

EPINET

Funded under FP7-SiS-2011-1.1.1-4
Grant Agreement 288971

Deliverable D8.3 (delivery date, month 36)

Case study of wearable sensors WP3 Policy Report, March/April 2015

Gadgets on the move and in stasis

Consumer and medical electronics, what's the difference?

Summary of findings and policy recommendations

Rapporteur: Kristrún Gunnarsdóttir
k.gunnarsdottir@lancaster.ac.uk

Partners: ¹

Lancaster University, UK

University of Sussex, UK

Vrije Universiteit, Brussels

EC JRC, Ispra, IT

University of Bergen, NO

Kristrún Gunnarsdóttir (rapporteur); Brian Wynne

Aristea Fotopoulou; Kate O'Riordan

Niels van Dijk; Serge Gutwirth; Mireille Hildebrandt

Melina Breitegger; Ângela Guimarães Peirera;

Lucia Vesnic-Alujevic

Kjetil Rommetveit; Roger Strand

¹ This policy report is based in Epinet's WP3 case study on wearable sensors for health and self care, fitness and well-being. The partners have shared their notes and reflections on three years of research in order to produce a shared summary of key findings along with policy recommendations. As the rapporteur and work package leader, I extend my gratitude for excellent scholarship, brilliant insights and good working spirit.

Objectives and aims of the case study

This document provides a set of policy recommendations, based on the findings of a three-year long case study on wearable sensors. The key objective was to assess state-of-the-art developments in this domain of innovation, using evaluation and analytic methods that correspond with the expertise and experience available on our study team and among our associates in industry and innovation, medicine, policy, grass roots activism, STS and ELS study traditions. Our aim is to provide guidelines for good governance of wearable sensors, in light of their potential roles in medical settings as well as their currency as consumer electronics for quasi-medical purposes. We provide recommendations for ongoing innovation in this field, considering the necessity of mutual recognition and reflexive knowledge exchange among innovators and industrial actors, medical expertise, scholarly and technical assessments, patient organisations and grass roots activism, policy developers and regulators.

Our policy recommendations are aimed at two rather different areas of policy development and policy intervention. First, we present a set of discussion points (*sections 1, 2 and 3*), directed at **scientific and innovation policy advisory bodies** to the European Science Foundation (ESF), the **Digital Agenda**, the Commission's **DG Research**, **DG Health** and other relevant directorates, innovation and research funds/agendas/programmes in matters of health and social care, ICT-driven innovations in healthcare (*eHealth / mHealth*) and Public Health initiatives. We are directing our recommendations here at the development of innovation policy—of navigating the future of healthcare with the support of institutional politics and configurations that should be reconsidered and re-evaluated more critically and more frequently than currently is the case. Secondly, we have unravelled legal and regulatory uncertainties concerning devices and services already in use and widely available on the market (*sections 4.1, 4.2 and 4.3*). We direct our recommendations here at **authorities of medicines and health products** across Europe and the associated Health Technology Assessment (HTA) bodies, the Commission's **DG-Connect**, the European Data Protection Supervisor (EDPS) and the **Article 29 Working Party**, as well the individual country-based Data Protection Authorities (DPAs).²

Policy concerns

During the early stages of this case study, **the future of care** and **the future of the informational embodied person** were two topical areas identified on the basis of a changing politics of care and the influx of gadget use-data, behaviour-data, location-data and other incidental data in the mix with data on people's physiological states and medical conditions. The responsibility for providing care is shifting from public institutions to private enterprise, toward more personalised care, patient choice and individuals being themselves in charge of their care needs. It follows that increased use of wearable computing and sensor technology to support the new care practices, necessitates collection, processing and dissemination of data on persons and bodies in ways that can be hard to reconcile with directives on the protection of such data. It can also be argued that predominant visions of 'measure and monitor' to support health and self care, are reductionist in their orientation to **care as data practice**. The two topical domains have gathered more specific considerations and policy questions which have evolved over time and eventually culminated in the discussion points and recommendations we present in this document.

² Our recommendations here are considering of recent legal and regulatory developments, in particular, the **General Data Protection Regulation (GDPR)** proposal. European Parliament and the Council of the European Union. (in-progress). *Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data.*

Policy-relevant considerations:

Reform in healthcare delivery across Europe comes with great emphasis on more personalised care, patient choice, private insurance and personal responsibility.

Personalised care is shifting roles, relations and responsibilities in *care-giving*.

Mass marketing of smartphone-enabled apps and accessories are blurring the boundaries between healthcare, self care, fitness and well-being applications.

New service 'hubs' for mobile data gathering and the processing of health-related and potentially sensitive information, are a challenge to the protection of privacy and personal data.

Key policy questions:

Are the policy goals of more personalised delivery of care realistic? Will they improve the access to adequate care for all or exacerbate existing health inequalities?

Are the policy goals of medical devices regulators realistic? Do they take into account the growing use of consumer gadgets and apps to detect and manage health-related conditions?

Are the policy goals of protecting personal data realistic? Do they take into account the complications introduced by incentives to share data, for example, in exchange for access to data processing.

Summary of findings

Wearable sensors for health and self care, fitness and well-being, are ***gadgets on the move and in stasis***. They blur the boundaries between healthcare and the self-administration of care when patients begin to actively self-monitor using wearables and biosensors as part of ongoing care. They shift these boundaries when consumer electronics are marketed and put to use for medical purposes—devices which then sit in a policy vacuum since there is no adequate legal framework with binding rules to cover consumer gadgets in medical settings (Green Paper on mHealth, 2014).³ Yet, the boundaries are drawn quite clearly when wearable sensors are marketed for quasi-medical purposes, for which the HTA frameworks and the European medical devices directive do not apply. Moreover, wearable sensors, whether or not they classify as mHealth technology, are not indiscriminately *on the move*. In fact, their flexibility is confined to prescription: that of structured activity, of locality, stasis and types of measure and monitoring built into them, including standards on data capture and data processing.

We learn from our explorations that policy and research programmes are promising flexible and more personalised care, patient involvement and greater citizen responsibility in managing disease and staying healthy. Alongside that is a very positive media environment, accommodating media commentaries which are almost entirely based on promotional materials that endorse the new gadgets and services. It is not clear however, how ICT-based and mobile technologies will impact in the long run on publicly or privately provided care and public health targets. Wearable sensors fit into grander visions of a healthcare revolution—of an evolving ecosystem of objects, functions, services and growing incentives to take charge of one's life. But, there is implied bias here toward prediction and control which reduces care to control measures and over-simplifies care relations and communication on care. We come across the notion of *empowerment*, of taking charge and being in charge as if citizens can be relatively free of ordinary social-cultural constraints and unaffected by the particularities of the healthcare actually available to them. The notion of empowerment raises a question of whether existing digital divides and health inequalities are exacerbated. It is of particular curiosity as well to discover the disconnect between the policy visions of the future of healthcare for European citizens and the grass roots activities in self care

³ **European Commission. (2014)** *Green Paper on mobile health ("mHealth")*. Brussels, 10.4.2014. COM(2014) 219 final.

such as the Quantified Self (QS) movement, hackerspaces and other initiatives that are leaning toward the self-administration of care and a co-construction of care-relevant knowledge. Finally, as a result of the lack of a regulatory framework for consumer electronics in use for healthcare purposes, we discover a whole host of issues associated with an emerging market of *health as leisure*, whose success should be considered in reference to value creation rooted in cultural trends and traits, not the practical improvements promised in policy documents (e.g. eHealth Action Plan and the ESF Forward Look on personalised Medicine for the European Citizen).⁴ The business models typically rely on common denominators to trawl for data in large numbers—to prescribe and exploit traits and trends of behaviour on a mass-scale for commodification purposes (see Gunnarsdóttir et al, 2015 submitted).⁵

We have achieved these learnings by engaging a number of disciplines that are all well equipped to assess new-emerging domains of innovation, although, their approaches vary significantly: knowledge assessment, ethics, law, socio-technical evaluation, digital culture and media studies. We have also engaged medical expertise, policy research, regulators and self-care activists, to gain the insights of a much wider network of professional and other relevant experience with wearable sensors. These exercises in knowledge exchange and debate form an important part of our case study, i.e., to evaluate the enablers and constraints of various stakeholder views and assessment methods, in particular, what is gained by bringing them together as we have done.⁶

We proceed with our policy recommendations as a series of questions to be openly considered and debated:

- Questions concerning the involvement across knowledge sectors, occupations and ideologies in debate and deliberation: ***rethinking the policy actors and the policy action***.
- Questions relevant to policy development to-date and corresponding pressures on the medical establishment: the need to ***consider the feasibility and viability of technological faiths and fixes***.
- Questions concerning the disconnect between visions articulated in policy programmes and the grass roots activism that aims at supporting the self-administration of care; also the disconnects in use/non-use patterns of affluent *techie* consumers as opposed to those without the means and the access.
- Questions concerning the regulatory and legal uncertainties about devices and services already available in care markets.

4 **European Commission. (2012)** *eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century*. Brussels, 6-12-2012; **ESF Forward Look. (2012)** *personalised Medicine for the European Citizen - Towards more precise medicine for the diagnosis, treatment and prevention of disease (iPM)*. European Science Foundation.

5 **Gunnarsdóttir, K., Breitegger, M., Dijk, N. van., Fotopoulou, A., Guimarães Pereira, Â., O'Riordan, K., Rommetveit, K. and Vesnic-Alujevic, L. (2015, submitted)**. Tracking biosensors: healthcare, wellbeing and new-emerging markets. Draft copy of preprint is available at <http://neicts.lancs.ac.uk/pdf/Preprint-Care-Markets.pdf>.

6 Other publications and conference papers under review and forthcoming are:

- a) **Vesnic-Alujevic, L., Breitegger, M. and Guimarães Pereira, Â. (2015, forthcoming)**. 'Do it yourself' healthcare? Quality of health and healthcare through wearable sensors. *Science and Engineering Ethics*;
- b) **Fotopoulou, A. and O'Riordan, K. (2015, submitted)**. Training to self-care: Fitness tracking and the knowledgeable consumer. *European Journal of Cultural Studies*;
- c) **Breitegger, M., Vesnic-Alujevic, L. and Guimarães Pereira, Â. (2015, submitted)**. Wearable Sensors - Assessing Knowledge of Epistemic Networks. *Science and Technology Studies*;
- d) **Gunnarsdóttir, K. and Guimarães Pereira, Â. (eds) (2015, book proposal)**. *Making sense of wearable care. Markets, mediascapes and the informational person*. Palgrave;
- e) **Guimarães Pereira, Â. and Gunnarsdóttir, K. (2015, submitted)**. *Self-tracking and critical sense-making: an emerging epistemic network (conference paper)*. 4S Annual Conference, Denver, Colorado 11-14 November. Session title: Exploring self-tracking: between submission and resistance.
- f) **Fotopoulou, A. (in preparation)**. 'All these emotions, all these yearnings, all these data': big data and the moral economy of data sharing. Invited submission to *Big Data and Society*.

Policy considerations and recommendations

The next three sections (1, 2 and 3), are directed at **scientific and innovation policy advisory bodies** to the **ESF**, the **Digital Agenda**, the Commission's **DG-Research**, **DG-Health**, and other relevant innovation and research funds/agendas/programmes in matters of health and social care, ICT-driven innovations in healthcare (*eHealth / mHealth*) and Public Health initiatives.

(1) Rethinking the *policy actors and the policy action*: expertise and experience

Explanation/findings: Navigating the future of healthcare, patient activism and the self-administration of care, concerns all Europeans. Care is woven into the fabric of everyday life and everyone is at one point or other facing the consequences of change. This reminds us that EC and EU policy-makers are not the only, or necessarily the most important policy actors in developing an innovation policy with claims upon the future politics of care and what the priorities need to be to ensure sustainable quality care—what should be the institutional (re)structuring, the technological and socio-cultural innovations, and the reimbursement and funding schemes to provide care or to otherwise support it.

In the case of wearable sensors as part of the eHealth and mHealth programmes, there are questions to debate and deliberate across a wide range of expertise, professional and other relevant experience to shape and cultivate an epistemic network. Such a network is necessarily dynamic and fluid, an emergent network of a rather different constitution than the narrow aggregates of policy actors who – so far – appear to have exclusive access to policy development and decision-making procedures.

Policy considerations: In navigating the future of healthcare for European citizens, we strongly recommend rethinking how the policy environment is shaped:

- Is the policy action **mindful** of the sensitive nature of future-making on behalf of European citizens?
- Is the policy action mindful of the **limits of prediction and know-how**?
- Is the policy action an **exploratory action**? Is it **experimental**, a **fact finding** mission across knowledge sectors, occupations and ideologies?
- Is the policy action a **work-in-progress**, aiming toward discovery – on an ongoing basis – of the **kinds of things** that **can be** imagined and stated about an innovation domain?

(2) Policy and the medical establishment: faith and fixes

Explanation/findings: Are politics and innovation policy pulling the medical establishment on the future of eHealth and mHealth, being pushed by it, or both? The policy literature and funding programmes tell a mixed story which indicates to us a lack of clarity in the innovation and policy rationale.

Policy considerations: We strongly recommend achieving clarity on the following points: ⁷

- Are the innovation narratives on *eHealth* and *mHealth* mindful of potential **bias of prediction and control**, of **reducing care to control**?
- Are among the policy actors also those who are inclined to question **faith in technological fixes**? What alternatives do their insights have to offer?
- Are the innovation narratives **over-simplifying communication and interrelations**, for

⁷ For individual applications aimed at elderly persons, we recommend consulting discussion points raised in: **EFORTT. (2011) Care with technology? An ethical framework for telecare**. EFORRT, Lancaster University. <http://www.lancaster.ac.uk/efortt/> .

example, between patients and doctors, policy-makers and innovators, and people's experiences of their lived bodily selves?

- Are the innovation narratives **reducing medical consultation to data collection and information gathering**, to substitute for in-depth communication that necessitates taking into account cultural, environmental and physiological specificities of a medically-relevant case?
- Does the emphasis on individual empowerment take adequately into account **which care provisions are actually available and the full range of personal circumstance** affecting motivations and abilities, including economic hardship or any form of exclusion from access to high tech solutions?

(3) Policy and grass roots action: a (dis)connection

Explanation/findings: We observe a disconnect between top-down thinking in policy development aiming at personalised healthcare and mHealth, and the kinds of grass-roots developments that show what people actually do when left to their own devices, and how lead markets take shape.⁸ The policy discourse takes little if any notice of self-generating trends in managing health-related conditions with the support of devices and online services, self-help and peer-communication portals. The industry is often well aware of such trends and capitalises on them, but the institutional structuring for devices regulation is disconnected.

Policy considerations: We strongly recommend achieving clarity on the following points:

- Is the policy discourse on eHealth and mHealth **making irresponsible promises** of healthcare revolutions, suggesting that electronic devices and services (including wearable sensors) are key to improved care delivery, increased efficacy and cost savings?
- What can be done *to better identify the uncertainties* (social, ethical, legal, technological and political) in **shifting responsibilities for care** into the hands of individuals themselves?
- Are among the policy actors also those who are **knowledgeable and involved in DIY design and development**—those who observe first hand the implications for healthcare policy?
- How can **lessons from grass roots action** be incorporated into the established practices, e.g., on criteria for data protection by-design, on issues of inclusion/exclusion, and other relevant concerns?

(4) Regulatory and legal uncertainties

The following set of recommendations (4.1, 4.2, 4.3) is presented for immediate consideration and action in response to devices and services already in use and widely available on the market. They are directed at **authorities of medicines and health products** across Europe and the associated Health Technology Assessment (HTA) bodies, the Commission's **DG-Connect**, the **EDPS** and the **Article 29 Working Party**, as well the country-based **DPA**s.

(4.1) Devices regulation

Explanation/findings: Consumer electronics and apps are used by patients as part of ongoing care, and consumer electronics and apps are marketed and put to use for medical purposes. These mHealth practices both push and blur the boundaries between healthcare, patient

⁸ See report on expert workshop in Brussels 5 Nov 2013. http://neicts.lancs.ac.uk/pdf/EPINET-D3.2_WP3.pdf .

participation, and the self-administration of care; between consumer rights and law and the EU Council Directive concerning medical devices.⁹ The 2012 ESF forward look on personalised medicine¹⁰ recommends that healthcare professionals work with ICT experts to define, for example, how smartphone-paired and smartphone-enabled sensors and apps can function as decision-support tools for citizens.¹¹ It recommends a flexible health technology assessment (HTA) framework to support the adoption of new technologies of added value to conventional care. But, if the new gadgets and services are not strictly classified as medical, and regulated as such, they effectively sit in a policy vacuum. There is no clear legal framework yet, with binding rules, to ensure that developments, uptake and use are sound, as the green paper on mHealth puts it (2014, 3.3, pp.10-11).

Recommendations: We strongly recommend deliberation for action in response to mHealth developments:

- What can be done to establish an adequate legal framework, with binding rules, to cover safety and performance requirements of quasi-medical devices?
- How can legal ramifications be adequately (re)drawn between consumer and medical wearables?
- Is there need to strengthen the enforcement of EU legislation applicable to mHealth, by competent authorities and courts; if yes, why and how?

(4.2) Conflating legal frameworks

Explanation/findings: The terms of use of social networking sites (SNS) often specify that users grant the service provider 'perpetual, irrevocable' right to 'commercially exploit any text, photographs or other data and information' submitted to the online service. From a legal perspective, 'terms of use' in these environments present a strange hybrid of data protection law and something akin to copyright law. This is also the case for SNS, processing wearable sensor data and associated information on the individual. By framing data and information as 'user-generated content' and defining their use according to terms seemingly taken from copyright licensing, the locus of regulation and control of private and potentially sensitive data is presented to the user under the legal regime of quasi-intellectual rights, not that of data protection. 'User-generated content' however, is not a widely accepted legal term. It can be said to resemble copyright to the extent that creating the content requires original input, although, that is potentially misleading because it can be questioned whether the data exhibit the 'certain amount of creative effort' necessary to qualify as copyright user-generated content (OECD, 2007).¹² It is also misleading to suggest that data protection is waived in this way. Rights and obligations concerning personal data cannot be so freely contracted away. For instance, consent is always revocable and never perpetual.

Recommendation: We strongly recommend clarifying the legal status of user-generated content in Europe, as well as the status of data protection law in relation to the creation, storing, processing and sharing of such content.¹³

9 **Council. (1993)** Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. *Official Journal of the European Communities* L 169/1. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042> . See also http://ec.europa.eu/consumers/consumer_rights/index_en.htm on EU consumer rights and law.

10 **ESF Forward Look. (2012)** *personalised Medicine for the European Citizen - Towards more precise medicine for the diagnosis, treatment and prevention of disease (iPM)*. European Science Foundation. http://www.esf.org/uploads/media/Personalised_Medicine.pdf

11 Recommendations 7.3, p. 50.

12 **OECD. (2007)** *Participative Web and User-Created Content. Web 2.0, Wikis, and Social Networking*. Paris: OECD.

13 We suggest here an **Article 29 WP Opinion**.

(4.3) Data protection and data protection impact assessment (DPIA)

Explanation/findings: The DPIA Framework for Radio Frequency Identification (RFID) applications¹⁴ was established in response to the sudden ubiquity of RFID units and to the nature of their use in data handling operations. In light of a recent surge in wearable sensors for health, fitness and well-being purposes, and given the technical similarities between RFID units and wearable sensors, the RFID framework can be considered a relevant basis for DPIAs of the use and handling of wearable sensor data. Furthermore, since these devices will process personal data 'concerning health' and 'for the provision of healthcare', a DPIA will be mandatory under the proposed European GDPR regulation (art. 32a.2b&d GDPR).

Policy considerations: We strongly recommend achieving clarity on the following points:

- DPIAs for the handling of wearable sensor data will need to consider the limitations of risk assessment methods, by paying attention to risk framing and uncertainties, public engagement protocol and legal lessons on the substance of rights and procedures for dealing with them.
- Preparing and organising DPIAs for the handling of wearable sensor data will need to consider a protocol for justifying the basis on which the considerations listed in the previous point are taken into account:
 - Is the rationale for the inclusion of risk assessment methods and risk framing mindful of user experiences, potential design complications and the risk of live system faults, including operational/administrator errors?
 - Is the DPIA covering and reflecting upon 'inconvenient' uncertainties?
 - Are public engagement plans going past the survey model, considering focus groups, scenario workshops, consensus conferences and science cafés, deliberative polls and citizen juries?

Explanation/findings: Adequately addressing issues of data protection is a pressing matter when the registration process onto online data platforms and SNS that accommodate wearable sensor data, is visually designed in such a way that it nudges the user to ignore privacy policies and terms of service. The same argument applies to the visual design of the platforms themselves. They often nudge users to make the least privacy friendly choices. The layout of privacy policies has also been criticized for being opaque, typically using small block text format creating impenetrable textures rather than readable text.¹⁵

Recommendations: Several paths should be explored for deliberation and action:

- Data controllers of online data platforms should be driven to take more consumer-centred approaches.
- What kind of incentives can be put into effect to help deliver more consumer-centred approaches, e.g., should international self-regulatory codes or best practices be considered, or a facilitation of collective action through EU redress mechanisms?¹⁶
- Data controllers should incorporate relevant aspects of the General Data Protection Regulation (when legislated), or more precisely the obligation currently in the proposal, that data controllers should offer 'transparent and easily accessible policies' so that the data subjects can exercise their rights (Article 11.1 GDPR).

14 See **Working group on the implementation of RFID communication. (2011)**. *Privacy and Data Protection Impact Assessment Framework for RFID applications*.

15 For example **Hoback, C., director. (2013)** *Terms and Conditions May Apply*. USA: Hyrax Films.

16 See **Wauters, E., Lievens, E. and Valcke, P. (2014)**. Towards a better protection of social media users: a legal perspective on the terms of use of social networking sites. *International Journal of Law and Information Technology* 22(3): 254-294.

- How can the creation of general tools that enhance awareness and understanding of data policies (like rating and labelling), be stimulated? ¹⁷

Similar arguments pertain to more general issues of data control and transparency in the operations and use of online data platforms and SNS:

- Data controllers should establish procedures and mechanisms for the architecture of online data platforms and user interfaces, to enable data subjects to effectively exercise their rights (to object, access, modify or delete their data), and be provided with information about the nature of the data processing. This means also that system transparency and user empowerment – as the law requires - should be designed into the architecture to afford action, but that will also be an obligation of the data controller, i.e., to practice '*data protection by design*' (Article 23.1 GDPR).
- An important objective for establishing the need for these measures should be the degree to which they enable data subjects to effectively understand their own informational actions online and to exert control over their informational citizenship and person-hood.
- A further consideration is whether the '*by design*' framework will have to be expanded upon to cover issues like non-discrimination.

17 *Ibid.*