

**Impact case study (REF3b)**

<b>Institution:</b> University of Southampton
<b>Unit of Assessment:</b> 20 Law
<b>Title of case study:</b> 20-01 Guiding national policy on the regulation of health ethics
<p><b>1. Summary of the impact</b></p> <p>Research in Southampton Law School's Health Ethics and Law (HEAL) network has made a significant contribution to improving the way in which ethical issues in health are addressed in the UK and further afield. HEAL members' specialist research has informed several Department of Health policy documents and policy makers, as well as the strategies of organisations governing bioethics. Their recommendations have influenced professional guidelines for clinicians and lawyers, defining and underpinning good practice so as to protect and benefit service users. Increased understanding of ethical issues in health among the wider public has been promoted through high-profile media coverage.</p>
<p><b>2. Underpinning research</b></p> <p>The Health Ethics and Law (HEAL) Network comprises both researchers and practitioners. Established by Jonathan Montgomery (1984-) and Caroline Jones (2003-) in 2005, it collaborates to improve the way in which ethical and legal issues concerning health are addressed in the UK.</p> <p>The underlying principles were outlined in Montgomery's textbook Health Care Law [3.1], which for the first time examined how the law in England and Wales governed the full spectrum of health care, not merely medical ethics. It contended that sociological and political factors need to be considered alongside ethical arguments, arguing that health care law is an area in which analysis of the institutional context and governance structures is as important as substantive bioethical questions. This work was described by the Journal of Medical Ethics as 'some of the most important and interesting legal analysis of medical law as a discipline'.</p> <p>The notion that closer attention should be paid to how ethical issues are regulated by legal and other softer normative structures underpinned subsequent research led by Montgomery, Jones and Hazel Biggs, appointed at Southampton in 2009. Montgomery continued to develop his ideas around governance, including of ethical debates over assisted suicide and organ donation, publishing 7 book chapters and 8 journal papers between 2002 and 2013. His Reflections on the nature of public ethics, published in 2013 [3.2], reflected on his own experience as a member of the Organ Donation Taskforce, after it chose not to propose a 'presumed consent' model for organ donation, as well as other bodies and committees governing bioethics in the UK. He identified four areas for future consideration in the exploration of public ethics, including the need to take into account contemporary policy debates and to assess how positions will be represented in the media.</p> <p>Adopting a similar approach, Jones' research in 2005 centred on donor insemination and its implications for family law. A study of British lesbian families using licensed donor insemination explored the construction of implied bio-genetic links between donor-conceived children and co-mothers, and to co-mother's extended families. In her 2007 book she concluded that donor insemination requires developments in family law and new definitions of parenthood [3.3]. The research [3.4] widened to an analysis of the routes by which parliamentary bodies move from consultation to formulating public policy on the issue of assisted conception, revealing how the connection between consultation and policy is less objective than is often claimed. It also teased out the complexities and ambiguities of the legal provisions that resulted [3.5].</p> <p>Biggs' 2009 research [3.6] explored the relationship between law and ethics in the context of medical research in order to provide a practical guide for members of research ethics committees, which review around 6,000 research applications each year for the Health Research Authority. Later research [3.7] studied the implications of new guidelines published by the Director of Public Prosecutions for cases of encouraging or assisting suicide and suggested that a permissive</p>

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change in the law would provide better safeguards for those who seek assisted dying. Montgomery also examined the implications of this development for constitutional theory [3.8]

**3. References to the research**

- [3.1] Montgomery, Jonathan (2002) [Health care law. \(Second edition\)](#), Oxford, UK, Oxford University Press, 568pp. (First Edition 1997).
- [3.2] Montgomery, Jonathan (2013) 'The Nature of Public Health Ethics' 22(1) *Cambridge Quarterly of Healthcare Ethics* 9-21.
- [3.3] Jones, Caroline (2007) [Why donor insemination requires developments in family law: the need for new definitions of parenthood](#), Lewiston, US, Edwin Mellen Press, 328pp. (Hors Série).
- [3.4] Jones, Caroline (2008) [Exploring the routes from consultation to \(in\)forming public policy](#). In, Freeman, Michael (ed.) *Current Legal Issues: Law and Bioethics*. Law and Bioethics Colloquium Oxford, GB, Oxford University Press, 257-285.
- [3.5] Jones, Caroline (2011) The (im)possible parents in law. In, Lind, Craig, Keating, Heather and Bridgeman, Jo (eds.) *Taking Responsibility: Law and the Changing Family*. Aldershot, GB, Ashgate, 201-220.
- [3.6] Biggs, Hazel (2009) [Healthcare research ethics and law: regulation, review and responsibility](#), Abingdon, UK, New York, US, Canada, CA, Routledge-Cavendish, 206pp.
- [3.7] Biggs, Hazel (2011) [Legitimate compassion or compassionate legitimation? Reflections on the policy for prosecutors in respect of cases of encouraging or assisting suicide](#). *Feminist Legal Studies*, 19, (1), 83-92.
- [3.8] Montgomery, Jonathan (2011) [Guarding the gates of St Peter: life, death and law making](#). *Legal Studies*, 31, (4), 644-666. ([doi:10.1111/j.1748-121X.2011.00205.x](https://doi.org/10.1111/j.1748-121X.2011.00205.x)).

**4. Details of the impact**

The HEAL network at Southampton has over 70 members, comprising one third healthcare and law practitioners. Using research expertise developed by Montgomery, Jones and Biggs, HEAL has made a substantive impact on policymaking and professional guidance in the UK.

HEAL's responses to public consultations are often quoted. The Department of Health highlighted HEAL's conclusion that a relevant governance structure for prescribing was already in place in Summary of Public Consultation on Proposals to Introduce Independent Prescribing by Physiotherapists [5.1]. The equivalent report for podiatrists cited HEAL's view that proposals provided "good opportunities to ensure and enhance responsiveness to patient need" [5.2]. *Liberating the NHS* (2010 para 4.79) [5.3], quoted HEAL to support its policy that "consortia should have a key role in helping improve quality of GP services". The Nuffield Council on Bioethics cited HEAL's response in *Human Bodies* (2010 p.88) [5.4], noting "the demand for female egg donation is potentially limitless". Jones was a lead reviewer for the legal aspects of the NCoB's report *Novel Techniques for the Prevention of Mitochondrial DNA Disorders* (2012) [5.5].

Montgomery's research on bioethics governance (2002 ch 21; 2013) has informed the strategic plans of three key bodies that he has chaired, appointed in open national competition: the Human Genetics Commission (2009-12), Nuffield Council on Bioethics (2012-) and Health Research Authority (2012-) [5.6]. His work with the latter was commended by Lord Turnberg in the second reading of the Care Bill 2013 [5.7]. Montgomery has shared best practice with organisations overseas. Representing the NCoB, he spoke about the UK's approach to public ethics at a WHO meeting in Tunisia and to the Italian National Bioethics Commission [5.8].

HEAL hosted Robert Francis QC, within a month of his report on NHS failures in Mid-Staffordshire being published (in conjunction with law firm Hickman Rose and the Centre for Law, Ethics And

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Globalisation). This brought Southampton researchers and students together with senior NHS regional leaders to discuss the issues with Francis, and was used by Montgomery to provide a confidential briefing on what had been learned to senior civil servants and legal advisors supporting the formulation of the Government's response [5.9].

Montgomery's research on NHS law (2002 chs 3-5) and board-level experience in NHS organisations led to invitations to discuss legislative reform; including a keynote presentation to 250 opinion formers at Age Concern Hampshire's AGM, regular briefings to the Hampshire Senate on how changes would impact locally and participation in a "health leaders' roundtable", organised by Beachcroft Solicitors and Health Investor Magazine [5.10].

Southampton's research has informed professional guidelines. Biggs drew on her research to work with the General Medical Council on its Treatment and care towards the end of life (2010) [5.11], the most significant UK guidance on this area. Montgomery drafted the legal sections of the revised British Society for Human Genetics guidance Genetic Testing of Children (2010) [5.12] based upon his research into parents' and children's rights. This guidance is accepted as good practice and was the basis for the court's decision in *X CC v Y & Z* [2013] EWHC 953 (Fam) [5.13].

Biggs and Montgomery have researched when 'broad consent' might be legally effective. This led to Montgomery (with Professor Lucassen, HEAL member from Medicine) presenting proposals to the HGC in 2010, the Government's Human Genomics Strategy Group in 2011 [5.14], drafting chapter 8 (Developing the legal and ethical framework) of the latter's report, *Building on our inheritance: genomic technology in healthcare* [5.15] (2012) and participating in the group advising the Chief Medical Officer on ethical and legal issues of the 100,000 genome project (announced by the Prime Minister in December 2012) [5.16]. Biggs is Ethics Advisor to the Wales Cancer Bank Advisory Board [5.17].

Part of HEAL's impact strategy is to promote rigorous and informed public debate. The HEAL blog and Twitter feed [5.18] cover current issues, drawing on the members' research. Its 130-plus followers include the Daily Telegraph medical editor and sixth form students at a Leicestershire academy. The blog is designed to attract media enquiries. During the REF period, HEAL members have given interviews to Radio 4's Today programme, Radio Five Live, Sky and BBC News, as well as local television and radio. The front page of the Times on November 24, 2009 [5.19] quoted Montgomery discussing the HGC's report on the forensic DNA database (also covered in the Guardian). The Daily Mail quoted from Biggs' Today Programme interview on 12 July 2013 [5.20]. In March 2012, Biggs took part in a public debate on euthanasia at the Brighton Dome, with an audience of over 120 [5.21], and Montgomery gave a public lecture at Portsmouth Cathedral on how faith groups could respond to the changing architecture of governance in bioethics [5.22].

**5. Sources to corroborate the impact**

5.1 Department of Health consultation (2012, p.36), *Summary of Public Consultation on Proposals to Introduce Independent Prescribing by Physiotherapists*

<http://www.dh.gov.uk/health/files/2012/07/Physiotherapist-Consultation-Summary.pdf>

5.2 Department of Health (2011. P. 15), *Summary of Public Consultation on Proposals to Introduce Independent Prescribing by Podiatrists* <http://www.dh.gov.uk/health/files/2012/07/Podiatrist-Consultation-Summary.pdf>

5.3 Department of Health white paper (2010) , *Equity and Excellence: Liberating the NHS* <https://www.gov.uk/government/publications/liberating-the-nhs-white-paper>

5.4 Nuffield Council on Bioethics report (2011), *Human Bodies: donation for medicine and research* <http://www.nuffieldbioethics.org/donation>

5.5 Nuffield Council on Bioethics report (2012), *Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review* <http://www.nuffieldbioethics.org/mitochondrial-dna->

disorders

- 5.6 Department of Health, press release (12 June 2012) <http://www.dh.gov.uk/health/2012/06/hra-chair/>
- 5.7 Lord Turnberg – Hansard HL, 21 May 2013 : Column 817 - <http://www.publications.parliament.uk/pa/ld201314/ldhansrd/text/130521-0002.htm>
- 5.8 <http://www.palazzochigi.it/bioetica/eng/Conference2012.html>
- 5.9 The NHS in crisis? Legal aspects of the Mid-Staffs inquiry into needless deaths - summary and webcast of Robert Francis QC in conversation with Professor Jonathan Montgomery [http://www.southampton.ac.uk/law/news/2013/04/07\\_the\\_nhs\\_in\\_crisis.page](http://www.southampton.ac.uk/law/news/2013/04/07_the_nhs_in_crisis.page)
- 5.10 Health Investor Round Table (March 2011), *All change: Understanding the rules in the new health landscape*
- 5.11 General Medical Council (2010) *The development of treatment and care towards the end of life: good practice in decision making* [http://www.gmc-uk.org/Story\\_of\\_the\\_EoL\\_guidance2.pdf](http://www.gmc-uk.org/Story_of_the_EoL_guidance2.pdf) 32510823.pdf
- 5.12 British Society for Human Genetics (2010), *Report on the Genetic Testing of Children* [http://www.bsgm.org.uk/media/678741/qtoc\\_booklet\\_final\\_new.pdf](http://www.bsgm.org.uk/media/678741/qtoc_booklet_final_new.pdf)
- 5.13 X CC v Y & Z [2013] EWHC 953 (Fam). <http://www.bailii.org/ew/cases/EWHC/Fam/2013/953.html>
- 5.14 Minutes of Human Genomics Strategy Group (HGSG) (Fourth) meeting Wednesday 13th June 2011 para 5.9ff
- 5.15 Human Genomics Strategy Group, *Building on our inheritance: genomic technology in healthcare* (2012) chapter 8 (Developing the legal and ethical framework) <https://www.gov.uk/government/publications/genomic-technology-in-healthcare-building-on-our-inheritance>
- 5.16 Downing Street Press Release December (2012) *DNA tests to revolutionise fight against cancer and help 100,000 NHS patients* <https://www.gov.uk/government/news/dna-tests-to-revolutionise-fight-against-cancer-and-help-100000-nhs-patients>
- 5.17 Wales Cancer Bank Advisory Board <http://www.walescancerbank.com/organisation.html>
- 5.18 HEAL blog <http://healuos.wordpress.com/> and Twitter feed <https://twitter.com/HEALUoS>
- 5.19. The Times (London) 24 November 2009, page 1: “Arrests are being made ‘to expand DNA files’”
- 5.20 <http://www.dailymail.co.uk/news/article-2359972/Organ-donors-jump-transplant-waiting-list-NHS-plans-boost-donations.html>.
- 5.21 Sussex Salon Series programme.
- 5.22 Public lecture “Whose ethics are bioethics” by Jonathan Montgomery, given at Portsmouth Cathedral (2012) <http://eprints.soton.ac.uk/339932/>.