

The background of the cover is a close-up, out-of-focus photograph of several petri dishes or microcentrifuge tubes. The rims of the dishes are visible, and the liquid inside shows various colors and textures, suggesting biological samples. A solid teal vertical bar runs along the right edge of the cover.

Medical profiling and online medicine: the ethics of 'personalised' healthcare in a consumer age

CONSULTATION PAPER

NUFFIELD
COUNCIL ON
BIOETHICS

Medical profiling and online medicine: the ethics of 'personalised' healthcare in a consumer age

Respondent's form

Please complete and return with your response by 21st July 2009

Your details

Name: _____

Organisation: (if applicable) _____

Address: _____

Email: _____

About your response

Are you responding personally (on your own behalf)
or on behalf of your organisation?

- Personal
 Organisation

May we include your name/your organisation's
name in the list of respondents that will be
published in the final report?

- Yes
 No, I/we would prefer
to be anonymous

If you have answered 'yes', please give your name or your organisation's name as it should appear
in print (this is the name that we will use for your response):

This response may be quoted in the report

- Yes, attributed to myself
or my organisation
 No
 Yes, anonymously

This response may be made available on the
Council's website when the report is published

- Yes, attributed to myself
or my organisation
 No
 Yes, anonymously*

* If you select this option, please note that your response will be published in full (but excluding this form), and if you wish to be anonymous you should ensure that your name does not appear in the main text of your response. The Nuffield Council on Bioethics cannot take responsibility for anonymising responses in which the individual or organisation is identifiable from the content of their response.



Why are you interested in this consultation? (tick as many as apply)

- You or family/friend has had a DNA test
- You or family/friend has had a body scan
- You or family/friend has purchased a health product or service over the internet
- You or family/friend has used a telemedicine service of some kind
- Work in healthcare (e.g. nurse, doctor, NHS manager, health technician, health IT specialist)
- Work in/represent a provider of DNA tests, body scans, online health products/ services or telemedicine
- Work in/represent a charity or NGO
- Work in/represent a professional body or government
- Legal/regulatory interest
- Academic/research interest
- Educational/teaching interest
- General interest/other

Please let us know where you heard about the consultation:

- Received consultation paper in the post
- Received notification by email
- Newspaper, radio or television
- Nuffield Council on Bioethics website
- Twitter
- Other website (please state): _____

Using your information

We ask for your address in order that we can send you a copy of the report when it is published and invite you to the launch event. We would also like to be able to contact you again about both this topic and future work by the Council that may be of interest to you. (Please note that we do not make your address available to anyone else and we do not include it with the list of respondents in the report.)

May we keep your contact details for these purposes?

Yes, you may keep my contact details

- only until the Report is published, so that you can send me a copy and invite me to the launch event
- until I notify you otherwise
- Please do not keep my contact details

Would you like to receive updates by email of the Council's activities (published three times each year)? If so, please provide your email address below

Closing date for responses: 21st July 2009

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Professor Roger Brownsword
Dr Amanda Burls
Professor Robin Gill
Professor Sian Harding FAHA FESC
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Professor Ray Hill FMedSci
Professor Søren Holm
Professor Christopher Hood FBA*
Professor Tony Hope**
Dr Rhona Knight FRCGP
Professor Graeme Laurie FRSE
Dr Tim Lewens
Professor Ottoline Leyser CBE FRS
Professor Anneke Lucassen
Professor Alison Murdoch FRCOG
Dr Bronwyn Parry
Professor Nikolas Rose
Professor Jonathan Wolff

* Co-opted member of the Council while chairing the Working Party on medical profiling and online medicine

** Co-opted member of the Council while chairing the Working Party on dementia

Secretariat

Hugh Whittall	Catherine Joynson
Katharine Wright	Sarah Bougourd
Harald Schmidt	Tom Finnegan
Carol Perkins	Kate Harvey
Audrey Kelly-Gardner	Varsha Jagadeshram

The Terms of Reference of the Council are:

- 1 to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
- 2 to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;
- 3 in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

Working Party members

Professor Christopher Hood FBA (Chair)

Gladstone Professor of Government and Fellow, All Souls College, University of Oxford and Director, ESRC Public Services Research Programme

Professor Kay-Tee Khaw CBE FRCP

Professor of Clinical Gerontology, University of Cambridge School of Clinical Medicine, Addenbrooke's Hospital

Dr Kathy Liddell

Lecturer, Faculty of Law, University of Cambridge

Professor Susan Mendus FBA

Professor of Political Philosophy, University of York

Professor Nikolas Rose

Martin White Professor of Sociology, BIOS Centre for the Study of Bioscience, London School of Economics and Political Science

Professor Peter C Smith

Professor of Health Economics, Centre for Health Economics, University of York

Professor Sir John Sulston FRS

Chair, Institute of Science, Ethics and Innovation, University of Manchester

Professor Jonathan Wolff

Head of the Department of Philosophy, University College London

Professor Richard Wootton

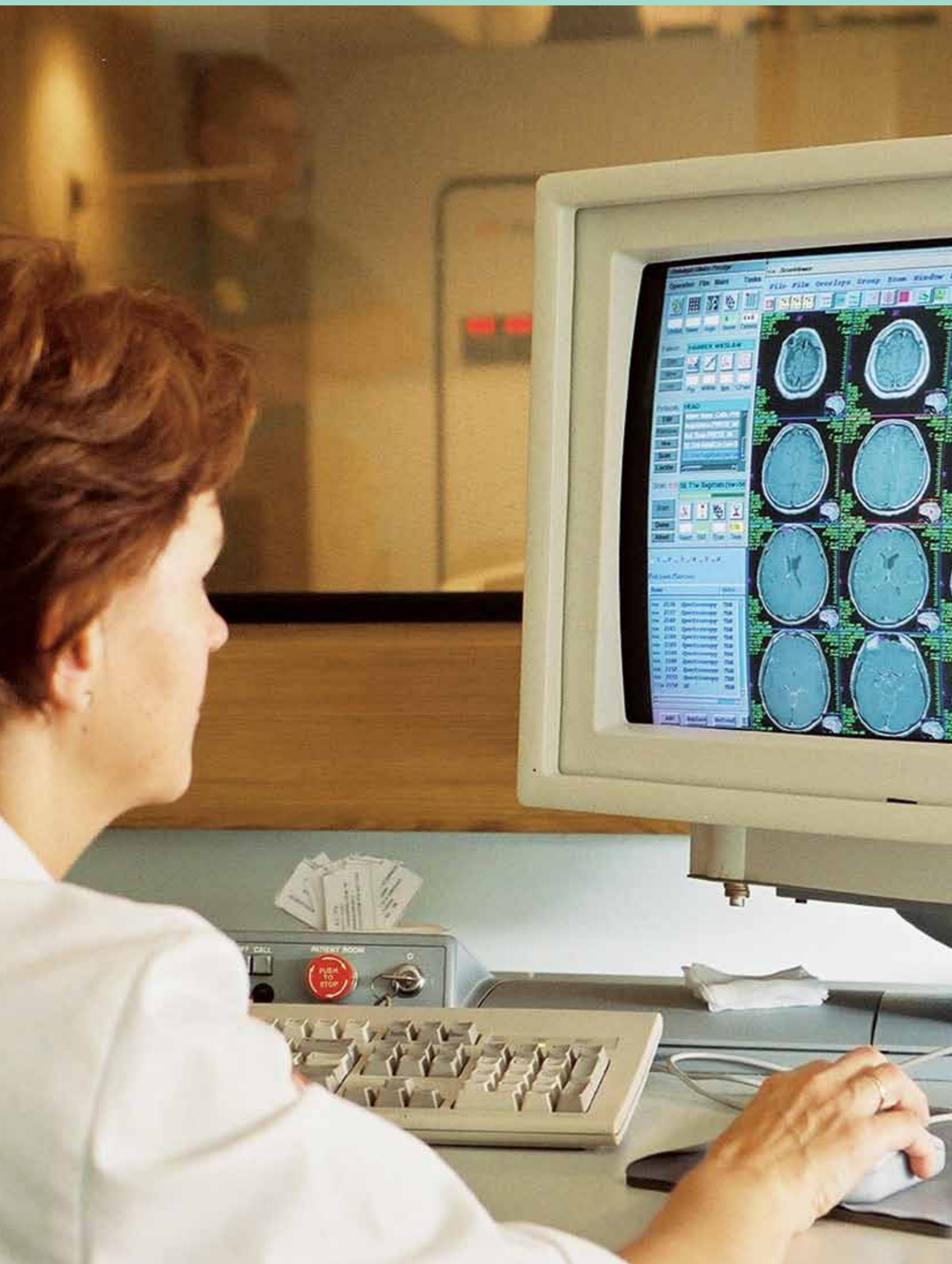
Director, the Scottish Centre for Telehealth

Working Party Terms of Reference

- 1 To identify and consider the ethical, legal, social and economic issues that arise in the application of new health and medical technologies that aim to deliver highly individualised diagnostic and other services.
- 2 To describe and analyse, by means of case studies, developments in medical research and practice and other factors giving rise to the development of personalised healthcare.
- 3 To consider, in particular:
 - (a) arguments about the scientific significance, reliability and predictive value of particular personalised services;
 - (b) implications for equity in health in relation to who will benefit most from particular personalised services, and for whom they may be harmful;
 - (c) the impact of personalised services offered by private providers;
 - (d) the tensions that might arise between increasing expectations for highly tailored care with the need to provide healthcare for all in the NHS;
 - (e) the extent to which personalised services can be offered as part of a fair and efficient operation of private and public healthcare systems;
 - (f) confidentiality and privacy issues in relation to the control, transmission, and storage of personal health data;
 - (g) any impacts on the doctor-patient relationship;
 - (h) whether current regulation is appropriate.

Table of contents

Background	3
Introduction	4
Electronic health records	6
Online health information	7
Online drug purchases	8
Telemedicine	10
Body imaging	11
DNA profiling	12
Body imaging and DNA profiling services: cross-cutting issues	14
Other issues	15
Annex 1: UK internet usage statistics	16
Annex 2: Electronic health records – examples of service providers	17
Annex 3: Body imaging – how it works	17
Annex 4: Body imaging – example service providers	18
Annex 5: DNA profiling – example service providers	19
Annex 6: Information provided by private DNA profiling services	19
Annex 7: Regulation of DNA profiling and body imaging services	20



Background

The Nuffield Council on Bioethics examines ethical issues raised by new developments in biological and medical research. It is an independent body, funded jointly by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust. It works by considering topics in depth, publishing reports on its findings and making recommendations to policy makers.

The Council has established a Working Party to examine *Medical profiling and online medicine: the ethics of 'personalised' health care in a consumer age*. Recent technological developments, new political and economic priorities, and the widespread drive towards patient-centred care have led to increasingly personalised health care services, with a strong focus on prediction and prevention. In many ways, these trends change the relationships between individuals and health care professionals. For example, technologies such as body scans promise people information about their specific risk-profiles for particular diseases, but often services are accessed without referral from their GP. This is also the case in direct-to-consumer DNA profiling. Many of these services, which also include online health records or health information services, are offered by private providers, and people increasingly regard themselves as 'consumers' of medical and health care services. This is either because they purchase them (directly or indirectly via private medical insurance) or because they consider themselves to have an individual 'right to

health' which imposes an obligation on doctors and other medical professionals. The increasing use of these technologies, in this context, raises a number of ethical issues that the Working Party aims to explore.

The Working Party wants to hear from anyone who is using, or contemplating using, medical profiling or online health care services, and from those involved in providing them in the public and private sectors of health care. The Working Party also wants to hear the views of researchers, academics, regulators, and policy makers, and it will pay careful attention to all responses received by the 21st July 2009.

This consultation document aims to provide background information on some of the issues the Working Party is currently thinking about. Please feel free to respond to as many or as few questions as you wish. In answering the questions, it would be very helpful if you could give specific examples wherever possible. In some cases we ask for your experiences of using particular services. Please feel free to adapt these questions if you are a provider rather than a user of such services, or if you are responding on behalf of an organisation.

Please note that the Council has already¹ published a report on pharmacogenetics.¹ We will not address again here issues in the area of pharmacogenetics.

¹ Nuffield Council on Bioethics (2003) *Pharmacogenetics: ethical issues* (London: Nuffield Council on Bioethics).

Section 1: Introduction

Medical care is broadly distinguished from public health by the fact that it is aimed at the specific needs of each particular individual. The relationship between the individual and health care professionals is shaped by various factors, including technology, public policy and social culture more generally. These factors can influence the extent to which individuals are expected to be responsible for keeping themselves healthy; the ways that individuals can get access to medical diagnosis and treatment; and the extent to which individuals are invited or expected to participate in assessing their care needs and choosing treatment options.

Recently in the UK, patients have been increasingly expected to participate in decisions and take responsibility for their health, and people can now access many diagnostic and treatment services directly rather than through their general practitioner. More medical services, such as predictive DNA profiling and body imaging, are now provided outside of the public health care sector by private providers. At the same time, the internet provides new ways for individuals to find information directly about health and health care, to purchase drugs and health care services, and even to store their health records so that they or others can access those details wherever they are. All this is occurring in a cultural context where individuals are increasingly coming to think of themselves as consumers of health care services, public as well as private, with an emphasis on their individual rights and expectations. There is

a wider questioning of the paternalism and discretion which many argue were the hallmarks of the health care system across the second half of the twentieth century, in which health care professionals were key interpreters of health information and also gate-keepers of medical resources.

Such developments raise numerous issues, for example, about the scope and limits of self-diagnosis and treatment; about information that may be erroneous or hard to interpret; about who should pay for some of these forms of treatment; about the balance of rights and obligations for health care between individuals and the wider population; and about issues of equity and fairness. Our first question looks broadly at the idea of health care as a 'consumer good' in a changing technological and social context.

Q1 Health care 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?

Q2 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?

Q3 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?

Q4 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 health care 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)?

Section 2: Electronic health records

The internet is used by more and more people. Although not all population groups use the internet equally or for the same purpose (see Annex 1), it is used widely and increasingly for access to diagnostic information, for purchasing or providing drugs and other health care services, and for storing individuals' health records (see Annex 2 for more information).

There are two main types of electronic health records. Private providers such as Google Health² and Microsoft HealthVault Records³ are offering these services with the claim that they will enable people to manage their own health information. Public health care systems are also seeking to develop electronic patient records – in the National Health Service (NHS) this has been argued for in the name of medical efficiency, but also because it will give patients “more control of their own healthcare”,⁴ as the House of Commons Health Committee has suggested (see Annex 2 for more information about providers of electronic health records).

Q5 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?



² See: <https://www.google.com/health/>.

³ See: <http://www.healthvault.com/Personal/index.html>.

⁴ House of Commons Health Select Committee (2007) *The Electronic Patient Record – Sixth Report of Session 2006-2007* (London: The Stationery Office) p.3.

Section 3: Online health information

Online health information includes both the simple provision of health information, and websites that offer automated diagnosis and referral. The first can be achieved either through a standard website, where health information is available for consultation, such as WebMD,⁵ or through collaborative website mechanisms such as AskDrWiki,⁶ where accredited medical professionals collaborate to produce information and advice regarding health concerns.

Automated diagnosis and referral websites, such as NHS Direct Self Help⁷ in the UK, use a series of options and questions about symptoms to provide a diagnosis and/or advice based on the data stored by the website and the information provided by the individual. Questions are asked in order of severity, from highest to lowest, so the most potentially urgent issues are dealt with immediately. Dependent on the answers provided, users may be given advice to "call 999", "seek help", "call NHS Direct" or be informed that "it is safe to manage this problem yourself at home". Where it is safe to manage at home, the NHS Direct Self Help website may give advice on what a person can do, such as "place the burn or scald under a gently running cold tap for at least 15 minutes".

Q6 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 health care professionals? Or did it have some negative effects?

If no...

Under what circumstances if any would you consider using such services in the future?



⁵ See: <http://www.webmd.com>.

⁶ See: <http://askdrwiki.com>.

⁷ See: <http://www.nhsdirect.nhs.uk/help/index.aspx>.

Section 4: Online drug purchases

Drugs can be provided over the internet by regulated 'internet pharmacies'⁸ that sell prescription medication. But the internet also enables the unregulated purchase of either prescription or non-prescription drugs. Internet purchases are often made across national borders, avoiding country-specific laws and regulations.

The increased availability of drugs over the internet can reduce the involvement of expert physicians in the prescription process. There is also an increased risk of receiving counterfeit drugs of questionable quality (highlighted recently by the US Federal Drug Administration),⁹ and this method of purchasing may contribute to increased abuse of prescription drugs.¹⁰ But there may be benefits of purchasing certain drugs over the internet, including reduced costs; personal convenience; and the avoidance of embarrassment (for example, when purchasing medicine for sexually-transmitted infections or anti-impotence drugs).

In some cases, the internet may also allow people to access services that are only legally available in other countries, for example 'morning-after-pills' for the prevention of unwanted pregnancies.

Currently, drugs may not be advertised directly to consumers in the European Union. But the European Commission is in the process of carrying out a consultation¹¹ on the relevant Directive¹² and it is possible that in the future some direct advertising of prescription-only medication to consumers may be permitted in some form (for instance over the internet, in health-related publications, or more widely).

⁸ BBC News (2004) *Internet pharmacies get go-ahead*, available at: <http://news.bbc.co.uk/1/hi/health/3572620.stm>.

⁹ FDA (2007) *FDA Warns Consumers about Counterfeit Drugs from Multiple Internet Sellers*, available at: <http://www.fda.gov/bbs/topics/news/2007/new01623.html>.

¹⁰ J Zarocostas (2009) Abuse of prescription drugs is second only to abuse of cannabis in US, UN drugs panel says *BMJ* 2009;338:b684.

¹¹ See, for example, European Commission (2008) *Pharmaceutical Sector Inquiry – Preliminary Report*, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

¹² Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended.



Q7 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?

Q8 Advertising health care 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?

Section 5: Telemedicine

Here we use 'telemedicine' to denote all forms of health care carried out at a distance.¹³ For example, teleconsultation involves communication between patient and health care provider, or between doctor and colleague. This often occurs by telephone or video link. One of the most common uses of teleconsultation between health care professionals is teleradiology, where X-ray images are sent electronically to a remote centre for diagnosis. Telepsychiatry has also become increasingly common, where the psychiatrist interacts with the patient via a video link.

Teleconsultations have the potential to improve access to health care in remote or rural areas where there are few doctors, in particular specialists. It may also enable older people to stay at home, rather than travelling some distance to see a health care professional. On the other hand, teleconsultations usually involve a doctor–patient relationship that is partly or wholly 'virtual', without the traditional face-to-face contact.

Q9 Your experiences

Have you used information technology to access individual health care 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?

Q10 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 health care 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 health care 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 health care?



¹³Department of Health (2005) *Building Telecare in England* (London: Department of Health), p.9.

Section 6: Body imaging

The main technologies considered here relate to computed tomography (CT) and magnetic resonance imaging (MRI). Similar to 'standard' X-ray technology, CT and MRI scans can provide non-invasive images of parts of the body that are not usually visible. CT and MRI are, however, more sophisticated in terms of resolution and level of detail and may reveal abnormalities indicative of disease processes (see Annex 3 for more information on body imaging techniques). Unlike MRI, CT scanning exposes an individual to a clinically significant dose of radiation, although the dose can vary depending on the type of scan, machine and methods used.

Within the NHS, CT and MRI are regularly used in the diagnosis of a number of specific diseases and conditions, such as pulmonary embolisms or various cancers. The test sensitivity is set quite high to avoid missing cases. This leads to relatively large numbers of false positives (where the test wrongly indicates that a person may have the disease in question) and the identification of benign abnormalities as potentially harmful.

Whereas body imaging is only provided through the NHS following referral from a GP, private body imaging is often performed without referral by a doctor, for example for the purposes of a 'check-up' and to provide a person-specific disease risk profile. Some providers offer so-called 'whole body' scans (see Annex 4 for more information on private body imaging services).



Section 7: DNA profiling

Genetic factors are known to affect susceptibility to many diseases. Advances in genetics are leading to improvements in understanding of both the relative importance of genetic factors for various diseases and predispositions, and also the associations between genes, diet and the environment. Recent technological developments have enabled scientists to analyse individuals' genetic make-up far more accurately, cheaply and quickly than before (see Annex 5). As in the case of body imaging, these services are frequently offered with the promise of profiling people's susceptibility to particular diseases in a way that helps them to be and stay healthy.

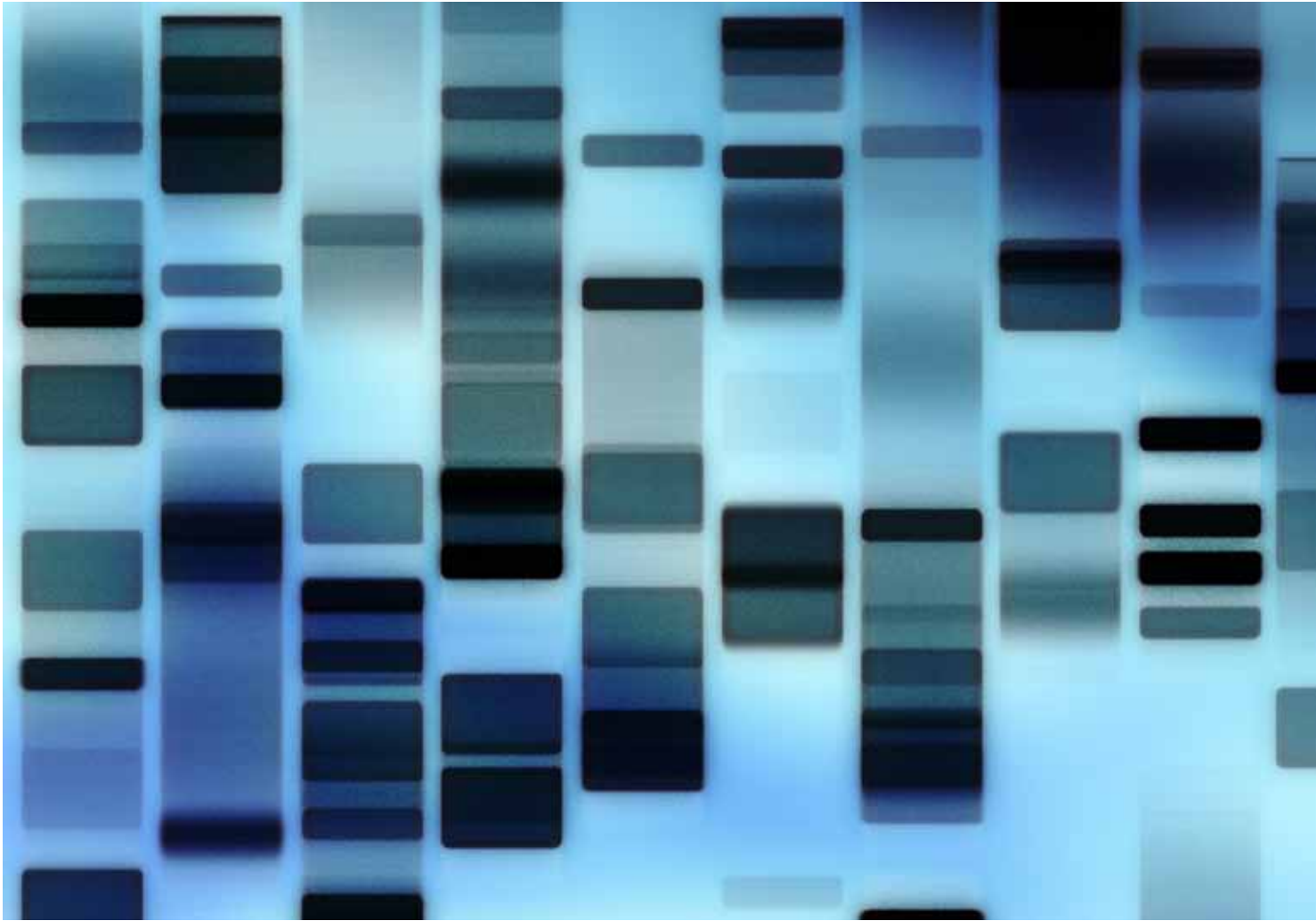
Some genetic variations indicate that an individual is highly likely or certain to develop a particular disorder. Most people are now familiar with the concept that single genes can often have dramatic consequences for people's health, as in the case of Huntington's disease. Many monogenic disorders, i.e. diseases resulting from mutation of single genes, have been identified, and DNA testing for diagnosis or prediction of these diseases already exists. The NHS, for example, offers some 300 different tests for such conditions, including cystic fibrosis.

Within the NHS, DNA tests for genetic disorders are only made available after evaluation by the UK Genetic Testing Network. This body assesses the test's analytic and clinical validity, its clinical utility, and the ethical, legal, and social implications. Analytical validity refers to the accuracy of the test in identifying the biomarker; clinical validity refers to the relationship between the biomarker and clinical status; and clinical utility measures the likelihood that the test will lead to an improved outcome for the test subject. The assessment is passed on to the Genetics Commissioning Advisory Group, which makes recommendations as to which tests should be provided by the NHS.

DNA profiling services offered by private providers are often marketed to people with no medical indications, and are not subject to the same assessment procedures. A journalist who submitted the same DNA sample to different companies found that there was considerable variation in the findings, and a scientific review concluded that the increased disease risk associated with the genes that the companies tested for had either not been sufficiently investigated or were "minimal to not significant" (see Annex 6). While the focus of most providers is on individualised health risk profiles, some companies additionally offer 'recreational genetics' services, such as ancestry and genealogy. Others, such as Genepartner,¹⁴ specialise in using genetic analysis to help people find a romantic partner or ascertain whether their children are likely to excel in particular sports, such as Atlas Sports Genetics.¹⁵ Profiling services are available directly to the individual through a number of companies based in Europe and the USA, mostly advertised and marketed via the internet (see Annex 5).

¹⁴ See: <http://genepartner.com/>.

¹⁵ See: <http://www.atlasgene.com/>.



Clients typically send a saliva or tissue sample, the DNA in which is then analysed either for specific biomarkers (variations in the genome which are associated with specific diseases), or to sequence the entire genome, depending on the service offered. Clients can usually access the results by logging on to protected sections of the companies' websites.

Some have called for statutory regulation of direct-to-consumer DNA profiling, and others, such as the PHG Foundation and the Royal College of Pathologists in a recent joint report,

for further consideration of how these tests should be regulated.¹⁶ The Human Genetics Commission (HGC) has recommended in its reports *Genes Direct*¹⁷ and *More Genes Direct*¹⁸ that "stricter controls on direct genetic testing"¹⁹ is desirable, but there should not be statutory prohibition of some, or all, direct genetic tests. Others maintain that the current regulatory system is satisfactory and that individuals cannot usually be harmed by the knowledge provided by multi-factorial DNA profiles (see Annex 7).

¹⁶ Furness P, Zimmern R, Wright C and Adams M (2008) *The Evaluation of Diagnostic Laboratory Tests and Complex Biomarkers* (London and Cambridge: Royal College of Pathologists and PHG Foundation), available at: www.phgfoundation.org/file/3998/.

¹⁷ Human Genetics Commission (2003) *Genes Direct*, available at: http://www.hgc.gov.uk/UploadDocs/DocPub/Document/genesdirect_full.pdf.

¹⁸ Human Genetics Commission (2007) *More Genes Direct*, available at: <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/More%20Genes%20Direct.pdf>.

¹⁹ *Ibid.*

Section 8: Body imaging and DNA profiling services: cross-cutting issues

DNA profiling and body imaging services differ in one sense, as the former generally aims to tell people what is likely to happen in the future, whereas the latter seek to tell them what diseases they already have. At the same time, the public and private use of these services raises common issues about the supply of information before and after using them, the quality and validity of the services themselves, and the regulation of such services.

There is currently insufficient evidence to assess whether or not CT scans are a cost-effective screening tool for reducing disease. But it is known that there can be significant harm associated with the use of CT scans, such as that caused by the radiation dose required or the identification of benign abnormalities which may lead to further unnecessary investigations. MRI scans have no radiation-related side effects but their sensitivity may entail high detection rates of false positives. In addition, some diseases are difficult to identify using MRI and in such cases a patient may wrongly believe they have been given the 'all-clear'. There is currently no specific regulation that applies to private providers of body imaging in the UK,²⁰ in contrast to the comprehensive testing regime that exists within the NHS. Some have even suggested that the use of MRI scans should be restricted to medical research.²¹

There is also lack of consensus about what information should be provided to customers by private DNA profiling companies before or after their services have been used (see Annex 7). Technology in this field is changing rapidly, and in the future it may be possible for people to use home DNA profiling kits that do not require an external provider. If so, it would give parents an opportunity to profile their children, raising questions about whether or how such a vulnerable group should be protected (for example, it might be argued that children should be given the option of deciding later in life whether they want to know or not know about their genetic susceptibilities to developing particular diseases). These services are also offered across national borders, meaning that regulation based on any one national jurisdiction may have limited effectiveness. Because of these issues, the HGC is currently working on a proposal for a Common Framework of Principles for Direct Genetic Tests,²² that it will recommend be implemented internationally.

²⁰ Wald NJ (2007) Screening: a step too far. A matter of concern *J Med Screen* **14**: 163–4.

²¹ Salman RA-S, Whiteley WN and Warlow C (2007) Screening using whole-body magnetic resonance imaging scanning: who wants an incidentaloma? *J Med Screen* **14**: 2–4.

²² See: <http://www.hgc.gov.uk/Client/Content.asp?ContentId=816>.

Q11 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?

Q12 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.

Q13 Responsibility for 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?

Q14 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...

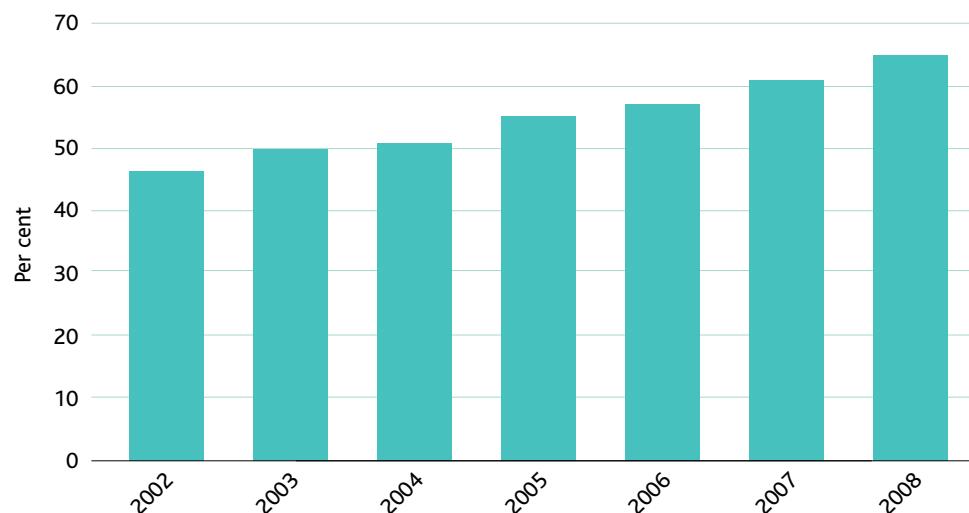
Is it sufficient to rely on the so-called 'buyer beware principle' in such cases, by putting the onus on the purchaser to find out about the quality and associated risks of the product they are buying?

Other issues

Q15 Are there any other issues we should consider?

Annex 1: UK internet usage statistics

Households with access to the Internet, Great Britain 2002-08



Internet activities of recent Internet users, by age groups, UK, 2008

	Age Groups					All
	16-24	25-44	45-54	55-64	65 plus	
<i>Per cent</i>						
Sending/receiving emails	91	87	85	86	89	87
Finding information about goods or services	77	87	86	85	75	84
Using services related to travel and accommodation	50	65	68	71	61	63
Downloading software	55	38	30	25	25	37
Reading or downloading online news, magazines	54	50	46	42	35	48
Looking for a job or sending a job application	35	33	18	11	..	25
Seeking health-related information	22	39	36	35	26	34
Internet banking	43	57	46	44	34	49
Selling of goods or services (e.g. via auctions)	17	24	17	14	..	19
Looking for information - education, training, courses	44	37	26	16	..	31
Consulting the internet with the purpose of learning	43	33	31	23	19	32

Source:

National Statistics *Internet Access 2008 Households and Individuals*, available at: <http://www.statistics.gov.uk/pdfdir/iah0808.pdf>, accessed on: 26 Mar 2009. Crown Copyright material is reproduced with the permission of the Controller, Office of Public Sector Information (OPSI)

Annex 2: Electronic health records – examples of service providers

Third party controlled records

Google Health²³ and Microsoft HealthVault Records²⁴ are examples of online health records services controlled by third parties. Google Health, which only offers full functionality for users within the USA,²⁵ aims to: "store and manage all of your health information in one central place", with the ability to "access your information anywhere, at any time". The advantage that is claimed for such services is that they enable individuals to build up a comprehensive personal health profile that can keep their doctors up-to-date; avoid repetitive paperwork and lab tests; ensure that medical records are not lost; and put individuals in control of their own health data.²⁶ Individual control of data is emphasised: "you are in control", "you manage your health information" and "your health information belongs to you".²⁷ Microsoft HealthVault is a similar system, although only

users in the USA can sign up for the service. Microsoft claims that "HealthVault offers you a way to store health information from many sources in one location, so that it's always organised and available to you online".²⁸

Health-service controlled records

The NHS Care Records Service²⁹ which, within the UK, has so far only been introduced in England on a trial basis, enables individuals' health data to be "shared between different clinicians, organisations and tiers of care",³⁰ in a variety of different forms. Records range from those designed to contain only basic demographic information to those containing extremely detailed clinical patient information intended to be shared across local health providers.³¹ The House of Commons Health Committee has suggested that the system will give patients "more control of their own healthcare."³²

Annex 3: Body imaging – how it works

CT scans use special X-ray equipment to gather image data from different angles around the body. Digital processing of this information produces cross-sectional images of body tissues and organs in either two- or three-dimensions.³³

MRI is defined by the American National Institutes of Health as "...a non-invasive test that creates detailed images of your organs and tissues".³⁴ MRI scans work by detecting the body's response to strong magnetic fields. Similarly to CT scans, computers are then used to construct visual images from the information gathered by the scan.³⁵

²³ See: <https://www.google.com/health/>.

²⁴ See: <http://www.healthvault.com/Personal/index.html>.

²⁵ Such as importing pre-existing electronic health records.

²⁶ Google (2008) About Google Health, available at: <http://www.google.com/intl/en-GB/health/about/>.

²⁷ *Ibid.*

²⁸ Microsoft (2008) What HealthVault can do for you, available at: <http://healthvault.com/personal/websites-overview.html>.

²⁹ See: <http://www.nhs.uk/healthcarerecords>.

³⁰ House of Commons Health Select Committee (2007) *The Electronic Patient Record – Sixth Report of Session 2006–2007* (London: The Stationery Office) p.18.

³¹ *Ibid.*, pp.18–19.

³² *Ibid.* p.3.

³³ Committee on Medical Aspects of Radiation in the Environment (COMARE) (2007) *Twelfth Report: The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals* (Didcot: Health Protection Agency), p.7, available at: <http://www.comare.org.uk/documents/COMARE12thReport.pdf>.

³⁴ National Institutes of Health (2007) *What is Cardiac MRI?*, available at: http://www.nhlbi.nih.gov/health/dci/Diseases/mri/mri_what.html.

³⁵ J Walton, JA Baroness and S Lock (Editors) (1994) *The Oxford Medical Companion* (Oxford University Press: New York) p.477.

Annex 4: Body imaging – example service providers³⁶

Company	Types of service	Risk information	Marketing	Example costs
European Scanning www.europeanscanning.com	Electron beam CT scan. MRI. Ultrasound.	Indirect mention of radiation risk, in context of statement that EBCT offers lowest risk.	"We all know that prevention is better than cure."	Not provided.
Lifescan www.lifescanuk.org	Range of CT scans. Virtual colonoscopy. Heart and lung scan. Bone density scan.	Some information on risks given on website.	"Spring is the time to give yourself an MOT with Lifescan", "Check you're as well as you feel."	£110 (Bone density scan) - £825 (Life Scan plus virtual colonoscopy).
Preventicum www.preventicum.co.uk	MRI scan of whole body. MRI of arteries, brain, colon, heart.	Risks of radiation and false positives given and debate surrounding clinical use of CT scans acknowledged.	"The most advanced and safest full body check-ups in the UK."	£2,150 (Preventicum Ultimate MRI) - £2,475 (Preventicum Ultimate Plus MRI).
Prescan www.prescan.co.uk	MRI and CT scan of whole body.	Some discussion of risks, false positives and false negatives.	"Prescan's Total Body Scan is rated with a 9 by Dr Thomas Stuttaford from The Times!"	£440 (MRI scan per body part) - £1,290 (Total Body Scan MRI and CT).

³⁶As of April 2009. Note that the information summarised here is not intended to provide an exhaustive description. Prices cited here aim to reflect the range of relevant services available and are not comparable. For further information please see the relevant company's websites.

Annex 5: DNA profiling – example service providers³⁷

Company	Types of service	Detail	Risk information	Marketing	Cost
Knome www.knome.com	Full genome sequencing.	"Although more resource-intensive, we use whole-genome sequence information as the basis of our analyses, instead of the SNP genotyping."	Provides "comprehensive analysis [of sequence] from a team of leading geneticists, clinicians and bioinformaticians". Clients schedule a meeting via the internet, which is followed by face-to-face consultations with a company representative and the scientists involved.	"Once your entire genome has been sequenced, you will be able to stay current on future genetic discoveries as they become available."	Prices quoted as varying between individual customers.
23andMe www.23andme.com	DNA variant profiling to provide: risks of various diseases and traits; and information about ancestry and family inheritance.	Around 550,000 DNA variants profiled. Raw data and analysis provided through personal online account. Information can be shared with linked friends and family (or others) by mutual agreement.	Provides web-based access to raw data, and information on risk of disease based on genetic profile, ethnicity and age. Risks provided as numerical and pictorial representation of odds ratios, and average odds ratio for someone of the same ethnicity and age.	"Genetics just got personal."	USD399 (£268).
Genetic Health www.genetic-health.co.uk	Various packages offered, each using DNA variants to check for genes associated with particular ranges of diseases/traits.	Each package genotypes different DNA variants.	Before and after the test, clients receive a consultation with a doctor at the company's London based clinic (telephone consultations also available).	"We can advise you how to create your own individual plan for cardiac disease prevention based on your results" [for cardiac test].	£180 (Pharmaco Gene)-£825 (Premium Male or Female).

Annex 6: Information provided by private DNA profiling services

The information provided by DNA profiling companies has been investigated both journalistically and academically. In one newspaper article,³⁸ a journalist approached several companies including: GeneticHealth (a UK firm), deCODEme (based in Iceland) and 23andMe (an American organisation), in order to compare their test results.

There was considerable variation in the way in which information was provided, and specific risk predictions also differed considerably. For example, deCODEme stated that the risk of developing exfoliation glaucoma for the individual being profiled was 91 per cent below average, while 23andMe claimed the risk was 3.6 times more likely than average. In the case of heart problems, deCODEme quoted a risk of

a heart attack, angina or sudden cardiac death at 54.8 per cent, or 6 per cent above average, while 23andMe claimed the risk of a heart attack between the ages of 45 and 84 for the individual concerned was 17.5 per cent below average.

In early 2008 a scientific review of tests offered by seven companies was published. The review assessed the evidence supporting the purported associations between genes and diseases. It concluded that the increased disease risk associated with the genes that the companies tested for had either not been sufficiently investigated or were "minimal to not significant". In addition, the review warned that "those with 'low-risk' profiles could be led to mistakenly believe that they have little need to make health lifestyle changes."³⁹

³⁷ As of April 2009. Note that the information summarised here is not intended to provide an exhaustive description. Prices cited here aim to reflect the range of relevant services available and are not comparable. For further information please see the relevant company's websites.

³⁸ Fleming N (2008) Rival genetic tests leave buyers confused *The Times* 07 September.

³⁹ Janssens ACJW, Gwinn M, Bradley LA, Oostra BA, van Diujn CM and Khoury MJ (2008) A critical appraisal of the scientific basis of commercial genomic profiles used to assess health risks and personalise health interventions *Am J Hum Gen* 82: 593–9.

Annex 7:

Regulation of DNA profiling and body imaging services

DNA testing

In the UK, medical DNA tests are governed by the European Union In Vitro Diagnostic Devices (IVDD) Directive.⁴⁰ The Medicines and Healthcare products Regulatory Agency (MHRA) ensures compliance.⁴¹

The IVDD Directive applies only to devices for medical purposes.⁴² The majority of DNA tests are currently placed in 'Category 1', the low risk category. Tests for phenylketonuria, HLA tissue type and Down's syndrome are classed as high risk, although no new genetic tests have been added to the high risk category since the publication of the Directive in 1998. For low risk tests, the HGC's report, *More Genes Direct*, notes that "no independent evaluation of manufacturers' claims is required",⁴³ i.e. no regulatory approval is required prior to the test being placed on the market.

The exact scope of the term 'medical' in this context is not clear. The MHRA has indicated that 'lifestyle' tests, for example a test that purports to explain how well a person's metabolism deals with alcohol,⁴⁴ are not medical in nature.

The marketing and advertising of genetic tests in the UK is regulated by a number of bodies, including the Advertising Standards Agency (ASA), the Office of Fair Trading (OFT) and the Office of Communications (Ofcom).

The ASA administers the British Advertising Codes. These codes are the responsibility of an industry body, the Committee of Advertising Practice, but are independently administered by the ASA.⁴⁵ The ASA requires that an advertisement be "capable of objective substantiation", and not be misleading.⁴⁶ The ASA only responds to complaints, and does not generally carry out investigations on its own initiative. There are a variety of sanctions available, including preventing the advertiser from continuing to use the advert in question, publishing the decision on the ASA website or referring the publisher of the advert to Ofcom or

the advertiser to the OFT.⁴⁷ Where a complaint concerns a device such as a genetic test, both the ASA and the OFT have stated that they would be likely to consult with the MHRA for further advice.⁴⁸

In terms of internet advertising, the ASA is restricted to considering advertisements in 'paid' space (i.e. those search results that appear as a result of the company in question paying the search engine provider) and not any claims made on their own websites. In those cases, the issue is the responsibility of the local Trading Standards Office.

Body imaging

The Ionising Radiation (Medical Exposure) Regulations 2000 require that all individual medical radiation exposures (such as from a CT scan) must provide sufficient benefit to offset any harm done, and exposures should be kept as low as reasonably practical.

However, there is no general regulatory framework applicable to private providers of body imaging services, in the same way that the National Screening Committee (NSC) regulates the public sector in the UK, although it has been suggested that this would be desirable.⁴⁹

A government advisory panel published in 2007 a report into the impact of personally initiated CT scanning for the health assessment of asymptomatic individuals. The panel, the Committee on Medical Aspects of Radiation in the Environment, reports that there is insufficient evidence to justify the use of medical exposure for 'whole body scans', and recommends that "services offering whole body CT scanning of asymptomatic individuals should stop doing so immediately", while those that offer scans for regions of the body should in the advertising "clearly state which regions are examined and for which conditions the scan is optimised".⁵⁰

⁴⁰ Directive 98/79/EC.

⁴¹ Human Genetics Commission (2007) *More Genes Direct*, p.11.

⁴² Articles 1 and 2(a) Directive 98/79/EC.

⁴³ Human Genetics Commission (2007) *More Genes Direct*, p.16.

⁴⁴ Human Genetics Commission (2003) *Genes Direct*, p.23.

⁴⁵ The codes can be read in full at <http://www.cap.org.uk/cap/codes/>.

⁴⁶ Advertising Standards Authority *Advertising Under Control*, available at: <http://www.asa.org.uk/asa/about/control/>.

⁴⁷ *Ibid.*

⁴⁸ Human Genetics Commission (2007) *More Genes Direct*, p.13.

⁴⁹ Wald NJ (2007) Screening: a step too far. A matter of concern *J Med Screen* 14: 163–4; Sense About Science (2008) *Making sense of testing* (London: Sense About Science).

⁵⁰ Committee on Medical Aspects of Radiation in the Environment (COMARE) (2007) *Twelfth Report: The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals* (Didcot: Health Protection Agency), pp.1–83, p.52.

