



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

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

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3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

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Foreword

In the two years or so that it took to write this report, news media continually threw up stories about new ways of getting access to health information and services online. Many news items emerged as well about developments in testing and scanning technologies that held out the promise of far greater ability to predict susceptibility to disease and even length of life than any earlier generation had known.¹ And those two developments are linked in the kinds of tests that operate largely online, such as genetic testing whose only non-virtual element is that of the buyer taking a saliva sample and mailing it off to be tested.

What are we to make of this brave new world? Some are entranced by the prospect of encounters with the healthcare system that increasingly take place online and that embrace an ever-expanding array of tests, scans and complex interactive communications systems. Powerful claims about the ability of such developments to transform and indeed extend our lives are made by enthusiastic researchers and companies in the forefront of those changes. But others see those developments in a much less attractive light, as meaning ever-greater medical penetration of everyone's lives, with new forms of testing and scanning leading either to a medical variant of the Calvinist doctrine of predestination or to more and more health anxiety, or both. Egalitarians will worry that more individualised predictive testing could threaten the 'risk pooling' embodied in traditional public welfare systems, while individualists will fear the opposite outcome, namely that such individualised prediction could lead to the collapse of established systems of private health insurance, such that 'socialised medicine' expands rather than contracts. Others worry about the greater medicalisation of human life that goes along with ever-more scanning and testing and online health activity. They fear a world resembling that of Jules Romains' egregious Dr Knock, for whom (long before today's ideas about so-called personalised medicine) healthcare was to be considered as a form of religion² and whose academic thesis 'On Imagined States of Health' took for its epigraph the statement: 'Those who are well are sick people who don't know it'.³ And there are other people who firmly take the more fatalistic view epitomised by the Roman poet Horace whose famous motto *carpe diem* sums up the argument that it is better to live for the present than to try to foresee the future.⁴

The view we have generally taken in this report is that these developments may indeed have the potential radically to transform healthcare, but that potential has yet to be realised. Of the idea of personalised healthcare, it could almost be said that 'Only the future is certain. The past is always changing,'⁵ since bold visions of the ability of new technology to bring about a new era of personalised, predictive and preventive medicine have been canvassed for nearly two decades now. Perhaps we are still seeing the smoke of a fire that has not yet really kindled.⁶ But even if the information and power to take control of our health afforded by these developments does indeed turn out to be the modern equivalent of Apollo's gift of prophecy to Cassandra in classical mythology, it must be recalled that such gifts have their accompanying problems and ethical challenges. In this case, they raise challenging issues of how far the principle of 'consumerism' can properly be carried in healthcare, and what responsibilities individuals should take for their health and healthcare. Some

¹ For example, over the course of the Working Party's two-year lifespan, there were about 300 news stories in the Anglophone press and journals alone that were significant and highly relevant to the main themes of our report. That number would certainly rise into the thousands if we included all the news stories and journal articles across the world that were concerned with body imaging, genetic profiling and accessing health information and services online.

² Requiring 'confession' and commitment to the spread of '*l'esprit pharmaco-médical*'.

³ '*Les gens bien-portants sont des malades qui s'ignorent*,' ludicrously attributed to the experimental physiologist Claude Bernard. See: Romains J (Louis Farigoule) (1973) *Knock ou le triomphe de la médecine* Alton JB (Editor) (London: Longman), p39.

⁴ 'Tu ne quaesieris – scire nefas – quem mihi, quem tibi finem di dederint...Sapias, vina liques, et spatio brevi spem longam reseces...carpe diem, quam minimum credula postero' Horace, *Odes* 1.11.

⁵ In Paul Flynn's epigram, coined in a quite different context: Flynn P (1999) *Dragons Led by Poodles* (London: Politico's), p24.

⁶ *An mac air an spàrr, 's a mhàthair gun bhreith* ('the son on the roost and the mother unborn'), in the words of the Gaelic proverb.

people think there are long-term trends in modern societies towards ever-greater 'consumerisation' and 'responsibilisation'; but whether or not you believe that (the evidence is contestable), there are certainly some perplexing ethical challenges represented by the new issues of consumer choice and personal responsibility that are raised by the emerging world of medical profiling and online medicine.

Writing this report has been a lengthy and arduous job, during which many tricky issues had to be thought through, and I would like to thank all those who helped to produce this document: the members of the Working Party, the Council, the secretariat, particularly Caroline Rogers, Tom Finnegan and Harald Schmidt, those who responded to our consultation document, and those who came to our fact-finding meetings or responded to our various queries.

A handwritten signature in black ink that reads "Christopher C. Hood". The script is cursive and fluid, with the first name being the most prominent.

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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.

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Executive summary

Introduction (Chapter 1)

This report is concerned with a number of new developments in medical profiling and online medicine that are claimed by some to herald a new era of ‘personalised healthcare’. We aim to explore this bold claim, what it might mean, and what the ethical implications of such developments could be. By ‘medical profiling’ we mean new services offering direct-to-consumer body imaging as a health check and personal genetic profiling for individual susceptibility to disease. By ‘online medicine’ we mean developments in digital technology, largely involving the internet, that offer new ways for individuals to obtain and share health advice, diagnosis and medication, and that provide new possibilities for storing, accessing and sharing health records, monitoring individuals’ health status and communicating with health professionals and other patients.

These developments can give individuals increased choice and control over their health. Some may provide reassurance that we are healthy, or detect disease at an earlier stage. But they may also create needless confusion or anxiety, lead to unnecessary invasive procedures that carry additional risks or create ethical dilemmas for society. We look at the benefits and harms promised by all these new applications, propose a set of ethical values, and make recommendations based on our ethical framework targeted at government, healthcare services, healthcare professionals and professional bodies and the providers of these new services.

Given the widespread discussion of and claims made for ‘personalised healthcare’, we examine the idea of personalisation and identify at least four different meanings of the term.

The social context (Chapter 2)

This chapter focuses on two key social pressures extending beyond healthcare which present ethical challenges for the developments we are considering, and which feature to a greater or lesser extent in all of the case studies we investigate. Those two themes are (1) what has been termed ‘responsibilisation’, namely social and policy pressures for a shift in the balance of responsibility between individuals on the one hand and collective bodies and professionals on the other hand; and (2) ‘consumerisation’, namely social and policy pressures for a shift in the style of service provision towards greater emphasis on consumer-style relationships between providers and users as against those relationships based on citizenship or the fiduciary relationship between professional and client.

Ethics (Chapter 3)

We propose five ethical values that we see as important for governing policy and practice for the developments considered in this report. Those values are (1) private information ought to be safeguarded (2) individuals should be able to pursue their own interests in their own way (3) the state in its various organisational forms should act to reduce harm (4) public resources should be used fairly and efficiently; and (5) the value of social solidarity – pooling of risks and sharing of responsibility that protects the vulnerable – in informing public policy.

We argue that for each case study we consider (1) these ethical values conflict with one another; (2) no one of these values automatically trumps the others as a basis for good practice or for intervention by the state or other third parties; and (3) the appropriate ethical approach is therefore to examine each of the developments under consideration in its context with the aim of achieving as many as possible of all the conflicting ethical values. We call this a ‘softening dilemmas’ approach.

Intervention (Chapter 4)

Governments and third parties can intervene in various ways to guide developments such as those we consider in this report. We distinguish here between (1) interventions that involve formal state-specific powers of coercion and those that do not; and (2) interventions that are specific to the product or

service and those that are more general in their application (for example general professional codes or rules about data protection).

We argue that (1) less coercive interventions should be preferred to more coercive ones, unless the degree of harm in a particular case justifies the latter (on the ‘proportionality’ principle); (2) more general forms of intervention are often preferable to more service- or product-specific ones, particularly where technology is rapidly changing and specific rules can quickly become outdated; and (3) intervention must be shown to be feasible and to reflect a measure of consensus about the evidence of the harms involved and the actions to be taken.

Case studies (Chapters 5–10)

We consider six case studies, summarising the current evidence of benefits and harms and extent of use and describing the current system of interventions, focusing on the UK but broadening the discussion to other countries where appropriate. We also make a series of recommendations in each chapter (see below).

Online health information (Chapter 5): People increasingly search for, exchange and post health information online. Some of this activity is an extension or new formatting of the types of information long provided by newspapers or magazines, but the existence of search engines and group networking sites opens up new possibilities, and raises the issue of how people can ensure they are receiving good quality, validated information. (Recommendations 1-8 in Appendix 1)

Online personal health records (Chapter 6): Healthcare systems and companies now offer personal online health record systems that individuals can access, edit and share with others. Such record systems involve capabilities very different from those available in traditional paper-based records, but raise questions about how the data involved is to be used and how it can be kept secure. (Recommendations 9-13 in Appendix 1)

Online purchasing of pharmaceuticals (Chapter 7): People can now buy medicines (or products sold as such) online, including many products that are prescription-only or otherwise restricted in the UK and other countries. While in the past similar purchases might have been made via mail order or in other unofficial ways, the internet brings a new dimension to such activity and raises questions about how harm can be prevented from injudicious purchases or from purchases of fake medicines. (Recommendations 14-19 in Appendix 1)

Telemedicine (Chapter 8): Telemedicine, the provision of healthcare over a distance, has extended and developed in recent years along with new information and communication technologies. It provides new forms of interaction between patients and healthcare professionals and new possibilities for health monitoring and even delivery of treatment, but also raises questions about how far telemedicine should replace traditional forms of healthcare and about liability for adverse events. (Recommendations 20-29 in Appendix 1)

Personal genetic profiling for disease susceptibility (Chapter 9): Several companies now analyse customers’ DNA to assess their personal genetic susceptibility to various health risks. Some types of genetic analysis are now readily affordable for middle-income consumers, but this development raises questions about the quality of the information offered, who should bear the costs of interpretation and follow-ups, who should be tested and what the consequences of testing should be for risk-pooling in healthcare. (Recommendations 30-37 in Appendix 1)

Direct-to-consumer body imaging (Chapter 10): Body imaging technologies that have been used for some time in healthcare for diagnosis have also in the last few years been used in new services offering body imaging directly to people who do not necessarily have any medical symptoms, as a form of ‘health check-up’. These services offer new forms of health information, but they also raise questions similar to those noted for genetic profiling, and involve some other risks as well in some cases. (Recommendations 38-45 in Appendix 1)

Future impact

The technologies and developments with which we are concerned here are still developing, but if they realise their full potential they could transform medical practice in important ways. Their future trajectory and application is hard to assess, but at least some and perhaps all may become more frequently used in the future. Should more evidence emerge about actual and serious harms being caused directly from the developments we consider, more intrusive interventions than those we have recommended in this report would be justified to reduce harm and protect vulnerable people.

Recommendations: key themes

A full list of recommendations is given in Appendix 1. Some of the key themes are introduced below:

Digital divide

Many people treat the internet as a first, or at least a major, source of information and communication. Public services and private firms increasingly offer information and their products and services online, some operate only online and many others make it much more costly and difficult for people not able or willing to operate online. As with all such developments, those who cannot or who do not want to use such technology run the risk of becoming 'second class citizens' in various ways. That is why we think governments should monitor the social impacts of the 'digital divide', and why health service providers should take into account the needs of vulnerable people. There may be cases when the new services outlined in this report have the potential to reduce inequities in healthcare and these should be explored by healthcare providers.

Good practice

The way information about the services covered in this report is presented to the public often falls short of what we think is good practice. Consumers need good information to judge what they should use or buy and what the implications for them are. In Appendix 2 we offer a 'Good practice guideline' for the providers of medical profiling and online medical services, aimed at fostering a climate in which more providers of these services follow good practice and more users come to expect such practice.

Lack of evidence

Systematic evidence is often and rightly said to be the basis of good public policy, but for many of the areas covered here there is a marked lack of evidence about the extent to which the services are being used and what benefits and harms they entail. Part of the reason for this lack of evidence is that commercial confidentiality is often involved, as well as the fact that the services are fairly new. The lack of evidence leads us generally to recommend continued surveillance, research and increased vigilance on the part of governments and regulators.

State provision of information

As well as voluntary good practice measures of the type mentioned above, we think that in the new world of medical profiling and online healthcare, governments have a vital role to play in ensuring the availability of high-quality independent information about the various developments and services covered in this report, including their relevance for personal insurance where appropriate.

Good professional medical practice

Healthcare professionals are already being asked about information that their patients find online or direct-to-consumer tests that they are considering taking or have already taken, and it is very likely that they will need to respond to more such requests in the future. That is why the organisations responsible for training healthcare professionals and setting professional standards should train and advise professionals to adapt their practice to cater for these new circumstances. This adaptation might include recognising the value of such developments as a tool for discussing healthier lifestyles, advice on how to deal with the limitations of the information produced, and giving guidance over how to be responsible in referring patients for specialist services.

Accreditation

Accreditation is not without its limitations or critics, but good accreditation schemes can provide a further source of information for users and consumers. That is why we recommend criteria for accreditation schemes that certify online health information and also recommend that accreditation for online personal health record systems should be introduced by publicly-funded healthcare services.

Protection from serious harm

Though, as mentioned above, evidence about the benefits and harms of the developments in this report is often lacking, in several cases we are sufficiently concerned about the seriousness of potential harms to recommend more coercive forms of intervention, as follows:

Online purchasing of pharmaceuticals

- Governments should introduce (or continue) quality control process for online sellers of pharmaceuticals, or products sold as such.
- Governments should set and enforce regulations relating to the supply of antibiotics.

Personal genetic profiling for individual susceptibility to disease

- Responsible authorities should request evidence for the clinical claims made by companies.
- Firms should not knowingly analyse the DNA of children unless the requirement of clinical validity is met.

Direct-to-consumer body imaging

- We think the radiological risk that arises from full-body CT scans is sufficient to justify a ban on the provision of such services. Part-body CT scans should take place only if they are in the best interests of the customer.

Conclusions (Chapter 11)

Personalisation: All of the developments considered here offer increased personalisation to some extent, but many of the claims for more individualised diagnosis and treatment seem to be overstated and so should be treated with caution, at least at present. Nor do we think ‘personalisation’ is, as often portrayed, an unalloyed good. We think it requires careful development of policy and practice to reap the maximum benefits from technological advances while minimising harms.

Consumerisation: All the developments considered here can lend themselves to the provision of healthcare as a consumer good, or at least offer more ‘consumerised’ aspects. We think choice is often a good thing, but to be exercised effectively in the context of healthcare it requires appropriate information and advice. Moreover, we need to find ways of balancing individual choice with the necessity of ensuring equity among the population as a whole, given that further consumerisation in healthcare could threaten the principle of sharing the financial risks of healthcare.

Responsibilisation: The scope and proper limits of ‘responsibilisation’ are particularly hard to determine in healthcare, but we think the general principle is that responsibility for handling risk should be placed in the hands of those best placed to manage it because of the knowledge or other resources available to them. In some cases the party best placed to manage that risk is the state, in some cases the medical professional, and in other cases the individual.

Chapter 1

Introduction

Chapter 1 – Introduction

Developments in medical profiling and online medicine: their implications for healthcare

- 1.1 This report is concerned with a number of new developments in medical profiling and online medicine that are commonly said to herald a new era of ‘personalised healthcare’. We aim to explore whether that bold claim is true, what it might mean, and what the ethical implications of such developments may be. By ‘medical profiling’ we mean new services offering direct-to-consumer body imaging (such as CT and MRI scans) as a health check and personal genetic profiling for individual susceptibility to disease. By ‘online medicine’ we mean developments in digital technology, largely involving the internet, that offer new ways for individuals to obtain and share health advice, diagnosis and medication, and that provide new possibilities for storing, accessing and sharing health records, monitoring individuals’ health status and communicating with health professionals and other patients.⁷
- 1.2 The developments we consider reflect major advances in genetic research, imaging technology and information technology (IT), of which the most familiar is the internet. Increasing numbers of people have internet access in their own homes and via mobile devices such as smartphones. Many people treat the internet as a first, or at least a major, source of information and increasingly communicate online. Public services and private companies increasingly offer information and their products and services online, some operate only online and many others make it considerably more costly and difficult for people not able or willing to operate online. Public policy in the UK and elsewhere has sought to encourage a switch to a ‘digital’ society and economy, with ‘e-health’ and internet-based health services sometimes cited as one of the benefits of such a switch.⁸ But as with all such developments, those who cannot or who do not want to use such technology run the risk of becoming ‘second class citizens’ in various ways, and there is also the risk that such technologies can be used to intrude on people’s privacy in ways that may be unwelcome or not fully understood. Given that (as we shall see later) many of the heaviest users of healthcare services are older people,⁹ fewer of whom are online at home than younger people,¹⁰ such risks cannot be dismissed.
- 1.3 We are by no means the first to comment on such developments, and others have interpreted the changes in various ways. As we shall see later, their champions see them as paving the way to a revolution in healthcare that will transform many people’s lives for the better as a result of the greater possibilities they bring for individualised diagnosis and treatment, and for empowering individuals over matters of health and healthcare. Sceptics, on the other hand, might see some of the ways in which these technologies are currently being taken up as ‘fads’¹¹

⁷ Some of these activities are included under the broad term ‘telemedicine’. We had lengthy debates over whether telemedicine belonged with the other topics we consider, but decided that its reliance on telecommunications, particularly the internet, and the promises of increased personalisation being made about it (such as increasingly individualised diagnosis, increased and more convenient access to healthcare professionals) meant that it merited inclusion in our investigation.

⁸ For example, ‘e-healthcare in the home’ and ‘internet based health services [that] can offer greater detail and information about healthy eating, dieting, exercise diagnosis, treatment and recovery’ are among the applications mentioned in a major 2009 UK report on the development of ‘next generation broadband’ (that is, higher-speed internet access technology). See: Department of Culture, Media and Sport and Department for Business, Innovation and Skills (2009) *Digital Britain – final report*, available at: <http://www.culture.gov.uk/images/publications/digitalbritain-finalreport-jun09.pdf>.

⁹ For example, a 2010 document by the Department of Health for England stated that 65% of NHS spending went on those aged over 65. See: Department of Health (2010) *Improving care and saving money – learning the lessons on prevention and early intervention for older people*, p4, available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_111222.pdf.

¹⁰ See, for example: National Statistics (2008) *Internet access 2008 – households and individuals*, p5, available at: <http://www.statistics.gov.uk/pdfdir/iah0808.pdf>; Department of Communities and Local Government (2008) *Understanding digital exclusion: Research report*, p26, available at: <http://www.communities.gov.uk/documents/communities/pdf/1000404.pdf>.

¹¹ A term used by Theodore Marmor to refer to “enthusiasms for particular ideas or practices” (although in a different context). Marmor T (2007) *Fads, fallacies and foolishness in medical care management and policy* (Singapore: World Scientific Publishing Company), p1.

or at least changes that are greatly over-hyped by their champions, and whose long-term usefulness may fall far short of what has been promised. Our view is that, whatever the long-term effect of these developments may be, the speed at which they are currently being developed and the nature of the ethical issues they raise, mean that they merit serious attention.

- 1.4 Table 1.1 summarises the main developments with which we are concerned (some offered by public healthcare systems, some by commercial companies and some by both) and illustrates the new possibilities they present for healthcare. It contrasts these possibilities with the methods used before the advent of these new technologies.¹²

Table 1.1: Traditional methods and new possibilities for five aspects of healthcare presented by medical profiling and online medicine

Aspect of healthcare	Traditional method	New possibilities
Seeking health information	Consultation with family doctor or general practitioner; newspapers or magazines; informal experience of family or friends.	Use of online search engines; quality-assured websites; other websites that mix advertising with information; exchanges with others with same condition in online communities; user-generated content reference sites.
Records of health history and status	Hospital or general practitioner records, traditionally in paper form, non-interactive and, until the widespread enactment of data protection laws in the 1990s, often not directly available to the patient.	Use of online personal health record facilities accessible to and in some cases managed and/or modifiable by individuals to keep all of their data in one place, capable of automatically alerting pharmacists, patients or healthcare professionals to new discoveries, developments and products and potentially easily usable for research.
Obtaining medication	Prescription by medical professionals and medication obtained in person or by mail.	Pharmaceuticals available to purchase directly by users via the internet and in some cases through online prescription by health professionals.
Various aspects of diagnosis, health monitoring and management	Travel to and receiving care within hospitals or medical centres; for those in remote and inaccessible locations, use of radio, telephone or other forms of communication.	Use of online or other modern information communication technologies (ICT) for remote consultations, diagnosis, monitoring of health status indicators or of patient activities, drug delivery and some other forms of treatment.
Imaging and genetic testing	Reference to a specialist on the basis of symptoms and risk by family doctor or general practitioner (also with the possibility of genetic counselling in the more recent past).	Individual purchase of directly-marketed imaging and genetic testing products that are delivered on demand as a commercial product.

¹² We recognise that the technologies we focus on are mostly available more widely in developed countries.

- 1.5 All the developments illustrated in Table 1.1 have the potential for changing the relationship between individuals and healthcare providers, in particular by making it increasingly possible (and in some cases expected) for people to get access to information, diagnosis and medication without going through a primary healthcare provider,¹³ and to take more individual responsibility for the management of their healthcare and health records. That is why the ethical issues surrounding consumer behaviour and responsibility are central concerns for us in this report, since some believe that such developments can damage traditional medical professionalism and the doctor-patient relationship.¹⁴
- 1.6 In addition, several of the developments have the potential to create information that, when aggregated in a particular way, can be used to benefit research and public health purposes, or for improving the prognosis of individuals who have not themselves taken the various tests available or lodged health records online. Equally, several of these developments have the potential for introducing extra indirect ‘spillover’ costs and benefits to publicly-funded healthcare systems. It is for these reasons that the collective as well as the individual dimension of these new developments needs to be considered.

Potential benefits of medical profiling and online medicine

- 1.7 Many of the technological advances behind the developments we describe above are already being used to transform healthcare in positive ways that deserve to be fostered and encouraged, and there is some survey evidence that indicates substantial numbers of respondents expressing an interest in utilising predictive genetic testing technologies.¹⁵ More accurate and less invasive forms of imaging than were previously possible can allow us to identify disease earlier and treat it more promptly and effectively in ways that can save lives and improve people’s quality of life. Established genetics services are offered by the National Health Service (NHS) in the UK and other healthcare systems and are of proven value for analysing a person’s risk of certain conditions and detecting rare but collectively numerous genetic disorders.¹⁶ Such developments have created new possibilities for identifying means of prevention or lifestyle changes that can reduce the likelihood or severity of disease. Genetic tests also create possibilities for identifying individual reactions to medication in ways that can make drug treatments more effective, an issue the Nuffield Council has discussed in a separate report.¹⁷
- 1.8 When it comes to online medicine, as has already been mentioned, the rising use of the internet and digital technology creates possibilities for people to obtain information, diagnosis and medication with greater convenience, privacy and in some cases at lower cost than before.¹⁸ Services can be accessed at times or places that suit people’s specific needs. Such technological applications can empower patients and their families relative to healthcare professionals, and can also increase their health literacy, for example by online dialogue with

¹³ A family doctor, general practitioner or personal physician.

¹⁴ For a discussion, see: Royal College of Physicians (2005) *Doctors in society: Medical professionalism in a changing world*, available at: <http://www.rcplondon.ac.uk/pubs/books/docinsoc/docinsoc.pdf>.

¹⁵ See, for example: McGuire AL, Diaz CM, Wang T and Hilsenbeck SG (2009) Social networkers’ attitudes toward direct-to-consumer personal genome testing *American Journal of Bioethics* **9(6–7)**: 3–10; Wilde A, Meiser B, Mitchell PB and Schofield PR (2010) Public interest in predictive genetic testing including direct-to-consumer testing, for susceptibility to major depression: Preliminary findings *European Journal of Human Genetics* **18**: 47–51; Buckmaster AM and Gallagher P (2009) Experiences of and perspectives on genetic testing for breast ovarian cancer in and outside the customary clinical setting *Psychology and Health* **iFirst**: 1–19; Laegsgaard MM and Mors (2008) Psychiatric genetic testing: Attitudes and intentions among future users and providers *American Journal of Medical Genetics Part B (Neuropsychiatric Genetics)* **147B**: 375–84; Priest SH (2000) US public opinion divided over biotechnology? *Nature Biotechnology* **18**: 939–42; Trippitelli CL, Jamison KR, Folstein MF, Bartko JJ and DePaulo JR (1998) Pilot study on patients’ and spouses’ attitudes toward potential genetic testing for bipolar disorder *American Journal of Psychiatry* **155(7)**: 899–904; Andrykowski MA, Munn RK and Studts JL (1996) Interest in learning of personal genetic risk for cancer – a general population survey *Preventative Medicine* **25**: 527–36.

¹⁶ We note that testing for genetic diseases does not always involve a genetic test but may use an indirect test such as the presence or absence of a substance in a person’s blood.

¹⁷ See: Paragraph 1.13.

¹⁸ See: Paragraphs 5.27–5.31 for information on the proportion of people in different countries who have access to the internet and other details about internet use.

and mutual support from others with the same or similar conditions that can not only help to overcome feelings of isolation but provide exchanges of experience about medication and treatment. New technologies can transform medical record keeping, enabling information to be used in far more sophisticated ways than was possible in an older era of paper files, for example by linking directly with pharmacies or triggering alerts about new discoveries in the relevant field of medical science. A further possible benefit is the extra accuracy of health records that can result if the individuals concerned are readily able to check those records. Telemedicine has also made it possible for individuals' health and for their health status to be monitored in their homes without the need for high-cost and stressful travel and hospital facilities. These potential benefits are exciting and promising.

Potential harms

- 1.9 Some of these technologies are being used in applications and settings that are more controversial: doubts have been raised about how useful they are, as well as concerns about the risks of harm they present. Issues relating to these technologies have attracted attention from several official bodies as well as healthcare experts and scientists.¹⁹ For example, some of the new forms of body imaging and DNA risk analysis for common diseases promoted or offered directly to consumers by commercial companies (without a clinical assessment of symptoms and risk) can produce results that are unclear, unreliable or inaccurate – producing false negatives or, more commonly, false positives,²⁰ thereby creating needless confusion or anxiety.²¹ Some of these analyses and scans may be medically or therapeutically meaningless, or of doubtful clinical validity and utility.²² They may not be appropriate for the person being tested. In some circumstances they may even lead to negative effects on people's health through unnecessary surgery or other interventions. By bypassing family doctors, general practitioners or other gatekeepers (such as clinical geneticists), individuals may be insufficiently aware of potentially negative consequences (for instance in insurability) that may follow from undertaking such predictive analyses. Those who choose to bypass the traditional gatekeepers often do not have the benefit of any independent view, free from commercial conflicts of interest, of their health; of whether such tests and scans are likely to be worthwhile; and of the therapeutic options (or lack of them) if a specific condition (or the risk of a specific condition) is indicated. Health and even lives may be put at risk and extra stresses and costs laid on family doctors or public healthcare systems, as a result of individuals purchasing drugs, tests or scans without prescriptions or medical advice. Similarly, reliance by doctors on online personal health records created and/or edited by the patient would have the potential to compromise clinical standards and create vexed issues of legal liability for adverse outcomes. The potential also exists for physical, psychological and possibly financial harms to arise from people accessing

¹⁹ See: House of Lords Science and Technology Committee (2009) *Science and Technology Committee 2nd report of session 2008–2009: Genomic medicine – volume one: Report*, available at: <http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf> (e.g. the recommendations on the evaluation and regulation of genetic and genomic tests developed outside of the NHS (p81) and on direct-to-consumer tests (p85–86); Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>; Human Genetics Commission (2003) *Genes direct*, available at: http://www.hgc.gov.uk/UploadDocs/DocPub/Document/genesdirect_full.pdf; Human Genetics Commission (2007) *More genes direct*, available at: <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/More%20Genes%20Direct%20-%20final.pdf>; Human Genetics Commission (2009) *A common framework of principles for direct-to-consumer genetic testing services – principles and consultation questions*, available at: <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/Principles%20consultation%20final.pdf>; Juengst ET (2009) Working Party's joint workshop with the Harvard University Program in Ethics and Health; Aldhous P (2009) How I felt when my hacked genome was read *New Scientist* [internet blog] 26 March, available at: <http://www.newscientist.com/blogs/shortsharpscience/2009/03/how-i-felt-when-my-genome-was.html>; Goldstein DB (2010) 2020 Visions – personalized medicine *Nature* **463**: 27.

²⁰ Falsely identifying people to be at increased risk of diseases or other health risks.

²¹ We recognise that anxiety may be a rational and appropriate response to the result of diagnostic tests; we are referring here to anxiety that is the result of an inaccurate or misleading result.

²² By clinical validity we mean: how well the test results are able to detect or predict the associated disorder. By clinical utility we mean: the clinical relevance and meaningfulness of information provided.

poor quality, inaccurate or misleading health information on the internet, or from avoiding seeking medical attention as a result of feeling falsely reassured by the information they have found. New methods of monitoring patients in their homes may tempt hard-pressed healthcare providers into early discharge of patients putting high stress on those individuals or their carers. Those negative possibilities merit some attention as well.

Ethical issues

1.10 As stated earlier, our report is concerned with ethical issues involved in the application of the new forms of medical profiling and online medicine we consider. By ethical issues we mean the difficult moral questions that arise which require individuals, organisations, companies and the state to evaluate and choose between alternatives. In Chapter 3, we set out the ethical values that we see as important for the developments considered in this report and in Chapter 4 we link that to a discussion of how to choose among different forms of intervention. In the case study chapters that follow we go on to explore how, based on those ethical values, the various public and private actors involved should respond to these developments. As we stress throughout, there is a difference between identifying an ethical issue – for instance in matters of truthfulness – and identifying an issue that should be tackled by some form of intervention by governments or other third parties. In some cases, such intervention might be desirable but not feasible, for instance when an industry is ‘footloose’ or capable of being located anywhere in the world and therefore cannot be easily or effectively regulated or taxed by any single national government. Some of the developments with which we are concerned have exactly those characteristics. In other cases, intervention of some kind might be feasible, but the overall risk of harm may not be considered serious enough to warrant such action. Hence a test of ‘proportionality’ is applied, as already applies in many domains in which the state does not prevent us spending our money in ways that may seem foolish or frivolous but in which we are expected to take responsibility for our choices. Further, there are some cases where harms could potentially be serious, but where there is insufficient evidence or expert consensus over the existence or extent of such harms for coercive government measures to be appropriate. That is why we recommend such measures (over other types of interventions) only when it appears feasible, justified by the harms it can prevent and where there is a sufficient level of evidence or expert agreement about the extent of those harms.

Social changes

1.11 In investigating ethical issues bound up with the developments under consideration in this report, we needed to explore how changes in society influence the development of technologies and, likewise, how society influences the ways such technologies are applied. Technological change on its own does not necessarily change social relationships in any particular direction. The effects and implications of such change depend on culture and attitudes. When it comes to the developments in medical profiling and online medicine with which we are concerned here, we discuss in the next chapter some of the ways in which those developments are shaped by, and have an impact on, social attitudes, public policy and economic changes. Some of those social factors include: (1) the development of a more globalised healthcare industry; (2) the common claim that services such as healthcare were previously domains where professionals exercised authority over clients but now involve more ‘consumerist’ attitudes; (3) changing attitudes to information technology in general (mainly through mainstream use of the internet in daily life); and (4) a common claim that there are pressures for the adoption of greater individual responsibility for the management of various personal risks, including those concerned with health. For the second of these social factors (the claim that more ‘consumerist’ attitudes are becoming prevalent in social life), using the internet and related information technologies can alter traditional doctor-patient relationships in terms of both initiating a diagnosis and investigating treatment options, for example by individuals purchasing tests and

pharmaceuticals without necessarily seeing a primary care doctor.²³ For the fourth kind of shift (the claim that various pressures are leading towards increased individual responsibility for risk management), some people are plainly eager to assume such greater responsibility (in seeking information about their health, keeping their own health records and making what they hope to be healthier lifestyle choices) and some patient groups are calling for empowerment and greater autonomy and choice. Meanwhile some governments, public and private organisations are seeking to encourage – and in some cases demand – greater responsibility from individuals or their families:²⁴ a process that has been dubbed ‘responsibilisation’ by some social scientists. Such calls can be controversial and the extent to which they alter legal obligations and entitlements is contestable, but they arise from a number of sources, including criticisms of the ‘dependency’ sometimes thought to be a result of an overly bureaucratic welfare state, widespread aspirations to shift the balance from curative to preventive efforts, in both private and public services and the wish by some to seek to limit the increases in tax funding of healthcare that many countries face.

- 1.12 Box 1.1 illustrates how some of the developments considered here can be applied to foster a ‘consumerist’ approach to healthcare and health-related services that puts individuals in the position of a customer in the marketplace, able to make choices among the products marketed to them by commercial firms, rather than a client subject to the authoritative guidance of professionals.²⁵ The Box contains examples of direct-to-consumer advertising by companies: (1) offering CT and MRI scans, with the claim that these can produce clear evidence of worrying irregularities or firm reassurance that all is well, and (2) offering personal genomic profiling for which the customer typically mails a saliva sample for DNA extraction and analysis and reads the results later on a dedicated website. The assumption underlying such advertising is that, if people are free to buy as many pairs of shoes or computers as they wish, they should likewise be free to purchase whatever healthcare services seem attractive to them. Such advertisements also imply that the information provided by such services is necessarily beneficial to those receiving it (even if it contains bad news about likely conditions for which no treatments are available). Such claims prompt reflection on the ethical issues that arise when people choose (or are obliged) to act as consumers of such services. How should we evaluate the claims that such developments ‘democratise’ healthcare, and how can the advantages of a ‘consumerist’ approach be balanced against the disadvantages? How far can or should such technology be used to encourage people to take more responsibility for ascertaining their health risks and taking appropriate actions to manage or minimise those risks?

²³ Indeed, such a shift might even herald a ‘back to the future’ scenario, reviving an older idea that, for the wealthy at least, patients were the masters and healthcare professionals their servants, and leading to a move referred to by some as ‘democratisation’ of the relationship between patients and medical professionals.

²⁴ See: European Commission (2007) *Together for health: A strategic approach for the EU 2008–2013*, available at: http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm; Department of Health (2010) *The NHS Constitution for England*, p9, available at: http://www.dh.gov.uk/dr_consum/dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113645.pdf.

²⁵ In many health systems, there are also institutional actors (such as insurance companies or public commissioning bodies) that act as purchasers of healthcare services and thus stand between individual patients and medical professionals.

Box 1.1: Medical profiling as consumer goods: examples of marketing claims

"23andMe Democratizes personal genetics" <https://www.23andme.com/about/press/20080909b/>

"23andMe was founded to empower individuals and develop new ways of accelerating research" <https://www.23andme.com/about/values/>

"You only have to ever take one genetic test, as the results will not change over your lifetime. By knowing your profile you can take control of your life and your health." <http://www.genetic-health.co.uk/dna-test-services.htm>

"We need to empower people – if a genetic test prompts patients to do what is right for them then we have accomplished our goal", Dr Robert Superko <http://www.decodehealth.com/documents/cms/deCODEhealthWeb2.pdf>

"A Preventicum Check-Up not only aims to diagnose existing conditions, it also enables us to evaluate key risk factors and develop a preventive strategy specifically tailored to your lifestyle." <http://www.preventicum.co.uk/about.asp>

"Lifescan is able to check for the very early signs of heart disease, lung cancer, colon cancer, aneurysms and osteoporosis as well as other illnesses." <http://www.lifescanuk.org/aboutlifescan/>

Personalisation

- 1.13 At the outset, we noted that the technological developments we are concerned with are commonly claimed to be bringing about a new era of 'personalised healthcare'. We noted that the terms 'personalisation' and 'personalised' in this field are widely used in a number of different ways. Pharmaceutical companies use 'personalised medicine' and 'personalised healthcare' to refer to advances in diagnostics and pharmaceuticals aimed at tailoring medicine to patients' needs.²⁶ Such developments include 'pharmacogenetics', the study of the effects of genetic differences between individuals in their response to medicines, which was the subject of a previous report of the Nuffield Council on Bioethics and so is not considered again in this report.²⁷
- 1.14 The Personalized Medicine Coalition,²⁸ based in the USA, uses the terms 'personalised' and 'personalisation' broadly to refer to the effects of new developments in medical profiling linked to other information-age developments, producing what the Coalition calls a "new healthcare paradigm"²⁹ that puts the stress on new methods of prediction and prevention as well as targeted medicines. The word 'personalisation' is said to be appropriate because the new developments can be claimed to be conducive to a mode of healthcare more tailored to the particular genetic and physiological characteristics of each individual (as ascertained by testing, assessing and imaging) and thus likely to be more effective than the more 'blunderbuss' methods of an earlier age, just as blood transfusions were transformed by the discovery of different blood types a century ago.

²⁶ For example, see: Roche (2010) Personalised healthcare, available at: http://www.roche.com/personalised_healthcare.htm.

²⁷ Similarly we will not be covering the kinds of tests under development that aim to analyse biomarkers to indicate what specific type of a disease, e.g. cancer, a patient has developed in order to select which treatment to use. The 2003 Nuffield Council on Bioethics report *Pharmacogenetics: Ethical issues* (London: Nuffield Council on Bioethics) concluded that pharmacogenetics had the potential to improve the quality of patient care significantly, but that it was unclear at that time how quickly and effectively this technology could be deployed. There were then few current applications of pharmacogenetic testing, and it was not known to what degree possible applications of pharmacogenetics could be realised in practice. This position does not seem to have greatly changed since publication of that report: pharmacogenetics continues to hold the promise of creating more effective and individualised medication (and distinguishing which patients would benefit from existing treatments) but has not been translated into widespread clinical applications as quickly as some had hoped.

²⁸ An advocacy body founded in 2004 and funded by healthcare companies, medical centres and government agencies, together with a number of patient advocacy groups and research and educational institutions. See: <http://www.personalizedmedicinecoalition.org/members/member-list>.

²⁹ See: Personalized Medicine Coalition (2010) Personalised medicine 101, available at: <http://www.personalizedmedicinecoalition.org/about/about-personalized-medicine/personalized-medicine-101/challenges>.

- 1.15 The terms ‘personalised’ and ‘personalisation’ are also widely used in public policy domains such as education and social care (where the term has been used at least since the 1970s in the UK) as well as in health, to refer to public services that are based on personal circumstances and need, and where each individual, whatever their circumstances, has greater control and influence over the services they receive, for example through individual budgets.³⁰
- 1.16 The term ‘personalised healthcare’ has an obvious appeal for many people. But there are several reasons why we use it with more caution than some of those cited earlier. One is that ‘personalisation’ is a term that (for most people) inherently conveys approval, whereas, as already said, there are some aspects of the use of the technologies with which we are concerned here that strike us as ethically problematic and not necessarily an advantage to either individuals or healthcare systems. Another is that using the term to describe a particular form of technology implies that such technology does indeed lead to more ‘personalisation’, a factual claim that can also be contested in some cases. Indeed, there are many developments in modern healthcare (particularly the use of standard protocols under the pressures of defensive medicine, pressures for mass medication for some conditions and blanket public health measures to deal with pandemics) that could be argued to be driving in precisely the opposite direction. Moreover, even if the promise of ‘personalisation’ in the sense of more individualised treatment can be held out for the future for some of the developments we consider, there is room for debate about how soon that promise can be realised. For example, a recent statement by the heads of the National Institutes of Health and the Food and Drug Administration in the USA asserted that “the challenge is to deliver the benefits of this work to patients.”³¹ A recent survey of life scientists revealed that, while sequencing the human genome in the 1990s (see Paragraph 2.5) has led to a “revolution in biology”, more than one third of respondents predicted it would take 10–20 years for ‘personalised medicine’ (referring here to medicine based on genetic information) to become commonplace. More than a quarter of respondents thought it would take longer than that.³²
- 1.17 A third reason for using this terminology with caution is that associating ‘personalisation’ and ‘personalised’ with modern developments implies that older forms of medical practice were in some way ‘de-personalised’. Such an implication represents a quite distorted view of historical development. After all, personalisation traditionally has been considered to be the hallmark of all good clinical medicine even if this has not always been the case in practice. And a fourth reservation is that the term ‘personalisation,’ despite or perhaps because of its obvious rhetorical appeal and widespread use in several fields of policy (such as social care and education as well as medicine), is ambiguous and has many different meanings and implications for different areas of policy and practice.

³⁰ E.g. Department of Health (2009) *Speech by the Rt Hon Andy Burnham, Secretary of State for Health, 30 March 2010: A National Care Service*, available at: http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/MediaCentre/Speeches/DH_114993; Keohane N (2009) *People power: How can we personalise public services?*, available at: <http://www.nlqn.org.uk/public/2009/people-power-how-can-we-personalise-public-services/>. The 2008 Darzi Review of the NHS in England frequently used the terms ‘personalisation’ and ‘personalised’ for healthcare services. The summary stated that “Personalising services means making services fit for everyone’s needs, not just those of the people who make the loudest demands.” See: Darzi A (2008) *High Quality care for all – NHS next stage review final report*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_085828.pdf.

³¹ Referring to the discoveries in genetics of genes associated with particular conditions and associations between people’s genetic makeup and their reactions to targeted therapies. Hamburg MA and Collins FS (2010) The path to personalized medicine *New England Journal of Medicine* **363**(4): 301–4.

³² Butler D (2010) Science after the sequence *Nature* **465**: 1000–1.

1.18 We can distinguish between at least four different senses of the term ‘personalisation’, namely:

- Technologies that are personalised in the sense that they allow better delivery of highly individualised management (prediction, prevention and treatment) more tailored or customised to each person’s specific genetic, physiological or psychological characteristics. Even this meaning of this term could be split into those forms of technology that are applied in wholly person-specific ways and those that operate by ‘stratifying’ people into different risk groups (which is what many technologies described as ‘personalised’ do in practice), in the same way as we can distinguish between individually made bespoke clothing and dividing people up into standard clothes or shoe sizes.
- Management or treatment that is personalised in the sense of treating each individual as a ‘whole person’, and being respectful of their particular wishes, worldview, lifestyle and health status overall for example (which might of course include wishes not to take responsibility for managing their own care).
- Management or treatment that is personalised in the sense that it aims to provide healthcare as a good or commodity in ways not dissimilar to other traded products or services that are offered in response to consumer demand (however this demand has arisen or is stimulated). Such an approach means respecting some version of consumer sovereignty or ‘buyer beware’ principle and operating more or less within the ordinary principles of consumer law and policy.
- Medical care that is personalised in the sense that more responsibility for management of healthcare is primarily laid on or taken by individuals or their carers rather than on medical professionals. Personalisation in this sense can arise from policies of ‘responsibilisation’ as mentioned earlier, from individuals’ choices to manage their healthcare (by taking an active or even leading role in obtaining information or commissioning forms of testing or treatment), or from a mixture of the two.

1.19 All of the case studies relating to medical profiling and online healthcare that we have chosen to investigate involve one or more of these senses of personalisation, as we shall show. Sometimes these four different senses of personalisation can readily run together, as we shall also show. But there are also circumstances in which the different senses of personalisation can conflict, and that can lead to ethical concerns. For example, highly individualised and person-specific treatment can conflict with a ‘whole person’ approach to treatment, in that care is conducted by a number of highly specialised experts in particular areas of medicine none of whom is concerned or responsible for the whole picture. Highly person-specific health information may be conveyed over the internet, but in a way that is automated and impersonal in the second sense noted above. A market-focused consumerist approach may produce standardised rather than highly customised products and services (allowing consumers to benefit from the economics of mass production or no-frills services). Similarly, taking personalisation to mean following a ‘consumer’ approach to the provision of healthcare may conflict with variants of the second sense of the word noted above in that it may not always take an individual’s current wants or desires as overriding. And laying responsibility for management or treatment on an individual patient or carer may well go against their own individual preferences to be looked after and have decisions made for them. So it is quite possible for healthcare services to become more personalised in one of the senses noted above while becoming less so in one or more of the other senses, and indeed several such conflicts can be found in the set of developments considered in this report. Choosing how to handle such tradeoffs between different senses of personalisation can involve difficult ethical and political judgments.

1.20 Given the ambiguities in the use of the term ‘personalisation’ (and the potential conflict between its various different meanings) as noted above, we use the term with care in this report. When we use it, we try to make clear what sense or senses of the term we are referring to. In some cases, in the interests of clarity, we use more specific terms, such as consumerisation or responsibilisation.

The structure of our report

- 1.21 The next chapter (Chapter 2) sketches out the way social and political changes seem to be interacting with developments in prevention and treatment in the application of medical profiling and online healthcare. The following chapter (Chapter 3) sets out the ethical values that we think should govern the appropriate use of these developments, shows how those ethical values can come into conflict and argues that we can only arrive at a view about how to minimise or 'soften' the dilemmas that arise from conflicting values by looking at the details of each case. Chapter 4 turns to the analysis of various forms of intervention by government or third parties that seem most relevant to the technologies considered here, ranging from accreditation (e.g. kitemarking) or transparency, to heavy-duty forms of regulation.
- 1.22 In the six chapters that follow Chapter 4, we consider selected cases of medical profiling and online medicine, namely online health information (Chapter 5), online personal health records (Chapter 6), online purchasing of pharmaceuticals (Chapter 7), telemedicine (Chapter 8), personal genetic profiling for disease susceptibility (Chapter 9) and direct-to-consumer body imaging (Chapter 10). In each of those chapters, we summarise the existing legal or regulatory framework, assess developments in the application of new technologies in the light of the approach to ethical analysis set out in Chapter 3, explore the trade-offs among those principles that seem most appropriate in the context of each of those cases, and make recommendations for best practice and/or for intervention by governments or third parties. The final chapter (Chapter 11) sets out some general conclusions, distinguishing those that are specific to the UK with its predominantly tax-financed and publicly provided (albeit partly privately delivered) system of healthcare, from those that may be of more general application to healthcare systems facing the technological developments discussed in this report.

Chapter 2

The historical and social
context

Chapter 2 – The historical and social context

Introduction

2.1 The previous chapter noted that the developments related to medical profiling and online medicine considered in this report and the claims of increased ‘personalisation’ that are associated with them are heavily shaped by the social context. This chapter aims to sketch in that social and historical context a little further. It argues that the confluence of social change and the technological developments outlined in the previous chapter underlie increasing emphasis by several groups on consumerisation and responsabilisation in healthcare, two of the aspects of ‘personalisation’ we identified (see Paragraph 1.18). Those two themes feature to a greater or lesser extent in all of the case studies we investigate (see also Table 11.1). The developments we are concerned with lend themselves not only to more individualised diagnosis and treatment (the first type of personalisation noted in the previous chapter), but also to more availability of healthcare services as consumer goods for individual purchase in a marketplace, and to more emphasis, at least in policy declarations, on individual obligations to take responsibility for managing health and healthcare. It is less clear whether or not these developments are delivering on all the promises that have been made for them.

Background

2.2 Historically, many of the most dramatic improvements in human health and longevity have come – and continue to come – from public health measures, environmental changes or economic growth, which all operate at the level of populations or groups, and across territories of town, region or nation. Clearly such measures do not constitute personalisation in any of the senses identified in the previous chapter – in some ways they have been effective because of their ‘impersonal’ character. Notable and well-known examples of such developments are better nutrition and regulation to ensure safety of foodstuffs, universal programmes of vaccination, the provision of clean air and water, sanitation and other ways of limiting infectious or contagious disease.³³

2.3 But healthcare in the sense of direct provision of medical services or treatments to individuals has also played an important role in these improvements.³⁴ Moreover ‘personalisation’ in the first sense identified in the previous chapter – care that is tailored to what is thought to be each person’s specific genetic, physiological or psychological characteristics – has always been thought to be a hallmark of good clinical medicine, whether or not it has actually been found in practice. But successive discoveries in medical science have made it possible to increase personalisation in the sense of adjusting treatment regimes to the individual characteristics of each patient. For example, while the potential of blood transfusions has been known since the eighteenth century, it was only through the discovery of different blood groups in 1901 that it became possible predictably and accurately to use one person’s blood to save the life of another by ensuring that blood transfusions take place only between donors and recipients

³³ See, for instance: Baldwin P (1999) *Contagion and the state in Europe, 1830–1930* (Cambridge: Cambridge University Press); Nuffield Council on Bioethics (2007) *Public health: Ethical issues*, available at: http://www.nuffieldbioethics.org/fileLibrary/pdf/Public_health_-_ethical_issues.pdf; Acheson D (1998) *Independent inquiry into inequalities in health report*, available at: <http://www.archive.official-documents.co.uk/document/doh/ih/ih.htm>; Royal Institute of Public Health (2006) *150 years of public health milestones* (London: Royal Institute of Public Health).

³⁴ The relationship between environmental conditions; cultural and social factors; and healthcare activity on public health and longevity has been discussed at length. See, for example: McKeown T (1976) *The role of medicine: Dream, mirage or nemesis? (Rock Carling Lecture)* (London: Nuffield Trust); British Medical Journal (1976) *Dream, mirage or nemesis* *British Medical Journal* 2: 1521–2; Bunker JP (2001) The role of medical care in contributing to health improvements within societies *International Journal of Epidemiology* 30: 1260–3; Szreter S (2002) Rethinking McKeown: The relationship between public health and social change *American Journal of Public Health* 92(5): 722–5.

whose blood groups are compatible. A more recent example is the development of modern computer-assisted laser eye surgery that allows surgeons to take into account the exact shape of each individual human eye in a way that would not have been possible in an earlier age.

- 2.4 Many argue that the developments with which this report is concerned offer the possibility for a dramatic increase in personalisation in that first sense of individually tailored treatments. Further, they have claimed that those developments also offer the prospect, not just of tailoring treatments to existing diseases, but of ‘predictive’ personalised healthcare that can identify the future disease risks of each specific individual at an early pre-symptomatic stage. And that in turn is claimed to enable more ‘preventive’ medicine that involves tailored early intervention to mitigate the risks that have been predicted for each particular person. It is easy to see why policy makers are interested in claims that this putative new era of personal, predictive and preventive medicine can improve individual and collective health outcomes and thereby realise both health and economic benefits.³⁵ Increased prevention is widely believed to offer the possibility of offsetting the rising costs of healthcare due to increasing public expectations, inflation in healthcare treatments and demographic changes. In fact, much of what is promised as ‘prevention’ refers to early diagnosis rather than truly pre-emptive actions, and that early diagnosis may extend the period of medical care and hence the overall cost to a healthcare system, rather than reducing total costs. Moreover, the prospect of being able accurately to predict future risk of disease at an early point, and perhaps eventually at the point of conception or soon after, clearly throws up serious ethical issues.³⁶ Such issues include the temptation to recommend earlier and earlier medical interventions when the evidence of benefit against risk is unclear, perhaps including screening embryos for increasing numbers of conditions whose risks may be hard to define and where therapeutic intervention may be unavailable.
- 2.5 The developments in this area that have attracted most attention have been those in genetics, notably those arising from the Human Genome Project of the 1990s.³⁷ These developments involve analysis of genetic material collected from large numbers of individuals and attempting to link specific genomic patterns and genetic variations to their health status and disease profile. The aim is to identify health risk profiles and predispositions for disease for specific individuals, based on the analysis of some or all of their own genome for the tell-tale genetic sequences that increase the chances that this person will develop particular medical conditions.
- 2.6 Other technological developments, notably those that use digital and computing technologies, have made it possible to construct more detailed images of individual patients than was possible with earlier technologies. We have seen the increasing use of computed tomography (CT), magnetic resonance imaging (MRI) and ultrasound for diagnostic purposes, and the growth of commercial organisations that offer screening for asymptomatic individuals. Such developments claim to be able to offer person-specific prediction through their capacity to capture the early signs of diseases such as tumours before they become evident in symptoms, and hence their apparent ability precisely to identify the current and future diseases of specific individuals as a precursor to more targeted prevention and treatment.
- 2.7 In a different way, the use of digital and information communications technologies for the provision of health information, the management of individual health records, the ordering and purchasing of pharmaceuticals, tele-consultations, patient monitoring and even dispensing of drugs on an automatic basis, offers the possibility of new forms of highly targeted, person-

³⁵ See, for instance: Hood L (1992) *Biology and medicine in the twenty-first century*, in *Code of codes: Social and scientific issues in the Human Genome Project* Kevles D and Hood L (Editors) (Cambridge, Mass: Harvard University Press).

³⁶ See: Goldstein DB (2010) 2020 Visions – personalized medicine *Nature* **463**: 26–32.

³⁷ That is, the international scientific project (originating in 1990 and completed in 2003) to determine the overall sequence of base pairs (nucleotides) that make up the 23 chromosomes of each human being to identify and sequence each of the 20,000 genes that make up the human genome, and to begin to characterise each of these genes in terms of its functional properties. See, for instance: Sulston J and Ferry G (2003) *The common thread: Science, politics, ethics and the human genome* (London: Corgi).

specific healthcare, not least through automatically linking different kinds of information relating to individuals in novel ways. Examples include sending alerts about new medical discoveries to patients taking particular classes of drugs, notifying particular individuals to clinical trials relevant to them to recruit patients and simultaneously alerting various healthcare professionals to changes in an individual's health indicators.

- 2.8 As we noted in the previous chapter, many individuals, groups and organisations, especially in the USA, see these new technologies as heralding a new era, indeed a new 'healthcare paradigm', of technologically-enabled 'personalised healthcare' (see Paragraph 1.14).³⁸ The 'paradigm' they have in mind links genomic profiling and other forms of testing with other applications of information technology to produce a new world of more personal, predictive and preventive medicine, replacing an older one of more reactive and repair-focused healthcare and involving more active and empowered individuals than in a previous era.
- 2.9 Although preventive medical care has long been central to healthcare systems, many say the new developments move it into a new era. They suggest the new technologies can produce better individual risk predictions. It has also been suggested that if people were presented with information about their individual health profile and their own individual risks, it would be more compelling than earlier methods for the assessment of risk, and thus would motivate them to make the personal changes to their lifestyle to avoid both debilitating sickness and the need for costly treatment.³⁹ Such increasing emphasis on the role of risk assessment and prevention might be seen as elements in a much wider set of social changes and policy developments in what is dubbed by some as a 'risk society' in which the principle of precaution has come to rule, and the aim is not simply to respond to adverse events after they occur, but to predict them in advance and react beforehand to forestall or limit such events. For example, the emphasis on prediction, data mining, risk assessment, profiling, precaution and pre-emption that goes into the model of healthcare outlined above, is shared with developments in crime control (see Paragraph 2.13), although perhaps for different reasons. In the case of health, it involves treating individuals who are not ill in the traditional sense, and who perhaps never will be ill, blurring the boundaries over who is or is not 'a suitable case for treatment' and moving from what in a previous age would have been considered the 'the limits of medicine' into what some have termed "the medicalisation of everyone".⁴⁰ We return to some of these issues in Paragraphs 11.20–11.24.
- 2.10 As we said above, the benefits of such an approach may at first sight seem obvious, following the adage that 'an ounce of prevention is worth a pound of cure', and numerous policy statements have endorsed it.⁴¹ However, looking at benefits in relation to financial costs, not all predictive and preventive measures in fact produce aggregate cost savings to a public

³⁸ See, for example: Personalized Medicine Coalition (2010) Personalized medicine 101, available at: <http://www.personalizedmedicinecoalition.org/about/about-personalized-medicine/personalized-medicine-101/challenges>; Collins F (2010) *The language of life: DNA and the revolution in personalized medicine* (New York: Harper Collins); IBM (2003) Personalized healthcare 2010: Are you ready for information-based medicine?, available at: <http://www-935.ibm.com/services/in/igs/pdf/g510-3565-personalized-healthcare-2010.pdf>; CORDIS (2009) ICT Challenge 5: Sustainable and personalised healthcare, available at: http://cordis.europa.eu/fp7/ict/programme/challenge5_en.html.

³⁹ It is also commonly argued that better-targeted medication could cut costs as well as increasing the efficacy of healthcare, given that patients' reactions to drugs may have a substantial genetic element. The move to pharmacogenetics – to dispense the right medicine for the right patient in the right dose – represents a further move to more targeted medicine, but we do not discuss it further here as it was the subject of a previous report by the Nuffield Council on Bioethics. See: Paragraph 1.13.

⁴⁰ Armstrong D (2002) Conceptualising the patient *Journal of Health Services Research and Policy* **7**(4): 245–7; Armstrong D (1995) The rise of surveillance medicine *Sociology of Health and Illness* **7**(3): 393–404.

⁴¹ See, for example: *Our health, our care, our say: A new direction for community services*, a document that stressed the importance of prevention and prediction and declared that health and social care services will provide better prevention services with earlier intervention (p7) and suggested a "shift in the centre of gravity of spending" is required to achieve this aim (p9). What was less emphasised was that any such programme implies screening of asymptomatic individuals, groups or populations. See: Department of Health (2006) *Our health, our care, our say: A new direction for community services*; Department of Health (2002) NHS Must Highlight "Prevention As Well As Cure" – Milburn, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Pressreleases/DH_4025964; European Commission (2007) *Together for health: A strategic approach for the EU 2008–2013*, available at: http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm; Prime Minister Brown's speech on the National Health Service (2008), available at: <http://www.number10.gov.uk/Page14171>.

healthcare system such as the UK National Health Service (NHS). There is evidence that some preventive health measures, such as quitting smoking, influenza vaccinations and some forms of cancer screening are cost-effective in reducing mortality.⁴² Whether or not preventive intervention reduces costs in comparison with treatment depends on the particular intervention and the specific population in question, and in some cases the cost-effectiveness of preventive and treatment approaches appears to be rather similar.⁴³ One study from the Netherlands modelling the medical costs of obesity over a lifetime found that, until middle age, yearly health spending was highest for obese people, in comparison to smokers and ‘healthy-weight’ non-smokers, yet over a lifetime health costs were highest for the ‘healthy-living’ people and lowest for smokers. The prevention of obesity and smoking increases life expectancy, but appears to substitute “...inexpensive, lethal diseases [with] less lethal, and therefore more costly, diseases”.⁴⁴ So we should be wary of sweeping claims about the cost-effectiveness of all preventive care in comparison with treatment of diseases as and when they arise.

- 2.11 Whether or not the predictive and preventive approach is more cost-effective for public healthcare systems than the treatment and repair approach, it has been taken up and promoted by policy makers in the UK and elsewhere in numerous statements aimed to encourage individuals, even and perhaps especially when they are asymptomatic, to become more involved in their health and actively to manage their healthcare. Developments in the availability of information and communication technologies such as the internet can also facilitate such a shift. Although, as we shall see in Chapter 4 (Box 4.1), the legal responsibilities of patients relative to medical professionals in the UK has not changed markedly in the recent past, the vision of predictive and preventive medicine seeks to change the traditional idea of patients in a reactive, repair-oriented health system, requiring them actively to understand and manage many aspects of their lives in the interests of their health, to educate themselves appropriately, and to take a considerable share of the responsibility for their current and future health status. That vision of public policy for healthcare chimes with market developments in the form of commercial services offered directly to consumers that encourage them – and promise to enable them – to take more responsibility for their own health. This is why we have identified ‘responsibilisation’ (one of our senses of ‘personalisation’) as a key ethical issue in the developments we are considering. We return to this theme in more detail below.
- 2.12 The new developments we are considering also throw up ethical issues linked to the third sense of ‘personalisation’ identified in the previous chapter, namely a view of health as a kind of consumption good, and hence of health products and services as commodities. Many of the products and services we are concerned with are advertised and traded in the international market place, using all the technologies of modern marketing, not merely to respond to consumer demand, but also to reshape such demand to create and sustain a market. In a social and cultural context that encourages many individuals to regard the management of their own health and fitness as a key part of their lifestyle, the online medicine and medical profiling technologies with which we are concerned readily lend themselves to direct-to-consumer commercial marketing, both to those already diagnosed with a disease, and to those asymptomatic consumers seeking to manage their future risks of disease. In the following two sections, we explore further these senses of personalisation as responsibilisation and personalisation as consumerisation.

⁴² Maciosek MV, Coffield AB, Edwards NM *et al.* (2006) Priorities among effective preventive services: Results of a systematic review and analysis *American Journal of Preventative Medicine* **31**(1): 52–61.

⁴³ Cohen JT, Neumann PJ and Weinstein MC (2008) Does preventive care save money? Health economics and the presidential candidates *New England Journal of Medicine* **358**(7): 661–3.

⁴⁴ van Baal PHM, Polder JJ, de Wit GA *et al.* (2008) Lifetime medical costs of obesity: Prevention no cure for increasing health expenditure *PLoS Medicine* **5**(2): e29

Responsibilisation and healthcare

The responsibilisation movement

- 2.13 As explained in the previous chapter, the inelegant but nevertheless useful word 'responsibilisation' refers to a movement that arose initially out of criticisms of social welfare practices that were seen as destroying individual responsibility and encouraging dependency. Such criticism of collectively planned and provided welfare provision has a long history, at least from the 1940s to the present day, and has been advanced from a variety of different political viewpoints,⁴⁵ but at least since the 1960s various measures have been proposed. These have, albeit from very different political stances, sought to diminish dependency and enhance freedom, autonomy and choice, by encouraging individuals not just to have greater powers and rights, but also obliging them to take greater responsibility for their own present and future health, welfare and security and that of their families and close communities, rather than allocating such responsibilities to an abstract 'society' or a distant state. Social scientists coined the term 'responsibilisation' to denote policies that combine increased autonomy with increased obligations. The term was taken up in particular by criminologists to characterise policies that sought to place more responsibility for crime control and the management of security onto local communities and individual householders rather than relying solely on collectively funded services provided by police and public-service professionals.⁴⁶
- 2.14 When it comes to healthcare, responsibilisation is a theme that has been taken up in various ways in recent years. The practice of involving patients in the choices to be made over their treatment and shared decision making, rather than presenting them with take-it-or-leave-it options, is a common feature of modern professional healthcare, and one that illustrates the double-edged character of such developments – on the one hand individuals are accorded more power to choose, on the other, they are obliged to take a share of the responsibility for that choice and its outcomes. Just as radical critics of 'medicalisation,' particularly in the women's movement in the 1960s and 1970s, argued for a shift in power relations to empower patients and enable them to understand and take control over their own bodies, the same theme has been taken up more recently by active patient groups, especially but not only in the USA. Such groups have made use of the internet (together with other digital age technologies) to share information and experiences among those immediately affected and lobby for attention and resources for the specific disease that afflicts them and their community. While attractive from many viewpoints, the notion of responsibilisation through new technology raises important ethical issues as well, for example when individuals choose to reject rather than embrace such responsibility or when not all patient groups have equal access to the internet and its power of communication. Such issues arise in a number of our case studies.

⁴⁵ For example from the 1960s to the 1980s, state-provided welfare services were criticised by numerous groups and individuals, particularly in the United States, as not merely inefficient, but also as demeaning, paternalistic and encouraging dependency. Some of the strands of this criticism came from feminist campaigners (such as the Boston Women's Health Collective) seeking to wrest power over women's bodies away from the professionals, and from left or liberal critics of the paternalism of a healthcare system that was perceived as forcing clients and patients into dependency. But other calls for responsibilisation in this sense came from right and third-way sources, such as Gertrude Himmelfarb (see: Murray C (1984) *Losing ground: American social policy 1950–1980* (New York: Basic Books)). It can of course be argued that as a matter of historical fact the founders of the UK Welfare State such as William Beveridge were at great pains to try to ensure that their provisions did not destroy individual responsibility (see: Mead L (1986) *Beyond entitlement: The social obligations of citizenship* (New York: Free Press)).

⁴⁶ See, for example: Rose N (1999) *Powers of freedom* (Cambridge: Cambridge University Press); O'Malley P (1992) Risk, power and crime prevention *Economy and Society* 21(3): 252–75. The underlying idea that the term tries to capture can be seen in policy proposals and developments in other fields as well, for example in relation to policies for safety in the workplace, or in the development of 'contracts' with students and pupils in school and higher education that recognise the strong 'co-production' element of teaching and learning.

Responsibilisation in policy

- 2.15 We summarise the legal responsibilities of patients and medical professionals in the UK in Box 4.1, and also set out the current obligations of patients relative to the NHS. We note there that the legal distribution of responsibility has not changed markedly in the recent past and that the established position relating to NHS care is that ill-health, however caused, is treated as a misfortune rather than as a penalty for irresponsible conduct, and that NHS care is provided on the basis of need alone. In other words, the NHS does not deny people treatment because they have led ‘irresponsible’ lives,⁴⁷ and this position can be justified on the grounds that in the current state of knowledge, the connections between lifestyle choices and particular health outcomes are too complex to hold people formally to account for the choices they make, even assuming that the notion of ‘choice’ is unproblematic. In cases where people have clearly taken action leading to their need for medical care, for instance in alcohol-related injuries or suicide attempts, the principle of treatment according to medical need is taken to be overriding, although, of course, individuals may be advised or even required to listen to advice and counselling.
- 2.16 In principle, some of the developments we are considering might challenge that established position in the future. As we have said, the purported predictive capacities of ‘personalising’ technologies seem to open the possibility of assigning increased responsibility to individuals, if reliable technologies were available that predicted individual responses to, for example, alcohol or consumption of fatty foods. But we think it unlikely that public healthcare systems such as the NHS will change their position of offering treatment even to those who have wilfully and knowingly brought on their own medical needs. The same, however, may not apply to private health insurance systems or for the employment-based insurance regimes typical in the USA.
- 2.17 Moreover, even for public healthcare systems, there have certainly been numerous policy declarations about what responsible individuals should do to look after their health that do not have legal force but are nevertheless intended to shape people’s behaviour. For instance, the King’s Fund noted in a 2007 report that “individual responsibility for health and self-care are key themes in recent health policy documents in England”.⁴⁸ Five years earlier the 2002 Wanless report on healthcare in the UK *Securing our future health: Taking a long-term view* emphasised the importance of individuals taking some responsibility for their health and recommended that the relationship between health professionals and the public could be improved by the “development of improved health information to help people engage with their care in an informed way”.⁴⁹ A 2006 Department of Health report on healthcare in England already referred to (*Our health, our care, our say*) took up the same theme, declaring that patients would be “given more control over – and will take on greater responsibility for – their own health and well-being”.⁵⁰ And the NHS Constitution for England published in 2009 outlined what it considered to be the responsibilities applying both to “patients and the public”, which included the stipulation that “you should recognise that you can make a significant contribution to your own, and your

⁴⁷ Those who undertake irresponsible activities may be accorded lower priority than others where resources are limited because the prospective efficacy of the procedure will be lower, e.g., those facing a liver transplant who cannot give up alcohol.

⁴⁸ Jochelson K (2007) *Paying the patient: Improving health using financial incentives*, p2, available at: <http://www.kingsfund.org.uk/document.rm?id=8274>.

⁴⁹ Wanless D (2002) *Securing our future health: Taking a long-term view*, available at: http://www.hm-treasury.gov.uk/consult_wanless_final.htm, p122.

⁵⁰ Department of Health (2006) *Our health, our care, our say: A new direction for community services*, p13, available at: <http://www.official-documents.gov.uk/document/cm67/6737/6737.pdf>.

family's, good health and well-being, and take some personal responsibility for it."⁵¹ Similar themes have been stressed in other countries.⁵²

New services offering increased responsibility

2.18 As we saw in the sample advertisements quoted in the previous chapter (Box 1.1), the theme of responsabilisation has also been stressed by private sector providers of some of the technologies with which this report is concerned. The promotional material of such providers suggests that it is desirable for individuals to 'take control' of their healthcare and take prudent steps to ascertain and diminish their likelihood of developing diseases in the future. Some of that promotional material draws an analogy with people taking their cars for roadworthiness checks; taking active steps to spot problems early and prevent or mitigate them rather than waiting for things to fail in what may be disastrous conditions. We therefore need to investigate how far these services really do allow people to find out useful information and hence put them in a position where they could take on more responsibility in that way.

Responsibilisation as it relates to personalisation

2.19 As briefly noted above, the development of more 'personalised' healthcare in the sense of more individually specific diagnosis and prediction thus has a potentially double-edged character. On the one hand, the doctrine of 'responsibilisation' seems to stress the value of allowing people to act as educated and empowered individuals, knowing more and able to increase their capacities to make informed decisions about the management of their health and illness. But on the other hand it may involve increased obligations and expectations on individuals to take this active role, requiring increasing skills in terms of self-education, and the need to make trade-offs between different options in terms of their relative costs and benefits. Sanctions or other consequences may flow from individuals not taking responsibility, either by not acting on the results of predictive tests, or perhaps, even by not informing themselves about their health risks. It also may mean that people come to feel guilt and anxiety if they do not fulfil these expectations – perhaps even a sense that they themselves, by acts of omission or commission, bear some blame for the illnesses that they or their family may suffer. Those who prefer not to know about the future and instead to live for the day may feel that position is condemned as irresponsible. Further, in the field of health and disease, there may be many cases where, even equipped with reliable foreknowledge of the future, individuals are relatively powerless to affect the outcome, as for example in some types of cancer. It is not hard to imagine cases where, nonetheless, individuals may feel that in some way they should be able to affect their health status or disease progression, and hence are driven to seek unproven or even harmful interventions, perhaps on the basis of information obtained on the internet and available on a commercial basis. Such ethical pressures on individuals are of course far from new, but the

⁵¹ Department of Health (2010) *The NHS constitution for England*, available at:

http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113645.pdf, p9.

⁵² See, for example, a recent Australian health policy document, *A healthier future for all Australians: National health and hospitals reform commission final report* included 'Design and governance principles' naming shared responsibility for health as one of the key principles. It stressed the responsibility of health professionals "to support us [all Australians] to take an active role in our health and treatment" and declared that "The health system has a particularly important role in helping people of all ages and abilities become more self reliant, health literate and better able to manage their own health care needs." Australian Government Department of Health and Ageing (2009) *A healthier future for all Australians: National health and hospitals reform commission final report*, available at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/nhhrc-report>. See also: Draft 2006 West Virginian *Medicaid member agreement* which specified that residents eligible due to low income should sign documents outlining their responsibilities and rights, such as "I understand that it is my responsibility to do the right things so that I am healthy". West Virginia Department of Health and Human Resources Bureau for Medical Services (2006) *Draft West Virginia Medicaid agreement*, available at: <http://www.wvdhhr.org/medred/handouts/wvmedicaidmemberagrmt.pdf> and Steinbrook R (2006) Imposing personal responsibility for health *New England Journal of Medicine* **355(8)**: 753–6; Bishop G and Brodkey AC (2006) Personal responsibility and physician responsibility – West Virginia's Medicaid plan *New England Journal of Medicine* **355(8)**: 756–8. It has also been argued that "personal responsibility for health...has been explicitly and prominently enshrined in [German] federal health law since 1988. Key elements of recent reforms that entered into force on 1 April 2007 have given even more emphasis to the concept, with immediate effects on policy and practice". Schmidt H (2007) Personal responsibility for health – developments under the German healthcare reform 2007 *European Journal of Health Law* **14**: 241–50.

developments discussed in this report may well intensify them, and we return to that issue in our final chapter.

Consumerisation and healthcare

Patients, citizens and consumers

- 2.20 In a historical and comparative perspective, there are at least three broad ways that individuals can relate to the provision of healthcare, which can be loosely denoted as the role of patient or client, citizen, and consumer. The developments in medical profiling and online healthcare with which this report is concerned raise questions about how the balance between these roles may be changing and the ethical consequences of such changes.
- 2.21 The role of *patient* denotes a relationship between an individual and a medical practitioner that is heavily governed by fiduciary obligations on the part of medical practitioners.⁵³ There is a presumption of strong information asymmetry between professional and patient, and some acceptance of the professional authority and expertise of the medical practitioner on the part of the patient, whose ability to instruct the professional what to do is constrained by legal and professional rules. The law governing those relationships tends to stress the professionals' obligation to put the interests of patients ahead of their own interests and to achieve and maintain professional standards and competence consistent with those obligations.
- 2.22 *Citizenship* shapes healthcare provision to the extent that individuals' health entitlements and responsibilities are framed in terms of their relationship with the state or less formally by some sense of claims on, or obligation to, the community.⁵⁴ Political choice and public debate determines who is entitled to what and who is expected to do what. Healthcare came to figure as an aspect of citizenship fairly late in European history (though entitlement to healthcare has commonly been linked to the military service obligations of traditional citizenship). Now, however, citizenship figures large in the relationship between individuals and the healthcare system in most developed democracies,⁵⁵ and some scholars have recently identified the concept of 'genetic' or 'biological' citizenship, bringing a new dimension to citizenship not covered in earlier accounts.⁵⁶ Moreover, as noted in the previous section, the responsibilities of citizens in relation to public healthcare systems such as the NHS have come to receive greater emphasis in recent years, and new market opportunities provided by the developments in medical profiling and online medicine likewise raise new questions about the limits of citizenship entitlements.
- 2.23 In contrast to the roles of patient or client and citizen, the term '*consumer*' is ordinarily used to denote those who purchase goods and services in the marketplace, subject to the ordinary legal principles governing commercial transactions, including the *caveat emptor* ('let the buyer beware') principle that presumes buyers take care to inform themselves about the goods or

⁵³ This role is similar to that of 'client' in professional services more generally, although the client of a legal professional, for example, may have more power in virtue of his or her payment for professional services.

⁵⁴ This is especially true in relation to the acceptance by political authorities of particular responsibility for the health and welfare of children as young or future citizens, as in the provision of maternal care services, medical inspection of schoolchildren and food supplementation in some cases.

⁵⁵ For Thomas H Marshall, in a classic account, the extension of citizenship rights (at least for males in England) began with legal rights and duties, then moved to political ones and only finally moved to social citizenship involving entitlements to health, education and social welfare. The latter was central to citizen-state developments in Germany, France and the UK over the twentieth century, and to a lesser extent and in different ways in the United States. See: Marshall TH (1950) *Citizenship and social class, and other essays* (Cambridge: Cambridge University Press).

⁵⁶ Petersen A and Bunton R (2002) *The New Genetics and the public's health* (London: Routledge); Heath D, Rapp R and Taussig KS (2003) Genetic citizenship, in *Companion to the handbook of political anthropology* Nugent D and Vincent J (Editors) (Oxford: Blackwell); Rose N and Novas C (2004) Biological citizenship, in *Global assemblages: Technology, politics, and ethics as anthropological problems* Ong A and Collier SJ (Editors) (Oxford: Blackwell).

services on offer.⁵⁷ In such relationships, providers are not expected to put the interests of users before their own: they are free to market their wares through any medium and within the general constraints applying to advertising. There is no necessary presumption of authority or superior information on the part of the provider, and buyers with the necessary funds are free to obtain goods or services they want from any legitimate source of supply.

- 2.24 A key feature of the 'consumer-supplier' relationship is that of choice: the ability, at least in theory, to choose between different suppliers. It is conventionally held that consumer choice can encourage the kind of competition among suppliers that will increase the quality or cut the cost of the goods or services provided. Of course there is nothing new about healthcare being treated as a consumer good in that sense, since wealthy individuals have long purchased their medical advice and treatment in that way, and during the eighteenth and nineteenth centuries doctors were in many ways an employee of their wealthy patients but those who did not pay were in the 'patient' relationship of dependence on the authority of the professional. However in the recent past, in the public services in the UK generally, and not only in healthcare, more emphasis by policy makers has been placed on treating users more like consumers, at least by offering elements of choice of provider and by packaging services in ways designed to improve their accessibility to the user.

Consumer choice in healthcare

- 2.25 Policies that aim to put more emphasis on consumer choice and consumer empowerment in the provision of public services belong to our third sense of 'personalisation' in the previous chapter, since they imply that users of healthcare and other services need to make choices among different elements of provision to compile a package that is adjusted to their personal circumstances and priorities.⁵⁸ Such policies aim to alter the relations of power and authority between professionals and those who use their services, requiring healthcare providers to compete by making themselves attractive to those who choose to use them. This requirement is often believed to act as a counterweight to the paternalistic power of professionals, forcing those professionals to be more attentive to the needs of those who use their services, and making them more accountable to those users. As in other domains where individuals act as choosing consumers, treating healthcare as a consumer product also imposes a certain responsibility on the users to make the choices that are appropriate for their needs, and in turn produces a requirement for the provision of education and information to assist individuals in making those informed choices.
- 2.26 In many domains, from car insurance to holidays, the development of the internet is transforming processes of consumer choice. In healthcare, the internet has increased the possibility of seeking out health information from a range of public, professional and commercial providers, such that the general practitioner, family doctor or specialist consultant may become only one source of information and advice for people among many (see Chapter 5). Many people have become familiar with comparing goods and services on the internet to choose among the different goods or services available for purchase (and many price comparison websites have developed to help users do so), and it may be that such behaviour is also coming to apply to some extent to healthcare decisions. We shall take up this point in our final chapter where we consider the implications of changes in the traditional doctor-patient relationship. We shall see in Chapter 5 that such developments carry the risk that individuals may be harmed, or not optimally treated, by accessing information that is incorrect or that they cannot interpret adequately but that it may also protect them from medical malpractice or incompetence (in the form of out-of-date or careless treatment) and provide valuable extra sources of information. To the extent that such a change is taking place, it suggests a need for professional organisations

⁵⁷ It should be noted that the importance of this principle has been reduced somewhat in the context of consumer transactions by legislation such as the Unfair Contract Terms Act 1977 and various common law principles.

⁵⁸ For a discussion of different ways of thinking about the consumerisation of public services, see: Hood C, Peters G and Wollman H (1996) Sixteen ways to consumerise public services: Pick 'n mix or painful trade-offs? *Public Money & Management* 16(4): 43–50.

and those concerned with health policies to consider the kinds of education of both doctors and patients that may be appropriate for this new situation of provider and information pluralism and individualised consumer choice.

- 2.27 Increasing stress on the ‘consumer’ aspect of healthcare has also come from commercial providers of health or health-related services seeking to break into new markets, often crossing national borders. This includes those offering direct provision of health-related services. Central to the issues that we discuss in this report is the growing market for those offering genomic sequencing technologies claiming to be able to predict susceptibility to common diseases. They are said to constitute a substantial market opportunity for commercial organisations and investors because it is thought that there will be a rapid increase in the use of such technologies for the predictive testing of individuals in the coming decades. Thus there are developing alliances between the biomedical researchers seeking to identify relevant genetic sequences linked to disease susceptibility, the commercial organisations seeking to develop the researchers’ work into tests and devices that can be sold for profit to health providers in both the public and the private sectors, and those private and public sector providers arguing for the importance of practices based on predictive genetic tests for future healthcare.
- 2.28 Moves towards a more consumerist approach to healthcare also come from the behaviour of some individuals. For instance, the much-observed phenomenon of ‘medical tourism’ in various forms in the recent past, often linked to the development of the internet, by people seeking treatments overseas that are not available or are much more costly in their home countries, represents a notable shift in the balance between patient, citizen and consumer roles in healthcare. So does the number of individuals who choose to buy pharmaceuticals online for reasons of access, cost, privacy or convenience, as we discuss in Chapter 7. In each case, we can observe an increased emphasis on the individual person as having the rights, powers, and responsibilities to manage key aspects of their medical care. We return to the role of the individual as it relates to healthcare in the final chapter.

Links between responsabilisation and consumerisation in healthcare

- 2.29 Ethical issues associated with responsabilisation and consumerisation are linked together in many of the developments we are concerned with. While the development of arguments for greater choice and responsibility in healthcare stem from government policies, economic arguments, the logic of commercial development and the activity of some pressure groups, including patient groups, it is not clear to what extent, and in what respects, greater choice and responsibility is demanded by, or welcomed by, recipients of healthcare services.⁵⁹ Personalisation is sometimes represented as a response to demand, but in some cases at least it seems to be a case of supply looking for demand.
- 2.30 Nonetheless, these developments embody something that numerous commentators on the development of welfare systems have written about, namely challenges to earlier ideas of uniformity and universality in collective forms of risk sharing which were embodied in the social insurance schemes that developed in the twentieth century. Such schemes pooled risk across whole populations, and were embedded in moral and ethical beliefs about social solidarity and collective responsibility which we discuss further in Chapter 3. In many policy domains however,

⁵⁹ Some studies in the USA indicate a majority of patients surveyed said they valued choice of doctors and hospital and that relatively socially-advantaged groups were somewhat more likely to be aware of healthcare-related performance information. See: Lambrew JM (2005) *“Choice” in Health Care: What Do People Really Want?*, available at: http://www.commonwealthfund.org/usr/doc/lambrew_853_choice_ib.pdf; Schneider EC and Epstein AM (1999) Use of public performance reports: A survey of patients undergoing cardiac surgery *Journal of the American medical Association* **279**(20): 1638–42. Some studies in England have indicated that the importance of being able to choose hospitals varied among survey respondents, but was not, on the whole, a high priority for most NHS patients surveyed in England. See: Fotaki M (2009) Are all consumers the same? Choice in health, social care and education in England and elsewhere *Public money & management* **29**(2): 87–94.

we now see exhortations for individuals to take on more responsibility for risk (for example in saving for retirement rather than relying on state entitlements), and in some we see policy shifts as well (for example in moving investment risk over pensions from employers to employees by abandonment of defined-benefit pension schemes in many companies).⁶⁰ Perhaps the clearest example of moves to 'de-pooling' of risk can be seen in the market for car insurance, where advertising urges individuals to shop around for the best deal that matches their own personal characteristics – age, area of residence, form of employment and professional status, history of accidents and so forth – so that everyone pays only for the risk of their particular risk pool, and staid middle-aged professionals do not share the financial risks posed by, say, 18-year-old males driving their first car.

- 2.31 While in the UK such individualisation or de-pooling of risk in domains such as insurance or private-sector retirement pensions has not been accompanied by a reduction in communal risk pooling in most aspects of national health⁶¹ and social insurance, the developments in healthcare with which we are concerned throw up ethical issues relating to both responsabilisation and consumerisation, as will be seen in Chapters 5 to 11. For patients or potential patients, individualisation of what may previously have been treated as shared chances of ill-health is accompanied by the possible expectation that each person will ascertain and manage their potential future health risks in a responsible way. However, the healthcare developments we are concerned with do not necessarily imply some one-way move from social solidarity to individual prudence. In some cases they can facilitate new forms of group solidarity, for instance through the creation of new group allegiances formed around disease-specific identities. Such activity builds on a longer history of pressure groups and self-help groups that have formed around particular diseases, that organise activities aimed at understanding and reducing risks to their own particular disease group, for example breast cancer, HIV or haemophilia. The creation of such groups may be thought of as a move from 'society' to 'groups of people just like me who are at risk'. Today, such movements make heavy use of internet technologies, such as social networking and patient group websites that not only share information, direct users to relevant research, and seek to raise funds, but also campaign for research investment and policy changes beneficial to the conditions for their own disease group. Such group activity both feeds into policy development and provides examples of new ways of organising healthcare that can be used, copied and encouraged by subsequent health policies. Again, such developments seem to be double-edged in terms of ethical issues relating to responsabilisation and consumerisation, since they can plainly lead to new forms of group empowerment, but also to new forums for political competition over which groups have the loudest voices or the most politically salient illnesses.
- 2.32 There are other more specific links between responsabilisation and consumerisation. For example, the development of direct advice services to individuals (as with the UK's NHS Direct web service and its equivalents in other countries, based on an 'expert system' algorithmic approach) represents consumerisation to the extent that it can enhance choice by providing another source of health advice to individuals on top of traditional sources such as pharmacies, friends and direct consultation with doctors. But that development can also be used to drive responsabilisation by putting new moral obligations on individual citizens, for example during epidemics or pandemics to use a teleservice before or instead of presenting themselves in person to the hard-pressed medical services, so as to avoid burdening, and potentially infecting, healthcare professionals (a move that constitutes 'depersonalisation' in at least one of the senses discussed in the previous chapter).
- 2.33 Other developments in the NHS less directly relevant to our inquiry here that represent a mingling of consumerisation and responsabilisation include 'personal care budgets' and choice of providers for specialist treatments. The former is a form of voucher system for public services

⁶⁰ See, for example: Ericson, RV and Doyle A (2004) *Uncertain business: Risk, insurance and the limits of knowledge* (Toronto: University of Toronto Press).

⁶¹ Dentistry is perhaps the main exception.

originally introduced for social care but now extending to healthcare,⁶² that both gives the purchasers an element of consumer choice (among different public or private providers) and puts the responsibility onto them to see that the money is spent effectively in relation to their own personal needs and priorities. The second also represents a mixture of consumer choice and responsibility for selecting the best provider of treatment. Many of the developments that we assess in later chapters also entail a similar mix of responsabilisation with consumerisation, and hence generate some of the same ethical dilemmas in balancing the virtues of individual choice with the obligations of personal responsibility.

Conclusion

- 2.34 This chapter has aimed to show how the developments in medical profiling and online medicine with which this report is concerned intersect with broader social and economic changes. Those changes include the development of the global healthcare industry, as in the new genetic profiling market, changes in public policy and in consumer behaviour, much of it linked to, and intensified by, modern communications technology. And those developments in medical profiling and online medicine throw up some perplexing ethical questions related to responsabilisation and consumerisation, as we foreshadowed in the previous chapter and will explore further in Chapters 5 to 10. The questions include issues about the proper uses of information which pertains to individuals but can be of strong collective or group benefit when pooled; about the new obligations and expectations that may be placed on individuals by new forms of 'personalisation'; about the dilemmas individuals face when purportedly predictive information is inaccurate or ambiguous or carries other harms; about the loss of solidarity that could result from a greater ability to predict individual health risks or to bypass collective provision; about the potential to change priorities away from collective provision of public health through environmental and other 'impersonal' measures; and about how to balance individual choice with avoidance of unnecessary harm. We turn to these issues in the next chapter.

⁶² Department of Health (2009) *Personal care budgets: First steps*, available http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117262.pdf.

Chapter 3

Ethics

Chapter 3 – Ethics

Introduction

- 3.1 This chapter considers how to manage the ethical issues posed by developments in medical profiling and online medicine. By ethical issues we mean the moral what-to-do questions arising in this area that require individuals, organisations, companies and the state (in all its various organisational forms)⁶³ to evaluate and choose between alternatives.
- 3.2 Chapter 1 sketched out some ways in which developments in medical profiling and online medicine have the potential to change the delivery of healthcare, and set out some of the positive and negative consequences that could flow from such changes. This chapter returns to those matters to consider the ethical issues they present. It then relates the advantages and disadvantages to five ethical values that the Working Party thinks should govern decision making in this area. We argue that: (1) those ethical values conflict with one another for the developments we are considering here; (2) no one of these values automatically trumps the others as a basis for good practice or for intervention by the state or other third parties; and (3) the appropriate ethical approach is therefore to examine each of the developments under consideration in its context with the aim of achieving as many as possible of all the conflicting ethical values that apply to each individual case. The aim is thus to manage, reduce or ‘soften’ the conflicts among the five ethical values. As a simple example of such an approach, the practice of allowing individuals to drive cars has both obvious advantages and dangers. The advantages are individual convenience and collective benefit, while the dangers are to the life and health of the drivers themselves, passengers, cyclists and pedestrians, as well as pollution and noise. Among the ethical values that conflict in this case are the autonomy of individuals and the reduction of harm by state action. Rather than giving one value priority over another, in practice all societies find ways of regulating the practice so that many of the benefits remain and many of the harms are reduced or mitigated. Consequently driving while intoxicated, at speed, or in a poorly maintained car, are prohibited. While, to a degree, such measures compromise individual freedom to drive, it does so in a way that most drivers and non-drivers can accept is a reasonable balance among conflicting values. We describe our approach more fully in Paragraphs 3.15–3.19.
- 3.3 It is possible to imagine societies in which there was a settled and widespread understanding that one or some of the five different ethical values we consider below would invariably and automatically trump the others – for instance, that the achievement of collective benefit or ‘solidarity’ would always outweigh considerations of individual preferences or vice-versa. Nor is that a wholly imaginary example: what is commonly claimed to be the prevalent individualism of societies like the USA is often contrasted with the more solidaristic societies of Scandinavia. However, we do not believe the UK today belongs at either of those extremes, and we suspect that applies to many other countries too. Indeed, as we suggested in the previous chapter, the way these new applications of medical profiling and online healthcare have been marketed and sold as representing a brave new world of ‘personalised healthcare’ and ‘democratising’ access to medical knowledge and therapeutic possibilities, represents a challenge to collectivist approaches to healthcare (while also opening up new modes of group activity and throwing up new ‘spillovers’ and collective-action issues).⁶⁴ To the extent that these developments represent a potential challenge to older forms of collectivism, some will see any move as something to celebrate, others as a matter of regret. But in a society where the relative importance of the five ethical values we identify is inherently contestable, intervention by the state or other bodies that puts all the weight on any one of them seems difficult to justify. That is why we have adopted the softening-dilemmas method as the basis of our ethical approach to these developments.

⁶³ We use the term state to denote all those bodies, whatever their organisational form, that have legal powers to permit, prohibit, require or punish, at all levels from municipalities to supranational bodies like the European Union.

⁶⁴ By ‘spillovers’ we mean forms of individual activity that impose costs or bring benefits to others. See Paragraph 3.11.

Potential advantages and disadvantages of applications of medical profiling and online medicine

3.4 Table 3.1 develops further the point we made in Chapter 1 – that the developments considered here have the potential for both benefit and harm. For each one of the five developments in medical profiling and online healthcare, the Table identifies several potential consequences that can plausibly be considered as beneficial, and a roughly equal number of consequences that might equally plausibly be considered as potentially harmful. In the case study chapters that follow, we attempt to analyse the evidence that exists as to the extent of these potential advantages and disadvantages in practice. The what-to-do question that then arises in each case is therefore ‘how can we maximise the potential benefits while minimising the potential harms?’

Table 3.1: Potential advantages and disadvantages of applications of medical profiling and online medicine

Service	Potential advantages	Potential disadvantages
Access to online health information	<ul style="list-style-type: none"> i) Convenience ii) Allows people who want to, to be more involved in their own health and healthcare iii) Can empower patients relative to doctors iv) Can provide protection from medical malpractice or incompetence v) Facilitates mutual support 	<ul style="list-style-type: none"> i) Misleading information ii) Misinterpretation iii) Breaches of privacy iv) Can undermine traditional doctor-patient relationship
Online personal health records	<ul style="list-style-type: none"> i) Secure and useful storage ii) Convenience iii) Interactive records, e.g. alerts iv) Worldwide access v) Benefit from research on pooled data vi) Safeguarding function 	<ul style="list-style-type: none"> i) Misuse of stored information ii) Advantages of centralised information may possibly be lost through separate information systems iii) Difficulties for healthcare professionals if they have to rely on inaccurate or incomplete records maintained by patients iv) Opportunity for promotion of unnecessary or inappropriate treatments/services
Online purchasing of pharmaceuticals	<ul style="list-style-type: none"> i) Convenience ii) Price competition iii) Availability iv) Privacy 	<ul style="list-style-type: none"> i) Obtaining inappropriate or harmful medicines ii) Adverse interactions with other medicines iii) Limited or no opportunity for advice iv) Risks from incomplete information about adverse effects and contraindications v) Increased danger of obtaining fake or low quality medicines vi) No limits on quantity bought vii) Possibility of increase of antibiotic resistance arising from misuse viii) Reduction in the quality of relationships with health professionals if health conditions not discussed
Telemedicine	<ul style="list-style-type: none"> i) Benefits of being at home rather than in institutional care ii) Convenience iii) More equitable access to 	<ul style="list-style-type: none"> i) Dangers of misuse ii) Reduction in the quality of the doctor-patient relationship iii) ‘Virtual brain drain’

Service	Potential advantages	Potential disadvantages
	healthcare iv) Cheaper care v) Earlier return home from hospital	iv) Inappropriate early discharge from hospital v) Surveillance of lifestyle
Predictive testing: personal genetic profiling and body imaging	i) More information ii) Allows early intervention iii) Allows more personal control iv) Possibility of saving public healthcare resources if testing and treatment conducted privately v) Can alert relatives to important genetic conditions (all of the above depend on the accuracy of the results given)	(i) Costs to individuals of tests that yield little determinate information (ii) Harms caused when tests themselves can be damaging (e.g. through radiation) (iii) Social harms when private testing can undermine equal access to healthcare (iv) Costs of consequences of having information: a) for individual when inaccurate or hard to interpret, b) for individual when nothing can be done, c) for individual if inaccurate risk assessments lead to false reassurance or misplaced anxiety, d) for individual if results lead to stigma or information abuse (e.g. blackmail) or other effects that may be regretted, given that information once known cannot be 'un-known' (e.g. for insurance declarations), e) for taxpayers when unnecessary follow-up testing and treatment is carried out (v) Costs and harms to third parties – when children or third parties are tested without consent, or when embryos are tested for conditions whose risks may be hard to determine (vi) Can change perception of wellness and illness through medicalisation of normal variation, including for children

Common ethical values

3.5 Although each case considered in this report is different, we find that the issues identified in Table 3.1 all connect with a series of widely acknowledged ethical values, which we set out below, and do so in ways that can generate moral dilemmas. Accordingly it will be necessary in the chapters that follow to explore whether the dilemmas do occur in any substantial form, and what might be done to mitigate them.

1. The value of safeguarding private information

3.6 The value of safeguarding private information refers to individuals being able to keep information about themselves and their health private and free from unauthorised access or use if they so wish. Being able to keep such information private is often said to be important in promoting dignity and autonomy, and invasion of privacy can lead to harm to individuals, for example if it leads to ostracism, blackmail or discrimination.⁶⁵ All our case studies raise questions about the creation, possession, transmission and security of highly personal information about individuals. For example, the increasing amount of information about people that is available on the internet and being processed online raises key issues about the scope and limits of privacy and confidentiality, and the same goes for genetic testing where information about an individual may be of crucial relevance to his or her relatives.

⁶⁵ Laurie G (2002) *Genetic privacy: A challenge to medico-legal norms* (Cambridge: Cambridge University Press).

- 3.7 That means that established information governance principles (such as the professional obligations – and common law – of confidentiality applying to healthcare professionals, data protection laws and the international agreements and human rights conventions protecting the confidentiality of personal data) are relevant for the many actors involved in providing the goods and services we are considering. But as with other ethical values we are considering, privacy and confidentiality does not always trump all other considerations, and there are situations when data protection can and should be overridden if the consequences of not doing so are sufficiently serious.

2. The value of individuals being able to pursue their own interests in their own way

- 3.8 It is widely held that individuals should where possible be able to pursue their own interests in their own way, and this value is sometimes known as respect for personal autonomy. It is commonly argued that there are at least two reasons why people should have such autonomy. First, individuals can be thought to be the best judges of their interests, and so are likely to make better decisions concerning their wellbeing than others would for them. Second, whether or not the first argument holds, it can be demeaning or insulting not to take decisions for oneself, even though we know that, in practice, individuals rarely take decisions in isolation, without any reference to the views and opinions of others they trust. But as with privacy and confidentiality, personal autonomy is not a value that always outweighs all others, and there are often powerful contrary reasons that can limit it.

3. The value of efforts by the state to reduce harm

- 3.9 Even in the more individualistic societies, the value of personal autonomy is not always recognised as decisive. In many countries the state in all its various organisational forms (law courts, legislatures, civil and military executive bodies) restricts autonomy to varying degrees to make it less likely that individuals will cause serious harm to themselves and others (for example by making seatbelts or motor cycle helmets compulsory),⁶⁶ and that too can be seen as a major ethical value. The value of reducing harm by such action is commonly thought to be particularly applicable to children and other individuals considered to be vulnerable in some important way, as for example in prohibitions on children being able to purchase alcohol or tobacco. Indeed, preventing individuals from taking decisions for themselves out of a desire to prevent harm is commonly called ‘paternalism’, assuming that the state or its various agents have the right to treat adults in the way a parent would decide what is best for a child and enforcing those decisions against the will of the individuals concerned. The value of acting to prevent harm in such a way can often be expected to conflict with that of personal autonomy, and we identify numerous clashes of that kind later in the report. For example, if, as some claim, purchasing restricted pharmaceuticals over the internet without a prescription involves high risk of harm to the purchasers that is preventable by various forms of regulation, the value of personal autonomy conflicts directly with that of the value of state action to reduce harm. But state action may also be directed to prevent the actions of individuals harming or imposing costs on others, rather than on themselves – the ‘spillover costs’ problem to which we have already referred. We find many examples of such costs in the cases considered in this report.
- 3.10 While it is often argued to be more important for the state and its various organisations to use their powers to prevent harm rather than to convey benefits or provide for enjoyment,⁶⁷ those two elements can blur into one another, for example over issues of access to clean air or

⁶⁶ We note that there are other reasons for restricting autonomy in some jurisdictions, such as the exercise of state power.

⁶⁷ For example Jeremy Bentham observed: ‘The care of providing for his enjoyments ought to be left almost entirely to each individual; the principal function of government being to protect him from suffering.’ (Bentham J (1843) *Principles of the Civil Code*, in *The Works of Jeremy Bentham published under the superintendence of John Bowring Vol. 1*, Bowring J (Editor) (New York: Russell and Russell), p301.)

unpolluted water supplies. Moreover, as we shall see in the next chapter, intervention can take a range of forms, from legal obligation or prohibition accompanied by penalties to various softer forms of action that are designed to steer opinion or behaviour by persuasion, advertising or other actions that fall short of compulsion. Indeed, some have argued that the state is legitimately entitled to use its compulsorily derived tax funding to support interventions designed to convey benefits to individuals even where harm to third parties was not palpable. For example, the 2007 Nuffield Council report *Public Health: Ethical issues* argued,⁶⁸ as part of what it called a 'stewardship' model of state activity, that an important function of government was to ensure that conditions were in place that made it easy (or easier) for people to be healthy.

4. The value of using public resources efficiently and fairly

3.11 While individuals might be considered to be entitled to spend their own money wastefully or carelessly if they choose to do so, there is normally considered to be a special obligation to allocate public resources efficiently and fairly. Efficiency is conventionally taken to mean output or effect relative to input or expenditure, for example in how health benefit can be secured by particular forms of medication or treatment. In principle, efficiency is a value that can be related to any goal, but in public healthcare systems it is often related to fairness, since the finite resources available to such systems are expected to be used in such a way as to produce effective results, given the alternative uses to which those finite resources could be put. That often involves difficult choices over the cost thresholds that are considered justifiable for publicly-funded treatment or medication for individuals, and the National Health Service (NHS) and other public healthcare systems have mechanisms (e.g. the National Institute for Health and Clinical Excellence in the UK) for deciding how those limited healthcare resources should be allocated (in the form of guidelines over which treatments should be provided and to whom). Indeed, throughout the NHS, organisations and individual practitioners are charged with ensuring that limited resources are used in the most effective manner. We recognise the difficulties this value presents, although the rationing issues involved are not the focus of our report. The issue of managing spillover costs that was discussed in the previous section can have an impact on the use of limited public healthcare resources, as the examples we gave there indicated. And even less directly than in the examples given in that section, provision of, and common access to, new forms of medical services could lead to the degradation of existing services, through diversion of resources and attention, if those new services require investment of time and money that might be more effectively spent in other ways.

5. Sharing risks, protecting the vulnerable: the value of social solidarity

3.12 Somewhat overlapping with the values of harm reduction and the efficient and fair use of public resources, it is often argued that the NHS, and similar systems of publicly-funded healthcare, embody a valuable notion of social solidarity in the sense of shared responsibility and pooling risks in a way that protects the vulnerable. Such systems also embody a principle of equity for all members of society, at least in access to a certain minimum of care, support and financial security, thus also protecting those most vulnerable.

3.13 The ethical principles embodied in the notion of social solidarity in the sense of sharing risks and protecting the vulnerable are complex and contestable – and indeed they are more contested than the four values mentioned above. Such a view of the world places an independent ethical value on measures that foster and enhance the sense of collective

⁶⁸ Nuffield Council on Bioethics (2007) *Public Health: Ethical issues*. Along similar lines to the framework introduced in the next chapter, that report described how the state had at its disposal a range of tools for stimulating individual behaviour. It could encourage some behaviours and discourage others by using methods of intervention such as providing information, incentives or disincentives, that typically did not amount to compulsion. There is also the possibility of shaping how choices are presented to citizens, such as governments choosing carefully what is to be the 'default' choice, and how hard it is to deviate from this default. As we also argue in this report, the 2007 report argued that where the state had regulatory power to prohibit, require, permit or punish, it should do so when the stakes were high enough and alternative less coercive measures did not seem to be adequate.

obligations and responsibilities for one another, irrespective of whether, in this or that particular, a measure or policy delivered an immediate health or other desired benefit.

- 3.14 We think the value of solidarity is sufficiently widely held in the UK and similar societies for us to ask whether new developments in medical profiling and online medicine could undermine the collective benefit and intrinsic social solidarity of a national health service, and if so whether governments ought to try to reduce these possibilities or even protect existing systems. We noted in the previous chapter that the NHS in the UK does not deny treatment to individuals because they have led ‘irresponsible’ lives, but some of the developments we are considering here offer the potential for placing more obligations on individuals for the management of their health. Such developments might in principle increase the view that health risks are not shared equally among all citizens, and therefore that those at low risk should not be expected to make financial contributions to support those who, for genetic or other reasons, are at higher risk, thus potentially threatening the democratic legitimacy of a publicly-funded health service free at the point of need. We will explore whether the possibility of increasing personal responsibility implies that individuals should be faced not merely with the consequences of their choices, but also with the consequences of their own biology, or whether the principle of social solidarity and the sharing of risks can and should still prevail in an era of increasing medical profiling and the individualisation of risks of disease. But at the same time some of the developments we are considering offer the possibility of new forms of social solidarity, for example in new ways of pooling data in medical research and providing mutual advice and support.

Managing ethical dilemmas: taking a ‘softening’ approach

- 3.15 Each of the examples listed in Table 3.1 can be seen as potentially generating a clash between some of the considerations set out in Paragraphs 3.6–3.14. The pressing question for this report, therefore, is how these dilemmas are to be resolved. How, for example, is it possible to adjudicate a conflict between individuals pursuing their interests in their own way, and the state attempting to reduce harm, if it is suspected that their chosen behaviour will lead to harm?
- 3.16 One possible approach would be to attempt to find arguments that show that one principle should always, or at least in a clearly defined range of cases, take priority over another. For example, the principle that fire service vehicles should be able to access a burning building could plausibly be thought to have clear priority over the principle that vehicles should not park on a double-yellow line. If similar priority rules could be discovered in the cases here in question then the dilemmas would be solved. But even if that approach can be applied in a few of the issues related to the cases considered here, we do not think such an approach can be applied to most of the issues that arise. All the values identified in this chapter are important, and any argument that one is more fundamental than another, even within a limited range, is likely to be highly controversial, and not command general assent.
- 3.17 Consequently, we need to examine each case in detail, as we do in the chapters to follow, to identify the ethical values invoked in each case and see where they conflict. That requires going through the tricky exercise of trying to establish the benefits and harms in each case, to see whether the potential dangers to which we have referred do in fact arise in any substantial form, or will come to do so over time, and to understand how serious any clash among the five ethical values is in practice for each of the cases. Where there is no evidence of actual or incipient clashes among ethical values or serious violations of any of them, there is no need to make a case for any practical action, even though we may want to comment on what we think are desirable and less desirable trends.
- 3.18 Where there is a case that practical dilemmas arise and harm may be substantial as it would seem they are in some cases, there is a real question as to how to deal with them. As we mentioned in Paragraph 3.3, when we introduced the idea of ‘softening’ dilemmas, the approach we follow in this report is not so much to attempt to solve the dilemmas but to propose forms of oversight and voluntary conduct so that society can manage its way around them and reduce

the conflict while gaining general assent. This approach means trying to accommodate as many as possible of the different values we have identified without giving one absolute priority over another.

- 3.19 Inevitably the question arises of what level of harm justifies what kind of intervention by the state or other third parties, and we deal with this issue in the next chapter. In the case study chapters (5 to 10), we apply the ethical approach sketched out here, of respecting genuine ethical values with a pragmatic approach of finding a solution that is at least acceptable to a wide community. Before we do so, we set out in the next chapter what we mean by intervention by the state and other third parties, what key choices have to be made among types of intervention and what principles should govern such choices.

Chapter 4

Intervention

Chapter 4 – Intervention

Introduction

- 4.1 Chapter 1 noted that it is one thing to identify ethical issues or problems with developments such as medical profiling and online medicine, and another to recommend remedial interventions by the state or other third parties. Only in a society where ‘everything that isn’t prohibited is compulsory’ would every ethical issue be *ipso facto* translated into official rules or formal state intervention. The Working Party does not advocate such an approach, but in the previous chapter we set out a way of thinking about the sort of values that should underlie any such intervention and how we should deal with the conflicts or trade-offs that arise among those different values. Generally, law follows the kind of approach we outlined in the previous chapter, in that there is rarely any overarching legal value or principle that takes precedence over all others, and thus a balance needs to be struck.
- 4.2 In this chapter we turn to forms of intervention by the state or other parties that could be used to shape the developments in medical profiling and online medicine discussed in this report. As explained in Chapter 1, for formal intervention of any kind to be justified, we think the issue in question needs to cross a threshold of significance in terms of its likely harms (a ‘proportionality’ test); intervention has to be feasible; and there must be a broad enough basis of consensus about the evidence of the harms involved and the actions to be taken (see Paragraph 1.10). Moreover, it is necessary in every case to consider alternative possible forms of intervention in the light both of the considerations just mentioned and the values set out in Chapter 3; and we do that in each of the chapters that follow.
- 4.3 The idea of proportionality in policy intervention is a familiar one and it has appeared in previous Nuffield Council reports as well as many ‘good governance’ documents.⁶⁹ The idea of proportionality involves the presumption that, since individual liberty has a high value in liberal states, the coerciveness of intervention should be appropriate to the risks or harms involved and that costs should be proportioned to likely benefits. For instance, the 2007 Nuffield Council report *Public health: Ethical issues* used the term ‘intervention ladder’ to denote a range of possible interventions from monitoring the current situation to compulsory elimination of choice, which were likened to the rungs of a ladder.⁷⁰ That report argued that policy makers should select the rung appropriate for any given intervention by weighing up the benefits to individuals and society against the erosion of individual freedom, so as to ensure that no more coercive intervention is employed than is necessitated in each case. Broadly we follow the same approach here, though we consider two dimensions of intervention rather than one and the nature of our subject matter is different (the developments we are considering offer the prospect of benefits as well as harms, as explained in the previous chapter, and the possible harms we are considering are less well-understood and harder to quantify than those considered in the earlier report).⁷¹

⁶⁹ For instance, proportionality is one of five principles of good regulation identified by the UK’s (then) Better Regulation Task Force in 1998 (along with accountability, consistency, transparency and targeting). See: Better Regulation Task Force (2006) *Principles of good regulation*, available at: <http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf>. It is also a guiding principle for the EU when defining how it should exercise its competences – EU action should not go beyond what is necessary to achieve the objectives of the European Treaties. See: European Commission *Better regulation glossary*, http://ec.europa.eu/governance/better_regulation/glossary_en.htm#_P. See also: European Commission (2006) *Better regulation – simply explained*, available at: http://ec.europa.eu/governance/better_regulation/documents/brochure/br_brochure_en.pdf.

⁷⁰ Nuffield Council on Bioethics (2007) *Public health: Ethical issues*.

⁷¹ The case studies in this report were infectious disease, obesity, alcohol and tobacco and fluoridation of water.

Four types of intervention

- 4.4 Intervention can take several forms. We consider two basic dimensions of intervention here. One refers to whether an intervention is general in nature or applied to a specific product or service. Specific measures focus on particular products or services and are concerned with precisely what can be sold, done or provided under what conditions, following what standards. In contrast, other forms of intervention take the form of measures affecting the conduct of affairs in general that then have implications for specific products or services – for example, professional codes of conduct based on broad principles such as putting the patient's interest first, general rules of competition law and policy, the general law of tort and contract,⁷² rules about transparency and data protection laws. General rules of conduct are often held to be preferable to product- or service-specific interventions for several reasons. One is that the latter are vulnerable to obsolescence (especially in fields such as those we are considering here, where technology is changing rapidly). Another is that service-specific interventions may be more prone to 'gaming' (where providers play the system to meet the rules and no more). A third is that service-specific interventions can lead to either over- or under-inclusive specification of the harms being addressed and inevitably lead to categorisation problems as to which specific products or services fall within the rules and which outside them.
- 4.5 But more general modes of intervention are not problem-free either, and that is why in some cases more product- or service-specific measures can be preferable. For example, the general value of transparency – measures that allow the public to gain more information about the operations and structures of firms, governments and other bodies – has been much stressed in recent years in ideas about good governance (and can be traced back at least to the ideas of Rousseau and Bentham in the eighteenth century),⁷³ and some have even argued that it can act as a substitute for more specific forms of intervention and regulation.⁷⁴ Empirical studies of the effects of transparency measures on the behaviour of consumers and citizens are few and far between; but it is often argued that transparency measures reach their limits where the information provided is not readily intelligible by the public at large or where such measures encourage one-way, defensive forms of communication by the organisations concerned.⁷⁵ At that point, more specific forms of intervention may be both necessary and desirable.
- 4.6 The second dimension on which intervention can vary that we are concerned with is broadly the same as that considered in the 'ladder of intervention' analysis mentioned in the previous section. This dimension relates to the formal powers being used for intervention and in particular whether or not an intervention involves formal coercive power. Many types of intervention, both by the state in all its various organisational forms and by other actors, involve no special legal powers, as in the case of prizes, grants, advice, information, advertising, non-binding agreements or voluntary codes. But some types of intervention involve powers of compulsion or coercion – powers to compel, prohibit, punish or permit what is otherwise prohibited – that are normally considered to be powers specific to the state (that is, the legislative, judicial and executive branches of government).⁷⁶ The term 'regulation' as ordinarily understood implies the use of such powers.⁷⁷ For example, voluntary standards or codes of conduct belong to the first

⁷² Or delict in Scotland and other countries that draw on Roman law.

⁷³ See, for example: Hood C and Heald DA (Editors) (2006) *Transparency: The key to better governance?* (Oxford: Oxford University Press and Proceedings of the British Academy).

⁷⁴ See, for example: Thaler RH and Sunstein CR (2008) Disclosure is the best kind of credit regulation *Wall Street Journal* 13 August.

⁷⁵ See, for example: Roberts A (2006) *Blacked out: Government secrecy in the information age* (Cambridge: Cambridge University Press); O'Neill O (2006) Transparency and the ethics of communication, in Hood C and Heald DA (Editors) *Transparency: The key to better governance* (Oxford: Oxford University Press and Proceedings of the British Academy), pp75–90.

⁷⁶ In the Roman law, such power is denoted as the public power.

⁷⁷ There is no single agreed use of the term 'regulation'. It is often used by academics to refer to any form of state or other third-party intervention, whether involving the coercive powers of the state or other types of measures such as prizes or economic incentives (see, for example: Breyer S (1982) *Regulation and its reform* (Cambridge, MA: Harvard University

type of intervention; whereas standards or codes of conduct that can lead to formal punishment or prohibition if they are breached (for example if medical professionals are struck off the register that allows them to practice) belong to the second type.

- 4.7 It should be emphasised that this second distinction refers to the types of powers used in intervention, not to the particular types of organisations wielding those powers. Many kinds of organisations, running across different levels of jurisdiction from supranational to local levels, can be used for public policy, such as government departments, statutory authorities, state-owned corporations and notionally private or independent organisations. But organisations that are normally considered to be private or independent can be given powers of legal compulsion or coercion in some circumstances, as with those nineteenth-century railroad corporations that had powers of compulsory land purchase. On the other hand, organisations that are normally considered to be at the heart of the state, such as government departments, local authorities, military or police forces, often seek to use forms of intervention such as exhortation, education, monitoring (such as traffic surveys) or other activities designed to promote compliance, that require the coercive power of the state only in the indirect form of taxation to produce the necessary resources. In some cases, interventions by judges in law courts (for example in establishing or changing rules about medical negligence) can be just as important, or more important, than what legislatures or bureaucracies do. But we are more concerned with the types of powers used in intervention than the types of organisations wielding those powers, because the principle of proportionality that has already been referred to holds that powers of the second, coercive, type should be only used when the powers of the first type are insufficient for tackling any given problem, whatever type of organisation is doing the intervening.
- 4.8 Table 4.1 puts together the two distinctions about types of intervention made earlier (between general and specific measures, and between coercive and non-coercive measures) into a table, and gives selective examples of each of the four types of intervention involved. It is meant to be indicative and illustrative, not comprehensive, and as with any scheme of categorisation, there are no doubt types of intervention that fall on the borderline between these four types. But as we shall see in later chapters, the overall ‘regime’ that shapes the provision of all the types of services discussed in this report tends to be a mixture of all of those four types of intervention, and this schema helped us to identify the existing pattern of interventions and consider possible alternatives or additions. For reasons already stated, our general presumption is that measures of type (1) in Table 4.1 are preferable to measures of type (2), that measures of type (3) are preferable to type (4), and that measures of types (1) and (2) are preferable to types (3) and (4), unless justified by the harm avoided or risk reduced by the measures concerned.

Press). Lawyers in the UK tend to use the term more narrowly to mean either a particular type of law passed by the European Parliament and Council, or secondary legislation in the form of statutory instruments that ministers or other delegated authorities are permitted to make.

Table 4.1: Selected examples of four types of intervention

Type of intervention	General	Product or service-specific
Do not involve formal coercive power	(1) Measures aimed at encouraging general forms of behaviour (e.g. self-reliance, health awareness)	(2) Voluntary product- or service-specific codes of conduct or accreditation schemes
Do involve formal coercive power	(3) General law of tort or delict governing principles of negligence General codes of professional conduct involving formal penalties for breaches Intellectual property rights (concerning trade marks, patents, copyright, database rights) and fair trading and competition law	(4) Product or service-specific permits or licensing schemes Product or service-specific prohibitions on supply, possession or research Mandatory conditions applying to sale of specific products or services (such as compulsory insurance, product or service standards)

Four goals of intervention

- 4.9 All of the four types of intervention discussed above and illustrated in Table 4.1 can be used to secure the following four (overlapping) purposes, which seem to us to be most relevant to the medical profiling and online medicine developments considered in this report:
- reducing errors and improving the quality of products and services;
 - shaping or determining who has access to what products and services and on what terms;
 - shaping or determining who has access to what kind of information and on what terms; and
 - shaping or determining relationships between providers and users of various types (for example those aimed at providing a level playing field for competition between different types of providers, such as 'physical' and 'virtual', public and private, national and international).
- 4.10 Table 4.2 gives selected examples of types of intervention aimed at each of these goals, again distinguishing between those that involve the use of coercive power and those that do not (the aim is to indicate the range of interventions possible rather than provide a comprehensive list). We also note that there are external factors, such as the power of the market and competition from other providers, that have an impact on safety and quality but which do not come under the heading of 'intervention'.

Table 4.2: Selected examples of interventions aimed at four types of goals or purposes

	Non-coercive interventions	Coercive interventions
Reducing error and improving the quality of goods and services	Provision of authoritative information Voluntary or independent quality evaluation systems such as accreditation Voluntary compensation schemes for patients or consumers who suffer harm or loss	Compulsory error or adverse event recording Conditions imposed by compulsory insurance requirements Legal obligations on intermediaries such as internet service providers Legal liability for defective products
Shaping or determining who has access to what products and services and on what terms	Pricing practices (e.g. through tax or subsidy) designed to shape patterns of consumption	Prohibitions on sales e.g. to minors Prescription-only drug supply
Shaping or determining who has access to what kind of information and on what terms	Encouragement of information pooling initiatives (e.g. patient social networking sites, evaluation websites, biobanking schemes)	Data protection laws Transparency obligations (e.g. compulsory disclosure of records or mortality rates) Libel laws Restrictions and prohibitions on advertising
Shaping or determining relationships between providers and users of various types	Public education and advertising Corporate social responsibility initiatives Voluntary codes of practice	Contract law and tort of negligence Compulsory cooling-off periods Compulsory accreditation systems Compulsory codes of practice (as in statutory regulation of professional conduct)

4.11 The provision of healthcare within any country takes place within a legal and policy context that shapes the distribution of rights, responsibilities and liabilities among healthcare professionals, patients and other parties. Consequently, since we are much concerned in this report with applications of medical profiling and online medicine that relate to ‘responsibilisation’ and ‘consumerisation’, we set out in Box 4.1 the broad legal and policy context applying to the UK and its component countries. We refer back to this legal and policy framework in our later case study chapters to see how it impacts upon the new developments we consider, and the final chapter considers how this framework might appropriately respond to those developments.

Box 4.1: General duties, responsibilities and liabilities within healthcare in the UK

The responsibility for providing healthcare falls on the different governments of the UK. They are obliged by statute to, for example, “continue the promotion in England of a comprehensive health service” (under the National Health Service Act 2006, though the meaning of ‘comprehensive’ is not defined; and similar statutes apply elsewhere in the UK). The Secretary of State can devolve these duties to various health service bodies. NHS healthcare is broadly provided free of charge, at the point of delivery, to all who are entitled to it based on clinical need,⁷⁸ though care can be restricted in the light of scarcity of resources (e.g. for medicines, treatments, organs for transplant) and patients are not ordinarily denied NHS treatment because they might have made ‘irresponsible’ choices. Adults are broadly free to seek private providers or alternative medical therapies and may, in some circumstances, also do so on behalf of their children.⁷⁹

Patients are not legally obliged to undergo medical examinations, tests or treatment. Adults, and in most circumstances children, must ordinarily give valid consent before being treated, otherwise the touching of their body constitutes a battery and a negligent standard of care. Patients can, therefore, legally refuse treatment. Special rules concerning consent apply for those judged not to have sufficient mental capacity to make a decision about treatment at a particular time.⁸⁰

Statements of policy (notably the NHS Constitution 2009 for England) have set out what the Government considers to be responsibilities of patients, including a general obligation to take “some personal responsibility [for one’s health]”, to register with a general practitioner, to provide accurate information about their health, condition and status, to follow agreed courses of treatment (or to talk to the clinician if it is difficult to do so) and to participate in public health programmes such as vaccination. None of those ‘responsibilities’ is legally binding.

Healthcare professionals and patients, as with everyone else, are bound by general laws such as criminal law, contract law, torts of negligence, battery and assault, laws of confidentiality and data protection. To avoid a finding of negligence, doctors and other service providers must show that their professional practice has met a standard accepted as proper by a responsible body of people in the same profession.⁸¹ It may also be necessary to show that such professional opinion is logical and reasonable. Hospitals and other bodies are often vicariously liable for the negligence of their employees. They may also be directly liable if they have not met the standards of care expected of them. Tort also has implications for the responsibilities of patients, since if (for instance) patients can be shown to have lied about their medical history, failed to follow medical advice or prescriptions, or declined treatment, the courts could take such behaviour into consideration in deciding questions of negligence by healthcare professionals.

There are a number of other safeguards for patients and consumers. One is the requirement of healthcare professionals to be registered with the relevant regulatory body, and the power of those bodies to remove a person from their register if they pose a risk to patients.⁸² Another is the various regimes of quality and safety inspection that apply to healthcare services provided by the NHS, local authorities and private companies or voluntary organisations.⁸³ A third is the safety regimes applying to medicines and medical devices.⁸⁴

⁷⁸ Except in limited circumstances.

⁷⁹ In 2008, it was announced in England that patients would be allowed to pay for additional drugs without losing their NHS treatment. Previously, patients had not been permitted to ‘top up’ their NHS care with drugs they had paid for privately. See: NHS Choices (2008) ‘Top-up fees’ Q&A, available at: <http://www.nhs.uk/news/2008/11November/Pages/TopupfeesQA.aspx>.

⁸⁰ If gaining such consent is not feasible, consent must either be obtained from a person legally able to act on the patient’s behalf, or the treatment must be considered to be in the patient’s best interests.

⁸¹ See *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.

⁸² To practise medicine in the UK all doctors (NHS or otherwise) must hold both registration and a licence to practise from the General Medical Council under the Medical Act 1983. Other health professional regulatory bodies register health professionals in the UK and (under various statutory instruments) have powers to remove professionals from their registers and prevent them from practising where they consider such action to be in the best interests of public safety. They are the General Chiropractic Council, General Dental Council, General Optical Council, General Osteopathic Council, Health Professions Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland and Royal Pharmaceutical Society of Great Britain (whose regulatory function is being replaced by the General Pharmaceutical Council).

⁸³ Assessed and inspected by the Care Quality Commission in England, the Scottish Commission for the Regulation of Care, Healthcare Inspectorate Wales and the Northern Ireland Regulation and Quality Improvement Authority. Pharmacy premises

Our approach to selecting forms of intervention

- 4.12 As stated earlier, our presumption (consistent with our approach to softening or reducing dilemmas posed by conflicts of ethical values, as set out in the previous chapter) is to look first for interventions of the type that do not involve formal coercive power (i.e. contained in the upper rows of Table 4.1) rather than those that do (in the lower rows) unless we judge the degree of harm and consensus in a particular case merits the more stringent and intrusive type of intervention.
- 4.13 However, there are cases where even if the conditions for the more coercive types of intervention can be considered to be met, such measures could not be enforced, could be enforced only at prohibitive cost, or could be expected to have adverse side-effects. Such circumstances, as we will see, are not just a theoretical possibility, and that is why we need the criterion of feasibility as well as that of proportionality. Further, following conventional processes for assessing regulatory or other proposals, we think it is necessary to show that general interventions such as transparency rules (illustrated in the left-hand column in Table 4.1) are inadequate before recommending product- or service-specific measures.
- 4.14 As will become clear in the following chapters, most of our recommendations focus on interventions of the type not directly involving coercive legal power (upper rows of Table 4.1). In a few cases, though, we think the three tests noted in Paragraph 4.2 (sufficiently serious harms, consensus and feasibility) are met and thus more intrusive state-introduced regulation is warranted. However, it is often difficult to find a clear way of ascertaining ‘acceptable risk’, meaning that proportionality and risk is inherently indeterminate and often politicised. For example, it is rarely the case that a fundamental justification can be given for, say, setting the speed limit on motorways at 70 miles per hour rather than 75 or 65, although no doubt some arguments can be given. But it is often possible to find a form of regulation that is acceptable, if not ideal, from a variety of viewpoints, and to a wide group of stakeholders and citizens who are otherwise opposed. Moreover, tricky judgments have to be made in so-called risk-risk decisions, where reduction of one risk may increase another,⁸⁵ or in conditions where interventions designed to protect one group of people adversely affect others. That is why the ‘softening dilemmas’ approach described in the previous chapter seems particularly appropriate to the developments we are considering here.
- 4.15 In each of the case study chapters that follow, we trace out the existing landscape of interventions affecting the developments we are looking at as well as identifying conflicts between ethical values and, where possible, assessing the benefits and the seriousness of the harms involved in each case. None of the developments we are concerned with exists in a void, and in most cases there is already a set of interventions in existence that involve some or all of the four basic types of interventions illustrated in Table 4.1. Moreover, many of the developments we are considering involve services that are provided across borders, meaning that we need to assess intervention at an international rather than national level. Taking these existing interventions into consideration, we recommend further intervention where we think it meets the threshold conditions referred to earlier and where we think it would help to reduce or soften the value-dilemmas we find.

in England, Scotland and Wales are regulated at present by the Royal Pharmaceutical Society of Great Britain (currently changing to the General Pharmaceutical Council). The Pharmaceutical Society of Northern Ireland fulfils an analogous role.

⁸⁴ The Medicines Act 1968 and subsequent UK regulations implementing EU legislation provide the legal framework for the control of medicines and medical devices in the UK. The Medicines and Healthcare products Regulatory Agency is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe.

⁸⁵ See, for example: Wiener JB (1998) Managing the iatrogenic risks of risk management *Risk: Health, safety and environment* **9(1)**: 39–82.

Chapter 5

Online health information

Chapter 5 – Online health information

Overview

What is new? Over the past decade or so people have increasingly used the internet to search for, exchange and post health information on various types of websites, including those run by governments and charities, patient group websites and individuals' own sites and blogs. Some of this activity is an extension or new formatting of the types of information that have long been provided by newspapers or magazines, but the existence of search engines and group networking sites opens up new possibilities, and raises the issue of how people can ensure they are receiving good quality, validated information. These developments link to our discussion of the issues of consumerisation and responsabilisation in Chapters 1 and 2, because they both allow for more convenient 'consumer-like' or patient-led access to information and because they raise the issue of how and when individuals might be reasonably expected to seek health advice online. They also have the potential to contribute to the other two types of personalisation that we identified in Chapter 1.

Which ethical values come into conflict as a result of this development? The main conflict among the values we identified in Chapter 3 is that between individuals' ability to pursue their own interests in their own way on the one hand, and the values of safeguarding private information and state activity to reduce harms on the other. Another potential conflict arises between the ethical values of safeguarding private information and social solidarity in the form of information pooling for common benefit, for instance in research.

What is the existing pattern of interventions like? There is no overall oversight of information on the internet, though different countries apply their laws to the information on it and how people in their jurisdictions use it. Most of the existing types of intervention in the UK and many other countries fall into the category of 'general governance' measures as described in Chapter 4, with some involving the exercise of state-specific legal power and some involving less coercive measures. The main state-specific legal power relevant to this area is the data protection regime, involving general obligations and prohibitions in criminal law that are enforced by a state regulator. Additionally, the standard codes and rules for medical professionals apply where such individuals are involved with provision of online health information. The main general governance measure falling outside state-specific legal powers is that of the advertising standards regime, and the only service-specific form of intervention that appears to apply to this domain is that of accreditation schemes (which also fall outside the realm of state-specific legal power).

What gaps or shortfalls are there in existing interventions? Existing interventions by the state or third parties do not make it easy for individuals to assess the quality or accuracy of information being provided to them online. Such interventions also do not provide strong incentives for information providers to follow 'best practice', for example by informing users of the ways in which information provided might be stored, passed on or sold. The footloose character of information provision on the internet means that individuals cannot easily ascertain which jurisdiction's laws apply to any given website.

What types of intervention might possibly fill those gaps or remedy those shortfalls? If the main potential harm arises from misleading or poor-quality information and the lack of recognisable quality standards, possible types of intervention might include state provision of good-quality information, voluntary adoption of good practice, third-party accreditation, litigation over allegedly false or misleading claims, and state-imposed standards, including those that could be applied to controls over the internet, if such measures were proportionate and feasible.

What types of intervention do we recommend, and why? Our recommendations are for: (i) voluntary adoption of good practice for websites and forums linked with (ii) good professional medical practice adapted to the modern information age; (iii) the adoption of third-party accreditation of online health information provision; and (iv) state provision of high-quality information and government monitoring of any impact of the 'digital divide'. Our reasons for making these recommendations are that we wish to promote and not restrict the benefits to the public and individuals of online health information, and our inquiries have not produced sufficient evidence of harm to justify the use of coercive state interventions.

Introduction

- 5.1 Health information has been described as including “information for staying well, preventing and managing disease, and making other decisions related to health and health care”.⁸⁶ Our focus in this chapter is the development over the last two decades of enormous amounts of health information on the internet becoming available to, and written by, lay people (see Box 5.1).⁸⁷
- 5.2 Before the development of the internet, people found health information by consulting with their doctor or other health professional; from books, newspapers and magazines; or from family and friends. The internet has quickly become a major source of information for those who have access to it, and it has been argued that the demand for online health information is “unstoppable”.⁸⁸ The boundaries between online health information sites and other aspects of ‘e-health’ discussed in this report, such as online pharmaceutical purchasing (see Chapter 7) and online personal health records (see Chapter 6), are becoming increasingly blurred. Online systems are emerging which, as well as providing online health information, also enable personal health records to be created, stored and updated, facilitate the online purchasing of pharmaceuticals, and can be used for disease surveillance and other monitoring.
- 5.3 Online health information figures in public policy too. For example, in 2009, the then UK Government announced its commitment to provide universal access to broadband services by 2012, as part of its strategic digital vision for the UK, laid out in the *Digital Britain* report.⁸⁹ The report includes themes directly relating to online healthcare provision, stating that the provision of ‘next-generation’ broadband is vital for a variety of applications,⁹⁰ including “e-healthcare in the home” and “internet based health services”, which may offer “greater detail and information about healthy eating, dieting, exercise, diagnosis, treatment and recovery”. Furthermore, the report claims that “nearly a fifth of web users use the Internet as their first port of call when investigating a health concern”⁹¹ (see also Paragraph 5.29).
- 5.4 The use of online health information raises issues of consumerisation and responsabilisation as discussed in Chapters 1 and 2, and such online information has the potential to contribute to all four types of personalisation that we identified in Chapter 1. It is easier for people to search for and find health information that may apply to them, at times and in ways of their own choosing. Some websites purport to offer individualised diagnosis (although we note that many existing websites only sort people by groups based on the information they provide rather than as unique individuals), and they allow people to select the sort of information that aligns with their cultural worldview as a ‘whole person’. And they also lend themselves to ‘responsibilisation’, in the sense of ways in which individuals can be expected or cajoled to take a more active role in their health and healthcare, taking account of official or received views about how to live healthily and behaving responsibly in the sense of consulting online or similar sources of information (for example during pandemics) when deciding whether and when to seek face-to-face consultations with medical professionals.

⁸⁶ Rippen H and Risk A (2000) e-Health Code of Ethics *Journal of Medical Internet Research* **2(2)**: e9.

⁸⁷ We focus on information about conditions, treatments, medicines and devices and not on information about health services. Health information on the internet is of course available to medical professionals too as one of their sources, but we focus on its use by the non-professional user.

⁸⁸ Shaw J (2009) A Reformation for our times *British Medical Journal* **338**: b1080.

⁸⁹ Department of Culture, Media and Sport and Department for Business, Innovation and Skills (2009) *Digital Britain – Final Report*, available at: <http://www.culture.gov.uk/images/publications/digitalbritain-finalreport-jun09.pdf>.

⁹⁰ In this context, ‘next generation broadband’ can be interpreted as referring to extremely high speed internet access technology (when compared to 2008–2009 standards), usually based on fibre-optic technology.

⁹¹ Department of Culture, Media and Sport and Department for Business, Innovation and Skills (2009) *Digital Britain – Final Report*, available at: <http://www.culture.gov.uk/images/publications/digitalbritain-finalreport-jun09.pdf>, pp13, 29, 30.

Types of health information websites

- 5.5 Online health information comes in various forms and one useful categorisation divides them up as follows:⁹²
- general health information provision sites;
 - disease-specific sites;
 - interactive patient group websites;
 - scientific databases; and
 - web tools.
- 5.6 Such information is provided for various reasons, including for commercial purposes and for non-profit reasons such as public policy (for example that aimed at improving the health of the population or at increasing the efficiency of the public healthcare service) and altruistic or collective self-help reasons, such as a desire to help and learn from those with similar health problems.
- 5.7 Information on health-related websites comes in many formats including data, text, audio and video.⁹³ The background of those who provide the content varies to some extent according to the type of website. For example, the general health information provision site WebMD identifies medical writers and editors, physicians and health educators amongst its editorial staff.⁹⁴ Other sites take a more user-orientated, 'Web 2.0', approach (see Box 5.1), whereby content is user-generated, and collaboration, information-sharing and interactivity is paramount, for example in the case of patient sites which are often developed and run by people with a particular condition. Other online health information resources, such as some health-related wikis, involve a collaborative Web 2.0-style approach (at least in terms of the tools with which content is created) but maintain a more traditional relationship between doctors and patients/consumers. For example, AskDrWiki is a site upon which anyone with a proven medical background can provide information (without being a member of the editorial staff).⁹⁵

Box 5.1: Web 2.0

The trend for websites to include, or be entirely based upon, 'user-generated' content is often seen as central to the so-called 'Web 2.0' phenomenon, a phrase popularised after the O'Reilly Media Web 2.0 Conference in 2004. The term is notoriously hard to define precisely, but it is generally accepted to mean the concept of improved communication among both individuals and the programs they use (via open web standards), improved interfaces, interactivity, user-generated content and 'collective intelligence'. Commonly cited examples of Web 2.0 include Wikipedia and YouTube, since they are based on user-generated or uploaded content. This approach can be compared to the 'top-down' content aspects of 'Web 1.0': O'Reilly uses the contrast between 'publishing' and 'participation' to bring out a key element of the difference between Web 1.0 and Web 2.0, but there is much disagreement over the scope of Web 2.0 and even whether it really exists, given the difficulty in defining the term and the fact that some argue that it is simply a marketing buzzword; a concept rather than a clearly identifiable piece of technology. The term 'health 2.0' has been said to connote the "use of a specific set of Web tools

⁹² Adapted from Schwartz J (2008) Logging on for a second (or third) opinion *The New York Times* 29 September, available at: http://www.nytimes.com/2008/09/30/health/30online.html?_r=1.

⁹³ For further information, see: Rippen H and Risk A (2000) e-Health Code of Ethics *Journal of Medical Internet Research* **2(2)**: e9.

⁹⁴ WebMD (2010) What we do for our users, available at: <http://www.webmd.com/about-webmd-policies/about-what-we-do-for-our-users>.

⁹⁵ Those signing up to the website in order to edit entries are required to "submit their medical training, degree, and current hospital or medical school". See: AskDrWiki (2007) AskDrWiki: Editorial policy, available at: http://askdrwiki.com/mediawiki/index.php?title=AskDrWiki:Editorial_Policy.

(blogs, Podcasts, tagging, search, wikis, etc.) by actors in health care including doctors, patients, and scientists, using principles of open source and generation of content by users, and the power of networks in order to personalize health care, collaborate, and promote health education”.⁹⁶

General health information provision sites

- 5.8 Health information sites provide information about health and diseases, as well as information about lifestyle, medicines and supplements. Examples include dedicated sites such as WebMD and Patient UK, as well as numerous blogs concerning health matters and websites that include health information as part of a wider range of services, such as BBC Health.⁹⁷ Some websites that fall into this category provide mechanisms that facilitate self-diagnosis and the Map of Medicine Healthguides function on NHS Choices allows the user to follow the assessment pathway and “see what your doctor can see”⁹⁸ (Box 5.2).

Box 5.2: Examples of National Health Service (NHS) websites

The NHS Direct website provides a self-help service, which provides appropriate medical advice and information based on answers the user gives in answer to a series of questions about their symptoms. Depending on the answers given, users may be advised to, for example: “Call 999. Your answers suggest you need to dial 999 immediately and ask for an ambulance” or “Your answers suggest that you can safely look after yourself with the care advice on the next page”.

The Map of Medicine Healthguides resource on the NHS Choices website allows the user to follow on flow charts “the ideal, evidence-based patient journey for common and important conditions”.⁹⁹ It is a patient-oriented version of the Map of Medicine, which was originally developed for healthcare professionals.¹⁰⁰ The Healthguides aim to allow patients to “self-educate and engage with care providers about their journey.”¹⁰¹

Disease specific websites

- 5.9 Disease-specific sites focus on a particular condition, and tend to be provided by charities or patient interest groups, or may also be blogs. Funding comes from a range of sources, including charitable donations, governments and pharmaceutical companies. Information might typically be provided about the condition, its cause, the drug treatments and complementary and alternative therapies that are available, as well as providing advice on lifestyle. Examples of groups that have established such websites include the UK’s Alzheimer’s Society and Parkinson’s Disease Society and breastcancer.org in the USA.

Interactive patient group websites

- 5.10 Interactive patient group websites are typically for people with a particular condition to find out information and share experiences with others having the same or similar condition. Online communities such as these can provide helpful support for people, for example by countering feelings of isolation. Some help people with rare conditions to find out information about their particular circumstances from others with experience of the condition. Some are set up by

⁹⁶ Hughes B, Joshi I and Wareham J (2008) Health 2.0 and Medicine 2.0: Tensions and controversies in the field *Journal of Medical Internet Research* **10(3)**: e23.

⁹⁷ See: <http://www.bbc.co.uk/health/>.

⁹⁸ NHS (2010) See what your doctor can see with Map of Medicine Healthguides, available at: <http://healthguides.mapofmedicine.com/choices/map/index.html>.

⁹⁹ *Ibid.*

¹⁰⁰ Map of Medicine (2009) About us, available at: <http://www.mapofmedicine.com/about/history/>.

¹⁰¹ Map of Medicine (2010) New design for Map of Medicine Healthguides, available at: <http://www.mapofmedicine.com/newsandevents/news/2010/healthguides/>.

patients themselves, others by companies, and they are funded in various ways, including advertising and sponsorship from pharmaceutical companies. Some collect data and use it in research or to sell to third parties for research. PatientsLikeMe is an example of a website that enables users to share clinical information on their condition and collects it in a “blinded, aggregated and individual format to [sell to their] partners (i.e., companies that are developing or selling products to patients)”.¹⁰² Such websites can also be used by researchers to give people the opportunity to participate in medical research.

Scientific databases

- 5.11 Scientific databases, including PubMed or clinicaltrials.gov, provide access to research published by scientists or ongoing clinical studies. Some of these sites were originally intended for use by medical and healthcare professionals, but they can of course also be accessed on the internet by anyone.

Web tools

- 5.12 Web tools are designed to help people to manage their condition and generally have an interactive component: for example, automated analysis and results based on the answers to an online questionnaire. A case in point is sugarstats.com, which enables the user to “track, monitor and access your glucose levels and diabetic statistics to spot dangerous trends and better manage your diabetic health”.¹⁰³ Another webtool, MoodGYM,¹⁰⁴ is an “interactive web program designed to prevent depression”, developed by the Centre for Mental Health Research at the Australian National University, that uses diagrams and online exercises with the aim of teaching the principles of cognitive behaviour therapy.¹⁰⁵ The NHS in England offers Healthspace, a website that includes tools that enable the user to enter and keep track of health information such as weight or cholesterol levels (see also Paragraph 6.6).

Benefits and harms

- 5.13 Some potential advantages and disadvantages of online personal health information were set out in Table 3.1.

Potential advantages

- Convenience;
- allows people who want to, to be more involved in their own health and healthcare;
- can empower patients relative to doctors;
- can provide protection from medical malpractice or incompetence; and
- facilitates mutual support.

Potential disadvantages

- Misleading information;
- misinterpretation;
- breaches of privacy; and
- can undermine the traditional doctor-patient relationship.

We explore these advantages and disadvantages further below.

¹⁰² PatientsLikeMe, responding to the Working Party’s consultation. See also: <http://www.patientslikeme.com/>.

¹⁰³ SugarStats (2009) About SugarStats, available at: <http://www.sugarstats.com/about/>.

¹⁰⁴ MoodGYM (2010) the MoodGYM training program/Mark III, available at: <http://moodgym.anu.edu.au/welcome>.

¹⁰⁵ MoodGYM (2010) MoodGYM frequently asked questions, available at: <http://moodgym.anu.edu.au/welcome/faq>.

Reasons people use the internet to access health information

- 5.14 The internet is distinctive because it combines enormous amounts of information with powerful mechanisms for rapid search and retrieval. It enables people to have convenient access to health information in the privacy of their own homes, at the time they wish and for as long and as many times as they wish. Online health sites allow information to be accessed without embarrassment and without needing to talk face-to-face with a doctor or health professional. People may also save money if they would otherwise need to pay for a consultation with a doctor or miss work to do so. There are people who, for whatever reason, have difficulty in accessing the information they need during face-to-face consultations, and health websites may be of great help to them. One study found that the average physician consultation in the USA was eight minutes long,¹⁰⁶ and in the UK the average length of consultation with a general practitioner was 11.7 minutes in 2007.¹⁰⁷ It has been argued that “Given the brevity of the patient-physician encounter, it is perhaps not surprising that patients express a need for more information... ”¹⁰⁸
- 5.15 Using online health information can thus enable individuals to increase their ‘health literacy’ if they want to do so, and to increase their sense of empowerment about their health. Looking up symptoms online may also encourage people to see their doctor early and take other positive action.¹⁰⁹ Given the prevalence of medical errors and misdiagnoses, online information can help people to identify such errors more easily. It may also have beneficial applications for public health, for example in times of pandemics.
- 5.16 There is evidence from the USA to suggest that many people have had positive experiences with online health sites.¹¹⁰ In 2008, the Pew Internet and American Life Project found that 31% of e-patients said they or someone they knew had been “significantly helped by following medical advice or health information found on the internet,” while 3% said they or someone they knew had been seriously harmed by following advice or information found online. Fifty-nine per cent of those internet users who were chronically ill and who had experienced a “health crisis” in the past year had found information online that had then led them to ask their doctor new questions, or seek a second opinion.¹¹¹ However, the author also identified a “generalized fear of misinformation” regarding health information on the internet.
- 5.17 Additionally, a European study found that, in 2005, 30% of internet users across seven countries felt reassurance or relief when accessing health-related information on the internet,¹¹² while 15% stated that they had feelings of anxiety.¹¹³ A 2007 survey found that 36% of Norwegian respondents reported feelings of reassurance or relief after using the internet for health purposes, while 19% had feelings of anxiety.¹¹⁴ The relative perceived importance of the internet as a source of health information has also been studied. One survey,¹¹⁵ again of the

¹⁰⁶ Hardey M (2007) ‘E-health’: The internet and the transformation of patients into consumers and producers of health knowledge, in Lederman LC (Editor) (2007) *Beyond these walls: Readings in health communication* (New York: Oxford University Press), pp154–64.

¹⁰⁷ The NHS Information Centre (2007) *2006/2007 UK general practice workload survey*, available at: <http://www.ic.nhs.uk/webfiles/publications/gp/GP%20Workload%20Report.pdf>.

¹⁰⁸ Sen N (2007) Patient dissatisfaction as a motivating factor in online health seeking *Paper presented at the annual meeting of the NCA 94th Annual Convention, San Diego, CA*, available at: http://www.allacademic.com/meta/p257285_index.html.

¹⁰⁹ Shaw J (2009) A Reformation for our times *British Medical Journal* **338**: b1080.

¹¹⁰ Fox S (2008) *The engaged e-patient population*, available at: http://www.pewinternet.org/~media/Files/Reports/2008/PIP_Health_Aug08.pdf.pdf.

¹¹¹ *Ibid.*

¹¹² The study used a sample of 7,903 people, of which 4,906 were internet users. The countries covered by the survey were Denmark, Germany, Greece, Latvia, Norway, Poland and Portugal.

¹¹³ Andreassen HK, Bujnowska-Fedak MM and Chronaki CE *et al.* (2007) European citizens' use of e-health services: A study of seven countries *BMC Public Health* **7**: 53.

¹¹⁴ Wangberd S, Andreassen H, Kummervold P, Wynn R and Sorensen T (2009) Use of the internet for health purposes: Trends in Norway 2000–2010 *Scandinavian Journal of Caring Sciences* **23**: 691–6.

¹¹⁵ Kummervold PE, Chronaki CE and Lausen B *et al.* (2008) eHealth trends in Europe 2005–2007: A population-based survey *Journal of Medical Internet Research* **10**(4):e42.

same seven European countries as the study mentioned above, found that, in 2007, approximately 47% of survey respondents considered the internet as an “important” source of health information, although direct contact with health professionals was still perceived as the most important source.¹¹⁶ However, there were significant differences between countries in terms of how respondents perceived the relative importance of the internet as a source of health information. For example, in Denmark the internet was seen as the second most important source of health information, behind only health professionals, while in Greece the internet was seen as the least important source, coming behind contact with health professionals; television/radio; books, medical encyclopaedias and leaflets; courses and lectures; newspapers and magazines; family, friends and colleagues; and pharmacies.¹¹⁷

Differences between the sources of information available

5.18 Health information has long been available in books, magazines and other print media. The underlying concept of acquiring information applies to both print material and the internet, but there are some important differences, which include the following:

Print

- It is often easier to determine the author/publisher of printed material and hence establish responsibility and liability.
- Information provided in print media or through radio/television has a ‘static’ nature, as opposed to the potential of websites to be continuously updated.

Online

- The internet can be used to track users’ identities, what other pages they view and where they are located. This information can then be used to target advertising to them.
- Vast quantities of searchable information are rapidly available, much but not all of that information being free.
- Information may appear to be more ‘personalised’ (in the sense of providing more individualised prediction, prevention and treatment, see Paragraph 1.18) when it is returned in response to information submitted by the user (for example, see Paragraph 5.12). That responsive character may lead to perceptions that such information is closely tailored to the inquirer’s personal circumstances, even if that is not always the case.

5.19 The key difference between online health information and information found through print media or via television and radio does not seem to lie in the degree of accuracy in the information available or whether it is free or involves charges, but rather in the way it is accessed. The speed at which an enormous variety of information (well beyond what even the most lavish libraries once contained) may be accessed through targeted, consumer-initiated use of search facilities is far beyond what was previously available. That is why quality problems with online information may have an important impact, even if it is not necessarily true that proportionally more online health information is less accurate than offline information.

¹¹⁶ *Ibid.*

¹¹⁷ The ordering of the last seven items was not stated. See: Kummervold PE, Chronaki CE and Lausen B *et al.* (2008) eHealth trends in Europe 2005–2007: A population-based survey *Journal of Medical Internet Research* **10**(4): e42. It can be noted that, although the authors of the study drew no direct causative or correlative link between internet uptake in a particular country and the level of interest in online health searching, Greece had the lowest uptake of internet access of all the countries surveyed.

Accuracy of information on the internet

- 5.20 Information, whether on the internet or elsewhere, is not all verified for clarity or accuracy. The quality of information available is variable:¹¹⁸ from strictly evidence-based to misleading and even malicious, and the traceability of authorship also varies widely. The development of websites on which people add their own experiences (see Box 5.1) enables people with similar conditions to provide support and information to each other across the world, but raises questions about how personal data is used and sold to third parties, and also frequently relates to non-standard forms of treatment.¹¹⁹ Inaccuracy, misinterpretation or conflicting sources have the potential to lead to confusion, false reassurance or undue anxiety. While these features are not unique to the internet, they may have more significance for other information sources for the reasons given above, and numerous studies have brought out such problems with internet-based health information.
- 5.21 For example, one study showed that approximately one in four patients who used the internet to research forthcoming operations they were due to undergo found the information worrying or confusing.¹²⁰ It has also been shown that many people who look for health-related information through search engines use short, often mis-spelt search phrases and rarely look further than the first page of search results.¹²¹ Another study conducted in 2008, aiming to identify “how effectively students can assess the accuracy of Internet-based material when gathering information on a controversial medical topic using simple keyword searches,” found that 59% of the 34 students who took part reported that they believed the websites they accessed, having used the search terms “vaccine safety” and “vaccine danger” in the Google search engine, were accurate on the whole, despite the fact that over half of those websites were in fact inaccurate on the whole: it was noted that “a high percentage of the students left the [...] exercise with significant misconceptions about vaccines”.¹²² A systematic review in 2002 found that “most authors who evaluated [health website] content found significant problems, criticizing lack of completeness, difficulty in finding high-quality sites, and lack of accuracy”. However, the review also noted that, while online health information quality may be variable “due to differences in study methods and rigor, quality criteria, study population, and topic chosen, study results and conclusions on health-related Web sites vary widely.”¹²³ Studies have also been performed on the adequacy of online health information as it pertains to various fields of medicine,¹²⁴ while others focused on the criteria that should be used to assess information found.¹²⁵
- 5.22 Such studies seem to suggest there is not always a close connection between accuracy and features such as the degree of citation or who provides the information.¹²⁶ They also suggest

¹¹⁸ Bovi AM (2003) Use of health-related online sites *American Journal of Bioethics* **3(3)**: W48–52.

¹¹⁹ Although it is by no means clear that the internet is a “major pathway” to patient complementary and alternative medicine usage. See: Broom A and Tovey P (2008) The role of the internet in cancer patients’ engagement with complementary and alternative treatment *Health (London)* **12**: 139.

¹²⁰ Tamhankar AP, Mazari F, Everitt NJ and Ravi K (2009) Use of the internet by patients undergoing elective hernia repair or cholecystectomy *Annals of the Royal College of Surgeons of England* **91**: 460–3.

¹²¹ Morahan-Martin JM (2004) How internet users find, evaluate, and use online health information: A cross-cultural review *Cyberpsychology and behaviour* **7(5)**: 497–510.

¹²² Kortum P, Edwards C and Richards-Kortum R (2008) The impact of inaccurate internet health information in a secondary school learning environment *Journal of Medical Internet Research* **10(2)**: e17.

¹²³ Eysenbach G, Powell J, Kuss O and Sa E-R (2002) Empirical studies assessing the quality of health information for consumers on the World Wide Web: A systematic review *Journal of the American Medical Association* **287(20)**: 2691–700.

¹²⁴ Hargrave DR, Hargrave UA and Bouffet E (2006) Quality of health information on the internet in pediatric neuro-oncology *Neuro-Oncology* **8(2)**: 175–82; Selman TJ, Prakash T and Khan KS (2006) Quality of health information for cervical cancer treatment on the internet *BMC Women’s Health* **6**: 9; Bernstam EV, Walji MF, Sagaram S *et al.* (2008) Commonly cited website quality criteria are not effective at identifying inaccurate online information about breast cancer *Cancer* **112(6)**: 1206–13

¹²⁵ Kunst H, Groot D, Latthe PM, Latthe M and Khan KS (2002) Accuracy of information on apparently credible websites: Survey of five common health topics *British Medical Journal* **324**: 581–2

¹²⁶ For example, it has been suggested “that features of website credibility – source, [displaying the date of the original document or content posting on the internet], and evidence hierarchy – have only slight or at best moderate correlation with

that the accuracy of online information may vary among different fields of medicine.¹²⁷ But the accuracy of information on governmental health websites was well rated by a 2010 study of 500 websites relating to common paediatric queries, which found governmental websites “gave uniformly accurate advice” and concluded that such websites “should be promoted as the first port of call for parents” looking for paediatric health advice. In contrast, the study found that “sponsored sites [those that pay to appear on the results pages of search engines] universally gave poor information”.¹²⁸ It may of course be that inaccuracies in online information can be corrected through interactive websites of the Web 2.0 type referred to earlier (see Box 5.1). Indeed, Matthew Holt, co-creator of the Health 2.0 conference, suggests that, “In the end, the more people you have in the conversation, the better information drives out the worse information,”¹²⁹ and there appears to be some limited evidence in support of this proposition.¹³⁰

Potential harms to health from using online health information

5.23 There is currently no consistent evidence to suggest that it is common for individuals to suffer harms to their health as a direct consequence of using online health information (see Box 5.3).¹³¹ But we think there is potential for physical, psychological, and possibly financial harms to arise from:

- people believing a particular condition is medical or treatable, when in fact it is not;
- people believing a particular condition is not medical or treatable, when in fact it is;
- people following advice that is inaccurate or misleading;
- people making misdiagnoses; and
- people viewing pages from (or participating in) online patient groups, but being unaware of variations in similar conditions and consequently of the risk that advice given by other patients may not be relevant, or may even be harmful, for them.

accuracy of information”. (Kunst H, Groot D, Latthe PM, Latthe M and Khan KS (2002) Accuracy of information on apparently credible websites: Survey of five common health topics *British Medical Journal* **324**: 581–2).

¹²⁷ For example, a study published in the journal *Cancer* identified 343 unique internet pages about breast cancer by using popular search engines, and found 41 inaccurate statements on 18 sites, representing an error rate of 5.2% and leading to the conclusion that most information about breast cancer that consumers were likely to encounter online was accurate (see: Bernstam EV, Walji MF, Sagaram S *et al.* (2008) Commonly cited website quality criteria are not effective at identifying inaccurate online information about breast cancer *Cancer* **112**(6): 1206–13). That finding contrasts sharply with the study of paediatric websites cited below.

¹²⁸ The study in question set out to determine the quality of advice on websites found through the Google search engine for five common paediatric queries. The first 100 UK-based Google results for each search were classified as being either consistent or inconsistent with current recommendations from the medical profession or as not providing an answer. The study found that “the reliability and accuracy of health information on the internet ranges from poor to excellent, depending on the topic”. Of the 500 sites searched, 39% were found to give correct information in terms of consistency with current evidence-based recommendations, 11% were incorrect and 49% did not answer the question. See: Scullard P, Peacock C and Davies P (2010) Googling children’s health: Reliability of medical advice on the internet *Archives of Disease in Childhood* (published online 6 April 2010).

¹²⁹ Schwartz J (2008) Logging on for a second (or third) opinion *The New York Times* 29 September, available at: http://www.nytimes.com/2008/09/30/health/30online.html?_r=1.

¹³⁰ A 2006 study designed to determine the prevalence of false or misleading statements in messages posted by an internet cancer support group, and whether and how quickly they were corrected by other members of the group, found that of 4,600 postings in four months, ten were false or misleading (0.22%) and of these, seven were identified as such and corrected within an average of four hours and 33 minutes. But the authors concede that the study covered only one internet support group, meaning that the findings may not be generalisable, that only a single reviewer determined the false or misleading nature of the posts, and that reviewer was not blinded to the study hypothesis. See: Esquivel A, Meric-Bernstam F and Bernstam EV (2006) Accuracy and self correction of information received from an internet breast cancer list: Content analysis *British Medical Journal* **332**: 939–42.

¹³¹ Ferguson T and Frydman G (2004) The first generation of e-patients *British Medical Journal* **328**: 1148–9; Smith R (2001) Almost no evidence exists that the internet harms health *British Medical Journal* **323**: 651; Crocco AG, Villasis-Keever M and Jadad AR (2002) Analysis of cases of harm associated with use of health information on the internet *Journal of the American Medical Association* **287**(21): 2869–71; Potts HWW and Wyatt JC (2002) Survey of doctors’ experience of patients using the internet *Journal of Medical Internet Research* **4**(1): e5; Bessell TC, McDonald S and Silagy *et al.* (2002) Do internet interventions for consumers cause more harm than good? A systematic review *Health Expectations* **5**: 28–37.

Such potential harms are of course not unique to information obtained online, but can nevertheless have potentially serious consequences in some cases.

- 5.24 A feature of online information referred to earlier is that it can be viewed without knowing what country it comes from or how the provider of the information in question is funded. While search engines differ to some extent according to where a user is based,¹³² users may not confine themselves to the search engines applicable to their own jurisdictions, and may therefore not be readily aware of the implications of important differences in the way healthcare systems operate, the different measures used for items such as blood sugar levels, the names used for drugs in different countries (see Paragraph 7.8), which treatments are available in what countries, what constitutes common medical practice in one particular country, the frequencies of medical conditions, and whether there is overlap between advertising and independent health information.

Box 5.3: What is the evidence of harms caused by using online health information?

There seems to be rather limited evidence of widespread harm as a consequence of accessing online health information, and no controlled comparisons between harms from online and offline information. Harms reported in the literature we found included the following:

- Inaccurate healthcare information acquired online by parents was “associated with an adverse outcome in a pediatric patient presenting with diarrhea”. But the online information was found to be “congruent” with the advice provided by emergency room staff at a local hospital, so the case showed “how inaccurate information on the Internet can contribute to the consequences of following advice received through face-to-face encounters”,¹³³ rather than demonstrating a direct causative link between the use of online health information and harm to the child in question.
- There was an apparent association between access to online health information and non-adherence to healthcare regimes in a study that found 11.2% of respondents reporting internet-instigated non-adherence and concluded “negative consequences for healthcare adherence behaviour resulting from internet health information utilization appear substantial”.¹³⁴
- An analysis of 1,512 journal article abstracts found three articles describing direct harm arising from following online health information, including two cases of emotional harm as a result of improper internet searches, one instance of kidney failure in a cancer patient who obtained misinformation about the use of medication on the internet, and one example of dogs being poisoned as a consequence of misinformation derived from the internet.¹³⁵
- Interviews with cancer patients suggested that exposure to complex biomedical information, even when it is accurate, can create significant anxiety.¹³⁶
- One survey that found 8% of doctors surveyed reported that some of their patients had suffered physical harm as a consequence of accessing online health information.¹³⁷

¹³² For example, at the time of writing, a search for “heart disease” on Google.co.uk returned different results from those coming from the same search term used on Google.com: the top three results (excluding news stories) for Google.co.uk included the relevant Wikipedia entries, the NHS and the British Heart Foundation; for Google.com, the results were for Wikipedia, WebMD and the American Heart Association.

¹³³ Crocco AG, Villasis-Keever M and Jadad AR (2002) Two wrongs don’t make a right: Harm aggravated by inaccurate information on the internet *Pediatrics* **109**: 522–3.

¹³⁴ Weaver JB, Thompson NJ, Weaver SS and Hopkins GL (2009) Healthcare non-adherence decisions and internet health information *Computers in Human Behaviour* **25**: 1373–80.

¹³⁵ Crocco AG, Villasis-Keever M and Jadad AR (2002) Analysis of cases of harm associated with use of health information on the internet *Journal of the American Medical Association* **287(21)**: 2869–71.

¹³⁶ Broom A and Tovey P (2008) The role of the internet in cancer patients’ engagement with complementary and alternative treatment *Health (London)* **12**: 139.

¹³⁷ Responses were received from 748 doctors, including 375 general practitioners: respondents estimated that 1%–2% of their patients used the internet for health information in the previous month. See: Potts HWW and Wyatt JC (2002) Survey of doctors’ experience of patients using the internet *Journal of Medical Internet Research* **4(1)**: e5.

Use of private information

- 5.25 As noted earlier, searching for information online may, to a certain extent, enable third parties to track people's identities, which pages they view and where they are located. Such data can be commercially valuable, in addition to the information that people knowingly add to some websites, for example when they are obliged to register to gain access. The balance of advantage and disadvantage to individual users of the information trail that their searches generate depends on their circumstances and their perceptions: they might, for instance, be grateful to be notified of clinical trials relevant for their condition, or upset by being sent targeted marketing for products they think are inappropriate for them. That is why protection of individuals' personal data has to be balanced against other considerations.

Public health possibilities

- 5.26 Further, searching for online health information and entering information onto websites offers possibilities beyond the individual. Information about which search terms are being entered and which pages are viewed as well as actual information submitted can all, if aggregated in a suitable way, have the potential to be useful for public health, research and commercial purposes.¹³⁸ Examples include infectious disease surveillance, understanding patterns of chronic disease, assessing health behaviour and marketing.¹³⁹ For instance, in 2009, it was shown that by analysing Google search terms related to influenza and its symptoms, researchers were able to predict accurately influenza outbreak in the USA one to two weeks prior to the publication of surveillance reports by the Centers for Disease Control and Prevention, which relied on more typical disease modelling.¹⁴⁰ We return to informing users of health information websites about the use of their information in our recommendation in Paragraph 5.54.

Extent of use

Access to and use of the internet

- 5.27 It is well known that increasing numbers of people have access to and use the internet, especially in developed countries, as is illustrated in Figure 5.1.¹⁴¹ It is also well known that there is a 'digital divide', with marked variations between socio-economic groups in terms of access to and use of the internet. For example, as of 2008, some 93% of UK adults under 70 who had a degree or equivalent qualification were reported as having access to the internet in their homes, compared with 56% of those with no formal qualifications.¹⁴² However, those over 65 were the least likely to use the internet, with 70% stating they had never used it. Although those numbers seem likely to change (the numbers of over-65s reporting they had never used the internet had been 82% in 2006), the digital divide remains serious for the age group that represents the heaviest users of healthcare, meaning there are important values of fairness and

¹³⁸ See, for example: Google Trends, <http://www.google.com/trends>.

¹³⁹ See: Kahn J, Vayena E and Dzenowagis J (2009) *Ethical, legal and policy issues in the use of electronic health information for public health research and practice*, discussion paper presented at: World Health Organization conference on Internet ethics, law and policy: Issue spotting on the use of electronic health information for public health purposes, 17–18 December 2009, Geneva.

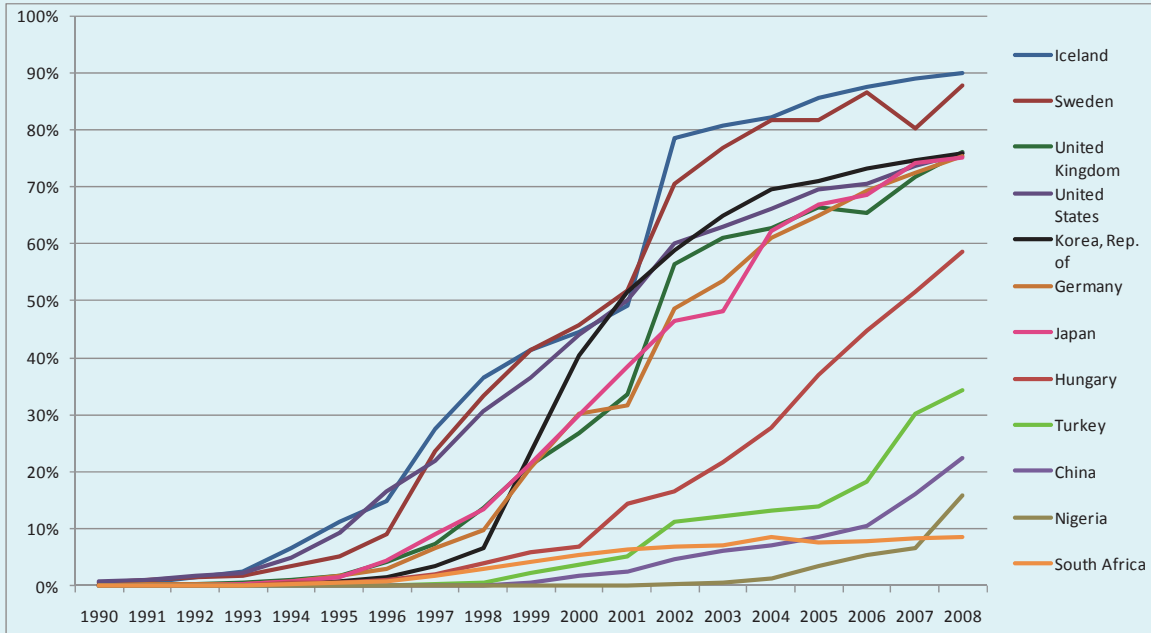
¹⁴⁰ Ginsberg J, Mohebbi MH, Patel RS *et al.* (2009) Detecting influenza epidemics using search engine query data *Nature* **457**: 1012–4.

¹⁴¹ Between 2002 and 2008 in Great Britain access to the internet increased from 46% of all households to 65%. In the USA, between 2000 and 2009, the percentage of American adults with access to the internet increased from 46% to 74%. Additionally, broadband internet access, which enables a far higher rate of data transfer than dial-up access, has become more prevalent. In 2006 in the UK, 40% of households had a broadband connection, and by 2008, this number had increased to 56%. In the USA, from 2000 to 2009, the figure rose from 5%–57%. See: Office for National Statistics (2008) *Internet access 2008 households and individuals*, available at: <http://www.statistics.gov.uk/pdfdir/iahi0808.pdf>; Fox S and Jones S (2009) *The social life of health information*, available at: http://www.pewinternet.org/~media/Files/Reports/2009/PIP_Health_2009.pdf.

¹⁴² Office for National Statistics (2008) *Internet access 2008 households and individuals*, available at: <http://www.statistics.gov.uk/pdfdir/iahi0808.pdf>. This report indicates that 71% of adults in the UK had used the internet within the previous three months before interview and of those, 69% used it every day or almost every day.

autonomy at stake for such information, particularly if those who are unwilling or unable to use the internet for health purposes are likely to be disadvantaged as a result.

Figure 5.1: Internet users as percentage of population in selected countries across the world¹⁴³



Use of the internet for health-related purposes

- 5.28 Some evidence suggests that people see the internet as only one source of information and valued having a range of different types of information about prescribed medicines.¹⁴⁴ In 2007 the Pew Internet and American Life Project found that “experts mattered most when people faced health problems”.¹⁴⁵ Other research has concluded that “online information and advice influence[es] patients’ decision making without threatening their desire to communicate with physicians” and the physician remained “the single most important source of advice on health” despite not being the “first port-of-call” for health information.¹⁴⁶
- 5.29 Figures vary about what proportion of people use the internet to obtain health-related information. In 2008, the UK Office for National Statistics reported that 34% of all recent UK internet users had used it to seek health-related information.¹⁴⁷ The 2009 Oxford Internet Survey found that 68% of British internet users searched for health information online.¹⁴⁸ Figures for other developed countries also suggest that 70% or more of internet users use it to

¹⁴³ Data obtained from World Bank Development Indicators, data derived from International Telecommunication Union, World Telecommunication Development Report and database, and World Bank estimates. See: International Telecommunication Union (2008) Internet Users (per 100 people), available at: <http://data.worldbank.org/indicator/IT.NET.USER.P2>.

¹⁴⁴ MORI Research sponsored by Medicines Partnership (2004) *The public and prescribed medicines*, available at: <http://www.ipsos-mori.com/researchpublications/researcharchive/poll.aspx?oltemId=670>.

¹⁴⁵ Estabrook L, Witt E and Rainie L (2007) Information searches that solve problems: How people use the internet, libraries, and government agencies when they need help, available at: http://www.pewinternet.org/~media/Files/Reports/2007/Pew_UI_LibrariesReport.pdf.pdf.

¹⁴⁶ Sillence E, Briggs P, Harris PR and Fishwick L (2007) How do patients evaluate and make use of online health information? *Social Science & Medicine* **64**: 1853–62.

¹⁴⁷ Office for National Statistics (2008) *Internet access 2008 households and individuals*, available at: <http://www.statistics.gov.uk/pdfdir/iahi0808.pdf>.

¹⁴⁸ Dutton WH, Helsper EJ and Gerber MM (2009) *The internet in Britain 2009*, p20, available at: http://www.oii.ox.ac.uk/research/oxis/OxIS2009_Report.pdf.

obtain health related information.¹⁴⁹ In addition to simply seeking information, substantial numbers of people are reported to participate in patient groups and other online communities associated with health information: for example, PatientsLikeMe.com reported that they had over 40,000 members registered with the site.¹⁵⁰

- 5.30 The use of online health information also appears to be shaped by demographics. The 2009 Oxford Internet Survey reported that in Britain women were more likely to look for health information online than men, and the employed and retired to seek more health information than students.¹⁵¹ Perhaps relating to the 'digital divide' to which we referred earlier, some research from the USA suggests that older, poorer, less healthy and less educated members of society are less likely to seek health information from online sources.¹⁵²
- 5.31 The medical profession's response to the rise of online health information seems to have been mixed. Some doctors see the use of the Google search engine as a diagnostic tool as being "laughable and bordering on dangerous",¹⁵³ while others consider the internet to "encourage early presentation and action that could improve survival and reduce complications from long term conditions".¹⁵⁴ It may also be that healthcare professionals find the internet useful for finding information themselves.¹⁵⁵ The British Medical Association (BMA) told us that it supported the idea of patients taking more interest in their own healthcare but was concerned about difficulties patients may experience when attempting to identify reliable and accurate information.¹⁵⁶ We return to this problem in our recommendation in Paragraph 5.63.

Current system of interventions

- 5.32 Although there is a system of governance for the basic infrastructure of the internet (notably the domain name system), there is no overall oversight of the information that appears on it. Different countries apply their laws to the information on it and how people in their jurisdictions use it. Governments use a variety of methods to try to control people's access to information on the internet, and these methods are illustrated in Box 5.4.
- 5.33 Most of the existing types of intervention relating to health information on the internet in the UK and many other countries fall into the category of what we called 'general governance' measures in Chapter 4, and of those measures some involve the exercise of state-specific legal power and some do not. As noted earlier, the main state-specific legal power relevant to this area is the data protection regime, and the standard disciplinary codes and rules for medical professionals apply where they are involved with the provision of online health information. The main type of general governance measure that does not involve state-specific legal powers is that of the advertising standards regime. The only service-specific form of intervention that appears to apply to this domain is that of accreditation schemes, which also do not involve state-specific legal power.

¹⁴⁹ In 2007, research into European citizens' use of the internet for health-related purposes reported that 44% of European citizens, and 71% of European internet users, had accessed the internet for health-related purposes. (Andreassen HK, Bujnowska-Fedak MM, Chronak CE *et al.* (2007) European citizens' use of e-health services: A study of seven countries *BMC Public Health* 7: 53). In the USA, the Pew Internet and American Life Project estimated that in 2008 75–80% of all internet users in the USA looked online for health information. (Fox S (2008) *The engaged e-patient population*, available at: http://www.pewinternet.org/~media/Files/Reports/2008/PIP_Health_Aug08.pdf.pdf).

¹⁵⁰ PatientsLikeMe.com (2009) Response to the Working Party's consultation.

¹⁵¹ Dutton WH, Helsper EJ and Gerber MM (2009) *The internet in Britain 2009*, p20, available at: http://www.oii.ox.ac.uk/research/oxis/OxIS2009_Report.pdf.

¹⁵² Cotton SR and Gupta SS (2004) Characteristics of online and offline health information seekers and factors that discriminate between them *Social Science & Medicine* 59: 1795–1806.

¹⁵³ Winthrop TC (2006) This is research? *British Medical Journal* [rapid response to Tang H and Ng JHK (2006) Googling for a diagnosis – use of Google as a diagnostic aid: Internet based study 333: 1143–5], available at: http://www.bmj.com/content/333/7579/1143.full.reply#bmj_el_148937.

¹⁵⁴ Shaw J (2009) A Reformation for our times *British Medical Journal* 338: b1080.

¹⁵⁵ Hartzband P and Groopman J (2010) Untangling the web – patients, doctors and the internet *New England Journal of Medicine* 362(12): 1063–6.

¹⁵⁶ British Medical Association (2009) Response to the Working Party's consultation.

Box 5.4: Potential methods of intervention applying to the internet

Pre-existing rules: The application of rules relating to pre-existing, well understood activities and the assertion of associated (and often legally uncontroversial) sanctions, such as those criminal penalties that relate to the distribution of child pornography. It is possible to punish criminally those in 'physical' possession of prohibited material in one jurisdiction,¹⁵⁷ i.e. on a hard drive of a computer.

Alternative dispute resolution: Consumer-related international litigation is more effectively managed through alternative dispute resolution, especially small-value internet disputes.¹⁵⁸ This is not because the legal framework to manage it in the courts does not exist, but because (as mentioned below) associated practical difficulties often render such procedures beyond the reach of the average litigant (i.e. cost, translation, time, difficulty in enforcing judgments in foreign courts and so on).¹⁵⁹

Upstream filtering: Filtering imposed from 'above' without the knowledge or consent of those so filtered. An example is mandatory or voluntary internet service provider (ISP) access restrictions of specific internet addresses. ISPs subscribe to, or have imposed upon them, 'no access' lists of specific web addresses which render particular web addresses inaccessible by the average user using the particular ISPs.

Bandwidth management: This may involve rate management of data over networks by ISPs (i.e. restricting the volume of data a particular user can move over certain networks, and therefore the 'speed' with which people can access certain data). This technique can be used to limit the bandwidth of users engaging in file sharing over peer-to-peer networks, for example.

Internet intermediary liability: The enforcement of specific rules on those intermediary entities responsible for providing the physical or software-based infrastructure of the internet and web (telecommunication networks and ISPs, for example) or those who provide access to, host or distribute content (such as search engines, YouTube or eBay and peer-to-peer networks). Examples include criminal responsibility for content that crosses a network; a legal responsibility not to provide access to prohibited items in a specific jurisdiction (such as search engines and Nazi memorabilia)¹⁶⁰ or liability for distributing copyrighted material.¹⁶¹

Monitor and warn: Online activity can be monitored and a user may be presented with a warning that their activity has been monitored.¹⁶²

Notice and disconnection: When an individual breaches a particular rule on what can and cannot be accessed online (such as downloading music in breach of copyright),¹⁶³ they may be warned (for example by their ISP, online or in writing) that their activity has been monitored and that repeat activity will result in their connection being terminated.

¹⁵⁷ Edwards L (2009) Pornography, censorship and the internet, in *Law and the internet* Edwards E and Waelde C (Editors) (Oxford and Portland, Oregon: Hart Publishing), p649.

¹⁵⁸ For example, 41% of respondents to a Eurobarometer who had submitted a formal complaint regarding a cross-border purchase reported they were not satisfied with way the complaint was handled. See: European Commission (2006) *Consumer protection in the internal market: Special Eurobarometer 252 / wave 65.1 – TNS opinion & social*, p32, available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs252_en.pdf.

¹⁵⁹ Hörnle J (2009) The jurisdictional challenge of the internet, in *Law and the internet*, Edwards E and Waelde C (Editors) (Oxford and Portland, Oregon: Hart Publishing), p121.

¹⁶⁰ *LICRA et UEJF v Yahoo! Inc and Yahoo! France* (20 November 2000: Tribunal de Grande Instance de Paris, Superior Court of Paris) 14.

¹⁶¹ *Metro-Goldwyn-Mayer Studios Inc et al v Grokster et al*. 243 F Supp 2d 1073 (CD California 2003).

¹⁶² Edwards L (2009) The fall and rise of intermediary liability online, in *Law and the internet* Edwards E and Waelde C (Editors) (Oxford and Portland, Oregon: Hart Publishing), p81.

¹⁶³ *Ibid*, p82.

Jurisdiction

- 5.34 The use of the internet imposes significant practical (though usually not theoretical) difficulties in determining the geographical location of a particular act and therefore the national law that applies to it.¹⁶⁴
- 5.35 Rules establishing jurisdiction are not part of international law, but are an element of domestic civil procedure,¹⁶⁵ the specifics of which vary between countries. In England and Wales, the process is governed by the Civil Procedure Rules when the litigants all live in England/Wales and a non-EU country, and by the Brussels Regulation (a set of rules applying to this area) when some of the litigants are from the EU. In Scotland, all such matters are dealt with under the Brussels Regulation. Courts in a foreign jurisdiction are under no obligation in international law to recognise and enforce judgments from other jurisdictions, unless there is a bi- or multi-lateral agreement requiring such action (for example the Brussels Regulation in Europe).¹⁶⁶ Contractual obligations may specify the jurisdiction in which subsequent litigation takes place, although different rules apply to consumers and they may have greater freedom in terms of choosing where to bring an action.¹⁶⁷

Liability

- 5.36 We have already noted that health information on the internet, along with many other types of health information, is not necessarily verified for clarity or accuracy. Users therefore need to appreciate that people are free in many countries to post misleading or inaccurate information on the internet that could be accessed by many people across the world. However, should an individual believe they were harmed because they followed advice from an online health information provider, they can in principle take action against that provider under the law of tort in England, Wales and Northern Ireland (see Box 4.1) and in other countries under similar laws. To give an example from another legal domain, there have been successful cross-jurisdiction defamation claims.¹⁶⁸ For an action under tort law to be successful, the claimant would have to demonstrate that they were owed duty of care by the defendant, that such a duty was breached, that the breach caused harm and that damages or other loss resulted as a consequence of that breach. It is likely that the determination of 'duty of care' in these circumstances would be complicated by the nature of the individual or organisation that provided the relevant health information. For example, if the information was provided by a non-medically qualified individual posting on a patient group website rather than being provided on the website of a national health service provider, it may be harder to establish a duty of care. Further, some online health information providers state terms and conditions of use that warn that the information they offer should not replace a consultation with a health professional, and thus seek to limit their liability. Liability for posting misleading, inaccurate or confusing information is further complicated by the transnational nature of the internet as noted above: even where a claim could be made and an appropriate jurisdiction identified, the practicalities of the situation (the extra costs of litigating in an unfamiliar legal system, hiring translators, and so on) are likely to make it difficult for the average internet user to pursue an action even if they were so inclined.

¹⁶⁴ Hörnle J (2009) The jurisdictional challenge of the internet, in *Law and the internet* Edwards E and Waelde C (Editors) (Oxford and Portland, Oregon: Hart Publishing), pp121–2.

¹⁶⁵ *Ibid*, p123.

¹⁶⁶ *Ibid*, p152.

¹⁶⁷ Lloyd IJ (2008) *Information technology law* (New York: Oxford University Press), pp482–4.

¹⁶⁸ See, for example: *Dow Jones & Co Inc v Gutnick* (2002) HCA 56 at 92. Allegedly defamatory content was created in New York, placed on a server in New Jersey and accessed in the Australian state of Victoria. The court held that the claimant, Gutnick, could litigate his defamation action in Victoria, where defamation law was stricter than the USA. The court found that accessibility was sufficient for jurisdiction, provided the claimant had a reputation in that jurisdiction.

Data protection

5.37 As we mentioned above in Paragraph 5.25, when using health information websites users may send personal data, either knowingly or inadvertently. Data protection laws are concerned with the processing of personal data, and apply to the services provided by online health website providers, depending on the country in which they are based. For organisations and companies based in the EU, the basis of the legal regime is the Data Protection Directive,¹⁶⁹ which was implemented in domestic law in the UK by the Data Protection Act 1998 (Box 5.5). The scope of the Act is seen as very wide by the UK Information Commissioner's Office,¹⁷⁰ which holds that where an organisation collects or holds information about an identifiable living individual, or where such information is used, disclosed, retained or destroyed, the organisation is likely to be processing personal data relevant to the Data Protection Act.¹⁷¹

Box 5.5: Eight principles of the UK Data Protection Act

- 1 Personal data shall be processed fairly and lawfully.
- 2 Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
- 3 Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
- 4 Personal data shall be accurate and, where necessary, kept up to date.
- 5 Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.
- 6 Personal data shall be processed in accordance with the rights of data subjects under this Act.
- 7 Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- 8 Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

5.38 Although the Data Protection Directive (and the domestic laws individual EU Member States have enacted to implement it) applies only to organisations based in the EU, personal data undergoing (or intended to undergo) processing after transfer which has been collected in an EU Member State cannot be transferred to a country that does not provide an appropriate level of protection.¹⁷² However, commentators have noted that it can be difficult to identify whether or not certain organisations are actually based in the EU: some companies voluntarily fulfil the necessary obligations required by the Data Protection Directive while maintaining that they are not formally bound by the legislation because they are not legally based in the EU. Given that such companies voluntarily comply with the relevant data protection legislation, the legal applicability of the Directive to their operations has not been tested in court.¹⁷³

¹⁶⁹ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31, as amended.

¹⁷⁰ Information Commissioner's Office (2010) Data protection basics, available at: http://www.ico.gov.uk/for_organisations/data_protection_guide/data_protection_basics.aspx. The Information Commissioner's Office was set up to "uphold information rights in the public interest [and] promot[e] openness by public bodies and data privacy for individuals". See: Information Commissioner's Office (2010) About the ICO, available at: http://www.ico.gov.uk/about_us.aspx.

¹⁷¹ Information Commissioner's Office (2010) Data protection basics, available at: http://www.ico.gov.uk/for_organisations/data_protection_guide/data_protection_basics.aspx.

¹⁷² European Union Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31 art 25.

¹⁷³ The Working Party's fact-finding meeting with regulators, 23 September 2009.

- 5.39 Mainstream use of the internet has highlighted significant gaps in data protection law as a means of protecting consumers. Such law was originally developed as a way of protecting individuals from misuse of their information by the state or other organisations, and it focuses on identifying ‘data controllers’ and ‘processors’ within such organisations, in a way that is not reflected in the distributed type of information exchange represented by Web 2.0 and similar operations.¹⁷⁴ There have been moves to close such gaps, such as the EU Privacy and Electronic Communications Directive 2002, but the adequacy of those moves can be questioned.¹⁷⁵
- 5.40 It has been claimed that there may be a generational ‘value-gap’ over the protection of certain types of personal data – as reflected, for example, in some users’ apparent (tacit) acceptance of targeted advertising when it is a feature of desired products or services, such as Facebook or Google. It has been questioned whether consent still has a role to play in protecting consumer internet data-protection interests,¹⁷⁶ given that e-commerce and ‘free’ e-services such as social networking services rarely offer any opportunities to negotiate data-use terms. However, society in general still reacts harshly to large-scale data leakage.

Advertising

- 5.41 Direct-to-consumer advertising of pharmaceuticals is prohibited in the EU. However, companies are permitted to include information about their products on their websites (see Paragraph 7.31). More broadly, advertisements on UK websites are covered by the existing UK advertising code, which applies equally to conventional print, radio and television media and originated in the early 1960s as a set of standards imposed by the advertising industry on itself. The Advertising Standards Authority (ASA) broadly seeks “to ensure ads are legal, decent, honest and truthful”.¹⁷⁷ The ASA has a variety of sanctions, such as prohibiting adverts or advertising techniques and requiring advertisers to seek advice before publishing future adverts.¹⁷⁸ The ASA can also refer the publisher of an advert to the Office of Communications (Ofcom), the communications regulator, which has the power to impose financial penalties.¹⁷⁹
- 5.42 We note that some commentators are concerned that advertising of health products and treatments could be specifically directed at particular users without their prior knowledge, based on the pages they have viewed and the information they have entered on patient websites, particularly given that some of these individuals may be particularly vulnerable as a result of a desperate search for information about treatments for their condition, or that of a dependent.¹⁸⁰ We return to this issue in our recommendation in Paragraph 5.61.

Accreditation of health-related websites and tools for users

- 5.43 There are various accreditation schemes for health-related websites. In England, the Department of Health launched a health information accreditation system (the ‘Information Standard’) in 2009 which aimed to ensure that people could identify high-quality health information through a kitemarking scheme. The Information Standard is “a quality filter which helps people to identify reliable information”.¹⁸¹ Organisations that meet the quality criteria

¹⁷⁴ Edwards L (2009) Privacy and data protection online: The laws don’t work? in *Law and the internet* Edwards E and Waelde C (Editors) (Oxford and Portland, Oregon: Hart Publishing), pp472–3.

¹⁷⁵ *Ibid*, pp471–2.

¹⁷⁶ *Ibid*, p487.

¹⁷⁷ See: <http://www.asa.org.uk/>.

¹⁷⁸ Advertising Standards Authority (2009) response to the Working Party’s consultation.

¹⁷⁹ *Ibid*.

¹⁸⁰ For example, a 2009 article in *The New York Times* that claimed RealAge.com receives payments from pharmaceutical companies for the compilation of test results from RealAge.com members and the opportunity to send them marketing messages by e-mail promoting particular products based on the information the members entered. RealAge’s Privacy Policy referred to this practice, but *The New York Times* article alleged that critics believed some users did not seem to be aware of it. See: Clifford S (2008) Online age quiz is a window for drug makers *The New York Times* 25 March, available at: http://www.nytimes.com/2009/03/26/technology/Internet/26privacy.html?_r=2&ref=business.

¹⁸¹ The Information Standard (2010) What is the standard?, available at: <http://www.theinformationstandard.org/standard>.

specified by the Information Standard are entitled to place a quality mark on their materials, including websites and print media.¹⁸² The Department of Health is the 'owner' of the Information Standard, but has licensed the scheme to the outsourcing company Capita.¹⁸³ The Information Standard requires that information be accurate, impartial, balanced, based on evidence, accessible and well written.¹⁸⁴

- 5.44 In the USA, an independent, not-for-profit organisation, the Utilization Review Accreditation Commission (URAC), aims to promote healthcare quality through accreditation and certification programmes. URAC accredits many types of healthcare organisations, including health websites.¹⁸⁵ It reviews a company's operations to ensure that the company is conducting business consistent with national standards. Among other things, URAC claims it has enhanced editorial transparency of online health sites by requiring providers to verify and disclose the credentials of their health content reviewers, and how they conduct verification of credentials. URAC provides a symbol that can be displayed by health websites, showing that the website has met these standards. Accredited health information websites include the BlueCross and Blue Shield Association, Microsoft HealthVault and WebMD.¹⁸⁶
- 5.45 The Health on the Net Foundation Code of Conduct (HONcode)¹⁸⁷ was developed in the mid-1990s by the HON Foundation, a Swiss-based non-governmental organisation. The stated aim was to encourage the dissemination of quality health information for patients and professionals, and to facilitate access to the latest and most relevant medical data.¹⁸⁸ At the time of writing, the HONcode was used by over 7,300 certified websites in 102 countries.¹⁸⁹ The HONcode specifies eight principles for the presentation of medical and health information on the internet (Box 5.6). Where a website conforms to the HONcode, and has applied for certification from the HON Foundation, the website is entitled to display the HONcode logo. The HON Foundation states that the HONcode "does not seek to rate the medical accuracy, validity or appropriateness of the information itself"¹⁹⁰ and the presence of its logo does not guarantee that the information provided on the website is accurate. Applicants must request approval to use the logo and permission is given after the Foundation has assessed the website in question in order to ascertain whether or not it conforms to the standards required. The logo is linked to the HONcode ID Index of registered and approved websites, such that a user who clicks on the logo can ascertain whether the website has had its registration declined or revoked.

¹⁸² The Information Standard (2010) What is the quality mark?, available at: <http://www.theinformationstandard.org/qualitymark>.

¹⁸³ Information Standard (2010) Scheme rules, available at: <http://www.theinformationstandard.org/scheme-rules>.

¹⁸⁴ The Information Standard (2010) What is the standard?, available at: <http://www.theinformationstandard.org/standard>.

¹⁸⁵ URAC (2010) General questions about URAC accreditation, available at: <http://www.urac.org/healthcare/accreditation/>; URAC (2010) URAC's health web site and health content vendor accreditation programs, available at: http://www.urac.org/programs/prog_accred_HWS_po.aspx?navid=accreditation&pagename=prog_accred_HWS.

¹⁸⁶ URAC (2009) URAC directory of accredited companies, available at: <http://www.urac.org/directory/DirectorySearch.aspx>.

¹⁸⁷ Health on the Net Foundation (2010), The HON Code of Conduct for medical and health web sites (HONcode), available at: <http://www.hon.ch/HONcode/Conduct.html>.

¹⁸⁸ Health on the Net Foundation (2010) Our beginnings, available at: <http://www.hon.ch/Global/index.html>; Health on the Net Foundation (2010) Our commitment to reliable health and medical information, available at: <http://www.hon.ch/HONcode/Patients/Visitor/visitor.html>.

¹⁸⁹ Health on the Net Foundation (2010) Our commitment to reliable health and medical information, available at: <http://www.hon.ch/HONcode/Patients/Visitor/visitor.html>.

¹⁹⁰ Health on the Net Foundation (2010) Methodology, available at: <http://www.hon.ch/HONcode/Patients/method.html>.

Box 5.6: Eight principles of the HONcode

- 1 Authoritative – Indicate the qualification of the authors.
- 2 Complementarity – Information should support, not replace, the doctor-patient relationship.
- 3 Privacy – Respect the privacy and confidentiality of personal data submitted to the site by the visitor.
- 4 Attribution – Cite the source(s) of published information, date and medical and health pages.
- 5 Justifiability – Site must back up claims relating to benefits and performance.
- 6 Transparency – Accessible presentation, accurate email contact.
- 7 Financial disclosure – Identify funding sources.
- 8 Advertising policy – Clearly distinguish advertising from editorial content.

5.46 Three other examples of online health information accreditation systems are noted below:

- Discern – a brief questionnaire designed to provide users with a valid and reliable way of assessing the quality of written information on treatment choices for a health problem.
- MedCIRCLE – the ‘Collaboration for Internet Rating, Certification, Labeling and Evaluation of Health Information’. MedCIRCLE comprises three European health portals in Spain, France and Germany with the goal of evaluating, describing or annotating health information on the web.
- MedIEQ – a multinational project co-funded by the European Commission. It attempts to automate the quality labelling process in medical websites by providing tools that search the internet to locate medical websites in eight European languages to verify their content against a set of machine-readable quality criteria.

5.47 The value of accreditation or ‘kitemarking’, as applied to online health information can be debated. For example, it has been noted that consumers cope with un-accredited sources of health information (such as newspapers, magazines and television programmes) despite frequent inaccuracies in information provided.¹⁹¹ But it can also be argued that accreditation is an important aid to information-seekers given that “the objective of most quality rating tools...is not to inhibit publication, but to provide a system by which consumers can assess the nature of the information they are accessing.”¹⁹²

5.48 Various agencies, professional or governmental, provide guidelines to help consumers evaluate health information on the internet. For example, the British Medical Association (BMA) provides a checklist of factors to take into account when looking for health information online (such as whether or not the site gives references and sources for the information provided), and offers examples of reputable “medical gateways” (such as NHS Direct) for identifying useful health information.¹⁹³ In the USA, the Food and Drug Administration (FDA) provides a list of questions for consumers to consider and the Medical Library Association provides a users’ guide to finding and evaluating online health information.¹⁹⁴

¹⁹¹ Delamothe T (2002) Quality of websites: Kitemarking the west wind *British Medical Journal* **321**: 843–4.

¹⁹² Wilson P (2002) How to find the good and avoid the bad or ugly: A short guide to tools for rating quality of health information on the internet *British Medical Journal* **324**: 598–602.

¹⁹³ British Medical Association (2008) Health information: Finding reliable sources on the internet, available at: http://www.bma.org.uk/patients_public/finding_reliable_healthcare_information/healthinfonet.jsp.

¹⁹⁴ Food and Drug Administration (2005) How to evaluate health information on the internet, available at: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/ucm202863.htm>; Medical Library Association (2010) A user’s guide to finding and evaluating health information on the web, available at: <http://www.mlanet.org/resources/userguide.html>.

Softening the ethical dilemmas

- 5.49 For online health information, the main conflict among the values we identified in Chapter 3 is that between individuals' ability to pursue their own interests in their own way (that is, using the internet freely to access the health information they want) and the values of safeguarding private information and state activity to reduce harms. Another potential conflict arises between the ethical value of safeguarding private information and social solidarity in the form of information pooling for common benefit, for instance in research. As described in Chapters 3 and 4, we aim to reduce or soften those dilemmas by recommending practical and proportionate forms of intervention. In some cases we may not consider that any policy change or introduction of interventions is feasible or desirable, but still think that the developments in question merit comment. That latter consideration applies particularly to restrictions on the way the internet is to be used, given the practical difficulties described earlier.
- 5.50 As we have indicated, some forms of online health information can help people increase their understanding of their own bodies, health and illness, and to become more involved with and take more control over their healthcare if they want to, for example by using some of the interactive tools available for managing chronic conditions. Indeed, good-quality health information can be argued to be key to enabling individuals effectively to pursue their own interests in their own way. Information on the internet can be accessed in private and at the user's convenience, and when it is accurate it can also help people to decide when face-to-face professional health advice is necessary and when it might not be. Patient group websites have the potential to be an especially valuable source of information and indeed a new form of solidarity for people with a particular condition who want to share experiences with others in similar situations. As mentioned earlier, information pooled from internet sources can also be used to convey public health benefits and as a source of research data that may be a common-pool resource for the future.
- 5.51 As noted earlier, there is little evidence that online health information has led to serious or widespread harm. Nevertheless, such harm could arise from individuals receiving false reassurance or suffering undue anxiety, as a result of inaccuracy or misinterpretation of information obtained online, as we have suggested above (see Paragraph 5.20). So we aim to reduce the risk of such harms while not restricting the corresponding benefits to individuals and wider society.
- 5.52 We think the lack of evidence of harms means that attempts to prohibit the publication of, or access to, online health-related information would plainly not be proportionate at this time. We argued in Chapter 4 that it is only proportionate to recommend interventions relying on the state's special legal powers (to compel, prohibit, permit or punish) when the harm justifies the use of such powers, so in this case our recommendations involve actions that do not rely on those powers. We are specifically concerned with finding forms of intervention that aid people to pursue their own interests in their own way by enabling them to assess more easily the quality of the online information they are receiving. Our aim is to help encourage a climate in which more providers of online health information follow good practice and more users come to expect such practice of the sites they visit. Our recommendations below therefore involve voluntary adoption of good practice for websites and forums, good professional medical practice, third-party accreditation and government monitoring of any impact of the 'digital divide'. In line with the approach set out in Chapter 4, we have recommended general governance measures except in situations where only a product-specific measure would achieve the desired outcome.

Content of websites

- 5.53 Given the importance today of online health information, as noted earlier (see Paragraph 5.17), we are concerned that it is not always easy for individuals to assess the quality or accuracy of such information. There are no strong incentives for information providers to follow 'best practice' in terms of the information they provide to users of their websites. It is also difficult for

people to ascertain the origin of a website and the information on it, including which country the information provider is based in. Even though patient group websites may be highly valuable in some cases, as we have also noted earlier, there is a risk that users of these sites may not be aware that advice for one person may not be appropriate for another person, even if their condition appears similar. We therefore think that users of online health information would be assisted by higher quality information and more transparency about the nature of websites.

5.54 To facilitate individuals to pursue more easily their own interests in their own way, we recommend that all websites, including patient group websites, should include at least the following information prominently in language that lay people can understand:

- **where the information originates and what it is based upon;**
- **which individual or organisation is the author of the information;**
- **how any information provided by users of the website will be used, stored, passed on or sold (for further detail see the recommendation in Paragraph 5.61 below);**
- **where the provider(s) of the website are based; and**
- **funding and advertising arrangements.**

Advertisements should also clearly be distinguishable as such.

5.55 We think the best websites contain information that: (i) is based on high-quality peer-reviewed studies; (ii) originates from an independent not-for-profit organisation with no commercial interests, and (iii) is independently and widely evaluated and continuously monitored and updated. For example, in the UK, we judge the NHS websites and those of the National Institute for Health and Clinical Excellence (NICE) to be examples of websites that generally meet these criteria.¹⁹⁵

5.56 In line with our ethical value of the state making efforts to reduce harm (see Chapter 3), we recommend that states should provide high-quality health information on the internet or ensure that such information is available, and that healthcare professionals should draw their patients' attention to these sites. How exactly this recommendation is to be carried out is a matter for each health system: but, within the UK, we think the UK Government Departments of Health have a special responsibility to ensure that their websites meet the criteria above, given their public funding, reputation and public role and the fact that they are trusted by the public.¹⁹⁶

5.57 While recognising that accreditation of websites has its limitations as a tool of intervention (see Paragraph 5.47), we nevertheless conclude that stringent accreditation can have a valuable role in the digital age in helping people to identify the more trustworthy sources of information, and that accreditation initiatives run or sponsored by the state are one way in which the state can reduce harm in this domain.

5.58 We recommend that accreditation schemes should: (i) be fit for purpose; (ii) set criteria for websites specifying that they need to state, in language that lay people can understand, where their information originates, authorship and funding arrangements; (iii) set criteria about identifying advertisements appropriately; (iv) set criteria about

¹⁹⁵ We note that these websites are also used to some degree by residents of other countries. The NHS Choices website, for example, typically receives approximately 10% of its traffic from non-UK countries. (Information supplied by the Department of Health).

¹⁹⁶ One NHS survey, for example, found that 46% of internet users would be "much more likely" to trust a health information website run or licensed by the NHS, while 32% would be "a little more likely". (Information supplied by the Department of Health).

informing website users of how their information will be stored, passed on or used; (v) be used to drive improvements over time; and (vi) be kept under review.

- 5.59 We recommend website owners should take the measures necessary and seek accreditation from recognised schemes. We also recommend that websites should display accreditation certification on their home pages, and that government health department websites should include prominent information about these schemes. This would help to generate the climate we described in Paragraph 5.52 in which more providers of health information on the internet follow best practice and more internet users come to expect this of the sites they visit.

Use of information

- 5.60 People find comfort, and indeed solidarity, through exchanging experiences with others in similar situations on patient group websites. But such advantages can conflict with the value of safeguarding private information, since users may not know who has access to data about their internet use or access to the information they provide, and under what conditions and for what uses. While organisations with websites based in the EU are subject to the data protection regime described earlier (see Paragraphs 5.37–40), others may fall under different jurisdictions. We are concerned that many people are not aware that it could be possible for third parties to identify (to some extent) individual users, using information that does not appear to identify them directly,¹⁹⁷ such as which condition they have or which hospitals they have attended, especially when combined with information they provide in other formats, such as social networking sites.
- 5.61 As well as information about how their content is derived, we recommend that health information websites, including those of patient groups, should also state whether and how they use, store, pass on or sell personal information (including the record of searches carried out and pages viewed) to third parties, in language that lay people can understand. We recommend that all use and passing on of data should require ‘opt-in’ by the user. Including information about all these aspects of using and passing on information should also be a requirement of any accreditation scheme (see also Paragraph 5.58).¹⁹⁸

Doctor-patient relationship

- 5.62 We have come across some anecdotal evidence that increasing numbers of patients are presenting to their doctors having read health information on the internet. Such a development can in principle lead to more involved, knowledgeable, empowered patients and improved understanding between doctor and patient. A recent report from the Royal College of Physicians found that patients’ relationships with their doctors were changing, that such change may be related to increased access to online health information, and that doctors need to respond to such developments.¹⁹⁹ Doctors and other healthcare professionals may increasingly be called upon to advise patients about the quality of the information they obtain online. The doctor-patient relationship might change because patients come to identify an appropriate course of action for themselves, perhaps one their doctor might not have thought of. On the other hand, there are potential problems associated with more health information available online that healthcare professionals will need to manage carefully. For example, professionals might find

¹⁹⁷ For a discussion of the possibility of ‘de-anonymisation’, see: Narayanan A and Shmatikov V (2008) Robust de-anonymization of large sparse datasets *Security and Privacy – EEE Symposium on Security and Privacy*, pp111–25, available at: http://www.cs.utexas.edu/~shmat/shmat_oak08netflix.pdf; Singer N (2009) When 2+2 equals a privacy question *The New York Times* 17 October, available at: http://www.nytimes.com/2009/10/18/business/18stream.html?_r=1.

¹⁹⁸ This is already a feature of the HONcode. See: Heath on the Net Foundation (2010) Principle 3: Confidentiality – guidelines, available at: http://www.hon.ch/HONcode/Guidelines/hc_p3.html.

¹⁹⁹ Royal College of Physicians (2010) *Future physician: Changing doctors in changing times – report of a working party* available at: <http://bookshop.rcplondon.ac.uk/details.aspx?e=314>.

their judgments increasingly contested by patients in the light of information and advertising they have found on the internet. Patients might request treatments they have seen that are not provided by their public healthcare system or insurance scheme, such as certain branded pharmaceuticals rather than generic products. Such responses may well increase as a result of more direct advertising of pharmaceuticals and marketing material becoming available online to people in many different countries. Again, the values of individuals being able to pursue their own interests in their own way and of the state making efforts to reduce harm can come into conflict, and we make some recommendations below for measures that would soften the dilemmas that might arise.

- 5.63 **We recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals on caring for patients under the new circumstances in which patients increasingly use the internet to access health information. Some patients will be well informed but others will not have gained additional information in advance of their consultation. Indeed the same patient may be more or less informed by good-quality information on different visits. Other patients will have found misleading or confusing information about which they require advice. Healthcare professionals should also help patients to recognise that bringing a large amount of irrelevant or inaccurate health information might lead to a less productive consultation.**
- 5.64 **With regard to patients who request treatments they have seen that are not provided by the public healthcare system, we recommend that the bodies that issue guidance on treatment (such as the National Institute for Health and Clinical Excellence (NICE) in England and Wales) should support doctors by providing information to enable them to explain to their patients their decisions and recommendations for treatment. This should include why particular treatments are selected over others, and why certain treatments are not provided for some or all patients by the public healthcare system.**

The digital divide

- 5.65 We recognise the differences among people in their access to, and ability to use and understand, the internet and the information it can provide (commonly referred to as the 'digital divide'). We are concerned in particular that the heaviest users of healthcare services – the elderly – tend to use the internet less than other age groups. Furthermore, significant amounts of high-quality information (such as the original texts of papers in scientific journals rather than the glosses put on them in promotional material) are available only for payment rather than freely, and that particular market divide may grow. Also, further advantages may accrue to those with more education and other resources who use the internet to lobby for particular causes. Consequently, those who are elderly, less educated and less well off are potentially triply disadvantaged in this informational divide. But at present there is no real evidence about whether this divide is causing any specific harms to any particular group in society.
- 5.66 **We recommend that government health departments should take seriously the ethical values of social solidarity and reducing harm by monitoring whether the 'digital divide' is differentially affecting doctor-patient relationships, access to care and type of care received by different socio-economic groups.**

Future impact

- 5.67 Accessing online information about health seems likely to increase as more people go online across the world and more health-related websites appear. Elderly people on average use healthcare services more than other age groups, and we know that elderly people do not currently use the internet as much as younger people. It may well be that as people who are now middle-aged and younger get older, they will continue to use the internet in whatever future form it takes, especially for health-related searches – but that is speculative.
- 5.68 Health sites on the internet may well be a magnet for the ‘worried well’: but it also needs to be recognised that many people are vulnerable and desperate for help at the time they look for health information. That vulnerability, combined with opportunities for profit from selling people health-related products – as well as from selling the information people provide (sometimes unwittingly) to companies and organisations with a commercial interest – means there are risks of exploitation. We do not think the risks are imaginary, but they must be assessed alongside the real benefits that open access to high-quality, peer-reviewed, evidence-based health information can bring to individuals and to health services. Should evidence emerge of serious harms being caused directly from internet health information, more intrusive interventions than those we have recommended in this report would be justified (see the possibilities available in Box 5.4). Policy makers also need to be aware that the internet can be used by groups to mobilise support for particular health conditions, and such activity may mean that certain groups – those with good access to, and knowledge of, the internet – may receive a lot of attention among the public, in the media and elsewhere while others can be overlooked.

Chapter 6

Online personal health records

Chapter 6 – Online personal health records

Overview

What is new? Healthcare systems and companies are now using the internet to offer personal online health record systems that individuals can access, edit and share with others. In some cases online health record systems are provided by public and private healthcare organisations (which may set limits as to the type of information that can be added or edited by the patient), and in other cases companies not necessarily involved with the provision of healthcare offer online health record facilities directly to users. The development and use of these records represents a move towards more convenient and patient-centred access to, control of and responsibility for health records, raising issues about responsabilisation and consumerisation in healthcare of the kind discussed in Chapter 2. Indeed, such records can in principle facilitate all of the four types of personalisation identified in Chapter 1.

Which ethical values come into conflict as a result of this development? The principal potential for conflict here is between the value of individuals being able to pursue their own interests in their own way and the value of safeguarding private information. The latter may also conflict with the advancement and maintenance of common good (solidarity), for example over information pooling; and the value of individuals being able to pursue their own interests in their own way may also conflict with the value of activity by the state to reduce harm, for example in the form of loss or misuse of information.

What is the existing pattern of interventions like? Although there is no specific overarching system of interventions for online personal health records, several measures apply that are all of the 'general governance' type described in Chapter 4. Like online health information (see Chapter 5), in the UK and many other countries the most significant state-specific legal power relevant to the area of online personal health records is the data protection regime. In addition, commercial companies are bound by fair trading and competition rules, and medical professionals are bound by their professional guidelines and the common law in the way they use individuals' health records. The advertising standards regime is also relevant to the types of claim that can be made by providers of these services.

What gaps or shortfalls are there in existing interventions? As with online health information, existing interventions by the state or third parties do not make it easy for individuals to assess the quality of the records services being provided to them online. In particular, it is not straightforward for users to find out how their data will be used, stored, passed on or sold to third parties, or what would happen in the case of the company involved going into administration. Existing systems do not actively promote 'best practice' in this area, and users cannot easily identify which jurisdiction any particular website might fall under.

What types of intervention might possibly fill those gaps or remedy those shortfalls? Possible interventions span a range of options, including voluntary adoption of good practice, development or greater use of existing systems of redress, third-party accreditation and state regulation introducing required standards. The rapidly changing nature of this domain means that any satisfactory form of intervention needs to be able to keep up with the changes.

What types of intervention do we recommend, and why? Online personal health records have the potential to empower patients and to increase convenience, safety and efficacy. We have found no evidence of any actual harms having been caused, but we see potential risks over the confidentiality and security of health records. We do not wish to prevent people from gaining the benefits of these services, but we want to ensure that users are able to verify that a system is of high-quality and offers suitable safeguards for their personal information. We recommend an accreditation system based on how well information is safeguarded, and we set out what we consider to be best practice over what information should be provided to users contemplating signing up to online health record systems. We also think it is important that companies establish systems to safeguard the confidentiality of the data they hold were they to change ownership or go into administration.

Introduction

- 6.1 Medical records are fundamental to good-quality healthcare. They store and communicate information about a person's health, conditions and treatments, and that information can be critical to safe and effective treatment (and sometimes for other purposes as well). That is why doctors in the UK registered by the General Medical Council (see Box 4.1) are required to "keep clear, accurate and legible records, reporting the relevant clinical findings, the decisions made, the information given to patients, and any drugs prescribed or other investigation or treatment [and] make records at the same time as the events you are recording or as soon as possible afterwards".²⁰⁰
- 6.2 Many healthcare systems, including the National Health Service (NHS) in the UK, are moving towards making all their patient records electronic. Electronic records have the potential to enable the sharing of health information more easily and quickly, allowing access to different people and in different locations. The pros and cons of electronic records that allow patient information to be shared among medical professionals have been much debated.²⁰¹ We do not explore this issue again here; rather, the focus of this chapter is on the type of online personal health records that can be accessed, created or edited by the person they concern. Such records are provided by both public healthcare systems and commercial companies.²⁰²
- 6.3 Online personal health records offered by healthcare providers lend themselves towards more convenient and patient-centred access to, and control of, such information.²⁰³ All types of online health records offer people a chance to be more involved in their own health and healthcare if they value such involvement. Like the growth in online health information (and perhaps more so), the opportunity to manage personal health records online makes it possible that individuals could wish to – or be expected to – take more responsibility for their health and healthcare (see also Paragraphs 2.15–2.17), by being expected to check their medical records. It thus links to the ethical issues posed by consumerisation and responsabilisation discussed in Chapter 2. Although there is little market competition as yet in the UK, it is possible that online personal health records could become an increasingly consumerised product, given that such records can be provided at the users' convenience, in their own homes, 24 hours a day.
- 6.4 Use of online personal health records has the potential to at least contribute to all four of the types of personalisation we identified in Chapter 1. As we have said, such records can lend themselves to more consumerised provision and greater individual responsibility, and could also be conducive to more individualised diagnosis and treatment and more 'whole person' treatment.

²⁰⁰ General Medical Council (2010) Good Medical Practice: Providing good clinical care, available at: http://www.gmc-uk.org/guidance/good_medical_practice/good_clinical_care_index.asp.

²⁰¹ See, for example: Greenhalgh T, Stramer K, and Bratan T *et al.* (2010) Adoption and non-adoption of a shared electronic summary record in England: A mixed-method case study *British Medical Journal* **40**: c3111.

²⁰² There have been several significant reports dealing with personal health records. These include: The Markle Foundation (2003) *Connecting for health – a public-private*, available at: http://www.connectingforhealth.org/resources/final_phwg_report1.pdf; National Committee on Vital and Health Statistics (2006) *Personal health records and personal health record systems*, available at: <http://www.ncvhs.hhs.gov/0602nhirpt.pdf>; Altarum (2007) *Review of the personal health record (PHR) service provider market – privacy and security*, available at: http://www.cdt.org/healthprivacy/PHRs_Altarum_2007.pdf; Pagliari C, Detmer D and Singleton P (2007) *Electronic personal health records – emergence and implications for the UK*, available at: <http://www.nuffieldtrust.org.uk/ecomms/files/Elec%20Personal%20Records%20II.pdf>. See also myPHR.com, a website run by the American Health Information Management Association, for more information on PHRs generally.

²⁰³ We note that there are other ways in which patients can access their medical records, such as the routine practice in England of giving pregnant women their maternity notes to keep with them throughout the pregnancy.

Types of personal health record

- 6.5 Like online health information (see Chapter 5), the different providers of online health records are motivated variously by considerations of public service (such as improving the health of the population, increasing patient access to health records, increasing the efficiency of the public healthcare system), or by commercial interests. And as we shall show below, there are several different types of record systems. The various providers of online health records provide different levels of access for users/patients, ranging from being able only to view the record, to the ability to add information in specified ways that can be identified as originating from the patient, to being the sole creator and custodian of the record, with the possibility of sharing the record with others including health professionals.

'Tethered' online personal health records

- 6.6 What is known as a 'tethered' record is one specific to an institution or a healthcare system and usually offers patients the facility to view their own, or parts of their own, medical records online.²⁰⁴ They may be linked with further opportunities for the user to record other more general health information, such as their weight, amount of exercise taken or amount of alcohol consumed. One such example is the HealthSpace website operated by the NHS in England.²⁰⁵ HealthSpace is a free, secure online personal health organiser. It is aimed at helping people to manage their health, store health information and find out about NHS services. In addition, the NHS's current intention is also that everybody in the future will be able if they wish to have online access through the HealthSpace website to their Summary Care Record (SCR),²⁰⁶ though the future of this system is not certain at the time of writing.²⁰⁷ This summary includes details of a person's allergies, current prescriptions, adverse reactions to medicines, current health problems, and summaries of their care. This summary record is the part of the NHS electronic record that will also be available nationally to healthcare professionals, and the system is currently becoming available across the country after some considerable delay.²⁰⁸ Uptake of a HealthSpace account was, however, very low during a small pilot phase, with only 0.12% of those invited to participate completing the process, and the figures have not much changed since (for more detail on extent of use, see Paragraph 6.19).²⁰⁹ The Department of Health Directorate responsible for managing the English NHS National Programme for Information Technology (IT) told us that the registration process was being made more straightforward (see Appendix 3), and a recent survey suggested that a majority of respondents would consider using it in the future.²¹⁰ Funding for a similar scheme in Wales has also recently been announced, the aim of the scheme being to produce a website that will allow patients to check their medical records, order repeat prescriptions and book appointments with their

²⁰⁴ See: Wiljer D, Urowitz S, Apatu E *et al.* (2008) Patient accessible electronic health records: Exploring recommendations for successful implementation strategies *Journal on Internet Medical Research* **10(4)**:e34; Eysenbach G (2008) Medicine 2.0: Social networking, collaboration, participation, apomediation, and openness *Journal of Internet Medical Research* **10(3)**:e22.

²⁰⁵ See: <https://www.healthspace.nhs.uk>.

²⁰⁶ The Summary Care Record is one element of the NHS Care Records Service, the other element being the Detailed Record. NHS Connecting for Health (2009) What is the Summary Care Record?, available at: <http://www.connectingforhealth.nhs.uk/systemsandservices/scr/intro>.

²⁰⁷ Coates S (2009) Google or Microsoft could hold NHS patient records say Tories *The Times* 6 July, available at: <http://www.timesonline.co.uk/tol/news/politics/article6644919.ece>.

²⁰⁸ House of Commons Public Accounts Committee (2009) *The National Programme for IT in the NHS: Progress since 2006*, available at: <http://www.publications.parliament.uk/pa/cm200809/cmselect/cmpublicacc/153/153.pdf>.

²⁰⁹ Greenhalgh T, Stramer K, Bratan T *et al.* (2008) *Summary care record early adopter programme: An independent evaluation by University College London* available at: <http://eprints.ucl.ac.uk/6602/1/6602.pdf>; Greenhalgh T, Stramer K, Bratan T, *et al.* (2010) *The Devil's in the detail: Final report of the independent evaluation of the Summary Care Record and HealthSpace programmes*, available at: <https://www.ucl.ac.uk/news/scriefullreport.pdf>.

²¹⁰ A survey of users of the NHS Choices website revealed that the majority of respondents said they would use it at least monthly. See: Greenhalgh T, Stramer K, Bratan T *et al.* (2010) *The Devil's in the detail: Final report of the independent evaluation of the Summary Care Record and HealthSpace programmes*, p165., available at: <https://www.ucl.ac.uk/news/scriefullreport.pdf>.

general practitioner.²¹¹ In Scotland, a small pilot project offering online access to medical records to patients began in April 2010.²¹²

- 6.7 Other examples of tethered online health records systems are those offered by Kaiser Permanente, a healthcare provider in the USA; Patientsite, developed by the Boston-based Beth Israel Deaconess Medical Center; and My HealthVet offered by the US Department of Veterans Affairs.²¹³ Such records are accessible to the patient via the internet with the possibility of the patient adding some information.

'Untethered' online personal health records

- 6.8 In contrast to the 'tethered' records discussed in the previous section, 'untethered' online personal health records allow individuals to add and organise personal health information, as well as integrate health records from different healthcare providers, and share them with other individuals and institutions at will. Such records do not have to be anchored to any one healthcare institution. Examples of untethered online personal health records available include Google Health and Microsoft HealthVault.²¹⁴ Currently, the full functions offered by these two particular systems are available only to residents of the USA or authorised patients of certain participating hospitals as they are designed to integrate with certain healthcare providers in the USA. However, a Microsoft spokesman stated in February 2010 that Microsoft were looking "very seriously" at the possibility of extending its service to the UK.²¹⁵
- 6.9 Although both Google and Microsoft are commercial companies, they currently offer their online health record service to users for no charge. Their publicity stresses the individual's control of the data. For example, Google Health states: "You are always in control" and "Your health information belongs to you",²¹⁶ while Microsoft notes that "HealthVault offers you a way to store health information from many sources in one location, so that it's always organized and available to you online."²¹⁷ Both Google and Microsoft state on their websites that they do not sell or share individuals' information without their explicit consent (with certain exceptions as set out in their privacy policies).²¹⁸ Microsoft states that the information in its HealthVault is "not intended to be a substitute for medical records. Information from HealthVault should not be used by health care providers to make treatment decisions without independent evaluation, and only after being copied into the healthcare provider's own system."²¹⁹ Google notes that "Google Health does not offer medical advice. Any content accessed through Google Health is for informational purposes only, and is not intended to cover all possible uses, directions,

²¹¹ Welsh Assembly Government (2010) Patients set to access medical records and book GP appointments online, available at: <http://wales.gov.uk/newsroom/healthandsocialcare/2010/100104online/?lang=en>.

²¹² Scottish Government (2010) Online patient access to health records, available at: <http://www.scotland.gov.uk/News/Releases/2010/04/07100547>.

²¹³ See: <https://members.kaiserpermanente.org/kpweb/signonpage.do>, <https://www.patientsite.org/> and <http://www.myhealth.va.gov/>, respectively.

²¹⁴ See: <https://www.google.com/health> and <http://www.healthvault.com/>

²¹⁵ Cross M (2010) Milton Keynes is first acute trust to install Microsoft's integrated patient records system *British Medical Journal* **340**: c844.

²¹⁶ Google (2008) About Google Health, available at: <http://www.google.com/intl/en-GB/health/about/>.

²¹⁷ Microsoft (2008) What HealthVault can do for you, available at: <http://healthvault.com/personal/websites-overview.html>.

²¹⁸ For example, Microsoft states that "Except as otherwise described in this statement, personal information you provide on the Site will not be shared outside of Microsoft and its controlled subsidiaries and affiliates without your permission." Such exceptions include disclosure "if required to do so by law or in the good faith belief that such action is necessary to: a) conform to the edicts of the law or comply with legal process served on Microsoft or the Site; b) protect and defend the rights or property of Microsoft and our family of web sites; c) act in urgent circumstances to protect the personal safety of users of Microsoft products or members of the public." See: <http://www.healthvault.com/privacy-policy.aspx>. Google operates a similar policy, by noting that "Google only shares personal information with other companies or individuals outside of Google in... limited circumstances". These circumstances include the consent of the relevant individual, a legal requirement to share such information and providing such information to "subsidiaries, affiliated companies or other trusted businesses or persons" where such parties have agreed to comply with the Google Privacy Policy and any other relevant measures. See: <http://www.google.com/intl/en/privacypolicy.html#infosharing>.

²¹⁹ Microsoft (2010) Welcome to Microsoft HealthVault, available at: <http://www.healthvault.com/Industry/index.html>.

precautions, drug interactions, or adverse effects. This content should not be used during a medical emergency or for the diagnosis or treatment of any medical condition.²²⁰

- 6.10 In 2009, Microsoft partnered with Walgreens (an online pharmacy in the USA) to create an online portal “through which patients can access and share their personal prescription history”.²²¹ Access is provided through the HealthVault service. Users are able to download securely their Walgreens prescription history to a Microsoft HealthVault record.²²² The aim of combining the services is to allow users to “share a complete profile with other health care providers”.²²³ In this way we can see how the online services we consider in this report are being linked together by providers (see also online health information (Chapter 5) and online purchasing of pharmaceuticals (Chapter 7)).

Benefits and harms

- 6.11 Some potential advantages and disadvantages of online personal health records were set out in Table 3.1.

Potential advantages

- Secure and useful storage;
- convenience;
- interactive records, e.g. alerts;
- worldwide access;
- benefit from research on pooled data; and
- safeguarding function.

Potential disadvantages

- Misuse of stored information;
- advantages of centralised information may possibly be lost through separate information systems;
- difficulties for healthcare professionals if they have to rely on inaccurate or incomplete records maintained by patients; and
- opportunity for promotion of unnecessary or inappropriate treatments/services.

We further explore some of these advantages and disadvantages below.

Reasons people use online personal health records

- 6.12 Online personal health records are available via the internet to the individual they concern and anyone they choose to share them with, at any location with internet access and at any time. We have said how such records have the potential to be more ‘consumer-friendly’ than earlier systems. Such records involve the individual patient (or potential patient) accessing, maintaining and sharing the health data contained. It has been argued that providing patients with access to their electronic health records may “improve professional and organizational approaches to health care”.²²⁴ Such records enable individuals to become more interested and involved in, and responsible for, their own health and healthcare, and have the potential to increase health literacy. Some commentators have suggested that patient involvement in decision making is

²²⁰ Google (2010) Google Health terms of service, available at: <http://www.google.com/intl/en-US/health/terms.html>.

²²¹ Frederick J (2009) Walgreens, Microsoft partner on new online tools *Drug Store News* 29 June, available at: http://findarticles.com/p/articles/mi_m3374/is_7_31/ai_n32103509/.

²²² Walgreens (2010) Walgreens offers pharmacy patients access to secure prescription history through Microsoft HealthVault, available at: http://news.walgreens.com/article_display.cfm?article_id=5255.

²²³ *Ibid.*

²²⁴ Wiljer D, Urowitz S, Apatu E *et al.* (2008) Patient accessible electronic health records: Exploring recommendations for successful implementation strategies *Journal on Internet Medical Research* **10(4)**: e34.

pivotal to improving quality of care,²²⁵ and “some errors and adverse events in healthcare can be avoided through patient involvement”.²²⁶ For example, patients may spot errors and omissions within their own records more easily than health professionals.²²⁷

- 6.13 As we noted in Paragraph 6.10, online health services are starting to be combined by providers to offer integrated services such as online health information combined with online health records and online ordering of pharmaceuticals. This development offers great potential convenience and independence for users, but also leads to the possibility that reliance on these facilities would leave such users vulnerable when a company went bankrupt or changed hands. We return to this issue in our recommendation in Paragraph 6.33.

How information is used

- 6.14 Like online health information (see Paragraph 5.25), there are certain features of online records relating to the way that personal information is used by the provider or third party that can be advantageous or disadvantageous for individual users, depending on how activities are carried out or perceived. For example, an online record system could use the information that users enter to notify individuals about clinical trials relevant to their conditions or market products to them. Whether users find such information useful or bothersome is likely to depend on several things, including the nature of information offered. Moreover, going beyond the individual user perspective, such records offer the possibility of aggregating information for public health, research and commercial purposes (see also Paragraph 5.26). We deal with how those who sign up for such records should be informed about the uses to be made of the information they enter in our recommendations in Paragraphs 6.27 and 6.33.

Potential harms from using online personal health records

- 6.15 On the harms side of the equation, increasing access to data through online systems also brings new risks to the privacy and security of health records. Such privacy and security matters: for example, the Markle Foundation argues that “inappropriate access to health information can result in discrimination, social embarrassment, or worse”.²²⁸ In our consultations we heard about the possibility of doctor-patient confidentiality being breached through family members or other contacts demanding or guessing somebody else’s password. More broadly, personal health information entered and accessed online is commercially valuable. The ease with which electronic files may be transmitted and accessed is a double-edged sword: while this feature increases convenience, it also means that (as with all electronic records of personal information) files can be ‘lost’ or misused as a result of carelessness, fraud or institutional change. As for the latter, if a provider of online health record facilities were to go bankrupt or change hands, it might be difficult for users to guarantee that their data were held securely. A company might even abandon the information it held or the relevant computer equipment. We return to this point in our recommendation in Paragraph 6.33.
- 6.16 Some commentators have expressed concerns that the validity of information in health records used by healthcare professionals may be compromised by enabling the person they concern to edit those records,²²⁹ even in a controlled way. We are not aware of any proposal at present to allow unfettered and unrecognised patient modification rights to the medical records created

²²⁵ Gillespie R, Florin D and Gillam S (2002) *Changing relationships – findings of the patient involvement project*, p1, available at: <http://www.kingsfund.org.uk/document.rm?id=6630>.

²²⁶ Godolphin W (2009) Shared decision-making *Healthcare Quarterly* 12: e187, available at: <http://www.longwoods.com/product/download/code/20947>.

²²⁷ Powell J, Fitton R and Fitton C (2006) Sharing electronic health records: The patient view *Informatics in Primary Care* 14: 55–7.

²²⁸ The Markle Foundation (2008) Common Framework for Networked Personal Health Information – Overview and Principles, p1, available at: <http://www.connectingforhealth.org/commonframework/docs/Overview.pdf>.

²²⁹ Wynia MK (2008) Electronic personal health records: Should doctors worry?, *Medscape Journal of Medicine* 10(8): 204.

and maintained by healthcare providers, but any move in that direction would raise major issues of legal liability over adverse events and risk compromising clinical standards.²³⁰ To take an extreme example, if individuals could modify their medical record at any time, and such modifications were not marked as being made by the patient, healthcare professionals might not identify that the record had been edited by a lay person and not a healthcare professional. If healthcare professionals had to rely on online personal health records created and edited by the patient, they would not have access to what a healthcare professional might be expected to record, but only to the information the patient chose to divulge and interpret. There is currently little substantive information published on the attitudes of physicians to the use of online personal health records, though some work has been done on this topic.²³¹

- 6.17 Depending on the level of integration between health services, some diagnoses may be available for the patient concerned to view on their online record prior to a face-to-face meeting with a health professional. For example, when someone has a blood test, the results could be automatically entered on their record before a consultation. Such a practice could be useful in some cases when it speeds up the transmission of information, reduces the time needed in costly face-to-face consultations, or even eliminates the need for such consultations altogether. But some health information, including a diagnosis of a serious condition such as HIV (and what is recognised as 'serious' may well differ from one individual patient to another) is inappropriate to communicate remotely without a health professional available to explain and interpret the results and provide further information. The Department of Health officials to whom we spoke told us they had provided for such circumstances by delaying patient access to information about certain serious conditions in the online records to which we referred earlier (see Paragraph 6.6), until after the patient has seen a health professional.

Extent of use

- 6.18 Currently, patients in the UK and in other countries have a right to access their medical records on request (with certain exceptions) and also to have them amended in some circumstances. Records offered by public healthcare systems (including the NHS in some areas) that can be viewed online, and even modified by patients, can be seen as part of a broader movement towards greater transparency in some aspects of healthcare. But there is currently little systematic data about the characteristics of people who use online personal health records.
- 6.19 As we noted in Chapter 5, internet use has grown rapidly in recent years (see Paragraph 5.27), and the technology necessary to provide sophisticated services online has been developed and implemented. But the adoption rate of personal health records appears to be low.²³² One study in England, which included 103 individuals and seven focus groups, found most people were not aware of HealthSpace (see Paragraph 6.6), nor were they interested in storing or accessing their medical information via this facility. Indeed, many saw the system as "pointless", "irrelevant" or a security risk, although "a small but important minority" saw potential benefit for those with chronic illness.²³³ Uptake of such records has so far been slow, and a story in the media in April 2010 reported that, in early 2010, a total of 752 people out of the 1.2 million in England who had Summary Care Records had opted to use the NHS HealthSpace portal to access their records.²³⁴

²³⁰ We recognise that 'official' medical records are not always accurate.

²³¹ For example, the American Medical Association recently performed a survey of physicians in the USA on this topic, although the data had not been published at the time of writing.

²³² Detmer D, Bloomrosen M, Raymond B and Tang P (2008) Integrated personal care records: Transformative tools for consumer-centric care *BMC Medical Informatics and Decision Making* 8: 45; Kaelber DC, Jha AK and Johnston D *et al.* (2008) A Research Agenda for Personal Health Records (PHRs) *Journal of the American Medical Informatics Association* 15(6): 729–36.

²³³ Greenhalgh T, Wood GW, Bratan T, Stramer K and Hinder S (2008) Patients' attitudes to the summary care record and HealthSpace: Qualitative study *British Medical Journal* 336: 1290–5.

²³⁴ Barr F (2010) Just 752 patients view their SCR online *eHealth Insider*, available at: http://www.e-health-insider.com/news/5804/just_752_patients_view_their_scr_online.

- 6.20 A study published in 2006 indicated that 28% of households in the USA tracked health and medical information at that time; of that number, 94% did so using paper records and 1% used web-based systems.²³⁵ Another study carried out by the Markle Foundation in the USA included a survey of consumer attitudes to online personal health records in 2003. The results were based on an online survey of 1,246 people taken to be broadly representative of the adult population in the US in terms of age, race and education.²³⁶ The survey found that over 40% of respondents kept medical records at home, although only 2% did so using a computer. Seventy one per cent thought having health information online would help clarify doctors' instructions. Over half thought that such online records would help improve the quality of care. In response to the question "If you kept your medical records online, how comfortable would you feel having the following people access your records *only after you have given your explicit permission*", 79% responded that they would feel comfortable having their primary doctor access their records, in comparison to 31% for family and 23% for health insurers. Another US study, in 2007, found that of the 26% of US adults that made use of an electronic medical record (which included those maintained by their doctor), only 1% used a personal health record stored on the internet.²³⁷
- 6.21 It has been suggested that "there is a gap between today's personal health records... and what patients say they want and need"; a gap that includes "cost, concerns that information is not protected or private, inconvenience, design shortcomings, and the inability to share information across organizations".²³⁸ While it has been argued that such a gap must be bridged before personal health records (PHRs) are widely adopted,²³⁹ it has also been noted that the "impediments to PHR adoption are not limited to [the] technical".²⁴⁰ before online personal health records are adopted, "societal, interpersonal, and individual level" barriers – such as poorly defined responsibilities for ensuring information accuracy, the possibility that providers will be uncomfortable sharing power, and low levels of technological literacy (notably in older populations) – must be eliminated also.²⁴¹ Methods for changing such 'non-technical' conditions are said to include "near term system redesign and revised social marketing of the technology".²⁴²

Current system of interventions

- 6.22 Although there is at present no specific overarching system of interventions for online personal health records, several measures apply that are all of the 'general governance' type described in Chapter 4. Like online health information, in the UK and many other countries the most significant state-specific legal power relevant to the area of online personal health records is the data protection regime which was referred to in Chapters 4 and 5 and is further discussed below. In addition, companies are bound by fair trading and competition law, and the conduct of

²³⁵ Bishop L, Holmes BJ, Snyder J and McEnroe W (2006) Are personal Health records breaking out? – Early adopters hold clues for tool promotion, available at:

http://www.forrester.com/rb/Research/are_personal_health_records_breaking_out/q/id/39415/t/2, quoted in Weaver CA and Zielstorff RD (2008) What nurses need to know about consumer empowerment and the personal health record, available at:

<http://tigerphr.pbworks.com/f/TIGER+CE+and+PHR+Webinar+3-25-08.pdf>.

²³⁶ Markle Foundation *Americans want benefits of personal health records* (2003), available at:

http://www.connectingforhealth.org/resources/phwg_survey.pdf.

²³⁷ Steinbrook S (2008) Personally controlled online health data – the next big thing in medical care? *New England Journal of Medicine* **358**(16): 1653–6.

²³⁸ Kahn JS, Aulakh V and Bosworth A (2009) What it takes: Characteristics of the ideal personal health record *Health Affairs* **28**(2): 369–76. Security and confidentiality of information has been a concern expressed by patients with regards to PHRs in many studies of patient attitudes to PHRs. See: Pagliari C, Detmer D and Singleton P (2007) Potential of electronic personal health records *British Medical Journal* **335**: 330–3.

²³⁹ Kahn JS, Aulakh V and Bosworth A (2009) What it takes: Characteristics of the ideal personal health record *Health Affairs* **28**(2): 369–76.

²⁴⁰ Tang PC, Ash JS and Bates DW *et al.* (2006) Personal health records: Definitions, benefits, and strategies for overcoming barriers to adoption *Journal of the American Medical Informatics Association* **13**: 121–6.

²⁴¹ Weitzman ER, Kaci L, Mandl KD (2009) Acceptability of a personally controlled health record in a community-based setting: Implications for policy and design *Journal of Medical Internet Research* **11**(2): e14.

²⁴² *Ibid.*

medical professionals in using individuals' health records is governed both by professional codes and guidelines and by the law of tort and delict. The advertising standards regime to which we referred in the previous chapter (see Paragraphs 5.41–5.42) is also relevant to the types of claim that can be made by providers of online records services. Other responsibilities and liabilities of the various providers of healthcare and healthcare-related products in the UK were summarised in Box 4.1 in Chapter 4.

- 6.23 Like the other areas in this report involving services provided via the internet, online personal health records are not necessarily limited to people in any one country or jurisdiction. Providers are 'footloose' in the sense that provision does not need to be in any one specific location and providers can thus move around if it is advantageous for them to do so. Even though the storage of personal health data via websites opens up risks of loss in various ways – and the commercial value of data also increases the risks of theft and misuse – the footloose character of the online records industry makes traditional state regulation of the type discussed in Chapter 4 difficult to apply, as we also noted in the previous chapter.

Data protection

- 6.24 The different regulatory frameworks relating to privacy and confidentiality that various countries operate, and the lack of an overarching international policy on the subject, means that the protection afforded to an individual's data may vary substantially among service providers, depending on where they are based (see also Paragraphs 5.37–5.40). For example, organisations and companies based in the UK and the EU are subject to data protection legislation based on a common EU Directive²⁴³ but the legislation or the means to ensure compliance varies greatly in other countries (see Box 6.1 for information about the system in the USA). Even under the UK's Data Protection Act, the Information Commissioner's Office told us that if a company holding online personal health records were to go into administration or change hands, there would be no assurance that the data held would either be available to the people they concern to ensure continuity of access, or be secure.²⁴⁴ We address these issues in our recommendations in Paragraphs 6.31 and 6.33.

Box 6.1: Regulation of ownership of personal health data in the USA

The US Health Insurance Portability and Accountability Act 1996 (HIPAA) regulates ownership of personal health data. It requires federal standards for the transfer and use of electronic health data for healthcare providers, health insurance plans and employers.

However, it might be that HIPAA does not apply to all types of health records. For example, Google claims that the health data entered by users of its Google Health records service are given similar protection as that provided by HIPAA but that the data are not actually covered by that law because "Google does not store data on behalf of health care providers"; rather, the relationship is between the user and Google directly.²⁴⁵ Indeed, some commentators have suggested that Google might close down the Google Health service should the organisation ever come under the aegis of HIPAA.²⁴⁶

²⁴³ For details on data protection in the European Union and how it relates to electronic health records, see: Article 29 Data Protection Working Party (2007) *Working Document on the processing of personal data relating to health in electronic health records*, available at: http://ec.europa.eu/justice_home/fsi/privacy/docs/wpdocs/2007/wp131_en.pdf.

²⁴⁴ Fact finding meeting 23 September 2009; see Appendix 3.

²⁴⁵ Google (2009) *Google Health and HIPAA*, available at: http://www.google.com/intl/en-US/health/Google_Health_and_HIPAA.pdf.

²⁴⁶ The Working Party's joint workshop with the Harvard University Program in Ethics and Health (2009).

Softening the ethical dilemmas

6.25 As we have already argued, online access to records has the potential to be one way of enabling people to become more empowered in relation to their health and healthcare and to increase convenience, safety and efficacy. We think that measures by public healthcare providers to enable people to view their own medical records online is important both for allowing individuals to pursue their own interests in their own way and for the reduction of harms (two of the ethical values we set out in Chapter 3). At present there is no clear evidence of harm from the use of online health records either of the ‘tethered’ or ‘untethered’ type we referred to earlier, and it would therefore not be proportionate to use state powers to prohibit the use of, or restrict access to, such records. Nevertheless, there are a number of potential risks associated with such measures, notably those risks concerning our ethical value of safeguarding private information. To soften or reduce the dilemmas arising from potential conflict between the first value noted in Chapter 3 and the second and third values, we therefore recommend a state-sponsored accreditation system for online health records systems and set out some ways in which providers of such systems could improve their services and address the concerns we have about ensuring that private information is safeguarded. As with our recommendations relating to online health information in the previous chapter (and recognising there is some overlap between the two domains), we hope that such measures will generate a climate in which more providers of health records on the internet follow good practice and more internet users come to expect good practice when deciding which services to use.

Services provided and accreditation

6.26 We have already referred to the benefits to their users that online personal health records can offer. But it is not always easy for potential users to assess the quality of the records services being offered to them. In particular, given our concern for the value of safeguarding private information, we observe that it may not be obvious to users how their data will be used, stored, passed on or sold to third parties, or what would happen if the provider went into administration or changed hands. More transparent information about these factors would help users to make more informed choices about their use of online records systems, and our recommendations here are designed to increase such transparency. We recognise that accreditation schemes for websites are subject to certain limitations (see Paragraph 5.47), and that transparency more generally has its limits as a mode of intervention, as we noted in Chapter 4 (Paragraph 4.5). But we think such measures have some useful part to play in helping people to pursue their own interests in their own way in this case.

6.27 **Public healthcare services should develop an accreditation system for online health record providers and promote it appropriately. In the UK the responsibility for developing such a system should fall on the Government Health Departments. We recommend that providers of online personal health record facilities should seek accreditation. Such an accreditation system should include requirements to include the following information prominently in lay language:**

- the operator of the services;
- location in which the operator is based;
- how information provided by users will be stored, passed on or sold (see also the recommendation in Paragraph 6.33 below);
- arrangements in place to ensure the security and confidentiality of data and information if the operator went into administration or changed hands;
- the possibility that changes to terms and conditions could be made after initial sign-up and how the user will be informed; and

- funding and advertising arrangements.

Advertisements should also clearly be distinguishable as such.

Access to online medical records by patients

- 6.28 As we have said, some healthcare providers enable patients to access at least part of their medical records online and this access can benefit patients in various ways. There is a risk, however, that not all types of health information and medical records can be interpreted fully by the person they concern without reference to medical knowledge and the current treatments available. Patients may also have perceptions and beliefs that their doctor would wish to talk to them about on receiving test results, given that what is seen as serious by one person may not seem so to another. We know that some online medical record schemes have features that are aimed at ensuring that test results relating to certain serious conditions cannot be viewed by the patient until a face-to-face consultation with a health professional has taken place. We are also aware of concern among some healthcare professionals (see Paragraph 6.16 above) about the implications for decision making if patients were able to modify their own health records. We think careful design of online medical record systems is required in order to take account of such concerns.
- 6.29 **Enabling patients to add (but not delete or edit) health information to an online medical record held by healthcare providers is a sensible measure, provided information originating from the patient can be identified, and provided the system is designed to help both doctors and patients (such as building in limits to the amount and type of information that can be added, to avoid unnecessary burdens on medical professionals to take time in reading through records to protect themselves against possible malpractice suits) and care for their patients. Medical record systems that allow these additions – as is the case with the systems being introduced by the English NHS at the time of writing – can help both patients and health professionals without compromising subsequent decision making by health professionals.**

Safeguarding private information

- 6.30 Online health records offered by the NHS and private companies based in the UK are subject to the same data protection legislation as other types of health records and stores of personal information (see Paragraphs 5.37–40 and 6.24). However, as the House of Commons Health Committee noted in 2007's *The electronic patient record*: "Increasing access to patient data also brings new challenges for safeguarding patient privacy... There is a difficult balance to be struck between the need to protect privacy and the opportunities for research, between safeguarding individual rights and promoting the public good." Indeed, we suggested in Chapters 1 and 3 that using pooled data in medical research can promote solidarity or the common good, one of our ethical values. Clearly this value comes into conflict here with that of safeguarding private information, and such a conflict applies both to online health records operated by private companies and to public healthcare service records. Providers may wish to share the information and data they hold with third parties (such as research institutions or pharmaceutical companies), and users may not always be readily aware of such information-sharing arrangements. The EU Data Protection Directive (the Directive behind the UK's Data Protection Act 1998) includes the processing of data about an individual both by an organisation established in an EU Member State as well as by an organisation that makes use of equipment for data processing in an EU Member State,²⁴⁷ so many of the potential harms of online personal health records should be protected against in the EU, and other countries with similar legislation, by data protection laws, provided such laws are adequately enforced. But it is not

²⁴⁷ Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31 art 3–4.

clear that providers based outside such jurisdictions are in practice always covered by the legislation that applies in the countries where their users are based.

- 6.31 **We recommend that responsible bodies in the EU, such as the Information Commissioner's Office in the UK, take as a premise that EU data protection legislation applies to online health records held by people who upload and edit their information in the EU.**
- 6.32 As an additional safeguard, we would like to encourage what we see as good practice for the process by which individuals join online personal health records systems. We believe that routinely providing the kinds of information set out below would help users to assess whether their private information was being safeguarded. We also think that providers should routinely make it easily possible for their users to store their own local copy as an additional safeguard against its loss.
- 6.33 **We recommend that providers of online personal health records should design a joining process for new users that includes information about the following, which the user should actively view and 'opt-in' to:**
- **arrangements for data security (the possibility of a change to the administration of the company);**
 - **whether and how their personal information will be used, stored, passed on or sold to third parties (and the limits of any anonymisation process that may be applied to such information);**
 - **examples about how personal information could be used, such as whether or not the user might receive information/advertising from pharmaceutical companies on the basis of the information they have entered;**
 - **the advisability of the user downloading and storing locally a frequently updated copy of their health record as an additional safeguard against its loss; and**
 - **users' rights under data protection legislation.**

The above information should all be presented in accessible language that lay people can understand, and advertisements should clearly be distinguishable as such.

- 6.34 **The providers of online health record facilities should design an easy method for their users to back up and print out copies of their record to ensure against its loss.**

Future impact

6.35 As we noted in Chapter 5, the use of the internet for health-related purposes is likely to grow as more people gain access to the internet across the world and as people who are young and middle-aged now (social groups more familiar with using the internet) become elderly. Healthcare providers may find their patients increasingly demand access to their records and other services online, and commercial competition may drive further development of this kind. The European Commission recently called the facility for individuals to have their personal health information safely stored within a healthcare system accessible online a “right” and offered support for pilot projects to develop such systems.²⁴⁸ Although use of online health records systems outside those offered by public healthcare systems seems to be very limited at present (certainly in the UK), it would be prudent to make arrangements that provided for increased use of such records were it to occur.

²⁴⁸ European Commission (2010) *A digital agenda for Europe*, p29, available at: http://ec.europa.eu/information_society/digital-agenda/documents/digital-agenda-communication-en.pdf.

Chapter 7

Online purchasing of
pharmaceuticals

Chapter 7 – Online purchasing of pharmaceuticals

Overview

What is new? This chapter focuses on the way people can now buy medicines (or products sold as such) on the internet. Products available online include many that are prescription-only or otherwise restricted in the UK and other countries. While in the past similar purchases might have been made via advertisements in magazines, mail order or in other unofficial ways, the internet brings a new dimension to the activity. Online purchase of pharmaceuticals can be linked to consumerisation and responsabilisation, the social phenomena and aspects of personalisation discussed in Chapters 1 and 2, since it involves both the exercise of consumer choice and the need for the purchaser to take more responsibility to verify that medications offered are what they purport to be, and in some cases to make their own decisions without consulting health professionals.

Which ethical values come into conflict as a result of this development? The major conflicts that occur are between the value of individuals being able to pursue their own interests in their own way and the values of efforts by the state to reduce harm, using public resources fairly and efficiently, and social solidarity.

What is the existing pattern of interventions like? As noted in previous chapters, there is no overall oversight of information on the internet, but the UK and other jurisdictions apply their laws to the information on it and how it is used. The most significant measures applying to online drug purchasing are service-specific licensing schemes that have been adapted from those originally applying to 'bricks and mortar' pharmacy services, which usually rely on the state's legal powers. Additionally there are some measures of the 'general governance' type applying to the online provision of pharmaceuticals, notably professional guidance and laws of tort or delict and fair trading. Advertising standards schemes also apply to selling medicines as they do to any other product.

What gaps or shortfalls are there in existing interventions? While recognising that the oversight regime applying to 'bricks and mortar' pharmacies in the UK and elsewhere is not free from shortcomings, we think the current arrangements create a possibility for serious harm to patients from pharmaceuticals (or products sold as such) purchased online. Protections for consumers are weak because suppliers may not follow the legislation that applies in the country they operate in, or they may be registered in countries with weak oversight powers and trade across national boundaries.

What types of intervention might possibly fill those gaps or remedy those shortfalls? Applying intervention measures to the internet is difficult, but possible options for reducing the risk of harms include: voluntary adoption of good practice; development or more extensive use of existing systems of redress; state or other third-party provision of high-quality information about risk; and further state intervention, for example in the form of increased inspection of premises or the closure of websites that are found to be operating illegally.

What types of intervention do we recommend, and why? We think the potential for harms from online drug purchasing justifies intervention requiring the state's legal powers, so we endorse the restrictions already in place on sellers in the UK. However, given the difficulties involved and the lack of evidence at this time of widespread harm being caused (and similar lack of evidence about potential benefits), we cannot justify recommending any further measures than currently exist to attempt to prevent the operations of websites from selling products without adherence to the restrictions in place. We recommend that governments should carefully monitor the incidence and extent of harms and benefits from this development to allow more informed judgments and evidence-based policy to be applied to this domain in future. We also recommend: (i) provision by public healthcare services of good information; (ii) voluntary adoption of good practice by providers; (iii) good professional medical practice adapted to this new development; and (iv) enforcement of legislation regarding the supply of antibiotics and state monitoring of antibiotic resistance.

Introduction

- 7.1 Buying pharmaceuticals over the internet has become increasingly common.²⁴⁹ The use of medicines, by its very nature, touches upon personal matters such as illness, despair, craving and addiction. These powerful motivational factors, combined with the transnational and comparatively regulation-free nature of the internet, provide the conditions for creating a very lucrative market for the sale of pharmaceuticals (or products sold as such).
- 7.2 Selling pharmaceuticals online takes a number of different forms. In some cases, people buy medicines from suppliers that are licensed by national regulatory authorities and provide products that are themselves licensed for sale. There are systems for registering and inspecting online pharmacies in various countries, including Great Britain (see Box 7.1). In other cases, people buy pharmaceuticals (or what are sold as pharmaceuticals) that are restricted or illegal in their own country, without a prescription or not under the authority of a pharmacist. Selling restricted medicines (which include some over-the-counter products) in the UK (and many other countries) without adhering to the applicable restrictions is illegal. However, people can easily purchase pharmaceutical products from websites and suppliers based in another country (the legality of such purchases depends on the substance bought). The suppliers may be operating legally or illegally in the country they are based in. The international nature of this trade contributes to making it difficult to assess, monitor and establish effective oversight measures.
- 7.3 The purchasing of pharmaceuticals online rather than face-to-face represents a significant shift in the way individuals interact with healthcare systems. It can be linked to consumerisation and responsabilisation, the social phenomena and aspects of personalisation discussed in Chapters 1 and 2, since it involves the exercise of consumer choice and the need for the purchaser to take more responsibility to verify that medications offered are what they purport to be and in some cases to make their own decisions without consulting health professionals. We noted in Chapter 2 (see Paragraph 2.14) that there had been a shift towards greater patient involvement in medical decision-making processes, and in some cases buying pharmaceuticals online can cut medical professionals out of the process altogether.

Box 7.1: Royal Pharmaceutical Society of Great Britain's online pharmacy registration scheme²⁵⁰

The Royal Pharmaceutical Society of Great Britain (RPSGB) has been the professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales. At the time of writing, the RPSGB was in the process of separating its regulatory and professional roles, with a new General Pharmaceutical Council taking over as the regulatory body.

The RPSGB has established an online pharmacy registration scheme for companies based in Great Britain. If an online pharmacy meets the required conditions, the RPSGB provides its internet pharmacy logo with a registration number. The logo is then permitted for use with the facility for users to click on it to navigate to the RPSGB website where the registration of the internet pharmacy they have come from can be verified. The onus for compliance with the conditions of the scheme is on the registered pharmacy and not on any web design companies involved.

The situation in Northern Ireland is slightly different. Northern Ireland has not come under RPSGB's jurisdiction, nor will it for the new General Pharmaceutical Council. Rather, the Pharmaceutical Society of Northern Ireland (PSNI) fulfils an analogous function. Consequently, those pharmacies registered in Northern Ireland are not subject to the RPSGB's internet

²⁴⁹ Medicines and Healthcare products Regulatory Agency (2009) Risks of buying medicines over the internet, available at: <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/BuyingmedicinesovertheInternet/CON019610>.

²⁵⁰ Royal Pharmaceutical Society of Great Britain (2010) Internet pharmacy logo, available at: <http://www.rpsgb.org.uk/registrationandsupport/registration/internetpharmacylogo.html>.

pharmacy logo scheme, and the PSNI does not currently operate a similar scheme.²⁵¹

At the time of writing, draft legislation being considered by the European Parliament sought to amend Directive 2001/83/EC on the EU code relating to medicinal products for human use, by extending the Directive to cover pharmaceutical sales over the internet and to oblige Member States to set tougher sanctions against producers of fake medicines. The draft legislation aims to require national authorities to carry out frequent and unannounced inspections of premises of manufacturers, distributors and importers of active substances used as starting materials. A key provision is that licensed internet pharmacies would need to be authorised by national authorities and to display an official EU logo guaranteeing their authenticity, whose validity users could check in a centralised national website. How this proposed scheme would interact with, or supersede, the current RPSGB logo scheme is currently unclear.²⁵²

Benefits and harms

7.4 Some potential advantages and disadvantages of purchasing pharmaceuticals online were set out in Table 3.1.

Potential advantages

- Convenience;
- price competition;
- availability; and
- privacy.

Potential disadvantages

- Obtaining inappropriate or harmful medicines;
- adverse interactions with other medicines;
- limited or no opportunity for advice;
- risks from incomplete information about adverse effects and contraindications;
- increased danger of obtaining fake or low-quality medicines;
- no limits on quantity bought;
- possibility of increased antibiotic resistance arising from their misuse; and
- reduction in the quality of relationships with health professionals if health conditions not discussed.

These advantages and disadvantages apply to people purchasing for themselves as well as for others, including children, the elderly and other vulnerable groups.

Reasons people purchase pharmaceuticals online

7.5 People choose to buy online for reasons that include convenience, price, avoidance of embarrassment or being able to buy products that would not otherwise be available without prescription (or at all) in the purchaser's country. Some of the most commonly bought products (see Paragraph 7.18) are associated with conditions where social stigma is involved, suggesting that people might feel uncomfortable about talking to their doctor about their condition or about these pharmaceuticals. They might also think, correctly or otherwise, that such products would

²⁵¹ The PSNI has published a document outlining how internet pharmacies registered in Northern Ireland must operate. See: Pharmaceutical Society of Northern Ireland (2009) *Professional standards and guidelines for internet pharmacy services*, available at: <http://www.psnir.org.uk/documents/316/Standards+on+Internet+Pharmacy.pdf>.

²⁵² See: Watson R (2010) EU prepares to tackle counterfeit drugs *British Medical Journal* **340**: c2425; Rankin J (2010) MEPs want crack down on counterfeit medicines *EuropeanVoice.com* 27 April, available at: <http://www.europeanvoice.com/article/2010/04/meps-want-tough-action-on-counterfeit-medicines/67795.aspx>; European Parliament (2010) Medicinal products for human use: Prevention of the entry into the legal supply chain of falsified medicinal products (amend. Directive 2001/83/EC).

not be prescribed by a doctor, or they might have been refused them in the past. The internet offers the possibility of obtaining medication that is not provided by the public healthcare system in the purchaser's country or by their insurance scheme. It may also offer the chance of obtaining the medication at a lower cost than through other channels.²⁵³

Potential harms to health

- 7.6 Along with such benefits, however, serious harms can also result from buying pharmaceutical products online (see Box 7.2). Owing to the relatively recent development of this practice, we have not found systematic evidence about either benefits or harms. One author concludes: "...we simply do not have sufficient evidence whether, and under which conditions, online prescribing of relatively safe drugs... actually creates more harm than benefit, or vice versa."²⁵⁴ But not all online purchases are of 'relatively safe' drugs, and the possibility of serious harm can be inferred from the history of pharmaceuticals before today's standards of testing and licensing were developed.
- 7.7 Buying online from a website that is not a registered pharmacy offers no opportunity for a healthcare professional to assess whether the medicine is safe and appropriate for the individual concerned, or to advise on how the medication should be taken. The information about medicines available on some websites can be incomplete, even where it might be factually accurate.²⁵⁵ Prescription errors by doctors are of course far from unknown: findings vary, but studies in the last ten years indicate an error rate in prescribing of between 7 and 12% but that many of those errors are corrected by pharmacists, nurses or other doctors.²⁵⁶ But not consulting with a healthcare professional can increase the risk of reaching either an incorrect diagnosis of the condition or the inappropriate pharmaceutical (either in form or dosage) being selected. There is no opportunity to talk to a healthcare professional about managing a condition, and there may be an increased risk of attempting to treat symptoms rather than their underlying cause. There have, for example, been instances of people delaying consultation with a health professional while self-treating with pharmaceuticals purchased via the internet.²⁵⁷
- 7.8 Furthermore, the international access to pharmaceuticals provided by the internet may lead to confusion about medicine names and labels. For example, a medicine as ubiquitous as paracetamol is known throughout the world by a variety of different names. In the USA, for example, it is called acetaminophen,²⁵⁸ but is often known simply through a brand name such as Tylenol,²⁵⁹ while in Israel paracetamol is often known through another brand name, Acamol.²⁶⁰

²⁵³ Although we note that it has been suggested that economic considerations are less likely to be primary motivating factors for people who live "in a regulated drugs market where final drug prices are negotiated", such as in Europe. Orizo G, Schulz R and Domenighini S *et al.* (2009) Cyberdrugs: A cross-sectional study of online pharmacies characteristics *European Journal of Public Health* **19**(4): 375–7. People in the USA, for example, pay approximately 60% more for brand-name pharmaceuticals than those in Great Britain or Switzerland and two-thirds more than Canadians. Bostwick JM and Lineberry TW (2007) Do cheap internet drugs threaten the safety of the doctor–patient relationship? *Expert Opinion in Drug Safety* **6**(1): 10.

²⁵⁴ Eysenbach G (2001) Online prescriptions of pharmaceuticals: Where is the evidence for harm or for benefit? A call for papers – and for reflection *Journal of Medical Internet Research* **3**(1): e1.

²⁵⁵ Clauson KA, Polen HH, Boulos MN and Dzenowagis JH (2008) Scope, completeness, and accuracy of drug information in Wikipedia *The Annals of Pharmacotherapy* **42**(12): 1814–21.

²⁵⁶ See: Dornan T, Ashcroft D, Heathfield H *et al.* (2009) *An in-depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education – EQUIP study*, available at: http://www.gmc-uk.org/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf 28935150.pdf; Shah SNH, Aslam M and Avery AJ (2001) A survey of prescription errors in general practice *The Pharmaceutical Journal* **267**: 860–2.

²⁵⁷ Veronin MA and Clauson KA (2007) Internet pharmacy drugs delay treatment for congestive heart failure *Journal of the American Pharmacists Association* **47**(4): 436.

²⁵⁸ Bradley N (1996) British Medical Journal should use "paracetamol" instead of "acetaminophen" in its index *British Medical Journal* **313**: 689.

²⁵⁹ MedlinePlus (2010) Acetaminophen, available at: <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a681004.html#combo-names>.

²⁶⁰ Israeli Ministry of Health (2008) Acamol, available at: <http://www.health.gov.il/units/pharmacy/trufot/alonim/4062.pdf>.

- 7.9 There is also the potential for adverse reactions, or adverse interactions with other products. We have heard in our consultation that the increased privacy that online purchasing offers also means that healthcare professionals are concerned that they might prescribe medicines without knowing about other products the patient is taking that they have bought for themselves online.²⁶¹
- 7.10 The internet also facilitates access to antibiotics without a prescription.²⁶² It is known that self-medication using antibiotics takes place in all countries, but currently there is limited evidence as to the extent that antibiotics are actually purchased over the internet, without prescription, for this purpose.²⁶³ Increased use of antibiotics is a case of individual behaviour that can damage public health by increasing antibiotic resistance in the population as bacteria develop the ability to survive exposure. We return to this risk in our recommendation in Paragraph 7.48.
- 7.11 Finally, and perhaps most dangerously, the authenticity, safety and quality of products are harder for purchasers to ascertain if registered pharmacies are not used (whether 'bricks and mortar' or internet pharmacies).²⁶⁴ Although the risk of obtaining fake products from registered pharmacies cannot be completely ruled out, buying from outlets that are not registered pharmacies increases the risk that products could be fake, contain dangerous substances or the wrong dose of the expected substance.²⁶⁵ They could also be new drugs that have not yet been tested appropriately or approved. The Medicines and Healthcare products Regulatory Agency (MHRA) reported in 2008²⁶⁶ that the World Health Organization (WHO) estimated fake medicines to comprise more than 10% of the global medicines market.²⁶⁷ In 2009, a group comprising Pfizer, the MHRA, the RPSGB, The Patients Association and HEART UK launched a campaign to inform the public of the risks involved in purchasing fake medicines from unlicensed suppliers operating over the internet.²⁶⁸ It has also been estimated that 62% of medicines purchased over the internet are fake.²⁶⁹ Of course we recognise that it was possible to obtain medicines by mail order or from other unregistered sources before the internet: but, for reasons described in Chapter 5, the distinctive features of the internet – the combination of search facilities and large amounts of information – are likely to make unlicensed pharmaceutical products more accessible than in the past.

²⁶¹ Although we note that there is also the risk of this problem with 'conventional' practices, for example if primary care doctors and hospitals or other healthcare providers do not communicate about patients' medicines. See: O'Dowd A (2009) GPs and hospitals do not communicate adequately about patients' medicines *British Medical Journal* **339**: b4450.

²⁶² Mainous AG, Everett CJ, Post RE, Diaz VA and Hueston WJ (2009) Availability of antibiotics for purchase without a prescription on the internet *Annals of Family Medicine* **7(5)**: 431–5.

²⁶³ *Ibid.*

²⁶⁴ Liang BA and Mackey T (2009) Searching for safety: Addressing search engine, website, and provider accountability for illicit online drug sales *American Journal of Law and Medicine*, **35(1)**: 125–84.

²⁶⁵ Harms are further discussed in Montoya ID (2008) The root cause of patient safety concerns in an internet pharmacy *Expert Opinion on Drug Safety* **7(4)**: 337–41.

²⁶⁶ Medicines and Healthcare products Regulatory Agency (2008) *Medicines and medical devices regulation: What you need to know*, available at: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf>.

²⁶⁷ We note that the proportion in developing countries is far higher than in developed countries and recent research suggests that the majority of fake medicines are produced in developing countries such as China, India and Russia. See: Royal Pharmaceutical Society of Great Britain (2008) Millions risk health buying drugs online, available at: <http://www.rpsgb.org/pdfs/pr080110.pdf>; European Alliance for Access to Safe Medicines (2008) *The Counterfeiting Superhighway*, available at:

http://v35.pixelcms.com/ams/assets/312296678531/455_EAASM_counterfeiting%20report_020608.pdf.

²⁶⁸ 'Get Real, Get A Prescription' campaign (2009) Over 7 million UK adults may be gambling their lives with fake medicine, <http://www.rpsgb.org.uk/pdfs/pr091103.pdf>.

²⁶⁹ Mayor S (2008) More than half of drugs sold online are fake or substandard *British Medical Journal* **337**: a618.

Box 7.2: Evidence of harm from buying pharmaceuticals online

There is currently little systematic evidence of widespread harm from pharmaceuticals bought over the internet. For example, in 2007 it was reported that the US Food and Drug Administration (FDA) did not have accurate figures on 'adverse events' resulting from these purchases.²⁷⁰ Numerous cases have been reported in the media,²⁷¹ and the FDA cites the case of a man in the USA, with a family history of heart disease, who died as a result of taking Viagra bought online without examination by a doctor. There is also the much publicised case of Ryan Haight, who died in 2001 from an overdose of Vicodin acquired via the internet (see also Box 7.3). The Senate Report that accompanied the Ryan Haight Online Pharmacy Consumer Protecting Act 2007 lists eight incidents in relation to the online purchase of prescription controlled substances that are described as a consequence of "ease of access to the Internet, combined with lack of medical supervision".²⁷²

A survey in the UK, published in *GP* magazine, reported that one in four general practitioners said they had treated patients for adverse reactions to medicines bought online, while a further 8% suspected they had treated side-effects of internet-bought drugs.²⁷³ However, the survey did not ask whether the pharmaceuticals that caused these reactions were purchased from abroad or from unregistered outlets, or whether the reactions were the result of fake drugs, a failure in the instructions provided, or an interaction with another medication.

One of the reasons why it is hard to obtain evidence of the scope of harms is that privacy is an important motivation for people to buy pharmaceuticals online. As already noted, the desire to deal with conditions that can be considered embarrassing, such as erectile dysfunction (see Paragraph 7.5) is an important consideration in this method of purchase. So adverse reactions are unlikely to be commonly reported if people perceive the consequences of revealing the incident to be socially or psychologically detrimental, even in the face of potentially significant health problems. Reporting the incident not only reveals the underlying condition about which there may have been embarrassment originally, but also that the customer bought a product online, possibly illegally and perhaps without due safeguards.

- ²⁷⁰ Easton G (2007) Clicking for pills *British Medical Journal* **334**: 14–5. The FDA itself states that it is "impossible to accurately quantify adverse event rates" for pharmaceuticals purchased via the internet, due to the limited number of reports the FDA's postmarketing surveillance system receives in general. See: Food and Drug Administration (2009) Buying medicines and medical products online FAQs, available at: <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134631.htm>.
- ²⁷¹ See: BBC News Online (21 April 2009) *Internet drug warning after death*, available at: <http://news.bbc.co.uk/1/hi/wales/8010210.stm>. See also Liang BA and Mackey T (2009) Searching for safety: Addressing search engine, website, and provider accountability for illicit online drug sales *American Journal of Law and Medicine*, **35**: 125–84, which highlighted the following examples: Booker J (2008) Action urged on internet drugs *New Zealand Herald* 30 September, available at: <http://www.nzherald.co.nz/marlborough/news/article.cfm?id=132&objectid=10534908&pnum=1>; Griffin D and Fitzpatrick D (2008) Widow: My husband died from online drugs *CNNhealth.com*, available at: <http://edition.cnn.com/2008/HEALTH/05/21/online.drugs/index.html> 22 May; Solomon S (2007) BC woman killed by fake drugs bought online, *National Review of Medicine* 30 July, available at: http://www.nationalreviewofmedicine.com/issue/2007/07_30/4_policy_politics_13.html; Marshall M (2008) Online pharmacies: Dangerous prescription? *CBS NEWS* 31 May, available at: <http://www.cbsnews.com/stories/2008/05/31/earlyshow/health/main4142407.shtml>; Paul R (2007) Illegal internet pharmacies pose a growing threat *Drug Topics* 20 August, available at: <http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id=450106&searchString=MarkMonitor>; Barnet A (2003) Deadly cost of the trade in online prescription drugs *The Observer* 10 August, available at: <http://www.guardian.co.uk/society/2003/aug/10/health.drugs>.
- ²⁷² Senate Report Number 110–521, p5, available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_reports&docid=f:sr521.pdf.
- ²⁷³ The research reflected the answers received from a survey of 420 GPs in the UK. See: Moberly T (2009) One in four GPs report online drug concerns *GP* 16 April, available at: <http://www.healthcarerepublic.com/search/GP/news/898287/One-four-GPs-report-online-drug-concerns/?DCMP=ILC-SEARCH>.

- 7.12 Several studies have examined the quality of pharmaceuticals bought online. The WHO, during the course of its investigative activities in a number of countries,²⁷⁴ found that medicines purchased over the internet from illegal sites that conceal their physical address were fake in over 50% of cases.²⁷⁵ A study by the European Alliance for Access to Safe Medicines reported that 62% of prescription products ordered from the internet were fake, substandard or unapproved generic medicines.²⁷⁶ In 2005 the Office of Compliance in the US FDA's Center for Drug Evaluation and Research commissioned a study to "determine the quality of a select group of pharmaceutical products purchased via the internet from foreign sources".²⁷⁷ The authors of the study purchased 20 pharmaceutical samples from eight different websites and one sample of each drug product manufactured in the USA from a local supplier. The study concluded: "Two of 20 samples failed [United States Pharmacopeia standards] for quality attributes. The additional analytical methods found 11 of 20 samples had different formulations when compared to the U.S. product. Seven of the 20 samples arrived in questionable containers, and 19 of 20 had incomplete labelling. Only 1 of the 20 samples had final packaging similar to the U.S. products."²⁷⁸
- 7.13 To note such risks with products bought online is not to deny that there can be many problems in the method of providing drugs to patients through a face-to-face consultation, where harm can be caused by factors such as errors in diagnosis and prescription, wrong doses, ineffective medicines, and the pharmaceutical companies' influence on doctors' prescribing practices, including a tendency to 'medicalise' all ills. Some may argue that 'empowering' the consumer in this domain can help to correct these familiar problems, as it has in other areas where paternalism has been challenged by consumerism.

Extent of use and the type of products purchased

- 7.14 The proliferation and expansion of internet pharmaceutical outlets is the result of a combination of factors: increasing internet access and use, new technology facilitating online purchase of goods, many people's increasing familiarity with internet purchasing, the availability of 'lifestyle drugs',²⁷⁹ and the convenience and privacy that the internet can afford for some types of purchase.
- 7.15 Indeed, online purchasing of pharmaceuticals is a natural extension of some of the other forms of increasing online delivery of healthcare services discussed in this report, namely the recording of health information using online personal health records (Chapter 6) or telemedicine (Chapter 8), and is underlain by the same information communications technology. This technology makes possible the remote prescribing of medication – using online methods rather than requiring a face-to-face visit to the doctor – to order prescribed medicines that can be delivered. There are now a number of online clinics in the UK and elsewhere whose doctors are permitted to prescribe certain pharmaceuticals following an online consultation with a patient ('e-prescribing').²⁸⁰

²⁷⁴ Information supplied by the World Health Organization.

²⁷⁵ World Health Organization (2010) *Medicines: Counterfeit medicines fact sheet No 275*, available at: <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

²⁷⁶ European Alliance for Access to Safe Medicines (2008) *The counterfeiting superhighway*, available at: http://v35.pixelcms.com/ams/assets/312296678531/455_EAASM_counterfeiting%20report_020608.pdf.

²⁷⁷ Westenberg BJ, Ellison CD and Fussner AS *et al.* (2005) Quality assessment of internet pharmaceutical products using traditional and non-traditional analytical techniques *International Journal of Pharmaceutics* **306**: 56–70.

²⁷⁸ *Ibid.*

²⁷⁹ The term 'lifestyle drug' is generally considered to refer to "drugs taken to satisfy a non-medical or non-health-related goal". Some people include sildenafil, orlistat and anti-baldness drugs in this classification. Lifestyle drugs are also sometimes referred to as 'lifestyle medicines'. See: Gilbert G, Walley T and New B (2000) Lifestyle medicines *British Medical Journal* **321**: 1341–4; Flower R (2004) Lifestyle drugs: Pharmacology and the social agenda *Trends in Pharmacological Sciences* **25(4)**: 182–5.

²⁸⁰ The RPSGB/General Pharmaceutical Council does not have any jurisdiction over these online clinics unless they also operate as a pharmacy. See Box 7.1 and Paragraph 7.25.

- 7.16 As we noted in Chapter 5, the incidence of internet use is lower among the elderly (one of the largest groups of pharmaceutical users) than among the young and middle-aged, but even so internet use by the elderly has grown markedly and seems likely to continue to do so. We know that the number of people who buy pharmaceuticals online has increased and the number of websites is growing.²⁸¹ But it is currently hard to quantify how many people buy medicines online, the volume bought and their authenticity.²⁸² That difficulty arises from the nature of the product and the fact that internet pharmacies, especially ‘rogue’ websites, “open and close with high frequency, often have several URLs for one company, and may only be transiently listed on select search engines”.²⁸³
- 7.17 Nevertheless, some estimates have been made of the extent of online purchasing. In 2003, the UK National Audit Office reported that 1% of UK respondents to a survey claimed to have bought prescription medicines over the internet.²⁸⁴ More recently, in 2008, the RPSGB reported that approximately two million people in Great Britain were regularly purchasing pharmaceuticals online (both with a prescription from registered UK pharmacies and without prescriptions from other websites).²⁸⁵ A recent survey commissioned by Pfizer, the MHRA, RPSGB, The Patients Association and HEART UK found that 15% of the British adults asked had bought a prescription-only medicine online without a prescription.²⁸⁶ For the USA, a 2006 study found that searching for information on prescription or over-the-counter drugs was the fifth most popular health topic searched for, and a 2004 study found that 4% of Americans had purchased prescription medications online.²⁸⁷ Within the EU, mail-order trade in medicines has been found to be “by and large marketed through the internet”. In the Netherlands, the market share of internet pharmacies is still small: there are reported to be about ten “serious” mail-order pharmacies in operation, although their operations are expanding.²⁸⁸ In Germany, approximately seven million people buy from mail-order pharmacies, and mail-order sales account for approximately 8–10% of total pharmaceutical sales.²⁸⁹
- 7.18 In developed countries, online pharmacies supply so-called ‘lifestyle drugs’,²⁹⁰ such as for weight loss, hair loss or erectile dysfunction. There is likely to be less demand for therapeutic medication in countries with “high social security coverage” (such as France) given that the price of the relevant pharmaceutical may actually be higher than in domestic pharmacies.²⁹¹ RPSGB has identified the most popular purchases online (or at least products being sold as such) as Prozac (an antidepressant), Viagra (for erectile dysfunction), Valium (a tranquiliser), Ritalin (a psychostimulant), Serostim (a synthetic growth hormone) and Provigil (a

²⁸¹ Medicines and Healthcare products Regulatory Agency (2009) Risks of buying medicines over the internet, available at: <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/BuyingmedicinesovertheInternet/CON019610>; Levaggi R, Orizio G, Domenighini C *et al.* (2009) Marketing and pricing strategies of online pharmacies *Health Policy* **92**: 187–96.

²⁸² Levaggi R, Orizio G, Domenighini C *et al.* (2009) Marketing and pricing strategies of online pharmacies *Health Policy* **92**: 187–96.

²⁸³ Liang BA and Mackey T (2009) Searching for safety: Addressing search engine, website, and provider accountability for illicit online drug sales *American Journal of Law and Medicine* **35**: 125–84.

²⁸⁴ National Audit Office (2003) *Safety, quality, efficacy: Regulating medicines in the UK*, p26, available at: http://www.nao.org.uk/publications/0203/safety_quality_efficacy_reg.aspx.

²⁸⁵ Royal Pharmaceutical Society of Great Britain (2008) Millions risk health buying drugs online, available at: <http://www.rpsgb.org/pdfs/pr080110.pdf>.

²⁸⁶ ‘Get Real, Get a Prescription’ campaign (2009) Over 7 million UK adults may be gambling their lives with fake medicine, available at: <http://www.rpsgb.org/pdfs/pr091103.pdf>.

²⁸⁷ Fox S (2006) *Online health search*, available at: http://www.pewinternet.org/~media/Files/Reports/2006/PIP_Online_Health_2006.pdf.pdf; Fox S (2004) *Prescription drugs online*, available at: http://www.pewinternet.org/~media/Files/Reports/2004/PIP_Prescription_Drugs_Online.pdf.pdf.

²⁸⁸ Seeberg-Elverfeldt NJ (2009) Mail-order trade in medicines in Europe: a guide for legislators to protect consumers *European Journal of Health Law* **16**: 351–66.

²⁸⁹ *Ibid.*

²⁹⁰ Glover-Thomas N and Fanning J (2010) Medicalisation: The role of e-pharmacies in iatrogenic harm *Medical Law Review* **18(1)**: 28–55.

²⁹¹ Mahé E, Saiag P, Aegerter P and Beauchet A (2009) Shopping for psoriasis medicine on the internet *Journal of the European Academy of Dermatology and Venereology* **23**: 1050–5.

psychostimulant).²⁹² A study in the USA has also shown that antibiotics are commonly available online without prescription.²⁹³

Current system of interventions

- 7.19 The current response to internet supply of pharmaceuticals (and products sold as such) in the UK and many other countries mainly involves attempts to adapt and apply the service-specific legislative framework that had been developed for control of medicinal products before the internet came to be used for the supply of these products. Measures involving state-specific legal powers regulate the advertising, supply and sale of medicines, and registration of pharmacies and professionals. There are also guidance and verification schemes specifically designed for internet pharmacy services. Some measures of the 'general governance' type described in Chapter 4 (see Box 4.1) also apply to this area, including professional standards and laws such as the common law of negligence, product liability law and the consumer regime. The main type of intervention in the UK that does not rely on the state-specific legal power is the advertising standards regime, which applies to advertising medicinal products as it does to any other product. Box 7.3 summarises the pattern of interventions in the USA.
- 7.20 However, national-level legislation relating to online sale of pharmaceuticals often has limited impact given that websites and suppliers can be located in different countries from consumers and therefore in a different jurisdiction (see also Paragraph 5.24). State regulatory agencies are restricted by the legislative and policy frameworks within which they practice. Laws can be hard to enforce in this domain because new websites can be created rapidly or move jurisdiction and it is hard to track the products they deliver. For example, research by the FDA in the USA highlighted the difficulty internet users can have in identifying the origin of the pharmaceuticals they are purchasing. The FDA's research reported that, of 11,000 websites purporting to be Canadian internet pharmacies, only about 1,000 actually sold pharmaceuticals, and of them less than 25% were registered or hosted by companies or individuals in Canada.²⁹⁴

Box 7.3: Online pharmacies in the USA: a comparison

The provision of medicines in the USA is controlled by a mix of state and federal regulation. Federal legislation requires prescriptions "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."²⁹⁵ This requirement has been interpreted as meaning that prescriptions must be made "in accordance with a standard of medical practice generally recognized and accepted in the United States".²⁹⁶ The Drug Enforcement Administration is responsible for ensuring that controlled substances are used in compliance with Federal law.²⁹⁷

Unlike in the UK, where existing legislation was adapted to license online supply of pharmaceuticals by adding a new registration scheme, the USA enacted specific legislation for control of online pharmacies.

The much-publicised death of the teenager Ryan Haight in 2001 from an overdose of the painkiller Vicodin (see also Box 7.2), after buying the drug online,²⁹⁸ was one of the factors leading to increased legislative control of online pharmacies at the federal level in the USA, in the form of the Ryan Haight Online Pharmacy Consumer Protection Act 2008 ('The Ryan Haight

²⁹² Royal Pharmaceutical Society of Great Britain (2008) Millions risk health buying drugs online, available at: <http://www.rpsgb.org/pdfs/pr080110.pdf>.

²⁹³ Mainous AG, Everett CJ, Post RE, Diaz VA and Hueston WJ (2009) Availability of antibiotics for purchase without a prescription on the internet *Annals of Family Medicine* **7**(5): 431–5.

²⁹⁴ Krebs B (2005) Few online 'Canadian pharmacies' based in Canada, FDA Says *Washington Post* 14 June, available at: <http://www.washingtonpost.com/wp-dyn/content/article/2005/06/14/AR2005061400254.html>.

²⁹⁵ 21 US Code of Federal Regulations § 1306.04(a).

²⁹⁶ *United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975).

²⁹⁷ See: <http://www.justice.gov/dea/agency/mission.htm>. 'Controlled substances' in the USA are those substances or their analogues (i.e. similar chemical structure or effect) included in the relevant Schedules of the Controlled Substances Act 1970.

²⁹⁸ National Association of Boards of Pharmacy (2009) *State of the internet: NABP position paper on the continued proliferation of rogue internet drug outlets*, available at: <http://www.nabp.net/assets/State%20of%20the%20Internet.pdf>.

Act'). This amended the US Controlled Substances Act 1970 and Controlled Substances Import and Export Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the internet. The Act made it a violation of the Controlled Substances Act 1970 for a medical practitioner to issue a prescription for a controlled substance over the internet without having performed at least one face-to-face consultation (with some exceptions). However, performing one such consultation was not necessarily deemed sufficient to demonstrate a "legitimate medical purpose".²⁹⁹

The Ryan Haight Act also provides a specific definition for the term 'online pharmacy', which is "a person, entity, or internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet".³⁰⁰

The Verified Internet Pharmacy Practice Sites (VIPPS), an information and verification website, is operated by the National Association of Boards of Pharmacy. To qualify under the scheme, a pharmacy must "comply with the licensing and survey requirements of their state and each state to which they dispense pharmaceuticals" and comply with VIPPS criteria.³⁰¹ These criteria include patient rights to privacy, authentication and security of prescription orders, adherence to a recognised quality assurance policy, and provision of consultation between patients and pharmacists.

UK legislation on the selling of pharmaceuticals

- 7.21 In the UK, medicines are divided by the Medicines Act 1968 into three broad categories: (1) those that can be sold from a wide range of premises such as supermarkets, provided those premises can be closed to exclude the public (i.e. they are lockable) and the medicines are pre-packed (that is, 'general sale list' medicines such as ibuprofen); (2) those that can be obtained only from registered pharmacy premises by or under the supervision of a pharmacist; and (3) those that can be obtained only with a prescription from a healthcare professional. The first two categories here are referred to as 'over-the-counter' medicines. Restrictions over which drugs can be prescribed only by a medical practitioner, which can be obtained only from a pharmacist and which can be sold from other sources vary from one country to another.
- 7.22 The Medicines Act 1968 (albeit now superseded in many of its provisions by EU legislation) requires medicines to be licensed before they can be legally supplied in the UK, and the MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. Additionally, some medicines fall under the provisions of the Misuse of Drugs Act 1971, which places further restrictions on supply.
- 7.23 A number of medicines can be legally supplied from a registered online pharmacy, including not only over-the-counter medicines (categories (1) and (2) above) but also prescription-only medicines, provided certain conditions – as specified in Box 7.1 – are met. The laws mentioned above apply equally to online pharmacies as they do to more conventional pharmacies or healthcare clinics. The legality of internet pharmacies selling pharmaceuticals to people based in another country from that where the pharmacy is based has been tested at the EU level (see Box 7.4).

²⁹⁹ US Federal Register (2009) *Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. Interim final rule with request for comments* 74(64): 15595–625.

³⁰⁰ 21 US Code of Federal Regulations § 1300.04(h), available at: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=21:9.0.1.1.1&idno=21>.

³⁰¹ National Association of Boards of Pharmacy (2009) VIPPS accreditation, available at: <http://www.nabp.net/indexvipps2.asp>.

Box 7.4: Internet pharmacies: an EU case study

Within the EU, the legality of internet pharmacies, specifically the cross-border trade in pharmaceuticals, was tested in the *DocMorris* case of 2003.³⁰² The case concerned the provision of prescription and non-prescription pharmaceuticals in Germany by the DocMorris company, which was established in the Netherlands but did much of its trade in Germany.³⁰³ DocMorris was taken to the European Court of Justice (ECJ) by the regional court of Frankfurt following an accusation of illegal practice by the German Association of Pharmacists.³⁰⁴ Pharmaceuticals could be ordered from the company in several ways, including telephone, fax and online. Some products offered by the company were 'prescription-only' in either Germany or the Netherlands; DocMorris' approach was "[to apply] the stricter classification of that prevailing in the Netherlands and that in the country of residence of the customer and would only supply prescription-only medicines on production of the original prescription".³⁰⁵

The ECJ considered several issues, including: (i) which law to follow in cross-border practice;³⁰⁶ and (ii) whether German legislation prohibiting the mail-order sale of pharmaceuticals authorised for sale only in pharmacies contravened Article 28 of the EC Treaty (which provides for the free movement of goods within the European internal market). The Court held that where a pharmaceutical product was not authorised in a specific country, it could not be supplied there: "Article 28 could not be used to circumvent the system of national marketing authorisations".³⁰⁷

The ECJ also held that while Member States could impose a more restrictive regulatory environment on some products than other nations, such as that pertaining to pharmaceuticals, this regulation must be executed with due regard to Article 28 of the EC treaty. The court found that, while the German legislative prohibition on the mail-order sale of pharmaceuticals initially appeared to violate Article 28, the need to provide individual advice and to verify prescriptions provided a sufficiently persuasive argument for the Court to find that the prohibition was lawful under Article 30, which allows for restrictions on the grounds of public health. The Court held:

*"Article 30 EC may be relied on to justify a national prohibition on the sale by mail order of medicinal products which may be sold only in pharmacies in the Member State concerned in so far as the prohibition covers medicinal products subject to prescription. However, Article 30 EC cannot be relied on to justify an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription in the Member State concerned."*³⁰⁸

Prior to the *DocMorris* judgment, most EU Member States rejected mail-order trading in medicines. That is no longer the case.³⁰⁹ However, the judgment contained no safety standards: these were included in the Council of Europe's *Resolution on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine*.³¹⁰

- 7.24 Legislation mostly relates to the supplier rather than the purchaser. UK medicines legislation does not restrict the importation of medicines for personal use purchased online. But 'controlled drugs' (see below) are subject to the additional requirements of the Misuse of Drug Regulations 2001 which limit the importation if medicines falling into this category.

³⁰² Case C-322/1 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003], available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62001J0322:EN:HTML>.

³⁰³ Catalán J (2004) Internet medicine sales and the need for homogenous regulation *International Journal of Medical Marketing* **4**(4): 342–9.

³⁰⁴ Mäkinen MM, Rautava PT and Forsstrom JJ (2005) Do online pharmacies fit European internal markets? *Health Policy* **72**: 245–52.

³⁰⁵ Pickering G (2007) *Internet Pharmacy in the European Union*, available at: http://www.reedsmith.com/db/documents/Internet_Pharmacy_article.pdf.

³⁰⁶ Mäkinen M Rautava PT and Forsström JH (2005) Do online pharmacies fit European internal markets? *Health Policy* **72**: 245–52.

³⁰⁷ Pickering G (2007) *Internet pharmacy in the European Union*, available at: http://www.reedsmith.com/db/documents/Internet_Pharmacy_article.pdf.

³⁰⁸ Case C-322/1 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003], available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62001J0322:EN:HTML>.

³⁰⁹ Seeberg-Elverfeldt NJ (2009) Mail-order trade in medicines in Europe: a guide for legislators to protect consumers *European Journal of Health Law* **16**: 351–66.

³¹⁰ Council of Europe (2007) *Resolution ResAP(2007)2 on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine*, available at: http://www.coe.int/t/informationsociety/documents/Goodpractices_en.pdf.

Oversight of the supply of medicines in the UK

- 7.25 Medicines of the second and third types described in Paragraph 7.21 can only be legally supplied only by registered healthcare professionals, including pharmacists. All retail pharmacies in the UK,³¹¹ including those providing internet services, must be registered with the RPSGB/General Pharmaceutical Council (the new regulator that was coming into operation at the time of writing) or with the Pharmaceutical Society of Northern Ireland, and broadly similar arrangements apply in many other countries. Anyone who breaches these rules is guilty of an offence, and courts may impose an injunction to forbid someone from further breaches of those rules. Any further breach would constitute contempt of court, for which severe penalties apply.
- 7.26 The MHRA, the agency mentioned above, is responsible for preventing others from selling or supplying medicines of the second and third types.³¹² The MHRA also monitors internet sites that are known to be selling prescription-only medicines and performs checks to see whether such sites are based in the UK. If they are, and they are not registered pharmacies, the MHRA can prosecute those concerned. Where the sites are based overseas, the MHRA refers them to the relevant regulatory body in their country of origin. In 2007, research found 570 websites hosted in the UK selling medicines,³¹³ yet at the time of writing there were only 116 internet pharmacies registered with the RPSGB, suggesting a notable disparity between the number of internet suppliers and those that were licensed.
- 7.27 The RPSGB/General Pharmaceutical Council maintains an inspectorate of some 26 people which, among other duties, aims to enforce the provisions of the Medicines Act 1968 that relate to the retail sale and supply of human medicines.³¹⁴ The inspectorate works by investigation, education, advice and enforcement.³¹⁵ It performs both routine visits to premises and specific investigations stemming from complaints made against pharmacies and pharmacists. Every three years it routinely visits registered pharmacy premises, including those of internet pharmacies.
- 7.28 In addition to the usual rules that apply to 'bricks and mortar' pharmacies, the RPSGB/General Pharmaceutical Council demands professional standards for registered pharmacies trading on the internet. The standards include:
- the website having details of the pharmacy (ownership, address, registration of pharmacist), and how to make a complaint;
 - data security and encryption;
 - respect for patient choice (avoiding 'prescription direction');
 - provision of information/clinical assessment;
 - security of delivery arrangements;
 - records of supplies; and
 - special care with regard to high volumes of prescriptions to overseas patients.³¹⁶

³¹¹ The use of the title 'pharmacy' is legally limited to registered pharmacies, hospitals and health centres (s78 Medicines Act 1968). Those using such a title in an unauthorised manner in the UK may be committing a criminal offence and therefore be liable to prosecution. See: Royal Pharmaceutical Society of Great Britain (2009) Internet pharmacy logo, available at: <http://www.rpsgb.org/pdfs/iplfaq.pdf>.

³¹² The MRHA reported that during 2009/2010 it completed 16 prosecutions, with a conviction rate of 73%. See: MRHA (2010) *Annual statistics 2009–10*, available at: <http://www.mhra.gov.uk/Publications/Corporate/AnnualReports/CON087861>.

³¹³ The Pharmaceutical Journal (2007) One in five online pharmacies operates from the UK *The Pharmaceutical Journal* **279**: 197.

³¹⁴ Royal Pharmaceutical Society of Great Britain (2010) Inspectorate, available at: <http://www.rpsgb.org/protectingthepublic/inspectorate/>.

³¹⁵ *Ibid.*

³¹⁶ Royal Pharmaceutical Society of Great Britain (2009) *Professional standards and guidance for internet pharmacy services*, available at: <http://www.rpsgb.org.uk/pdfs/coepsqintpharm.pdf>.

UK professional oversight

- 7.29 Only certain qualified and registered people (such as a doctor, dentist, nurse or midwife) are allowed to prescribe prescription-only medications in the UK. Practitioners who prescribe in an irresponsible way may have their prescribing rights revoked.³¹⁷ Additional restrictions apply if the medicine concerned is a 'controlled drug' within Schedule 2 or 3 of the Misuse of Drugs Act 1971.³¹⁸ The person writing the prescription must have an address within the UK, so an online clinic or pharmacy based overseas cannot legally employ a staff-doctor to write prescriptions for Schedule 2 and 3 drugs for UK patients.³¹⁹
- 7.30 The *RPSGB Code of ethics for pharmacists and pharmacy technicians* sets out standards of conduct, practice and performance expected of pharmacists and pharmacy technicians, and failure to comply with the requirements of the Code can result in de-registration. The *Professional standards and guidance for internet pharmacy services* expands on the principles of the Code of Ethics to set out the professional responsibilities for pharmacists and pharmacy technicians who are involved in the sale and supply of medicines via the internet.³²⁰ Significantly, the standards state that patients are entitled to expect the same quality of pharmaceutical care irrespective of whether the service is provided online or face-to-face in the pharmacy's premises.³²¹ For over-the-counter medicines, this standard means that advice on safe use should be available and that suppliers should be aware of the possibility of abuse of the product in question. For provision of prescription-only medicines, the standards require, among other things, ensuring the clinical appropriateness of the prescription for the patient and advising the patient to consult a local pharmacy whenever a prescription indicates that their interests would be better served by a face-to-face consultation.³²²

Direct-to-consumer advertising of pharmaceuticals

- 7.31 As noted in Chapter 5 (Paragraph 5.41), direct-to-consumer advertising of pharmaceuticals is prohibited in the EU but companies are permitted to include information about their products on their own websites (Box 7.5 gives more details). However, there has been some discussion over whether proposed changes to EU law, which seek to allow certain information regarding pharmaceuticals to be provided directly to the general public, would in effect allow advertising, rather than 'information'.³²³
- 7.32 Search engine advertising policies also have an important effect on direct-to-consumer advertising. We note that Google's policies for promotion of pharmacies and prescription drugs depend on the country in which the search takes place. The company "requires online pharmacy websites targeting ads to the United Kingdom to target only the UK and to be

³¹⁷ Appelbe G and Wingfield J (2005) *Dale and Appelbe's pharmacy law and ethics*, 8th edition (London: Pharmaceutical Press), pp189–90.

³¹⁸ Some prescription medicines contain drugs that are controlled under the Misuse of Drugs legislation. These medicines are called 'controlled medicines'. They are categorised into five schedules corresponding to their therapeutic usefulness and misuse potential. Schedule 1 has the highest level of control, but drugs in this group are virtually never used in medicines. Schedule 5 has a much lower level of control. See: NHS Choices (2009) 'What is a controlled medicine (drug)?', available at: <http://www.nhs.uk/chq/Pages/1391.aspx?CategoryID=73&SubCategoryID=100>.

³¹⁹ The prescriber must also comply with certain other rules that apply when writing prescriptions for Schedule 2 and 3 drugs. The prescription must be written in ink (or otherwise indelible), signed and dated, and the address of the person issuing it must be specified. It must also specify the name and address of the person for whom it is issued, the dose, strength and total quantity.

³²⁰ Royal Pharmaceutical Society of Great Britain (2009) *Professional standards and guidance for internet pharmacy services*, available at: <http://www.rpsgb.org/pdfs/coepsqintpharm.pdf>.

³²¹ *Ibid.*

³²² *Ibid.*

³²³ See: European Commission (2009) Information to Patients, available at: http://ec.europa.eu/pharmaforum/information_en.htm; British Medical Association (2008) *Response to the European Commission consultation regarding the legal proposal on information to patients*, available at: http://www.bma.org.uk/images/BMAresponsepatientinformation_tcm41-176194.pdf; British Medical Association (2009) *BMA response to the European Commission proposal for a directive on information to the general public on medicinal products subject to a medical prescription*, available at: http://www.bma.org.uk/images/bmareponseeuiinformationtopatientproposal2009_tcm41-183021.pdf.

registered with the Royal Pharmaceutical Society of Great Britain (RPSGB). These ads will not be displayed in other countries. Additionally, ad campaigns for online pharmacies and related services in the UK cannot promote specific prescription drugs.³²⁴ Similarly, Google requires that online pharmacy websites targeting advertisements to Germany must target only Germany, must be licensed by the competent regional health authority and sign an online pharmacy policy compliance declaration provided by Google.³²⁵ In the USA, online pharmacies must be accredited by the National Association Boards of Pharmacy VIPPs program (see Box 7.3) and may target advertisements at the USA and its territories only in order for Google to accept them, and online pharmacies in Canada must be accredited by the Canadian International Pharmacy Association and may target Canada only.³²⁶ Given Google's powerful market position, the policies it adopts for online pharmacies and the extent to which it can enforce them are likely to be important in determining the efficacy of the formal regulatory arrangements described earlier, although it has been reported that some search engines have problems in restricting 'rogue' online pharmacies from advertising through their systems.³²⁷

Box 7.5: Direct-to-consumer advertising of pharmaceuticals

Direct-to-consumer advertising of prescription-only pharmaceuticals means advertising targeted at patients/consumers, rather than physicians. It is legal in only two developed countries: New Zealand and the USA. However, as noted earlier, pharmaceutical companies are permitted to post information about their products on their own websites in the UK and elsewhere (see Paragraph 5.41). Direct-to-consumer advertising of prescription-only pharmaceuticals is a contentious issue and is the subject of much debate.³²⁸

Advertisements for over-the-counter medicines aimed at both consumers and healthcare professionals are permitted in the UK,³²⁹ subject to certain conditions,³³⁰ but direct-to-consumer advertising of prescription-only pharmaceuticals is currently prohibited in the EU.³³¹ In the UK, advertising medicines is governed by the Medicines Act 1968 and the statutory instruments implementing EU Directives.³³² There are some exceptions to the direct-to-consumer ban, for instance for the promotion of certain vaccine campaigns.³³³ As described earlier, the MHRA is responsible for ensuring compliance with the legislation.

Advertising prescription-only pharmaceuticals to health professionals is permitted in the UK. Such advertising, along with the provision of information to the public about prescription-only medicines, is subject to the general advertising standards regime described in Chapter 5 and is

³²⁴ Google (2010) What is Google's policy for online pharmacy ads?, available at: <http://adwords.google.com/support/aw/bin/answer.py?hl=en&answer=7463>. Online pharmacies can be advertised in the UK, but not specific prescription products, as mentioned above.

³²⁵ *Ibid.*

³²⁶ Google (2010) Google Adwords Help – advertising policies – prescription drugs and related content, available at: <http://adwords.google.com/support/aw/bin/answer.py?hl=en&answer=7463>.

³²⁷ Whitney L (2009) Rogue pharmacies still a problem for search engines *cnet news* 19 August, available at: http://news.cnet.com/8301-27083_3-10303655-247.html.

³²⁸ General Accounting Office (2002) *Prescription drugs – FDA oversight of direct-to-consumer advertising has limitations*, p1, available at: <http://www.gao.gov/new.items/d03177.pdf>.

³²⁹ Exemptions also apply for advertisements for non-prescription medicines aimed at the prevention of neural tube defects, treatment of sprains and strains, treatment of rheumatic or non-serious arthritic conditions, and vaccination campaigns approved by Health Ministers.

³³⁰ The Proprietary Association of Great Britain, a national trade association for manufacturers of over-the-counter medicines and food supplements, operates a self-governing system to which members must adhere. See: Proprietary Association of Great Britain (2009) *Medicines Advertising Codes Summary Version*, p3, available at: <http://www.paqb.co.uk/advertising/PDFs/advertisingcode.pdf>. All advertising in the UK must also adhere to the usual advertising standards codes administered by the Advertising Standards Authority, as described in Chapter 5.

³³¹ Directive 2001/83/EC on the Community code relating to medicinal products for human use (as amended) OJ L311/67.

³³² The Medicines (Advertising) Amendment Regulations 1994 (as amended, primarily in 1999, 2004 and 2005). Association of the British Pharmaceutical Industry, Medicines Healthcare products Regulatory Agency and Prescription Medicines Code of Practice Authority (2005) *Memorandum of understanding between the association of British pharmaceutical industry, The Prescription Medicines Code of Practice Authority and the Medicines and Healthcare Regulatory Agency*, p1, available at: http://www.pmcpa.org.uk/files/sitecontent/Memo_of_understanding.pdf.

³³³ Mullins CD and Palumbo FB (2002) The development of direct-to-consumer prescription drug advertising regulation *Food and Drug Law Journal* 57(3): 423–43.

also controlled on a self-governing basis for members of the Association of the British Pharmaceutical Industry (ABPI)³³⁴ by the Prescription Medicines Code of Practice Authority. Breaches often come to light through reports from competitors, and sanctions for breaches of the Code (some 88 cases out of 101 complaints in 2005)³³⁵ include public censure, requiring companies to issue a “corrective statement” or suspension/expulsion from the ABPI.³³⁶

Compensation

7.33 To obtain compensation for harm caused by pharmaceuticals bought online, the consumer in the UK must turn to the general law of contract, negligence, or product liability. Under the law of contract, the consumer can recover the cost of the drug if it fails to meet agreed or implied terms of sale. Under the law of negligence,³³⁷ a consumer harmed by a negligent misstatement or a negligently supplied drug (for example where the wrong drug or dosage is supplied) can sue for compensation reflecting physical injuries and associated pain, suffering and loss of earnings caused by the pharmacist’s conduct, but discomfort on its own is not sufficient as a basis for claiming compensation. If no physical injury is suffered, the consumer can recover for psychological harm only if it amounts to a recognised psychiatric illness, and general anxiety is not sufficient to sustain a claim. Under product liability legislation,³³⁸ a consumer who suffers more than £275 of damage (excluding the cost of the product which can only be recovered in contract law) can sue the manufacturer, or in some instances the supplier, if the product was not as safe as consumers can be argued to be generally entitled to expect. The consumer is not required to prove the manufacturer or supplier was ‘at fault’, but if the consumer has been contributorily negligent, compensation will be reduced. The complications that arise when suppliers are based overseas were described earlier in Paragraphs 5.34–35.

Softening the ethical dilemmas

7.34 The major conflicts that occur in this case study are between the ethical value of individuals being able to pursue their own interests in their own way and the values of efforts by the state to reduce harm, using public resources fairly and efficiently, and of social solidarity (see Chapter 3). Buying pharmaceuticals on the internet (with a prescription if one is needed) from a licensed online pharmacy offers benefits to consumers, including convenience, privacy and possibly cost savings. It may be particularly suitable for some people with long-term stable conditions. But we have already noted that people may be desperate or vulnerable when they make purchases, and if individuals buy medicines that are ‘prescription-only’ in their country of residence without a prescription, or over-the-counter products from websites that are not licensed pharmacies, there is potential for serious harm. Those possibilities of harm include:

- adverse reactions;
- adverse interactions with other products obtained in consultation with a health professional or otherwise;
- no opportunity for a health professional to assess whether the medicine is safe and appropriate for the individual, or to advise on how the medication should be taken; and
- difficulty in ascertaining the authenticity, safety and quality of the products supplied.

³³⁴ The ABPI is the trade association for companies in the UK producing prescription medicines.

³³⁵ Prescription Medicines Code of Practice Authority (2007) Code of practice FAQ, available at: <http://www.pmcpa.org.uk/?q=fagsaboutcodeofpractice>.

³³⁶ Prescriptive Medicines Code of Practice Authority (2009) Sanctions, available at: <http://www.pmcpa.org.uk/?q=sanctions>.

³³⁷ The pharmacist’s conduct is negligent if, in the view of the courts, it displays an unreasonable lack of care. Typically, when dealing with health professionals, the courts have regard to the views of the profession. If a reasonable body of professionals (not necessarily a majority) regard the conduct as reasonable, no negligence will be found (provided the court considers the view is based on logical and reasonable grounds). See also Box 4.1.

³³⁸ s.5 Consumer Protection Act 1987

- 7.35 Taken without caveats, the value of each individual to be able to pursue their own interests in their own way could imply that people should be free to purchase pharmaceuticals online without restriction despite the harms listed above. But though we fully acknowledge (see Paragraph 7.13) that face-to-face prescribing is far from free from risk or error, we think the potential for very serious harms from online purchasing justifies some state activity to prevent this and to impose certain restrictions on sellers (see recommendation in Paragraph 7.40).³³⁹
- 7.36 UK law does not prevent people from purchasing many pharmaceuticals (both over-the-counter and many prescription-only drugs) for personal use from suppliers based in the UK or overseas. Placing further legal restrictions on buyers purchasing online would be justifiable if the level of harm were sufficiently serious (following the proportionality principle set out in Chapter 4). But given the lack of firm evidence about the balance of harms and benefits of online pharmaceuticals purchasing to which we have already referred, we cannot at present justify recommending further legal restrictions on buyers.
- 7.37 As in the previous two cases, our recommendations attempt to soften or reduce the dilemmas arising from potential conflicts between the ethical values referred to above. Specifically we would like to see government monitoring of the incidence and extent of harms and benefits from the online purchasing of pharmaceuticals to allow more informed judgments and evidence-based policy to be applied to this domain in future. We also recommend: (i) provision by public healthcare services of high-quality information to help potential purchasers; (ii) voluntary adoption of good practice by providers; (iii) good professional medical practice adapted to this new development; and (iv) enforcement of legislation regarding the supply of antibiotics and state monitoring of antibiotic resistance.

Assessing the harms

- 7.38 **We recommend that the responsible bodies, which in the UK are currently the Government Health Departments and the Medicines and Healthcare products Regulatory Agency, should monitor and assess the incidence and extent of harms caused as online purchasing continues to become more common. Such monitoring will enable more informed judgments and evidence-based policy to be applied to this domain in future.**

Quality control systems

- 7.39 Current systems for classifying pharmaceuticals as over-the-counter, pharmacy-only and prescription-only in the UK and other countries have certain well-known and much-discussed shortcomings that go beyond the remit of this report. Nevertheless, we recognise the value of state-operated quality-control processes that aim to protect people from harm.
- 7.40 **We endorse attempts to mirror in the online selling of pharmaceuticals the quality-control processes that exist in some countries for more traditional pharmacies. An example of this is the registration and internet logo scheme for online pharmacies based in Great Britain by the pharmacies regulator (see Box 7.1).**

State provision of information

- 7.41 The state can also aim to prevent harm through providing information about the risks of purchasing pharmacy-only products, or what are sold as such, from an unregistered supplier or purchasing prescription-only medicines without a prescription. A number of professional and regulatory bodies already provide information on the risks and benefits of purchasing

³³⁹ The question has been raised as to whether professional protectionism might be at play here: we do not find this to be the case.

pharmaceuticals online.³⁴⁰ But we doubt whether many potential users of websites that offer pharmaceutical products are aware that they can ascertain that a website in Great Britain has the logo of the pharmacies regulator (and it is being legitimately used).

- 7.42 **We recommend that all relevant public healthcare service websites should include clear and prominent information about the risks of buying pharmaceuticals online (or products sold as such) and about how to identify a registered online pharmacy. We also recommend that private providers of healthcare and online personal health records direct their patients/users to registered online pharmacies if they wish to use the internet to purchase pharmaceuticals.**

The doctor-patient relationship

- 7.43 We have already noted that healthcare professionals are concerned that they might prescribe medicines without knowing about other pharmaceuticals the patient is taking that they have bought for themselves online.
- 7.44 **In line with the value we place on efforts by the state to reduce harm, we recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals to be aware of the possibility that their patients may have bought pharmaceuticals online without disclosing this information, as well as how to address this situation, for example in clinical assessments and the questions they ask of their patients.**
- 7.45 If people cause themselves harm after taking pharmaceuticals, or products sold as such, without a prescription or from an unregistered website, they may require healthcare and thus costs to healthcare providers may result. We cannot in this report take a general position on whether public healthcare services should provide unconditional care for those who have self-inflicted harms.
- 7.46 **At this time, given the lack of evidence for the scale of harm, we conclude that the solidarity principle underlying the NHS in the UK should mean that the healthcare service should not make any distinction between caring for people whose health problems are caused by taking pharmaceuticals bought online (or products sold as such), and those caused by other self-inflicted harms. We think a similar principle should apply to comparable healthcare systems in other countries.**

Antibiotic resistance

- 7.47 Going beyond the level of the individual as consumer and patient, we have already noted that increased taking of antibiotics as a result of availability on the internet (overriding the restrictions on access and on sale imposed by many countries)³⁴¹ has the potential to have a serious long-term negative impact on public health in the form of increased antibiotic resistance. This potential harm brings our ethical value of individuals being able to pursue their own interests in their own way into stark contrast with the value we place on social solidarity (see Chapter 3) and of state action to reduce harm at a collective level. At present we lack evidence of the extent of antibiotic resistance that can be attributed to online purchasing that bypasses existing

³⁴⁰ See, for example: Food and Drug Administration (2009) Buying prescription medicine online: A consumer safety guide, available at: <http://www.fda.gov/Drugs/ResourcesForYou/ucm080588.htm>; Food and Drug Administration (2009) Buying medicines and medical products online FAQs, available at: <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134631.htm>; Medicines and Healthcare products Regulatory Agency (2010) Risks of buying medicines over the internet, available at: <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/BuyingmedicinesovertheInternet/CON019610>.

³⁴¹ The UK already makes it illegal for suppliers based in the country to sell antibiotics without a prescription or, in certain circumstances, following consultation with a licensed pharmacist, and this restriction applies equally to online pharmacies.

restrictions, so we are not in a position to justify the adoption of more coercive measures to tackle the problem, but we consider that such evidence needs to be collected given the potential seriousness of increased antibiotic resistance at a population level.

- 7.48 **Countries worldwide should attempt to set and enforce regulations regarding the supply of antibiotics in their jurisdictions (we note restrictions on such supply vary widely and are entirely lacking in some countries). Governments and international health organisations should assess and monitor whether online availability is associated with any increases in antibiotic resistance in order to allow for evidence-based policy making in this area.**

Future impact

- 7.49 Widening choice through more online purchasing of pharmaceuticals may bring future benefits in the form of cost reduction, improved access to effective treatments or the adoption of new and better products or prescribing technologies. However, online purchasing of pharmaceuticals also involves potential risks, some of them serious. Many of those risks are to individuals, but as we have seen there are potential population-level risks as well, notably that of increased antibiotic resistance.
- 7.50 The impact of online selling of pharmaceuticals, or products sold as such, on the pharmaceutical industry has yet to be seen. Pharmaceutical companies report that they are taking action to prevent the supply of products that mimic their own or do not respect their patents. Some have concerns that in the world of online sales it will become more difficult to enforce patents and that incentives for developing new products may be weakened, creating a different kind of potential collective risk. Taxes might also be avoided.³⁴²
- 7.51 Given recent trends, online purchasing and online prescribing of pharmaceuticals seems likely to grow. A world where ever more people are online, combined with an increasingly global market for pharmaceuticals, the lack of restrictions on pharmaceutical purchases in some countries, and the expected increase in telemedicine (see Chapter 8), make it probable that online provision of such products will continue to increase. A world of greater international mobility may also contribute to increased online purchasing of pharmaceuticals, for example when patients who have had treatment abroad wish to buy or import their medicines from another country, once they return home,³⁴³ and corresponding challenges for healthcare providers, for example in how to verify the authenticity of the medicines provided by the patient if they were asked to administer them. Furthermore, it is possible and even likely that, as today's adults who are familiar with internet purchasing become tomorrow's elderly (the sub-population who use pharmaceuticals the most), they will be more able and willing to obtain pharmaceuticals online than today's elderly group, provided that the format of the internet does not change in a way that creates difficulties for that group.

³⁴² We note that the Pharmaceutical Package under review in the European Union at the time of writing, as described earlier, included proposals aimed at strengthening EU legislation to tackle fake medicines. See: European Commission (2010) EU pharmaceutical package, available at: http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/package_en.htm.

³⁴³ One commentator has suggested that some Members of the European Parliament see the draft Directive on patients rights' in cross-border healthcare (*Proposal for a Directive of the European Parliament and of the Council 2008/0142 on the application of patients' rights in cross-border healthcare*) as a mechanism to promote patients' access to treatments and medicines that they might not be able to access under their home systems (personal communication).

Chapter 8

Telemedicine

Chapter 8 – Telemedicine

Overview

What is new? Telemedicine, the provision of healthcare over a distance, has become feasible over the last two decades with the development of new information and communication technologies. Patient and doctor are able to communicate and send information to each other electronically, and medical devices and treatment delivery systems can be operated remotely or automatically. These developments raise the possibility of more personalised prevention and treatment measures, at least to some extent in all four of the senses defined in Chapter 1. Consumerisation, as discussed in Chapter 2, has not yet developed to a marked extent in the application of telemedicine in the UK, though it may well do so in the future. But the ethical issues associated with responsabilisation are of key importance for telemedicine, since some telemedicine services lead to patients (or their carers) taking, or being obliged to take, greater responsibility for their healthcare.

Which ethical values come into conflict as a result of this development? Potential conflicts could arise between the ethical value of efforts by the state to reduce harm and the ethical values of using public resources fairly and efficiently, and of individuals being able to pursue their own interests in their own way.

What is the existing pattern of interventions like? There is no overall system of interventions that cover telemedicine in all its different forms. However, many of the general governance measures relating to healthcare that rest on state-specific legal powers apply to telemedicine as they do to other means of healthcare provision, for example, those governing the conduct of medical professionals, negligence, product safety and liability, and quality and standards of health services. As for more service-specific types of intervention, the EU-wide legislation that covers medical devices is also of relevance here.

What gaps or shortfalls are there in existing interventions? It is not always clear how the system of interventions applies to telemedicine services that operate across borders. We also have concerns that the current pattern of interventions does not encourage providers of healthcare services to consider all the factors that we think are essential when deciding whether to introduce telemedicine services, including a number of considerations relating to global social solidarity.

What types of intervention might possibly fill those gaps or remedy those shortfalls? It is possible that a comprehensive and specific system of oversight could be introduced for telemedicine, but it would be difficult to define what should be included in such a system. Other options might include clarification of existing interventions and voluntary adoption of good practice by healthcare providers.

What types of intervention do we recommend, and why? We make recommendations that are aimed at promoting the benefits promised by telemedicine while trying to mitigate any potential harms. Many aspects of telemedicine are extensions of existing healthcare services and should therefore be assessed in the same way as any other such new service or technology before they can be properly introduced. Evidence for benefits and harms seems to be specific to each particular telemedicine service, meaning that overarching conclusions cannot be drawn, and we see no case for further broad-based measures applying the coercive powers of the state at this time. Rather, we advise that providers of public healthcare systems should take various factors into account when deciding whether to introduce telemedicine services, including cost-effectiveness, equity, safety, quality, the value of physical time with health professionals, and impact upon doctor-patient relationships. We also make recommendations about: (i) consent; (ii) vulnerable people; (iii) monitoring devices; (iv) cross-border issues; and (v) global social solidarity. In line with the aim set out in Chapter 4, these recommendations are based on general governance type measures where possible, although sometimes more specific measures are required.

Introduction

- 8.1 Most people currently access healthcare by seeing their doctor face-to-face at a surgery, visiting a healthcare centre or hospital, or purchasing medicines and health-related products in a pharmacy. But some medical care has always been provided over a distance, that is with the patient and the healthcare professional in different places (for example with advice over emergency treatment being given by radio or telephone), and in recent years various technologies have been developed and integrated that greatly extend the possibilities of remote advice, observation or treatment. Such technologies include devices that can be operated remotely or automatically, communicate with healthcare professionals to relay medically relevant information, and even deliver treatment automatically. The term ‘telemedicine’ has come to be adopted to describe these technologies and services (though its definition and proper application is disputed: see Box 8.1). Telemedicine differs from other applications in this report in that most usually, at least in the UK, the services described are provided by the healthcare system rather than initiated and funded by users themselves.

Box 8.1: Definitions of telemedicine

The word ‘telemedicine’ is often used as an umbrella term to mean any form of healthcare that involves information and communications technology and an element of distance.³⁴⁴ It thus applies to numerous forms of information transmission (voice, sound, video, pictures, text), communication technologies (telephone lines, satellites, microwave, digital wireless, internet) and user interfaces (computers, personal digital assistants, telephones, stand-alone systems).³⁴⁵

The term ‘telemedicine’ is sometimes said to be too limited, and the terms ‘telehealth’ and ‘telecare’ have been proposed to expand the concept, to include medicine and healthcare more broadly.³⁴⁶ ‘Telehealth’ is defined as the delivery of healthcare at a distance, typically embracing diagnosis (e.g. teleconsultations, teleradiology), treatment (e.g. telesurgery), health education and research.³⁴⁷ ‘Telecare’, by contrast, is used to refer to the continuous and remote monitoring of individuals and their health status to manage the risks associated with independent living,³⁴⁸ for example with a person measuring their vital signs at home and the data being transferred to a clinician.³⁴⁹

While we recognise the different nuances in the meanings of ‘telehealth’ and ‘telecare’, we use the term ‘telemedicine’ in this report as an overarching term to include all forms of medicine and healthcare carried out at a distance.

- 8.2 Telemedicine raises numerous issues of responsabilisation, as discussed in Chapter 2, because some telemedicine services lead to patients (or their carers) taking, or being obliged to take, greater responsibility for their healthcare, while also sharing key personal data with remote monitors. Up to now, some aspects of consumerisation in telemedicine developments have been rather less marked in the UK, with less of the direct-to-consumer marketing and competitive online provision than applies to several of our other cases. Many of the patients most concerned (notably elderly people) are likely to find difficulties in exerting meaningful consumer choice, particularly if some form of telemedicine appears to be the only alternative to institutional care. But it may well be that the technologies concerned will in time lend themselves more to the sort of consumer developments we have seen in our other case studies.

³⁴⁴ Wootton R (2001) Recent advances in telemedicine *British Medical Journal* **323**: 557–60.

³⁴⁵ Miller EA (2010) *Telemedicine and the provider-patient relationship: What we know so far* [Evidence review commissioned for this Working Party].

³⁴⁶ Stanberry B (2000) Telemedicine: Barriers and opportunities in the 21st century *Journal of Internal Medicine* **247**: 615–28.

³⁴⁷ *Ibid.*

³⁴⁸ Department of Health (2008) Government launches national debate on the future of care and support, available at <http://www.mmnetwork.nhs.uk/med-man-new-details.php?newsid=1641>.

³⁴⁹ Telecare is sometimes also referred to as ‘connected health’.

Telemedicine may also lend itself to more consumerised provision in the sense of service that is more convenient in time and place for users.

- 8.3 Telemedicine also raises the possibility, although to a lesser extent, of more personalised prevention and treatment measures in the other senses set out in Paragraph 1.18: i.e. where it is used for more than a substitute for traditional face-to-face medical care, it can be a tool that facilitates the delivery of increasingly individualised prevention and treatment measures and it may also be conducive to ‘whole-person’ treatment. On the face of it, it may seem that telemedicine, by its very nature, is ‘de-personalised’ where it refers to healthcare provided in other ways than the more traditional face-to-face meetings between healthcare professional and patient (we return to this issue in Paragraph 8.15). But where telemedicine is used as more than a substitute for traditional face-to-face medical care, it may be a tool for greater personalisation in at least some of the senses described in Chapter 1, including more individualised preventive measures and possibly more ‘whole-person’ treatment as well. Much would seem to depend on how the technology is applied.

Types of telemedicine

- 8.4 Telemedicine encompasses numerous technologies, from basic telecommunications such as the telephone to the most sophisticated modern information and communications systems (see Box 8.2 for some examples). Each application of telemedicine has its own social and ethical implications, meaning that any new system would need to be considered on a case-by-case basis before introduction (see the recommendations later in this chapter). Examples of applications of telemedicine include the following.

- Information about a patient’s health-related biological or physiological processes is transmitted to either a healthcare professional or the patient, for monitoring purposes or as an alert when there is a potentially adverse change. This information might be used to help make decisions about treatment or for remotely activating a treatment device, such as an implanted insulin pump.
- Health-related information about individuals may be collected outside of the direct clinical healthcare context, for example remote parental monitoring of adolescent blood glucose.
- Healthcare professionals can communicate with patients, for example in ‘telepsychiatry’ via a video-conference link. The Aberdeen Royal Infirmary has trialled the HealthPresence system (supplied by Cisco) which combines video-conferencing with medical devices to facilitate a ‘virtual consultation’.³⁵⁰
- Healthcare professionals can communicate with each other to give or seek advice or discuss any aspect of patient care. As with earlier forms of remote communication, such developments can be especially useful to assist in providing care that might be more specialist than that available locally, for example in ‘telesurgery’. A more regularly used service of this type is an established video-conferencing service that links minor injuries units in small community hospitals in the North East of Scotland with a large teaching hospital. Many minor injuries can be managed locally by nurses, and if necessary staff can request advice from specialists at Aberdeen Royal Infirmary. Using a video link allows the doctor providing advice to see the patient. In 90–95% of these requests for telemedicine advice, the result is that the patient does not need to be transferred to a larger hospital.

³⁵⁰ The HealthPresence system includes medical equipment which enables the patient to provide information such as blood pressure, weight, pulse rate and temperature. An assistant is present with the patient to operate the medical devices. Cisco, Scottish Centre for Telehealth and NHS Scotland launched the first Cisco HealthPresence trial in Scotland in 2008. For further details, see: Scottish Centre for Telehealth (2010) Trial of a new consulting technology, available at: <http://www.sct.scot.nhs.uk/healthp.html>. NHS Grampian does not have any further plans to use the HealthPresence system, although other forms of telemedicine continue to be used. (Information supplied by the Scottish Centre for Telehealth.)

- Developments in robotics and computer technology now enable some surgery to be carried out as ‘telesurgery’ with patients and key experts in different places. This potentially makes surgical expertise available throughout the world. An example is an operation involving the successful removal of a patient’s gallbladder, with the patient in Strasbourg and the surgeon in New York.³⁵¹
- Healthcare professionals can communicate with whoever is present at an emergency situation to advise them on giving care to those who need it.
- Communications technologies can be used to transmit results and images such as x-rays (‘teleradiology’).
- A broad definition of telemedicine can include monitoring sensors that measure a person’s activity in the home and transmit the data to relatives, carers or healthcare professionals. In this way changes in a person’s activity levels can be observed and addressed, for example by raising an alarm if there is no observable motion or if an adverse event such as a seizure is detected. We make recommendations relating to consent and the introduction of such monitoring services for vulnerable people in Paragraphs 8.37 and 8.38.

Box 8.2: Telemedicine devices and systems

Assistive technology – a product or service designed to promote independence and self-management for disabled people, older people or those with chronic conditions. For example, a pilot of a ‘Whole System Demonstrator Programme’ was carried out in England in 2008–2010 to test the potential of telemedicine to support people with long-term chronic conditions (including diabetes, heart problems, chest problems and those who were elderly and frail).³⁵²

Biosensor – a device that detects physiological changes in the body and turns it into an electronic signal.

Micro electro-mechanical system (MEMS) – a small integrated device or system that combines mechanical and electrical components that can sense and control on a micro-scale.³⁵³

These devices and systems can sometimes be combined, for example by linking biosensors with MEMS to monitor patients and transmit the information to patients themselves or healthcare professionals.

Telemedicine in developing countries

- 8.5 Although the potential range of uses of telemedicine in developing countries is not dissimilar to that in the developed world,³⁵⁴ it raises some distinctive ethical and social issues. Some commentators suggest that telemedicine may have a more profound impact on developing countries than on developed ones, owing to the possibility of provision of medical care, education and support from countries with more specialised resources.³⁵⁵ Telemedicine could enable specialist medical care to be delivered in parts of the developing world where this care would not otherwise be available. For example, the global ‘e-referral network’ operated by the

³⁵¹ Marescaux J, Leroy J, Gagner M *et al.* (2001) Transatlantic robot-assisted telesurgery *Nature* **413**: 379–80.

³⁵² The pilot was funded by the Department of Health in England and was the largest trial of telemedicine in the UK to date. See: Department of Health (2008) Government launches national debate on the future of care and support, available at <http://www.mmnetwork.nhs.uk/med-man-new-details.php?newsid=1641>; Department of Health (2008) *Whole systems demonstrators: An overview of telecare and telehealth*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_100947.pdf.

³⁵³ Vittorio SA (2001) Micro electro-mechanical systems (MEMS), available at: <http://www.csa.com/discoveryguides/mems/overview.php>.

³⁵⁴ Wootton R (2008) Telemedicine support for the developing world *Journal of Telemedicine and Telecare* **14**: 109–14.

³⁵⁵ See, for example: Edworthy SM (2001) Telemedicine in developing countries *British Medical Journal* **323**: 524–5.

Swinfen Charitable Trust provides expert second opinions to doctors in developing countries via an internet-based messaging system. The expertise is provided free of charge by volunteer consultants mainly from developed countries. The system allows medical personnel in developing countries to send clinical photographs, x-rays, a patient's history and any other relevant material to the Swinfen Trust. The Trust then notifies the most appropriate available specialist and forwards the case to him/her. In its first ten years of operation, the Trust provided telemedicine advice for over 2,000 patients.³⁵⁶

- 8.6 However, it has been found that telemedicine initiatives in developing countries often have not matured into sustainable programmes,³⁵⁷ and some argue that potential demand for these services is not being met.³⁵⁸ Many developing countries lack sophisticated electrical and telecommunications infrastructures, especially in remote and poor areas, making it hard to provide remote medical services to those who are likely to need them most.³⁵⁹ It has also been argued that “although current efforts using telemedicine have demonstrated positive effects in countries in need, they have not substantially reduced or compensated for a fundamental lack of healthcare.”³⁶⁰
- 8.7 There are concerns that, should telemedicine become widespread in developing countries, such a development could lead to a new form of medical ‘brain drain’, insofar as health professionals might begin providing remote healthcare related services to developed countries to the detriment of patients in their own countries. But that is not the only possible effect of telemedicine on development: the technology might also be seen as a way of providing healthcare professionals in developing countries with access to higher pay and better training, without necessarily leaving their home countries, having the effect of reducing rather than increasing the ‘brain drain’. The technology might also serve to increase professional links between developing and developed countries.³⁶¹ Exactly how these various factors will play out is not known, but we return to this issue in our recommendations in Paragraphs 8.45–8.48.

Benefits and harms

- 8.8 A number of potential advantages and disadvantages of telemedicine are included in Table 3.1.

Potential advantages

- Being at home rather than in institutional care;
- convenience;
- more equitable access to healthcare;
- cheaper care; and
- earlier return home from hospital.

Potential disadvantages

- Dangers of misuse;
- reduction in the quality of the doctor-patient relationship;
- a ‘virtual brain drain’;

³⁵⁶ Swinfen Charitable Trust (2010) Achievements, available at:

http://www.swinfencharitabletrust.org/index.php?option=com_content&view=article&id=46&Itemid=55.

³⁵⁷ Latifi R, Merrell RC and Doran CR *et al.* (2009) "Initiate-build-operate-transfer" – a strategy for establishing sustainable telemedicine programs in developing countries: Initial lessons from the Balkans *Journal of Telemedicine and e-Health* **15(10)**: 956–69.

³⁵⁸ Wootton R (2008) Telemedicine support for the developing world *Journal of Telemedicine and Telecare* **14**: 109–14.

³⁵⁹ Mortensen J (2008) *International trade in health services – Assessing the trade and the trade-offs*, p16, available at: http://www.diiis.dk/graphics/Publications/WP2008/WP08-11_International_Trade_in_Health%20Services.pdf.

³⁶⁰ Rao B and Lombardi A (2009) Telemedicine: Current status in developed and developing countries *Journal of Drugs in Dermatology* **8(4)**: 371–5.

³⁶¹ For further discussion on the potential impact of telemedicine in developing countries, see Edworthy SM (2001) Telemedicine in developing countries *British Medical Journal* **323**: 524–5; Wootton R (1997) The possible use of telemedicine in developing countries *Journal of Telemedicine and Telecare* **3**: 23–6.

- inappropriate early discharge from hospital; and
- surveillance of lifestyle.

Convenience and access to specialists

- 8.9 Telemedicine offers some patients opportunities for accessing healthcare more conveniently and reducing the need to travel and overnight stays in or near a hospital or other healthcare facility.³⁶² It has particular advantages in remote or rural areas where there are fewer specialist doctors. Some services can be provided in the privacy of the patient's home, and at times that suit them. Telemedicine can thus be a useful 'add-on' to more traditional, face-to-face healthcare and can also offer additional services than might otherwise be available, such as more frequent monitoring (see Box 8.3 for an example). Doctors may also benefit from telemedicine, with the possibility of reducing travel, increasing their access to specialist opinions and offering opportunities for more efficient training.

Box 8.3: Congestive heart failure (CHF) monitoring after a hospital stay

CHF is a clinical syndrome that is increasingly prevalent in Western countries, with a yearly mortality rate of up to 50% of people with the condition. Regular and effective monitoring is an important element of CHF management, because the signs of deteriorating health may be "subtle and difficult to recognize".

CHF remote monitoring programmes have been trialled in which patients complete a monitoring session each morning, weigh themselves, answer a health questionnaire or provide other health data via the internet. This information can be transmitted directly to a doctor. On the basis of this information, the patient may continue to be monitored, or further treatment may be needed if there has been a deterioration in their condition.

See: Antonicelli R, Testarmata P and Spazzafumo L *et al.* (2008) Impact of telemonitoring at home on the management of elderly patients with congestive heart failure *Journal of Telemedicine and Telecare* 14: 300–305 and Biddiss E, Brownsell S and Hawley MS (2009) Predicting need for intervention in individuals with congestive heart failure using a home-based telecare system *Journal of Telemedicine and Telecare* 15: 226–231.

Patient satisfaction and concerns about replacing face-to-face consultations

- 8.10 The broad range of services available and being developed makes it difficult to give an overall summary of levels of patient satisfaction with telemedicine services. Whether or not patients consider telemedicine services to have been implemented successfully seems to be heavily contextual: it depends on the nature of the service being delivered, location and finance. For example, there has been enthusiasm for the provision of healthcare services to those in remote or rural locations because it may, to some extent, mitigate the problems of distance between doctor and patient.³⁶³ However, even there it is not always certain that the potential benefits are realised, due to factors such as the structural organisation and the culture of the relevant healthcare providers.³⁶⁴
- 8.11 There are concerns that telemedicine could be used by health services to replace face-to-face consultations between healthcare professionals and patients that both find beneficial. The World Medical Association's *Statement on the ethics of telemedicine* notes that telemedicine

³⁶² Wootton R (1998) Telemedicine in the National Health Service *Journal of the Royal Society of Medicine* 91: 614–21.

³⁶³ Whitten P and Adams I (2003) Success and failure: A case study of two rural telemedicine projects *Journal of Telemedicine and Telecare* 9: 125–9; Miller EA (2007) Solving the disjuncture between research and practice: Telehealth trends in the 21st century *Health Policy* 82(2): 133–41.

³⁶⁴ King G, Richards H and Godden D (2007) Adoption of telemedicine in Scottish remote and rural general practices: A qualitative study *Journal of Telemedicine and Telecare* 13: 382–6; Whitten P and Adams I (2003) Success and failure: A case study of two rural telemedicine projects *Journal of Telemedicine and Telecare* 9: 125–9.

measures should generally augment face-to-face care, rather than replace it: “telemedicine should be employed primarily in situations in which a physician cannot be physically present within a safe and acceptable time period”.³⁶⁵ Going further, the Department of Health for England’s 2005 report, *Building telecare in England*, stated: “As we move towards the future, there is no doubt that new technologies will play an increasing role in all parts of our lives. However, we must take care not to allow these new technologies to control or isolate us and whilst the world around us is fast changing our basic human needs remain the same. Some care services will always be, quite rightly, delivered personally. Human contact is vital to maintaining quality of life. As we embrace the new possibilities and promise that the future brings we must make sure that our values are not weakened but strengthened by using these technologies to complement traditional forms of care.”³⁶⁶ We return to the issue of patient satisfaction with telemedicine services in our recommendation in Paragraph 8.35.

- 8.12 There are some instances in which the use of telemedicine is said to be inappropriate, or where ‘hands-on care’ is to be preferred. Some years ago, for example, the British Medical Association argued that telemedicine should not be used for intensive care: “We believe that the introduction of telemedicine for intensive care would have a detrimental effect on outcomes, given that critical care is a ‘hands-on’ skill and requires a multidisciplinary team approach, both of which telemedicine would not be able to provide”.³⁶⁷ But this view is by no means universally held: some people believe, on the contrary, that there are circumstances in intensive care units where telemedicine has an important role to play and is increasingly becoming standard practice.³⁶⁸ We consider more fully below how the lack of a face-to-face consultation could affect the doctor-patient relationship.

The doctor-patient relationship

- 8.13 A good doctor-patient relationship involves openness, trust and good communication, to enable patient and doctor to work together to address the patient’s needs.³⁶⁹ The review of evidence carried out for this report found that communication is a key determinant of healthcare outcomes, and hence the way some telemedicine services affect health outcomes may be, in part, through changes in the way doctors and patients communicate with one another.³⁷⁰ But because telemedicine services come in so many forms, the impact on the doctor-patient relationship is likely to vary from one application of telemedicine to another.³⁷¹
- 8.14 The evidence review carried out for this report found little empirical research about the impact of telemedicine on doctor-patient relationships. There have been several relevant literature reviews, which have found methodological and conceptual weaknesses in most of the studies examined, but concluded that such research as there has been reveals high levels of patient satisfaction with telemedicine (particularly with respect to travel, waiting time, and access to comprehensive specialist care) along with “some disquiet” over provider-patient communication that falls a long way short of hard or conclusive evidence.³⁷²

³⁶⁵ World Medical Association (2007) Statement on the ethics of telemedicine, available at: <http://www.wma.net/en/30publications/10policies/t3/index.html>.

³⁶⁶ Department of Health (2005) *Building telecare in England*, p5, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4115303.

³⁶⁷ British Medical Association (2007) The response of the British Medical Association to Lord Darzi’s review ‘Healthcare for London: A framework for action’, available at: http://www.bma.org.uk/healthcare_policy/nhs_system_reform/LordDarziReview.jsp.

³⁶⁸ Cummings J, Kresk C, Vermoch K and Matuszewski K (2007) Intensive care unit telemedicine: Review and consensus recommendations *American Journal of Medical Quality* **22**(4): 239–50.

³⁶⁹ Referred to as the “doctor-patient partnership” by the General Medical Council. See: General Medical Council (2006) *Good Medical Practice*, available at: http://www.gmc-uk.org/static/documents/content/GMC_GMP_0911.pdf.

³⁷⁰ Miller EA (2010) *Telemedicine and the provider-patient relationship: What we know so far* [Evidence review commissioned for this Working Party].

³⁷¹ Hilty DM, Nesbitt TS, Hales RE, Anders TF and Callahan EJ (2000) The use of telemedicine by academic psychiatrists for the provision of care in the primary care setting *Medscape General Medicine* **5**(2).

³⁷² Miller EA (2010) *Telemedicine and the provider-patient relationship: What we know so far* [Evidence review commissioned for this Working Party].

8.15 If consultations take place virtually via video-conferencing rather than physically, the constraints of the technology may affect the process, for example through limited scope for sensory input and non-verbal communication, and by the way it affects social and professional distancing between doctor and patient, particularly given that norms and standards for such teleconsultations are not yet fully developed.³⁷³ Changed behaviour caused by the 'tele' format might also limit the trust needed to facilitate patient disclosure and cooperation. On the other hand, the use of telemedicine in some circumstances might serve to promote more patient-centred interactions which recognise patients as collaborators who bring strengths and resources to the interaction.³⁷⁴ So, as we suggested in Paragraph 8.3, whether the patient receives more or less care that is 'personalised' (in the sense of being tailored to their particular needs) seems to depend less on anything inherent in the technology as on how the care is delivered and who delivers it. On the one hand, non-verbal communication, including voice quality and tone, eye contact, posture, touch, activity and other cues can all be absent or more difficult to interpret using telemedicine (the extent of the difficulty depending on the device being used). Some patients may also feel that telemedicine reduces their sense of privacy, which may hinder patient communication during some encounters. On the other hand, it is possible that the use of telemedicine may create a setting in which other patients can feel more relaxed, especially if they are in their own homes or feel they can discuss potentially embarrassing matters with greater ease. Consultations via telemedicine often require greater patient participation, for example in situations where patients are asked to use a blood pressure machine as part of the consultation.³⁷⁵

Cost-effectiveness

8.16 The wide variety of telemedicine applications means that no general conclusions about their cost-effectiveness can be drawn. Indeed there is no easy way of measuring the cost-effectiveness of such applications. Cost-effectiveness is, of course, important when considering introducing a new service and we make a recommendation about this element in Paragraph 8.31. Proponents of telemedicine argue that it can increase the efficiency and cost-effectiveness of healthcare delivery through better management of long-term conditions, reduced hospital stays, improved accessibility to services and sharing of healthcare resources. But a recent evaluation noted that "several systematic reviews have found little evidence that telemedicine is cost saving."³⁷⁶ Problems in determining the cost-effectiveness of telemedicine services include: the difficulty of generalising results (e.g. what may be considered cost-effective in a rural setting may not be applicable to the inner city);³⁷⁷ whether or not cost-effectiveness should take into account (or be subordinate to) clinical effectiveness;³⁷⁸ and the institutional context within which the service is provided (e.g. a public healthcare provider such as the National Health Service (NHS), the military or a commercial organisation such as an oil rig).³⁷⁹ Conclusions about cost-effectiveness may also depend on the particular telecommunications equipment used.³⁸⁰

³⁷³ Miller EA (2003) The technical and interpersonal aspects of telemedicine: Effects on doctor-patient communication *Journal of Telemedicine and Telecare* 9: 1–7.

³⁷⁴ Miller EA (2010) *Telemedicine and the provider-patient relationship: What we know so far* [Evidence review commissioned for this Working Party].

³⁷⁵ Miller EA (2010) *Telemedicine and the provider-patient relationship: What we know so far* [Evidence review commissioned for this Working Party].

³⁷⁶ Bergmo TS (2009) Can economic evaluation in telemedicine be trusted? A systematic review of the literature *Cost Effectiveness and Resource Allocation* 7(18).

³⁷⁷ Haycox AR (2002) Lack of evidence for effectiveness differs from evidence of lack of effectiveness [rapid response to Whitten PS *et al.* (2002) Systematic review of cost effectiveness studies of telemedicine interventions (2002) *British Medical Journal* 324: 1434–7], available at: http://www.bmj.com/content/324/7351/1434.full/reply#bmj_el_23590.

³⁷⁸ Riva G (2002) Telemedicine: Is cost effectiveness more important than clinical effectiveness and quality of life? [rapid response to Whitten PS *et al.* (2002) Systematic review of cost effectiveness studies of telemedicine interventions (2002) *British Medical Journal* 324: 1434–7], available at: http://www.bmj.com/content/324/7351/1434.full/reply#bmj_el_23153.

³⁷⁹ Kirshen AJ (2002) Telemedicine too important to be derailed by flawed research [rapid response to Whitten PS *et al.* (2002) Systematic review of cost effectiveness studies of telemedicine interventions (2002) *British Medical Journal* 324: 1434–7], available at: http://www.bmj.com/content/324/7351/1434.full/reply#bmj_el_23027; May CR (2002) Failure to compare cost

- 8.17 In 2008, the European Commission noted that, although some studies demonstrated benefits of telemedicine on a small scale for patients and healthcare systems, “there is limited evidence of the effectiveness and cost-effectiveness of telemedicine services on a large scale”.³⁸¹ The Commission said that “commonly accepted methodologies for assessing effectiveness, such as those used to assess pharmaceutical products, must be further developed”³⁸² and it has stated its intention to “support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including effectiveness and cost-effectiveness”.³⁸³ Two examples of studies are given in Box 8.4.

Box 8.4: Two examples of studies assessing the cost-effectiveness of telemedicine services

Cardiac telemedicine in Cumbria and Lancashire

In 2005 the then Cumbria and Lancashire Strategic Health Authority implemented a cardiac telemedicine trial to evaluate the use of an electrocardiogram (ECG)³⁸⁴ interpretation service within a primary care setting.³⁸⁵ The ECG interpretation service aimed to provide assistance to general practitioners (GPs), who often experience difficulty in interpreting ECGs, thus aiding diagnosis and patient treatment. Patients were able to receive a full ECG at their GP surgery within minutes, rather than having to attend an accident and emergency department.

The six-month pilot trial indicated that the potential for the service was to prevent up to 90,000 accident and emergency visits and 45,000 hospital admissions per year across England. It was estimated that the potential financial savings could be upwards of £45 million per year for England as a whole if the programme were implemented across the country.

Tele dermatology in Northern Ireland

A study of ‘tele dermatology’ in Northern Ireland ten years ago examined the various factors that could affect both the clinical outcomes and cost-effectiveness of telemedicine.³⁸⁶ The study involved a randomised control trial of tele dermatology services in four health centres and two regional hospitals. It concluded that, while the service in question offered “no major differences in clinical outcome” in comparison with face-to-face care, it was not cost-effective. This conclusion was based on several factors, particularly the cost of purchasing and using the telecommunications equipment and the distance patients had to travel. Had the distances been longer and the equipment less costly (for example if it was bought at 2000, rather than 1995, prices) the service would have been regarded as cost-effective.

effectiveness of civilian against military telemedicine is a red herring[rapid response to Whitten PS *et al.* (2002) Systematic review of cost effectiveness studies of telemedicine interventions (2002) *British Medical Journal* **324**: 1434–7], available at: http://www.bmj.com/content/324/7351/1434.abstract/reply#bmj_el_23115.

³⁸⁰ Persaud DD, Jreige S, Skedgel C *et al.* (2005) An incremental cost analysis of telehealth in Nova Scotia from a societal perspective *Journal of Telemedicine and Telecare* **11**: 77–84.

³⁸¹ European Commission (2008) *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee of the regions on telemedicine for the benefit of patients, healthcare systems and society* [COM(2008)689], p6, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF>.

³⁸² *Ibid.*

³⁸³ European Commission (2009) Telemedicine: Follow-up of the 10-point action plan, available at: http://ec.europa.eu/information_society/activities/health/policy/telemedicine/telemedicine2/index_en.htm.

³⁸⁴ A test that records the rhythm and electrical activity of the heart.

³⁸⁵ NHS North West (2009) *Cardiac telemedicine in primary care: Delivering benefits for patients and the NHS in Lancashire & Cumbria – a report for commissioners*, available at: http://www.lscardiacnetwork.nhs.uk/uploads/files/cardiac/key_documents/local_documents/reports/Cardiac_Telemedicine.pdf.

³⁸⁶ Wootton R, Bloomer SE, Corbett R *et al.* (2000) Multicentre randomised control trial comparing real time tele dermatology with conventional outpatient dermatological care: Societal cost-benefit analysis *British Medical Journal* **320**: 1252–56.

Surveillance technologies

- 8.18 Remote monitoring of patients can reveal treatable medical problems and enable changes in lifestyle targeted at each individual's circumstances. The use of technologies such as biosensors for clinical monitoring may improve quality of life and promote independent living. However, the use of surveillance devices has met with considerable opposition by those who think surveillance is an intrusion of privacy and contrary to principles of dignity and freedom. The European Convention on Human Rights, implemented in the UK by the Human Rights Act 1998, places a duty on the state to protect the freedom and liberty of individuals. The relevant parts are Article 3, which prohibits degrading or inhuman treatment; Article 5 which provides a right to liberty and security; and Article 8, which enshrines a right to respect for private and family life. Privacy and liberty are always breached to some degree when a patient is under surveillance, and such a breach in our second ethical value needs to be balanced against the benefits of using the technology (e.g. maintaining freedom and allowing independence).
- 8.19 The implementation of surveillance technologies that some telemedicine applications entail requires careful consideration to ensure ethical use among those who are most vulnerable, including elderly people and those with learning difficulties. For instance, in a paper on the use of electronic surveillance measures in elderly patients with dementia and people with learning difficulties, Welsh *et al.* (2003) declare: "What is heralded as an opportunity for increased liberty must not degenerate into the denial of basic human rights and dignity".³⁸⁷ The ethical issues raised by the technologies led those authors to call for the introduction of clear guidelines and protocols to ensure consistent and ethical practice, and we return to this issue in our recommendation in Paragraph 8.37.

Extent of use

- 8.20 Since the 1990s, there has been a rapid increase in research related to telemedicine as a result of developments in information and communications technologies. The wide range of applications that come under the heading of 'telemedicine' and the different definitions of the field that we noted earlier make it difficult to assess the extent of these applications.³⁸⁸ For example, some people consider any application involving the use of telephones or the internet as 'telemedicine' whereas others would apply a more restrictive definition. In 2005, the Department of Health for England stated an intention to increase the numbers of older people who benefited from telecare by at least 160,000 nationally over two years,³⁸⁹ but the outcome of that measure was not clear at the time of writing, and within the UK or its component countries there are no centrally held records available as to the number of people aged 65 and over in the UK using telemedicine equipment in their homes or a residential context, perhaps because such services are a local government responsibility.³⁹⁰
- 8.21 While integrated, comprehensive systems seem to be rare, it is generally considered that the use of certain forms of telemedicine is fairly common, has been occurring for some years and is increasing.³⁹¹ Teleradiology and telepsychiatry are sometimes cited as examples of

³⁸⁷ Welsh S, Hassiotis A, O'Mahoney G and Deahl M (2003) Big brother is watching you – the ethical implications of electronic surveillance measures in the elderly with dementia and in adults with learning difficulties *Aging Mental Health* **7**(5): 372–5.

³⁸⁸ Doolittle GC and Spaulding RJ (2006) Defining the needs of a telemedicine service *Journal of Telemedicine and Telecare* **12**: 276–84.

³⁸⁹ Department of Health (2005) *Building telecare in England*, p6, available at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4115303.

³⁹⁰ Liam Byrne, Parliamentary Under-Secretary, Department of Health, Hansard HC Deb, 25 April 2006, c1083W; Phil Hope, Minister of State (the East Midlands), Regional Affairs, Hansard HC Deb, 20 July 2009, c998W.

³⁹¹ Mair F, Finch T and May C *et al.* (2007) Perceptions of risk as a barrier to the use of telemedicine *Journal of Telemedicine and Telecare* **13** (Suppl. 1): S1: 38–9; Wootton R (2008) Telemedicine support for the developing world *Journal of Telemedicine and Telecare* **14**: 109–14; Doolittle GC Spaulding RJ (2006) Defining the needs of a telemedicine service *Journal of Telemedicine and Telecare* **12**: 276–84; Hersh WR, Hickam DH and Severance *et al.* (2006) Diagnosis, access

telemedicine that are fairly widespread and successful,³⁹² but many telemedicine pilots that have been carried out have ceased to operate once their initial funding has run out.³⁹³

Current system of interventions

8.22 There is no overall system of interventions that cover telemedicine in all its various forms. However, many of the general governance measures relating to healthcare that rest on the state-specific legal powers apply to telemedicine as they do to any other means of providing healthcare, for example those governing the conduct of medical professionals, negligence, product safety and liability, and quality and standards of health services (see Box 4.1). The EU-wide legislation that covers medical devices also covers telemedicine, and we consider these forms of intervention further below.

Legal liability of healthcare professionals

8.23 Telemedicine can involve the transmission of health information across national borders, as well as the making of decisions about diagnosis, treatment and patient care. So how does legal liability over issues such as negligence or malpractice operate when the healthcare professional is located in a different country from the patient?³⁹⁴ If medical consultations and treatment are provided by healthcare professionals in one country to patients in another country, this raises issues of legal jurisdiction and governance of data, as well as issues of responsibility and professional liability. The legal principles upon which jurisdiction in cross-border practice is established were introduced long before the development of telemedicine.³⁹⁵ Jurisdiction is often determined by which country the practice is most closely associated with, or which is most fair and convenient for all the parties involved.³⁹⁶ A contract may state the applicable law and jurisdiction that has been agreed on.

8.24 Countries within the EU operate a restrictive policy which stipulates that healthcare professionals require full registration to practise within the country the patient is residing in. Effectively, it is as if healthcare professionals are travelling to the patient when they deliver a telemedicine service.³⁹⁷ Within the EU, healthcare professionals who have gained professional qualifications in one Member State are entitled to have their qualifications recognised in all other Member States, but they can be suspended or struck off the medical register after fitness to practice proceedings in one state while still being permitted to practise in another.

8.25 The likely future volume of cross-border telemedicine is debated,³⁹⁸ and some argue that there are substantial barriers to cross-border telemedicine, not just those constituted by legal and regulatory disparities but also “cultural differences, socio-political conditions (public vs. private health provision), lack of human resources, and technologic and infrastructural limitations”.³⁹⁹ We return to cross-border telemedicine in our recommendation in Paragraph 8.44.

and outcomes: Update of a systematic review of telemedicine services *Journal of Telemedicine and Telecare* **12(Suppl. 2)**: S2: 3–31.

³⁹² Brown NA (2005) Information on telemedicine *Journal of Telemedicine and Telecare* **11**: 117–26; Hailey D, Ohinmaa A and Roine R (2009) Limitations in the routine use of telepsychiatry *Journal of Telemedicine and Telecare* **15**: 28–31.

³⁹³ Mair F, Finch T, May C, Hiscock J, Beaton S, Goldstein P and McQuillan S (2007) Perceptions of risk as a barrier to the use of telemedicine *Journal of Telemedicine and Telecare* **13 (Suppl. 1)**: S1: 38–9; Wootton R (2008) Telemedicine support for the developing world *Journal of Telemedicine and Telecare* **14**: 109–14.

³⁹⁴ Stanberry B (2006) Legal and ethical aspects of telemedicine *Journal of Telemedicine and Telecare* **12**: 166–75.

³⁹⁵ *Ibid.* (See also: the Rome Convention 1980 and the Brussels Regime.)

³⁹⁶ *Ibid.*

³⁹⁷ *Ibid.*

³⁹⁸ See: Mortensen J (2008) *International trade in health services – assessing the trade and the trade-offs*, p17, available at: http://www.diis.dk/graphics/Publications/WP2008/WP08-11_International_Trade_in_Health%20Services.pdf.

³⁹⁹ *Ibid.*

Medical devices

- 8.26 In the UK, laws on product liability apply equally whether a device or part of a system is based many miles from the patient or in another room of the same hospital. Medical devices are regulated separately from medicines (we describe the latter regime in Chapter 7). There are three main European Medical Devices Directives transposed into UK law, all intended to proportion the stringency of regulation to the level of risk involved:
- Active Implantable Medical Devices (90/385/EEC) (Powered implants);
 - Medical Devices (93/42/EEC) (Most other devices); and
 - In Vitro Diagnostics (98/79/EC) (In Vitro Diagnostic medical devices).
- 8.27 These Directives require ‘Notified Bodies’ to check that manufacturers and devices meet the requirements. Notified Bodies are firms that apply for this status and there are about 80 of them across Europe and seven in the UK. Council Directive 93/42/EEC specifies ‘essential requirements’ for medical devices,⁴⁰⁰ placing controls on safety, performance, design, specification, manufacture, labelling and packaging. Products are classified as ‘low risk’, ‘medium risk’ and ‘high risk’ according to specifications in the Directive.⁴⁰¹ Manufacturers must themselves classify their devices into these categories, and review and comply with the relevant requirements. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA), which has already been described, carries out pre-market registration and post-market monitoring and enforcement. It awards the CE mark to products under the Medical Devices Directive if a manufacturer meets its responsibilities.⁴⁰² The MHRA has no remit over the regulations applied outside the EU, but the Agency stated to us: “[We] do expect that tests/products used in conjunction with a service being offered in the UK for healthcare services are safe, effective and fit for purpose... It would be the responsibility of the service provider to ensure that the laboratory chosen was suitable for the tasks that they are being requested to undertake.”⁴⁰³ (See also Paragraph 9.30 where similar issues are discussed.)

Softening the ethical dilemmas

- 8.28 Many of the developments in telemedicine that we have outlined offer potential benefits to patients, in terms of convenience, access and privacy in some cases, and they can also improve patient outcomes. Many of the developments do not raise new ethical issues because they are simply an extension of previous communications technologies, though due consideration needs to be given to the satisfaction of patients and healthcare professionals when introducing new applications of telemedicine (an issue we deal with in recommendations later). Beyond that, however, there are potential ethical dilemmas posed by applications of

⁴⁰⁰ In determining what constitutes a ‘Medical Device’, and hence falls within the scope of these Directives, the MHRA states that “If a product has a medical purpose, i.e. it is specifically intended to provide or assist with the diagnosis, monitoring, prevention or treatment of a medical condition, it is likely to be a Medical Device under the Medical Devices Directive (93/42/EEC)... Software systems that are only intended for archiving/retrieving patient records/images are thus not regarded as Medical Devices... However, if [computers etc.] are put on the market by a manufacturer... and CE-marked as a complete system including software that gives the system a medical purpose, then the whole system will require CE-marking under the MDD. If the software carries out further calculations, enhancements or interpretations of captured data... we consider that it will be a Medical Device... Products intended specifically for remote diagnostic purposes are also considered medical devices.” Information provided for fact-finding meeting, held on 23 September 2009.

⁴⁰¹ But the derivation of risk from these specifications sometimes seems to involve tricky questions of interpretation.

⁴⁰² A CE mark is “a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation implementing certain European Directives... The initials ‘CE’ do not stand for any specific words but are a declaration by the manufacturer that his product meets the requirements of the applicable European Directive(s)”. See: Department for Business, Innovation and Skills (2010) What does CE marking mean? What do the initials CE stand for?, available at: <http://www.berr.gov.uk/policies/business-sectors/environmental-and-technical-regulations/technical-regulations/ce-marking-faqs>.

⁴⁰³ Information supplied by the Medicines and Healthcare products Regulatory Agency.

telemedicine where the value of individuals being able to pursue their own interests in their own way runs up against the value of state efforts to reduce harm and of using public resources fairly and efficiently.

- 8.29 As noted above, it is not always clear how the existing regime of interventions applies to telemedicine services that operate across borders. Additionally, we think that the current arrangements do not encourage providers of healthcare services to consider all the factors that we think are desirable when deciding whether to introduce telemedicine services, including considerations of common good or solidarity at the global level. We have found no systematic evidence of harm caused by telemedicine at the present time (and indeed any such evidence would need to be collected on a case-by-case basis for each type of application) and therefore cannot justify any measures based on the application of state-specific legal powers, for the reasons given in Chapter 4. Rather, our recommendations focus on what factors providers of public healthcare systems should consider when deciding whether to introduce telemedicine services, including cost-effectiveness, equity, safety, quality, and the value of physical time with health professionals and impact upon doctor-patient relationships. We also make recommendations about: (i) consent; (ii) vulnerable people; (iii) monitoring devices; (iv) cross-border issues; and (v) global social solidarity. In line with our aim set out in Chapter 4, these recommendations are based on general governance type measures where possible, although sometimes more specific measures are required.

Using public resources fairly and efficiently

- 8.30 While telemedicine systems offer the possibility of reducing harm, there are obviously costs associated with introducing them into a public healthcare system, but those investments may result in overall cost savings once they are in use. While some studies indicate that some applications can be cost-effective, the evidence we have reviewed suggests that it is not yet possible to make general claims about cost-effectiveness of telemedicine (see Paragraph 8.16), and as we have already noted conclusions about cost-effectiveness depend on the framework used for evaluation.⁴⁰⁴ We therefore limit ourselves to recommending some factors that should be considered when deciding whether to introduce new telemedicine systems.
- 8.31 **To ensure that public resources are used fairly and efficiently, we recommend to providers of public healthcare systems that telemedicine services should be subjected to the same criteria of cost-effectiveness, equity, safety and quality to which other health technologies are subjected. This recommendation may require careful monitoring of changes in the quality and standards of care for patients arising from their introduction, for example if people were at risk of being discharged inappropriately early from hospital due to the provision of a telemedicine service for aftercare and follow-up.** (See also our recommendation about patient satisfaction below, Paragraph 8.35.)

Inequities in access to healthcare

- 8.32 Ease of access to healthcare services varies from one population group to another, and geography – where people live and how far they are from healthcare facilities – is an important factor shaping ease of access. Public healthcare systems including the NHS place a high value on equity in healthcare and we set out in Chapter 3 the value of social solidarity, by which we mean sharing risks and protecting the vulnerable. Telemedicine offers important opportunities to promote this value by assisting people living in remote areas, or areas without specialist services, to access healthcare in ways that do not disadvantage them in comparison with those living in other areas.

⁴⁰⁴ Miller EA (2010) *Telemedicine and the provider-patient relationship: What we know so far* [Evidence review commissioned for this Working Party].

- 8.33 **Public healthcare systems should offer telemedicine services in circumstances where they can assist in a feasible and cost-effective manner to reducing inequities in access to healthcare, taking into account our recommendation below on patient satisfaction (Paragraph 8.35). As when introducing any new health service, consideration should be given to ensuring that inequities of access to care are wherever possible not exacerbated for some groups while they are reduced for others.**

Patient satisfaction

- 8.34 Our biggest concern about the introduction of telemedicine systems that link patients to remote healthcare professionals or remote systems is that it may serve to replace time spent in the physical presence of health professionals, an aspect of healthcare valued by many people. We may therefore have to balance the value of using public resources fairly and efficiently against the value of state activity to reduce harm in this case.
- 8.35 **We recommend that for telemedicine, the value of time spent in the physical presence of healthcare professionals should be included in any cost-effectiveness analyses (see Paragraph 8.31). We also recommend that when people would prefer not to receive their healthcare via telemedicine, a more conventional alternative service of comparable quality should also be made available whenever it is cost-effective.**

Patients without capacity and surveillance technologies

- 8.36 Careful consideration should be given to the fact that certain groups for whom telemedicine applications could be considered – for example, people with dementia and people with learning difficulties – may have special healthcare needs and may have impaired capacity for informed consent.⁴⁰⁵ The values of individuals being able to pursue their own interests and efforts by the state to reduce harm to individuals therefore shape our recommendations on this issue.
- 8.37 **We recommend that providers of telemedicine services observe the following conclusion made in relation to assistive technologies by the Nuffield Council on Bioethics in its 2009 report on Dementia:**

Where a person with dementia lacks the capacity to decide for themselves whether to make use of a particular technology, the relative strength of a number of factors should be considered on a case-by-case basis, including:

- the person's own views and concerns, past and present, for example about privacy;
- the actual benefit which is likely to be achieved through using the device;
- the extent to which carers' interests may be affected, for example where they would otherwise have to search for the person with dementia in the streets at night; and
- the dangers of loss of human contact.⁴⁰⁶

- 8.38 **There may be similar problems in deciding whether or not a person with learning difficulties has appropriately agreed to use telemedicine. We recommend that providers of telemedicine services take into account the following issues when making these decisions:**

⁴⁰⁵ Provisions of the Mental Capacity Act 2005 covering England and Wales, and similar legislation in Scotland and planned for Northern Ireland, would apply to those who lack capacity to make a particular decision.

⁴⁰⁶ Nuffield Council on Bioethics (2009) *Dementia: Ethical issues*, Paragraph 6.12.

- effective provision of information;
- privacy;
- issues of response bias; and
- the potential for unintentional coercion.⁴⁰⁷

The doctor-patient relationship

- 8.39 The interactions between healthcare professionals and patients can change as a result of telemedicine services, and have the potential to result in both benefits and disadvantages for patients and healthcare professionals. But as we indicated earlier, those changes seem to depend heavily on context, technology and perhaps individual characteristics as well (see Paragraph 8.15), and there has been little empirical research conducted to date that investigates the impact of telemedicine on doctor-patient relationships. Such research is important to assess likely effects if telemedicine comes to be applied on a larger scale than it is at present.
- 8.40 **In the light of our value of efforts by the state to reduce harm, we recommend that public healthcare providers should carry out an evaluation of any impact upon the doctor-patient relationship for every telemedicine service that is implemented.**

Responsibilisation

- 8.41 Applications of telemedicine involving monitoring and feedback functions may mean that some people are given immediate warnings that their conduct – whether it be by behaviour, diet, or non-adherence to treatment – is potentially harmful to their health. (For example, a glucose or alcohol monitor can be linked to appropriate warnings.) Such applications make it possible for willing individuals to become more involved in their health and healthcare and may give them information they need to make responsible decisions about their health. However, people may also find themselves held more responsible by healthcare professionals for poor health outcomes that might be ascribed to their own actions in the light of such information and alerts.⁴⁰⁸ ‘Responsibilisation’ can thus cut several ways, as we have noted in earlier chapters.
- 8.42 **We consider that healthcare professionals should not rely on monitoring and feedback devices as the basis on which to make decisions about denying treatments to patients. Instead, healthcare professionals should use the information gained (as they do for other sources of information) to help them in working with the patient to provide him/her with the most suitable care available in that healthcare system.**

Cross-border responsibility

- 8.43 As noted in Paragraphs 8.23–8.25, there are some ambiguities about where legal responsibility for the conduct of healthcare lies, and which jurisdiction applies in terms of liability when the healthcare professionals and patients are located in different countries. There is potential for serious harms to be caused here.

⁴⁰⁷ Adapted from Perry J, Beyer S and Holm S (2009) Assistive technology, telecare and people with intellectual disabilities: Ethical considerations *Journal of Medical Ethics* 35: 81–6.

⁴⁰⁸ Noting that Paragraph 7 of the UK General Medical Council’s *Good Medical Practice* states “You must not refuse or delay treatment because you believe that a patient’s actions have contributed to their condition.”

- 8.44 **In order to try to reduce harm to individuals, we recommend that countries ensure that the services people receive from overseas-based health professionals meet the same requirements as those provided by health professionals based within their own country. In the UK, this responsibility will fall to the Government Health Departments based in England, Scotland, Wales and Northern Ireland.**

Telemedicine and developing countries

- 8.45 We discussed in Paragraph 8.5 how the knowledge and clinical experience of healthcare professionals based elsewhere can improve patient care and efficiency of resources in developing countries, especially in remote areas. Telemedicine may also be used to contribute to medical education in both developing and developed countries. For example, consultants may gain knowledge from the experience of being involved in treating a wider range of cases, including the more severe or rare ones. More broadly, telemedicine may serve as an instrument that counters or compensates for the medical brain drain from developing to developed countries, which is often held to be a mechanism that exacerbates global inequity in healthcare, and which for some might be considered a harm sufficiently serious to justify the use of state-specific powers to reduce that harm.⁴⁰⁹
- 8.46 **In the light of our value of social solidarity, in this case involving transnational issues of massive health inequities, we recommend that the possibilities for telemedicine to improve patient care and clinician education in developing countries should be explored by those countries and international organisations. The World Health Organization and other international agencies should encourage the development of low-cost, within-country telemedicine networks (supported from out of the country where appropriate) that demonstrably benefit health outcomes, and that can be shown to be cost-effective and sustainable.**
- 8.47 Telemedicine may open possibilities for healthcare professionals in developing countries to provide services for developed countries remotely. There have been some examples of this, but it is not clear how much further it will go. Such a change might possibly reduce the medical brain drain from developing to developed countries that was referred to earlier, enabling more trained medical professionals to stay in developing countries and perhaps also provide healthcare there. But any such change might also mean the tying up of healthcare professionals in developing countries who as a consequence provide fewer services to local people (see Paragraph 8.7).
- 8.48 **Again taking seriously the value of global social solidarity, we recommend that healthcare systems in developed countries should monitor any impacts of outsourcing their healthcare services to developing countries via telemedicine. In the UK, this monitoring should be carried out by the UK Government Departments of Health. We consider such monitoring to be especially important in the light of the UK's *Code of practice for the international recruitment of healthcare professionals*, which precludes the *active* recruitment of healthcare professionals from developing countries, unless there has been a reciprocal government-to-government agreement that healthcare professionals from that country may be targeted for employment.⁴¹⁰**

⁴⁰⁹ For example in the form of taxes on organisations in developed countries that employ medical professionals trained in developing countries (suggested to us in private communications).

⁴¹⁰ Department of Health (2004) *Code of practice for the international recruitment of healthcare professionals*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4097730.

Future impact

- 8.49 Telemedicine could be of particular significance when considering the impact that an ageing population will have on health and social care.⁴¹¹ As noted in earlier chapters, older people use healthcare more than other demographic groups, and therefore healthcare providers will need to assess ways in which telemedicine can be used to improve cost-effectiveness.⁴¹² Some forms of telecare could be particularly suited to the provision of health services to older people, in so far as telemedicine can help promote independence and detect early changes in health status. It has also been argued that telemedicine is important as a way of better supporting vulnerable adults, those with long-term chronic conditions and those with dementia.⁴¹³
- 8.50 Hence it is likely that, at least in the UK and other developed countries, we will see increased use of telemedicine in many different forms in the future. Indeed, a recent report by Deutsche Bank Research suggested that telemedicine turnover in Europe might be expected to grow by an average of 10% each year across Europe until 2020.⁴¹⁴ The prospects for future growth make it important for the ethical issues discussed here to be carefully considered.

⁴¹¹ Department of Health (2008) *Raising the profile of long-term conditions care: A compendium of information*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082069.

⁴¹² For example, the Department of Health's 2006 White Paper *Our health, our care, our say: A new direction for community services* stated: "for people with complex health and social care needs, we plan to bring together knowledge of what works internationally, with a powerful commitment to new, assistive technologies to demonstrate major improvements in care". See: Department of Health (2006) *Our health, our care, our say: A new direction for community services*, available at: <http://www.official-documents.gov.uk/document/cm67/6737/6737.pdf>.

⁴¹³ For example, the English Department of Health 2005 report, *Building Telecare in England*, declared that "Telecare has huge potential to reduce unnecessary hospital admissions and improve people's quality of life...[it] has huge potential to support a diverse range of individuals to live at home". See: Department of Health (2005) *Building telecare in England*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4115303.

⁴¹⁴ Deutsche Bank Research (2010) *Tele-medicine improves patient care*, available at: http://www.dbresearch.com/PROD/DBR_INTERNET_EN-PROD/PROD000000000255117.pdf.

Chapter 9

Personal genetic profiling
for disease susceptibility

Chapter 9 – Personal genetic profiling for disease susceptibility

Overview

What is new? Anyone who has a moderate amount of money can now pay companies to analyse their DNA and provide an assessment of their personal genetic susceptibility to a wide range of common health risks. Advances in genetics are improving scientific understanding of some of the links between genetics and predisposition to diseases, and the cost of genetic analysis has fallen enormously in the past few years. The availability of direct-to-consumer genetic profiling tests raises the potential for increasing personalisation in several of the senses identified in Chapter 1, although as we shall see, some of these tests have only limited predictive power and can therefore not provide accurate individualised predictions. But this method of providing testing certainly lends itself to a ‘consumerist’ approach to healthcare and potentially opens up new ways for people to take a responsible approach to their health and healthcare.

Which ethical values come into conflict as a result of this development? Many potential dilemmas arise among our ethical values in this domain. The value of individuals being able to pursue their own interests comes into conflict with the values of state action to reduce harm, safeguarding private information, fair and efficient use of public resources and social solidarity. The value of safeguarding private information also comes into conflict with those of state action to reduce harm and social solidarity. The value of fair and efficient use of public resources is already coming into conflict with that of social solidarity.

What is the existing pattern of interventions like? People who use genetics services and the services themselves if operating in the UK are subject to numerous laws and regulations, notably the provisions of the data protection regime and the more service-specific measures of the Human Tissue Act 2004 and Medical Devices Directives. But direct-to-consumer DNA profiling companies can offer their services to customers based anywhere in the world, meaning that such companies may be operating under a jurisdiction different from that applying where some or even all of their customers live.

What gaps or shortfalls are there in existing interventions? The existing system of interventions does not promote the provision of good information to consumers about the type of genetic profiling for susceptibility for common diseases offered directly to consumers. There is also a lack of evidence of potential harms and benefits that may result from taking these tests. In the absence of such evidence, we find it problematic that parents are able to order the type of profiling we focus upon for their children.

What types of intervention might possibly fill those gaps or remedy those shortfalls? Research on benefits and harms needs to be done to inform consideration of other appropriate interventions. Other possible interventions could range from encouragement of more comprehensive information to be provided about these tests, through a requirement that such information be provided, to the placing of restrictions on the sale of disease susceptibility tests that do not achieve a certain level of clinical validity and utility.

What types of intervention do we recommend, and why? The potential harms have not been quantified at this time, and indeed it may not be possible to quantify them precisely, but we think the harms do not appear sufficiently serious to justify restriction on sales. We therefore recommend independent research (to be periodically updated as scientific developments occur) on the impact and effects of multifactorial genetic testing on individuals. We also recommend that: (i) responsible authorities should request evidence for clinical claims made by companies; (ii) government health service websites should provide public information about genetic profiling services and companies should indicate to consumers where to find this information; (iii) companies should voluntarily adopt good practice; (iv) companies should not knowingly carry out for children DNA tests that do not meet the criteria of the UK National Screening Committee; and (v) professionals in the public healthcare system should adapt their practice in the light of the development of direct-to-consumer genetic testing.

Introduction

- 9.1 As noted in our opening chapters, advances in genetics are leading to improvements in the understanding of the factors relating to predisposition to different diseases, as well as to associations between genes, diet and the environment. A number of commercial services now offer genetic profiling for disease susceptibility directly to people who do not necessarily have any medical symptoms: analysing their DNA to give them information about their own personal risks of developing certain diseases or health conditions in the future. The cost of genetic analysis over the past decade has fallen to the point where genetic profiling services are readily affordable to middle-income people in developed countries (see Table 9.1). We therefore need to consider how these services are promoted, how accurate the tests are, how useful the results are, the associated benefits and harms, and the ethical dilemmas they raise.
- 9.2 More traditional routes of genetic testing recommended or initiated by healthcare professionals include diagnostic testing when a particular condition is suspected or a person is of particular risk due to their family history, and tests that are used in screening programmes (see Box 9.1).⁴¹⁵ Established clinical genetics services are offered by the National Health Service (NHS) in the UK and other countries' healthcare systems and are of proven value for analysing a person's risk of some more common conditions and detecting rare but collectively numerous genetic disorders. These genetic tests are usually offered with advice from genetic counsellors or clinical geneticists.

Box 9.1: UK National Screening Committee: criteria for genetic screening programmes

Countries vary substantially in the type of public screening programmes that are provided, and those differences often reflect cultural differences. In the UK, the UK National Screening Committee (UK NSC) advises the Government and the NHS about population screening programmes, including genetic screening. It assesses the evidence for introducing screening programmes against a set of standard criteria that cover the condition, the test, the treatment options and the effectiveness and acceptability of the screening programme. Assessing programmes in this way is aimed at ensuring that they “do more good than harm at a reasonable cost”.⁴¹⁶

The NSC criteria include:

- the condition should be serious;
- the condition should be understood;
- psychological implications of carriers should be understood;
- the test should be simple, precise and validated;
- the programme should be acceptable to health professionals and the public;
- there should be an effective treatment or intervention available for people identified through early detection;
- the screening programme should be effective in reducing mortality or morbidity;
- evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice;
- the benefit should outweigh any physical and psychological harm caused;

⁴¹⁵ For further information see Nuffield Council on Bioethics (1993) *Genetic screening: Ethical issues* and (2006) *Genetic screening: A supplement to the 1993 report by the Nuffield Council on Bioethics*. See also Raffle AE and Gray JAM (2007) *Screening: Evidence and practice* (Oxford: Oxford University Press).

⁴¹⁶ UK National Screening Committee (2010) *About us*, available at: <http://www.screening.nhs.uk/about>.

- the programme should represent value for money; and
- all other options for managing the condition should have been considered.

There are population screening programmes in the UK and other countries for a number of genetic conditions. However, rather than using genetic profiling, most of the screening programmes operate indirectly, by looking for an indicator of the particular condition.

- 9.3 The particular focus of our discussion in this report is on commercial genetic services that seek to assess a person's genetic risk of a range of multifactorial conditions where the contribution from genetics is complex and often uncertain (as opposed to monogenic disorders, see Box 9.2), including age-related macular degeneration, breast cancer, coeliac disease, Crohn's disease, Parkinson's disease, prostate cancer, heart diseases, diabetes and Alzheimer's disease.⁴¹⁷ In the UK, the NHS does not offer genetic screening for most of these conditions, because they do not meet the NSC criteria described in Box 9.1.

Box 9.2: Monogenic and multifactorial genetic conditions

For some genetic conditions, a large part (or all) of predisposition is caused by variation in a specific section of the genetic code. These conditions are conventionally called 'single-gene' or monogenic disorders. Examples include Huntington's disease, cystic fibrosis and haemophilia. If a person's DNA is tested and they have certain variations in a particular gene or genes, they will be highly likely or even certain to develop that particular disorder. For example, almost everyone who carries the genetic variant for Huntington's disease will develop it at some point in adulthood. These conditions show clear patterns of inheritance within families, and may be dominant (one copy from one parent is sufficient to have an effect) or recessive (one copy from a parent can be carried, without being manifested; if two copies are inherited, that is, one from each parent, the condition will show). Many people are familiar with the concept of monogenic diseases, and much of the ethical and regulatory debate has focused on the implications of testing for them. The NHS and other public healthcare systems offer genetics services that provide testing, as well as genetic counselling to help people decide whether to take such tests and to help them interpret the results.

Other genetic conditions (generally relatively common ones) are multifactorial. Genes play a role in predisposition (and many sections of DNA may be involved), but so does a person's environment, lifestyle and other health factors. Whether or not these conditions will develop (and if so how serious they will be and at what age) depends on interaction between complex genetic factors and those other elements such as environment and lifestyle. Examples of such conditions include diabetes, heart disease and certain cancers.⁴¹⁸ The genetic susceptibility profiling tests that are the focus of our report offer risk predictions for this type of condition. As they are not a simple case of genetic determination, only risk predictions are able to be given, and these will be of varying clinical validity (see Paragraph 9.7).

- 9.4 The availability of personal genetic profiling for disease susceptibility relates to at least three of the four types of personalisation described in Paragraph 1.18. The marketing material for these profiling tests promise greater personalisation in our first sense, namely the delivery of highly individualised healthcare management tailored or customised to the individual involved. However, the extent to which these tests will actually be able to offer such 'personalised' information depends on their predictive power, an issue we discuss below. In addition, the results often allocate the person being tested into a 'risk group' rather than provide an individualised risk assessment. Moreover, even where personalised information is available, the

⁴¹⁷ Some companies also offer information on carrier status for monogenic diseases (see Box 9.2): providing information about whether a person is a carrier for a genetic condition they might pass onto a child if the child's other parent were also a carrier. Others offer paternity testing services, profiling for ancestry and sporting or musical potential. These other services are not the focus of our report.

⁴¹⁸ Within these more common multifactorial conditions there is often a small subgroup that have a 'single-gene' cause. For example: BRCA1/2 genes in breast cancer or the LDLR gene as a cause of high cholesterol.

availability of ‘personalised’ *treatment* is not guaranteed.⁴¹⁹ Even more strongly invoked is our third sense of personalisation in which healthcare services are provided as a good or commodity as a matter of consumer choice rather than on the basis of advice or action from a healthcare professional. It might also be that, with the increasing availability of the tests described in this chapter, people might see (or be encouraged to see) the taking of such tests as socially responsible behaviour, and thus use them to play a more active role in trying to predict and prevent disease or ill-health, the fourth sense of personalisation we identified in Chapter 1. Moreover, taking such tests confronts those who take them with the responsibility of trying to make sense of complex risk data, face the consequences for themselves or their families and make appropriate changes to their lifestyle. To the extent that such tests are predicatively accurate, they could lead to ‘unpooling’ of the financial risks associated with ill-health, notably through obligations to inform private insurers. We return to a discussion of these themes in Chapter 11.

Table 9.1: Examples of personal genetic profiling tests for disease susceptibility on offer in the UK and internationally at the time of writing

Company	Example product	Price	Details
23andMe	Health Edition	\$429	“Find out if you carry inheritable markers for diseases such as breast cancer, cystic fibrosis, and Tay-Sachs...Learn your genetic risk for type 2 diabetes, Parkinson's disease, and other conditions.” ⁴²⁰
deCODEme	Complete Scan	\$2000	“Calculate your genetic risk for 51 conditions...” ⁴²¹
Genetic Health	Premium Male	£825	“These are our most comprehensive test and includes all the other tests in our range... Evaluates the risk of prostate cancer as well as the risk for thrombosis, osteoporosis, metabolic imbalances of detoxification and chronic inflammation. It also evaluates the risk profile of the most common cardiovascular diseases...” ⁴²²
Graceful Earth	Alzheimer's genome test	\$280	“Check your future susceptibility BEFORE symptoms occur... Pre-emptive insight into one's genetic predisposition can empower and allow for pro-active prevention.” ⁴²³
Navigenics	Health Compass	Varies	“Knowing your genetic predispositions for important health conditions and medication reactions can help motivate you to take steps towards a healthier life. By gaining insight into these risks, you can plan for what's important.” ⁴²⁴

⁴¹⁹ For example, it has been argued that “In the absence of concomitant effective, affordable, and non-harmful interventions, prognosis alone, even if correct, is of questionable value”. Furthermore, although “many findings from genomic research are likely to provide new clues to disease biology by the identification of genes and biological pathways unexpectedly associated with the disease process” such a process can take decades from the point of understanding the molecular causes of a particular disease. See: Ioannidis JPA (2009) Limits to forecasting in personalized medicine: An overview *International Journal of Forecasting* **25**: 773–83; Burke W and Psaty (2007) Personalized medicine in the era of genomics *Journal of the American Medical Association* **298**(14): 1682–4.

⁴²⁰ 23andMe (2010) Store, available at: <https://www.23andme.com/store/>.

⁴²¹ deCODEme (2010) Store, available at: <https://www.decodeme.com/store>. See also footnote 448.

⁴²² Genetic Health (2010) Premium male, available at: <http://www.genetic-health.co.uk/dna-test-services/premium-male.htm>.

⁴²³ Graceful Earth (2010) Alzheimer's genome test now available!, available at: <http://www.gracefulearth.com/index.asp?PageAction=VIEWCATS&Category=3>.

⁴²⁴ Navigenics (2010) Clinically guided genetic analysis, available at: http://www.navigenics.com/visitor/what_we_offer/our_tests/.

Benefits and harms

- 9.5 A number of potential advantages and disadvantages of personal genetic profiling for disease susceptibility were included in Table 3.1.

Potential advantages

- More information;
- allows early intervention;
- allows more personal control;
- possibility of saving public healthcare resources if testing and treatment conducted privately; and
- can alert relatives to important genetic conditions.

Potential disadvantages

- Costs to individuals of tests that yield little determinate information;
- social harms when private testing can undermine equal access to healthcare;
- costs of consequences of having information: a) for individual when inaccurate or hard to interpret, b) for individual when nothing can be done, c) for individual if inaccurate risk assessments lead to false reassurance or misplaced anxiety, d) for individual if results lead to stigma or information abuse (e.g. blackmail) or other effects that may be regretted, given that information once known cannot be ‘un-known’ (e.g. for insurance declarations), e) for taxpayers when unnecessary follow-up testing and treatment is carried out;
- costs and harms to third parties – when children or third parties are tested without consent, or when embryos are tested for conditions whose risks may be hard to determine; and
- can change perception of wellness and illness through medicalisation of normal variation, including for children.

- 9.6 Taking a personal genetic profiling test for genetic susceptibility can in principle help people who wish to do so to learn more about their health and become more involved in making decisions about their healthcare. The marketing material of the commercial providers of tests stresses this theme, suggesting that taking a proactive approach to health could result in being able to look out for, prevent, treat or simply know about any conditions for which the person is at risk. Examples of the types of tests available are included in Table 9.1. Two companies have given the following reasons for individuals to take up their services:⁴²⁵

“You’ll learn what your genes say about your traits. And learn about your disease risks. So you can team up with your doctor to make better decisions about your health.” *23andMe*

“Based on your unique results we can advise you how to create your own individual plan for cardiac disease prevention” *Genetic Health*

It may be that simply taking tests and thinking about health encourages some people to take more interest in their health and live healthier lifestyles, though we are not aware of systematic evidence on this. But even so, the benefits and harms of such tests also depend on how predictive the tests are about individual susceptibility to disease.

Clinical validity

- 9.7 As noted in Chapter 1, clinical validity refers to how well test results detect or predict the associated disorder. We have also noted in Box 9.2 that many factors can influence whether a person will develop most conditions. Hence, the predictive value for the type of genetic profiling that offers a risk assessment for various, often relatively common, complex diseases is much

⁴²⁵ Information correct at time of going to print.

lower than testing for a particular monogenic disorder, where there is a clearer genetic link. In recent years some progress has been made in identifying the genetic variants relevant to different diseases, in particular using genome-wide association studies (see Box 9.3).⁴²⁶ In early 2008 it was reported that this approach had in total revealed around 50 disease-susceptibility loci.⁴²⁷ With a few exceptions, the increases in risk caused by variations at the newly identified loci are modest (see Box 9.3), and large sample sizes are required to identify them.⁴²⁸

Box 9.3: Genome-wide association studies

These studies involve large numbers of people with and without particular diseases, each of whom is genotyped at several hundred thousand markers throughout the genome. Comparisons are then made between these groups to identify genetic markers associated with the disease. Studies so far have included type 1 and type 2 diabetes, prostate cancer, inflammatory bowel disease and asthma.⁴²⁹ By 2010, approximately 400 studies of this kind had been performed.⁴³⁰ They have become possible since the completion of the sequencing of the human genome in 2003 and a map of human genetic variation (the International HapMap Project, completed in 2005), and as a result of technological developments.

The first results of one of the largest such studies, examining 500,000 different DNA sites in 17,000 individuals for associations with seven major diseases, were published in 2007.⁴³¹ This study found 24 sites at which there was strong statistical evidence for association with one or more diseases, and a larger number of sites with weaker evidence for association. Some of the associations confirmed earlier findings, while some were previously unidentified, and of those that were novel, the presence of a particular disease-associated genetic variation resulted in a modest increase (1.2- to 1.5-fold) in the risk of the disease.⁴³² In total, these studies have identified hundreds of genetic variants associated with complex human diseases and traits, but the size of the genetic effect of common variants associated with major diseases is mostly small.⁴³³

It is currently unclear whether the results obtained so far through genome-wide association studies are the “tip of the iceberg or the bottom of the barrel”.⁴³⁴ Also unclear is to what extent it is possible to utilise information derived from these studies in a clinical setting.⁴³⁵ In addition, this approach has so far mainly been used to uncover areas of the genome of interest using one particular type of genetic marker called a single nucleotide polymorphism (SNP). Using it to search for different types of genetic marker is likely to be more complex.⁴³⁶ Overall, the variants identified so far explain only a small proportion of individual variation in disease risk, limiting the immediate utility of genetic profiling to predict individual disease susceptibility.⁴³⁷ It is said to be

⁴²⁶ See Iles MM (2008) What can genome-wide association studies tell us about the genetics of common disease? *PLoS Genetics* **4**(2): e33.

⁴²⁷ Disease-susceptibility loci are locations in the genome associated with an increased risk of disease. See: Burke W and Psaty (2007) Personalized medicine in the era of genomics; McCarthy MI, Abecasis GR and Cardon LR *et al.* (2008) Genome-wide association studies for complex traits: Consensus, uncertainty and challenges *Nature Reviews Genetics* **9**: 356–69.

⁴²⁸ McCarthy MI, Abecasis GR and Cardon LR *et al.* (2008) Genome-wide association studies for complex traits: Consensus, uncertainty and challenges *Nature Reviews Genetics* **9**: 356–69.

⁴²⁹ *Ibid.*

⁴³⁰ Copperthwaite MC, Mohanty D and Burnett MG (2010) Genome-wide association studies: A powerful tool for neurogenomics *Neurosurgical Focus* **28**(1): E2.

⁴³¹ The Wellcome Trust Case Control Consortium (2007) Genome-wide association study of 14,000 cases of seven common diseases and 3,000 shared controls *Nature* **447**: 661–78; Bowcock AM (2007) Guilt by association *Nature* **447**: 645–6.

⁴³² Manolio TA, Collins FS, Cox NJ *et al.* (2009) Finding the missing heritability of complex diseases *Nature* **461**: 747–53.

⁴³³ Zeggini E and Ioannidis JP (2009) Meta-analysis in genome-wide association studies *Pharmacogenomics* **10**(2): 191–201.

⁴³⁴ Iles MM (2008) What can genome-wide association studies tell us about the genetics of common disease? *PLoS Genetics* **4**: e33.

⁴³⁵ Knight JC (2009) Genetics and the general physician: Insights, applications and future challenges *QJM: An International Journal of Medicine* **102**: 757–72.

⁴³⁶ McCarthy MI, Abecasis GR and Cardon *et al.* (2008) Genome-wide association studies for complex traits: Consensus, uncertainty and challenges *Nature Reviews Genetics* **9**: 356–69.

⁴³⁷ *Ibid.*; see also: The Academy of Medical Sciences (2009) *Genome-wide association studies: Understanding the genetics of common disease – symposium report*, available at:

<http://www.acmedsci.ac.uk/download.php?file=/images/page/GWASWEBF.pdf>.

unlikely that it will be possible to give each individual a precise, individually tailored disease risk, but it may be possible to stratify them into groups with different levels of risk.⁴³⁸ Such stratification might lead to screening targeted at the most 'at-risk' group.

A recently announced NHS research study aims to sequence patients' entire genomes in order to investigate the underlying genetic links of cardiovascular disease in 10,000 patients over the age of 16 over a ten-year period.⁴³⁹ This aim is in line with the recommendations in the House of Lords 2009 *Genomic medicine* report that basic and clinical genomic research should be effectively translated into clinical practice.⁴⁴⁰

- 9.8 In short, much research is ongoing in this area but scientists commonly assert that it difficult to use the results that have emerged so far to make accurate predictions from a genome sequence alone about a person's risk of developing a disease that is caused by multiple genetic and other factors (see Box 9.2).⁴⁴¹ In addition, results from such studies are specific to the population upon which they were carried out (for example people designated 'Caucasian'), and therefore may not be relevant for people from outside such populations who have these tests. Problems of replicability are also commonly encountered with these studies.⁴⁴²
- 9.9 An optimistic view of these developments is given by Francis Collins, director of the National Human Genome Research Institute, stating: "The hope is that sometime within the next few years, healthcare providers will be able to scan each of our genomes to identify the most significant genetic variations that predispose each of us to certain diseases. Not only should this offer better opportunities for diagnosis and prevention, it should lead to the development of more individualized strategies for treating or managing the disease if it does occur."⁴⁴³ However, others are less convinced: "it could take years, if not decades, before lifestyle and medical interventions can be responsibly and effectively tailored to individual genomic profiles".⁴⁴⁴
- 9.10 Nonetheless, as we have seen, companies are already offering risk information for many multifactorial conditions to consumers based on the sequence of their DNA at specific points in their genome. Many of those companies acknowledge that environmental (lifestyle) factors have a large role to play in the development of the conditions for which they offer risk information, but their marketing information tends to highlight the clinical value of the genetic information from the tests. We return to this point in our recommendation in Paragraph 9.51.
- 9.11 There is little independent systematic research on the clinical validity of the types of genetic profiling tests under consideration here. One recent review concluded that "There [was] insufficient scientific evidence to conclude that genomic profiles are useful in measuring genetic risk for common diseases or in developing personalized diet and lifestyle recommendations for disease prevention."⁴⁴⁵ The authors examined previous meta-analyses and HuGE reviews,⁴⁴⁶ in

⁴³⁸ PHG Foundation (2008) *Evidence to the House of Lords Science and Technology Committee – genomic medicine*, available at: <http://www.phgfoundation.org/file/4070/>.

⁴³⁹ Royal Brompton and Harefield NHS Trust (2010) 'Next Generation' Gene Sequencer to determine the genetic links of heart disease, available at: <http://www.rbht.nhs.uk/media/press-releases/?assetdetescstl2753237=342161&p=1>.

⁴⁴⁰ House of Lords Science and Technology Committee (2009) *Science and Technology Committee 2nd report of session 2008–2009: Genomic medicine – volume one: Report*, available at: <http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf>.

⁴⁴¹ Edelman E and Eng C (2009) A practical guide to interpretation and clinical application of personal genomic screening *British Medical Journal* **339**: b4253.

⁴⁴² See, for example: Hirschhorn JN, Lohmueller K, Byrne E and Hirschhorn K (2002) A comprehensive review of genetic association studies *Genetics in Medicine* **4(2)**: 45–61.

⁴⁴³ Quoted in Honey K (2008) GINA: Making it safe to know what's in your gene *Journal of Clinical Investigation* **118(7)**: 2369.

⁴⁴⁴ Janssens ACJW, Gwinn M and Bradley LA *et al.* (2008) A critical appraisal of the scientific basis of commercial genomic profiles used to assess health risks and personalise health interventions *American Journal of Human Genetics* **82**: 593–9.

⁴⁴⁵ Seven companies were identified which together provided tests for at least 69 different variations in 56 genes. Of the 56 genes tested, 24 were not reviewed in meta-analyses. For the remaining 32 genes, 260 meta-analyses were found that examined 160 unique variation-disease associations. Of these, only 60 were found to be statistically significant. The 60 associations involved 29 different polymorphisms and 28 different diseases, and were generally of modest quality. Genes in cardio-genomic profiles were more frequently associated with non-cardiovascular diseases than with cardiovascular diseases. While two of the five gene sequences of the osteo-genomic profiles (i.e. profiles relating to bone formation) did show significant associations with disease, the associations were not with bone diseases. Janssens ACJW, Gwinn M and

which the genetic sequences of people with a disease were compared with those of a healthy or general-population control group. They assessed the scientific evidence supporting purported gene-disease associations for genes included in profiling tests offered by private companies offering predictive testing over the internet. The review concluded that “the excess disease risk associated with many genetic variants included in genomic profiles [that the companies tested for] has not been investigated in meta-analyses or has been found to be minimal or not significant”, and, as such “scientific evidence for most associations between genetic variants and disease risk is insufficient to support useful applications.” As well as the danger of people being given misleading information suggesting they are at high risk, a further possible danger is also highlighted: “those with ‘low-risk’ profiles could be led to mistakenly believe that they have little need to make health lifestyle changes”.

- 9.12 In a newspaper article in 2008,⁴⁴⁷ a journalist described how he had approached several companies, including GeneticHealth (UK), deCODEme (Iceland)⁴⁴⁸ and 23andMe (USA), to compare their test results. There was considerable variation in the way in which information was presented, 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% 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% (6% 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% below average.
- 9.13 It is also worth noting that when people make decisions about whether or not to take a predictive genetic test, they have been found not to pay attention to the uncertain nature of the information derived from the tests in their decision-making process. Thus the fact that the test does not give them a clear answer does not significantly inform their decision as to whether or not to take the test. Indeed, people have been found generally to approach the test as providing a binary result, even where it does not.⁴⁴⁹

Clinical utility

- 9.14 In addition to problems with clinical validity, further questions arise about whether the results of direct-to-consumer profiling for susceptibility to multifactorial diseases enable the person tested to do anything specifically useful to counteract the possible harm about which they have been warned. For example, are there any preventive measures or therapies they can take to remove, reduce or defer the risk of disease? The risk predictions given generally do not greatly differ from the average risk levels. They also relate to overall lifetime risk and give no indication of when any potential disease will develop, or how severe it might be. It is therefore not generally possible to take specific actions in response to direct-to-consumer predictive genetic profiling beyond those that would result in healthier lifestyles for anybody, such as to maintain a healthy

Bradley LA *et al.* (2008) A critical appraisal of the scientific basis of commercial genomic profiles used to assess health risks and personalize health interventions *American Journal of Human Genetics* **82**(3): 593–9.

⁴⁴⁶ “A HuGE (Human Genome Epidemiology) review identifies human genetic variations at one or more loci, and describes what is known about the frequency of these variants in different populations, identifies diseases that these variants are associated with and summarises the magnitude of risks and associated risk factors, and evaluates associated genetic tests. Reviews point to gaps in existing epidemiologic and clinical knowledge, thus stimulating further research in these areas.” See: Centers for Disease Control and Prevention (2010) HuGENet™, available at: <http://www.cdc.gov/genomics/hugenet/reviews/index.htm>.

⁴⁴⁷ Fleming N (2008) Rival genetic tests leave buyers confused *The Times* 7 September, available at: <http://www.timesonline.co.uk/tol/news/science/article4692891.ece>.

⁴⁴⁸ deCODEme is a service provided by deCODE genetics, a company based in Iceland that filed for bankruptcy in 2009. The majority of deCODE’s assets were subsequently purchased by Saga Investments LLC. deCODE genetics has since asserted its intention to continue all its previous product and service lines, including the deCODEme personal genome scans. See: deCODE genetics (2010) Announcing the new deCODE, available at: <http://decodeyou.com/announcing-the-new-decode/#more-843>.

⁴⁴⁹ Henderson BJ, Maguire BT, Gray J and Morrison V (2006) How people make decisions about predictive genetic testing: An analogue study *Psychology & Health* **21**(4): 513–39.

weight, eat healthily, take exercise and refrain from smoking or drinking excessive amounts of alcohol.

Psychological impact

- 9.15 Some of the risk predictions given as a result of the profiling tests available are for very serious conditions, including those that have no treatment or cure.⁴⁵⁰ Added to the fact that, as we have seen above, clinical validity is not clear for many of these tests (a fact acknowledged by some of the companies offering the tests), there is potential for concern about how people will react psychologically to the information they receive from tests. We recognise that genetic information can be delivered in different ways (for example, over the internet or through face-to-face consultation with a genetic counsellor) and these differences may well have an impact on the way people react to the information.⁴⁵¹ There have been some studies into people's psychological response to predictive genetic information, but it is not clear how the evidence should be interpreted. The 2004 REVEAL study suggested that most people did not suffer significant psychological harm from being informed that they carried the apolipoprotein E (*APOE*) gene, which is associated with an increased susceptibility to the development of Alzheimer's disease (although the predictive power is poor).⁴⁵² A further study, conducted by the same researchers in 2009, found that when 162 asymptomatic adults who had a parent with Alzheimer's disease were randomly assigned to two groups, one that would receive the results of their own *APOE* genotyping and one that would not, "there were no significant differences between the two groups in changes in time averaged measures of anxiety...depression...or test-related distress". The study concluded: "the disclosure of *APOE* genotyping results to adult children of patients with Alzheimer's disease did not result in significant short-term psychological risks."⁴⁵³ However, there has been some debate about the nature of the control group used in the second study; alternative analysis of the data indicated "significant increases in depression in eight of nine measures" for those who were informed of their *APOE* genotyping results.⁴⁵⁴
- 9.16 In 2010, Martin Richards, a professor at the University of Cambridge, published a paper describing his experiences when purchasing genetic profiling tests from two different companies: one from 23andMe and one from deCODEme.⁴⁵⁵ Similarly to the journalist's investigations mentioned in Paragraph 9.12, Professor Richards identified substantial differences in the disease risk profiles provided by the companies and also described differences in the types of information provided and the ways in which that information was presented to the user. He noted that most companies provide a 'package', rather than a specific set of customisable tests. Thus, the customer may be given information concerning a range of traits, such as disease risk, drug metabolism, hair/eye colour and even ear wax type: "a mixture of medical information (disease genetic risks and drug metabolism) and other rather different kinds of personal information". Professor Richards also drew attention to the heavy emphasis in some companies' "lengthy" terms of service agreements that customers should not treat the information supplied as 'medical' in nature. However, he questioned whether the average user would read these agreements in detail and suggested that it was "unlikely" that anyone who bought such tests would then approach the results as "a series of bits of information about their genome with no relevance at all for their health".⁴⁵⁶

⁴⁵⁰ Risks of additional conditions may also be revealed to customers some time after having genomic analysis as a result of further research.

⁴⁵¹ Of course, once some people have seen a genetic counsellor, they decide not to have genetic testing.

⁴⁵² Roberts JS, Barber M and Brown TM (2004) Who seeks genetic susceptibility testing for Alzheimer's disease? Findings from a multisite, randomized clinical trial *Genetics in Medicine* **6(4)**: 197–203.

⁴⁵³ Green RC, Roberts JS, Cupples LA *et al.* (2009) Disclosure of *APOE* genotype for risk of Alzheimer's disease *New England Journal of Medicine* **361(3)**: 245–54.

⁴⁵⁴ Gordon SC and Landa D (2010) Disclosure of the genetic risk of Alzheimer's disease *New England Journal of Medicine* **362(2)**: 181–2.

⁴⁵⁵ Richards M (2010) Reading the runes of my genome: A personal exploration of retail genetics *New Genetics and Society*, forthcoming.

⁴⁵⁶ *Ibid.*

- 9.17 The providers of the types of profiling under discussion generally do not offer clinical assessment of symptoms and risk nor genetic counselling and we have noted that such tests can produce results that are unreliable or difficult to interpret. As already noted, even when results purport to be clear, false negatives can be produced which could lead to complacency and there is also the possibility of false positives which could create needless confusion or anxiety.⁴⁵⁷ There is also the possibility of people experiencing stigma as a result of the results they receive if those results are communicated to others, such as family members, teachers, employers or insurers. In the absence of evidence, such harms are speculative, but that does not mean they should be dismissed.

Impact on insurability

- 9.18 Since 2001 the Association of British Insurers (ABI) has operated a voluntary moratorium on the use of genetic tests by insurance companies which runs until 2014, having been extended on a number of occasions. It specifies that customers will not be required to disclose the results of predictive genetic tests for policies up to £500,000 of life insurance, or £300,000 for critical illness insurance, or paying annual benefits of £30,000 for income protection insurance. The relevant public advisory body (formerly the Genetics and Insurance Committee, whose functions are now performed by the Human Genetics Commission) has to date only approved one application for disclosure of test results, for Huntington's disease in life insurance applications over £500,000. This decision does not mean that everyone can be asked to have a genetic test for Huntington's disease before they can get insurance. What it means is that where people have already been tested as part of their medical care, there is nothing to prevent insurance companies asking for that information from customers.
- 9.19 We have been informed by the ABI that "insurers ask about tests and investigations carried out (or planned) and do not specifically refer to how the test or investigation was originated."⁴⁵⁸ It is for the insurer to decide whether the information provided is relevant and insurers require full and accurate answers to their direct questions. Different insurers vary as to the time period covered by their questions, and the time period will depend on how relevant the information could be to the product being purchased. Insurance companies have always been able to ask for details of a family history, from which genetic information may be gleaned; and other indirect genetic tests, such as clinical investigations which reveal particular features can be utilised as part of the actuarial decision making. We conclude that there may be questions as part of applications for various types of insurance that require the applicant to disclose information relating to genetic tests: not answering or hiding the existence of test results would constitute non-disclosure which can affect the payment of a claim. The ABI told us that neither they nor insurers have had many queries from consumers about whether or not they need to reveal the results of genetic tests or whether they should take such a test.

Extent of use

- 9.20 Genetic testing was previously an area in which patients were advised by healthcare professionals about tests that would be clinically useful, and has now shifted to one where people are also able to order tests directly. Direct-to-consumer genetic testing has come about owing to the availability of the technologies on which the tests are based and the decrease in cost to carry out the tests. Tests can be cheaply and easily marketed and sold online, and the

⁴⁵⁷ Although true negatives can also lead to complacency through a reduction in health-promoting behaviours, the complacency associated with false negatives has the additional risk of a patient also failing to undergo potentially effective interventions. See: Madlensky L, McLaughlin JR, Carroll JC, Goel V and Frank JW (2005) Risks and benefits of population-based genetic testing for Mendelian subsets of common diseases were examined using the example of colorectal cancer risk *Journal of Clinical Epidemiology* **58**: 934–41.

⁴⁵⁸ Association of British Insurers, personal correspondence.

internet seems to be the predominant medium by which such tests are provided to the public.⁴⁵⁹ Commercial companies sell DNA collection kits via the internet, then mail the kit to the customer who uses it to collect a DNA sample (e.g. from inside the mouth) and then typically returns it in the post to the company involved for analysis.

- 9.21 We asked major companies operating in this field in the UK and overseas about the scale of their operations but none was willing to give us this information. There is one company based in the UK and it is registered as 'small'⁴⁶⁰ at Companies House.⁴⁶¹ A 2008 report from PriceWaterhouseCoopers notes that the overall global market for genetic tests is approximately \$730 million, but describes the direct-to-consumer element as a "relatively small portion" of the overall market (although it also notes that this section of the market is expected to grow rapidly).⁴⁶² An article in *The New York Times* asserts that uptake of personal genetic profiling for disease susceptibility has so far been limited: "Two and a half years after beginning its service, 23andMe has only 35,000 customers. And at least a quarter of them got the service free or for only \$25, instead of the hundreds of dollars on which the business model is based. Navigenics and DeCode have even fewer customers."⁴⁶³

Current system of interventions

- 9.22 There is no overarching system of interventions relating to personal genetic profiling. Where health professionals are involved they will be subject to their own codes of professional conduct (see Box 4.1). There are also several relevant laws and other forms of governance, relating to data protection, collecting DNA, advertising and the products themselves and we explore these below. But companies based anywhere in the world can offer their services to customers based locally or overseas online or by post, which means that some companies may be operating under a jurisdiction different from that applying where their customers live. In the UK, domestic law will apply to such services in some cases, and there are other cases in which it will not, and we consider this issue below.

Data protection

- 9.23 As noted earlier in this report, personal health data is commercially valuable and the entry and storage of such data on servers accessed via websites opens up opportunities for loss, theft and misuse. The different regulatory frameworks relating to privacy and confidentiality that various countries operate, and the lack of an overarching international policy on the subject, means that the legal protection afforded to an individual's data may vary significantly between service providers, depending on where they are based. For example, organisations and companies based in the UK and other European countries are subject to data protection legislation, as described in Chapter 5 (see Paragraphs 5.37–5.40), whereas the legislation or

⁴⁵⁹ Direct-to-consumer genetic tests are not exclusively provided via the internet. There have been instances of genetic tests being sold by 'bricks-and-mortar' establishments. For example, in 2007 Sorensen Genomics began selling paternity tests through Rite Aid pharmacies in parts of the USA (and, in 2008, the whole of the USA except New York State). In 2010, Pathway Genomics and Walgreens announced that Pathway's genetic testing service would be available in Walgreens stores (see also Paragraphs 9.33–9.39). See: Sorensen Genomics (2007) Sorenson genomics to bring the first-ever retail DNA test to market, available at: http://www.sorensongenomics.com/press_release_20071120.html; Sorensen Genomics (2008) Identigene begins nationwide over-the-counter retail sales of DNA paternity test kits in rite aid drug stores, available at: http://www.sorensongenomics.com/press_release_20080325.html.

⁴⁶⁰ Defined under s382 Companies Act 2006 as meeting two or more of the following requirements: having a turnover of less than £5.6 million, a balance sheet total of less than £2.8 million and fewer than 50 employees.

⁴⁶¹ As it was permitted to submit only 'abbreviated' accounts. Companies House performs a variety of functions, one of which is to "examine and store company information". Information regarding companies established in the UK are available for a fee. See: Companies House (2010) Our main functions, available at: <http://www.companieshouse.gov.uk/about/functionsHistory.shtml> and Companies House (2010) WebCHcheck – Select and Access Company Information, available at: <http://wck2.companieshouse.gov.uk/c221d2b44f40d1871bd8f703b9ae2db7/wcframe?name=accessCompanyInfo>.

⁴⁶² PriceWaterhouseCoopers (2008) *The new science of personalized medicine: Translating the promise into practice*, p19, available at: <http://www.pwc.com/us/en/healthcare/publications/personalized-medicine.jhtml>.

⁴⁶³ Pollack A (2010) Consumers slow to embrace age of genomics *The New York Times* 19 March, available at: <http://www.nytimes.com/2010/03/20/business/20consumergene.html>.

the means to ensure compliance varies greatly in other countries. Even if a company guaranteed security, if it went into administration or changed hands, there is no guarantee that the data held would be used for the same purposes for which it was originally gathered. For example, following the bankruptcy filing of the company deCODE genetics in 2009 and the purchase of most of the assets by another organisation, it remains unclear what exactly will happen to the personal genetic data held by deCODE genetics. Although the company has stated that the data will be used in the manner that it was prior to their bankruptcy,⁴⁶⁴ it has been argued that “deCODE’s new owners remain (legally) free to alter or expand their use of genetic data within a range of allowable uses”.⁴⁶⁵ In Europe, if a company goes into administration or changes hands, the data should be used only in accordance with the original consents or other lawfully authorised purposes. But this obligation does not apply to all jurisdictions and consumers may find it difficult to enforce even in Europe. We return to this issue in our recommendation in Paragraph 9.60.

Collecting DNA

- 9.24 The Human Tissue Act 2004 requires that anyone in the UK procuring and analysing a biological sample to obtain scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person) must have appropriate consent from the person from whom the sample was taken for the test to be lawful.⁴⁶⁶ This requirement means that sending someone else’s sample to one of these companies for analysis without their permission would be an offence, regardless of where the company was based. There is an exception for children,⁴⁶⁷ for whom consent may be given by a person who has parental responsibility. We return to this issue in our recommendation in Paragraph 9.53.
- 9.25 In the USA, a 2009 investigation found there was substantial variation among states in terms of how non-consensual DNA collection, analysis or disclosure were regulated. For example, no relevant regulation of such practices was identified in a total of 21 states and the District of Columbia while ten states restricted non-consensual collection and analysis (or disclosure) of DNA for both health and non-health related purposes.⁴⁶⁸

Provision of information by providers and advertising

- 9.26 As described earlier, NHS screening programmes are regulated by national standards that aim to ensure that, prior to screening, a patient is informed of the risks and benefits, the potential for diagnostic errors and the implications of any subsequent investigations or treatment (see Box 9.1).⁴⁶⁹ Given the complexity of all the information, the gaining of informed consent can often be problematic and the same goes for effective risk communication. The way people understand and interpret risk often depends on how it is presented. Transparent risk communication can reduce the likelihood that risks will be interpreted wrongly by the public, and such communication is especially important given wide differences in ‘health literacy’ within the population.⁴⁷⁰ But the information that is provided to customers about genetic tests performed outside the NHS is not overseen in any way. If companies meet the controls relating to advertising that we summarise below they will have met their regulatory obligations.

⁴⁶⁴ See, for example: Henderson M (2009) Privacy fears as DNA testing firm deCODE Genetics goes bust *The Times* 18 November, available at: <http://www.timesonline.co.uk/tol/news/science/genetics/article6920653.ece>; Stefánsson K (2010) Icelandic genetic database not at risk from bankruptcy *Nature* **463**: 25.

⁴⁶⁵ Vorhaus D (2010) Meet the new deCODE, same as the old deCODE? *Genomics Law Report* [internet blog] 25 January, available at: <http://www.genomicslawreport.com/index.php/2010/01/25/meet-the-new-decode-same-as-the-old-decode/>.

⁴⁶⁶ Human Tissue Act 2004, Section 45.

⁴⁶⁷ Human Tissue Act 2004, Schedule 4, Part 1 s.2(2)(a).

⁴⁶⁸ Genetics and Public Policy Center (2009) *Summary: Analysis of State laws on surreptitious testing*, available at: <http://www.dnapolicy.org/resources/SurreptitiousDNAtestingsummary.pdf>.

⁴⁶⁹ Austoker J (1999) Gaining informed consent for screening *British Medical Journal* **319**: 722–3.

⁴⁷⁰ Sihota S and Lennard L (2004) *Health literacy: Being able to make the most of health* (London: National Consumer Council).

- 9.27 There are measures relating to ‘truth-in-promotion’,⁴⁷¹ which are applied and enforced by a number of UK bodies, including: the Advertising Standards Authority (ASA), the Office of Fair Trading (OFT) and the Office of Communications. As noted in Chapter 5, the ASA deals with complaints about advertising in both broadcast and non-broadcast media. The Committee of Advertising Practice Code, which the ASA administers, requires advertisements to be “capable of objective substantiation”.⁴⁷² When the ASA receives a complaint, it first considers whether the case falls within the remit of the relevant advertising code and then whether the behaviour being complained about breaches any rules of the code. If a complaint passes both of those tests, there are a variety of sanctions available depending on the nature of the violation, and they were described in Chapter 5. Where complaints concern a device such as a genetic test, both the ASA and the OFT have said they would be likely to consult with the Medicines and Healthcare products Regulatory Agency (MHRA) for further advice.⁴⁷³
- 9.28 Concerns have been raised about the information contained in advertisements of genetic tests available directly to consumers. In its report *More genes direct*, the Human Genetics Commission noted:⁴⁷⁴

“We share the widespread concerns about the advertising of direct genetic tests and believe that it should be discouraged. We believe that the Advertising Standards Authority and the Office of Fair Trading should emphasise the need for responsible and accurate advertising of such products.”⁴⁷⁵

The Human Genetics Commission has since published *A common framework of principles for direct-to-consumer genetic testing services* which includes reference to the types of information that should be provided for prospective consumers (see also Paragraph 9.31).⁴⁷⁶ We return to this subject of the information supplied by providers in our recommendation in Paragraph 9.51.

Interventions related to the products provided

- 9.29 Medical genetic tests fall under the broader regulatory framework associated with medical devices in the UK (see also Paragraph 8.26–27),⁴⁷⁷ and are governed in the EU by the In Vitro Diagnostic Devices (IVDD) Directive (98/79/EC). This Directive came into force in the UK in 1998 and was implemented in the UK by the Medical Devices Regulations 2002.⁴⁷⁸ The MHRA is currently the UK body responsible for ensuring compliance with the IVDD Directive.⁴⁷⁹ The Directive requires that testing kits are safe and accurately measure what they say they do. The IVDD Directive applies only to devices for medical purposes,⁴⁸⁰ and works on the basis of risk-based regulation, in which the level of regulation applied to a specific test is intended to be proportional to the risk it poses to the user.⁴⁸¹

⁴⁷¹ Melzer D, Hogarth S, Liddell K *et al.* (2008) *Evidence and evaluation: Building public trust in genetic tests for common diseases – research report*, p9, available at: http://www.phgfoundation.org/file/redirect/?link_ID=4003.

⁴⁷² Committee of Advertising Practice (2009) *The CAP Code – general rules: 3 Substantiation*, available at: <http://bcap.org.uk/The-Codes/CAP-Code/CAP-Code-Item.aspx?q=CAP+Code+General+Rules+3++Substantiation>.

⁴⁷³ Human Genetics Commission (2007) *More genes direct*, p13, available at: <http://www.hgc.gov.uk/Client/document.asp?DocId=139&CAtegorId=10>.

⁴⁷⁴ The UK Government’s advisory body on new developments in human genetics.

⁴⁷⁵ Human Genetics Commission (2007) *More genes direct*, p25., available at: <http://www.hgc.gov.uk/Client/document.asp?DocId=139&CAtegorId=10>.

⁴⁷⁶ Human Genetics Commission (2010) *A common framework of principles for direct-to-consumer genetic testing services*, available at: <http://www.hgc.gov.uk/Client/Content.asp?ContentId=816>.

⁴⁷⁷ Hogarth S, Liddell K, Ling T *et al.* (2007) Closing the gaps – enhancing the regulation of genetic tests using response regulation *Food & Drug Law Journal* **62**: 833.

⁴⁷⁸ SI 2002/618.

⁴⁷⁹ Human Genetics Commission (2007) *More genes direct*, p11, available at: <http://www.hgc.gov.uk/Client/document.asp?DocId=139&CAtegorId=10>.

⁴⁸⁰ Articles 1 and 2(a) Directive 98/79/EC.

⁴⁸¹ Human Genetics Commission (2007) *More genes direct*, p11, available at: <http://www.hgc.gov.uk/Client/document.asp?DocId=139&CAtegorId=10>.

- 9.30 The remit of the MHRA does not extend to medical device regulations outside the European Union and consequently does not cover any tests performed outside the EU. However, the MHRA has stated that it expects that tests or products used in conjunction with any healthcare service offered in the UK be safe, effective and fit for purpose, and that such tests meet all of the relevant regulations covering *in vitro* diagnostic medical devices in the country within which the laboratory in question is based.⁴⁸² The MHRA has also stated that where samples are obtained within the EU, both the specimen receptacles and any equipment used to obtain the samples must be CE-marked (see description in Chapter 8, footnote 402).
- 9.31 As mentioned above, the Human Genetics Commission has recently published *A common framework of principles for direct-to-consumer genetic testing services*, with the aim of promoting “high standards and consistency in the provision of genetic tests amongst commercial providers at an international level in order to safeguard the interests of people seeking genetic testing and their families.”⁴⁸³ The Principles are provided as guidance for developing codes of practice.⁴⁸⁴ The European Society of Human Genetics (ESHG) has also recently published recommendations for the regulation of direct-to-consumer genetic testing for health purposes.⁴⁸⁵
- 9.32 Other states and countries have also responded to the availability of direct-to-consumer tests. For example, in February 2010, German legislation came into force that requires predictive genetic examinations to be conducted or commissioned only by doctors who specialise in human genetics, by other similarly qualified and specialised medical doctors.⁴⁸⁶ This legislation may have a significant impact on any direct-to-consumer genetic profiling company operating in Germany.

The changing situation in the USA

- 9.33 At the federal level, the Food and Drug Administration (FDA) is responsible for regulating *in vitro* diagnostic (IVD) tests performed in a laboratory. Medical devices are required to be safe and effective. In this context, a device is considered safe when the probable benefits to health from its use outweigh any probable risks,⁴⁸⁷ and effective where, for “a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results”.⁴⁸⁸
- 9.34 Despite the existence of this legislation, it has been claimed that the majority of new direct-to-consumer genetic tests are being developed as a different type of test, ‘laboratory developed tests’:⁴⁸⁹ although the FDA has stated that such tests are medical devices and therefore under FDA jurisdiction it has, so far, exercised a discretionary approach to their regulation (although this situation may change in the future: see below).⁴⁹⁰

⁴⁸² Information supplied by Medicines and Healthcare products Regulatory Agency.

⁴⁸³ Human Genetics Commission (2009) *A common framework of principles for direct-to-consumer genetic testing services – principles and consultation questions*, p4, available at: <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/Principles%20consultation%20final.pdf>.

⁴⁸⁴ *Ibid.*, p2.

⁴⁸⁵ European Society of Human Genetics (2010) Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes *European Journal of Human Genetics advance online publication*, 25 August 2010.

⁴⁸⁶ S.7 Gesetz über genetische Untersuchungen bei Menschen.

⁴⁸⁷ 21 US Code of Federal Regulations § 860.7(d)(1).

⁴⁸⁸ 21 US Code of Federal Regulations § 860.7(e)(1).

⁴⁸⁹ US Congress Committee on Energy and Commerce Staff (2010) *Memorandum re hearing on “direct-to-consumer genetic testing and the consequences to the public health”*, available at: <http://energycommerce.house.gov/documents/20100720/Briefing.Memo.oi.2010.7.20.pdf>.

⁴⁹⁰ *Ibid.*

- 9.35 The Clinical Laboratory Improvement Amendments (CLIA),⁴⁹¹ passed by the US Congress in 1998, defines and mandates quality standards for laboratory testing. The Centers for Medicare and Medicaid Services manage an accreditation and regulation system for clinical laboratories but exercise little supervision over companies that sell direct-to-consumer genetic testing kits.⁴⁹² CLIA is designed to “ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed”,⁴⁹³ but it has been noted that it does not require an assessment of the clinical utility or effectiveness of a test.⁴⁹⁴
- 9.36 In 2010, there were several developments at the federal level concerning the regulation of direct-to-consumer genetic tests: the US National Institutes of Health announced plans to create a Genetic Testing Registry (a database of genetic tests);⁴⁹⁵ the FDA contacted various direct-to-consumer genetic testing companies about whether those companies were fulfilling various regulatory requirements applicable to the provision of genetic tests; the FDA also held a meeting “to discuss the agency’s oversight of laboratory developed tests”,⁴⁹⁶ the US House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigations launched a hearing into the direct-to-consumer genetic testing industry;⁴⁹⁷ and the US Government Accountability Office published a report on the direct-to-consumer industry that criticised some direct-to-consumer genetics companies’ test results as being “misleading and of little or no practical use”.⁴⁹⁸
- 9.37 In May 2010, following the partnership between Walgreens and Pathway Genomics to provide a genetic testing kit in retail stores in the USA, the FDA informed Pathway Genomics that they considered the Pathway Genomics saliva collection kits as fulfilling the relevant “definition of a device”,⁴⁹⁹ and Walgreens withdrew the product.⁵⁰⁰ In June 2010, the FDA sent letters to other direct-to-consumer genetic testing companies advising them that the FDA viewed their testing kits as medical devices.⁵⁰¹ Following recent meetings, the FDA is considering its position, and no formal decision on the subject of the oversight of laboratory diagnostic tests had been made at the time of writing.⁵⁰²
- 9.38 At the state level, approximately half of the states in the USA specifically regulate direct-to-consumer genetic testing. What is defined as direct-to-consumer testing differs among states,

⁴⁹¹ See: http://www.access.gpo.gov/nara/cfr/waisidx_04/42cfr493_04.html.

⁴⁹² US Congress Committee on Energy and Commerce Staff (2010) *Memorandum re hearing on “direct-to-consumer genetic testing and the consequences to the public health”*, available at: <http://energycommerce.house.gov/documents/20100720/Briefing.Memo.oi.2010.7.20.pdf>.

⁴⁹³ Food and Drug Administration (2010) Clinical laboratory improvement amendments (CLIA), available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm>.

⁴⁹⁴ Vorhous D (2010) Personal genomics follows pathway to corner drugstore; is regulation next? *Genomics Law Report* [internet blog] 11 May, available at: <http://www.genomicslawreport.com/index.php/2010/05/11/pathway-walgreens-and-dtc-regulation/>.

⁴⁹⁵ US National Institutes of Health (2010) NIH announces genetic testing registry, available at:

http://www.nih.gov/news/health/mar2010/od-18.htm?utm_source=twitterfeed&utm_medium=twitter.

⁴⁹⁶ US Federal Register (2010) *Oversight of laboratory developed tests; public meeting; request for comments; notice of public meeting; request for comments* 75(116): 34463–4, available at: <http://edocket.access.gpo.gov/2010/2010-14654.htm>.

⁴⁹⁷ US House of Representatives Committee on Energy and Commerce (2010) Committee investigates personal genetic testing kits, available at: http://energycommerce.house.gov/index.php?option=com_content&view=article&id=2009:committee-investigates-personal-genetic-testing-kits&catid=122:media-advisories&Itemid=55; US House of Representatives Committee on Energy and Commerce (2010) Hearing on “direct-to-consumer genetic testing and the consequences to the public health”, available at: http://energycommerce.house.gov/index.php?option=com_content&view=article&id=2083:hearing-on-direct-to-consumer-genetic-testing-and-the-consequences-to-the-public-health&catid=133:subcommittee-on-oversight-and-investigations&Itemid=73.

⁴⁹⁸ US Government Accountability Office (2010) *Direct to consumer genetic tests: Misleading test results are further complicated by deceptive marketing and other questionable practices*, available at: <http://www.gao.gov/new.items/d10847t.pdf>.

⁴⁹⁹ Food and Drug Administration (2010) Letter to Pathway Genomics corporation concerning the pathway genomics genetic health report, available at: <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM211875.pdf>.

⁵⁰⁰ Jaspen B and Jones MS (2010) Walgreens postpones carrying Pathway Genomics genetic test kit *Los Angeles Times* 13 May, available at: <http://articles.latimes.com/2010/may/13/business/la-fi-dna-kits-20100513>.

⁵⁰¹ The relevant letters are available directly from the FDA. See:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm>.

⁵⁰² Information supplied by Food and Drug Administration.

leading to differences in application and enforcement.⁵⁰³ In 2008, some states in the USA made moves towards stricter regulation of direct-to-consumer genetic tests. ‘Cease and desist’ notices were sent by the California Department of Public Health to 13 genetic testing companies, including 23andMe, Navigenics and deCode Genetics, explaining that the companies should not solicit business from residents in the state.⁵⁰⁴ The letters advised the companies that, as clinical laboratories, they needed to have state licences, and that genetic tests could be ordered only by a doctor, not by consumers. One of the companies responded by saying that a physician was involved in the approval of the test as well as the release of the results to the customer, and another questioned the legality of the claim that a physician was needed.⁵⁰⁵ In August 2008, 23andMe and Navigenics were granted state licences in California to continue to do business.⁵⁰⁶

- 9.39 New York State also took action similar to that of California by issuing warning letters to similar firms, such as Navigenics, instructing them to cease marketing their services directly to consumers and to obtain permits to operate in the state.⁵⁰⁷ In New York State, consumer genomics firms are regulated as clinical laboratories.⁵⁰⁸ In 2010, Navigenics was given permission to operate in New York State as a clinical laboratory and gave an undertaking not to market its genetic testing services directly to the public in that state. Rather, Navigenics will be required to “operate through physician’s orders”. This company may well adopt this approach for all its operations in the USA.⁵⁰⁹

Softening the ethical dilemmas

- 9.40 We conclude that, although personal genetic profiling for disease susceptibility to common multifactorial conditions has a number of benefits and offers people the freedom to access information about themselves, and the tests work as specified in terms of the data they produce,⁵¹⁰ they often offer low clinical validity and utility. Tests from different companies produce different information about the same person, perhaps because those companies use different research findings as their baseline. The way information is presented can be difficult to interpret. For many of the conditions to which the tests relate, there are no treatments available until clinical symptoms have appeared, or there may be none at all. The information that is provided by these test providers about preventing adverse health conditions from developing is generally no more specific than the usual healthy living messages applicable to everyone. It is possible, too, that if people are told their risk of a particular condition is below the population average, they might be complacent and continue to follow unhealthy lifestyles, which we know often play a considerable role in some of these conditions. Indeed, since the population average for some of these conditions is relatively high, any complacency based on a prediction of risk from a test that may not be clinically valid would seem to be inadvisable.
- 9.41 This mixture of benefits and harms means that some of our ethical values come into stark contrast within this case study: the value of individuals being able to pursue their own interests comes into conflict with the values of state action to reduce harm, safeguarding private information, fair and efficient use of public resources and social solidarity. And the value of

⁵⁰³ Vorhaus D (2010) *A lawyers guide to the personal genomics landscape*, available at: <http://www.genomicslawreport.com/wp-content/uploads/2010/07/Genomics-and-the-Consumer-23andMe-Forum-Vorhaus.pdf>.

⁵⁰⁴ Wadman M (2008) Gene-testing firms face legal battle *Nature* **453**: 1148–9.

⁵⁰⁵ *Ibid.*

⁵⁰⁶ Pollack A (2008) California licenses 2 companies to offer gene services *The New York Times* 19 August.

⁵⁰⁷ *Ibid.*; see also: Ray T (2010) Navigenics agrees not to market genetic testing services directly to NY residents *Pharmacogenomics Reporter* 20 January, available at: <http://www.genomeweb.com/dxpgx/navigenics-agrees-not-market-genetic-testing-services-directly-ny-residents>.

⁵⁰⁸ Ray T (2010) Navigenics agrees not to market genetic testing services directly to NY residents *Pharmacogenomics Reporter* 20 January, available at: <http://www.genomeweb.com/dxpgx/navigenics-agrees-not-market-genetic-testing-services-directly-ny-residents>.

⁵⁰⁹ Navigenics (2010) *Service FAQs*, available at: http://www.navigenics.com/visitor/what_we_offer/faqs/.

⁵¹⁰ A property sometimes referred to as ‘analytic validity’.

safeguarding private information also comes into conflict with those of state action to reduce harm and social solidarity. The value of fair and efficient use of public resources is already coming into conflict with social solidarity.

- 9.42 Some have argued for tough curbs on these tests,⁵¹¹ but following the proportionality principle we set out in Chapter 4, we do not think it is currently justifiable to prevent individuals from buying these tests (and thus pursuing what they see as their own interests in their own way), without good evidence of actual harm beyond the administrative error occurring in a genetics laboratory in 2010 when 96 customers received results that were not their own and some expressed distress as a result.⁵¹² Such evidence has not yet been provided, even though, as we have noted, a number of potential harms could arise. And even if future evidence reveals harm that is sufficiently great to warrant some form of coercive government regulation, the genetic profiling analyses described in this chapter are sold over the internet by companies that could be located anywhere in the world, meaning that it would be expensive and difficult to enforce some forms of coercive regulation. In the light of these considerations, we consider it appropriate to make recommendations aimed at promoting our other ethical values but without restricting people's ability to pursue their own interests. First, we recommend independent research on the impact and effects of multifactorial genetic testing on individuals so the harms can be quantified. We also recommend that: (i) responsible authorities should request evidence for clinical claims made by companies; (ii) government health service websites should provide public information about genetic profiling services, and companies should indicate to consumers where to find this information; (iii) companies should voluntarily adopt good practice; (iv) companies should not knowingly carry out for children DNA tests that do not meet the criteria of the UK National Screening Committee; and (v) professionals in the public healthcare system should adapt their practice in the light of the development of direct-to-consumer genetic testing.

Claims made about genetic profiling tests

- 9.43 As noted above, we consider that the predictive value of many privately offered personal genetic susceptibility analyses for multifactorial conditions is unclear. That lack of clarity is problematic because people who receive these profiling results could misinterpret information about their health status, perhaps through giving too much weight to the clinical validity of the results. Inaccurate conclusions, either positive or negative, about a serious condition may have substantial implications for the people receiving test results (see Paragraph 9.15). There may also be financial risks associated with the insurance status of people taking tests (see the recommendations in Paragraphs 9.49 and 9.51). And, although we noted at the outset that the cost of genetic profiling tests is now easily within the means of middle-income consumers in developed countries and may well continue to fall, such tests nevertheless cost consumers money and those people are wasting their money if results are presented (either directly or by implication) as being medically valuable when they are not. Although, as we have said, we do not think it would be proportionate to ban the sale of these products until or unless systematic evidence of harm is produced, we do think that the potential seriousness of these harms makes it proportionate for regulatory and advertising authorities to assert their powers to request that the information provided by companies does not overstate the clinical validity of their products at this time.
- 9.44 Standards could be improved if regulators insisted that better data on clinical validity of tests be provided as a prerequisite for market authorisation. At present however, providers within the EU are required only to prove as a condition of market release that their test is medically valuable if they expressly claim it to be so. In other circumstances it suffices to prove analytic validity (i.e. that the biomarker of interest is correctly identified each time the test is used).

⁵¹¹ The Lancet (2010) New guidelines for genetic tests are welcome but insufficient *The Lancet* **376**: 488.

⁵¹² Aldhous P (2010) Genome scan customers sent the wrong results *New Scientist* [internet blog] 7 June, available at: <http://www.newscientist.com/blogs/shortsharpscience/2010/06/personal-genome-customers-sent-1.html>.

- 9.45 **We recommend that responsible authorities pay more attention to whether genetic test providers are making clinical claims for their products, even if implied rather than explicit (such as in their ‘customers’ testimonials’). If so, they should ask for evidence to be supplied. We direct this recommendation to authorities responsible for pre-market review and advertising standards, including the Medicines and Healthcare products Regulatory Agency and the Advertising Standards Authority in the UK.**

Information available to consumers

Research and information provided by public healthcare systems

- 9.46 We have already noted that evidence on possibly harmful effects on people of undergoing predictive genetic profiling has not been clearly established for either their health behaviour or their psychological health (see Paragraph 9.15). In line with our belief that people should, as far as possible, be able to pursue their own interests in their own way, they need good, accurate and impartial information about the services they might consider purchasing. Such information is also needed for evidence-based policy making in this domain.
- 9.47 **We recommend that independent research on the health and psychological impact and effects of multifactorial genetic susceptibility testing on individuals, including children, should be carried out by public healthcare systems. Such research should include investigation into how many people are purchasing this type of analysis, and the results of this research should be made easily accessible. We recognise this information might need updating periodically if scientific developments meant that more associations between genetics and predicting common diseases were discovered. Potential buyers could then better assess what kind of results they would receive and what impacts they could expect, whether positive or negative. In the UK the National Institute for Health Research could be best placed to fund and commission this research.**
- 9.48 As noted in Paragraph 9.30, the specimen receptacles and any equipment used to obtain samples need to be CE-marked if sold in the UK and the EU. However, the interpretation of the results and the information that is provided to consumers is not regulated (except where advertising codes apply) in the UK and in many other countries. We are concerned that it is difficult for people to find out general information from an independent source about services offering genetic profiling for disease susceptibility (i.e. from somewhere other than the companies themselves). There are precedents for action in other commercial sectors, as in the case where non-company-specific information on credit cards and mortgages is provided by the UK and other governments.⁵¹³
- 9.49 **We recommend that appropriate publicly-funded health service websites should include general information for the public about direct-to-consumer genetic profiling services provided by commercial companies. This information should include reference to:**
- **potential risks and benefits;**
 - **any difficulties with establishing clinical validity;**
 - **the possibility of finding out about conditions for which treatment is not available;**
 - **the special case of children (see also recommendation in Paragraph 9.54); and**

⁵¹³ See, for example: Financial Services Authority (2009) *No selling. No jargon. Just the facts about credit cards*, available at: http://www.moneymadeclear.org.uk/pdfs/credit_cards.pdf.

- whether it could be necessary for consumers to inform life, mortgage or travel insurance companies of the results of any tests, either at the time or in the future.

We further recommend that governments should require details about where to find this information to be included in the advertising and information provided by companies selling genetic profiling services in their countries (see also our recommendation in Paragraph 9.51).

Information provided by commercial providers

9.50 The information on some direct-to-consumer genetic test providers' websites gives the impression that only useful health and medical information can be gained from taking these tests. This is particularly true in the statements presented in the form of 'customer testimonials'. However, we think that such an impression can be misleading. As we have said, for the types of analysis that involve risk predictions for common multifactorial conditions, the predictions given about any individual's future health are of limited clinical validity. The best way to promote individuals being able to pursue their own interests in their own way is for these companies to provide better information both about how the services they offer can be useful and about their limitations. That is why we recommend a two-pronged approach: governments should provide independent general information about these services as set out above, and the providers themselves should also provide certain information about their services.

9.51 **We recommend that all companies that provide genetic analysis for susceptibility to common multifactorial diseases should make the following information prominently available in lay language for the consumer before they buy:**

- the operator of the services;
- the location in which the operator is based;
- the evidence on which interpretations of the test results are based;
- the tests' limitations, including the fact that they are probabilistic and based on current research results which may change;
- that the test results may require interpretation by a qualified medical practitioner or genetic counsellor;
- the possibility of finding serious health problems and revealing family genetic relationships;
- the nature of the risk being communicated to the consumer, i.e. absolute or relative risk;
- advice about whether it might be necessary for consumers to declare any results they receive as a result of genetic tests to their life, mortgage or travel insurance companies;
- which other third parties, if any, have access to the information/data;
- that the results should not be used alone for medical decision making given their limited clinical validity;
- that tests that do not meet the requirement of clinical validity should not be carried out for children (see recommendation in Paragraph 9.54);
- arrangements for data security (including in case of any changes to the administration of the company);

- funding and advertising arrangements; and
- where to find independent information about this type of service on public healthcare service websites (see our recommendation in Paragraph 9.49).

We further recommend that all companies selling direct-to-consumer genetic tests follow the Common Framework of Principles intended for international use by genetic test providers developed by the Human Genetics Commission and approved by the Department of Health in England.

Testing third parties and children

- 9.52 Procuring a biological sample from someone else for DNA analysis without their knowledge is prohibited in the UK by the Human Tissue Act 2004.⁵¹⁴ Similar restrictions apply in some other countries and in some states in the USA (see Paragraph 9.25), and we consider such restrictions to be a sensible way of trying to safeguard information that many people would consider private. Nevertheless, services that rely on sending samples through the post make it possible (although it would be an offence) for a person to send someone else's sample and receive the results without their knowledge.
- 9.53 We recommend that genetic testing companies should require their customers at the point of sale to click on a statement confirming that they have the consent of the person whose DNA they intend to have analysed, or have parental responsibility in the case of children (see below). Where people live in countries such as the UK where procuring someone else's biological sample for DNA analysis without their knowledge is a legal offence, this statement should also require confirmation that the customer has understood this fact. This agreement should be stated in clear language and separated from other terms and conditions.
- 9.54 In the case of children, given our ethical value of the state striving to reduce harm, we recommend that companies should only analyse the DNA of children if (i) a genetic test meets the criteria of the UK National Screening Committee (see Box 9.1)⁵¹⁵ and (ii) valid parental consent has been given. For such testing to take place, a condition would need to be serious, the test would need to be precise and validated, and there would need to be an effective treatment or intervention available for children identified through early detection. As we have said, many companies are offering services that do not meet these criteria, although we recognise there are exceptions. The basis for this recommendation is that some individuals do not want to know susceptibility information, particularly where the clinical validity is unclear. Additionally: (i) any benefits of this type of analysis offering a risk profile of common multifactorial conditions do not seem particularly relevant to children at this time; (ii) the problems with clinical validity of this type of analysis at present need to be taken into account; and (iii) the potential harms involved, particularly those of stigma, also need to be considered, given that children and those responsible for their care would receive information that they cannot un-know, and yet the child did not decide himself or herself to take the DNA profiling test. We consider that this advice should be given to parents on appropriate publicly-funded health service websites (together with the other information we recommend above in Paragraph 9.49), as well as the information that companies provide to consumers that we recommend in Paragraph 9.51.
- 9.55 We believe this recommendation is the most feasible way to try to ensure that children have the opportunity to be able to pursue their own interests in their own way once they reach adulthood.

⁵¹⁴ Human Tissue Act 2004, Section 45. This section of the Act is applicable throughout the UK.

⁵¹⁵ Which we interpret as children who do not have a certain level of competence, such as the standard 'Gillick' test.

The recommendation would not prevent diagnostic genetic testing of the type usually carried out in conjunction with a genetic counsellor or clinical geneticist, for example by NHS clinical services. Such testing is covered by professional codes that involve a presumption of caution in response to parental requests for testing that has no immediate medical benefit so that a child's choices as an adult are preserved.

Impacts for the public healthcare system

- 9.56 One of our ethical values described in Chapter 3 is that of using public resources fairly and efficiently. That value implies that we need to consider whether the new developments considered here result in inefficiencies and unnecessary costs to public healthcare systems. We think that the availability of commercial genetic tests available to consumers on request could indeed have implications for publicly-funded healthcare systems. While there is a lack of peer-reviewed evidence on this point, we were told during our consultation and evidence collection that people do indeed attend their general practitioners after they have purchased such tests to seek help in interpreting their results or to discuss their concerns about the results. We were also told that these patients sometimes request further tests and referral provided by the public healthcare system, even though in many cases referral is unnecessary given the generality and lack of clinical validity of the results. That situation could become increasingly common if direct-to-consumer genetic profiling becomes widespread.
- 9.57 Considering this dilemma between ensuring that public resources are used fairly and efficiently and the value of social solidarity offered by a public healthcare system in the sense of treatment and health advice provided to everyone irrespective of their circumstances, we think it would not be appropriate for a public healthcare system to turn away people who were worried about their health as a result of a privately bought genetic profiling service. But the need for health professionals' time to be spent in this way might at least be somewhat reduced if the predictive test providers offered the types of information we recommend in Paragraph 9.51.
- 9.58 **To lessen the dilemma involved, we recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals about best practice in the areas of giving advice about direct-to-consumer personal genetic profiling services: recognising their value as a tool for discussing healthier lifestyles, addressing their limitations, and taking a responsible position with regard to when to refer patients for specialist services.**

Safeguarding private information

- 9.59 Another of our ethical values is that of safeguarding private information. Many people consider their genetic data to be private information, and the data can reveal highly sensitive information about who they are and are not related to. We therefore consider it important that providers of these services take seriously their responsibilities relating to transferring and holding the private information to which they have access. Even if a company guaranteed security, if it went into administration or changed hands, there is no guarantee that the data held would be used for the same purposes for which it was originally gathered (see Paragraph 9.23).
- 9.60 **Genetic profiling companies should provide details about what would happen to personal genetic data and interpretations should the company go into administration or change hands. This information should be made available to consumers before they buy (see also our recommendation in Paragraph 9.51).**

Future impact

- 9.61 The cost of sequencing a person's DNA is decreasing dramatically as a result of technological developments.⁵¹⁶ This genetic analysis may take various forms, from genotyping small numbers of genetic markers relevant to a particular disease or trait, to full sequencing of a person's entire genome.⁵¹⁷ It is predicted that a person's entire genome could be sequenced for \$1,000 in the near future.⁵¹⁸ In the Human Genetics Commission's 2005 report *Profiling the newborn*, it concluded that genetic profiling could in the future have clinical potential but that its effectiveness could not be judged at that time and recommended research should be carried out to define the full costs and potential benefits of genetic profiling for the health of children and adults.⁵¹⁹ A recent study has suggested that some clinically relevant information may be derived from full genome sequencing.⁵²⁰
- 9.62 The reduction in costs mentioned above may lead to more people coming to take the types of test we have discussed in this chapter, and may also mean that instead of being sent simply risk information, or sequences of specific points in a person's genome, people may come to receive more and more sequence information or, in the future, their entire sequence at an affordable price. There are differences of opinion as to how fast our knowledge of the relationships between genetics and health conditions will develop, but what we do know is that more information will be available to consumers. That is why we think it is vital for more research to be conducted on the impact of testing, and for better information to be provided for the customers or potential customers of these tests to understand their implications and limitations.

⁵¹⁶ Robertson JA (2003) The \$1000 Genome: Ethical and legal issues in whole genome sequencing of individuals *American Journal of Bioethics* **3**(3): W-IF1; Mardis ER (2006) Anticipating the \$1000 genome *Genome Biology* **7**(7): 112; Service RF (2006) Gene sequencing: The race for the \$1000 genome *Science* **311** (5767): 1544–6.

⁵¹⁷ Sequencing a person's entire genome has recently been used in the genetic diagnosis. See: Lupski JR, Reid JG, Gonzaga-Jauregui C *et al.* (2010) Whole-genome sequencing in a patient with Charcot–Marie–Tooth neuropathy *New England Journal of Medicine* **362**: 1181–91. See also: Lifton RP (2010) Individual genomes on the horizon *New England Journal of Medicine* **362**: 1235–6.

⁵¹⁸ Wolinsky H (2007) The thousand-dollar genome: Genetic brinkmanship or personalized medicine? *EMBO reports* **8**: 900–3.

⁵¹⁹ Joint Working Group of the Human Genetics Commission and the UK National Screening Committee (2005) *Profiling the newborn: A prospective gene technology?*, available at: <http://www.hgc.gov.uk/Client/document.asp?DocId=154&CAtegorId=10>.

⁵²⁰ The study aimed to “undertake an integrated analysis of a complete human genome in a clinical context” and was prompted by the authors' belief that the clinical translation of genetic risk estimates for common variants reported in genome-wide association studies was unclear. It was designed to assemble information regarding the patient's future health and potential response to various drugs and found that, while challenges remained, whole-genome sequencing could yield useful and clinically relevant information for individual patients. As a consequence of the sequencing, the individual whose genome was sequenced for the study was subsequently prescribed a statin, as he was identified as having a higher than normal risk of heart attack and being likely to respond well to lipid-lowering therapy. See: Ashley ES, Butte AL and Wheeler MT *et al.* (2010) Clinical assessment incorporating a personal genome *The Lancet* **375**(9725): 1525–35.

Chapter 10

Direct-to-consumer body
imaging

Chapter 10 – Direct-to-consumer body imaging

Overview

What is new? Body imaging technologies that have been used for some time in healthcare for diagnosis (once a person has presented to their doctor with symptoms) have also in the last few years been used in new services offering body imaging directly to people who do not necessarily have any medical symptoms. These screening services are advertised and sold directly to consumers by commercial companies as a form of ‘health check-up’. They offer the possibility of more personalised healthcare in a number of the senses we identified in Chapter 1, although such an outcome depends heavily on the meaningfulness of the results. They raise ethical issues relating to consumerisation and responsabilisation, given that they can be marketed directly to consumers and that undergoing such screening can be presented as responsible behaviour on the part of individuals who want to look after their health.

Which ethical values come into conflict as a result of this development? Potential conflicts arise between the value of individuals being able to pursue their own interests and those of state action to reduce harm, safeguarding private information, fair and efficient use of public resources, and possibly social solidarity.

What is the existing pattern of interventions like? Given that these services involve activity by medical professionals and some of them carry physical risks, most of the interventions that currently apply to them in the UK involve application of state-specific legal powers. In terms of general governance measures the data protection regime applies, and where health professionals are involved they are bound by their own general professional codes and regulatory requirements. More specifically, the equipment itself is regulated for safety.

What gaps or shortfalls are there in existing interventions? We find that the existing arrangements do not promote the provision of good information to potential consumers about direct-to-consumer body imaging services offered as a form of health check, and do not prevent potentially serious harm from some types of scanning. We think more evidence is needed about the range of potential harms that may result from such testing and scanning.

What types of intervention might possibly fill those gaps or remedy those shortfalls? Possible interventions range from research on the benefits and harms involved, requirements for information, restrictions on what is allowed or how it is provided, to outright bans of some types of imaging services.

What types of intervention do we recommend, and why? Some of our recommendations over direct-to-consumer body imaging are similar to those made in the previous chapter on genetic profiling for disease susceptibility, given that some of the same problems are encountered. We attempt to reconcile the value of individuals being able to pursue their own interests in their own way (namely to have the freedom to take these tests should they wish) with that of reduction of harm by state activity, and we consider that the radiological risk that arises from one type of imaging, namely full-body CT scans, is sufficient to justify the introduction of coercive state powers to prohibit the provision of such services. For other types of imaging, including part-body CT imaging, the risk-benefit ratio is unclear and we recommend measures that we think will improve the quality of the services and give consumers better information. Specifically, we recommend: (i) independent research on the impact and effects on individuals of direct-to-consumer body imaging performed as a health check; (ii) appropriate regulation of services; (iii) better provision of information; and (iv) good professional medical practice in the public healthcare system adapted to the situation where patients have had these tests.

Introduction

- 10.1 Body imaging technologies, including computerised tomography (CT), magnetic resonance imaging (MRI) and ultrasound, have been used for some time in healthcare for diagnostic purposes (see Box 10.1). Specialised equipment is used to obtain image data from different angles to produce detailed cross-sectional images of body tissue and organs in two or three dimensions. Patients usually have scans following a referral from a healthcare professional who has considered their symptoms. For example, pictures of the inside of the body can reveal the size and location of cancerous tumours. Our study here focuses on new services that use these same technologies to offer body imaging directly to people who do not necessarily have any medical symptoms. These screening services are often advertised and sold directly to consumers by commercial companies as a form of ‘health check-up’,⁵²¹ often with the suggestion that this is a form of responsible behaviour by people who want to look after their health for the sake of themselves and their families, and analogous to having regular eye tests or dental check-ups. The provision of such services has been made possible by the development of the technologies on which the tests are based and reductions in the cost of that technology. Hence some of the features of these services are similar to those of genetic profiling tests for disease susceptibility that we investigated in our last chapter.

Box 10.1: Types of body imaging

Computed tomography (CT): A medical radiographic imaging technique that uses a computerised x-ray scanning system to produce a digitally processed sectional anatomic image in either two or three dimensions.⁵²² The radiation dose received may be quite substantial (see Paragraph 10.10).

Magnetic resonance imaging (MRI): A medical imaging technique that uses magnetic fields to produce images of tissues and organs. The magnetic nuclei of a patient are aligned in a uniform magnetic field and then subject to a radiofrequency pulse, causing them to absorb and release energy. The energy is picked up by sensitive detectors and converted into a current which in turn is converted into an image. The energy released varies in intensity depending on the environment (i.e. the characteristics of the body organ or tissue) in which it was generated. Thus, different types of tissue will provide different signals, allowing for imaging differentiation of different parts of the body.⁵²³

Ultrasonography: An ultrasonic medical imaging technique, used to produce images of organs and tissue within the body. Ultrasound is sound in the frequency range of 20,000 to 10 billion cycles per second (hertz). The velocity of ultrasound varies according to the medium through which it travels (such as different types of body tissue). Consequently it can be used to outline the shape of different tissues and organs within the body by recording the echoes as they return from the medium through which they travel.⁵²⁴

- 10.2 Private companies offer body imaging in specialist clinics and using mobile equipment, in local halls or other accessible locations. The services and products are marketed as a tool for people who are, as far as they know, in good health and not necessarily in any specific risk group, to obtain reassurance and better information about their body and health. The services are advertised as screening checks to look for the early signs of cancer and heart disease, for

⁵²¹ We also note that the UK National Screening Committee (NSC) has reported that general practices across England are being approached by companies offering private health screens to their NHS patients. The NSC has produced guidance for general practitioners on private screening. See: UK National Screening Committee (2010) *Advice on private health screening being offered through GP practices*, available at: <http://www.screening.nhs.uk/getdata.php?id=9618>.

⁵²² Venes D (Editor) (2009) *Taber's cyclopedic medical dictionary* (Philadelphia: FA Davis Co), p2331.

⁵²³ Adapted from: Venes D (Editor) (2009) *Taber's cyclopedic medical dictionary* (Philadelphia: FA Davis Company), p1391; Pugh MB (Editor) 2000 *Stedman's medical dictionary 27th Edition* (Maryland: Lippicott Williams & Wilkins), p876.

⁵²⁴ Venes D (Editor) (2009) *Taber's cyclopedic medical dictionary* (Philadelphia: FA Davis Co), pp2399–400.

example, and the potential risk of certain conditions such as stroke. See Table 10.1 for examples of some of the imaging tests that are currently available.

- 10.3 Like genetic profiling, direct-to-consumer body imaging, performed as a health check or a risk assessment, can in principle be conducive to at least three of the four types of personalisation we described in Paragraph 1.18: individualised management tailored to the individual involved (when results are meaningful), services provided as a good or commodity directly to consumers, and healthcare services that encourage individuals to take responsibility for their own health and healthcare. But this development can also place new responsibilities on individuals to interpret complex and ambiguous data and weigh up the risks of further treatment (preventive surgery etc.) on the basis of that data. We return to these themes in Chapter 11.

Table 10.1: Examples of direct-to-consumer body imaging services on offer in the UK

Company	Service	Price	Details
Prescan	Total Body Scan	£1,290	"...provides a complete picture of your whole body" "During the Total Body Scan use is made of the MRI-scanner and, if deemed necessary the CT-scanner." ⁵²⁵
Preventicum	Ultimate Plus Check-up	£3,400 ⁵²⁶	Includes several different tests, such as a full physical and hearing test. Imaging scans provided include ultrasound examination of "carotid arteries, liver, gallbladder, biliary tree, pancreas, kidneys, spleen, uterus, ovaries, urinary bladder [and] prostate" and an MRI scan of brain, heart structure and function, arterial system, as well as an MRI colonoscopy. ⁵²⁷
Lifescan	Lifescan Enhanced Check Plus	£790 ⁵²⁸	"This is the most detailed CT health check service offered by Lifescan. It incorporates all the CT scan elements of the Lifescan Enhanced Check but also includes other health assessment techniques to provide a more complete picture of your health." The scans include heart, lung and virtual colonoscopy. ⁵²⁹
European Scanning Centre	CT coronary angiogram	£1,250	"The coronary CT angiogram (CTA) is a diagnostic scan that is used to determine if any of the coronary arteries supplying blood to the heart are narrowed or becoming blocked." ⁵³⁰
Life Line Screening	Abdominal Aortic Aneurysm ⁵³¹	£60 ⁵³²	Screening takes place at venues across the country, such as community centres. ⁵³³ "Life Line Screening uses ultrasound technology to measure the size of your abdominal aorta. The process is painless... Anyone who has risk factors for abdominal aortic aneurysms should have this screening." ⁵³⁴

⁵²⁵ Prescan (2010) Total body scan, available at: <http://www.prescan.co.uk/examinations/total-body-scan>.

⁵²⁶ Preventicum (2010) Prices, available at: <http://www.preventicum.co.uk/prices.asp>.

⁵²⁷ Preventicum (2010) Ultimate plus check-up, available at: <http://www.preventicum.co.uk/ultimate-plus-check-up.asp>.

⁵²⁸ Lifescan (2010) Special offers, available at: <http://www.lifescanuk.org/healthchecks/services/lifescan-enhanced-check-plus/>.

⁵²⁹ Lifescan (2010) Lifescan enhanced check, available at: <http://www.lifescanuk.org/healthchecks/featuresandprices/lifescanenancedcheck/>.

⁵³⁰ The European Scanning Centre (2010) CT coronary angiogram, available at: <http://www.europeanscanning.com/coronary-angiogram.html>.

⁵³¹ Life Line Screening (2010) Screening for abdominal aortic aneurysm, available at: <http://www.lifelinescreening.co.uk/Services/Pages/abdominal-aortic-aneurysm.aspx>. Abdominal aortic aneurysm screening is now being introduced by the NHS. See: Paragraph 10.6.

⁵³² Life Line Screening (2010) Pricing and discounts, available at: <http://www.lifelinescreening.co.uk/Services/Pages/Pricing-and-discounts.aspx>.

⁵³³ Life Line Screening (2010) Preventive health screening, available at: <http://www.lifelinescreening.co.uk/faqs/preventive-health-screening.aspx>.

⁵³⁴ Life Line Screening (2010) Screening for Abdominal Aortic Aneurysm, available at: <http://www.lifelinescreening.co.uk/health-screening-services/abdominal-aortic-aneurysm.aspx>.

Benefits and harms

10.4 Several potential advantages and disadvantages of direct-to-consumer body imaging were listed in Table 3.1.

Potential advantages

- More information;
- allows early intervention and monitoring (if something of clinical significance is found);
- allows more personal control;
- may provide reassurance; and
- possibility of saving public healthcare resources if testing and treatment conducted privately.

Potential disadvantages

- Costs and harms of obtaining information: a) when tests themselves can be damaging (e.g. through radiation), b) when private testing can undermine equal access to healthcare;
 - costs of consequences of having information: a) for individual when inaccurate or hard to interpret, b) for individual when nothing can be done, c) for individual if inaccurate risk assessments lead to misplaced anxiety (or false reassurance in some cases), d) for individual if results lead to stigma or information abuse (e.g. blackmail) or other effects that may be regretted, given that information once known cannot be un-known (e.g. for insurance declarations), d) for taxpayers when unnecessary follow-up testing and treatment is carried out; and
 - can change perception of wellness and illness through medicalisation of normal variation.
- 10.5 As with taking genetic profiling tests (Chapter 9), having imaging scans has the potential to help people to learn more about their health and thereby take more responsibility for looking after their health and managing their healthcare. In their marketing material, the companies offering scans emphasise this theme, giving the following types of reason for individuals to take up their services:⁵³⁵

“At Lifescan we have helped thousands of people to either gain peace of mind about their health or an essential early warning about serious illnesses.” *Lifescan*

“Most of us accept that early detection leads to better health outcomes, and that more focus on preventive health is beneficial.” *European Scanning Centre*

As with genetic profiling, it may be that simply having body imaging and thinking about health encourages some people to take more interest in their health and live healthier lifestyles than they would otherwise do. But to assess properly any benefits and harms, we need to make some assessment of how useful such tests actually are, which we do in the following section.

Clinical validity

10.6 As mentioned in the previous chapter (Box 9.1), in the UK the National Screening Committee (UK NSC) advises the Government and the National Health Service (NHS) about population screening programmes. It assesses the evidence for introducing screening programmes against a set of criteria covering the condition, the test, the treatment options and the effectiveness and acceptability of the screening programme. Assessing programmes in this way is aimed at ensuring that they “do more good than harm at a reasonable cost”.⁵³⁶ We include a summary of

⁵³⁵ Information correct at the time of writing.

⁵³⁶ NHS Evidence (2010) NHS Evidence – screening, available at: <http://library.nhs.uk/screening/>.

the criteria in Box 9.1. These criteria apply to all screening programmes, whether they are genetic or use imaging. An example of a public health programme that uses imaging is the NHS Abdominal Aortic Aneurysm Screening Programme which uses ultrasound, began in 2009 and is being introduced for all men aged over 65 in England, with the rest of the UK to follow.⁵³⁷ Screening can facilitate early detection of disease allowing earlier, possibly more effective treatment although whether to introduce a programme, and the section of the population that should be targeted, is not without controversy.⁵³⁸

- 10.7 A number of trials involving other types of imaging are being conducted to see whether it can be effective for screening for other conditions.⁵³⁹ There are also studies considering the predictive utility of various scanning modalities. For example, some studies suggest it may be possible to use functional MRI to predict the progression of mild cognitive impairment to Alzheimer's disease.⁵⁴⁰ However, there is currently insufficient evidence to suggest that using CT or MRI as a screening tool reduces disease or mortality.⁵⁴¹ Consequently it has been argued for CT that "four decades after the development of this 'technology', we still do not have experimental evidence for or against the implementation of this screening modality".⁵⁴²
- 10.8 As noted above, the screening programmes provided by the NHS in the UK must meet stated criteria for effectiveness. However, these requirements do not apply to screening tests carried out by private providers, and the value of such tests is contestable. Some doctors and scientists argue that conducting many of the tests available on well people will not accurately predict the diseases they will get; it has been suggested that "the recent increase of direct-to-consumer marketing of screening puts patients at risk of making harmful choices in the absence of adequate guidance and constraints".⁵⁴³ Some authors conclude that, because of the potential harms, MRI scanning (for example) for health check-ups should be used only in research studies.⁵⁴⁴

⁵³⁷ For further information see: NHS (2010) Welcome to the NHS Abdominal Aortic Aneurysm screening programme, available at: <http://aaa.screening.nhs.uk/>. See also: Health Scotland (2010) Abdominal Aortic Aneurysm screening, available at: <http://www.healthscotland.com/topics/health/screening/abdominalaorticaneurysm.aspx>; Public Health Wales (2010) Planning of abdominal aortic aneurysm screening to start, available at: <http://www.wales.nhs.uk/sitesplus/888/news/16431>.

⁵³⁸ Raffle AE and Gray JAM (2007) *Screening: Evidence and practice* (Oxford: Oxford University Press).

⁵³⁹ For example, in 2009, there were seven randomised control trials of low dose CT screening in progress, the largest of which were the US National Lung Cancer Screening Trial and the NELSON trials in Belgium and Denmark. These trials are scheduled to report results in 2012 and 2014, respectively. See: Edey AJ and Hansell DM (2009) CT lung cancer screening in the UK *The British Journal of Radiology* **82**: 529–31; Field JK and Duffy SW (2008) Lung cancer screening: The way forward *British Journal of Cancer* **99**: 557–62; McMahon PM and Christiani DC (2007) Computed tomography screening for lung cancer – results of randomised trials are needed before recommending its adoption *British Medical Journal* **334**: 271.

⁵⁴⁰ Zang B, Li M, Sun ZZ *et al.* (2009) Evaluation of functional MRI markers in mild cognitive impairment *Journal of Clinical Neuroscience* **16**: 635–41; Vemuri P, Wiste HJ and Weigand SD *et al.* (2009) MRI and CSF biomarkers in normal, MCI and AD subjects: Predicting future clinical change *Neurology* **73**: 294–301.

⁵⁴¹ Burger IM, Kass NE, Sunshine JH and Siegelman SS (2008) The use of CT for screening: A national survey of radiologists' activities and attitudes *Radiology* **248**(1): 160–8.

⁵⁴² Field JK and Duffy SW (2009) Lung cancer screening: The way forward *British Journal of Cancer* **99**: 557–62.

⁵⁴³ Burger IM and Kass NE (2009) Screening in the dark: Ethical considerations of providing screening tests to individuals when evidence is insufficient to support screening populations *American Journal of Bioethics* **9**(4): 3–14. See also: Sense About Science (2008) *Making sense of testing: A guide to why scans and health tests for well people aren't always a good idea*, available at: <http://www.senseaboutscience.org.uk/pdf/makingsenseoftesting.pdf>.

⁵⁴⁴ Salman RA-S, Whiteley WN and Warlow C (2007) Screening using whole-body magnetic resonance imaging scanning: Who wants an incidentaloma? *Journal of Medical Screening* **14**(1): 2–4. A parallel issue has been raised by the British Medical Ultrasound Society Council, which has noted that developments in real-time three dimensional ultrasonic imaging have led to some parents asking for souvenir images of fetuses, sometimes at several stages during the pregnancy, without any diagnostic element being involved in scan. The British Medical Ultrasound Society Council notes that little information is currently available on possible subtle biological effects of diagnostic levels of ultrasound on the developing human embryo, but has recommended that ultrasound scans should not be performed solely for producing souvenir images or recordings and has drawn attention to the recommendation of the EFSUMB Clinical Safety Statement for Diagnostic Ultrasound that ultrasound examinations should be performed only by competent personnel who are trained and updated in ultrasound safety matters. See: European Federation of Societies for Ultrasound In Medicine and Biology (2006) *Statement on the use of diagnostic ultrasound for producing souvenir images or recordings in pregnancy*, available at: <http://www.efsumb.org/ecmus/souvenir-scanning-statement.pdf>, approved and endorsed by the British Medical Ultrasound Society Council. See: <http://www.bmus.org/about-ultrasound/au-safetystatement.asp>. Similar guidelines have been issued by American Institute of Ultrasound in Medicine. See: http://www.eurekalert.org/pub_releases/2005-08/aiou-tar081005.php.

Clinical utility

10.9 We have seen some reports sent to patients (and sometimes their general practitioners) following scans that have been carried out by one of the major companies involved. We have a number of concerns about the clinical relevance and meaningfulness of the information provided: (1) the information provided was difficult for a lay person to interpret and advised that they contact their general practitioner without offering any further advice or opportunity for consultation by the company itself; (2) patients without any risks classed as higher than 'moderate' were advised to attend for a repeat annual CT scan without reference to the associated radiological harms (see below); (3) patients were informed of the risk of adverse health problems within the following five years without any advice about how to lessen this risk beyond continuing to live a healthier lifestyle; (4) some of the terms used, such as current risk being 'likely' and the risk of a 'significant' condition, were undefined; and on a slightly different point (5) the qualifications of the people analysing the images was not made clear. We recognise however, that a patient who receives a warning about the risk of a substantial adverse health event may be more likely to take care of their health and live a healthier lifestyle as a result. We make a recommendation aimed at obtaining more evidence about the impact of taking these scans in Paragraph 10.29.

Physical harms of the tests themselves

10.10 One difference between some of the imaging procedures available, specifically CT scans, and the genetic tests considered in the previous chapter is the risk of physical harm resulting from the procedure itself. The radiation dose from a CT scan is clinically significant, and more so for whole-body scans than smaller body sections; evidence suggests that it can lead to an increased risk of radiation-induced fatalities.⁵⁴⁵ A major study in this area by the UK-based Committee on Medical Aspects of Radiation in the Environment (COMARE) reported in 2007 that, if 100,000 people were to undergo a typical whole body CT scan with a dose of 10 mSv,⁵⁴⁶ every five years between the ages of 40 to 70 years, then the estimated impact would be 240 radiation-induced fatalities over this time⁵⁴⁷ – risks that are clearly substantial. However, we note that companies currently do not appear to be offering whole-body CT scans (see Paragraph 10.16). We make a recommendation about warning customers about health risks in Paragraph 10.33. MRI and ultrasound do not use ionising radiation and do not carry physical risks in the way that CT scans do.

10.11 The more of the body that is scanned, and the more frequent the scanning, the higher the risk. The COMARE report concluded: "We recommend ... that services offering whole body CT scanning of asymptomatic individuals should stop doing so immediately. Where scans are offered for a number of discrete anatomical regions within a single scanning procedure, the advertising should clearly state which regions are examined and for which conditions the scan is optimised. In CT scanning it is not possible to optimise exposure parameters for scans of the

⁵⁴⁵ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, p13, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>; Fazel R, Krumholz HM, Wang Y *et al.* (2009) Exposure to low-dose ionizing radiation from medical imaging procedures *New England Journal of Medicine* **361**(9): 849–57.

⁵⁴⁶ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, p13, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>; Kmietowicz Z (2007) Computed tomography screening – Better safe than sorry? *British Medical Journal* **335**: 1182–4.

⁵⁴⁷ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p13.

whole of the body.”⁵⁴⁸ The Committee did not judge any benefits of whole body scanning to be worth the exposure to radiation and other potential harms such as those mentioned below.

10.12 In April 2010, the Department of Health in England announced that it had accepted all the recommendations made in the COMARE report. The Department of Health also requested that the Royal College of Radiologists and the Royal College of Physicians develop “guidance for practitioners based on the balance of risk and benefit involved in the CT scanning procedures concerned.”⁵⁴⁹ No further announcement has been made since the new Government entered office in May 2010.

Psychological harms and harms caused by further investigations

10.13 All types of imaging can result in finding ‘incidentalomas’⁵⁵⁰ – abnormalities without clinical signs or symptoms that are picked up incidentally during imaging. MRI scans are particularly likely to result in such discoveries, especially when using high-resolution MRI sequences.⁵⁵¹ It may of course be that some people are pleased to be informed of the possibility that they may have a serious medical condition. But it may also be that such abnormalities will never in fact cause any symptoms or have simply always been present in the individual concerned. Moreover, if there is no treatment or means of prevention available for the possible ills that the scans might indicate, people receiving this news could suffer from considerable anxiety. One study found that “adverse psychological effects are a common immediate consequence of positive test results following [the] risk assessment” of an illness.⁵⁵² Additionally there is the possibility of a false negative result where, for some diseases that are very difficult to identify using imaging, a patient is given the ‘all-clear’ when in fact there is significant pathology present. There is the risk that they may then stop their healthy behaviours or ignore clinical signs and symptoms they experience. Screening tests carried out in the NHS are accompanied by information explaining this problem. Thus it is important that people who have screening tests understand that the information they will be provided with is subject to error, and we return to this point in our recommendation in Paragraph 10.31.

10.14 Some of the most potentially serious harms could result from people being either advised or wanting to undertake further invasive tests and procedures following an initial body scan. This may, for some people, result in the early identification and treatment for a medical condition. However, invasive procedures always carry an associated risk, and in some cases – such as operations and complications arising thereafter – the risk can be potentially serious. If we remember that a person might be exposed to this risk on the basis of imaging that was not optimised for a particular condition or body part (see Paragraph 10.11) and not clinically indicated (i.e. there are no symptoms), the harm caused could be greater than any benefit. It is this type of consideration that the UK NSC takes into account when considering whether to recommend a screening programme in the NHS: the Committee states that it would not recommend a programme that would produce more harm than good or where there was no effective treatment or intervention available.

⁵⁴⁸ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p52.

⁵⁴⁹ Department of Health (2010) Better protection for patients having ‘MOT’ scans, available at: http://www.dh.gov.uk/en/MediaCentre/Pressreleasesarchive/DH_115243. See also: Department of Health (2010) *Consultation response to the COMARE 12 report: Recommendations on CT scanning of asymptomatic self-referred individuals*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_116721.

⁵⁵⁰ Salman RA-S, Whiteley WN and Warlow C (2007) Screening using whole-body magnetic resonance imaging scanning: Who wants an incidentaloma? *Journal of Medical Screening* **14**(1): 2–4.

⁵⁵¹ Morris Z, Whiteley WN, Longstreth WT Jr *et al.* (2009) Incidental findings on brain magnetic resonance imaging: Systematic review and meta-analysis *British Medical Journal* **339**: b3016.

⁵⁵² Shaw C, Abrams K and Marteau TM (1999) Psychological impact of predicting individuals' risks of illness: A systematic review *Social Science and Medicine* **49**: 1571–98.

Impact on insurability

10.15 Some issues relating to insurability following taking screening tests are similar to those related to genetic profiling. As we noted in Chapter 9, we have been informed by the Association of British Insurers (ABI)⁵⁵³ that insurers ask about tests and investigations carried out (or planned) and not specifically how tests or investigations originated. It is for the insurer to decide whether the information provided is relevant and insurers require full and accurate answers to direct questions for a policy to be valid. Different insurers vary as to the time period covered by their questions, and what they ask for and how they treat it will depend on how relevant they think the information could be to the insurance policy concerned. Some media reports have suggested that insurance premiums could rise as a result of undergoing ‘body MOTs’, including medical imaging services.⁵⁵⁴ We conclude that there may be questions as part of applications for various types of insurance that require the applicant to disclose information relating to imaging tests: not answering or hiding the existence of test results would constitute non-disclosure that could affect the validity of an insurance claim. We return to these issues in the recommendations in Paragraphs 10.31 and 10.33.

Extent of use

10.16 It has proved difficult to find out how many of these types of body imaging tests are being carried out. We wrote to all the major companies operating in this business in the UK asking for information about the scale of their operations but received only one response – which said that information about the company’s number of patients was commercially sensitive and therefore could not be disclosed to us. As with UK genetic profiling companies, we examined the information about UK imaging companies held at Companies House.⁵⁵⁵ The major UK body imaging firms were, according to the most recent filings at the time of our inquiries, either small companies or not currently making a profit.⁵⁵⁶ Whole- (or ‘full-’) body CT scanning was previously being offered in the USA but the two main companies involved have stopped offering this service. In the UK, companies offer scans of various body regions and organs but they do not appear to be offering ‘whole-body’ CT scans.

Current system of interventions

10.17 As in our other case studies, we note that medical professionals working in the UK are subject to a system of responsibility and liability which we summarised in Box 4.1. Therefore any medical professionals involved in providing imaging services will be bound by their own professional standards and the laws of the country they are operating in. In addition to those general provisions, there are other types of intervention applying to imaging services that are briefly described below.

⁵⁵³ Information supplied by the Association of British Insurers.

⁵⁵⁴ One report claims such a premium increase took place after a customer declared the presence of gallstones. See: *Which?* (2009) *Which?* checks up on private health MOTs *Which? Magazine* 1 August.

⁵⁵⁵ Companies House performs a variety of functions, one of which is to “examine and store company information”. Information regarding companies established in the UK are available for a fee. See: Companies House (2010) Our main functions, available at: <http://www.companieshouse.gov.uk/about/functionsHistory.shtml> and Companies House (2010) WebCheck, available at: <http://wck2.companieshouse.gov.uk/c221d2b44f40d1871bd8f703b9ae2db7/wcframe?name=accessCompanyInfo>.

⁵⁵⁶ Defined under s382 Companies Act 2006 as meeting two or more of the following requirements: having a turnover of less than £5.6 million, a balance sheet total of less than £2.8 million and fewer than 50 employees.

Data protection

10.18 We have already summarised the data protection regime earlier in this report (see Paragraphs 5.37–40 and 9.23) and the data protection laws described there apply to providers of body imaging services that are based in the UK and Europe, just as they do to other types of personal data.

Provision of information by providers and advertising

10.19 As we said in Chapter 9, NHS screening programmes are required to provide advisory information to people before they take a test, concerning the risks and benefits, the potential for diagnostic errors and the implications of any subsequent investigations or treatment. However, this information is not required for screening tests offered outside the NHS. If companies meet the general requirements of the advertising standards regime as described in Chapter 5 (i.e. that their advertising is not considered to be misleading) they do not have to satisfy any further legal or self-regulatory standards relating to the information provided prior to sale other than those applying in the general tort law described in Chapter 4.

Regulation of services

10.20 There is no general and complete regulatory framework applicable to private providers of body imaging services for asymptomatic individuals in the UK. Some have argued that those providers are not adequately regulated, such that either regulation in the strict sense used in Chapter 4, or a medical screening code of practice, would be valuable.⁵⁵⁷

10.21 CT scanning is subject to the law relating to exposure to ionising radiation. The Ionising Radiations Regulations 1999 are designed to protect people whose work may expose them to ionising radiation. The regulations aim to “establish a framework for ensuring that exposure to ionising radiation arising from work activities is kept as low as reasonably practicable and does not exceed dose limits specified for individuals.”⁵⁵⁸

10.22 As for people having CT scanning, the Ionising Radiation (Medical Exposure) Regulations 2000 outline the basic protections necessary,⁵⁵⁹ which apply to both NHS and private provision.⁵⁶⁰ The regulations are designed to protect patients from unintended, excessive or incorrect exposure to radiation; ensure that the risk from exposure is assessed against the clinical benefit; ensure that patients receive no more exposure than is necessary to achieve the desired benefit within current technical limits; and protect volunteers in research programmes and those undergoing medico-legal exposures.⁵⁶¹ The Justification of Practices Involving Ionising Radiation Regulations 2004⁵⁶² provided a framework in which decisions relating to the

⁵⁵⁷ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p51; Wald NJ (2007) Screening: A step too far. A matter of concern *Journal of Medical Screening* 14: 163–4; Sense About Science (2008) *Making sense of testing: A guide to why scans and health tests for well people aren't always a good idea*, available at: <http://www.senseaboutscience.org.uk/pdf/makingsenseoftesting.pdf>.

⁵⁵⁸ Health and Safety Executive (2000) *Work with ionising radiation: Ionising Radiation Regulation 1999 – approved code of practice and guidance*, p6, available at: <http://www.hse.gov.uk/pubns/priced/l121.pdf>.

⁵⁵⁹ The Regulations implement Council Directive 97/43/EURATOM on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/446/Euratom [1997] OJ L180/97.

⁵⁶⁰ Department of Health (2007) *The Ionising Exposure (Medical Exposure) Regulations 2000 (together with notes on good practice)*, p1, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh.digitalassets/@dh/@en/documents/digitalasset/dh_064707.pdf.

⁵⁶¹ Commission for Healthcare Audit and Inspection (2008) *Ionising Radiation (Medical Exposure) Regulations 2000: A report on regulation activity from 1 November 2006 to 31 December 2007*, p4, available at: http://www.carequalitycommission.org.uk/db/documents/IRMER_14month_report.pdf. The 2000 Regulations were amended in 2006 by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 which, among other changes, altered some definitions. In 2009, the responsibility for this area passed to Care Quality Commission.

⁵⁶² Which implements elements of Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the danger arising from ionising radiation [1996] OJ L159/96.

justification of exposure to ionising radiation may be made. These decisions involve “weighing the overall benefits of classes or types of practices which might result in the exposure of people to ionising radiation against the harm likely to be caused by the radiation exposure”.⁵⁶³ Against this legal background, CT whole-body scanning of asymptomatic individuals in particular seems hard to justify.⁵⁶⁴ We return to these issues in our recommendations in Paragraphs 10.26 and 10.27.

Softening the ethical dilemmas

- 10.23 The evidence reviewed in this chapter indicates that offering body imaging directly to people who do not have any apparent medical need presents some distinct problems. As we have noted, there are potential benefits, including the possibility of people being better informed about their state of health if they want to be, and of being prompted to make healthier lifestyle choices. Imaging tests will also sometimes reveal information that is valued by, or useful to, the customer and reveals serious conditions that would not otherwise come to light and which can be acted upon. However, when looking at the risks at the population level, we consider the potential for harm to be large, including as it does the radiological risk for CT scans, and the harms associated with false negatives and positives, finding ‘incidentalomas’ that may never cause any clinical symptoms, finding features that are likely to cause clinical symptoms but there being no treatments available, and finding features that lead to people having invasive further testing or procedures that themselves carry risk.
- 10.24 In these circumstances we face several conflicts between the ethical values we set out in Chapter 3. We attempt to reconcile the value of individuals being able to pursue their own interests in their own way (namely to have the freedom to take these tests should they wish) with that of reduction of harm by state activity. We consider that the radiological risk that arises from one type of imaging, namely whole-body CT scans, is sufficient to justify the introduction of coercive state powers to prohibit the provision of such services. For other types of imaging, including part-body CT imaging, the risk-benefit ratio is unclear, and on the basis of our other ethical values we recommend measures that we think will improve the quality of the services and give consumers better information. These measures are: (i) independent research on the impact and effects on individuals of direct-to-consumer body imaging provided as a health check; (ii) appropriate regulation of services; (iii) better provision of information, and (iv) good professional medical practice in the public healthcare system adapted to the situation where patients have had these tests.

Physical harms of CT scanning

- 10.25 As noted above, CT scans carry serious physical risks from the radiation involved, especially when whole-body scans are involved and when carried out on repeated occasions (see Paragraph 10.10). Whole-body CT scans do not appear to be on offer at present from private companies in the UK, and we do not consider the harms to be outweighed by any benefits they might offer. In this case we consider the harm serious enough to justify the use of coercive state powers, according to the proportionality principle discussed in Chapter 4.
- 10.26 **We recommend that the commercial sale of whole-body (full-body) CT imaging sold as a ‘health check’ to asymptomatic individuals should be prohibited. Any benefits for asymptomatic people do not justify the potential for harms caused as a consequence. Although there is a common law negligence framework that applies to harms caused by**

⁵⁶³ Department for Environment, Food and Rural Affairs (2004) *Explanatory memorandum – the justification of practices involving Ionising Radiation Regulations 2004*, available at: http://www.opsi.gov.uk/si/em2004/uksiem_20041769_en.pdf.

⁵⁶⁴ Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, available at <http://www.comare.org.uk/documents/COMARE12thReport.pdf>, p52.

these services as with others, it is difficult to use this legal remedy because a claimant would need to prove that damage had been caused by a particular service. Therefore we think legislation for whole-body CT scans is required and proportionate to potential harm. Any such legislation should also cover attempts to carry out various part-body CT scans on the same day or in close proximity. Legislation would need to be kept under review were the risk-benefit ratio to change.

- 10.27 With regard to part-body CT scans, we recommend to providers that the carrying out of these on asymptomatic people should be governed by the best-interests principle, applied for each customer. We do not consider there is sufficient evidence to prohibit these scans.

Information available to customers

Research and information provided by public healthcare systems

- 10.28 As with genetic profiling (Chapter 9), there is a lack of evidence on the effects on people of undergoing direct-to-consumer body imaging, in terms of either their health behaviour or their psychological health (see also Paragraph 10.13–10.14). We therefore make a similar recommendation to the one in the previous chapter (Paragraph 9.47) based on the fact that, if people are to be able to pursue their own interests in their own way, they need good information about services they might consider purchasing.

- 10.29 **We recommend that independent research on the health benefits, psychological harms and harms resulting from any follow-up procedures of direct-to-consumer body imaging when offered as a health check should be carried out by public healthcare systems. Such research should involve investigation into how many people are purchasing this type of service. The results of this research should be made easily accessible. We recognise this information will need updating periodically if technical or other developments change the level of risks or the potential for finding out useful information. Potential buyers could then better assess the impacts they might expect, whether positive or negative. In the UK the National Institute for Health Research could be best placed to fund and commission this research.**

- 10.30 As mentioned in Paragraph 10.19, the information provided by commercial companies to consumers of body imaging sold as a health check, either in advance of purchase or after the imaging has been done, is not subject to any formal regulation or self-regulatory code, other than through the advertising standards regime and through the general law of tort and delict in the UK and elsewhere. As with genetic profiling for disease susceptibility, we are concerned that it is difficult for people to find out general information about these body imaging services from an independent source (i.e. from somewhere other than the companies themselves). Such general information about other commercial sector services is available from government sources, for example (see Paragraph 9.48). Provision of such information would serve both to enable people to pursue their own interests in their own way and to prevent harm by state activity.

- 10.31 **We recommend that appropriate publicly-funded health service websites should include general information for the public about body imaging services offered by commercial companies directly to the consumer for people without symptoms. This information should include details of:**

- **potential risks and benefits, including the possibility of further interventions being recommended and their implications;**
- **how imaging might not be optimised for analysing all conditions;**
- **the difficulties of interpreting these tests without reference to clinical symptoms;**
- **the possibility of finding out about conditions for which treatment is not available; and**

- whether it could be necessary for consumers to inform life, mortgage or travel insurance companies of the results of any tests, either at the time or in the future.

We further recommend that governments should require details about where to find this information to be included in the advertising and information provided by companies selling body imaging services directly to the consumer as a health check in their countries (see also recommendation in Paragraph 10.33).

Information provided by commercial providers

- 10.32 As with genetic profiling services (Chapter 9), the information on some body imaging providers' websites and in their promotional information gives the impression that only useful information can be gained from taking these tests. This impression is conveyed particularly in the 'customer testimonials' that are provided. However, we do not find this information comprehensive.⁵⁶⁵ Potential customers would be better able to make informed choices if these companies were to provide better information about the services they offer, indicating both how those services can be useful and what their limitations are. We recommend a two-pronged approach: governments should provide independent general information as set out above, and the providers themselves should make available specific information relating to their services.
- 10.33 **We recommend that all companies that provide direct-to-consumer body imaging for asymptomatic individuals should make the following information prominently available in lay language to the consumer before they buy:**
- the operator of the services;
 - information about the evidence on which interpretations of the test results are based;
 - the tests' limitations;
 - the price and what the cost covers;
 - the specialism of the person analysing and reporting the imaging results;
 - the proportion of all those having body imaging who are advised to undergo further imaging;
 - the possibility of further interventions being recommended and their implications;
 - the average interval recommended between imaging;
 - any physical or other harms or risks of the imaging procedure (including relating to the radiological risks of CT scans depending on how much of the body is scanned);
 - information about the possibility of finding serious health problems and how 'bad news' will be broken;
 - the nature of the risk (absolute or relative) being communicated to the consumer;
 - advice about whether it might be necessary for consumers to declare any results they receive as a result of the imaging to mortgage or travel insurance companies;

⁵⁶⁵ See also: Committee on Medical Aspects of Radiation in the Environment (2007) *Twelfth report – the Impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*, p51, available at: <http://www.comare.org.uk/documents/COMARE12thReport.pdf>.

- which other third parties, if any, have access to the information/data;
- arrangements for data security (including in cases of any changes to the administration of the company); and
- where to find independent information about this type of service on public healthcare service websites (see our recommendation in Paragraph 10.31).

Regulation of imaging services

10.34 In the UK, a number of statutory bodies regulate health services,⁵⁶⁶ whether provided by the NHS, local authorities, private companies or voluntary organisations (see Box 4.1). However, because the imaging scans on which this chapter focuses do not involve interventions or treatment, the services are not currently subject to any regulatory provisions other than those applying to the safety of the ionisation technology. The distinction between being a ‘health’ service or not does not appear relevant when imaging is sold on the basis of being able to provide health information.

10.35 **We recommend that commercial companies that sell imaging tests directly to consumers should be regulated by an appropriate legally constituted regulator such as the Care Quality Commission in England, the Scottish Commission for the Regulation of Care, Healthcare Inspectorate Wales and the Northern Ireland Regulation and Quality Improvement Authority, to ensure services are meeting established standards of quality and safety. We further recommend that the regulator should require the companies involved to provide the information that we recommend in Paragraph 10.33.**

Impacts for public healthcare system

10.36 We observed in the previous chapter on personal genetic profiling for disease susceptibility that the availability of these services could have implications for publicly-funded healthcare systems. Our consultation respondents informed us that patients who had undergone commercial body imaging as a health check were often also reporting to their general practitioner (GP) for advice and follow-up. A survey of 260 GPs by *Pulse* magazine supports this finding.⁵⁶⁷ We have seen the results from one of the major companies offering imaging in the UK in which the client is encouraged to consult his/her GP. As we explained in the previous chapter, this situation involves a dilemma between our ethical value of solidarity (risk pooling and helping the vulnerable) and that of using public resources fairly and efficiently. We think it would not be appropriate for a public healthcare system to turn away people who were worried about their health as a result of a privately bought body imaging service. If the information provided as a prerequisite to taking the tests were more comprehensive (as we recommended above, see Paragraph 10.33), we would expect the impact on primary care doctors in the public healthcare system to be reduced.

10.37 **We recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals about best practice in the areas of giving advice about direct-to-consumer body imaging services offered as a health check: recognising their value as a tool for discussing healthier lifestyles, addressing their limitations, and taking a responsible position with regard to when to refer patients for specialist services.**

⁵⁶⁶ The Care Quality Commission in England, the Scottish Commission for the Regulation of Care, Healthcare Inspectorate Wales and the Northern Ireland Regulation and Quality Improvement Authority.

⁵⁶⁷ The survey reports that “Four GPs in five reported seeing patients who have requested treatment for suspected problems uncovered by private screening.” The survey also reported that 46% of the respondents thought that the NHS should pay for the cost of follow-on treatment. See: Anekwe L (2009) Investigation: GPs cope with fallout from private screening explosion *Pulse* 24 June, available at: <http://www.pulsetoday.co.uk/story.asp?storycode=4123069>.

Safeguarding private information

- 10.38 Companies that provide imaging services hold personal information about their consumers. Consistent with the value of safeguarding private information, we think providers of these services should take seriously their responsibilities about transferring and holding private information. Even if a company guaranteed security, if it went into administration or changed hands, there is no guarantee that the data held would be secure.
- 10.39 **Body imaging companies should provide details about what would happen to body imaging data should the company go into administration or change hands in the information available to consumers before they buy (see also our recommendation in Paragraph 10.33). Healthcare regulators, such as the Care Quality Commission in England, should include a requirement to this effect for companies in their regulation requirements (see our recommendation in Paragraph 10.35).**

Future impact

- 10.40 It is difficult to predict how popular direct-to-consumer body imaging services will become given the lack of information about the size of the industry at the moment. But the volume of scientific research on the use of body imaging techniques for screening for diseases suggests that new commercial applications may well become available in the future, and the more commercial applications develop, the more impact we can expect on public healthcare services. More evidence about the way people respond to body imaging could help both to guide interventions relating to commercial applications and to shape the development of state-funded programmes.

Chapter 11

Conclusions

Chapter 11 – Conclusions

A summary of our analysis

- 11.1 We began this report by outlining the new possibilities presented for healthcare by the six elements of medical profiling and online medicine that we have examined, and identifying consumerisation and responsabilisation as two major areas of ethical challenge associated with these developments. We noted that some influential groups – enthusiastic researchers, politicians and commercial companies – have portrayed the developments, especially new forms of testing and scanning, as heralding a new era of personalised, predictive and preventive healthcare.
- 11.2 The possibilities are exciting, even if these new developments, particularly in genomic medicine, have yet to deliver on many of the claims about health benefits that have been made for them. But the beguiling and much-used term ‘personalisation’ is ambiguous. At the outset of this report, we identified four different meanings that we considered to be important for our analysis (Paragraph 1.18). Those meanings were: individualised or tailored diagnosis and treatment, ‘whole person’ treatment, consumerised provision and provision for which responsibility is laid on patients or their carers. It is because of this combination of beguiling attraction and considerable ambiguity that we have used the term personalisation with caution throughout this report.
- 11.3 Table 11.1 relates those four different forms of personalisation to the six cases we have explored in this report. The Table shows that all of the four types of personalisation identified in Chapter 1 apply, at least in principle, to some of our case studies and some of those four types apply to all of them. But as Table 11.1 notes, in several cases the potentially personalising effect has not been realised to any great extent, and in other cases we show that any personalising potential is not inherent in the technology, but depends on how it is used. Indeed, some of the applications of these developments are potentially de-personalising in at least one of the four senses we have identified, for example if drugs are purchased online without individual diagnosis and prescription. And in many cases, such as telemedicine, the personalising or de-personalising effect of these developments is ambiguous and contestable rather than clear-cut.
- 11.4 Our second chapter argued that the confluence of social changes and technological developments (of which the six cases considered in this report are important examples, but by no means the only ones) provided scope for increased consumerisation and responsabilisation of healthcare, involving greater personalisation in two of the senses we identified in Chapter 1. We noted that the developments with which we are concerned could change the balance of emphasis among the roles of patient, citizen and consumer in the way that individuals relate to the provision of healthcare. One way in which this could happen is through the potential those developments offer for ‘unpooling’ health risks that have hitherto been pooled across whole populations through social insurance schemes or public provision of medical and healthcare services.

Table 11.1: The six case studies and the types of personalisation they involve

	Type of personalisation			
	Increasing individualised diagnosis etc.	Increasing 'whole person' treatment	Increasingly consumerised provision	Increasing responsibility on individuals
Online health information	Only up to a point – often sorts people by groups (e.g. in patient websites) rather than as unique individuals	Possibly, insofar as it can make it easier for individuals to choose information sources that align with their individual worldview	Yes	Yes, if people decide to/ are expected to seek health advice online and take responsibility for their care without seeing health professionals
Online personal health records	Not of itself, but may be conducive to that outcome	Not of itself, but may be conducive to that outcome	Potentially yes, but little market competition as yet in UK	Yes, if people decide, or are expected, to keep records or check their accuracy
Online purchasing of pharmaceuticals	Not necessarily, especially if professional diagnosis is absent or limited	No	Yes	Yes, if people are more responsible for making choices and managing risk (e.g. fake drugs)
Telemedicine	Only if it does more than substitute for traditional face-to-face diagnosis or treatment.	Not of itself, but may be conducive to that outcome	Yes to some extent, and may go further as consumer telemedicine markets develop	Yes, if people are more responsible for compliance with treatment, managing severe conditions at home, or responding to warning signs
Personal genetic profiling for disease susceptibility	In principle yes, but predictive power still limited and often sorts people by risk groups	No	Yes	Yes, if part of an expectation that people play an active role in trying to predict and prevent disease or ill-health
Direct-to-consumer body imaging	Yes, where results are meaningful	No	Yes	

11.5 Our view is that the confluence of technological development and social behaviour is not eliminating any of those different roles – in countries like the UK, individuals are still, in different contexts, patients, citizens and consumers in relation to healthcare – but it may be redefining their content and boundaries in several ways. As we noted, those changes correspond to political visions of a new kind of citizenship involving individuals taking a greater share of personal responsibility for their health and wellbeing. They also resonate with the wish to 'empower' individuals vis-à-vis professionals, with the development of new kinds of relationships between patients, medical professionals and the state, with the growth of online groups defined by their health problems, exchanging information that can change doctor-patient relationships,

and mobilising for priority to be given to their conditions by governments and corporations, as in the growth of what has been termed genetic or biomedical citizenship (see Paragraph 2.22). They offer new possibilities for individuals to behave as consumers in the purchasing of drugs and other healthcare products and services as commodities via the internet, and provide new market niches for international corporations that may have an impact on traditional healthcare provision in public healthcare systems like the National Health Service.

11.6 Table 11.2 shows how issues of consumerisation and responsabilisation arise in the six cases we have examined. It suggests that in every case there is some potential for increased consumerisation in the relationship between users and providers, and that there are also important issues of 'responsibilisation' in every case, as a result of a different balance between medical professionals and individuals or their carers in making decisions, managing their care and handling risks that can be hard to interpret. Both of those developments raise ethical issues. For example, there are potential social spillover effects from individual consumer choices, and individuals may be faced with responsibilities for making judgments or decisions for which they may be ill-prepared, particularly if they have been exposed to advertising and marketing of the type illustrated in earlier chapters that does not give balanced information about risks and benefits.

Table 11.2: Consumerisation and responsabilisation in our six case studies

	Consumerisation	Responsibilisation
Online health information	In principle, more user-friendly than older sources of health information because of online search facilities, but often with no quality check on the information provided and presenting major challenges to individuals in interpreting what they find online.	In principle, can facilitate health literacy and promote online interaction with people with the same condition, potentially offering a counterweight to error and incompetence by medical professionals. May also lead to people having to make decisions by themselves without consulting a healthcare professional face-to-face.
Online personal health records	In principle, offers alternatives to traditional monopolies with possible choice of packages in the future, and allows individuals to access their online records at their own convenience.	In principle, can allow patients more ownership and some editorial control over their health records, but may increase expectations that patients are responsible for checking their records, and liability issues could arise (for malpractice etc.) over who has control of such data.
Online purchasing of pharmaceuticals	Allows purchasers to bypass healthcare professionals and local price and supply controls by buying direct on world markets, with potential positive and negative spillover effects, such as reduction in prices and more population resistance to antibiotics.	Individuals choosing to purchase pharmaceuticals directly face the issue of how to handle the risk of buying fake or low-quality pharmaceuticals or of experiencing adverse reactions.

	Consumerisation	Responsibilisation
Telemedicine	In principle allows consultations etc. across jurisdictions. Some telemedicine systems are available for consumer purchase now and the market may grow, but many of the patients concerned (e.g. elderly people) are likely to find difficulty in exerting direct consumer choice.	Can put more responsibility on patients and their carers to manage their own care away from an institutional setting, for example by earlier discharge from hospital or when choosing to remain at home rather than receive institutional care.
Personal genetic profiling for disease susceptibility	Individuals who are able to pay can access many genetic tests on demand from online providers anywhere in the world without going through any professional gatekeeper such a genetic counsellor.	Can put more responsibility on individuals to interpret complex risk data, face the consequences for themselves or their families, and make appropriate changes to their lifestyle, as well as enabling further risk 'unpooling', notably through obligations to inform insurers.
Direct-to-consumer	Asymptomatic individuals who are able to pay can access body imaging services.	Can put more responsibility on individuals to interpret complex and ambiguous data and weigh up risks of further treatment (preventive surgery etc.) on the basis of that data.

A summary of our responses

- 11.7 In Chapter 3 we explained that our general ethical approach was to examine each of the six elements of medical profiling and online medicine to identify possible conflicts among five ethical values that we see as important for making decisions in the areas covered in this report (namely safeguarding private information, individuals' being able to pursue their own interests, the value of efforts at harm reduction by the state, fair and efficient use of public or collective resources, and social solidarity).
- 11.8 Table 11.3 summarises how we applied this approach to the six cases we have explored, indicating where the values we have identified potentially come into conflict and thus create dilemmas. The Table is intended to be illustrative rather than exhaustive, but it shows that potential conflicts among those values are not an abstract possibility or a rare occurrence: such conflicts can be identified for each case we have considered here, as we have also shown in Chapters 5–10. One example (in Chapter 7) is the stark conflict between the value of allowing individuals to purchase the drugs they think will work best for them and the value of state activities designed to reduce potentially serious harm from inappropriate or fake drugs.⁵⁶⁸ Another example (in Chapter 6) is the conflict between allowing people to reap the benefits of having their own online health records and the value of safeguarding private information from being used in ways that people may not readily anticipate.⁵⁶⁹
- 11.9 As we said in Chapter 3, rather than trying to deal with value conflicts by ranking the values in terms of importance, we attempted to deal with such conflicts by assessing the potential risks of harm within each case study and the seriousness of the dilemmas in each case. Since we do not believe any one of these values automatically trumps all others, we then aimed to find ways

⁵⁶⁸ That is, between (b) and (c) in the online purchasing of pharmaceuticals row in Table 11.3

⁵⁶⁹ That is, between (a) and (b) in the online personal records row in Table 11.3.

of dealing with each of the six cases that achieved as much as possible of each of these five values, while also taking feasibility into account. Thus we attempted to suggest ways to ‘soften’ or manage the dilemmas by means of intervention by the state or by third parties.

Table 11.3: Applying the ‘softening dilemmas’ approach to our case studies

	Our five important ethical values				
	(a) Safeguarding private information	(b) Individuals being able to pursue their own interests	(c) State action to reduce harm	(d) Fair and efficient use of public resources	(e) Social solidarity
Online health information	Potentially conflicts with (b) and (e)	Potentially conflicts with (a) and (c)	Potentially conflicts with (b)		Potentially conflicts with (a)
Online personal health records	Potentially conflicts with (b) and (e)	Potentially conflicts with (a) and (c)	Potentially conflicts with (b)		Potentially conflicts with (a)
Online purchasing of pharmaceuticals		Potentially conflicts with (c), (d) and (e)	Potentially conflicts with (b)	Potentially conflicts with (b)	Potentially conflicts with (b)
Telemedicine		Potentially conflicts with (c)	Potentially conflicts with (b) and (d)	Potentially conflicts with (c)	
Personal genetic profiling for disease susceptibility	Potentially conflicts with (b), (c) and (e)	Potentially conflicts with (a), (c), (d) and (e)	Potentially conflicts with (a) and (b)	Potentially conflicts with (b) and (e)	Potentially conflicts with (a), (b) and (d)
Direct-to-consumer body imaging	Potentially conflicts with (b) and (c)	Potentially conflicts with (a), (c), (d) and possibly (e)	Potentially conflicts with (a) and (b)	Potentially conflicts with (b) and (e)	Potentially conflicts with (b) and (d)

11.10 In Chapter 4 we examined different possible types of intervention by the state or third parties, arguing that a proportionality rule was needed to avoid the conclusion that everything that was not prohibited ought to be compulsory. We identified four major types of intervention. On the one hand, we distinguished between measures that could legally be carried out by any individual or corporation and those that required the special legal powers specific to the state in all its various forms (to punish, permit, require or prohibit). On the other hand, we distinguished between measures that affected general governance (e.g. trading standards rules) and those that were product- or service-specific. We examined what general existing interventions applied to the six cases explored in this report, and argued that proportionality considerations led to two presumptions. One presumption was that interventions should wherever possible (i.e. when there was no evidence of serious harm) use measures that did not involve the special legal powers of the state. The second presumption was that priority should be given to measures that were not product- or service-specific unless the more general measures were clearly inadequate to deal with the harm involved. We also argued that considerations of effective enforceability might sometimes govern the choice of types of intervention.

11.11 Table 11.4 shows how we applied this analysis to the six cases considered in this report. It summarises the interventions we believe should be added to existing measures in each of the cases, to satisfy as much as is possible of the five values identified in Chapter 3 as well as meeting the feasibility criterion mentioned above. The full list of our recommendations can be found in Appendix 1. As the Table indicates, we were able in a few cases to find general forms

of intervention that satisfied our criteria – particularly professional adaptation to the new technologies and their social effects by the medical profession. But in many cases we have gone beyond that to make recommendations that are specific to the products and services involved.

- 11.12 As Table 11.4 shows, many of our recommendations are addressed to the providers of the new technologies and services, and seek to show how they can satisfy the ethical values we have set out. We recognise that healthcare providers have adapted their practice to numerous technological and social changes in the past, and we believe such providers, and particularly primary care doctors, can and should be able to adapt to the developments we discuss without fundamental change to the established fiduciary relationship between patients and medical professionals and the other established norms that govern the doctor-patient relationship.
- 11.13 Where we saw a role for government, it was in most cases one of monitoring, promoting research to fill information gaps about harms and benefits, and providing information and education, rather than application of the state's specific legal powers of permission, compulsion, prohibition and punishment. However, for a few of the problems we have discussed here, we found that increased application of the state's legal powers was both feasible and justified by the harms involved.

Table 11.4: Summary of recommendations from the six case studies of this report (for full list see Appendix 1)

Types of intervention	Not requiring state-specific legal power		Requiring state-specific legal power	
	General	Product or service-specific	General	Product or service-specific
Online health information	Professional adaptation	Best practice by providers Third-party accreditation Government provision of high-quality information Government monitoring of impact of 'digital divide'		
Online personal health records		Better provision of information by providers Appropriate security and confidentiality systems Government introduction of accreditation scheme		
Online purchasing of pharmaceuticals	Professional adaptation	Direction of users to registered online pharmacies by providers of online personal health records Government monitoring and assessment of possible harms, including antibiotic resistance Government provision of information		Government quality-control processes (e.g. registration of online pharmacies) Government setting and enforcement of regulations relating to supply of antibiotics
Telemedicine (TM)	Professional adaptation Requirement for cost-effectiveness criteria	Evaluations by healthcare providers, including the impact of TM on doctor-patient relationship Third-party promotion of TM networks in developing countries Health service monitoring of impacts of outsourcing TM services to developing countries	Clear procedures for cross-border liability in healthcare	
Personal genetic profiling for disease susceptibility	Professional adaptation	Better provision of information by providers and government Appropriate security and confidentiality systems Voluntary code of practice for direct-to-consumer provision Warning of requirement of Human Tissue Act 2004 for consent Funding for research on the impact and effects Justification requirements when testing children's DNA		Request for evidence by relevant authorities for clinical claims made
Direct-to-consumer body imaging	Professional adaptation	Better provision of information by providers and government Appropriate security and confidentiality systems Funding for research on the impact and effects Part-body CT imaging should use best-interests criteria		Prohibition of whole-body CT imaging Regulation of services

Some cross-cutting issues: personalisation, consumerisation and responsabilisation

11.14 Many of the developments identified in this report are linked to the development and use of the internet, which provides new sources of information, new marketplaces and new arenas for social and political action over healthcare, as members of particular disease groups organise to exchange information and lobby for priority to be given to their own conditions when it comes to research and funding. There is, as we have already argued, much to be said for many of these developments. They can serve to empower individuals in their relationships with medical professionals, establish new lines of defence against medical error, and provide valuable opportunities for diagnosis, monitoring and treatment of individuals at home, before, instead of, or after hospital admission. But those developments also throw up some perplexing challenges: about how individuals can assess the quality of the information provided to them and the products offered; about how governments and other bodies can manage the spillover effects arising from individual behaviour on the internet (for example in the population effects of individual purchases of antibiotics); and about how the state and other actors can balance the responsibilities laid on individuals in a world of online medicine, as against those responsibilities that have traditionally applied to medical professionals and other actors. Indeed, three cross-cutting issues relating to personalisation, consumerisation and responsabilisation have run through this whole report. Each of those issues merits a brief concluding discussion here.

(a) Personalisation

11.15 As we noted at the outset, the term ‘personalised healthcare’ has become a slogan to point to what some consider a new paradigm in medicine: but as we saw in Chapter 1, the term is ambiguous, with at least four separable meanings. As Table 11.1 shows, most of the developments in medical profiling and online healthcare we have considered seem to have had a limited effect of increasing personalisation in the sense of more individualisation of diagnosis and treatment. In some cases they have led to consumerisation of healthcare products and services. Further, those developments have at least a strong potential for laying increased responsibility – in the sense of both power and obligation – on individuals for their own current and future health status.

11.16 We conclude that many of the current claims for personalisation in diagnosis and treatment seem to be overstated and therefore should be treated with caution. In most cases, information provided by imaging or genetic profiling does not convey useful or medically appropriate information for asymptomatic individuals and may even be inaccurate. At the most, it may suggest further investigations to interpret the findings in the light of the individual’s particular biography, medical history and circumstances. Any such further investigations may not be without risk, and in one case, that of CT scanning, the procedure itself involves risk from the radiation involved. Further, in most cases the information provided does not, as is often implied, allow precise prediction of a future disease for a particular individual. Rather, individuals are allocated to a risk group whose members have an increased or decreased statistical probability of developing a disease across a lifetime. Often the multiple environmental and other circumstances affecting these probabilities remain unknown, and the information given mandates no specific treatment or therapy prior to the development of symptoms.

11.17 That is why, in the present state of knowledge, we think such reservations and limits should be made explicit in commercial services offering such risk assessments and treatment predictions. After all, information, even if inaccurate, once known cannot be un-known. In line with our approach of attempting to soften dilemmas arising from conflicting values, we have tried to recommend measures that retain individual choice but improve the information on which choice can be exercised. However, we consider that ‘personalisation’ in the sense of more individualised diagnosis and treatment is not, as often portrayed, an unalloyed good, and that careful development of policy and practice is required to reap the maximum benefits from

technological advances in medical profiling and online medicine, while minimising the individual and social costs and harms these developments potentially embody.

(b) Consumerisation

- 11.18 The social and public healthcare insurance systems that developed in Europe in the late nineteenth and twentieth centuries were grounded in the assumption that there was a shared risk of unforeseen events across each member of the insured population, and that hence risk should be pooled, and all should bear a portion of the cost that might fall equally on any one individual. In public schemes for health insurance, as opposed to private health insurance, no one was excluded because of prior conditions or unsuitable lifestyles (though treatment in some cases was rationed in ways that took such conditions into account), or had to pay additional premiums because of higher risks, for example family history. Predictive and personalised health information based on medical profiling potentially poses a challenge to this principle of equity and shared risk. The implications will be different for private, commercial health insurance systems and for publicly-funded universal healthcare systems such as the UK's NHS.
- 11.19 In the case of public healthcare systems, such as the NHS, which run alongside private health insurance systems, the development of new commercial medical profiling services poses potential 'spillover' effects, producing a form of 'moral hazard'. That is, individuals who are rendered uninsurable on the private market as a result of predictive health information arising from medical profiling have to rely on public healthcare for treatment or care for those conditions. Moreover, individuals who obtain information about health status from private companies, or on the internet, may place additional burdens on public healthcare professionals, for example in the form of expensive follow-up testing to confirm or deny commercially obtained results. Where public healthcare resources are limited, those burdens inescapably lead to fewer resources for others.⁵⁷⁰
- 11.20 For some who consider the ethical principle of social solidarity through risk-sharing to be the essential foundation of a universal health service, the development of consumerisation that further individualises health risk and the tailoring of treatment – from 'patients like us' to 'patients like me' – is to be regretted as a fundamental threat to such a principle. Others see moves towards more consumerised services (for example in choice of provider or ability to mix public and private treatment) as a necessary condition for publicly provided healthcare systems to survive in the sort of changing social context we sketched out in Chapter 2. And as we have noted, new forms of collectivity are also developing through online social networking to bring together new groupings of active individuals into networks of association around diseases or health conditions. The ethical implications of these new networks have yet to be fully assessed, but merit further work and thought.

(c) Responsibilisation

- 11.21 In principle it seems hard to object to the proposition that individuals should take a share of the responsibility for managing their health status, and that more information about their current health and about future risks can assist them in doing so. Indeed, as we mentioned in Chapter 2, such a proposition is consistent with increasing emphasis on individual autonomy and choice across many areas of society in recent decades, often described as 'empowerment' of individuals and linked to suspicion of too much power being vested in anonymous officials, bureaucratic public services, or autocratic professionals. In Chapter 2 we discussed the distribution of responsibilities among patients, healthcare professionals and providers of other aspects of healthcare, and we summarised that distribution of responsibilities in Box 4.1 in Chapter 4.

⁵⁷⁰ We do not have information about the kind of individuals who might be most adversely affected by such spillover effects; it is possible that those who are most affected by this impact on resources are those with lower socio-economic status, given that they may not choose to purchase these new services from private providers.

- 11.22 Much more difficult is the issue of what the scope and limits of responsabilisation should be. There are numerous practical limits to the ability of the new developments in medical profiling and online medicine described here to contribute to greater responsabilisation, for reasons we have referred to in several places in this report. For instance, the claim of the new medical profiling technologies is that they can produce a move from epidemiological or group-based predictions of health risk to individual ‘personal’ predictions, but as we have seen there are limits to such a development. First, not all predictive information is accurate, so there is a danger of individuals making decisions on the basis of partial, changeable or false information.⁵⁷¹ This is why we make recommendations that are aimed at enabling people to take more responsibility if they want to do so, for example in accreditation to help them to identify good-quality websites. Further, predictive information about future disease, even if accurate, may not be amenable to preventive action by individuals, or even by healthcare professionals, and such a gap between diagnostic and therapeutic capacities presents sharp dilemmas of many kinds. Predictive information about the health status and disease risk of children also raises serious ethical concerns, given its potential to transform children’s self-perception and the way others see and treat them.
- 11.23 Indeed, the developments in medical profiling with which we have been concerned here could lead to a world in which the combination of a stress on individual responsibility and incompletely predictive information served to generate and exacerbate continuous low-level anxiety about health and illness, though we are not aware of empirical evidence of such a development as yet. If the new scanning and testing technologies reveal, as they tend to do, that ‘the normal is rare’ – that is to say, if everyone has some abnormalities and potential health risks – more people will come to face difficult decisions about potentially drastic preventive action (such as precautionary mastectomies) on the basis of ambiguous or imperfect information, or even to feel they are to blame for health outcomes over which they have no real control. Of course such issues are anything but new in medicine, but the developments in testing and scanning with which we are concerned here seem likely to make them more widespread, particularly if those developments occur in a context of increasingly defensive medicine when medical experts may be under pressure to put the onus of choice and risk assessment onto patients. If they serve to bypass expert mediation by family doctors, these new technologies may even turn out to have the potential to ‘de-personalise’ rather than personalise in some important ways. The risk those developments pose is of a world in which patients and their families struggle to cope with the consequences of accelerated discharge from hospitals or services, with reduced ‘face time’ with healthcare professionals and with increasing demands and responsibilities to manage their own healthcare in ways for which (particularly in the rapidly ageing societies of the developed world) they may feel ill-equipped, and to understand data that is ambiguous or unreliable. Not all of that social risk is readily amenable to feasible intervention, but our recommendations are designed to mitigate it.
- 11.24 The well-known and important principle that responsibility for handling risk should be placed in the hands of those best placed to manage it because of the knowledge or other resources available to them (for example adults rather than children) can be applied to this issue to some extent.⁵⁷² For example, it can be argued that in some cases the party best placed to manage that risk is the state (in areas such as ensuring provision of clean water and other types of public health measures), in some cases the medical professional (in areas such as treating an incapacitated or unconscious patient), in other cases the individual (in areas such as lifestyle). But that principle does not seem to offer an unambiguous solution for the problem at hand,

⁵⁷¹ This danger may be exacerbated when the information providers concerned are commercial for-profit organisations whose business model depends on a strategy for increasing their customer base.

⁵⁷² This principle is commonly associated with the well-known US Judge Learned Hand, who argued that legal liability for negligence in causing injury should lie with those who face the lowest costs in preventing it or have the greatest capacity to do so. Judge Learned Hand’s argument remains important, even though it has been much criticised for its ambiguity in practice. See: Posner R (1986) *Economic Analysis of Law*, 3rd edition (Boston: Little, Brown), pp147–51.

because many health outcomes may not be best managed by any one single actor, but rather by co-production among two or more actors. Another reason why the principle does not provide such a solution is that individuals plainly vary in their ability (as well as their predisposition) to assume responsibilities for managing their health in the ways assumed by some of the more zealous advocates of a new age of individual responsibility for health through the medium of modern medical profiling and online healthcare. Some 'expert patients' are well-placed and eager to assume such responsibilities, with all the complex information-processing, evaluation and management demands this can entail. But other people are much less so. While some of the difficulties associated with exercising such responsibility can no doubt be mitigated by measures that aim to 'bridge the digital divide' and increase ease of access to online information, not all such difficulties can be removed by these measures, where different worldviews or cultural biases are involved.

11.25 Accordingly, we think the 'responsibilisation' challenges thrown up by the developments in medical profiling and online healthcare we have considered make the conduct of expert gatekeepers and primary healthcare advisers all the more important in striking the right balance between responsibilisation and paternalism for each individual. Of course good medical professionals have always had to make tricky judgments about how much responsibility to lay on each individual patient – which is why the slogan of 'personalised healthcare' so often grates on doctors who believe they have always provided such care. But the technologies that we are concerned with here will require these judgments about responsibilisation to be made in new contexts for which the professionals need to be supported and trained, to provide the most appropriate care for all their patients. And there are likely to be new demands and sharp ethical issues to be faced by various kinds of expert mediation or advice in a new world of medical profiling and online medicine.

In a nutshell

- The technologies/developments with which we are concerned here are still developing; their final effects are uncertain.
- We can identify a mix of actual or potential benefits and harms associated with each of them.
- They pose ethical dilemmas because their application can bring widely-held ethical values into conflict.
- If they develop their full potential they could transform medical practice in important ways.
- Their future development and application is hard to assess, but at least some and perhaps all may become more frequently used in the future.
- Consequently they merit close and regular scrutiny, because little evidence of extent of use, distributional effects and harms is currently available.
- The powerful rhetoric used to promote these developments should be treated with caution, since it can downplay potential harms and exaggerate the usefulness of the technologies concerned.

Appendices

Appendix 1: Recommendations

Chapter 5 - Online health information

Content of websites

Recommendation 1: To facilitate individuals to pursue more easily their own interests in their own way, we recommend that all websites, including patient group websites, should include at least the following information prominently in language that lay people can understand:

- where the information originates and what it is based upon;
- which individual or organisation is the author of the information;
- how any information provided by users of the website will be used, stored, passed on or sold (for further detail see Recommendation 5);
- where the provider(s) of the website are based; and
- funding and advertising arrangements.

Advertisements should also clearly be distinguishable as such. *[Paragraph 5.54]*

Recommendation 2: In line with our ethical value of the state making efforts to reduce harm (see Chapter 3), we recommend that states should provide high-quality health information on the internet or ensure that such information is available, and that healthcare professionals should draw their patients' attention to these sites. How exactly this recommendation is to be carried out is a matter for each health system: but, within the UK, we think the UK Government Departments of Health have a special responsibility to ensure that their websites meet the criteria above, given their public funding, reputation and public role and the fact that they are trusted by the public.⁵⁷³ *[Paragraph 5.56]*

Recommendation 3: We recommend that accreditation schemes should: (i) be fit for purpose; (ii) set criteria for websites specifying that they need to state, in language that lay people can understand, where their information originates, authorship and funding arrangements; (iii) set criteria about identifying advertisements appropriately; (iv) set criteria about informing website users of how their information will be stored, passed on or used; (v) be used to drive improvements over time; and (vi) be kept under review. *[Paragraph 5.58]*

Recommendation 4: We recommend website owners should take the measures necessary and seek accreditation from recognised schemes. We also recommend that websites should display accreditation certification on their home pages, and that government health department websites should include prominent information about these schemes. This would help to generate the climate we describe in which more providers of health information on the internet follow best practice and more internet users come to expect this of the sites they visit. *[Paragraph 5.59]*

⁵⁷³ One NHS survey, for example, found that 46% of internet users would be "much more likely" to trust a health information website run or licensed by the NHS, while 32% would be "a little more likely". (Information supplied by the Department of Health).

Use of information

Recommendation 5: As well as information about how their content is derived, we recommend that health information websites, including those of patient groups, should also state whether and how they use, store, pass on or sell personal information (including the record of searches carried out and pages viewed) to third parties, in language that lay people can understand. We recommend that all use and passing on of data should require 'opt-in' by the user. Including information about all these aspects of using and passing on information should also be a requirement of any accreditation scheme (see also Recommendation 3).⁵⁷⁴ [Paragraph 5.61]

Doctor-patient relationship

Recommendation 6: We recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals on caring for patients under the new circumstances in which patients increasingly use the internet to access health information. Some patients will be well informed but others will not have gained additional information in advance of their consultation. Indeed the same patient may be more or less informed by good-quality information on different visits. Other patients will have found misleading or confusing information about which they require advice. Healthcare professionals should also help patients to recognise that bringing a large amount of irrelevant or inaccurate health information might lead to a less productive consultation. [Paragraph 5.63]

Recommendation 7: With regard to patients who request treatments they have seen that are not provided by the public healthcare system, we recommend that the bodies that issue guidance on treatment (such as the National Institute for Health and Clinical Excellence (NICE) in England and Wales) should support doctors by providing information to enable them to explain to their patients their decisions and recommendations for treatment. This should include why particular treatments are selected over others, and why certain treatments are not provided for some or all patients by the public healthcare system. [Paragraph 5.64]

The digital divide

Recommendation 8: We recommend that government health departments should take seriously the ethical values of social solidarity and reducing harm by monitoring whether the 'digital divide' is differentially affecting doctor-patient relationships, access to care and type of care received by different socio-economic groups. [Paragraph 5.66]

Chapter 6 - Online personal health records

Services provided and accreditation

Recommendation 9: Public healthcare services should develop an accreditation system for online health record providers and promote it appropriately. In the UK the responsibility for developing such a system should fall on Government Health Departments. We recommend that providers of online personal health record facilities should seek accreditation. Such an accreditation system should include requirements to include the following information prominently in lay language:

- the operator of the services;
- location in which the operator is based;

⁵⁷⁴ This is already a feature of the HONcode. See: Heath on the Net Foundation (2010) Principle 3: Confidentiality – guidelines, available at: http://www.hon.ch/HONcode/Guidelines/hc_p3.html.

- how information provided by users will be stored, passed on or sold (see also Recommendation 12);
- arrangements in place to ensure the security and confidentiality of data and information if the operator went into administration or changed hands;
- the possibility that changes to terms and conditions could be made after initial sign-up and how the user will be informed; and
- funding and advertising arrangements.

Advertisements should also clearly be distinguishable as such. *[Paragraph 6.27]*

Access to online medical records by patients

Recommendation 10: Enabling patients to add (but not delete or edit) health information to an online medical record held by healthcare providers is a sensible measure, provided information originating from the patient can be identified, and provided the system is designed to help both doctors and patients (such as building in limits to the amount and type of information that can be added, to avoid unnecessary burdens on medical professionals to take time in reading through records to protect themselves against possible malpractice suits) and care for their patients. Medical record systems that allow these additions – as is the case with the systems being introduced by the English NHS at the time of writing – can help both patients and health professionals without compromising subsequent decision making by health professionals. *[Paragraph 6.29]*

Safeguarding private information

Recommendation 11: We recommend that responsible bodies in the EU, such as the Information Commissioner’s Office in the UK, take as a premise that EU data protection legislation applies to online health records held by people who upload and edit their information in the EU. *[Paragraph 6.31]*

Recommendation 12: We recommend that providers of online personal health records should design a joining process for new users that includes information about the following, which the user should actively view and ‘opt-in’ to:

- arrangements for data security (the possibility of a change to the administration of the company);
- whether and how their personal information will be used, stored, passed on or sold to third parties (and the limits of any anonymisation process that may be applied to such information);
- examples about how personal information could be used, such as whether or not the user might receive information/advertising from pharmaceutical companies on the basis of the information they have entered;
- the advisability of the user downloading and storing locally a frequently updated copy of their health record as an additional safeguard against its loss; and
- users’ rights under data protection legislation.

The above information should all be presented in accessible language that lay people can understand, and advertisements should clearly be distinguishable as such. *[Paragraph 6.33]*

Recommendation 13: The providers of online health record facilities should design an easy method for their users to back up and print out copies of their record to ensure against its loss. *[Paragraph 6.34]*

Chapter 7 - Online purchasing of pharmaceuticals

Assessing the harms

Recommendation 14: We recommend that the responsible bodies, which in the UK are currently the Government Health Departments and the Medicines and Healthcare products Regulatory Agency, should monitor and assess the incidence and extent of harms caused as online purchasing continues to become more common. Such monitoring will enable more informed judgments and evidence-based policy to be applied to this domain in future. *[Paragraph 7.38]*

Quality control systems

Recommendation 15: We endorse attempts to mirror in the online selling of pharmaceuticals the quality-control processes that exist in some countries for more traditional pharmacies. An example of this is the registration and internet logo scheme for online pharmacies based in Great Britain by the pharmacies regulator (see Box 7.1). *[Paragraph 7.40]*

State provision of information

Recommendation 16: We recommend that all relevant public healthcare service websites should include clear and prominent information about the risks of buying pharmaceuticals online (or products sold as such) and about how to identify a registered online pharmacy. We also recommend that private providers of healthcare and online personal health records direct their patients/users to registered online pharmacies if they wish to use the internet to purchase pharmaceuticals. *[Paragraph 7.42]*

The doctor-patient relationship

Recommendation 17: In line with the value we place on efforts by the state to reduce harm, we recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals to be aware of the possibility that their patients may have bought pharmaceuticals online without disclosing this information, as well as how to address this situation, for example in clinical assessments and the questions they ask of their patients. *[Paragraph 7.44]*

Recommendation 18: At this time, given the lack of evidence for the scale of harm, we conclude that the solidarity principle underlying the NHS in the UK should mean that the healthcare service should not make any distinction between caring for people whose health problems are caused by taking pharmaceuticals bought online (or products sold as such), and those caused by other self-inflicted harms. We think a similar principle should apply to comparable healthcare systems in other countries. *[Paragraph 7.46]*

Antibiotic resistance

Recommendation 19: Countries worldwide should attempt to set and enforce regulations regarding the supply of antibiotics in their jurisdictions (we note restrictions on such supply vary widely and are entirely lacking in some countries). Governments and international health organisations should assess and monitor whether online availability is associated with any increases in antibiotic resistance in order to allow for evidence-based policy making in this area. *[Paragraph 7.48]*

Chapter 8 - Telemedicine

Using public resources fairly and efficiently

Recommendation 20: To ensure that public resources are used fairly and efficiently, we recommend to providers of public healthcare systems that telemedicine services should be subjected to the same criteria of cost-effectiveness, equity, safety and quality to which other health technologies are subjected. This recommendation may require careful monitoring of changes in the quality and standards of care for patients arising from their introduction, for example if people were at risk of being discharged inappropriately early from hospital due to the provision of a telemedicine service for aftercare and follow-up. [Paragraph 8.31]

Inequities in access to healthcare

Recommendation 21: Public healthcare systems should offer telemedicine services in circumstances where they can assist in a feasible and cost-effective manner to reducing inequities in access to healthcare, taking into account our recommendation below on patient satisfaction (Recommendation 22). As when introducing any new health service, consideration should be given to ensuring that inequities of access to care are wherever possible not exacerbated for some groups while they are reduced for others. [Paragraph 8.33]

Patient satisfaction

Recommendation 22: We recommend that for telemedicine, the value of time spent in the physical presence of healthcare professionals should be included in any cost-effectiveness analyses (see Recommendation 20). We also recommend that when people would prefer not to receive their healthcare via telemedicine, a more conventional alternative service of comparable quality should also be made available whenever it is cost-effective. [Paragraph 8.35]

Patients without capacity and surveillance technologies

Recommendation 23: We recommend that providers of telemedicine services observe the following conclusion made in relation to assistive technologies by the Nuffield Council on Bioethics in its 2009 report on Dementia:

Where a person with dementia lacks the capacity to decide for themselves whether to make use of a particular technology, the relative strength of a number of factors should be considered on a case-by-case basis, including:

- the person's own views and concerns, past and present, for example about privacy;
- the actual benefit which is likely to be achieved through using the device;
- the extent to which carers' interests may be affected, for example where they would otherwise have to search for the person with dementia in the streets at night; and
- the dangers of loss of human contact.⁵⁷⁵ [Paragraph 8.37]

⁵⁷⁵ Nuffield Council on Bioethics (2009) *Dementia: Ethical issues*, Paragraph 6.12.

Recommendation 24: There may be similar problems in deciding whether or not a person with learning difficulties has appropriately agreed to use telemedicine. We recommend that providers of telemedicine services take into account the following issues when making these decisions:

- effective provision of information;
- privacy;
- issues of response bias; and
- the potential for unintentional coercion.⁵⁷⁶ [Paragraph 8.38]

The doctor-patient relationship

Recommendation 25: In the light of our value of efforts by the state to reduce harm, we recommend that public healthcare providers should carry out an evaluation of any impact upon the doctor-patient relationship for every telemedicine service that is implemented. [Paragraph 8.40]

Responsibilisation

Recommendation 26: We consider that healthcare professionals should not rely on monitoring and feedback devices as the basis on which to make decisions about denying treatments to patients. Instead, healthcare professionals should use the information gained (as they do for other sources of information) to help them in working with the patient to provide him/her with the most suitable care available in that healthcare system. [Paragraph 8.42]

Cross-border responsibility

Recommendation 27: In order to try to reduce harm to individuals, we recommend that countries ensure that the services people receive from overseas-based health professionals meet the same requirements as those provided by health professionals based within their own country. In the UK, this responsibility will fall to the Government Health Departments based in England, Scotland, Wales and Northern Ireland. [Paragraph 8.44]

Telemedicine and developing countries

Recommendation 28: In the light of our value of social solidarity, in this case involving transnational issues of massive health inequities, we recommend that the possibilities for telemedicine to improve patient care and clinician education in developing countries should be explored by those countries and international organisations. The World Health Organization and other international agencies should encourage the development of low-cost, within-country telemedicine networks (supported from out of the country where appropriate) that demonstrably benefit health outcomes, and that can be shown to be cost-effective and sustainable. [Paragraph 8.46]

⁵⁷⁶ Adapted from Perry J, Beyer S and Holm S (2009) Assistive technology, telecare and people with intellectual disabilities: Ethical considerations *Journal of Medical Ethics* 35: 81–6.

Recommendation 29: Again taking seriously the value of global social solidarity, we recommend that healthcare systems in developed countries should monitor any impacts of outsourcing their healthcare services to developing countries via telemedicine. In the UK, this monitoring should be carried out by the UK Government Departments of Health. We consider such monitoring to be especially important in the light of the UK's *Code of practice for the international recruitment of healthcare professionals*, which precludes the *active* recruitment of healthcare professionals from developing countries, unless there has been a reciprocal government-to-government agreement that healthcare professionals from that country may be targeted for employment.⁵⁷⁷ [Paragraph 8.48]

Chapter 9 - Personal genetic profiling for disease susceptibility

Claims made about genetic profiling tests

Recommendation 30: We recommend that responsible authorities pay more attention to whether genetic test providers are making clinical claims for their products, even if implied rather than explicit (such as in their 'customers' testimonials'). If so, they should ask for evidence to be supplied. We direct this recommendation to authorities responsible for pre-market review and advertising standards, including the Medicines and Healthcare products Regulatory Agency and the Advertising Standards Authority in the UK. [Paragraph 9.45]

Information available to consumers

Research and information provided by public healthcare systems

Recommendation 31: We recommend that independent research on the health and psychological impact and effects of multifactorial genetic susceptibility testing on individuals, including children, should be carried out by public healthcare systems. Such research should include investigation into how many people are purchasing this type of analysis, and the results of this research should be made easily accessible. We recognise this information might need updating periodically if scientific developments meant that more associations between genetics and predicting common diseases were discovered. Potential buyers could then better assess what kind of results they would receive and what impacts they could expect, whether positive or negative. In the UK the National Institute for Health Research could be best placed to fund and commission this research. [Paragraph 9.47]

Recommendation 32: We recommend that appropriate publicly-funded health service websites should include general information for the public about direct-to-consumer genetic profiling services provided by commercial companies. This information should include reference to:

- potential risks and benefits;
- any difficulties with establishing clinical validity;
- the possibility of finding out about conditions for which treatment is not available;
- the special case of children (see also Recommendation 35); and
- whether it could be necessary for consumers to inform life, mortgage or travel insurance companies of the results of any tests, either at the time or in the future.

⁵⁷⁷ Department of Health (2004) *Code of practice for the international recruitment of healthcare professionals*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4097730.

We further recommend that governments should require details about where to find this information to be included in the advertising and information provided by companies selling genetic profiling services in their countries (see also Recommendation 33). *[Paragraph 9.49]*

Information provided by commercial providers

Recommendation 33: We recommend that all companies that provide genetic analysis for susceptibility to common multifactorial diseases should make the following information prominently available in lay language for the consumer before they buy:

- the operator of the services;
- the location in which the operator is based;
- the evidence on which interpretations of the test results are based;
- the tests' limitations, including the fact that they are probabilistic and based on current research results which may change;
- that the test results may require interpretation by a qualified medical practitioner or genetic counsellor;
- the possibility of finding serious health problems and revealing family genetic relationships;
- the nature of the risk being communicated to the consumer, i.e. absolute or relative risk;
- advice about whether it might be necessary for consumers to declare any results they receive as a result of genetic tests to their life, mortgage or travel insurance companies;
- which other third parties, if any, have access to the information/data;
- that the results should not be used alone for medical decision making given their limited clinical validity;
- that tests that do not meet the requirement of clinical validity should not be carried out for children (see Recommendation 35);
- arrangements for data security (including in case of any changes to the administration of the company);
- funding and advertising arrangements; and
- where to find independent information about this type of service on public healthcare service websites (see Recommendation 32).

We further recommend that all companies selling direct-to-consumer genetic tests follow the Common Framework of Principles intended for international use by genetic test providers developed by the Human Genetics Commission and approved by the Department of Health in England. *[Paragraph 9.51]*

Testing third parties and children

Recommendation 34: We recommend that genetic testing companies should require their customers at the point of sale to click on a statement confirming that they have the consent of the person whose DNA they intend to have analysed, or have parental responsibility in the case of children (see below). Where people live in countries such as the UK where procuring someone else's biological sample for

DNA analysis without their knowledge is a legal offence, this statement should also require confirmation that the customer has understood this fact. This agreement should be stated in clear language and separated from other terms and conditions. [Paragraph 9.53]

Recommendation 35: In the case of children, given our ethical value of the state striving to reduce harm, we recommend that companies should only analyse the DNA of children if (i) a genetic test meets the criteria of the UK National Screening Committee (see Box 9.1)⁵⁷⁸ and (ii) valid parental consent has been given. For such testing to take place, a condition would need to be serious, the test would need to be precise and validated, and there would need to be an effective treatment or intervention available for children identified through early detection. As we have said, many companies are offering services that do not meet these criteria, although we recognise there are exceptions. The basis for this recommendation is that some individuals do not want to know susceptibility information, particularly where the clinical validity is unclear. Additionally: (i) any benefits of this type of analysis offering a risk profile of common multifactorial conditions do not seem particularly relevant to children at this time; (ii) the problems with clinical validity of this type of analysis at present need to be taken into account; and (iii) the potential harms involved, particularly those of stigma, also need to be considered, given that children and those responsible for their care would receive information that they cannot un-know, and yet the child did not decide himself or herself to take the DNA profiling test. We consider that this advice should be given to parents on appropriate publicly-funded health service websites (together with the other information in Recommendation 32), as well as the information that companies provide to consumers that we recommend in Recommendation 33. [Paragraph 9.54]

Impacts for the public healthcare system

Recommendation 36: To lessen the dilemma involved, we recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals about best practice in the areas of giving advice about direct-to-consumer personal genetic profiling services: recognising their value as a tool for discussing healthier lifestyles, addressing their limitations, and taking a responsible position with regard to when to refer patients for specialist services. [Paragraph 9.58]

Safeguarding private information

Recommendation 37: Genetic profiling companies should provide details about what would happen to personal genetic data and interpretations should the company go into administration or change hands. This information should be made available to consumers before they buy (see also Recommendation 33). [Paragraph 9.60]

Chapter 10 - Direct-to-consumer body imaging

Physical harms of CT scanning

Recommendation 38: We recommend that the commercial sale of whole-body (full-body) CT imaging sold as a 'health check' to asymptomatic individuals should be prohibited. Any benefits for asymptomatic people do not justify the potential for harms caused as a consequence. Although there is a common law negligence framework that applies to harms caused by these services as with others, it is difficult to use this legal remedy because a claimant would need to prove that damage had been caused by a particular service. Therefore we think legislation for whole-body CT scans is required and proportionate to potential harm. Any such legislation should also cover attempts to carry out various part-body CT scans on the same day or in close proximity. Legislation would need to be kept under review were the risk-benefit ratio to change. [Paragraph 10.26]

⁵⁷⁸ Which we interpret as children who do not have a certain level of competence, such as the standard 'Gillick' test.

Recommendation 39: With regard to part-body CT scans, we recommend to providers that the carrying out of these on asymptomatic people should be governed by the best-interests principle, applied for each customer. We do not consider there is sufficient evidence to prohibit these scans. [Paragraph 10.27]

Information available to customers

Research and information provided by public healthcare systems

Recommendation 40: We recommend that independent research on the health benefits, psychological harms and harms resulting from any follow-up procedures of direct-to-consumer body imaging when offered as a health check should be carried out by public healthcare systems. Such research should involve investigation into how many people are purchasing this type of service. The results of this research should be made easily accessible. We recognise this information will need updating periodically if technical or other developments change the level of risks or the potential for finding out useful information. Potential buyers could then better assess the impacts they might expect, whether positive or negative. In the UK the National Institute for Health Research could be best placed to fund and commission this research. [Paragraph 10.29]

Recommendation 41: We recommend that appropriate publicly-funded health service websites should include general information for the public about body imaging services offered by commercial companies directly to the consumer for people without symptoms. This information should include details of:

- potential risks and benefits, including the possibility of further interventions being recommended and their implications;
- how imaging might not be optimised for analysing all conditions;
- the difficulties of interpreting these tests without reference to clinical symptoms;
- the possibility of finding out about conditions for which treatment is not available; and
- whether it could be necessary for consumers to inform life, mortgage or travel insurance companies of the results of any tests, either at the time or in the future.

We further recommend that governments should require details about where to find this information to be included in the advertising and information provided by companies selling body imaging services directly to the consumer as a health check in their countries (see also Recommendation 42). [Paragraph 10.31]

Information provided by commercial providers

Recommendation 42: We recommend that all companies that provide direct-to-consumer body imaging for asymptomatic individuals should make the following information prominently available in lay language to the consumer before they buy:

- the operator of the services;
- information about the evidence on which interpretations of the test results are based;
- the tests' limitations;
- the price and what the cost covers;
- the specialism of the person analysing and reporting the imaging results;

- the proportion of all those having body imaging who are advised to undergo further imaging;
- the possibility of further interventions being recommended and their implications;
- the average interval recommended between imaging;
- any physical or other harms or risks of the imaging procedure (including relating to the radiological risks of CT scans depending on how much of the body is scanned);
- information about the possibility of finding serious health problems and how ‘bad news’ will be broken;
- the nature of the risk (absolute or relative) being communicated to the consumer;
- advice about whether it might be necessary for consumers to declare any results they receive as a result of the imaging to mortgage or travel insurance companies;
- which other third parties, if any, have access to the information/data;
- arrangements for data security (including in cases of any changes to the administration of the company); and
- where to find independent information about this type of service on public healthcare service websites (see Recommendation 41). *[Paragraph 10.33]*

Regulation of imaging services

Recommendation 43: We recommend that commercial companies that sell imaging tests directly to consumers should be regulated by an appropriate legally constituted regulator such as the Care Quality Commission in England, the Scottish Commission for the Regulation of Care, Healthcare Inspectorate Wales and the Northern Ireland Regulation and Quality Improvement Authority, to ensure services are meeting established standards of quality and safety. We further recommend that the regulator should require the companies involved to provide the information in Recommendation 42. *[Paragraph 10.35]*

Impacts for public healthcare system

Recommendation 44: We recommend that organisations responsible for the training of healthcare professionals and professional standards (such as medical schools, Royal Colleges and the General Medical Council in the UK) should train and advise healthcare professionals about best practice in the areas of giving advice about direct-to-consumer body imaging services offered as a health check: recognising their value as a tool for discussing healthier lifestyles, addressing their limitations, and taking a responsible position with regard to when to refer patients for specialist services. *[Paragraph 10.37]*

Safeguarding private information

Recommendation 45: Body imaging companies should provide details about what would happen to body imaging data should the company go into administration or change hands in the information available to consumers before they buy (see also Recommendation 42). Healthcare regulators, such as the Care Quality Commission in England, should include a requirement to this effect for companies in their regulation requirements (see Recommendation 43). *[Paragraph 10.39]*

Appendix 2: Good practice guideline for the providers of medical profiling and online medical services

Throughout the report we make a series of recommendations relating to the types of information that providers of new medical profiling and online medicine services should make available to their users. Below we set out a consolidated version of these recommendations in the form of a good practice guideline. Further requirements are included in individual recommendations, depending on the nature of the service in question (see Appendix 1 for the full list of recommendations).

As we say in the report, our aim is to help encourage a climate in which more providers of these services follow good practice and more users come to expect such practice of the services they use, or consider using.

All services should include at least the following information prominently in language that lay people can understand:

- where the information originates and what it is based upon;
- who the provider is, whether an individual or an organisation;
- where the provider(s) is based;
- how any information provided by users will be used, stored, passed on or sold;
- the arrangements in place to ensure the security and confidentiality of data and information in the case of the operator going into administration or changing hands;
- the possibility that changes to terms and conditions could be made after any initial sign-up and how the user will be informed; and
- funding and advertising arrangements for the service.

Advertisements should also clearly be distinguishable as such.

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

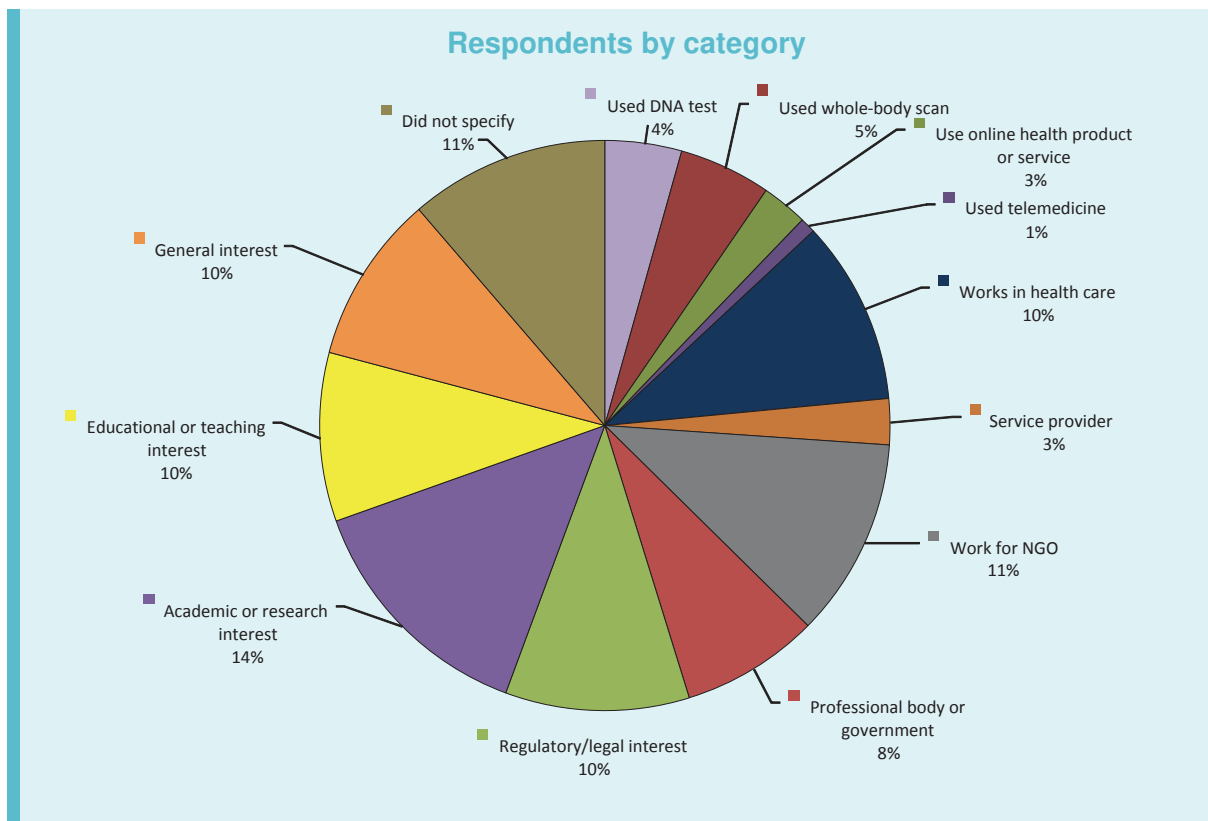
Professor Joanna Wardlaw
Professor of Applied Neuroimaging and Director of the Brain Imaging Research Centre, University of Edinburgh

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 is 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 sit.
- 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 advertising 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

Glossary

Assistive technology: a generic term for technological devices designed to enable independence for disabled or older people.

Asymptomatic: without symptoms.

Bioethics: the study of ethical issues raised in the context of human, animal and plant life, typically concerning medical and biological research.

Biomarker: molecules or sets of different molecules that, when detected at a particular level in body fluids or tissues, indicate the presence of a disease.

Biosensor: a device that detects physiological changes in the body and turns it into an electronic signal.

Body imaging: techniques for creating visual representations of the physical structures of the interior of the body. Examples include computed tomography, magnetic resonance imaging and ultrasonography.

Caveat emptor: a Latin phrase meaning 'let the buyer beware', commonly used to infer that a person purchasing goods or services does so at their own risk.

Clinical utility: the clinical relevance and meaningfulness of information provided.

Clinical validity: how well the test results are able to detect or predict the associated disorder.

Computed tomography (CT): a medical radiographic imaging technique that uses a computerised x-ray scanning system to produce a digitally processed sectional anatomic image of the body, or parts of the body, in either two or three dimensions.

Controlled drug: a substance listed in the various Schedules of the UK Misuse of Drugs Act 1971 and consequently subject to particular limitations in terms of their importation, prescription etc., that other drugs are not.

Defensive medicine: a healthcare practice used to protect against malpractice litigation and the risk of liability, rather than improving care.

Delict: a wrong, unlawful act done by one party to another; a Latinate variant of Anglo-American tort law, primarily used in discussion of Roman law systems.

Dilemma: a situation where a choice has to be made between two incompatible alternatives.

Direct-to-consumer: a product, service or technique targeted initially and primarily at the end-user of such a product or service, and not at an intermediary, such as a doctor, in the case of direct-to-consumer advertising of medicines.

DNA (deoxyribonucleic acid): DNA is the biochemical substance that genetic material is made of. The DNA in a cell is usually in several long sequences, known as chromosomes, each of which contains many genes.

Dose equivalent: a measure of radiation absorbed by tissue, allowing for the varying biological effects of different forms of ionising radiation.

Empirical: Based on observation or experiment rather than theory.

Footloose: of an entity, such as a business: capable of being located anywhere in the world and therefore not able to be effectively regulated or taxed by any single national government.

Gene: the fundamental unit of inheritance. A gene is an ordered sequence of nucleotides located in a particular position on a particular chromosome that encodes a specific functional product (i.e. a protein or RNA molecule).

General practitioner (GP): a doctor practising primary care, having no specialism: a family doctor.

Genetic counselling: the process of helping patients and families understand and adapt to the medical, psychological and familial implications of genetic contributions to disease.

Genetic susceptibility: predisposition to a particular disease due to the presence of a specific allele or combination of alleles in an individual's genome.

Genetic testing: analysing DNA to look for a genetic alteration that may indicate an increased risk for developing a specific disease or disorder.

Genome: term to describe all the genetic material of an individual organism or species.

Genome-wide association study: a study involving large numbers of people with and without a particular disease, each of whom is genotyped at several hundred thousand markers throughout the genome. Comparisons are then made between these groups to identify genetic markers associated with the disease.

Gillick competence: term primarily used in English medical law to decide whether a child can consent to their own treatment without the involvement of a parent.

Health 2.0: the use of a specific set of web tools by those involved in healthcare, using principles of open source and generation of content by users, and the power of networks in order to personalise healthcare, collaborate, and promote health education.

Health professional: an individual who provides healthcare services to patients in a professional context. A number of disciplines may fall under this term including, but not limited to, doctors, nurses, pharmacists and psychologists.

HuGE review: a review that identifies human genetic variations at one or more loci, and describes what is known about the frequency of these variants in different populations, identifies diseases that these variants are associated with and summarises the magnitude of risks and associated risk factors, and evaluates associated genetic tests.

Human Genome Project: a 13-year international project established in 1990 to coordinate the sequencing of the 2.85 billion nucleotides that make up human DNA.

In vitro: literally 'in glass'; performed in the laboratory.

Incidentaloma: abnormalities without clinical signs or symptoms that are picked up incidentally during imaging.

Ionising radiation: electromagnetic waves, such as x-rays and gamma rays, capable of producing ions after interacting with matter; a common cause of radiobiological damage.

Kitemark: formally, a certification mark used by the British Standards Institution; colloquial usage implies any kind of certification mark.

Magnetic resonance imaging (MRI): A medical imaging technique that uses magnetic fields to make images of tissues and organs, that makes use of the different properties of sub-atomic particles in a high-intensity magnetic field.

Medicalisation: the tendency to consider what were previously believed to be 'normal' human activities, problems and events – such as birth, aging and obesity – to be medical conditions.

Medical device: a healthcare product intended for use in the diagnosis, treatment or prevention of a disease.

Medical profiling: services offering body imaging (e.g. CT and MRI scans) and personal genetic profiling for individual susceptibility to disease.

Medical record: a transcript of information regarding a patient's medical information.

Medical tourism: travelling abroad to receive treatment, usually due to the perceived cost savings of doing so.

Micro electro-mechanical system (MEMS): a small integrated device or system that combines mechanical and electrical components. It can sense and control on a micro-scale.

Monogenetic disease: a disease caused by variation in a single gene.

mSv: milliSievert – the International System of Units derived unit of radiation 'dose equivalent' in the field of radioprotection.

Multifactorial disease: a disease caused by the presence and confluence of more than one factor, such as genetic and environmental factors.

The National Health Service (NHS): the name usually applied to the publicly-funded healthcare services that operate in the constituent countries of the UK.

Online medicine: developments in digital technology, largely involving the internet, that offer new ways for individuals to obtain health advice, diagnosis and medication, and that provide new possibilities for storing, accessing and sharing health records, monitoring individuals' health status and communicating with health professionals

Online personal health record: health records that can be created and/or edited online, by the person they concern, and provided either publicly or privately.

Over-the-counter medicine: medicine that can be purchased directly by a consumer, without a prescription.

Paternalism: in medicine, a form of decision making where the health professionals exercise authority over patients.

Pathology: study of the nature and cause of disease or a condition produced by a disease.

Personal genetic profiling: services that offer to analyse a person's DNA in order to give them information about their own personal risks of developing certain diseases or health conditions in the future.

Polymorphism: a DNA sequence variation that involves a change in a single nucleotide.

Predisposition: the potential to develop a disease when exposed to a certain environmental factor.

Prescription: an instruction to dispense a drug to a patient, written by a legally authorised medical professional; usually written, it may now be electronic.

Prescription-only medicine: a medicine available to the public at large only through use of a prescription.

Pre-symptomatic: the condition of a patient's health before the appearance of symptoms.

Screening: a process of identifying apparently healthy people who may be at increased risk of having a disease or condition.

Single nucleotide polymorphism (SNP): a DNA sequence variation that involves a change in a single nucleotide located at a defined chromosomal position.

Stewardship: "A function of a government responsible for the welfare of the population, and concerned with the trust and legitimacy with which its activities are viewed by the citizenry. [...] Stewardship is the overarching function that determines the success or failure of all other functions of the health system. It places the responsibility back on government and calls for the strengthening of ministries of health."⁵⁸⁰

Summary Care Record: an element of the NHS Care Records Service. Initially, it will contain key health information such as details of allergies, current prescriptions and bad reactions to medicines. Subsequently, will be updated each time the patient uses any NHS services.

Telemedicine: medicine and/or healthcare carried out at a distance.

Tethered health record: an 'institution-specific' record.

Tort: a civil wrong; the breach of a duty that the law imposes on everyone.

Ultrasonography: a medical imaging technique used to produce images of organs and tissue within the body using sound at the ultrasonic frequency by recoding and processing the echoes made by the sound as it travels through the body.

Untethered health record: records that offer individuals the facility to add and organise personal health information, as well as integrate health records from different healthcare providers, and share them with multiple individuals and institutions at will. Do not have to be affiliated with any one healthcare institution.

Web 2.0: a trend generally regarded as involving websites including, or being entirely based upon, 'user-generated' content.

Wiki: a website that allows the comparatively simple creation and editing of interlinked web pages using specific programming language and editing tools. They are often collaborative in nature. The website Wikipedia is perhaps the most famous example of this type of website.

The definitions above are derived from a number of sources. Significant sources include *Taber's cyclopedic medical dictionary*, 21st edition; *Steadman's medical dictionary*, 27th edition; *A dictionary of modern legal usage*, 2nd edition; *The Oxford medical companion*; and *Oxford English reference dictionary*, 2nd edition.

⁵⁸⁰ See: World Health Organization (2001) Health systems performance – glossary, available at: <http://www.who.int/health-systems-performance/docs/glossary.htm#stewardship>.

List of abbreviations

ABPI	Association of the British Pharmaceutical Industry
ASA	Advertising Standards Authority
BMA	British Medical Association
CHF	Congestive heart failure
COMARE	Committee on Medical Aspects of Radiation in the Environment
CT	Computed tomography
DNA	Deoxyribonucleic acid
ECG	Electrocardiogram
ECJ	European Court of Justice
ESHG	European Society for Human Genetics
EU	European Union
FDA	Food and Drug Administration
GP	General practitioner
HGC	Human Genetics Commission
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human immunodeficiency virus
HON	Health on the Net (Foundation)
HuGE	Human Genome Epidemiology
ICT	Information communication technologies
ISP	Internet service provider
IT	Information technology
IVDD	In vitro diagnostic device
MEMS	Microelectromechanical systems
MHRA	Medicines and Healthcare products Regulatory Agency
MOT	Ministry of Transport test
MRI	Magnetic resonance imaging

mSv	MilliSievert
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NSC	National Screening Committee
Ofcom	Office of Communications
OFT	Office of Fair Trading
PHR	Personal health record
RPSGB	Royal Pharmaceutical Society of Great Britain
SCR	Summary care record
SNP	Single nucleotide polymorphism
URAC	Utilization Review Accreditation Commission
VIPPS	Verified Internet Pharmacy Practice Sites
WHO	World Health Organization

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