

Institution: De Montfort University
Unit of Assessment: 20
Title of case study: LEGAL AND ETHICAL ASPECTS OF HUMAN ORGAN TRANSPLANTATION
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>This Case Study describes, <i>inter alia</i>, the late Professor David Price's sustained research in the broad field of organ transplantation, from which a substantial knowledge base and research expertise was developed. Its principal focus was on the availability and supply of human organs and tissue for transplantation, the continuing shortages thereof and the implications of shortfalls on quality and loss of life. This work has led to demonstrable policy and practice developments at national and international levels. Collaboration with policy makers, academics and health professionals across Europe has resulted in legislative developments and changes to policies and professional practice.</p>
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>The desperate need for organs sufficient to meet demand requires robust ethical and legal initiatives designed to increase supply. David Price worked at DMU for 34 years until his death in 2012, rising through the ranks to be appointed Professor of Medical Law in 1997. His research provides a balanced appraisal of contentious matters such as presumed consent laws, property rights and commercial dealings in body parts [1]. His work has been recognised by Government, policy makers and Funders, as evidenced by his national and international appointments. The research that underpins this case study includes analyses of laws and policies, empirical work, formulation of policies and strategies, advice and guidance to official bodies and collaborative professional development activities with transplant-related health professionals.</p> <p>The first major project was the European Multicentre Study of Transplantation of Organs from Living Donors: the Ethical and Legal Dimensions in 1993. This 27-month collaboration with the Department of Surgery at the University of Leicester received European Commission funding [2]. Price, who was joint grant holder with Peter Donnelly of University of Leicester, was Chair of the Project Management Group for two years. He interviewed living donors and recipients around Europe, as well as politicians, civil servants and transplant clinicians. A survey was undertaken to assess donor health and transplant unit screening policies followed by analysis and evaluation of European laws and their underpinning ethical theories. The Project culminated in a co-authored Report for the European Commission: <i>Questioning Attitudes to Living Organ Donation</i> (1997).</p> <p>On account of his esteem as a researcher Price was invited to join the World Health Organisation Task Force on Organ Transplantation (1996). This appointment was the impetus for several further invitations to join national and international bodies and working parties. His membership of these bodies facilitated the dissemination of his research and its impact on policy and society.</p> <p>Price was invited to join the Retained Organs Commission working group. The Commission was set up to develop, <i>inter alia</i>, a new regulatory regime for organ and tissue retention. His membership involved reviewing regulatory structures and advising the Department of Health [3].</p> <p>Price was a founding member of the European Expert Group on Ethical, Legal and Psychosocial Aspects of Transplantation (ELPAT) in 1997. He was the external reviewer for the Report on Xenotransplantation (Department of Health, 2003) and was Working Group Chair/core participant for the Department of Health Consensus Meeting [4]. He was the lawyer for the NHS Blood and Transplant Group on Guidelines for Consent to Organ Transplantation [5]. In 2009, he conducted research for the design and delivery of the national Professional Development Programme for Organ Donation (NHS Blood & Transplant) and delivered a Masterclass at the Launch Event in 2010.</p> <p>Price's work is continued and developed by several protégés including Farrell and Quigley, with whom he collaborated on an ESRC project. This culminated in an edited collection [5]. He supervised Garwood-Gowers' thesis 'An investigation into the ethical and legal aspects of liver donor organ transplantation.' Garwood-Gowers has since published widely and has international recognition in his field. Price was mentor to several colleagues, including Samanta, who co-authored 'Supporting Controlled Non-Heart-Beating Donation: An Ethical Justification' Cambridge Quarterly of Healthcare Ethics (2013). She took over as Principal Investigator for his AHRC networking grant: "The Influence of Faith and Belief on the Formulation, Content and Operation of Health Law in the United Kingdom" (Grant Ref: AH/I026448/1).</p>

3. References to the research (indicative maximum of six references)

1. Price D. *Legal and ethical aspects of organ transplantation*. Cambridge University Press, 2000.
2. £50K + PECO element of EUROTOLD project grant from the European Commission, 1993 (University of Leicester originally received £237,000 under its BIOMED Programme (Area 4); additional PECO award in 2006) Ref: BMH1-CT92-1841.
3. Department of Health. *Remembering the past, looking to the future: the Final Report of the Retained Organ Commission*. 2004. A copy can be made available upon request.
4. Department of Health, *Donation After Circulatory Death: Report of a consensus meeting* and endorsed by the Intensive Care Society and the British Transplantation Society (Report of a meeting held 7.6.10 at Wellington House, London)
<http://www.bts.org.uk/Documents/Guidelines/Active/DCD%20for%20BTS%20and%20ICS%20FINAL.pdf> (accessed 30/08/13)
5. NHS Blood and Transplant/British Transplantation Society, *Guidelines for Consent for Solid Organ Transplantation in Adults*, 12 March 2011.
http://www.organdonation.nhs.uk/pdfs/guidelines_for_consent.pdf (accessed 30/08/13) – Price is listed in Appendix A as a contributor to the report
6. Farrell A, Price D, Quigley M (eds.). *Organ Shortage: Ethics, Law and Pragmatism* (Cambridge University Press, 2011). This book was produced as part of an ESRC funded project.

4. Details of the impact (indicative maximum 750 words)

The primary contribution of Price's research has been its impact on the development of national and international policy to address the imbalance between the supply and demand for organs and tissues for transplantation. His most notable appointment and achievement was his membership of the Secretary of State's Organ Donation Taskforce. Following presentation of a scoping paper in 2008, David was invited to join the Taskforce as Deputy Chair of its Legal Working Group. The contributions of the group culminated in Annex C to the Report [1]. This Report, which included advice about future UK policy relating to consent to organ donation, was accepted subsequently in 2008 by all UK Governments.

Price's work for the Taskforce involved participation at public political deliberative events that were held around the country. Following the announcement of *The Potential Impact of an Opt Out System for Organ Donation in the UK* [1] in the House of Commons (17 November 2008 Column 1WS) the Government made available £4.5 million extra funding (2008 – 2010). This was used to sponsor a major public awareness campaign to increase organ donation rates and in April 2013 it was reported that deceased donation rates had risen by 50% since the Government's acceptance of the Taskforce's recommendations. The Welsh Assembly considered and relied heavily upon the findings of the Report in its deliberations about introducing a soft opt-out policy to apply to Wales.

Price's second notable appointment was to the Nuffield Council on Bioethics. The Nuffield Council is the most influential principal medical ethics body organisation in the UK. Price contributed to a significant and influential Report [2], which has impacted subsequently on policy development mainly in the areas of incentives to donation. Significant media coverage followed and a range of initiatives such as teaching resources for schools, which introduces the subject and considers different levels of intervention to encourage people to donate. The Council has used recommendations from the Report in evidence to the National Assembly for Wales Health and Social Care Committee on the Human Transplantation (Wales) Bill.

Price's appointments on Government bodies such as the NHS Blood and Transplant and the British Transplantation Society provide further evidence of his status and reputation in the field. Price acted as Chair for the Donation After Cardiac Death Consensus Meeting [3]. The key outputs and contributions of these bodies include: '*Donation After Circulatory Death*' [3] and influential professional development materials [4]. The Report [3] was included in the National Institute for Health and Care Excellence repository 'NHS Evidence', which is accessible and used by all NHS staff. Price participated in a House of Lords event in 2010 to inform parliamentarians of the salient aspects of donation following circulatory death [4]. The Professional Development Programme [5] was rolled out in 2010 to all NHS transplant professionals, 184 NHS Trust donation ethics committees and 194 clinical leads across the UK. The Joint Working Party of the British Transplantation Society and the Renal Association in "UK guidelines

for Living Donor Kidney Transplantation” (2011) recognised Price’s esteem and expertise by referring to his two monographs on transplantation.

Price was actively involved with the production of interdisciplinary clinical and policy guidelines for health professionals employed in the transplantation and intensive care fields. These guidelines, which are included in the National Institute for Health and Clinical Excellence repository ‘NHS Evidence’ were the collaborative efforts of clinicians, nurses and policy makers. Price’s role as legal advisor was to ensure that guidance was premised upon current law and ethical principles [6]. The guidelines have been recognised by the British Medical Association and the British Heart Foundation.

Price contributed two sections in the prestigious *The New Oxford Companion to Law* encyclopaedia, which is designed to reach and inform the public about complex areas in easily accessible terms [7].

5. Sources to corroborate the impact (indicative maximum of 10 references)

Proof that Price worked on the secretary of State’s Organ Donation Taskforce can be found from Annex B to the Report:

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312?IdcService=GET_FILE&dID=177206&Rendition=Web Annex C to the Report can be found at:

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090306.pdf

1. Secretary of State’s Organ Donation Taskforce, *The Potential Impact of an Opt Out System for Organ Donation in the UK*, 2008.

http://webarchive.nationalarchives.gov.uk/+http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312 (accessed 30/08/13)

A summary of the government’s investment as a consequence of the taskforce’s report and the subsequent increase in donated organs can be seen in a BBC report from the time – see <http://www.bbc.co.uk/news/health-22086086> (accessed 12/08/13).

Evidence that the report contributed to the development of the Welsh “soft opt-out” policy can be seen through this Parliament UK link from the 4th April 2011:

<http://www.publications.parliament.uk/pa/cm201011/cmselect/cmwelaf/896/896vw19.htm>

The “Working together to Save Lives” report, the Organ Donation Taskforce Implementation Programme’s Final Report from 2011 details the success of the taskforce both within the UK and internationally. This report can be accessed via <https://www.gov.uk/government/publications/working-together-to-save-lives> (accessed 12/08/13)

2. Member of the Nuffield Council on Bioethics’ Working Party for the Report *Human Bodies in Medicine and Research*, 2011.

This report can be accessed via www.nuffieldbioethics.org/sites/default/files/Donation_A5_booklet.pdf (accessed 12/08/13).

Evidence that Price was a member of the working party can be found in the following obituary: <http://www.nuffieldbioethics.org/news/professor-david-price-1954%E2%80%932012> (accessed 12/08/13) and more information about the working party can be found at <http://www.nuffieldbioethics.org/donation/donation-about-working-party-0> (accessed 12/08/13).

A summary of the media coverage described in section 4 can be found at <http://www.nuffieldbioethics.org/donation/donation-media-coverage> (accessed 12/08/13).

The advice given to the Human Transplantation (Wales) Bill can be seen at <http://www.nuffieldbioethics.org/news/council-gives-evidence-wales-organ-donation-bill> (accessed 12/08/13).

3. *Donation After Circulatory Death: Report of a consensus meeting* (endorsed by the Intensive Care Society and the British Transplantation Society) based on Working Group Chair and Rapporteur at meeting on 7.6.2010 at Department of Health, Wellington House, London

The report can be downloaded as a PDF from the NICE NHS evidence search engine, which can be accessed via <https://www.evidence.nhs.uk/nhs-evidence-content/nice-and-nhs-evidence> – the cited report was successfully accessed from this site on 12/08/13. Evidence for Price's involvement in these government bodies can be obtained e.g. from the Blood and Transplant and British Transplantation Society Guidelines, which can be provided upon request (see also reference 5 in section 3, and reference 6 in this section).

4. Bioethics in Parliament, Nuffield Council event, House of Lords, 17.10.2011

More information about this event can be seen on the following link:

<http://www.nuffieldbioethics.org/news/parliamentary-event-human-body-donation> (accessed 12/08/13).

5. The Design and delivery of the Professional Development Programme for Organ Donation by NHS Blood & Transplant on Legal Aspects Pertaining to Non-Heart-Beating Organ Donation was launched at a Masterclass presentation Launch Event, Britannia International Hotel, London 2010.

A copy of the powerpoint slides that were developed for the professional development programme for organ donation are available upon request. These NHS-branded slides clearly list David Price as the author and refer explicitly to his work for the organ donation taskforce, thus providing further evidence for this claim.

A PDF copy of the "UK guidelines for Living Donor Kidney Transplantation" can be made available upon request. Price is cited in the first two references in the report.

6. NHS Blood and Transplant/British Transplantation Society, *Guidelines for Consent for Solid Organ Transplantation in Adults*, 12 March 2011

The report can be downloaded as a PDF from the NICE NHS evidence search engine, which can be accessed via <https://www.evidence.nhs.uk/nhs-evidence-content/nice-and-nhs-evidence> – the cited report was successfully accessed from this site on 12/08/13.

These guidelines have been backed by the British Medical Association in their "Building on Progress: What next for organ donation policy in the UK?" report (2012). This report can be downloaded from <http://bma.org.uk/working-for-change/improving-and-protecting-health/organ-donation> (accessed 12/08/13) and also cites one of Price's monographs as the first reference (accessed 12/08/13).

The British Heart Foundation's Policy statement (2012)

[Http://www.bhf.org.uk/pdf/Organ_donation_policy_statement_Mar2012.pdf](http://www.bhf.org.uk/pdf/Organ_donation_policy_statement_Mar2012.pdf) explicitly cites several of the reports listed above.

7. Price D, 'Human Tissue Act' and 'Organ retention', in Cane and Conaghan (eds) *The New Oxford Companion to Law*, 2008 Oxford: Oxford University Press, pp 564 and 855.

On Amazon, this is currently listed as the 11th best seller in Law. One of the reviews states that "Doing an LLM by distance learning and never having done law previously, I was getting slightly bogged down with some terminology. This book, like the Companion to Philosophy, provides much more than a dictionary of terms. I wish I'd bought it at the beginning of my course. No doubt with the law changing rapidly, it will require revision but certainly for now I would be struggling without it. Not cheap, but worth every penny." (accessed 12/08/13).