

Note of Human Genetics Commission (HGC) meeting in London on 20 November 2002

- Areas considered by MVBio¹ 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 and (in due course) through their web site at <http://www.hgc.gov.uk>).

Summary of key points from the meeting:

- **The HGC has come to the end of its first three year spell and several members are stepping down. New members will be appointed in early 2003.**
- The UK approach of generating public debate and seeking some consensus is commended by the US President's Commission on Bioethics.
- **The UK government and the Forensic Science Service are considering a role for an independent custodian for forensic DNA databases.**
- HGC members are involved in a number of bodies addressing gene patenting issues.
- Concern still exists about how family history information is collected and used by insurers.
- The emerging conclusion of the HGC subgroup on direct-to-consumer genetic testing is that there is little support for doing nothing, or for stringent statutory control. They are moving towards recommending to ministers that regulation be through voluntary self regulation within a broad legal framework.
- If people want to buy a test on the internet, or at a health club, one can't stop them but wouldn't they rather access a test through a reputable professional?
- Therapists offering tests may not belong to a reputable professional body: this has consequences for voluntary regulation through codes-of-practice.
- **Wanting to access genetic information privately may be linked to worries about discrimination and concerns about medical confidentiality.**
- The consensus among the commission is that multiple routes should be available for individuals to access their genetic information: the GP/gatekeeper route should not be the only option.
- Overall oversight of direct-to-consumer testing should be provided by one regulatory body.
- **Further detailed discussion on the ethical regulation background on Biobank is required.**
- **Encryption of Biobank data may not completely protect identity and there therefore needs to be a major emphasis on consent to secure confidence about how information will be used.**
- Wider consultation on genetics and reproductive choice is required: this may require public hearings.
- **HGC is considering revamping its subcommittee structure to become more topic-focussed.**

Matters arising

- The HGC has come to the end of its first three year spell and several members (including John Polkinghorne and Ruth Evans) are stepping down. There needs to be continuity so retirements need to be staggered. New members will be appointed in early 2003.
- John Sulston was congratulated on his Nobel prize

¹ McFarlane Valentine BioConsulting (MVBio) advises legislators, strategists and administrators formulating public policy and industrial strategy in biomedicine and agricultural biotechnology. See <http://www.mvbio.co.uk>.

Genetics and human tissue retention

- The HGC response to the Department of Health/Welsh Assembly consultation on the review of the Human Tissue Act, '*Human Bodies, Human Choices*' was tabled (and included in the meeting papers at page 5). This raised a number of points explored in HGC's previous report '*Inside Information*'² including the recommendation that a new criminal offence of '*DNA theft*' be created.

International Association of Bioethics meeting in Brazil

- John Harris had represented HGC at this meeting. After some debate about whether it was competent for representatives of national bodies to comment on matters before they had been formally discussed in those national bodies, a communique had been released at the meeting but it didn't say much.
- The meeting had been useful in making international links and to realise that the UK was not the only country that had no one ethics commission. The matters under consideration in other places are much the same as in the UK (including stem cells, reproductive technologies, genetic information, body parts and cloning). Reproductive cloning is not on the agenda in many places because like in the UK it is '*banned or as good as banned*'.

HGC/HFEA visit to US to discuss developments in human genetics and embryology

- Helena Kennedy (HGC) and Suzi Leather (HFEA) gave evidence at the President's Commission on Bioethics on 19 Oct 02. The UK approach of generating public debate and seeking some consensus was commended. The US is '*locked into*' a situation where the (polarised) abortion debate colours much of the discussion. It is hard therefore to see how much progress can be made with stem cells.
- The UK approach to genetics and insurance was also seen as offering some pointers and has raised issues now being addressed in the US.

International Bioethics Committee of UNESCO

- Sandy McCall Smith will attend their ninth session from 26 to 28 November 2002 in Montreal³. This will consider an international instrument on human genetic data⁴ that picks up on many of the points made in '*Inside Information*'.

Sample retention by the forensic science service/ police

- **The recent Criminal Justice and Police Act has resulted in more retention of DNA samples from acquitted persons and from those submitting them voluntarily. Helena Kennedy raised this in the House of Lords and the minister said that government would consider a role for an independent custodian.**
- **Sandy McCall Smith and Mark Bale have met with the team reviewing strategy for the Forensic Science Service and they too are responsive to the idea of some form of independent oversight. Additionally the chair of the Association of Chief Police Officers has written inviting HGC to submit ideas on how forensic DNA databases might be supervised.**

Gene patenting

- This is now a standing item on the HGC agenda for plenary meetings. Hilary Newiss tabled an updated matrix of current developments. HGC members are involved in a number of bodies addressing issues in this area⁵.
- One of these bodies, the Intellectual Property Advisory Committee (IPAC)⁶, was set up 18 months ago to advise the UK Patent Office and ministers on how the law needs to move. For example, they are addressing how to encourage research, limit anti-competitive behaviour but encourage innovation.

² See <http://www.hgc.gov.uk/insideinformation/index.htm>

³ See <http://www.unesco.org/ibc/en/actes/s9/index.htm>

⁴ See <http://www.unesco.org/ibc/en/actes/s9/ibc9esquisseRev.pdf>

⁵ See <http://www.iprcommission.org/>; <http://www.nuffieldbioethics.org/patentingdna/index.asp>; <http://www.intellectual-property.gov.uk/ipac/>; http://www.royalsoc.ac.uk/policy/intell_prop.htm

⁶ See <http://www.intellectual-property.gov.uk/ipac/>

- The European Commission has published their first report on the implementation of the Biotechnology Patents Directive⁷. A new group of experts is being convened to address these findings and this will be an important new forum for consideration of EU patenting issues⁸.
- **The upcoming green paper on genetics will contain something on gene patenting. [It is not yet clear whether this green paper will include Scotland -AVP] The Department of Health (in England) have commissioned a review of intellectual property in relation to health care delivery. This will address situations where genetic tests are constrained by BRCA1 and 2 patents held by Myriad Genetics (familial breast and ovarian cancer susceptibility), and others.**
- **Negotiations continue between the UK Departments of Health and Myriad Genetics to secure good licence terms. The Myriad patents are under opposition at the European patent office and there was a report at a recent UK Association of Medical Research Charities meeting that the UK patent office are tightening their definition of innovation/ utility/ purpose. Hilary Newiss will investigate and report back.**
- **Mention was made of the fact that Alberta and Ontario in Canada and perhaps Germany are taking a different approach and not recognising Myriad's right to control BRCA1 and 2 testing. Myriad have gone to law. Uniquely, in the UK BRCA2 patents are also held by parties other than Myriad. John Sulston suggested that rather than being 'picked off one by one' why not 'get together'. Helena Kennedy will raise this with ministers and officials at the Department of Health.**

Genetics and insurance

- This issue should not be parked while the moratorium is on. If the Association of British Insurers (ABI) and individual companies don't use the time for fruitful work the moratorium may need to be extended.
- Comments have been made about the ABI's draft leaflet (see meeting papers).
- Helena Kennedy and others are to meet with the Genetics and Insurance Committee (GAIC)⁹ chairman to discuss the relative roles of HGC and GAIC.
- Hilary Newiss attended the UK Forum for Genetics and Insurance annual conference at which interesting financial models and research were presented¹⁰. Research into customers' behaviour, experiences and attitudes is also underway by Lindsay Prior (University of Cardiff) and colleagues with funding from the Wellcome Trust. These studies augment the sparse evidence base.
- Concern among commissioners still exists about how family history information is collected and used by insurers. Genetic tests are seen by the industry as merely a special sort of family history information, which they had been collecting previously. HGC needs to take a view on the use of family history information. The way GPs report family history to insurers is variable. Some print off the whole notes and send while others send only very selected details that they are asked specifically for. The Royal College of General Practitioners are keen to work with HGC to give a more consistent approach.
- **IT advances are expected to lead to more centrally held medical records [This is far less developed than many think - AVP]. The inclusion of genetic information will lead to curation of medical records being a recurrent interest for HGC.**
- Decisions need to be taken on whether we wish genetics and insurance matters to be settled on the basis of humane treatment or purely by market forces. If there isn't balancing of good and bad risks in the population it is feared that some people will be uninsurable¹¹. Do we want provision of normal levels of insurance to be part of the welfare state?
- HGC need to revisit these issues before the moratorium expires and to indicate a timetable for actions to ABI.

⁷ See http://europa.eu.int/comm/internal_market/en/indprop/invent/index.htm

⁸ See http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/02/1448|0|RAPID&lg=EN&display=

⁹ See <http://www.doh.gov.uk/genetics/gaic/index.htm>

¹⁰ A MVBionote of this meeting is available at http://www.mvbio.co.uk/mvbionote-ukfji_nov02.pdf

¹¹ But see also the report of the UKFGI meeting (http://www.mvbio.co.uk/mvbionote-ukfji_nov02.pdf) at which these matters were discussed in depth

Genetic tests supplied direct to the public

Approach

- There have been three evidence-taking meetings and sixty-five written responses to the consultation were received. The opinions expressed were not especially surprising and mainly concerned access, consent, claims and advertising. Eight focus groups are still to be convened and there are plans to set up an internet poll. The consultative work will conclude by end of 2002. A summary is in the papers for the meeting beginning at p65.
- The emerging conclusion of the HGC subgroup is that there is little support for doing nothing or for stringent statutory control. They are moving towards recommending to ministers that regulation be through voluntary self regulation within a broad legal framework. Such a broad legal framework might share features with matters regarding human organs and tissues, for example the law on '*DNA theft*' and other aspects of how tissue (and DNA) are handled (taking, storage, confidentiality). It would build on '*Inside Information*'.
- There is a feeling (within the working group and in industry) that legislation would take too long and be too inflexible. The counter argument, advanced by Helena Kennedy was that '*that could be an answer to everything*'. The time taken to legislate depends on the priority accorded to the matter. Such views of the role of legislation are reflections of an '*agin regulation*', free market philosophy that is currently much in vogue. There are exceptions: might this be one?

Monitoring and implementing codes-of-practice

- It will be important that there is overall monitoring of codes of practice (from advertising to lab standards) and issues don't fall between regulatory authorities. HGC has no regulatory role: it examines issues and advises ministers. It's up to government to decide how to regulate. The Medicines Control Agency (MCA) and Medical Devices Agency (MDA) are combining in Apr 2003. HGC should make sure the new body gets involved in oversight of genetic tests direct to the public. The Office of Fair Trading should also be involved in drawing up the broad legal framework and there should be consumer input.
- Tests offered through the internet cannot be regulated by any one domestic regulator. The best that can be done is to make sure users know the right questions to have in mind when procuring a test. Consumer groups are particularly helpful in raising awareness. If standards are set here in the UK they may be replicated elsewhere.
- Voluntary regulation would have to be brokered by trade bodies, for example the British In-vitro Diagnostics Association, and professional organisations. Are those proposing to offer tests a sufficiently cohesive group to allow self-regulation through codes of practice? Service providers and their intermediaries say they are happy to self-regulate: they want to be seen as ethical.
- There is concern that some people offering DNA and lifestyle advice might be '*therapists in health clubs*'. Such therapists don't always belong to organisations keen on self-regulation or accreditation. For example some nutritionists just put up a sign and have no professional accreditation. There are reputable nutritionists (see the Food Standards Agency web site¹²) but also '*voodoo*' ones. The British Society of Nutritional Therapists might potentially be involved in monitoring codes of practice.
- In contrast, pharmacists study at university for four years, then spend one year in pre-registration before obtaining membership of their professional group. This membership must be maintained to allow them to practice. The Pharmaceutical Society of Great Britain are apologetic that it takes them 4 months to '*throw out*' rogue pharmacists.
- Even with well established professional bodies (e.g. GPs) it is '*hard to get them to raise their game*'. There is great need for education, for audit, for evidence-base. Disciplinary procedures alone don't work.
- Accreditation would be a badge of quality. If people want to buy a test on the internet, or at a health club, one can't stop them (*caveat emptor* -buyer beware) but wouldn't they rather access a test through a reputable professional, such as a pharmacist?

Do 'serious tests' require gatekeepers?

- Self-regulation may be appropriate for '*less serious*' tests but shouldn't the more serious be only through GPs or other medical practitioners? Some respondees to the consultation, including the Genetics

¹² See <http://www.foodstandards.gov.uk/healthiereating/asktheexpert/healthyeating/nutritionistsq>

Interest Group¹³ disagree with this on principle. They argue that an individual should have access to information about themselves without having to go through a gatekeeper such as a GP.

- Helena Kennedy pointed out that in fact internet- and internationally-accessible tests would always make this possible regardless of what domestic regulation is in place. There is perhaps though a point of principle: if we say folk have the right to access information, don't they have a right to do this without having to go overseas/ through the internet? Not all internet testers are 'cowboys': some companies do offer counselling.
- The right though is to access complete information. This requires context. Tests may provide only partial information: is there a right to only partial information? Counselling and support should be available whether or not tests are direct or through gatekeepers.
- There is a balance then between education, autonomy and self-awareness on the one hand, and preventing exposure to hurtful information out of context on the other.
- The rationale for having gatekeepers to control access to serious disease tests is to ensure that counselling and support are maintained. People can only be '*warned and informed*' if gatekeepers are involved. Perhaps public knowledge will increase and this will become less necessary. Genetic tests '*can be dangerous*' if those taking them are not knowledgeable. However, many families with serious genetic diseases feel they don't want counselling because they already understand the consequences.
- Hilary Harris still subscribes to the view laid out in the previous Advisory Committee on Genetic Testing (ACGT) code-of-practice¹⁴ that the gatekeeper is an important role (she's a GP and was a member of the ACGT) group. It's good medical practice for GPs to be aware of what's going on with their patients. Without this it's hard to offer good quality joined-up care.
- For the less-serious lifestyle tests the issues are primarily of consumer protection, although the boundary between serious and less serious may be hard to define. In different circumstances the same test might fall into serious or non-serious categories. Do we then have to examine motives: gets messy.
- In the US companies prefer to market tests through healthcare providers rather than direct to consumer. This may be to avoid litigation if things go wrong.

Worries about information leakage and effects on use of NHS testing

- **The urge to go private may be reinforced if there is a fear that sensitive genetic information will leak, for example to insurers or employers, and people don't trust the system. Additionally, as Ross Anderson¹⁵ pointed out at the HGI Biobank information-gathering session on 19 November, encryption of medical information is no guarantee of complete confidentiality. This being so people may feel that they do not wish genetic information to be part of their health record.**
- **Experience with prescribers of drugs tells us education of professionals should not just be from materials provided by test providers or through adverts. If we agree that the context (counselling, advice, behavioural change) of receiving a test result is the most important factor, what group is best able to provide the context? Might not be GPs. This also has an impact on which professional groups need to be engaged in the voluntary self-regulatory system.**
- **The libertarian view that everyone should be allowed access to their own information is only viable if most continue to use the NHS. Not all will have the financial means to buy private tests. Focus groups support the view that most testing will continue to be via the NHS: '*why would anyone want to not go through their doctor?*' The focus groups also suggest that folk would '*check test results and interpretation*' with their GP. This means that not only those taking the test will be impacted. Because '*precious GP time is taken to deal with rubbish tests*' all the GP's patients will be affected: having to wait longer, finding it harder to get an appointment, etc. Even if we wanted to '*wave a wand*' and create many more genetic specialists to interpret test results to patients, there are enormous issues in finding suitable folk and getting them trained.**
- **There is currently little demand for direct tests. Experience shows that the directly available Cystic Fibrosis carrier test had few takers, and no other applications were made to ACGT. There are capacity issues with NHS testing but the services exist. Internet testing services exist for**

¹³ See http://www.gig.org.uk/docs/hgc_otctests_gig.pdf

¹⁴ See <http://www.doh.gov.uk/genetics/hgts.htm>

¹⁵ See <http://www.cl.cam.ac.uk/~rja14/#Med>

Huntington's Disease but only a handful of families surveyed had used them. This is in comparison with thousands who have used the NHS testing service and regard it as a good, available service.

- It is already possible to access genetic testing on the NHS without going through the GP. There are even cases of people being tested under pseudonyms by NHS-funded labs.

Conclusions

- In summary, the concensus among the commission is that multiple routes should be available for individuals to access their genetic information: the GP/gatekeeper route should not be the only option. There should be more public education about genetics (this is hard and requires resources). Guidance to set up the right codes of practice is required and this will need involvement of the right trade and professional bodies. Overall oversight should be provided by one regulatory body that takes care of all issues rather than fragmentation of regulatory responsibility.
- The working group will make their final draft recommendations in time for the February plenary of the HGC to approve. It is important that this piece of work is completed with the current commissioners.

Memorandum on Biobank¹⁶

- The House of Commons Select Committee on Science and Technology (HoC S&T) had requested a submission from HGC by 22 November as part of an investigation of Biobank. This had been drafted following the principles outlined in *'Inside Information'*.
- Further detailed discussion on the ethical regulation background on Biobank is required. Some of the issues are hard to engage with. For example it is hard to consider issues on the ethical background to recruitment and testing of volunteer participants before having a detailed understanding of who will be collecting and storing the samples and the safeguards they'll have in place.
- Encryption of data may, as Ross Anderson suggests, not completely protect identity and there therefore needs to be a major emphasis on consent to secure confidence about how information will be used.
- One area of particular concern is access by the police. This worry would be addressed if the home secretary will make a statement to the House of Commons that this will not be allowed. Legislation would then not be required and donors would perhaps enrol in Biobank with more confidence.
- Clarification is also required on whether feedback from the Biobank study will be given to individual participants. For example the Data Protection Act might be interpreted to say that an individual could ask for all information on them that's stored in a Biobank database to be divulged to them, including all gene test results. Individuals might get placed under pressure from researchers or family members and this would be very unfortunate.
- Whether or not individual feedback can happen may affect which sorts of projects get ethical approval. For example psychological and behavioral studies might only be permitted if there was no individual feedback of results. A good legal opinion is required on this issue of individual feedback. Decisions taken with respect to Biobank will also affect other studies. Most other studies don't allow individual research feedback.
- Ian Gibson, the chairman of the HoC S&T committee, is on record in Hansard as being in general supportive of Biobank but with certain reservations. He does however want it to work rather than run into problems. HGC should also constructively engage and make it work.
- Biobank will not be able to proceed until links can be made with routinely captured health information. This raises questions of the IT available within the NHS to capture such routine health information. Central stores of information within the NHS, as elsewhere, raise issues of risk and trust. Mechanisms must be in place within the NHS to ensure confidentiality and there must be disciplinary sanctions and protocols to deal with breaches. It might be argued that a criminal offence is *'shutting the door after the horse has bolted'* because the information would then be out, but it might have deterrence value.

¹⁶ See <http://www.ukbiobank.ac.uk/>

Scoping work on Genetics and reproductive choice

- Wider consultation is required with stakeholders: this may require public hearings.
- Bill Albert is taking the lead on this, as discussed in the genetic services subcommittee. Elements of good practice will be adopted from those outlined in *'Inside Information'* and during the direct to consumer genetic testing discussions. A small scoping group including Suzi Leather, from HFEA, will be convened. It will be important to minimise overlap with HFEA work and to prepare something by the February plenary HGC meeting, that is aligned with the approach taken by the National Screening Committee.
- Another immediate step might be the commissioning of an evidence review of the factors affecting decision making by couples during pregnancy.

New ways of working

- **The secretariat had prepared a paper considering the work currently undertaken by subgroups between plenaries and this was tabled at the meeting (in the meeting papers at page 117). In essence the proposal was to concentrate such work into task-specific working groups. These would complement a revised genetic services subgroup that met in the four countries in rotation, a business committee that provides a coordinating role, and a series of topic-specific monitoring groups (each with a lead member). These proposals found favour. Monitoring groups would allow more 'reactiveness' but the new plans would require volunteers!**
- **Public involvement should be an integral part of the remit of all sub-groups. Public education will require identification of resources and can be achieved most productively by partnerships. Use might be made of science festivals and of HGC members giving lectures.**
- The 50th anniversary of the publication of the structure for DNA (May 03) represents an opportunity to generate further public debate about genetics. However if HGC wish to take advantage of this opportunity, proposals will have to be discussed early next year.
- The HGC website should have pointers to others' sites, for example educative resources such as those hosted by the Medical Research Council, the Wellcome Trust and the Science Museum¹⁷.
- As HGC members retire they should go through an exit interview. All members should also be surveyed (as they were when they joined) to ascertain their views on *'what the HGC should do and where the key thorny issues are'*. An induction programme to help new members get going as quickly as possible was also recommended.
- Introducing new people into HGC was a good idea to stop consensus being reached too soon as members got to know each other too well, and to prevent decisions being taken *'on the nod'*.

Date of next meetings

- **Following the meeting on 4/5 Feb, a meeting will be held in Birmingham on 6/7 May to coincide with the European Society of Human Genetics meeting. Sessions may be held on how to educate the public and on Genetics and Children (for example, who makes decisions on their behalf?). A meeting in Cardiff on 24/25 September will be hosted by the Welsh Assembly and ministers.**

¹⁷ See <http://www.mrc.ac.uk/>; <http://www.wellcome.ac.uk/>; <http://www.nmsi.ac.uk/>