Standards & Operational Guidance for Ethics Review of Health-Related Research with Human Participants

DRAFT document for feedback

3rd National Bioethics Conference, India

17th -20th November 2010

World Health Organization

WHO and Research Ethics

- WHO supports, promotes, conducts research in many countries
- Provides a parallel review to all research that it supports
- Member States have requested WHO to strengthen existing mechanisms for good research practice, including ethical and peer review structures and procedures

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction

Vaccine research and development

Medicines for Malaria Venture

ARTICLES

Articles

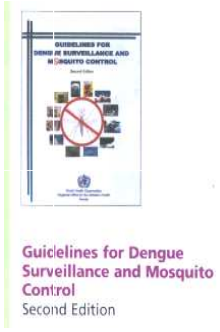
evaluation of a new model of routine antenatal care

José Villar, Hassan Ba'aqeel, Gilda Piaggio, Pisake Lumbiganon, José Miguel Belizán, Ubaldo Farnot, Fagob Al-Mazrou, Guillermo Carroli, Alain Pinol, Allan Donner, Ana Langer, Gustavo Nigenda, Miranda Mugford, Julia Fox-Rushby, Guy Hutton, Per Bergsjø, Leiv Bakketeig, Heinz Berendes, for the WHO Antenatal Care Trial Research Group*

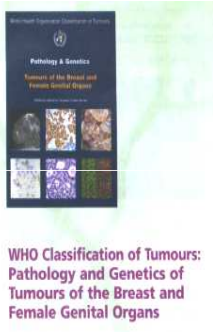
Summary

Background We undertook a multicentre randomised controlled trial that compared the standard model of antenatal care with a new model that emphasises actions known to be effective in improving maternal or neonatal outcomes and has fewer clinic visits.

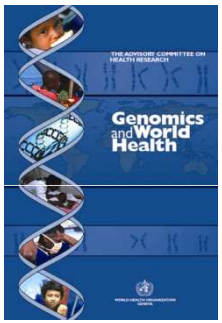
Findings Women attending clinics assigned the new model (n=12 568) had a median of five visits compared with eight within the standard model (n=11 958). More women in the new model than in the standard model were referred to higher levels of care (13·4% vs 7·3%), but rates of hospital admission, diagnosis, and length of stay were similar. The groups had similar rates of low birthweight (new model



Guidelines for Dengue Surveillance and Mosquito Control
Second Edition



WHO Classification of Tumours: Pathology and Genetics of Tumours of the Breast and Female Genital Organs



Poor Countries to Get Medical Journals Free

WHO and Publishers Join in the Giveaway

By David Brown
Washington Post Service

WASHINGTON — Six giant publishing houses were to announce Monday that they would provide free electronic access to about 1,000 medical journals to medical schools, research laboratories and government health departments in poor countries.

Piloted by the World Health Organization, the program will benefit about 600 institutions, principally in Africa. It will also include training in techniques for researching the vast amount of medical literature by computer.

tions to six journals for the library at Makerere University Medical School, in Kampala, in the late 1970s when the Ugandan economy was in a state of near collapse and the library was getting no current journals.

Barbara Aronson, a librarian at the WHO's Geneva headquarters and a prime mover behind the program, said that most medical schools in developing countries get fewer than 100 journals, and many only a few dozen, compared with 1,000 or more in America.

Libraries and research institutions often must pay a higher price for a subscription than individuals. The Lancet, a

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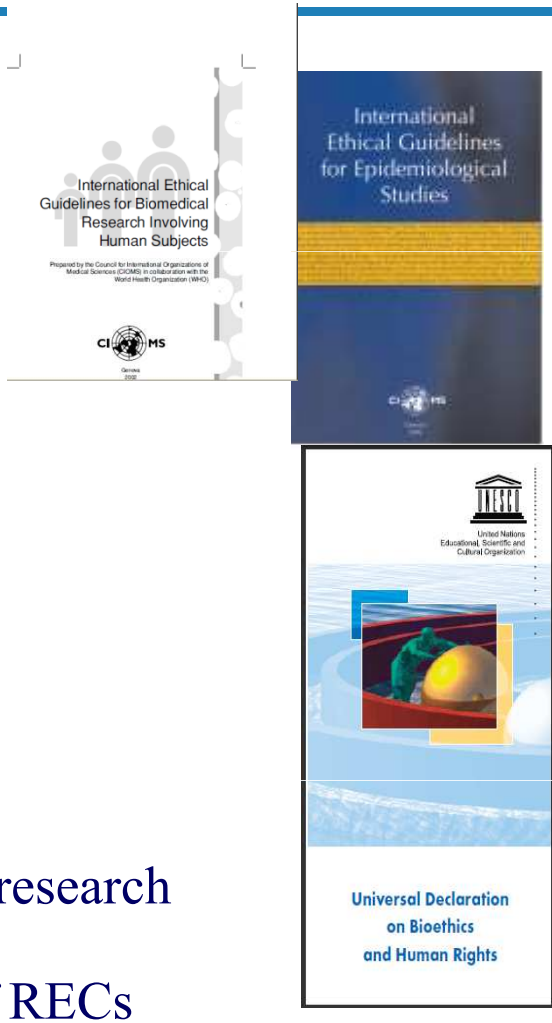
Ethical guidance for research exists in many international documents



- All key international ethics documents include:
  - **Principles** to guide what is defined as ethical research
  - **Specific actions to follow** in conducting ethical research

- REC review is one such specific action
  - Such an **independent, third party review** ensures that proposed research is consistent with principles and actions outlined
  - However no comprehensive set of standards for the functioning of RECs exist in any single document.

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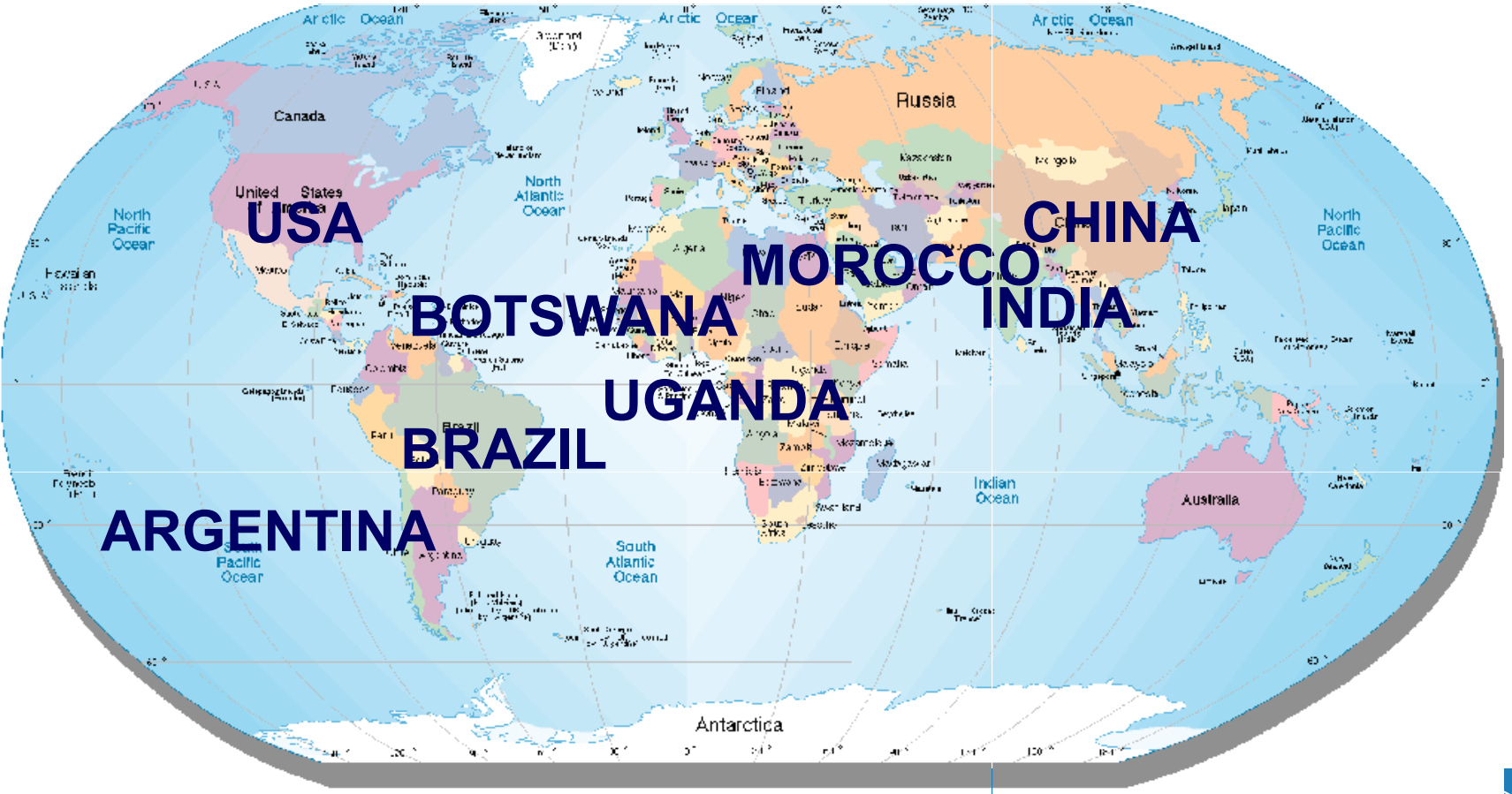
Challenges

- Some research is still not reviewed
- Many RECs have insufficient training, experience, or resources to provide a thorough or quality review
  - Some committees are very new
  - Some committees have few resources
  - Some committees have no members with any training in ethics, so reviews tend to focus on budget or science
  - Some committees tend to be highly bureaucratic or regulatory with less attention to ethics

Informal WHO Consultation November 2009



- UNESCO
- WMA
- CIOMS
- COHRED
- WIRB
- COE
- PATH
- AAHRPP

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Recommendations from Informal Consultation

Meeting participants recommended

- the development of standards for RECs globally
  - Would address "non-negotiable" aspects of REC operations, functioning, and governance
  - Would be accompanied by guidelines for RECs, revised from 2000 guidelines, related to each standard

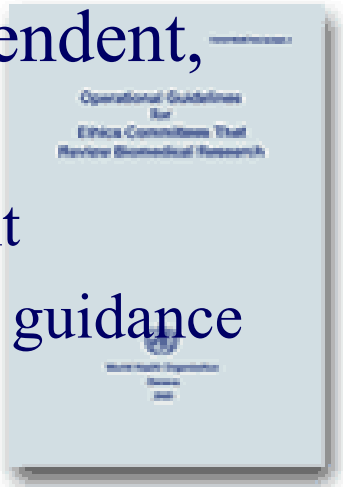
- that WHO coordinate the development of standards, in collaboration with other international agencies, especially other UN Organizations that also have a special focus on research ethics.

What is a standard?

- Standards are requirements for action in a given topic area
  - Standards are benchmarks that *must be met*
  - Generally developed from consensus of experts in relevant field
- Guidelines often accompany standards
  - Guidelines are possible strategies for *meeting required standards*
  - Guidelines should generally be followed, but they are more flexible, since target audiences may know better ways to meet standards in their environment

Are standards really needed for RECs?

- Many ethical guidelines and documents already outline key required features of RECs (E.g., multidisciplinary, independent, review according to ethics)
  - Yet no *complete* set of standards in one international document
  - And no set of standards accompanied by concrete, operational guidance on how to meet them



- Of course, standards only one piece of complex puzzle to improve REC functioning globally, but it is the first piece, **that we hope will provide a benchmark**

The role of WHO in publishing standards

- Setting norms and standards is one of six core functions of WHO

THE WHO ADVANTAGE

  - Its convening power (to bring together experts from around the world)
  - its leadership status (Countries often adopt WHO standards as their own standards or use them as the basis for national laws and rules)

WHO Core Functions

Building on WHO's mandate and its comparative advantage, six core functions have been defined for the Organization.

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
3. Setting norms and standards, and promoting and monitoring their implementation;
4. Articulating ethical and evidence-based policy options;
5. Providing technical support, catalysing change, and building sustainable institutional capacity;
6. Monitoring the health situation and assessing health trends.

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The Process - 1

- Members of the November Meeting were invited to provide comments on the "Silver Book" and suggest modifications to it in light of the recent developments in the area or research ethics and role of RECs.
- Based on their comments, the "Ethics Group" at WHO from 4 different departments (TDR; HRP; ETH and RPC) worked together to produce the first draft of the document.
- Presented to the International Bioethics Congress (Singapore) and 8th Global Forum for National Bioethics Bodies
- Second draft of document submitted for review.

The Process -2

- Took cognizance that the document "Operational Guidelines… popularly called the "Silver Book" is recognized as a handy, easy to use, comprehensive invaluable resource in setting up Ethics Committees in more than 100 countries and that the second version of this document should stick as far as possible to the same style when updating it.

- Brainstormed on which functions of RECs could rightfully be 'elevated' to the level of Standards, and then grouped them based on who had responsibility for adhering to that standard.

- The guidance from the "Silver Book" was re-organized to fit under different Standards, such that each Standard was accompanied by guidance on how to 'operationalise' the Standard.

Important Differences

- Standards and Guidelines
- Focus on all types of RECs, and not only RECs that review biomedical research or clinical trials.
- Recognizes that many players involved in running an REC – need different standards for each
- Provides justification for each ethics consideration that should be reviewed by the REC
- Includes a new section on respect of human dignity and human rights.
- Includes guidance on community consideration

Many players involved in running an REC – need different standards for each

- National authorities (1 Standard)
- Entity establishing REC (5 Standards)
- The REC (2 Standards)
- Staff or Secretariat to REC (1 Standard)
- Researchers (1 Standard)

Standards for national authorities

- Legislative/regulatory framework
- Adequate RECs exist (national, subnational, or institutional level)
- System exists to monitor quality and effectiveness of RECs

Standards for entity establishing ERC

- Composition
- Resources
- Independence
- Training
- Transparency, accountability, and quality assurance

Standards for REC

- Decisions based on clear and consistent application of ethical principles articulated in international guidance documents and human rights instruments, as well as any national laws or policies consistent with those principles
- Committee deliberations are thorough and inclusive
- Possibility of expedited review for certain low-risk studies

Standards for REC Staff or Secretariat

- Written Standard Operating Procedures
- Maintenance of files and records in ways that are retrievable, accountable and confidential

Standards for Researchers

- Qualified to conduct the study
- Familiar with ethical standards
- Adhere to ethics review requirements

Comments

WHO would like to have a structured feedback from you on the draft document on

Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

What is Missing?

What is redundant?

Will it help national authorities, ethics committees in raising the standards?