Scientific Validity

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Why Scientific Validity?

- To be ethical, scientific research must be conducted in a methodologically rigorous manner
- Scientifically significant, good question + bad method and/or conduct = **invalid results**
- Invalid research is a waste of resources
- Exploits people

CIOMS

Scientifically unsound research on human subjects is unethical

...in that it may expose subjects to risk or inconvenience to no purpose

To be ethical

- Method must be valid
- Practically feasible
- A clear scientific objective
- Well designed, accepted principles
- Sufficiently powered – adequate numbers
- A plausible data analysis plan
- Must be executable

Equipoise and Research

- There must be a state of genuine uncertainty about the merits of a new treatment to be researched against the existing
- “there must be a honest null hypothesis”
- If the treatments are not equivalent, the better one must be offered
- Or else, one group will receive inferior treatment

Equipoise and Research

- Even in multi-arm trials there must not be an inferior intervention

Ethics of Placebo-Control

- First trial probably conducted in 1931
- Controversial area
- Is it justified even when there is an effective treatment?
- Available minimum treatment?
- Withholding an available treatment is unethical

Who should decide it is valid?

Is it the job of the Ethics Committee?

- Most Committees may not have the expertise

Should there be a Scientific Review Committee?

- Most institutions are too busy

A ‘Research Forum?’

- Researchers present their protocols

A preview?

- Address methodological issues at the time of application coming in

Ultimately.....

- The ERC must ensure the research is valid

What about alternative medicine?

- Safety of medicines
- Safety of the formulations?
- The medicines and formulations may have existed for thousands of years

Validity in multinational research

- Design must ensure that the results will be useful in the context of the developing country
- Data must be generalizable to the host community
- Design must not deny the benefits that participants are entitled to
- Must be feasible to deliver in the context of the host country

multinational research....

- The study must be feasible given the local environment

Exceptions

E.g.

- Antimalarial drug experiment in Indonesia
- About $80 per dose
- Probably for use by tourists
- Study cannot be done in another setting
- “Post-research benefits”

What should be done with proposals with problems?

- Reject?
- Can the ERC propose changes?

Example 1

- Student project
- Study of attitudes of A’ level students towards STDs
- 200 girls, 200 boys
- Questionnaires given to students chosen by teachers
- Questions about transmission if STDs etc.

Example 2

- Foreign market research company
- Proposal for ‘continuous prescription research’
- Objective: **to improve the health in Sri Lanka**
- Prescriptions to be written in duplicate
- Copy collected by researchers
- Data to be sold to drug industry
- Data collection started during review
- Claims of publications in home country