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Digital medicine: as an opportunity to revisit the role of bioethicists

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Introduction

In their article 'The Ethics of Smart Pills and Self-Acting Devices: Autonomy, Truth-Telling, and Trust at the Dawn of Digital Medicine', Klugman et al. argue that digital medicine is changing medical practice. As the authors remark, these changes have repercussions for medical ethics as they raise questions with regard to well-known ethical themes such as informed consent, therapeutic misconception and confidentiality of data. Ethical scrutiny for digital health practices is indeed needed to assure that data is collected, use and stored in appropriate manners.

An aspect that remains implicit in Klugman and colleagues' paper is that in the context of the changing practice of medicine also the role of the ethicist deserves to be revisited. While a focus on informed consent and privacy, in line with the traditional ethical frameworks that have been established in clinical care is indeed needed, other issues also need to be taken into account in the ethical evaluation of emerging health care technology, such as exclusion, social justice and responsible innovation. Being open to a changing domain is key for ethicists and it also implies that we need to adapt our roles and approaches in order to be able to innovate and provide meaningful orientation in digital medicine. In the following we will outline what we believe these roles and approaches could be and how they apply to the practice of digital medicine.

Coproduction of science, technology, ethics and society

The notion of "co-production", originating from Science and Technology Studies, refers to the simultaneous processes through which modern societies form their epistemic and normative understandings of the world (Jasanoff 2006). This framework shows how scientific ideas and beliefs, and (often) associated technological artifacts, evolve together with the representations, identities, discourses, and institutions that give practical effect and meaning to ideas and objects. It also means that science, technology, ethics, society and politics 'co-produce' each other rather than the traditional view where science, ethics, society and politics have clearly demarcated roles. In co-production, technical and (bio)medical experts work together with ethicists, patients and other groups in society to generate new knowledge and technology together to better understand their own practices, their goals and the impacts of their practices. This approach is context-driven, problem-oriented and interdisciplinary (Gibbons et al. 1994). Such a framework is helpful for rethinking the role of the bioethicist, as it requires us to go beyond the abstract promises

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and rhetoric of digital medicine and situate the ethical analysis in real world practices and specific contexts (Lucivero 2016). Within digital medicine, encompassing many different devices, applications and tool that vary in their functions, it is crucial to develop and assess technology by including prospective users such as patients, caretakers and clinicians, as well as developers and manufacturers to develop technology that fits well to wishes, needs and values of those who will use the technology. Only then value-sensitive and desirable technology can be developed that may help to improve care.

Ethics parallel research

Ethics parallel research has proven to be well-suited to the ethical evaluation of medical innovations, such as digital health. It means that ethicists identify and evaluate the ethical issues of a novel biomedical intervention parallel or even proactively as the field develops (van der Poel and Doorn 2014; Van Delden and Bredenoord 2015). Ethical parallel research bypasses criticisms that ethics would always be ‘too little too late’ and enables the ethicist who is engaged in the innovation process to co-shape innovation processes and governance in a morally sound way during the developments. In the context of digital medicine, it means that ethicist should not solely focus on interventions that are currently implemented but also anticipate and become involved in new and emerging developments within digital health. This means that the goals and impacts of technologies need to be assessed and developed not only by biotech companies, and ethicists should actively be involved in the design and development process. One of the possible roles for bioethicists may be to explicate the normativity with regard to intended users, use and goals that are often still hidden in the development process (Lucivero and Jongsma 2018). Helpful questions at this stage may be: Which users may be excluded by this design? Is there implicit bias in the algorithms developed and used? Can users decide which data they share? Can this technology be abused, and if so who will be harmed by it? Such questions may uncover unforeseen effects, may help to prevent potential harm and eventually help to steer the development process into more responsible and desirable technology. The assessment already from the early phases on of such a development is therefore crucial.

Governance and ethical oversight

It follows that, in our view, the ethicist should also be concerned with questions about governance: under which conditions an intervention can be acceptable and which safeguards need to be in place. This means that new ways of arranging consent procedures have to developed. Consent for governance shifts the emphasis from initial consent to ongoing governance obligations, which include protection of donor privacy, participant engagement, benefit sharing and ethical oversight (Boers and Bredenoord 2018). Governance measures should not only protect the users data and privacy, but also should prevent exclusion and discrimination of marginalized groups and arguably also take involve fair benefit sharing. In other words, new ways of governance are required that pay attention to themes that go beyond merely procedural requirements and also do pay attention to societal impacts of new technologies. This is especially pressing in the context of medicine, because that is a field that has societal importance and may affect all of us. Benefit sharing seems to be a rather underrepresented topic for digital medicine, while many applications of digital medicine have an ambivalent status between lifestyle gadget and medical products (Lucivero and

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Prainsack 2015) and digital data from social media and patient platforms get increasingly commodified (Lupton 2014).

Broadening the scope for bioethics

Klugman et al. raise important challenges for the use of digital medicine. The proposed solutions for these challenges build on bioethical solutions that we know from traditional health care such as improved ways of informed consent and anonymizing data. It is no wonder that these tools are suggested as a solution, as digital health differs most obviously from traditional health in terms of data drivenness and data-sharing, that we protect in traditional health care with privacy regulation and anonymized data. The underlying values such as privacy, autonomy and safety have not become less important at the dawn of digital medicine, but it should be noted that traditional methods may not be desirable, possible or wise to apply in the digital context and this should urge bioethicists to look beyond traditional solutions and find new ways of ethics parallel research. Obviously, this does not only apply to the field of digital medicine, as other innovations require similar approaches, but the digitalization of health care is a very relevant and urgent example.

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