The CAPABILITY Project
Capacity Building for the Transfer of Genetic Knowledge into Practice and Prevention: The CAPABILITY Project

CAPABILITY: a 3 year model project (2007-2009)
The Challenge…

- genetic tests are increasing in number and complexity
- increasing knowledge about gene-disease associations will lead to new opportunities to apply genetic/genomic knowledge in practice and prevention
The Challenge...

• a growing number of tests have broader population based applications

• testing will move into primary care and prevention services
The Challenge...

- genetic testing is currently highly fragmental
- diverse and heterogeneous quality schemes
- lack of adequate counselling
The Challenge...

- widening gap between the technology led supply of testing and services to meet patient needs

- rising demands for genetic services
The Challenge…

• lack of health professionals educated in genetics

• lack of an informed public (genetic illiteracy)
before genetic tests are introduced into general practice the benefits of their use must be evaluated
Worldwide, health care systems are facing the same challenges:

1) The need to develop an evidence-based evaluation process for genetic tests or other applications of genomic knowledge in transition from research into practice.

2) The need for capacity building to enable health care systems to make effective use of genetic/genomic applications with proven clinical utility.
Evolution to CAPABILITY

• Reports and recommendations

- Secretary’s Advisory Committee on Genetic Testing (Bethesda 2000)
Suggested enhancements in oversight by pre-market review and approval of new tests in the US

Enhancing the Oversight of Genetic Tests:

Recommendations of the SACGT

July 2000

Secretary’s Advisory Committee on Genetic Testing
National Institutes of Health
6001 Executive Boulevard, Suite 302
Rockville, MD 20852

http://www.hhs.gov/ascll/reports/sacgt.html
Evolution to CAPABILITY

• Reports and recommendations

➢ Secretary’s Advisory Committee on Genetic Testing (Bethesda 2000)

➢ Institute for Prospective Technological Studies (Seville 2003)
Genetic testing in Europe, while based upon high quality scientific know-how, suffers from disorganisation and fragmentation of services, caused by a lack of structuring and complementarity at the European level and the absence of a common European objective to provide quality services to all its consumers:

“A European, or even higher international level, approach is required.”

(Towards quality assurance and harmonisation of genetic testing services in the EU, Report EUR 20977 EN, Executive Summary, Page 4.)
Evolution to CAPABILITY

• Reports and recommendations

- Secretary’s Advisory Committee on Genetic Testing (Bethesda 2000)
- Institute for Prospective Technological Studies (Seville 2003)
- Organisation for Economic Co-operation and Development (Paris 2005)
The “internationalisation” of genetic testing for medical and research purposes and the establishment of genetic testing networks has become inevitable and necessary.
Evolution to CAPABILITY

US Funded Projects

Analytic validity
Clinical validity
Clinical utility
Ethical, Legal & Social implications

Analytic framework
40 + targeted questions

Funded by CDC, Office of Genomics and Disease Prevention
Evolution to CAPABILITY

US Funded Projects

Establish and evaluate a systematic and sustainable mechanism for pre- and post-market evaluation of genomic applications in the US (2004-2007)

Funded by CDC, Office of Genomics and Disease Prevention
Evolution to CAPABILITY

EU Funded Projects

EuroGentest
Genetic Testing in Europe
Network for test development harmonization, validation and standardization of services

A European Network of Excellence aiming at harmonizing genetic testing services (2005-2011)

www.eurogentest.org
• establish a network of quality across Europe

• promote research, proper utilization, quality control and assurance and adequate management of genetic services
• establish procedures and guidelines for the validation of methods and technologies

• provide genetic healthcare workers, the end-users and healthcare authorities with a portfolio of quality-assured information sources and informatic tools that are subject to validation and quality procedures

In addition, EuroGentest aims at becoming a model for similar initiatives in developing countries and will provide appropriate support for their development.
Evolution to CAPABILITY

• WHO recommendations

Case Study: European Union

It may be beneficial in the longer term for other jurisdictions, such as the Latin American countries, the Middle East, South Africa, to participate in similar harmonization activities, as they may benefit more from this model than from one developed for a single country (e.g. the United States).

CAPABILITY

- Starting month: January 2007
- Kick-off meeting: May 7-9, 2007, Trolleholm Castle, Sweden
- Funded by FP6
ALL RESEARCH TOPICS WERE OPEN FOR 3rd COUNTRY PARTICIPANTS

- At least 3 organizations from EU and/or associated states

- In addition, “third country” participants were welcome

- Partners from the INCO target countries, could receive funding
SIXTH FRAMEWORK PROGRAMME 2002-2006
Participation by legal entities from third countries

- European Union/
  Associated States (1)/
  Overseas Countries & Territories
- Target countries of specific measures in support of international cooperation:
  eligible for participation and funding (within limits of budget)
- Other third countries: eligible for participation; funding if provision under RTD activity or essential for carrying out indirect action
- Currently no cooperation
Capacity Building for the Transfer of Genetic Knowledge into Practice and Prevention: The CAPABILITY Project

CAPABILITY: a 3 year model project (2007-2009)
CAPABILITY is a 3-year model project developed jointly by units 3 & 6.

UNIT 3: CLINICAL GENETICS, COMMUNITY GENETICS AND PUBLIC HEALTH

Unit Leader: Ulf Kristoffersson, Head of the Department of Clinical Genetics at the University Hospital in Lund in Sweden.

Co-leader: Joerg Schmidtke, Director of the Institute of Human Genetics at Hannover Medical School.
CAPABILITY is 3-year model project developed jointly by units 3 & 6.

UNIT 6: EDUCATION

Unit Leader: Alastair Kent, Director of GIG and President of the European Alliance of Genetic Support Groups.
Arnold L. Christianson

The Clinical Diagnostic and Genetic Counselling Division
Randa Kamal Abdel-Raouf, Children with Special Needs Department, Ministry of Health and Population, Egypt
Cristina Barreiro, Medical Genetics Service.
Co-ordinator: Irmgard Nippert,
Women’s Health Research,
Department of Genetics.
Capacity Building for the Transfer of Genetic Knowledge into Practice and Prevention: The CAPABILITY Project

- Goals

To establish and evaluate a sustainable systematic, evidence-based process for assessing genetic tests or other applications of genomic technology in transition from research to practice at an international level.
CAPABILITY Methods

• bring together key stakeholders for the systematic transfer of genetic testing from research into clinical practice by means of frameworks for an evaluation process agreed by academics, clinicians and policy makers

• seek agreement on standards
CAPABILITY Objectives

- identify priorities for capacity building for providing appropriate services by systematic needs assessment surveys

- evaluate the approach via demonstration projects to be conducted at 4 target sites
Advisory Board

• participate actively in all meetings & workshops,

• comment the draft versions of the reports, the demonstration project design, its outcome data and advise on the final model approach
Advisory Board

Ron Zimmern, Director Public Health Genetics Unit, Cambridge, UK.

Victor B. Penchaszadeh, Professor of Clinical Epidemiology at the Mailman School of Public Health of Columbia University, New York, USA.

Elizabeth Nneka Anionwu, RN HV Tutor PhD CBE, Professor of Nursing, Head of Mary Seacole Centre for Nursing Practice, Thames Valley University, London, UK.

Hilary Harris, MD, is the senior partner in a South Manchester general practice, UK.
Evaluator

- March of Dimes, Global Programs
Observers

• World Alliance of Organizations for Prevention and Treatment of Genetic and Congenital Conditions (WAO)

• Central Europe and Eastern Countries Genetic Network Gdansk, Poland (Member of the EuroGentest Advisory Board)

• Instituto de Biomedicina Universidad Católica de Santiago de Guayaquil, Guayaquil, Ecuador (Advisor to unit 3 EuroGentest)
CAPABILITY Working Group

15 experts:
- clinical genetics
- genetic epidemiology
- health service research
- health technology assessment
  - evidence-based medicine
  - molecular genetics
- parent and patient organisations
- primary care providers
- public health genetics
- ethics

Regular workshops & 3 international meetings
CAPABILITY Overview

Systematic reviews
Identify knowledge gaps & data needed
Draft model approach

CAPABILITY Working Group

Evaluation

International Demonstration Projects

Model for test evaluation & capacity building

STAKEHOLDERS
- MoD Global Programs
- Researchers/Scientists
- Laboratories
- Consumers’ patient organisations
- Industry
- Policy makers
- Health care providers

Evaluation

Refer for appraisal

Scientific community
- Consumers
- Health policy makers
- Health care providers
- NGOs
- Private sector
CAPABILITY will use knowledge gained from previous evaluation projects
A key objective of CAPABILITY is to engage the interest of a wide range of stakeholders.
CAPABILITY Networking Goals

• to promote an internationally shared set of basic quality standards for genetic testing and the provision of appropriate genetic services in primary care and public health

• to lay the foundation for a sustained collaboration, that will continue and be open for international partners

• to start collaboration by joint projects
CAPABILITY Objectives

• disseminate the model approach to targeted audiences
CAPABILITY will help

• to promote proper implementation of new genetic knowledge, quality assurance and adequate provision of genetic services at a global level

• to identify present and future needs for capacity building mechanisms
CAPABILITY will help

• to enable health care systems to integrate genetic knowledge appropriately, based upon local needs and priorities

• to strengthen the kinds of basic capacities that will allow participating developing countries to more easily incorporate the benefits of genetic/genomics research as they unfold

• to reduce inequalities in genetics health care between developed and developing countries
CAPABILITY will help

• to avoid the opportunistic introduction of underevaluated technology driven genetic testing and concentrating on those areas where greatest gain for health is to be secured
CAPABILITY will help

• to create the expectation at all levels of health care systems that genetic tests should be subject to a systematic evaluation process prior to translation into general practice