Dr Muireann Quigley

Question 3

One facet of the Human Tissue Act 2004 is the fact that there is a disparity between the protection and control offered to the individual regarding the storage and use of their tissues while alive and that same individual once deceased. Schedule 1 of the Act stipulates the purposes for which appropriate consent is required. Here Parts 1 & 2 stipulate the purposes requiring consent from the deceased, whereas only Part 1 is applicable to the living. Therefore, those activities outlined in Part 2 (clinical audit, education or training relating to human health, performance assessment, public health monitoring, and quality assurance) can be carried out without 'appropriate consent' if the person is still living. It is clear that the Act tried to re-dress some of the deficiencies of the 1961 Human Tissue Act and, in the light of the organs retention scandal, one can see why there was a particular focus on the deceased. However, if there is to be a disparity in the protections offered to the living and deceased with regards to human biomaterials, it might seem that they would be the reverse of those laid down in the Act; that is, that the living be afforded more protections (and hence control) than the deceased. While third parties such as family members and society at large might retain an interest in an individual or their bodies and tissues post-mortem, the particular interests of that individual cease to exist upon death. If this is the case then it could be argued that an individual has more interests over their body and its tissues whilst living since they still have an immediate and continuing interest in controlling what happens to themselves and their tissues. Accordingly, in order to recognise this, this is where the weight of the law ought to lie. It might be that there is a good case to be made for the exemption of activities in Part 2 of the Schedule from any consent requirements. Such an argument might be made on public health grounds or on the basis that the activities circumscribed here are of some kind of general societal good. Nevertheless, it seems that if such an argument is to be made at all then it must apply to both the living and the dead; the merits of such an approach regarding the living and the deceased stand or fall together. Taken in the context of the retained organs inquiry, which this Act grew out of it is understandable why Parliament wanted to ensure that organs and tissues from deceased person by tightly regulated for these purposes. However, it is not so clear why tissue from the living is excluded from having the protections that this provision provides. The explanatory notes state that this is because the uses of tissue from the living for such purposes "are ones considered intrinsic to the proper conduct of a patient's treatment . . . or necessary for the public health of the nation" (Explanatory Notes, para. 13). If these activities are in the interests of public health then tissue samples from the deceased will have as much value in this respect (if not more, especially in cases where the aim is to shed light on the cause

of death). Furthermore, it is difficult to see how any of these activities have a bearing on the treatment of individual patients. The diagnostic benefit of using patients' tissues samples is something quite apart from the uses we are talking about here. If the Schedule 1 Part 2 uses are to be considered 'intrinsic' to treatment then it can only be in the sense that activities such as audit, education and training, and public health monitoring is of benefit to all patients. In which case there is again no discernible difference in the value of these activities whether using tissue from the living or the deceased.

Question 7

The answer to this question lies not in the research purposes that the material will be used for, but whether it is being used for commercial or other benefits. A mere perusal of the current and potential uses of human biomaterials is enough to highlight the fact that our bodies, along with their parts and products, have acquired a value that is different from any traditional conceptions of value in the body. This change has been prompted by the commercial and quasi-commercial activities of medicine, scientists, pharmaceutical companies, and industry. In a recent issue of Bionews Andrew Webster referred to the 'tissue economy'(Webster, A., 'Stem Cell Research and Society: Lessons from Social Science' 2008. Available at http://www.bionews.org.uk/page_38010.asp). This phrase perhaps tells us more about the changing face of biomedicine than the most comprehensive of lists of uses and applications of human biomaterials. These tissues and cells are worth big money and what's more they can be legally traded on the market. These tissues and cells are not subject to the restrictions on sale that are applicable to human organs. This is because the 2004 Human Tissue Act exempts material which is the subject of property because of an "application of human skill"(S. 54(7)). Specifically, materials created outside the body do not count as 'relevant materials' for the purposes of the Act. The effect of this is that any cell lines created are not covered by the Act. The implication of this is that researchers and biotech companies can come to own and sell tissues and cells but the very source of those biomaterials (you or I) cannot. The body, its parts, tissues and cells are already treated as property and because of commercial and quasi-commercial activities they have become commodities. I do not use the terms 'property' or 'commodity' in a pejorative sense, but merely to point out the discrepancy between the powers and control that attach to the source of the materials and that which third parties can come to have. As a result, there are potentially more problems with the gratis provision of bodily materials (i.e. donation) where third parties will gain a significant financial benefit, than there are associated with specified types of research.

Question 14

As pointed out on page 21 of the consultation document the issue of supply and demand is complex, simply increasing the numbers of organs available for transplantation, for example, might not alleviate the demand for organs. It could be

argued that so long as there is still a benefit to the patient (for example, that all things considered their life would go better if they were off of dialysis) that we ought to try and meet the demand for organs for transplantation. This could be taken to the extreme where patients are being transplanted to ever more marginal medical and other benefits. While any benefit to the patient can be seen as a moral good there are a few concerns with this approach. Firstly, in transplantation the supply of organs themselves is not the only resource consideration that needs to be taken into account. Other resource issues such as staffing and theatre space need to be looked at. Even if we were able to keep up with demand for organs it is unlikely that the NHS would be able to provide the other resources required to carry out the transplant operations. One could counter this by arguing that this is a reason to increase other resources in line with the supply of organs, rather than use it as an excuse not to increase the supply of organs. However, this brings us to a second related point which is that we operated in a limited health resource environment. As such, any allocation of resources to meet the transplantation needs would necessarily mean that funds are re-directed away from other areas of need. It might be that efficiencies could be made in the NHS as a whole, or that superfluous spending could be reduced, in order to fund the extra transplants. Yet it is not obvious that donation and transplantation are the areas best suited to the re-directed funds. This then relates to the third and final point. Organ donation and transplantation, while undeniably a moral good, might not necessarily be a priority area in health care. It is an attractive area to advocate for both ethicists and policy-makers since it can be framed as a 'life-saving' activity. Especially when we are taking about the use of organs from the deceased, this could be seen a paradigmatic case of easy rescue. However, there is a concern that the focus on donation and transplantation is distracting from prevention activities which could negate the need for many transplants in the first place. If the resources that are currently used in facilitating donation and transplantation could be re-directed into research and other activities that could prevent individuals getting to the stage of ever needing a transplant then it might be that this is where the priority ought to lie. When asking the question 'is it right always to try to meet demand?' we need to ask what we mean by demand and we need to ask 'demand for what?' If we mean 'the demand for organs for transplantation' then this might yield one answer. If, however, we mean something akin to the 'demand for lack of ill-health' then we might get a different answer.

Question 16

Specifically, I want to make a comment on the second part of this question. The answer to this will depend on what we define as an incentive. The consultation talks of a variety of financial and non-financial benefits. However, the way that they are framed ignores the fact that a successful outcome after a transplant can also be an incentive. The use of the word incentive suggests some sort of motivating factor at play. If this is the case then the possibility that ones relative or close friend would live rather than die, or at least lead a much improved life,

following a transplant, would surely serve as a strong motivating factor. Thus, the stake that a donor has in the outcome of the transplant recipient can serve as an incentive in itself. This mere fact does not point to whether such situations are ethical, but it just serves to question what we mean by 'incentive'. It also draws attention to the often implicit, and incoherent, assumption that all incentives must be unethical.

Question 18

Please note that my comments here relate to deceased donation and the payment of funeral expenses to the family of the deceased. In examining the ethics of a range of incentives for cadaver donation in general, and speaking of paying funeral costs more specifically, Arnold et al favour incentives that 'reflect society's attempt to thank the deceased individual for giving an organ'(R. Arnold et al, 'Financial Incentives for Cadaver Organ Donation: An Ethical Reappraisal', Transplantation, 73(8) (2002), 1361-7, p. 1365). They want to differentiate here between indirect and direct compensation. There are two points to be made relating to this. Firstly, while certain incentives may indeed work to convey gratitude to the particular individual whose organs are being donated, this can only be the case when the incentive is given pre-mortem. Incentives might still be used to show society's appreciation for the donation, but it is a fiction to suggest that this appreciation is directed at the individual after their death. Rather it is both a way to motivate families into making the organs of their relatives available for donation, and a way for society to express its gratitude for doing so. Secondly, the cost of a funeral after all can be significant. As a result, the use of terminology such as 'indirect' and 'compensation' can be used to try and distract from the function and role of the incentive or that fact that the incentive is of financial benefit to the family. However, even if the family do gain a benefit in this manner it does not automatically mean that the incentive is unethical. If we are happy to vest decisions, such as whether to donate organs, in the relatives of the deceased then it may be that a suitable incentive is called for. It is going to be a difficult time for them and they will be grieving, but paying funeral costs may give them one less thing to worry about. It does, however, call into question the purported primacy of individual autonomy in relation to deceased donation. For more on this see answer 25 below.

Question 19

Where an individual elects to become a living organ donor there are clear financial and non-financial costs involved. These costs include the time that the individual spends attending various medical consultations, having numerous tests prior to the organ retrieval surgery, the surgery itself, and then time spent recuperating post-surgery. Living donors also incur the cost of getting to and from the hospital, as well as the cost of any food and accommodation required if they are travelling far from home. In addition they may incur loss of income due to days off work required for consultations, the surgery, and the recuperation period afterwards. It is not

obvious that there is a clear distinction to be drawn between the economic losses and the compensation for other factors as outlined in the question. For example, factors such as time are directly linked to travel, time off of work, and subsequent lost earnings. Having said that the impact of the more overt economic factors are easier to measure and, as such, might lend themselves to more easily to reimbursement schemes. In addition, individuals who want to become living donors may worry more about the economic burdens than the other factors. In countries, such as the UK, there is unfortunately no legal requirement for employers to cover the cost of sick leave due to organ donation. No matter how committed one might be to ideal of altruism this should not require that an individual who is giving so much already should end up financially worse-off. It is also not clear that employers should have to bear the financial costs if one of their employees decides to donate an organ.

Question 25

Where we have no clear indication of the wishes of the deceased regarding organ donation the decision of the family is significant. If individual autonomy in this context is important then, whether the family agrees to donate or not, we are at risk of violating the deceased's autonomous wishes either way. If they did not want to donate and the family agree to donation, then it is a violation. Equally, if they wanted to donate but the family disagree, then it is also a violation. It is unclear what ethical consequences we should then impute from this. Which side of the argument one favours will depend on whether we think it is a greater wrong to take organs from those who did not want to make them available than it is to not take them from those who wished them to be used in this manner. The manner in which arguments regarding donation are often made would suggest that it is a greater wrong to take organs from those who would not have wished to become donors. That this is the case is not, however, self-evident. This is especially so if we take into account the benefit to the recipients which would be gained in cases where the organs are taken. Where a deceased individual would not have wished to donate, but the family allowed the donation, the wrong of this could, at least, be balanced against the benefit to the recipient(s). However, in the cases where the deceased would have wished to have been a donor, but the donation is vetoed by the family, there is no balancing moral good for the moral wrong done. Despite the above, it should be noted that the argument only holds if it is the wishes and autonomy of the deceased which matters. If the deceased have no continuing interests, then it might be that case that the interests of those still living ought to take priority. As such, either the interests of the family or potential organ recipients would take moral priority.

Question 28

Please see my answer to question 7 where I pointed to some concerns regarding the commercial and quasi-commercial value of human biomaterials. The corollary to the answer given there is that it might be acceptable for companies to benefit

commercially if the source of the biomaterials has been adequately paid/compensated for their tissue and/or time.

Question 30

Section 5 of the consultation 'the role of consent' focused on issues to do with incentives, coercion, and uses of human tissue without consent. However, it is important to note that the meaning of consent as used in the Human Tissue Act 2004 could be seen as problematic. Although the Act uses the idea of 'appropriate consent' as its foundation, it does not actually define or explain what is meant by it. Nowhere in the Act, the explanatory notes, or the Codes of Practice, including the one on consent, is a definition of consent offered. Kathleen Liddell and Alison Hall questioned this in an article in 2005 prior to the Codes of Practice being drafted. They commented that the Act neither defined the meaning of consent nor stipulated the steps that ought to be taken in order for consent to be valid (Liddell, K., Hall, A., 'Beyond Bristol and Alder Hey: The Future Regulation of Human Tissue' in Medical Law Review 13: 170-223, pp.189-90). The authors referring to Hansard debate during the passage of the Bill through Parliament suggested that this would be remedied once the Authority developed guidance on the issue (pp. 190-1). Similarly David Price has commented that "the Act identifies only the locus and not the nature of such consent" and also points to the guidance that was to be issued by the Authority (Price, D., The Human Tissue Act 2004' in Modern Law Review 68(5) 2005:798-821, p. 805). The Authority has indeed produced guidance on consent, yet it still does not engage with the meaning of consent. Considering that one of the criticisms levied at the 1961 Human Tissue Act was the vagueness of the language employed, it seems to be a conspicuous omission. In addition section 9 of the explanatory notes for the Act seems to claim that consent is defined in the Act itself. It says: "It defines consent by reference to who may give it, and provides for a 'nominated representative' who may make decisions about regulated activities after a person's death." (Section 8, Explanatory Notes) This claim is repeated in the Code of Practice on consent (p. 30). The Act does go into detail about who can consent and for what purposes, but, nonetheless, this is not the same as elucidating what the law means by consent. Philosophically there is some debate on this; is consent a choice, an action, an authorisation, a process, or something different? Philosophically, and legally, this is important since our conception of the role and function of consent may inform our arguments regarding coercion, incentives, and the use with or without consent of human biomaterials.