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Introduction

We appreciate the opportunity to contribute to this timely and welcome consultation on a number of topics that we have long considered to be both important and requiring of critical scrutiny. Whilst it is clear that the utilisation of human tissue in medical research, clinical treatment and other applications share an important factor in common, namely, human tissue, we, however, suggest that there is a potential for this common factor to conceal more important social and ethical differences. Therefore, in this response we place our emphasis on the contexts in which human tissue is donated, as it is the context of donation that points to significant differences between superficially similar acts of donation and tissue acquisition.

We accept as a starting premise the idea that it is both laudable and morally just to use human tissue for the purposes of medical research or medical treatment. However in converting this premise into policy, and a body of practices to support such a policy, it must be recognised that other factors will come into play. So, first, the concepts of medical research and treatment must be qualified since not all such uses can be equally justified. Second, the idea that the starting premise also justifies the presumption of a *duty* to donate such tissues must be rejected, particularly in circumstances where human grief is a factor in acts of donation, or where there is significant uncertainty as to the end use of the tissue in question.

It is of course impossible to provide an exhaustive account of the contexts that are likely to influence the meaning and ethical significance of human tissue donation. However, much can be done to identify potentially significant differences of context as well as to scrutinise areas of practice which are likely to be more or less successful at factoring these differences into the procedures associated with human tissue acquisition. We recognise that this consultation will of necessity be broadly conceptual in nature, or limited to a consideration of the existing empirical data. We would however like to underline here the imperative need for ongoing empirical research within this important and rapidly evolving domain.

In the following response we have attempted to identify some of the factors relevant to the contexts in which human tissue is utilised. In many of these contexts it is factors other than the use of human tissue which makes them ethically complex, while in others it is the meaning and significance of human tissue donation which is the focus of the complexity.

Nature of human bodily material and first-in-human trials
Hum an bodily material

Questions
1. Are there any additional types of human bodily material that could raise ethical concerns?
Although this list captures the range of human tissue it does not draw attention to the possibility that what is meant by "tissue" can be very ambiguous and therefore may not be clearly understood by donors (or wider publics). The nature, quantity and volume of tissue can vary considerably (from urine, saliva, punctate biopsies to whole organs, brains, hearts, the foetus etc.). Coupled with the range of contexts in which people are approached to donate tissue then, tissue that is routine to bioscience and medicine may have a very different meaning for the person who is approached to donate. So it is not tissue type that matters so much as the meaning, value and moral salience of the act and context of donation. There is a significant difference between donation of tissue to research and the donation of tissue for clinical use. Within the latter context there are further significant differences between for example giving blood as an anonymous donor to the National Blood Transfusion Service and acting as a living donor. There is also additional complexity when donation takes place within the family. There is often a presumption that family members will as a matter of course come forward as donors. For example in the context of bone marrow (or blood stem cell) transplantation it is routine to HLA (tissue type) family members without affording the same level of confidentiality or freedom in which to consider their decision as that given to unrelated volunteers . In some admittedly rare cases, this presumption is extended to family members who lack the capacity to consent, including adult siblings, or children, or infants born following IVF and PGD (so-called "saviour siblings"). The presumption of familial duty may be a good one but there is a question of whether the notion has been sufficiently examined to justify the implication that this is indeed the same duty in operation in these and similar contexts.
This list also does not really address the issue of "whole body lending" that is raised in the context of involvement in clinical trials and other studies. In our view there are very different issues involved for the participant of a clinical trial. We will raise further points about this in the relevant section.

2. Should any particular type(s) of human bodily material be singled out as 'special' in some way?
In the light of the above comment no tissue is special *per se* but clearly any human tissue may have significance beyond its status as "waste", "spare", or "surplus" tissue. It is imperative that those scientists and clinicians engaging with the development of ethically robust policies and practices for using human tissues in research are aware of the multiple meanings that such tissue may have. It is also necessary that researchers address the issue of how they refer to human tissue, aiming for accuracy of detail and using terms that are not emotive, do not imply a value (or dis-value such as "waste" "spare" etc.)

It is equally important that the terms used to describe the act of donation are also scrutinised. It has become commonplace to apply the concept and language of the gift-relationship in the context of tissue donation. For example the MRC and NRES refer to acceptable phrases such as "gifting my tissue" as appropriate for consent forms. We suggest that appealing to the concept of a gift adds another complexity to the meaning, and implied moral nature, of the act of donation.

As an alternative we would suggest that “donation” or “unconditional donation” is less ambiguous and more appropriate since they do not appeal to a complex social convention such as gift giving. However we accept there is scope for empirical research on this issue.
An area in which the “gifting” concept is problematic arises from the fact that, in England and Wales, proxy consent for incapacitated adults is now possible. In our view it makes no sense to talk of gifting by proxy although this concept has crept into practice, probably because of a failure to amend the standard forms used in the consent process.

3. Are there significant differences between providing human bodily material during life and after death?
With a live donor there is the opportunity for those seeking permission to respond to the particular information and other needs of the donor. The opportunity to change one’s mind and withdraw from a study usually remains open. Also the possibility of gaining some direct or indirect benefit is open to the live donor and this may be significant to the context in which donation is requested.
The dead have no contemporaneous control over their tissues but may have stipulated conditions for the use of their tissues via an advance directive. We would advise researchers to take all reasonable steps to make themselves aware of any advance directives regarding the use of tissues after death. In addition, researchers should, as far as is practicable, ensure that the use of tissue is compatible with the wishes of the donor but keep in mind that although it may be legally permissible it could be morally wrong to go against the wishes of the deceased’s close family if they raise objections. It is possible that the use of tissue from the dead may raise issues which could be regarded as a form of harm to the deceased (for example, issues related to privacy, confidentiality and reputation).

Participation in first-in-human trials
Question
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?
This is far too general a question to give a meaningful response. As we suggest above the issue of human subject research merits its own, particular consideration.

2. Purposes of providing bodily material/volunteering in a trial

All of the possible uses listed may be considered ethical depending on circumstances. It seems reasonable to draw a distinction between donations of tissue for direct clinical application and the donation of tissue to research. Conditional donation for clinical application may not be ethical when the terms of the donation are themselves open to moral challenge, for example when the conditionality is based upon unjustified discrimination such as race or some other morally irrelevant criterion. Different issues are raised in the research context where tissues may be used for very diverse purposes from basic science, to non-medical applications. The use of tissue in *research* may mean that the donation is a long way from producing an application of direct benefit to anyone and it is important that donors are well informed of the immediate use to which their donation will be put. Donors ought to be made aware of the potential for commercial

application of their tissue, including information concerning the nature of its use, who will benefit, and the magnitude of such benefit.

Questions

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

In addition, it should be recognised that people with particular diseases , and members of their families, will often be motivated by a number of issues related to having their experience of the disease, not least their need to have an effective therapy. This is sufficient incentive. The reasons patients and their family have for taking part in trials may be fundamentally different from those of healthy volunteers.

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

There are wide individual differences likely to influence a decision to donate human tissue. The key prerequisite is that people are adequately informed, which entails that researchers (or those approaching the donor) use adequate means to inform the donor of the specific and possible uses of their tissue. In some cases the tissue may be exhausted in a single application but in other circumstances there may be residual tissue or products such as cell-lines which may raise ethical issues for the donor.

Donors should be informed when their tissue is to be used in (for example):

- Animal experiments
- Commercial applications
- Non-medical applications (e.g. cosmetics)
- Research that might touch on specific religious sensitivities, e.g. embryos

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?*

The level of risk ought to be a factor when considering whether it is justified to use healthy volunteers. Research that is unrelated to human medical benefit must be minimally invasive and of no material risk.

3. Ethical values at stake

Questions

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

All of the listed values have relevance and draw upon standard ethical values. None of them stand or fall alone outside of the context in which they are operationalised. In addition many of the concepts are open to interpretation. We would also draw attention to the concept of duty of care which emphasises the responsibility of researchers, doctors, regulatory authorities to take measures to protect the safety, welfare and interests of those made vulnerable by the circumstances in which they are approached to be donors. There is therefore something like a justified form of paternalism which it would be very useful to explore in the context of this consultation.

10. How should these values be prioritised, or balanced against each other? Is there one value that should always take precedence over the others?
No response.
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?
The idea of volunteering is widely considered to be morally laudable, but perhaps this perspective is peculiar to this time and culture. It is not obvious that being compensated in some way for doing a "good" thing negates the good. However one of the serious issues associated with payment and other forms of compensation is the kind of influence the payment will have on the freedom of choice of the decision-maker. There is an opportunity here for some serious empirical and conceptual research on the concept of free and informed consent in the context of donating tissues.

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?

The idea that there is a moral duty to donate has significant purchase in particular contexts such as the NHS blood transfusion service. However the very notion of a moral duty needs more deconstruction. Can a moral duty be enforced for example?

4. Responding to demand

Supply and demand

There is constant pressure within the UK to meet the demand for some types of human bodily material. Demand significantly exceeds supply both for whole *organs* for transplantation and for *gametes/embryos* for infertility treatment and research; the gap between supply and demand is particularly acute for those of non-white ethnic origin. Supplies of *blood* are under constant pressure, and while supplies of *tissue* for research and treatment are usually adequate, short-term shortages of particular forms of tissue for treatment can arise in emergencies. Commercial researchers may also at times experience difficulties in accessing material donated within the public sector. Transplant and fertility *'tourism'*, where patients go to other countries where organs and gametes are more readily available to them, is widely reported. Some form of payment is generally assumed to be necessary in order to recruit the requisite number of volunteers to participate in first-in-human trials.

Question

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

The term 'tourism' is a problematic term when used to refer to the strategy of seeking treatment abroad. Commentators frequently express disapproval when talking about seeking fertility treatment in this way. This attitude seems to be based on a number of convictions: "a belief in moral truth, a desire to ensure that others observe our standards, the belief that ethical rules apply to everyone, everywhere" (Pennings, 2004: 2691). Referring to fertility travel as 'tourism' implies such criticisms Would-be parents are often uncomfortable with the way that the treatment is represented in the public domain, as any association of infertility treatment with a holiday package may seem to undermine the severity of the treatment they have received and the seriousness of their intentions. There are a number of related considerations: First, terms such as 'reproductive tourism' or 'fertility holiday' suggest that there is something pleasant about getting treatment abroad. It implies something 'frivolous'. In contrast, many would-be parents describe infertility treatment as physically and emotionally 'painful'. Second, 'tourism' is usually a leisure activity which is 'voluntary'. The voluntary side of tourism might not fit into would-be parents' presentation of their infertility. Many would-be parents tend to describe their condition as an 'illness' which requires an emotionally and physically exhausting treatment. They claim that fertility treatment is a need, not a treat: they did not 'choose' to get treatment; rather their body failed them in a manner beyond their control. Third, would-be parents do not want to be associated with tourists of morally questionable markets. Similar terms – like 'organ tourism ', 'poverty tourism and 'sex tourism' have negative connotations. These terms imply the exploitation of the labour and resources of the poor. In short, usage of the term 'tourism' gets a negative reaction from the would-be parents and compounds stigma therefore it would be more appropriate to refer to the phenomena using more morally neutral terms such as "cross-national fertility travel".

There are a number of issues that fertility patients in the UK suffer from. The donor shortage is one of them. Long waiting lists, removal of donor anonymity (for those who have confidentiality concerns) and the lack of donors with matching characteristics (an issue for the ethnic minorities,

in particular) are also the reasons behind the cross-national fertility travel. Some would-be parents express the view that, regardless of whether they intend to tell the resultant child about his/her origins, being open with the donor-conceived child is a matter of family privacy that should not be dictated by the state. Some feel that openness is imposed on them and they find this stigmatising and discriminating. The choice of language to describe this travel is also evidence of the stigma that the would-be parents have to deal with. These would-be parents did not press claims against these restrictions partly because it is relatively easy to travel from countries with restrictive policies to places where the desired services could be obtained, and partly because confidentiality matters to them. In other words, cross-national fertility treatment is not an issue that can be explained by meeting the demand and need. Would-be parents face an inappropriate kind of moral absolutism while they are exercising their right to seek treatment abroad.

5. The role of consent
Questions
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?

Clearly there are, but it is impossible to draw up a definitive list. Starting from the intuition that outright bribery, such as coercive payments or preferential access to clinical services, is wrong one can begin to focus on the factors that are likely to make a particular approach wrong such as undue influence, emotional pressure, high rewards likely to influence awareness and risk-benefit evaluation, and so on.

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 complex area in need of empirical research. Some commentators have argued that impersonal or justice based ethics should not apply in the family context yet there are still important ethical issues within the family context. The intuitions about what is right within the family context ought to be subject to critical scrutiny.

Consent for future unknown ('secondary') uses of bodily material

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?

In short yes; the Human Tissue Act sets out the legal basis for this approach. However it must always be open for regulators and ethics committees to challenge such decisions when such tissue is likely to be used in controversial areas of research (e.g. human-animal hybrid embryo research). In these circumstances the possibility of prospective tissue collection under conditions of informed consent must be explored.

Role of families: living donation
Question
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?
Refer to earlier comments.

Role of families: donation after death
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?

Refer to comments in our earlier response.

6. Ownership and control
Property rights
Questions

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

As the Consultation document notes, there is no legal tradition of ownership or the holding of property rights in a human body. Philosophical writers in this area generally trace this back to a putative fundamental distinction between persons and objects – the idea that objects can be owned, bought, sold, donated and so on in a way that persons cannot be. This is in accord with the strong cultural intuition, at least in the post-Enlightenment global North, that persons are (in)valuable in themselves.
(Other very strong cultural values are associated with bodies, parts of bodies, the persistence of bodies over time and through generations, and the meaning of dead bodies.)

New biotechnologies not only permit disaggregation of the body into parts of more or less utility, but also introduce new properties such as the potential disruption of conventional temporal patterns or family structures via the cryopreservation of body parts and tissues. By offering new possibilities for living and dead bodies, and putting old possibilities into novel contexts, these new biotechnologies challenge long established social, cultural and legal understandings of what it is permissible to do with and to one's own body, and also the bodies over which one has control – a key example here being the dead body.

We consider that the legal framework of having a "right to disposition" is more appropriate for a dead human body and its parts than a right of ownership. Where there is a family, it again seems most consistent with cultural and legal traditions that it should be relatives of the dead person who have the right to make decisions about what happens to the body and/or organs and tissues, and that this should be informed by their knowledge of the person's wishes when they were alive. There are precedents for placing limits on the relatives' right to disposition, and there is an extensive literature here, especially in the area of donation of organs or use of (stored) reproductive tissue, which it would not be useful to repeat here. We would argue that a simple ethical and legal framework based on the notion of ownership is not appropriate for human bodies or body parts.

We also want to point out that there is a further area that the consultation document does not cover, which is the use (in research rather than medical treatment) of historical human remains. While these often come under a coronial authority, at least initially, recent cases in which DNA profiling has been used to identify historical remains suggests that there will be many more cases in future where bodies are excavated and their family members could potentially be identified, and might wish to claim a right to disposition, to an extent that has not been possible before.

Question 27: Should the laws in the UK permit a person to sell their bodily material for all or any purpose?

Again, it is almost impossible to make a general statement that covers all possible tissues and purposes, let alone the social and political contextual factors (e.g. gender, class etc.) that may influence whether a practice is ethical or not. Both the social meaning and the practical consequences of selling blood are different from selling reproductive tissues, and different again from being paid for taking part in research trials. It seems to us that recent trends in regulation in the UK have been towards allowing de facto payment in the form of donation with payment of "reasonable expenses" or "in kind" as in the Newcastle egg sharing scheme.

In a study on embryo donation that one of us (JLS) led in Switzerland 2005-2008, while the majority of donors were happy with the absence of payment, a minority saw this as unfair, given that – as they saw it – the researchers would be benefiting and probably profiting from the use of the material they were donating. These participants articulated a sense of wanting payment not for the embryo being donated in itself, but for the labour that they had undertaken in producing it – even though that labour was originally to satisfy their own desires, i.e. for pregnancy. This is in line with the Lockean idea of "property in the body" which Donna Dickenson writes about.

Question 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?

This question returns us to the status of the donated material/bodies, since the right to compensation in this way does seem to depend on the donor/volunteer owning the tissue or labour. We would therefore want to separate tissue donation from volunteering here. *If* it is reasonable to consider what volunteers do in a trial as work, or a service provided, then it seems fair that they should be compensated for that work (and not just expenses covered). We think it is reasonable to consider it like this, because participation in a trial entails an enduring act of agency on the part of the volunteer throughout the process, unlike the donation of material, where after the act of donation the donor does not have to (may not want to) exercise agency at all.

It seems fair that companies who do benefit commercially should be required to share their profits in some way. However, we would be reluctant to see direct payment to individual donors here, since that would seem to reinforce the idea of a straightforward "ownership" of body parts which we have already indicated is oversimplified. One alternative here would be a more generalized repayment, e.g. through a community fund, which would acknowledge the donation in a way that places it within a framework of social solidarity rather than the individual market.

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.

Considerations here again depend very much on the nature of the material being provided. Historically, the presumption behind donation of e.g. blood or organs for clinical purposes has been that of an unrestricted gift: they are seen as lifesaving and so any restriction *by the donor* on who can receive them as effectively allowing the donor's presumptions/prejudices to determine who lives. At the other end of the spectrum, gamete donation for reproductive purposes is seen as lifestyle rather than lifesaving, and in many cases strongly connected with personal or cultural identity, and here there seems more tolerance for the idea that donors can exert some constraints over who receives their gametes. In between these two extremes we note the extensive discussion of recent years around consent to future use of materials stored in tissue or DNA biobanks, where there is considerable variation from case to case in the amount of control offered to donors, bearing in mind that for the researcher by far the least onerous option is for the donor to relinquish all control. However, we would argue that here the most ethical approach is still to offer donors the option of defining uses to which they would not consent, while including the option of relinquishing control to researchers.