An ethics committee for medical research in Greenland: history and challenges

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ABSTRACT
Ethical appraisal of medical protocols for research is now well accepted, and needed when research may carry side effects and risks that may be difficult to understand for the people invited to take part in research. We argue that time has come for Greenland to establish a formal medical research ethics committee with a legal basis. With proper use of modern means of communication it should be possible to run a committee at a reasonable cost. We believe that such a committee should closely follow international standards. One urgent matter to get under a formal set of rules is to set proper standards for storage of biological samples taken from people in Greenland.

Keywords: Medical research ethics committee, ethical appraisal, Greenland, biobanks

Greenland offers several medical research opportunities related to genetic and environmental conditions in the country. The Inuit have their own genetic history, the country has been rather isolated for many years, and travelling within Greenland is still more expensive than in most other parts of the world. The environment, food intake and social conditions provide pertinent research options not found in many other places. On the other hand, health research is also needed for the sake of the people of Greenland. Rational health care in Greenland cannot rely entirely upon research done outside the country. Health services research and research related to implementing health promotion and disease prevention programmes must be based upon studies performed in Greenland.

A medical research ethics committee has never had a legal basis in Greenland, but since 1993 the commission for scientific research in Greenland (KVUG) has performed ethical reviews of medical research, and there is consensus among leading health professionals in Greenland to accept committee decisions. A law on a medical research ethics committee in Greenland was approved by the Danish parliament in 2001, but it was never implemented in Greenland due to lack of funds.

Although it is now well accepted that research protocols must be approved by medical research ethics committees, at least for studies that may involve risk to the participants, these committees must also respect certain conditions, such as:

Free research is an important part of a democracy. Researchers should have free access to critically evaluate the health consequences of political, medical and other decisions that may interfere with the health of the population. Research should be done independently of these interests. Committee decisions must therefore also be made independently of political, financial or personal interests.
As a starting point, it is usually not unethical to do research, but it is often unethical not to do research. Severe side effects of drugs are often detected far too late because proper research activities have not been implemented in time (e.g. Thalidomide). Many environmental pollutants have been discovered far too late (e.g. asbestos). Unnecessary, or even dangerous, medical products have been maintained for far too long because of a lack of research (e.g. Bonelock).

As a general rule, people have the right to know how they can best avoid unwanted health hazards. In order for this information to be available, research is needed.

A medical research ethics committee is an upfront censoring committee that, in most countries, has the mandate to stop research, including research that could have provided important results for many people. The committee also has the power to state conditions that may cause severe bias and thus lead to wrong conclusions that could have severe health consequences. In one of the most important data sources for detecting teratogenic effects of drugs, the ethics committee refused to accept that a reminder was sent to controls leading to low participation rates among controls. The committee should be aware of their responsibility to accept standard quality criteria for research. It should be fair in its judgement, and it should restrict its evaluation to ethical issues only. Most committees do not have the expertise to evaluate the scientific quality of a research project and should leave this evaluation to other experts. If committees recommend deviations from sound scientific principles they need to get expert advice to make sure that their recommendations will not lead to poor science, which may in itself have unacceptable ethical consequences.

We furthermore believe that ethics committees should be based upon global standards, and we find it risky to establish specific scientific standards for certain groups of people, although it has been suggested with good and bad intentions. Such rules tend to reduce scientific freedom to a level where science has little credibility and may do more harm than good. We should accept rules for good scientific behaviour (http://www.dundee.ac.uk/iea/), but these rules are to be part of legal decisions made by medical research ethics committees.

History has shown that medical research has misused people. Research participants have been subject to unacceptable risk and have acted as means to obtain a certain goal. The Nuremberg trials were the inspiration for the Declaration of Helsinki (http://www.wma.net/e/policy/b3.htm). It is justified to state that ambitious scientists are not best at evaluating whether their research follows proper ethical standards or not.

Medical research ethics committees have the role of ensuring that medical research is based upon informed consent, at least for projects that carry a risk to the involved people. The committees have to ensure that this risk is transparent for those who participate, and that the risk is properly balanced against the benefits. The committee has to make sure that participants can say no to research at any point in time without consequences for their contacts to the regular health care system, that they are informed by a third and neutral person, that they receive the information in a language they understand; and that they can expect a research project to be stopped if the study turns out to have serious side effects that were not foreseen. They also have the right to expect their personal information to be protected from unwanted disclosure.

A medical research ethics committee should furthermore provide coherent arguments for their decisions and communicate these to the applicants. They should respect intellectual property, and they should provide the applicants with a right to appeal that decision to a higher-ranking committee.

Since ethical guidelines for research in Denmark rest upon a number of laws that are not in function in Greenland, a committee in Greenland therefore has to accept responsibility for setting rules for e.g. data protection. The committee also has to deal with problems related to storing blood or other biological material in biobanks.
We know that thousands of blood samples taken from people in Greenland are stored in different freezers scattered in Denmark and probably many other countries. At present these samples could be used for research without any informed consent from the participants or even without any permission from any authorities in Greenland.

This is unacceptable, and Greenland should for that reason establish a legal basis for ethical appraisal of health research. In the future the committee should make sure that any research done on people or biological samples from Greenlanders is subject to ethic appraisal.

The most pressing problem is to make sure that the use of biological samples is under proper ethical control. Greenland is at present not prepared to make proper decisions concerning commercial use of biological samples and to make sure that important findings from biobank studies are communicated to the people who donated the biological samples.

As a conclusion, a law for Greenland should replace the present voluntary system. With modern information technology, such a committee could function at a cost that cannot be prohibitive.

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