

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.