Problems facing biobanks

by **Pierre Mallia** *MD MPhil PhD MRCP FRCGP*
Bioethics Research Programme
Medical School, University of Malta

Biobanks – collection of samples for genetic research – are the future of research into linking genetic-related diseases, especially those of a non-Darwinian mode of inheritance, to their epigenetic environment.

Pharmacogenetics is also the 'Newfoundland' where information will considerably help with the choice of pharmaceuticals individualized for patients. For this kind of research large quantities of samples from populations are needed together with a detailed amount of data from the person. The data is kept by a controller who will then give the samples (anonymised) to those carrying out research. Since this is a relatively new mode of research and the person making the donation of the sample, or acknowledging that a sample may be used for scientific research, does not know for what kind of research the sample is to be used, this has made this area problematic.

Many documents however have considered this problem and there are ongoing projects, even at EU level, to make further recommendations. Mainly the areas of concern are how one should obtain consent to use such samples, and secondly how one can use such samples in the best interests of patients and indeed give something back to the donor if it is found relevant to his or her health. The problem lies within the fact that many biobanks accept donations only from patients who would agree that they are not given any information derived from their sample. The reason is indeed to protect the patient from any abuse from insurances or employers, who may make use of genetic information. Whilst insurances do want to assess risk, it would be unfair to use genetic information of subjects if such subjects have altruistically consented to a sample to be used for research purposes, whilst the rest of the population does not reveal (because it does not know) this information.

Laws which protect patients from insurances, such as in the United States, have largely failed because the latter are allowed to ask patients to waiver this protection right. Conversely countries like Canada, where insurance provision is on a national level, genetic tests do not matter because insurances do not analyse risk on an individual level but make a national risk assessment.

When it comes to obtaining consent, a broad consent is necessary. This still involves the usual provisions for obtaining informed consent: information, understanding why the sample is being taken, a voluntary choice, competence, and of course a consent process. Indeed however a more detailed process carried out by a competent individual is necessary to explain what genetic testing does; it has been shown that people do have a general idea of what genetics is, but when it comes to research they will usually wish to know that their sample will be used for legitimate purposes and that it would not be used to label any particular group or for purposes to which they may have a moral objection – such as pharmacogenetics on contraception, to mention but an example.

... many biobanks accept donations only from patients who would agree that they are not given any information derived from their sample

The Biobanks Ethics and Guidance Council is an 'oversight body' in the UK which sees that biobanks use their samples and data appropriately and that researchers are transparent, accountable and consistent in their practices. However one major area of concern, which varies from legislation to legislation, and which therefore should be explained to patients before obtaining the sample, is the definition of what constitutes *data*. Some would say that *data* is simply obtained from the sample, but is not the sample itself. What if the patient requests that his or her *data* be destroyed, thus opting out of the biobank system? – a right which is always given. Clearly we have to explain to patients their rights and inform them correctly that if they want to opt out they may also have to request that the sample be destroyed. Furthermore it does not resolve the question of destruction of *information*. Legislations so far have not seen this coming, unfortunately.

There have been instances where data controllers have handed samples to research companies, who have then used them for further tests, either not going to patients for consent, or requesting consent themselves. This leaves the data controllers out of control and usually they do not have the money or the time to pursue such issues legally. Certainly such occurrences can harm science in the long run by losing public trust.

Finally one has to consider how information can be given back to people without putting them in danger of discrimination. It has been argued that much of the research is still at a stage where it is really not relevant to individual health. Conversely, when information does become relevant, even if someone has signed a consent form, protecting him from information, he should be given enough guidance on how to seek information if he wants to. Publishing an article in a peer reviewed journal is not convenient and certainly does not make information accessible 'publicly'. The answer lies in explaining to people which sites and public media to search.

On the other hand, some people will only donate samples if they are given the right to know about anything which is relevant to their health. We are still in the early stages of biobanking and in the UK a biobank would simply not take the sample unless the person consents to the limits discussed. What may be necessary is for people to be allowed *not* to give genetic information to potential employers and insurances, and not be guilty of fraudulent behaviour in the process. These legal implications are being studied in the EU FP6 PRIVILEGED project, which is an extended project on the EU directive on data protection with particular relevance to genetic information. At the end of the day we want to protect the trust that people have in science!