The mandate of the WMA

Consent issues

Urban Wiesing

The mandate of the WMA

- **The practical view:**
- Many professions are involved in a biobank
- Physicians, biologists, chemists, physiologists, clinical researcher, epidemiologists...
- A declaration that addresses all these professions makes sense!

The mandate of the WMA

- **The legal view:**
- The WMA has no mandate and no right to set up a norm for anyone -
- except for its own members!
- The legal objections are stronger than the practical advantages.
- Therefore, in accordance with the Declaration of Helsinki:

The mandate of the WMA

- **Declaration of Helsinki:**
- 2: “Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.”

The mandate of the WMA

- **Declaration of Helsinki:**
- "Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects in biobanks to adopt these principles."

Consent issues

Consent in biobanks

- **General remarks:**
- There is no ethically uncontroversial regulation of informed consent in the case of biobanks.
- There is a corridor of more or less acceptable regulations.
- The final decision on ethical principles in biobanks is a political decision!
- Further research is needed to clarify the practical results of specific provisions.
- = The final political decision is partially not ‘evidence based’.

Consent in biobanks

- **The basic problem:**

- "Classical" informed consent: The patient has to be informed precisely about aim, methods etc. of each research project.
- Biobanks: Made for numerous projects; future projects, future aims and methods are not foreseeable.
- Asking for informed consent for each project is not impossible but burdensome, impractical

Consent in biobanks

- **The basic problem:**

- Tension between legal/moral obligation towards the donor (autonomy, non-maleficience) and practicability, costs and burdens

- As more precise as more complicated, burdensome and inhibiting research

- A type of consent is needed that is ethically appropriate and also feasible

Consent in biobanks: the basic options

- No consent
- Blanket consent
- Broad consent
- Checklist
- Study specific consent

- (Grady et al., AJOB 2015, p. 36)

Consent in biobanks: the basic options

- No consent
- Blanket consent
- Broad consent
- Checklist
- Study specific consent

Less burden,
less control

More burden,
more control

- (Grady et al., AJOB 2015)

Consent in biobanks

- **The basic options:**
- No consent
  - Do not obtain donor consent
  - As a general rule unacceptable
- Blanket consent
- Broad consent
- Checklist
- Study specific consent

Consent in biobanks

- **The basic options:**
- No consent
- Blanket consent
  - Consent without limitations for future research
  - As a general rule hardly acceptable
- Broad consent
- Checklist
- Study specific consent

Consent in biobanks

- **The basic options:**
- No consent
- Blanket consent
- Broad consent
  - "consent for an unspecified range of future research subject to a few content and/or process restrictions" (Grady et al. 2015, AJOB, p. 35)
  - Which content and/or process restrictions?
- Checklist
- Study specific consent

Consent in biobanks

- **The basic options:**
- No consent
- Blanket consent
- Broad consent
- Checklist
  - Donor chooses the type of future studies
  - Restriction of future research. If no consent = burdensome, hardly practicable to get new informed consent
- Study specific consent

Consent in biobanks

- **The basic options:**
- No consent
- Blanket consent
- Broad consent
- Checklist
- Study specific consent
  - Consent for each specific future study
  - Impracticable for most of the biobanks, massive restriction of research, burdensome

(Grady et al., AJOB 2015)

Consent in biobanks

- **Meta consent?**
- New
- Hardly known
- Experience?
- Applicable on a global level?
- Sophisticated IT expertise is needed

Consent in biobanks: the basic options

- No consent
- Blanket consent
- Broad consent
- Checklist
- Study specific consent

- (Grady et al., AJOB 2015, p. 36)

Broad Consent

- **The central question:**

- Which limitations in broad consent are ethically acceptable and practicable?
- Which compromise between ethical consideration regarding the right of the donor and the practicability of a biobank is the most acceptable one?
  - Regarding the content of the initial consent
  - Regarding the governance of the biobank
  - Regarding ongoing communication with donors

The main problem: balancing in broad consent

- More or less specifications/restrictions regarding the future research projects

  - and/or

- more or less specifications regarding the governance of the biobank

  - and/or

- more or less communication with donors

Broad Consent

- Empirical data:

- "The empirical data thus support the claim that reasonable persons are willing to provide broad consent for future research with their biospecimens, provided that important exceptions are taken into account." (Grady et al. 2015, AJOB, p. 36)

- **Empirical data are not ethical arguments!**

Broad Consent

- Non-empirical arguments in favor of broad consent:
- **Regarding the donor:**
  - The rights of the donor can be sufficiently respected
  - Low risk to donor welfare
  - Governance: protects the interests of donors
- **Regarding research:**
  - System of broad consent: low costs to maintain
  - Practicability
  - Governance protects the interests of research
  - Communication: learning system, transparency, trust

Elements of Broad Consent (according CIOMS-Guidelines, draft version)

- **Broad informed consent describes the range of future uses in research for which consent is given. This broad informed consent should specify:**
- the conditions and duration of storage
- who will manage access to the materials
- the foreseeable uses of the materials, whether limited to an already fully defined study or extending to a number of wholly or partially undefined studies
- the intended goal of such use, whether only for research, basic or applied, or also for commercial purposes
- the possibility of unsolicited findings and how they will be dealt with

Additional elements of initial consent in accordance with the Declaration of Helsinki

- Benefit sharing (including dissemination of knowledge)
- Institutional affiliations of the biobank
- Sources of funding
- Conflict of interests
- Inclusion of data and material of persons not able to give their informed consent (including minors)

- Implications for connected others and/or the individuals into the future

Elements of Broad Consent, Governance

- how the donor can retract this authorization;
- how the quality of the material is controlled, ensuring the physical protection and maintenance of the materials
- how confidentiality of the link between biological specimens and personal identifiers of the donors is maintained
- who may have access to the materials for future research, and under which circumstances
- which body may review research proposals for future use of the material

(following CIOMS Guidelines, draft version)

Elements of Broad Consent, On-going Communication

- under which circumstances donors need to be recontacted
- how participatory engagement with patient groups or the wider community is organized

(following CIOMS Guidelines, draft version)

Exceptions

- Broad consent is a general principle!
- Biobanks are different!
- There might be few exceptions:
- It might be acceptable not to obtain consent
- It might be more appropriate for certain biobanks to limit the use for future research to specific studies
  - Depending on donor population (indigenous people, diseases with high potential of discrimination …) and other circumstances
- This must be considered before starting a biobank!

Summary

- Ethics cannot ‘solve’ the problem of consent in biobanks
- Finally: A declaration is a political statement
- The basic problem: rights of the donor vs. practicability
- Broad consent is probably the most acceptable consent
- A balance between specifications/restrictions regarding future research projects, specifications regarding the governance and intensity of communication with the donors must be found.
- Exceptions: Different regulations for different biobanks
- List of issues to be mentioned in the initial consent: see DoH, CIOMS, Grady et al. 2015, Strech et al. 2015

- Do not invent the wheel once again!

The mandate of the WMA

Consent issues

Urban Wiesing