Medical ethicists: biobanks need harmonization rather than new laws

There are statutory European provisions on biobanks that regulate biobank research in Europe to a certain extent. Christian Lenk, managing director of the Ethics Commission at Ulm University, calls for the harmonization of existing European regulations rather than the creation of new laws.

Christian Lenk has been involved with biobanks for quite some time: he was coordinator of the EU project PropEur from 2004 to 2007 (Property Regulation in European Science, Ethics and Law), which dealt with property regulation in European science, including the property regulation of human body substances. From 2008 to 2011, he also coordinated the EU project Tiss.EU, which dealt with the ethical and legal challenges of human tissue and biobank research.

Recommendations with a standardizing effect

Lenk believes that biobank debates tend to revolve around their use for research, and points out that many issues concerning biobanks have become normal practice. He also believes that ethical assessment and research could be made easier through supranational harmonization. One thing he is sure of is that patients and volunteers could be protected against the misuse of their samples and data if expert associations were able to come up with recommendations with a standardizing effect. Such recommendations would, he believes, prevent unnecessary work.

Biobank-based research is not carried out in a legal vacuum, and this is particularly true for a Europe that is seeking to develop a common research area. As is often the case with European interests, the devil is in the details. The 27 EU member states have all enforced some aspects of the European Data Protection Regulation. Whilst this regulation facilitates human tissue and biobank research, a European solution that enhances international privacy enforcement in a cooperative fashion in the field of health is yet to be found, which is why most countries regulate issues of patient information through the application of national data protection laws.

The Declaration of Helsinki is a statement of ethical principles for medical research involving humans issued by the World Medical Association (WMA). It provides suggestions on how research involving human individuals should be carried out. There are also national and international guidelines, directives, standards and laws relating to medical research involving humans.
Change in the use of human tissue samples
Lenk notes that the legal position regarding the use of human tissue samples has recently changed in many countries. Previously, researchers would continue to use a patient’s tissue samples even after he or she had left the hospital. There has since been general agreement that patients need to be informed about the purposes for which their samples and associated data are used and give their informed consent, and that the way human tissue is handled is to be accurately documented, especially as far as genetic analyses are concerned.

The debate relating to biobank research has only become a broader public debate in the last five years: the Office of Technology Assessment at the German Bundestag published its biobank report in 2007; the German Ethics Council published its Opinion on biobanking in 2010 when it called for stricter regulations; in March 2012, the majority coalition in the German Bundestag voted against special biobank regulations that called for biobank secrecy. Medical ethicists like Christian Lenk along with many others are convinced that the debate will flare up again as part of the discussions revolving around amendments to the Gene Diagnostics Law, which was highly criticized due to its failure to take into account research aspects.

Lenk attaches great importance to the responsible use of sensitive genetic data and points out that the situation is no longer the same as it was in recent years. As far as gene diagnostics is concerned, a visit to a human genetics institute would previously involve genetic testing for a single gene defect and an assessment of the potential familial risk of disease. Nowadays, biobanks are excellent resources for a huge variety of tests, for investigating numerous genes and in future, very probably for investigating the entire genome. Lenk regards this as a “huge change, as, under normal circumstances, we know nothing about a person’s genetics”. If such research is to become standard, the option not to know one’s genetics can actually have the opposite effect.

**German government to launch biobank initiatives**

The German debate on biobanks has not yet reached the stage of discussing the meaning of biobanks: do they really make sense and is it worth merging national and international biobanks, especially with regard to scarce resources? Christian Lenk, who receives between 30 to 35 ethics commission applications per month, is experiencing an increasing focus on human tissue research. “It seems that there is a kind of consensus that research involving human tissue is common practice.”

Great Britain has invested large sums of money in the establishment of its huge UK Biobank, which was heavily criticized by those who saw little or no benefit in biobanks. In Germany, the crucial question relating to the meaning of biobanks has not yet been asked. This could be due to the fact that the German government is tentatively approaching the topic through a kind of suck it and see process, as Christian Lenk calls it. The German way of doing things in this case is to fund many individual projects (as part of the medical competence networks) which will become part of a national biobank registry, rather than funding beacon projects. The German government has launched the National Biobank Initiative, but is proceeding rather cautiously. Funding is initially being provided to five centres for a period for several years.

**Biobank secrecy is not very helpful**
Christian Lenk is not a great fan of national attempts to go solo on the issue of biobank secrecy. He is well aware of the key arguments for biobank secrecy: to prevent law enforcement authorities, employers, the insurance industry and inquisitive people from obtaining access to highly sensitive medical data. However, under the rule of law judges dealing with serious crime can overrule such regulations. This happened after the Swedish Foreign Minister Anna Lindh was murdered and police tracked down her murderer on the basis of a DNA sample and data stored in the country’s national biobank, which is not anonymous. On the other hand, the EU can also intervene in particular cases such as the following: the police force in Britain had planned to collect DNA samples and associated information of children and adolescents and screen these data whenever a crime was committed. The European Court of Human Rights intervened and ruled that the British practice of keeping innocent people’s DNA records was a violation of the right to respect for private and family life.

Essentially, the ongoing ethical and legal assessment of biobanks is mainly focused on the question as to whether biobank-based research needs additional regulations, and if so, how strict do such regulations need to be. Lenk believes that providing patients with appropriate information must take a more central role. Patients and volunteers need to be provided with clear information so that they understand what happens to the samples they have donated and what researchers are planning to do with them. The majority of patients usually agree to their samples being used for research purposes at public research institutes. Not all patients and volunteers are equally likely to agree to the use of their samples in commercial projects where public institutions work alongside private companies. “We need to inform patients how their samples and data will be used, and also make them aware that they can withdraw their permission at any time,” Lenk said.

Patients must be given comprehensive information

“...The Ethics Commission at Ulm University quite often needs to intervene when it comes to providing information to patients,” Lenk said. Like other research institutions, the Ethics Commission provides advice first and foremost, it has no control over researchers. Even though medical ethicists (Medical Ethics Commissions Working Group, www.ak-med-ethik-komm.de/index.html) agree on many things, opinions differ with regard to the disclosure of incidental research findings, for example. Some medical ethicists support the necessity to inform patients when a clear finding comes up whereas others favour the alternative option, i.e. that patients themselves should be able to choose between wanting and not wanting to know.

The Ethics Commission gives its approval to research proposals when the documents supplied indicate that procedures that minimize the risk for patients and volunteers have been followed, that they provide information on the experiments that have been carried out and on how the patients and volunteers are informed.

Lenk believes that the best way to protect personal data is not to publish them on the net at all. As data that are associated with biological samples are pseudonimized and anonymized when exchanged and archived separately from samples, the protection of data is actually at greater risk when personnel at an institution that operates a biobank gain unauthorized access to the data. Biobank staff have a duty to protect the personal data of the donor against unauthorized use and are imposed strict confidentiality. Lenk believes that particular sensitivity and accurate patient information is required for genetic analyses; this also applies to certain patient groups, HIV sufferers for example.
The facts of the matter are both straightforward and glaringly obvious: researchers want as much freedom as possible; institutions, states and the ethics commissions are interested in regulating biobank research as best they can and with the highest possible quality, said Christian Lenk talking about the different interests. Ethics commissions do not want patient material to be assigned to a particular researcher and potentially facilitate his or her career. Instead they prefer the material to be assigned to a particular institution. The ethics commissions also have to decide whether old collections should be integrated into new research and what researchers have to comply with in order for data to continue to be used in accordance with ethical and legal aspects in the future.

**EU guidelines – great differences in how they are implemented**

Lenk’s examples show that there is a major need to harmonize European biobank regulations. In a centralized country like France, all biobanks need to be officially registered and have to abide by a plethora of regulations. In Germany, biobanks are not subject to authorization, whereas studies are. Authorization of this kind is issued by ethics commissions and funding institutions. Sweden and Spain have put in place discrete laws on biobanking; in France and Portugal, biobank research is subject to general provisions on public health. Great Britain and Estonia have established ethical guidelines for the operation of national biobank projects.

Germany does not have a research law, but regulates some issues related to the use of human material through the German Drug Law and the Medical Devices Law. Switzerland has a research law, which benefits surgeons, for example, who are interested in knowing whether a certain surgical procedure is more successful than a previous one.

As coordinator of the Tiss.Eu project, Christian Lenk has obtained valuable insights into the country-specific management of biobanks in the different EU member states. He found that Scandinavian countries deal with research in a similar way to German-speaking countries. The European Data Protection Directive appeared to be beneficial to all and although its high standards have not been adopted by all countries, it nevertheless guarantees basic regulation. Lenk identified similarities with the 2007 European Council Bioethics Convention. With a few exceptions, the convention has brought a number of benefits for patients, summarized Lenk.

**Comparable standards are important**

Lenk knows from his own experience that the exchange of biological samples is currently subject to huge changes. Less developed regions in Europe are carrying out advanced research; however, many national regulations impede such research. In principle, the exchange of biological samples is not a problem in Europe. This is why Lenk calls for comparable standards. Lenk believes that things would become easier if some biobank essentials such as informing patients, the legal status of withdrawn tissue (they became an object that is regarded as a person’s property) and already existing European recommendations were to be harmonized.

Whether politicians will follow Lenk’s recommendations is extremely uncertain, as is the outcome of the highly ambitious plan of the European BBMRI aimed at integrating all European biobanks. Lenk is somewhat skeptical about the possibilities of implementing the BBMRI’s plan, and about whether it is technically feasible, sensible and viable. It is still too early to make any prognoses; the only thing that is clear is that biobanks are being used more and more in biomedical research.
References:

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