

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.

National Gamete Donation Trust

Question 2

The use of reproductive material (i.e. eggs, sperm and embryos) needs special consideration because it leads to new life. Children born as a result of donation may want to know the circumstances in which the gametes were donated and this may affect their sense of well-being. This will have implications when considering how donation may be encouraged or rewarded

Question 3

The significant differences between providing reproductive tissue during life and after death relate to the consent procedure. It is generally unusual to have made a written comprehensive statement during life as to how one would want one's genetic material used after death. Difficulties may therefore arise when one of a couple dies if the partner claims that the dead partner would want his/her reproductive tissue used, whether by the remaining partner or more generally. Even when consents have been completed in line with the Human Fertilisation & Embryology (HFEA) Code of Practice during life, they have sometimes been found to be inappropriate after the death of the individual and even after great care has been taken to make the consent as meaningful as possible, problems arise. Currently the only way to deal with situations where consent is not clearly given is by access to the Courts and by a compassionate hearing of the plea for use. Sometimes the request for use may seem completely inappropriate and it may be worth urging a mandatory period of counselling of perhaps a year, to allow the plaintiff time to deal with their grief, before proceeding to a decision. It might be that, if there was a mandatory opt-in organ donation card, appropriate consent for reproductive tissue consent could be included. At the moment, the law regarding use of reproductive tissues after death varies from country to country. Thus, in the case of Diane Blood, she was able to store her dying husband's tissue in the UK but not allowed to use it in the UK, and was later able to make use of the tissue for fertility treatment abroad. There is a clear need for uniformity in the law, at least across the European Union. Regarding reproductive material, immature eggs can be harvested from the ovaries of women and prepubertal girls, as well as from female fetuses of late miscarriages and late pregnancy terminations. When the Human Fertilisation and Embryology Authority (HFEA) conducted a national consultation some time ago, the idea of removing eggs from the dead was felt to be abhorrent. It may be time to review this to see whether the public's attitude has changed. Apart from the conceptual and moral issues associated with use of these tissues, there are technical differences: immature eggs need "ripening" in vitro before they are fertile and this, plus the additional technical manipulations needed to fertilise these eggs, means that the success of using such eggs is less than using eggs matured in vivo. Since the technology is still fairly new, it is also difficult to predict

whether there will be problems, such as a higher rate of foetal abnormality, associated with the use of these eggs.

Question 4

Any type of human reproductive tissue donation requires a number of visits to a licensed clinic, often situated some distance from the home or place of work of the donor, usually at times during the working day that cause disruption to the donor's work. Although the disruption may well be the same for every donor, some donors' input may mean larger financial losses than others'. Finding a way of recognising the contribution of all donors and at the same time allowing for discrepancies between individuals' financial losses may be very difficult. The National Gamete Donation Trust (NGDT) supports the principle of uncapped provable expenses and also uncapped provable loss of earnings compensation for all donors. Whilst donating sperm and embryos are not associated with risk to the individual, egg donation is associated with risks relating to hormone stimulation to produce the mature eggs and to the operative procedure to access the eggs. In all types of reproductive tissue donation, for the relatives, as well as the donor, the number of partially related siblings that might arise and hence the small risk of future consanguinity has to be considered. The benefits for the individual donating are those of feeling pleased to help someone else, either because they feel close to a particular person or because, having enjoyed their own children, they feel concerned to help others who have not been so fortunate. These benefits may be indirect to their friends or relatives (in their perception of their friend or relative being happy about what they have done) or direct, in that one of them may have been the recipient. But, not only will the children of the recipient but also of the donor have half-siblings and the partner of the donor may have concerns about this, as may the brothers, sisters and parents of the donor, who by the donor's deed have found themselves with an extended family, whether they like it or not.

Question 5

In the reproductive field nearly all "first-in-human" research is aimed at returning embryos and the possibility of pregnancy. Since the safety of any technique cannot be known until that generation of children has reached adulthood and those children's reproductive potential tested, it is impossible to give reassurances to people about to embark on these treatments. Infertile people are vulnerable to agreeing to any option offered them. Partaking in one such trial may reduce their financial costs but may lead to significant emotional and financial cost, both to the parents and to supporting relatives, should there be a problem with any child born as a result of treatment.

Question 6

Some donors of reproductive material do not want their tissue used in certain circumstances, such as by single women, or in same sex couples. Some wish to be able to put a cap on the number of children or families that can be created using

their gametes or embryos. If a review of policy in this area is carried out, a decision will be needed as to what degree of autonomy donors have in choosing who uses their tissues. There are also concerns for some people who donate gametes that their gametes might be mixed with gametes from other species and for people who give embryos that these might be cloned.

Question 7

The objective of the NGDT is to raise awareness of the need for gametes and embryos for creating children. The NGDT also supports research that improves the success of fertility treatment, provided that the development of the embryos is halted at the limit of 14 days stipulated by the HFEA.

Question 8

The priority of the NGDT is to raise awareness that there are people who want to conceive using donor gametes and embryos, who will only be able to conceive if others donate reproductive material. The NGDT also supports research that improves fertility treatment.

Question 9

Any child conceived as a result of any treatment involving donated reproductive material should also be accorded the same respect and ethical consideration as the donor and the recipient of the material.

Question 10

Key to the priority in which one orders these considerations is whether one considers the individual first or the society. If one argues for the individual as the most important unit, then autonomy and dignity take precedence over justice and maximising the health and welfare of the community. In a utopian state one would hope that communality would lead to altruism and in turn to reciprocity. One would hope that all individuals were conscious of living in a community, and would want to live by the values of justice and maximising the health and welfare of the community. In particular one would hope that all individuals feel protective to those who have not yet achieved autonomy, by whom we mean children. Although the NGDT exists to help individuals and would therefore order its priorities by putting the individual, and hence autonomy and dignity first, we regard the best interests of the children born as a result of donation as of great importance.

Question 11

It is morally speaking better to donate without gain. Only in this circumstance can the act truly be said to be a donation. To be paid makes the person a vendor. This is the moral situation for donation of any tissue. It also follows from this that no organisation involved in the transfer of the tissue to a recipient should benefit financially from the transaction. Given the situation where all donor tissue is in short supply, a compromise position might be to reimburse fairly donors for their

time, expenses and loss of earnings and this is what the NGDT proposes for gamete donors.

Question 12

Although there may be a moral duty to consider donating, there is never a moral duty to donate and this is true for any tissue. For any tissue and for any circumstance there will be moral factors both for and against donating and only the individual can decide what they feel is morally appropriate for them.

Question 13

We cannot think of a situation where it would be an absolute moral duty to participate in a first-in-human trial

Question 14

It is right to try to meet demand, by making society aware of the shortfall and explaining to people how they might help. At the same time, it may also be useful to prioritise access. This is always difficult and sometimes perceived to be unfair. It is worth commenting here that, by supporting research, alternative solutions may be found. An example of this is the development of intracytoplasmic sperm injection that has allowed many men with low sperm counts (who would have depended on donor sperm in the past to become fathers) to become the genetic father of their child and thus reduce the need in the country for donor sperm.

Question 15

Ultimately a donor is only a donor when they DONATE, that is when their motive is one of altruism and not of personal gain. Once we start discussing incentives or rewards we are talking of vending. However, certain "incentives" seem pure common sense, such as improving the infrastructure of clinics, blood donation centres and other points of access so they are user-friendly – open at times that suit donors, being efficient in throughput- and some other "incentives" would not destroy altruism, such as encouraging recipients to write a letter of thanks. The situation becomes more complicated once "incentives" become effectively "treatment in kind", as in shared egg donation, which will be discussed further in question 16. Compensation may be a compromise position.

Question 16

We will reply to questions 16-19 as the NGDT in relation to reproductive material only: As previously stated, the NGDT supports the principle of reimbursement of uncapped provable expenses and uncapped provable loss of earnings. (Currently reimbursement is capped at £250, whatever the expense) We are concerned that this recompense should be given equally to all donors of reproductive material, irrespective of the nature of the material. Currently we feel egg donors are looked at more favourably than sperm donors, who may have to attend many more appointments than egg donors, even though egg donors have to undergo injections

and operations. There is also currently a discrepancy between the reward for shared egg donation, a form of "benefit sharing" (where a "donor" may receive anything up to the whole cost of a treatment cycle for herself, which might be thousands of pounds sterling) and an altruistic egg donor, with expenses capped at £250. Because the generation of children is such an emotive area and individuals bring to it the mixture of their own religious and moral philosophies and their own experience of childhood and family, it would seem particularly important to allow individual choice in whether to give and how much to give. It is crucial that donors of reproductive material know precisely what their tissues are being used for and how often. This should be covered by the consents that they complete when their tissue is first received, such consents being standard consents under the HFEA guidelines. For this reason, the issue of "opt-out" versus "left-over" option should not arise.

Question 17

The role of the NGDT is to make people aware of the need for donors. We would not be prepared to help donors, or indeed organisations, who are behaving in a manner that is not in line with the HFEAct, situations where the profit motive might lead to casual or frankly dangerous practices.

Question 18

The NGDT feels that currently the indirect compensation to egg sharers is inappropriately more than that allowed by law to altruistic egg donors and that this situation should be rectified.

Question 19

There is a difference in that compensation for economic loss is easier to quantify than the financial value of time, discomfort or inconvenience. It would seem right to acknowledge the importance of the latter, perhaps by finding a standard sum for each donation activity that would be offered to each donor, irrespective of economic loss.

Question 20

Research in reproductive technology turns up many useful techniques, such as intracytoplasmic sperm injection, that reduces the need for donor sperm. However, this is often followed by another demand. For instance, greater understanding of genetics and the risk of transmitting a hereditary problem might lead a different group of couples to opt for sperm donation. Statistics show that women are having their children later. Women waiting until they are older before having children has resulted in more women needing egg donation. It is also possible in the long term that manipulation of ova and of non-reproductive tissue may reduce the need for eggs and sperm.

Question 21

In the field of reproductive tissue donation all innovative treatment is in itself first-in-human research. This is because it is usually impossible to extrapolate from animal findings to human reproduction. Hence vulnerable infertile people find themselves accepting treatments where the repercussions are often poorly understood. Although there are clear guidelines as to how to obtain consent in the Code of Practice of the HFEA, it may be very difficult for people so motivated to have children to be objective and well informed, particularly when those delivering the treatments do not themselves know fully what the outcome of their treatment will be.

Question 22

When we think of one person within a family helping another, we are usually thinking of practical support, such as financial help or caring when a member of the family is ill. In all areas of donation other concerns come into play, such as concerns about the donor's safety in surgery. The donor may also have to struggle with their own personal or religious feelings about their concept of themselves as complete. In a family it may be assumed that an appropriate donor will come forward but when it comes to use of reproductive tissue this may be particularly fraught. The difference between the fortunate person and the unfortunate are there to be seen on a daily basis. For instance, a woman of the right age and with two children may well feel very guilty if she does not donate eggs to her sister who has undergone a premature menopause, but she may also feel her children are unique and she may not be able to contemplate half-siblings, with whom she has little contact, for her children. Indeed she may feel this to be irresponsible. For similar reasons, her partner, the father of her children, may also put pressure on her not to donate. There may be problems of reciprocity in the family as well: if the sister with children has used her infertile sister as her primary source of childcare, she may feel obligated to help her infertile sister. The fertile sister may feel the disapproval of many members of her family but be emotionally unable to help her infertile sister in this way.

Question 23

The NGDT has a commitment to help people on an individual basis. If an individual feels they have been appropriately counselled prior to giving their consent that the tissue they have given might be used in a different way in the future, and, provided the research project has the approval of the HFEA, it is for the individual to make their choice.

Question 25

a) If the deceased person's wishes are known, they should be adhered to. b) Regarding reproductive material, the issue of consent remains the same as laid out in question 3. Other situations could arise, however, where the issue of consent has not arisen before. In the context of reproductive tissue, a family may be very keen that a dead relative's reproductive tissue be used. For instance, if an only

daughter is killed in a car crash before she has had any children, the parents of that girl may feel denied of the opportunity to have grandchildren. They may actively press for the immature eggs to be harvested but at that moment may have failed to appreciate that any offspring born of those eggs will never be grandchildren to them in the normal sense. The NGDT thinks that this could be overcome by storing the ovarian tissue and allowing the grieving parents to have time for reflection and/or counselling before a final consent is given. The NGDT feels that the individual's wishes, if known, should be respected and the family does not have the right of veto.

Question 26

The reproductive material of a person should belong to them and them alone, unless they have given consent for other uses of the tissue.

Question 27

The inherent risk in allowing the selling of body parts, including reproductive tissue, is that the people who have most incentive to sell are also those who are most likely to be less than honest about their health. This was demonstrated in Australia in 1986 when four women who had conceived by donor insemination were found to be HIV positive, a disaster not only for them but also for potentially motherless children. The situation however is complicated when a donor receives very little for their donation but then sees a clinic becoming wealthy by using their donation.

Question 28

We would suggest the idea of raising a "tissue tax" from companies who benefit from donations, which could be ploughed back into the hospitals and clinics who see donors and prepare them, and into long-term support and counselling of donors.

Question 29

The degree of control a person has over all his bodily tissues can be managed through consent. Many of these controls could be managed through the donor register, whether as an opt-out or opt-in system. The disposal of all tissue, including reproductive tissue, that has been removed from the body can be managed through careful consent.

Question 30

The NGDT wishes to draw to the attention of the Nuffield Bioethics Group that gametes and embryos are not only used by infertile people. Couples where a transmittable genetic defect has been found may opt to replace one or others' gametes, or indeed use donated embryos to have a family. Single women and homosexual couples also need recourse to donated reproductive tissue.