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The pesky issue of consent

EDITORIAL

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The Declaration of Helsinki has been revised. The discussion on how to conduct medical research in an ethical manner is never truly finished.

Photo: Sturlason

In 1932, 600 young black men in the city of Tuskegee, Alabama, in the United States were promised free medical follow-up with blood tests and X-rays for six months. They were unaware that the majority of them had latent syphilis and that they were part of an observational study investigating the progression of untreated disease. The duration of the study was continually extended, and even when penicillin became available in 1947, they were not offered treatment. By the time the study had concluded in 1972, following leaks to the press about what was going on, over 100 participants had died from complications related to the disease. Nineteen children were born with congenital syphilis (1).

> ***«The global community has good reason to feel collective guilt about its research activities»***

This example is not unique. The global community has good reason to feel collective guilt about its research activities. Many medically interesting, but ethically problematic, experiments have been conducted on humans. During the Nuremberg Trials after World War II, several doctors were convicted of war crimes for their involvement in medical research on prisoners in concentration camps.

A common 'constitution' for medical research became necessary. In 1947, the Nuremberg Code was established, where the emphasis was on patient consent for participation in research (2). The following year, the Declaration of Geneva stipulated that doctors have an obligation to always protect the health of patients, including in research projects (3). In 1964, the World Medical Association (WMA) successfully codified basic principles of medical research in a declaration (4). Now, 60 years later, the Declaration of Helsinki has undergone its tenth revision (5), which took place in October during the WMA General Assembly – in Helsinki, no less.

> ***«The declaration must be general enough for everyone to support while also being specific enough to regulate developments that may pose problems»***

Documents like this are clever affairs: they are not binding for the countries that voted for them but are intended to lay the legislative framework for individual nations. The declaration must therefore be general enough for everyone to support while also being specific enough to regulate developments that may pose problems. The Declaration of Helsinki is not referenced in Norwegian legislation, but its principles are clearly reflected in the Health Research Act (6). The establishment of Regional Ethics Committees, which must pre-approve all medical and health-related research in Norway, is a direct consequence of the Declaration of Helsinki. As such, it could be argued that it is the Regional Ethics Committees that administer the Declaration of Helsinki in Norway today.

Since the last revision began in 2022, eight regional meetings have been held in various parts of the world. The key changes include increased protection for vulnerable groups, more transparency in clinical trials, and stronger commitments to fairness and equality in research. An emphasis has also been placed on scientific integrity and sustainability, with new guidelines for environmental considerations. Additionally, new study designs have been considered, with discussions focusing on how to safeguard patient consent in the future and what that consent entails. This is particularly relevant for registry research and the future use of information in health databases and biobanks. The Declaration of Helsinki also now includes a reference to the Declaration of Taipei, which addresses ethical frameworks for precisely this purpose (7).

There has been relative calm surrounding this extensive revision process, but it has not always been that way. In 2000, several South American medical associations were tired of multinational corporations exploiting opportunities for low-cost intervention research on their continent. Consequently, the 2000 revision included a clause that prohibited the use of placebos where established treatments were already available. This led to the Food and Drug Administration (FDA) in the United States not recognising the declaration (8). The conflict was resolved with the inclusion of an addendum to the declaration.

In Norway, the government has recently sent out a proposal for amending the Health Research Act for consultation. They want to explore the possibilities of using broad-based consent for the processing of health data and human biological material in medical and health-related research, including for future research purposes (9). Under certain circumstances, such as when it is 'difficult or impossible' to obtain consent from a sufficient number of research subjects, and if the research poses only 'minimal or no risk' and is beneficial to society, the government will investigate whether research on humans without consent is permissible.

For a headteacher wanting to purify virus-laden air in classrooms with an air purifier, it is simply a matter of installing a suitable system. However, if researchers wish to put in place the same air purifier to investigate whether it prevents the transmission of infection, this constitutes medical research that requires consent from the children's parents/guardians (10).

While there is certainly a vast difference between Tuskegee and the Norwegian government's proposed legislation, both examples illustrate how the pesky issue of consent can hinder what researchers perceive to be good and important research. History has shown that we need guidelines. It is therefore reassuring to have an updated Declaration of Helsinki to reference as we continue the discussion.

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