Dr. Maureen Baker CBE DM FRCGP, Honorary Secretary of Council

submitted by email: tfinnegan@nuffieldbioethics.org

For enquiries please contact: Dr Maureen Baker

E.mail: honsec@rcgp.org.uk

Direct line: 020 7344 3123
Fax: 020 7589 3145

3 August 2009

RCGP EVIDENCE

Nuffield Council on Bioethics consultation: Medical Profiling ad Online Medicine: The Ethics of Personalised Healthcare in a Consumer Age

1. The College welcomes the opportunity to respond to this Nuffield Council on Bioethics consultation document.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the 'voice' of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 36,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

3. We note that this consultation appears in the main aimed at the public. We have responded to the areas where we are able to as a professional organisation.

4. It is apparent from the consultation document that there is a need for an improved regulation of private health care providers and for better standards of consumer health protection. There is a particular need to safeguard the public with regard to medical products and services sold online. Often these are beyond the scope of regulators and ways need to be identified to mitigate the risks that this causes. This is an area of concern and patients and the public should be safeguarded to prevent adverse medical consequences and costs for the NHS through improved regulation and the provision of relevant, accurate and useful information from the Government and healthcare organisations.

5. The consultation document appears unfocused in many areas. This is however understandable as many of the issues being looked at here is relatively new and need further consultation and consideration.

6. Please see below answers to some of the specific questions posed in the consultation document.

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.

INTRODUCTION

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 – 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?

7. We urge strong caution at the developments outlined here. Private provision of healthcare is a complex and diverse area. Each individual development needs to be carefully considered with questions of safety, quality, equity of provision and impacts on NHS budgets. However it must be acknowledged that such consumerism in healthcare is already taking place. Medical products provided as commodities are generally less well regulated for quality, safety and fitness for purpose. Their use can generate problems, anxieties and questions the burden for advising and reassurance to patients often falls on public health services. Therefore services and products which directly relate to, or affect the health of an individual, require proper regulation. The Care Quality Commission needs to look at ensuring such regulation takes place. Other bodies with responsibilities in this area include: Medicines and Healthcare Products Regulatory Agency (MHRA) and the National Institute of Clinical Excellence (NICE).

Other factors to consider include

- The evidence-base supporting the treatment/testing that is offered
- The skills set of those providing the service
- Safeguards in place to ensure safety
- The level of on-going support associated with the treatment or service
- The extent to which individuals are encouraged to involve their GP and other relevant healthcare professionals

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 raise 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?

8. There are two key issues arising here: one is the regulation of the promotion of commercial health services and the other is restrictions on the provision of services. Both

need to be looked at separately. There is a case for looking at how both are currently carried out and will adapt to future developments. It is difficult to provide a yes or no response. The Care Quality Commission will have a big role to play in this area as it should regulate both public and private health organisations.

Promotion of Services

9. There is both an ethical and legal obligation for a provider to ensure accuracy of information about the services they provide. Consideration should be given to the operation of sanctions and methods of redress to tackle false or misleading claims made about medical products or services. Mechanisms for this to be done such as through civil action of through healthcare or advertising regulators should be clarified.

10. In general standards of quality, accuracy and fitness for stated purpose required of commercial services in this area should be the same as those applied to similar services in the NHS.

Restricting Services

11. The question also appears to be asking if it is legitimate to restrict companies from offering services where they do not meet specified levels of scientific validity in particular for DNA profiling and body imaging. Such services certainly need proper and robust regulation to minimise risks to the public and the Care Quality Commission should ensure that providers meet certain basic standards of quality and safety.

12. A relevant consideration is the level of harm people may be exposing themselves to. If there is no evidence of benefit but equally no, or minimal, risk of harm, and the individual has been provided with accurate information then it is difficult to justify restricting access. Some forms of complementary medicine are subject to voluntary or statutory regulation and this may be an issue that requires further consideration in respect of other direct to the public medical services.

13. One of the key issues here is predictive validity. If tests give accurate information with high specificity this can be useful to patients and the healthcare professionals. However low specificity results that are over-sensitive about poorly defined risks are at best of little and use and at worst can be harmful. A greater evidence base in this area is needed to inform regulation.

Other issues to be considered

- Use of an ethical and regulatory framework for those providing test results
- Ensure that limitations of tests are communicated to users
- Regulation should include proper use of consent forms
- A Department of Health consultation has recently been launched on the regulation of traditional medicine practitioners; the results of which may add further insight to the issues this question raises

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?

14. Health organisations and Government encourage patient responsibility in terms of smoking, drinking etc which impact heavily on public health. As a society, however, we do not oblige people to have testing or treatment, even where there are very serious implications for themselves or others. Both legally and ethically competent adults are entitled to refuse any test or treatment even if that results in their death. There are no grounds for treating DNA profiling or body imaging differently from any other form of testing or treatment in this respect. Encouragement and appropriate incentives to patients based on information gained through DNA profiling or body imaging should be possible as is currently the case when information from other sources triggers such responses from those working in public health. This can't be forced or mandatory.

15. The imposition of predictive and preventative testing on individuals could be a violation of human rights. Such tests should be freely chosen by individuals on the basis of sound advice about their benefits and risks. Penalising patients by asking them to pay additional fees if they have not taken up certain tests could be unethical and also currently illegal. Such steps are not taken with any current screening programmes and it is unclear why this situation would change with the availability of other screening and testing procedures.

Question 4 Who pays?

Many DNA profiling and body imaging services 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)?

16. This is a complex area. We refer you to the response that we provided to the Department of Health review of the consequences of additional private drugs led by Professor Mike Richards which covers many of the relevant issues.

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 are currently not prohibited in the UK)?

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?

17. No. Prescription only drugs should not be advertised directly to consumers by organisations that have a direct financial benefit from their sale. Prescription medicines are not simply another consumer product. Most have side effects and significant associated risks and patients need sound clinical and impartial advice on drugs to make informed choices. Such advertising can have adverse impacts on the discussions that take place between the doctor and patient. Prescribing decisions should be based primarily on clinical need (cost can also be another consideration) but this decision should not be influenced by information provided with a commercial intent.

18. The RCGP is very concerned about recent proposals from the European Commission proposals to allow the pharmaceutical industry to communicate directly with the public about prescription-only-medicines. These proposals undermine the pan-European ban on advertising of prescription-only-medicines that currently protects the public, patients, clinicians and health service budgets from commercial interests and pressures.

19. The Chair of the RCGP Patient Partnership Group is also strongly opposed to direct advertising of prescription only medicines to the public stating that this could be very harmful.

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 betters suited to achieving more equitable access to health care?

20. Those who are entitled to NHS treatment should receive it on the basis of need, free at the point of delivery irrespective of where they live. Telemedicine may have a role in some remote areas but this should be in addition to, rather than instead of, face-to-face consultations. Where telemedicine is the most effective way of delivering healthcare, and this incurs additional cost, this should be paid for by the health service. The development of Telemedicine can provide improved opportunities of access, especially for those in remote areas. Such decisions are best made at a local level by PCTs or Health Boards in consultation with health professionals and the public.

21. The RCGP Rural Practice Group has an interest in this area. We would be happy to facilitate liaison with them for further advice on specific issues on how Telemedicine currently operates and what benefits it could have for rural and remote patients in the future.

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 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.

22. No. Improved common regulation across private and public providers is needed. All private health establishments are regulated by the Care Quality Commission. Although it is too early to say how this will work out in practice. The CQC in partnership with other regulators and standard setting bodies, such as the MHRA and NICE, should ensure that certain common quality standards are met by such organisations. Where possible we believe that common quality, safety and fitness for purpose standards should be applied across private and public providers. Tests such as CT scanning have associated health risks and private provision needs regulation. Other harms that will benefit from improved regulation are those associated with an untrained professional providing test results to an individual. As previously stated this can cause anxiety and other mental and physical harms that must be considered in the mechanics of regulation.

23. There are grounds for restricting the availability of some tests to require the involvement of health professionals. Decisions should be made on the basis of the implications of the test. For example, it may be acceptable for some genetic tests, which reveal carrier status among those with no family history for example, to be made available directly to the public but for predictive genetic tests, particularly those for serious and untreatable conditions such as Huntington's disease, to be restricted to testing within a healthcare setting (whether NHS or private). There is a precedent for this with HIV where in 1992 it was made an offence to sell HIV testing kits directly to the public. The growing use of the Internet does, however, complicate this since individuals who want to seek testing could get around such restrictions by using companies based in other countries.

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?

24. No, provided that proper regulation is in place and adhered to. However the question of such liability needs more detailed consideration. There will also be existing mechanisms for redress.

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"?

25. The provision of adequate and accurate information, as previously stated, should be a requirement. Key issues in direct to the public services are the quality, accuracy and format of the information provided – this is the responsibility of the company providing the service. This information should provide data about the evidence-base, discussion of the possible outcomes and the implications of them, should explain where additional support can be sought (including whether there are health professionals available within the company to provide information and support) and, ideally, should encourage people to keep their GPs informed of any results obtained.

26. Reference in the question to publicly funded investment is confusing. If this is referring to public investment in improving the technology then this will depend upon its usefulness to the NHS and whether funds are available for this purpose. If it refers to the cost of regulating the service and/or information provided by private companies then this is part of a bigger question about the need for regulation. If a decision is reached that regulation is necessary then this is usually funded by those who are subject to regulation (as with the Human Fertilisation and Embryology Authority and the Human Tissue Authority).

OTHER ISSUES

Question 15

Are there any other issues we should consider?

27. The fact that improved regulation of commercial providers of health care services in UK and EEA areas will not apply to services in other areas that consumers can access via the internet should not stop such regulation from taking place. Such improved regulation

should be sought in the UK and EEA and should also be campaigned for in other jurisdictions.

28. I gratefully acknowledge the significant contributions of Dr Kate Adams, Dr Peter Davies, Mrs Ailsa Donnelly, Dr Duncan Keeley, Dr Bridget Osborne and the RCGP Committee on Medical Ethics towards the above comments.

Yours sincerely

Dr Maureen Baker
Honorary Secretary of Council