

Biosensing: how citizens' views illuminate emerging health and social risks

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Short title: how citizens' views illuminate emerging health and social risks

Abstract

This article explores material from a citizen's inquiry into the social and ethical implications of health biosensors. In 'Our Bodies, Our Data' a space was afforded for members of the public to examine two forms of health biosensing, and for the authors to research what happens when such examination shifts from the domain of experts to that of citizens. Drawing on data from this inquiry, which forms part of a wider

research project, ‘Living Data: making sense of health biosensors’, we open up conceptual and methodological questions about how to study innovative health technologies and contribute to debates about the direction of health biosensing by bringing forward the views of a group rarely heard in this domain: the public. The panel of 15 participants was shown examples, handled devices, and heard evidence about the development of home ovulation monitoring and direct-to-consumer genetic testing. Citizens identified key areas of concern around the development, design and marketing of these devices, implicating technology companies, public bodies and civil society organisations. The panel articulated serious concerns relating to ethics, trust, accountability, quality and governance of health biosensors that operate ‘outside the clinic’. Their deliberations reflect concern for what kind of society is being made when genetic testing and home reproductive technologies are promoted and sold directly to the public. The panel process allowed us to re-imagine biosensors, wresting their narratives from the individualising discourses of self-optimisation and responsabilisation which have dominated their introduction in Euro-US markets.

Keywords: Citizen’s panels, biosensors, risk, ovulation monitoring, genetic testing, individualisation

Introduction

Monitoring one’s physiological state through the collection of personal bodily data - heart rate, temperature, sleep cycles, calories consumed, steps walked – is an increasingly important element of many people’s attempts to achieve health and avoid risks of illness and medical intervention (Lupton, 2015). Self-monitoring

promises to reduce and manage risk, but does it also produce new risks for individuals and for society?

Devices used in personal health monitoring practices are often referred to as 'biosensors' (Nafus 2013). This contemporary term blends two entities: *devices* and *biologically active agents* (OED 2007): implied in 'device' is the idea of collection, recording and storing or 'data-fying' what is being sensed from the *bio* (in the cases we describe here, saliva). Adding this process of data-fying to the commercial, 'direct-to-consumer' context of biosensing devices and practices, raises serious political, ethical and social concerns. Most research in this field, however, studies 'users' of self-tracking technologies and/or focuses on the technologies as 'kit'. Focusing on two key areas of health risk - in/fertility and dementia - in this article, we, in contrast, explore what citizens have to say about the risks and promises of biosensing.

'Lay' interpretation of risk and biosensors

Biosensors are iconic examples of the contemporary materialisation of risk. Building on the growing body of ethnographically informed work on information-based enhancement and augmentation of the body (such as Viseu and Suchman 2012) in this article we add a public perspective on the development, use and implications of health monitoring devices 'outside the clinic'. The citizens' views reported here give an empirical perspective to sociological critiques of risk and rationality, articulating ways in which the decisions of so-called 'consumers' of health biosensors are deeply

embedded in complex lived realities of ontological insecurity and erosion of trust in professional and expert knowledges and services.

The ethnographically-informed scenario used in our citizen's panel discussions (which we discuss more fully in the methods section) articulate two main forms of health risk: knowing one's future risk of dementia (driven in this case by anxiety and family circumstances); and warding off the risk of infertility and the physically and emotionally challenging medical interventions now commonly associated with it. The characters in our scenario engaging with these forms of medicalising risk have a sense of themselves as about to become pathologised and of needing to consider and address their health futures.

Managing future health risk through attention and action in the present is a strong theme in contemporary health discourses and is documented in studies of genetic testing, heart disease, fertility and HIV/AIDS. Much of this research, however, shows that in contrast to expert, statistical discourses, 'lay' people interpret future health risks in relational terms: thinking about family, personal connections and the authenticity of the source of knowledge. Franklin and Roberts (2004), for example, show that couples at high risk of passing on serious genetic disease consider multiple factors (personal, familial and societal) in their decision-making about how to manage the risks of having a(nother) child with the condition. Similarly, in a study of ovarian cancer, Hallowell suggests that:

[R]isk awareness is, at least in part, dependent upon the recognition of suffering in oneself and others, while managing risk is, among other things,

an attempt to avoid suffering in the future for oneself and other family members. (Hallowell 2006 p 23)

In relation to the management of risk associated with the introduction of remote (sensor based) home care monitoring for older people, or ‘telecare’, it has been noted that there is also a shift in sociotechnical networks of relations (Mort et al 2013). Although engaging with scientific and biomedical information, this relational thinking often at least partially distances itself from expert views. Brown and Michael (2002), for example, describe a shift from authority to authenticity in their analysis of publics’ assessment of the risks associated with xenotransplantation (the transplantation of living cells, tissues or organs from one species to another). Cox and McKellin (1999) describe a gap between patients’ and clinicians’ views of who counts as ‘family’ when considering genetic risk of Huntington’s Disease. Biomedical knowledge is central to the production of new forms of risk, but does not determine individual’s responses to these (Novas and Rose, 2000).

Our ethnographic studies show that biosensors are framed by manufacturers and consumers as ways to contain and manage risk but also that users almost always find that the biological data provided open up complex health-related questions that experts are unable or unwilling to answer (Kragh-Furbo et al, 2016; Wilkinson et al, 2015). Using biosensors in our two research areas – personalised genetic testing and fertility monitoring – then, often leads to participation in online forums in which users collectively attempt to parse the meaning of data and, importantly, to decide what to do to manage their individual risks.

'Lay' people's focus on relationality when considering risk, in our view, indicates a keen awareness of the broader social, political and ethical implications of biomedical risk categories, assessments and related practices. Following users, consumers or patients through their engagement with risk discourses and associated biomedical and other technologies (such as online forums), and asking them to articulate their thoughts and actions in interviews and focus groups, allows researchers to begin to see what these extra-medical considerations might be. But what might we find if we ask a broader population of respondents to tell us what they think about biosensors and their implications for health, risk and society?

Two types of Biosensors

Our research addresses two increasingly important areas of biosensing: personalised genetic testing and fertility monitoring. As detailed below, we focus on widely available, relatively affordable biosensors designed and marketed to assist consumers to assess and manage health risks outside of public or private clinical regimes.

Genetic testing In December 2014 23andMe, a commercial company based in the USA, launched its direct-to-consumer testing kits in the UK and subsequently the £125 Saliva Collection Kit and Personal Genome Service went on sale online and over-the-counter at Superdrug stores. After spitting into the tube that comes with the kit, customers send their samples to 23andMe's contracted laboratory in California that processes the samples using microarray technologies, and within a few weeks, their testing results are ready to view via email. Heavily criticised by the Royal College of General Practitioners, the Personal Genome Service provides data that claim to show users how their genetic profile may impact their health and how their

family history may be implicated in possible future health conditions (The Guardian 2014a; 2014b). These claims are regarded by many experts as highly dubious. Hardy and Singleton (2009), for example, argue in the *New England Journal of Medicine*, results are based on data from genome-wide association studies for common, complex conditions that involve multiple genes with relatively common genetic variants that each confers a modest to small effect on disease risk

Reacting to the over-the-counter availability of the tests, the Royal College of General Practitioners chair Maureen Baker said their availability could cause unnecessary worry and anxiety, put extra pressure on doctors, and that considering a genetic family history:

is a key skill that is best left to medical professionals, who can also provide the necessary support and advice to patients in a private and confidential environment' (Baker cited in the The Guardian 2015).

While 23andMe does not provide counseling as part of its service, the company encourages its customers to contact a health care professional, and in effect, as Fiore-Gartland and Neff note, the interpretative work is brought back into the medical system. 23andMe might cut out 'a middleman while integrating seamlessly all the parts of the middleman's very system' (Gartland and Neff, forthcoming). Thus, while the company attempts to disrupt traditional medicine through a so-called 'democratisation of access to information', the disruption discourses ignore, Fiore-Gartland and Neff argue, the issue of interpretation; data generated by the tests

require mediation: forms of interpretative work done by individuals themselves or by medical professionals.

23andMe's UK launch was controversial, sparking much comment in the news media and from the public, since 23andMe had previously been banned from marketing its Personal Genome Service in the US by the Food and Drugs Administration (FDA) which regulates products intended to diagnose, mitigate, treat or prevent disease, over concerns about the 'public health consequences of inaccurate results from the PGS [Personal Genome Service] service' (FDA 2013; Guardian 2013). In the letter to 23andMe, FDA had expressed concern about the company's failure to demonstrate that its service has been analytically and clinically validated, and noted how 23andMe had suddenly stopped communication with the Administration in May 2013 after four years of interaction. Later that year, 23andMe launched an aggressive national television, radio and online advertising campaign that is said to have piqued the FDA's interest (WSJ 2013). 23andMe has since worked with the FDA to get its tests analytically and clinically validated for their intended uses, and in October 2015, the company relaunched its Personal Genome Service on the US market with health risk reports that meet the FDA standards.

Fears have also been raised about the misuse of confidential data; 23andMe (which has Google as a major investor) has declared it does not share the individual-level genetic data with insurance companies or any other interested party without a user's explicit consent, unless required by law. However, the company may share a person's anonymised and aggregated data with third parties that include its business partners (23andMe 2015). While this type of data has been stripped of personal information, it

has been demonstrated that ‘it is possible, in principle, to identify an individual’s genomic data within a large dataset of pooled genomic data’ (Vorhaus 2009). This also raises questions about data security. While 23andMe uses ‘robust authentication methods to access its database’, the company also acknowledges that ‘it is never possible to fully guarantee against breaches in security’ (23andMe 2015).

Users of 23andMe are also invited to participate in the company’s research. If they consent to 23andMe Research, their individual-level data may be shared with third parties such as pharmaceutical companies and 23andMe may ‘create, commercialize, and apply this new knowledge to improve health care’ (23andMe 2015). It did this in 2012, when the company announced its first patent – related to its Parkinson’s Disease research – that came as a surprise to many of its customers, and while 23andMe ‘aim[s] for these discoveries to benefit everyone’ (23andMe 2012), it is unclear who will benefit the most. In their study of 23andMe’s research practice, Harris, Wyatt and Kelly (2012) argued that while 23andMe represents research participation as a form of gift exchange, this framing is used to draw attention away from the free, clinical labour that drives the profitability of 23andMe.

Wyatt et al. (2013) analysed the performative dimensions of trust relations between 23andMe and its users, drawing on Shapin and Schaffer’s (1985) discussion of material, literary and social technologies. They are sceptical of the ways in which 23andMe tries to build trust with its users, for example by use of personal language (use of ‘you’), promotion of links to the National Institute of Health, providing profiles of its advisory board with details of their university affiliations, the use of

firewalls, secure online payment systems, encryption of data, lab certifications and others.

Home reproductive technology Whilst there has been less visible controversy surrounding home reproductive technologies, some of these devices do involve the collection and storage of large amounts of personal biological data with the attendant concerns about accountability and potential commercial use. In this article we consider how having data about ovulation cross cuts into medical protocols around the diagnosis and treatment of infertility.

Companies promise that home ovulation monitoring devices will increase the chances of becoming pregnant and reduce the need for invasive medicine (testing and intervention). The Clearblue Fertility Monitor for example, in which urine tests are made to detect changes in hormones, claims to increase the chances of becoming pregnant by 89%. Ovulation microscopes offer saliva-based fertility testing as a way of detecting the surge in oestrogen which occurs before ovulation. If oestrogen is present in saliva, then crystallised ferning patterns will appear on the slide. Other monitors include Ovusense, a vaginal sensor which continuously records a woman's temperature while sleeping, and DuoFertility, also a temperature monitoring sensor worn under the arm. With DuoFertility, users receive a hand-held reader to record additional fertility information such as ovulation pain, sexual intercourse or cervical mucous. A little-known device, the OV-Watch, is a watch-like sensor that records changes in hormone levels found in skin perspiration. In addition to wearable sensors, an increasing number of fertility apps have also become available such as Ovia Fertility or Glow, creating platforms for women to input data about their bodies,

again with a view to increasing their chances of becoming pregnant. Of course, sensors and apps work with the body in different ways. Whilst sensors record and detect changes in bodily fluids or temperature, with apps the user must input the data they have produced using their body as a measuring tool. However, both sensors and apps respond to, albeit different forms of, biological matter.

These two different examples of biosensing systems share significant social and ethical dimensions. They both draw on narratives of enhanced visibility and self-optimisation: knowing about your genetic risks brings enhanced responsibility and pressure for behaviour change; knowing your ovulation patterns implies enhanced control of fertility. Both systems draw on ‘biologically active agents’ sampled at home but which then travel through sociotechnical networks involving laboratory and web spaces, in which they become transformed into data. In this way they come to frame the body as a ‘complex information network’ (Lupton 2012) and are both to a varying extent individualising, in the sense that they produce health/fertility as unconnected with wider conditions in society or with public policy. Outside of clinical control and commercially located, they are the subject of severe criticism from medical professionals on grounds of accuracy and effectiveness.

Another recent development which exemplifies the social risks associated with proliferation and commercialisation of ‘digital health’ is the ‘care.data’ initiative (NHS England 2015) which indicates that personal health data (in the UK arising from the universal health service) is now regarded by government and some industry sectors as a strategic economic resource. Decades of accumulated health and medical data for the population in England and Wales is currently being re-packaged as a

globally unique platform for biomedical innovation. The care.data initiative has been particularly controversial since earlier in 2014 it was revealed that the Government's Health and Social Care Information Centre had sold hospital records covering 47 million citizens, identified by date of birth and postcode, to an insurance organisation (Telegraph 2014). So even if the NHS continues to be the primary repository for health data in the UK, it is clear that this data is beginning to circulate more widely. While not associated specifically with biosensors, the security of personal data was a key issue raised by the citizen's panel.

Comment

Biosensing helps users to collect, store and assess personal health-related data. Many biosensors also facilitate the capture and storage of such data by commercial entities. Importantly, all of this labour occurs outside (although sometimes in tandem or conversation with) traditional biomedical networks (for example clinician's surgeries, public databases, hospitals), and outwith the regulatory processes associated with medical technologies. As increasing numbers of people buy and use these technologies, then, we need to consider the social, ethical and political costs of health monitoring and to think critically about how these technologies re-articulate and re-make health, risk and society.

Methodology

The study we draw on in this article was part of a broader interdisciplinary and multi-institutional, international research programme, 'Biosensors in Everyday Life,' supported by Intel's University Research Office (2010-2013). In our part of this programme, we have conducted three interlinked projects under the title 'Living

Data: making sense of biosensors’: a doctoral study on direct to consumer (DTC) genetic testing; a doctoral study on home fertility monitoring, and the citizens panel ‘Our Bodies, Our Data’, we draw on in this article.

As we have noted, much of the debate and analysis of biosensing focuses on its technical and scientific base. Given the potential social effects of such technologies we felt that it was important to engage a broader spectrum of voices in developments in the biosciences and management of data where innovations were exposing the public to challenges such as the management of uncertainty and risk, and the extensive circulation of their personal data. We therefore organised a two-day event, ‘Our Bodies, Our Data’, in which a carefully selected sample of citizens in Lancashire were invited to interrogate and debate complex issues arising from the introduction of direct-to-consumer genetic testing and fertility monitoring devices, matters which the public seldom gets chance to consider formally.

We adopted the deliberative panel approach from the citizens’ jury model and drew on a now established tradition of participatory democratic practice (Coote and Lenaghan 1997; Harrison, Mort and Dowswell 1999; Kashefi and Mort 2004; Gooberman-Hill et al 2008). An overview of methods and case studies in public engagement can be seen at the National Coordinating Centre for Public Engagement <http://www.publicengagement.ac.uk/how>. If carefully conducted using transparent processes, it can provide opportunities for citizens who are not necessarily involved with, or users of, particular innovations, to learn about them, ask critical questions and respond thoughtfully to the social, ethical and technical questions they provoke. The approach enables the formation of public understandings and opinion to enter a

domain dominated by experts. As such, it is a legitimate space within which to identify issues for debate and to offer recommendations to key actors involved in the development, marketing and regulation and consequences of those technologies. As a research method, citizens' panels allow us to move beyond the experience of particular patient groups or interested actors to consider the views of a much broader group of respondents, who are both more implicated than they may have thought they were, but also potentially more able to consider a range of implications without referring to direct personal investment. As suggested above, speaking to citizens allows us to focus on the implications of biosensing for society as a whole, raising significant ethical, social and political questions about risk, responsibility, trust and accountability.

We acknowledge that this approach has a number of limitations. While consultation is important, as Boaz et al (2014) argue, it does not equate with participation, and runs the risk of allowing 'the research enterprise, health services and governance structures to continue largely with business as usual'. Another important criticism centres on the timing of citizens' engagement. If the engagement takes place 'downstream' then citizens' ability to influence policy or technological development is limited; if too far 'upstream' the process can be frustrating as there are few materialised examples to examine (Pidgeon and Rogers-Hayden 2007). Additionally in our case, the panel took place in the North-West of England, a location that shaped the outcomes of the consultation in various ways. For example, the participants all clearly identified the National Health Service (NHS) as the primary and most trusted provider of health care and health information. It was widely taken for granted that

the NHS should also take care of biomedical and health data. This strongly reflects participants' 'history' with publicly funded universal healthcare.

The panel process

The 15-member panel was recruited and organised independently by a consultant experienced in participatory methods, Dr Sue Weldon, to reflect a broad cross section of citizens, rather than a representative sample of society. Each participant was approached with information about the panel process and if interested, subsequently followed up with a formal informed consent process. Members were recruited, from within a local area of 40 miles, to selection criteria encompassing: gender (broadly equal numbers of men and women); age (from 18 to 75); a range of residency including urban and rural, private and social housing; a mix of occupation/education, and diversity in physical ability and ethnicity (see Table 1).

—insert Table 1 here—

We reimbursed participants' travel expenses and paid them a small fee for their time and all were sent a copy of the draft report for comment. In contrast with ethnographic, interview or focus group based studies, which concentrate purposively on affected individuals or groups, these were citizens with no professional or vested interest in the technologies to be discussed. They did, however, bring a very wide variety of life experience and knowledge to the consultation. Interestingly it later emerged that all the panel participants had some connection, either direct or indirect, to the underlying issues brought up in the scenario or debate around biosensing and data, either from personal experience or through family members or friends. This

shows how ‘innovations’ which at first might seem distant from us are in fact embedded in everyday life.

Insert Figure 1 The Scenario

The ‘Our Bodies, Our Data’ examination of direct-to-consumer genetic testing and home reproductive technologies was initiated by through a scenario entitled the ‘Brown Family from Preston’. This fictional family included 32-year-old Ben, who was concerned about his risk of Alzheimer’s Disease and was engaging with direct-to-consumer genetic testing, and 36-year-old Louise who was trying to conceive and had purchased fertility monitoring devices. Based on data from the two doctoral ethnographic studies, the scenario explored the reactions of family members to Ben and Louise’s engagement with biosensing, and introduced the practicalities of testing and receiving results. The scenarios articulated possible concerns, but were neither positive nor negative about biosensing.

Scenarios are often used in futures planning or to develop policy where there are a number of possible outcomes. Scenarios are seen as helpful informative tools to work with imagined problems and important concerns. Features of systems can be explored in a variety of ways through the storyline, and can be supplemented by using examples of products, websites, and illustrative documents. The idea of using a family scenario in the ‘Our Bodies, Our Data’ inquiry was to present common features occurring between direct-to-consumer genetic testing and home reproductive technologies, allowing participants to reflect on the possible day-to-day implications of these, and to act as prompts for discussion and points of departure. The scenario

did not deliberately highlight any particular risks: in this article we focus on risk arises from the panel's deliberations.

'Expert' witnesses are frequently used in citizen panel projects to assist members in gaining an understanding of for example how new technical systems have developed, are supposed to work or what legal or ethical frameworks are relevant to their implementation. By responding to questions developed by groups of panel members, and addressing their concerns about the scenarios, the witnesses share their expertise with panel members. Through this discussion and form of questioning, the gap between lay and expert can be narrowed. The speakers we invited to 'Our Bodies, Our Data' panel discussion, provided input from four perspectives: primary health care; health research (specifically genetics); patient/user support groups (specifically infertility); NGO/third sector organisations (specifically genetics). The witnesses were: a General Practitioner and GP Tutor/ Primary Care medical educator with additional qualifications in sexual health, obstetrics and gynaecology, contraceptive techniques and paediatrics; the public programmes, manager at a centre for public engagement, education and training in biomedicine with a background in genetic counseling and science education; the chief executive of a national infertility charity dedicated to the support of those affected by infertility, and the director of a pressure campaigning group which specialises in the ethics, risks and social implications of human genetics. In the weeklong period between Day 1 and 2 the panel was invited to reflect on the expert witnesses' responses. Finally, in small self-selected groups the panel developed a series of recommendations: for the biosensor industries; for government, regulators and commissioning agents; and for civil society organisations (NGOs)

Plenary and group discussions were audio recorded and transcribed and all material was anonymised. Analysis began in the final group session of the panel itself and is partly contained within the recommendations for change. Analysis by the authors in terms of theory generation was conducted later from multiple readings of the transcripts and fieldnotes. Below we have used text boxes for ‘collective quotes’ such as questions generated by small groups of panel members. Other extracts are taken from individual verbatim transcripts, although we have not attributed quotes to particular participants (who are listed in Table 1). We use participants’ words to show the views of the panel, not in order to trace any particular view back to a particular participant. In a citizen’s panel, members are always speaking within a collective setting, even if expressing personal views. In this article, we show how the citizen panel method produces different forms of data from other qualitative research, forms which include collectively developed questions, discussion summaries written on flip charts/post-it notes, fieldnotes and comments on draft reports, in addition to verbatim transcripts. Here, participants speak as citizens not as representatives of interest groups or as members of particularly affected populations: the aim is to explore questions relevant to all social groups.

Insert Fig 2 Panel Discussion Running Notes

The Lancaster University Research Ethics Committee provided approval for the associated doctoral studies of direct to consumer genetic testing and home reproductive technologies on May 23rd 2012 and 20th July 2012 respectively.

Findings

Risks identified by the panel

Asking questions about the technologies Day 1 of the panel meeting began with discussion of issues raised by the scenario; members were interested and concerned to learn that consumers could purchase a service that provided personal genetic information and future health predictions. They also raised questions about the accuracy and usefulness of the data produced in biosensing, and group questions focused on the regulation of biosensing systems. The panel summarised these questions in the following way highlighting potential dangers, such as data security and test errors and the need for measures to enhance trust such as professional scrutiny and state regulation.

Panel's questions for the experts: on trust, reliability and regulation

What measures are in place to keep the data secure?

Is there any professional body to scrutinise these products/sites?

Are these [fertility] products regulated in the UK?

What is the quality of genetic tests? Are the results reliable?

To what extent, for instance, can common conditions such as cancer be tested for?

Can you tell that you are ovulating from saliva? Aren't there better ways?

Would you agree that 20,000 readings [of temperature, in relation to ovulation] creates an illusion of accuracy?

How useful is the information to Ben really?

The panel members were particularly concerned about the relationship between the National Health Service and the commercial provision of tests/testing kits and several of the questions they articulated referred to the role of the NHS.

Panel's questions for the experts: on relationships with clinicians

What information (from web sites and tests) do people bring to their GP?

How far should doctors interact with new commercial technologies?

The panel members were very uneasy about commercial motivation of the companies providing the tests and problems this created for protecting the interests of those using the tests as was evident in the following questions:

Panel's questions for the experts: on commercialisation

Who is going to benefit from the tests?

Are there links between companies that offer tests and companies that sell drugs?

Can employers/insurance companies have access to genetic data?

The panel members were concerned about the need for consumer education and whether the companies providing the tests could be trusted as reflected in the following questions:

Panel's questions for the experts: on education and trust

Is there a need for better education?

How do we know whether we can trust these companies? Is there a trusted website to make sense of other sites?

They were also very concerned about the effects on the wider family of the longer-term implications of accessing genetic information asking the following questions:

Panel's questions for the experts: on human costs

How do you cope with the worry/concern for the whole family?

How can people be supported to cope with the results?

Formulating recommendations On Day 2, after small group discussion, panel members gathered in a plenary session in which they expressed a high level of concern about the commercial marketing of genetic tests and fertility devices. Some members of the panel questioned whether these were being designed to meet the needs of the consumer or to deliver returns for shareholders. They felt that a business model primarily motivated by profit, rather than one to provide public benefit, could lead to manipulation of markets to create more demand for (sometimes unnecessary or inappropriate) products fuelled by heightened public awareness of future risks of genetic conditions or infertility. One participant argued that:

They (the companies) can set the agenda by creating fear and then, out of this fear, a demand for a service.

Many panel members reflected on current changes in the way health services were being provided in the UK and noted that the intrusion of commercial interests into their relationship with their General Practitioner and in some cases, patient support organisations, had the capacity to undermine their trust in them. ‘You trust them more if they are not trying to sell you something’, was a typical comment.

Managing and containing uncertainty

Panel members were very concerned with accountability, trust, standards and care of data. In the absence of specific regulation, the panel discussed the need to have some way of assessing the standard of products and services. One repeated suggestion was for a ‘kite mark’ or symbol to denote a safe product, endorsed by a trusted institution such as the NHS. Another concern was about personal data protection and fears were expressed that, once the data is supplied to a company (online), it would remain indefinitely available to be used in unknown ways.

Trust The panel members agreed that a person’s trust in an organisation, company or product is critical. Trust is built out of knowledge (of the organisation, company or product) and often on the continuity of relationships. Panel members spoke about how trusting relationships could be established with doctors, health professionals or even with organisations through experience and over time. One woman expressed concern that digital communications erode that sense of relationship continuity. Many panel members felt that the NHS had always represented a standard of reliable healthcare as a ‘trusted organisation,’ with one participant stating:

I'd only really trust something that was sponsored by the National Health Service....because I think the NHS is a trusted organisation which is there to look after us.

Panel members recognised that the NHS was undergoing significant structural change in the direction of privatisation and that this might affect future perceptions of trust.

A relevant remark was:

The only problem with that is that in the future, because of all the privatisation, there are going to be a lot of diverse companies involved in making a profit from the NHS and therefore who can we trust in the future?

Accountability Panel members pointed out that accountability is an essential part of a trusting relationship, and rests on ability to hold individuals or organisations to account through a chain of responsibility. In this context one person referred to the 2013 European 'horse meat scandal' in which supermarkets were selling meat products that were contaminated with horse meat (and other meats). The complexity of the meat supply chain meant that it was difficult to locate the source of contamination. The panel members argued that people could only trust a system if they perceived those operating it were committed to the general good rather than in pursuit of self interest. One man argued, 'With a doctor you can always go back if he (sic) misdiagnoses you. What happens if the test results are wrong?' whilst another asked:

What else does 23andME sell?....because how do we know they've got the specialists to do the tests? How do we know where the tests are going?

This concern was succinctly expressed by the question: ‘How many companies are in the chain?’

The panel members agreed that biosensor technology companies should formulate and publish a set of over-arching values and ethical guidelines. This recommendation arose out of concern that lack of regulation might lead to a fall in standards, particularly in respect of business practice and ethics. Panel members wanted to see written commitments to standards of good practice and argued that these guidelines should include an explicit commitment to develop new biosensor technologies for public benefit. ‘This would give you some basis for trusting them, and holding them accountable’, one participant stated.

Panel members argued that companies should be transparent and accountable in dealings with the public. They felt that the issue was particularly important when products were marketed online and there might be more than one company or organisation in the chain, obscuring responsibility for the quality, accuracy or safety:

They need to be accountable about the way they are marketing as well as what they are marketing. So they need to be completely transparent about the product.... The people who vouch for it, so called experts.... So you want their name, their education, references to their work and so on....

Standards In the absence of regulation to protect the consumer, (when products and services were being marketed in other countries where regulation may be weaker or non-existent) panel members felt that it would be difficult to maintain how can

standards of quality and accuracy in the UK. They expressed the desire to ‘see some qualifications’ of those offering a service and suggested:

This comes back to the [idea about statutory] warning on the packet. You could make it mandatory to give a warning [that results may not be reliable]

Minimal standards of accuracy were not high on the panel’s agenda; instead they were concerned that advertising claims made by biosensor companies were regulated.

Care of Data Panel members expressed concerns about the handling of personal data by companies that might use this data for further research without consent or pass it on to other companies selling treatments and drugs. They discussed the possibility that data might get into the wrong hands and such misuse of data might affect an individual’s insurance or employment status. One member expressed this concern very strongly in terms of ‘stealing’:

My feeling is that people who want to steal my information are more clever than I am.

Panel members felt that biosensor companies should guarantee to treat personal data respectfully and safely, specifically in offering a choice of consent arrangements. They argued that personal data was a precious part of personal identity, where informed consent arrangements were vital. Transparency about what would happen to

personal data, and possible future use, would facilitate informed consent arrangements. Summarising group debate one participant explained:

So for instance, before buying a service like a [genetic] test, right at the front there would be choices about what's going to happen to your data, whether you consent to any use, some use, or perhaps no use of the data apart from sending the results back to you. At the moment that's not the case, you don't know what they do with the data. There should be guidelines that the company have set up for the use of this data, and they should be published as well as part of telling you what the service is.

Panel members were also concerned about how data could be de-coupled from personal information in order to respect the anonymity of the consumer: 'It seems they all want us to be locked in, and that is a concern for a lot of people'.

Provision of counseling and advice when considering the wider implications of biosensor test results, was called for. For instance, test results might suggest a need for further treatment, often with implications for other family members. It might be inappropriate for a company to offer counseling but there should be 'up front advice' to consult a doctor or a genetic counsellor before accessing these services along the lines of: 'You should consult your doctor or, in the case of genetic tests, see a genetic counsellor', as one man put it.

Non-governmental support (including charities, patient support groups, disability groups) was needed to help users of biosensors understand and make sense of online

purchases, providing independent information and informal counselling. As one member suggested:

...so if you did the 23andMe test and found that you had a condition....to have support networks in place to help you deal with that....[in the genetic testing scenario] Ben didn't know what to do and 23andMe didn't help....so someone to talk to about the information and provide support.

The first and most useful role for non-governmental organisations would be to provide clear information about what tests, or biosensor services could offer and what they cannot offer. One woman argued that an important role would be in questioning some of the unrealistic claims being made by companies offering tests and biosensor devices:

We want them to provide unbiased facts, or tell us what is missing. I would be looking for facts. What does this do? What does it offer? What are the problems?

It was felt that users might need the guidance of an independent signposting service to direct users to specific support groups: 'They are not going to know where to get this help'.

Non-government organisations could provide a protected space, outside the professional services, for peer support offered by people who had similar experiences to share, in the view of the panel. In the scenario Ben was confused by the conflicting

advice he accessed from an online support group and, although it is normal practice to access such groups, there is little sense of who the forum discussants are, or of their motivations. Such spaces could be ‘infiltrated’ by companies seeking to promote products. Two essential elements of an authentic forum would be trust and reassurance: ‘You want to speak to someone who has been in a similar situation’, said one member.

The panel agreed that in the process of undergoing tests or using biosensor monitoring devices, there was a danger of being over-directed or ‘channelled’ in one direction towards further treatment, for instance with a course of drugs or IVF. They agreed that was a role for patient support groups in providing alternative options so that users would be enabled to make choices. One member said:

[It’s about] groups recognising the needs and desires behind decisions people make to have these tests done....particularly we were talking about their ... need to have or want a childso if these groups also acknowledge that need, and recognise that need and perhaps offer alternatives or the support around that need, then perhaps that would give a more balanced experience ...

There was a role for patient or user organisations in offering education about internet safety as an ‘antidote’ to industry promotion, advertising and unrealistic claims. The panel recognised that advertising could be a powerful way of offering hope, but they noted that it was important to provide a warning and some guidance – particularly for children. A young woman summarised this view in the following way:

We don't accept anymore our limitations. That you can't always improve on a situation. People will want to have something because they see it advertised...children...don't learn how to deal with advertising messages and images.

Discussion in the panel centered on the future relationship between commercial interests and the NHS in respect of 'buying in' services from both public and private providers. Initially, there was much panel debate about how the NHS could take a pro-active role in setting up a self-funded unit to supply data services (in competition with US companies such as 23andMe). Panel members suggested that by building on the ready availability of health data, these services could be used to extend population screening (for such things as breast and bowel cancer) by including genetic information. They suggested that the NHS could then raise much needed revenue by selling services to organisations such as pension groups. However, members also reflected on the dangers of selling information, either to individuals, public bodies (for research) or to organisations. One woman pointed out:

As a principle, it's your body, your data. It belongs to you. If you want information it should be available (to you) free of charge.

The panel argued that safeguarding personal information and explaining how adequate levels of protection would be maintained could be done through consent arrangements. They suggested that the choice to 'opt in' rather than 'opt out' of data storage was a safer option. Serious reservations were expressed about the sharing of data records, when such data had been collected from different sources such as

screening, health records and numerous other sources such as bone marrow donors. It was felt that such anonymised data could be linked to patient records. One member stated:

It's all about trusting them to look after your data. Don't lose the opportunity to safeguard this [data].

The panel stressed the need for a greater awareness of 'skilling up' to meet future demands for professional and public information in the area of biosensing. It noted that professional advice and counselling would be vital in understanding what test results mean for individuals and, for the wider public, but there was doubt that most health professionals had the skills to address public concerns about the social and ethical issues and identified the need for training programmes for clinicians in offering information, support and counselling (where necessary). The panel also identified the need for public information (written in lay terms) in primary care centres, schools and public places inviting people to learn more about biosensors such as genetic tests and fertility monitors and what they could offer. The panel wanted a trusted body to act as 'watchdog' in determining which companies are offering reliable information, and to direct people to reliable testing companies. A vetting/monitoring service might determine which websites to trust how to make sense of claims.

Discussion

'Our Bodies, Our Data' was an attempt to move consideration of digital health technologies - specifically the design, development and provision of two kinds of

biosensors - from the domain of experts to that of citizens. While some of the views expressed by panel members resonated with those criticisms made by professionals and the third sector (as exemplified above by the Royal College of General Practitioners and the Alzheimer's Society), members also raised wider concerns. These included trust and accountability; effect on family relationships; regulation, standards and scrutiny; expertise and training; data security; exploitation of anxious or vulnerable people; commodification of the body; support and counselling; provision of alternatives and maintenance of publicly funded services.

The introduction and evaluation of biosensors to date has been dominated by individualising manufacturer and user accounts of self-optimisation and responsabilisation. Other researchers (Novas and Rose 2000; Rabinow 1999) have shown that genetic discourses do not necessarily individualise ('geneticise'), but can lead affected individuals to identify as members of biosocial groups such as patient organisations. Whilst existing studies, including our own ethnographic accounts, highlight both the surveillance possibilities and the biosociality implied in much biosensing (pointing to their entwinement with online discussion forums, for example) (Saukko 2004; Nafus in Press), *Our Bodies, Our Data* engaged with people as citizens rather than as members of an embodied interest group. This engagement necessarily focused on more collective social and policy related concerns, facilitating the articulation of technology's multiple stories and places and the reimagining of what biosensors might do and mean.

As in existing work on health and risk, questions of relationally were important in our study; people expressed high levels of concern about interpersonal relations.

However, they also noted the importance of individuals' actions for others in their communities and indeed for society more broadly. They were concerned, in other words, not only with the ways in which health risks were (or were not) being addressed by biosensing, but with the new social risks associated with personal health monitoring. Members discussed the potential for high levels of anxiety driven by proliferation of information as an increasing risk in contemporary life; debated the importance of trust-building; and displayed skepticism about expert knowledge, recognising the need for interpretation of numbers and demonstrating awareness of recent scandals they saw as relevant such as 'care.data' and horse meat. Not only did the panel members explicitly discuss the relevance of the horse meat scandal for biosensing, their discussion raised issues that were also those highlighted by Regan et al (2015) in their analysis of the horse meat scandal, who argued that holding individuals and organisations to account would be vital for the rebuilding of trust. The citizen panel approach, in other words, elucidated the social effects of attempts to know and manage future risk through biosensing.

The panel's responses to the dilemmas in the scenarios were informed by the members' multiple embedded perspectives. As such they hold forms of credibility and legitimacy, different from both expert and stakeholders' views. Their recommendations emanate also from a wariness of exploitation and also a concern for social solidarity which is missing from the discourse of the biosensor industry, where benefits are framed in the case of direct to consumer genetic testing at an individual risk level, or in the case of home ovulation monitoring at the level of the couple-as-unit. The panel reflected concern for what kind of society is being made when genetic

testing and home reproductive biosensors are promoted and sold to members of the public online or in pharmacies outside of any clinical relationship or service.

Conclusion

Although sometimes invited to participate in research as members of specific affected groups, individuals rarely gain opportunities to debate and express concerns about socio-technical change *as citizens*. Speaking as a group formed only for the purpose of this research, the panel clearly identified a range of individual, familial and social risks involved in health biosensing developing specific recommendations for governments, technology companies and non-governmental organisations.

Significantly, they strongly pressed for governmental regulation of biosensing technologies and for informed (NGO and governmental) oversight and care around the promises made and the data produced through these devices. In the ideal society articulated by this panel, biosensing would not remain in a commercial realm populated by keen users and profit-oriented developers, but would be part of a more thoughtful and cautious intersection between state health systems, health activism and responsible innovation. Whilst this finding could be described as idealistic, we argue that it articulates a politically, socially and ethically important desire for a different materialization of health, risk and society.

Acknowledgement

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Data: making sense of biosensors': a doctoral study on direct-to-consumer genetic testing; a doctoral study on home fertility monitoring, and the citizens panel 'Our Bodies, Our Data', reported here.

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Table 1 The Panel

Name	Age	From	Occupation	Interests
Steve	37	Preston	Charity Worker	Football coach
Mary	61	Lancaster	Caterer	Writing and performing

Comment [1]: these are all pseudonyms and id is protected

Peter	61	Birmingham	Carer	Health and social care
Stan	45	Morecambe	Unemployed	Volunteering
George	46	Kendal	Disability Service worker	Disability rights; wheelchair user
Carol	18	Morecambe	Casual work	Volunteering
Winston	57	Dominica	Community education worker	Equality issues
Laura	71	Germany	Retired teacher	Languages
Debbie	42	Heysham	Carer	Volunteering with children
Maura	24	Holme	Office worker	First responder
Rhona	28	Bare	Student	Body movement and health
Callum	19	Preston	Volunteer	Astronomy/star gazing
Reg	75	Morecambe	Retired probation officer	Canoeing, sailing, rowing
Dave	67	Preston	Retired aircraft engineer	Trade union movement
Iris	44	Lancaster	Full time homemaker	Adoption, counselling

Table 2

The Scenario: the Browns from Preston

Theresa, Grandmother died at 75 with Alzheimer's Disease

John, 65, Theresa's son, becoming forgetful

Cath, 60, John's wife, concerned about her husband and son

Ben, 32, John and Cath's son, single, uses genetic testing kit from 23andMe, found to be 'increased risk of Alzheimer's disease'

Louise, 36, John and Cath's daughter, married, infertility issues, uses ovulation microscope

Yusef, 30, Louise's husband, infertility issues.

Part 1: Making sense of genetic data

Ben, aged 32, is a single man with a good job working in a small engineering company. He likes computers and his smart-phone, and enjoys downloading films and surfing the web. One of his favourite websites recently is called 23andMe. This is a company based in the US that sells genetic testing kits directly to the public. A friend at work had read about 23andMe in the magazine *Wired* and mentioned it over



lunch one day. He had been quite excited about it..... Read more at

<https://biosensordata.wordpress.com/2015/10/>

Figure 1 The Scenario

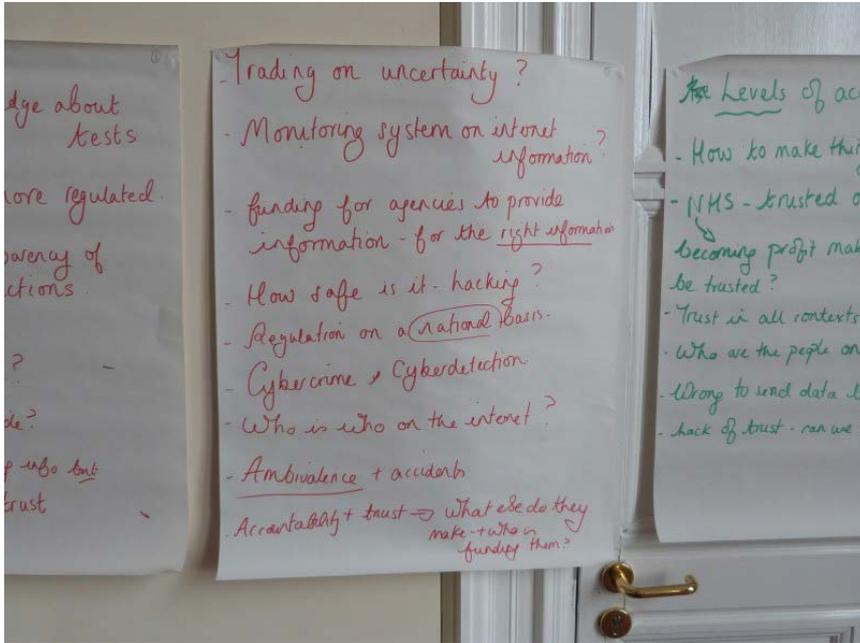


Figure 2 Panel Discussion Running Notes