Commentary

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Study to Assess the Influence of Biobanks

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Description

A biobank is a type of biorepository that stores biological samples (usually human) for use in research. Biobanks have become an important resource in medical research, supporting many types of contemporary research like genomics and personalized medicine.

Biobanks

Biobanks can give researchers access to data representing a large number of people. Samples in biobanks and the data derived from those samples can often be used by multiple researchers for cross purpose research studies. For example, many diseases are associated with single-nucleotide polymorphisms. Genome-wide association studies using data from tens or hundreds of thousands of individuals can identify these genetic associations as potential disease biomarkers. Many researchers struggled to acquire sufficient samples prior to the advent of biobanks.

Biobanks have provoked questions on privacy, research ethics, and medical ethics. Viewpoints on what constitutes appropriate biobank ethics diverge. However, a consensus has been reached that operating biobanks without establishing carefully considered governing principles and policies could be detrimental to communities that participate in biobank programs.

The term "biobank" first appeared in the late 1990s and is a broad term that has evolved in recent years. One definition is "an organized collection of human biological material and associated information stored for one or more research purposes. Collections of plant, animal, microbe, and other nonhuman materials may also be described as biobanks but in some discussions the term is reserved for human specimens.

Biobanks usually incorporate cryogenic storage facilities for the samples. They may range in size from individual refrigerators to warehouses, and are maintained by institutions such as hospitals, universities, nonprofit organizations, and pharmaceutical companies.

Biobanks may be classified by purpose or design. Disease-oriented biobanks usually have a hospital affiliation through which they collect samples representing a variety of diseases, perhaps to look for biomarkers affiliated with disease. Population-based biobanks need no particular hospital affiliation because they take samples from large numbers of all kinds of people, perhaps to look for biomarkers for disease susceptibility in a general population.

Tissue Banks

Virtual biobanks integrate epidemiological cohorts into a common pool. Virtual biobanks allow for sample collection to meet national regulations. Tissue banks harvest and store human tissues for transplantation and research. As biobanks become more established, it is expected that tissue banks will merge with biobanks.

Population banks store biomaterial as well as associated characteristics such as lifestyle, clinical, and environmental data.

In 2008, United States researchers stored 270 million specimens in biobanks, and the rate of new sample collection was 20 million per year. These numbers represent a fundamental worldwide change in the nature of research between the time when such numbers of samples could not be used and the time when researchers began demanding them. Collectively, researchers began to progress beyond single-center research centers to a next-generation qualitatively different research infrastructure. Some of the challenges raised by the advent of biobanks are ethical, legal, and social issues pertaining to their existence, including the fairness of collecting donations from vulnerable populations, providing informed consent to donors, the logistics of data disclosure to participants, the right to ownership of intellectual property, and the privacy and security of donors who participate. Because of these new problems, researchers and policymakers began to require new systems of research governance.

By the late 1990s, scientists realized that although many diseases are caused at least in part by a genetic component, few diseases originate from a single defective gene; most genetic diseases are caused by multiple genetic factors on multiple genes. Because the strategy of looking only at single genes was ineffective for finding the genetic components of many diseases and because new technology made the cost of examining a single gene versus doing a genome-wide scan about the same, scientists began collecting much larger amounts of genetic information when any was to be collected at all. At the same

time technological advances also made it possible for wide sharing of information, so when data was collected, many scientists doing genetics work found that access to data from genome-wide scans collected for any one reason would actually be useful in many other types of genetic research. Whereas before data usually stayed in one laboratory, now scientists began to store large amounts of genetic data in single places for community use and sharing.

An immediate result of doing genome-wide scans and sharing data was the discovery of many single-nucleotide polymorphisms, with an early success being an improvement from the identification of about 10,000 of these with single-gene scanning and before biobanks versus 500,000 by 2007 after the genome-wide scanning practice had been in place for some years. A problem remained; this changing practice allowed the collection of genotype data, but it did not simultaneously come with a system to gather the related phenotype data. Whereas genotype data comes from a biological specimen like a blood sample, phenotype data has to come from examining a specimen donor with an interview, physical assessment, review of medical history, or some other process which could be difficult to arrange. Even when this data was available, there were ethical uncertainties about the extent to which and the ways in which patient rights could be preserved by connecting it to genotypic data. The institution of the biobank began to be developed to store genotypic data, associate it with phenotypic data, and make it more widely available to researchers who needed it.

Biobanks including genetic testing samples have historically been composed of a majority of samples from individuals from European ancestry. Diversification of biobank samples is needed and researchers should consider the factors effecting the underrepresented populations. Biobanks, like other DNA databases, must carefully store and document access to samples and donor information. The samples must be maintained reliably with minimal deterioration over time, and they must be protected from physical damage, both accidental and intentional. The registration of each sample entering and exiting the system is centrally stored, usually on a computer-based system that can be backed up frequently. The physical location of each sample is noted to allow the rapid location of specimens. Archival systems de-identify samples to respect the privacy of donors and allow blinding of researchers to analysis. The database, including clinical data, is kept separately with a secure method to link clinical information to tissue samples. Room temperature storage of samples is sometimes used, and was developed in response to perceived disadvantages of low-temperature storage, such as costs and potential for freezer failure.