

Organ Shortage: Ethics, Law and Pragmatism

Organ shortage is an ongoing problem in many countries. The needless death and suffering which have resulted necessitate an investigation into potential solutions. This examination of contemporary ethical means, both practical and policy-oriented, of reducing the shortfall in organs draws on the experiences of a range of countries. The authors focus on the resolution and negotiation of ethical conflict, examine systems approaches such as the 'Spanish Model' and the US Breakthrough Collaboratives, evaluate policy proposals relating to incentives, presumed consent and modifications regarding end-of-life care, and examine the greatly increased use of (non-heart-beating) donors suffering circulatory death, as well as living donors. The proposed strategies and solutions are capable not only of resolving the UK's own organshortage crisis, but of being implemented in other countries grappling with how to address the growing gap between supply and demand for organs.

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#### Cambridge Law, Medicine and Ethics

This series of books was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law's complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organisations such as the WHO and UNESCO now regularly address issues of medical law.

It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. Organ retention, embryonic stem cell research, physician assisted suicide and the allocation of resources to fund healthcare are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and healthcare.

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Anne-Maree Farrell, David Price and Muireann Quigley Organ Shortage: Ethics, Law and Pragmatism



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Anne-Maree Farrell,
David Price

and
Muireann Quigley





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## **Abbreviations**

ABOi ABO blood group incompatible ACE angiotensin converting enzyme

AIDS acquired immune deficiency syndrome

AIT antibody incompatible living donor renal transplantation

ATR angiotensin receptor blockers

BBSRC Biotechnology and Biological Sciences Research

Council (UK)

BME black and minority ethnic

CCDT Canadian Council for Donation and Transplantation

DCD donation after cardiac death

DMV Department of Motor Vehicles (USA)

DSA donor specific antibody
ECD expanded criteria donor
ESRF end-stage renal failure
EU European Union

HIV human immunodeficiency virus

HLA human leukocyte antigen

HLAi human leukocyte antigen incompatible HLH haemophagocytic lymphohistiocytosis HTA Human Tissue Authority (UK)

ICU intensive care unit KPD kidney paired donation

LDT living donor organ transplantation MHC major histocompatibility complex

NCCUSL National Conference of Commissioners of Uniform

State Laws (USA)

NDFC National Donor Family Council (USA)

NHBD non-heart-beating donors NHS National Health Service (UK)

NHSBT National Health Service Blood and Transplant (UK)

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More information

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NHSBT-ODT National Health Service Blood and Transplant – Organ Donation and Transplantation Directorate

(UK)

NICE National Institute for Health and Clinical Excellence

(UK)

NOTA National Organ Transplant Act (USA)
NSF National Service Framework (UK)
OMC Open Method of Co-ordination (EU)

ONT Organización Nacional de Trasplantes (Spain)
OPO Organ Procurement Organization (USA)

PDA Potential Donor Audit (UK)
PGD pre-implantation genetic diagnosis

PMP per million population

QOF Quality and Outcomes Framework (UK)

RCIDT Red/Consejo Iberoamericano de Donación y Trasplante

(Latin America)

RRT renal replacement therapy

UAGA Uniform Anatomical Gift Act (USA)

UK United Kingdom USA United States

WHO World Health Organization



## Table of cases

#### **England and Wales**

Felthouse v. Bindley (1862) CB(NS) 869

R v. Sussex Justices, ex parte McCarthy [1924] 1 KB 256

Cassidy v. Ministry of Health [1951] 2 KB 343

Barnett v. Chelsea & Kensington Hospital Management Committee [1969] 1 QB 428

Collins v. Wilcock [1984] 1 WLR 1172, 1178 (CA)

Re F (mental patient: sterilisation) [1990] 2 AC 1

Re A (A Minor) [1992] 3 Med LR 303

Airedale NHS Trust v. Bland [1993] AC 789

Re Y (mental patient: bone marrow donation) [1997] 2 WLR 556

Capital & Counties plc v. Hampshire County Council [1997] QB 1004

Re A (medical sterilisation: male sterilisation) [2000] 1 FCR 193

Re S (adult patient: sterilisation) [2001] Fam 15

Kent v. Griffiths [2001] QB 36

R (on the application of N) v. M and others [2003] 1 WLR 562

Burke v. General Medical Council [2005] EWCA Civ 1003

Ahsan v. University Hospitals of Leicester NHS Trust [2007] PIQR P19

#### **United States**

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Kelly-Nevils v. Detroit Receiving Hosp., 526 NW 2d 15 (Mich. App. 1995)

Ramirez v. Health Partners of Southern Arizona, 972 P 2d 658 (Ariz. App. 1999)

Schembre v. Mid America Transplant Ass'n, 135 SW 3d 527 (Mo. App. 2004)

Carey v. New England Organ Bank, Inc., 843 NE 2d 1070 (Mass. 2006) Montalto et al. v. Stoff et al., MA Sup. Ct. CA NO. 03-00557 (2007)

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#### Canada

The Constitution Act, 1867 30 & 31 Victoria, c. 3. (UK) Human Tissue Gift Act, R.S.S. 1978 Criminal Code, R.S.C. 1985 Canada Health Act, R.S.C. 1985 Food and Drug Act, R.S.C. 1985 Human Tissue Gift Act, C.C.S.M. 1987 Human Tissue Act, R.S.N.W.T. 1988 Human Tissue Donation Act, R.S.P.E.I. 1988 Human Tissue Gift Act, R.S.N.S. 1989 Human Tissue Act, R.S.N.L. 1990 Trillium Gift of Life Network Act, R.S.O. 1990 Civil Code of Quebec, S.Q. 1991 Human Tissue Gift Act, R.S.B.C. 1996 Human Tissue Gift Act, R.S.A. 2000 Human Tissue Gift Act, R.S.Y. 2002 Human Tissue Gift Act, S.N.B. 2004

#### Council of Europe

Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24 January 2002

#### **European Union**

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and

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blood components and amending Directive 2001/83/EC (OJ L 33, 8 February 2003)

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7 April 2004)

Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6 August 2010)

#### Italy

Law 91/1999, 1 April, on the retrieval and transplantation of organs and tissues (*Legge 91/1999*, 1 Aprile, di disposizioni in materia di prelievi e di trapianti di organi e di tessuti)

#### Nordic countries

- Act relating to Transplantation, Hospital Autopsies and the Donation of Bodies (*Lov om transplantasjon, sykehusobduksjon og avgivelse av lik m.m.*), Nr. 6 of Statutes, 9 February 1973
- Act on Transplantation (*Lag om transplantation m.m.*), Nr. 831 of Statutes, 8 June 1995
- Regulations and General Guidelines by the Swedish National Board of Health and Welfare (Socialstyrelsens föreskrifter och allmänna råd) 1997:4, Removal of organs and tissue for organ transplantation and other medical purposes (Organ-och vävnadstagning för transplantation eller för annat medicinskt ändamål)
- Governmental Bill to amend the Act on the Medical Use of Human Organs and Tissues Nr. 93 of 2000
- Health Act (Sundhedsloven), Nr. 546 of Statutes, 24 June 2005, Part IV, Chapter 12
- Governmental Bill to amend the Act on the Medical Use of Human Organs and Tissues Nr. 276 of 2009
- Act on the Medical Use of Human Organs and Tissues (*Laki ihmisen elimien ja kudoksien lääketieteellisestä käytöstä*) Nr. 101 of Statutes, 2 February 2001 (as amended up until June 2010)

### Spain

Law 30/1979, 27 October, on organ extraction and transplant (*Ley 30/1979*, *de 27 de octubre*, *sobre extracción y trasplante de órganos*)



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- Royal Decree 426/1980, 22 February, on organ extraction and transplant (Real Decreto 426/1980, de 22 de febrero, sobre extracción y trasplantes de órganos) (abolished by Royal Decree 2070/1999)
- Law 29/1980, 21 June, on clinical autopsies (Ley 29/1980, de 21 de junio, por la que se regulan las autopsias clínicas)
- Royal Decree 2230/1982, 18 June, on clinical autopsies (*Real Decreto 2230/1982*, de 18 de junio, por el que se regulan las autopsias clínicas)
- Law 35/1988, 22 November, on human assisted reproduction techniques (Ley 35/1988, de 22 de noviembre, de regulación de las técnicas de reproducción asistida humana) (abolished by Law 14/2006)
- Law 42/1988, 28 December, on donation and use of human embryos and foetuses, or their cells, tissues and organs (*Ley 42/1988*, *de 28 de diciembre*, *de donación y utilización de embriones y fetos humanos o de sus células*, *tejidos u órganos*) (abolished by Law 14/2007)
- Royal Decree 2070/1999, 30 December, which regulates the activities of procurement and clinical use of human organs and territorial coordination in matters of organ and tissue donation and transplantation (Real Decreto 2070/1999, de 30 de diciembre, por el que se regulan las actividades de obtención y utilización clinica de órganos humanos y la coordinación territorial en materia de donación y trasplante de órganos y tejidos)
- Civil Law of Criminal Procedure, 2000 (Ley de Enjuiciamiento Civil, 2000) Law 41/2002, 14 November, on patients' autonomy, and rights and obligations with regard to information and documentation (Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación básica)
- Royal Decree 1088/2005, 16 September, on the technical requirements and necessary conditions for blood donation and regulation of blood transfusion centres and services (Real Decreto 1088/2005, de 16 de septiembre, por el que se establecen los requisitos técnicos y condiciones mínimas de la hemodonación y de los centros y servicios de transfusión)
- Law 14/2006, 26 May, on human assisted reproduction techniques (*Ley 14/2006*, de 26 de mayo, reguladora de las técnicas de reproducción asistida humana)
- Royal Decree 1301/2006, 10 November, which establishes rules for quality and security for donation, obtaining, evaluating, processing, preserving, storing and distributing human cells and tissues, and rules on co-ordination and functioning for human use (Real Decreto 1301/2006, de 10 de noviembre, por el que se establecen las normas de calidad y seguridad para la donación, la obtención, la evaluación, el procesamiento, la preservación, el almacenamiento y la distribución de células y tejidos humanos



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y se aprueban las normas de coordinación y funcionamiento para su uso en humanos)

Law 14/2007, 3 July, on biomedical research (*Ley 14/2007*, *de 3 de Julio*, *de investigación biomédica*)

Royal Decree 1825/2009, 27 November, which approves the statutes of the ONT (*Real Decreto 1825/2009*, *de 27 de noviembre*, *por el que se aprueba el estatuto de la Organización Nacional de Trasplantes*)

#### **United Kingdom**

Anatomy Act 1832 Human Organs Transplant Act 1989 Adults with Incapacity (Scotland) Act 2000 Human Tissue Act 2004 Mental Capacity Act 2005 Human Tissue (Scotland) Act 2006 Human Tissue Act 2004 (Persons who Lack)

Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (SI 2006 No. 1659)

#### **United States**

Uniform Anatomical Gift Act (1968) UNOS Bylaws, 23 March 2007

#### Recommendations

Council of Europe

Council of Europe, Recommendation Rec (2005) 11 of the Committee of Ministers to Member States on the role and training of professionals responsible for organ donation (transplant donor co-ordinators) (adopted 15 June 2005)

Latin America

Recommendation Rec RCIDT 2005 (2) on the role and training of professionals responsible for organ donation (transplant donor co-ordinators)

Recommendation Rec RCIDT 2005 (3) on the functions and responsibilities of a national transplant organisation