Medische ethiek

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Research Ethics

Externally sponsored research in resource poor countries (LIC-MIC)

- International Ethical Guidance from the Council for International Organization of Medical Sciences (CIOMS)

WHO and Unesco founded CIOMS (1949)

Revised version of the CIOMS guidelines appeared in 2002 based on the Declaration of Helsinki

Nuremberg Code (1949) first code after WW II

All codes are born in scandal

- Nazi experiments
- Tuskegee Alabama 400 black men in a non-therapeutic study of the effects of untreated syphilis (1932-1972) long after a therapy (Penicilline) was available
- Milgram's study sustained no physical harm but they suffered shame and embarrassment for having behaved inhumanely toward their fellow human beings (1963)

Guidelines for research

- Individuals should consent to participate in studies and those who cannot give their consent need to be protected
- No harm for participants, minimize risks and maximize possible benefits
- Fairness in procedures for selecting participants

New Ethical Challenges for Biomedical Research in Resource-poor Countries

- Research increased in LIC and MIC
- Ethical principles formulated in industrialized countries requires careful consideration and adaptation
- HIV/AIDS, malaria, tuberculosis, ebola,… are most prevalent in LIC and MIC and their control requires local research
- Limited scientific tradition and infrastructure
- Countries with many untreated patients have become attractive partners for multinational clinical trials

Questions

- Is it not exploitative to conduct a clinical trial of a new product in a population that could not afford to buy it, making the benefits available only to the rich who lives elsewhere?
- How has the study affected the research participants, their communities or health care?
- Is their any agreement to make the new treatments available in the country concerned after termination of the study? If so, for how lang will the new treatment be available?

Ethical Review Committees

- Sufficient ressources, paying reviewers
- ERC independent of research team
- Review also during the research
- ERC can withdraw their approval and other sanctions
- ERC must report to the health authorities any serious noncompliance with ethical standards
- Providing public reassurance about the soudness of research
- Scientifically invalid research is unethical, it exposes research subjects to risks without possible benefits

The investigator should submit the research protocol for ethical and scientific review

- In the country of the sponsor
- To the health authorities of the host country and to a national or local ERC
- The investigator should also ensure that the proposed research is responsive to the health needs and priorities of the host country

Use of comparators

- “Best current method” is ethically preferred in (placebo) controlled clinical trials
- But there is more than one established “current” intervention and which one is superior?
- Maybe the “best” one is not available or too expensive
- CIOMS : “Established effective intervention”
- Use of placebos? Yes in some mild conditions e.g. baldness, mild elevation of cholesterol and blood pressure
- ERC-decision

Informed Consent I.C.

Individuals should consent to participate in studies and those who cannot give their consent need to be protected

- I.C. is a proces
- The use of a comprehensive language and information
- Translation in a local language
- Waiver of consent is a ERC-decision
- Cultural considerations
- Use of biological and genetic materials
- Use of medical records for research
- Incidental findings

I.C. is…

- A decision to participate in research
- Taken by a competent individual
- Who has received the necessary information
- Who has adequately understood the information
- Who, after considering the information, has arrived at a decision without having been subjected to coercion, inducement, or intimidation

I.C.

- The design and methods of placebo-controlled trials are often rather complicated to explain randomization, double blinding, equipoise and to assure full comprehension by the prospective research participants
- It has to be clear that a participant could be randomized to a placebo arm of the study
- Therapeutic Misconception!!!

Randomized Controlled Trial

New drug : Effective Treatment?

- Animal testing before human subjects
- Phase 0 : Pharmacokinetics : bioavailability and half-life of the drug
- Phase 1 : healthy volunteers : safety and tolerance, for cancer drugs, cancer patients
- Phase 2 : efficacy and side effects : therapeutic effect unknown
- Phase 3 : efficacy, effectiveness and safety : therapeutic effect?

Clinical Equipoise

Researchers can compare therapies when

- There is a honest uncertainty about which treatment is the best
- There is a honest professional disagreement among experts which treatment is best

- Research should be responsive to the health needs and priorities of the population or community
- Any product developed or knowledge generated from this research should be made reasonably available for the benefit of that population or community

Vulnerable populations

Vulnerable persons, children and pregnant women

- Vulnerability : those who are relatively or absolutely incapable of protecting their own interests because they may have insufficient
- Power
- Intelligence
- Education
- Resources
- Strength to protect these interests

Research with children

Not capable to give informed consent

- Necessary for research into diseases of childhood
- Necessary for clinical trials of drugs intended for children vaccines

Research with vulnerable populations is possible if

- The research question cannot be answered by research carried out with less vulnerable population (e.g. competent adults)
- The research must adress an issue that is relevant to the particular study population
- Permission to enroll the individual in research has been granted by the appropriate authority
- Refusal to participate in the research should be respected

Women

- Investigators, sponsors, or ethical review committees should not exclude women of reproductive age from biomedical research
- The potential to become pregnant is not a ground for exclusion
- Access to effective contraceptive methods is important


100


WRONG
RiGHT

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