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Biobanks – treasure chests for biomedical research

Biobanking is still a very specialist subject. The Research Committee at the German Bundestag, the Office of Technology Assessment at the German Bundestag and the German Ethics Council are all interested in this biomedical research tool, which is both necessary and meaningful. However, opinions with regard to the ethical, legal and technical approach to biobanks differ. Since March 2012 it has become absolutely clear that Germany will not pass a biobanking law during the current mandate. Discussions are still ongoing and debate is likely to occur on a much broader basis as biobanks increasingly network on a national and international level.

The term biobank is relatively new; it is more a generic term for collections of biomaterials, although it usually refers to scientific biorepositories that collect human bodily material for use in biomedical research. However, the term biobank also relates to biorepositories that store biogenic samples from the field of sports, food, environment and species conservation.

A real biobank stores samples as well as data derived from samples

A biobank that stores tissues, cells, blood plasma or genetic material can only be called a biobank if samples stored are linked to personal data (familial, sociodemographic, genetic, medical) about the donors of the material.

It is quite difficult to objectively define the collections of samples of human bodily material and associated data. The discussion pertaining to a potential biobanking law has shown that collections can differ widely in size, duration of storage and aims. A biobank can be a collection of a very small number of samples that are part of a doctoral thesis and it can also be a huge collection with hundreds of thousand of samples and data. The number of samples stored is only a partial way of defining the nature of databanks, as small biobanks can easily merge with other small biobanks to form a larger one. According to the Swedish Biobank Act, the size of a sample collection has no significance; a single human sample and the related data set could be defined as a biobank.

In Germany, as things currently stand, in order for a biobank to be classified as such the three following criteria need to be met: the biobank contains genetic material originating from humans; its samples are electronically linked to personal data and further information, particularly relating to health; its samples and data are collected, preserved or used for purposes of scientific research.

Biomaterial banks can be differentiated according to their structural organization, but not according to content-related criteria (every biobank is "specific", TAB 2007, p. 38), which makes standardization and quality control somewhat difficult. From the research viewpoint, biobanks can be roughly grouped into two types – population-related and disease-oriented material and data collections. Population biobanks store biomaterial and epidemiological data (e.g. lifestyle, clinical and environmental data); they usually relate to a specific population, region or country. Disease-related biomaterial banks, such as those established by medical competence centres, are focused on samples and data, and always relate to a specific disease. This does not mean that only samples from sick people or only clinical data are collected; the transitions between the two types are fluid.

Research databanks are still the dominant type of biobank

The majority of currently existing biobanks are research biobanks used by researchers who have set them up for use in own research or which store samples that are provided to other researchers for research purposes. In addition to these databanks, there are biobanks containing material that is used for diagnostic and therapeutic purposes. Classic examples of these types of biobanks are pathology departments, blood donor services and umbilical cord blood banks, which are both commercial and non-commercial such as those in Freiburg and Mannheim (Deutsche Stammzellspenderdatei Nabelschnurblut; German National Registry of Umbilical Cord Blood Stem Cell Donors).

The biobank of the non-profit blood donor service of the Bavarian Red Cross (www.biobank.de) has a special status. With around 3 million plasma samples, it is one of the largest collections in the world. Since 2006, the biobank has been available

for collaborative research projects and strategic alliances aimed at developing tools for the prevention, diagnosis and therapy of diseases. The Bavarian m4 Biobank Alliance could well have a key role to play in the further development of biobanks in Germany. The alliance was established in 2010 with the support of leading-edge cluster funding from the Federal Ministry of Education and Research (BMBF) and the aim of developing a joint biobank network between greater Munich's university hospitals and scientific institutes.

In addition to the aforementioned, biotech and pharmaceutical companies have maintained commercial biobanks relating to in vitro fertilization, stem cell databanks or cell line libraries for quite some time. Moreover, many German hospitals offer people the possibility to donate umbilical cord blood samples to the German Bone Marrow Donor Centre (DKMS).

"Indispensable resource for medical research"

There is general agreement – not just amongst researchers involved in biobanking – about the key and growing importance of biobanks for biomedical research. In a press release published on 1st April 2012, the German Research Foundation (DFG) concluded: "Biomaterial banks are an indispensable resource for biomedical research. They play a hugely important role in the quality and competitiveness of German research." Biobanking also has a huge commercial potential as far as its future application in the field of medicine and biotechnology is concerned.

Biobanks are valuable scientific tools because they make it possible to associate information obtained from the scientific examination of stored samples with data related to the clinical course of diseases. This continues to be possible many years after the samples were first stored as they remain viable for a long time when frozen. In the meantime, new more sophisticated methods and approaches may have become available, and could lead to new insights. Therefore, biobanks are regarded as sources of material for research into the causes of diseases and their progression. In addition, many researchers believe that biobanks make a considerable contribution to the development of new diagnostic procedures and therapies.

Biobanks are an interface between society and science; different rights and requirements come together which leads to tensions between scientific use and access expectations on the one hand and the protection of personal rights on the other.

New quality in the 21st century

Biobanks are nothing new. For many centuries natural scientists and doctors have collected samples from patients and healthy volunteers for scientific purposes. However, human biomaterial banks have become even more important in the 21st century thanks to molecular research methods which enable the identification of the causes and progression of diseases on a molecular level and the development of new therapies. Biomedical researchers in hospitals, research institutes, pharmaceutical and biotech companies or other institutions want to make use of this treasure in the long term, at different sites and for finding answers to different questions.

Both the number of biobanks and the information they contain are continuously growing; researchers around the world collect not only clinical, biological and sociodemographic data, but also lifestyle data (in particular with regard to research into diseases of civilization). The progressive and cross-border networking of biobanks opens up new search options for the scientific community at the same time as counteracting the decentralized storage of data. Biobanks become a very useful tool for researchers who need to screen huge amounts of data and different populations.

There is a growing trend towards private biobanks. The majority of existing biobanks are operated by public agencies, but a growing number of private and commercial biobanks are offering genetic services (e.g. examinations for predispositions to illnesses or genetic drug intolerances) and genome sequencing or they are establishing new research biobanks in order to tap into new fields of business. The possibilities offered by the analysis of genes and gene products and the enormous progress made in the field of cell biology provide an inexhaustible and growing source of information. In addition, the terms biomarkers and personalized medicine are frequently mentioned in connection with biobanks.

Biobanking becomes more international

The number of known biobanks and connected activities is increasing nationally and internationally. Although biobank registers which reliably document the quantitative development of biobanks are at present only just in the process of being set up, the number of references to human biobanks in specialized literature is growing rapidly, thus indicating strong expansion. Individual biobanks are being established for a large number of research projects which deal with the identification of genetic risk factors or issues involving genetic epidemiology. A prominent example of such recent developments is the Helmholtz Cohort, a large-scale population study designed to research common chronic illnesses such as diabetes, cancer, cardiovascular diseases and dementia and will contain samples from 200,000 individuals.

With this cohort, German biobanking efforts are now on the same scale as national biobanks that have been in development for some time in Great Britain, Norway, Sweden and other countries. The UK Biobank ((https://www.gesundheitsindustrie-bw.dewww.ukbiobank.ac.uk/) is designed to cover 500,000 people aged between 40 and 69 (over 450,000 people were

recruited between 2006 and 2010) from across Britain to provide blood, urine and saliva samples as well as medical and lifestyle information about themselves. The biobank was made available to biomedical researchers in March 2012. All researchers carrying out health-related research that is in the public interest who publish and enter their results in the UK Biobank are eligible to use the resource. The Norwegian biobank Biohealth Norway will comprise biological samples and standardized health and exposure data from 500,000 Norwegian individuals of all ages. The Swedish national biobank programme already contains between 50 and 100 million samples; this figure increases by 3-4 million samples every year. The website of the Swedish National Biobank Programme is the first in the EU to provide a list of all European biobanks grouped according to human (clinical and population-related) and non-human (from mouse mutants to viral pathogens) resources. It also presents 332 biobanks in greater detail and a list of 145 biobanks (https://www.gesundheitsindustrie-bw.dewww.bbmri.se/en/BBMRI-biobank-catalogue/, figures correct as of 24.05.2012).

Federal Germany follows the centralization trend

The German Federal Ministry of Education and Research (BMBF) also promotes the establishment of a sustainable German biobank infrastructure. The National Biobank Initiative supports five existing German biomaterial banks, including the BioMaterialBank in Heidelberg, with funds totaling around 18 million euros aimed at bringing together the individual collections at a single location. The BMBF hopes that the concentration and technical standardization of German biobanking activities, which many experts regard as the major hurdle on the path to establishing a sustainable biobank infrastructure. The five existing biobanks will be integrated into a centralized German biobank and in the long term will also be integrated into the planned EU biobanking infrastructure (BBMRI: Biobanking and Biomolecular Resources Research Infrastructure, www.bbmri.eu).

The BMBF-funded German Biobank Registry (www.biobanken.de) provides an overview of the medical biobanks in Germany, boosts the international visibility of German biobanks and specifically facilitates the exchange of information and promotes transparency and trust in research where human samples are used. The registry currently lists 106 biomaterial banks, including 15 from Baden-Württemberg (as of 30th May 2012).

Challenges and problems

Institutional bodies have been dealing with human biomaterial banks for around ten years. Throughout this time opinions have continued to differ as to whether this type of data retention requires new legislation to protect patients and volunteers against the misuse of data or whether current legislation is sufficient. There are currently no specific statutory provisions for biobanks in Germany.

The decision to keep the status quo was made in March 2012 when the majority coalition in the German Bundestag voted out the opposition's proposal as a move to prevent the envisaged red tape and the disadvantages that a change in the law would bring for research interests. In contrast to the Greens, the FDP do not consider it necessary to promote excessive regulation relating to the protection of individual rights of donors of biobank samples. The Greens had already expressed their concern over this issue in the debate about the German Genetic Diagnostics Law.

In 2010, the German Ethics Council found that specific legislation was necessary for biobanks and for biobank research. The Council's five-pillar concept is the following: the introduction of biobank secrecy, the definition of permissible use, the involvement of ethics commissions, quality assurance in connection with data protection and transparency of the aims and procedures of a biobank. The five pillars were set out to protect the interest of donors and their fundamental rights as well as to guarantee the protection of the freedom of science and research and the regulation of biobanks with regard to the definition of what is a biobank and what is not.

A public expert hearing on the Ethics Council's opinion in the German Bundestag in 2011 which is published on the council's website, came up with the following conclusion: academic and industrial researchers believe that the existing regulations, standards and laws are sufficient. Advocates of data protection, ethicists and lawyers call for stricter regulations. The research community regards the majority of the council's recommendations as the gold standard for their work, and considers that the recommendations are already sufficiently taken into account by national and international regulations.

Debates about biobanks are essentially a clash between the freedom of science and research and the protection of personal data, and fundamental and personality rights. Four major issues can be deduced from this: the different interpretation of purposes for which biobanks are used, the duration of use, anonymization and provision of information to donors.

Lack of technical standards and quality assurance

Binding technical standards and the quality assurance of frozen samples is still lacking. It is still unclear how an unbroken cold chain can be guaranteed over the long term, in particular in cases of insolvency and technology change in commercial biobanks.

Günther Fuhr from the Fraunhofer Institute of Biomedical Technology points out that fully automated cryotechnology procedures for temperatures below -80°C are still lacking. Fuhr also explains that the storage of viable samples requires temperatures of below -140°C in order to prevent them from being destroyed, something that is not yet widely recognised. In general it can be said that appropriate technologies and standardized strategies for the collection of human materials in biobanks are not yet available. However, this is an important prerequisite for the high-quality and long-term storage of human biomaterials and corresponding data sets.

Another problem that is just as urgent relates to sustainability. What happens when the (often public) funding of biobanks comes to an end? Many researchers complain that the funding of biobanks suffers from lack of coordination, thus preventing the establishment of sustainable infrastructures. A biobank with well characterized samples (which seems to be the exception rather than the rule) and data must be well designed, structured, standardized and be subject to quality assurance in order for users to be able to obtain valid and comparable findings, especially if a databank is integrated with others. The rapid establishment and integration of biobanks needs to go hand in hand with the professionalization of biobanking, a task that requires a lot of time, resources as well as harmonization on a national and international level.

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