

Impact case study (REF3)

Institution: Keele University		
Unit of Assessment: UoA18 Law		
Title of case study: Integrating Ethics into Policy and Practice for Issues on the Margins of Life		
Period when the underpinning research was undertaken: 2014-2018		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): Professor Anthony Wrigley	Role(s) (e.g. job title): Professor of Ethics	Period(s) employed by submitting HEI: 2002 - Present
Period when the claimed impact occurred: 2014 - Present		
Is this case study continued from a case study submitted in 2014? No		
1. Summary of the impact (indicative maximum 100 words)		
<p>The beginning and ending of life generate challenging regulatory and ethical issues for medicine, science, and society. Identifying ethical concerns and providing guidance in these areas is vital for good practice, regulation and policy. Research by Wrigley <i>et al</i> in the ethics of genome editing, new reproductive technologies, and end-of-life care has:</p> <ol style="list-style-type: none"> 1. Influenced national and international policy formation (e.g., through forming evidence to parliamentary enquiries; and contributing to consultations and policy documents for science advisory bodies). 2. Contributed to enhancing professional practice and public understanding (e.g., through influencing practitioner guidance, coverage in national and international media, and stakeholder engagement). 		
2. Underpinning research (indicative maximum 500 words)		
<p>Wrigley <i>et al</i>'s research has provided a basis for establishing ethically well-grounded guidance for policy positions and professional practice by directly addressing major ethical and conceptual concerns in a way that informs and directs how policy makers, professionals, and the public can engage with the challenging regulatory and ethical issues concerning the beginnings and end of life.</p> <p>This research has provided critical insights in the fields of medicine and biomedical science into two new areas of development – genome editing and mitochondrial replacement techniques – through identifying key ethical and conceptual issues underpinning them and developing frameworks for their use:</p> <p><u>Genome editing</u> is a new scientific technique that can precisely modify genes in a permanent way, including potentially heritable changes. Selecting genetic traits by permanently altering human DNA (or that of animals or plants) raises significant ethical issues, including the health and welfare of future people; social justice; scientific freedom; and the future of the global ecosystem.</p> <p><u>Mitochondrial replacement technologies</u> are a new development in assisted reproductive medicine that seeks to avoid life-limiting mitochondrial genetic diseases being passed from mother to baby. The techniques involve permanent and potentially heritable changes to human DNA and challenge many received views of parenthood by utilising genetic material from a third donor.</p> <p>At the other end of the margins of life spectrum, research on ethical issues at the <u>end of life</u> has provided critical ethical analysis of bereavement and end-of-life care policy in both medical and criminal justice settings. This has included critical analysis of national policy concerning the <u>Liverpool Care Pathway for the Dying Patient</u> (LCP). The LCP, developed by the Marie Curie</p>		

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Palliative Care Institute, Liverpool, was designed to assist practitioners to offer the best palliative care to dying patients. Misapplication of the pathway led to media scandals and an independent governmental review. The government accepted the resulting (2013) Neuberger report's recommendations that the Pathway be phased out of use. Wrigley's research [3.5] offered a critical analysis of this report, raising concerns over its errors of inference and ethical judgements. End-of-life research has also generated important practitioner-focused guidance on bereavement for those working with vulnerable young people.

In summary:

1. Research [3.1; 3.2] carried out between 2014 and 2018 (by Wrigley with co-researcher Newson), critically revised the conceptual classification of mitochondrial replacement as genetic therapy, as well as establishing the ethical and social implications of developing and using new genome editing techniques in medicine and the biosciences.
2. Research [3.3; 3.4] carried out between 2014-2018 (by Wrigley with co-researchers Newson, Wilkinson and Appleby) generated approaches to classification and ethical arguments for establishing the permissibility of mitochondrial replacement techniques as a reproductive technology.
3. Research [3.5; 3.6] carried out between 2014-2018 (by Wrigley with co-researchers Read & Santatzoglou) raised critical concerns surrounding ethical approaches to end-of-life care. Research included policy critique over the misuse of professional best-practice guidance and a grant-funded project from the Barrow-Cadbury Trust, developing a guide for practitioners working with young people in prisons facing issues of loss and bereavement.

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

3.1 Newson, A.J. & **Wrigley, A.** (2017) "Is Mitochondrial Donation Germ-Line Gene Therapy? Classifications and Ethical Implications" *Bioethics*, 31.1: 55-67.

3.2 Newson, A.J. & **Wrigley, A.** (2016) "Being Human: The Ethics, Law, and Scientific Progress of Genome Editing", *Australian Quarterly*, The Australian Institute of Policy and Science, Vol. 87, Issue 1, pp. 3-8.

3.3 Newson, A.J., Wilkinson, S. & **Wrigley, A.** (2016) "Ethical and legal issues in mitochondrial transfer" *EMBO Molecular Medicine*, 8: 589-591.

3.4 **Wrigley, A.**, Wilkinson, S. & Appleby, J. (2015) "Mitochondrial Replacement: Ethics and Identity" *Bioethics* 29.9: 631-638.

3.5 **Wrigley, A.** (2015) "Ethics and End of Life Care: the Liverpool Care Pathway and the Neuberger Review" *The Journal of Medical Ethics* 41: 639-643.

3.6 Read, S., Santatzoglou, S. & **Wrigley, A.** eds. (2018) *Loss, Dying and Bereavement in the Criminal Justice System* (London & New York: Routledge)

Evidence of Quality

All the journal articles, Nuffield Council report [5.1], and the book published by Routledge [3.6] were subject to peer review.

The research for [3.6] was supported by the following grant funding:

- **2015 - Wrigley, A.** (PI and sole award recipient) - Philosophy of Hope and Optimism Funding Initiative for Philosophy Non-Residential Fellowship, "Hope and Death: Despair and Absolute Hope in the Face of Inevitable Death" (Templeton Foundation administered via the Universities of Notre Dame and Cornell, USA) \$65,500 [£46,988]
- **2016 - Wrigley, A.** (co-lead CI on grant with PI Prof S. Read and CI S. Santatzoglou) - Barrow Cadbury Trust, "Integrating Loss and Bereavement Assessment" (£19,735)

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

Impact on national and international policy development for new genetic and reproductive technologies in the areas of genome editing and mitochondrial replacement techniques

National policy impact stems from work with the *Nuffield Council on Bioethics* (NCoB) – on the issue of genome editing. Wrigley's background paper for the NCoB [5.1] identified many of the major ethical challenges raised by this new technology and formed the foundation for NCoB's dedicated working group to explore the issue as a major project. The findings of the first stage of this project have been published as a policy report [5.2].

This project formed part of the basis for a joint statement of the ethics advisory councils of Germany, France, and the UK (2016) [5.3]. Wrigley was also invited as an expert for the NCoB consultation event (31/07/17) to develop guidance on the moral permissibility of genome editing. This consultation, together with Wrigley's research [3.4], is cited in NCoB's (2018) follow-up report on ethical and social issues [5.4].

The report and joint statement formed a policy report by NCoB [5.5a] utilised by the House of Commons' *Science and Technology Committee* (HCSTC 2017) [5.5b]. Impact followed from the UK government's response to the HCSTC that all research involving genome editing would be strictly regulated by the UK's Human Fertilisation and Embryology Authority [5.5c].

International policy impact: Wrigley's paper for NCoB [5.1] was cited by the Australian Federal Government's Department of Health *Gene Technology Advisory Committee* (2015) [5.6a] leading to the Australian Government's *Office of Gene Technology Regulation* introducing a review to consider amendments to genetic technology regulations – culminating in a Department of Health review (2018) on the legislation on gene technology [5.6b]. In April 2019, this review led the Australian government to announce plans for new regulation over the use of gene editing.

Research on mitochondrial replacement technologies has influenced and informed policy at an international level:

Wrigley's research into the nature and use of mitochondrial donation [3.1; 3.3] has been cited by the Australian Parliament's Senate Committee Inquiry (2018) [5.7a]. His paper [3.1] was also utilised by Senators in Parliamentary debate [5.7b]. The Australian Government response to the Inquiry's report instigated a major public engagement exercise in Australia (from Sept-Nov 2019) informing legislative review [5.7c].

Generation of public, professional, and stakeholder debate

Research findings have been disseminated through media engagement to inform public and practitioner understanding of ethical and social issues in areas of new genetic and reproductive technologies and of end-of-life care [3.2; 5.10].

Research has generated substantial public and professional debate on matters of national end-of-life care practice and policy. This research [3.5] offered a critical analysis of Neuberger's government-commissioned independent review of the Liverpool Care Pathway for the Dying Patient (LCP). Wrigley's research raised concerns about ethical practice at end of life and highlighted that the independent report had made errors of inference and ethical judgement. Wrigley's research paper was selected for press release by the *British Medical Journal* as being of particular importance and interest to the public and the medical professions. Research findings were also covered in the media, including national press and professional publications, with daily circulation in the millions [5.10].

Wrigley's *The Conversation* piece on Paralympian athlete, Marieke Vervoort, discussed an approach to viewing euthanasia from the perspective of life-extension rather than life-shortening [5.10] - was reported by *Newsweek Japan* [5.10]. Wrigley's invited commentary for *The Telegraph* focused on the Gosport Hospital Scandal, concerning palliative care for the elderly and the need for a proper understanding of the nature of palliative care amongst the medical profession to prevent such scandals reoccurring [5.10]. With a daily reach of over 800,000, this media output generated 118 discussion comments from the public.

Impact on professional practice around loss and bereavement in the criminal justice system:

Through a Barrow-Cadbury funded project (2016-18), Wrigley research [3.6] was used to produce a guide for professionals [5.8] who support young people in the criminal justice system on matters of loss and bereavement. Wrigley's work forms a significant part of this practical guidance by establishing the ethical concerns surrounding imprisonment as a punishment when offenders are facing matters of dying and bereavement.

No previous dedicated guidance has been available to professionals in this area. This guide has been tested in practice at a large HM Prison and Young Offenders Institute. The range of different practitioners and agency professionals engaged is detailed in a final report for the Barrow-Cadbury Trust (2020) [5.9], which outlines the scope of institutional developments that followed the implantation of the Guide.

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

The Nuffield Council on Bioethics genome editing project reports:

5.1 A.J. Newson and A. Wrigley, "Identifying key developments, issues and questions relating to techniques of genome editing with engineered nucleases", *Nuffield Council on Bioethics*, 31st March 2015, commissioned background report. <http://nuffieldbioethics.org/wp-content/uploads/Genome-Editing-Briefing-Paper-Newson-Wrigley.pdf>

5.2 'Genome Editing: an ethical review' (2016), <http://nuffieldbioethics.org/project/genome-editing>

5.3 Deutsche Ethikrat (German Ethics Council), Conseil Consultatif Nationale d'Ethique (French Ethics Council) and Nuffield Council on Bioethics (UK) Joint Statement on Genome Editing (October 2016) <http://nuffieldbioethics.org/news/2016/ethics-councils-give-urgent-attention-genome-editing>

5.4 'Genome Editing and human reproduction: ethical and social issues' (2018): <http://nuffieldbioethics.org/wp-content/uploads/Genome-editing-and-human-reproduction-FINAL-website.pdf>

UK House of Commons' Science and Technology Committee on genomics and genome editing:

5.5a Nuffield Council on Bioethics Response to the Science and Technology Committee: (<http://nuffieldbioethics.org/wp-content/uploads/NCOB-response-ST-Commons-inquiry-Genomics-and-Genome-Editing.pdf>)

5.5b House of Commons Science and Technology Committee report (see section 5) <https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/349/349.pdf>

5.5c Government Response to the Science and Technology Committee's Report: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/725632/Government_Response_to_the_Genomics_and_Genome_....pdf

Australian Parliament on Gene Editing:

5.6a The Australian Government, Department of Health, Office of the Gene Technology Regulator Committee Report (2015): [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/BD2828D0846052E0CA2581A10000E30/\\$File/5.%20Minutes%2047th%20GTTAC%20FINAL_Redacted.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/BD2828D0846052E0CA2581A10000E30/$File/5.%20Minutes%2047th%20GTTAC%20FINAL_Redacted.pdf)

5.6b The Australian Government, Department of Health, The Third Review of the National Gene Technology Scheme Final Report (2018) [https://www1.health.gov.au/internet/main/publishing.nsf/Content/011C554B9847D6F0CA258169000FCBBE/\\$File/Final-Report-Oct2018.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/011C554B9847D6F0CA258169000FCBBE/$File/Final-Report-Oct2018.pdf)

Australian Parliament on Mitochondrial Replacement:

5.7a The Australian Parliament Senate Community Affairs References Committee Inquiry report (2018): https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MitochondrialDonation/Report

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5.7b The Australian Parliament Hansard entries of the Senate Inquiry debate (2018): <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;db=COMMITTEES;id=committees%2Fcommsen%2F097c280f-570c-414f-92ad-43321af4cc3e%2F0006;query=Id%3A%22committees%2Fcommsen%2F097c280f-570c-414f-92ad-43321af4cc3e%2F0000%22>

5.7c The Australian Government's National Health and Medical Research Council Public Consultation on Mitochondrial Donation (2019) <https://www.nhmrc.gov.au/about-us/leadership-and-governance/committees/mitochondrial-donation>

UK Practitioner Guide:

5.8 Practitioner Guide on Loss and Bereavement (2019): S. Read, S. Santatzoglou, A. Wrigley, "Loss and Bereavement: A Guide for Professionals Working Across the Criminal Justice System" (2019). Barrow Cadbury Trust, London. Available at <https://www.t2a.org.uk/resources/>

5.9 Report on use of Practitioner Guide on Loss and Bereavement (2020)

Media and Press Coverage:

5.10 Table of public and professional media publications with readership and circulation statistics.