Genome Medicine

Meeting report

The ethics and regulation of direct-to-consumer genetic testing

Paula Boddington

Address: Ethox Centre, Division of Public Health and Primary Health Care, University of Oxford, Badenoch Building, Old Road Campus, Headington, Oxford OX3 7LF, UK. Email: paula.boddington@ethox.ox.ac.uk

Abstract

A report of the workshop 'Direct-to-consumer genetic testing: ethical and regulatory issues', Oxford, UK, 21 May 2009.

Introduction

The one-day workshop 'Direct-to-consumer genetic testing: ethical and regulatory issues' was an initiative of the Oxford Bioethics Network, organized by The Program on the Ethics of the New Biosciences and The Ethox Centre. A small event with approximately 70 delegates attending from greatly varying disciplinary backgrounds, it produced vigorous discussion. This was the first time a group of diverse experts has been gathered together in the UK to discuss the scientific, ethical and regulatory aspects of commercial genetic testing, and throughout the day there were far more questions and comments than could be accommodated, with breaks between sessions continuing the lively discussions.

Clinical and scientific background

Jenny Taylor (Oxford Biomedical Research Institute, Oxford, UK) explained the translation of genetic research into clinical practice, within the context of the UK National Health Service (NHS). Taylor explained the lengthy translational process and the many barriers that can stand in its way. Importantly, unlike pharmaceutical products, there is no clear regulatory pathway for diagnostics; thus, there is little guidance about whether tests are clinically appropriate. Taylor herself suggested that the NHS should offer genetic testing to optimize the correct dosing of the blood-thinning drug warfarin, but did not feel that the clinical utility of many cancer tests had yet been shown. In an overview of the very different services that direct-to-consumer (DTC) companies are offering, she pointed out that the tests offered commercially have almost no overlap with the list of genetic tests currently available through the NHS.

One of the commentators from the floor observed that the commercial companies act as gatekeepers to genetic information just as much as health care services and government regulators do in deciding what tests to offer, and how, and for what price. This reflected a theme taken up at various points during the meeting.

Andrew Wilkie (Weatherall Institute, University of Oxford, UK) announced the axe he has to grind: that he is a clinical geneticist who sees patients who want answers that give certainty and information on risks that is meaningful. He argued that the predictive ability of genetics is likely to be low. Genome-wide association studies have fueled the hype of personalized medicine, but the low-hanging fruits have already been found. Whole-genome sequences are likely to give very little useful information. Even for conditions such as cystic fibrosis, the usefulness of widespread testing is limited by the difficulty that, without experience of a disease, test results often mean very little to people. A huge percentage of disease is preventable by simple environmental changes.

Commercial services

Agnar Helgason (Decode Genetics, Reykjavik, Iceland) gave an outline of the different services offered by deCODEme [http://www.decodeme.com/], from 'healthwatch' scans to ancestry tests and tests of relatedness. He focused mainly on the question of the quality of the information provided. There are regular updates and additions to the information provided on the website, and all the references and sources used are given together with explanatory material. Customers have many different motivations, including educational, recreational and for preventative health care, and he claimed that his company's services represented a democratization of privileged scientific information to the public. The question is, 'would we want to stop people buying these tests?' and the only argument against them is that 'people are too stupid to understand'.

Ethical, societal and economic issues

In a contrasting view, Jonathan Wolff (University College London, UK) provided a broader base for ethical argument. Although arguments that the individual has a right to his or her own genetic information are hard to counter, we need to examine the ethics of information, asking how information is used and who has the power of gatekeeper

DTC, direct-to-consumer; NHS, National Health Service.

over knowledge. He referred to works of 19th century philosophy, arts and drama, where a common theme was the often dangerous power of knowledge. He also noted that even if an individual has a right to something, this does not mean it is a good thing on a societal level; and likewise, regulation is not necessarily an appropriate response to everything that might in some circumstances produce harm.

Helen Wallace (Genewatch, Buxton, UK [http://www.genewatch.org/]) argued also that we need to see a bigger picture - in this case, one that includes the economic interests of various industries in marketing pre-symptomatic medical services to the rich well. The wrong ethical issues are examined: it is not so much 'do you want to know?' but 'can you trust what you are told?' The market fails to provide clear and transparent communication, with consumers dependent on companies for information and the public relations context making it hard for consumers to be aware of potential problems with the information. Wallace also spoke of a diversion of resources into individually based research at the expense of social, economic and environmental issues. Genetic testing is a dual use technology that can be used for biosurveillance. The UK government should sign the European Convention on Human Rights and Biomedicine, Article 12 of which requires that predictive genetic tests be performed only for health or health research purposes and be subject to appropriate counseling.

Market and legal regulation

Rob Reid (policy adviser with the consumer association 'Which?', Hertford, UK [http://www.which.co.uk]) provided an antidote to any simple response that commercial genetic testing services should operate in an unfettered market. Making the point that advertising needs regulation, he argued that DTC companies should make it clear that the clinical validity and utility of their tests is in doubt. A 'Which?' survey found a substantial, potential market for such services, but also that most respondents thought these tests should be conducted by medically trained personnel and should be strictly regulated. As a speaker from the floor pointed out, those who consider that regulation is paternalistic can hardly argue that consumers are wrong to want such regulation without themselves being paternalistic.

Jim Kinnear Wilson (a partner of the law firm Manches, Oxford, UK [http://www.manches.com], specializing in intellectual property law) gave a useful synopsis of UK regulatory issues and consumer protection laws. The UK has generally less regulation for services than for goods, with no equivalent to the Consumer Protection Act. Into this regulatory vacuum are entering the DTC companies offering their services.

Concluding remarks

The event highlighted the need for a diversity of approaches to appreciate how and why different views on DTC testing are taking shape, and why such cross-fertilization is needed for an informed and broad perspective. The debate was shown to be so much more than the simple question of whether services should be 'banned', and concerns were raised that go beyond even the complex issues of regulation. It is strongly to be hoped that the mix of ideas at this workshop feeds into the ongoing discussions. A fascinating lesson from the day was that the presentation and control of information itself raises ethical issues; the different professional perspectives of the speakers led each of them to valuable insights into the significance, value and use of genomic information, insights that were sometimes compatible, sometimes conflicting. Scientists, who are well versed in controversies over the interpretation and significance of genomic data, are well placed to add their expertise to such debates.

Competing interests

The author declares that she has no competing interests and was not a member of the organizing committee of this workshop.

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