Meeting the Current Challenges of Governing Biobanks Responsibly

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Personalized medicine, pharmacogenomics and public health genomics have the goal of improving the individual and collective state of health. Biobanks are commonly regarded as important tools for better understanding diseases and thus for achieving the so-called individualized medicine hoped for, such as public health genomics. By collecting samples systematically and in a way to ensure sustainability, ensuring their quality, and their respective personal data, we should be able to achieve a better understanding of the highly complex relation of genomic, intra- and extra-organismic environmental conditions, ways of living, and nutrition. Therefore, biobanks are very important both *de facto* and also in a symbolic way for achievements in biotechnology, medicine, pharmacology, and public health.

It is difficult to judge whether biobanks – designed to contribute to the development of pharmacogenomics, of the so-called personalized or tailored medicine or of public health genomics – can fulfill all expectations. The complexity of genomics and related ‘-omics’ sciences, which seems to be ever increasing, leads to the assumption that it would be an error of judgment to be overly optimistic about a too early application of the research findings for medical or public health practice, since that has not been the case for the sequencing of the human

genome. However, only the most skeptical person would see a reason for not promoting the research and the research funding in this area. If biobank research is to be successful, it is necessary to intensify it. Hence, only if research recruits a high number of cases and carries out an in-depth analysis the goals can be regarded seriously, according to the present state of knowledge. Corresponding with broad social agreement, it is self-evident that these goals – above all a successful fight against complex diseases and the development of personal and social intervention strategies – are ethically highly relevant. The internationalization of biobanking is an objective need: unless extensive and qualitatively close nets of biobanks and biobank networks are woven, it will be impossible to gain the data intensity necessary to meet the research goals. This is achieved in the medium and long run only by cooperating and exchanging data internationally. This purpose is served by the network Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), the Public Population Project in Genomics (P3G) and also supported by Public Health Genomics European Network (PHGEN) [1]. At the same time, it must be taken into account that new scientific questions and respective technologies of storage and analysis will arise which biobank infrastructures should consider for the collection

and analysis of samples and data. All of this emphasizes how highly dynamic and internationally interconnected the field of biobank infrastructure is and must be and must remain likewise in the long run.

Apart from the high complexity of the matter and the resulting necessity of internationalizing its processing, there is another important challenge when building and maintaining biobanks that operators of biobanks, funding organizations and regulating instances must be aware of. Whereas in other fields of research the public is often content with a solid policy of information and therefore adopts a rather passive position, biobanks rely on citizens as active partners in the research process: without voluntary study participants, there is no biobank research! Accordingly, parameters must be created that explain the facts of the matter to each group of subjects that consider the subjects' own perceptions, interests and possible contributions for establishing biobanks and, if any, take them into account in a dialogue (consequently, they do not consider the discourse between science and the public as a one-way street), and that, most of all, by doing so, generate sustainable confidence in research organizations and procedures. That includes addressing the open challenges of biobank research in an offensive way and searching for solutions beyond established models. Neither national nor international biobank enterprises, no matter if they are publicly or privately funded, will persist without these extensive efforts: 'Biobanks need publicity!' as Gaskell and Gottweis [2] demand programmatically in *Nature*.

If citizens are to trust biobanks, the worries and concerns of the respective population must be taken seriously. Particularly important clues are given by the latest Eurobarometer 'Europeans and Biotechnology in 2010. Winds of Change?' [3] and also by the Flash-Eurobarometer 'Data Protection' [4] of 2008. These show that, before being queried, 67% of all EU citizens had previously not heard anything about biobanks and that within the EU there is inconsistency when it comes to trusting institutions and privacy regimes. Furthermore, some populations are concerned or skeptical about high-risk research, whereas other populations show less concern. At the same time, those surveys show that the overall need for health information is high and that citizens increasingly demand information regarding their own health.

Given the current lack of broad knowledge of the pan-European population, one should be skeptical when far-reaching consequences are deduced. Nevertheless, the Eurobarometer data demonstrate potential for scandal concerning this research field, which many regard as extremely important. If biobank research is to establish a

global network, it must surmount attitudes of even deeper concern and greater skepticism than present in the countries amenable to research, and it must do so in such a way as to increase trust.

If lasting trust in biobanks is to be generated by publicity, the challenges of the research efforts must be made public. What are the challenges? Human biobanks (the existing ones and the large ones planned) are not limited by a single motivating research idea in time or in substance, and they can and should not be confined to a specific purpose. Many of them are or will be built in such a way that allows new research questions (or also new collection, storage, or evaluation of technologies), existing samples, and data to be reprocessed and linked to new samples and data; all this happens not just in one biobank, but also through interfaces with national, European and international partners farther afield. These deep and wide linkages will have enormous implications for traditional principles of privacy policy; what is questioned in the context of biobanks are at least the principles of economizing data (in matters of time and substance), of data confinement to one purpose and of informed consent. The necessity of reprocessing and reworking samples and data in this open research design of biobanks conflicts a priori with the gold standard of privacy: the anonymization of data sets.

One could say that data economy is not a matter of concern for biobanks because the general research hypothesis, which enables the development of larger and larger biobanks or at least of a more and more intensive and extensive exchange of data within a biobank network, consists of gaining significant insights into etiologies of diseases from as many data as possible and of developing precise therapies or public health strategies building on those. This idea does not agree with the principle of data economy (unless it was defined in relation to the extensive research idea so that speaking of economy would be impossible regarding absolute numbers). Furthermore, confinement to one purpose is traditionally seen concretely, which means that it does not have to be too precise, but at the same time it must not be too general. Formulating a very general purpose, such as 'contribution to cancer research,' would not demonstrate correspondence to the principle. In the case of such an openness or alteration of research questions in collections of samples and data over a longer term, which is not only taken into account, but also consciously desired, the classic understanding of informed consent no longer applies because the donor cannot be informed about how his or her samples will be used in 20–30 years. Not only may the

purpose of the research project change, but also the manner of data processing and the circle of institutions and persons that are granted access to the donor's personalized data. Therefore, traditional conditions of informed consent are subject to negotiation when it comes to biobanks. Consequently, biobanks mark a change of paradigms regarding the classic meaning of privacy. Trust can no longer be ensured only by protecting the individual privacy (informational privacy) and informed consent (decisional privacy), but it must also rely on structurally and organizationally created confidentiality and trustworthy, transparent and quality-assuring procedures (confidentiality) of the institutions involved.

The contributions of this special issue tackle these questions from different disciplinary and interdisciplinary perspectives. By the interaction of legal, ethical, political, social, and biotechnological scientific approaches in the various articles, breaches and gaps of regulation and application are identified; the scope of the interpretation of leading notions are questioned critically, patterns of the attitudes of the population are collected and inter-

preted, and the technical procedures in dealing with the requirements of research and legal and social expectations are presented. This selection of articles is exactly what is needed to help indicate the direction biobanks need to go in, not only that they gain the publicity necessary, but also that they generate trust in order to function as an essential tool for medicine and public health in the post-genomics era.

The contributions are based on the scientific discourse of a scientific workshop. This workshop was held in the context of the international and interdisciplinary research project 'Privacy Regimes Investigated: Variations, Adaptations, and Transformations in an Era of (Post-) Genomics' (www.private-gen.eu), funded by ELSA-GEN initiative (www.elsagen.at), in Nuremberg, Germany, from June 15–17, 2011. Sincere thanks to all the participants for their inspiring contributions and the ensuing discussions, to the editors of *Public Health Genomics* for the opportunity to compile this special issue and to the reviewers for their helpful comments.

References

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