University of Leicester Medical School - group 13

Purpose of providing bodily material and volunteering in a trial

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

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

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?*

As a group of medical students we discussed the ethical issues raised by providing bodily material and volunteering in clinical trials. We discussed three main ideas; the purpose of donating bodily materials, prioritizing these purposes and the issues involved in first in human trials.

6. The purposes of donating bodily material and the ethical issues that arise

Bodily materials can be used in addition to life-saving, life-prolonging, life-enhancing and life-creating purposes. The main idea we considered was in the support of the education of individuals within the medical profession and the general public. This may involve the donation of one's body for dissection at a medical school or plasticising for an exhibition or live post mortem for the public. This raised a large number of ethical issues which differed between members of the group. We feel that major considerations would be in maintaining the patients' confidentiality and ensuring that the bodies were handled in a respectful manner. A key point we feel to be important is that an individual should have their body donated to specific institutions or organisations with explicit informed consent from the patient as well as providing a level of understanding and gaining consent from close family. Some members of the group also feel it is important for a donated body to be kept as a whole upon its fate after medical use such as cremation, such that all limbs and organs are kept with the body even if they have been dissected out and that this should be done within a finite period of time.

7. Providing bodily materials for some purposes over others

This idea was approached in two ways; donations during life and donations after death. There was a general consensus within the group that during life many individuals are willing to donate bodily materials that are labile or the body is easily able to replace such as blood or bone marrow. The donation of organs/tissues that cannot be replaced warrants a greater degree of consideration, where we agree that individuals are most likely to donate to their family, bodily materials that will have no serious consequence on their way of life such as a kidney or portions of the liver. Whether bodily materials are being donated to family or to help others registered under the health service's database, we believe that donations given during life are primarily intended to support individuals in need of these materials and that their use in research should only be allowed as a secondary outcome, should the material be unusable. At this point the donor should be informed of this intention to use their donation for research and consent obtained. We believe as well that the method in which bodily materials are obtained has an impact on whether or not one would be willing to donate. This means that individuals may be more hesitant with

regards to invasive procedures or procedures that require a longer and perhaps more difficult/uncomfortable period of recovery, where they would be less likely to donate.
During life sperm and eggs can also be donated and a person can specify where they want their gametes to go. Since 2005 when a child reaches 18 just as with adoption they have the right to find out their genetic parents even though they are not legally their parents. [1] Our group agrees with the donation of germline materials as well as the ethical practice that has been put in terms of the right to knowledge and ability to contact, a child born as a result has with regards to their genetic parents.

8. Taking part in human trials

As a group of medical students we appreciate the importance of clinical trials on humans. As stated by the Medicines and healthcare products regulatory agency 'medicine may work well in the laboratory, but a clinical trial will find out if it also works well in people and is safe to use'.[2]
However, within the group there was a lot of personal hesitation towards this idea, most of which stemmed from the fears of potential unwanted effects of the untested treatment. We feel that the point at which we would be willing to participate in trials would be if we ourselves would benefit from the introduction of the treatment, such as if suffering from a currently incurable illness for which there was possibly a new "wonder" drug. If this was not the case, we would still be willing to participate should the trial have a high public priority, based on the potential number of people that would benefit and the severity, spread and impact of the condition it was designed to treat. Drug trials often contain three phases and as a group we agreed that ourselves and individuals in general would be more willing to partake in phase two, where the drug is tried on patients who stand to potentially benefit from the treatment, rather than in phase one where it is tested on healthy individuals and can perhaps bring about ill effects.
In conclusion, as a collective we have discussed the ethical issues involved in the above scenarios. While the different values held by individuals stand to make each scenario complex and potentially controversial, in the end we feel that as a society we all believe in the common good. This is why these types of scenarios present themselves in the first place, to offer us new ways to serve the common good in our ever changing world where our morals have to adapt. However, it is the point at which one changes the basis for their views from utilitarianism to fundamental principles they hold which creates controversy and where common ground needs to be found and resolutions made in order to progress as a society.
(see next page)

Uses and Ownership rights of body material

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

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

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?

29. What degree of control should a person providing bodily material (either during life or after death) have over its future use?

26. 'Ownership' of bodily material

The general consensus within our group is that the body parts of a deceased person belong to no one. They should be passed into the care of the next of kin, in terms of the planning of a funeral or any other arrangements that where expressed in life. This is, we believe, unless a prior

agreement was made with the deceased to use their tissues for donation (either to help others or in education etc...). However, even if this is the case, although the organs are the property of the organisation to which they were left, this is a permanent ownership, and it may be morally/ethically wrong for these organs to be sold for financial gain or compensation sought if the tissues are stolen. These views are of course in line with the current legal standing: "Legal definition on the position of ownership of human tissue, is an issue which is deemed to not to be an asset. Thus human tissue cannot be subject to ownership." [3] Others would argue however, that the resources and techniques that go into preservation of these donated organs, must be protected by the law, as was the case in R v Kelly[4] – the court of Appeal held that parts of a corpse are capable of being property under section 4 of the theft Act 1968. Hardcastle[5] defines three property-creating events, which would then make human tissue capable of being owned. These events were 1) the application of adequate "work or skill" 2) the act of detachment itself 3) the detachment coupled with an intention to treat the detached material as property. If any of these acts are performed it is the opinion of some within our group that whoever detached or applied the "work or skill" to the bodily material should own it.

27. The selling of organs

Again, there is an overwhelming consensus in our group that the answer is no. The thought of monetary gain can be an overwhelming lure for people to sell tissues/organs, even when doing so can put their own life at risk. This is especially evident in the most vulnerable members of society. Allowing people to sell their organs would provide an easy way for someone (for example) to fuel their gambling habits, pay for their mortgage etc...It would also create a two-tiered healthcare system where the rich could afford to abuse their body with drugs/alcohol/cigarettes, safe in the knowledge they can afford to replace organs when necessary from those desperately poor members of society. This idea could be made even worse by the possibility of wealthy people picking and choosing an organ – almost auditioning potential donors. Furthermore, in societies/religions where certain decisions are not free and instead regulated by family members/spouses, people may be forced to part with specific organs in exchange for monetary gain. The GMC states that "consent to a donation must be given without undue influence of any kind" – monetary gain would clearly go against this directive.

On the flip side of this, many of us found the selling of gametes (as occurs in USA) less cut and dry. Many felt provided a donator could decide whether it is allowed to be used for the creation of life or simply for research (see discussion in question 28) that there is room for discussion about it as there are less life endangering outcomes from providing gametes and it's difficult to exploit.

28. Commercial gain of research companies arising from donations

Again as a group, we do not believe organisations should share the money gained with the people that took part in a research project (except to pay for expenses/time etc...). We see this as no different to donating tissues/organs for monetary gain (see our objections to this above). However, we do not believe a research company should make a profit from these donations either. Instead, we feel there is merit in discussing the possibility of using the money for future projects, and perhaps for advertising the great need for donor organs in this country, potentially saving lives in the future, and furthering the benefit of the donation. This is a view previously expressed by the Nuffield Council[6], who stated "it is not possible for tissue donors to claim ownership of patent rights. The donor has given the material as a gift, or they have volunteered in a trial altruistically, therefore they should not gain in doing so."

29. Organ/Tissue control with regards to donation

To answer this we have split tissues/organs into gametes and other organs/tissues. This is because we feel that as gametes have potential to create life, they should have a greater level of control given to the donator. E.g. people should be able to choose to provide gametes purely for research, to donate to people they know, or to the wider population, simply because of how personal the decision is and its potential to create progeny – they should not donate sperm for research and find themselves fathering a child. With any other organs (from living or deceased donors), any donator should have the decision to donate to a person they know (provided they are a perfect match and the person is already on the list waiting for the organ) or alternatively give to whoever is at the top of the waiting list. Stricter control levels may be discriminatory towards certain ethnic groups etc...This view was adopted by the Department of Health, 2000 - they announced that organs subject to a condition should not be accepted after a case of conditional donation. If this was permitted, it could lead to many more people conditionally donating and preventing those requiring donations from groups that are discriminated against from having treatment. Paired organ exchange between two parties has however occurred in the past, especially in America. We feel this has room for discussion, but we are still unsure as it appears to undermine the whole intention of having a waiting list for organ donation.

Citations
1. National gamete donation trust
2. Medicines and medical devices: what you need to know page 9 – MHRA – April 2008
3. Weisman J. Organs as assets. Isr Law Rev 1993; 27:610-23
4. R vs. Kelly 1999 QB 521
5. Hardcastle R. Law and the Human Body: Property Rights, Ownership and Control. Oxford, Hart Publishing, 2007.
6. UK Patents Act 1977, section 60(5)