

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.

Jonathan Lee

Question 1

Unlikely. The most obvious candidate for novel ethical ire is facial work, although the rational grounds for such concerns are not clear. The natural biological spectrum is on the basis of potency, with germline cells at one end and specialised tissue at the other. For transplant purposes pluripotent cells can in principle form whatever is required, modulo some engineering challenges. Pluripotent cells are already provided, so any specific objections to novel tissue types must be have ethical work done by the means of acquiring the specific tissues. For donation from the deceased, there are no clear non-generic objections. From the living, the non-generic objections would have to assert either excessive loss of QUALY's from the donor, or specific hidden non QUALY costs to the donor. Ignoring generic objections to potentially experimental work, and thus considering a well characterised procedure, both of these seem unlikely. Hence it does not seem likely that new bodily materials per se are likely to raise specific ethical concerns; novel concerns are likely to be based on claims that a particular procedure is too risky or on generic grounds.

Question 2

Again, the natural biological spectrum in terms of utility to a recipient is potency; given pluripotent cells all else follows. Loss to donor is most naturally characterised by short term and long term effects separately; the former encompasses surgical risks and may be improved by new techniques whilst the latter is based on the fundamental effect of the loss of donated tissue. Humans are essentially products of our neurological system; the other tissues have import for day to day operation but it is well established that complete brain death is the proverbial end of the line. There is current research in stabilising such tissues for long periods; if cryogenic revival proves as feasible as its proponents hope then there are good grounds for special treatment of central nervous tissue. Aside from this, the only tissues marked out biologically are the germ line, for reasons of potential totipotency. The standard objection to work with totipotent or pluripotent cells is one of slippery slopes to human cloning. It is claimed that this violates "human dignity" without further defence, which notably simply moves the argument to what precisely constitutes human dignity or infringement on same. It has notably not given an answer more compelling than "because I say so". Hence the only potentially special type of human tissue would appear to be the central nervous system, as there is the technical possibility that its preservation would render legal death moot. No other tissues fall in the same category, as they can be produced by pluripotent cells in a fashion not destructive to what made the donor the donor.

Question 3

There are obvious issues at the technical level; trivially combined heart and lung transplants are ethically less dubious when the donor is dead. Ignoring such technical issues and focussing on ethics, there is no additional ethical work done by the contingent fact that the donor is dead. Note that questions of QALY costs and associated benefits to donor and recipient are extensions of the technical issues mentioned earlier. If it is ethical for a human to render their body to donation after death, then it is in principle possibly ethical for a human to do the same before. Their costs may have altered, but that is an issue for the donor. If the expected QALY balance is changed substantially, then this would be grounds for reevaluation given limited resources. It has not become instantly unethical. Similarly in the contrary case; the costs and benefits change when the donor is dead, but if it is legitimate for a live donor to donate a given tissue then in principle it is ethical for a deceased donor to do the same. The most obvious distinction that could be drawn is ease of obtaining consent, but if it is made clear what the donors desires are then there is no further work done by life or death.

Question 4

Trivially, in any medical procedure there are risks of complications and harm to the donor as a result. This varies from procedure to procedure, and thus has to be weighed by the donor. More problematic are longer term potential morbidity effects; humans are notoriously bad at handling risks or long horizon times. Clearly donating one kidney means that single kidney failure moves from problematic but manageable to debilitating. Whether potential donors can accurately assess these effects is particularly troublesome for newer procedures, where information from past donors is not available. As with all human activities, the donor's actions will impact on those around them, in an indirect fashion mediated through the effects of donation on the donor. This is not considered grounds to prevent people from engaging in any other activity; we do not ban people from eating new foods on the off chance that they suffer anaphylaxis and cause their friends and relatives emotional trauma. The comparison is valid; the harms are identical in their indirection and potential effect. The absolute risks may be different, but again there is a continuum of potential risk, which shows a reductio on general objections on the grounds of impact on those close to the donor. As a fully general counterpoint, consider the impact on those close to the recipient. No ethical work is done by whether something is "allowed" to happen or "caused" to happen, when we have the means and foreknowledge to alter the outcome. The most obvious problem for donation as a whole is that the benefits of donation are low; feeling good about oneself and the ability to signal general compassion are the benefits of signing up. The benefits of donation to non-family members are slim to none.

Question 5

No fundamentally different varieties of harm are risked by a first-in-human trial volunteer and a donor. In both cases a risk is taken on, where harm can be immediate in the course of the procedure or long term side effects; as in donation

there is potential for impacting on those close to the donor. The difference between the two cases is one of prior knowledge of risk, but this is simply uncertainty and falls in the same category as uncertainty about whether the donor personally will suffer from a complication whilst donating. In the same sense as for donors, there are a large body of people who are harmed by a lack of clinical trials; it does not seem to strike the majority of the population that if a new drug is released and is predicted to save 1000 lives each year, then every day's delay in its release killed 3 people. Were this variety of ethical calculus more widespread, the concerns over clinical trials would be more clearly analogous to donation.

Question 6

In principle, people may have private ethical concerns about whatever they wish; it is not within my purview to guess at the absurdities of the rest of humanity. However, the four way split on basis of aims appears to be reasonably comprehensive. I am sure that some respondents will attempt to specially plead for specific procedures to be placed in special reference classes; they will then claim that because of this these procedures should be avoided. I will observe that some complexity is concealed in the directed or undirected split; presently directed donation is allowed on only a few entirely contingent grounds. It is not currently legal, for example, for donation to be directed to a specific arbitrary other, especially if payment has been exchanged. The fact that the controls that can be placed by the donor are constrained in this fashion needs examining. Whilst these constraints may have been put in place with the best intentions that does not make them inherently ethical or cogent. The split on immediate or future use is fairly comprehensive, although there are clearly intermediate states where the broad outline of work is known but the specifics are not. The final usage split is oddly not comprehensive; commerce is orthogonal to the other categories. In principle whole organs may be used commercially; it is a contingent fact of law that it happens to be illegal in the UK. This matters; if the argument over commerce is a single one, a reduction to banning fertility clinics is admissible as argument for general commercial legality. If there is a separate argument over commerce for each possible use, then it is being claimed that there is context specific ethical work done by commerce, and that furthermore this work is sufficient to render donations unethical.

Question 7

Beyond the consent issues involved, there is no great ethical work done by the specifics of what the tissue donation will achieve. As a matter of ethics, the set of procedures in principle stand or fall together. As a matter of priority, given limited resources, the only natural question is under what metric to rank. Whilst officially we do not place a value on human life, in practise we must. If £50,000/QUALY is spent on one treatment whilst treatments costing £30,000/QUALY are not carried out, then those responsible for policy have killed patients. It should be clear at this point that I would advocate prioritising on the basis of cost per QUALY. As a

matter of public health this seems the only reasonable metric. I will happily note that this substantially reduces the priority of reproductive therapy; as uncomfortable truths go it is not a particularly serious one. Nor should it be beyond the pale to suggest that reproductive therapy is not healthcare and does not deserve funding from the public purse.

Question 8

Again, the expected cost per QALY gain should be the guiding factor in public funding of trials. Whilst such numbers are inherently more speculative, it is comparatively easy to track whether researchers or companies underestimate cost per QALY, and downgrade future proposals accordingly. As a matter of personal preference, I would clearly be more willing to participate in first-in-human trials if I was likely to gain something from them. The fundamental distinction is that the collection of things publically funded should in principle be good enough to convince each individual to pay for it; if the health system needs the courts to force people to pay for it then this would not speak volumes for the general benefits of universal healthcare. Trials that I personally chose to participate in have to be good enough to convince me personally to take part; this is a different metric.

Question 9

It should be observed that the values already put forward are safely fundamentally irreconcilable. It is not clear what adding additional ideals to the pile will do to improve things. If one more were to be added, I would suggest rationality, or consistency if you prefer. It should not be the case that the defences of an ethical standpoint admit trivial reductions to absurdity; it should not be the case that ethics turn on personal convictions. These issues, whilst stressful for some, are about well understood physical and biological phenomena and should be treated as such.

Question 10

As an unfortunate side effect of applying reason, I am already elevating rationality above the other concerns. Taking the given values roughly in order: Whilst altruism is all well and good as a reason why people might donate, it is surprising to claim that the altruism of a donor is a factor in the ethical calculus of tissue donation. Altruism is a state of mind in the donor, rather than a verifiable fact of the world, and is thus immediately open to contrary cynical interpretations. Indeed on the tangentially related issue of assisted suicide, there is a presumption in law of such cynical interpretation. What ethical work is done by altruism? Altruistic intent does not alter the state of the patients before or after. Claims that programmes should be based on altruism do not appear to have internalised the observation that those who predictably die because policy was not different died at the hands of policy makers. Autonomy is foundational to UK law; indeed the early common law, retained to this day as tort is based entirely on treating individuals as autonomous. Autonomy is the cooperative solution to the prisoners dilemma of dealing with

strangers; in this context it is a value that underlies the others on the list. As a natural consequence of this, individuals can decline to be donors or choose to be donors. On grounds of autonomy we should allow the consensual sale of organs. The standard response of lacking consent is overbroad; with one equally curious exception we do not presume that consent was lacking when any other deals are made. Claims of Human dignity appear to underlie both of the aforementioned exceptions to contractual autonomy. It strikes me as remarkably crass that we are willing to allow patients on waiting lists to *die*, whilst simultaneously attempting to claim that human life is of supreme ethical worth. As an unfortunate fact of reality, altruism does not produce enough organs. Failing to face up to this is to live in a fantasy. It should also be noted that the claimed degradation in the eye of the Kantian, not the allegedly degraded. At what point did the ethics of this situation get dictated by external observers? Since consequentialists also exist, and are remarkably offended by needless death, are we to run mob rule on ethics, or suggest instead that the inner convictions of third parties do not infringe on others? As the flip side ethical principle, we have consequentialism. As a matter of fact, the majority of those on the waiting lists would prefer transplants to death; it seems presumptuous of us to claim that it is better that they die than we should suffer the agony of paying for their treatments. Consequentially it is madness; on cost per QUALY grounds it is trivial to show that 5-6 figure payments for kidneys are entirely reasonable; the data from Iran suggests that supply will handily be met at such levels. The consequences of not doing this is death to those on the waiting lists; this to me seems to be something that is skirted around too often. Justice is touted as a reason to avoid paying for organs; that the poor will lose out. There are immediate counterarguments on the grounds both of autonomy and consequences, but I see a more fundamental issue. The argument from justice appears to deny that people have different preferences; it is analogous to claiming that allowing people to buy houses punishes the poor because they are forced to rent at higher than mortgage cost. In the latter case the difference is over the relative value of a large debt and monthly rent payments; in the former it is the relative value of tissue and some large cash lump sum. More problematically, any existing justice issues are currently simply being exported. For those individuals willing to pay, the cost of a flight to a nation where sale is permitted or at least ignored is negligible. Allowing the purchase of organs has the effect of bringing such trades above board and into a competent theatre. Reciprocity is a perfectly reasonable measure by which to justify paired donations; it is to be noted that reciprocity is payment in kind, and that it has been known for the last 5000 years that payment in kind is less efficient at getting things done than payment in cash. Solidarity, like altruism, is possibly an excellent marketing strategy. Also like altruism, it is not clear what ethical work it does to justify a procedure we would otherwise deem unethical. Does paying for organs become legitimate if I spread out the payment over a large enough group? Is giving an organ to a foreigner who suffers acute liver failure in Heathrow unethical? Whence then solidarity?

Question 11

If it's being paid for by the public, then in as much as you've freed up resources to do something else, yes. No more, no less. Giving an endowment of the same amount to a PCT would be just as praiseworthy. If it's being paid for by the entity with a fixed budget to spend, then the type and purpose aren't relevant; the budget gets spent improving someone else's life.

Question 12

Barring contractual obligations, it seems unlikely; a moral duty is the mechanism used to deal with interactions that require one party to suffer loss substantially before the other can rectify it. Hence one is said to have a moral duty to respect one's parents, for example. In the case of donation, such conditions are tenuous at best; one might try to assert any moral duty one can think of, but it does not make it so. Asserting such a moral duty would appear to deny individual autonomy, and remove any aspect of solidarity or altruism from the acts; it is not clear that this is a productive line of marketing to pursue.

Question 13

As in the case of tissue donation, it seems unlikely outside of contractual obligations. The mere fact that something is good does not make it obligatory; the contingent fact that I personally consider something good certainly does not make it a generally applicable norm.

Question 14

This clearly depends on the cost of filling demand against the benefits accrued; this is the fundamental point of market economics. If there is research or treatments that, even factoring in the cost of tissue acquisition, is better in cost per QUALY terms than the determined threshold, then it makes sense to raise the internal price of tissues until enough tissue is acquired, by either scaling back less efficient uses or bringing in increased supply. Bluntly such an internal price ought to exist anyway, so that the NHS can make cogent decisions about how much to push donation, and distribute tissues efficiently internally. Exposing that internal cost to the outside world allows the supply to move instead; this results in more tissue being available when all of the uses of tissue are productive, and thus the price can run high. How pressing a need or demand is should precisely run into the cost per QUALY of the entire process. Any other measure does not maximise the QUALY produced, which is statistical murder.

Question 15

Yes. It has been well established that cash incentives are efficient, both in terms of ease of application and matching finding a pool of supply. In tissue donation in general, preventing payments beyond lost earnings makes lack of supply virtually guaranteed, as once risk and discomfort have been factored in the donor has lost out. It is better to pay donors for tissue than it is to have patients dying on waiting

lists. The decoupling of risk from pay, and locking pay to minimum wage, in first-in-human trials simply has the effect of making sure that none but the poor take part. Avoiding these trials is drummed into any middle class child with parents that have seen the health system close up. Simply that they're advertised as "We need non-smokers to play video games in the middle of the day" has the side effect of avoiding anyone with a regular 9-5 job. The situation is not worsened by allowing pay to match risk, or rise to the point where demand is met.

Question 16

If an incentive were to be unethical in and of itself, then this would imply that the nature of the procedure utilising the tissues was immaterial. It seems implausible that death or shortening the lives of patients is preferable to offering an incentive. The fact that lack of tissue implies morbidity needs to be kept in focus. If the seemingly evident fact that incentivising the saving of lives is granted, then if an incentive is unethical it must be so as a result of both the incentive and the procedure. Since a continuum of possible procedures exist, this would imply that at some point the most trivial changes to a procedure shift it from being right to damnable; this raises the question of what work is being done by these changes. The more abstract issue is one of what counts as an incentive. Presumably it is not deemed to be an incentive that organ donors should stay in hospital whilst they recover, for example, yet it is clearly something that the donor would choose given the circumstance of having just donated. Hence to even categorise actions as incentives we must determine what counts as the baseline "natural state". In any other field of human activity, it would be reasonable for a person to charge for undertaking a somewhat risky and painful task. Is it then the case that if the donor makes their wish for remuneration known upfront that payments are no longer incentives? In terms of public perception, personal appeals are judged more highly than cash rewards. This does not imply that it is the case. Again it needs to be noted that people will die as a result of tissue shortages; this would seem to do a great deal of work towards justifying incentives. Whether they are official or unofficial does not alter the end state of reality; it is unclear what ethical work might be done by the distinction. As a matter of the comfort of the people, it is indisputable that unofficial incentives are easier to stomach. This, however, is simply because the majority of the populace do not recognise that all health decisions implicitly put a cost on human lives. Making this explicit does not alter the facts or ethics of the matter, but makes people squirm. What it does do is allow cogent decisions to be made.

Question 17

For me personally, incentives would not make me less likely to agree; if I would prefer not to have whatever is deemed to be an incentive I can always decline it. As a matter of marketing, it is somewhat challenging to mix overt incentives with approaches based on, say, altruism. People are good at categorising events into broad categories and acting radically differently on these categories, whilst

maintaining almost arbitrary heuristics for sorting into categories. Hence if people think of donation as a business exchange, they may demand payments where if the donation was categorised as a voluntary donation, they would not. The extent of these effects is highly variable, and without actual data claiming a hard and fast rule seems dubious. Since it seems implausible that public adulation for donors is a major factor, donors being essentially unidentifiable on cursory inspection, it seems that at present the most important motivation for donation is an inner belief that it is a good decision to make. In such a circumstance, incentives can be highly effective. This is even before more aggressive strategies are employed; it is known that donations are far higher if free gifts are given first. Application of such strategies to getting people on the donor register is entirely feasible.

Question 18

No. Whilst some people may find it comforting to categorise "indirect" and "direct" compensation differently, what this is revealing is that they are uncomfortable with the brute fact that these activities value life, and that furthermore they can avoid cognisance of this if the compensation is made indirect. It does not imply ethical facts about the scenario; it shows that people are not thinking through the implications of indirect compensation. Direct financial compensation is more efficient for the simple reason that the incentive offered translates into a greater utility for the recipient, and hence less need be offered. This lets you save lives.

Question 19

The categorisation implied has a number of flaws. For example, in what sense are "actual lost earnings" actually lost? These earnings would not have been acquired regardless of whether the donor had taken time of work to go on holiday or to be a donor. Does a donor who would have been laid off had they appeared at work the next day no longer deserve compensation? What of the case where the employer keeps the donor employed to bulk up their numbers, but the donor knows that they will be given notice as soon as they return? Does this donor deserve compensation. If the donor had planned to take time off for a holiday, but then donates for a stranger instead, do they no longer deserve compensation? In this case they have not lost earnings, but merely an excess of time. The distinction between the two is forced, and shows simply that people promote "what they perceive would have happened anyway" to some special state. This is not a deserved elevation when we have control over the world. To the outside world, the only relevant changes are to the continued ability of the health service to maintain health, and the recipients health improvements. Neither is impacted by the nature of the compensation.

Question 20

Warranted medial demand is trivial to reduce, simply by reducing the threshold admissible cost per QUALY gained. It is an unlikely development, as there is widespread public belief that the NHS should do more than basic healthcare. If

such developments are neglected, it is unlikely that demand for organs will decrease. Even if alternatives were to emerge, the greater familiarity with standard organs would mean that initially they would still be indicated for more serious cases; the prospect of having a liver mountain and blood lake are slim. On the other hand, new procedures and reducing risks will likely stoke the demand for organs or substitutes. The only long term way to reduce demand would be to engineer alternatives that are fundamentally better than standard human tissues; guaranteeably at such a juncture an outcry will be raised over "transhumanism".

Question 21

In the rest of the law and ethics, informed consent is usually taken as the starting position for evaluating an agreement. In such a context, unless the encouragement or incentives concealed the risks of the donation, they would not infringe on consent. It may be claimed that offering something sorely needed by the potential donor invalidates their consent. Such argumentation is odd; it presumably is not claimed to generalise to mainstream work, so there is something of donation in and of itself that is considered problematic. Presumably it is similarly not considered that sponsored skydiving should be prohibited, so it is not the acceptance of risk for gain. The fact that donation and human trial participation are so explicitly singled out makes it difficult to conceive of cogent arguments that do not prove far more than would be desired.

Question 22

It can't. The distinction is one of how the potential donor themselves sees their interactions with their family. Whilst third parties may claim that "surely no one would volunteer for" or "surely no one would risk a relative over", these are nothing more than guesses by third parties. Asking the donor is not a solution, if their decision could become known to their family. The only good solution is for medics to be prepared to lie to the rest of the family about tissue compatibility. Practically, such a policy would have to be publicly known, as the political ramifications of it becoming known through scandal would be devastating. If such an approach is not taken, then a claim of familial coercion is nigh impossible to defend against.

Question 23

Ownership claims are not asserted over shed epithelial cells, so a claim that human cells are inherently controlled by their biological progenitor is too strong. Once this has been granted, the requirements for other uses of tissue are somewhat looser. If a good faith effort to acquire permission is made, and an answer cannot be acquired, then presuming consent is reasonable. In the similar case where anonymity prevents identification, a presumption of consent should apply. Clearly this does not extend to cases where the patient explicitly chose to withhold consent for additional work; the most natural alteration is to forgo explicit mention of additional purposes in consent unless the patient chooses specifically one way

or the other.

Question 24

In all such cases, the standard position of the common law is that the ability of the decision maker does not extend indefinitely; at some point there is the ability for the legally irresponsible party to become a ward of the court. Hence there is a general requirement to act in the "best interests" of the irresponsible party; more properly this is taken to mean making decisions that are considered "reasonable" in the broad and occasionally ill-defined legal sense. The fundamental difference is that the right of a decision maker to do as they will does not extend so far; they are deciding for another. In the case of living donations, there are a number of obvious candidate issues. One is the imposition of parental values (typically religious) on the child; it is unfortunate that in such cases the number of likeminded adults has substantial bearing. It seems to me wrong that parents should cause their children to suffer on the parents' whim, especially if the child is too young to be capable of fully understanding the implications of what they have been taught. The other is one of allowing donation or testing from a child. In such cases the risk to the donor and motivations of the parents must be paramount. If the parent is not acting in good faith with respect to a child, then they should not have decision making rights over the child.

Question 25

If the deceased wishes are known, the family has no special right to disregard these wishes. This is no different to the inability of a family to ignore a will; the deceased retains ownership of their body post-death. As an immediate consequence the family should have no a priori right of veto in these cases. Certainly in a hypothetical extremal case, where the deceased has made their estrangement and disagreement with their family, for example, the familial wishes should be disregarded. If the deceased wishes are not known, then the wishes of the family should be the driver; if they are equivocal then the default option should be donation, as in the case of excess tissue. Once a good faith effort to determine wishes has been made, the decision should ultimately fall to the medics.

Question 26

In the first instance, they should be considered the deceased to dispose of as they directed. If a third part has a fresh cadaver, they should be obliged to make a good faith effort to discover the persons intent, and failing that the wishes of the family. If good faith efforts do not result in this becoming known, then tissue donation should be an option. Ownership per se is not required; the assertion is simply that the proper behaviour of those faced with a body to deal with is to discover the intent of the deceased or their family.

Question 27

Yes; my mind is my own in the same contingent fashion as that of my body, yet I

may sell the fruits of my mind. I may sell the right to direct my future thought or action, subject to some mild restrictions. Why then would mere tissues be considered so fundamentally different?

Question 28

That depends entirely on the wishes of the donors; if the donors donate with the stipulation that the proceeds be shared, then so they should be. For reasons of efficiency there should be some standardisation of these stipulations. If I voluntarily give my efforts to some company, it is not incumbent on them to share out the proceeds of any gains they make. In the same way, why should an entity be forced into sharing the proceeds of things given to them freely by third parties?

Question 29

As much as they mandate. Those in immediate possession of the material should be obliged to make good faith efforts to discover any such mandate if the status of the materials is not known, and the default position thereafter is that anything approved by an ethics committee is suitable. The presumption is that the opinions of a reasonable and fully informed person are approximated well enough by the committee.