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The lifestylisation of healthcare? 'Consumer genomics' and mobile health as technologies for healthy lifestyle

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ABSTRACT

Consumer genomics and mobile health provide health-related information to individuals and offer advice for lifestyle change. These 'technologies for healthy lifestyle' occupy an ambiguous space between the highly regulated medical domain and the less regulated consumer market. We argue that this ambiguity challenges implicit distinctions between what is medical and what is related to personal lifestyle choices within current regulatory systems. In this article, we discuss how consumer genomics and mobile health devices give rise to new ways of creating (and making sense of) health-related knowledge. We also address some of the implications of harnessing, rather than denying, the hybridity of mobile health devices, being situated between medical devices and consumer products, between health and lifestyle.

1. Introduction

While genomics has traditionally been associated with reductionist approaches to health and disease, other newer 'omics symbolise interconnectedness and complexity (Meloni and Testa, 2014; Prainsack et al., 2014). Epigenomics in particular, by exploring how environmental stimuli 'mark' and alter the regulation of genes, emphasises the importance of behavioural factors for health. This resonates with the thrust of public health campaigns, for which behaviour change is an important way to increase health. National and international organisations devoted to the promotion of public health have highlighted the importance of behavioural change to improve wellbeing and prevention of disease (WHO, 2002, 2008; IUHPE 2002; Department of Health, 2004).[1] Central assumptions in these programmes are that people have the power to choose healthy or unhealthy lifestyles, and that they are thus at least partly accountable for their health (Buyx and Prainsack, 2012).

Perhaps unsurprisingly in this context, healthy living, or healthy *lifestyle*,[2] has become central to the commercialisation of consumer products as well. As Sarah Nettleton put it, "lifestyle is a concept which has come to refer to people's styles of living, which, in turn, are shaped by their patters of consumption" (Nettleton, 2013).[3] The commercialisation of consumer goods with remedial qualities[4] has been seen to symbolise the rise of a new *petite bourgeois* culture of healthy lifestyles, in which people are seen as consumers (Featherstone, 1991). There is no area of research, it seems, that is not used for commercialisation of 'personalised' services to consumers: companies offer personalised health and diet recommendations on the

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[1] See also the amount of informative material on how to change eating and fitness habits, offered by the Weight control Information Network (WIN) an information centre of the National Institute for Diabetes and Digestive and Kidney Diseases at the US Department of Health and Human Services: http://www.win.niddk.nih.gov/publications/ [Accessed on 6th January 2015].

[2] For a sociological perspective on concept(s) of lifestyle, philosophies of wellbeing and health promotion schemes, see O'Brien (1995). In this essay, the author shows how the concept of lifestyle, initially referred to individual choices, has increasingly been used as a "vehicle for differentiating a population" (193) in a consumerist and market oriented culture. The association between health and lifestyle has, according to O'Brian, been a political construction together with the emergent role of the concept of "wellbeing" in health promotion strategies.

[3] The Oxford English Dictionary (OED) defines "lifestyle" as a "style or way of living (associated with an individual person, a society, etc.); *esp.* the characteristic manner in which a person lives (or chooses to live) his or her life." The OED definition of compounds such as "lifestyle advice", "lifestyle change", "lifestyle factor", etc., recites "Of or relating to the way in which one lives (or chooses to live) one's life, esp. with regard to quality of life". http://www.oed.com/view/Entry/108129?redirectedFrom=lifestyle#eid [Accessed on December 1st, 2014].

[4] See Tomes (2001) for a history of consumer culture and its relationship with medicine in the period 1900–1940.

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basis of the microorganisms inhabiting their bodies,[5] on their blood type,[6] or on their DNA.[7]

Genomics has been a particularly active playground for personalised services marketed directly to consumers. For example, in the years 2000–2010 a plethora of companies offering so-called direct-to-consumer (DTC) genetic testing entered the market, providing information about genetic predisposition to diseases and traits (Prainsack et al., 2008; Kalokairinou et al., 2014). Many of them also offered advice on lifestyle changes. As pointed out by Saukko et al. (2010) for the case of nutrigenetic testing, *lifestyle* products have emerged as an alternative regulatory category to *medical* genetic tests. According to the authors, the label of 'lifestyle products' has been advanced by scientists who, while legitimizing the 'seriousness' of these tests, negotiated the space for a "hybrid or compromise category" that would stand "between medicine and consumer culture" (Saukko et al., 2010:751).

A renegotiation of the boundaries between medical and lifestyle products can be seen also in other areas. Digital mobile devices increasingly leave the gadget world to enter the medical domain. These devices include wearable sensors for the tracking of movements or physiological functions, mobile applications ('apps') for the calculation and analysis of caloric intake, or for monitoring sleep patterns and offering personalised advice. These products are marketed as tools to enable users to eat healthier, move more and become aware of 'sustainable' lifestyles. Initially appeared on the market as consumer products, these devices are increasingly being co-opted into the medical domain. Policy makers regard these products as having "the potential to play a part in the transformation of healthcare and increase its quality and efficiency" (EC, 2014: 3) while insurance companies consider scenarios wherein these devices can be used to monitor their customers' lifestyle to ultimately adapt their premium.[8] These innovations occupy the ambiguous space between the highly regulated medical domain and the less regulated consumer market, where pre-market approval is easier to obtain and integration in the clinical pathway through public procurement is not required.

This ambiguous status of m-health devices and applications challenges the intuitive distinction between what is medical and what is instead related to personal lifestyle choices. In the following section we will show how regulatory questions raised by what we call 'technologies for healthy lifestyle', such as DTC genomics and m-health, signify a blurring of institutionally established normative categories. We will then reflect on how m-health devices and apps change the meanings of health information and propose new ways of creating (and making sense of) knowledge. Finally, we will address questions related to the blurring of the distinction of lifestyle v. medicine that are helpful for policy making.

2. Regulatory challenges and controversies

Technologies challenge established social values and meanings. Take the example of brain-machine interfaces and how, by blurring the distinction between physical bodies, minds and machines they question our definition of 'body' and 'person' (Lucivero and Tamburrini, 2007). Swierstra and colleagues[9] argue that new technologies destabilise concepts that serve as a guide to classify reality, and that they create new interpretations (Swierstra et al., 2009: p 276). By doing so, new technologies challenge our symbolic order, that is, the grid of concepts that are used in a certain society to order and categorise reality. Changing meanings in turn raise new normative questions. This has happened in connection with molecular medicine, for example, which presented us to the idea that it is possible to be sick at the molecular level without the patients' experience of symptoms and introduced the concept of 'biomarkers' (Boenink, 2009). The latter shift challenges definitions of 'healthy individuals' vs. 'patients' (as subjects suffering from a symptom or disease) and requires healthcare systems to adapt to this new framework.[10] As the concepts of 'healthy' and 'sick', also the labels of 'medical' vs. 'lifestyle-related' can be considered a dichotomy that seems to be assumed in European and North American regulatory tools. The unfolding regulatory debate around DTC genetic testing and m-health, described below, shows that new technologies for health and wellbeing present a hybrid character that destabilises some normative categories referring to the medical v. lifestyle-related distinction.

2.1. Direct-to-consumer genetic testing

In autumn 2007, two companies started offering online tests which would soon become a concern of health authorities and policy makers: *23andMe* in Mountain View, CA, and the Icelandic company *deCODE Genetics*, offered individual genetic risk calculations for fees starting at a few hundred dollars. Customers could purchase a 'spit kit' directly from the company, post it and, only few weeks later, access their genetic risk scores for a wide range of diseases, drug metabolism, and other characteristics. Other companies soon followed suit; a few weeks after *23andMe* and *deCODE Genetics*, *Navigenics* (Foster city, CA) started offering a similar service; and in 2009, San Diego-based *Pathway Genomics* became the fourth Personal Genomics (PG) company to offer SNP-based[11] genome-wide risk predictions to consumers online. With the exception of *Navigenics*, which restricted the scope of their tests to important health conditions from the beginning, these companies offered 'personalised' risk calculations for a wide range of phenotypes and traits (e.g. diabetes, alcohol flush syndrome, eye colour), as well as results of SNP-based analysis of carrier status and drug response.[12]

Only a few months after these online services were set up, health authorities stepped in. During spring and summer 2008, the Department of Health of the state of New York and the California Department of Public Health sent letters to *23andMe* and *Navigenics* warning them of continuing to offer their services over the Internet without a genetic testing licence. Companies insisted that their legislation and regulation for clinical genetic testing should not apply to them, as their services did not intend to give medical information, but that they merely sought to educate and entertain their customers (see Prainsack, 2011). At the same time, however, these companies also made sure that they complied with relevant legal provisions — which meant that licensed physicians had to 'order'[13] the PG test, and DNA analysis had to be carried out in especially accredited laboratories. In the US, conflicts with regulators have since then continued, and reached a new peak at the end of 2013, when the US Food and Drug Administration (FDA) ordered 23andMe to

[5] http://ubiome.com/#how-it-works (Accessed on January 6th 2015).

[6] http://www.dadamo.com/.

[7] http://mydietclinic.com/services/nutrigenomix-testing/ (Accessed on January 6th 2015).

[8] Such insurance policies are currently explored in Europe by the Generali Group that, within the next 12 to 18 months, plans to offer policies that reward healthy people, based on the information provided by their tracking devices (http://www.sueddeutsche.de/news/wirtschaft/versicherungen-versicherer-generali-will-fitnessdaten-von-kunden-sammeln-dpa.urn-newsml-dpa-com-20090101-141121-99-02990 [Accessed on January 6, 2015]).

[9] In their article, the authors build on the concept of 'symbolic order' elaborated by anthropologist Mary Douglas (Douglas, 1966) and on the idea of technologies as 'monsters' discussed in Smits, 2006.

[10] Similarly, the concept of 'patients in waiting' proposed by Timmermans and Buchbinder (2010) captures the liminality of patients involved in screening trajectories that place them in a category in between normal health and pathology.

[11] Single nucleotide polymorphisms (SNP) are variations in the DNA at the level of single bases (nucleotides: A, T, C, and G).

[12] While people celebrated this development as a new era of patient empowerment and the democraticisation of medicine, others were concerned about the questionable robustness of the scientific evidence underpinning personalised risk calculations (e.g. Janssens et al., 2008), or about the fact that these companies cut out medical professionals; in the early days of personal genomics tests online, companies operated according to the 'pure' direct-to-consumer model (Prainsack and Vayena, 2013), and commentators were concerned that lay people would not be able to understand the probabilistic information given to them by the companies (e.g. Hunter et al., 2008).

[13] In practice the physicians only needed to sign off the order, without ever having met with the test-taking person; see also Dvoskin and Kaufman, 2011.