Appendix 3: Method of working and summary of evidence

The Council established the Working Party on Medical profiling and online medicine: the ethics of 'personalised healthcare' in 2008. The Working Party held nine meetings over a period of 18 months.

As part of its work, the Working Party held additional evidence-gathering sessions, each of which took the form of discussions with experts and stakeholders. The Working Party also held a consultation during the spring of 2008, to which 59 individuals and organisations responded. Brief descriptions of these meetings, a list of consultation respondents and a summary of the findings can be found below.

The Working Party is extremely grateful to all those who took the time and contributed to its work, provided valuable insights and helped to clarify the complexities of scientific, regulatory, social and ethical issues raised by medical profiling and online medicine.

Evidence-gathering sessions

26 November 2008:

Meeting with providers and expert scientists:

Professor Martin Bobrow
Professor of Medical Genetics (Emeritus), Cambridge University

John Giles FRCP FRCR
Consultant Radiologist and Clinical Director, LifescanUK

Dr Agnar Helgason
Senior Research Scientist in Biological Anthropology, deCODE Genetics Inc., Associate Research Professor at the Department of Anthropology, University of Iceland

Professor Eike Nagel
Chair in Clinical Cardiovascular Imaging, King's College London

Dr Ajoy Sarkar
Consultant in Clinical Genetics, Clinical Genetics Service, City Hospital, Nottingham, and member of Council, British Society of Human Genetics

Dr Rajendra Sharma MB, BCh, LRCP & S(I), MFHom
Medical Director, The Diagnostic Clinic

28–29 May 2009:

Joint meeting held at Harvard University, in partnership with the Harvard School of Public Health:

Professor George Annas, JD, MPH
Edward R. Utley Professor, Health Law, Bioethics & Human Rights, Boston University School of Public Health

Amy DuRoss
Vice President of Policy and Business Affairs, Navigenics

Dr Joan Dzenowagis
Project Manager, World Health Organization

Dr Michael Grodin
Professor of Health Law, Bioethics & Human Rights, Boston University School of Public Health

Dr John Halamka
Chief Information Officer, Harvard Medical School, Chairman of the New England Health Electronic Data Interchange Network (NEHEN), Associate Professor of Emergency Medicine at Harvard Medical School

Dr Kathy Hudson
Director, Genetics and Public Policy Center, Johns Hopkins University

Professor Eric T. Juengst
Professor of Bioethics, Case Western University

Dr Michael Manolakis
Assistant Dean for Planning and Associate Professor, Wingate University School of Pharmacy, Member, American Pharmacists Association

Douglas McClure
Corporate Manager for Operations and Technology, Center for Connected Health

Professor Max Rosen
Medical Director, BeWell Body Scan, Associate Chief for Community Network Services: Beth Israel *Deaconess Medical Center, Associate Professor of Radiology: Harvard Medical School*

Professor Daniel Wikler
Mary B. Saltonstall Professor of Population Ethics and Professor of Ethics and Population Health, Department of Global Health and Population, Harvard School of Public Health

Dr Matthew K. Wynia
Director, Institute for Ethics at the American Medical Association

01 July 2009:

Meeting with representatives of the Royal College of Radiologists:

Andrew Hall
Chief Executive, Royal College of Radiologists

Dr Giles Maskell
Registrar, Royal College of Radiologists

Dr Tony Nicholson
Vice-President and Dean of the Faculty of Clinical Radiology, Royal College of Radiologists

27 July 2009:

Meeting with representatives of NHS Connecting for Health:

Dr Gillian Braunold
Summary Care Record Programme and Healthspace

Dr Simon Eccles
Medical Director

Dr Robert Pitcher
National Clinical Lead for Hospital Doctors

David Rabjohns
National Patient Lead

23 September 2009:

Meeting with regulators and expert commentators, held as part of the second meeting of the Working Party:

Helena Bowden
Senior European Policy Manager, NHS European Office, NHS Confederation

Harry Cayton
Chief Executive, Council for Healthcare Regulatory Excellence and Chair of the National Information Governance Board for Health and Social Care

Dr Neil Ebenezer
Principal Medical Device Specialist on New and Emerging Technologies, Devices Technology and Safety Division, Medicines and Healthcare products Regulatory Agency

Stephen Goundrey-Smith
Healthcare IT Pharmacist, Professional Services Directorate, Royal Pharmaceutical Society of Great Britain

Tore Johansen
Regulatory Affairs Manager, Medicines and Healthcare products Regulatory Agency

Beryl Keeley
Advertising Standards Unit Manager, Information for Public Health Group, Medicines and Healthcare products Regulatory Agency

Dr John Powell
Associate Clinical Professor in Epidemiology and Public Health, University of Warwick; Honorary NHS Consultant

David Smith
Deputy Commissioner - Data Protection, Office of the Information Commissioner

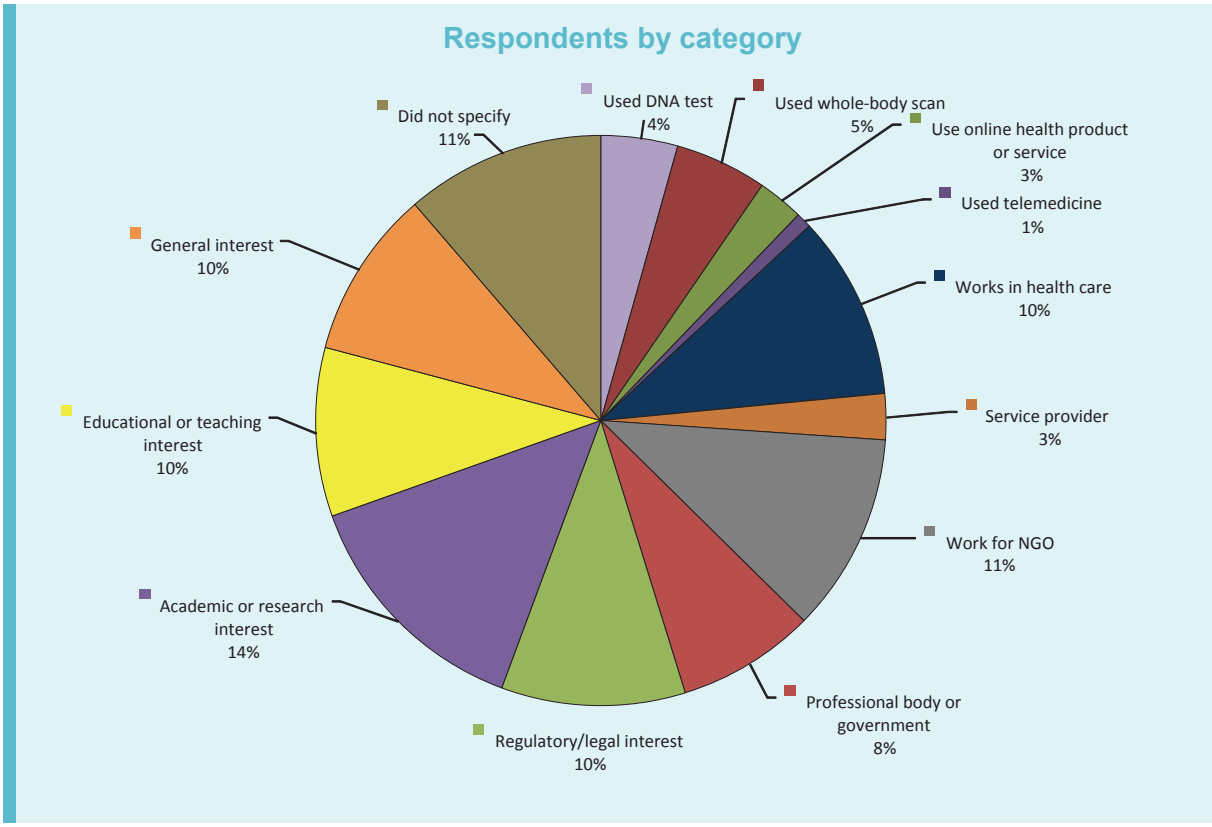
Professor Joanna Wardlaw
Professor of Applied Neuroimaging and Director of the Brain Imaging Research Centre, University of Edinburgh

Robert Wells
Head, Biotechnology Unit, Science and Technology Policy Division, Directorate for Science, Technology and Industry, Organisation for Economic Co-operation and Development

Dr Caroline Wright
Head of Science, PHG Foundation, Cambridge

The consultation

The consultation was held in order to gain the views of interested professionals, organisations and members of the public. The consultation was based on a paper containing background information and 15 questions relating to the topic. Respondents were invited to answer as many of these questions as they wished. Fifty-nine responses were received, 32 of which were from organisations and 27 of which were from individuals. The Working Party would like to thank all those who contributed to the consultation. The chart below reflects the distribution of respondents by their reason for responding to the consultation, and is intended to provide the context within which the following summary should be interpreted. For example, it was difficult to draw out first-hand experiences with telemedicine, given the limited number of respondents who reported using such a service, and the fact that no respondents stated that such use was the motivating factor in responding to the consultation.



The responses were distributed to the Working Party in order to inform their deliberations. A selection of the main points from these responses is drawn out below. This summary does not attempt to reproduce exhaustively all the comments made by respondents, nor is it a systematic selection. Instead, the summary aims to identify significant or unique points made. Furthermore, the opinions and recommendations expressed in this summary are intended to reflect those of the consultation respondents, and do not necessarily reflect the views of the Council.

The consultation was open to anyone to respond, rather than being conducted as a survey or a poll. Consequently, the responses cannot be considered to be an accurate representation of the views of the population as a whole, and should not therefore be interpreted as such. The complete text of all responses for which the Council were given permission to publish may be found on the Council website.[579]

[579] See: http://www.nuffieldbioethics.org/.

Summary of evidence received

General comments on consumerism

- Direct access to diagnosis and treatment, without the frequent delays experienced within the NHS, is an important corollary to one's autonomy in medical care.
- Medical ethics as a mainstream orthodoxy contains a bias towards institutional practices in which individuals are not at liberty to enter into contracts that provide medicine on demand.
- The positive consequences of purchasing health as a commodity outweigh the negative outcomes provided that the purchaser of healthcare as a consumer good can afford to and is commercially educated – the main issue is to what extent the purchaser can objectively assess the quality of the purchase and the risk involved.
- Those who want to be pro-active about their health are mocked and stigmatised with labels such as 'the worried well'.
- A well informed patient with a proactive interest in the management or treatment of their illness is beneficial to all involved in the treatment process.
- If patients in the UK are increasingly expected to become decision makers responsible for their health within the prevention context, then the scope and limits of self-diagnosis and treatment are vital parameters of this process.
- Competition online means that inducements familiar in all other spheres of buying and selling will be common and effective when the customer, by shopping about, is lured towards the bargain end of the market.
- 'Consumers' use resources and 'customers' exercise the right to purchase; the dynamics are different.
- 'Body shopping' is a phrase that sums up succinctly the commercialisation of biotechnology.

Summary of responses to questions

Section 1: Introduction

> ***Question 1: Healthcare as a consumer good***
>
> *If an increasing number of medical products and services are becoming available as consumer goods – that is to say, as commodities which customers may choose to purchase provided they can meet the costs (see Annexes 4 and 5) – is this development, on balance, desirable?*
>
> ***If yes...***
>
> *In what ways do you think the positive consequences outweigh the negative ones?*
>
> ***If no...***
>
> *In what ways do you think the negative consequences outweigh the positive ones?*

Respondents were split almost equally as to whether or not it was desirable for healthcare products and services to be made available as consumer goods, although some claimed that such a development was inevitable, regardless of its desirability. It was also argued that healthcare products and services have in fact always been consumer goods.

Development is undesirable

- It is wrong that rich people can afford better treatments than poor people.
- Patients feel that the increase in availability of such private services could potentially be unfair on those who cannot afford to pay.
- The recent move towards a 'choice' agenda risks characterising patients as consumers, rather than citizens, and is undesirable.
- The concept of health goes beyond the physical. As such, 'health' cannot be purchased.
- Consumerism has not worked well in developing countries; any further move towards consumerism may create a further divide between developed and developing countries.
- Consumerist attitudes tend to lead to the neglect of public health.
- Consumerism will mean patients will become less dependent on their doctors but more dependent on information provided by commercial companies.

Development is desirable

- Consumerism in healthcare (specifically the use of DNA profiling) empowers people and promotes responsibility for one's own health.
- Self-testing fits into the Government health policy agenda of actively encouraging people to take more responsibility and every person has the right to carry out a self-test if they want to find out more about their health.
- Pre-dispositional and pre-symptomatic testing can promote a tailored approach to patient care and may facilitate early treatment, if conducted at the individual level and when treatment is available.
- Allowing patients to access treatments and tests based on individual need helps to restore the balance between public and individual health.
- The transition away from elite groups of 'experts', in whom knowledge and power is concentrated, towards a more egalitarian model, in which knowledge is distributed more widely through society, is both an inevitable and welcome consequence.

Healthcare is/has always been a consumer good

- Healthcare is and always has been a consumer good.
- To some extent, the ability to pay already determines access to health benefits and individuals are demanding more control over their own health and greater demand from consumers for health products to be treated as consumer goods.
- Health is a consumer good, but the qualification is that its potential should be equitably distributed.

Regulation

- Claims made about the significance of a test should be supported by evidence and a broadly liberal approach favouring regulation primarily through non-legislative mechanisms.

- The increasing consumerisation of healthcare delivery demands that a regulatory system for DNA profiling be put in place, as there currently no regulation of direct-to-consumer DNA testing and there is no body responsible for the regulation of genetic tests outside the NHS.

- France, Austria, Switzerland and Germany ban direct-to-consumer genetic testing altogether, as do roughly half of American states.

Other

- The ideal consumer is an imaginary construct based on rational choice theory and assumes that people are fully informed and fully able to understand the information, rational and not subject to bias, self interested (rather than altruistic), in short, fully autonomous. Which they are not.

- People who have taken a direct-to-consumer test may be driven back to the NHS to find out more about their results, potentially putting primary healthcare services under pressure.

- Commercial companies are seeking to undermine the role of GPs as gatekeepers.

> ***Question 2: Validity of information***
>
> *While much health related information is freely available to individuals, this varies greatly in quality and accuracy. Many of the lifestyle and health books and magazines that are currently available may contain medical information that is misleading or even incorrect from a scientific point of view. Do you think that information provided by DNA profiling and body imaging services raises different questions and should be subject to different regulations?*
>
> ***If yes…***
>
> *What are the grounds for restricting access to DNA profiling and body imaging services that may also have limitations in terms of scientific validity and clinical value?*
>
> ***If no...***
>
> *Why do you feel that DNA profiling and body imaging should be freely available to those who wish to receive it? Would you favour regulation of the information appearing in lifestyle and health books and magazines? And if so, what sorts of information in particular require regulation?*

Many respondents felt that information derived from predictive testing services raised different issues to those resulting from other forms of health information. However, some respondents felt that the method by which information is compiled was irrelevant; i.e. where information is of a dubious nature, the implications for decision making would be the same regardless of how it might be acquired. Other respondents suggested that the implications of the information derived from predictive testing varied between whole-body imaging and genomic testing. Suggestions were made regarding the potential harm offered by the tests, the capabilities and knowledge of those giving and receiving them and how best to control and regulate such tests, should it be necessary.

Information from predictive testing in not comparable with that derived from health information in magazines etc.

- Predictive testing information is different because it is specific to one person, not just general consumers; the information contained in health magazines can be protected by free speech. The process of acquiring the information, in the case of predictive testing, requires an intervention that may be directly or indirectly harmful.

- These services require a different, and more stringent, regulatory framework.

Information from predictive testing is comparable to other forms of health information

- Keeping patients from DNA profiling information is little different from not telling them their blood pressure, and personal genetic data should not be treated differently for regulatory purposes than other sources of health information.

- Predictive testing services do not raise different questions or issues than other forms of health information.

DNA profiling and body imaging raise different issues

- DNA profiling and body imaging should be distinguished, as their potential to cause direct harm are different. DNA profiling seeks to assess future risk, and is expressed as a probability, while imaging services seek to provide an early diagnosis of a current disease while the individual is still asymptomatic. DNA profiling is a future prediction that may allow an individual to modify their lifestyle to prevent the occurrence of disease; body imaging purports to be a screening test for early detection of disease that may allow the individual to receive treatment.

Availability and regulation of tests

- The debate is not about whether we have unfettered access to our genomes – only a handful of scientists with the correct training and access to the necessary equipment might be said to have such a privilege – it is about who are the gatekeepers and what sort of controls are in place.

- The mere presence of risk is not sufficient to justify regulation.

- Restrictions should be put in place to protect the vulnerable and justification for regulation springs from a requirement for the safety, accuracy and reliability of the test result. The promotional claims of the companies is an issue that should be addressed with regulation, as is the necessity of an adequate complaints procedure.

- There are no reasonable grounds for restricting access to information about the state of one's body or health: DNA profiling should be freely available (with a disclaimer) and research does not support restricting access.

- It is a mistake to think that these tests should be regulated chiefly under consumer legislation. The In Vitro Diagnostic Medical Devices Directive (IVD Directive) is the key regulatory instrument for IVD tests.

- Possible regulatory approaches include: controls that operate before sale or supply, as they are more effective at modifying behaviour; pre-market review of tests to ensure truth-in-labelling and truth in promotion (under the IVD Directive); encouraging companies to sign up to the Information Standard; the heavy involvement of the Care Quality Commission; and communication of the risks and benefits of the test directly to the potential consumer.

- British libel laws complicate regulatory approaches as they place the onus on critics to establish that tests are misleading or harmful, rather than on whoever is marketing them to demonstrate that their claims are valid or the tests are useful.

Harms

- Both methods of predictive testing under discussion have the potential to cause harm. Aside from the radiation exposure involved in CT scanning, the psychological harm caused by the test result is a complex phenomenon that depends heavily upon individual temperament, and this is likely to apply equally to both services.

- Misinformation can be harmful.

Requirement for medical professionals

- Predictive testing services require a healthcare professional's involvement, although in some circumstances this is dependent on the degree of risk posed by the test or resultant information.
- The interpretation of results requires a medical professional to delivery utility.

Abilities and attitudes of consumers

- The abilities of those taking the tests are an important issue.
- Not all consumers are capable of adequately evaluating what the test offers, or the information provided (especially in relation to absolute and relative risk). Even with counselling it is impossible to absorb all the information in one go, especially as those who have paid for direct-to-consumer genetic tests are more likely to think they should believe the results.
- These vulnerabilities are exploited by ‘quacks’ and it is difficult to regulate this sort of information. Consequently, there is a need to ensure that the public is adequately informed, educated and engaged with the issues.

Quality of the tests

- Requiring the involvement of a health professional may be of no value if the test itself is worthless.
- All screening tests should be offered with a clear explanation of their risks and benefits according to the Wilson-Jungner criteria.

Validity of information

- Genes are, in general, poor predictors of disease.
- Where a link is clear, for example between the BRCA1/2 genes and breast/ovarian cancer, patent restrictions deter all but one of the direct-to-consumer companies from offering tests. The exception is 23andMe, which has decided to flout the Myriad Genetics patent.
- Health-related claims should be verifiable and any organisation providing services to the public has both a legal and an ethical responsibility to provide accurate information.
- Some procedures that do not have a sound evidence base are nevertheless perceived to be beneficial by those who use them.

Counselling and follow up procedures

- Those providing access to technologies of unproven value should bear the cost of pre- and post-test counselling, and any dilemmas arising from equivocal tests results or false negatives need to be resolved by the provider of the service.

Other

- The ethics of technology must be approached in a technologically neutral manner.
- It is unacceptable for it to be possible to obtain DNA profiling of a third party without that person's consent.
- One of our greatest health problems is that people find it very difficult to live with uncertainty.

- Some companies market DNA tests accompanied by offers of products such as nutritional substances or smoking cessation kits. Recent research conducted in the USA of smokers who had accessed an online test for the presence or absence of the GSTM1 gene (that has been associated with a slightly increased risk of lung cancer) indicated that all participants decided to use at least one of several smoking cessation aids.

- In general the SNPs (single nucleotide polymorphisms) are already on the chips used for analysis. When coupled with the new medium of internet delivery as a means to engage directly with the public there is a 'perfect storm' for consumer diagnostics.

- It is not necessarily the case that requiring a medical consultation for a genetic test infringes an individual's 'right' to have access to their genetic data. It does not: it simply defines who the gatekeepers are. Direct-to-consumer genetics companies are gatekeepers too.

> ***Question 3: Prevention***
>
> *Many governments argue that every individual has some responsibility to look after their own health, in their own interest and that of society at large, for instance in matters of lifestyle and diet. Do you think such individual responsibility should extend to the use of DNA profiling and body imaging services such that people in some circumstances should be expected, encouraged or obliged to have such tests?*
>
> ***If yes...***
>
> *What are those circumstances, and what should be the nature of such encouragement (for example: information, persuasion, financial incentives)?*
>
> ***If no...***
>
> *Do you think there are other, more appropriate ways in which people can take personal responsibility for their health, and if so, which? In cases where early diagnosis of disease and subsequent preventive action can reduce later costs of treatment, but people choose not to find out whether they need to take preventive action, is it acceptable that the higher costs for later treatment are paid for by taxpayers or those contributing to health insurance schemes?*

The majority of respondents rejected the concept of expecting, encouraging or obliging individuals to have DNA profiling or body imaging tests. The reasoning behind this varied and included analogous references to areas where there is no discrimination in the provision of treatment (weight and alcohol consumption etc.), and the established practice of never attempting to force a treatment on a competent adult, even where refusal may result in their death.

Provision of care and expectation, encouragement or obligation

- No one has the right to exclude others from healthcare unless there is a direct risk to those providing that care.

- We do not currently discriminate on treatment availability on the basis of diet, weight, alcohol, smoking, substance abuse or teenage pregnancy, all of which may have direct or indirect health consequences. To discriminate on the basis of an aetiological component, our genetic profile, or to force or coerce interventions upon that individual on that basis is unreasonable.

- Once you start down the road of not paying for the obese, for smokers, for people who do dangerous sports, where do you stop?

- People who do not have tests that would enable them to prevent disease should not be considered responsible for their condition and therefore less deserving of state-funded healthcare.

- It would be unacceptable in our society to compel people to have tests against their will.

- Both legally and ethically, competent adults are entitled to refuse any test or treatment even if that results in their death; we do not force individuals to undergo any health screening. There

are no grounds for treating DNA profiling or body imaging differently from any other form of testing or treatment in this respect.

- Little would be gained from encouraging anyone to take a test that has no demonstrable predictive value or clinical utility.

Effective health interventions

- Some health risks (notably single gene disorders) are independent of lifestyle modification.
- The most effective interventions are often not those targeted at individuals but which instead change systems and hence the environment for the population as a whole.
- The greatest contributor to ill-health is financial and cultural inequality, and services that emphasise the individualisation of risk fail to respect the evidence from decades of public health research that ill-health is socially stratified.

Individual responsibility

- There is at least some onus on individuals to take responsibility for their health.
- Promotion of personal responsibility for one's health is a good thing, although measures that people can adopt to take responsibility for their health should be simple and easily communicated, as well as being promoted in tandem with proper medical healthcare education.
- Those interested in lifestyle and health do not need to be encouraged, they just do it. The easiest way for individuals to take responsibility for their health is to eat a balanced diet, take exercise, reduce stress and avoid excess consumption of alcohol and tobacco.

> ***Question 4: Who pays?***
>
> *Many DNA profiling and body imaging services (see Annexes 4 and 5) are paid for privately by the individual. However, positive findings may lead the individual to seek publicly funded services for follow-up diagnosis and treatment. Should public services be expected to fund such follow-up?*
>
> ***If yes...***
>
> *Under what circumstances should such funding be provided (for example: in all cases, only if the tests meet certain criteria, only for certain conditions)?*
>
> ***If no...***
>
> *Should publicly funded healthcare services impose fees for such follow-up diagnosis and treatment (for instance by charging patients or by levies on private providers of body imaging and DNA profiling services)?*

The majority of respondents felt that public services should be expected to fund diagnosis and treatment that may follow an individual undergoing DNA profiling or body imaging tests. However, this was not universal, and some respondents argued that the potential negative impact on public healthcare services, due to the cost of such follow-up, should be taken into account. Some recommended laying down specific requirements for companies providing the services as a way of mitigating this cost (such as a tax) or requiring them to provide adequate genetic counselling services.

The NHS should pay

- The NHS should fund follow-up services. There is no bar on patients requesting medical advice from a publicly-funded medical practitioner in the absence of symptoms and the mode by which a person becomes aware of a significant condition should not restrict the availability of help from a system that provides healthcare free at the point of delivery. It would undermine the principles of the NHS, as the NHS accepts its duty of care to meet all patient concerns.

- If the individual consults a doctor and the doctor deems it necessary to perform the follow-up service then the NHS should pay.

- Restrictions may, however, be necessary insofar as only treatment for those abnormalities that have significant, remediable or manageable health implications should be made available through the health service. Also, tests should meet certain scientifically accepted criteria.

The NHS should not pay

- The impact on the NHS of following up the results of private predictive testing services, the endless chasing of minor 'abnormalities', can be very costly.

- A case could be made for those in the commercial sector who profit from this being required to fund the follow-up.

Effect on the NHS

- The use of private predictive testing services may have an impact on the NHS, as public services are often the inevitable final pathway for people who detect abnormalities using private services.

- There is a possibility that individuals who pay for their own tests and need clarification of the results would consult NHS professionals for help, which may lead to large increases in the costs for NHS healthcare. The likelihood of this occurring is increased if the information and post-test support provided by the private companies is inadequate.

- There is an urgent need to ensure that professionals across the health service are educated about genetics and the ethical and social issues it raises.

Requirements for companies

- Genetic counselling services should be provided with direct-to-consumer genetic testing products.

- A charge should be levied on private providers of DNA profiling services, in order to help pay for further publicly-funded follow-up to their services. However, there will be strong objections from companies based outside the UK.

- Forcing DNA profiling companies to fund follow-up may be counterproductive, as such a requirement might reinforce the view that commercial profiling provides legitimate and valuable health information, rather than an arguably recreational service.

Section 2: Electronic health records

General comments

- Sometimes, an absence of information is preferable to information that is unreliable.

- Shared health records require that people in the same and different healthcare professions have a common understanding of the terminology, irrespective of the context. In the NHS, there is a data dictionary, which sets out the agreed terminology and its associated meaning, and enormous effort goes into ensuring that data manually inputted by staff are coded correctly. Google Health and Microsoft HealthVault Records may not take the same degree of care or commit the same kind of resources.

- Both Microsoft and Google have given assurance that they will keep control over users' personal information. If this is truly the case, one has to ask what benefit Google and Microsoft will derive from providing this service and who is to say that these rules will not be changed in future?

- In many cases, 'privacy' is synonymous with 'trust'. Privacy is often thought of in terms of secure NHS terminals, strong passwords, and firewalls. That is security, not privacy. Privacy means that sensitive information resides with, and is used by, only people that we trust. It would be unrealistic to expect 100% security, and therefore 100% privacy, from any electronic system; it is a standard to which paper systems are simply not held.

> ***Question 5: Your experiences***
>
> *Have you used online health recording systems such as Google Health?*
>
> ***If yes...***
>
> *What led you to do so and how would you evaluate your experience? Which aspects did you like especially, which ones did you dislike?*
>
> ***If no...***
>
> *What factors would influence your decision whether or not to use such services in the future?*

Of those who responded to this question, most had not used online digital health record systems. Some suggested that in the right circumstances they would consider doing so. Respondents also had concerns regarding the advent of digital health records, both online and offline, including issues regarding data protection and the use of data derived from such records to market products.

Benefits

- Patient-held health records can be an extremely useful tool to help patients learn more about their health, and allow the patient to act as an 'auditor-of-one'.

- Records services such as Google Health are particularly useful as a place for holding data, particularly as regards advance decisions/directives and for those with rare genetic conditions to help share it with new physicians who may not be aware of the specifics of the condition.

Concerns

- There is a threat of health information being used to target products at users.

- The integrity and accuracy of the data may also be negatively affected by patient access/control.

- Data protection and security are problems with the use of any electronic health record.

- The use of third-party health records is part of an attempt to wrest the power of medical information from the medical profession. The transfer of control is not from doctors to patients but from doctors to the private sector.

- The intention of the companies involved is to data-mine the information as a direct-marketing tool.

- UK patients have not hitherto been responsible for their medical records. Changes will require a shift in mindset.

- The proliferation of these systems and indiscriminate use of private health record services may fragment the total electronic patient record available. A single health record supports the seamless transfer of care between primary and secondary settings and promotes multidisciplinary working.

- If data are online and accessible to the patient through use of a password, then the data are vulnerable to a wide range of familiar attacks.

Recommendations

- Accuracy is essential to both safe and effective treatment, and for the validity of any research based on the information stored. Consequently, any staff responsible for filling in or maintaining electronic patient records must be fully trained in data security and patient confidentiality.
- Only healthcare professionals directly responsible for a patient's care should have access to the full contents of their electronic records: not insurance companies, police (without court order), social services or any other party without express consent.
- It is important that information (particularly genetic information) included in electronic records be accessible for research purposes and be anonymised whenever possible.
- If active consent is required for all forms of access to data held in electronic records, then large scale research would become very difficult.

Section 3: Online health information

> ***Question 6: Your experiences***
>
> *Have you used online sources for diagnostic purposes, for instance those provided by government agencies, patient groups, commercial companies or charities?*
>
> ***If yes...***
>
> *Which services have you used, what led you to do so, and how would you evaluate your experience? Did you find the service useful in providing the information you were looking for, leading to better care or empowering you when talking to healthcare professionals? Or did it have some negative effects?*
>
> ***If no...***
>
> *Under what circumstances if any would you consider using such services in the future?*

A small majority of those who responded had used an online health service. Several suggested that they would do so in certain circumstances, while others expressed concerns about the practice – such as the risks of replacing face-to-face consultations and the lack of understanding relating to how people use online health information.

- The unavailability of doctors outside normal working hours is a factor in the use of online health information.
- Online health information could lead to empowerment and self-management.
- The use of online health information is acceptable, as long as it is used to supplement, not replace, professional medical advice.
- Some NHS websites fail to meet the Health on the Net code of practice.
- Treatment algorithms and flowchart assessments are not a replacement for face-to-face medical consultations.
- How online health information is used is not understood properly. More research is needed.
- The use of websites for accessing health information is sometimes recommended to patients by some doctors.

- Dangerous health websites are easy to identify. People's ability to judge the reliability of information sources should not be underestimated, although some believe that it is difficult to identify which websites were useful.

- A definitive method of identifying reliable websites is needed. One option is a portal provided by an independent or professional organisation, linking to reputable websites.

Section 4: Online drug purchases

General comments

- Pharmaceutical companies should be obliged to contribute a part of their profits to financing regulatory bodies.

- Provision of information will be most profitable for new, expensive drugs whose long term benefits may not yet be known.

- Newer drugs are not necessarily better.

- The use of the Royal Pharmaceutical Society of Great Britain's logo is not compulsory.

> ***Question 7: Your experiences***
>
> *Have you purchased prescription drugs over the internet?*
>
> ***If yes...***
>
> *What led you to do so and how would you evaluate your experience (for example, in terms of convenience, facing risks of obtaining the wrong or poor quality drugs, lack of medical supervision etc.)?*
>
> ***If no...***
>
> *Under what circumstances if any would you consider doing so for yourself or a relative or friend?*

A significant majority of respondents stated that they had not purchased pharmaceuticals online, although a small number did say that given the right circumstances, they would do so. This included dire emergencies or if it was possible to ensure that the drugs were manufactured by a reputable company.

- Since the NHS provides free prescriptions to some patients, there is no need to pay for the drugs online.

- There is no way to guarantee the integrity of the drugs provided, nor to ensure or monitor the biological potency. Consequently, the trust that underpins the act of dispensing a medicine between the pharmacist and the patient will evaporate.

- Other than for issuing repeat prescriptions, drugs should not be prescribed as a result of an online consultation.

- The risks posed to the public through the ungoverned and unfettered availability of prescription drugs through the internet is a serious concern, and includes threats to public health through inappropriate drug use and increased resistance to certain medicines.

- The potential to access drugs unavailable in certain countries is a motivating factor for the use of online drug purchases.

- The responsibility for, and the consequences of, purchasing drugs online lies with the individual who does so – people buying a knife may cut themselves.

- Regulation needs to have a high level of international cooperation and regular enforcement activity.
- All retail pharmacies in Great Britain, including those providing internet services must be registered with the RPSGB.
- The most common drugs purchased are for obesity, erectile dysfunction, prostate disorders and hair loss.
- The few who abuse the system will dictate what happens.

> ***Question 8: Advertising healthcare products***
>
> *Do you think it should be permissible to advertise prescription drugs direct to consumers?*
>
> ***If yes...***
>
> *Should there be no restrictions whatsoever? Do you think that it should equally be acceptable to advertise DNA profiling or body imaging services direct to consumers (which is currently not prohibited in the UK, see Annex 7)?*
>
> ***If no...***
>
> *What are your main concerns? Are you confident that access to drugs via GPs is a better alternative, ensuring that you will always receive the drug that is best suited to your specific condition? Do you think that advertising DNA profiling or body imaging services should equally be restricted or prohibited?*

The reasons given on both sides of the argument ranged from the practical to the theoretical For example, advertising is designed to increase profits and persuade, not to inform; on the other hand, prohibiting advertising is unduly paternalistic.

Direct-to-consumer advertising should be permissible

- UK society is currently split as to how to advertise other potentially harmful consumer products, such as alcohol and tobacco. The question is about where on that scale does DNA profiling sits.
- Advertising DNA profiling may not require the same restrictions as pharmaceuticals since it can be purchased privately outside the NHS and is a diagnostic tool rather than a treatment.
- Restricting access to DNA profiling technologies is unduly paternalistic and is not consistent with the marketing of other risky activities in other sectors.
- It is more appropriate to ensure that adverting and information is accurate and acceptable than identifying certain classes of products or services it should or should not be permissible to advertise.
- It is acceptable to advertise DNA profiling where it offers genuinely recreational uses of DNA profiling.
- Advertising may provide a medicine with a higher profile, create awareness and lead to understanding and engagement with individuals around their care.
- If one starts with the view that individuals should be able to be as informed as possible, but with professionals deciding what is or isn't acceptable, then one changes the issue to being one about the ethical defensibility of controlling information itself.

Direct-to-consumer advertising should not be permissible

- It should not be permissible to advertise prescription drugs directly to consumers.

- It would bring few benefits.
- The evidence is that advertising is designed to increase profits, not increase knowledge.
- Advertising leads to the commodification of both the body and the person.
- Such advertising treats potent medicines as simply another consumer product and adversely influences the discussions that should take place between doctor and patient.
- Doctors should be the gatekeepers for access to pharmaceuticals (other than those authorised for over-the-counter use), as well as DNA profiling and body imaging.

Influence and effect of direct-to-consumer advertising

- The Kaiser Family Foundation found that of the 25 largest drug classes in 2000, every $1 the pharmaceutical industry spent on direct-to-consumer advertising in that year yielded an additional $4.20 in drug sales.
- There is always a bias in the presentation of information.
- Direct-to-consumer advertising may well adversely affect doctor-patient relationships, distort public health priorities and disrupt the cost controls operated by the NHS.
- Pharmaceutical advertising creates pressure on GPs to prescribe the 'popular' and branded, rather than efficient, drug.
- There is a fundamental conflict-of-interest between expanding drug markets and making the best medical decisions.

Regulation

- Direct advertising of drugs is widely available on the internet, and the opportunities to ban it have been missed.
- It is the implications of testing that raise concern and emphasis should be on the risk of harm rather than the type of testing.
- One should not restrict the availability of predictive tests (unless they are in some way unsafe), but establish a database of evidence so that policy makers, funders of health services, physicians, patients and citizens can all be reliably informed about the evidence base.
- Although there are sometimes problems with doctors inappropriately prescribing pharmaceuticals, the likelihood of this occurring is much lower than with access through advertising and private channels. There are remedies through professional certification and the law which will not be available through these other systems. The right to free choice is no use to a person terrified or poisoned by that choice.
- Protection of people who are vulnerable should be part and parcel of the regulatory framework in which any advertising takes place.
- Under the UK Advertising Codes, DNA profiling and body imaging are not classed as medicines and so are not subject to the specific code of rules for medicine advertising. However, adverts for these services are still subject to the UK Advertising Codes.
- There should be a regulated route by which patients can obtain non-partisan information about the medicines they are using.

Section 5: Telemedicine

General comments

- There must be a distinction made between non-UK reporting of radiology images and what is used wholly in the UK. Patients care about who provides the report on their imaging and this should not be forgotten.

> ***Question 9: Your experiences***
>
> *Have you used information technology to access individual healthcare expertise at a distance?*
>
> ***If yes...***
>
> *Which services did you use, what led you to do so, and how would you evaluate your experience? Would you recommend it to others?*
>
> ***If no...***
>
> *If you were faced with the choice of using such technology or undergoing the costs and/or inconvenience of travel over a substantial distance to access or provide those services on a face-to-face basis, what factors would affect your choice?*

The majority of respondents stated that they had not used telemedicine, although some respondents pointed out that the term 'telemedicine' was broad and could be construed as covering a wide range of techniques, many of which people would be familiar with: a telephone conversation with a family doctor, for example.

- Yes: a telephone conversation with my doctor.
- Telemedicine is particularly useful where travelling to the doctor is a significant problem.
- Telemedicine has distinct advantages in remote areas and especially in third world contexts.
- Telemedicine has an important role alongside the traditional doctor-patient consultation although it will never replace face-to-face consultations.
- In certain circumstances face-to-face contact between a patient and a healthcare professional is necessary.
- Telemedicine has been widely used in clinical practice in this country for many years. While the technology underpinning telemedicine may be innovative the practice is not new.
- It needs to be properly evaluated and regulated.

> ***Question 10: Who pays?***
>
> *Should remote access to GP services be provided through telemedicine for those in remote and rural locations?*
>
> ***If yes...***
>
> *Provided this results in higher costs: should it be the patient or the public healthcare provider who pays for the extra cost of providing services this way, or should costs be shared in some way?*
>
> ***If no...***
>
> *What are your reasons? Do you think some degree of unequal access to public healthcare is simply justified (for example, if individuals choose to live and work or retire in remote rural areas)? Or do you think that there are means other than telemedicine that are better suited to achieving more equitable access to healthcare?*

A large majority of respondents replied that remote access to primary care services should be provided through telemedicine, although it was questioned more than once whether or not the 'rural'

aspect of the question was relevant. In these cases, it was suggested that telemedicine should be provided where it was suitable to do so; this could include urban environments, as well as other factors such as patients with disabilities.

- There are plenty of justifications for telemedicine.
- 'At a distance' does not mean 'rural'.
- There is already unequal access and the equity of access to healthcare arises from the structure of how healthcare is organised.
- So-called 'postcode rationing' has always existed for those in remote or semi-remote areas: life has its inequalities.
- People should not be penalised for living in remote or rural areas.
- Remote access to GP services for those in rural locations is the logical extension of the classical duties of physicians in modern times.
- Remote areas should aim for an equal access or there may be a health migration to the cities.
- The public purse should bear the cost. It would be a lot cheaper than sending out a doctor.
- NHS care should be free at the point of use and charging patients is wrong.
- Those who are entitled to NHS treatment should receive it on the basis of need, free at the point of delivery irrespective of where they live.
- The costs should be borne by the patient if consulting a doctor from home. They would have had to pay for travel and parking to reach the GP or hospital.

Section 6: Body imaging and DNA profiling services – cross-cutting issues

General comments

- The argument in favour of using the available genetic predictors is that some information must be better than no information. This position is deeply flawed. If the information supports the conclusions of another, established, medical test then there is little harm. Yet if the direct-to-consumer test contradicts that test, there may be dangers.
- People do not act as rational agents in the face of genomic risk information.
- Genetic information is interpreted by individuals and family members in accordance with lay theories of inheritance, lay understandings of risk values, and the dynamics of family communication.
- Medicines will remain the mainstay of clinical care for the foreseeable future.

> ***Question 11: Your experiences***
>
> *Have you used the services of a body imaging or DNA profiling company (see Annexes 4 and 5 for examples)?*
>
> ***If yes...***
>
> *What led you to do so and how would you rate the services of the company? How useful was the information you received? Please indicate which provider and which service package you used.*
>
> ***If no...***
>
> *If you were thinking about using such services, what information would you want to receive in advance and what kind of information would you find most useful to receive after the profiling?*

Most respondents had not used DNA profiling or whole-body imaging predictive testing services. Responses tended to express strong opinions as to whether or not these services were acceptable, and how best they might be used, if at all. One of the primary points made was the apparent variation in the risks for various diseases reported by different genetic testing companies when provided with the same sample.

- Most genetic factors seem to change a person's risk of common diseases only very slightly, so they are not more but less predictive than most other types of test.
- Those providing predictive testing services prey on people's health anxiety.
- Genetic testing services offered on a commercial basis to the general population are in effect screening tests that do not meet medical screening criteria.
- The use of private predictive testing services undermines public health approaches.
- There is some evidence to suggest that where a condition is caused by genetic predisposition, it may reduce the expectation that a behavioural means of coping, such as changing diet, will be effective, but increase the expectation that medication will be effective.
- The debate is the degree of pre- and post-test counselling and clinical oversight that accompanies testing.
- Preliminary test results might be sought before seeking more formal medical advice or going to a hospital, although there is an enormous gap in public awareness of what a test can or cannot achieve.
- Having the service approved by the NHS or another reliable body is a key factor in deciding to use the testing service.
- Ancestry and ethnicity information provided by deCODE is based on data that are already present in a company's database: 1000 reference individuals from 50 different populations world wide. This is meaningless for someone of general European origin. A review of commercially available genetic tests published in 2008 found significant statistical associations with disease risk for fewer than half of the 56 genes included in the tests.
- In the case of DNA profiling, there are sometimes significant differences between the test reports of different companies, based on the same sample. Professor Martin Richards of the University of Cambridge has highlighted this. In about one-third of cases, both his absolute and relative risk values for certain diseases were different between the two reports. He was also emailed by deCODE to advise that two of his risk predictions had now been revised on the basis of new research.

Question 12: Regulation

Do you think it is satisfactory for DNA profiling and body imaging services to have to pass stringent evaluations before they are provided in the NHS, but for them to be readily available on a commercial basis without having to go through such evaluations?

If yes...

Why do you believe more stringent evaluations are required in the public sector than in the private sector? If commercial DNA self-profiling products were to be developed in the future, enabling people to profile themselves (or others) whenever they want, do you think any legal, regulatory or other restrictions should be imposed beyond those applying to existing self-profiling products, such as pregnancy testing kits?

If no...

Do you think the NHS requirements should be less strict, or that more regulation should be imposed on private providers?

What measures would you consider most suitable? For example: disclosure requirements such as labelling rules; voluntary codes of conduct or 'kitemarking' arrangements; legal requirements to restrict market entry; restrictions or bans on advertising; tougher penalties for breaches of established rules; or stricter post-market monitoring and surveillance.

A strong majority of respondents answering this question felt that there should be more regulation of the private provision of predictive testing services. Many felt that there should be equal levels of regulation between public and private provision. However, of these respondents, some made it clear that 'equal' would not necessarily mean 'more'. Some respondents suggested that it would be unrealistic to expect, and unfeasible in practice to assert, the same level of regulatory control on private tests as exists for publicly provided services.

Evaluations

- One should not overstate the 'stringent evaluations' that the NHS conducts.
- Equal standards should apply to both the public and private provision of DNA profiling.
- Equal standards are desirable, but are impractical and untenable in modern society.
- DNA testing services should have to satisfy a higher level of regulation in the private sector than in the NHS. It is an area where market failure is inevitable: there is an imbalance of information between consumer and provider, and consumers may not suspect that the limited information they have might not be complete and true.
- A survey by Which? in 2009 revealed that 79% of consumers agree that direct-to-consumer genetic tests should be strictly regulated. Given what people actually want is regulation, the usual argument about paternalism is turned on its head.
- The justification for a less stringent approval system outside the NHS is that the costs of testing are not similarly restricted. However, the requirements for commercial testing services should be extended beyond their current scope.
- NHS laboratories can currently design and manufacture their own tests without any need for the same rigorous testing required for commercial products. This is in itself a loophole.
- The mechanism of evaluation does not have to be the same between sectors in order to be similarly stringent.

Current regulation

- A complex matrix of consumer protection legislation and regulation already exists.
- All commercial tests must, by law, be guaranteed by the CE mark.
- The MHRA currently interprets the requirements of the IVD Directive so as to cover only analytical validity. This interpretation is not consistent with that of some other EU Member States.
- The German Parliament passed the Genetic Diagnosis Law in April 2008. The law provides that genetic tests 'for medical purposes' may be carried out only by a physician, thereby banning all forms of direct-to-consumer genetic testing that provides medically relevant information. Consumer genomics companies have not ceased to sell their services to German residents. The companies argue that the information they provide is not medical advice.
- Imaging services are the most tightly regulated speciality discipline in medicine.

Regulatory recommendations

- Some may argue that purchasing predictive testing services is up to the individual and that a lot of poorer quality products are in any case available on the market. However, 'is' does not imply an 'ought'.
- Predictive testing services are healthcare products, and it is in the public interest to regulate them.
- Until we know more about why people undergo personal genome profiling, and how they react to and use the results, it would be premature to regulate in this area.
- Existing legislation, if properly enforced, may be sufficient. The role of the Care Quality Commission is likely to be important.
- There may be grounds for restricting availability the basis of the implications of the test rather than the nature of the test itself. There is a precedent for this with HIV testing. In the UK in 1992 it was made an offence to sell HIV testing kits directly to the public.
- Products or services involving genetic analysis or material are not necessarily exceptional and genetic tests should not be treated as a distinct group of diagnostics set apart from any other form of consumer self-test.
- Formal regulation is not the only means of controlling the use of these services.
- A voluntary code would not be good enough: no commercial company is going to agree to sign itself out of business. Regulation would have to be enforced.
- In the case of DNA profiling, how genetic counselling is provided, and by whom, is of the utmost importance.
- The UK Government should sign and ratify the Council of Europe's Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes.
- Owing to the lengthy process of revision of the IVD Directive, the UK Government should also put in place its own system of regulation of tests based on Organisation for Economic Co-operation and Development guidelines.
- The risk classification in the IVD Directive should be reviewed. High level principles applicable in different jurisdictions should be agreed.
- There shouldn't be any private provision; it is immoral to put profits before patient need.

Risks

- The fear that individuals might be seriously but needlessly worried has not yet been supported by empirical evidence.
- The predictive value of the genetic markers tested by consumer genomics companies is very small.
- The main danger posed by the increasing uptake of consumer genomics is not that patients are too simple-minded to understand the results, but that individuals may feel pressed to spend their money on such tests as part of their individual duty to stay healthy.

- Test-takers could find themselves in a situation in which they need to disclose the data when buying certain life or other insurance policies.
- The special attention which health authorities and legislators have paid to consumer genomics so far has contributed a lot to its representation as a 'medical' genetic testing service in the public domain.
- There is no guarantee that the person whose DNA is sent for analysis is, in fact, the person who has purchased the test.
- This leads to the risk of non-consensual DNA profiling, especially of children, which is unethical where it is not done for their immediate care.
- Information cannot be un-learned.
- It is unclear how consumers are supposed to be aware that testing SNPs associated with breast cancer has much lower predictive value than testing mutations in the BRCA1/2 genes.

> ***Question 13: Responsibility from harm***
>
> *The results of DNA profiling and body imaging may lead people to seek appropriate treatment. But it may also lead to harmful actions, such as inappropriate self-medication, or people may become more fatalistic, believing that there is no point in altering their lifestyles. In the most extreme cases some people could become suicidal as a result of the predictive information they receive. Should providers ever be held responsible at law for such harms?*
>
> ***If yes...***
>
> *In what circumstances? Should providers of other services such as pregnancy tests also be held responsible for what distressed or misinformed individuals might possibly do with the information they obtained?*
>
> ***If no...***
>
> *How, if at all, do you think the interest of vulnerable groups should be safeguarded?*

Whether or not companies should, in some circumstances, have responsibility for potential harms occurring as a result of their services split respondents approximately equally. Some respondents suggested that while companies may be held accountable for any potential harm their products or services cause, consumers must also accept some responsibility.

- The validity of contractual statements made by predictive testing companies has yet to be tested in the UK.
- Holding companies responsible at law may be very difficult in practice; it is hard to demonstrate a chain of causation.
- Providers should have responsibility for harm in certain circumstances: there has been marked negligence in the provision of the service; they have not operated proper standards of consent; the tests are of unproven (or negligible) value; the harm has clearly been caused as a result of their products or services; where there are faults in the quality of the analysis or interpretation; the harm is caused by misuse of samples or personal information; and misleading claims in promotional materials and advertising.

Providers should not have responsibility for harm

- Holding companies responsible for how people feel about the results is a waste of time.
- Should there be a general duty not to harm people by giving them bad news? People become distressed when they are told they have cancer by their doctor.

- Most people are more distressed when they get on their scales in the morning. There is a responsibility on the patient to disclose information. If the company is not aware of a mental health condition, for example, the company cannot be held responsible.

> ***Question 14: Quality of information***
>
> *Some have criticised current commercially-available body imaging and DNA profiling services for giving information that is of limited quality and usefulness. Do you think more should be done to improve the quality and usefulness of body imaging and DNA profiling services?*
>
> ***If yes...***
>
> *Who should pay? Should there be publicly funded investment, or should private companies be left to develop better methods?*
>
> ***If no...***
>
> *Is it sufficient to rely on the so-called 'buyer beware principle' in such cases, by putting the onus on the purchaser to find out about the quality and associated risks of the product they are buying?*

Most respondents to this question believed that more should be done to improve the quality of predictive testing services. It was a roughly even split between whether or not the 'buyer beware' principle was sufficient. Some respondents thought that funding for research should be provided solely through private means, although none believed this to be the case with respect to public funding; several argued that funding should be provided by both. One respondent believed that, given his view of the quality of the information provided by predictive testing, the services should be banned entirely.

The buyer beware principle is sufficient

- If quality and usefulness are the criteria, there are a lot of things that would need to be taken off the market. If companies are treating customers unfairly then the Consumer Trading Act 2008 is the way to go.
- While a test without proven clinical utility should not be used by a state-funded healthcare system, there seems no reason why such a test should not be allowed on the free market. Consumers can purchase countless goods and services of questionable (or even negative) utility: purchasing healthcare tests is no different.

The 'buyer beware' principle is insufficient

- The 'buyer beware' principle is an inadequate safeguard in other areas of life.
- It is irresponsible to rely solely on *caveat emptor*.
- Companies should not be offering these services if they are not able to offer an integrated, fully supported service.

Recommendations

- Mechanisms of complaint and restitution are not clear: there is an urgent need for improved regulation of DNA tests outside the NHS.
- There should be nationally approved standards of practice that are audited.
- Public education, supported by transparency and access to data, is fundamental.
- Funding should be made available to bodies like the HGC, NHS Direct or other independent and trusted bodies to provide impartial advice about direct genetic tests. Test developers and providers should be encouraged to facilitate consumer access to this information.

- Information must be provided in a format that is easy to understand.
- Commercial services should operate to the same standards as the NHS.
- Commercial companies should be required to provide information and support at the same level as state-funded systems.

Other

- Competition between private companies will lead to technological improvements and lower costs in both imaging and profiling services.
- Probabilistic information is inherently challenging to communicate.
- Tests that purport to offer medically relevant information but are based on incorrect science, and have no clinical validity, should simply be viewed as fraudulent and not allowed on the market.
- It is difficult to stop or even control the provision of these DNA profiling services when the work is being carried out outside the UK: it is virtually impossible to regulate.

Question 15: Are there any other issues we should consider?

The following reflects a general selection of issues respondents believed should be taken into account when considering the topic as a whole.

- Commercial healthcare is dehumanising. People are broken down by the process of corporatisation into biological parts not for diagnosis and treatment but so that they can be measured and converted into profits.
- The Government's proposal to introduce competition and markets into the NHS risks seriously damaging it because it dehumanises us all.
- Private scanning and genetic testing can provide a useful safety valve for failings in the NHS.
- Attempts to limit private access to private services are likely to be self-defeating as many of those involved will simply look to Europe.
- It is unclear that the use of private facilities will deprive the poorer social groups of healthcare. The extended NHS already favours the motivated middle classes.
- The 'one gene, one protein, one function' idea of the late 1990s is now entirely defunct.
- The information provided should be regulated in proportion to the level of its sensitivity, relevance to family members and clinical utility, rather than the nature of the test analyte.
- Those who seek private medical services directly do not necessarily consider themselves to be 'consumers'. It may be the case that the individuals' own perception of their status depends upon the service being sought: where purchasers of elective procedures such as cosmetic services consider themselves to be 'consumers', but those seeking testing or treatment for a health problem consider themselves primarily as 'patients'.
- Healthcare providers must be equipped to deal with growing public awareness of genetic risk.
- It is unclear who 'owns' genetic/body scan reports: who can share an individual's test results? For example, in the event of a company going 'bust', should information be taken over by a government/NHS organisation or can another company buy it? If a company can buy that

information will it be only for UK companies and would the information be stored only in the UK on UK patients under only UK law?

- Public confidence in genetics research may be damaged if individuals are disappointed by DNA profiling.

List of respondents

Seven respondents requested not to be listed.

Organisations

1 Advertising Standards Authority
2 Breakthrough Breast Cancer
3 British Heart Foundation
4 British In Vitro Diagnostics Association
5 British Medical Association
6 British Society for Human Genetics
7 Cesagen
8 CHIME, UCL
9 Egenis, the ESRC Centre for Genomics in Society
10 ESRC Genomics Policy and Research Forum
11 ESRC Innogen Centre
12 Ethics Committee of the Royal College of Pathologists and the Joint Committee on Medical Genetics
13 fpa (Family Planning Association)
14 Genetic Interest Group
15 Genewatch UK
16 Human Genetics Commission
17 Humanist Society of Scotland
18 Leicester Medical Students
19 National Information Governance Board for Health and Social Care
20 PatientsLikeMe Inc
21 PHG Foundation
22 Progress Educational Trust
23 RCGP Scotland / Royal College of General Practitioners (Scotland)
24 Royal College of General Practitioners
25 Royal College of Physicians
26 Royal College of Physicians of Edinburgh
27 Royal College of Radiologists
28 Royal Pharmaceutical Society of Great Britain (RPSGB)
29 Royal Society of Engineering
30 Wellcome Trust

31 Wellcome Trust Sanger Institute

Individuals

1 Ms Margaret Auld and Dr Angus Russell
2 Professor Jayapaul Azariah
3 Dr Maureen Beauchamp, National Council of Women
4 Dr Mark Bermingham
5 Dr Bob Brecher
6 Daniel B. Carr, MD, Tufts Medical Center, Boston, MA, USA
7 Professor Donna Dickenson
8 Professor Jenny Hewison
9 Mr Shaun Hexter
10 Professor Shirley Hodgson, Professor of Cancer Genetics, St George's, University London
11 Dr Stuart Hogarth, Centre for Biomedicine and Society, King's College London
12 Dr Simon Kenwright FRCP
13 Leicester Medical School: Medical Ethics and LAW SSC
14 Dr Jeantine Lunshof
15 Dr Ainsley Newson, Senior Lecturer, Centre for Ethics in Medicine, University of Bristol
16 Dr Barbara Prainsack, Centre for Biomedicine and Society, King's College London
17 Dr Rustam Al-Shahi Salman
18 Senior Medical Academic Specialist in Imaging at a UK University
19 Professor Frank Sullivan
20 Dr Jonathon Tomlinson
21 Dr Michael Tremblay