

Nordic Biobank Research - Obstacles and Opportunities



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The Nordic countries have a long history of utilizing biological samples, patient records and health registries to study disease in the population and develop new forms of intervention, treatments and medications. The Nordic countries have advantages in epidemiological research combining biobank information with quality register and other environmental registries since we are able to use personal identification numbers, maintain systematic public health registries and have a long tradition for large-scale population based screening studies. Modern state-of-the-art biobanking requires large resources including sample sizes. An increasing number of the general population has donated samples for research which also includes phenotypic information, clinical data and analytic results. Resources for this type of infrastructure investments must be financed by governments since it is almost impossible to get these resources from usual research funders.

Biobanking, however, raises ethical questions on how to address integrity, privacy, access, legislation and protection. Using patient related information in research without consent is not uncommon although the first principle is informed consent. Large studies with thousands of participants, old material with a lot of dead donors and the process of re-contacting so many participants poses practical management and ethical challenges. Re-gaining informed consent can hamper the conclusions of a study because of excluded patients and the large loss of patients which will decrease the quality of the study.

Traditionally, the evaluation of requiring re-consent has meant that the rights of individuals (privacy and autonomy) have been weighed against the interests of research. Biobank research, however, generally answers questions about the collective as the goal to better understand the problems of populations. In other words, one could claim that biobank-based research also has collective goals and other ways to gain legitimacy than informed consent alone. One can therefore ask whether we need, in particular circumstances, a pluralistic set of equal values that can outweigh individual rights. This approach would

provide another perspective in the cost-benefit calculation giving the new public scientific knowledge a higher weight.

A common view in the Nordic Countries is that it should be desirable to be able to use all Nordic countries as a base for future studies. Broad consent has been discussed as a possibility in large studies without the need to go back to patients for re-consent later. This rests on a presumption that donors feel confident in the researcher and that privacy is ensured by excluding unauthorized persons from access.

Many donors are also interested in new knowledge that could bring new solutions or novel therapies to their own diseases, but donors are also interested in helping others. A consent that allows donors to agree or not to agree to participate is a necessary component of a study. The importance is to assert the individual's right not to participate, as well as the right to participate and to choose the scope of the participation, which could also include broad consent. The regulations in many European countries do not allow for this choice. Legislation in many countries, such as Sweden, do not allow participants to give broad and general consent for future research studies.

Trust between the doctor/researcher and the patient/donor is a prerequisite for biobank research in clinical research. This pinpoints the responsibility of the researcher to defend the donor's rights of privacy and autonomy. One way of handling trust is to engage the donors. They are crucial and necessary part of biobank research and should not be regarded as a passive party to be held outside, but must be involved in the search for new knowledge. Patient associations, interest groups in large cohort studies and active citizens should be invited more readily and formally linked to the project management. These donor groups could be engaged by altruistic reasons, as a duty or as an investment for the future. The broader focus on trust on patient's interest and expectations is necessary to sustain personal and institutional trust in the relation between the patient and health care services and scientific research. This implies more transparency both with regard to biobanks in

general and with regard to situations where tissue samples are collected in connection with patient care.

An increased awareness of researchers and research ethics committees of realistic benefits and potential security risks to the donor's utility is necessary in order not to create unreasonable expectations for biobank research. Ethics committees must be educated in this matter where the key issue is the rights of individuals served by an independent party (research ethics review board) to review the risk of the donor's autonomy.

Biobank law would benefit from being unified in involved countries. Different solutions in the various Nordic countries make research collaboration more difficult. Challenges for the future involve the increasing diversity of the nature of biobanks, the legal frameworks, as well as the growing international cooperation with exchange of material and data. The increasing quantity of associated data and limits to anonymization also raises question regarding confidentiality. It is of utmost importance to ensure appropriate levels of protection of fundamental rights while facilitating access by researchers.

Speakers:

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Presentations from the conference are available at the homepage for the Nordic Committee on Bioethics:

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