Information Rights on the Edge of Ignorance

Anne Maria Skrikerud

Abstract In this chapter I discuss whether there is such a thing as a right to information in biobank research. The concept of "information" is discussed and different theories about what it means to have the right to information are presented. The way in which the right to information may influence moral problems connected to epidemiological biobank research is also discussed.

Introduction

In the bioethical literature "information" is frequently imbued with a variety of meanings, partly because "information" is often discussed in the special context of a *right to information*. But what *right to information* means is not always clear in medical research.

In Norway, medical research is regulated by several acts and regulations, in particular the Personal Data Act and the Patients' Rights Act, which give patients the right of access to their medical records. In addition, international ethical guidelines, such as the Declaration of Helsinki, also regulate medical research. What awoke my interest here is the recurrent use of the concept of the "right" of donors or patients to either demand to know about all data that is catalogued or analysed in an identifiable or coded manner, to demand a copy of their medical records, or to be informed in an understandable way about medical procedures related to studies that are about to be conducted, before giving their voluntary consent (Norway, 1999, 2000, 2001, 2003; World Medical Association 2004).

Behind these ideas of informed consent and the right to be informed about all personal data that is filed somewhere, no matter what kind of data and where it is stored, it seems that a common idea of *a right to information* is lurking. My aim

A.M. Skrikerud
Section for Medical Ethics, Faculty of Medicine, University of Oslo, Oslo, Norway
e-mail: a.m.skrikerud@medisin.uio.no

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in this chapter is to scrutinize the concept "the right to information" in biomedical research and in particular in biobank research.

The Concepts of "Information" and "Data"

In my view, in order to understand the concept "right to information" it is important to understand the meaning of *information* and the difference between *information* and *data*. In fact, "information" and "data" are two quite similar concepts in medical research.

According to Bartha Knoppers, three groups of *data* are of interest in biomedical research. These are personal data, medical data, and genetic data. *Personal data* is a legal term, defined in the Norwegian Personal Data Act as "any information and assessment that may be linked to a natural person". *Personal data* can be any data that can be stored in a filing system, be it school grades or which DVD you rented last week. *Medical data* are identifiable or coded data that are health related in any way. *Genetic data* are identifiable or coded data on individuals' genes that are systematically analysed and filed.[1] However, these legal definitions of data do not necessarily correspond completely with the prevailing understanding in medicine.

Without being a legal or technical term in the same sense as "data" has turned out to be, "information", without claiming to be precise, covers all types of data. Information is a *vague* concept which means that its meanings differ from individual to individual and from context to context (Waismann 1946). But in general and for the most part we can say that in bioethics "information" encompasses facts of any kind that are communicated. Medical data that are filed in a computer that is turned off and never turned on again will still count as medical data. But at the moment Mr. Smith demands to be told the results of some medical test and a researcher tells him, medical data become *information*. Information can also be communicated facts in the informed consent context. In this context, the patient or donor has the right and duty to be informed about forthcoming procedures. The terms *information* and *data* are often confused and used interchangeably in everyday language.

The Concept of "Right"

When we say that somebody has the *right* to something, we usually mean that something is due to somebody. In saying this, I do not aim for an all-embracing analysis of the concept of "right", but will focus specifically on rights pertaining to biomedical research. So, if a research subject has the *right to information*, what does the word *right* mean in this context? Traditionally rights have been evaluated as either fundamental or derivative rights. Fundamental rights are rights that are given and

[1] I refer to a lecture held by Bartha Knoppers at the seminar "Ethical Challenges in gene-epidemiological research and health registry research", Oslo, August 20–21, 2004.

derivative rights are rights that follow from more fundamental rights. One can hardly claim that the *right to information* is a fundamental right, but if the right to information is a derivative right, it is not clear which right *the right to information* is a derivative of. It may be, and it has often been argued, that the right to information is a derivative of the right to privacy (McGleenan 1997; Allen 1997), while others have claimed that the right to information is a necessary derivative from the right to make autonomous decisions (Häyry and Takala 2001; Harris and Keywood 2001). The right to information does exist as a legal right since it is ensured by most western laws and the Declaration of Helsinki, but if the right is a necessary corollary to a fundamental moral right such as the right to make decisions on autonomous grounds, the right also has moral value.

I will consider two theories that may help to explain the importance of a *right to information* as given in international guidelines: rights theory and liberal utilitarianism. The theory that first and foremost justifies the use of "rights" as a moral value and a legal concept is, of course, rights theory, which has evolved since the end of the eighteenth century. This is a theory that has evolved under strong influence from legal jurisprudence and should be distinguished from human rights ethics (Almond 1991). Hohfeld and Sumner have argued that there is a connection between rights and obligations (Hohfeld 1917; Sumner 1987: 18–31), but only some rights are bound to a duty-concept. The following four categories are all possible understandings of the concept "rights" according to Sumner:

- *Claims:* A claim is a right that generates a corresponding duty by someone else
- *Powers:* Power is a right that provides someone with the possibility to affect the rights of others
- *Liberties:* Liberty is the right to act or refrain from acting. A liberty permits an action
- *Immunities:* Immunity is a right to be protected from the actions of others (Sumner 1987: 18–31; Almond 1991)

According to rights theory, the *right to information* is a claim for the subjects of medical research. Influenced by John Stuart Mill, liberal utilitarianism evaluates states of affairs according to what gives most utility. However, there is a set of values that cannot be sacrificed for any type of utility. Values that are especially important are the values of life, health and autonomy (Häyry 1994). Liberal utilitarianism in bioethics will often be interpreted with what gives most health to mankind without sacrificing the autonomy, health or life of third parties.

An example of a right to know that is equivalent to the right to information is given by Matti Häyry and Tuija Takala in their essay "Genetic Information, Rights and Autonomy". On the basis of the right to autonomy, they argue that if A has a right to know, this may mean at least three different things: "When A has no duty to remain ignorant" this is called a licence. "When others have a duty not to interfere with A's quest for information" this is called a negative claim-right. "When somebody has a positive duty to assist A in her quest for information" this is called

a positive claim-right (Häyry and Takala 2001). Usually the right to information in a biomedical context will mean a positive claim-right to information.

To decide whether information exchange according to the right to information has taken place, it is important to keep in mind that the subject that possesses the right must be able to fulfil it; in addition, there must be someone or some public service that has the *duty* to inform, and finally the information must be handed over (Almond 1991; Sumner 1987; Hohfeld 1917). Now if we use this definition in various situations where information exchange is taking place, we should be able to identify at least one right-holder and preferably one duty-holder. Since information is communication, the right demands someone that is obliged to inform, unless of course the information is of a kind that is publicly available. But if the information is not available and if no one has a duty to give information, the right turns into a right without a way of fulfilling it (Sumner 1987). Looking at some examples from biobank research, I will try to analyse the *right to information* in a biomedical research context.

The Right to Information in Research Biobanking

When a subject decides by request that he or she wants to be a donor in a research-biobank, the donor has to give his or her voluntary informed consent. The reason why we have informed consent is partly related to the idea of the right to be informed, since the informed consent form is about making an informed free choice. But the way it has developed in modern research ethics is that the donor is presented with an obligatory act. On request the donor uses his or her *power* to voluntarily decide whether to participate in the research or not. But before the blood test can be taken or the mouthwash given, the donor has to be informed about matters required by law and the Declaration of Helsinki, matters that might be of no interest whatsoever to the donor, e.g., whether the biobank has any conflicts of interest. Häyry's and Takala's interpretation will not leave room for a way to distinguish between this right and a right which the subject may opt for having fulfilled or not. So according to their liberal utilitarian view, this will be a *positive claim-right*. On the other hand, Sumner would call this a *mandatory right*; a right that has gone from the stage from being legally permitted to that of being legally prescribed. In this case the donor has the liberty to be informed without the liberty not to be informed: a so-called *half-liberty* (Sumner 1987).

The donor also has the right to be informed about any medical or genetic data about him or herself that are filed in a biobank. In addition, the donor has the right to be informed about these rights. These rights have legal status in all countries that have ratified the "Directive 95/46/EC of the European Parliament on the protection of individual with regard to the processing of personal data and on the free movement of such data", which says: "…any person must be able to exercise the right of access to data relating to him which are processed, in order to verify in particular

the data and the lawfulness of the processing…". "Processed" here means being filed in a systematic way. In several countries the laws that have been introduced to comply with this Directive have been formulated in a way that can be interpreted as if the donor has a claim to information, and that the researcher or the director of the department has the a duty to give information to the donor. The Norwegian Personal Data Act reads as follows: "Any person who so requests shall be informed of…the categories of data concerning the data subject that are being processed…" (Norway 2000).

A multinational biobank that opts for the storage of anonymous data has an informed consent form in which donors are asked to agree to the following statement: "I will not get the results of my DNA sent to me from this project".[2] Hence, from the start of a biobank project, the researchers argue for the possibility to withhold all genetic data if they want to. According to rights theory, the claim of the donors is turned into a *nullity*, because the researchers are ensured the *immunity* of the constraint of the duty by the ethical committee. Liberal utilitarianists would say that the *positive right* has turned into a *licence* (Sumner 1987; Häyry and Takala 2001). This example raises the question: Why do biobanks inform their donors that they will not receive any information about their DNA? There are several reasons for this. One reason is that in multinational epidemiological research data from an identifiable donor are not just located in one file in one computer but are used by researchers in several countries and in several studies. Thus, for practical or technical reasons the data may simply be inaccessible.

Another reason why biobanks do not want to report results of personal DNA analysis back to donors is illustrated by the Danish twin registry. In this case the researchers have to give back information about medical data but are not keen to do it and are concerned about the implications of giving the information. Their concern is on behalf of the research subjects because the researchers can only give research data that have not been medically verified to clinical standards, meaning that there is a statistical risk that the data may be wrong. Some of the research subjects will probably give the results to their general practitioner, where it will most probably end in the patients' medical notes without any caveat concerning the validity of the information. If these research subjects later apply for life insurance, in Denmark insurance companies can ask for permission to contact the general practitioner and read the patients' medical records. A lot of Danes automatically tick off yes to this question, but then information concerning some inheritable genetic disease, which has not been clinically validated, ends up in the hands of an insurance company.[3] The dilemmas faced by the researchers because of the duty of informing are so difficult that they are experienced as ethically deeply problematic.

[2] Translated from the Norwegian by the author.

[3] Reference to this example has been made by Kirsten Ohm-Kyvik during discussions at the seminar "Ethical challenges in gene-epidemiological research and health registry research", Oslo, 2004.

The Right Not to Be Informed

The right to be informed is a derivative of more fundamental human rights, but the right not to know is often claimed to be a derivative of the right to information. In 1947 the first case on the right not to be informed was ruled, *Breard v. City of Alexandria*. The case was a door seller who had delivered shop catalogues in Alexandria in the 1930s. He claimed his right to do so. The US Supreme court, however, upheld the right of the individual to be protected from unwanted information on the basis of the right to privacy. Since then the right to be informed and the right not to be informed have been considered as derivative rights from the right to privacy (McGleenan 1997). The right to privacy, which is a legal right, is said to protect the right to be left alone when another civilian's "freedom of speech threatens to disrupt one's liberty of thought and space" (McGleenan 1997). An interpretation which Sumner provides may also explain the right not to be informed. In his view, the subject may either have the *liberty to refrain from being informed* or the *claim to ignorance*. The latter generates a duty for others not to inform. The liberty to refrain from information is dependent on others not having the claim or possibility to inform. The claim to ignorance is dependent upon that there is no one other than those who have the *duty not to inform*, which have the *possibility to inform* (Sumner 1987).

That the right to ignorance can be argued on the basis of autonomy has been disputed since autonomy has to do with the possibility to choose and ignorance does not support a person's autonomy (Harris and Keywood 2001). However, Häyry and Takala have developed a Millean interpretation of the right to ignorance of genetic data based on a person's right to autonomy. I will use their conclusion in my analysis of the right not to be informed in the biobank setting. They argue that if B has the right not to know, this may mean three different things: "… [either] B has no duty to know….[or] Others have a duty not to inform B against his will….[or] Somebody has a positive duty to assist B in remaining in ignorance" (Häyry and Takala 2001).

When a researcher in a biobank wants to recruit donors, he usually gets the permission from the ethical committees to look in health registers or birth registers and by means of those registers to identify possible donors to match into the planned cohort. Often several members of a family are recruited. So when several members of a family are contacted in order to be recruited as donors for a particular research project, they may come to suspect that they have a special gene in their family. But maybe some family member does not want to know that the heart attack of her brother might also strike her. The right not to know has not been respected. According to Häyry's and Takala's interpretation, it is not certain that something wrong has happened. If the government has a duty to protect this woman against knowledge, their duty has not been discharged very well, since it is government bodies such as the ethical committee that has allowed the researchers to inform, and it is those in charge of the health registers who have allowed the researchers to look in the registers. But none of these public institutions know or can know that this woman does not want to be informed. The researchers are the ones that have force-fed this woman with information and by doing this not upheld their duty not to inform. They

have breached the woman's negative right not to be force-fed with information. But if these researchers were duty-holders to this woman and others like her, it would actually not be possible to conduct any research at all. If her right only is a right to herself, without having the force to impose a duty on somebody, no one on the other hand can be charged of having violated it.

According to Sumner, the woman will have the liberty to refrain from being informed. One can perhaps also say she has the claim not to be informed but it is difficult to point out who is the duty-holder, except for her general practitioner. The researcher is given permission by the ethical committee to inform and thus to override the liberty of the woman. The researcher has the right and liberty to send out information, and the liberty to inform appears to rule out the liberty to refrain from being informed.

Conclusions

The European Convention on Human Rights and Biomedicine states in Section 10.2 that "everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed". Sumner's rights theory seems to indicate that the right to information is of greater value because it is easier to decide who holds the duty *to* inform compared to who holds the duty *not to* inform. Even a claim-holder of the right not to be informed may easily come in contact with somebody who is well informed about the medical data, but who cannot plausibly be said to be under a duty *not to* inform. If this claim not to be informed is to have real meaning, one has to be sure that all people to whom the information is available are duty-holders to that specific person. This poses an ethical challenge on biobanks as to how to handle information about donors.

However, for it to have any effect the right to information is also dependent on at least one duty-holder. For example I might have the right to be informed about where Atlantis is, but I will never find anyone with the duty to tell me. So if the duty-holder is the same as the one who is in charge of the medical data in the biobanks, I have the right to information and I may have this right fulfilled. But if the one in charge of the medical data is immune against the duty to tell me, as in the case with the anonymous biobank, I may claim my right as much as I want. However, whether I get the information that I have asked for will depend on the goodwill of the holder of the information.

Those who have the power to influence the claims of others are often the ethical committees. They may find studies acceptable or unacceptable and they are aware of the conditions of the different studies. The researchers are given the duty and the right to protect the value of medical research in society. In some circumstances this will override the individual rights of the donors.

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