BACKGROUND

Mobile technologies have been making their entrance in the realm of healthcare and wellbeing. An increasing number of websites offer apps for smartphones and tablets and wearable gadgets that enable **individuals** to track their eating/sleeping/moving patterns, **patients** to collect their vital signs and manage their conditions and **clinical professionals** to share and integrate patients' data and conduct screenings outside the clinics (thanks to add-on devices for their phones). American market analysts predict that high volumes of these products will be sold in the next few years, while European governments invest in the vision of integrating mobile innovation in healthcare systems (mHealth) with the hope of reducing costs and improving care provision.

The mobility and portability of healthcare outside the walls of the clinic with the use of such technologies, however, entails several challenges: it creates technical, regulatory and administrative difficulties, and it also raises several ethical, social and political questions.

OBJECTIVES

With the overall goal of offering a systematic and empirically grounded ethical assessment of portable health technologies and their use in the clinic and beyond, this project pursued four main objectives:

1) to map technologies, regulations and discourses around mHT;
2) to explore moral, social and political values in the practices of use and technology design of mHT;
3) to assess these values against the background of current normative and conceptual descriptions in regulations;
4) to set an agenda for regulation at the policy, technology and user level.

WORK CARRIED OUT

The project's overarching results can be summarized as follow:

1) Identification of key technologies receiving attention in public health debates and the regulatory framework as well as relevant stakeholders. This was done through literature and internet searches and participation in key e-health events targeting developers, policymakers and healthcare professionals.
2) Investigation of the Patient Access app that allows patients to book their GP appointments, manage their prescriptions and access their GP notes and blood tests (data collection through 25 interviews and analysis).
3) Substantive work written in 4 research papers published in or submitted to peer- review journals; delivery of more than 10 academic presentations at international conferences and workshops. A number of papers are in the pipeline. Concepts of these papers have been presented at national and international academic conferences.
4) Consultation and collaboration with international policymakers: a) participation to the activities European Commission Working Group aiming at developing guidelines for the assessment of health apps; b) response to the World Medical Association public consultation on ethical considerations on health databases and biobanks.
5) Commentary on topical events around mHealth development, regulation and emerging ethical issues in public events and social media: Twitter activity, project website, publication of blog post, realisation of a podcast.
6) A visiting period at the Data Studies research group at the Exeter Centre for the Study of the Life Sciences (Egenis).
7) Foundation of an international research group exploring the social, ethical and political dimensions of IT, data and health: the Data and IT in Health and Medicine Lab(https://datahealthmedicine.wordpress.com/). The original reading group, based on a

creative and collaborative format, developed in few months into a Lab with international members which led to one commentary for the World Medical Organization, two journal articles and one blog post. A follow-up of the activity of this group is the development of a University-wide network for the interdisciplinary study of digital health.

MAIN RESULTS

The project overarching results can be summarized as follows:

1) In highlighting the great diversity in the objects and services that fall under the broad definition of "mHealth", 5 W (Why? What? Who? Where? When?) and 1 H (How?) questions can guide a situated ethical and normative analysis of specific mobile health system. (single authored paper titled *An ethics of mobile Health? a heuristic approach for bioethics;* draft to be submitted to Bioethics or American Journal of Bioethics.)
2) "Mobile health" systems provide health-related information to individuals and offer advice for lifestyle change. These 'technologies for healthy lifestyle' occupy an ambiguous space between the highly regulated medical domain and the less regulated consumer market. This ambiguity challenges implicit distinctions between what is medical and what is related to personal lifestyle choices within current regulatory systems. mHealth challenges current regulatory frameworks in three areas: the definition of health data; the distinction between medical device and consumer product; and current systems to assess liability. For this reasons, the risk-based approach falls short as regulatory tool for health apps (*Lucivero-Prainsack 2015;* This paper is currently being expanded in an in-depth thematic analysis of existing regulatory documents for mHealth. This single authored paper is provisionally titled: *Health and lifestyle: a blurring distinction in the age of wellness apps* – Paper presented at Trading Zones conference, Liege, October 2015 – final paper to be submitted to Biosocieties)
3) By allowing patients to collect relevant data for biomedical research in a continuous fashion and outside clinical sites, health apps and self-tracking devices raise ethical and practical challenges for the governance of biomedical research. This requires to rethink norms, categories and nomenclatures governing medical research (e.g. the concept of "personal data" or "anonymization"). We should also reconsider currently accepted practices of informed consent in biomedical research ethics that are tailored for specific studies conducted in clinical domains (Aicardi et al 2016; Dove et al under review; paper in preparation co-authored with Dr Kosta and provisionally titled *Governing data-intensive approaches to medicine: informed consent*).
4) The case of digital access to personal health record offers an exemplary opportunity to reflect on the meaning of the value of "empowerment" that is often mobilized in digital health discourses. The analysis of qualitative interviews with patients who have to access their medical records via desktop or mobile interfaces shows that there is a gap between the promise of empowerment and situated practices of patient accessing medical records. More specifically: 1) practices of care are characterized by relational assemblages rather than atomistic individuals; 2) the space for patients' action is very limited (and this is at odds with the dominant rhetoric of "putting patients in control"); 3) in the context of digital health, the centrality of the value of "trust" should be intended as "patients' trust in the technology" but as "doctors' trust in patients". (Lucivero, under review).

EXPECTED POTENTIAL IMPACT AND USE

The main contribution of the proposed research is to offer a framework for the responsible development of portable health technologies. In an era of high interest of regulators and policy-makers for the future of healthcare, the research activities conducted in this project offer the basis to setting an agenda for a responsible development and integration of mobile health technologies in current care systems. By exploring the ethical social and political underpinnings of current discourses and practices surrounding this emerging field, this study offers guidance for policy makers, on the one hand, and technology developers on the other hand. It also offers a resource for clinical professionals and the larger public to understand current socio-technical changes in healthcare. The researcher's current participation in the activities of the European Commission Working Group on mHealth guidelines as well as her active engagement in dissemination activities beyond academia ensure that the main ideas have been (and will continue to be) communicated to relevant stakeholders.