation is to be encouraged when this is for medical treatment or research, though not for unethical purposes, such as destructive embryo experimentation.

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?*

In principle it is a good and noble thing to participate in such research, where they are necessary and conducted in a way to mitigate the risks. Nevertheless, the use of human subjects in scientific experiments or research raises many issues and is difficult to treat adequately, when the primary focus of discussion is the use of human tissue. This response primarily confines itself to the ethics of obtaining, storing and using human tissue.

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

Of the list of values presented, ***Altruism, Dignity, Justice and Solidarity*** are key values, that are widely recognized and are emphasized within the social teaching of the Catholic Church. There is more dispute as to how the values of ***Autonomy, Maximising health and welfare*** and ***Reciprocity*** should be understood.

While the dignity of free human choice is acknowledged by Catholic and other religious traditions, there is perhaps more awareness within these traditions of the dangers of **autonomy**, in the sense of self-assertion or unwillingness to acknowledge the claims of others. Similarly, the exercise of power is generally evaluated relative to the goods it serves, rather than as a good in itself. In particular, it is a mistake to regard the human body as property as though it had no inherent dignity, or connection with the human person.

It is true that each person is the steward of his or her own life, and that it is unjust for others to dispose of the body, in a way the person would have opposed. Nevertheless, this rightful say in the disposal of the body is not to be understood as a property right. From a theological perspective, it is often said that the human body is owned by God (for example “Do you not know that your body is a temple

of the Holy Spirit within you, which you have from God? You are not your own” 1 Corinthians 6.19). This should be understood as implying that no, the human body is not owned by any human person or political authority. It is rather, that the person and then, after death, others, exercises stewardship in relation to the body.

Many traditions, including the Catholic moral tradition, give weight to the common good (and not only individual goods). However, the common good is not to be understood as **Maximising health and welfare** in the sense of a mere aggregation of health, or other such benefits. Rather, the common good includes respect for each and every person, within the context of the whole. The attempt to maximize ‘overall’ benefit can easily be harmful to minorities, if it is not combined with justice and a respect for the human person.

Lastly **reciprocity** is a positive concept if it connotes active cooperation among individuals and includes relationships of gratitude and just recompense. However, from a Catholic perspective the relationships of exchange, whether of property, services, payment or gratitude, are secondary to a common destination of goods and a common human solidarity. It is important also to distinguish different kinds of reciprocity so that, for example, the relationships of gift, acknowledgement and gratitude are not reduced to relationships of payment and obligation.

In addition to these values, explicit attention should be given to the principle of **non-maleficence**, both in the sense of avoiding undue physical harms and in the more important sense of avoiding injury (unjust harm). The principle of the **inviolability of human life** should be understood, as a particular case of avoiding unjust harms.

Under the heading of dignity should be included not only the dignity of the body but also the **dignity of the person**. This is the basis of a robust doctrine of human equality and **non-discrimination**. Discrimination could occur in relation to those who are in danger of being exploited for their organs, whether because of poverty or because of severe ill-health, especially those who are not able to consent.

Another corollary of human dignity is the **dignity of human procreation**. This principle acknowledges the human significance of biological aspects of reproduction, such as genetic identity, parenthood and inheritance. It has a particular impact on the need for specific consent before tissues are used.

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

The metaphor of prioritizing or 'balancing' values is not helpful here. In the first place it is important to clarify what is meant by a 'value'. Valuable human goods (such as health or security) should be distinguished from moral principles (such as the golden rule) and from virtues (like honesty). Goods (and harms) can be balanced and part of individual prudence and public policy is weighing up the advantages and disadvantages of different proposals. However, moral principles are not to be weighed up or traded, they are to be combined in a principled way. Similarly virtues are not to be balanced, but are to be integrated into a coherent virtuous character. Indeed the virtues do not make sense except as aspects of this unified personality.

In different ways Hippocrates, Aristotle, Thomas Aquinas and Kant each bore witness to the need simultaneously to pursue each of the virtues (or principles). The virtues embody balance, but are not to be 'balanced' in the sense of compromising one out of desire for another. It was the philosophy of utilitarianism in the nineteenth century that promoted the idea, that ethical principles could be balanced or traded. While the twentieth century has seen a variety of approaches to moral philosophy, a number of them share this weakness with utilitarianism. The philosopher Elizabeth Anscombe termed this flaw "consequentialism".¹¹ She understood by this term, the doctrine that there is no ethical prohibition, that cannot be set aside, if the consequences demand it.

It is not difficult to think of examples, where consequentialism (in Anscombe's sense) runs deeply counter to common moral intuitions. In the area of organ donation there would clearly be some consequential value, measured in health terms, in killing some people against their will, in order to treat others. Happily, there are few who would be willing to entertain this proposal, as a serious solution to the demand for human organs. This example shows that there must be some ethical limits to what is 'balanced' or traded in pursuit of maximizing overall health benefit. There are at least some principles and virtues that are not 'balanced' against benefit.

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?

Yes, it is better to provide tissue for free, than to receive compensation. Indeed any compensation, which amounted to selling tissue, would be not only be 'less good', but would be inherently wrong.

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?

¹¹ Anscombe, GEM, 1958. 'On Modern Moral Philosophy' in GME Anscombe 1981. *Collected Philosophical Papers Volume III: Ethics, Religion and Politics* Oxford: Basil Blackwell.

In general donation of tissue is not a duty and it is certainly not a duty in justice. No one else can have a better claim to my blood or my kidney than me! Donation after death is also not a duty in justice, as the body neither belongs to the state nor to any other person. However there is a virtue in solidarity (which Christians would express as the theological virtue of charity), in donating organs and in times of necessity (such as war or national emergency) there may be a duty on people to donate replaceable tissue such as blood. It also would seem ungrateful where someone has benefited from donation, or someone close to the person has benefited, not to express a willingness to donate after death.

Nevertheless, even were there to be a duty on someone to donate, this would not justify coercion or confiscation by the state. This would undermine the principle of free donation and demean the body. It would also be likely to have a negative impact on public support to donation.

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?

As stated above, this subject requires attention in own right. In brief, there does not seem to be a duty on someone to participate in first-in-human trials. It is not like military service, or even like blood donation. It is participation in scientific experimentation, as a research subject.

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

The essence of moral or ethical action is to act in a way that is good, principled and virtuous, within a particular situation. This is not compatible with seeking to pursue every possible good, or meet every possible demand. Indeed with or without consideration to ethical principles, it is impossible simultaneously to pursue every possible good and meet every possible demand. Within modern healthcare there is an ever increasing number and variety of interventions, that could supply some benefit and which could be desired or demanded. Given that it is never possible to supply all demands, it seems doubly foolish to subordinate ethical principle for demands that are insatiable. In general to prioritise any one particular good over and against the common good of society and the requirements of virtue, is morally corrosive.

Among the needs and demands of people some are more pressing than others. Emergency medicine is more pressing, just because it is intolerable to abandon someone in severe need. Basic care (including adequate nutrition and hydration) and comfort are more pressing than cure. Some needs are greater than others. Nevertheless, the identification of need is complex and need is not to be conflated with ability to benefit.

John Harris has argued that “the need for health care cannot legitimately be equated exclusively with *one* measure of the degree to which health care can benefit the individual”.¹² Going further, Anthony Fisher and Luke Gormally mention ten measures of need: (1) greater urgency, (2) greater likelihood to benefit, (3) likelihood of greater benefit, (4) likelihood of lesser burden from treatment, (5) lesser likelihood of harm from treatment, (6) likelihood of greater harm without treatment, (7) likelihood to gain the same benefit from less treatment, (8) likelihood to need less treatment, (9) lack of alternative methods to satisfy need, and (10) greater likelihood to infect others if untreated.¹³

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?

In general incentives are dangerous in this area, whether financial incentives or compensation in kind. There is a great danger of exploitation of the poor, which has been a concern of Catholic teaching on organ donation, at least from the time of Pius XII. Recognition of generosity should be placed in a different category if it is recognition after the event and is not used as an incentive. It is the attempt to use compensation or recognition as an incentive, that threatens to corrupt these practices.

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

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?

Financial compensation can be reasonable if it reflects actual expense and is not abused as a system of incentives. Incentives are more dangerous in some contexts than in others. It is no better if offered by family or friends, and indeed the scope for coercion in these contexts may be greater.

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

It has been argued convincingly, that the supply of bodies for the training of doctors has been improved immeasurably, since the growth of the idea of

¹² John Harris “Microallocation: deciding between patients” in Peter Singer and Helga Kuhse Eds. *A Companion to Bioethics*, Basil Blackwell, Oxford 1998.

¹³ Fisher, A, Gormally L. 2001. *Healthcare Allocation: An Ethical Framework for Public Policy* London: Linacre Centre, p. 129.

voluntary donation.¹⁴ Deprived of a culture of donation the use of the human body can easily appear inhuman and degrading and this is something people have in the past strongly resisted. The reaction to the retention of children's remains in Alder Hey shows that such resistance can easily be re-ignited. Any moves towards commercialization, trade or coercion and any undermining of voluntary donation and consent, threaten to reduce public support for tissue donation.

This reaction would not come only or primarily from the Catholic community, but it is likely that there would be a reaction within the Catholic community, among others, to resist the undermining of the ethos of free donation. If practices were introduced, which commodified the human body, or which placed undue pressure on people to permit organs to be taken, then these practices should be opposed. Such practices may also fuel suspicion of the medical profession, especially in the context of end of life decisions.

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

There is a difference in legislation and in practice. Giving money directly is symbolically more overt. Nevertheless, indirect compensation can be worse, because it can expose people to greater pressures. A case in point is incentivizing egg 'sharing' for treatment or for research. While the law does not allow overt financial payment, payment in kind equivalent to a four figure sum is not against the letter of the law.

For women who are seeking to have a child, however, the offer of free or reduced cost fertility treatment is far greater incentive than money. For the chance of fertility treatment, women have allowed the use of their eggs to create embryos, that will be used in destructive experimentation. From a perspective that accords a special moral status to the human embryo this inducement is scandalous. A rather different problem emerges when 'egg sharing' schemes link fertility treatment with gamete donation. This practice strongly incentivizes women to become genetic parents to children they will not have any role in rearing. There is a significant chance that they will not conceive, while some other women will give birth to a child, who is their genetic child, but who they will not have any role in rearing. This is ethically unacceptable.

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?

¹⁴ Ruth Richardson. *Death, dissection and the destitute*. London and New York: Routledge & Kegan Paul, 1987.

Compensation for expenses is less open to exploitation and corruption than compensation for inconvenience. Nevertheless, the expenses scandal that has engulfed Parliament shows that expenses against actual costs can also be abused. It is essential that compensation should be modest in scale and should not represent a covert incentive scheme.

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?

There will be developments, such as artificial organs, adult stem cell therapy, and other emerging cell technologies, which may reduce demand for organs and tissues. However, at the same time as these are developed, 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.

An improvement in infrastructure and spending in intensive care beds would probably alleviate demand. On the other hand a move to an 'opt out' system may well be counter-productive. A 'soft opt-out' system involving consent from families would be very unlikely to increase the number of donations. Currently the rate of consent from the family is around 60%, but it is 90% where the family knows their relative is on the Organ Donation Register.¹⁵ It is clear that families are much more likely to consent when they know that this was their relative's wish stated wish. The effect of an 'opt-out' system is to *discourage* people from signing the Organ Donation Register and hence families would no longer know whether it was the wish of their relative to donate his or her organs. Mandated choice may be helpful, but only if the choice is properly informed and genuinely free (not, for example, facilitated by a doctor, who is involved in the treatment or care of that person).

What would help in this area is a great level of knowledge of people's wishes and evidence of their informed decisions. This not only helps the relatives, but also could facilitate treatment before death (such as elective ventilation), which could help in the transplant process, but which could not be done without consent. A major set-back in the accumulation of good quality of evidence of consent to donate, was the recent admission that the data on the register had been corrupted, so it no longer shows where people object to specific tissue or organs being taken (such as eyes).¹⁶ The extent of this problem requires investigation.

¹⁵ The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce, 17 November 2008, Paragraph 1.15.

¹⁶ <http://news.bbc.co.uk/1/hi/uk/8613909.stm>

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

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?

Yes, potentially. The potential for undermining consent will depend on the circumstances of the person donating (income, strong desire for a child etc.) and also the nature of the decision being taken. A small incentive for a blood donation might be innocuous, but if giving the organ posed serious risk then the need for consent would be stronger.

Furthermore, not only the fact of influence, but the appearance of influence can also be problematic. For this reason it is illegal to give financial or other inducements to vote. Similarly, the appearance of inducements can reduce the value of a 'confession'. In a recent case in the United States, a criminal argued that he made a false confession to the police to obtain a fast food meal.¹⁷ This appeal may well be unsuccessful, but if the police offered 'compensation' worth a four figure sum (or if they offered to pay for a woman's fertility treatment), then this would certainly undermine the value of a criminal confession. The appearance of large financial incentives (or equivalents in kind) undermines the confidence people can place on the voluntariness of the donation.

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

This is a very difficult question and one that needs to be taken very seriously. Public policy should not depend on an unrealistic and rosy view of domestic and family relationships, but should be aware of the extent of manipulation, pressure and even violence within families.

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?

¹⁷ <http://www.wmctv.com/Global/story.asp?S=12679297>

When material has already been given for a different purpose and where the secondary use is noncontroversial and relevantly similar to the original consent, and where the research is well thought through and likely to be beneficial, but it is impractical to re-contact donors for a new consent, then it may be ethically permissible to use material without explicit consent. Nevertheless, each of these conditions is important and most of all, the condition that the additional purpose is noncontroversial. For example, if the original research was for a particular disease, it cannot be assumed that the donor would be happy to use the material to study ethnicity or population movements. 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. If tissue was retained as a biopsy on a particular patient, it cannot be assumed that it could be used to investigate the genetic origins of disease.

Some kinds of research should always require explicit consent, because of their character and this is especially true of any research involving human or human admixed embryos. The Church regards all destructive experimentation on human embryos as unjust. It is a further injustice if the embryos are generated without even the consent of the (genetic) parents.

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?

There is a clear difference between what someone can agree to for himself or herself, and what he or she can agree to for another. It is a virtue to be altruistic, but taking risks with someone else's health is not altruistic. Thus research using subjects who cannot consent must either be for the sake of that person, or must be of minimal risk.

In relation to a child, parents have to make many decisions on their behalf and can reasonably make some choices for the sake of others, if these choices do not adversely affect the child. So, for example, it is for the parent to decide whether organs should be taken from a dead child. This is not because they own the body but because this kind of decision is appropriate for parents.

In relation to a living child, the parents have a right to decide only because they have a responsibility to the child to act in his or her best interests. This may be compromised if, for example, organs from one child might help a sibling. In such cases extreme care must be taken, that any intervention is in the best interest of the donor child. If the child expressed a wish to donate to help a sibling, then this should be taken into consideration, especially if the child is 'Gillick competent'. Nevertheless, doctors should not operate on a child, unless they are sure that the risks are justified, in the best interest of that child.

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?

Where the deceased person's wishes are not known independently (i.e. where he or she is not on the Donor Register), the family may be able to provide evidence of his or her wishes. It may be that some member of the family can recall a conversation, where the person expressed a wish to donate or expressed opposition to donating. If more people had such conversations then this would be a great help to relatives and to doctors after the person died. Relatives are strongly inclined to facilitate donation, if they know this is what the person wanted.

If the wishes of the deceased are known, either independently or via the relatives, then the 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 may not be clear, for example, that the person would have wanted to force the issue, or cause distress to his or her relatives. For this reason 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, at the same time as the wishes of the deceased are respected.

If the person who died was a child, or someone who lacked capacity, then the parent or carer may decide on his or her behalf. This is an appropriate role and is no disrespect to the person. If the person had capacity before death, but at no time expressed a wish either to donate or not to donate, then it is difficult to know how to proceed. It seems that a next of kin or someone who was close to the person may give consent on the person's behalf, on the basis of his or her character and attitudes. However, in the face of opposition from relatives then organs should certainly not be taken.

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

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

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. In the words of Pope John Paul II: "the human body is always a personal body, the body of a person. The body cannot be treated as a merely physical or biological entity, nor can its organs and tissues ever be used as items for sale or exchange. Such a reductive

materialist conception would lead to a merely instrumental use of the body, and therefore of the person.”¹⁸

This tradition of respect for the dignity of the body has long been enshrined in law, in the doctrine that the human body is not property. This legal principle is currently under considerable pressure. Nevertheless, it reflects a deep human truth. Efforts should thus be made to address the legal problems of appropriate and inappropriate use of the body, and who has right and responsibility to make decisions in relation to human tissue, without recourse to the idea that the body is property.

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

The buying and selling of human bodily material directly contradicts the dignity of the body. It not only threatens the vulnerable (who might be tempted to sell their organs), but more fundamentally it threatens the respect for the human body.

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?

Those who profit financially from the ethos of donation, for example biotechnology companies, should acknowledge their indebtedness to human generosity, for example by supporting specific charities. This is something many companies do simply to show their awareness of their responsibility to society (and of course for the sake of their reputation).

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. The extent of this charitable support should realistically reflect the extent of the profit and the role of voluntary donation in securing that profit.

In contrast, any direct financial remuneration to 'donors' would undermine the ethos of voluntary donation and would be detrimental to the common good of society.

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.

¹⁸ John Paul II, 'Address to the participants at the First International Congress on the Transplant of Organs', June 20, 1991.

To give something is to give away control of that thing. There are sometimes problems with attaching conditions to a gift. This is common in charitable giving (there are charities for people in very specific circumstances), but with something as basic as organ donation the virtue of human solidarity strongly argues against setting conditions. For example, a small financial charity might be set up for the education of young women from the South West of England, but people who donate organs cannot restrict the sex, age or location of the donor in this way. 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.

In donation of tissue for research the ethos of donation is related not directly to medicine, but directly to science and to the pursuit of knowledge. In this context the attaching of conditions is the norm rather than the exception. Consent for use of tissues in research should specify the purposes for which the tissues are given. It is reasonable for tissue banks to develop broad generic terms of consent, but the consent is not real if the practices that are not in fact generically alike ethically and politically. If research raises specific ethical questions, or generates specific political controversy then these need specific explicit consent.

Another aspect of control is the wish to be involved as a stakeholder in decisions about the sharing of the results of research. Donors may wish to see a different balance between commercial interest and public good, for example wishing to see more sharing of knowledge in the public domain, free of the restriction of patents. Even here, where there is a strong case for involvement, giving direct control of decision-making to individuals, who donated tissue would undermine the ethos of donation. Nevertheless, it is good practice for companies to listen to groups and individuals, who have been involved in the development of medical products through donation. They are stakeholders.

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

The terms of reference of this consultation are too broad to cover all the issues adequately. The protection of human experimental subjects, the need for consent for cadaveric organ donation and the use of tissues in assisted reproduction are diverse ethical areas, each with their own complexities. The Nuffield Council report will be most useful if eschews the temptation to comment on every possible ethical aspect of these issues and instead narrows its focus upon a more limited set of questions that emerges from the consultation.

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