Deceased Donation in Uterus Transplantation Trials: Novelty, Consent, and Surrogate Decision-Making

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In my 2016 paper "Should Deceased Donation be Morally Preferred in Uterus Transplantation Trials?" I explored a number of the ethical concerns and questions posed by the use of living donors in uterus transplantation trials, and asked whether there might, as a result, exist compelling moral reasons for teams conducting UTx research to prefer the use of uteri from deceased donors. After consideration of a number of factors such as the harms associated with living donation, the possibility of donor regret, and the potential for serious threats to donor autonomy and consent, I suggested that all things being equal a deceased donor model should be preferred for uterus transplantation. All things, however, were *not* equal and I therefore suggested that at that moment in time - given uncertainties regarding the likelihood of success associated with each donor model and questions regarding the availability of deceased donor uteri - the use of uteri from both living and deceased donors could be justified provided that certain background conditions were met (Williams, 2016).

Two years of research into UTx later and consensus is not forthcoming among physicians and commentators regarding either questions of demand or the relative efficiency of each donor model. As such, it is expected that for the foreseeable future both donor models will be utilised by those pursuing UTx research. Given this, work like Bruno and Arora's, which highlights how the ethical terrain surrounding uterus transplantation changes depending on the donor model used, and proposes regulatory responses to protect the interests of the various parties holding stakes in UTx, is to be welcomed as a valuable addition to the existing UTx literature. Indeed, the breadth of topics covered in the article makes this paper especially useful for physicians and policy makers currently conducting UTx research. Such topics include whether and when the use of living donors can be justified in UTx trials; concerns regarding respect for the autonomy of both living and deceased donors; the proper expectations of donors (and donor families) regarding 'access' to children born through UTx; allocation criteria for recipients of non-directed donated uteri; and how to track outcomes for donors and recipients of uterus transplants effectively moving forward.

However, while there is much to like in Bruno and Arora's paper, there are points at which a number of questionable positions and prescriptions are forwarded without sufficient elaboration or justification. Of particular interest to this author, however – given research I am currently conducting on the retrieval of composite tissues from deceased donors for Vascularised Composite Allografts (VCA's) – is the remarkably strict position Bruno and Arora take regarding appropriate consent to deceased uterus donation within their paper (Bruno & Arora, 2018, 7-9) In what follows I therefore offer a number of brief comments on this position and the discussion that precedes it.

In 1995, the British National Health Service's (NHS) introduction of an organ donor register allowed individuals the opportunity to record their donation preferences on a single database, a significant improvement on the previous system which relied only on an individual's possession of a donor card and testimony from an appointed representative as to their preferences (NHS, 2015). Like the donor card which originally included only kidneys and

was later expanded to include the heart, liver, pancreas, and corneas, the range of organs and tissues included in the register have been expanded over time. Those who now sign the register and opt to donate *all* of their organs and tissues therefore express a willingness to donate a greater variety of organs and tissues than was the case even ten years ago. Despite this, however, a blanket consent provided for post-humous donation ten years ago is treated in the same way as blanket consent today even though those who have previously signed the register may not have considered donating certain tissues or been made aware of changes made to the register. Thus, questions can be raised regarding whether or not transplant physicians may be considered justified in retrieving such tissues from the recently deceased.

UTx has not yet been included on organ donation registers in either the UK or the US. Therefore similar questions can and have been raised regarding whether potential organ and tissue donors are aware that uterus donation is even an option and indeed, whether they may prove less willing to donate 'novel', 'experimental', 'non-vital', 'visible', and, indeed, 'controversial' organs and tissues after their death than they would be donate more common organs and tissues (Caplan et al, 2007; Williams, 2016, Woessner et al 2015). Given this, if we are minded to both respect the preferences of would-be organ donors, and preserve public trust in medicine by avoiding scandals such as that which occurred in the UK at Alder Hey in the 1990s, such authors suggest that it would be inappropriate to presume consent to uterus donation on the basis of an individual's recorded desire to donate 'any/all organs and tissues' on an organ donation register. Indeed, similar sentiments have been expressed with respect to face transplantation (Freeman & Jaoudé, 2006, 79-80) and other VCA's and both US OPTN/UNOS policy and NHS Policy in Wales reflect this concern by requiring that separate and specific authorisation be provided for VCA donation by either the donor themselves prior to death or their designed surrogate/proxy (OPTN, 2017; NHSBT, 2013).

That individuals often hold complex preferences regarding organ donation is easily illustrated by reference to the UK's NHS Transplant Activity Report. For, although the 2017 report shows that 88% of registered donors are willing to donate all organs and tissues posthumously, a significant minority of 12% exhibit more complex preferences with 90% of that minority proving unwilling to donate their corneas and over 20% refusing to donate pancreases, hearts and lungs (NHS, 2017). Yet, despite a lack of awareness regarding VCA donation it is also important not to presume that willingness to donate VCA's post-mortem is likely to be far lower than in cases of other 'more common' organs and tissues. Indeed, a 2014 survey looking to preferences and rationales for organ donation among 1027 individuals in New Jersey showed that although respondents were more willing to donate solid organs than VCA's, the percentage willing to donate for some or all VCA's was far higher than might have been assumed. For, of the 69.7% of respondents willing to donate upon death were also happy to donate for some or all VCA's. In the case of uterus donation this amounted to 60% of female respondents, a percentage not much lower than the 65% willing to donate their cornea's and higher than those willing to donate hands (54.6%) and faces (44%) (*Sarwer et al*, 2014, p. 26).

Yet, while it seems reasonable to hold that separate consent for VCA donation should currently be required in the context of UTx, Bruno and Arora make a further claim that I suggest is both mistaken and mysterious and would serve to unnecessarily limit the pool of potential deceased uterus donors. I refer here to their claim, following Woessner et al (2015), that surrogate or proxy consent is currently inappropriate for deceased uterus donation and

thus that uteri should only be retrieved from donors who have expressed a desire to donate whilst living (Bruno and Arora, 2018, 9 & 23). In making this claim, and justifying it by appeal to a lack of evidence regarding "public attitudes toward uterus transplantation, and donor's views of uterus donation" Bruno and Arora take a remarkably narrow view of the role that surrogate decision makers should play in post-mortem organ donation decision-making. For, they seem to view the surrogate's role as encompassing little more than the job of 'reporting' the donation preferences of the recently deceased.

In cases where a decedent has competently, completely, and clearly expressed their preferences either formally or informally regarding post-mortem organ donation prior to their deaths this should indeed be the primary role of surrogates, especially in highly individualist societies such as the USA. However, in many cases, the role played by surrogates is complicated by a number of factors. Foremost amongst these, for the purpose of this commentary is that surrogates are often in possession of incomplete information regarding the decedent's donation preferences. This may, for example, be because the donor has never considered donation and thus lacks any interests either in or against its performance, because the donor has failed to reveal their preferences to others, or, as is the case here, because (whether or not a donor card has been signed) consent is sought for an uncommon purpose or novel form of transplant.

In the former cases, however, it is not generally held that a designated surrogate will not be able to reach a decision as to whether donation should proceed. Instead, in such cases the surrogate's role extends beyond mere reporting, and into the realm of substituted judgement. Here, the surrogate attempts (albeit necessarily imperfectly) – using their knowledge of the potential donor's personality, previous actions, and interests – to 'don the mental mantle' (Beauchamp & Childress, 1994, p. 171) of the decedent and make a decision regarding whether or not they would have desired to donate. Individual preferences regarding organ donation do not arise *ex nihilo*, but from a particular psychology and set of beliefs. Thus, *if* it is deemed possible and appropriate for surrogates to make donation decisions on the behalf of the deceased in other circumstances why then, should the same approach not extend to surrogate decision making in the case of UTx?

It may, perhaps, at least in certain cases, be *harder* for a surrogate to make a decision regarding uterus donation than to make a decision regarding the donation of more common organs and tissues. In such cases the surrogate should arguably err on the side of caution especially if one believes that to fail to remove organs/tissues from willing donors is a less grievous act than removing them from those who are unwilling. It is, however, no less possible for a surrogate to determine a decedent's preferences than in other donation contexts. Thus, if a surrogate should be confident to determine a would-be solid organ donor's preferences from his knowledge of the donor, surrogates of known anti-natalists may feel similarly secure in their belief that the deceased would likely have objected to uterus donation and surrogates of those who expressed a lack of concern for their bodies after their death may just as safely assume that their loved one would express no objection to uterus donation.

Bibliography

Beauchamp, T. L. & J. F. Childress. 1994. *Principles of Biomedical Ethics*, 4th ed. Oxford: Clarendon Press.

Bruno, B. S. & K. S. Arora. 2018. "Uterus Transplantation: The Ethics of Deceased vs. Living Donors" *Forthcoming in American Journal of Bioethics*.

Caplan, A. L., C. Perry, L. A. Plante, J. Saloma, & F. R. Batzer. 2007. "Moving The Womb" *Hastings Centre Report* 37 (3): 18-20.

Freeman, M., & P. A. Jaoudé. 2006. "Justifying surgery's last taboo: the ethics of face transplants" *Journal of Medical Ethics*. 33: 76-81.

NHS. 2015. "History of Donation." Available at: https://www.nhs.uk/Tools/Documents/transplant.htm [accessed 8th May 2018].

NHS Blood and Transplant. 2015. "Questions and Answers on the Human Transplantation Wales Act 2013. Available at: http://odt.nhs.uk/pdf/INF1295.pdf [accessed 8th May 2018].

NHS Blood and Transplant. 2017. "Organ Donation and Transplantation Activity Report 2016/17. Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4657/activity_report_2016_17.pdf

Organ Procurement and Transplantation Network. ND. "Guidance to Organ Procurement Programs (OPOs) For VCA Deceased Donor Authorisation" Available at: https://optn.transplant.hrsa.gov/media/1137/vca_donor_guidance.pdf [accessed 8th May 2018].

Sarwer, D. B. S. Ritter, K. Reiser, J. C. Spitzer, B. M. Bauman, S. N. Patel, A. J. Mazarelli, L. Scott Levin, S. Doll & A. L. Caplan. 2014. "Attitudes Toward Vascularised Composite Allotransplantation of the Hands and Face in an Urban Population, *Vascularised Composite Allotransplantation*. 1 (1/2): 22-30.

Williams, N. J. 2016. "Should Deceased Donation Be Morally Preferred in Uterus Transplantation trials?" *Bioethics* 30 (6): 415-424.

Woessner, J., V. Blake, and K. S. Arora. 2015. Ethical Considerations in Uterus Transplantation. *Medicolegal and Bioethics*. 5: 81-88.