

## Note of Human Genetics Commission (HGC) meeting in Belfast on 11 September 2002

- Areas considered to be of special interest to the Scottish Executive, the Scotland Office or NHSScotland are in **red bold type**.
- These notes should be read in conjunction with the published papers for the meeting (available from the secretariat; [Mark.Bale@doh.gsi.gov.uk](mailto:Mark.Bale@doh.gsi.gov.uk) and (in due course) through their web site at <http://www.hgc.gov.uk>).

### **Key points relevant to genetics policy people in Scotland:**

- 1 The proposal to create a criminal offence of obtaining genetic material by deception is under review by ministers (in England).
- 2 There is concern about retention of forensic samples and genetic profiles after suspect elimination.
- 3 Interactions continue to be required among advisory and regulatory bodies (GAIC/ HFEA etc).
- 4 The green paper on the consequences of genetics for the NHS will come out later this year (Even if it does not directly apply to Scotland the implications for training and capacity building will be similar).
- 5 Invitations to respond to consultations on retention of human tissue give a chance for HGC to revisit and reconcile their positions as published in '*Inside Information*' with more recent developments.
- 6 A consultation on 'direct to consumer testing' is open until 4 October.

### **Matters arising**

- **Correspondence with ministers reveals that there will be a UK government response to HGC's '*Inside Information*'<sup>1</sup> early next year, and that serious consideration is being given (in England) to the recommendation in that report that a criminal offence of obtaining genetic material by deception/ without consent is created.**
- The first meeting of the 106-member consultative panel of those with genetic disorders or their families was held on 16 July. This was judged a huge success by both the panel and HGC.

### **Genetics and forensic science**

- HGC representatives (McCall Smith and Bale) met with the team leader of a review of the Forensic Science Service (FSS). The review is 'broad ranging' and they are 'receptive to comment'. This (internal) review is unlikely to result in a change to the law but may address research uses of genetic information, such as analysis of normal and disease genes in forensic samples as a guide to suspect identity. This latter issue of grave concern to some commissioners and is something HGC should raise with the independent review body.
- Background is that a recent change to the law allows genetic samples and profiles to be kept after subjects are eliminated from investigations. There is public excitement that 'crooks are brought to book' but concern about sample retention (from HGC and public).
- **Suggested that there should be an independent supervisory body for use of genetic samples and derived information (external to police and FSS).**
- The chair (Helena Kennedy - HK) remarked that we can't change the recent law. UK now the most permissive of all countries in the use of DNA evidence. However as part of the judicial review of a current case law lords are considering the remarks on sample retention/consent made in '*Inside Information*'. [They upheld the law on retention - AVP, 13 Sep] A paper by Williamson sets out the international comparison.
- HGC believes that consent should be obtained independently for initial sample, and separately for subsequent retention.

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<sup>1</sup> See <http://www.hgc.gov.uk/insideinformation/index.htm>

### **Horizon Scanning**

- An evidence gathering session on pharmacogenetics (the use of genetic information to determine whether a particular drug will be beneficial to a person) had been held the previous day. This had revealed much complexity and no simple answers. For example the Medicines Control Agency (MCA) presentation had suggested that **although the use of pharmacogenetics would reduce some adverse drug reaction (ADR) events, many were due to 'faulty prescribing' and therefore not responsive to a pharmacogenetic approach. MCA felt development of an IT-supported pharmacopoeia would be more useful.** Also perception that a 'genetic underclass' will become untreatable. HK opined that this reveals a stark choice for where to put financial resources: into amelioration of non-responders or to only treating those for whom the drug will work best. This is part of a wider societal debate about how drug development in industry should proceed.
- Other issues in the (ever-expanding) horizon-scanning programme **include use of IT in the health service, particularly to manage large genetic databases; large cohort databases; population pharmacogenetics;** stem cells; and reproductive issues.
- In testimony to the House of Commons Science and Technology Committee, Suzi Leather had suggested a joint Human Fertilisation and Embryology Authority (HFEA)/HGC horizon scanning group: this was felt to be useful.

### **Genetics and Insurance**

- The 5-year moratorium (announced Oct 2001) on the use of genetic information in life insurance underwriting continues<sup>2</sup>. HGC feel the time should be used to examine the implications, what society wants to do and what regulations are required.
- The Genetics and Insurance Advisory Committee<sup>3</sup> has been reconstituted. Although 'a lot of constructive discussion is going on' there still requires to be further consultation between HGC and GAIC to make sure there is no duplication of effort, or overlap with other 'pockets of activity' such as the UK Forum for Genetics and Insurance<sup>4</sup>.
- There is concern that, since the moratorium was announced, the use of family history in underwriting by some companies appears to be evolving and more detailed questions are being asked. It would be an unwelcome consequence if a moratorium on testing were in fact forcing more people into testing in order to display negative results and therefore not be rated as potential carriers with loaded premiums. Compelling companies to use negative test results while preventing use of positive results is not a fair or sustainable position.
- HGC continue to feel that the onus is on the insurance industry to explain the consequences to them of not having test information. The Association of British Insurers<sup>5</sup> is drafting an information leaflet. Clarity is required on how the weighting of premiums for genetics is justified where weighting for other factors is not. How much restriction to commercial freedom would be involved? What variables of family history are required to deduce 'bands of risk'?

### **Green paper on genetics**

- **Dianne Kennard from DoH gave a presentation. Not yet clear whether this green paper will cover all 4 UK departments of health but will have (at least indirect) impact on NHSScotland. Furthermore the ongoing spending review may affect some of the proposals.**
- **This green paper may not foreshadow legislation but instead lay out vision of what a genetics-aware NHS might look like in future and how the NHS needs to prepare to fulfill that vision. The green paper will be published late this year (2002).**
- **The key theme is preparing the NHS for genetic knowledge and technologies. These will affect many specialties and professions and so there is a need to engage with multiple groups to integrate genetics into their practices/ way they deliver care. There will be impacts through the**

<sup>2</sup> See [http://www.abi.org.uk/Display/File/87/v2\\_Genetic\\_testing\\_TF.doc](http://www.abi.org.uk/Display/File/87/v2_Genetic_testing_TF.doc); [http://www.hgc.gov.uk/business\\_press14.htm](http://www.hgc.gov.uk/business_press14.htm)

<sup>3</sup> See <http://www.doh.gov.uk/genetics/gaic/index.htm>

<sup>4</sup> See <http://www.ukfqi.org.uk>

<sup>5</sup> See <http://www.abi.org.uk>

increasing importance of pharmacogenetics and of concepts of genetic susceptibility and familial risk, particularly in primary care.

- It is not anticipated that there will be one 'big bang' but rather a gradual emergence. Consequently education and training cannot be attained through just one 'quick module' but rather through ongoing engagement. A multitude of methods (undergraduate, pre-registration and continuing education) will be required and this work needs to start now to attain a cadre of staff who grasp the basics (e.g. penetrance, predisposition, susceptibility). Staff will need to understand what genetics makes possible, how this will impact their patients and how to communicate this. Local solutions are to be encouraged, for example collaborations for training between primary care staff, clinical geneticists and testing centres. A lot is already going on but provision is patchy. Approach is expected to be empowerment of existing professional bodies rather than invention of new agencies, particularly because 'different professions will need a different approach'.
- More laboratories will be required, to offer a wider range of tests. This raises questions of capacity and of organisation. New criteria are already being worked on by the National Screening Committee to examine additional screening programmes and hopefully the green paper will mention this. There will also be work on guidelines on use of genetic tests and referral criteria.
- Issues of consent and privacy, as outlined in *'Inside Information'* will be examined and hopefully the government position made clear(er). Regulatory frameworks will also be suggested, including recommendations for what research and ethics committees should or shouldn't do. Consideration and guidance may be given on how genetic information is recorded in electronic patient records and to ensure clinical term sets include genetics.
- John Harris asked whether genetic enhancement, rather than therapies to fix existing defects, would be a part of the green paper. Dianne saw this as being a bit futuristic, although HK reminded us that genetic knowledge is already being actively used in sports medicine (e.g. altitude running and cross-country skiing).
- Elizabeth Antionwu asked when financial resources might be released to allow the training to begin. This would allow colleges to plan courses. £11 million has already been announced for genetics infrastructure and staff; the rest will be released over the next few years, although the spending review will impact this. Training issues in relation to genetics are already being addressed by workforce confederations (independently of the green paper).
- **A major route for provision of information to the public on consequences of genetics on healthcare will be through schools. However healthcare professionals are seen as a very important, and highly trusted, source of genetic information to the public and so thorough and continuing professional training will be important, particularly in interpreting and advising people on individual consequences and options for treatment/ further testing.**
- Hilary Harris welcomed the green paper but worried that there seemed to be a lack of urgency. There are 'already lots of benefits that aren't being delivered' and we have 10 years of catching-up to do. Drip-drip training may not be sufficient. In response Dianne Kennard suggested that the role of the green paper was to accelerate the good work already happening, support those who are already cheer-leading, support current spending and get awareness of imminent resource implications and training needs on to NHS managers' and policy makers' agendas.

#### **Genetics and human tissue retention**

- **Both the recent report of the Mclean Committee on retention of human tissue in Scotland<sup>6</sup>, and a consultation report 'Human Bodies, Human Choices'<sup>7</sup> in England and Wales on what changes to the law regulating uses of human tissue are necessary, address some issues concerning genetic information. The vice-chair of HGC, Sandy McCall Smith (SMS) was on the Mclean committee.**
- **HGC has been asked both to comment on aspects of the Scots committee's report and to submit views as part of the English/Welsh consultation. This represents an opportunity to revisit some of the recommendations in *'Inside Information'*. For example, obtaining genetic information from**

<sup>6</sup> See <http://www.show.scot.nhs.uk/scotorgrev/>

<sup>7</sup> See [http://www.doh.gov.uk/tissue/review\\_of\\_law.htm](http://www.doh.gov.uk/tissue/review_of_law.htm)

retained or post-mortem tissue, the use of such tissue for secondary research purposes, and the concept of 'benevolent intent' in use of genetic information post-mortem.

- A submission as part of the English/Welsh consultation is required by 14 October. The concept of discarded versus other samples has been proposed. However careful consideration will be required to ensure that use of discarded tissue (e.g. on dental floss) without consent is not condoned in any new law. SMS suggested the working group responsible for '*Inside Information*' reconvenes to make sure any proposed legislation is consistent with the proposals for a criminal offence of obtaining genetic material by deception/ without consent as laid out in '*Inside Information*'. This group, in concert with the 'direct to public genetic testing' working group will formulate a position and circulate it to other commissioners.

#### **Reproductive choice and joint work with HFEA**

- At the previous meeting it was agreed that joint scoping work with HFEA was required, but that this should await a meeting with the House of Commons Science and technology (HoCS&T) committee. This meeting has now taken place, a report has been published<sup>8</sup> and the HoCS&T committee will not be undertaking immediate further work in this area.
- Consideration now needs to be given to how best HFEA and HGC can work together, perhaps through bilateral meetings to minimise overlap. Previous joint work has shown big issues of joint concern and commissioners felt that HFEA could benefit from HGC expertise. Perhaps previous HFEA decisions could 'be rebalanced' by HGC. However it would be preferable to do joint work ahead of time rather than after HFEA regulatory decisions have been announced.
- Another area where HGC might provide assistance is in public consultation, an area where a regulatory body that derives some of its income from applicants may have some trouble being seen as disinterested. Sex selection of embryos was suggested as an example of an issue that might be addressed. The press is not believed to be representative of public opinion and the views of particular ethnic and religious groups may not be taken into account. However, as HK pointed out, careful consultation is not cheap. There would be the need for further financial resources. For example the consultation resulting in '*Inside Information*' cost £50 000 and if a more complex consultation was proposed, reaching 'into pockets of the community that would not otherwise be reached' the cost would be five-fold greater.
- This will be an important source of work over the next year.

#### **Genes and patenting**

- The Nuffield Council on Bioethics published a discussion paper on this topic in July<sup>9</sup>. It is not yet clear whether there will be a government response but the document is seen as useful by the patent office. In any event it was too early to expect official comment. HGC will follow up at a future meeting and it was noted that another meeting with the Nuffield panel should be arranged.
- Hilary Harris felt the report skimmed the issue of whether it is ethical to patent genes. She felt that the report accepted this was OK and then went on to look at improvements in applying criteria more strictly. She felt the recommendations were good, and noted that a recent case (Kirin-Amgen; 31 July) showed the courts were already looking at stricter interpretations.
- Patenting is also to be include in the report of an international commission on intellectual property rights convened by the UK Department for International Development<sup>10</sup> (Gill Samuels of HGC is a member).
- HK noted, parenthetically, that gene patenting was an example of a development that took place without public debate. It has had 'huge ramifications' but it is now 'too late' to uninvent. We are left to 'make do and mend'. This has implications for many of the areas HGC are active in and is a reminder that 'we have to be attentive'.

#### **Stem Cells**

- A stem cell bank located at the UK National Institute for Standards was launched on 9 September. An MRC conference on how stem cells are used is to take place.

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<sup>8</sup> See <http://www.publications.parliament.uk/pa/cm200102/cmselect/cmsctech/791/791.pdf>

<sup>9</sup> See [http://www.nuffieldbioethics.org/publications/pp\\_000000014.asp](http://www.nuffieldbioethics.org/publications/pp_000000014.asp)

<sup>10</sup> See <http://62.189.42.51/DFIDstage/news/PressReleases/files/pr16april01.html>

- Stem cell lines contain genetic information specific to the individual/embryo they are derived from. This raises consent and ownership issues. This should be explored in the HGC submission to the tissue retention reports (see above).
- However we are a long way from therapies, and indeed from safe sources. No licence is currently required to derive stem cells from adult tissues although the derivation of embryonic stem cells requires a HFEA licence. The ethical issues associated with uses of adult stem cells are similar; someone should look at the uses and outcomes particularly if enhancement is being considered. Research ethics committee approval is required where human subjects are being treated but there is no national framework: local ethics committees are 'notoriously variable'. HGC might provide oversight?
- The use of foetal neuronal tissue to treat Huntington's Disease raises some of the same issues. This is already in clinical trials after obtaining ethical approval. Although this does not involve stem cells it is to treat a genetic disorder.

### **Annual report**

- It was decided that the previous year's format and writing team (which 'balanced readability with statutory requirements') should be employed. The report will be submitted to ministers in October and published shortly thereafter.

### **Meeting on genetic databases**

- **It was felt important that this went ahead in public and soon. It is important to take the Biobank funders (Wellcome Trust, Medical Research Council and Department of Health) with HGC on this and the HGC business committee will confer with the funders to ensure that questions can be asked about the independent supervisory body.**

### **Consultation on genetic tests supplied direct to the public - including discussion with audience**

- HGC feels that the role of receiving notifications of new genetic testing services to be offered direct to the public, which was inherited from a predecessor committee (the Advisory Committee on Genetic Testing), may lead to conflict of roles (regulator v advisor). HGC has therefore informed UK government that it does not wish to be considered the regulator but in the meantime will continue to explore ways of setting standards in this area, and advise accordingly.
- Several meetings of an HGC workgroup have been held and a list of stakeholders (interested parties and involved companies) prepared to plan evidence taking. So far the Medicine Control Agency and the Royal Pharmaceutical society have testified and further sessions are planned on 1 and 25 October.
- A public consultation<sup>11</sup> was launched on 16 July and some responses have already been received. The consultation lays out four options ranging from 'do nothing' to 'stop all tests being offered direct to the public'. The consultation examines tests for disease susceptibility and to provide lifestyle-planning information but excludes paternity testing. Responses are invited by 4 October 2002. 6 to 8 focus groups will also be convened around the UK.
- In the public discussion issues of obtaining genetic material by deception re-emerged. For example, fathers taking swabs from children during access visits without maternal consent in order to establish paternity. There should be pressure on government to consider preventing folk from doing inappropriate testing without full prior consent.
- The issue of internet advertised and overseas testing was raised. Can legislation or codes of practice (as at present<sup>12</sup>) prevent this? It was felt that the UK setting a good example was important as the UK is seen to be in the vanguard of genetics.
- Sciona<sup>13</sup>, a company planning to offer genetic testing services for dietary/ lifestyle planning, is very much in favour of regulation since it allows them to build a market. Reputable companies want to be seen as responsible. They want people to have thought through consequences before embarking on testing. If consumers are not reassured that they can access such services in confidence and that samples and information will be professionally and securely treated, they will not use the services. Supporting this

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<sup>11</sup> See <http://www.hgc.gov.uk/testingconsultation>

<sup>12</sup> See <http://www.doh.gov.uk/genetics/hgts.htm>

<sup>13</sup> See <http://www.sciona.com/index.htm>

assertion, it was found in a MORI survey that the public is excited about the potential of genetics but frightened of misuse.

- However Sciona feel that there is a spectrum of genetic testing that runs from disease prediction testing (only through highly trained medical practitioners) to metabolism of drugs (of value to pharmacist) to lifestyle/dietary advice (to informed consumer). Different levels of regulation might be indicated for these different categories.
- Whose ethics are most important? There are lots of perspectives. Is there only a need for provision of adequate information, explanation of consequences and full consent or is there a requirement for full legislation. Danger of paternalism in an age of consumerism.
- Can the law keep up with the changing mores of society?
- Is this a real problem? The issue first came up through the Advisory Committee on Genetic Testing five years ago when it was predicted that we were on the brink of a rash of tests offered direct to the public. Unexpectedly this has failed to happen. Only one test (for carrier status for Cystic Fibrosis) materialised until this year. Maybe people prefer the full support and interpretation they can get through the NHS (if they can get it). Perhaps the main danger in disease testing is if the NHS can't provide all that is required. There have been a lot of market research companies saying genetic testing is a golden opportunity but there seems to be a rolling five-year horizon.
- **Direct-to-consumer testing may be favoured if individuals do not trust the security of information storage within the healthcare system. For example they may fear information will leak to their employer, insurer, the police or intelligence services.**
- **In time the consequences of having genetic information may change. We might think that only tests disclosing serious disease would require counselling to be bundled with them. However although we think that at present a particular genetic test only offers information relevant to drug treatment or dietary adjustment, it may subsequently be discovered that this is linked to disease susceptibility. In such a case there might be a flood of worried testees to primary care staff after a news report highlighting a new link between an existing genetic marker and a serious disease. This would create a large 'pick-up' problem for front-line health staff (GPs and clinical geneticists).**
- It is unclear where the bar for understanding of the consequences should be set with regard to people with learning disabilities and informed consent.
- What makes genetic testing so different? Why not regulate blood glucose and cholesterol testing in those without full understanding of consequences?
- How would a code of practice be monitored and enforced? There would need at least to be full disclosure of who was supplying what tests and what their policies were on security of samples and provision of information.
- There may well be a role for signposting of reputable private testing services from trusted sources such as NHS. John Burn and Tom Shakespeare (at University of Newcastle) have submitted a grant to allow them to build a high quality web site offering counselling services around genetic tests. We can choose to ignore private testing but it's better to engage and 'kitemark' reputable tests. If people, being fully informed on who's reputable and the consequences of taking the test, choose to go to disreputable testers then that is up to them.

#### ***Date of next meeting***

- Information gathering visit to Pfizer on 19 November and public session on 20 November in Kent/Sussex