EVERYDAY CYBORGS 2.0 PROJECT REPORT

MONTHS 30-42



PRINCIPAL INVESTIGATOR

PROF MUIREANN QUIGLEY

POSTDOCTORAL RESEARCHERS

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INTRODUCTION

With pandemic restrictions now behind us and academic life back to normal, this year the EDC team has resumed in-person activities, including our first project conference hosted at the University of Birmingham on the 19th-20th of September.

In this report we set out what we have achieved between March 2022 and February 2023, as well as outlining directions for future research and the activities we have planned for the coming year.

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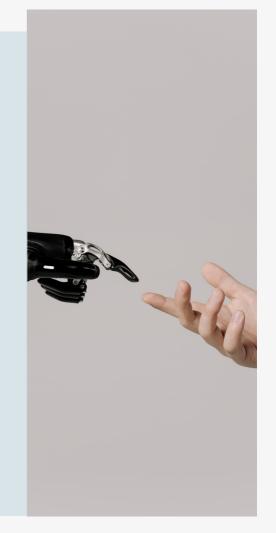
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THE PROJECT SO FAR

In months 30-42, the project has been focused on: (i) furthering our understanding of how persons, bodies, and selves are constructed and conceived of within the law and public policy; (ii) deepening our understanding of software as a medical device, and (iii) continuing our empirical work with stakeholders.

Over the last year, we have also been expanding our research into the notion of embodiment and the role it plays in ethical theorising, as well as investigating methods of policy innovation such as regulatory sandboxes and vignette testing. In addition, the team has been delving into the literature on boundaries and boundary making in Science and Technology Studies (STS) and exploring technological how development leads emergence of novel legal concepts within law.

With regards to our empirical research, Dr Rachael Dickson continued to lead the team's data collection by conducting narrative and semi-structured interviews, and began the coding and analysis of the data generated so far.

We are now in a position in which we have a thorough understanding of the project landscape, including an understanding of the challenges and opportunities everyday cyborgs present for medical device law, regulation, and policy. This has enabled the team to start answering the project's second research question:

What insights are revealed when traditional legal, ethical, and conceptual boundaries (e.g. subject-object) are dissolved and reconceptualised in novel ways?

In September 2022 the EDC team organised both its first project the University meeting at Birmingham and a panel at the Mancept Workshops in Political Theory. You can find information about these panels in the Events section of this report. We are looking forward to organising more in-person academic events over the coming year.

EMPIRICAL WORK



Jambe bionique by Romain Pernet Licensed under CC-BY-SA-4.0

During months 30-42, Dr Rachael Dickson pushed ahead with her empirical work with everyday cyborgs by conducting narrative and semi-structured interviews with users of implanted and attached medical devices. This year our focus has been widening our sample beyond users of diabetes technology, cardiac implants, and hearing devices such as cochlear implants to include users of prosthetic devices.

These interviews have enabled us to deepen our knowledge of what it is like to live with a medical device, and the thoughts, opinions, preferences, and worries that people with devices have. One of the striking results of this research has been the extent to which users of different devices have similar desires and raise similar concerns. These included the need to adapt and customise medical devices, the importance of engaging in patient advocacy, and a desire for greater access to the inner workings of devices.

In addition to interviewing users of medical devices, over the last year we have also been interviewing a range of stakeholders, including clinicians, regulators, and those working at the coalface of policy-making. We are currently beginning to plan our focus groups, which we aim to complete over the next year.

TAKING EMBODIMENT SERIOUSLY

Over the last year Dr Joseph Roberts has been continuing the project's research into how ethics, law, and public policy reflect the fact that we are embodied beings. In particular, Dr Roberts has been exploring: (i) how traditional approaches to ethical theory and political philosophy can incorporate insights about people's embodiment and (ii) how we can take people's embodiment seriously in medical practice and health and welfare policy.

To better understand how we can take people's embodiment seriously in both ethics and public policy, we have been reviewing literature on:

- Disability theory, paying particular attention to literature advocating a social model of disability,
- Feminist bioethics, focusing primarily on literature exploring how women's testimony can be discounted in medical encounters,
- Epistemic injustice, including literature on the importance of trusting people's testimony,
- Participatory governance and deliberation, especially literature discussing how to incorporate and deliberate about people's firstperson perspectives into the public policy process,
- Failures of governance in the UK health system, including the Ockenden Report and the Cumberlege Report.

Over the coming year, we aim to publish the results of this research and use the insights gained through our literature reviews to assist in the analysis of the results of our empirical research.

MEDICAL DEVICES REGULATION

Over the last year we have been deepening our research into the medical device regulatory environment. In anticipation of the placing before Parliament of new medical device regulations, in early 2022 we received additional funding which enabled us draw on the research assistance of Ashita Jain. She worked with Dr Laura Downey and Dr Rachel Dickson to conduct a comparative analysis of medical device regulations in the UK and USA. Additionally, she provided an overview of the draft EU AI Act. You can read more about this research on our blog.

Dr Downey has been leading the project's research into of medical devices regulation, which this year has included:

- Engaging with stakeholders to help shape medical device regulations, including by responding to the MHRA's consultation on medical device regulation, and reviewing the Government's response to the consultation in a <u>blogpost</u> for the EDC website;
- Deepening our understanding of the uncertainties surrounding the regulation of software as a medical device;
- Exploring the science and technology studies literature on boundaries and boundary-making, and analysing its implications for everyday cyborgs and the law.

EVENTS

In early September 2022, Joseph Roberts organised a panel Embodiment in Ethics. Political Philosophy, and Law at the Mancept Workshops in Political Theory. The workshop brought together philosophers and bioethicists to discuss how we might take better account of embodiment in ethical theorising, political philosophy, public policy, and law. A full report containing outlines of the papers presented can be read on the EDC blog here.



Arthur Lewis Building, University of Manchester



Aston Webb Building, University of Birmingham

Later the same month, the EDC team organised a workshop at the University of Birmingham on Visions of the Everyday Cyborg. workshop brought together an interdisciplinary group to discuss the present and future of medical device regulation. These included legal scholars. clinicians. sociologists. cvbersecurity researchers. and regulatory experts

A full report with outlines of the paper can be read on the EDC blog here.

DISSEMINATION AND ENGAGEMENT

- On the 8th of February 2023, Muireann Quigley presented a paper entitled 'Software as a Medical Device: Living in a Material World?' to the <u>Medical</u> <u>Law and Ethics Discussion Group at the University of Oxford</u>.
- In October 2022, Muireann Quigley and Laura Downey presented their paper <u>'Integrating the Biological and the Technological: Time to Move Beyond Law's Binaries?'</u> to the <u>Hybrid Minds</u> research group.
- On the 26th of October 2022, Laura Downey participated in the Science Museum's panel 'Are we turning into cyborgs?' which explored cyborg technologies, transhumanism, and neural interfaces.
- Between the 5th and 9th of September, Rachael Dickson and Laura Downey attended the 2022 Society of Legal Scholars conference held at Kings College London. Dr Downey presented her paper 'Emerging Legal Concepts and Law at the Intersection of Technology and Society: Authority, Legitimacy, and Legality', and Dr Dickson presented a paper entitled 'Legal Futures for 'Smart' Medical Devices: Centring the Perspectives and Insights of 'Everyday Cyborgs'.
- Over the course of the second half of 2022, Joseph Roberts presented his work in progress on the theme of taking embodiment seriously at the University of Bristol's <u>Centre for Ethics in Medicine</u> and the <u>Centre for Biomedicine</u>, <u>Self and Society</u> at the University of Edinburgh.
- In April 2022, Rachael Dickson presented her paper 'Legal Futures for 'Smart' Medical Devices: Centring the Perspectives and Insights of 'Everyday Cyborgs' at the <u>Socio-Legal Studies Association</u> conference hosted by the University of York.



OUTPUTS

As well as disseminating our work in progress at conferences and events, the team have also been working on articles and chapters for publication.

- Roberts, Joseph and Quigley, Muireann. 'Being Novel? Regulating Emerging Technologies Under Conditions of Uncertainty' in Lawrence, David and Morley, Sarah (Eds) <u>Novel Beings: Regulatory</u> <u>Approaches for a Future of New Intelligent Life</u> (Edward Elgar Publishing 2022).
- To accompany the publication of Joseph Roberts and Muireann Quigley's chapter 'Being Novel? Regulating Emerging Technologies Under Conditions of Uncertainty', Dr Roberts wrote a short piece for the EDC blog outlining the main arguments in the chapter.
- In a series of blog posts in February and November 2022, Rachael Dickson, Laura Downey and Muireann Quigley discussed the MHRA's consultation, the government's response to the consultation and its implications for the future of medical device regulation.
- In October 2022, Rachael Dickson wrote a series of blogposts. The first, published on the Birmingham Law School Research Blog outlined the argument of a paper about <u>DIY APS and the law</u> published earlier in the year in Diabetic Medicine. In her <u>second post</u>, published on the EDC blog, Dr Dickson reflected on the fieldwork so far, focusing particularly on her interviews with users of medical devices.

- In September 2022, Aishita Jain, Rachael Dickson, and Laura Downey co-authored a <u>blog post</u> outlining how medical devices which use Artificial Intelligence and Machine Learning techniques are currently regulated in the UK and the USA.
- In a series of posts in April and May 2022,
 Dominic Berry published some of the resources
 he developed whilst studying the history of
 medical devices. These include a timeline of
 significant historical moments in the creation of
 the medical device industry in the UK and
 Ireland, and a guide to EU documents relating to
 medical device regulation.
- In February 2022, Victoria Moore wrote a <u>blog</u> <u>piece</u> discussing the role of the Patient Safety Commissioner, established by the Medicines and Medical Devices Act 2021. In her piece Dr Moore argues that the limited remit of the role means that it may not be sufficient to ensure patient safety.



THE REST OF THIS YEAR...

Over the coming year, we are particularly looking forward to:

- Expanding our literature reviews and furthering our knowledge of the challenges raised by the integration of medical devices with people's bodies.
- More deeply exploring the person-thing distinction, how novel legal concepts emerge, the regulation of software as a medical device, and the importance of embodiment in ethics and medical policy.
- Finishing our data collection and moving on to analysing the interviews and focus group responses.
- Organising a couple of joint workshops with two projects we have a number of synergies with. Currently slated for May and October 2023, respectively,

THE TEAM

Since our last report, there have been some changes in the project team. In May 2022 Dr Dominic Berry left the project to take up a job as a user researcher for the Land Registry Office. Later in the year, Dr Rachael Dickson also made a decision to leave the project to take up a job with the Scottish Government working on their welfare reform programme.

We look forward to welcoming a new colleague, with expertise in socio-legal methods, to the team in the very near future.

PRINCIPAL INVESTIGATOR



Professor Quigley is Professor of Law, Medicine, and Technology at Birmingham School. She is the Principal Investigator on the EDC 2.0 project. Her interdisciplinary research focuses on the philosophical analysis of law and policy in medicine and the biosciences. She is particularly interested in boundarymaking in law and how socio-technical imaginaries impact on and shape law and regulation regarding persons medical devices.

POSTDOCTORAL FELLOWS



Dr Downey's academic background is in Law. Her doctoral research at the University of Edinburgh drew on both law and science and technology studies to examine the regulation of new and emerging biotechnologies. She joined the EDC 2.0 team full-time in September 2020, having worked with Professor Quigley and Dr Dickson scrutinising the Medicines and Medical Devices Bill since January 2020.



Dr Roberts' research on the EDC 2.0 project focuses on a number of conceptual and normative challenges posed by the joining of persons with attached and implanted medical devices. Prior to joining the University of Birmingham, he completed a PhD in Political Theory at the University of Manchester. His thesis examined the moral permissibility of body modification practices.