



CITIZENS' PANEL

# OUR BODIES OUR DATA

SEEKING THE PUBLIC'S VIEWS ON DIRECT-TO-CONSUMER  
GENETIC TESTING AND FERTILITY MONITORING DEVICES

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# Contents

EXECUTIVE SUMMARY . . . . . 3

WHY WE CONDUCTED A CITIZENS' PANEL . . . . . 4

THE PANEL PROCESS . . . . . 5

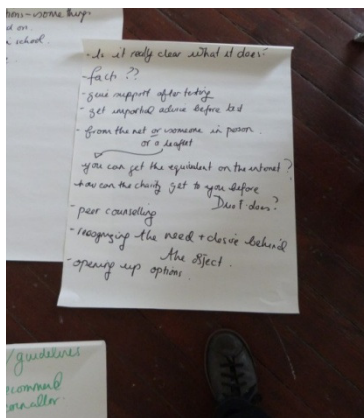
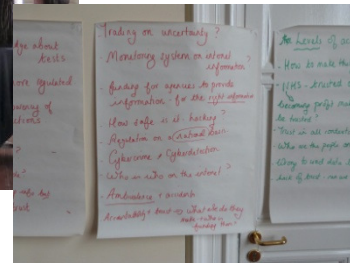
THE PANEL COMPOSITION. . . . . 7

THE SCENARIOS . . . . . 11

INITIAL RESPONSES TO THE SCENARIOS. . . . . 14

PANEL RECOMMENDATIONS. . . . . 22

FOR MORE INFORMATION . . . . . 29



## EXECUTIVE SUMMARY

Researchers from Lancaster University, UK undertook participatory inquiry into direct-to-consumer genetic testing and home reproductive technologies as part of a wider project entitled 'Living Data: making sense of health biosensors' funded by Intel Labs as part of its Biosensors in Everyday Life research programme. The citizens' panel inquiry, of 15 participants and four expert witnesses, entitled 'Our Bodies, Our Data', was held over two days (3rd and 10th May 2013) at the Storey Institute in Lancaster, UK.

After questioning expert witnesses and debating the design, development and use of new biosensors, the Panel identified a 'triangular network' that they believed should be involved in the development, design and marketing of these products: technology companies, public bodies (including regulators, Government and the NHS) and civil society organisations (including patient groups, charities, campaigning groups and other non-government organisations). Panel members formulated a set of recommendations for each of these groups of actors.

### Recommendations for biosensor technology companies

- Formulate and publish a set of over-arching values and ethical guidelines
- Take responsibility to be transparent and accountable in dealings with the public
- Guarantee a standard of quality in biosensor technologies
- Guarantee to treat personal data respectfully and safely, specifically in offering a choice of consent arrangements
- Offer an advice and counselling service – or indicate where this support could be found
- Develop new products to meet needs identified with citizens

### Recommendations for civil society organisations

- Provide factual information and guidance
- Set up an 'umbrella' organisation to signpost relevant support groups
- Provide reliable online spaces for peer group discussion
- Provide users with information about alternative options
- Provide education/ raise awareness
- Lobby government bodies for regulation/standards concerning access and sharing of biosensor data

### Recommendations for the NHS and governing and commissioning bodies

- Commissioning bodies to say how they will safeguard personal data (named or anonymised)
- Provide training for professionals and public education
- NHS bodies to act as a 'watchdog' through a central process of scrutiny

## WHY WE CONDUCTED A CITIZENS' PANEL

Public consultation is conducted in all areas of public life including the assessment of new technologies. It is generally acknowledged that citizens, when provided with the necessary information and given the space and encouragement to deliberate, can make a valuable contribution to the development of future technologies. So, it is increasingly important to engage a broad spectrum of voices in developments in science and technology – especially in the biosciences where innovations are exposing the public to challenges such as the management of uncertainty and risk, and the extensive circulation of their personal data<sup>1</sup>.

The idea of consulting citizens about the development of new technologies is not uncommon but the choice of a qualitative methodology requires some justification. Quantitative methods of consultation, such as large-scale postal surveys, have an advantage in being able to reach large numbers of people, but questionnaires are very limited in scope and detail and response rates are poor. In qualitative methods the aim is to gain an in-depth understanding of attitudes and views from a smaller number of people who then have the opportunity to discuss and debate the issues, and even to change their minds. This process addresses an 'informed and engaged citizen' who is able to reflect meaningfully, with others, on the wider social and ethical issues surrounding a new technology. The views of informed and engaged citizens should not be confused with the views of a 'consumer or user' of a specific service, which are more effectively accessed by a market research survey<sup>2</sup>.

The deliberative citizens' panel method of consultation has been adapted from the citizens' jury. Carefully conducted and transparent, the method can allow 'ordinary people', who are not deeply involved with the particular technologies being researched, to learn about them, ask critical questions and to respond thoughtfully to the social, ethical and technical questions they provoke.

In our case, addressing social and ethical issues posed by two new health technologies: direct to consumer genetic testing and home reproductive technologies, the citizens' panel inquiry 'Our Bodies, Our Data' links these at a societal level. 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. The citizen's panel approach enables the formation of public understandings and opinion to enter a domain dominated by experts.

The panel took place in Lancaster in the North-West of England<sup>3</sup>. This location shapes the outcomes of the panel in various ways. 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 take care of biomedical and health data. This expectation shaped the panel's responses to certain aspects of the scenarios.

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<sup>1</sup> In June 2000 it was announced that the Human Genome Project had completed the first draft of the human genetic code. On this occasion President Clinton stood beside the UK Prime Minister Tony Blair and said that: 'our scientific advances must always incorporate our most cherished values, and the privacy of this new information must be protected.' (White House June 25<sup>th</sup> 2000)

<sup>2</sup> For an overview of methods and case studies in public engagement see the National Coordinating Centre for Public Engagement <http://www.publicengagement.ac.uk/how>. For an overview of citizen participation in science and technology see the special issue of *Science and Public Policy* (1999) 26 (5) 289-380.

<sup>3</sup> The Panel was recruited and organised by an independent researcher experienced in participatory methods, Dr Sue Weldon.

At the same time, it is worth bearing in mind that the universal health service is now regarded by the government of England and Wales as a strategic economic resource. Decades of accumulated health and medical data for the population is being re-packaged as a globally unique biomedical innovation platform. So even if in England and Wales, the NHS continues to be the primary repository for health biosensor data, this data is beginning to circulate more widely.

## **THE PANEL PROCESS**

### **Developing the scenarios**

Scenarios are often used in futures planning or to develop policy where there are a number of possible outcomes. The idea of using scenarios in the 'Our Bodies, Our Data' inquiry was to present common features occurring between DTC genetic testing and home reproductive technologies in fictitious form allowing participants to reflect on the possible day-to-day experiences with them. By focusing the scenarios on a number of common concerns or problems, it was hoped that these situations would encourage questions and act as prompts for discussion and points of departure. The scenarios are therefore seen as helpful informative tools to think about and work out imagined problems and important concerns, rather than restricting discussion. There is an opportunity, within this format, to present features of the systems in a variety of ways through the storyline, by using examples of real products, websites, and illustrative documents.

### **Selecting expert witnesses**

Expert witnesses are often used in citizen panel projects to assist panel members in gaining an understanding of e.g. how new technical systems have come about, are supposed to work or what legal or ethical frameworks are relevant to their development. By answering questions developed by groups of panel members, and addressing their concerns about the scenarios, the experts played an important role in 'Our Bodies, Our Data'. They were selected to provide feedback from these perspectives:

- National Health Service (primary care)
- Health Research (specifically genetics)
- Patient/user support groups (specifically infertility)
- Civil society organisations (specifically genetics)

## **The expert witnesses**

**Dr Kirstin Wong** is a Lancaster based GP (General Practitioner) and also a GP Tutor/ Primary Care Medical Educator. She has additional qualifications in sexual health, obstetrics & gynaecology, contraceptive techniques and paediatrics. She has worked in New Zealand and participated in voluntary medical teaching in Xining, West China.

**Kate Dack** works at Nowgen (a centre of excellence in public engagement, education and training in biomedicine) in Manchester as its Public Programmes Manager. She engages with patients and the public about biomedical research, which involves working with schools, patient organisations, artists, museums, universities, hospitals and community groups, with the aim of generating public interest in medical research and ensuring the public have a say in the way medical research is conducted and applied. Kate has worked at Nowgen since 2003 after completing a Genetics degree, MSc in Genetic Counselling and working as a science teacher and presenter at Bristol's Science Discovery Centre.

**Clare Lewis Jones** is Chief Executive of Infertility Network UK, the national charity dedicated to the support of everyone affected by infertility. She was a member of the Human Fertilisation and Embryology Authority from 2002 to 2011. She is Chair of the National Infertility Awareness Campaign; Chair of Fertility Europe; the consumer representative on the NICE (National Institute for Health and Care Excellence) Fertility Guideline Development Group in 2004 and a member of the group undertaking a review of the Guideline (2011/12). She has two adopted children (and grandchildren).

**Dr Helen Wallace** is the Director of GeneWatch UK which specialises in the ethics, risks and social implications of human genetics. She has worked as an environmental scientist in academia and industry and as Senior Scientist at Greenpeace UK, where she was responsible for science and policy work on a range of issues. She has a degree in Physics from Bristol University and a PhD in Applied Mathematics from Exeter University.

## **Recruiting members of the Citizens' Panel**

The 15-member panel was recruited to provide a broad cross section of citizens, rather than a representative sample of society. Members were recruited, from within a local area of 40 miles, to selection criteria encompassing: gender (broadly equal numbers of men and women); age (a wide distribution of ages from 18 to 75); a range of residential areas including urban and rural; a mixture of professional, educational; diversity (in physical ability and ethnicity).

These were citizens with no professional or vested interest in the technologies to be discussed. They did, however, as detailed below, bring a very wide variety of life experience and knowledge to the consultation. Interestingly it emerged that all the Panel participants had some connection, either direct or indirect, to the issues brought up in the scenarios or debate around biosensing and data, either from personal experience or through family members or friends. It shows how issues which at first might seem distant from us are in fact embedded in everyday life.

## THE PANEL COMPOSITION

The panel members were asked to introduce themselves in their own words.

*My name's **Andy**, age 37, from Preston. I am married with two kids. I've had a number of jobs, started off as a football coach and work in IT. I had my own business, a take-away which I sold a couple of years ago. For the last year I've been working for Barnardo's and the Children's Society. My main interest is sport.*

*I am **Sue**, age 61. I am an ex teacher (catering). I've been in education and teaching for many years. I am now doing a little day job in catering and the rest of the time I'm a writer/performer (Gran the Gusset Tester, Nigella Ladylumps, the Queen Mother and a few other characters). So that's what I do. I've got one child, a grown up daughter. She's had fertility problems and I've had that one daughter and no more - the rest of them didn't take. So I've got an interest in what we've been doing. I'm not particularly IT literate but it is useful for writing because it's so good for editing. I learned to use the Internet because I had to do spread sheets for my business but I still find it a foreign language.*

*My name is **David**, age 61. I am originally from Solihull near Birmingham. I came here two years ago after 15 years as a parental carer. Now I describe myself as a '3rd age aspirationalist'. I want to do all the things I never did before - 60 is the new 25! I've quite a lot of experience of the health service. [D cared for his parents and had been a member of a Community Health Council].*

*I'm **Lee** 45, live in Morecambe, single. I have no qualifications, never had a paid job so I did volunteering at Signposts which has now closed down. So volunteering is my comfort zone. We are carrying on volunteering elsewhere. I have issues with the Health Authority ... since I suffer from mental health issues. My problem with health professionals is that I do not feel as if I am listened to and this adds to my feeling of paranoia. But in spite of my problems I am able to get on with life.*

*(Simon interpreting, because John's condition - cerebral palsy - makes it difficult for him to speak clearly) **John**, age 46 grew up in Kendal. He went to special college in Lancaster and never left Lancaster. John helped set up a disability information service, One Voice. He thinks even in the voluntary sector you can be promoted to your 'level of incompetence': 'they don't get much higher than me in this organisation'. He has read a lot about genetic issues/developments - which he describes as 'eugenics by the back door'.*

*I'm **Olivia**, age 18. I've been volunteering for a year now. Before that my first job was in a toyshop when I was 15, going on 16. I've worked for Tesco's at the weekends for two years and sometimes during the week. I've worked in play schemes, working with kids. To be quite honest, I'm 18, 19 in two and a half weeks and I have no idea what I want to do with my future, no idea whatsoever.*

*My name's **Cecil** 57, born in Dominica. I had a lot of disputes with adults over there. I was a bit of a rebel, so they sent me over here. I came up against a lot of racism and wondered why. I always wanted to know why and was always prevented from asking that question, why. I went into the Army at 16, went to Hong Kong. My life opened up then and I travelled for 9 years, between going to Northern Ireland twice, experienced quite a lot. I met a lot of people who gave me insight into who we are as human beings. For instance when I went to Fiji I was talking to this Chief and he was telling me their history - that they were taken from Africa to the Caribbean and turned into slaves and shipped to the Fijian Islands to cut cane, sugar cane, and that we were all*

*related in that sense. That was important to me because I wanted to know the truth. I work in education now. I began with community work where I set up this community centre to get everyone involved and then somebody said that education was the key. That's where I am now.*

*I am **Helene** 71 and come from Germany. I have been in this country since 1964. I'm now a naturalised British citizen. I've since lived 6 years in France, 6 years in Kenya, 4 years in Russia and I worked in those countries. I'm a teacher and education in this country is getting worse. I came as a language teacher from Germany where everybody loves languages and I soon realised it was not the case in the UK. I'm retired now, I've got two grandchildren and I'm a born again Christian and I look at things in many different ways and basically I'm a rebel.*

*My name's **Dawn**, I'm 42. I've been volunteering for 13 years helping young children, teenagers, rebels and young carers. For the last 13 years that has been quite a lot of my life. I've got four genetic children, four step children, I'm fostering two and I'm adopting a little boy soon - altogether, 11 children. I'm guardian of my friend's two children because she was a single parent and she's got severe mental health issues and she was worried that - because she tends to go into hospital about every five years because of mental health - they will put them into care. The two foster children are late 20s because they were teenagers ... My four younger teenagers ... youngest is 13 and eldest 24 this year. My stepchildren youngest is 15 and the eldest is 24. The new one is 9 months. I was in the care system when I was younger. I've got two genetic brothers and four stepbrothers. I was a definitely a rebel at school.*

***Emma:** I'm 24, I live at home with my parents. I left school when I was 16 because I didn't know what to do with my life. I didn't want to go to college or university and didn't know what to do. I work for the family business at the moment because I am still not sure what I want to do in my life. In my spare time I'm a volunteer first responder in the NHS and I would like to train to be a paramedic. That's about it really. I'm quite interested in technology.*

*I'm **Rachel** 28 and I live in Bare by the sea. My grandad was Polish which is important to me, the rest of my family is from Lancashire. I'm currently studying for an MA in somatic movement and well-being, so movement and health and feeling well. My current research is around non-sexual intimacy within movement practises so I'm quite interested in our perception of how intimate we are with our own bodies and our perception of moving bodies. I work as many things, I work as a performer and a teacher, an access worker for artists with disabilities, a florist occasionally, and a barmaid. My dad died of a heart attack and one of my granddads died also of heart related conditions, and my other grandad was registered blind and my mum has really poor sight, so there are health issues. My mum and my brother both work in the NHS, which is also really important to me. Personally I'm really interested in pregnancy and childbirth and that process for a woman.*

*I'm **Conor**, 19 from Preston. I am pretty much your typical young person, very technology orientated, I don't think I could get through the day without at least going on my phone once or twice. I like video games, I'm very sciency, I like space and stars. I'm currently doing volunteer work with the Children's Society - I sit on the Board of Trustees. Before that I worked as a mechanic since the age of 15, I left school early to go to work. I've worked in garages for three years, specialised in Range Rovers and Land Rovers, so I really enjoyed doing that. I hope to go to university to study Astronomy.*

***Frank:** I'm the grandad of the group at the age of 75. I've been working for about 35 years as a probation officer and hearing what a couple people have said about being rebels, most of my*



*work was dealing with rebels to some extent. There are many excuses and reasons why people get into trouble and offend, and then go to prison or they're dealt with in other ways. We help them to accept what they've done and try to find other ways of dealing with life rather than offending. People we do deal with need a lot of help and some understanding. A lot of them are decent people generally speaking. I'm also involved in scouting, I have been since the age of 8 myself. I've done all sorts of things in scouting, generally as a sea scout. That means being on boats, canoeing, sailing, rowing etcetera, so over the years I've dealt with hundreds of young people and that's quite interesting. I'm a grandfather, three grandchildren, enjoy life, enjoy gardening, music, now bowling. I'm also interested in Tai Chi as a way of relaxing and, at my age and stage in life, helping my joints to remain supple.*

*I'm **John** a retired aircraft fitter. I'm married, children and grandchildren. I left school at 17 and joined BA Systems as an apprentice and worked for them for 42 years. During that time I became quite heavily involved in the trade union movement. I've been a union representative for donkey's years and I ended up being a pension scheme trustee in the latter parts of my employment, and I still represent pensioners on the BA pension scheme. And really over that amount of time I developed a social conscience and developed a feeling for the greater good in the things that we do. That's probably the main reason why I'm on this panel because I think between us we can do some good and perhaps steer it the way we want to do it.*

*My name's **Sarah**. I'm 44, I've got two daughters age 12 and 6. I had breast cancer about 10 years ago. I'm adopted, never knew my biological family and my GP had suggested whilst I was having treatment for breast cancer that perhaps I try to trace my birth mother to find out if it was in the family, and then I'd just finished my chemotherapy and the NHS traced me because my biological mother had been diagnosed with a genetic condition which is potentially hereditary. So then my GP had to break this news to me and I was given the impression that I wouldn't have been given this information if I wasn't still of child bearing age, but because I could go on potentially and have more children, it was deemed necessary to tell me this information. I decided to go down the route of finding my biological family and I had three or four years of post adoption counselling and after a lot of discussion with my family and my counsellor we decided not to go for genetic testing, so obviously I'm really interested in what's being said here. I also have one or two fertility issues because after I had chemotherapy, potentially I couldn't have any more children, but I had a second daughter who's now six.*



## Facilitating a process of informed debate

The two-day process involved four stages:

1. Facilitating citizens' initial responses to the scenarios
2. Helping the panel to develop questions for the four experts
3. Summarising the experts' responses and the ensuing discussion to inform further debate
4. Imagining the development and design of new technologies within a system of regulation and civil society oversight

At the start of Day 1 the Panel members, in small groups, were given an opportunity to reflect and discuss the issues raised by each of the scenarios. The project facilitators guaranteed focus and ensured that everyone was given the opportunity to contribute. A series of questions was then formulated for the expert witnesses to address. In the period between Day 1 and 2 the Panel was invited to reflect on the issues raised by the scenarios and the responses from the expert witnesses. At the start of the second meeting the panel members discussed their overall concerns and debated the issues raised during the first panel meeting. 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.

## THE SCENARIOS

### The Browns from Preston: an 'ordinary family'

**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

### Scenario 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 smartphone, 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 which 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.

Three months ago, Ben sent off for a genetic testing kit from 23andMe's website and when it arrived, followed the instructions as pictured in the package. He registered the kit on the website and filled in the online form with his name, gender and date of birth. It also asked him if he wanted to take online surveys and be part of 23andMe's research studies. He read through the consent document and ticked the box: 'Yes, I'd like to participate in making new genetic discoveries with 23andWe Research'. He took out the small 'spittoon' that came with the box, spat into the tube and sealed it according to the instructions. His favourite part of the kit was the biohazard logo on the plastic bag that came with the tube.

Five weeks later, he got an email from 23andMe saying his results were ready and they'd tell him all about his 'personal genome', about the patterns in his DNA and what they mean for his health, the way his body works, and even his family history running back centuries. Ben is healthy, and did not expect any bad news. His main reason for having the test was curiosity. He read through his results which said all kinds of things such as he was unlikely to be a sprinter and that his earwax type was wet. His risk of deep vein thrombosis was also lower than average. But there was one thing a bit alarming in his test results. Ben carries one copy of something called the ApoE4 allele which gives him an above normal risk of getting Alzheimer's Disease.

Now, his grandmother **Theresa** had died with Alzheimer's Disease at the age of 75. Ben had never thought much about that until now. And come to think of it, his mother **Cath** had been saying recently that his father **John** was having problems remembering lots of small things day to day. He would forget names and misplace things. Ben kept thinking about his 23andMe results, and the thought that he might get Alzheimer's stuck in his mind. He started spending quite a lot of time on the 23andMe website and its community forum reading postings about other people's test results. Many of them had taken their results to their doctors, and some were taking nutritional supplements to lower their risk of getting Alzheimer's Disease.

There was a lot of discussion about family history of the condition, and quite a lot of references to and talk about medical and scientific papers that people had read. Ben started to search for scientific papers, and read several dozen he had found on the web, but found them pretty

confusing. Some reported a 'two-fold increased risk with the ApoE4 allele', but some of the papers reported on a three-fold lifetime risk. He wasn't sure how to make sense of all the information and his own test results so he made an appointment to see his GP. But the visit was not a success, the doctor didn't seem to know much about recent research on the genetics of Alzheimer's, and couldn't make sense of the 23andMe results. Although his GP has reminded him that the information only suggested a risk, Ben still felt worried.

A few days after, he brought up the test results when talking with his mother. Her immediate reaction was concern. She also thought John should take the test, but John wasn't interested. He would face it when and if the time comes. Ben felt differently. He wanted to know more about what he could do to prevent Alzheimer's, and since his GP was not much help, he went back onto 23andMe's website to look for answers.....

## Scenario 2 –Making Sense of Fertility Monitoring

Ben's sister **Louise**, aged 36, was having troubles of her own. Louise was a full-time pre-school teacher and really wanted to have children. Five years ago she married **Yusef**, aged 30, who she'd met on holiday in Turkey. The couple had been trying to start a family for about a year now and were becoming concerned that there might be some deeper, underlying medical issues that might be affecting their fertility. About 2 months ago, Louise came across an article in a magazine about conception and pregnancy and it described a few ways in which women are monitoring ovulation in order to help them conceive. Louise knew vaguely that there was a more fertile time of the month but she didn't know much about ovulation or when those fertile times might be. According to the article, if Louise knew when she ovulated, she and Yusef would have a much better chance of conceiving. One of the technologies the article recommended was the ovulation microscope. It was a small device which looked like a lipstick and had a compact microscopic lens inside. It seemed relatively straightforward to use and at only £12.99 was pretty affordable. Louise decided she would try and buy it at Boots but couldn't find it, and the shop assistants hadn't heard of it either.

Browsing online she found she could buy it directly from the manufacturer's website; they even had other products such as for testing the quality of sperm or for the menopause. When it arrived, she found the device to be much smaller and more compact than she had imagined, it looked like a lipstick, somehow she had imagined it to be more scientific or technical. She examined it, reading the instructions and studying the black and white photos of ovulation patterns. Feeling excited, she placed it on her bedside table ready for the morning. According to the instructions, she had to use the device before eating or drinking anything, not even a glass of water, and also before brushing her teeth as this would affect the saliva and make it more difficult to see the ovulation patterns on the lens. When morning came, just seconds after waking up, Louise opened the microscope and unscrewed the lens. She placed a small amount of saliva onto the clean glass. She waited nervously for several minutes and then examined the patterns which had formed on the lens, but she couldn't see anything; no shapes, no patterns, just a blank yellow space. According to the instruction sheet this meant that she was not fertile on that day. She was somewhat disappointed but thought that perhaps she was expecting too much on her first day! She made a note of the data on her smartphone - she had downloaded an App which made it easier for her to keep a record of her fertile and non-fertile days and other bits of information such as menstruation dates, aches and pains, moods and anything else that might indicate ovulation, or perhaps even one day, pregnancy. After 8 days, she gradually began to see patterns emerge; they were like crystals in the shape of ferns. According to the instructions, this meant she was ovulating. She began to feel excited about this: even though ovulation was something that happened every month, this time it was

different, she could see it happening, somehow she was more involved in the process and more in tune with her body. It also made her feel she was getting closer to what she really wanted, a child. She told Yusef about it but he was less enthusiastic, "let's just keep trying and see how it goes" he always said, which annoyed her. They both wanted children but *she* seemed to want it more, perhaps this was because he was younger; he had more time.

She continued to use the ovulation microscope over several days and months, storing the data in her smartphone. She could now easily recognize the days when she was ovulating yet there was no sign of pregnancy. Why? She had felt so optimistic when she bought the microscope; now disappointment was setting in. She looked at some of the pregnancy forums on the Internet where women discussed using the microscope and shared their experiences. She found that some were uploading pictures of their ovulating patterns and discussing what the images meant. Although some women had become pregnant whilst using the microscope, others hadn't and were looking for alternatives.

Ten months later Louise was using the microscope less and less. She was able to feel when ovulation took place, the microscope had helped her with that, but she was still not pregnant. She knew that she would have to go and see **her GP** soon to talk about other options. She was anxious about this and about what her GP might say. She had chatted to other women on online forums and many of these had chosen to go down the IVF path. What other path was there actually? The prospect of infertility treatment and all that came with it was frightening.

Some of the other women on the forum had recommended the 'Duo-Fertility Monitor' as the last step before IVF. This was another fertility monitor but one that was supposedly much more sophisticated although some women described it as a 'fancy, expensive thermometer.' It was certainly expensive at £500 but then again IVF could end up a lot more. Louise looked up this device on the Internet and read the reviews of women users. There were two parts to it; one was a coin like piece which had to be worn under the arm and the other was an egg shaped monitor which had lots of symbols on it. The coin piece took 20,000 temperature readings a day which were then sent to the egg shaped monitor. It was also possible to add in your own data – it was a bit like a diary. All of this data would then be uploaded onto your computer and sent to the Duo Fertility centre. Fertility specialists would look through the data and identify signs of ovulation or any problems with fertility. To Louise, this all sounded really positive. She had already make contact with **one of the fertility experts** and he seemed helpful, taking time to responding to her questions. If she were to buy the Duo Fertility monitor, it would also mean she would be able to hold off on any (medical) fertility treatment for the time being. After 10 months of trying and failing was £500 really all that much? She didn't think so, but was sure Yusef wouldn't see it that way. And he should probably also have his sperm tested... Louise was worried about what lay ahead, nothing was clear-cut and there was a lot at stake.

## INITIAL RESPONSES TO THE SCENARIOS

After presentation of each scenario, the Panel spent some time discussing their initial reactions and responses in facilitated discussion groups. The groups were directed, in the first instance, to talk about what they found interesting and relevant and then to discuss any concerns they had. Questions were then formulated by the Panel for the expert witnesses.

### Questions relating to the web sites/tests/testing kits

The Panel was both interested and concerned to learn that personal information, such as genetic profiles, could be purchased readily online. Their first questions for the witnesses related to the regulation, accuracy and usefulness of these devices.

#### **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?*

**Summary** of answers: in relation to regulation and data protection the panel was told that, in the UK there are data protection regulations, which means that private health data cannot be processed and retained without fully informed consent. This data protection legislation has been agreed at EU level. However, data protection is weaker in the US where, in the case of 23andMe, Ben's genetic material has been sent for testing.

Another area for regulation is about testing companies' claims that they can accurately predict future risks of developing some of the more complex conditions where the scientific evidence is still being debated.

#### **Accuracy/quality:**

*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?*

**Summary:** It would be difficult to evaluate the quality of individual genetic test results, but the Panel was told that oversight bodies, such as the FDA (Food and Drug Administration) in the US, are currently discussing whether or not to regulate the tests by checking the claims companies make. In the EU a new regulation is being debated by the European Parliament, however this would not require any body to make independent checks of the companies' claims (but only their quality assurance process<sup>4</sup>).

In many cases genetic factors are poor predictors for common complex diseases which (with notable exceptions) are mostly caused by a combination of physical and environmental factors. Some claims, made about the links between specific gene mutations and certain conditions (as in a small percentage of breast cancer cases), are quite well established by scientific evidence. Other claims, where the science is still under review, could be misleading. For instance, one area where there is very little established evidence is the link between genetic factors and schizophrenia. In this area there is disagreement between different scientific studies.

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<sup>4</sup> For this regulation, the oversight bodies for quality assurance are 'notified bodies' which are approved by governments but work under contract to the companies.

*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?*

**Summary:** These questions related to important considerations about whether the ovulation testing devices, referred to in the second scenario, were fit for purpose i.e. to indicate accurately when a woman is ovulating. There was some concern about how the claims made on websites could be checked out. In the case of the ovulation microscope, the observable patterns appear when there is a surge in hormones, so this would be approximately the time at which ovulation occurs. In answer to the second question, temperature monitors are not normally recommended anymore by NHS guidelines as being a good marker. The Panel was told that there are three different ways to evaluate these devices:

*'The first they call analytical validity and that's just about whether you get the same kind of pattern every time on the basis of the same hormone levels, so that's quite a technical thing and that does get checked for some tests. But the second question is what they call clinical validity and that would be, does it really tell you when you're ovulating, that's the sort of question you were asking, is it really able to tell you whether you're actually ovulating. Some tests may well require information from a company about that, but then the third question is the one you really want to know which is what's called clinical utility, does it actually help more women get pregnant. And that question they don't have to provide any evidence about at all. It is the kind of thing that NICE [National Institute for Clinical Excellence] would look at before they positively recommended it for use in the health service. So that's the kind of question you look at in the health service that doesn't get looked at if you just find something online.'* (HW GeneWatch UK)

#### **Usefulness:**

*How useful is the information to Ben really?*

**Summary:** the Panel asked the expert witnesses, in particular the General Practitioner, to give their opinion about how useful the genetic profile would be for Ben. If he discovered he had a risk of developing Alzheimer's Disease in the future what could he do about it? The short answer to the question was: 'not a lot!' But it was also pointed out that risk calculations can be misleading and very difficult to interpret. A consultation with Ben's doctor, or a trained genetic counsellor, is important in helping to put this kind of information into perspective and can help to guide a patient into other areas where they can make decisions about lifestyle changes:

*What Ben would need to then do is look at his lifestyle and address the things that most of us all know about anyway to reduce his risk. And knowing his genes is neither here nor there really for that. There isn't really strong genetic links for these things.* (KW GP)

The tests are particularly useful when there is a well-established link between a gene and a rare condition, and when the predictive value is high. In these cases, however, the tests are normally already available in England within the National Health Service (NHS). Tests are only provided by the NHS if the results are proven to be both measurable and useful.

Where over 200 conditions and traits can be tested for (as in the case of the tests offered by the 23andMe website) almost everyone could be seen to be at some risk of getting something in future, but some of the conditions carry only a very small level of risk. These test results are hard to make sense of and can generate a relatively high level of anxiety compared to the actual risk.

## Questions relating to the NHS and commercial provision of tests/testing kits

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

**Summary:** the GP is now seeing an increasing number of people who have researched their condition using the Internet. She told the Panel that, speaking personally, she would welcome this as an opportunity to discuss the implications of this information. This would begin with a conversation about the patient's overall concerns and expectations. Information obtained from other sources is therefore just the beginning of an investigation that might consider not only the patient's medical history but also the family history and background. Sometimes, as in the case of a genetic test for an inherited condition, a test may not offer anything more than would already be evident from a detailed family history. In other situations patients might request a drug or treatment (having read about it online) that would be either unsuitable for their condition or unlicensed by the NHS.

*How far should doctors interact with new commercial technologies?*

**Summary:** the medical profession, through primary care, is well placed to offer advice about interpreting the risks associated with information obtained online, or tests obtained from commercial websites. Not all doctors, or even doctors within one practice, would offer the same advice but national guidelines are available in many cases. The National Institute for Health and Care Excellence (NICE), for instance, offers guidance about the clinical effectiveness of drugs and medical aids (including fertility monitors). NICE does not recommend temperature monitors, such as the Duo-Fertility Monitor, as being either accurate or effective markers of ovulation patterns.

In the case of genetic testing, tests are only provided by the NHS if the results are proven to be measurable and useful. However, it seems that within the private healthcare market, companies are in a good position to make money by offering treatments and medication to healthy people to prevent a future genetic risk of developing such things as obesity, diabetes and hypertension.

The decision whether or not to take medication as a preventative measure is a complex process of weighing up risks and benefits in order to make informed choices. The GP is currently the key person to facilitate the decision making process at every stage in evaluating the risks and benefits of taking medication. This is the kind of process that is commonly used in treating the risk of cardiovascular disease or the risks associated with osteoporosis: it involves looking at the whole person, weight, blood pressure, fitness, cholesterol levels, and family history. That process is an ongoing conversation with the GP over a period of time.

On a population level there is increasing pressure, reflected in the media, for the NHS to offer screening for conditions such as ovarian and prostate cancer when, at the present time, there is no useful and measurable way to do it. It was pointed out that if the screening services became more commercialised in the future there would be even more pressure to provide population screening – accompanied in many cases by genetic tests – thus creating new markets for preventative treatments.

## Questions about commercial motivations versus health and well-being

*Who is going to benefit from the tests?*

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



Panel members were worried about who might be making money out of Ben's results – who is going to benefit? Questions were asked about the implications of possible links between the companies behind the websites selling tests (such as 23andme) and biosensor testing devices (such as the DuoFertility Monitor) with commercial companies offering health supplements and drugs. To what extent do these commercial companies benefit from the data supplied by genetic testing, and other, companies? The Panel also asked about other companies, such as those offering insurance and mortgages.

**Summary:** In the case of genetic testing, although many sites do not have direct links with these commercial interests, there are others that are already making full use of the data obtained from tests in order to offer treatments. Other sites have accessed data to carry out research in order to improve the predictive quality of their tests.

The Panel was told that there is a lot of money to be made from fertility treatments (such as IVF). Commercial companies will normally focus their efforts where there is most money to be made, rather than prioritising public benefit. It is understandable that the pharmaceutical industry is constantly developing new drugs for the market but, in the case of preventative treatments where many more people are being diagnosed as 'at risk', there is the potential massively to expand the drugs market (say from treating three people who have a condition to ten who are at risk of developing it in the future). This can have very positive benefits in reducing real and measurable risks, as in the case of statins for heart disease but on the downside there is a danger of over-treatment with drugs that might have unpleasant (even health threatening) side effects.

A question was asked about the extent to which medical research for public health should be funded by private companies, particularly the pharmaceutical industry. The experts confirmed that, in the current economic climate, Government needs to look for more private investment. This investment comes from various sources including Government funding to bodies such as the NIHR (National Institute for Health Research), patient groups and charities, but it was agreed that decisions about how medical research should be taken forward in the public domain must be decisions for society as a whole to consider.

*It's about deciding what we should invest in and how should we regulate it... That's why I think it's a question for society and not just a question for scientists to decide. (HR GeneWatch UK)*

*Can employers/insurance companies have access to genetic data?*

**Summary:** there is currently a voluntary agreement, between Government and the insurance industry that prohibits these companies from asking for test results or using them to access premiums but, since this is a purely voluntary agreement and there is no legal data protection. This situation could change in the future. In the case of employment there is a law to prevent an employer asking for genetic information unless it concerns a condition that is directly relevant to a person's employment.

## **Questions about reliable information on infertility and genetic testing.**

*Is there a need for better education?*

Education about fertility is not part of mainstream school based education in England and Wales. In the case of fertility it was pointed out that sex education in schools currently focuses

more on preventing unwanted pregnancy but there is scope for further information and discussion about the impact of infertility on families. One suggestion was that TV 'soap operas' have an important role in public education and debate. Clare Lewis Jones told the Panel about the important role of support groups such as Infertility Network UK<sup>5</sup> in providing reliable information and promoting wider education where it is needed. However, support groups like this have very little public funding.

In genetics and genetic testing, public education is struggling to keep up with new research developments. Kate Dack pointed out that the Government and the NHS have been promoting knowledge transfer through various efforts, such as Genetics Knowledge Parks like Nowgen in order to promote wider education and to get people talking about genetics.

When health information is required people often seek information online. The Panel wanted to know which websites they could trust to give impartial advice. One problem is that information is constantly being updated and the scientific community is still uncertain about the causes of many of the more complex conditions.

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

There are many websites that can offer information to patients and the general public. These include sites that operated by the National Health Service (e.g. NHS Choices), sites run by support groups that address specific issues such as infertility (Infertility Network UK) and sites maintained by civil society lobbying organisations (such as GeneWatch UK). Research results are also available through commercial websites such as 23andMe so, in that sense, the source of their claims about risk levels is transparent but this kind of information, based as it is on original scientific research, might be very difficult for a lay person to understand. Kate Dack explained to the Panel that the interpretation of genetic information containing risk evaluations is never straightforward because, aside from the difficulties associated with statistical probability, there is an added dimension of what this diagnosis means to a person:

*The thought of getting Alzheimer's might be this horrendous idea for the future, [so] that level of risk feels really high. It's not just a number it's actually what that condition might mean to you in the future. ....it's the thought of that happening in the future could be really scary so it can feel a terrifying risk even though actually the chances are quite small that it will happen. (KD Nowgen)*

#### **What are the longer-term implications of accessing genetic information?**

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

Panel members had concerns about the impact of test results on the wider family. Panel members were able to reflect on this by considering Ben's reaction to his own test results and, subsequently, the reaction of his family. Ben's default reaction, in the absence of any proper counselling, was to look for answers online through an online discussion forum but this did not alleviate his anxiety.

*So you can see how people would be sucked into this forum world and when they don't really know who they're talking to.....so it could be really anxiety provoking which could have a*

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<sup>5</sup> Infertility Network UK is a not for profit organisation; in addition to offering numerous fact sheets it also runs an advice line

*knock on effect on their mental health in a significant way. A good chunk of my work concerns mental health problems for a variety of reasons and I could quite see that this sort of problem, these genetic tests, could be feeding anxiety rather than quelling it or giving people answers that are going to help them. It's going to create more questions and more worries than it's going to solve.... I can quite see that it would create illness in a variety of ways. (KW, GP)*

It was felt that it would be useful if people were directed, by the website, to consider the implications and to reflect on them before they sent off their sample or made their purchase. Many people feel that a decision about whether to proceed with genetic testing is a very personal one, but actually the test results can have a significant impact on the wider family and this should be taken into account. Moreover, it raises further questions about how the notion of 'family' is understood. Is a family a biological or a cohabiting unit? There is often an assumption that cohabiting families are also a biological unit, but this is not always the case – as in adoptive families - and when health issues associated with inherited traits occur this can sometimes make the family feel less of a unit. It certainly indicates a need to be open and honest about adoption. However, it was pointed out that many conditions run within families where there is no genetic connection. Lung cancer and heart disease can be associated with habitual smoking and unhealthy diets shared within the family.

### ***How can people be supported to cope with the results?***

In the 'genetic scenario', in seeking support and advice, Ben looked for feedback from an online forum but was so confused by the conflicting information and advice that his anxiety was increased. He also failed to get reassurance and advice from his GP.

GP practices in the UK are often stretched to the limit and sometimes there is not enough time within an allocated consultation to consider the complex issues and concerns. Perhaps that is why people go online. The Internet communities can seem to be a private space to seek information when a person does not wish to talk openly to his/her family.

The NHS currently offers counselling for patients undertaking genetic testing through referrals and all clinics offering IVF have counsellors (otherwise they would not be licensed).

Longer term changes in the way health services operate include a shift in the idea of public health education being about healthy living through diet and exercise, to being asked to take certain drugs or medication to reduce the likelihood of developing a condition. These are choices which are often made in consultation with a doctor and after lengthy consideration and weighing up of alternative options. It was argued that patients currently have the opportunity and the option to make those informed choices. However, it was pointed out that the situation would change in the future towards a more commercially led approach and towards targeting a new category of patient as consumer, (perhaps by situating them as 'at risk') and with more emphasis on the sale of drugs and profit margins. The Panel was told that, currently companies are unable to market prescription drugs direct to the consumer in the UK- but that could change in the future. There is a growing range of other products such as food supplements and health aids that are available online but there is no obligation for GPs (or the NHS) to give product information or to suggest where to get support.

## Imagining the development and design of new biosensor technologies

### General concerns

Day 2 was devoted to discussion and to formulating recommendations concerning the development of new biosensor technologies. After initial small group work the Panel members gathered in a plenary session which revealed a high level of concern about the commercial marketing of biosensors such as genetic tests and fertility devices. Some members asked whether these technologies were being designed specifically to deliver returns for shareholders or to meet the needs of the consumer. They felt that a business model primarily motivated by profit, rather than to deliver public benefit, could lead to manipulation of market forces to create more demand for (sometimes unnecessary or inappropriate) products fuelled by a heightened awareness of the future risk of genetic conditions or infertility.

*They 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 are being provided in the UK and how they would feel somewhat adrift, even powerless without the support of a one-to-one relationship – as with a GP or a patient support organisation – in which they could put their trust.

*You trust them more if they are not trying to sell you something.*

Trust is paramount, but trust would not be forthcoming without accountability and, in the absence of specific regulation, the Panel discussed the need to have some way of assessing the standard of products and services. One (often repeated) suggestion was for a 'kite mark' or symbol to denote 'safe product' – endorsed by a trusted institution such as the National Health Service. Another significant issue often raised was that of personal data protection and fears were expressed that, once the data is supplied to a company (online), it would remain in the system (available to be used in unknown ways) forever.

These concerns can be grouped into four areas: trust, accountability, standards (or regulation) and data protection.

### Trust

It was agreed that a person's trust in an organisation, company or product is the key to all that follows. Trust is built out of knowledge (of the organisation, company or product) and continuity, and it is often built on the continuity of relationships. Members spoke about how trusting relationships could be established with doctors, health professionals or even with organisations through experience and over time. One member expressed her concern that in digital communications we are losing that continuity of relationships. Nonetheless, many panel members (particularly the older members) felt that the NHS has always represented a standard of reliable healthcare as a 'trusted organisation'.

*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.*

At the same time it was recognised that the NHS is currently undergoing significant structural change in the direction of privatisation and that this may have an effect on perceptions of trust in the future.

*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**

It was pointed out that accountability is an essential part of a trusting relationship, and the key is being able to hold someone to account through a chain of responsibility. For instance, if you are face-to-face with an individual you can hold them accountable.

*With a doctor you can always go back if he misdiagnoses you. What happens if the test results are wrong?*

How do we know where tests are being carried out in the case of online purchases?

*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?<sup>6</sup>*

How many companies are in the chain?<sup>7</sup>

### **Standards**

In the absence of regulation to protect the consumer i.e. where products and services are being marketed in other countries, where regulation is weaker or non-existent, how can standards of quality and accuracy be demanded? Suggestions included the use of symbols, or 'kite marks', to denote certain standards of quality and safety of the product, or that the product be vouched for by a trusted individual (with a suitable qualification) or organisation (such as the NHS).

*We need to have standards. I want to see some qualifications.*

### **Data protection**

Panel members were very concerned about the misuse of their personal data by companies that use the information for further research without asking for consent or, even worse, pass it on to other companies selling treatments and drugs. A concern about data '*getting into the wrong hands*' was raised also in relation to how this might affect insurance or job applications. One participant expressed this concern very strongly:

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

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<sup>6</sup> In answer to this concern about outsourcing the Panel were told that 23andMe does involve another large US company (a testing lab) in testing and analysing samples.

<sup>7</sup> At this point there was a reference to a recent horsemeat scandal in the UK. Supermarkets were discovered to have meat products that contained horsemeat (and other meats) not shown on the label. There were so many meat suppliers in the chain that it was difficult to locate the source of contamination.

## PANEL RECOMMENDATIONS

After questioning the expert witnesses and then debating in groups the issues raised, the Panel collectively identified a network of actors that should be involved in the development, design and marketing of these products. These actors were categorised broadly as:

1. technology companies
2. public bodies (including regulators, Government and the NHS) and
3. civil society organisations (including patient groups, charities, campaigning groups and other non-government organisations).

The Panel then formulated a set of recommendations for each of these groups of actors.



### Recommendations for biosensor technology companies

The recommendations for the biosensor technology industry emerged after much discussion. Taken as a whole they are about how companies should operate as trustworthy organisations to develop and market new products that meet specifically identified needs.

In order to convince the Panel that they are meeting public/social needs, it is recommended that the companies should:

- **Formulate and publish a set of over-arching values and ethical guidelines.**

This recommendation arose out of the concern that lack of regulation might lead to a fall in standards, particularly in respect of business practice and business ethics. Panel members wanted to see written commitments to standards of good practice. For instance, these guidelines should include a commitment to develop new biosensor technologies that people need (for public benefit).

*If they print them as a set of rules...this does give you some basis for trusting them, and holding them accountable.*

- **Take responsibility to be transparent and accountable in dealings with the public**

The issue about accountability was of great concern where products are marketed online because it is often difficult to trace the product back to source – there may be more than one company or organisation in the chain – so it might be difficult to find out who would, ultimately, take responsibility for the quality and/or accuracy of the product.

*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....*

- **Guarantee a standard of quality**

The Panel recommended that companies should offer some guarantee of quality and accuracy in their products. In the absence of regulation it was seen as vital that the product is proven to be safe and would not harm the customer.

*If they are selling us something....we want a proven tested product...*

- **Guarantee to treat personal data respectfully and safely, specifically in offering a choice of consent arrangements**

The Panel felt that personal data is a precious part of a person's identity and their wishes should be identified through the consent arrangements. Information about what would happen to personal data, and possible future use, would facilitate consent arrangements and allow for some choice in whether the customer consents to any future use of this data and for what purpose.

*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.*

There were also thoughts and discussion 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.*

- **Offer an advice and counselling service – or indicate where this support could be found**

The Panel identified a need for counselling and advice when considering the wider implications of biosensor test results. For instance, test results may suggest a need for further treatment and in many cases there are implications for other members of the family. It may be inappropriate for a company to offer a counselling service but there should be up front advice to consult a doctor or a genetic counsellor before accessing these services.

*You should consult your doctor or, in the case of genetic tests, see a genetic counsellor.*

- **Develop new products to meet identified needs**

The Panel suggested a number of areas where biosensors might be developed in the future. It would be important to identify specific needs and to recognise that products should be tailored to those needs.

Suggestions for future biosensors included:

- a) Sports monitors
- b) Age-related monitors
- c) Monitors to provide information about reproductive health
- d) Neural feedback devices

There was insufficient time to build on these ideas, however, the most important message for companies was to focus on identified needs.

*'Something that people might need. That's a new concept!'*

### **Recommendations for civil society organisations (CSOs: charities, patient support groups, disability groups)**

In respect of the role of civil society in the development and use of new biosensor technologies, the panel were very clear about the need for a non-government support network to help users of biosensors understand and make sense of online purchases.

*Provide support, 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 value of this kind of support would be in providing unbiased help, information and informal counselling – ideally from people who have had similar experiences (peer support). Recommendations focused on how this support would best function and how civil society



groups would communicate with other actors in a network comprising new technology companies, regulators and health professionals.

- **Provide factual information and guidance**

The first and most useful role for CSOs would be to provide clear factual information about what tests, or biosensor services, can offer – and what they cannot offer. So an important role would be to question 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?*

- **Set up an ‘umbrella’ organisation to signpost relevant support groups**

When the Panel discussed the need to have some sort of information backup for people who were using or planning to use the tests, testing devices or biosensors, it was pointed out that:

*‘They are not going to know where to get this help.’*

Therefore, they might need the guidance of an initial signposting service to direct users to specific support groups. One panel member explained how the service she volunteers for helped to direct people to the relevant support organisation, i.e. the key role of information and communication.

### **Provide reliable spaces for peer group discussion**

The Panel also talked about how CSOs could provide a necessary space, outside the professional services, for peer support offered by people who had similar experiences to share.

*You want to speak to someone who has been in a similar situation.*

There was also some discussion about how this peer group could be authenticated. In Ben’s scenario he was confused by the conflicting advice he accessed from an online support group and, although it is normal practice now to go online for information and, increasingly, to access online discussion groups:

*I think now...this generation has a culture where we go online for information.*

There is no real sense of who the online forum discussants are and what their motivations are. For instance, discussion groups could be ‘infiltrated’ by companies seeking to promote their products. The two essential elements of an authentic discussion group would be trust and reassurance.

- **Provide users with alternative options**

It was felt that in the process of undergoing tests or using biosensor monitoring devices, there is a danger of being directed quite strongly, or being 'channelled' in one direction towards further treatment – for instance with a course of drugs or IVF. The Panel recommended a role for e.g. patient support groups in providing alternative options so that users would have an opportunity to make choices.

*[Its 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 child .....so 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 ...*

- **Provide education/ raise awareness about risks**

One role for CSOs is in offering education and knowledge about Internet safety as an antidote to heavy advertising and unrealistic claims. Advertising can be very powerful in offering hope, but it is important to provide a warning and some guidance – particularly for children.

*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.*

- **Lobby government bodies for regulation/standards**

So far there has been no demand for regulation in respect of minimum standards of accuracy, but the Panel suggested that there could be a role for CSOs in lobbying for better regulation of advertising claims made by companies selling biosensors.

*This comes back to the [idea about statutory] warning on the packet. You could make it mandatory to give a warning.*

## **Recommendations for the NHS, governing and commissioning bodies**

The Panel was informed that the focus for health provision, in both primary and secondary care, is moving from local NHS Health Trusts to regional Clinical Commissioning Groups (CCGs), supported by Local Government health and well-being agencies in England. The CCGs have representation, on their boards, from local GPs, nurses and health professionals. Discussion focused 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 discussion and debate about how the NHS could take a pro-active role in setting up a self-funded unit to supply data services (in opposition to US companies

such as 23andMe). It was 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. One argument was that this NHS unit could then raise much needed revenue by selling services to organisations such as pension groups. However, members of the panel reflected on the dangers of selling information, either to individuals, public bodies (for research) or to organisations such as pension schemes. What safeguards would be needed?

*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.*

In the light of this discussion, the Panel's first recommendation arose out of concerns about the dangers of using data as a commercial resource: i.e. how can personal data be protected from commercial exploitation?

- **Commissioning bodies to say how they will safeguard personal data (whether named or anonymised)**

This recommendation, directed to the new commissioning groups, would require them to safeguard personal information and to explain how they will achieve an adequate level of protection through consent arrangements. It was suggested that the choice to 'opt in' rather than 'opt out' of data storage is a safer option.

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

There was grave concern about the sharing of data records, when they have been collected from different sources such as screening, health records and numerous other sources such as bone marrow donors. Can anonymised data be identified through linking these records? Panel members wanted reassurance on these matters and an explanation from the CCGs about how security would be maintained.

### **Provide training for health professionals and public education**

A key set of recommendations for the CCGs related to the need for a greater awareness of the need to 'skill up' in order to meet future demands for professional and public information in this new area of technology development. Professional advice and counselling would be a valuable resource in understanding what test results mean for individuals and, for the wider public, in addressing their concerns about the social and ethical issues. Do health professionals have the skills to address these issues?

One recommendation was for the provision of training programmes for doctors and nurses in order to offer information, support and counselling (where necessary).

Another recommendation was 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 can offer.

- **NHS bodies to act as a 'watchdog' through a central process of scrutiny**

The Panel wanted to ask the CCGs, as the cornerstone of NHS services, to act as a watchdog in determining which companies are offering trustworthy reliable information and to direct people to reliable testing companies. One way to accomplish this would be to offer a vetting/monitoring service to determine which sites to trust how to make sense of claims. Another way of raising awareness could be to establish a 'kite mark' denoting standards of quality and effectiveness.

One panel member spoke about how she had used a temperature monitor for fertility awareness but was unaware that knowledge in this area had moved on:

*I used one of these. I had no idea that it was considered to be out of date...If I wanted to find this out I would have no idea [where to look]...*

### **Concluding Coda**

The Citizens' Panel entitled *Our Bodies Our Data* enabled a participatory inquiry into two new health technologies; direct-to-consumer genetic testing and home reproductive technologies. It involved members of the general public and expert witnesses from the field of science and medicine, and was organised by researchers from Lancaster University. The aim of the research has been to address social and ethical issues posed by these new health technologies and create a legitimate space in 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.

The method of the Citizens' Panel allows 'ordinary people', not involved in particular technologies being researched, to learn about them, ask critical questions and respond to the social, ethical and technical questions they raise. In *Our Bodies Our Data* the questioning of expert witnesses and the debating between panel members resulted in the identification of a 'triangular network' involving technology companies, public bodies and civil society organizations. This triangular network should be considered in conjunction with a set of key recommendations relating to trust, accountability, transparency, support and respect in the development, design and marketing of new technologies.

## FOR MORE INFORMATION

The work in this report will be developed in future publications. For more information on publications as they come out, please email Dr Celia Roberts, [celia.roberts@lancaster.ac.uk](mailto:celia.roberts@lancaster.ac.uk).

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