

RESPONSE TO HGC CONSULTATION ON COMMON FRAMEWORK OF PRINCIPLES FOR DIRECT-TO-CONSUMER GENETIC TESTING SERVICES

BANT is a professional body representing nutritional therapists/nutrigenetic counsellors. Incorporated as a non-profit organisation in 1997, BANT membership numbers in excess of 2200 full members and students. National Occupational Standards were first set in 2003 and revised in 2009. The DH-supported Complementary and Natural Healthcare Council acts as the regulating body. BANT officers gave evidence in 2002 to the *Genes Direct* inquiry.

We have the following detailed comments on the proposed framework in the context of practice in the UK.

Scope - Page 4

There is inconsistency in the terms used in this section with those used in the following '**Definitions**' section (pages 6-7):

- '**non-medical intermediary**' (pharmacist/alternative health practitioner) and '**genetics health professional**' are listed in the Scope (top of page 5) in different categories. However under the Definitions on page 7 a genetics health professional is someone who meets appropriate competencies.
- Competencies in nutrigenetics are substantially different from those relating to counselling for, say, Huntington's disease.
- Is a 'medical intermediary' someone who is registered with the General Medical Council?
- The Health Professions Council has told BANT (October 2009) that the title 'Nutrigenetic Counsellor' is not expected to come under statutory protection even if 'Genetic Counsellor' does become protected shortly.

Table 1

- 2 – Pre-symptomatic tests- in conjunction with Consultation Question 3 – are you suggesting that 5% penetrance represents 'high probability'?

- 7 – Nutrigenetic Testing. The definition used is not fit for purpose:
 - ‘Nutrient’ has no formal internationally agreed biological definition. Nor are there universally agreed reference values. For example, in the US choline has an established reference intake but none in the UK/EU.
 - The 2nd revised (2009) edition of *Introduction to Human Nutrition*, published by the Nutrition Society, the UK learned society for nutrition, anticipates ‘new nutrients’ and ‘new functions’ (Chapter 1, Perspectives on the Future).
 - The term ‘food bioactive’ has no legal definition. In the US attempts by the FDA to define ‘food bioactive’ separate from ‘nutrient’ have stalled.
 - The NHS Genetics Education Centre defines nutrigenetics as “the effects of inheriting a particular gene variant on a person’s responsiveness to a particular nutrient or diet, and how this affects metabolism, health status and risk of disease”.

THE PRINCIPLES

- 1.3 Only if the consumer wants it. In the case of serious inherited disorders they would be able to get free testing and counselling on the NHS anyway. If the consumer wants privacy they will pay to get the information direct.
- 2.3, 2.4, 3.1 and 4.6 In terms of nutrigenetics, these principles are in direct conflict with existing EU food law. The 2006 EU Nutrition and Health Claims Regulation allows for claims made on food (including supplements) based on **proprietary data**, provided that such data are not published. It is now increasingly likely that industry-funded research with commercial value will remain unpublished for the 5-year validity period of the proprietary data claim.
- 5.1 This would represent an intrusion into the privacy of the consumer which we believe is unacceptable. A person’s genomic data is their own private property, and ultimately it is not for third parties to determine another’s actions in respect of their own property/data. We believe this could represent a breach of Articles 7, 8 and 17 of the EU Charter of Fundamental Rights.
- 5.7 Would this be administered on the same basis as those who are unable to look after their own financial affairs?

5.10 Parents are responsible for their children's welfare and have rights under Articles 14 of the EU Charter. Why should they not be allowed to take care of them in respect of dietary response, eg lactose intolerance, poor clearance of caffeine, fructose intolerance or a myriad other diet-gene interactions? Moreover, as time goes on, could failure to test become viewed as a form of negligence?

Would it not be somewhat incongruous if parents have PGD/preconception screening and then later, on principle, not be able to access their child's genetic data?

9.2 'Accurate' is not a future-proof term. 'Best available knowledge' might be better given the exposure to unknown unknowns.

10.1 Why should there be a legal obligation for the test provider to consider the impact of the test results? If the consumer wants private information about their own property, ie their genomic data, it should not be up to the test provider to determine how they use that information.

Where tests for certain variants may have significant detrimental impact, these should be highlighted by the provider: with the consumer having to pass through certain hurdles (eg familiar online devices) to access that particular information.

Pre and post-counselling can be advised, indeed facilitated, by the test provider but should not be mandatory. Is it not possible for someone at risk from even Huntington's disease to have a private test without interference (however well-intended) if they want absolute privacy?

Discrimination only results from loss of privacy. The recent decision by the General Medical Council to waive privacy in the case of genetic disorders may make Direct Testing the only real choice for a number of consumers.

10.2-10.6 How would these be enforced? What criteria? Has anyone tried them out in any form? The Joint Practical Guide of the EU Parliament, Council and Commission Section 1 requires of good regulation that it is clear in advance how rules will be applied. The exposure to unintended consequences may be substantial.

10.8 ABSOLUTELY. Perhaps the GMC might want to follow the same line.

12. Is this really any different from any other consumer complaint?

CONSULTATION QUESTIONS

1. Only if the consumer wants it. The danger is that mandatory counselling may come to be resented and could tarnish the image of counsellors if

they are seen as unwanted gatekeepers. If it is mandatory, consumers should have a choice of where they get their counselling. Right to privacy and consumer choice should be key determinants.

2. No. Right to privacy and consumer choice hold primacy. Appropriate hurdles are easily put in place to ensure that individuals are aware and request the level of information they receive.
3. This is not future-proofed. Has anyone trialled individualised pre- and post-counselling at 5%? What is appropriate for eg Hungtington's is hardly appropriate at that level. What **added value** is the consumer likely to get?
4. Pharmacogenetic testing relates to variants which have other functions. 'Pharmacogenetic' is simply a label. Attempts to ban access to variants linked to drug response may be seen by the consumer more as protecting the negligent physician than them.
5. These seem to be drafted more from theory than practice. Have they been tried out in any kind of scenario modelling?
6. Consumers are fairly savvy. A reputable company will provide as much as possible of this kind of information as part of its marketing. This should not be the subject of regulation: market forces will assure the right outcome. Compulsion to employ people seems a rather odd method of regulation: surely it is the outcome that matters?
7. Unless you ban preconception screening, it is bizarre to say parents have no right to genetic information about their child.
8. When paying by credit card, the usual way, they have to stipulate 1) that the sample is their own, or of a dependant; and 2) that they are aware that submitting another individual's DNA is a criminal offence.
9. If they are able to open a bank account, why can't they have a genetic test? It is their genome, they have a right to access their own data.
10. In the EU the Unfair Commercial Practices Directive provides all the protections required.

General Comments

We believe that there are inconsistencies in these Principles which will make them difficult to use for regulatory purposes. Nor do we think these Principles are future-proof even in the relatively short-term: they take no account of the dynamic nature of the personal genome services which update information on a weekly basis. In particular a number of the proposals seem to be somewhat exposed to the Laws of Unintended Consequences.

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