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A report on the networking/embedding event, 'Making sense of wearables: New-emerging markets and mediascapes', Brussels 5 Nov 2013.

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- ¹ This report omits discussion for internal use among team members, for example, the words of particular named persons on the team or in the wider **epistemic network**. All photos and biographical information on team members and associates are also omitted.
 - ² In preparing this document, the partners have shared their notes and their reflections on the embedding workshop, and the contributions of our invitees to development of this case study.

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Abstract: This working paper reports on the events of the networking/embedding event, organised by the Epinet WP3 team in Brussels Nov 2013. It summarises observations and key findings. The aim of the event was to involve the expertise of professionals from a range public and private agencies involved in the development of wearable sensor technologies and ICT innovation policy. We learn from their input of new-emerging roles for wearable sensors, how they are situated in visions of the future of healthcare and self care, of changing lifestyles and occupations. We learn of complications in clinical practice and in medical devices regulation. We learn of expectations, of what personalisation can stand for, of conceptions of behaviour and of well-being more generally. Finally, we observe a distinct disconnect between top-down policy developments on the future delivery of personalised healthcare to European citizens and grass-roots developments in self care and in the self-management of medical conditions. The results of this consultation are key to finalising the embedding stage of the case study on wearable sensors, and they provide major input into our attempts to integrating the many different assessments of this innovation domain.

Introduction

This document reports on the Epinet workshop, titled: ***Making sense of wearables: new-emerging markets and mediascapes*** (see brochure with full programme in **Appendix II**). The workshop took place in Brussels, 5 Nov 2013 and was orchestrated by the rapporteur who is also in charge of Epinet's WP3 case study on wearable sensors. This event was a milestone in the development of the case study, i.e., to put our research, policy questions and considerations to the test against the perspectives of our invitees from industry, regulation, policy circles, academe and grass-roots activities. Accordingly, this report accounts for the thematic and focal areas of discussion and debate on the day, and for the learnings that can be underscored.

Policy concerns

During the first phase of the case study, the partners identified a couple of topical areas to bear in mind for discussion and debate further down the line:

- ***The future of care***
- ***The future of the informational embodied person***

Key topics for the WP3 case study:

The future of care

The future of the informational embodied person.

Policy-relevant considerations:

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

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

Mass marketing of smartphone-enabled apps are blurring the boundaries between healthcare, self care, fitness and wellbeing 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 personalized delivery of care realistic? Will they improve the access to adequate care or exacerbate existing health inequalities?

Are the policy goals of medical devices regulators realistic? Do they take into account the growing use of mundane gadgets and apps, and online services 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 in exchange for access to data processing and analysis.

Provisions for the delivery of healthcare to European citizens have been under review for some years (e.g. ESF Forward Look, 2012).³ Among other things, the trend is toward more personalized care, toward patient responsibility, more patient choice and greater

³ 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).

precision in medicine. But reform in the organisation and delivery of care is often instigated by tightening budgets as much as by increasing and changing demand for care. Changes in priorities are already affecting the ways in which roles, relations and responsibilities are defined and delegated in care-taking. Provisions of care are shifting from public provisions to private investment, from healthcare to self care, away from clinics, into the home and toward so-called mobile health (mHealth).

Wearable sensors are very much at the core of developments towards mobile care, however, they emerge primarily as a part of a new wave of consumer products and services. There is an emerging market. Products and services are developed for affluent care consumers, many of which take genuine interest in the quantification of physiological states and all sorts of biological, chemical and behavioural functions. These practices set the stage for what is useful and meaningful to the individual and also what is realistically marketable both within and outside the confines of medical devices regulation. Meanwhile, the public care provisions are struggling to accommodate new practices and priorities that are inevitably part and parcel of more mobile and personalised care. Additional complications also arise as new applications begin to blur the boundaries between healthcare, self care, fitness and well-being, while they are entering the mainstream mass markets of smartphone-enabled apps and 'hubs' for mobile data gathering, processing and communication. These developments have implications for the regulation of the new devices and services on offer, in particular, to avoid liability issues but also to adequately manage the protection of privacy and of personal data—to ensure non-discrimination and due process in the gathering and processing of health-related and potentially sensitive information.

Embedding expertise

The workshop brought the question home of what it is to be a particular kind of scholar, an expert, a practitioner in the networks that form around this domain of innovation. This became evident as the participants clarified their positions but perhaps more so in performing their orientations to singular aspects of wearable computing and sensor

Key aims of the embedding workshop:

Bring into contact different and possibly incompatible perspectives and viewpoints.

Explore and clarify the diversity of experience in researching the innovation domain in question.

Explore and clarify the diversity of interests in reference to a small set of policy-relevant concerns of the WP3 team.

Explore and clarify points of convergence and complementarity among different professions and expertise in shaping more broadly focussed evaluations of the state of the art and what the future could be like.

technology. They talked about bio-hackers and open source enthusiasm, home made wearables and personal means to analyse data. They talked about institutional structuring and lack thereof, complications in medical practice, technical complications in the delivery of reliable products and services, of limitations in energy storage, new kinds of rubbish, ways of thinking about data ownership, data analysis and management, gender stereotyping, so on and so forth. Importantly, the combined expertise of the partners and the evaluations they havemade over time has accumulated particularly instructive

depictions of state-of-the-art developments, in anticipating complications and pointing the way toward important policy considerations. Embedding these findings with the expertise of our invitees, has now provided for additional insights and understandings that are greatly enriching this work and helping to shape a unique epistemic network.

Developments and disconnect

What really stood out amongst the partners as the main concluding point of the day, is a clear disconnect between top-down thinking in policy development aiming at personalised and more mobile healthcare delivery, and the kinds of grass-roots developments that show what people actually do when left to their own devices, how lead markets take shape, and so on. For example, it became clear throughout the workshop that industry knows quite a bit about self-generated trends. Use scenarios and design scenarios are open-ended in their making and they often require multi-directional engagements with all kinds of publics and occupational specialities.

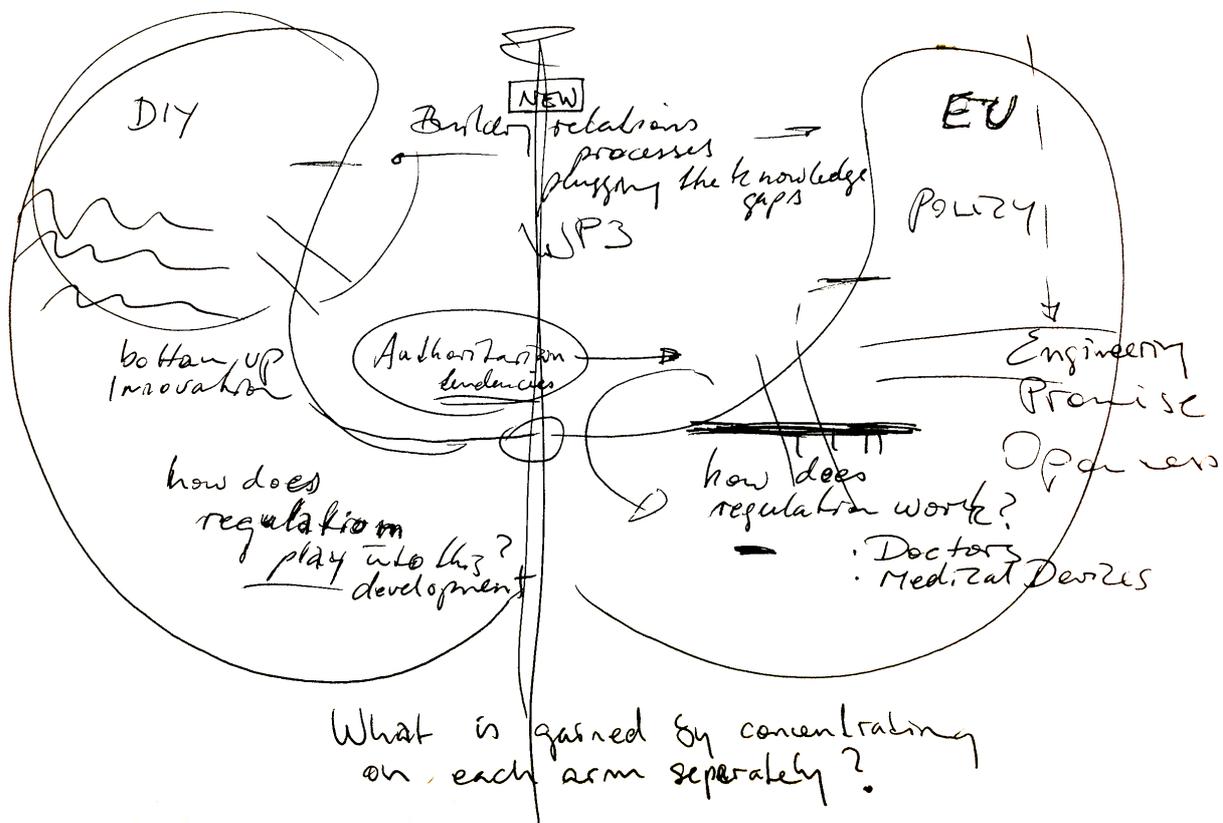


Fig. 1: An illustration used during a debrief session of the EPINET consortium 8 Nov 2013, to elaborate and collectively reflect upon the disconnect between grass root practices and top-down thinking in EU policy development. It was used to clarify how the partners each take interest in and stock of what is happening on each side, but also what the implications are of this disconnect as seen from their respective disciplinary approaches.

It also became clear to us how the institutional structuring for devices regulation is disconnected from what people are actually doing to manage health-related conditions on their own with the support of devices, online services, self-help and peer-communication portals. And, the policy discourse takes little if any notice of grass-roots innovation.

Discovering this disconnect has significant implications. Considering the two arms briefly, the one on the right represents EC policy developments, initiatives and investments infused with engineering visions and promise of a revolution in healthcare. Some of the industry giants are implicated here, a technological push for mass public investment in structural reform with expectations of returns on industry involvement in IPRs, public contracts and marketing to affluent care consumers. The media discourse communicates health revolutions and the assumption appears to be that medical expertise will continue to oversee care and provide a lead in defining what the necessary provisions are. The assumption is also that devices regulation will follow its normal course of defining and classifying devices distinctly for medical use and making sure they comply with set standards. Issues of personal data protection are met with the new challenges in data control and management which are unique to mobile physiological monitoring, smart home capabilities and the like. But, in this depiction, authorities are eventually accountable for providing the appropriate directives to industry, clinics and hospitals, and enforcing the law.

The left arm however, represents do-it-yourself care and all kinds of grass-roots innovation, including the crowd-sourcing of health and fitness related data, the availability of DIY monitoring devices, data capture, processing, analysis and representation. Movements like Quantified Self (QS) are implicated here along with online services for self help and peer communication, and myriad of devices on the market (heartbeat, blood pressure, cholesterol, blood sugar, steps, calories, etc.), typically found on the shelves of pharmacies, of retailers in sports equipment and consumer electronics. What appears to be happening here is a co-creation of medically-relevant knowledge, but also the sourcing and aggregating of information on health, fitness and well-being more generally, involving new types of information exchange platforms for mediation and communication amongst peers and advisers. There is a blurring of boundaries here, including the boundaries between consumer electronics and medical devices. It is uncertain how and where the medical expertise is situated and the devices regulation, who is responsible for quality assurance of the information, of devices in-use and services on offer. Furthermore, the data protection challenges are not only associated with mobile data gathering, aggregation and dissemination, but also with data ownership, e.g. how individuals can claim ownership of their physiological and behavioural data when they are serviced via social networking protocols.

In looking at the two arms separately, we learn that there is a real need for new kinds of relationships between experts of sorts and other societal actors. There are knowledge gaps to be plugged and support is needed to the kinds of explorations that can deliver realistic depictions of where the new developments are headed, what the incentives and motivations are, which issues need the attention of authorities and what the ideal areas are here for public innovation.

Discussion and debate on the Day

The welcome address painted a picture of the long-term structural challenges to healthcare delivery across Europe and pointed to the development and use of wearable computing and sensor technology as a marker of changing markets, changing behaviours and practices. The structural challenges were already framed in preparation of the event, by asking what the future of care holds in store for publics at large as well as the future of the informational embodied person—two key questions held against a panorama of health complaints and health problems across the Global North.

For example, in 2010 “people with long-term conditions (LTC) accounted for more than 50% of all GP appointments, 65% of all outpatient appointments and over 70% of all inpatient bed days in England”.⁴ Further estimations are that LTCs afflict approximately 30% of the population while the treatment and care of people with LTCs accounts for 70% of the total health and social care spend. LTCs are thereby seen to require disproportionate use of primary and secondary care services.⁵ Also, LTCs are found to be primarily ageing and lifestyle related, mainly diabetes type 2, hypertension and heart disease, pulmonary and musculoskeletal disorders, all on the increase, however, these conditions can often be significantly delayed or avoided completely with adequate self care. Consequently, the dominant policy view is that in order to ensure future access to high quality healthcare, managing ageing and lifestyle related conditions will have to shift toward prevention and responsible self management at home and on the move.

There is nothing to indicate that figures on the development of LTCs and healthcare costs are significantly different across Europe and, if EC policy documents and research calls are anything to go by, they already present a public health crises with reference to lifestyle choice, personal responsibility and behavioural intervention. Accordingly, intervention programmes in Europe are aiming at behaviour change and reform of the publicly funded provisions in order to alleviate the pressures on public care spend and protocol. With new applications for wearable and mobile sensing becoming more common in both clinical and private use, it is legitimate to ask what the impact of their use will be on the conventional practices, on perceptions and understandings associated with health-care, self care and well-being.

Thematic areas and focal points for discussion and debate

The programme of the day was divided into four sessions with presentations, followed by debate and input from designated discussants. The sessions were titled:

1. Shifting roles and relations in medical care
2. Visions, expectations and evidence of use
3. Informational bodies and selves – empowered, enslaved
4. Legal considerations – devices directives and data flows

(see the full programme with abstracts in **Appendix II**, p. 7-9)

As the session titles indicate, each session was organised around key focal issues, however, much wider thematic areas were implicated throughout the day.

Redrawing the boundaries between healthcare and self care: *Changing devices, changing services, changing behaviours.*

The consortium has considered a whole new ecology of devices and services, operating across the spectrum of healthcare and self care—of clinical practice shifting towards remote and self-monitoring, a growing ageing technologies market, a growing

4 UK House of Lords (2013) *Ready for Ageing? Report of Session 2012-13 in the Select Committee on Public Service and Demographic Change*. The Stationery Office Ltd, HL Paper 140.

5 UK Department of Health/Long Term Conditions. (2010) *Improving the health and well-being of people with long term conditions. World class services for people with long term conditions: information tool for commissioners*. Crown, gateway ref. 12121.

amateur athletes and fitness market. Media coverage and communication on self-tracking devices draws attention to the predominance of grand visions about innovation, consumer electronics and the future of medicine—visions that open up a whole host of questions, for example, what might be useful biological knowledge and what users could do with the mounting data. They introduce a confusing set of issues concerning the boundaries between certified care and care for one's own medical condition or health and well-being more generally. But, the proliferation of new devices in the marketplace – online data services and consultation, active participation and use – is also redrawing these boundaries. The implications are significant for material production and design in the emerging markets, for regulatory intervention, as well as the future of healthcare delivery, public health targets, and expectations of citizen responsibility.

Reframing the question of who needs care: *Clarifying what we mean by care and who provides it.*

By asking the question of who needs care, the meeting considered how complex the problematic is of prioritising in healthcare delivery, and in clarifying what exactly is involved when we talk about care and care-giving. The European medical systems are financially burdened and have to make hard choices about prioritising in the delivery of care. Prevention – taking measures to manage and maintain one's own health over the long term – is also a Public Health target that relies on political and financial instruments in attempting widespread behavioural change. The question of who is in need of care will therefore have to consider the complex textures of professional care, home care, and self care, involving both medical and non-medical interventions as well as preventative measures—to capture the distinction between healthcare and self care, in clarifying who cares and what kind of caring takes place.

Informational bodies, informational selves: *Who owns the information and what can be done with it?*

Activism and empowerment is a thematic area with focus on self care activism, patient-empowered care and care aimed at preventative health and well-being targets. Within this growing field of consumer health informatics there is increasing focus on how individuals can participate in and have control over the management of their own data. The profiling of physiological states in wearable sensing systems gives rise to concern for issues of privacy, discrimination and due process, but it is important to take into account as well the role of citizen movements concerned with open data together with privacy. There are tensions between privacy policies and IPR in the terms and conditions people are agreeing to, thus, a pertinent question to ask is who owns the monitoring data/information and what can be done with it, considering the different perspectives of enterprise, of health researchers and of DIY self-hackers.

Cutting across healthcare and self care: *Knowledge assessments and regulatory considerations.*

While eHealth, telecare and mHealth solutions play an increasing role, they pose a significant challenge to medical devices directives. New devices are challenging the boundary definitions of the medical device, the classification and qualification of

standalone software (apps) and hardware which is already used to manage health-related conditions. Issues of knowledge quality and knowledge pedigree are also implicated in this hybridisation. The knowledge that circulates extensively already does not map exclusively onto medical knowledge, but includes other types of knowledge which is co-created in different spheres of life and experience, of world views and value commitments. In this respect, the meeting gave particular consideration to claims that are made about wearable sensors and if they are challenged or taken for granted. Such claims are found in EU policy documents, in enterprise communication about devices and services, and in user communication online.

Participants respond to the events of the day

The topical considerations implicated in the section above cover a vast range of interests—of societally, culturally, ethically and operationally relevant issues associated in one or another way with the development and use of wearable sensors. With hindsight however, the presentations on the day, including the discussions and debates that followed, were more narrowly centred on two distinct areas of concern, each of which came up repeatedly throughout the day and left lasting impressions. By addressing these two areas individually, we can unravel points of connection, of convergence and divergence in the research and communication we have engaged to-date, and reflect on the influence on further developments. One is on *Roles and responsibilities: motivation, autonomy and empowerment*. The other is on *Data ownership and device reliability: protecting quantified selves and others*. In the following we refer to presenters, commentators and discussants, relevant to their positioning at the time when their input was made.

1. Roles and responsibilities: motivation, autonomy and empowerment

The first of these concerns is centred on the changing face of care, on the shift from conventional healthcare to self-monitoring and self care. **Commentator 1** underscored that we did indeed expect some of the associated issues to come up during the event:

- The move towards greater responsabilisation of individuals, connected with the prospects of more predictive and preventive medicine, while also implying less responsibility on the hands of the public services.
- The push for healthcare to come out of hospitals and clinics into people's everyday living environments.

They also foregrounded the problematics that are already associated with these issues:

- Over 20 years of attempting structural change in the delivery of healthcare and in reaching public health targets, is not necessarily delivering the desired results.
- Motivation is not easily induced technologically. It seems notoriously hard to change people's habits. For example, patients might start using a certain wearable healthcare app, for instance, to improve their life with diabetes type 2. But the impetus to use new gadgets is often short-lived, and the person returns to old habits after the initial enthusiasm and interest has waned. Technologically induced motivation may however be in play among those using devices/apps for lifestyle and entertainment.

These observations resonate strongly with study interests across the case study team, for example, efforts to better understand the implications of these developments for the shifting politics of care. They relate strongly to issues of roles and responsibilities as well as the apparent disconnect between grass-roots activities and the policy and regulatory goals. As **commentator 2** highlighted, a disconnect is emerging between policy making in this area, and what is actually happening in the terrain as far as concerns user appropriations of new devices and services with which a whole range of co-productions are associated—social, cultural, legal, ethical and epistemic. **Commentator 1** actually made a very similar point, i.e., how the experiences and knowledges of early adopters (movements and communities) are missing in the knowledge base of policy-making in the field.

Relating to these findings is how the medicalization of commercial wearables risks losing the distinction between medical and leisure devices. **Commentator 3** emphasised that when these boundaries are increasingly blurred, important socio-cultural contexts can be missed, e.g., in relation to questions about how the drive towards health-as-leisure relates to biomedicine and vice versa. It also raises questions about the way in which health monitoring behaviours and devices are being sorted into a hierarchy of responsible or desired actions from citizens in terms of healthcare. **Commentator 3** further noted that the medical rather than the fitness applications of wearables invite more urgent responses from researchers, since developments in patient skills, healthcare, professional attitudes, and clinical infrastructure are very tangible. This shift of attention corresponds to a wider shift of the business world towards digital health applications. At the same time, this means that while communities such as the QS provide valuable insights, they are partly overlooked, since they fall more within the fun category of individuals who do not have clear care needs, just geeky interests.

The blurring of boundaries between medical and non-medical applications is happening while, simultaneously, the disconnect between top-down policy initiatives and grass-roots practices becomes more profound. For example, **presenter 1** represented examples on the day from a knowledge assessment of selected EC policy documents that apparently lack in any input that does not immediately confirm dominant socio-technical imaginaries of the current policy discourse, as **commentator 1** put it.⁶ The presentation concluded that these documents are poorly written and lack a sound knowledge base. **Presenter 1** has further suggested that attention is needed to explore the inclusion (or not) of DIY movements (citizen science, hacker spaces, fablabs, etc.) in EU innovation ideals and narratives, i.e., to better understand the disconnect between (partially inattentive) policy making, action and practice. Concurring with these findings is also a comment made by **commentator 4**, who found it particularly notable at the end of the day when one of the participants and presenter remarked that regulators of wearable sensing devices for medical purposes never come into contact with any of the bottom-up approaches to health-related monitoring which were presented on the day. In response to that, **commentator 4** suggested that if concrete device use and user initiatives do not take place through clinics and under the supervision of medical expertise, they typically remain invisible in regulatory circles.

Shifting roles and responsibilities draw attention to people's motivations to engage in any form of care and, no less importantly, the lack of such motivations. The research team has observed that motivation is a problematic in policy development, i.e., regarding

⁶ See also Appendix I for overview of the presentation, titled, "Visions and promises for wearable sensors".

common understandings of what motivates care-taking and care-giving and how to influence that. Then the issue becomes rather perplexing in relation to the bottom-up developments, i.e., what motivates (or not) innovative new practices, DIY self care and in some situations disobedience and revolt.

The question of motivation or lack thereof also kept coming up during the event as part of the rhetoric of empowerment in the policy discourse on the future of healthcare delivery and in the industry literature on new-emerging wearables for all sorts of purposes. The notion of empowerment is then picked up by self-help groups to emphasise the ability of persons to be autonomous and in charge of their health and well-being, in control of their data and so on. The empowerment rhetoric has indeed made its way through policy, industrial, institutional and grass-root activities, while its workings can be very misleading and not adequately considering of questions such as what the realistic choices are for many individuals, what counts as being autonomous and what the actual abilities are or means to engage new-emerging developments with implications for one's health, well-being and safety. But the shift of responsibility from provider to user indicates that this should be researched further. **Commentator 3** highlighted in this respect criticism made by a **discussant 1**, who noted that health systems have some variation throughout the EU and is quite different in the USA, thus empowerment, in the sense of acquiring agency, is contextual and dependent on these systems. For example, before the USA's Affordable Care Act (ACA and also Obama Care), private insurance did not insure people with clinical chronic conditions. People in temporary employment or self-employed people, whose health cover is dependent on private insurance, are at a significant disadvantage compared to citizens with access to a welfare state model of health care which tends to be the case in Europe.⁷ **Commentator 4** also took note of this input, in relation to further critique of the profoundly individualistic character of the empowerment rhetoric, with which **discussant 1** juxtaposed the relational depiction of what is happening, including also how participatory medicine is leading to the insight that the person in the driving seat is not necessarily the one who is empowered.

As **commentator 3** has stated however, it cannot be overlooked that empowerment has strong currency amongst those without access to medical insurance (e.g. non-citizens and precarious workers), and an individualist notion of empowerment takes hold in grass-roots movements like the QS who, as communities, provide their members with necessary technical and emotional support. **Commentator 1** took particular interest in this as a philosophical conception, i.e., of a radically individualist position in the world which is nevertheless fundamentally connected and networked, hence, it is also a collectivist conception—quoting **presenter 2** on this topic: “If you truly believe people are social and connected, you don't need to worry about that: empower the individual, then the collective will be stronger”. A similar observation came from **discussant 2**, who remarked how interesting the QS model is for cooperation between different parties and actors who are focused on autonomy and agency, albeit, by way of doing things together.

Again, we observe a disconnect. As **commentator 1** has suggested, there is a gap in communication between the empowered DIY activist perspective like the one presented by **presenter 2**, and the analyses of top-down governance and policy perspectives presented in the two talks given by **presenter 1** and also by **presenter 3**. **Presenter 2** painted a picture of the QS meetup group as a movement, a social association and a very strong community, driven neither by health anxiety nor necessarily by specific unresolved disease or health issue. Rather, **presenter 2** described it as a community of pio-

⁷ See <http://chronicaction.org/affordable-care-act/>

neers who strive for self-development and self-knowledge, learning and behavioural change which is aiming at more autonomy. **Discussant 3** further suggested here that this is an important point of reference for the Epinet project, i.e., to study and propose remedies to the rhetorical and ideological character of European policy discourse in the sector of medical technology which is so strong and influential that it blocks off any valid knowledge that does not confirm, as they put it, “hegemonic discourses of reductionism, mind-body dualism and technological optimism”.

2. Data ownership and device reliability: protecting quantified selves and others

The second area of concern centres on data ownership and device reliability in accordance with the expertise and research approach of the different partners. For example, **commentator 2** highlighted an issue of particular interest to the knowledge assessment they are conducting for this case study, i.e., the question of what constitutes a medical device. The question is very pertinent, given the growing use of devices for self-veillance. There are issues of liability, certification, and so on. **commentator 4** stressed a similar issue of specific interest to legal scholarship, i.e., the legal implications of the more general shift from public healthcare to patient self care, mediated by an avalanche of (non-medical) self-monitoring devices on the market. They also made note of two discussants, **discussant 3** and **4** who raised the issue of safety standards, later taken up by **discussant 5**. These devices are readily available and inexpensive in comparison with those that have to satisfy the stringent criteria of classifying as a medical device, and there is a threshold for companies to invest in the production of medically graded devices and applications. Thus, it appears that smartphone applications and bluetooth-enabled accessories for all sorts of monitoring purposes (physiological, behavioural, environmental, etc.) are serving the consumer market by establishing a room for definitional looseness and functional ambiguity. A presentation by **presenter 4** further fleshed out the legal and regulatory issues here. More specifically, the presentation dealt with the challenges to the medical devices directive brought on by the very concepts and qualifications (e.g. standalone software, intended purpose) on which the directive is based. In short, as **commentator 4** put it, innovations in wearable sensing are blurring the boundaries between the legal regime of consumer law and the one of medical devices.

According to **commentator 1**, no major surprises emerged with respect to the emphasis of academic and industry sectors to create data aggregates (big data), mass storage and processing (cloud computing), and to appropriate a legitimate role for technical labour and mobile monitoring devices to source physiological and behavioural data (wearables, smart phones, health apps). Similarly, **commentator 3** noted that two of the discussants, **discussant 1** and **4** mentioned taking a systemic approach to the medicalisation of gadgets and to data-rich medicine. The goal is to collect and analyse huge amounts of medically-relevant information with the promise of improving predictive and preventative medicine, however, there are implications here for data and privacy protection. Based on prior knowledge of the field and the ethics scoping exercise, it did not come as a surprise to **commentator 1**, to observe a change in values, shifting from individual rights and responsibilities towards collectivist expectations. Prominent here is the elevation of values such as *public interest*, *common good* and *solidarity*, while other values are emerging bottom-up, like the drive towards *networked selves* and *privacy-in-networks*, neither of which was well represented in the case study scoping exercise. The

presentation by **presenter 3** was also informative in this respect, i.e., on the legal state of affairs in dealing with wearable sensing, smart home capabilities and the like. For example, concepts like *contextual integrity* remind us that privacy is not merely the right to be left alone. Norms and expectations emerge in different societal, institutional and technical contexts which are crucially important and need to be taken into account when estimating and fine-tuning the appropriate expectations of privacy and data protection. **Presenter 3** pointed to a shift from the overly narrow focus on protecting individuals and on consent, toward the inclusion of broader networks in which individuals are embedded.

Further along these lines of reasoning, the aims and goals of the Quantified Self movement caught a lot of attention on the day for how they sit in relation to industry and institutional goals, trends in data ownership and business modelling, and recent thinking on the legal aspects of privacy and data protection as presented by **presenter 3**. For example, **commentator 2** noted how the QS and other DIY communities are introducing novel ethical issues with members emphasising access and abilities to process their own data as they see fit, and in ways which perhaps are not in the interest of the industry/business models that develop and market the devices and the data services. DIY movements are taking into their own hands data extraction and tailored analyses that fits users' requests and go beyond the kinds of questions and analyses that otherwise is being imposed on them. Similarly, the presentation on the QS community came as a surprise to **commentator 1**, the level of sophistication and power of vision. **Presenter 2** spoke of a supply-side and a demand side, the former of which turns on already well-known industry and market-oriented approaches to mHealth monitoring and participatory medicine, while the demand side represents a unique approach, devoted to self-hacking, self-awareness and private ownership of the data. **Commentator 1** was particularly interested in how this demand-oriented model suggests a radically peer-to-peer based information platform, much in line with early visions of the Internet.

Presenter 5 also left a lasting impression with the group, with all partners taking note of the broader issue raised in that presentation about the political economy of *data as resource* and of cloud-based big data applications. According to **presenter 5**, personal data is the *new oil* and it is only a question of time before we transition towards other models of property rights that are more adapted to the distributed and open character of cloud computing and big data—where individuals recognise the economic value of information on themselves and do not give it away without returns. “We will have to rethink what we think of as ownership, it will be painful for large corporations...”.

Commentator 1 suggested that these developments are very likely to come true, although, it is still uncertain how that will play out in the years to come. **Commentator 4** has suggested as well, to look closer at the proposal for technical functionalities, presented by **presenter 2**, to support the ideal of user empowerment through self-hacking. According to **commentator 4**, the model suggested here provides an exciting paradigmatic exemplar of a system of personal data control that could be inline with several data protection by design (DPbD) requirements which are now being developed: data portability, access, personal data control, and open formats. According to the QS model, the individual is at the centre and in control of the integration of all the different data sources, not some third party platform (cloud). Individuals can take control of the processes of adding value to data, however, that is calling on more advanced data literacy. **Commentator 4** also found many points of connection with other approaches across the study group, on the question of designing for data use and data ownership. For example, **presenter 6** has been researching applications like Fitbit and some of the issues raised on the day were very relevant to different scholarships, including law, such as

labour and value creation, data pollution, privacy and data tax for companies using user-generated data. **Presenter 6** described problems such as the requirements to be a member of a service and to trust them with your data, how difficult it can be to have data removed from an archive, and how one needs all kinds of (often third-party) data processing add-ons to interpret all the data that is being generated. According to **commentator 4**, an interesting similarity was further drawn with online social networks and the use of infographics and gamification. These findings and the method of combining the problematics with a further study of the role of information drawn from online blogs, offers an interesting point of intersection with legal analysis of data control interfaces.

Design issues for better control of data have been given considerable attention in this case study. Problems with interoperability between systems, platforms and applications are already well known, and there are profound security issues in fast-changing technological environments. **Commentator 1** asks, how data protection is ensured in the operation of systems over the long term. Who is responsible and how? How is security engineered into systems that are quickly obsolete and need constant upgrading?

Issues of data control also came up in several talks during the event. For example, a presentation by **presenter 7** described different possibilities to log data, and the different parties who have access to these data. **Commentator 4** reported specifically on this talk about new kinds of data collection practices for purposes well beyond immediate patient services (metronics, device optimisation, treatment optimisation, commercial goals and value added services). **Presenter 7** argued that the *quantification of illness* signals an increase in all sorts of surveillance, that patients (and professionals) will be confronted with ever more data and the need to acquire additional skills in data analysis. Privacy issues are further raised in relation to a combination of different data sources like apps and the expansion of data processing goals beyond the ones initially indicated. **Commentator 4** is looking at profiling technologies and the like to meet this challenge and explore the legal ramifications. Obtaining informed consent is also becoming more of a problematic when the process is reduced to tick-box exercises. In that respect, **commentator 4** is paying special attention to terms and conditions documents and the legal issues surrounding both transparency and obscurity in representations of data ownership and control.

The drive to engineer ethics into systems (ethics and privacy by design) also came up during the day. This is seen by some as more pro-active and constructive than conventional ethics assessments and consent protocols. **Commentator 4** stressed an issue for further discussion and debate on this matter. It concerns the difference between ethics 'by' design, a co-production between ethicists and engineers as presented by **presenter 8** on behalf of the Guardian Angels⁸ project, and what **discussant 2** called ethics 'in' design which starts from an architecture (like open source) flexible enough to allow users to make their own choices. This contrast has many similarities and points of interest for the discussion on privacy and data protection by design which follows from methodological considerations pertaining to privacy impact assessments (PIA) and data protection impact assessments (DPIA)—of articulating which kinds of data are necessary to deliver satisfactory performance and which are superfluous in order to unravel the need for such assessments.

8 <http://www.ga-project.eu/> .

What next?

The general perception is that the embedding event was well received—a gathering of outstanding individuals who generated enthusiasm, enjoyed interesting arguments and important learning experiences. However, we recognise that we could have done more to improve the overall outcome. For example, to have discussants to the presentations was of great value but there could have been designated time for collective reflection, dividing the meeting into smaller groups to address more targeted questions. The total number was too high to carry out structured discussions in that direction. We also recognise that – in spite of extensive note-taking on the day – many details of the sessions are too quickly lost which makes reporting very laborious, in particular, to adequately reflect back on the convergences and divergences amongst the disciplines, the expertise and orientations represented during this event. As far as goes the thematic orientations, the event came under criticism from **commentator 3** for not addressing directly and critically issues of technology and gender. This refers to both gendered language use such as in the presentation title 'Measuring Man' (vs Human), and the more substantial reproduction of gender norms which align men and women differently in relation to technology, the body, control, care, and more. As **commentator 3** put it, given that the project overall is sensitive to issues of social inequality, it demands that we, as researchers working on the case study, are more alert to the processes that reproduce gender stereotypes within science and technology studies and do not come across as dismissive of this very persistent problem.

It follows from this report that the case study on wearable sensors is transitioning into the final phase, aimed at the integration of different assessment methods. The next steps involve a final reporting of key policy issues. We have already learned that there is pressing need to build new kinds of relationships across sectors, to plug the knowledge gaps, and to elaborate issues of interdisciplinarity and cooperation, of enablers and constraints within and between the methodological protocols and other input from the wider epistemic network along the way.

On the many and complex issues of interdisciplinarity, this networking/embedding event provided numerous examples of how different perspectives and bodies of knowledge intersect and communicate. For example, an observation from **commentator 1** states that the first session on the day set the stage for potential breakdown in communication across knowledge sectors. On the one hand, we heard a medical perspective, by **presenter 9**, presented on behalf of a growing number of suffering patients with the **presenter** himself particularly eager in his search for technological, structural and educational solutions to their problems. On the other hand, we heard the perspective of social researchers voiced by **presenter 7**, whose research is primarily focussed on the societal and economic aspects of technological development. The Epinet embedding idea entails the aim to enable dialogue and learning between these and other differentiating perspectives and what we learned from this session, according to **commentator 1**, is that communication problems are not always linked to incompatible or incommensurable bodies of knowledge. Rather, their distance may hinge on differing views on what is the more relevant knowledge or, say, the most relevant perspective. While **presenter 9** focussed on the size and importance of diabetes type 2 as a global health problem in search of novel techno-medical solutions, **presenter 7** emphasised the diversity of health issues and how differently the use of wearable sensors intersects, for example, with the management of diabetes compared to, say, hypochondria. While managing diabetes is perhaps indicative of good self care of an empowered individual, the latter case

can be linked to the increased focus on health in the public domain, as *commentator 1* put it.

In wrapping up this case study, team members still need to finish their research tasks, one of which is to bring all the learnings together, then share them across the wider epistemic network. The team will continue to focus on the new health economy arising from the developments in eHealth and mHealth, and on the implications of case study findings for the politics of care. There are already a few conspicuous problems here: the emphases on empowerment, enablement, behavioural change and motivation and, not the least, the omission of socio-economic situations, but these problems all appeal the study interests of one or another of the partners. The following lists key tasks in taking us along this final stretch.

- Clarify the shifting politics of care, shifting roles, relations and responsibilities with emerging new forms of self care and care-giving, with special attention on major gaps between policy programmes and grass-roots activities.
- Finalise knowledge assessment of the policy literature and of the trends in how people expose their arguments and knowledge claims in communication on the use of new devices, in orienting to device use and self-hacking.
- Clarify media representations of healthcare revolutions, novel healthcare technologies and related depictions, along with new forms of digital citizenship and mediation of the informational body and self.
- Elaborate the extent to which new devices in-use serve to stabilize action and communication: 1) in self-hacking, self help and self care; 2) when medical doctors communicate with patients, nudging them towards healthier lifestyles; 3) when public health authorities communicate to nudge individuals toward responsible lifestyles; 4) when public and private actors establish new modes of interaction, e.g., through harmonisation and interoperability, but also through new public-private partnerships; 5) when corporations come up with plausible and attractive business models corresponding with what they imagine are people's desires.
- Clarify the role of legal scholarship in policy development, in particular, on the intersection with regulatory institutions (devices and practice regulation, data protection regulation, liability issues and related concerns).
- Approximate legal analysis of data control interfaces with empirical analyses of them by other Epinet partners, for example, attending to the issues of labour and value production, and the political economy of data as resource—even to exercise the right of access to personal data used for processing, as an additional source of research data which could shed light on the scope of transparency of data processing and issues of data control.
- Integrate results from the case study on Data Protection Impact Assessments (DPIAs) with regard to wearable sensors, however, based on the DPIA framework for RFID units. Also, explore novel issues of data ownership, of taking charge of ones data against the claims of enterprises to owning data on individuals, against public authorities imposing purpose specification and data minimisation on private/corporate actors.

APPENDIX I

Case study presentations

Case study presentations

Apart from the welcoming address, given by Kristr n (ULANC) at the opening of the embedding event, the partners gave three presentations over the course of the day, to share the objectives, aims and findings of some of the case study research to-date. Presentations were given by:⁹

1. Aristeia Fotopoulou (Sussex University, UK)
2.  ngela Guimar es Peirera (EC-JRC, Ispra, Italy)
3. Niels Van Dijk (VUB, Brussels)

FitBit: assessing blogs, media coverage and the user interface

Aristeia Fotopoulou (Sussex) presented on behalf of a research collaboration including Kate O'Riordan (Sussex) and  ngela Guimar es Peirera (EC-JRC). She presented key findings of the media analysis with Fitbit, focussing on the media coverage and user interface (device screen, phone app and website). She discussed the ways in which Fitbit invites users to create knowledge about their body through self-tracking, and to understand this biological information as it is presented back to them through the dashboard and apps. The research to-date has identified how, in news stories and technical reviews about the device, an ecology of mobiles, smart phones and wearables is being evoked through headlines such as 'if you're appy and you know it'. Through this analysis this research locates fitness tracking sensors within digital culture and further discusses emerging self-management behaviours.

What seemed to resonate with workshop participants' experiences and steer their interest, were the badges and levels schemes used in Fitbit in order to motivate the user to continue tracking. The playful character of the Fitbit visuals seemed to reinforce a more general distinction – observed in the workshop – between devices that are medical in scope, and devices that enhance leisure activity. Participants tended to think of medical sensors as more significant than the leisure market. The lesson to learn from the presentation of our material, and for the media analysis in particular, was that it is important to clarify why analysing consumer-oriented leisure/fitness devices is important both in its own right and in relation to medical devices. These leisure devices are modelled as doing health work as their wider take up foreshadows. Their uses indicate patterns and affects that relate to the imagined take up of medical devices in the future. In their own right they are also indicative of the blurring of boundaries between medical health, leisure and lifestyle. The postnormal science paradigm also extends to post-normal medicine and looking at objects in the expanded domain of citizen health care provides ways of examining the emergence of new subjects, objects and relations in this area.

Visions and promises for wearable sensors

 ngela Guimar es Peirera (EC-JRC) gave a presentation on visions and promises. The importance of biosensors is primarily seen in the area of healthcare monitoring, although, the most recent wave of developments is appropriated in other realms such as fitness, sports and self-monitoring. While there are no specific policy documents¹⁰ looking at and discussing wearable sensors, Europe's economic growth strategy promotes

⁹ See also **Appendix II**, pages 7-9 for the full programme with abstracts

¹⁰ At the time we did this presentation, the EC Green Paper on mHealth was not yet out.

the advances of future and emerging technologies, wearable sensors being among them. Policy developments in the field of telemedicine and information and communication technologies (ICT) for healthcare are part of the Digital Agenda for Europe, the European Innovation Partnership on Active and Healthy Ageing and Horizon 2020.¹¹

Hence, the presentation focussed on knowledge assessment of available documents in this field. The aim of the exercise was to examine claims, assumptions and overall narratives used to support policy. It involved the use of the concept of 'pedigree' first developed for quantitative information by Ravetz and Funtowicz (1990) in their NUSAP¹² system and later extended by Corral Quintana (2000) to qualitative information. Pedigree "is an evaluative description of the mode of production (and where relevant, of anticipated use) of the information" (Funtowicz and Ravetz, *ib idem*).

The presentation paid special attention to the references that were given to support major claims on the benefit of wearable sensor technologies. What we found is that many of the claims were not backed up by any reference. An example is a major claim in the 2012 EC staff paper on telemedicine, which states that telemedicine is good for quality of life and the economy.

Telemedicine can help to address major challenges faced by European healthcare systems. For example, telemonitoring can improve the quality of life of chronically ill patients through self-management solutions and remote monitoring from home, reducing hospitalization costs and saving on unnecessary emergency visits. (COM (2012) 736 final, SWD (2012) 413 final, 3).

In the 2011 EC calls for proposals, ICTs are said to play a major role in combating a wide range of societal challenges, among them sustainable health care. However there is no reference or detail on how this can be achieved. Other types of problems were claims with their meaning changed from the original claims they refer to in valid publications. A common aspect is also self-referencing, meaning that the document refers to claims made in earlier house publications, instead of referencing external sources of information. An example of this is a quote in the 2012 EC paper on telemedicine that references the Commission staff working paper on telemedicine (EC SEC (2009) 943 final), a paper by the same institution published in 2009:

Nevertheless, despite widespread awareness of the benefits of telemedicine, its use in the provision of everyday health and care services is still relatively low and one of the reasons identified is the lack of legal clarity. (COM (2012) 736 final, SWD (2012) 413 final, 4).

In fact, nearly all the references that were made in the 2012 EC paper on telemedicine came from EU bodies. In total 25 references from EU Directives and Regulations, 14 from the European Commission, 7 from European Court of Justice, and only 1 from academia. Hence, there is a great opacity with regards to the pedigree of knowledge used to underpin these proposals.

11 For example, the European Commission's Communication C (2012) 4536 of 9 July 2012, under Cooperation: Theme 3: ICT, mentions ICT for health, ageing well, inclusion and governance as one of its challenges and its main goal is to empower citizens. Similarly, it is important to mention that the EC also launched several calls for proposals for projects related to biosensors, mostly in the area of telemedicine, e-health and active ageing.

12 NUSAP is a notational system proposed by Funtowicz and Ravetz (1990), which aims to provide an analysis and diagnosis of uncertainty in science for policy. It captures both quantitative and qualitative dimensions of uncertainty and enables one to display these in a standardized and self-explanatory way. It promotes criticism by clients and users of all sorts, expert and lay and will thereby support extended peer review processes.

The discussion worth mentioning that followed the presentation, brought out another issue which the JRC is also looking at, which is knowledge assessment of the communities' knowledge that actually make use of the new devices. It also hinted the issue of great disconnect between what policy making is developing and what in practice users and citizens are or could be interested in pursuing.

Tracking Devices and Data Flows

Niels van Dijk (VUB, Brussels) gave a presentation that dealt with some cross-cutting legal issues triggered by wearable sensing applications. First, it sketched a more general background of the expanding availability of self-monitoring devices on the market. These developments are leading to a hybridisation between the legal regimes for medical devices and for consumer products. This has all kinds of consequences for product safety, liability claims and reimbursement. Secondly, the presentation discussed the results of empirical studies on issues of data control raised by wearable sensing applications like Fitbit and MapMyRide. The research focussed on user interfaces offering terms & conditions, privacy policies, privacy settings and registration processes, in order to study how information is framed and communicated to users on what happens to the data on people. In this context, the hybrid term of 'user-generated content' seems to especially allow for what we call a legal concept creep between regimes of privacy and data protection on the one hand and, on the other hand, intellectual rights. This is leading to an increasing commodification of personal data. The research also focused on the data profiling practices used by these technological systems. These practices raise issues of privacy, discrimination and due process, due to the fact that highly personal knowledge can be inferred about individuals on the basis of which decisions are made (e.g. in marketing and insurance), without a lot of clarity or transparency on the nature of this decision-making process.

The reception of this presentation is difficult to estimate since it was the last talk of the last session of the day. The questions by two respondents provided some room for discussion on priorities in law-making, e.g., on protecting users first against an avalanche of hand held devices collecting data. Where indeed is legislation focussing its efforts? Who will have responsibilities for all these data: first-hand data, metadata, not to mention data transfer operations? Is legislation like a back-up plan when policy fails?

APPENDIX II

The embedding event brochure

Making sense of wearables: new-emerging markets and mediascapes

Event location in Brussels: Fondation Universitaire, Egmontstraat 11, 1000 Brussels. Tel. +32 2545 0400

EPINET: Integrated Assessment of Societal Impacts of Emerging Science and Technology from within Epistemic Networks. FP7-SiS-2011-1.1.1-4, Grant Agreement 288971. <http://www.epinet.no>

Memo for participants

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Programme summary:

08:30 – 08:50 Welcome and Introduction

08:50 – 10:00 **Session 1: *Changing roles and relations in medical care***

10:00 – 10:15 Refreshment break

10:15 – 12:00 **Session 2: *Visions, expectations and evidence of use***

12:00 – 12:40 LUNCH

12:40 – 14:25 **Session 3: *Informational bodies and selves – empowered, enslaved***

14:25 – 14:45 Refreshment break

14:45 – 15:55 **Session 4: *Legal considerations – devices directives and data flows***

15:55 – 16:30 ***Observations, reflexivity and mutual learning***

The EPINET project and the case study of wearable sensors

EPINET is funded under the 7th Framework Programme of the European Commission and coordinated by the Centre for the Studies of the Sciences and Humanities (Senter for vitenskapsteori), [University of Bergen](#) Norway. Partner institutions are [Lancaster University](#) UK, [Vrije Universiteit](#) Brussels, [Universiteit Utrecht](#) Netherlands, [University of Sussex](#) UK, [Universitat Autònoma de Barcelona](#) Spain, and the European Commission's [Joint Research Centre](#) (JRC) in Ispra Italy.

One of the aims of this project is to bring together networks of innovators, policy makers and scholars working to explore and evaluate the purposes for which innovation practices proceed, and the impacts new-emerging innovations can have on individuals and society at large. The European research programmes increasingly demand that research and innovation proceed in a responsible and sustainable manner. We contend that the interactions between different actors/stakeholders need to be significantly increased and improved upon to meet that demand.

EPINET introduces the concept of *epistemic networks* to describe complex developments within emerging fields of socio-technical innovation. It establishes a 'soft' framework with which the plurality of assessment practices can be explored and reflected upon. Four case studies serve as a testbed for this purpose: **Wearable sensors for activity and physiological monitoring**; Cognitive technical systems (mainly robotics); Synthetic / in-vitro meat; Smart grids for power supply.

The EPINET study plan outlines the following objectives for the study of wearable sensors:

1. To provide assessments of wearable sensors using a number of different evaluation and analytic methodologies.
2. To provide guidelines for good governance of wearable sensors in the context of EU policies.
3. To provide recommendations for improved cooperation and better integration of assessments and analysis relevant to the field of wearable sensors

Overall, a key aim of the case study on wearable sensors is to better understand the role and impact of qualitative judgement, visionary work, promise and creative action, in shaping the socio-technical innovations of wearability and sensor capabilities in a changing marketplace for health and well-being. These factors come into play in the multidirectional public engagements that are necessarily part and parcel of design and development of ICT-based products and services. They affect the relationship between industry visions, popular media and public discourse, and the interactions between innovators, policy developers, medical practitioners, marketers, patients and health consumers. The workshop is designed to bring together representatives of different *epistemic networks* to share their experiences and perspectives with a view to these factors as well as the shaping of interactions within the group throughout the event.

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The aims and objectives of the workshop: what to expect

The programme of the workshop is focused with a view to a set of policy-relevant concerns the EPINET study group is addressing already. The development of wearable sensors is intimately tied in with visions of more personalised healthcare and shifting roles and responsibilities in care-taking—from healthcare to self care, away from clinics, into the home and on the move. We have focussed our attention on wearable sensors as an *emerging market* rather than simply an emerging new domain of technological innovation—wearable sensors as *consumer products and services* evolving from lead markets of specialised occupations and affluent consumption into mainstream mass markets of smartphone-enabled apps and 'hubs' for mobile data gathering, processing and communication. We also observe that ongoing monitoring of health and fitness-related statuses results in new kinds of informational bodies and selves, along with expectations of data gathering and data sharing for the benefit of individuals and groups. We observe new fronts for knowledge dissemination to support and encourage the use of monitoring devices and services. In this respect, the workshop is part of an ongoing research project, bent toward greater clarity on the policy implications of recent developments, in particular, for the future of care and the future of the informational person. But, we are to some extent all stakeholders in these developments and the workshop is also aimed at exploring and clarifying how such diverse expertise and experience of researching this particular domain of innovation can be complementary, even integrated, in shaping more broadly focussed evaluations of state of the art and what the future holds in store.

To this end, we offer a mutual learning environment in which everyone should feel free to speak their mind, to critique, point out knowledge gaps, express uncertainties and doubts. The workshop is closed with only invited participants and EPINET team members, and we will not record the sessions.

In the spirit of openness to honest discussion and debate, we propose the following rules:

1. Chatham House Rule: "When a meeting is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed."
2. Should a participant wish to share confidential information or opinion during discussion and debate, we propose that she or he state upfront that the following is confidential and should not to be cited without permission. We expect everyone to accept such requests or explicitly state otherwise.

Consensus is not an objective of this workshop. On the contrary, our aim is to bring into contact different and possibly incompatible perspectives and viewpoints. We hope for lively discussion and disagreements to produce new and interesting ideas.

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The background to the choice of focus issues

This section elaborates further on the choice of policy-relevant issues by citing excerpts from an article draft with follow-up comments:

Wearable sensors, origins and inspirations

The devices we commonly see now sitting on the shelves of Boots, Lloyds Pharmacy and outlets offering consumer electronics and outdoor gear, have their origin in hospitals and clinical care, in professional sports, military and rescue applications. They are designed to keep track of blood pressure, blood glucose, heart rate and cholesterol among other things. They are location and navigation devices relying on GPS signals and geo-information systems (GIS). They are not cheap, although, prices have come down in recent years. A reliable high-quality outdoor activity and monitoring support for the endurance cyclist (e.g. a Garmin) can cost £200-400. Healthcare-related gadgets range in price anywhere between £30-200 and consumers are strongly advised to consult the ratings of the brands they purchase (e.g. Omron), taking into account standardised quality control of measuring capabilities being compatible with professional care.

Until recently, the largest market predicted in this emerging mobile-health sector was associated with changes in clinical and hospital practices, with care facilities extending to home monitoring (e.g. in rehabilitation and assisted living). There is indeed a growing ageing technologies market, offering sensors for real time monitoring and detection, reminders and warnings, and data delivery to a second party such as a caregiver. The most recent trend however, is to translate all kinds of monitoring capabilities into smartphone-enabled and/or interoperable hardware and software supports to self-manage a wide range of health, fitness and well-being targets. [...] [W]e are seeing a growing 'ecosystem' of platforms and interoperable data aggregators in the commercial marketplace, competing for people's activity, physiological and tracking data. ...

New-emerging markets and the EU market 'blind-spot'

The many pilot projects in eHealth funded by the European Commission and national research councils over recent years foreground issues of incentives, acceptance and how interest in eHealth technologies could translate into concrete investments. They have been informative about user perceptions, in particular, how older persons perceive of using monitoring and communication technologies for safety and ongoing care. The pilots raise questions about the distribution of cost-benefits within larger systems of social care, housing and healthcare. They draw attention to the potential limits in national service provisions across Europe and, consequently, what kinds of self-funding schemes and self-planning of one's future health-monitoring and care needs

are emerging in the market place. A recent report of a public consultation on eHealth (European Commission, 2011), shows that the incentives of those who fund or reimburse eHealth technologies and services remain unclear. Neither financial/economic nor quality incentives are shown to be very strong. Self-funding and increased availability of health and well-being supports in the form of wearable technologies, need not translate into large-scale commercial opportunities either. The report draws attention to the organisational and institutional challenges in the attempts to deliver ICT-supported healthcare. It relays serious doubts that the original benefit assumptions (efficacy, better service and reduced cost) will ever come to pass while, paradoxically, most participants in the consultation still support those selfsame assumptions.

Nevertheless, there are clear signs of substantive change in the ways in which healthcare provisions are constituted. There are signs of new-emerging trends in the self-management of health through fitness and well-being activities (Schmillmeier, 2010). Many of the challenges and changes can be associated directly with visions of personalization which are deeply political and intimately tied in with recent historical shifts in the moral responsibilities of citizens (e.g. Clarke, 2004, 2005; Harrison, 2008). Accordingly, policy development across Europe over the past two or so decades has been aimed at strengthening public-private partnerships, encouraging innovation in the private sector, and responsabilising citizens to take greater initiative in managing their own health.

While the new trends are redrawing the boundaries between state, private enterprise and citizen responsibilities, we also find strong associations here with the ways in which markets drive innovation in the USA and in Asia. European consumers and EU markets are far from exempt from taking part. There is a surge in private online-based practices (services and self-help) for a vast range of common conditions, injuries and more, and do-it-yourself (DIY) market models of electronically mediated health assessments and consultation. The growth in the sales of test-kits, self-monitoring devices, and other (both lawful and unlawful) products has rapidly increased.

If these trends are anything to go by, wearable sensors are becoming mainstream with giants like Google, Motorola, Apple and Microsoft plus a number of smaller manufacturers now investing in the technology (see Ranck, 2012). Some are also competing in the communications software platforms, involving giants like Amazon and Facebook. So far however, little is known about who the customers are, what their intentions, expectations and experiences are, what healthcare they actually receive and what the incentives are for them to sign up for fitness and well-being programmes.¹ An exception here might be what is known about the Quantified Self movement which is dedicated to 'self knowledge through self-tracking', incorporating technology into data acquisition on aspects of a person's daily life such as the food

¹ According to Eurostat, 2010 (ISS), a third of active internet users in the UK searched for health-related information online over the six months prior to the survey. Accessing health-related information and services has been one of three fastest growing categories of internet use.

consumed, the quality of the surrounding air, various states of being – mood, arousal and blood oxygen level – and mental/physical performance. What can be inferred still, is that the socio-technical, political and moral imaginations of personalized and responsabilized care, fail to adequately grasp how new visions of personhood, tools and technologies – including wearable sensors – are domesticated in unstructured and semi-structured environments. They fail to take adequately into account the technical and organisational challenges faced by market developments towards mainstream consumption, irrespective of public care provisions or the market share of private health insurances.

Ideally, wearable devices are always turned on. They are easily worn and can always be accessed. They gather data, permit access to information and communication in real-time and provide access to data in storage (see Ranck, 2012). The very idea of wearability refers to comfort and utility but also to invisibility or otherwise fashion which is evidenced in recent developments towards convergence of fashion, usability and health-related purposes, and seen as critical to future success of the new products and services (see also Sarasohn-Kahn, 2013). So, there are both new form factors to consider but also cross-over purpose opportunities. But, wearables pose unique technical challenges, much more so than other mobiles and especially with respect to heat, power, local storage, privacy and security. The pressure to bring down costs and miniaturise hardware, risks compromising some of the capabilities and reliability which otherwise would be mandatory in professional practice. It is all well to load more and more functionality onto a smartphone which then runs out of battery within a few hours. GPS sensitivity might be far less reliable as well as other built-in hardware capabilities when compared with costly professional-grade equipment, in particular, when the gadget is operated in rapidly changing heat, air-pressure and humidity. Similarly, the incentive to communicate and consult at a low cost or even for free over advertisement-driven platforms, risks compromising the intelligibility and genuine usefulness of wearable sensor technologies, considering the stated purposes and promise of tracking and monitoring health, fitness and well-being to support decisions by the individual. Furthermore, the encouragement to share and the fact that a lot of monitoring and tracking data might be stored at several locations – on the wearable sensors themselves, on personal servers or user interfaces or on remote web-servers of servicing enterprises – risks obfuscating issues of control and protection of those data. To look further into these potential problematics, the case study group has chosen a set of technologies on the market, all of which aim at a low cost, minimum overhead market model while promising to be useful and meaningful with implications for health and fitness.

... ..

As these excerpts indicate, we wish to consider the emerging ecology of devices and services, operating across the spectrum of healthcare and self care—of clinical practice shifting towards remote monitoring and self-monitoring, a growing ageing technologies market, a growing amateur athletes and fitness market. In addition to that we observe how media coverage of self-tracking devices predominately

communicates big visions about the future of medicine and innovation in consumer electronics. The news portray a healthcare revolution which opens up questions about the usefulness of biological and physiological knowledge, considering also how such data is empirically communicated to users of self-tracking devices through apps and well-designed web dashboards.

Within the growing field of consumer health informatics there is increasing focus on the question of how patients can participate in and have control over the management of their own data. Novel service designs play a central role in this development, but so does citizen self care activism or self-hacking with its focus on open data and privacy protection—the question of who owns the data and what can be done with it.

In relation to these considerations, we also wish to address the question of *who needs care*—a complex problematic of prioritisation in healthcare delivery, and in clarifying what exactly is involved when we talk about *taking care*. The European healthcare systems are financially burdened and have to make hard choices about priorities in the delivery of medical care, bearing in mind that the largest cost factor by far turns on common lifestyle, ageing-related and often chronic conditions. Simultaneously the argument goes that these costly conditions and subsequent interventions can be significantly delayed or prevented entirely with adequate self care. Prevention lies in taking measures to manage and maintain one's own health over the long term, however, prevention is also a Public Health target, relying on political and financial instruments in attempting widespread behavioural change. The question of who is in need of care will therefore have to consider the complex textures of professional care, home care, and self care, involving both medical and non-medical interventions as well as preventative measures—to capture the distinction between healthcare and self care in clarifying *who cares* and what kind of caring takes place. On the one hand, the boundaries blur between professional care and care for one's own medical condition or health and well-being more generally. On the other hand, the proliferation of new devices in the free market, of online data services and consultation, active participation and use, is redrawing these boundaries with significant implications for material production and design in this market, and regulatory intervention.

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The Programme

08:30 – 08:50 Welcome and Introduction	
08:50 – 10:00 Session 1: <i>Shifting roles and relations in medical care</i>	
Stans van Egmond & Marjolijn Heerings The Rathenau Institute, NL	Title: Measuring Man – On data, lifestyle, the prediction of illness and shifting relations in health care
<p>Devices that measure bodily functions by ever cheaper, faster and smaller devices combined with the emergence of large databases and imaging techniques, enable more accuracy in predicting risk of diseases. The human body becomes a quantifiable object which can be used as a basis for intervention, control and cost-cutting.</p> <p>To gain insight into manifestations of new ways of quantifying the body, we investigate – in nine cases, ranging from measuring frailty, brain death, rheumatic arthritis, to diabetes – how illness and health are being quantified. How does it change our perception of illness, health and interventions? How does it change institutional arrangements in healthcare? And what political issues emerge from this trend?</p> <p>Preliminary findings show that new ways of measuring take a slow pace into the clinic; many projects have better quality of life as their aim; this involves more patient action; new parties enter the health field, such as big data scientists and companies that develop measuring devices; illness is more visible in the lab but the role of patient experiences with disease as a measuring tool diminishes.</p>	
Valerio Miselli Diabetologist and Professor at the University of Turin, Italy.	Title: Therapeutic education and empowerment in a chronic disease: diabetes as a model
<p>The incidence and prevalence of both type 1 diabetes (T1D) and type 2 diabetes (T2D) is increasing globally. More people are living with diabetes every year, and all people living with diabetes should have access to high-quality health care. Primary care providers need to become knowledgeable about the treatment options and new technologies available. The ultimate goal is to optimize glucose control to prevent complications. The empowerment model serves to guide patients in making informed decisions about their diabetes management. Adults focus on problem-solving rather than learning that is maximized when the process is active rather than passive. A non-judgemental approach is recommended to gain the patient's trust so that the health care providers and the patient may work as a team.</p> <p>Many trials have shown that frequent self-monitoring of blood glucose improves health outcomes in patients with T1D. Both patients and physicians would benefit from knowing blood glucose levels throughout the day in order to improve overall glycemic control. This technology is available through the use of continuous glucose monitoring (CGM). The continuous glucose readings may encourage healthier behaviour. When asked about CGM technology, many providers are reluctant some dubious, and others excited about the possibilities of the technology, but seem unsure about the availability, accuracy, and feasibility. Similarly, patients may not have adequate knowledge of the availability and benefits of the use of CGM. In the future, there should be more investigations on real world use of technical device features in addition to clinical studies, in order to inform pump and glucose meter manufacturers about the acceptance of new technologies by patients in daily routine.</p>	
Discussants: Mário Romão , Intel; Roger Strand , University of Bergen	
10:00 – 10:15 Refreshment break	
10:15 – 12:00 Session 2: <i>Visions, expectations and evidence of use</i>	
Todd S Harple Intel, Portland, Oregon, USA	Title: Navigating Naive Visions of the Future: Devices, data and dilemmas
<p>In 1965 Intel founder Gordon Moore observed that the number of transistors on integrated circuits doubles approximately every two years. Later known as "Moore's law," this trend underlies the proliferation of lower cost, higher capability compute devices—initially proved out by dramatic growth of personal computers and more recently led by the sharp rise in global smartphone uptake--portable sensing and computing devices are flourishing. Indeed, as you read this, portable and wearable devices are literally and figuratively sewn into the fabric of our daily life, but to what end? I'd like to provoke discussion around the emerging data landscape generated by these developments and consider more broadly the role data is playing in our daily lives, touching on its promise and some of the social, technical and ethical issues it surfaces.</p>	

Eija Kaasinen VTT Helsinki, Finland	Title: Usage possibilities of micro- and nanotechnology based sensors in health and well-being
<p>Micro- and nanotechnology will enable very small size sensors that can monitor our environment and us. This creates possibilities for many kinds of services for health and well-being. This presentation is based on the work carried out in the Guardian Angels Flagship pilot project. The project was targeting far into the future with the following vision: Guardian Angels (GA) technology will enable very small size sensor and computing units to monitor, provide feedback and involve us actively in understanding and acting on our own well-being and our environment. The GA units will be self-sufficient with energy, and thus suitable for long term use without maintenance. Several usage possibilities are foreseen in health, well-being, safety, sustainability and empathic user interfaces. The presentation gives an overview of the usage possibilities that we identified together with multidisciplinary experts and consumers, focusing on health and well-being. The presentation will also analyse user acceptance and ethical issues of the proposed scenarios.</p>	
Aristea Fotopoulou, Kate O'Riordan and Ângela Guimarães Peirera Sussex University, UK and the EC – Joint Research Centre, Ispra, Italy	Title: FitBit: assessing blogs, media coverage and the user interface
<p>We examine technoscientific visions and claims in different media platforms linked to FitBit, a cloud-based fitness tracking device. As a health-related consumer electronics device, FitBit monitors a small range of activities linked to weight loss and fitness activity. In this presentation, we focus on FitBit blogs, media coverage, and user interface (device screen, phone app and website). We discuss how FitBit invites users to create knowledge about their body through self-tracking, and to understand this biological information as it is presented back to them through the dashboard and apps. In blogs, we observe knowledge co-production of claims and imaginaries about healthy lifestyle. In news stories and tech reviews about the device we identify how an ecology of mobiles, smart phones and wearables is being evoked in news media and tech reviews, through headlines such as 'if you're appy and you know it'. Through this analysis we locate fitness tracking sensors in digital culture and discuss emerging self-management behaviours.</p>	
<p style="text-align: center;">Discussants: Barbara Prainsack, King College London; Sywert Brongersma, IMEC, BE</p>	
<p>12:00 – 12:40 LUNCH</p>	
<p>12:40 – 14:25 Session 3: Informational bodies and selves – empowered, enslaved</p>	
Adriana Lukas QS London meetup group founder and activist	Title: The <i>Self</i> in Quantified Self
<p>The rising phenomenon of self-tracking for measuring aspects of one's life and ubiquity of data has attracted interesting reactions, usually by those who don't do it themselves. What is it about, where is it going and what is needed for data to be a meaningful tool in individuals' lives? Is QS a way to increase data literacy or just another step in turning us into data sources for those who want to learn more about us? Is the current user data model created around platforms capable of evolving to provide sufficient control to individuals over their very personal QS data? What are the privacy implications of QS data and why should individual data analyses, rather than aggregate ones, be the primary focus of QS?</p> <p>For the last three years, as the organiser of the London QS meetup group, Adriana has been observing the movement and trying to influence the answers to those questions.</p>	
Eugenio Mantovani Vrije Universiteit, Brussels	Title: The impact of apps for mobile (medical) devices on the autonomy of older persons
<p>The presentation discusses the legal privacy and medical device implications of apps for mobile smart devices on the autonomy of older persons. From a legal point view, the policy and ethical goal of developing apps or, in general, technologies that enhance autonomy faces the problem of articulating autonomy in a system of specific rights and obligations. This lack of legal basis or guidance cannot be compensated. However, drawing on legal frameworks (law, case law, authorities) dealing with privacy, but also data protection, liability, and safety of device (e.g., medical device), we can put in the right perspective the requirements that, from a legal point of view, apps for mobile medical devices could incorporate in a creative way to protect or promote autonomy of (also) older persons-users.</p>	

Ângela Guimarães Peirera EC - Joint Research Centre, Ispra, Italy	Title: Visions and promises for wearable sensors
<p>Knowledge Assessment (KA) looks into evaluating of knowledge inputs in decision-making processes. 'Knowledge' here does not map onto 'scientific knowledge', but includes other types of knowledge created in spheres of life and experience other than the techno-scientific one. While looking at quality aspects of knowledge, KA recognises that policy-relevant science implicitly resonates specific world views and value commitments that may include ontological commitments of groups other than scientists. The work feeds into the exploration of imaginaries of health as framed in European policies where concepts such as tele-medicine, wearable diagnostics and medications, personalised medicine etc., are taken up in the discourses. We have used the concept of 'pedigree' as described by Funtowicz, Ravetz and Corral Quintana to assess the quality of qualitative assertions used to formulate policies or to support decision-making.</p> <p>Hence, with a quality perspective in mind, we have looked at the few policy documents in the EU that deal with wearable sensors and in view of understanding whose knowledge and values are being enacted in those proposals, as well as what framings and justifications are given. Amongst other things, we have found that a great deal of claims are made without proper grounding.</p>	
<p>Discussants: Frauke Behrendt, University of Brighton; Mariachiara Tallacchini, Università Cattolica S.C. of Piacenza, Italy</p>	
14:25 – 14:45 Refreshment break	
14:45 – 16:30 Session 4: Legal considerations – devices directives and data flows	
Mariana Madureira Portugese National Authority of Medicines and Health Products	Title: How do the Medical Devices Directives apply to mHealth? Views from a competent authority
<p>ICTs have had a huge impact on healthcare, where eHealth, Telemedicine and, in particular, m-Health solutions play an increasing role. These new technologies enable new possibilities for remote diagnosis, monitoring or treating patients and reducing hospitalisation, thus providing tools to cope with the effects of an ageing population and to optimise the use of scarce human and financial resources. These new technologies have also been challenging Medical Devices Directives as they might bring new risks. They challenge the qualification and classification of standalone software (apps), intended (or not) to be used with a mobile platform, and of the new resulting combination of products. Furthermore, the consumerization of m-Health apps poses new questions and increases the difficulty in defining the boundary with the medical device definition. The Medical Devices Framework under revision is reflecting the challenges of innovation, and addressing already the identified risks, namely related to interoperability / compatibility and safety.</p>	
Niels van Dijk Vrije Universiteit Brussels	Title: Tracking Devices and Data Flows – A reflection on legal issues in wearable sensing
<p>Niels van Dijk will talk about profiling of bio-data in wearable sensing systems and the issues these practices give rise to (privacy, discrimination, due process); the tensions between privacy policy and IPR in the terms and conditions people agree to about the control over their data; and some legal implications of the blurring between healthcare and selfcare.</p>	
<p>Discussants: Welderufael Tesfay, Deutsche Telekom; Kjetil Rommetveit, University of Bergen</p>	
Kristrún Gunnarsdóttir Lancaster University, UK	Title: Observations, reflexivity and mutual learning.
<p>An observational reflection on what has been achieved on the day will draw together key learnings and open the floor to final comments from participants.</p>	

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