Research involving Indigenous Peoples – ethical aspects

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Why am I here

- I have been head of the regional research ethics committee
- For 2 years member of the national research ethics committee in Denmark
- Two years ago I helped organize an international meeting of hepatitis B among Indigenous peoples
- My patients belong to minority groups in DK

I will talk about

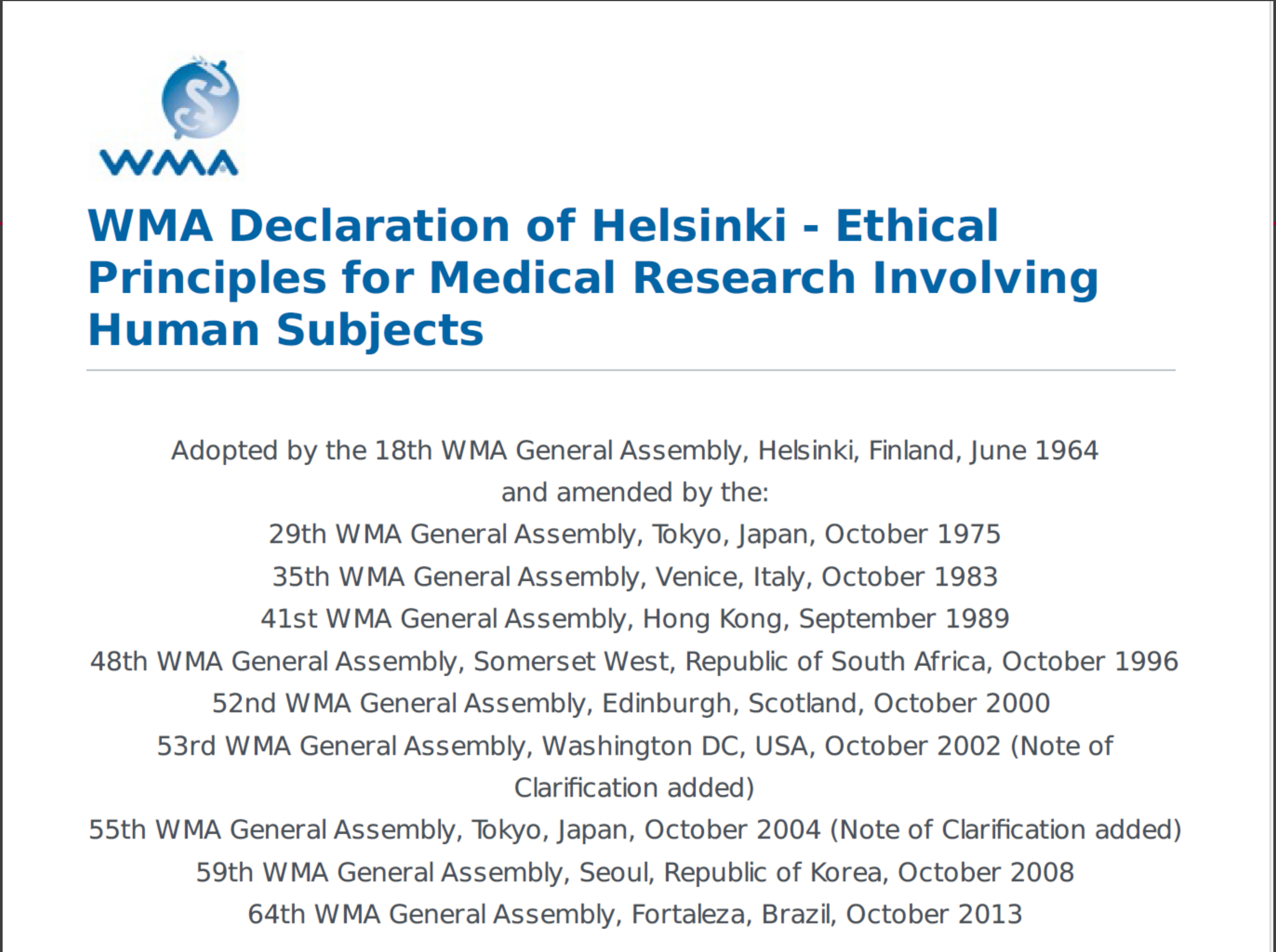
- Research ethics in research involving Indigenous peoples
- A little on research ethics in Greenland
- Thoughts on research in Greenland in the future

Indigenous Peoples

There is no internationally accepted definition of “Indigenous Peoples”

Four criteria are often used in international law:

- Residing within or associated with a specific geographic area, the ancestral territory and natural resources in these areas
- Maintenance of cultural and social identity, and social, economic, cultural and political institutions separate from mainstream or the dominant society and culture
- Descendants from population groups present in a given area
- Self-identification as being part of a distinct indigenous culture, and the desire to preserve the culture



WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Helsinki Declaration
Vulnerable Groups and Individuals

- 19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

  All vulnerable groups and individuals should receive specifically considered protection.

- 20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

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Indigenous health
life expectancy at birth or inequality in health

- If you belong to the Baka tribe in Cameroon, you can expect to live to the age of 35 years, 12 years less than the non-indigenous population in the same area

- In Greenland you can expect to live to the age of 73 years, compared to 82 years in the general Danish population

Lancet, 2016; 388: 104

- If you live in the eastern part of Aalborg you can expect to live 12 years less than the population in the western part of Aalborg

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples

Michelle M. Mello, J.D., Ph.D., and Leslie E. Wolf, J.D., M.P.H.

N Engl J Med 2010; 363:204-207 | July 15, 2010 | DOI: 10.1056/NEJMp1005203

Havasupai Tribe

The Tribe states:

- blood samples were collected for the study on the genetics of diabetes

- the samples were also used for studies on schizophrenia, inbreed and possible migration patterns of the tribe’s ancestors from Asia to America

- this was humiliating and harmful to tribe members and community

Canadian Nuu-chah-nulth people

- blood samples were collected for the study on the genetics of arthritis
- the samples were instead used for studies to establish ancestry
- this deception has led to intense suspicion of research among Nuu-cha-nulth people and a reluctance to engage in further research, even when it may be beneficial

Indigenous peoples

A number of countries with "indigenous people", such as Australia, New Zealand, Canada and the United States have made particular rules for research in these populations

Historically, research involving "indigenous peoples" has often been conducted to promote colonial control - research imperialism

It’s all in the blood

the evil
the healing
source of power
blood ties
blood brothers
pure blood
blood feud
etc.

It’s all in the blood

The genome

Cell free DNA from plasma for tumor diagnostics

Fetal DNA in mother’s blood

All the omics

Biochemistry

But also

- Family relations
- Ancestry
- Future findings

Therefore when creating biobanks, we take a hugh resposibility for the future

> ”Researchers are like mosquiteos; they suck your blood and leave”
>
> Alaskan Native saying

The Helsinki Deklaration
Informed consent

- 24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. **After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing**. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. All procedures accords with good public administration

http://www.wma.net/en/30publications/10policies/b3/

World Medical Association

Considerations regarding health databases and biobanks

- Individuals must be given the opportunity to decide whether their identifiable information will, or will not be included in a Health database or their biological material in a Biobank

- As part of the consent process, individuals must be informed about the purpose of the Health database or Biobank

World Medical Association
Considerations regarding health databases and biobanks

- If Health databases or Biobanks are established to allow for multiple studies and if, during the consent process, all principle information about future use is provided, all relevant safeguards are secured, the use of health data or biological material is transparent, and if all use is explicitly approved by a dedicated, independent ethics committee, then conditional broad consent is acceptable

- In contrast, blanket or open consent for future use of health data or biological material not envisaged at the time of collection is not ethically acceptable

Informed consent adequate information

- Quantity of information:

  ”What a reasonable person would need to know or want to know in order to decide whether to participate”

  - Purpose of the research
  - Significant risks
  - Financial interest
  - Source of any external funding
- Excessive information provision can lead to ”Information overload”

Informed consent

- Informed consent is usually based on individuals from a Western mindset of "individual before society“
- Research involving indigenous people will require consent of recognized representatives
- And maybe a third level of consent from a wider indigenous organization if it exists
- In research involving indigenous people consent from the society can be just as significant because research in small communities affects the whole society

Based on indigenous culture

- Land and other property are often seen as belonging to the group. This extends to “genetic property” such as DNA
- Blood or tissue is usually treated with cultural respect as part of the inheritance of the group

Benefits of research collaboration

- Improved health status of the population
- Publication of research results

Proposal from WHO

- Prior to publication, both the indigenous people and scientists review the manuscript and comment on the interpretation of data

Traditional knowledge

- Protection of traditional knowledge, for example by Intellectual Property Agreement
- Prevent improper patenting of public-domaine traditional knowledge, for example of medical herbs
- Lack of recognition of traditional knowledge, such as counting whales

Biomedical research in culturally distinct communities barriers to participation

- Science is presented in a format that lacks cultural acknowledgement
- Fails to show beneficial relevance to the communities or include them in true partnership
- Mistrust of the government and researchers associated with the government

J Canc Educ 2016; 09 July E-pub

Translating biological material into bioinformatic data - consideration by DNVK

DNVK wants elucidated if there are special considerations involved in genomics research that change the perception of when the committee system can give permission to use the biological material for research without a new consent of the donor (new exemtion praxis)

Bioinformatic data generated by extensive sequencing of the human genome differs from other types of registry data that they comprise a very large amount of information, we do not know the full meaning of. DNVK finds that this kind of bioinformatic data should be subjected to research ethical evaluation

Health and elderly Ministry, December 15, 2015

Exemption

Biological material given for a certain purpose can not legally be used for other purposes based on the rules of informed consent.

Stored material from a project used for a new purpose, requires basically a new consent from the donor, and a new notification to the committee system. The new consent from the donor must be achieved on the basis of a new participant information.

Exemptions may be granted for consent, if it is a data research project that does not involve health risks or otherwise under the circumstances, can be a strain for the participant. This can also be done if it is impossible or excessively difficult to obtain consent. (§ 16 stk 3)

Ilulissat 2011

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Is research in Inuit in Greenland different from research in other Indigenous People?

- Inuit in Greenland constitute 80 % of the population

  In comparison Aboriginal and Torres Strait Islander Peoples constitute less than 2 % of the population in Australia
- Greenland has own Government
- Among others autonomy over the health care system
- Although there is resentment against Denmark, it seems less harmful than in many other indigenous peoples

Why do you do research in Greenland?

- Diseases or conditions where you have special insight and can contribute to society (Greenland)
- Society (DK, Greenland) has particular interest and funding is available
- Non-Inuit researchers find research involving Inuit population exotic / romantic
- Desire for adventure
- A little of everything
- Focus on the core task –

More health for the people of Greenland

Focus on the core task –
More health for the people of Greenland

- Will the Greenlandic people get better health
- Is there an improvement in the self-perceived health
- How to ensure the Greenlandic population direct influence on research
- How can we ensure that the Greenlandic "preconception" / insight comes in at the design stage of research projects

Greenland Health Scientific Research Council

If Greenland's Health Scientific Research Council took the lead

Planned large overall research projects/areas and invited teams to bid

Established "User Groups" for example young people to discuss STDs

Collected all Danish research groups "under one umbrella“

Established an ambitious national Greenlandic biobank

so you could get a better overview, more synergy and perhaps better research - and more health for the people of Greenland

An ambitious biobank

Roskilde Cathedral
A structured collection of all Danish kings since 1536