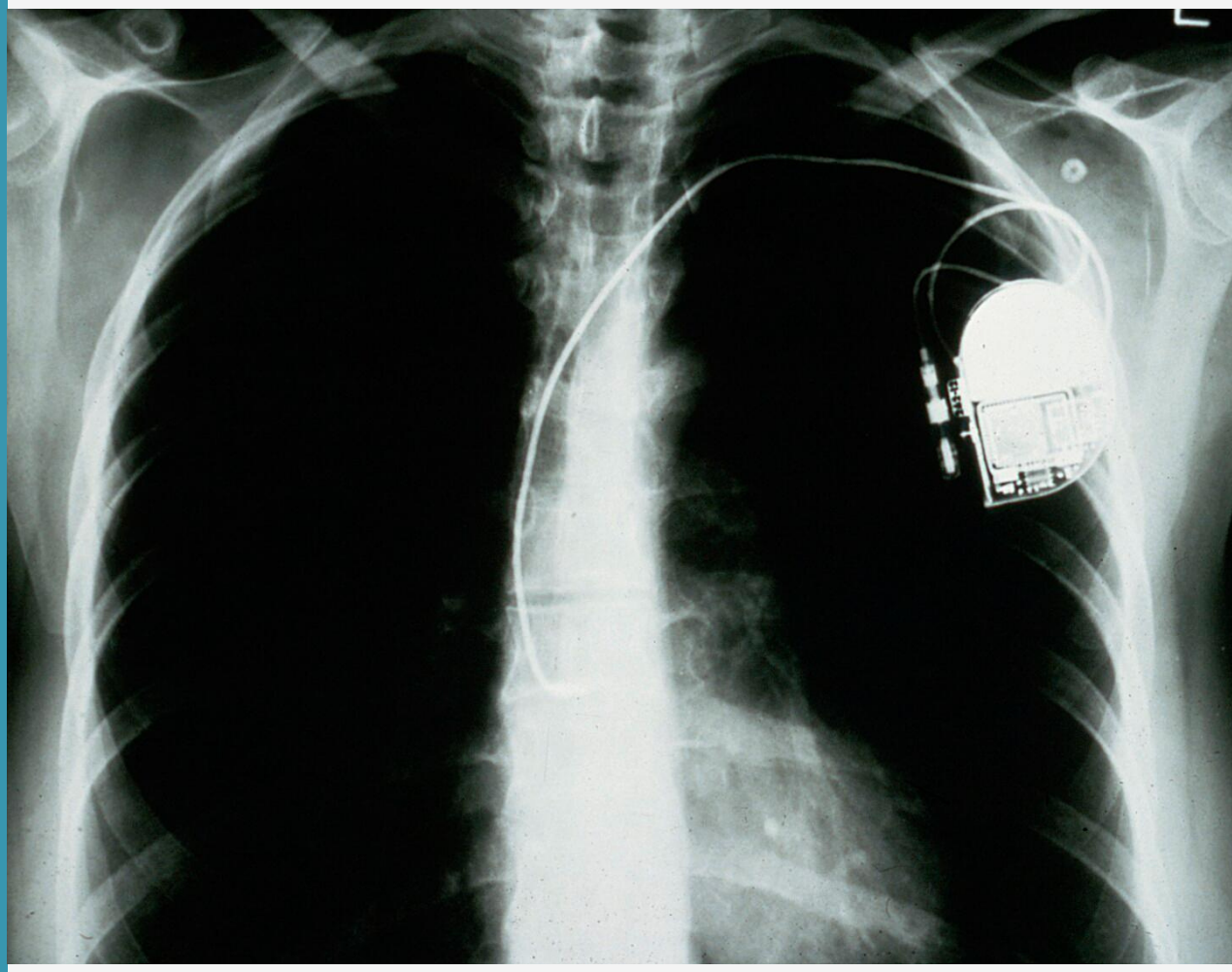
MARCH 2022

EVERYDAY CYBORGS 2.0 PROJECT REPORT

MONTHS 18-30



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EVERYDAY CYBORGS 2.0

WHERE SCIENCE & TECHNOLOGY MEET HUMANITY

wellcome

INTRODUCTION

With the pandemic rumbling on, during months 18-30 of the Everyday Cyborgs 2.0 (EDC 2.0) project, the team has continued to adapt the project and planned activities to enable work to continue and progress to be made. Much like the first 18 months of the project, we adopted a hybrid work model, with most of our research activities being conducted online. However, we did manage to meet on occasion in person.

In this report we set out what we have achieved between March 2021 and February 2022, as well as outlining directions for future research and activities we are planning for the coming year.

CONTENTS

In this report you will find:

THE PROJECT SO FAR

In months 18-30, the EDC team has mainly been focused on conducting literature reviews and analyses to more fully answer our first research question:

> What does the (existence of the) everyday cyborg tell us about the limits and opportunities (conceptual, normative, and practical) of law, regulation, and policy with respect to attached and implanted medical devices?

To do this, we have been deepening our knowledge of medical device regulation, the history of the medical device marketplace in the UK, citizen science, boundary objects, embodiment and sociotechnical imaginaries. The team has also initiated research into software as a medical device, open-source software, patient expertise, patient-led innovation, and how bodies and persons are conceived in law and legal theory.

The team now has a firm foundation from which to: (i) continue to conduct our empirical work with persons with attached and implanted medical devices, as well as wider stakeholders; (ii) better contextualise the history of medical devices in the UK, (iii) gain a deeper understanding of how persons and bodies are conceived in law, (iv) further explore how the boundaries and dichotomies within law affect regulatory practice, and (v) explore how law, regulation, and policy could be reconceptualised.

This work will enable us to start making progress answering our second research question:

> What does the (existence of the) everyday cyborg tell us about the limits and opportunities (conceptual, normative, and practical) of law, regulation, and policy with respect to attached and implanted medical devices?

On the 28th of April 2021, we held the first, delayed, advisory board meeting. In the meeting, members of the EDC team started by outlining the research we conducted in months 1-18 of the project. Professor Muireann Quigley provided an overview of progress on the project, Dr Rachael Dickson outlined her research on mapping the regulatory landscape, Dr Joseph Roberts provided a sketch of the EDC team's work on DIY APS, and Dr Laura Downey summarised the project's work on the Medicines and Medical Devices Act 2021.

In the second half, we outlined plans for future empirical and historical research. We also provided an update on the ongoing work exploring software as a medical device, sociotechnical imaginaries, the notions of embodiment and boundary work, and how the body is conceived of in law and legal theory.

The easing of the government restrictions during months 18-30 of the project also allowed us to resume some in-person events. On the 22nd of September 2021, the EDC team held an empirical workday with Professor Jonathan Ives to finalise the team's plans for empirical research, make final amendments to recruitment materials, and discuss strategies for participant recruitment.

Over the coming year we are looking forward to having more in-person meetings, and planning for the second advisory board meeting and a project conference is currently underway.

Credit: Hip joint replacement, United States, 1998. Science Museum, London. Attribution 4.0 International (CC BY 4.0)

EMPIRICAL WORK

The overarching goal of the EDC 2.0 project is to develop a novel, empirically informed account of the everyday cyborg in law with solid conceptual and philosophical underpinnings. To ensure that our account is empirically informed, the EDC 2.0 project is conducting empirical fieldwork with a range of participants.

In May 2021, the EDC 2.0 team, led by Dr Rachael Dickson, successfully submitted their research proposal to the University of Birmingham's Research Ethics Committee. Receiving ethical approval in the Summer has enabled the team to start recruiting participants for a range of empirical research activities using our website, Twitter and our existing networks.

Dr Dickson has been inviting people with attached and implanted medical devices to:

- Narrative interviews
- Semi-structured interviews
- Focus groups

More information about how people can participate and what they can expect during the interviews is available on the 'Get involved' tab of our website.

The aim of the interviews, which have already begun, is to gain a deeper understanding of how people live with medical devices by asking people to tell us their story of receiving and living with a device. Our aim is to better comprehend life with such devices, the experiences people have in healthcare settings, and the perceived risks and benefits of using their device. Participants also have the opportunity to discuss the law applicable to their device, share their views on future innovation, and discuss what rights, responsibilities and obligations law ought to prioritise in relation to medical devices.

We have also begun conducting semi-structured interviews with stakeholders. Over the coming year we hope to speak to clinicians, policymakers, regulators, and advocacy organisations, as well as industry representatives such as device manufacturers. The aim of these interviews is to gain a better understanding of the perspectives of people who have knowledge regarding the development, use, and regulation of medical devices.

In particular, the team is interested in the balancing of interests in relation to medical devices in law and policy, and the priorities these stakeholders have for future innovation.

To provide a historical context to the findings, these interviews will be complemented by the oral histories being conducted by Dr Dominic Berry, discussed further in this report under the heading 'Historicising the Everyday Cyborg'.

So far the team has completed 35 interviews with everyday cyborgs, mostly with persons with a range of diabetes devices, pacemakers, and cochlear implants.

We are currently focusing on finding participants with other devices to broaden the sample. To assist with this, we are delighted to welcome Dr Alice Toms to the team. Dr Toms is working alongside Dr Dickson on the empirical aspects of the project. She is also investigating the potential to use some additional participatory methods, specifically the use of video diaries and vision boarding with some of the participants, which Dr Dickson gained funding to explore.

MEDICAL DEVICE REGULATION

Over the last year, we have continued our research into medical device regulations, focusing, in particular, on how existing medical device regulations apply to software components. Understanding this aspect of regulation is crucial as medical devices are increasingly smart devices that run software, and store and transmit data. In other words, they are integrated goods.

Dr Laura Downey has been leading the research on these aspects. Her research has included:

- Deepening the project's understanding of medical device regulations in general;
- Providing a comprehensive overview of the regulations applicable to smart medical devices, including medical device and data protection regulations;
- Identifying gaps and uncertainties in medical device regulations, including assessing their suitability for regulating software developed using an open-source model; and
- Engaging with stakeholders to help shape medical device regulations by meeting with representatives of the MHRA, responding to the MHRA's 'Consultation on the Future Regulation of Medical Devices in the UK' launched in September 2021, and by submitting a proposal for consolidation of medical device regulations to the Law Commission's 14rth Programme of law reform.

HISTORICISING THE EVERYDAY CYBORG

In January 2021 we welcomed Dr Dominic Berry to the project. He is a historian and philosopher of science. This year his work has included:

- Using the British Newspaper Archive to track the development of the medical device industry and marketplace in the UK and the Republic of Ireland between 1948-2020;
- Analysing the content of the media coverage of the medical device industry between 1948-2020; and
- Developing an annotated timeline of major events in the development of medical devices, their regulation, and the market for them; and
- Sharing two publicly available and interactive maps, the first illustrating where 'medical device' has featured in the BNA, the second pinpointing the geography of identified companies contributing to the medical device marketplace. The latter has received considerable interest from industry analysts, a number of which requested a copy of the spreadsheet on which it is based. This spreadsheet is made available to anyone who requests it.

In March 2021, we were awarded additional funding (a Quality-related Research grant from Research England) in order to expand aspects of our historical research. This enabled us to employ Dr Kevin Matthew Jones as a research assistant in March 2021. Dr Jones completed an extensive analysis of sources from the British Newspaper Archive, wrote two blog posts based on this research, and has since secured a Research Fellowship at the National Archives, London.

In 2022 Dr Berry is planning to use authorship and affiliation data from major biomedical and biological engineering journals to identify which universities feature most prominently, with a view to identifying major centres of expertise in medical device research and their changes over time.

In addition to this textual and archival research, Dr Berry will also be conducting a series of oral history interviews with people with knowledge of medical device policy, regulation, or research.

The aim of these interviews will be to reveal information about the past experiences of the interviewees and any perceived changes that have occurred over time in the field of medical device development and regulation.

The combination of the textual research and the oral histories will enable us to situate the development of the everyday cyborg within a broader historical context, thus helping to ensure our account of the everyday cyborg in law is congruous with the past. This will also be important when considering what lessons could be learned in terms of future law, regulation, and policy.

EMBODIMENT AND EVERYDAY CYBORGS

Two athletes with artificial right legs walking. 1925. Wellcome Collection. Attribution 4.0 International (CC BY 4.0)

Over the last year, Dr Joseph Roberts has been leading the project's research into how the body is conceived in law, ethics, and medical practice. One of the major themes that has emerged from this research is the idea that much extant philosophical and legal theorising has paid insufficient attention to the crucial fact that we, as human beings, are embodied in particular bodies.

Although we often identify the locus of the self with the mind, what our body is like can have profound effects on who we are. Our body is the means through which we perceive and interact with the world. What our bodies are like, therefore, influences what we are able to do. Our conceptions of our bodies are also influenced, in turn, by the particular conceptions of the body present in the law, medical practice, the media, and culture at large.

To better understand how law, medical practice, and ethical theorising conceive of the body, we have been reviewing a variety of intersecting literatures including:

- Phenomenological inquiries into first-person experience of illness and disability;
- Work in the philosophy of medicine uncovering how the body is conceived of in medical practice;
- Qualitative empirical research focusing on the experiences of living with and using medical devices;
- Feminist ethical and political theorising focusing on the importance of embodiment; and
- Legal theory literature analysing how the body is conceived of in the law.

Over the coming year, we aim to deepen these theoretical analyses of how the body is conceived of in law, ethics, and medical theory to complement the results of our own empirical research into the embodied experiences of people with attached and implanted medical devices.

DISSEMINATION AND ENGAGEMENT

- In March 2021 Dr Laura Downey and Professor Muireann Quigley met with representatives from the Medicines and Healthcare products regulatory Agency to discuss challenges surrounding the regulation of software as a medical device.

- In April 2021 Dr Rachael Dickson and Professor Muireann Quigley presented ongoing work on DIY Artificial Pancreases as an example of citizen science and patient-led innovation at the Socio-Legal Studies Association conference.

- Later in April 2021 Dr Joseph Roberts, Dr Victoria Moore and Professor Quigley's paper 'Prescribing Unapproved Medical Devices? The case of DIY Artificial Pancreas Systems' was covered in publications including: Pharmacy Times, Medscape, MedicalXpress, childrenwithdiabetes.com, Patient Safety Learning's online platform The Hub, and the American Association for the Advancement of Science's EurekAlert!.

- In April 2021 Professor Muireann Quigley was invited to contribute to the academic conference on the Law Commission's 14th Programme of Law Reform, which was held jointly with the Law Commission, SLS, SLSA and ALT. She spoke on the need for consolidation of the medical device regulations and the problems regarding software as a medical device.

- In the first half of 2021 Professor Muireann Quigley contributed to the Open Project's international consensus statement on open-source automated insulin delivery as part of their Legal Advisory Group.

- In the autumn of 2021 Dr Laura Downey and Professor Muireann Quigley presented their paper 'Software as a Medical Device: Regulatory Gaps and Uncertainties?' at both the Birmingham Law School Research Conference and the University of Bristol's Centre for Ethics in Medicine.

- In November 2021 Dr Dominic Berry was interviewed by Faculti about his work on the EDC 2.0 project charting the history of medical device companies.

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.

Published

- Quigley, Muireann and Downey, Laura, 'Integrating the Biological and the Technological: Time to Move Beyond Law's Binaries?' in Dove, E. and Nic Shuibhne, N. (eds) Law and Legacy in Medical Jurisprudence: Essays in Honour of Graeme Laurie (Cambridge University Press, 2022), pp. 279-306.

- Braune, Katarina,; Lal, Rayhan A; Petruzelkova, L….Quigley, M. [as part of the OPEN Legal Advisory Group], et al. (2022) 'Open-source Automated Insulin Delivery: International Consensus Statement and Practical Guidance for Health-care Professionals' The Lancet Diabetes & Endocrinology 10 (1): 58-74.

- Dickson, Rachael; Bell, Jessica; Dar, Amber; Downey, Laura; Moore, Victoria; and Quigley, Muireann. (2021) '#WeAreNotWaiting: DIY artificial pancreas systems and challenges for the law' Diabetic Medicine, doi: 10.1111/dme.14715.

- Braune, Katarina,; Hussein, Sufyan, Quigley, Muireann, et al., (2021) 'International Consensus on the Ethics of Open-Source Automated Insulin Delivery' Diabetes 70 (Supplement 1):712-P [Conference Abstract]

In progress

- Bell, Jessica; Moore, Victoria; and Quigley, Muireann. 'Standards of Care and 'DIY' technologies: Who is liable and what for?'

- Berry, Dominic, 'Historicising the Medical Device Marketplace in the UK and Ireland: A view from Below'

- Dar, Amber, Moore, Victoria, and Quigley, Muireann, 'Children and DIY Artificial Pancreas Systems: Parental Responsibility, Best Interests, and Dealing with Disagreement'

- Dickson, Rachael and Quigley, Muireann, 'Regulating DIY Artificial Pancreas Systems? On Citizen Science and Patient-led Innovation'

- Roberts, Joseph and Quigley, Muireann. 'Being Novel? Regulating Emerging Technologies Under Conditions of Uncertainty'

- Roberts, Joseph, 'Taking Embodiment Seriously in Ethical Theory and Medical Practice'

Blogposts and Opinion Pieces

- In February 2022, Dr Berry wrote a blogpost reporting on the progress of the historical timeline of medical device regulation, innovation and governance.

- In September 2021 Dr Dominic Berry wrote a guest post for the Imagining Technologies for Disability Futures blog in which he emphasises the importance of exploring how knowledge is constructed in the process of medical device development.

- In July 2021, Dr Joseph Roberts outlined some thoughts on the EDC 2.0 blog about how best to study embodiment, arguing we need both sociological and phenomenological approaches to capture what it is like to live with particular bodies.

- In a series of blog posts in February, April and May 2021 Dr Dominic Berry and Dr Kevin Matthew Jones outline the historical research they have conducted so far. Drawing on a survey of the British Newspaper Archive, Dr Jones charts the rise of the medical device industry in the UK and Ireland between 1945 and 2004; and Dr Berry has produced interactive maps of newspaper articles discussing medical devices and the locations of major medical device manufacturers in the UK and Ireland.

- In March 2021, Dr Laura Downey and Professor Muireann Quigley contributed a piece to the EDC blog about the challenges associated with regulating software as a medical device.

- After it gained Royal Assent, Dr Laura Downey, Dr Rachael Dickson, Dr Victoria Moore, Professor Muireann Quigley, and Professor Jean McHale reflected on The Medicines and Medical Devices Act 2021 & Uncertain Regulatory Futures. Also available here.

- To accompany the publication of the paper co-authored with Dr Victoria Moore and Prof Muireann Quigley, in February 2021 Dr Joseph Roberts wrote a short blogpost outlining the main arguments in the paper.

Policy Work

- In November 2021, Dr Rachael Dickson, Dr Laura Downey, Dr Joseph Roberts, Professor Jean McHale, and Professor Muireann Quigley submitted evidence to the MHRA consultation on the future regulation of medical devices. The team is working on a summarised version of these responses which will be published on the EDC blog.

- In June 2021 Dr Rachael Dickson, Dr Laura Downey, and Professor Muireann Quigley submitted a proposal for the consolidation of medical devices regulations to the Law Commission for their consultation on the 14th Programme of Law Reform.

THE REST OF THIS YEAR...

With all the optimism we displayed in last year's report, we continue to hope that we are slowly returning to a more normal academic life and that more in-person activities will be possible this year.

We are particularly looking forward to:

- Continuing our literature reviews and furthering our understanding of the project landscape.
- More deeply exploring the history of device manufacturing in the UK, the question of software as a medical device; developing an account of how to take account of embodiment in ethics, law and policy.
- Continuing to recruit participants for our focus groups, semi-structured interviews, oral histories, and narrative interviews and analysing the data collected from these activities.
- Expanding our methods to include some participatory activities, such as written and video diaries.
- Organising a project workshop during the Summer of 2022 and holding our next advisory board meeting.

THE TEAM

We are delighted to welcome our new PhD student, Miss Jessica Shipley and Dr Alice Toms to the team this year. They join Principal Investigator Professor Muireann Quigley, and Research Fellows Dr Dominic Berry, Dr Rachael Dickson, Dr Laura Downey and Dr Joseph Roberts.

Miss Shipley joined the EDC 2.0 project in September 2021. She is completing a PhD examining the person/object binary in law and how people with implanted medical devices are affected by this. Prior to starting her PhD, she completed her LLB and LLM in International Human Rights Law at the University of Leicester.

Dr Toms joined the EDC 2.0 team in February 2022 as a research assistant. Prior to joining the team, she completed a PhD in bioethics at the University of Bristol. Her thesis examined the ethical and legal issues pertaining to surgical innovation. She has a particular interest in the exploration of patients' lived experiences of medical devices.