

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

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About your response

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Personal Organisation

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

Yes No, I/we would prefer to be anonymous

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Royal Pharmaceutical Society of Great Britain (RPSGB)

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales.

The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy. It is the only body that represents all pharmacists in Great Britain.

The RPSGB leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

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- X Yes, attributed to my organisation No
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Why are you interested in this consultation? (tick as many as apply)

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

Please let us know where you heard about the consultation:

- Received consultation paper in the post
- X Received notification by email
- Newspaper, radio or television
- Nuffield Council on Bioethics website
- Twitter
- Other website (please state): _____
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Closing date for responses: 21st July 2009

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

Background

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The comments provided represent the views of the organization from both the regulatory and professional perspectives. In answering the questions if these are divergent this has been identified.

Technological developments in medical care

The delivery of medical care is changing and the consultation document raises some important questions in relation to the future delivery of medicines and healthcare. Pharmacists are the experts on medicines and medicines will remain the mainstay of clinical care for the foreseeable future. The use of information technology (IT) has already made significant changes to healthcare providing networks, data collection systems and messaging. It enables batches of patient data in a standard format to be processed rapidly and at the other end of the spectrum IT systems are able to produce an individual care plan based on the specific personal requirements of each patient.

The use of IT with remote access to systems now has the potential to allow health services to be extended to a wider range of users, without the expansion of service locations.

In the future IT systems may be able to:

- Ensure that as many people as possible will benefit from systems, while as few as possible are harmed by them;
- Provide an individualized health service to as many as possible NHS patients; and
- Provide a highly personalized health service as fairly and efficiently as possible.

The consultation document highlights a number of technologies, including telemedicine applications (for consultations and diagnostics), proprietary internet-based health information solutions (e.g. Google Health, MS Healthvault), web-based direct genetic testing and private body imaging services. There are a number of general issues with these novel technologies from a healthcare IT perspective:

- 1) At the current time, there is no formal NHS funding allocated for novel telemedicine technologies to support diagnosis or disease monitoring. Until this is addressed, the widespread implementation of such technologies is likely to be limited, notwithstanding technical constraints.
- 2) With telemedicine applications, and other applications with a multi-modality IT platform, there are technical issues arising from the lack of an agreed non-proprietary dataset. Also, implementation of such technologies is dependent on the willingness of stakeholder manufacturers to work together on prototypes.
- 3) The adoption of these technologies is dependent on the manufacturer's marketing strategy and the willingness and ability of patients and healthcare professionals to embrace novel methods of healthcare provision.

These factors mean that, while there is the market and commercial will to make these technologies available, they are often available on a private basis. The private funding model encourages a consumerist view of healthcare, as highlighted by the consultation document. On the one hand, this is beneficial because it encourages the positive notion of a 'right to health' for the patient, and patient ownership of personal medical data. On the other hand, this consumerist model may raise unreasonable expectations about what these technologies can offer. It should also be considered that an estimated 9 million households in Britain not have access to the internet excluding and the elderly and most vulnerable from products and services.

The RPSGB suggests that there is relative lack of health professional input into the design and development of these systems. It is essential that new technologies are fit for purpose, and facilitate an effective and safe patient consultation/provision of a health related service. For this reason:

- Health professional bodies should take an active lead in research into new healthcare technologies such as telemedicine and online healthcare services,

and should work closely with software companies who are developing such services in their professional field;

- Providers of services such as online health records, online health information services, private genetic profiling and private body imaging services should be subject to appropriate regulatory standards and subject to a code of ethics.

Comments on the specific questions in the consultation document are addressed below.

Question 1 Health care as a consumer good

If an increasing number of medical products and services are becoming available as consumer goods – that is to say, as commodities which customers may choose to purchase provided they can meet the costs (see Annexes 4 and 5) – is this development, on balance, desirable?

If yes...

In what ways do you think the positive consequences outweigh the negative ones?

If no...

In what ways do you think the negative consequences outweigh the positive ones?

As outlined above as currently there is no formal NHS funding for novel telemedicine technologies and they are on the whole available on a private basis.

The private funding model encourages a consumerist view of healthcare, as highlighted in the consultation document. This is beneficial because it encourages the notion of a 'right to health' for the patient, and patient ownership of personal medical data (ameliorating public concerns about data confidentiality, security and access).

Improved healthcare information and increased access to diagnosis and treatment is, in general, desirable, and in the best interests of patients. However medical care is not like other commercial products and consumer goods. Information should be obtained from a reputable source, such as a trained healthcare professional, subject to ongoing training, development and monitoring by a Regulatory body and subject to a Code of Ethics which ensures up to date, knowledgeable and impartial advice unaffected by commercial incentives or targets. The sale of some medicines requires the advice, guidance and intervention of healthcare professionals to ensure that they are taken in a safe and appropriate way. The consumerist model may also raise unreasonable expectations about what these technologies can offer.

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?

The RPSGB suggests that the science around DNA profiling and body imaging services and their implications for health are still at an early stage of development. As the techniques are still at this early stage information should be used carefully and appropriately and always mediated by health care professionals trained to deal with questions.

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 RPSGB does not take a view.

Pharmacists currently offer a great deal of support to promote individuals to look after their own health (self-care).

Examples include:

- Public health and lifestyle advice
- Self-diagnosis tools
- Advice and information about diseases
- Medicines for minor ailments
- Advice and information about medicines for minor and chronic conditions
- Advice on managing long-term conditions such as responding to an exacerbation
- Personalised care plans for people with long-term conditions

As new services become available pharmacists will continue to be involved with the self-care agenda.

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 health care services impose fees for such follow-up diagnosis and treatment (for instance by charging patients or by levies on private providers of body imaging and DNA profiling services)?

The RPSGB does not take a view.

Electronic health records

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?*

The consultation document identifies a number of proprietary internet-based health information solutions (e.g. Google Health, Microsoft HealthVault). The main concern that the RPSGB would like to highlight is that the proliferation of these systems and indiscriminate use of private health record services may fragment the total electronic patient record available.

The potential consequences of data not being available include missing information on drug allergies, possible interactions, duplications in treatment or dose adjustments that could have serious patient safety implications. A single health record supports the seamless transfer of care between primary and secondary settings and promotes multi disciplinary working.

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

If no...

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

The consultation document highlights a number of technologies, including telemedicine applications (for consultations and diagnostics). The use of online health tools, such as NHS Direct Self Help, is useful for extending provision of health advice, but not appropriate for some scenarios, because they are often built with rigid treatment algorithms, and cannot be a substitute for a personal consultation. In addition many households do not currently have access to online resources.

There is a need for research on who uses internet-based self-diagnosis services and genetic profiling services. The RPSGB concern is that users are a self-selecting group with access to the internet such as the 'worried well'.

Online drug purchases

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?

All retail pharmacies in Great Britain, including those providing internet services, must be registered with the RPSGB. While a number of legitimate registered pharmacies provide online pharmacy services, there are also a number of suppliers operating from websites offering to sell medicines who have no professional qualifications or healthcare expertise. Buying medicines from websites that are not connected to registered pharmacies can present a number of risks. There is no opportunity for an appropriately qualified health professional to assess whether the medicine is safe and appropriate to advise on how the medication should be taken. In addition, the safety and quality of medicines sold by unqualified internet suppliers cannot be guaranteed.

In 2008 the RPSGB introduced an internet pharmacy logo which can be seen on the front page of participating online e pharmacy sites. Use of the logo is voluntary and is one of a number of checks patients are advised to undertake before purchasing medicines online. The logo was introduced to assist patients to identify whether a website offering to sell medicines or provide other pharmacy services is connected to a registered pharmacy. By clicking on the logo visitors are linked to a page on the RPSGB website where they can make checks to ensure the site is a registered pharmacy.

The issues for the public and pharmacy are explored in more detail on <http://www.rpsgb.org/registrationandsupport/registration/internetpharmacylogo.html>

Question 8 Advertising health care products

Do you think it should be permissible to advertise prescription drugs direct to consumers?

If yes...

Should there be no restrictions whatsoever? Do you think that it should equally be acceptable to advertise DNA profiling or body imaging services direct to consumers (which is currently not prohibited in the UK, see Annex 7)?

If no...

What are your main concerns? Are you confident that access to drugs via GPs is a better alternative, ensuring that you will always receive the drug that is best suited to your specific condition? Do you think that advertising DNA profiling or body imaging services should equally be restricted or prohibited?

The Council of the RPSGB agreed its position on the issue of direct-to-consumer advertising (DTCA) of prescription medicines in 2001. The Council recognised that the demand for information about prescribed medicines from patients and the public is likely to increase, the view of the Council was DTCA was unlikely to be the best way of providing it because the aim of advertising is to persuade, not to give balanced information about benefits and risks.

DTCA, moreover, carries a significant risk of exposing more patients to the adverse effects of new drugs. If DTCA is successful, it may well adversely affect doctor-patient relationships, distort public health priorities and disrupt the cost controls operated by the NHS. The RPSGB therefore supports increased provision of balanced information to the public, while taking into account the above.

The full report is available at <http://www.rpsgb.org/pdfs/dtcaexec.pdf>

It is of note that when the internet is used for medicines information and advertising, national distinctions in content and format are often lost, with cultural implications for patients.

It is important that the public health agenda focuses on educating the public about factors that can cause ill health and where to go to seek medical attention. The active promotion of online medical services (e.g. genetic profiling) may be needed in order to encourage uptake of health services. However, such promotion should be regulated (as with medicines) and there should be an explicit Government policy in this area, as a means of addressing specific health needs.

Telemedicine

Question 9 Your experiences

Have you used information technology to access individual health care expertise at a distance?

If yes...

Which services did you use, what led you to do so, and how would you evaluate your experience? Would you recommend it to others?

If no...

If you were faced with the choice of using such technology or undergoing the costs and/or inconvenience of travel over a substantial distance to access or provide those services on a face-to-face basis, what factors would affect your choice?

Telemedicine may improve access to healthcare and health services. When considering the delivery of health care at a distance it is important to consider the range of healthcare professionals including nurses and pharmacists who are likely to be involved in the implementation, prototyping and piloting of such systems.

In certain circumstances face to face contact between a patient and a healthcare professional is necessary. The RPSGB has issued guidance with respect to Internet Pharmacy Services which includes mandatory standards that must be adhered to. Where the best interests of a patient would be served by a face to face consultation, pharmacists must advise patients to consult a local pharmacy or other healthcare professional where appropriate.

Issues relating to the transfer of confidential patient information must also be considered and such information safeguarded.

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 health care provider who pays for the extra cost of providing services this way, or should costs be shared in some way?

If no...

What are your reasons? Do you think some degree of unequal access to public health care is simply justified (for example, if individuals choose to live and work or retire in remote rural areas)? Or do you think that there are means other than telemedicine that are better suited to achieving more equitable access to health care?

There are risks associated with remote consultations especially in connection with the supply of medicines via the internet if proper procedures are not in place.

Without direct face-to-face contact a full and accurate diagnosis may not be possible. In some circumstances there are possibilities for such systems to be misused.

The RPSGB does recognise that 'telemedicine' may have a role in certain circumstances as in the case of internet pharmacy where over the counter (OTC) medicines are supplied to patients following an online consultation.

Body imaging and DNA profiling services: cross-cutting issues

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?

The potential implications for the NHS and patient wellbeing associated with private genetic screening and body imaging services include the implications for patients of incorrect results and reporting and the management of accurate results and their reporting.

DNA profiling systems will be more patient-centred with more of an emphasis on prediction and prevention – for this reason, the algorithms used for decision support must be up to date, and fit for purpose. Therefore specialist professional advice should be sought in the design of these systems.

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.

It might be argued that the regulatory provision for online medical services should be done by the Medicines and Healthcare Products Regulatory Agency (MHRA), even for those services that are privately provided for 'recreational' purposes, because they are still healthcare products, and it is in the public interest to regulate them.

Question 13 Responsibility for harm

The results of DNA profiling and body imaging may lead people to seek appropriate treatment. But it may also lead to harmful actions, such as inappropriate self-medication, or people may become more fatalistic, believing that there is no point in altering their lifestyles. In the most extreme cases some people could become suicidal as a result of the predictive information they receive. Should providers ever be held responsible at law for such harms?

If yes...

In what circumstances? Should providers of other services such as pregnancy tests also be held responsible for what distressed or misinformed individuals might possibly do with the information they obtained?

If no...

How, if at all, do you think the interest of vulnerable groups should be safeguarded?

As with all diagnostic services the practitioner providing the service should provide sufficient information to the patient and explain any results fully.

In the case of pharmacy, Principle 4 of the Code of Ethics requires that pharmacists and registered pharmacy technicians encourage patients to participate in decisions about their care. Specifically, Principle 4.6 requires that pharmacists and registered pharmacy technicians "consider and wherever possible take steps to address factors that may prevent or deter individuals from obtaining or taking their treatment". Principle 4.1 also requires that pharmacists and registered pharmacy technicians "explain the options available and help

individuals to make informed decisions about whether they wish to use particular services or treatment options”.

The RPSGB believes that practitioners providing such services should minimise the risk of ‘harmful actions’ through dialogue and engagement with patients.

As outlined above, clear professional standards should be in place to ensure that patients receive all the necessary information they require in a balanced and understandable manner.

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?

The RPSGB does not take a view.

Other issues

Question 15

Are there any other issues we should consider?