

Institution: University of Sussex
Unit of Assessment: UoA 23 Sociology
Title of case study: Negotiating human bodies and improving donation policies
<p>1. Summary of the impact</p> <p>Work by Farsides has had a significant impact on public policy and professional practice and has led to measurable improvement in outcomes. Farsides' research has contributed to an increase of 50 per cent in organ donations. Her work has facilitated the resolution of ethical issues for clinicians caring for potential organ donors, for example through the establishment of an ethical framework for caring for donors after circulatory death. In terms of embryo donation, her research has influenced current practice and policy around consent and payment for donation, and led to the revisiting of guidance relating to donation and freezing policies.</p>
<p>2. Underpinning research</p> <p>By combining rigorous empirical research and detailed normative enquiry within a number of highly qualified cross-disciplinary research teams, Farsides has been able to establish her position as an academic ethicist with a direct influence upon clinical practice and policy-making in health care and biomedicine.</p> <p>For the last thirteen years, her research has focused primarily on the experience of health-care professionals and scientists operating in morally contested fields of biomedicine. The research underpinning the impact described here has taken place at the BSMS/Sussex since 2006. Over a range of funded research projects (Wellcome Trust, National Institute for Health Research, Economic and Social Research Council), she has employed a novel methodological approach entailing the combination of mixed empirical methods and philosophical/medico-legal analysis. She introduced and developed the use of Ethical Discussion Groups (EDGs) [see Section 3, R1, R4] within the context of observational and interview-based studies. This is an approach whereby practitioners who have previously been interviewed and observed in their professional setting are invited to participate in a group discussion facilitated by an ethicist. The data collected from these interventions have highlighted issues that needed to be addressed and have contributed to identifying workable solutions to complex ethical, legal and clinical issues identified as important by practitioners in the field [R4, R5].</p> <p>In relation to embryos, Farsides' research has considered the attitudes and beliefs of those who work in Assisted Reproductive services, Embryology, and Stem Cell laboratories, particularly in relation to donation for research and treatment [R1, R2, R4, R5]. It has addressed questions of how and when to approach clients with regard to donation, how to define an embryo as 'spare', how to conceptualise and then acquire consent for the donation of embryos for treatment or research, and how best to construct robust regulatory and advisory frameworks [R5]. This work has been funded by the Wellcome Trust. This research has led to a significant number of peer-reviewed publications, all of which rely heavily on the data collected within the Ethical Discussion Groups led by Farsides. The findings have been particularly influential in prompting professional and regulatory bodies to revisit the basis upon which an embryo is defined as spare and thereby available for research. Through her work with the Nuffield Council on Bioethics, Farsides has also directly influenced the Human Fertilisation and Embryology Authority's (HFEA) position on payment for egg donation for treatment and research.</p> <p>With regard to solid-organ donation, Farsides has been a major expert contributor to the national debate regarding consent to donation. Her work has been highly influential, gaining support from individuals and bodies key to the development of donation strategy in the UK. Her defence of the current 'Opt-in' system and her innovative approach to the interpretation of best interest within a donation context have been widely acknowledged [R6].</p>
3. References to the research

- R1 Ehrich, K., Williams, C. and Farsides, B. (2008) 'The embryo as moral work object: PGD/IVF staff views and experiences', *Sociology of Health and Illness*, 30(5): 772–787.
- R2 Cribb, A., Wainwright, S.P., Williams, C., Michael, M. and Farsides, B. (2008) 'Towards the applied: the construction of ethical positions in stem cell translational research', *Medicine, Health Care and Philosophy*, 11(3): 351–361.
- R3 Tekola, F., Bull, S.J., Farsides, B., Newport, M.J., Adeyemo, A., Rotimi, C.N. and Davey, G. (2009) 'Tailoring consent to context: designing an appropriate consent process for a biomedical study in a low income setting', *PLoS Neglected Tropical Diseases*, 3(7): e482 +6pp.
- R4 Ehrich, K., Williams, C., Farsides, B. and Scott, R. (2011) 'Fresh or frozen? Classifying "spare embryos" for donation to human embryonic stem cell research', *Social Science and Medicine*, 71(12): 2204–2211.
- R5 Ehrich, K., Farsides, B., Williams, C. and Scott, R. (2011) 'Constructing an ethical framework for embryo donation to research: is it time for a restricted consent policy?', *Human Fertility*, 14(2): 115–121.
- R6 Farsides, B. (2012) 'Respecting wishes and avoiding conflict: understanding the ethical basis for organ donation and retrieval', *British Journal for Anaesthesia*, 108(Supplement 1): 173–179.

Outputs can be supplied by the University on request.

4. Details of the impact

Farsides' research has directly informed the development of policy and practice in relation to both solid-organ donation and transplantation and the donation and use of human embryos, eggs and sperm and other human tissue in scientific and clinical settings. Her empirical and theoretical work has informed both the high-level principles upon which guidance and recommendations have been based and the ground-level advice and guidance offered to practitioners [see Section 5, C1–C6].

Solid-organ donation

In 2008, the Organ Donation Taskforce (ODT) reported on barriers to organ donation and made recommendations to improve donation rates by 50 per cent. In 2013, NHS Blood and Transplant was able to announce that it had met that target. Farsides' research on the ethics of donation underpinned several of the reports and documents that cumulatively resulted in this improvement [C2–C6].

Opt-out

Following their main report, the ODT was charged by the Chief Medical Officer, Sir Liam Donaldson, to look at the issue of 'Opt-out' and Farsides was asked to chair an ethics sub-group. The group's report was seen as decisive in the Taskforce's decision not to support an Opt-out system for organ donation [C2]. However, the open tone and careful argument of the report were widely acknowledged even by proponents of the change, thus allowing the Taskforce to keep communications open with bodies such as the British Medical Association (BMA) who were campaigning heavily for an Opt-out system [C2–C6].

Donation after circulatory death

Farsides was the first ethicist appointed to the UK Donation Ethics Committee which has now published definitive guidance entitled *An Ethical Framework for Controlled Donation after Circulatory Death*. Farsides contributed by developing the substantive ethical content and in drafting recommendations to make them fit-for-purpose in the clinical setting. Her input relied not only on her research into organ donation but also on her longstanding research on end-of-life care more generally. This guidance addresses the specific legal and ethical issues faced by health-care professionals caring for potential organ donors which were identified in the original Taskforce report as a key obstacle to increasing levels of donation. The 50 per cent increase in donation

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required by the ODT and announced in 2013 is in large part due to the increased willingness and ability of staff to facilitate donation after circulatory death [C2–C6].

Embryo donation

In 2011 Farsides was appointed as a member of the Nuffield Council on Bioethics Working Party on Human Bodies in Medicine and Research; amongst other activities, she was responsible for drafting Chapter 5 of the report, which set out the substantive ethical framework informing the recommendations (with Tim Lewes, Cambridge University). The Council's report has already influenced key policy-makers, most notably the HFEA, which cited the influence of the Council's work when raising the level of payment to egg donors [C1]

Definition of 'spare' in the context of embryo donation

To ensure valid consent for the donation of embryos for treatment or research purposes, the embryo must first be defined as spare in a sense acceptable to the creating couple. The research [R4] has led us to an understanding that certain practices work against this principle. In turn these findings have informed subsequent work on the establishment of robust donation frameworks [R6; C1, C6].

National guidance on consent for donation in the context of stem-cell research

In 2013, Farsides was asked to Co-Chair a sub-group of SABTO, the Governmental Advisory Committee on the Safety of Blood Tissues and Organs, which was writing new national guidance relating to consent in the context of cell-based advanced therapies. The group relied heavily on the work reported from Farsides' Wellcome Trust-funded project 'A framework for the acquisition of embryos for research' [R2, R5, R6] which engaged directly with stakeholders in the field to attempt to establish a consensus approach to consent for the donation of embryos in the context of stem-cell research. Farsides established the ethical principles informing the guidance, enabling a workable document which gives due consideration to risk management, operational feasibility and ethical governance in a field that is growing in scientific, commercial and, hopefully, clinical importance [C7].

Good practice in egg, sperm and embryo donation

In 2012, Farsides was appointed to the HFEA's National Donation Strategy Group charged with investigating obstacles to egg, sperm and embryo donation and establishing guidance for good practice in clinics. She has worked with the Chair, Professor Sheila McClean, to establish the underlying ethical and legal principles informing the group's work and collaborated on the production of practical tools to enhance information provision and consent processes within clinics [C1]. Farsides' normative and empirical ethics research has allowed the group to provide clearly argued and evidence-based advice.

5. Sources to corroborate the impact

- C1** When describing her substantial contribution to the Nuffield Council's report on Human Bodies, the Director concluded 'In addition to Bobbie's conceptual contribution to the report, her wide-ranging practical experience of working with clinicians and others on donation issues was particularly valued in the Working Party, as an ethicist who understands and takes account of the real-life implications of their ethical analysis'. A view reiterated by the Head of Research and Policy at the HFEA, who reports that 'The HFEA find invaluable her ability to bring academic rigour and insight to an issue without losing sight of the human dimension. She is able to combine principle with practicality in a way which is enormously helpful to policy makers'. <http://www.nuffieldbioethics.org/news/hfea-approves-increased-compensation-egg-and-sperm-donors>
- C2** This is echoed in the comments of Chair of the UK Organ Donation Taskforce (ODT), who states: 'The recommendations, the support they received from all professions and the consequent success of the NHS in achieving the 50% increase in donors which we hoped for, was achieved in part because of the humanity, the reasoning from ethical principles and the common sense Bobbie Farsides brought to the debate, both round the Taskforce table and through the work of the Donation Ethics Committee'.

- C3** The National Clinical Director for Transplantation, writes: ‘She was a very influential member of the ODT established by the Secretary of State for Health in late 2006. ... It is no accident that the first major specific recommendation was to resolve ethical and legal concerns concerning donation, which are very well described in the Report as a result of Prof. Farsides’ contribution. Implementation of this Recommendation has been, in my opinion, fundamental to the 50% increase that has in fact been achieved by March 31st 2013’.
http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_june13.pdf
- C4** Chair of the UK Donation Ethics Committee reports that ‘It is this ability to translate the product of her knowledge, experience and research into the practical clinical arena which makes her contribution so valuable. Much of our work has centred around producing practical guidance to those involved in organ donation and transplantation
 (c.f. *An Ethical Framework for Controlled Donation After Circulatory Death* http://www.aomrc.org.uk/publications/reports-a-guidance/doc_details/9425-an-ethical-framework-for-controlled-donation-after-circulatory-death.html) and Bobbie contributes to this in a major way, both by writing, commenting and debating all the issues. Thus she and we are able to ensure not only that patients and their relatives in particular will understand what we are trying to do and feel that their decisions are reliable and informed, but equally that clinicians and healthcare staff are confident that their concerns and difficulties have been properly and sympathetically considered and addressed. I can easily think of a number of occasions when Bobbie’s comments made all the difference to how we wrote a particular piece of our guidance work, thus improving it considerably. She has represented us on a number of occasions and I know that she will give thoughtful, clear and unambiguous advice, which will be supportive of UKDEC and the work it is trying to do’.
- C5** These observations are further backed by Policy Lead Organ Donation, Department of Health, who states: ‘Professor Farsides’s research as a bioethicist has informed all these activities and as such has contributed to a significant increase in donation rates and transplantation rates over the last five years and the resolution of some long-standing ethical and medico-legal issues that previously proved a barrier to donation’.
Guidelines for Consent for Solid Organ Transplantation in Adults
https://www.organdonation.nhs.uk/pdfs/guidelines_for_consent.pdf
- C6** Head of the BMA Ethics Department observes that ‘Professor Farsides is a highly regarded and much valued member of the BMA Ethics Committee who makes a significant contribution to the views and materials produced by the committee. Professor Farsides’ input has been particularly influential on topics related to:
- organ donation – in particular, acting as an important link between the Organ Donation Taskforce and the BMA;
 - assisted reproduction – including work around restrictive embryo storage policies culminating in a meeting with the HFEA (which Professor Farsides will attend) seeking amendments to its code of practice to give priority to the clinical needs of patients;
 - medical ethics training – including significant input into an ethics “tool kit” for medical students produced by the MEC, which aims to give students a good, simple introduction to medical ethics but also to provide practical advice on some of the dilemmas that are specific to students (such as if they witness practice they consider to be unethical, the use of social media, and requests for medical advice from friends.’ (Available as an on-line resource at: <http://bma.org.uk/practical-support-at-work/ethics/medical-students-ethics-tool-kit>.)
- C7** Scientific Policy Manager, Cell Therapy and Regenerative Medicine Health Science and Bioethics Division, Department of Health, confirms to Prof. Farsides that she was ‘invited to be a member of the SaBTO Cell Based Advanced Therapies working group due to the essential expertise gained from your research ... and that, drawing on your previous research in this area, you agreed to Co-Chair a group to advise on issues relating to consent and traceability of donated material for cellular therapies’.