

# 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.<sup>7</sup>
- 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.<sup>8</sup> 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,<sup>9</sup> fewer of whom are online at home than younger people,<sup>10</sup> 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’<sup>11</sup>

---

<sup>7</sup> 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.

<sup>8</sup> 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>.

<sup>9</sup> 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](http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_111222.pdf).

<sup>10</sup> 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>.

<sup>11</sup> 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.<sup>12</sup>

**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
<b>Seeking health information</b>	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.
<b>Records of health history and status</b>	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.
<b>Obtaining medication</b>	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.
<b>Various aspects of diagnosis, health monitoring and management</b>	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.
<b>Imaging and genetic testing</b>	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.

<sup>12</sup> 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,<sup>13</sup> 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.<sup>14</sup>
- 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.<sup>15</sup> 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.<sup>16</sup> 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.<sup>17</sup>
- 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.<sup>18</sup> 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

<sup>13</sup> A family doctor, general practitioner or personal physician.

<sup>14</sup> 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>.

<sup>15</sup> 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.

<sup>16</sup> 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.

<sup>17</sup> See: Paragraph 1.13.

<sup>18</sup> 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.<sup>19</sup> 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,<sup>20</sup> thereby creating needless confusion or anxiety.<sup>21</sup> Some of these analyses and scans may be medically or therapeutically meaningless, or of doubtful clinical validity and utility.<sup>22</sup> 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

<sup>19</sup> See: House of Lords Science and Technology Committee (2009) *Science and Technology Committee 2<sup>nd</sup> 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](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.

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

<sup>21</sup> 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.

<sup>22</sup> 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.<sup>23</sup> 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:<sup>24</sup> 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.<sup>25</sup> 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?

<sup>23</sup> 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.

<sup>24</sup> 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](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](http://www.dh.gov.uk/dr_consum/dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113645.pdf).

<sup>25</sup> 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.<sup>26</sup> 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.<sup>27</sup>
- 1.14 The Personalized Medicine Coalition,<sup>28</sup> 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”<sup>29</sup> 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.

<sup>26</sup> For example, see: Roche (2010) Personalised healthcare, available at: [http://www.roche.com/personalised\\_healthcare.htm](http://www.roche.com/personalised_healthcare.htm).

<sup>27</sup> 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.

<sup>28</sup> 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>.

<sup>29</sup> 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.<sup>30</sup>
- 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.”<sup>31</sup> 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.<sup>32</sup>
- 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.

<sup>30</sup> 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](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](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_085828.pdf).

<sup>31</sup> 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.

<sup>32</sup> 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.