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The Future of the Declaration of Helsinki – Introduction: Remarks About the Next Revision

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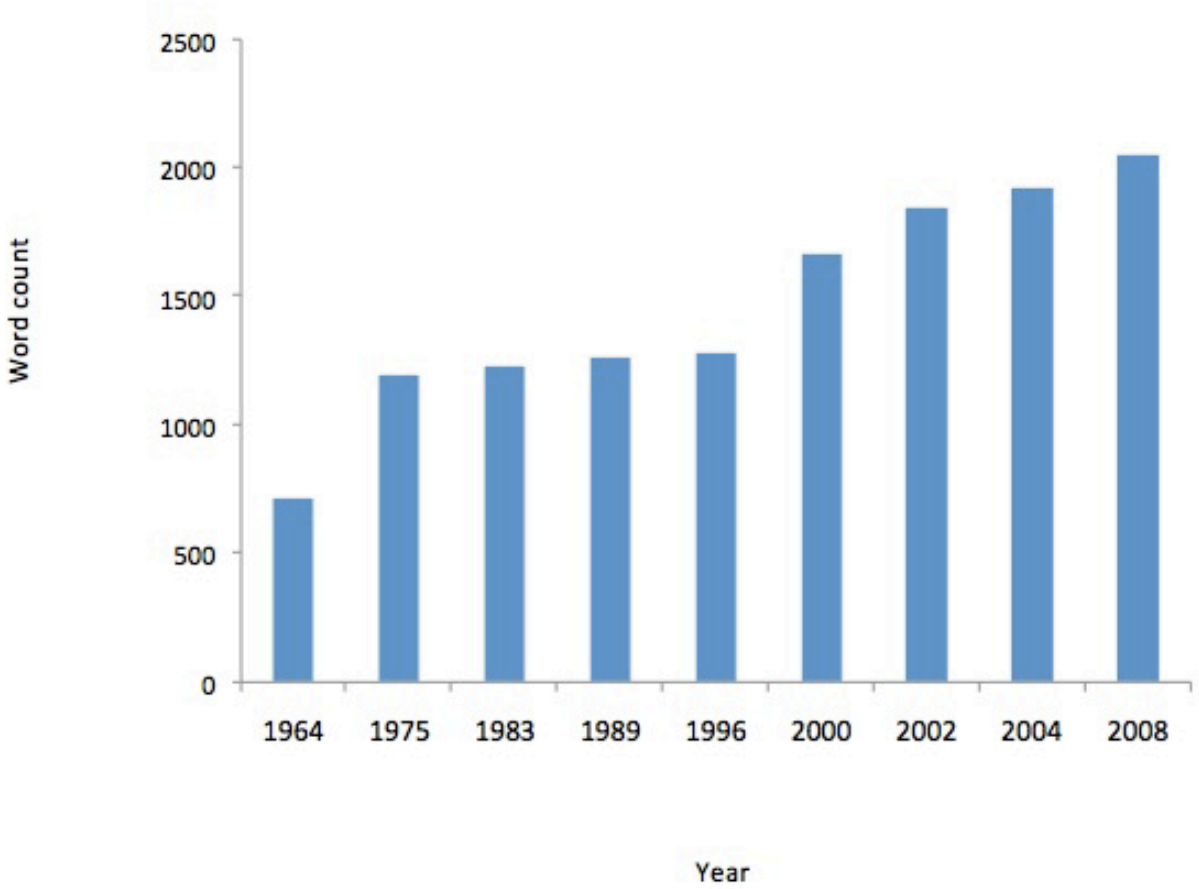
Outline

- Character of the DoH
- Experiences of former revisions
- General considerations and limits of a revision
- Process of revision
- Aim of the satellite-meeting

The DoH has a certain Character

- **It is a document of ethical principles** for research involving human beings
- It contains only few procedural rules, it is not a detailed rule-book for research
- The DoH has a certain size:
- 2008: 2047 words.

Declaration of Helsinki – word count



The DoH has a certain Character

- The DoH is distinct from other competing guidelines.
- All other documents on medical research are younger than the DoH and longer.
- They have another character:

Other Guidelines/Laws

- **CIOMS guidelines**: more technical instruction (24649 words, incl. commentary)
- **ICH-GCP**: technical instruction (48 pages)
- **UNESCO Declaration**: not only related to research (3542 words)
- **Declaration of Oviedo** of the EC (4096 words). Add. Research Protocol (4602 words): European law!

Current consensus in the workgroup

- The character of the DoH is unique and should not be changed.
- The DoH must remain distinct from other guidelines!
- The DoH has a certain size, it should not become much longer.
- The DoH must remain readable within 15 min!

Experience of former revisions

- Suggestions for the revision in 2008.
- It must be expected that many of these suggestions will be addressed once again in the next revision process.

Suggestions for the revision 2008

- Approximately **45 sets of comments** to the 1st draft of a revised version,
- **80 sets of comments** after a 2nd draft was published.
- Some of them very long (up to 46 pages)
- From “congratulations” to fundamental criticism

Suggestions for the revision 2008

Main discussions:

- Editorial changes/wording: e.g. medical/biomedical, human/human beings?
- For whom? Doctors? Other researchers?
- Justice
- Placebo
- Post-study-arrangements
- Should “palliative care” be mentioned explicitly?
- Unidentifiable data/material?

Suggestions for the revision 2008

- **Vulnerable populations?**
- "There were suggestions to include the elderly, women of child-bearing potential, poor people, illiterate people, students, prisoners, those suffering from mental illness or disabilities, ethnic and religious minorities, aboriginal peoples, people in developing countries and people with neglected diseases." (John Williams)
- Interestingly, not suggested: children, women, pregnant women!

Suggestions for the revision 2008

- The DoH is not based on one single ethical theory.
- “There was general agreement on most of the principles; suggestions were mainly for clarification.” (John Williams)
- It is unrealistic that the next version will be a purely deontological or a purely utilitarian document!

Frequent criticism in the literature

- Placebo
- Post-study arrangements
- Research in resource poor settings, justice
- Missing issues: biobanks
- Unclear status of the DoH, relation to law
- Wording: “must” or “should”

Frequent criticism in the literature

- Internal contradictions:
- Art. 6: “In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.”
- Is research possible, as it exposes participants to additional risks?
- Placebo? Research without informed consent?

Suggestions for the revision 2008 and criticism in literature

- If all the suggestions will be implemented:
- The DoH will become a book!
- The workgroup agrees that the size and the character of the DoH should be maintained.
- The same amount of suggestions has to be expected in the current revision process.
- Therefore: Not all suggestions will be implemented!

Options for a revision

- 1. New issues
- Which issues?
- Why?
- New technologies? Medial innovations? New circumstances (globalization…)? New ethical arguments?
- The length of the DoH!

Options for a revision

- 2. Existing issues in more detail
- DoH 2008: 21 general paragraphs and 14 more detailed paragraphs (in particular “informed consent”)
- Which issues in more detail?
- Length?

Options for a revision

- 3. Changing existing issues
- Which issues need new norms?
- Why?
- New technologies? Medial innovations? New circumstances (globalization…)? New ethical arguments?

Options for a revision

- 4. Deleting existing issues
- Which one?
- Danger: Can be misunderstood politically!

Options for a revision

- 5. New structure of paragraphs
- Some paragraphs repeat or specify what is stated in other paragraphs.
- Merging paragraphs? New order? New subtitles?

Options for a revision

- 6. Wording, editorial changes
- should/must

Options for a revision

- 1. New issues
- 2. Existing issues in more detail
- 3. Changing existing issues
- 4. Deleting existing issues
- 5. New structure of paragraphs
- 6. Wording, editorial changes
- New regulations, new issues, changes etc. must be coherent with the rest of the DoH!

The next revision:

- The character of the DoH should remain.
- The size should not increase.
- The DoH must remain distinct from other guidelines!
- Sensitive for ongoing ethical debates, scientific and political developments
- The aim is a more appropriate and updated version of the DoH.
- Not a revolution, but an evolution.

The revision process

- Oktober 2011, Montevideo:
- General assembly: A new revision!
- Four conferences:
- Rotterdam 26.6.2012
- Cape Town 5.-7.12.2102
- Tokio 28.2.-2.3.2013
- (Washington August 2013)

Public discussion

- A first draft will be published for public debate:
- April 2013 until June 2013 (subject to a decision of the Council of the WMA)

The process of revision

- The workgroup has to set up a proposal
- Discussed in public and within the WMA
- The final decision is made by the General Assembly of the WMA
- A political decision!

The revision process

- Nothing has been decided yet.
- We do not know the result of the revision process, nor our proposal, neither the political decision by the General Assembly!
- Certain limits have to be respected.

- Don‘t be sad if your suggestions will not be implemented in the final document!

Goals of the satellite meeting

- We start the process of public debate within the scientific community.
- The first public conference of the revision process
- The Workgroup of the WMA is interested in your ideas.
- We are grateful for your commentaries, criticism, suggestions…!

- The task of the WMA-workgroup for today:
- Listen!

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Issues for a revision

- Insurance/compensation
- Enhancement
- Medical devices
- Biobanks
- Resource poor settings
- Justice
- Vulnerable groups
- Status of DoH
- Research Ethics Committee
- Risk/benefit
- Publication
- Post-study-arrangements
- Placebo
- New structure
- Wording