Regulating DIY Artificial Pancreas Systems? On Citizen Science and Patient-led Innovation

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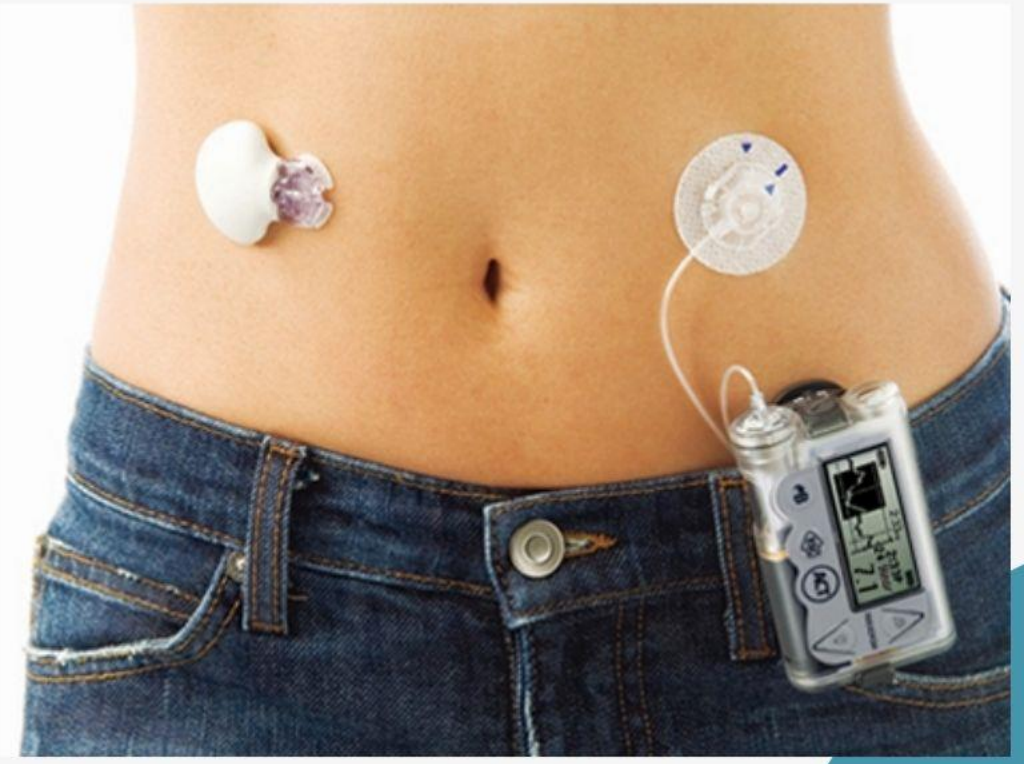
Outline

- The development of DIY artificial pancreas systems (APSs)
- DIY APSs *as* citizen science
- Interrogating DIY APSs as troubling:
    - Legal, ethical, & regulatory structures
    - power dynamics
    - knowledge, practice, & innovation
- Lessons for law & regulation?

Developing DIY APSs I

https://www.diabettech.com/looping-a-guide/



https://jdrf.org.uk/our-research/about-our-research/treat/artificial-pancreas/

Developing DIY APSs II

- T1D is a complex condition that requires significant patient effort to self-manage and is affected by multiple factors on a daily basis.
- CGMs and insulin pumps have been transformative but limitations remain.
- DIY APS was developed to address these limitations when device manufacturers were not interested in furthering the technology.

#WeAreNotWaiting

Citizen Scientist & DIY APSs

- Citizen science refers to the involvement of nonprofessional citizen participants in various stages of the scientific reserach process (Wiggins & Wilbanks, 2019).
- Data collection in biological studies of nature and animal activities, observational data regarding astronomical phenomena, etc.
- Biomedical projects: genomics & genetic sequencing or data donation
- Usually collaborative with professional scientists - way of engaging public as co-researchers

DIY APSs as Citizen Science

- Collaboration within diabetes community
- Designed, developed, & adopted by persons living with T1D
- Software maintained & users supported in using systems by non-medically trained citizens
- Examples *par excellence* of citizen science
- Loopers are a particularly concrete and tangible instantiation of the 'citizen scientist'

Law, Ethics, & Regulation I

- Unanswered questions:
  - Who is liable for device malfunction?
  - What impact does looping have on the responsibilities of clinicians?
  - Are DIY innovations adequately captured by existing regulatory structures?
- DIY APS falls outside of the tightly regulated medical device environment
- Software as a medical device: 'manufacturer', 'place on market', & form of SaMD

Law, Ethics, & Regulation II

- DIY APSs falls outside the scope of traditional research and clinical ethics procedures

- *However*, it is not the case that the DIY APS community have given no regard to ethics
  - Awareness of their limitations
  - Aim for transparency

- Raises questions about doctor-patient relationship and how this interacts with innovation.

Altering Power Dynamics

Outside ethical structures ***versus*** Developing new ethical processes?

Undermining clinician authority ***versus*** Empowering patients?

Preventing gatekeeping ***versus*** Establishing new forms of dominance?

Questions with broader societal impact relating to the "distribution of power and resources; transparency and accountability; social global justice and accountability" (Prainsack, 2017).

New Paradigms?

- Major issue is whether DIY APS can address the wider set of needs in diabetes care

- As with citizen science more generally, it currently centres around “a relatively select group of people, in particular those who are highly educated and already working in science or outreach spheres” (Fiske et al, 2019).

Lessons for Law & Regulation?

- Citizen science can and should operate to spark interrogation - by examining DIY APSs as citizen science, hopefully we have begun this process of interrogation.

- Potentially concerning aspects of patient-led & treatment orientated technological innovation

- Disrupting the usual models & structures (legally, ethically, or in practice) can have positive & fruitful outcomes - think carefully before intervening in ways that could move away from the citizen-led approach to DIY APSs

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Thank you for your attention!
Any questions?

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