

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009. The views expressed are solely those of the respondent(s) and not those of the Council.

### **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?

No.

The document begins by alluding to the paternalism under challenge as the 20<sup>th</sup> century wore on. This is, of course, true. On the other hand, for many of us the atomistic consumerist view of individuals often seems to deny both our responsibilities to each other, ideas of social solidarity and the effects of our choices on the choices of others. Given that all services of any sort are necessarily limited, it must follow that autonomy can only operate with a principled regard for the needs of others. That is a fundamental starting point in any document considering the “rights” of individuals.

With this in mind we have concerns regarding the concept of ‘health’ as a consumer good. Health cannot be purchased: if health means some concept of well being (even short of the WHO’s much quoted and somewhat impractical definition), it is undeniable that some people are ‘healthy’ in the sense of a settled well being despite disability and the ravages of disease.

Negative consequences that outweigh positive ones include: the potential for misuse of antibiotics, tests not validated by the profession being a cause for concern and the potential for ‘health anxieties’ to block the system.

### **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?

Yes.

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009. The views expressed are solely those of the respondent(s) and not those of the Council.

There are potential problems arising from the difference between relative and absolute risk - this is an issue of public education. The public are inexperienced about the damage genetic information can cause and clinical geneticists therefore encourage counselling. We believe that genetic information should be provided by experts and should not be treated as a consumer product: as much control as possible should be exercised in the UK over the activities of companies in the USA.

DNA profiling may be requested for a variety of reasons, some serious and some trivial. Recreational genealogy, for example, is not a serious reason in terms of health. Moreover establishing minor advantages or disadvantages in a DNA profile towards the probability of developing certain diseases may well do more harm than good. The understanding necessary to interpret the result may be considerable. So information needs to be accurate, balanced and comprehensible or public harm may result as the consequence of misunderstanding.

### **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?

No. We do not believe that people should be positively encouraged to have such tests, let alone be obliged to do so.

### **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...**

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009. The views expressed are solely those of the respondent(s) and not those of the Council.

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)?

Yes, in certain circumstances e.g. it may be helpful to obtain early diagnosis. However, the endless chasing of minor 'abnormalities' can be very costly, both in time as well as money. Some of these costs are going to fall on the public purse and it is overwhelming likely that the purchase of CT scans for ill defined screening purposes will be the preserve of the better off. This could represent an inappropriate subsidy of the poor towards the rich. A case could be made for those in the commercial sector who profit from this being required to fund the follow-up

### **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?

We have no experience to share on these issues. We would comment that internet drugs do not offer the cost savings to the UK consumer that may be true in other jurisdictions owing to the free or subsidised prescriptions enjoyed by British patients. (The exceptions are those drugs not available to all on NHS prescriptions such as sildenafil.)

### **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?

See answer to question 5.

### **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

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009. The views expressed are solely those of the respondent(s) and not those of the Council.

medical supervision etc)?

**If no...**

Under what circumstances if any would you consider doing so for yourself or a relative or friend?

See answer to question 5.

### **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?

No.

The advertising of prescription drugs is in nobody's interest except the pharmaceutical industry. It will put pressure on doctors to prescribe either unnecessarily or the newest (& most expensive) preparation. Unnecessary prescriptions have adverse effects both in terms of wasted resource and side effects. The consumerist patient is likely to believe the advert rather than the doctor in many cases. It is to be hoped that the current EU ban is maintained even if advertising is concealed as 'non-promotional information'. There is a case for thinking that similar issues may arise with DNA profiling and body imaging services.

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009. The views expressed are solely those of the respondent(s) and not those of the Council.

## **Telemedicine**

We have little experience of telemedicine, but it seems that major investment in these technologies should be dependent on good operational research, rather than anecdote or the fact it can be done. The issue is whether it is a cost effective method of assisting the delivery of care. If it really works then it should be funded publicly like other services.

In the report from the Human Genetics Commission of 2007, Sir John Sulston wrote that the report constituted a proportionate and reasonable approach to the current situation as the Commission saw it developing. Re-reading that report now, we believe that judgement stands. The Code of Practice proposed three principles for such testing: informed consent, data on the validity and utility of such tests in a comprehensible format, and the importance of counselling. We support these principles. Clinical validity of a test must be established before it enters clinical practice!

## **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.

No.

The earlier concern about tests not validated by the profession holds. We believe that evaluations should be equally stringent in the private and public sectors. No argument has been advanced to defend lower standards in the document.

## **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?

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Medical profiling and online medicine: the ethics of 'personalised' medicine in a consumer age* between April 2009 and July 2009. The views expressed are solely those of the respondent(s) and not those of the Council.

We believe that providers should carry responsibility for the consequences of the tests that they offer if they have not operated proper standards of consent, as above.

However, responsibility only lies with those having a duty to prevent someone acting (e.g. committing suicide). Some risk might be possible but much depends on the way issues have been communicated.

There may be a duty of care to the vulnerable, but health providers can not take responsibility for everything. We are also concerned about the position for those that were led to believe they had no risk.

#### **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?

Yes.

Commercial services should operate to the same standards as the NHS. Standards should be improved and private funding is appropriate.

I trust these comments will be of use.

Yours sincerely

A handwritten signature in black ink that reads "Rodney Burnham". The signature is written in a cursive style with a horizontal line underneath the name.

Dr Rodney Burnham  
Registrar