CIOMS ethical guidelines for Biomedical Research: some issues for the revision

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What is CIOMS?

- An NGO: international, non-governmental, non-profit organization
- Forum to consider and prepare advice on contentious issues in research ethics and safety of pharmaceuticals...
- ... for WHO, public health authorities, academia, pharmaceutical industry and others.
- Established 1949 by WHO and UNESCO
- Offices located in Geneva, Switzerland

CIOMS BM research ethics guidelines

- Purpose: indicate how fundamental ethical principles and Declaration of Helsinki can be applied effectively in medical research world-wide in different:
  - cultures, religions, traditions, socioeconomic circumstances;
  - with special attention for low and middle income countries.
- Content: 21 guidelines plus commentaries (!)
- Use: 2002 Guidelines have been widely used, notably in developing countries.
  - Indication: translation into several languages, including French, Spanish, Portuguese, Chinese, Arabic, Czech, and Vietnamese.

Revision of CIOMS guidelines

- For many reasons CIOMS decided to revise the 2002 glns:
  - changes in other relevant documents
  - changes in the field of research
  - changes in existing regulations and ethical practices by health authorities
  - developments within research ethics
- Process started in 2012
- So I will show issues to deal with, rather than fixed positions

Obligations of researchers: overview

1. Pre-trial obligations
2. (Obligations during the trial)
3. Post-trial obligations

Pre-trial obligations: issues

- Responsiveness to health needs & priorities (CIOMS, DoH)
- Justifying exclusion of groups (CIOMS)
- Not a limitative list

CIOMS guideline 10

- Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:
  - the research is **responsive to the health needs and the priorities** of the population or community in which it is to be carried out; and
  - any intervention or product developed, or knowledge generated, will be **made reasonably available** for the benefit of that population or community.

Responsiveness: comments

- Intuitively a good requirement: avoids exploitation
- Not so clear what it means
  - What is a health need/priority? When is research justifiably called responsive?
- Relation with reasonable availability!
- People in LMIC may want to study diseases that are no priority

CIOMS guideline 12

Groups or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. **The exclusion of groups or communities that might benefit from study participation must be justified**.

Justifying exclusion: comments

- Participation in research seems to have become a good which should be distributed equitably: very difficult to realize (whose duty?)
- no group (including vulnerable people) should be deprived of its fair share of the benefits of research, both direct and indirect
- May mean that we have to do away with the subsidiarity

Post-trial obligations

- Responsiveness and reasonable availability (CIOMS)
- Fair benefits approach (NIH, DoH?)

Reasonable availability

- Ensures certain type of benefits is provided
- Identifies addressee
- Prior agreements necessary
- Down side:
  - exact level is not defined (how much? How long?)
  - applies to Phase III (IV) research mainly, not to other phases or epidemiological research

Fair Benefits Approach

- Wider range of benefits (e.g. infrastructure)
- Wider applicability (not just phase III)
- Collaborative partnership
- Prior agreement

FB or RA: a heated debate?

- In reality: a lot in common
- Main differences:
  - type of benefit made available
  - Position of responsiveness as starting point
- In common:
  - Sense of obligation “to close the circle” (naïve idea about time line?)
  - No clear idea about exact level of benefits required
  - Also in RA other benefits than the study product could be part of the agreement
  - Prior agreement through negotiation, about which participants are informed
- Real ethical question (for both!): why exactly do we have these obligations? And to whom?

Conclusions

- Ethical concerns augment when conducting research in LMIC
- Intuitively clear that we owe participants in developing countries special obligations
- Supercontractual obligations may be necessary, but need further justification
- Revised CIOMS guidelines (2015?) will provide yet another provisional fixed point