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Academy of Medical Sciences Study on the Use of Patient Data in Research

A submission from the Genetic Interest Group

The Genetic Interest Group is the national alliance representing individuals and families affected by genetic disorders. We have over 130 groups in membership, and a smaller number of individual members. Some of our member groups and members are involved in conducting research. Some of our members, as individuals, have been or are participants in research. The Academy's investigation into the use of patient data is most welcome. We are aware that the Academy itself and many other bodies have already given a great deal of thought to the many aspects of the issues under consultation. Broadly speaking we agree with the concerns that have been raised.

As a group we have a long-standing interest in research and some of the issues raised by the Academy. In 2000 we published *Getting Involved in Genetics Research*, a guide for individuals, families and the groups that support them.¹ Over the past two years we have been engaged with researchers, clinicians, ethicists and members of the research ethics community in addressing concerns that have arisen about some of the barriers to pursuing research into rare genetic disorders.² Among the issues that arose, two are directly relevant to this consultation. Firstly, such research has been likened to a fishing expedition: it is open-ended and a number of different methodologies may be tried in the search for a result. It is a widespread experience that research ethics committees do not like this approach, preferring specific and time-limited consent. Secondly, standards of confidentiality involved in such work are often considered inadequate by regulators, even though they are acceptable to patients.

At the heart of the problem is the tension between the pressures of clinical practice and the complexity and open-ended character of research on the one hand, and the ideal of express and informed consent on the other. No matter how often the Government states that generic consent is valid, the concern remains that in specific circumstances it might be thought insufficient. Indeed, there is a body of literature that criticises the validity of general, open-ended consent, even if the individuals giving it have had a full discussion with a professional beforehand. Writing about the proposal to take a general consent from prospective participants in UK Biobank, Richard Tutton and colleagues argue that while 'it is only practical that individuals give an open consent at the time of the collection of information', the defects inherent in this should cause the project to take several further steps:

¹ Available at http://www.gig.org.uk/gig_publications.htm

² A paper outlining the issues and conclusions can be found at: <http://bmj.bmjournals.com/cgi/content/full/329/7460/288>

‘We advocate that UK Biobank provide the participants with information about all of the research as and when it become known. After receiving this information, participants should be given the opportunity to opt out of certain research or to withdraw from the project completely.... We suggest that if UK Biobank uses open consent, it is imperative that participants and their relatives should be given the right to exercise a clear choice about their withdrawal from the project. To ensure public trust, the choice must rest with the participants and, in case of their death, their relatives.

Currently, participants are perceived as little more than sources of biological material and personal information. There is no opportunity for participants to have an influence in setting up, managing, or shaping the direction the future research UK Biobank will undertake. The notion that people are eagerly waiting to participate in a project of which they will have little influence over might need revising... Therefore, we would encourage the funders to consider the inclusion of representatives of the participants in the EGC and other management bodies as a way of securing public trust and support.’³

Government implicitly endorses the idea that participants or their representatives might engage in a research project, and that this might in some way compensate for the deficiencies of general consent. Lord Warner put it this way during debates on the Human Tissue Bill in the House of Lords:

‘Through the consultation that has been taking place, we saw that people were happy for tissue to be used, but they wanted to be involved. They wanted to know what was to be done with that tissue. First and foremost, that means consent as the basis for the use of the tissue. People want knowingly to contribute and to be involved. In the situation, however, where tissue is to be used without consent, without people's knowledge, research ethics committees will represent their interests by ensuring that it is done on an ethically acceptable basis.’⁴

It is true that some patients are knowledgeable and do want to be informed and involved. But it is also our experience, based on discussions with patients involved in GIG or one of our member groups, that many, almost all in fact, of those same people are very happy to give open-ended consent. Their main concern is usually that research is done as quickly and effectively as possible.

Many other people have very little interest. Passively, many would support research, but if asked to ‘participate’ beyond giving consent and enrolling, they would probably be quite perplexed as to what this could mean. Contrary to the notion that people would be

³ Richard Tutton; Jane Kaye and Klaus Hoeyer, Governing UK Biobank: the importance of ensuring public trust, *TRENDS in Biotechnology* 2004; **22(6)**: 284-285.

⁴ *Lords Hansard*, 22 July, columns 426-7.

reluctant to support such projects if their participation was limited to being ‘sources of biological material and personal information’, with ‘no opportunity... to have an influence in setting up, managing, or shaping the direction of the study’, we would suggest that many would be very happy with that. The social survey work done by ScHARR on attitudes to participating in UK Biobank tends to support this opinion: ‘individuals who are most likely to be interested in UK Biobank are more likely to want individual feedback, consent just at the start, and for information to continue to be used after withdrawal (with or without the DNA being destroyed).’⁵

Research projects studying rare genetic disorders and the large scale UK Biobank share at least one thing in common: both are set up so as to allow a formal and detailed consent process (even if this is of necessity general and open-ended). Many other research projects will not allow this, for one reason or another. In some cases there will be no consent process at all. The Government’s view is that in these circumstances the ideal should be that data is anonymised as far as the researcher is concerned. Currently exceptions to this are allowed, but the aim seems to be to phase this out (analogously to the either or requirement of ‘ask or anonymise’ governing research on tissue under the new Human Tissue Act).

We are of a similar opinion to many scientists on this. Beyond the formal aspect of general consent, the real content remains a confidential relationship between patient and scientist, based on trust that scientists are behaving ethically and in the public interest. Part of that trust is an understanding that scientists will handle sensitive information in confidence. So, coming at the issue from the other side, anonymisation, scientists wonder why they should invest a lot of time and effort, and maybe lose important information in the process, for little gain, when a system of confidentiality has served them and the public well for many years. Of course, this should not mean that identifiable information is shared in a cavalier manner. But it does mean that confidential sharing of identifiable information should be allowed in certain circumstances, and that we should trust scientists to handle anonymised, but data rich, sources that may carry sufficient information to risk revealing the identify of an individual.

There is of course a political dimension to the debate over confidentiality and anonymisation. While keen to promote an ‘ask or anonymise’ system, Government is also keen to establish mechanisms to link myriad data sets, including, in time, the electronic patient record, to facilitate research. In today’s world of research there is much to be gained by linking numerous data and tissue collections. In reality, much data will enter such a system without being consented in any meaningful way.

Anonymisation is possible within such a system, but to link the different sets, someone needs to be able to return the data and samples to a non-anonymised form, even if only

⁵ ScHARR: *Public attitudes to participating in UK Biobank*, p. 113.

temporarily. The idea that ‘Trusted Third Parties’, collected together as a formal or quasi-Government agency, should handle the necessary anonymisation and de-anonymisation required carries with it the obvious message that such parties are more trustworthy than researchers.

During debate on the Human Tissue Bill, Lord Winston made the pointed observation that: ‘People are more worried about political statements and about those scientists who advise government. There is a deep mistrust of politicians rather than a mistrust of the medical profession. As every review reports, scientists and doctors are much more trusted than politicians. Noble Lords ought to bear that in mind when we consider these matters and seek to put them in some kind of focus.’⁶ It would be interesting to know what the public would make of what would amount to a Government run, centralised system of non-consented anonymisation and de-anonymisation of tissue and data collections, if this were to emerge, in contrast to a system in which professionals shared data confidentially on a decentralised basis. In what must be the acknowledged to be a highly self-selecting group, we found that when it was put like this, all (approximately 30) participants at a workshop at the Genetic Interest Group’s 2004 AGM preferred confidential exchange of information between professionals to the suggested alternative.

In summary, the idea that individuals, even knowledgeable ones, have the background information, time or inclination to give detailed consent to the range of possible future uses of their information is widely recognised to be seriously flawed. And yet, as an ideal or an aspiration (with some, unclear, legal aspects), it is also widely upheld. The role of RECs in relation to anonymised data, or the proposed role of representative research participants when a general consent has been sought and given can be seen as a response to the gap between rhetoric or aspiration and reality. But existing regulatory frameworks and proposals are also premised upon something else: a lack of trust, or a perceived general loss of trust, in clinicians and researchers, who in the past had greater latitude to use their own judgement to fill the inevitable gap between public and specialist knowledge and interest. This constellation of legal, sociological and political factors underpins contemporary confusion and dissatisfaction.

The Genetic Interest Group believes that researchers should gain consent wherever this is possible and that it is quite legitimate and in some cases desirable for this to be general and open-ended. People do value privacy and where consent has not been gained steps should be taken to safeguard it. However, people also value research and the gains that this brings, even if they do not always link the two directly. If it can be shown that the confidential sharing between professionals of identifiable or nearly identifiable patient data, sometimes without consent, is necessary or highly desirable, we believe that most people would understand and support this. Perhaps the priority should be to make this case afresh.

⁶ *Lords Hansard*, 22 July 2004, column 385.

If the Academy would like us to expand on any of the above points, we would be more than happy to do so.