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Commercialization of Biobanks

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Biobank policy and regulations profoundly vary between different societies. One area with profound differences in culture and tradition concerns commercialization, and the possibility of using the human body as a capital resource. In the United States there is acceptance of this possibility, whereas European law is based on principles that categorically prohibit selling parts of the human body. We suggest that questions of commercialization in the area of biobanking must be considered in relation to different ethical values, notably the principle of best possible use of collected biobank materials for the benefit of vital patient interests.

Introduction

When biological material is donated to a biobank, the biobank is expected to act as a responsible custodian and protect the material and the data, its storage, use, and access, following the regulations that are operative in the society in question. While there is wide agreement on some issues, for example, the need to adapt traditional informed consent to the specificity of biobanks, biobank regulations profoundly varies between different societies. One area with profound differences in culture and tradition concerns commercialization, and the possibility of using the human body as a capital resource. In the United States there is acceptance of this possibility,[1–3] whereas European law is based on principles that categorically prohibit selling parts of the human body. Operationally defining "commercialization" as the process of introducing a new product or production method into the market where the prices of goods and services are established, we suggest that questions of commercialization in the area of biobanking must be considered in relation to different ethical values, notably the principle of best possible use of collected biobank materials for the benefit of vital patient interests.

Current International Policies

It has been argued that U.S. legislation permits hospitals and research laboratories to "routinely sell their patients' tissue to biotechnology companies, often without the patients' consent".[2] In that framework, it is important to specify under what circumstances commercialization of the human body might be appropriate, and to elaborate adequate institutional policies to regulate this procedure. In contrast, The Council of Europe states in its Convention on Human Rights and Biomedicine, concerning Biomedical Research (1997: VII, Article 21): "The human body and its parts shall not, as such, give rise to financial gain." In that opposite framework, the question can be raised why commercialization of all biological materials must be wrong, but the question under what circumstances commercialization of the human body might be appropriate does not arise in practice, since no possible conditions are admitted. In the Universal Declaration on the Human Genome and Human Rights, United Nations Educational Scientific and Cultural Organization (1997, Article 4) adopts an equally categorical position: "The human genome in its natural state shall not give rise to financial gains." A biobank may own the material but cannot make financial gains from selling it, since the human body is not allowed to be a *direct* capital resource in that context.

This does not prevent the human body from being an *indirect* capital resource, giving rise to valuable and marketable knowledge and products. Commercial aspects of biobanks are actualized in Europe because knowledge gained from the sampled materials can yield considerable financial profits. While a biobank cannot make financial gains from selling biological material, it is allowed to make gains from data about this material.

In its Statement on Human Genomic Database, the Human Genome Organisation (HUGO) (2002, Rec 1, 6) states that: "Knowledge useful to human health belongs to humanity. Human genomic databases are a public resource. All humans should share in and have access to the benefits of databases." Researchers, institutions, and commercial entities are acknowledged to "have a right to a fair return for intellectual and financial contributions to databases," but "fees should not restrict the free flow of scientific information and equitable access."

According to the Council for International Organisations of Medical Sciences (CIOMS) (2008 (20)), analyses of biological material can lead to commercial products, but it needs to be made clear to the donor in the informed consent

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procedure "whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products."

European Society for Human Genetics (ESHG) (2003(27b-c)) opens the door to conditioned financial gains on behalf of the researcher: "intellectual property would be of the researcher but with due consideration for benefit sharing. While a property position may allow for actual or potential financial return, the gift relationship approach to research avoids individual returns but not the possibility of commercialization by the researcher, through traditional intellectual property rules."

The commercial aspects of biobanks are internationally recognized, and the need to take potential commercial uses of data into account. Efforts are made to elaborate policies for distribution of profits and benefits and for establishing guiding principles. This is, however, problematic, in part due to the complex nature of project financing (which can be public, private, or semi-private), but also due to the unclear and complex status of genetic material. There is general agreement in Europe on promoting availability of scientific results to the widest possible audience, facilitating access of samples and data for research purposes, and the need to elaborate benefit sharing policies. Opinions diverge concerning the conditions of access, for example, extending from public to commercial users, the rules for restricting access, and the involvement of private companies, for example, the pharmaceutical industry.

Ethical Implications of Commercialization

In the context of biobank research there are two distinct aspects of commercialization to consider, based on whether biological samples give rise to financial gain indirectly or directly. In the first case, samples are used for research to gain knowledge that is then sold. In the second case, access to samples, or even the samples themselves, are bought and sold.

Attitudes to the first kind of commercialization vary. On the one hand, commercial interests can increase willingness to invest money into a given area of research, which can greatly benefit health care and patient groups. On the other hand, they can also increase the reluctance to share the access to the research material, notably in the quest for patents, and thereby stifle research and life-saving innovations.[4] This could have dire consequences. For example, if research groups looking for an urgently needed vaccine refuse to share valuable data hoping to get a patent, the human costs could be considerable. Individual donors may also object to others profiting from using their samples. The presence of a patent could further conflict with public health, for example, block patients from receiving health care. Some hospitals or laboratories cannot pay the royalty fee to the owner of the patent and for economic reasons they are consequently forced to deny patients that particular test or treatment (for example, a hormone test to determine whether a fetus has Down syndrome[5]), even though it would have been medically appropriate to offer.[6] The issue of financial gains from selling research results is not specifically related to the biobank domain but concerns all commercial medical research.

With a finite number of samples, biobanks cannot give unlimited access to them but need to be selective. To make good use of the material, there must be conditions and rules for giving access to researchers. Different principles can guide this procedure, for example, the principle that biobank material should be put to the "best possible use" an aim that would then need to be specified. Researchers would gain access to a biobank in terms of the legitimacy of their aims and expected results. A question pertaining to commercialization in this context is whether it should be possible to purchase access. Selling research access could be a highly profitable practice that could increase the resources available to the biobank, but also one that could conflict with the aforementioned principle, since it is not necessarily the case that the financially strongest research groups have the aims of "best possible use." On the other hand, they may have them, and it would be possible to regulate so that access could be purchased, but only by those who prove to have the aims of "best possible use." The effects of commercialization on the principle of best possible use merits case-by-case investigation: it cannot offhand be excluded that the former could in some instances even strengthen the latter.

One should distinguish between directly selling access to biobank material and granting commercial access to human biological material through, for example, private-public cooperation. The second category is commonly used both for previously collected samples where commercial interests cofinance academic research and thereby get access to the samples, and when pharmaceutical companies pay clinical researchers for prospective collection of samples and data in association with clinical trials. These transfers of access can be motivated by patients' interests in the development of biomedical knowledge and new treatment opportunities. A principle of reciprocity should then be applied so that academic researchers may also use samples collected and stored by the companies.

From the patients' perspective it is essential that stored samples may be reused for other research projects, thus excluding policies based on exclusive rights of access. The principle of open access for the benefit of patient needs seems then to rule out the selling of the material itself as an option. However, a distinction could be drawn between different types of material. It could be argued that a commercial market, say in blood, where individuals could sell their blood to companies, may result in large new collections of samples being available for research. It is not obvious that such a practice would be obstructive to patient interests, although possible effects on, for instance, academic research would need to be considered. An objection to this argument is that sample-sales could introduce the idea that people have a right to be paid for their samples, reduce the willingness to donate, and thereby potentially obstruct patient interests.

People are often opposed to the idea of "commercialization" in the medical field without having a precise understanding of the term. The fact that public understanding of this term is vague can make strategies to deal with this issue more difficult. Whichever approach to commercialization a society adopts, appropriate handling of biological material and data is essential for maintenance of public trust, without which there would be few if any donors. This includes transparency of the policies elaborated. If science is to enjoy the confidence of the public, science policy must be open to public scrutiny and take into account the views of those whose lives it will affect. A person donates tissue in a

particular context and society, presumably trusting the regulations of that society to ensure appropriate handling of the material and the data derived within it. For commercialization of access not to diminish this trust, it must be made clear that it would not negatively affect these standards. For example, by opening the door to research previously considered unethical, or to blocking research that could be important for human health.

Conclusion

Financial interests motivate commercialization of biobank-based research. Other interests can also motivate it, for example, if such commercialization could lead to increasing knowledge and improved health care. These interests, while distinct, do not necessarily stand opposed: a society could regulate them not to. The question needs to be raised in the regulatory discussions of research biobanking whether or how donated biological material should be possible to commercialize, also in Europe. In that framework, it is important to specify under what circumstances commercialization of human tissue might be appropriate, and to elaborate adequate institutional policies to regulate this procedure. The procedures of commercialization can be constructive or destructive, ethical or unethical depending on how they are pursued and regulated. If the standards for appropriate use of material and data are respected, transparent policies adopted, public trust and willingness to donate maintained, benefit sharing policies developed, and wide biobank access remains promoted so that health care is not blocked nor innovative research stifled, then commercialization does not in itself appear to be a problem. It will be a problem if the urge for financial gains comes into conflict with the other values endorsed, notably that of making the best possible use of donated biological material from a global human perspective.

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