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Q1.

There is a potential framing issue here: there seems to be an assumption that whole dead bodies might be used in ways that raise ethical concerns, but whole living bodies are not necessarily viewed in the same way. There are ways in which whole living bodies are used that can also raise ethical considerations, including in the education and training of medical and other healthcare professional students and first-in-human studies. Also surrogacy might be anomalous here as the bodily materials could involve the 'loan' of one's body for the purposes of the surrogacy arrangement and/or the provision of a baby at the conclusion of that process.

Q2.

There is a conceptual point here regarding the cultural significance that may mark out some bodily materials as 'special' but not others. These constructions may of course vary over time and in different contexts; for example, the Isaacs Report (on the retention of Mr Isaacs' brain for research purposes without his family's consent) and the Nuffield Council's Report on *Human Tissue: Ethical and Legal Issues* published in 1995 on the treatment of 'waste' products without further consent. Also, face transplants, brains vs. hearts – there is the possibility that some materials gain more significance than others at particular junctures or for particular people, but this does not seem to be fixed.

This is exemplified by fairly recent shifts in regulation and practice. Until September 2006, the widespread practice, since Victorian times, of the collection and storage of 'abandoned', 'waste' or 'worthless' bits of human bodies for education, display or possible scientific research, was possible without transgression of the Common Law or latterly, the human tissue legislation. This view of excised tissue as 'abandoned' was echoed by the Nuffield Council's report in 1995, recommending that, where tissue was removed during a procedure for which a patient had given their consent, the tissue should be regarded as 'abandoned' by the person from whom it had been removed. However, the Council's premise that citizens saw no value in their abandoned body parts began to look outdated, particularly in the context of the evolving biotechnology industry, and its requirement for discarded human tissue. For example, the disquiet caused following the disclosure that thymus glands excised during paediatric cardiac surgery were being sold to pharmaceutical companies, albeit with the parents' consent for the tissue to be retained for research, and more latterly the 'organ retention scandals' that eventually caused the legislation to be changed.

There is clearly potential for a clash of values between the views of patient/donors and their communities vs. those of researchers and doctors; any system to be

adopted must therefore be able to accommodate potentially differential value systems across these standpoints.
For example, within the HEAL group we discussed the possible issues raised by 'identifiable' body parts (including gametes and genetic information), noting that the identities at stake are not simply those of the donor alone, but also raise potential issues for the wider family and/or kinship construction. There are also future issues raised by gametes and genetic information which raises concerns about segmented consent models. There needs to be general limits as a society, e.g. an accepted definition of death for cadaver donation, in order to limit the possibility of undermining public confidence in the system that is adopted. Also, we noted the use of dead bodies for research and education purposes in other jurisdictions, including Thailand, where a teacher analogy is adopted – the body is the student's teacher and is treated accordingly with respect and dignity, including full ceremonial burials after use (also noted similar practices in the UK, but perhaps without the teacher analogy being overtly used).

Some members of HEAL were also concerned that the question was posed as 'should'; this rather denies the fact that some types of bodily material simply are different. These differences in how bodily material is known and valued is formed through a two-way intra-active process between the different situated perceptions of people and the different capacities of different bodily materials that these people respond to. The consenting processes can account for these differences in perception, but could perhaps also recognise how the capacities of different human bodily materials have supported the generation of the beliefs and values attached to them in various ways. Appreciating this may lead to more nuanced consenting procedures.

Q3.
During one's life it is possible to change one's mind about consent, whereas following death the consent appears to be 'fixed', either by the deceased or by a proxy decision-maker. However, in practice there is a more complex system than this question suggests – see further the questions on consent.

A further viewpoint expressed is that providing human bodily material during life is an anticipatory practice, a gift-giving of hope that some good will come from it from the owner to the potential beneficiary. After death, providing human bodily material is about memorialisation of the deceased through the use of their body in various ways. Recognising these two different stand-points – one of anticipation and one of memorialising - could help frame regulation of human bodily material during life and after death.

Q4.
We discussed the relevance of this question to the consultation, as it seemed to be very broad and provided little direction. In turn our question would therefore be, is

this a question about consent? If so, it raises questions of whether there is a single model or a more subjective one to utilise in particular situations? It would seem that there are certain risks that people are not entitled to run even if they want to do so (e.g. 'suicidal' donations), therefore there is some regulation of risks and costs. Operations for patients with body dysmorphia were also discussed as an example of where difficulties in line-drawing might arise. There was also some discussion about clashes of value systems between individuals and professionals in relation to donation and within that how public confidence might be maintained.

Further, the issue is not just the kind of bodily material, but the context in which it was/is collected and what other kinds of data are collected alongside it. Was it collected originally as part of treatment/healthcare (e.g. newborn blood-spot cards) or as a resource for a specific research project? What other data is/was collected alongside it? (Biological samples are usually only valuable for research if they have particular kinds of personal information attached to them about an individual's health, lifestyle, family history). The context (biobank or collection) into which it is put/stored also matters. For example, is the sample contributing to a database that claims to represent a population? Does participating in a project serve to associate the donor with a particular population or agenda?

Q5.
See answer to Q9.

Q6.
This section seemed to raise some really interesting issues regarding direction in donation although these did not seem to be the primary focus of the questions that followed. We did discuss the direction issue at length and the following issues were raised: the use of language and conceptualisation of directed/undirected donation; the differences between conditional and restricted donation; potential borderline cases and other uses. However, it should be noted that there were differences of view within the group and the following does not represent the views of all who were present.

The language here is misleading. This relates to the usage of information/knowledge derived from the combination of the donation and the contribution of others. Therefore, direction from the donor has the effect of compromising the autonomy of the others who contribute (for example, the surgeons or researchers – the mutuality between the individual donor and these persons/groups is downplayed here). Contract may be a better metaphor, reflecting that neither can achieve their goals without the other, but both can by agreement limit usage to that which they are prepared to contribute. But, note i) society can also limit the usage, for example, unfair contract terms, anti-discrimination, illegal contracts, ii) the contracts can limit later changes in mind, iii) in contract remedies can be limited, e.g. damages vs. specific performance.

There is also a distinction between conditional donation and restricted donation, i.e. between the donor who wants to give to someone they know, who happens to be in need, vs. the altruistic donor who will give to whoever needs the bodily materials. Put differently, the motivation in a particular circumstance vs. that of a 'general' or unknown donor (presumably altruistic?).

Further, where there is an identifiable recipient (e.g. for one's child, sibling, family member, friend, or indeed in pooled donations) this is **directed** donation; whereas where the recipient is unidentified/unpooled there is no conditional aspect to the donation. This distinction is significant yet the drafting of the question does not reflect this difference. The drafting also does not capture those people who may wish to put conditions on 'undirected donations'.
As a group we were agreed that conditional undirected donations should **not** be permitted (e.g. on ground of race, religion, gender etc), while directed donations to family members and known recipients were more readily accepted.

Conditions excluding e.g. (active/drinking) alcoholics from receiving donated livers were regarded as potentially borderline cases, although there was some discussion of medical and/or societal forms of exerting influence, such that opposition to conditional undirected donations could be maintained in such scenarios. For example, the current practice of only excluding, for example, alcoholics on the basis of clinical outcome seems appropriate, as opposed to excluding them just because they are alcoholics.

In terms of other purposes that may raise ethical considerations, we would suggest the following: cosmetic use, art (e.g. Gunther von Hagens), education, use in commercial environments and operations prompted by body dysmorphia.

Q7.
No discussion/response.

Q8.
A range of issues were discussed including the use of clinical trials in developing countries for common Western diseases often unknown (or with very limited incidence) in the participating countries (see also Nuffield Council Report published in 2002). Questions are raised by the self-interest/motivation to participate in trials generally and specifically re the use in developing nations. Is it acceptable to set up trials in countries where the community 'under trial' will not benefit per se?

It is recognised that people's willingness to participate will be affected by the purpose of the medicine in question, and their decisions might depend on a range of motivations including:
- financial incentives;

- end of life (perhaps increased willingness to try experimental drugs that might help them and/or others where they have little to lose);
- views held against animal testing might prompt some to participate in human trials;
having family affected by the disease in question;
- and/or having family in countries generally affected by the condition (e.g. malaria);
- position as a researcher and willingness to contribute on that basis (although there is clear potential for exploitation here as in other 'groups' of participants).

Q9.
There was an extensive debate of this question. For some HEAL members notions of altruism and solidarity did not quite encapsulate some selfless acts, and therefore '**compassion**' was offered as an additional value. For example, if one had a friend or friends who had experienced infertility one might later be motivated by compassion for that person/those persons to donate gametes and/or act as a surrogate to another party, stemming directly from the insight gained by viewing the difficulties encountered by their friends. Neither solidarity nor altruism seems to capture that value fully, although others might argue differently depending on how wide an interpretation one ascribes to either or both terms. Certainly the construction of solidarity in the consultation document seemed very narrow.

Dignity: it was thought by some that this definition did highlight the intrinsic value of a human body, linked to the reasons for not attaching monetary value to bodies and body parts; however, in general it was thought that the definition provided here was a narrow, very market driven interpretation. This is not the only definition possible for the value of 'dignity'. There are cultural connotations too, and not just commerce-based ones. The definition provided here positioned the term contra to a commercial utilitarian reading of the body as holding monetary value.

Other values to be taken into consideration included '**protection and vulnerability**', e.g. for incapacitated adults and children, which was not mentioned here. Protection of people from **exploitation** was considered by the group to be very important and it was acknowledged that a person need not be vulnerable in order to be exploited.

Alturism: one concern expressed was that participants in biobanks often seem to assume that their participation will have a direct impact on their personal healthcare (even when explicitly told the opposite), especially if recruited through their GP or if data is collected in a clinical setting. The promotion of biobanks can often exacerbate this – people are sold a promise of innovations in research and new medical knowledge and treatments, if not for them then for future generations. This raises the question of whether biobanks may be making promises they cannot keep?

Justice: ***implications of the outsourcing of clinical trials to Eastern Europe and the Developing World. Given that in some places (especially the Global South) or for some diseases (cancer, HIV-AIDS) participation in clinical trials is the only way to access potentially life saving treatments, do people have right to participate in clinical trials? If so, how is this impacted by the ways in which volunteers are recruited and selected, especially as specific groups are excluded due to age, gender etc; how can we ensure all have the opportunity to benefit, and are not excluded by recruitment and consent procedures? This is especially an issue when it comes to commercial trials in the developing world. (Petryna, A. (2007) Clinical Trials Offshored: On Private Sector Science and public Health.*** **BioSocieties** ***2: 21-40).***

We might question whether there are some things that are just not acceptable? There was no clear view within the group. We discussed, for example, the possibility of 'suicidal donations' vs. saving a child walking in front of car. Whilst the end result in both cases may be identical (the death of the donor/rescuer), the latter seemed to many people to be more acceptable than the former, so is this about intention and motivation (assuming the rescuer is not also suicidal), or the ethical issues prompted by the involvement of third parties in operating on the 'suicidal donor'?

We also discussed issues raised by saviour siblings and the use of bone marrow and other tissue by older siblings – which is one of many examples that questions what is acceptable in society and the degrees of risk persons should be invited to take.

Q10

Although as a group we did not discuss this question in depth, views were expressed by some HEAL members that they would tend to favour autonomy as a value. Whilst all are important, maximising the autonomy of the donor would seem to enhance many of the other values. For instance, altruism can perhaps be more readily promoted if one is certain that the donor is acting autonomously.

However, not all HEAL members agreed. A contrasting view was also offered that suggested autonomy is a false goal, as our social practices and beliefs reflect cultural norms/influences and these shape how 'autonomy' is understood and recognised. Different cultures conceive their autonomy over their bodies differently in relation to the State at one end and in relation to 'natural' bodily processes of decay/wear and tear at the other. Additionally, using the language of the autonomous subject can lead also to the negative benefit of the subject, for example, mentally incapacitated subjects whose autonomy is either completely withdrawn or completely respected; whereas it can be argued that it needs to be

different positions on the spectrum. Mental incapacitation is a process not a binary switch on or off; further, it could be argued that the well-person is still not a rational, thinking subject for much of the time.

Q11

Although we did not discuss this question in our meeting, views were expressed in emails by some HEAL members that they would see no difference in providing bodily material or in volunteering for first in human trials, though it is acknowledged that there is a perceptible difference in donating so-called 'waste' bodily tissue, or tissues that regenerate.

Q12

There clearly CAN be a moral duty to provide human bodily material, but that does not mean necessarily that one has an obligation to do so. It is arguable that if one is prepared to accept donated materials then one has a moral duty to donate, but this can be problematic. For example, should one have a duty to donate like for like (e.g. blood for blood) or should the duty be based on the fact that one has received any donation? At present, many people who have received donations of blood are prevented from donating due to fears around variant CJD etc.

Q13

No response.

Q 14

Views were expressed that in the current system we should not always be trying to meet demand and that unless donation is expected there will always be a shortfall between supply and demand. Trying to meet demand is an ideal to strive towards, but raising expectations that demand can/will be met is unethical, it raises false hopes and can create unnecessary hardship/suffering.

Support was also expressed for using the concept of 'resource' rather than framing this in terms of demand – we have a 'demand' for expensive types of new medication yet have no problem deciding that we as a society cannot afford or do not prioritise given side-effects etc, and yet we will contemplate 'side-effects' to others such as having only one kidney/part of liver etc.

Further, whilst it might be right to try to meet 'demand' for renewable materials such as blood, the 'demand' for female egg donation is potentially limitless and some HEAL members expressed concern over this. In addition, the need for something as renewable/low risk/life saving as blood could be seen to be more pressing to society than the one-off case of a toddler who needs a bone marrow transplant to survive, yet the emotional pressure to donate may be far greater in the latter scenario.

Q15
Providing incentives is problematic in a number of ways. What kind of incentive could/should be offered? Who will be encouraged to 'donate' because an incentive is offered and will it be limited to those who are otherwise financially disadvantaged?

There is a need for companies/organisations utilising first-in-human trials to take responsibility to adequately remunerate and insure these trials given the risks and again possibility of exploitation (minimum wage is only attractive to the poorest in society, therefore it is not indicative of the value to society nor of the profits to pharmaceutical companies).

Q 16
No response

Q 17
No response

Q18
Yes, there does seem to be a difference. Perhaps direct compensation is more likely to persuade people to donate as it may be regarded as unfettered reward.

Q19
Yes, there is a difference, but only if the compensation is genuinely calculated to compensate and is only commensurate with losses incurred.

Q20
No response

Q21
In short, no. There are still choices to be made irrespective of the incentives offered, although concern was expressed over possible exploitation.

Q22.
This would be culturally sensitive. The focus should fall on the **process** of consent to be encapsulated in any relevant legislation/guidelines, e.g. need to ensure the donor has an independent opportunity to discuss issues alone with the doctor/medical or research team, or with an appropriate counsellor. There is an argument that for some conditions this process may need to start much earlier, e.g. at diagnosis, rather than when the condition becomes life threatening. The key point is to avoid exploitation and try to ensure genuine choices are made.

Q23.
Yes there are some circumstances where it is appropriate to do so, but not all possible examples would stand up to scrutiny.
This question raises property in the body issues, including what is the starting point here? If the starting point is that there should be no use without justification then no such use would be permissible, i.e. if any use is a breach of property rights. But if such use was not a breach of property rights (for example) then use would be permissible.
Such an approach would question, what is property?
Also, what was the original consent? (see Qs in section 6) What re the fundamental concepts that we are trying to apply? E.g. heel prick test – use of bodily material for other purposes might be construed as acceptable for some purposes/by some persons but opposed by others on the basis of invasion of privacy (Article 8).

Q24.
Yes. This is a key policy choice: how far you can/do link the proxy decision to the best interests of the person in question, c/f saviour siblings and subsequent donation of bone marrow.
This is a values question, see Q9 on exploitation and protection from harm raised there. Also analogy with research on children: current framing is 'not actively against the interests of the child' rather than (as formerly) being portrayed as being in the child's best interests to participate in a trial.

Q25.
Do families have an independent stake that society and/or the state should respect, or not? When wishes are not known you work with the family to get a reconstituted consent by proxy of what their wishes were/might have been. Is there public confidence in the system? There is the possibility of raising human rights issues (Art 8).
The cultural context is once again important. Further, other legal systems would, for example, recognise a closer connection between the family and the body, vesting ownership of the body to family members. However, in the UK see the HTA 2004 re hierarchisation of family members and the provision of consent – is this problematic? What of those without family, or of the appropriateness of defining 'family' in these ways?
Also differences of view of typification of the body: strict property law? Current Anglo-Welsh law does not recognise the body in this way hence the family can override the deceased's wishes. As such the current law is not necessarily adequate, but formulating simple and generally applicable rules is problematic.

Q 26.
The concept of ownership is complicated because of our cultural and legal understandings therefore to talk about ownership is problematic. However, in

general we felt that it would be helpful if ownership could be designated in some way.
Corpse: best protection is to say it does belong to someone/family; but which elements of ownership can be unlimited and which would we seek to circumscribe? Which instances of ownership would fall where?

Q27.
There was some debate on this issue and no single unified position within the group.

There is an argument that there is nothing intrinsically amoral about selling aspects of our body. Other jurisdictions deal with this differently, e.g. gametes overseas can be sold and purchased. The current system under Anglo-Welsh law privileges the procurers, the big companies, rather than the providers of bodily materials/parts/entire bodies (living or deceased).

It might be argued that to allow people to sell their body parts/materials may not be exploitative, but there was some disagreement on this point: what might in the abstract seem defensible may in practice lead to further exploitation of particular groups including vulnerable members of society. In addition to concern about the potential for exploitation a further worry might be that attaching a monetary value to the human body or to body parts undermines a belief that humans have an intrinsic worth that cannot or should not be reliant on any relative value.
The counter-argument would be that in permitting them to sell their bodily materials/parts that the balance of 'profiteering' might be shifted (at least slightly) away from the procurers in a way that the current system does not permit. This discussion also tied in with the demand and need debate: just because there is a need do we have to try to meet it?

There was considerable discussion of commodification of the body and the potential for exploitation again. Risks that might occur, e.g. prevention of sale vs. exploitation, see response to Q9. The group was split over whether sale should be included, there is an argument that 'sale' is already occurring but the 'donors' are not the ones necessarily benefiting.

Q28.
There should be an increase in compensation (and insurance for first-in-human trial participants?) for those concerned, why should this be linked to minimum wage?
There is a mutuality issue raised here. Currently the commercial companies give too little back and the donors take all the risk, therefore a fairer share is required.

Q29.
This raises the point about future generations and their potential interest in genetic information. i.e. what is in the donor's contemplation at the point of donation is

one thing, but there may be other family members who wish to have access to certain information in the future and a question of 'control' might arise in these circumstances

Genetic and biological material data can relate to communities as well as families. Be that an extended family, a community which has a particular susceptibility to a disease (e.g. Tay-Sachs in Ashkenazi Jewish communities) or a community formed around a disease or condition (e.g. Multiple Sclerosis Society). Patient groups in particular are likely to become increasingly important actors in the management and regulation of collections of biological material as well as the recruitment of volunteers for clinical trials. Could/does consent and the sharing of research benefits for research also operate at the level of communities?

How will new guidelines on the collection and use of biological data relate to the re-use of existing collections? Do we need to re-consent for using existing data? What about inadvertent DNA databases and biological collections such as Guthrie cards? (see also response to Q.23).