Policy Aspects of Commercial and Recreational Testing: The approach from the UK

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ENGAGE Summer School June 2010
Concerns re DTC

scientific and clinical validity of these tests and their clinical utility
the quality of the testing services
unnecessary anxiety/false reassurance
further costs to individual and publicly funded health services (NHS)
data protection
loss of public trust and confidence in the science
## Confusions

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<tr>
<td>Health</td>
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<td>Inherited Disorders</td>
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<td>Mutifactorial/polygenic</td>
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<td>Clinical Disease</td>
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<td>Health related test</td>
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<tr>
<td>Assay</td>
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<td>Service</td>
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Current situation in UK

Majority of genetic tests (for health purposes) provided by the NHS

United Kingdom Genetic Testing Network (UKGTN) assesses test and provider before recommending funding

Majority provided within specialist clinical genetic services

Majority provided by specialist laboratories

Genetic tests and services advertised direct to consumer offered as part of a medical screening service.

   Limited but Growing.

Genetic tests offered directly to the consumer

   Limited but ? Growing
**UKGTA Testing criteria**

**Name of Disease(s):** Autosomal Alport Syndrome

**Name of gene(s):** COL4A3 and COL4A4

**Referrals will only be accepted from one of the following:**

<table>
<thead>
<tr>
<th>Referrer</th>
<th>Tick if this refers to you.</th>
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<tbody>
<tr>
<td>Consultant Clinical Geneticist</td>
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<tr>
<td>Consultant Nephrologist</td>
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<tr>
<td>Consultant Paediatrician</td>
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<td>Consultant Nurses in renal</td>
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<td>transplant units</td>
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</table>

**Minimum criteria required for testing to be appropriate as stated in the Gene Dossier:**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Tick if this patient meets criteria</th>
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<tbody>
<tr>
<td>At least 2 of the following criteria must be met by the proband and other family members:</td>
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<tr>
<td>- Positive family history of haematuria or chronic renal failure</td>
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<tr>
<td>- Electron microscopic evidence of Alport Syndrome on renal biopsy</td>
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<tr>
<td>- High tone sensorineural deafness</td>
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<td>- Characteristic ophthalmic signs (retinal flecks or anterior lenticonus)</td>
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<td>And</td>
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<tr>
<td>No pathogenic mutation identified in COL4A3 - point mutation screen and</td>
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<td>Multiplex Ligation-dependent Probe Amplification (MLPA) previously</td>
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<td>carried out; Or</td>
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<td>Family history consistent with autosomal recessive or dominant inheritance, (e.g. male-to-male transmission); Or</td>
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<tr>
<td>Immunohistochemical evidence of loss of COL4A3 or COL4A4 staining on a skin biopsy</td>
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</table>

**If the sample does not fulfil the clinical criteria or you are not one of the specified types of referrer and you still feel that testing should be performed please contact the laboratory to discuss testing of the sample.**
Common Genetic Variation and Human Traits

David J. Goldstein, Ph.D.

The human genome has been widely open in recent years, making many of its features available for study.

Genetic Risk Prediction — Are We There Yet?

Peter Kraft, Ph.D., and David J. Hunter, M.B., B.S., Sc.D., M.P.H.

A major goal of the Human Genome Project was to facilitate the identification of inherited risk factors for disease. This has led to a complex landscape of genetic predisposition to important diseases, which would have major clinical, social, and economic ramifications. But the great majority of newly identified risk factors are unlikely to confer very small relative risks. The most relative risks are almost certainly overrepresented in the first wave of findings from genome-wide association studies, since considerations of statistical power and sample size that we will be important in determining the significance of findings.

Genomewide Association Studies — Illuminating Biologic Pathways

Joel N. Hirschhorn, M.D., Ph.D.

Human geneticists seek to understand the basis of human biology and disease, aiming either to gain insights that could eventually improve treatment or to produce useful diagnostic or predictive tests. As recently as Gelehrter predicted that no more than three new common variants would be reproducibly associated with common diseases by the time the American Genome Project was completed. However, it is now clear that the genetic architecture of complex traits is much more complex than even this.

The genome-wide association study (GWAS) seeks to identify common variants that contribute to the observed variation in a trait or disease.
For example deCODEme said my risk of developing exfoliation glaucoma, which causes loss of vision, was 91% below average. Yet according to 23andMe, I was 3.6 times more likely to get it than average.

For age-related macular degeneration, deCODEme put my risk at 20% lower than average, while 23andMe said it was 62% higher.

According to deCODEme, my risk of developing Alzheimer’s was 74% above average, while GeneticHealth said my genes were associated with “a fourfold increased risk of developing Alzheimer’s disease by your late 80s”.
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<td>Celiac Disease</td>
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<td>Colorectal Cancer</td>
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<td>Crohns’ Disease</td>
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<tr>
<td>Type 2 Diabetes</td>
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</table>
Options for Direct to consumer Genetic Tests

Do nothing

Ban DTC tests

Regulate in some way
Options for Direct to Consumer Genetic Tests

Do nothing

Ban DTC tests – Switzerland, France, Germany

Regulate in some way
Germany limits genetic testing

The Associated Press
7:48 a.m. April 24, 2009

BERLIN — The German parliament approved legislation Friday limiting the use of genetic testing in an effort to prevent the technology’s abuse.

The law, which was debated for more than seven years, must still go before the upper house of parliament, but it is not expected to meet any resistance.

Under the law, genetic tests can only be carried out by a doctor and require the full consent of all parties involved. That makes it illegal to conduct anonymous paternity tests and anyone found in violation could be fined up to euro5,000 ($6,525).

The law further limits the use of genetic testing on fetuses to purely medical purposes, meaning parents are prohibited from using it to determine the sex of their unborn children. In addition it prohibits the use of genetic testing for indications of a predisposition to illnesses that appear only later in life, such as breast cancer or diseases of the nervous system.

The law also addresses dissemination of information obtained through genetic testing, including preventing employers and health insurance companies from demanding an employee or potential client undergo a genetic
Options for Direct to Consumer Genetic Tests

Do nothing

Ban DTC tests

Regulate in some way- Devices regulation eg
FDA’s recent intervention
Review of the EU IVD directive
Start-Up May Sell Genetic Tests in Stores

By ANDREW POLLACK
Published: May 10, 2010

Genetic tests that assess a person’s risk of getting various diseases are heading to the corner drug store.

Pathway Genomics, a start-up company, is expected to announce on Tuesday that it will sell such a test through most of the nation’s 7,500 Walgreens stores.

Walgreens Delays Selling Personal Genet

By ANDREW POLLACK
Published: May 12, 2010

Walgreens said late Wednesday that it would postpone selling a personal genetic test through its drugstores after the Food and Drug Administration challenged the legality of the test.

Related
Start-Up May Sell Genetic Tests in Stores (May 11, 2010)
Options for Direct to Consumer Genetic Tests

Do nothing

Ban DTC tests

Regulate in some way – ‘soft’ regulation, codes of practice
OECD Guidelines

Molecular genetic testing should be:

• delivered within the framework of health care,

• practised under a quality assurance framework,

• in compliance with applicable legal, ethical, and professional standards,

• that advertising, promotional and technical claims for molecular genetic tests and devices should accurately describe the characteristics and limitations of the tests offered,

• test results should be reported back to the referring health-care professional

• appropriate pre and post-test counselling should be available

• genetic tests should meet generally accepted criteria of scientific validity and clinical validity

• clinical utility should be an essential criterion for a test to be offered

• a quality assurance programme should be implemented

• adequate prior information is provided whenever a test is considered,

• appropriate genetic counselling should be available in the case of predictive tests

• persons providing genetic services should have appropriate qualifications, to enable them to perform their role in accordance with professional obligations and standards.

https://wcd.coe.int/ViewDoc.jsp?id=1287907&Site=DC&BackColorInternet=F5C A75&BackColorIntranet=F5CA75&BackColorLogged=A9BACE
Genes direct
Ensuring the effective oversight of genetic tests supplied directly to the public

A report by the Human Genetics Commission

March 2003

More Genes Direct
A report on developments in the availability, marketing and regulation of genetic tests supplied directly to the public since the Human Genetics Commission's 2003 Genes Direct report

December 2007
Genes Direct 2003: Ensuring the effective oversight of genetic tests supplied directly to the public

- Defined direct to consumer genetic testing as any test to detect differences in DNA, genes or chromosomes that is not provided as part of a medical consultation.

- Recommended controls on the sale of tests and professional self regulation of those who supply the tests, but **no** statutory ban
Genetic Testing

Testing Kits
- Medicine and Healthcare Products Regulatory Agency
  - Medical Devices Regulation
  - Enforcement
  - Codes of Practice & guidance
- Human Tissue Authority
- Council for the regulation of healthcare professionals
- Healthcare professionals
- Consumer Advice NHS Direct

Commercial Services

NHS testing
- GenCAG
- UKGTN

GenCAG
UKGTN

Pharmacists
- National Institute for Clinical Excellence
- Complementary therapists

Consumer/Patient
- ASA Codes
- Office of Fair Trading
**More Genes Direct 2007**: Report on the developments in the availability, marketing and regulation of genetic tests supplied directly to the public.

Recommendations in 3 areas

1. Premarket Review
2. Quality Assurance
3. Advice and Advertising
Premarket Review

• Certain tests should only be offered by qualified medical professionals

• Classification of genetic tests for health purposes by the In Vitro Diagnostic Devices (IVDD, 2003) Directive as low risk (and therefore exempt from pre-market review) should urgently be reviewed

• Transparency of evidence

• ‘Lifestyle’ tests falling outside the IVDD Directive require an alternative mechanism to provide reliable oversight
Quality Assurance

• Code of practice should be developed to taking into account the OECD guidelines and other relevant international standards

• Development of a code of practice should involve relevant stakeholders including government public bodies, charities and industry

• UK should engage with the Council of Europe and offer to participate in work in this area
Advice and Advertising

• Advertising for tests only available via medical consultation should be restricted to appropriately qualified health care professionals.

• Advertising Standards Agency and Office of Fair trading should consider enhancing the codes of practice for tests marketed DTC.

• Web based information resources should be used to provide comprehensive and independent information for consumers.

• Test developers/providers should be encouraged to facilitate consumer access to this information.
2008-2009: Meeting to discuss Code of Practice

Do we need one?

What should it look like?

Who should develop it?

Who should develop and maintain it?

Who should oversee compliance?

• Industry representatives from Europe and USA
• Government
• Regulators
• Consumers
• Charities
• Professionals
• Public bodies
Code of Practice for DTC genetic tests

• Overwhelming support

• Tests to be stratified according to risk

• Common standards re consent, confidentiality, data protection, sample handling and storage

• Need for quality assurance of laboratory processes

• Need for transparency

• The value of a marker of quality e.g. Kite mark

BUT

• Code of practice in individual countries will have to function in different legislative frameworks

Common Framework of Principles
Framework of Principles

High level overarching document could be applicable in many countries and jurisdictions

Will be used develop Codes of Practice

Consultation is finished

Final version currently being drafted
**Scope**

Tests marketed directly to consumers rather than to appropriately qualified health professionals.

Includes

Tests provided direct to consumer

Tests provided via non-medical intermediary eg nutritionist

Tests commissioned by consumer but where a medical practitioner or health professional involved.
• General principles applicable to all tests

• Specific principles apply only to certain categories of tests based on an impact assessment
  – Severity of condition
  – Reliability of prediction
  – Impact on clinical management
  – Impact on relatives
  – Potential to provide information about a fetus
• Information to consumer
  – Scope, accuracy limitations.
  – Processes and procedures including what happens to samples and data
  – Implications for insurance, access by law enforcement/security agencies
  – What happens if company ceases trading
  – High impact tests access to appropriately qualified health professional, pre and post test counselling

• Marketing and advertising
  – Transparency of evidence
• Consent
  – Children and vulnerable adults
• Data Protection
• Sample Handling
• Laboratory Processes
  – ISO standards or equivalent
• Interpretation
  – responsible appropriately qualified person
  – robust transparent methods
• Provision of results
• Complaints procedure
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Thinking about starting a family?

Every test you take funds treatments and cures for children living with genetic disease. Learn More

"Every adult of reproductive age needs the Counsyl test."
—Professor Pasquale Patrizio, MD
Director, Yale Fertility Center

"Universal genetic testing can drastically reduce the incidence of genetic diseases, and may very well eliminate many of them."
—Professor Steven Pinker, PhD
Harvard University

FREE with insurance or just $349. How2?

Millions of children die needlessly each year from preventable genetic disease. Protect your baby from 100+ diseases with a simple saliva test, even before pregnancy.

Claim Your Test Now Learn More

Our Values

We believe that genetic testing is a human right, not a luxury.

We believe children deserve healthy lives, free from genetic disease.

And we believe in universal access, especially for those most in need.

Learn More
Thinking about starting a family?

Every test you take funds treatments and cures for children living with genetic disease.

“I’m a Physician
I would like to find out more information about the Test and learn how to offer it to my patients.

“Every adult of reproductive age needs the Counsyl test.”
—Professor Pasquale Patrizio, MD
Director, Yale Fertility Center

“Universal genetic testing can drastically reduce the incidence of genetic diseases, and may very well eliminate many of them.”
—Professor Steven Pinker, PhD
Harvard University

“I’m a Patient
I am interested in finding a physician who offers the Test or learning more.

Learn More Enroll Your Clinic

Register to Test Learn More
<table>
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<th>Disease Name</th>
<th>ACMG</th>
<th>ACOG</th>
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[https://www.counsyl.com/diseases/maple-syrup-urine-disease-type-1b/]
SELECT A DNA REPORT

Ancestry Report
Trace your ancestral path
Includes:
- Maternal & Paternal Lineages
- Over 1000 Maternal Haplogroups
- Over 200 Paternal Haplogroups

only $249  + SELECT

Health Report
Improve your health today
Includes:
- 70+ health conditions, including Diseases, Drug responses, Carrier status

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Ancestry + Health Reports
Get Both and SAVE $199
Learn everything your DNA has to say. One report includes health and ancestry results.

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COMBO PACKAGE

Drug Response (Medication)
Reports how effective and safe certain drugs may be for you, including warfarin, Plavix, and statins.
Read more

Pre-Pregnancy Planning
Pre-Pregnancy Planning Screens rare but serious conditions that could be passed on to your children.
Read more

Health Conditions
Identifies your genetic risk for common health conditions such as melanoma, prostate cancer and rheumatoid arthritis.
Read more

Ancestry
Traces your geographic and deep ancestral history from 10,000 up to 150,000 years ago.
Read more
PRESS STATEMENT

The value of knowing one’s genetic makeup is empowering, especially when combined with traditional healthcare practices. Not only is genetics a useful tool that can lead to a healthier life, it’s another step toward helping people be more informed and proactive about their health and wellness. Scientists at Pathway’s federally CLIA certified and California state licensed laboratory use validated methods to identify an individual’s genotype and compare it with scientifically sound genetic knowledge and information. Our genetic reports simply provide accurate and clear genetic information to assist those making decisions about their health. Our reports do not provide diagnosis. All customers are informed that genetic information is just one of many factors that can influence propensity for disease.

Pathway Genomics strongly encourages all individuals to consult with a qualified physician before making any lifestyle changes or medical decisions based on their genetic report results. Furthermore, Pathway’s in-house medical doctors review all results before information is released to individuals. To further support customers, genetic counseling is available, at no extra charge, before, during and after testing.

Safety, security, privacy and the delivery of accurate information continue to be top priorities at Pathway Genomics Corporation.

For more information:
What about new technologies and techniques

Whole genome sequencing

Free Fetal DNA
The Baby Gender Test: Am I Having a Boy or a Girl?

Order pink or blue®
Money Back Guaranteed
(See Refund Policy)

Check Your Results
Enter the codes from your Pink or Blue®
Gender Test Kit to find out if it's a boy or girl.

code 1  code 2  GO

- Sex Detection at 7 Weeks Post Conception
- Scientific Gender Test Based on Fetal DNA
- Clinically Proven 95% Accurate*
- Do-At-Home, Safe, Non-invasive
- Prepare for Child Rearing Early
- Begin Building Family Bonds

*An accuracy study was completed in 2009 with the Fair Oaks Women's Health Center (FOWHC) in Pasadena, CA. Blood samples collected from the FOWHC were tested using the Consumer Genetica, Inc proprietary biomarker and results were released back to the Center. A FOWHC Registered Diagnostic Medical Sonographer blinded from the Pink or Blue® result conducted multiple real-time ultrasound exams. FOWHC ultrasound results and Pink or Blue® results were compared at the Center and it was determined that 95% of the results of the Pink or Blue® early gender test were accurate.

Early Gender Determination

Standing in the baby aisle, wouldn't it be nice to know whether to choose the pink blanket instead of settling for the generic green one?

Now you can find out earlier than ever. Pink or Blue® is a new DNA test which can be collected in the comfort of your own home. Using just drops of the mother's blood you can find out as early as seven...
Fetal Cell/DNA Prenatal Paternity Test
A Noninvasive Prenatal Paternity Test Sampling Only the Mother's Blood

This prenatal paternity test uses only the mother’s blood - and samples from the alleged father(s) - to determine the paternity of the child as early as 13 weeks into the pregnancy. No blood is taken from the alleged father(s).

Unlike an amniocentesis or CVS which could cause problems in the pregnancy and/or fetal injuries, induce labor, or terminate the pregnancy, this test is noninvasive. You do not need to have an amniocentesis or CVS to do this test.

This test is both cost effective and safe, and is a doctor-recommended alternative to an amniocentesis or CVS.

The collection of all specimens for this test is safe and noninvasive for both the mother and unborn fetus, and you do not need a doctor to collect the sample specimen.

Because no doctor involvement is necessary in the testing process, we can guarantee absolute and total confidentiality.

A collection technician is needed to complete this test. DNA Plus coordinates all aspects of this test with one of our thousands of collection sites nationwide. All arrangements will be made during your consultation.
**More Genes Direct 2007**: Report on the developments in the availability, marketing and regulation of genetic tests supplied directly to the public.

Recommendations in 3 areas

1. Premarket Review
2. Quality Assurance
3. Advice and Advertising
Acknowledgements

UK Human Genetics Commission

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