19-20TH OF SEPTEMBER 2022

VISIONS OF THE EVERYDAY CYBORG

WORKSHOP REPORT

EVERYDAY CYBORGS 2.0

WHERE SCIENCE & TECHNOLOGY MEET HUMANITY

wellcome

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INTRODUCTION

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, despite their increasing prevalence, the law has been slow to respond to the integration of biological and technological objects. As a consequence, the use of these life-enhancing and life-saving devices still raise a number of legal and regulatory challenges.

The Visions of the Everyday Cyborg workshop, held on the 19th and 20th of September 2022, brought together an interdisciplinary group of scholars including lawyers, medics, sociologists, cybersecurity researchers, and regulatory experts to discuss the present and future of medical device regulation.

The papers presented at this interdisciplinary event were diverse. They included papers looking at the immediate personal experience of receiving a pacemaker; papers presenting the results of empirical research with people who use medical devices; and theoretical papers examining the relationship between technology and society and developing a new conception of the person capable of making sense of our increasing integration with technology. Participants also heard papers drawing out the challenges involved in regulating medical devices which include (or consist entirely of) software.

In this report you will find short summaries of the papers presented at the workshop.

KEYNOTE: LEARNING FROM THE PAST: LESSONS FROM THE IMMDS REVIEW - DR SONIA MACLEOD

The Independent Medicines and Medical Device Safety (IMMDS) Review, chaired by Baroness Cumberlege, set out to examine safety concerns surrounding three medical interventions: i) Hormonal pregnancy tests such as Primodos, ii) the use of sodium valproate during pregnancy, and iii) the use of vaginal mesh. In her presentation, Dr MacLeod, the lead researcher on the IMMDS review, outlined the findings of the review, focusing particularly on the case of vaginal mesh. Most notably, the review found that women's complaints about side-effects were dismissed and ignored. Had they been listened to earlier, the harms caused to many of the women involved could have been avoided. However, these warning signs were not noticed, and the use of vaginal mesh was not paused until the IMMDS review team started their review.

Dr MacLeod also drew out the recommendations for future practice the review arrived at, paying particular attention to the need to create the role of Patient Safety Commissioner and the need for a database of implantable medical devices. Since the review published their report in 2020, the role of Patient Safety Commissioner has been created. Dr Henrietta Hughes OBE has been appointed as the first commissioner to champion patient voice and lead the drive to improve patient safety. The IMMDS review also recommended the creation of a central database to track who has received vaginal mesh and the outcomes of these interventions. This recommendation has also been accepted, and a pelvic floor registry is being developed.

A MAN-IN-THE-MIDDLE OF MY HEART ATTACK - DR MARIE MOE

We are all increasingly reliant on internet connected technology. Medical devices such as pacemakers are also increasingly capable of wireless connectivity. These devices have the potential to both extend people's lives and improve people's quality of life. However, these devices are not always secure, exposing users to potential harm.

Dr Moe is a researcher and engineer with a background in cryptography and information security. In her presentation, She told the story of how she came to have a pacemaker and how this medical event led her to become interested in researching the cybersecurity of medical devices. The core of the problem, Dr Moe argued, is that medical devices such as pacemakers rely on legacy technology. Some pacemakers use old modems to transfer information, encrypt data using obsolete cryptographic techniques, and run on outdated operating systems. As a consequence, these devices are especially vulnerable to unwanted third-party interference, raising concerns about data security and the safety of these devices.

‘WE’ HAVE ALWAYS BEEN CYBORGS: BOUNDED, ESSENTIAL BODIES OR MORE-THAN-HUMAN ASSEMBLAGES? - PROFESSOR NICK FOX

Essentialist conceptions of humanity conceive of humans as indivisible, individualised, and bounded. Although formally neutral, this view prioritises bodies which are white, male, able-bodied, and from the global north. In his presentation, Professor Fox sought to challenge this metaphysics of the body by proposing an alternative post-humanist view according to which the body is not indivisible and separate from the world. Instead of seeing the body as a discrete entity, we ought to conceive of human agents as cyborg-assemblages influenced by their natural environment and the cultural world they inhabit.

In a humanist paradigm, medical technology is seen as a means of ameliorating or transcending the limitations of the body. Adopting a post-humanist ontology, however, reveals that more is at stake. Conceiving of the human as a cyborg-assemblage widens our perspective, allowing us to see how the physical and cultural environment influence our capacities.

VISIONS FROM EVERYDAY CYBORGS: SOCIOTECHNICAL IMAGINARIES, LAW, AND THE FUTURE OF MEDICAL DEVICES REGULATION - DR RACHAEL DICKSON

Medical devices are increasingly integrated with our bodies and capable of gathering and processing data. They are also increasingly prevalent. As such, they raise questions for the law. For instance, should we treat them as body parts, or are they mere property? How should we govern the data they generate? Who ought to be responsible for ensuring they are safe? Current medical device law focuses primarily on manufacturers, distributors, and clinical actors. The perspective of people who live with these devices is generally not the focus of attention.

In her presentation, Dr Dickson examined the socio-technical imaginaries, or visions of the future of medical devices, that arose in her interviews with both ‘elite’ stakeholders and people with medical devices. An important finding was that there were many competing visions of the future of medical devices. Many elite stakeholders saw medical technology in economic terms, as a growth industry that could help the UK remain competitive in a global market. Other stakeholders saw medical devices as offering societal gains, such as enabling people to return to work after accidents or illness. This stood in contrast to how many of the people who use medical devices spoke of them. Whereas stakeholders saw them as broadly beneficial, many of the people with medical devices interviewed focused on the burdens of living with a device and expressed a desire for them to become less visible and obtrusive.

THE USER-LED COMMONIFICATION OF HEALTHCARE? VISIONS OF THE #WEARENOTWAITING MOVEMENT - DR SHANE O'DONNELL

Until relatively recently, the development, production, and distribution of modern medical technologies has almost exclusively been the domain of industry or public institutions. This, however, has started to change. Groups such as the #WeAreNotWaiting community, for example, have created medical devices for themselves and participated in knowledge exchange activities with developers of medical technology.

In his presentation, Dr O'Donnell analysed the #WeAreNotWaiting movement as an instance of peer-to-peer production techniques. Dr O'Donnell argued that these new forms of production are a form of commoning. A commons consists of a collective resource (in this case knowledge), a community surrounding the resource, and a set of rules for engaging with the resource. The new knowledge commons being created by movements such as the #WeAreNotWaiting community have the potential to shape the wider medical devices system. Their success, however, is not guaranteed. Knowledge commons, like physical commons, are vulnerable to enclosure and co-optation. To ensure their success, these risks need to be tamed by reducing barriers to entry to the commons and ensuring that the knowledge generated by users is not enclosed by regulators and manufacturers.

EVERYDAY CYBORGS AND THEIR LIFE WITH A HEART DEVICE - DR GILL HADDOW

Cyborgisation is the process of joining the cybernetic with the organic. Far from being the realm of science fiction, this is an everyday occurrence. Increasing numbers of people are everyday cyborgs in virtue of them relying on medical devices which support the functioning of their organic bodies. Moreover, this process is likely to become even more prevalent in the future as life-expectancy increases and populations age.

In her presentation, Dr Haddow took a phenomenological approach to exploring the experience of living with an implanted heart device such as an ICD or pacemaker. Although these devices are literally life-saving and play a vital role in supporting people's quality of life, their use also raises new vulnerabilities. Acclimatising to an ICD or pacemaker is not easy. For instance, when first implanted, heart devices have a pronounced silhouette which softens over time. Their location on the chest can also require people reduce arm movements, or sleep differently, to reduce discomfort. Far from being a simple technological fix, successfully living with medical devices requires time and effort.

THE COMPLEX RELATIONSHIP BETWEEN TECHNOLOGY AND SOCIETY - DR ADAM MATTHEWS

Technology is seen as both something developed to meet human needs and functions, and as something that we 'need to keep up with' that operates independently from our desires and goals. Interestingly, these two semi-incompatible views of technology as a tool and as a social force are both prominent in popular discourse surrounding technology.

In his presentation, Dr Matthews explored how these two social imaginaries of technology are developed in educational policy documents looking at the use of technology in teaching. Teaching, like other activities, is becoming an increasingly technologically mediated. In some senses, this is beneficial as it provides educators with new, and sometimes useful, tools. However, technological innovation can also carry costs.

Dr Matthews' analysis of Teaching Excellent Framework statements and university strategy documents reveals that the use of technology can become an end in itself, divorced from the underlying purposes of teaching (such as assessment or feedback). The solution to this problem of technological overreach, Dr Matthews argued, is to democratically and equitably develop new views of desirable, feasible and viable futures of technology use.

THE UNBEARABLE LIGHTNESS OF BEING INTANGIBLE: REGULATORY UNCERTAINTIES AND SOFTWARE AS A MEDICAL DEVICE - DR LAURA DOWNEY AND PROF MUIREANN QUIGLEY

Many medical devices are now smart devices, i.e. they are capable of running software. Often this software is embedded in the medical device hardware. Other times, the software is developed and distributed separately. In their presentation, Dr Downey and Prof Quigley explored some of the challenges of regulating software as a medical device. Although there is no doubt that software is covered by medical device regulations, software developed on an open-source model might be difficult to regulate properly. This is due to the fact that the collaborative, diffuse, and globalised nature of the open-source software development. Processes in this open-source model do not fit well with the underlying assumptions made by medical device regulations, which mainly focus on physical products made by identifiable manufacturers. Consequently, it is difficult to determine when a piece of software has been 'placed on the market', who the 'manufacturer' is, and whether uncompiled software fits the definition of 'medical device' used in the regulations. Given the increasing prevalence of smart devices, these are challenges which need addressing in the short term.

THE CASE FOR MORE RIGOROUS REGULATION OF DIGITAL CONCEPTION - DR CATRIONA MCMILLAN

Femtech is the term given to a variety of technological products primarily aimed at women, such as menstrual trackers or digital contraceptives. Over the last few years, the number of menstrual tracking apps available has increased. Some of these apps market themselves as ways of tracking fertility, whereas other apps market themselves as contraceptives.

Dr McMillan argued that Femtech poses a problem for both law and regulation because they don't fit neatly within the remit of a single regulator. As a consequence, a systems approach to their regulation is needed. The first problem is that, depending on how the apps market themselves, they may not be covered by medical devices regulation. Where apps such as menstrual trackers are covered by existing regulation, they are categorised as Class IIb devices, alongside condoms and diaphragms. As a consequence, they are not subject to adequate scrutiny. Given that digital contraception apps can have the same consequences as pharmaceutical contraceptives if they do not function as intended, Dr MacMillan argued they are currently underregulated and should be considered category III devices.

REGULATING AI/ML IN SOFTWARE AS A MEDICAL DEVICE: MAPPING THE SPACE FOR AI ADOPTION - DR PHOEBE LI

The development and deployment of AI systems opens up many opportunities in healthcare environments, including diagnostic assistance and improvements in care delivery. However, AI systems pose challenges to current regulatory models. On the one hand, AI systems work best when they use dynamic algorithms which learn and adapt based on past performance. On the other hand, regulators need a static system which performs predictably over time for quality assurance purposes.

Dr Li argued that successfully regulating machine learning based AI applications will require a new approach to regulation which is better suited to their dynamic and evolving nature. The goal of these new approaches is to balance regulatory efficiency with patient safety. Although precisely how best to do this is currently unclear, developing these regulatory competencies is likely to require multiple regulatory agencies, including the MHRA, NHS digital, NICE, NIHR, and the AI Council. This regulatory overlap, however, poses the risk of making regulatory requirements confusing for developers and manufacturers. Dr Li proposed that the use of a one-stop-shop approach to regulation could give regulatees a clearer understanding of the regulatory requirements, thus making compliance easier.

THE ROLE OF CYBERSECURITY IN MEDICAL DEVICE REGULATION: FUTURE CONSIDERATIONS AND SOLUTIONS - MR KASPAR LUDVIGSEN

As connected devices become more prevalent, so do cybersecurity concerns. Resolving these concerns, in turn, will require more updates, servicing, and security assurance systems, as well as new legal frameworks capable of facilitating these new developments. In his presentation,

Mr Ludvigsen focused on the future of cybersecurity regulations in the EU, and argued that future cybersecurity law will need to be increasingly technology specific to be able to respond to the development of new techniques. The goal of these new regulatory solutions should be balancing security and safety. Also important, Mr Ludvigsen argued, is the use of privacy protection technologies which enable users to reduce the extent to which they are surveilled and increase their control over their information. To achieve this, we need both soft law in the forms of standards and codes of practice, as well as properly enforced hard law.

THE MEDICAL DEVICE CYBERSECURITY IN THE EU: THE CHANGES AND CHALLENGES BROUGHT BY THE AI ACT, NIS2 DIRECTIVE, AND DATA ACT PROPOSALS - MS ELISABETTA BIASIN

As healthcare becomes increasingly digitised, cybersecurity becomes a growing concern. In recent years, EU legislators have embarked on a process of reform of cybersecurity law that will have an impact on the cybersecurity of medical devices. These reforms are the AI Act, the NIS2 Directive, and the Data Act.

In her presentation, Ms Biasin outlined how these new regulations would impact on cybersecurity regulation, drawing out the implications for the Medical Devices Regulations, GDPR, and the Cybersecurity Act. Ms Biasin argued that the proposed regulatory changes raise a number of challenges for EU law including regulatory overlap, the risk of fragmentation of critical infrastructures within the internal market, and uneven levels of protection for different individuals. What is needed to overcome these problems, Ms Biasin suggested, is detailed guidance on how to interpret key terms in the legislation, most importantly ‘critical infrastructure’ and ‘cybersecurity’.