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EVERYDAY CYBORGS 2.0 PROJECT REPORT

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EVERYDAY CYBORGS 2.0

WHERE SCIENCE & TECHNOLOGY MEET HUMANITY

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INTRODUCTION

The first year of our Wellcome Trust funded Everyday Cyborg 2.0 (EDC 2.0) project coincided with the start of the global coronavirus pandemic. The announcement of a UK lockdown on the 23rd of March 2020, just six months into the project, forced us to adapt our working model. With the university campus closed, as many people did, we moved to remote working. Although this meant that some of our planned in-person activities had to be delayed, the team transitioned to remote working admirably and progress on the EDC 2.0 project continues.

In this report we set out what we have achieved during the first year and a half of our project, as well as outlining the research avenues and activities we are planning over the coming year.

CONTENTS

In this report you will find:

EVERYDAY CYBORGS AND THE LAW

Everyday Cyborgs - or integrated persons - are persons with attached and implanted medical devices, such as pacemakers, insulin pumps, and limb prostheses. These devices have the potential to improve people's lives by replacing or supporting bodily functions. However, because the law takes a bounded approach to persons and objects, this integration of the biological with the technological generates a number of unexpected practical, conceptual, and normative challenges for the law. Investigating these is at the heart of this project.

Much of our time since we began the project has been spent conducting literature reviews aimed at answering the 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?

One of our main aims is to investigate where boundaries occur in law and why they do so. With this in mind, over the first, and into the second, year of the project, we have been exploring and examining a number of areas. These include medical device regulation, citizen science and DIY artificial pancreas systems, embodiment, boundary-work and boundary objects, socio-technical imaginaries, and how persons, selves, and the body are conceived in law.

Over the coming year we aim to continue this work. We will be expanding our analyses of medical device regulations in general. Additionally, we will begin to think specifically about aspects of our research relating to software as medical devices, as well as examining some of the complex issues relating to data protection, intellectual property law, and cybersecurity in more depth.

In the next few months we hope to complete a comprehensive mapping of the project landscape, in order to identify any key areas of law, regulation, policy, and guidance which we might have missed so far.

This mapping exercise includes taking account of the historiography of medical devices (regulation) courtesy of the newest member of our research team. This will not only ensure our analysis is comprehensive and historically situated, but also help us to highlight lesser considered aspects of the development of)law and regulation in this area.

Building on this and other early project work, we have been conducting a documentary analysis of the cases, statutes, legal instruments, regulatory and policy documents, and non-legal reports. We plan to draw on and utilise critical discourse analysis to reveal the relationships between different areas identified during the mapping exercise, including the different (socio-technical) imaginaries relating to persons, bodies, and medical devices at play in these documents.

By the end of year 2 of the project our goal is to have a more nuanced and thorough understanding of the legal and regulatory landscape, including its historiography, with regards to attached and implanted medical devices.

This research will provide a firm foundation upon which to conduct empirical research with different groups of everyday cyborgs, as well as regulators, policy-makers, and other stakeholders. Planning for this work is already underway.

Through the empirical components, we aim to enrich our understanding regarding the different visions that particular groups and actors have of (the relationship between) persons, bodies, and attached and implanted medical devices. We also want to explore the imagined futures and shared or divergent understandings which they have of the technologies.

Our end-goal in doing this is to explore how law and regulation with regards to integrated persons and medical devices could be repurposed or reconceptualised in fruitful ways, and in ways which might go beyond boundaries, be they legal, moral, or ontological.

Progress on the initial mapping and analyses, as well as preparatory work for the empirical phases of the research, was somewhat delayed due to the Covid-19 situation. Yet, at the same time, opportunities arose for the project team to pursue two interesting avenues of research, something which necessitated a re-arrangement of our timeline and priorities in order to do so.

These first of these was working on aspects of the new Medicines and Medical Devices Act 2021 during its passage through Parliament. The second was exploring the world of DIY artificial pancreas systems.

MEDICINES AND MEDICAL DEVICES ACT

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In February 2020, somewhat unexpectedly, the UK government introduced the Medicines and Medical Devices Bill (MMD Bill). Framed by the Government as a post-Brexit Bill, it set out a suite of provisions for the regulation of medicines and medical devices in the UK beyond the end of the EU exit transition period.

The Bill as introduced contained provisions granting the Secretary of State extensive regulation-making powers in relation to three major policy areas: (1) medicines, (2) veterinary medicines, and (3) medical devices.

In addition to granting overly wide powers (something which was roundly criticised in the House of Lords by both the Delegated Powers and Regulatory Reform Committee and the Select Committee on the Constitution), the Bill also had inadequate regard to patient safety and risked making the regulatory framework for medicines and medical devices even more complex, unwieldy, and difficult to navigate than it already is.

Just as the Bill began, the pandemic put it on the back burner. However, it reappeared on the Parliamentary agenda in June 2020.

Professor Muireann Quigley, Dr Rachael Dickson, and Dr Laura Downey from the EDC 2.0 team, along with Birmingham Law School colleague Professor Jean McHale, submitted written evidence to the House of Commons Public Bill Committee. Following the passing of the Bill in the House of Commons, the team then submitted briefings and memoranda to Members of the House of Lords on the Delegated Powers and Regulatory Reform Committee.

They then had the opportunity to work closely with some Peers to help provide adequate scrutiny of the Bill as it passed through the House. Their work contributed to changes made to the Bill in the Lords and it made its way back to the Commons in a substantially amended and improved form.

Back in the Commons some of these amendments (including those time-limiting regulation-making powers and those requiring draft primary consolidating legislation within 3 years) were removed. These were replaced by a Government tabled compromise. This is a provision requiring a report five years after Royal Assent on the effect of regulations made using the powers in the Act, and specifically addressing questions about the need for either consolidating or new primary legislation.

Whilst the compromise rolls back checks on the powers in the Bill from those achieved in the Lords, it is nevertheless a concession requiring reconsideration of these issues at a later date. Although some of the Lords' amendments were subsequently rejected by the Commons, the debate in the House of Lords provided a real depth to the scrutiny which the Bill received.

In order to support the bursts of intense engagement needed for work relating to the Bill, the project team managed to secure both an ESRC Impact Acceleration Award and Quality-related Research grant from Research England. This enabled us to draw on research assistance from Dr Laura Downey (who subsequently joined the main EDC 2.0 team in September 2020) and Victoria Moore (University of Manchester) to help with our work in this area.

Blogposts detailing the various stages of, and debate on, the Bill can be found on the project website. The briefings and evidence submissions which the team produced are also available online. The Bill received Royal Assent on the 11th February 2021. The team published a Birmingham Perspective piece on the now Medicines and Medical Devices Act 2021 which is available to read online.

DO-IT-YOURSELF ARTIFICIAL PANCREAS SYSTEMS

During early research for the EDC 2.0 project it became apparent that DIY Artificial Pancreas Systems (DIY APS) are a particularly innovative and interesting set of technologies. These have been, designed, developed, and adopted by persons with type 1 diabetes (T1D) as a means of better managing their blood glucose levels.

Having become tired of waiting for commercial manufacturers to produce technological solutions that meet their needs, some people with T1D have created their own software (installed on either a smartphone or mini pocket-sized computer) which enables their insulin pumps and continuous glucose monitors to 'talk' to each other. The aim of these systems is to enable automatic insulin dosing with reduced user input.

These systems are of interest to the EDC 2.0 team for a number of reasons. First, DIY APS are interesting examples of citizen science and patient-led research. They have not been through the usual regulatory approvals procedures which commercial systems must go through.

Second, as these systems are not approved by regulators, their use also raises interesting questions for clinicians who care for persons with T1D. For example:

How should healthcare professionals support people who use DIY APS?

Should clinicians be allowed to initiate discussions about DIY APS with their patients?

Who would be held liable if the system malfunctions?

In the early stages of the project, we met with a number of stakeholders interested in DIY APS. These include advocates and users of the technology, healthcare providers involved in the care of persons with diabetes, regulators, and other legal scholars interested in DIY APS.

We also attended conferences and events organised by the DIY APS community to meet participants and better understand both the technology and the motivations of those who use it.

In addition, we have presented our preliminary research findings at diabetes conferences and workshops, and have conducted literature reviews of the empirical literature surrounding DIY APS.

We managed to secure a Quality-related Research grant from Research England to extend the scope of the research and to draft briefing documents relating to these technologies.

The grant enabled us to work with a number of research assistants (Dr Laura Downey before she joined our EDC 2.0 team full-time, Dr Jessica Bell, Ms Victoria Moore, and Ms Amy Walker) in order to extend the policy and impact-related aspects of our work on DIY APS.

We intend to further this research into DIY APS over the next year. Our briefing documents and other resources relating to this will be available online in the near future.

DISSEMINATION AND ENGAGEMENT

The EDC 2.0 team attended a number events both in person and online to present and disseminate our research so far.

- In February 2020 prior to the UK lockdown, Dr Rachael Dickson and Professor Muireann Quigley presented a paper entitled 'Citizen Science and DIY Diabetes – Ethical and Regulatory Challenges of Patient-led Innovation' at both the Centre for Health Law, Science, and Policy at the University of Birmingham and the School of Law at Queens University Belfast. They will be presenting an updated, re-worked, and (we hope) more in-depth and analytical version of this at the upcoming Socio-Legal Studies Association Annual Conference in March-April 2021: 'Regulating DIY Artificial Pancreas Systems? On Citizen Science and Patient-led Innovation'.

- Later in February 2020, Dr Joseph Roberts was invited to talk at a panel on DIY APS at Advanced Technologies and Treatments for Diabetes (ATTD) in Madrid and spoke about 'DIY Artificial Pancreas Systems: Ethical Issues'.

- In December 2020, Dr Rachael Dickson presented a paper entitled 'DIY APS: The Future and the Law' at a webinar about DIY APS hosted by the Danish Diabetes Academy.

- In February 2021, Dr Joseph Roberts and Professor Muireann Quigley presented a paper entitled 'Being Novel? Regulating Emerging Technologies Under Conditions of Uncertainty' at a scientific roundtable hosted by the Max Planck Institute for Social Law and Social Policy.

In addition to presenting our research at academic conferences, the EDC 2.0 team has set up a project website and blog to share our work with a wider audience. As well as hosting our own blog, we have disseminated our research findings through other platforms including Scientia and Reformer Thoughts (the publication of the Westminster think-tank Reform).

Regrettably, due to the global coronavirus pandemic, there were some planned in-person research and engagement activities that had to be postponed. We had organised a research meeting on DIY APS and Patient-led Innovation, as well as a concurrent workshop on wider project themes. We hope to reschedule these, most likely as online events, later this year.

OUTPUTS

In addition to disseminating our research findings through our blog and at research events, we have been busy writing, with several articles and chapters at various stages of development:

Published/Forthcoming

- Shepard, J; Breton, M; Nimri, R; Roberts, JTF; Street, T; Klonoff, D; and Barnard-Kelly, K. (2020) 'Users and Healthcare Professional Perspectives on Do-It-Yourself Artificial Pancreas Systems: A Need for Guidelines' Journal of Diabetes Science and Technology. Doi: 10.1177/1932296820957728

- Roberts, Joseph T F; Moore, Victoria; and Quigley, Muireann. (2021) 'Prescribing Unapproved Medical Devices: The Case of DIY APS' Medical Law International.

In Progress

- Berry, Dominic J. 'Historicizing the Medical Device Marketplace in the UK and Ireland: A View from Below'

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

- Downey, Laura and Quigley, Muireann 'Integrating the Biological and the Technological: Time to Move Beyond Law's Binaries?'

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

Blogposts and Opinion Pieces

- Quigley, Muireann; McHale, Jean; Dickson, Rachael; and Downey, Laura. (2020) 'Medicines and Medical Devices Bill 2019-2020: Patient safety must be the priority', Birmingham Law School News, 9th June 2020.

- Downey, Laura; Dickson, Rachael; Quigley, Muireann; and McHale, Jean (2020) 'Attracting investment and protecting patients with smart regulation' Reformer Thoughts, 2nd September 2020.

- We published posts on our blog reporting on the progress of the Medicines and Medical Devices Bill as it made its way through Parliament, This collection of thirteen posts about the Bill is available here,

- We have a series of posts exploring some of the issues and disseminating our research findings about DIY APS. These are available here.

- We are just beginning a series of posts setting out the new strands of historical research the project is developing. These can be found here.

Policy Briefings and Evidence Submissions

- Quigley, Muireann; McHale, Jean; Dickson, Rachael; and Downey, Laura. (2020) 'Medicines and Medical Devices Bill 2019-2020 Briefing Note'. February 2020. Also available here.

- Quigley, Muireann; McHale, Jean; Dickson, Rachael; and Downey, Laura (2020) 'Written evidence submitted to the Medicines and Medical Devices Public Bill Committee', 6th June 2020.

- Quigley, Muireann; McHale, Jean; Dickson, Rachael; and Downey, Laura. (2020) 'Medicines and Medical Devices Bill 2019-2020 Briefing Note (July Update)', 28th July 2020

- Quigley, Muireann; McHale, Jean; Dickson, Rachael; and Downey, Laura. (2020) 'Memorandum submitted to Members of the House of Lords Delegated Powers and Regulatory Reform Committee' 15th July 2020.

THE REST OF THIS YEAR...

Although predicting the future is harder this year, as restrictions are lifted, we hope to begin our empirical research and look forward to (eventually) being able to resume in-person events.

We are particularly looking forward to:

Expanding literature reviews and furthering our understanding of the many challenges regarding integrated persons and medical devices.

More deeply exploring key concepts of interest, including boundaries and boundary-work, socio-technical imaginaries, and embodiment.

Uncovering and contextualising the historiography of medical devices (regulation) and the everyday cyborg.

Finalising our plans for empirical research, including recruiting participants to do oral histories, interviews (narrative and semi-structured), and focus groups.

Recruiting a PhD student to join the team.

Holding our first (delayed) project workshop, as well as arranging an Advisory Board meeting.

THE TEAM

We were delighted to welcome Drs Laura Downey and Dominic J Berry to the EDC 2.0 team this academic year. Drs Downey and Berry join our other Research Fellows Dr Rachael Dickson, and Dr Joseph Roberts.

PRINCIPAL INVESTIGATOR

Professor Quigley is Professor of Law, Medicine, and Technology at Birmingham Law 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 boundary-making in law and how socio-technical imaginaries impact on and shape law and regulation regarding persons and medical devices.

POSTDOCTORAL FELLOWS

Dr Berry joined the EDC 2.0 team in January 2021. He brings a background in the history and philosophy of biological sciences and technologies. His focus on the project is on historicising the Everyday Cyborg. He will be examining the history of attached and implanted medical devices as objects of research, industry, medicine, and regulation. Prior to joining us, he was a postdoctoral research fellow at the LSE working on the Narrative Science project.

Dr Dickson specialises in the governance and regulation of legal subjects, and explores how the law impacts our ideas of personality and bodily autonomy. She is interested in the socio-legal aspects of medical devices, including the impact of the law on the diverse range of people involved in their use. This includes patients, family members, healthcare professionals, and manufacturers, as well as regulators and policy-makers.

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.