Procardis Ethics Newsletter 4

July 2009

Direct-to-consumer testing workshop, Oxford May 21st

This was a very interesting and stimulating day. There are more and more such companies offering a range of services, and these developments are sure to have an impact upon understandings of and expectations of genomic science. A short report of the meeting, ‘The ethics and regulation of direct-to-consumer genetic testing’ is available in Genome Medicine 2009, 1:71 (20 July 2009) (free open access).

The UK House of Lords Science and Technology Committee Genomic Medicine Report

This report was released on July 7th. It can be found online at http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf

This report makes a number of recommendations relevant to the work of Procardis and similar projects. Some of the points of interest to note concerning ethical and social issues discussed in the report are:

Public understanding and engagement of genetics of common complex disorders

The report suggested that there needs to be more public engagement activities around the implications of genetic tests for common complex diseases, which would include of course cardiovascular disease. Most debate and discussion about genetic testing has so far concerned single gene disorders. It recommends that the Human Genetics Commission (HGC) promote a wide ranging debate on ethical and social issues relating to genetic tests and gene associations for genetically complex diseases, and how these contrast with gene tests for single gene disorders.

The report also suggests that the Department of Health (DoH) creates a public information website which would review the most recent science on the genetics of complex diseases and help the public understand and interpret the results of genetic tests.

In making such suggestions, the report is very much focused on the implications of genetic tests. Arguably there is also a need more generally for greater public understanding of the broader aims and implications of current genetic research on common complex disorders.

Regulation of genomic research

Various difficulties with regulation were discussed, stemming from the complex nature of the relevant regulations and from challenges posed by advances in science and technology in this area. For example, it remains unclear what counts as legally acceptable levels of anonymisation. The report was ‘struck by the weight of evidence about difficulties arising from the bureaucratic burden of the current regulatory framework’ (p. 58) and the lack of clarity of much of the legislation, and recommended reducing this burden.

The report urges the Information Commissioner to publish a set of ‘clear, feasible and proportionate guidelines, in accordance with the Data Protection Act 1998 (DPA), specifically for researchers handling genetic data for the purposes of non-personal research in order to reduce the burden of data protection legislation on researchers.’ (p. 61). It also urges the government to amend the DPA to facilitate non-personal research with genetic data. The approach used by UK Biobank to ensure
protection of personal privacy was held up as an exemplar and the report encouraged the Department of Health to consider adapting such an approach.

These calls to reduce the burdens of a cumbersome and unclear regulatory framework should be good news for research and we must hope there will be opportunities for researchers to feed into work streamlining the regulation of the research process whilst maintaining high and appropriate standards of protection for research subjects. The report calls for a new Government White Paper on genomic medicine.

**Legal issues in genomic research**

A group from the Ethox centre are drafting a paper exploring legal issues arising in genomic research. There are a large number of issues that need to be addressed, as indeed the House of Lords Genomic Medicine report also makes clear. For example, it may not be precisely clear in law what duty of care researchers in genomics have towards research participants. The work focuses on UK law. The group are however also examining a number of legal issues that potentially arise given the international nature of much genomic research, with researchers working across different jurisdictions where different regulatory regimes apply.

**Procardis ethics internship**

Examination of ethical issues in medical research requires good communication and strong links with scientific researchers. With the aims of fostering such links and building capacity within the Procardis team, the Ethox centre is offering informal ‘ethics internships’ to interested scientists. In other words, this will take the form of flexible training in ethics and associated philosophical argument and analysis. We hope this will develop the capacity for fruitful collaboration between disciplines. Anybody interested should feel free to contact Paula Boddington.

‘And finally’

Each term Oxford University holds an online debate, and this term the topic was the controversial one ‘The NHS should not treat self-inflicted illness’. With funding pressures on the NHS, and with frequent public and government discourse about responsibility for health, this is a potentially controversial topic. The motion was defeated with 84% voting against.

One of the key questions behind this debate, discussed by the protagonists and by contributing members of the public, is whether or not it is possible to identify if a condition is self-inflicted, and what aspects of causation are the responsibility of the patient. Cardiovascular disease is a complex condition that well illustrates the difficulty of making any quick judgments. The work of Procardis in helping to identify the underlying biological causes of cardiovascular disease is a good illustration of its great complexity. It is often supposed that if a condition is ‘genetic’ you are not ‘responsible’ for it. But not only is the aetiology of conditions like cardiovascular disease highly complex, so too our ideas of responsibility are complex, and, some might say, fickle.

To view the debate, go to [www.oxford.ac.uk/debates](http://www.oxford.ac.uk/debates).