

British Society for Human Genetics

Joint Committee on Medical Genetics

A joint response to the Ministry of Justice consultation paper on the use and sharing of personal information in the public and private sectors

Introduction

The British Society for Human Genetics (BSHG) represents health professionals working in specialised genetic services in the NHS and scientists and health professionals in medical research. (www.bshg.org.uk).

The Joint Committee on Medical Genetics (JCMG) advises the Royal Colleges of Physicians and Pathology and includes representatives of interested Medical Royal Colleges the BSHG and the Department of Health (www.bshg.org.uk/joint_committee/joint_committee.htm).

The BSHG and the JCMG acknowledge the contribution of the PHG Foundation in preparing this response. The PHG Foundation (PHGF) is an international, independent charity that works with partners to achieve better health through the responsible and evidence-based application of biomedical science (www.phgfoundation.org).

This response focuses on the personal information held for the purpose of clinical care and diagnosis in NHS Genetics Services rather than information collected solely for research use. However it recognises that the boundaries between clinical use and research are not always clear cut, and that there is often a need for personal data to be shared for the benefit of family members to assist diagnosis. This process may involve research to identify genetic changes which are responsible for or linked to an inherited condition.

The 23 NHS Regional Genetics Centres are estimated to retain DNA samples collected for genetic testing from 1-1.5m UK citizens. Samples from between 80 and 120,000 individuals per year are added to these collections. ¹ Medical Genetic departments have at least the same number of records of individuals and their family relationships. Samples and records from individuals are retained indefinitely to assist the diagnosis and treatment of other family members.

The legal framework for obtaining, storing, analysing and sharing these collections and medical data derived from them was extensively reviewed by the JCMG in 2006. The recommendations from this document reflect and form a base-line for good practice in Genetics. ² Following the enactment of the Human Tissue Act 2004 a detailed review of its consequences for clinical practice was also made. ³

Question 1

What kinds of personal information do you collect, hold and share?

UK Regional Genetic Centres in the NHS collect and hold personal information from patients referred to them for diagnosis, counselling and laboratory testing. This data includes the identifiers, demographics, medical data and information on the family relationships of a patient and medical data on their relatives.

How do you collect hold and share such personal information

This information is held as medical records that may be paper-based but which are increasingly held electronically as part of a hospital patient administration system or a stand-alone database. Because genetic conditions may be inherited through many generations it is the practice of many Genetic Centres to hold composite medical records for an indefinite period. Unusually records are mostly indexed by family rather than by individual patient. This practice allows more comprehensive oversight of a family history and to resolve ambiguities from the accounts of many family members. Family records are held in addition to individual patient records to facilitate clinical care. The heritable nature of genetic conditions means that it is considered good practice to hold genetic medical records for an indefinite period.

For what purposes do you collect hold and share such personal information

Medical records held by Regional Centres are retained to help patients manage their individual risks from a genetic condition and/or risks to their relatives or future generation. Several members of the same family may be at risk of a particular inherited condition. Their care is often shared across the geographic boundaries of Regional Genetic Centres and it is considered good practice to share data for the care of individual families between Regional Centres. The JCMG considered the issues raised by this network-care approach in detail in its guidance.

The demand for evidence based care means that in Genetics like all medical services, research is considered to be an integral part of good practice. It enables the best and most up-to-date services to be offered to patients. The rapid pace of scientific advance means that in Genetics making a diagnosis and clarifying treatment options for some patients is intimately bound up with research. This is because diagnostic tests are only available for a proportion of patients. Where biological samples can be collected from a patient and their relatives at risk of rare inherited conditions, comparing affected individuals with other family members may allow researchers to identify the genetic changes which cause the condition. This discovery often leads directly to new diagnostic tests which can be used to benefit other family members and other at risk individuals. For this reason it is regarded as good practice for patients and their relatives at risk of rare inherited conditions to be offered the opportunity with consent to contribute biological material and data for research. The rarity of most genetic conditions means that it is good practice for personal and family data for research to be shared with consent and pooled (sometimes internationally) for effective research to be carried out.

Question 2

What in your view are the key benefits of sharing personal information to a) individuals and b) society? Please provide details.

In our view questions 2 and 3 could usefully be expanded to include a category for the discussion of the benefits and risks of sharing information within a *family*. Most systems hold personal information indexed by the individual. In Genetics details on one individual are often held together with, or may imply information about family members.

Geneticists work with families because their members unwittingly share the risks of inherited conditions and because the family is often the unit within which key life decisions are discussed, made and acted out. In addition the family is the unit within which the consequences of genetic conditions are contained and managed on an every-day basis. Effective and ethical professional methods to allow sharing of personal genetic medical information within families are therefore essential (see also question 17). Geneticists often play a role in mediating this information sharing process and in exploring best practice. The special benefits of sharing personal information with family members is also acknowledged by the Human Genetics Commission (HGC) which concluded that the disclosure of sensitive personal information for the benefit of family members may exceptionally be justified even in the absence of consent (*Inside Information* 2002).⁴

Question 3

What in your view are the key risks of sharing personal information to a) individuals and b) society? Please provide details.

Geneticists are acutely aware of the potential harms of sharing information amongst people related by blood or partnership and have documented an ethical basis for their practice and encourage ongoing best practice debates (www.genethicsclub.org). The HGC also recognised that genetic information can be especially sensitive within the family.⁴ An obvious example is where evidence of non-paternity is revealed. We note that the controls now put in place by the Human Tissue Act 2004 have exceeded the recommendations made in the HGC report to create a criminal offence to deter the non-consensual or deceitful obtaining and/or analysis of personal genetic information for non-medical purposes.

We would like to point out that the distinctive status of the family is not confined to data sharing in medical settings. The enhanced risk of harm in data sharing amongst families is more general and is relevant to all interactions between individuals and the public and private sectors. This follows because all *items of personal data have much greater impact on the relative of an individual than to society generally*. For example the details of an individual credit agreement between a man and a finance company are more relevant to and have greater potential impact on his partner and children than to his neighbours, employer, work-mates, or society in general. Many examples of this effect can be found in commerce, finance, criminal justice and the work of social agencies.

We suggest that the enhanced risks (and benefits) of personal data sharing within families should be considered by regulators.

Question 4.

There are wide variations in the scope and methods of personal information sharing. What scope and what methods, in your view, pose the greatest opportunities or risks? Please explain the reasoning behind your response.

To date most information sharing within the Genetic Service network in the UK has not been through the linked information systems being implemented through NHS Connecting for Health. However this is likely to change as Connecting for Health and other medical systems are modernised through the National Programme for Information Technology. These new systems give Clinical Genetics an opportunity to enhance its every-day services and through information sharing increase the pace and penetration of research of direct benefit to patients.

Electronic systems potentially enhance the risk of inappropriate data sharing and increase the likelihood of harm to individuals. In our view these risks are not different in scale or nature in the practice of Genetics than in other fields. Some genetic information may be considered to be of a particularly sensitive nature but is not more sensitive than personal data handled by, for example, Child Protection and Sexual Health services.

One particular issue in Genetics that warrants careful consideration is the storage of and access to electronic family history data. In our view these risks are significant but can be managed within the governance and security mechanisms being built into NHS information systems.

However the electronic patient records systems that are being introduced are predicated upon an individualistic model of data ownership. Individuals are empowered to seal and lock their records to prevent data sharing without consent even if this is likely to cause direct harm as a result. As noted above, English common law and professional guidance has recognised that in certain exceptional circumstances, data may be shared without consent to avert serious harm. We have concerns that the electronic patient record systems that are being introduced may impede the sharing of data between family members and that this might compromise clinical care.

Question 5.

What if any barriers would a requirement for gaining consent create to the sharing of personal information? Please explain your reasoning

Recording identifiable details of family members in pedigrees is essential to good medical practice. Advice from the Information Commissioner cited in the JCMG's guidance suggests that such recording is permitted without relatives' individual consent.² Such details are considered to be 'hearsay' information provided by the patient seeking genetic advice. If gaining relatives' consent prior to their inclusion in a pedigree was a requirement this would be an impediment to good medical practice. However, wherever a *critical* medical detail on a relative is needed for an accurate risk assessment, for example a documented diagnosis of a particular cancer, consent is sought to access their medical record.

Question 9.

In your view, how well does the DPA work? Please outline the DPA's main strengths and weaknesses and any proposals for changes you would like to see made, including suggestions for their implementation.

Taking a family history is an integral part of Clinical Genetics practice. Sharing genetic information for the benefit of family members is also consistent with the highest standards of professional practice if sharing is justified in the public interest. We have concerns about the way in which some aspects of the Data Protection Act work in practice:

Fair and lawful processing (First Data Protection Principle)

Sometimes the terms of consent attaching to a sample or particular genetic information is not clear and questions arise as to whether the obligation to process data in a fair and lawful manner inevitably requires a new consent to be sought from the data subject. Exemptions in the DPA allow the requirement for consent to be dispensed with if providing information to the data subject would involve 'disproportionate effort.' Supplementary advice from the Information Commissioner's office has confirmed that each case should be considered on its merits, taking into account the extent to which the disclosure is likely to reveal new information about the sample donor or have consequences for the individual concerned. This forms the basis for current guidance endorsed by the Clinical Genetics community.²

Subject Access Requests (Section 7 DPA)

There is confusion about the extent of the duties imposed by the Data Protection Act 1998 to notify and provide information to those family members about whom information is collected, used and stored when a full medical history is taken (and confirmatory diagnoses sought). These provisions were explicitly addressed by the HGC which included the recommendation; 'that there may be a need for secondary legislation to ensure that the holders of information about genetic relatives in a clinical context are specifically exempted from their normal obligations of notification and provision of such information to such relatives under the Data Protection Act.'⁴ If clinicians were obliged to notify those relatives mentioned by patients when a family history is collected this would be burdensome and impracticable.

In our opinion more clarity is needed concerning the obligations the DPA places on health professionals.

Question 13.

Are there any other aspects of the UK or EU law (such as EU Directive 95/46/EC) that impact positively or negatively on data sharing or data protection? Please provide examples.

Although it is widely understood that the Data Protection Act applies to identifiable data and not to anonymised data, the concept of anonymisation is sometimes difficult to apply to genomic information. For medical research involving genomic data, the status of pseudonymised or encrypted data is not always clear. Some of these epistemological difficulties may be resolved

once the Secondary Uses Service is fully operational. However it is currently unclear as to the extent to which researchers must seek to irrevocably anonymise patient genomic data without requiring consent from a third party such as the Patient Information Advisory Group. We are concerned that these ambiguities and operational problems will inhibit genomic research.

There is a degree of overlap between the provisions of the Human Tissue Act 2004 and the Data Protection Act 1998 specifically in the area of tests on tissue samples and DNA where this yields personal data and when that analysis is for the benefit of family members. This overlap is problematic because each Act imposes differing requirements.

We recommend that the provisions within the Data Protection and Human Tissue acts are harmonised with regard to legitimate data sharing in medical practice.

Question 16.

Is it clear whether and when you need individual's consent to share information about them? Are you clear about what form that consent should take? Please provide examples.

Please provide details of any initiative you have been involved in that has been based on consent.

Individual consent for medical procedures, testing, the retention and use of biological materials and sharing data is central to the practice of Genetics. Geneticists are aware of the legal framework formed by the Human Tissue Act and the Data Protection Act and how this has been translated into general NHS practice (Caldicott guidance) and specific Guidelines for Genetics (JCMG). Regional Genetics Centres have translated these principles into their own data protection policies and procedures including systems for recording consent.

Question 17

What if any barriers would a requirement for gaining consent create to the sharing of personal information? Please explain your reasoning.

Best practice guidance issued in 2006 suggests that in a clinical context, consent should be sought from a patient seen in person to assist other family members. However the guidance acknowledges that in exceptional circumstances it may be justified to proceed with data sharing in the absence of consent in the public interest.

Question 21.

Should the law mandate specific technical safeguards for protection personal information?

For example should there be an explicit requirement that all personal information held on portable devices be encrypted to a particular standard?

The electronic patient record systems to be introduced as part of the Connecting for Health initiative provide for specific technical safeguards such as role-based access and smartcard protected systems. As part of NHS service provision, Clinical Genetic Services are required to comply with NHS guidance on encryption of patient information held on portable devices.

Question 22.

How in your view could 'privacy enhancing techniques such as anonymisation or pseudonymisation of personal information help safeguard personal privacy whilst facilitating activities such as performing medical research?

It is not always possible to anonymise genomic information. Whilst we welcome the creation of the Secondary Users Service as a means of systematically stripping identifiers from personal data for ongoing secondary use, we are concerned that it may not be possible to effectively anonymise genomic information, and that some types of research may be impeded or curtailed by the application of a 'consent or anonymise' approach. We recognise that the Patient Information Advisory Group (shortly to be replaced by the National Information Governance Board) currently has a statutory role in applying exemptions to certain types of research which would otherwise require consent but note that the existing application process is cumbersome and may cause delay.

References

1. One Regional Centre has collected a total of 112,000 individual samples since 1985 representing approximately 25,000 samples per million from the population it serves. Allowing for duplicates held in more than one centre samples from between 1 and 1.5m individuals are estimated to be held in the UK.
2. *Consent and confidentiality in genetic practice* – guidance on genetic testing and sharing genetic information. Joint Committee on Medical Genetics 2006.
[http://www.bshg.org.uk/documents/official_docs/Consent_and_confid_corrected_21\[1\].8.06.pdf](http://www.bshg.org.uk/documents/official_docs/Consent_and_confid_corrected_21[1].8.06.pdf)
3. *The Human Tissue Act 2004: an assessment of the Act and its implications for the specialties of clinical and laboratory genetics*. Joint Committee on Medical Genetics 2007.
[http://www.bshg.org.uk/documents/official_docs/HTA_questions_geneticists_and_clinical_scientists_JCMG_wor\[1\].pdf](http://www.bshg.org.uk/documents/official_docs/HTA_questions_geneticists_and_clinical_scientists_JCMG_wor[1].pdf)
4. *Inside Information* a report by the Human Genetics Commission 2002 Department of Health

Other relevant sources

The retention and storage of pathological records and archives; guidance from the Royal College of Pathologists and Institute for Biomedical Science. 2005 <http://www.rcpath.org/resources/pdf/>

Guidelines for the release of specimens and data to the police and other law enforcement agencies. Royal College of Pathologists and Institute for Biomedical Science 2006.
<http://www.rcpath.org/resources/pdf/>

Contacts