

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

CONSULTATION PAPER

Questions

...and answers

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

No.

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

Yes, material with reproductive potential (sperm, oocytes, embryos) may be considered "special", in the sense that they do not involve just the donor and the recipient, but another person (the child), yet unborn and unable to express an informed opinion about the donation.

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

No, as long as the health of the donor is not affected.

4. What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them) of providing bodily material? Please distinguish between different kinds of bodily material if appropriate.

Blood: no cost, no risk, obvious benefit to the recipient.

Reproductive cells: no cost (the recipient pays the cost), almost no risk (except oocyte donation, which involves treatment with hormones, anaesthesia, and puncture for egg collection), the main benefit (commercialisation being ruled out) is moral satisfaction of the donor, who has helped create a family.

Stem cells (cord blood): no cost, no risk, potentially huge benefit, if the cells are deposited in a public institution, capable of international co-operation, which would lead to priority treatment in case transplantation is needed. Huge cost, big risk and almost no benefits, if the cells are deposited in private cord blood banks, generally not designed for co-operation, therefore incapable of providing the right graft (autologous transplantation being almost always ruled out because of genetic disorders); also, "cures" for non-genetic disorders are quite poorly documented so far, as we do not know the long-term behaviour of the cells.

Post-mortem donations: no cost to the donor/relatives, no risk (although sometimes the relatives having to decide are subject to intense psychological stress), life-saving/prolonging/enhancing benefit for the recipient inducing a serious amount of moral satisfaction for the relatives of the deceased, often leading to a better acceptance of their loss.

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?

There may be a cost and a risk if the medicine tested proves to be toxic.

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

Can't think of any.

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

Yes. Prioritising would be: life-saving first, then life-prolonging, then life-enhancing, then life-creating (although, for life-creating donation I would also seek approval from my wife and mother of our child).

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?

Yes. Theoretically, I would volunteer more easily for a "benign" medicine (e.g. an oral antiseptic/mouth wash) than for some "interesting-but-potentially-dangerous" one (e.g. an Alzheimer's-preventing drug, or a "world-saving atheroma killer"). Practically, I would not readily participate in first-in-human trials (I have a young son and I am not willing to take any unnecessary risks until he is able to provide for his life). However, if I were already condemned to die (for instance, with advanced untreatable cancer), I think I would participate in any first-in-human trial, exactly for the same above reason, i.e. the possibility of saving myself and being able to provide (again) for my child.

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

No.

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

I think altruism should be the absolute priority; I also think no donation should ever lead to payment, or to any form of compensation (this applies even more specifically to reproductive cells). By the same token, I believe that, for solidarity reasons, societies and not individuals should support the full burden of the medical cost for all donations (as they do –theoretically– for blood transfusion or kidney transplantation). If this was the rule, all the other main ethical values would be covered (dignity, justice...). In accordance with the above, reciprocity is an opportunistic "value" that should be banned: what if I have nothing to "give" and need to "take"? For instance, would we ever dare put an infertile woman in a situation where she would trade a kidney for eggs? If no, why do we put her every day in the "egg sharing" situation, where she trades her eggs for a rebate on IVF costs?

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, I believe that the "right" way to go, morally, is to have all volunteering done by non-paid (non-compensated) volunteers. There should be no distinction/difference whatsoever. If a volunteer decides to "give", whatever that may mean, they should not expect anything in return.

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?

No.

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?

No.

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

Yes, it is legitimate to try to meet demand. Obviously, demand for life-saving donations (e.g. blood) are more pressing than life-creating donations (one can live childless, but not blood-less..., and existing life is more precious than life-to-be).

"Fertility tourism" is not a medical issue, but purely a political one; therefore, it should not come into consideration here. The European countries should try to come to a "normalized" consensus on egg, sperm and embryo donations, as they have been doing for much less important issues ranging from normalization of electric appliances to airplane specifications. If 200 million people can agree to use 220-250 V electricity, one can also expect them to seek agreement on standards for infertility treatment. I'm not saying it is easy; I'm saying it is a goal. By the way, the EU Tissue Directives have been a huge first step in that process! They may have been incomplete, ignorant of the reality in assisted reproduction laboratories, etc, etc, but nevertheless a very important step forward. The European Union can build on such initiatives, in its effort to homogenise practices throughout Europe.

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?

No. I believe all this should be free, and we (as an organised society) should spend time, energy and money educating our people to donate bodily material for the common good, without expecting any compensation. Life itself is a gift of Nature (many would call it a gift from "God"), it is not a "right" per se. Recognition/moral incentive (such as a honorary certificate for blood donors, for example, or inclusion in public memorials), with no financial profit, should be more than enough for any modern, educated, civilized European citizen (that is, if we want to abide by our long-standing democratic values; but then again, this is politics, not medicine!).

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?

No, under the condition specified above ("non-for-profit" donations). If this is the case, there should be no incentive "offered" by anyone; instead, there should be promotion of the altruistic donations, and, in this sense, there would be no difference between "private" or "official" promotion efforts.

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

Yes, the one that would offer payment/compensation/reward other than recognition (as above), because I believe that bodily material of any kind is (and should be universally considered) "*res extra commercium*".

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

No. Compensation is compensation, anyway you look at it!

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?

Yes, of course, put this way. However, as we do not usually “compensate” blood donors for spending 30 minutes of their time (well, we can offer them orange juice and a sandwich, but this is only to help them “recover” from the donation), I don’t see any reason to “compensate” a semen donor, who spends less than 10 minutes of his time in the collection room (under not extremely uncomfortable conditions, one could say...) and doesn’t even need a sandwich to “recover”! In the same way, if we do not “compensate” blood donors undergoing thrombocytapheresis, we may not “compensate” an egg donor in natural-cycle IVF for one hour of her time needed for a single egg collection.

Let me clarify this point further: the idea is that, according to the “long tail” principle, it may be effective to collect single eggs in natural cycles from multiple donors, as opposed to collecting multiple eggs from a single donor in a stimulated cycle. Such a procedure would be more tedious and time-consuming for the lab, but it would not subject the donor to full-scale hormone therapy, and it would minimise anaesthesia-related risks; overall, if promoted properly, it may prove easier for us health professionals to recruit donors, because we’d “ask for less” each time! (Obviously, this idea would need to be verified by adequate scientific research.) On the contrary, assuming that the private clinic where the eggs are going to be donated will charge the recipients for a full IVF treatment, plus donor fees, plus profit, paying a poor student 2.000 Euros and boosting her body to produce 30 eggs during a stimulated cycle is not very different than prostitution, to my sense; it is using the body of a young female for profit. I am becoming a bit provocative on purpose here; all I want to say is that it is not forbidden to “re-think” reproductive donations. Having applied the compensation scheme for 30 years doesn’t necessarily mean that this scheme is the best one, on ethical grounds.

One more thought on compensation: paying part of the funeral fees, for instance, as an incentive for people to donate bodily material of their dying relative sounds like coercion, almost like blackmail; the family would bury their dead anyway, wouldn’t they? Offering compensation is offering a “rebate”. Sorry, if I am losing a dear parent, or a child, for that matter, please allow me at least the dignity of paying for their funeral... Please allow me the dignity and moral satisfaction of offering those organs to save lives, don’t offer me just a “cheaper” box to put that dead body in...

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?

Yes, a different policy on egg donation has been discussed above (see my answer to question 19). Evolution of assisted reproductive technology allows now to work in natural cycles with acceptable success rates. As research progresses, especially in the stem cell/regenerative medicine field, which is extremely promising, we may soon be able to reduce the demand for some donated tissues. First-in-human tests shall always need human volunteers, but again, research on pathogenesis may lead to a better understanding of disease, therefore to a better design of pharmaceutical tools, ultimately reducing the need for clinical trials. Effectiveness depends on the time, effort and money put into targeted research. From there, we go back to politics, as politicians are those who decide on funding of main research directions...

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?

No, provided that that person has the right to withdraw his/her consent anytime.

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

By education: we need to raise our collective level of social consciousness and solidarity, both within families and within larger societal groups at the local, national and international level; this can only be achieved through carefully planned and targeted education.

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

Yes. Imagine a scenario with a possible donor, who is clinically dead, in ICU, and who has no relatives able to decide to donate the organs. In any case, the decision should not be left to one person only; an ad hoc “emergency ethics committee” may convene and decide to use the organs. One may imagine any other scenario in extreme situations (battlefield, shipwreck...), where the emergency use of bodily material from one dying human may save another human.

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?

Theoretically yes, because each individual is an individual. But in a practical situation where a decision must be made, and provided that the risk to the donor-to-be is minimal, I think there is no difference. This, however, should not apply to reproductive cells, as procreation is an active process and is subject to the will of the procreator (no-one should become a parent if they do not specifically choose to).

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?

In (a), no-one should have any right of veto over the known wish of a person (obviously under “normal” conditions, i.e. where this wish has been expressed while the donor-to-be is in an “acceptable” state of physical and mental health, under no coercive conditions etc..., for example by a written will).

In (b), the family should decide, and health professionals should be prepared to help them reach a sound decision. Mechanisms should be put in place to properly inform and counsel the family, so that their decision to donate becomes accepted. Of course, this is not clear-cut in practice, as “important” family members (such as the spouse of the deceased) may disagree on emotional grounds, whereas all the rest of the family agrees. In those cases, I believe health professionals should seek consensus and should double their efforts to help the family reach consensus (not necessarily leading to donation; this would be coercing the disagreeing family member).

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

To no-body. We only “belong” to the Universe; we are only tenants of the atoms from which the molecules of our bodies are built, and this just for an infinitely small fraction of absolute time. Securing property “rights” of any sort to anything other than a person’s own intellectual production, while living, is simply absurd (our intellectual production being the only thing susceptible to survive us). Even under cloning conditions, a reproduced clone of a person’s body would never be a copied version of that person’s personality, because the exact environmental conditions that led to the development of the “donor” cannot be reproduced for the clone’s upbringing.

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

Not being a UK national, I would not express an opinion on what UK law should allow. Being a European citizen, however, allows me to express an opinion on what European laws should allow. My opinion is that no sales of any human body part and for any reason should ever be allowed. If we allow this, we might as well authorize cannibalism again, as there would be no substantial barrier preventing us from opening butcheries for human meat; selling is selling!

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?

No profit should be shared with donors. A percentage of the gains (to my humble opinion, at least 50%) should be routed to the public health systems, to be used for research on the betterment of public health.

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.

There should be no property rights for bodily material whatsoever. This means that neither the donor, nor the health professionals should have "rights" on the donated material. Donation is (i.e. "should be") an altruistic act, with a specific meaning: "I am consciously giving away some part of my body which is of no use to me, so that some other human may benefit from it, either to save, or prolong, or enhance their life". Any control exerted on the donated material should be exerted in order to validate the above, namely that no profit should be made of the donation, and that the material donated is indeed used to save, prolong, or enhance another human life. Anything else is just commerce, let's admit it, and ban it once and for all; the world will be a better place if we do so, there are plenty of other fields available for commerce!

Once again, reproductive material constitutes its own category. The person providing the material must be aware of the intended use, and must have the right to specify the possible use, or uses, whether fresh or cryopreserved tissues and cells are concerned (this is actually an inherent part of all legislation on assisted reproduction, throughout Europe). There is moral value, for instance, in the French practice of semen donation, where the donors must be parents, and their wife/mother of their children must also give her consent: semen donation is therefore a "family-to-family" donation. This is much closer to the fundamental principles of donation, such as social solidarity and altruism, than the commercial system applied in the USA, for instance, where semen is practically just another industrial product, being advertised on the internet, sold by mail, and sold only for profit. There is obviously no moral value in selling toothpaste, or frying pans, or shoes, through the web. Commercialising our body parts just as if they were toothpaste, frying pans, or shoes, is not exactly my way of understanding human dignity. In this sense, yes, there should be a control of the material by the person donating it, but not in the "perverted" way of controlling the profits from its sales...

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

No.