Visions of the Everyday Cyborg
Imaginaries, Law, and the Future of Medical Devices Regulation

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Overview & Background

- What visions of the future can be found in the ecosystem of the Everyday Cyborg / **Hybrid Human**?
- What do these visions mean for the law?

Everyday Cyborgs / **Hybrid Humans** are ‘persons with replacements and augmentations ranging from the simple to the extraordinarily complex, for example, artificial joint replacements, implanted devices such as pacemakers and the total artificial heart, and limb prostheses.’ (Quigley & Ayihongbe, 2018)

Hybrid between machine and biological organism living in modern society (Haddow, 2015)

Creatures of social reality as well as science fiction (Haraway, 1991)

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Sociotechnical Imaginaries

Future oriented visons: "…of connected social and technological orders, with more or less determinism built into them…" **But also contested, changeable, flexible** (Sismondo, 2020)

Stable enough to shape "terrains of choice and actions" (Smith, 2009)

Important for law: to connect with and shape novel and innovative technoscience, maintain effectiveness as a regulatory tool, mediate the boundaries of responsibility and accountability (Flear and Ashcroft, 2021)

Empirical work to date

33 interviews with EDCs – narrative and semi-structured components
24 interviews with stakeholders

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Cardiac Devices (Implanted) (7)	Hearing Loss Devices (Attached & Implanted) (13)	Diabetes Devices (Attached – subcutaneous) (10)	Lower Limb Prostheses (Attached) (3)
Pacemakers Implanted Cardioverter Defibrillator Types of person: Cardiomyopathy Heart failure Irregular heart rhythms	Over-ear hearing aids Bone Anchored Hearing Aids (BAHA) Cochlear Implants (single & bilateral) Middle ear prostheses Types of person: Degenerative hearing loss Profound deafness from birth Meniere's Disease	(Flash) Continuous Glucose Monitors (CGM) Insulin Pump 'Do-it-yourself' Artificial Pancreas System Types of person: T1D from young child T1D in adulthood	Custom made lower limb prosthetics: Over knee Below knee Types of person: Vehicle collision survivors

Stakeholders
Clinicians / HCPs Academics Regulators Notified bodies Trade body CEO Regulatory consultant Manufacturer

Patient Engagement Across the Medical Devices Landscape

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Almost all participants across landscape agreed that patient engagement was needed and important

But there were significant differences about *where* engagement was needed or appropriate, the *purpose* of the engagement, and what *expertise* patients could contribute.

Patient Engagement Across the Medical Devices Landscape

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EDC

Patients should determine research direction

As researchers / developers themselves

Perception that R&D driven by profit, not user needs

Research and Ideation

Engagement with patients useful, but limited in scope (to useability, evidence of understanding of patient needs)

R&D should be driven by stated needs of NHS

Stakeholders

Patient Engagement Across the Medical Devices Landscape

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EDC

As necessary advocates in developing legislation & regulatory regimes

None: leave it to HCPs, regulators, developers, etc.

Involvement requires formalising in standards, guidelines, law

In developing legislation / regulation

More systemic patient engagement – currently ad hoc

Patient engagement reduced to a 'tick-box' exercise, lacking meaningful dialogue and engagement, and requiring a robust framework for navigating disagreement

Educating patients about role of regulators

Stakeholders

Regulatory Uncertainty

EU
EU Medical Devices Regulation 2017
EU In-vitro Medical Devices Regulation 2017

UK
Medical Devices Regulations 2002
Medical Devices Regulations (Amendment) (EU Exit etc) 2019
Medical Devices Regulations (Amendment) (EU Exit etc) 2020
Medicines & Medical Devices Act 2021
Ongoing MHRA Regulatory Review

Northern Ireland
Northern Ireland Protocol CE & UKCA

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"But when you're a decision maker in a company and you're responsible for budgets of millions and you're being asked to put your name to something, but by the way it might change, oh by the way it's just changed again, who's telling them it's changed, and...how can you set an informed strategy when you're facing these constant, constant changes? And do you know what, they're not clear either. So, somethings are happening and not everybody's aware" - SH020724

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Access to devices

One area where EDC and stakeholders clearly converge is on **access** to medical devices

"*...globally only one in 20 people that can have them has got them...Well, you know, if you keep going at the current rate it will only take up to 650 years to catch up with the people that need them today let alone the people over the next 650 years who will need them. That's not a waiting list, it's a death sentence, you know*" (070122 – EDC)

"*CGMs and automated insulin delivery systems are the next best thing to a cure, and I think it's a crime that not everyone gets access to them*" (SH141223 - SH)

"*But I think it should be equal opportunities and equal healthcare costs. It shouldn't matter which postcode you're in as to whether or not you can get one hearing aid or two*" (SH141223)

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Some Initial Reflections

Using imaginaries can tease out the different narratives (assumptions, expectations, stories) around policy goals and can contribute to overcoming the obstacles to achieving these goals (e.g., Sorbie, 2019).

Haddow (2015) – "the medical professional's influence was also key and appears to be uncritically accepted suggesting that the everyday experience of becoming cyborgs *is mediated by experts*" (at 496 – emphasis added).

Hilgartner's 'vanguards' (2015) - small collectives that formulate and act intentionally to realise particular sociotechnical visions of the future that have yet to be accepted by wider collectives

^ O'Donnell and Quigley (in progress) - #WeAreNotWaiting and the diabetes commons as a potential example of these vanguards

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Next Steps

- Ongoing analysis, particularly to identify and compare the imagined futures different groups hold about:
  - technologies themselves
  - shape of law and regulation of medical devices

- What these different futures mean for regulation (e.g., what changes might be needed to facilitate these futures?)

- Explore power dynamics – for example, what futures are becoming ‘stabilised’? Are there ‘vanguards’ emerging? What might a patient commons mean for regulatory institutions / processes?

Thanks for listening!
Any questions welcomed

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