

# **Do we need knowledge brokers?**

## **Academics as policy entrepreneurs**

**Presentation at 'Bridging the Gap between Research,  
Policy, and Practice'  
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**Stuart Hogarth,  
Department of Political Economy,  
King's College London**

# **Policy issues in the evaluation of genetic tests for common diseases**

**Project funded by Wellcome Trust Bioethics programme**

**March 2004 - September 2007**

## **Team**

- **PI: Professor David Melzer, University of Cambridge (now Exeter) – public health doctor, genetic epidemiologist**
- **Co-investigators: Ron Zimmern, Public Health Genetics Foundation; Tom Ling, RAND Europe; Kathy Liddell, University of Cambridge**
- **Research Associate: Stuart Hogarth**

**Policy problem**

# Slow down, you move too fast ?

“[There has been] a noticeable lack of consensus within the genetics community about exactly when a test for a new marker was sufficiently validated for it to enter into clinical service.

Some labs rushed to provide testing after the first publication, while others waited until the result had been replicated in multiple studies or multiple ethnic groups.”

Emily Winn-Deen, Cepheid

*IVD Technology* December 2003



# Our research

## Aims

*How do we ensure that doctors, patients and healthcare systems can make informed decisions about the use of new genetic tests?*

- Enhancing the regulation of genetic tests to ensure robust independent evaluation
- Enhancing the incentives needed to encourage test developers to generate high-quality clinical data
- Map regulatory landscape, identify regulatory gaps, explore stakeholder views on policy responses

## Methods

- Interviews and workshops (3 UK, 2 USA) with 80 individuals from key stakeholder groups in Europe, USA, Canada and Australia

# Outputs

# Academic papers

S Hogarth 'The regulation of nutrigenetic testing – a role for non-governmental organisations?' *Health Law Journal, Special edition Autumn 2007*

S Hogarth, K Liddell, T Ling, D Melzer and R Zimmern 'Closing the gaps – enhancing the regulation of genetic tests using responsive regulation' *Food and Drug Law Journal* November 2007

D Melzer, S Hogarth, K Liddell, T Ling and R Zimmern 'The new common disease genetic tests: new insights, old concerns' *British Medical Journal* 2008;336:590-593 (15 March)

S Hogarth, G Javitt and D Melzer 'The current landscape for direct-to-consumer genetic testing: legal, ethical and policy issues' *Annual Review of Genomics and Human Genetics* 2008. Vol.9

K Liddell, S Hogarth, D Melzer and R Zimmern 'Patents as incentives for translational and evaluative research: the case of genetic tests and their improved clinical performance' *IP Quarterly* Autumn 2008

# Academic papers

S Hogarth 'From genomic research to public health practice – international policy implications' in B Knoppers (ed.) *Genomics and Public Health: Legal and Socio-Ethical Perspectives* (Leiden: Martinus Nijhoff, 2007)

S Hogarth 'The regulation of genetic tests, an international comparison' in D Castle and N Ries (eds.) *Nutrition and Genomics: Issues of Ethics, Law, Regulation & Communication* (Elsevier, 2009)

S Hogarth 'Myths, misconceptions and myopia: searching for clarity in the debate about the regulation of consumer genetics.' *Public Health Genomics* 2010; 13(5): 322-326.

S Hogarth 'The IVD Directive and genetic testing' in J-J Cassiman, U Kristofferson and J Schmidtke (eds.) *Quality issues in clinical genetic services* (Springer, 2010)

D Ibarreta and S Hogarth 'International conventions on genetic testing' in J-J Cassiman, U Kristofferson and J Schmidtke (eds.) *Quality issues in clinical genetic services* (Springer, 2010)

F Frueh, H Greely, R Green, S Hogarth, S Siegel 'The future of direct-to-consumer clinical genetic tests.' *Nature Review Genetics* 2011; published online 1 June 2011.

# Media work

## Broadcast media

- BBC Politics Show
- BBC Radio 4 Analysis
- Sky News

## Print media

- All UK broadsheets (including op-ed on The Guardian website) and some tabloids
- Wired, BioWorld, Pharmacogenetics Reporter, The Grey Sheet

Organised Science Media Centre Briefing in December 2007

# Public engagement

Helped organise (and spoke at)

## ***DNA testing – science or swindle?***

A public event about consumer genetics held in January 2009 at the DANA Centre, London (tie-in to BBC Radio 4 Analysis documentary).

# Policy engagement

## Human Genetics Commission

- 2005 – briefing on the regulation of commercial genetic testing services in the UK
- 2007 – helped organise (and spoke at) *Genes Direct* follow-up meeting
- 2008 – helped organise (and spoke at) meeting to discuss to value of code of practice
- 2009/10 – member of working group developing guiding principles for a code of practice

## Other

- Written and oral evidence to House of Lords enquiry on genomic medicine

# Policy engagement

## European Union

- 2007 – presented policy briefing to meeting of all member state regulatory agencies : The IVD Directive and genetic testing: problems and proposal. (Briefing then adopted by ESHG and EuroGentest as position paper).
- 2008 – expert adviser to STOA/ETAG project on consumer genetics
- 2008/9 – co-author EuroGentest response to consultations on recast of medical device directives and reform of IVD Directive
- 2009 – presented at STOA/ETAG workshop at European Parliament

# Policy engagement

## North America

- 2006/7 – reports for Health Canada on regulation of pharmacogenomics and on policy implications of new molecular diagnostic technologies
- 2007 – FDA Leveraging/Collaboration award
- 2007 – on organising committee for Genetic Alliance meeting on genetic testing policy
- 2008 – presented to Secretary's Advisory Committee on Genetics Health and Society
- 2009 – presented at Health Canada meeting on genetic testing quality
- 2011 – presented at FDA advisory panel meeting on consumer genetics

# Policy engagement

## International

- 2007 – lead author of international response to consultation on Global Harmonisation Task Force models for risk classification of IVDs
- 2008 – on the organising committee for international meeting on consumer genetics held in Tokyo
- 2007-10 – participated in three OECD meetings on genetic testing policy issues (and broader biomedical innovation governance agenda)

# **Policy impact**

# Policy impact

## UK

- HGC Guiding Principles (but no code of practice)
- House of Lords report

## European Union

- IVD Directive reform proposals and consultation response

## International

- Global Harmonisation Task Force risk classification model
- OECD Guidelines on quality assurance for genetic testing

# Policy impact

## Ingredients for success

- Early engagement with key stakeholders
- Engagement as iterative process
- Timeliness
- Collaborators with strong policy networks
- Generous funding
- Lengthy period for dissemination activities

# **Swings and roundabouts**

# Academic policy entrepreneurship

## Benefits

- Intellectually stimulating
- Potential benefits to society
- Policy as alternative career
- Policy consultancy as additional income stream
- Increasing focus on policy impact by research funders

## Challenges

- Opportunity costs - time consuming, so need to balance with academic publications and networking
- Long haul - policy timeline is far longer than research project timeline: how long are you willing to stay involved?