Wearable Sensors

Exploring EU Policy Narratives by Engaging the Extended Peer Community

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Abstract: Wearable sensors that allow communicating patient's state of health to their physicians without the need for their physical presence, are offered with grand promises to both patients, doctors and other communities. This paper looks at how this technological promise is influencing policy making in the EU about future healthcare. In particular, we use knowledge assessment concepts to examine the pedigree of claims and assumptions in e-health related EU policy documents, deepening the examination of the narratives with engagement of relevant actors, i.e. those that are part of the extended peer community. We found that even if the proposal of e-health is attractive to many, there are many disconnects about both bodies of knowledge and the apparently disjointed imaginaries about the role of these technologies to address different challenges in the healthcare sector.

Keywords: E-health policy; European Union; knowledge assessment; wearable sensors; techno-scientific imaginaries.

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1. Introduction

Wearable sensors (WS) are a core element of wearable technologies and devices[1]. WS allow activity and physiological monitoring, and as such they are used in a wide spectrum of health-related aspects by many people. They are already widely used for fitness and health-as-leisure purposes (Piwek et al. 2016), but the growing attention is primarily due to their potential applications in the area of healthcare monitoring, the focus of this paper. The literature suggests and describes the usage of these sensors in medical contexts, for example, rehabilitation (Bonato 2005), eldercare (Milligan et al. 2011), the treatment of people with chronic medical conditions (Siddiqui et al. 2018) and the use of big (sensors') data for personalised healthcare (Chawla and Davis 2013). The possibility to remotely monitor a patient's health while collecting the patient's data over a long-time span nurtures the expectation that WS shall enable a more complete medical analysis and a less cost intensive healthcare.

The promises that these sensors come with are visible in the narratives entrenching discourse and action of market, media, academia and policy. People increasingly use WS, as tools for self-improvement and self-enhancement. The moto of the Quantified Self movement[2] is "self-knowledge through numbers". Therefore, we can say that WS may be seen as "an extension of human senses" (Vesnic-Alujevic et al. 2016). They also provide a feeling of more control over one's life (Lupton 2014b).

Optimistic imaginaries of key actors, especially those of policy makers and industry about the potential and applications of WS to deal with healthcare matters drive the development of these technologies. Yet, WS growing usage in everyday life activities are blurring the existing boundaries of medical and more mundane well-being practices, posing challenges to our received notions of 'health', medical practice, healthcare policy and the ethics that sustain these. Indeed, as Lupton (2014a, 1347) pointed out, the discussions on digital health, of which WS are a part of, rarely address broader implications of these technologies on the meanings of health and illness or on the medical practice and doctor and patient relationships. Furthermore, a variety of ethical issues, namely social inclusion and social justice as well as, data ownership need to be still thoroughly investigated (Rich and Miah 2017).

With the use of WS, individuals' everyday practices generate data. The transformation of activities into data is first enabled through the collection of few body signals by different types of sensors and then processed algorithmically, and communicated to different parties. This is what Mayer-Schoenberger and Cukier (2013) called *datafication* of individuals' lives. While the quantity of (big) data collected in such ways is indeed enormous, their quality is questionable (Cai and Zhu 2015), and more importantly, the sense that different agents make with them needs critical interrogation (Van Dijck 2014). The "data-driven lifestyle" (Lupton 2014b) and the emerging narrative about big data as the latest resource to reveal 'truths' about us, our behaviour, our needs and expectations could turn out to be the next deception.

The potential to integrate personal data with clinical data and the blurring line between the use of wearables for fitness or medical purposes is raising ethical concerns, paving the way for a need for specific regulation. Governments and the European Union (EU) institutions have become involved in several ways. For example, the EC has published documents, classifying WS for medical purposes (MEDDEV 2.1/6 July 2016) trying to propose data collection regulation on health and fitness apps (EC SWD(2014) 135 final 10.04.2014).

In our study we are interested in understanding how different types of knowledge inform and influence policy making in this sector, because while looking at different discourses, we observed that policy narratives did not seem to address different challenges to the promises of this type of technology in addressing healthcare issues, voiced by different actors. We applied what Funtowicz (2006) described as 'knowledge assessment methodologies'; in particular, we investigate whose and which knowledge (scientific or non-scientific) on WS technology informs policy making, in the EU context. Our main research questions are: 'Who' informs policy making in the domain of wearable sensors at the European Commission? Whose and what knowledge is reflected in the policy papers and the EC narrative on WS technology use for healthcare?

While looking at WS policy we found that the notion of techno-scientific imaginary (Jasanoff and Kim 2009) to situate the EU policy narratives is critical to understand the role of actors and institutions in their development. Our departing point is EU policy making in this domain directly or indirectly referring to WS; the analysis of those narratives helped with situating WS in the wider context of current imaginaries of innovation, helping also with identifying relevant actors. We used the notion of *pedigree*, which is a key concept of 'knowledge assessment' to analyse knowledge claims, assumptions and framings appearing in relevant EU documents. The pedigree analysis is further attuned with in-depth interviews to identified actors. The paper offers a discussion about the production and circulation of knowledge that sustains current policy making in Europe with regards to WS usage in healthcare.

2. Conceptual Background: Imaginaries and Knowledge Assessment

Felt and Wynne (2007) argue that all key reference points in science and governance, such as the purposes of research, ethical issues and public concerns, are objects of collective imagination. Jasanoff and Kim (2009) have described techno-scientific imaginaries when they studied energy policies in the USA through the exploration of the *imaginaries* that guided past energy policies in that country. This concept explains how visions about possible futures are produced as "collectively imagined forms of social life and social order reflected in the design and fulfilment of nation-specific scientific and/or technological projects" (Jasanoff and Kim 2009, 120). Hence, it is important to investigate whose and what imaginaries are entertaining techno-scientific narratives and developments and who drives the process of collective imagination. In other words, whose values are being enacted? What and how is knowledge produced to ground these visions of the future? How is knowledge circulated?

Visions of future healthcare practices in EU policy circles and wider sectors of society are informed and enacted by various actors. How these actors are involved in the process of knowledge production (and contestation), how they interact, and how knowledge circulates and how it influences decision-making helps with situating dominant healthcare innovation narratives in Europe. In this context, we are referring to all the parties, those that produce "scientific knowledge", but also those holding political, experiential and practical knowledge.

It is important to understand how policy relevant knowledge is generated (Porteous 2016). 'Knowledge assessment' (KA) as defined by Funtowicz deals with "evaluating of knowledge inputs in decision-making processes" (Funtowicz 2006, 139). In this context, knowledge is not simply understood as 'scientific' knowledge, but also includes other types of knowledge produced outside the academic sphere. An important goal of knowledge assessment is to identify and involve relevant actors in a given debate about policy relevant science, which Funtowicz and Ravetz (1991, 6-7) called the 'extended peer community' – a concept from post-normal science – i.e. a community "consisting not merely of persons with some form or other of institutional accreditation, but rather of all those with a desire to participate in the resolution of the issue" and produce 'extended facts'. In the case of healthcare WS, the extended peer community can consist of doctors, patients, researchers, developers, policy makers, industry, users (e.g. specific communities such as the quantified-self movement –http://quantifiedself.com/) or other individuals with an interest or concern about these devices and their applications.

3. Wearable Sensors in the EU Policy

The current narratives on WS can be linked to a more general perspective on science and technology in the EU. At the core of the EU 2020 strategy lies the so called 'Innovation Union', which heralds research and innovation as a means to bring more products to the market, with an imaginary of salvation of EU economy. Amongst its underlying assumptions, the innovation narrative promises that innovation will create jobs and improve quality of life (Van den Hoven et al. 2012). The narrative is presented in a salvific role, solving all the problems that we face today (Guimarães Pereira et al. 2013). These assumptions are problematic because they can be proved wrong in many cases; economic profit does not automatically map into improvements of quality of life and the idea that all problems of society can be solved through technology (*techno-fix*) is obsolete and misguided. Often, by solving one problem with technology, we generate another (Benessia and Funtowicz 2015).

Europe's growth strategy, Europe 2020, promotes the advances of future and emerging technologies – and WS are among them. WS are a key feature of what is called the Internet of Things, the largest world project on connectivity. Policy developments in the field of telemedicine, eHealth and ICT for healthcare are present in the Digital Agenda for Europe, the European Innovation Partnership on Active and Healthy Ageing in Horizon 2020. Hence, the proposed applications of WS do not emerge in a vacuum but they are rather coherent with the social and technological innovation hype that characterises many areas of EU policy and in general, human endeavour.

As noted in the staff working paper on telemedicine, due to "the importance of this sector and the benefits it could provide, Member States, regional and local authorities, payers of healthcare services, industry and the European Commission have been supporting research in the field of telemedicine for over 20 years. However, despite the considerable level of technical maturity of different technologies, the sector is not as well developed as could be expected" (EC SEC(2009)943 final of 30 June 2009).

The European Commission (EC) launched several calls for proposals for projects related to biosensors, mostly in the area of telemedicine, e-health and active ageing during the 2000s. Research for 'personalised healthcare' was funded with a budget of € 549 million in 2014, responding to the strategy to reduce the ever rising costs of healthcare in the ageing population of the EU. The analysis of these documents show that expectations are high. e-health and the use of big data in healthcare are expected to improve diagnostics, therapies, disease prevention and support healthy ageing (EC 2014). The 2013 EC call for proposals describes ICT for Health, Ageing Well, Inclusion and Governance, as one of the big challenges of Europe. Here, ICT in health is described as a tool for empowering the elderly generation, that will enable them to "live independently, delay/avoid institutionalisation and staying active as much and as long as possible" (EC C(2012)4536, pp. 53). The empowerment could "facilitate patient control through self-management and shared decision making, as well as promote equitable and collaborative approaches to healthcare and improved cost-effectiveness of care delivery" (Risling et al. 2017, 2). However, there are different views on whether patients will be really empowered through the use of these technologies or not. For example, Ammenwerth (2018) argues that "whether patient portals really can have a positive impact on patient empowerment or not seems to be quite unclear at the moment" (p. 22). Risling et al (2017) argues that the concept of *patient empowerment* is still not clearly defined in the literature, although it is becoming a focus of exploration of many studies on healthcare reform, but study of changes in health behaviour and outcomes are still missing.

The cost-effectiveness ratio is an important element when evaluating possible novelties in the healthcare systems. When it comes to WS, despite the promise that eHealth would reach more people, decrease costs and increase the effectiveness (Dobkin and Dorsch 2011), there is no straightforward answer about the increased cost-effectiveness ratio. While Kvedar et al (2014) state that "the increasing adoption of electronic technologies is widely recognized as a key strategy for making healthcare more cost-effective", improve the quality and patient satisfaction, as well as lower costs, Mistry (2012) and De La Torre-Diez et al. (2015) argue that there is lack of "concrete" evidence about the increasing cost-effectiveness of telemedicine and eHealth and that it is unrealistic to make broader generalisation about it.

We suggest that these *big promises* come with high uncertainties on a number of ethical questions that go far beyond concerns of privacy and data protection. So far, it is not clear who will own the data, or whether these will be open data; who would be responsible for medical decisions that are based on data produced by WS; or what would be the social implications of distant care for elderly or people with chronically ill patients in need of continuous care? Even the reliability of such devices is still questionable and different studies have concluded that their accuracy and reliability are variable (Wang et al. 2017; Byun et al. 2018).

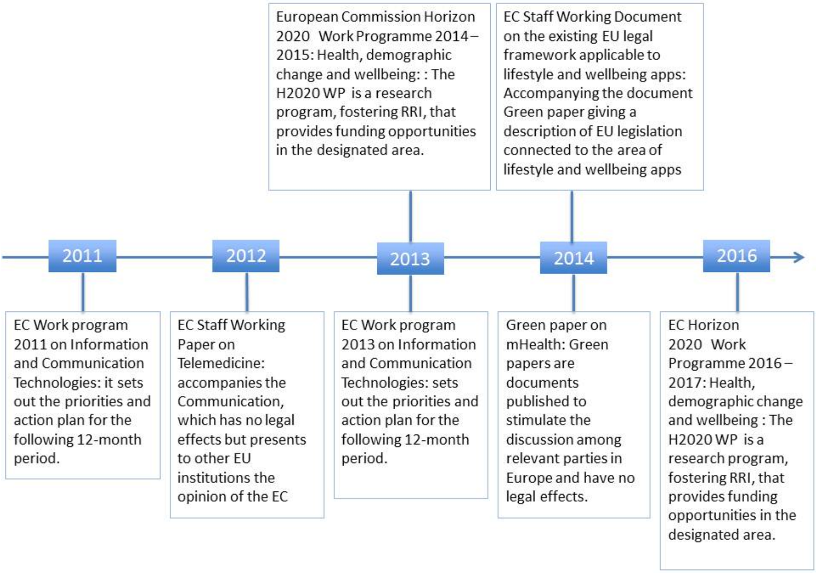
Hence, this paper contributes to exploring whose and what knowledge is supporting the development of policy making with regards to development and adoption of wearable technologies in healthcare, and what *normativities* are developing through the design and use of these devices.

4. Research Design

KA contributes to a body of research that intends to get insights about what types of knowledge inform policy making. While some have analysed how the EU uses expert groups to inform policy making (Gornitzka and Sverdrup 2008), the KA approach aims at tracing the pedigree of knowledge claims. Our particular application of KA is focused on pedigree analysis and the engagement of the "extended peer community" (Funtowicz and Ravetz 1991). A pedigree analysis explores knowledge production and circulation; in practice, by investigating where knowledge comes from, one can establish which actors are relevant for the particular claims and assumptions and whose narratives are voiced in the policy process. The methodology further helps with making visible which actors and which views are excluded through the very process of engaging a number of relevant actors. We conducted a series of in-depth interviews to ascertain and further explore who, what and how particular knowledge claims get into policy documents. This methodology is particularly interesting in cases where there is genuine difficulty in having an a *priori* understanding about *who* is informing policy.

4.1 Analysis of Policy Documents

For the purposes of this study, we identified policy documents issued by the European Commission that are related to the use of WS in health and wellness (see Figure 1). We selected not only documents that focus on this field but also those that relate more broadly to the application of WS in health. The pedigree of the policy narratives was explored by looking at the sources quoted in policy documents, allowing identifying which institutions and actors are informing policy making.



EC Work program 2011 on Information and Communication Technologies: it sets out the priorities and action plan for the following 12-month period.

EC Staff Working Paper on Telemedicine: accompanies the Communication, which has no legal effects but presents to other EU institutions the opinion of the EC

European Commission Horizon 2020 Work Programme 2014–2015: Health, demographic change and wellbeing: : The H2020 WP is a research program, fostering RRI, that provides funding opportunities in the designated area.

EC Work program 2013 on Information and Communication Technologies: sets out the priorities and action plan for the following 12-month period.

EC Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps: Accompanying the document Green paper giving a description of EU legislation connected to the area of lifestyle and wellbeing apps

Green paper on mHealth: Green papers are documents published to stimulate the discussion among relevant parties in Europe and have no legal effects.

EC Horizon 2020 Work Programme 2016–2017: Health, demographic change and wellbeing : The H2020 WP is a research program, fostering RRI, that provides funding opportunities in the designated area.

Figure 1 – Analysed documents

4.2 In-depth Interviews

We conducted nine in-depth interviews with relevant actors which were connected to WS and telemedicine policies and practices; the interviews focused on deepening the assessment of policy narratives, extending their review to relevant actors, bringing more insights about the construction of specific visions and narratives around WS.

In-depth interviews are one of the major qualitative methods in order to explore individuals' opinions and insights about a specific issue or idea (Kvale 2007) and useful to investigate a certain topic with more in-depth information (Boyce and Neale 2006).

We identified relevant actors by looking at who holds strong interests in this particular issue and of what nature, i.e. expertise, influence in the policy process or opinion making regarding WS. That included the authorship of policy papers, scientific papers, articles in specialised media (e.g. Wired Magazine) and persons involved in projects related to e-health. Although policy papers are public, their authors are usually not known. Therefore, we also asked the interviewees to recommend other relevant actors. Five broad groups of actors were identified: policy makers, industry, academia (medical researchers, IT researchers, STS researchers), media, NGOs. We contacted 20 persons in total out of which 9 agreed to be interviewed (see Figure 2). We also contacted industry but none showed their availability to talk to us, which, we acknowledge could have enhanced our analysis. All the interviewees were either authors of relevant publications or known activists in the field. More interviews weren't necessary because, as Boyce and Neale (2006) state, the saturation is reached when the same information is provided by different interviewees.

The interviews were conducted in the period between 15 October 2013 and 16 December 2014 in English. They were semi-structured with open-ended questions, lasting between 35 to 60 minutes. They were conducted either in person or through electronic means by the authors. The respondents were first approached by email to arrange the time of the interview, inform them about the confidentiality, anonymity and the objectives of the interview and project.

The semi-structured interviews were centred around questions regarding the interviewee's involvement in the field of WS, the personal motivation to engage with this topic, the knowledge that was used when producing material on WS, and general questions on benefits and challenges regarding WS in healthcare, testing some of the claims made in policy papers. Additionally, we asked about how quality of knowledge could be assured when evidence was sought for the narratives these devices are being proposed and sold with; finally, we also enquired about which topics were not successfully discussed in debates surrounding WS. In the interviews, we focused especially on the issues regarding the use of WS in healthcare.

The interviews were transcribed and analysed by the authors. We used Ritchie and Spencer's (1994) framework for analysing the interviews. We first 'familiarised' with the data by reading transcripts and listening to the audio recordings, in order to understand what the most important issues to our interviewees were. This phase helped us building a set of preliminary codes. In the second phase, we identified a thematic framework based on the research questions, the analysis of policy documents, as well as the emerging themes from the interviews. We compared codes emerged from the documents' analysis and interviews and decided on the most important to be kept. We then indexed and charted the data, i.e. coded the interviews into the categories. The last phase, mapping and interpretation meant finding patterns and making sense of the coded data.

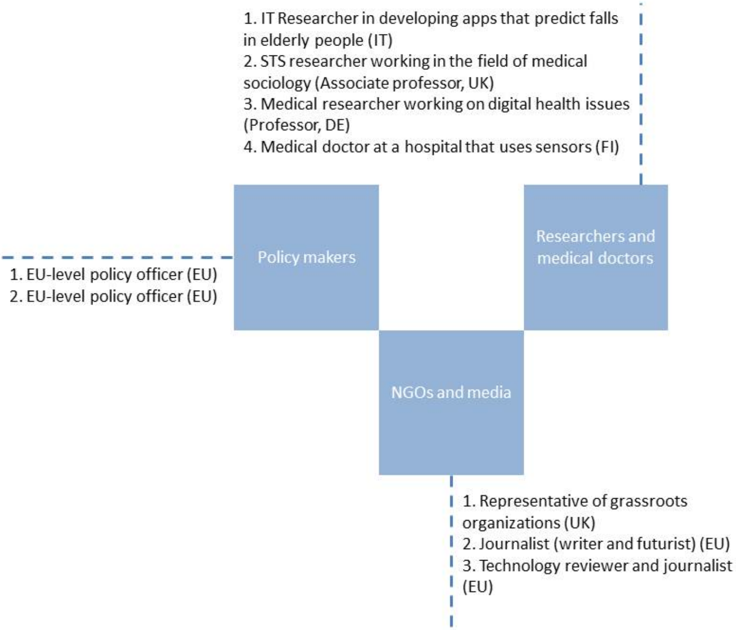


Figure 2 – List of interviewees

5. A Knowledge Assessment Journey

5.1 Wearable Sensors Related Policy Documents – Journey 1

While examining knowledge claims on the policy documents listed in figure 1, special attention was paid to the references that are enlisted to support major claims on the promises of wearable sensor technologies to address challenges in the healthcare sector. We found that many of the claims are not backed up by any reference, hence it is difficult to establish their *pedigree* in the KA sense. In the Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services it is stated that,

> 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. (EC 2012)

These are strong promises and assumptions, but they are not supported with background knowledge, which could be verified. Other claims grounded on existing publications were not faithful to the original claims:

> Telemedicine can also significantly improve access to care, by delivering high-quality services to patients living in remote or sparsely populated areas affected by shortages of specialized healthcare professionals or by facilitating across border healthcare for the benefit of citizens in the EU. (EC 2012)

This section cites the 2010 EU citizenship report, which deals only with cross-border healthcare, not discussing telemedicine as a means for better care for people living in remote areas.

A common snag of the EC papers is self-referencing, i.e. the documents justify certain types of claims that (we argue) would require citation of expert studies or sources of evidence; instead citations of earlier EC publications of policy nature are made. In the 2012 EC paper on telemedicine, we found the following sources (figure 3): policy documents: 25 EU Directives and Regulations, 14 from the EC, 7 from European Court of Justice; and one from academia. Whilst one can argue that the choice to have our healthcare mediated by ICT is a social and political one and not a technical one, it also can be expected that the reasoning offered is at least of social and political nature and not based on poorly referenced technical arguments.

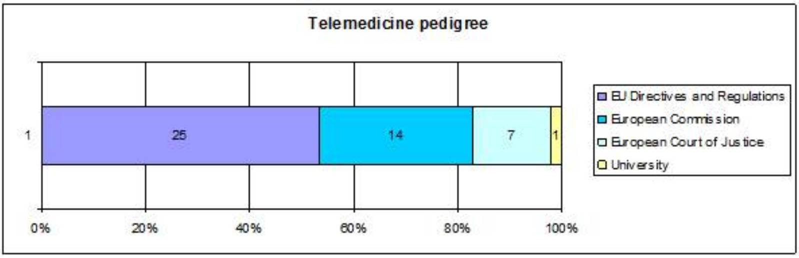


Figure 3 - Pedigree of the 2012 EC paper on telemedicine

The green paper on mHealth (EC COM (2014) 219), has a greater variety of references, although the majority is again from the EC itself: 21

from EC, 17 from industry and consultancies (12 industry, 5 consulting), 4 from the World Health Organization, 3 from university and 1 from the media (figure 4). Similar observations can be made for the other documents we analysed; working programmes (EC 2012, 2013, 2016) have even less references and the Staff working document on the EU legal framework (EC 2014) refers to the EU legislation, consisting of different directives, only.

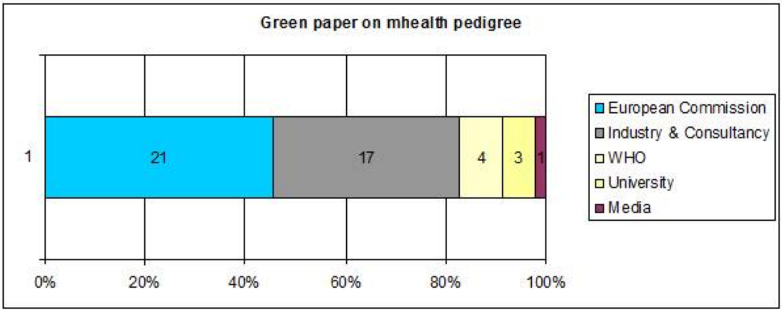


Figure 4 – Pedigree of the mHealth Green paper

5.2 Deepening the Process Through Actors Engagement – Journey 2

Knowledge Assessment

As previously noted, the EC is promoting e-health, m-health and WS as important means to improve the healthcare system. We asked our interviewees what their knowledge on WS builds on, especially taking into consideration the place WS seem to have and expectations they create in a rather complex transformation of healthcare.

With regards to scientific and clinical studies on WS in healthcare, three of the interviewed persons from different professional networks (academia and healthcare) argued that there was not enough research on WS for healthcare and a tele-health; some of them considered positive the financing of projects in this area by the EU because there is “little academic research” in this area and although the companies show customer satisfaction data, “this is quite different from the data that is required if you really want to look at the medical effects of the devices” (Medical Doctor, interview).

Referring to an EU-funded project on sensors for monitoring and predicting elderly people falls, our interviewees suggested that new technologies are often being pushed by the industry, although their effectiveness in either improving health or reducing the healthcare costs is largely unproven.

The interviewees from the academia and the medical doctor we talked to also agreed that there is a need for more large-scale studies on the use of WS in healthcare:

> I would like to see more large-scale studies being done to really convince policy makers to change their funding behaviour. Whenever we want to study a topic, we have very small studies with a small number of participants. This is very costly, but we really need the evidence so that people will listen to us. (Medical Researcher, interview)

These views contrast with the claims in the policy documents, which describe the economic and health related value of WS as a fact. Could the lack of existing studies explain the WS benefits poor referencing in policy documents?

However, the views expressed by the researchers and the medical doctor are not in line with the visions of the policy makers that we interviewed. According to one of them, there is enough knowledge including clinical evidence available on WS used as medical devices that can be used to measure their cost-effectiveness. One of the policy makers claimed that it only needs to be gathered in the right way to get a complete picture:

> The new thing we are launching with DG CNECT tries to map out all the clinical evidence which is available on the market, to better measure the effectiveness and the cost-effectiveness of medical devices for e-health (…) but *we look at what industry produces* and everything that is in the Cochrane database or the Centre for Reviews and Dissemination (CRD) database. (…) Now [that] we have a complete picture, we will ask experts nominated by the Commission, a panel of experts on healthcare systems, to look at this. They will cast a particular eye on the quality of the literature which is being produced. (Policy officer 1, interview, emphasis added)

The policy papers analysis showed that not all actors' concerns and their knowledge have been represented. Whilst, there seems to be a focus on the need to involve industry in the quote above, it remained unclear who is invited to be part of the experts panel. Also, one of the interviewees (social science researcher) pointed out, that their research group used a range of methods, including discussions with different *stakeholders* to draft the Forward Look on Personalized Medicine (European Science Foundation, 2012). In the researcher's opinion, one group was underrepresented in the discussions, namely health economists.

At the EC, policy makers often engage researchers on expert opinion on a topic. Hence, investigating how knowledge is circulated and used in the policy making process is needed to investigate its quality. The researchers we interviewed, raised the concern that it is often not clear to what extent their work is being considered in the policy making process and it is “hard” to estimate for them what impact their input has. As one of them states: “You give your input as an expert at that level and the hope is that somewhere downstream will inform policy” (IT Researcher, interview). This demonstrates a certain opacity of the policy making process, even for those who are participating in consultations, since it is not clear to anybody whose voices really get marshalled into the policy making process.

Another way of understanding if the EU policy documents are well informed by other actors’ visions is by asking which and whose imaginaries and knowledge did not find its way into the policy papers. In the next section we therefore compare visions of WS by different actors and contrast them with the narrative laid out by EU policy documents.

Imaginaries of Health trough Wearable Sensors and Telemedicine: Which and Whose Knowledge Is Voiced in the Policy Narrative?

The EC narrative on WS and e-health circles around the issues of cost-effectiveness, improved quality of care, patient empowerment, inclusiveness, healthy ageing, preventive care and e-health as a promising new market. In order to test the plausibility of the narrative with different actors we asked them: What was your motivation to engage with this topic? To which problem are WS the solution? What types of knowledge and sources of information did you use? What kind of impact did your work have on policy making? Which topics concerning WS are not sufficiently discussed at a political level?

On question: “To which problem WS are the solution?” it was argued that the use of WS in healthcare corresponds to the need to improve the quality of care and at the same time decrease the costs of healthcare. In Europe, the rising costs of healthcare are a burning topic, the current healthcare system being unsustainable (OECD 2015). One of the interviewees (IT Researcher, interview) works on a project that develops applications to predict elders falls, assess mobility and gait function; he sustains that the use of WS is related to the idea that proactive healthcare can reduce accidents and therefore reduce medical costs.

Another element often mentioned in policy papers is that WS could improve care of people with chronic medical conditions, by improving the life quality of patients but also reduce costs. The interviewed policy maker suggests that in order to decrease costs, there is a possibility to treat some chronic patients at home instead of hospital but for that, it is important that the medical staff can monitor them remotely.

The idea of reduction of costs has not been proven thus far. A study conducted by one of our interviewees showed that, the use of WS for health monitoring actually increased the number of medical visits and therefore led to an increase in cost, without additional benefits for the patients.

> Actually, the results are sometimes quite surprising. We had a small study on diabetics in one of the cities in Finland, where glycaemic control was monitored using an application. What happened was that the patients who were monitoring their blood/glucose level themselves were using more healthcare services, but the end result was the same. They did not get any health benefit, but they used more services because when they noticed something problematic during their monitoring, they visited doctors and clinics. They used much more services, but they did not get any better outcomes than the other patients. (Medical Doctor, interview)

This view is shared by a policy officer who admits that, despite the EU strategy on e-health, whose objective is to reduce the costs of healthcare, the evidence of the savings potential is still missing, as well as it bringing any clinical value for patients. Our interviewees agree that it is not impossible that the use of e-health could reduce costs in some instances and "make healthcare smoother and more efficient". Even if sometimes this happens, "very often this does not happen (Medical Doctor, interview).

Another vision is that WS will allow gathering a greater amount and more "accurate" information about a person's health status. The medical doctor interviewed, argues that "WS provide a means to get more information, in contrast to what we do at the moment, which is what I call snapshot care […] when you contact your physician only after you already have a problem" (Medical Researcher, interview). Furthermore, he states that the information collected by the sensor is more accurate than a patient's memory.

> If you want to know about the condition or the physiology of a patient in between physician visits, such as in everyday life, you have to ask the patient. We all know that patients do not give accurate history. We get objective information about their state of health when we use WS. We can get out of lab conditions in an unsupervised way. (Medical Researcher, interview)

An interviewed policy adviser points out, that the sensors are only a "component of a complex system" and making conclusions based on that will produce "a huge error rate". Hence, WS reduce a person's health to a few factors that can be measured by sensors. The most problematic being "because this comes from an instrument with a nice number associated with it, people will believe it" (Policy officer 2, interview). This is shared by the medical doctor who thinks that WS and tele-care cannot be a substitute for traditional healthcare:

> WS just provide *part of our toolbox.* We will never replace the physical person-to-person contact. This is not really our intention and we do not

> want to replace the nurse or physician, but rather to provide better information for a broader base of making *better and more reliable decisions* about the patient. (Medical Researcher, interview – emphasis added)

Concerning the reliability and quality of the data from current devices, there is still a number of technical problems to be solved. According to the interviewed developers and IT researchers, WS are not measuring the data with desired accuracy, and it is not proven that they provide reliable outputs. The positive experience of wearing a sensor is related to the (wrong) belief that the data it produces are reliable:

> It makes you feel good to wear it because you believe that this is making a difference. […] [the effect] is almost psychosomatic because you think the number is correct, but often the number is not correct. (Medical Doctor, interview)

Another important strong element of the EC narratives on WS is that they are an empowering technology. There are different opinions on this narrative:

> As part of the services that we have defined using WS, we can provide feedback with the information we have, which can improve patient self-management. We use the term *patient empowerment*. I do not really believe that a patient can manage herself or himself completely alone, but this can provide support in the same way as using wearable devices when we go running. (Medical Researcher, interview – emphasis added)

The concept of patient self-management and patient empowerment raised three main issues in the interviews: responsibility, missing face-to-face interaction with the doctor, and increasing inequalities arising from possible digital divide. Patient self-management implies a shift of tasks and responsibilities from the healthcare professional to the patient.

Many of the devices are intended for eldercare. Nevertheless, certain groups in society might have difficulty to use the devices, because "many of the services that are provided by the Internet may be difficult for you to use". In this way, "*e-healthcare can actually increase inequalities* because it makes healthcare accessible for some, but does not help those who probably need the services more." (Medical Doctor, interview – emphasis added). While sustaining that e-health encourages alternatives to face-to-face relationships among citizens and professional careers, an interviewed policy maker agrees that there could be some ethical issues:

> I do not know whether it is an ethical issue or not. However, it is true that if we promote mobile health, we are also promoting a non-systematic face-to-face relationship between the patient or the consumer and the doctor. I do not know whether it is an ethical issue but anyway *we need* to move

> towards this new way of delivering healthcare. That can be an ethical issue for some people. (Policy officer 1, interview – emphasis added)

Also, related to the idea of empowering patients, the question arises of whether citizens will be able to choose the healthcare they wish to enrol with. Our interviewed researchers seem to agree that an empowering technology needs to be based on voluntary usage. In that sense, we need to *"make sure that this participation remains an opportunity.* It must *not* become a burden or a *duty* to people" (STS Researcher, interview – emphasis added).

Interestingly, these are quite contrasting narratives: choice ("an opportunity" vs. inevitability: "we need"). The latter is prevalent on the policy narrative.

In addition to the mentioned contrasting views about WS for healthcare, there is a number of other ethical issues that were pointed out by our interviewees, which are not reflected in the policy papers, official communications and strategies of the EC.

The Issue of Privacy and Regulation

One of the issues that was mentioned by almost all the interviewees is their concern for privacy.

> We will know much more about a person's mental and disease state and therefore we will be able to hire or fire or associate with people depending upon what we think we are seeing from the sensors. That is not permitted in most countries, at least in the Western world, but that will not stop people from doing it. (Policy officer 2, interview)

Privacy is very relevant for healthcare insurance schemes; to some interviewees, this could result into new normativities about our health and healthcare and therefore constitutes an ethical issue.

> The only big concern I have is around health insurance […]. If we know everything about you from the day that you are born, we will know what burden you will be on the health system […]. It goes against the whole idea of insurance, which is the unknown that as a herd, we insure each other and some people will be unlucky and others will be lucky. Together we will cover the cost, but when you start to get more information about people and the premium changes – you can see it all happen. Some will be very heavily disadvantaged because they have a poor health condition and there is nothing they can do about it. (IT Researcher, interview)

Moreover, the issue of privacy leads to other ethical issues, namely property, autonomy and agency. For example, who owns the data from these devices? This is certainly not a new discussion – e.g. in the famous case of Henrietta Lacks in the 1950's (see Skloot 2010) and that of John Moore in the 1990s (see *Moore v. Regents of the University of California* (51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479)) with regards to property rights of their body materials and participation in research (see e.g. Tallacchini 2015 for a discussion of these two cases). The members of the quantified-self movement, for example, claim the right to own and also analyse their own data. Medical data could be marketed, but this raises ethical issues because "if you do not know where the data are going and what people will be doing with them, terms and conditions can be changed at will, as is often done. That is quite a big ethical issue for me." (Grassroots organisation, interview). The use of medical data for marketing purposes is currently in debate. The EC proposal for data protection states that the data should only be used for medical purposes and "not for purposes such as insurance or banking" (Policy officer 1, interview).

But in times where the "open everything" paradigm is being heralded as a key for restoration of trust, what kind of governance will protect existing rights and norms? This brings us to the issue of regulation. Given the numerous ethical issues and uncertainties associated with present and future uses of WS, some of the interviewees called for a need for more regulation, because "people should control the use of their sensitive health data. There is definitely a need for a legal framework for that." (Medical Doctor, interview)

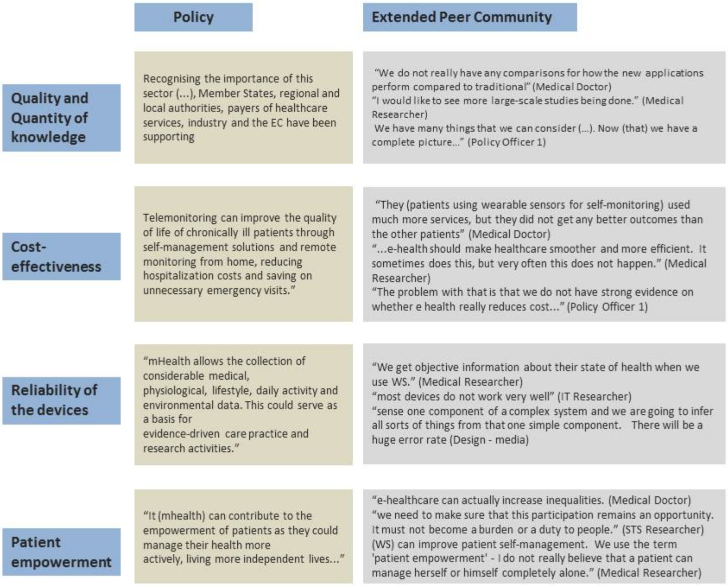
The legal framework needs to address the question of which devices are considered medical devices, and which devices are for fitness purposes. The staff working document concerning the existing EU legal framework states that "there are no binding rules in the Union as to the delimitation between lifestyle and wellbeing apps and a medical device or in vitro diagnostic medical device" (EC, 2012, p.3). But our interviewees point out that:

> This is the regulatory issue at stake. Are these WS, apps or devices considered as medical devices or are they to be considered as consumer products? At this stage, they are considered medical devices in the legislation. On the other hand, in other cases, they are followed up or monitored as consumer products. […] the information in these sensors measures health issues […]. They should then be considered as medical devices. They should then be regulated as medical devices with CE marking and so on. (Policy officer 1, interview)

Another interviewee argues that:

> If you are really claiming that it provides health benefits, then you should have to have the same type of proof that you have for medicines, medical devices or medical procedures. You have to have medical data and studies to show that something could happen if people start to use these things. (Medical Doctor, interview)

Figure 5 summarises the divergence between the policy papers and the interviews' statements that we found while coding both sources. What this table intends to show is not who is right or wrong, but rather to illustrate that relevant actors in the WS field are not clear or disagree on major issues concerning cost-effectiveness, the role of the patient, reliability and the quality of the data that are produced by the sensors. These types of uncertainty are not reflected in the policy papers, which promise that WS and e-health will ease the burden of the health system and solve the problems of an ageing population.



	Policy	Extended Peer Community
Quality and Quantity of knowledge	Recognising the importance of this sector (...), Member States, regional and local authorities, payers of healthcare services, industry and the EC have been supporting	"We do not really have any comparisons for how the new applications perform compared to traditional" (Medical Doctor) "I would like to see more large-scale studies being done." (Medical Researcher) We have many things that we can consider (...). Now (that) we have a complete picture..." (Policy Officer 1)
Cost-effectiveness	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."	"They (patients using wearable sensors for self-monitoring) used much more services, but they did not get any better outcomes than the other patients" (Medical Doctor) "...e-health should make healthcare smoother and more efficient. It sometimes does this, but very often this does not happen." (Medical Researcher) "The problem with that is that we do not have strong evidence on whether e health really reduces cost..." (Policy Officer 1)
Reliability of the devices	"mHealth allows the collection of considerable medical, physiological, lifestyle, daily activity and environmental data. This could serve as a basis for evidence-driven care practice and research activities."	"We get objective information about their state of health when we use WS." (Medical Researcher) "most devices do not work very well" (IT Researcher) "sense one component of a complex system and we are going to infer all sorts of things from that one simple component. There will be a huge error rate (Design - media)
Patient empowerment	"It (mhealth) can contribute to the empowerment of patients as they could manage their health more actively, living more independent lives..."	"e-healthcare can actually increase inequalities. (Medical Doctor) "we need to make sure that this participation remains an opportunity. It must not become a burden or a duty to people." (STS Researcher) (WS) can improve patient self-management. We use the term 'patient empowerment' - I do not really believe that a patient can manage herself or himself completely alone." (Medical Researcher)

Figure 5 – Divergence between the claims in policy papers and the interview

6. Discussion

Through pedigree analysis, a knowledge assessment methodology, relevant actors in the field of WS were identified. As we have seen from the section above, there is a disconnect between EU policy narratives and others'. All actors are active in producing different types of knowledge about the development, practices and policies related to the potential of WS in addressing different aspects of human health. It seems also that not all voices are voiced into the policy making process, given its positivist e-health and telemedicine narrative.

A great deal of promises is made throughout the EU policy documents looked at in this paper (including the research calls sponsored by the EC), especially concerning cost-effectiveness of e-health and patient empowerment through personalised care. The underlying narrative and expectation is that technology will fix current problems of healthcare. In the policy papers we looked at, we found a number of issues that undermine their quality, namely: poor referencing for rather important claims, self-referencing, references to poorly conducted studies, which make knowledge claims amenable to scepticism.

Our analysis suggests that a great deal of the knowledge used in policy papers comes from industry and not so much from medical and healthcare institutions, citizen led projects (e.g. Quantified self movement) or academia. In fact, as one of the interviewees pointed out, industry seems to dominate the imaginaries surrounding WS technology applications. While at least part of the academic knowledge might be known to policy makers in the field, (evident from the interviews), the academic body of knowledge is not sufficiently reflected in the policy papers. The lack of references to sustain the big claims in the policy documents, leaves a reader, be it any citizen or the researchers involved in consultations for the EU, unsure about the grounds on which the EU e-health strategy is based on.

Moreover, policy papers that are mostly informed by visions of industry leave out important alternative visions to reform the current healthcare systems.

By assessing knowledge production *loci*, one can also see that there are disconnects between what the imagination of the current and future uses of these sensors are. There are several spontaneous experiments of self-care, *self-veillance* both by industry and citizen movements, which if assessed could help with understanding the impacts of these objects according to received notions of care and health. Yet the criteria with which such monitoring would take place is also a matter of negotiation. As with other technological developments, WS are also object of unanticipated appropriations both by institutions and citizens. The actors’ views that we have presented show a great number of disconnects, not only concerning different imaginations of the role and function of these devices in health and healthcare, but also regarding supporting evidence that these devices can deliver what they promise to.

Moreover, besides analysing the origin of the aforementioned disconnects, it seems that further research on the impact of wearable devices and e-health on society, especially in Europe is needed; the vision articulated in the policy narrative develops in specific spheres but its deeper meanings for healthcare are in need of further investigation. Within the framework of KA, this suggests that the ‘extended peer community’ considered thus far has been limited to few actors with strong interests on advancing the technology (WS) uptake by the health sector.

7. Conclusions

All current EU narratives place science and technology at the heart of its future but also its identity[3]; for some time the EU sustains a particular innovation narrative (EC 2015). In fact, "innovation" is presented in a salvific role, oftentimes with an imaginary of substitution, used to justify and encourage techno-science development. WS and e-health are part of the technological determinism and techno-scientific imaginary that suggests that, through technology, health and healthcare issues can be fixed (The Economist 2009). This expectation from technology is visible through the narratives of patient empowerment, effective and efficient healthcare and improved certainty (i.e. better and more complete health related data imply *tout court* better diagnosis and cures). This imaginary appears as an imperative in both policy papers and in the words of policy makers. Simultaneously, there is a number of unknowns and concerns, expressed diversely by different actors, e.g. unresolved ethical issues, namely privacy, inequalities, in particular originating from digital divide, or new ideas of care where face-to-face interaction is substituted with digital interfaces. Also, a number of uncertainties such as, quality of data and data ownership, responsibility, inadequacy of current regulation, actual economic effectiveness of WS deployment for health purposes, need scrutiny.

These 'simple' devices are designed and delivered to us with a narrative of 'healthy', of what needs to be shared and of what needs to be measured, of how we should be ageing and also of how our wellness, happiness and health are better dealt with through digital smart artefacts. Although current WS are mainly used for fitness purposes, the narratives around WS technology suggest that WS will become an integral part of the medical practice, preventative medicine, personalised medicine, mobile health, cure and care (Vesnic-Alujevic et al. 2016). The WS based healthcare vision presumes cost effectiveness but it does not discuss other social and ethical implications of the technology, such as privacy, data ownership and patient-doctor relationships. In particular, we wonder if the normative and performative aspects of these technologies are at all a discussion in the policy making process. We suggest that, before the narrative gets entrenched in the policy debate, that serious societal enquiry takes place through different public engagement strategies promoted by local, regional, national and supranational institutions, in order to understand what the actual matters of concern and care are among citizens and whether the smart innovations 'confident' proposal for healthcare are responsive to those. Additionally, tapping into existing public engagement visible in existing communities' practices, epistemologies and debate helps policy narratives being inclusive of extended facts and societal expectations. Above all, 'we', collectively, need to identify by which imaginaries of health, including values and ethics, we wish to live and that is only possible if spaces are made for these dialogues to take place. The institutions that lead policy initiatives should embrace this type of activity as *modus operandi*.

These types of enquiry, which fall on what we generally described here as 'knowledge assessment' and the engagement of the 'extended peer community' are useful beyond any geography; comparative studies across other regions of the globe could help understanding healthcare culture and broader contextual influences the constitution of institutional narratives that contemplate adoption of WS.

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[1] The terms wearable sensors, wearable devices or gadgets, wearables or wear-

[2] Quantified Self is a movement of users and makers of self-tracking tools.

[3] See e.g. the EC report *The future of Europe is science*, available at: http://ec.europa.eu/archives/commission_2010-2014/president/advisory-council-/documents/the_future_of_europe_is_science_october_2014.pdf. Or notably also the Innovation Union strategy (http://ec.europa.eu/research/innovation-union/index_en.cfm) or the more recent call for the digital single market (http://ec.europa.eu/priorities/digital-single-market/index_en.htm).