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A New Revision of the Declaration of Helsinki: Challenges and Limitation

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Cape Town, WMA conference, 5 December 2012

Outline

- Process of revision
- Character of the DoH
- Experiences of former revisions
- General considerations and limits of a revision
- Task of the workgroup
- Issues of this conference

The revision process

- Oktober 2011, Montevideo.
- General assembly: A new revision of the DoH!
- Four conferences:

Rotterdam	26.6.2012
Cape Town	5.-7.12.2102
Tokyo	28.2.-2.3.2013
Washington	August 2013

The revision process

- April 2012
- Request for comments from National Medical associations
- 21 answers

The revision process

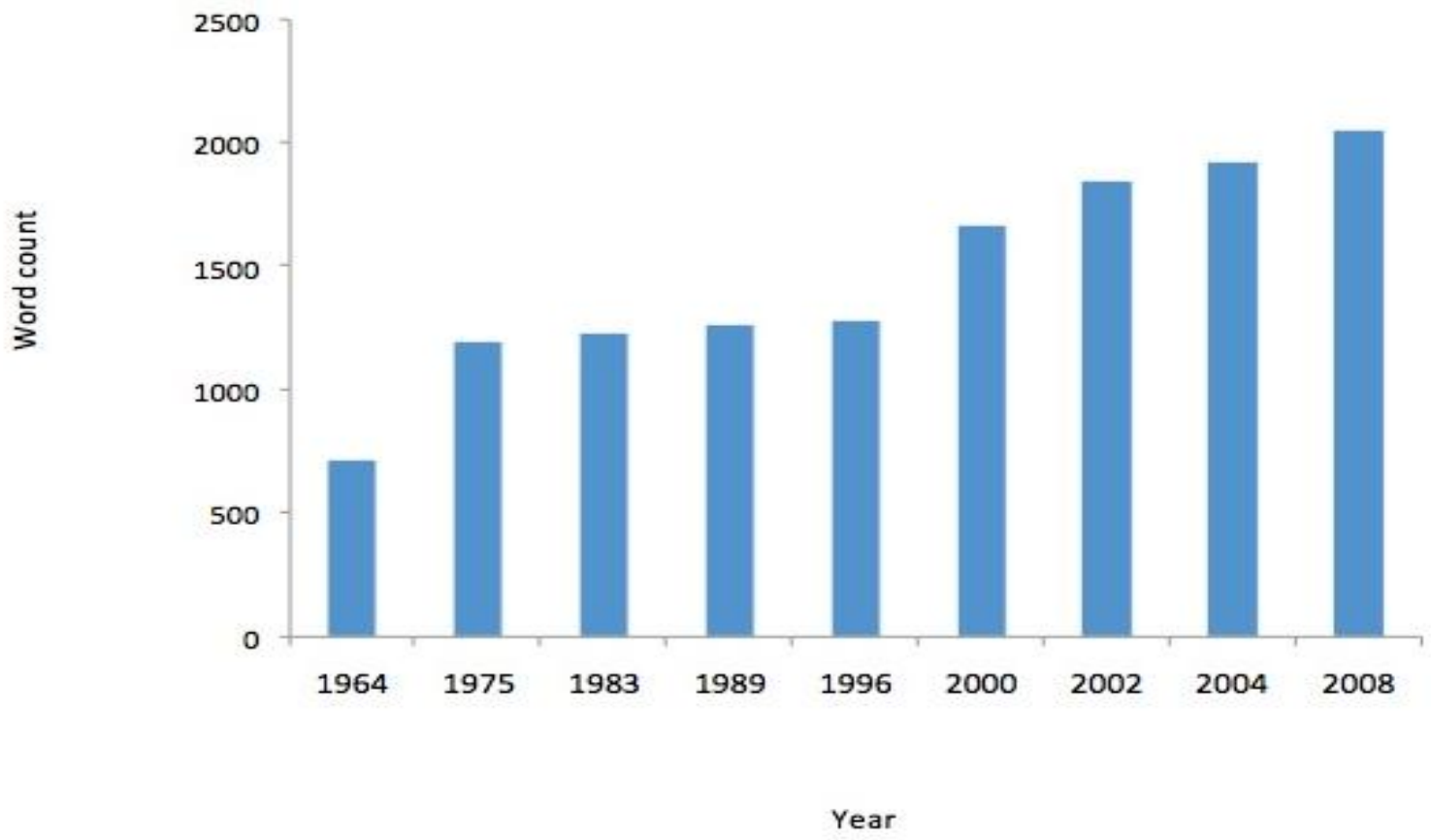
A first draft for public debate will be published:

April 2013 until June 2013 (subject to a decision of the Council of the WMA)

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.
- It 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

- Approx. **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

Suggestions for the revision 2008

- 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 pure deontological or a pure 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

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, criticism in literature and suggestions in 2012

- If all suggestions are implemented: the DoH will become a book!
- The workgroup has agreed that the size and the character of the DoH should be maintained.
- The same amount of suggestions has to be expected in the further 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:

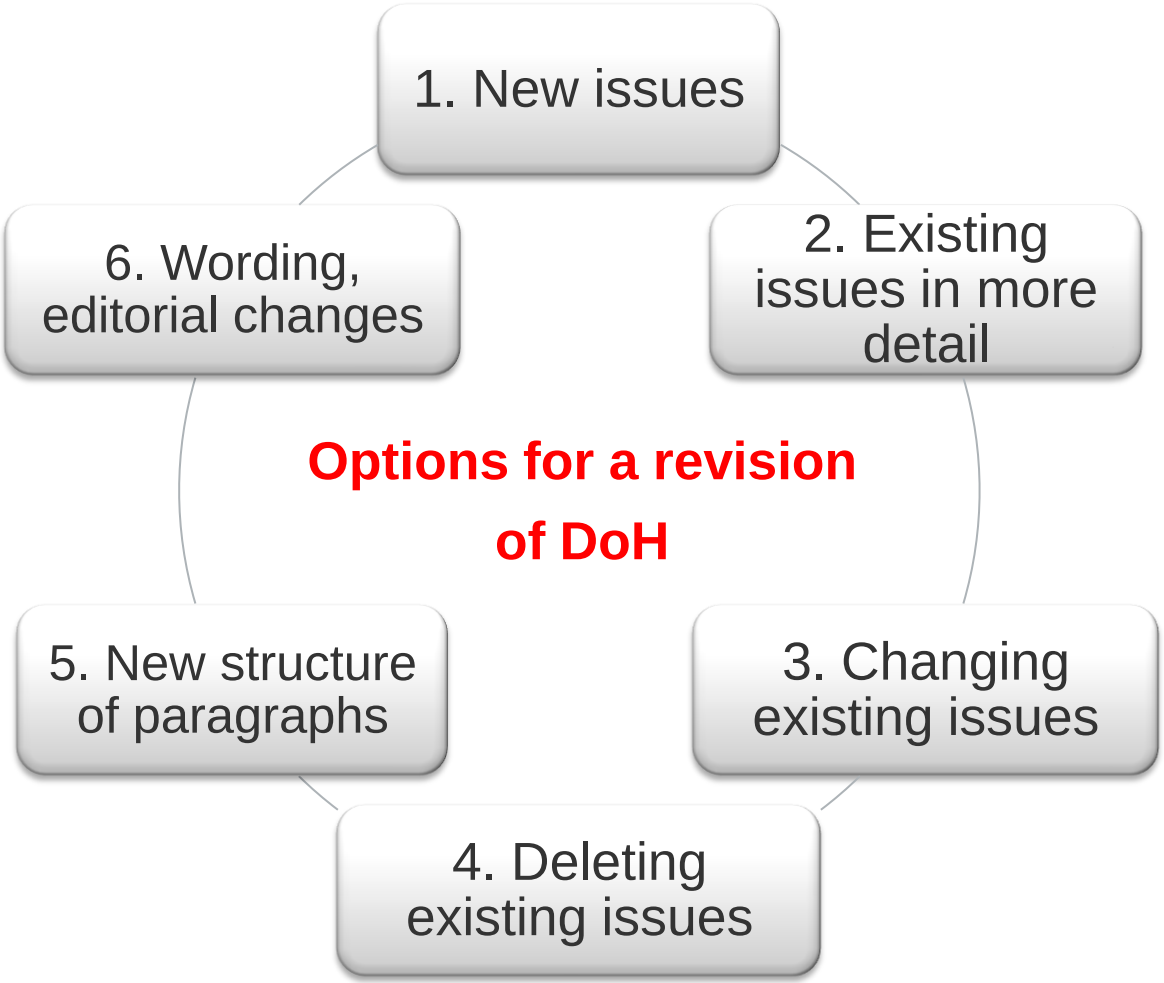
- Some paragraphs repeat or specify what is stated in other paragraphs.
- Merging paragraphs? New order? New subheadings?

Options for a revision

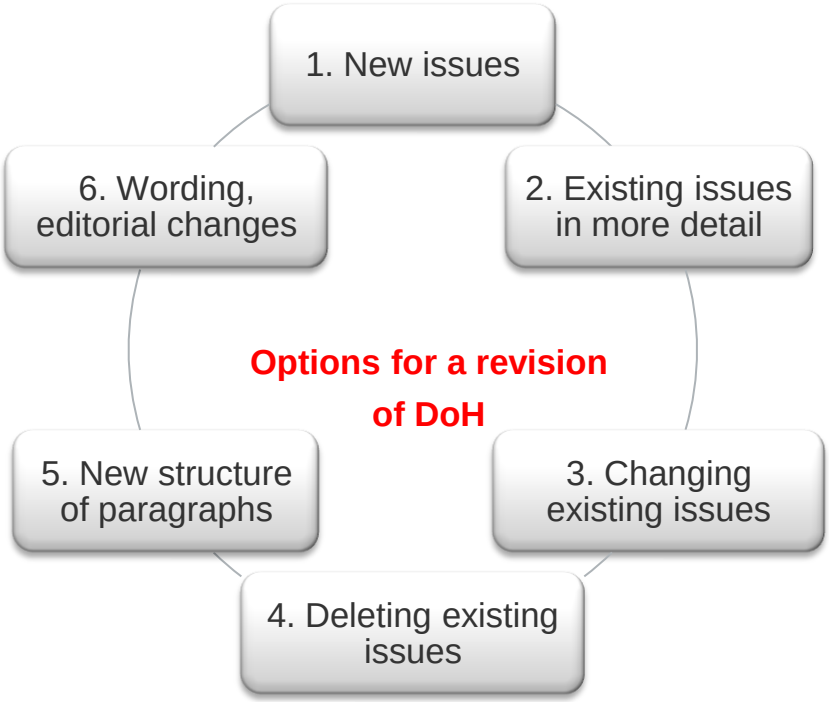
6. Wording, editorial changes:

- should/must

In Summary


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
Options for a revision of DoH

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!
- Not a revolution, but an evolution.
- The aim is a more appropriate and updated version of the DoH.
- If there are no strong arguments for a change, the paragraph will remain.

The process of revision

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

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

Issues of this conference

- Vulnerable groups
- Post-study-arrangements
- Biobanks
- Research Ethics Committee
- Enhancement
- Insurance/compensation
- Use of unproven interventions/off-label use (para. 35)
- Broad consent
- Children
- …

Goal of the conference

A public debate with a particular African perspective.

The workgroup is grateful for your comments, criticism, suggestions…!

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