OECD WORKSHOP VIENNA 2000 ON GENETIC TESTING
POLICY ISSUES FOR THE NEW MILLENNIUM

PROGRAMME

Dates	23-25 February 2000
Venue	Festsaal - Federal Chancellery, Radetzkystrasse 2 A-1031 Vienna, Austria
Chair Session 1 *(Setting the Scene)* Rapporteur	Dr. D. Harper, *Chief Scientist, Department of Health, United Kingdom* Dr. P. Minor, *Division of Virology, National Institute for Biological Standards and Control, United Kingdom*
Chair Session 2 *(Access to Genetic Tests)* Rapporteur	Dr. J-C. Galloux, *Professor, University of Versailles, France* Dr. N. Zacherl, *Forschungsinstitut für Molekulare Pathologie, Vienna, Austria*
Chair Session 3 *(Laboratory Quality Assurance)* Rapporteur	Dr. Margeret McGovern, *Associate Professor and Vice-Chair, Department of Human Genetics, Mount Sinai School of Medicine, United States* Ms. C. Netterfield, *Office for Policy and Co-ordination, Health Canada*
Chair Session 4 *(Impact of Free Market & Technological Developments)* Rapporteur	Dr. P. Propping, *Professor, Human Genetics Department, University of Bonn, Germany* Dr. H. Karlic, *L. Botzmann Institute, Austria*
Chairs Session 5 *(Ethical/Legal/Social Aspects Technological Developments)* Rapporteur	Dr. B. Knoppers, *Professor, Université de Montréal, Canada and* Dr. A. Pompidou, *Professor, Faculté de Médecine, La*boratoire d'Histologie, Hopital Cochin - Port-Royal, France Dr. A. Daar, *Chairman Department of Surgery, College of Medicine, Oman*
Chair Session 6 *(International Policy Forum)* Rapporteur	Dr. A. Taylor, *Genetics Secretariat, Department of Health, United Kingdom* Dr. P. Minor, *Division of Virology, National Institute for Biological Standards and Control, United Kingdom*
Workshop Rapporteur	Dr. P. Minor, *Division of Virology, National Institute for Biological Standards and Control, United Kingdom*
Organisers/Sponsors	OECD, Directorate for Science, Technology and Industry (DSTI); Federal Chancellery, Austria; Department of Health, United Kingdom

STATEMENT OF OBJECTIVES AND SCOPE OF THE CONFERENCE

Ad hoc working definition of genetic testing

"Genetic testing is testing for variations in germline DNA sequences, or for products/effects arising from changes in heritable sequences, which are predictive of significant health effects."

1. This definition is a working definition, intended to draw a boundary around the issues to be discussed at the workshop.
2. It is worded to enable wider issues to be discussed at the workshop, in addition to the science and technology.
3. It specifically excludes identity testing and acquired changes in a person's DNA.
4. It covers genetic testing that is diagnostic of a particular disease or condition as well as predictive genetic testing that is carried out before there are any clinical signs of the disease or condition.
5. It refers to testing in the individual for germline changes.
6. It may have relevance both to the individuals being tested and their wider family and offspring.
7. Even when undertaken at the population level (population screening), genetic testing should be performed for the benefit of the individual.

Aims and objectives

- ***To review the current situation in genetic testing and to explore the impact of new genetic technologies upon healthcare practice in the next few years.***
- ***To consider the impact of commercialisation of new genetic technologies on healthcare economics and on the delivery of genetic testing.***
- ***To endorse best practice and make policy statements on:***
  - *The importance of genetic counselling.*
  - *Storage and confidentiality relating to samples and genetic data.*
  - *Facilitating access to genetic testing.*
  - *Appropriate involvement of patient/consumer groups in policy making, regulation and oversight.*
  - *Referring tests to accredited facilities.*
- ***To consider the benefits of international harmonisation in the areas of:***
  - *Regulation of the validation of genetic tests.*
  - *International recognition of external quality assessment programmes.*
  - *Standards for recording of genetic data.*
  - *Evaluation of the efficacy of new genetic tests and technologies.*
  - *International recognition of laboratory accreditation.*

First Day, Wednesday 23 February 2000
8.00-8.45 Registration

Opening Session: Official Welcome and Opening Speeches

8.45-9.00 Welcome
Mr. R. NEZU, Director, Directorate for Science, Technology and Industry, OECD

Conference Goals and Objectives
9.00-9.15 Dr. A. HASLBERGER (Austria)
9.15-9.30 Dr. D. HARPER (United Kingdom)

Session 1: Setting the Scene

(Chair: Dr. D. Harper; Rapporteur: Dr. P. Minor)

This session will review scientific/clinical developments in our understanding of the way in which genetic factors contribute to disease, and developments in technology which have the potential to revolutionise the way in which genetic testing services are delivered. The session will also review policy issues relevant to genetic testing, which are being considered in other international forums.

9.30-10.15 New Developments in Genetics for the New Millennium
Professor B. MODELL (United Kingdom)

10.15-11.00 Benefits and Costs of Genetic Testing: the Case of Breast Cancer
Dr. V. GRANN (United States)

11.00-11.30 Coffee Break

11:30-12:30 International Issues:

World Health Organization (WHO)
The Ethical Issues in Human Gene Testing and Community Screening
Dr. B. WILLIAMSON (Australia)

HUGO
International "Genomic" Ethics and HUGO
Professor B. KNOPPERS (Canada)

12.30-13.00 From Gene-specific Tests to Pharmacogenetics
Dr. L. MIDDLETON (United Kingdom/Glaxo)

13.00-14.15 Lunch

14.15-14:45 Case Study
Dr. T. FRANK (United States/Myriad)

14.45-15.15 Prenatal Testing and Screening for Down Syndrome: Lessons From Practices in Europe
Professor S. AYMÉ (France)

15.15-15.45 Discussion on the Scope and Objectives of Genetic Testing

Session 2: Access to Genetic Tests

(Chair: C. Galloux; Rapporteur: N. Zacherl)

This session will review how access to genetic tests is likely to change, and will include consideration of the limitations of testing and the "therapeutic gap", i.e. testing for conditions for which there may be no satisfactory treatment. Public oversight and legal issues will also be considered.

15.45-16.15	Access to Genetic Tests - Legal Aspects Professor O. GUILLOD (Switzerland)
16.15-16.45	*Coffee Break*
16.45-17.15	Forecasting Legal Scenarios Justice F. ZWEIG (EINSHAC, United States)
17.15-18.45	**Panel 1** *Possible impacts of a free market and changing access. Public oversight, legal and regulatory issues.* Participants: International Consumer's Associations and Patient Organisations: Dr. A. KENT (United Kingdom); Dr. Ad Van Bellen (Netherlands), Dr. N. ZACHERL (Austria)
20.00	*Reception*

Second Day, Thursday 24 February 2000

Session 3: Laboratory Quality Assurance

(Chair: Dr. M.M. McGovern, Unido; Rapporteur: C. Netterfield)

This session will consider the desirability of:
- Clients and clinicians referring genetic tests to accredited facilities.
- Mutual Recognition Agreements between regional bodies.
- Harmonization of regulatory regimes for the validation of genetic tests.
- Mutual recognition of EQA systems across OECD countries.

9.00-9.30	Validation of Genetic Tests Dr. U. KRISTOFFERSSON (Sweden)
9.30-10.00	Laboratory Accreditation Dr. M.M. MCGOVERN (United States)
10.00-10.30	External Laboratory Assessment Schemes Dr. R. ELLES (United Kingdom)
10.30-11.00	Genetic Screening for Cancer: False Positives and Predictability Dr. P. VINEIS (Italy)
11.00-11.30	*Coffee Break*
11.30-12.00	The Development of "Best Practice" Guidelines for Molecular Genetic Testing Dr. D. BARTON (Ireland)
12.00-13.00	Discussion on Session 3
13.00-14.30	*Lunch*

Session 4: Impact of the Free Market and Technological Developments on Service Availability, Service Delivery and Genetic Support Services

(Chair: Professor P. Propping; Rapporteur: Dr. H. Karlic)

This session will examine goals of genetic counselling in relation to genetic testing. The effects of gene patent licensing arrangements and commercialisation on the delivery of genetic testing will also be covered.

14.30-14.45	Free Markets and New Diagnostic Technology Dr. E. RONCHI (OECD)
14.45-15.15	Availability of Genetic Services (includes resource issues) Dr. I. BLANCQUAERT (Canada)
15.15-15.45	Genetic Counselling: Evolution of Involution? Professor M. FRONTALI (Italy)
15.45-16.15	*Coffee Break*
16.15-17.30	**Panel 2** *The future role of counselling: education and training needs.* Participants: Professor H. YOSHIKURA (Japan), Professor P. PROPPING (Germany), Dr. T. FRANK (Myriad, United States), Dr. E. KUBISTA (Austria)
19.00	Heuriger (Buffet Dinner)

Third Day, Friday 25 February 2000

Session 5: Ethical, Legal and Social Aspects

(Chairs: Professor B. Knoppers and Professor A. Pompidou; Rapporteur: Dr. A. Daar)

This session will review the wider ethical and legal issues raised by genetic testing and will include consideration of areas where further international co-operation could add value.

9.00-10.00	Icelandic Database Dr. D. GUNNARSSON (Secretary-General, Ministry of Health, Iceland)
	The Icelandic Healthcare Database: Risks and Benefits Dr. K. STEFANSSON (Decode Genetic)
10.00-10.15	Creation of the Estonian Human Genome Heredity Dr. A. RANNAMÄE (Estonia)
10.15-10.45	Banking Biological Collections and Digitalizing DNA: Data Warehousing, Data, and Data Dilemmas in Molecular Medicine and Public Health Policy Dr. R. BLATT (United States)
10.45.-11.15	*Coffee Break*
11.15-11.45	Privacy and Confidentiality of Genetic Data Dr. B. LOWRANCE
11.45-12.15	Legal, Ethical and Social Issues Professor S. RODOTA (Italy)
12.15-12.45	Genetic Testing and Life Insurance Dr. B. BALDINGER (Swiss Reinsurance/Switzerland)
12.45-14.15	*Lunch*
14.15-15:15	**Panel 3** *Questions and discussion on Session 5.* Suggested Participants: Session speakers

Session 6: International Policy Forum and Final Policy Considerations

(Chair: Dr. T. Taylor; Rapporteur: Dr. P. Minor)

This session will draw together the views of participants and will identify areas where OECD could provide policy guidance. It may also identify areas where OECD may wish to consider further work.

15.15-15.45	Final Discussion Session
15.45-16.15	Rapporteur's Conclusions and Closing Remarks