Nuffield Council on Bioethics: Medical Profiling and Online Medicine

Response by the Wellcome Trust

July 2009

Introduction

1. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending over £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. The Wellcome Trust is pleased to respond to the Nuffield Council on Bioethics' consultation on medical profiling and online medicine. Given the Trust's interests as a research funder, this response focuses on issues related to research and governance.
3. We are a major funder of genetics and genomics research – providing support through our grant funding programmes for outstanding scientists in the UK and overseas to take forward cutting edge genetics research and related technology development activities. We also support the Wellcome Trust Sanger Institute in Hinxton, Cambridgeshire – one of the world's leading genomics research centres. The Sanger Institute played a key role in the international Human Genome Project, taking responsibility for producing one third of the genome sequence.
4. We also support a broad range of activity to engage the public in biomedical science and its implications for society and we are currently funding Society Awards[1] addressing the theme of genes and health. These grants include:
    - "Needles in a DNA-stack" – developing materials to assist with teaching of genome-wide association studies in schools.
    - "Not my fault" – a Theatrescience project involving writers, scientists, medical students and school students. This will culminate in performances of plays that challenge misconceptions about genetics, performed in the Biomes of the Eden Project.
    - A series of workshops run by W5, Northern Ireland, to explore young peoples' attitude to public health genetics, including personal genetic testing. The findings will be used to develop education materials to aid the teaching of the interactions of environmental and genetic factors in disease.
5. Through our Biomedical Ethics programme, we fund research to examine the ethical dimensions of biomedical science and healthcare – this has included several projects exploring issues arising from genetics and its healthcare application.

[1] http://www.wellcome.ac.uk/Funding/Public-engagement/Grants/Society-Awards/index.htm

Comments in response to consultation questions

Validity of Information (Q2)

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?

6. The contributions of specific genetic factors to many complex diseases are poorly understood, therefore results of some DNA profiling services are of limited predictive value. We welcome the House of Lords Science and Technology Select Committee report on Genomic Medicine[2], and the recommendations relating to direct-to-consumer tests.
7. The Trust believes that DNA profiling and body imaging services do not raise different questions to other forms of medical tests or information. However, because of the limited predictive value of some tests, it is important that accurate and trusted sources of information are available to the public on the tests that are provided by companies offering DNA profiling and body scanning services.
8. In order for individuals to be able to respond to information provided about DNA profiling and body scanning services there is a need to ensure that the public is appropriately informed and engaged on advances in genetics and genomics. If the public have realistic expectations of genomics and its healthcare potential this will equip them to act as an 'intelligent customer' for these services. The Department of Health, media and research community have vital roles to play in ensuring that this information is communicated in a balanced way in terms of benefits and risks. Continued focus by Government and other funders on public engagement work should remain a core component of efforts to ensure that the vision of genomic medicine is realised in the most appropriate way. The Wellcome Trust Monitor survey found that 36 per cent of adults thought that direct-to-consumer genetic tests were definitely or probably a good idea[3]. Of the people who thought that the tests were a good idea, 20 per cent thought that it would avoid the need to go to a doctor and another 17 per cent thought that the tests should be available to all. 61 per cent thought that direct-to-consumer genetic tests were definitely or probably a bad idea. Of these, a quarter felt that people with medical knowledge should be involved and another 36 per cent raised issues of the lack of regulation and counselling.
9. We recognise that the appropriate interpretation of test results by consumers relies upon the effective communication of genetic risk by the provider and adequate education of the consumer.

Who Pays? (Q4)

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?

10. Privately funded DNA profiling and body scanning will have resource implications for publicly funded healthcare as patients seek follow-up diagnosis and treatment, or advice about their

[2] http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf
[3] The Wellcome Trust Monitor: A survey of adults' and young people's awareness, interests, knowledge and attitudes to biomedical research. The report will be released later this year.

test results. Where available the most appropriate treatment should be publicly funded in instances where a medical condition has been diagnosed through these tests. However, not all cases will involve a clear diagnosis and therefore the complex issue of funding of follow-up services requires further consideration.

11. It is likely that increasing numbers of patients will seek advice from physicians based on the results of direct-to-consumer genetic tests. There is, therefore, an urgent need to ensure that professionals across the health service are educated on genetics and the ethical and social issues it raises and it is important that they are able to accurately convey genetic risk to patients. Access to specialist genetic counselling services may need to be provided if appropriate.

Regulation (Q12)

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?

12. Regulation of direct-to-consumer services constitutes a real challenge and it will likely not be practical to exert the same level of evaluation on these tests as those that are provided within the NHS. There are significant concerns about the scientific and clinical validity of some direct-to-consumer tests, the limited availability of accompanying medical supervision and counselling, and the lack of regulatory approval. This is an area that needs further attention and we note that formal regulation is not the only means of controlling the use of these services. The House of Lords Genomic Medicine[2] report considered other means of controlling direct-to-consumer tests, such as development of a code of conduct and accreditation, which we support. As noted in paragraph 7 it is vital that accurate and trusted sources of information are available to the public on the tests that these companies provide.

Responsibility for Harm (Q13)

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?

13. It is important that direct-to-consumer tests return information of high quality and in theory, we believe that providers should be accountable for harm that has clearly been caused as a result of their products or services. However, in practice it may be very difficult *at law* to hold a provider responsible for harm caused because there would be a number of matters of both fact and law that would need to be established in order to hold a provider responsible at law. Anyone wishing to bring a legal action against a provider in such circumstances, certainly under English law, would need to establish (i) that the provider owed the consumer a duty of care, but also (ii) that the provider had breached that duty of care and (iii) that the breach had caused the harm, in whole or in part. This latter point may be very difficult to establish as a provider may be able to point to many different possible causes of the harm, for example, in the event of a suicide allegedly caused as a result of predictive information received, the provider could argue that the individual was already depressed.

14. There may also be issues of governing law and jurisdiction where products are sold globally on-line, for example, where the provider and the consumer may not be in the same jurisdictions. This may complicate the ability to easily hold a provider legally responsible.

15. Doubtless any provider will include disclaimers and exclusions of liability on their products or relating to services provided by them which may make it difficult in practice to successfully bring an action against a provider.

16. These issues highlight the importance of finding a way to ensure that providers of such products or services are responsible in the way that they describe their products and services and their limitations and risks. However, it also demonstrates the importance of ensuring that the public are adequately educated in order to have realistic expectations of DNA profiling and body scanning (see paragraph 8) and that healthcare professionals are suitably trained to deal with patients seeking advice on test results (see paragraph 11).

Quality of Information (Q14)

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?

17. Progress is being made to understand how genetic factors contribute to disease. For example, the Cancer Genome Project[4] at the Wellcome Trust Sanger Institute has identified mutations in cancers and the Wellcome Trust Case Control Consortium[5] has identified novel genes that affect susceptibility to some complex diseases. However, currently DNA profiling is of limited use because in many cases the genetic contribution to disease is poorly understood. The total contribution by most genetic factors is small and much more research is required to characterise the ways in which particular factors influence risk of protection. Further research is required to understand how genetic, environmental and lifestyle factors contribute to the development of complex multifactorial diseases, which will require studies of large cohorts, which bring together genomic data with medical and lifestyle information.

Are there any other issues we should consider? (Q15)

18. The Wellcome Trust Monitor survey[3] found that 80 per cent of adults said that they would be 'very likely' or 'quite likely' to take a genetic test if there were treatments or other means of reducing the risks of any diseases diagnosed. This number fell to 42 per cent if there were no treatments or other means of reducing the risks of any diseases diagnosed.

19. The collaboration between organisations with direct-to-consumer DNA profiling services is setting a new precedent for research, for example the partnership between National Parkinson Foundation and 23andMe[6]. Under this scheme participants get a reduced rate from 23andMe and share their data for research purposes. This may set an expectation that individuals participating in genetics research should get feedback about their results and the implications of this need further consideration, for example if it becomes more difficult to recruit individuals for studies where individual feedback is not feasible.

20. It is important that there is clarity in who owns the data generated from DNA profiling and body imaging and that this ownership is not abused.

21. Whilst we believe that the opportunities to share genomic data should be maximised, it is vital that appropriate technical and regulatory safeguards exist to protect the confidentiality and security of personal information collected. There are also legitimate concerns regarding the use

[4] For more information on the Cancer Genome Project, see: www.sanger.ac.uk/genetics/CGP
[5] For more information on the Wellcome Trust Case Control Consortium, see: www.wtccc.org.uk
[6] http://www.parkinson.org/23andMe

of genetic information in non-medical contexts – including insurance and employment, and appropriate regulatory provisions will likewise be required to address these concerns.

22. Public confidence in genetics research may be damaged if individuals are disappointed by DNA profiling services or experience problems with data management or confidentiality. It is therefore important to engage the public in the development of any regulatory framework and to ensure that the framework is proportional to the risks involved.