



Conceptual Problems in Research Ethics

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What good is medical research?

Medical research seeks to set the practice of medicine on a firmer scientific basis.

The development of safe and effective treatments depends on our ability to conduct medical research.

The knowledge that comes from medical research is an important public good.

This end may not be pursued legitimately by just any means.

Medical research must conform to high ethical as well as scientific standards.

What is owed to the study subject?

Physicians owe patients a duty of care, implying that patients must receive competent care.

Some deny that there is a duty of care in clinical research.

Structural inequalities between clinical researcher and subject imply it is a fiduciary relationship.

One of the fiduciary obligations is a duty of care according to which the researcher must act and advise in the best medical interests of the subject.

Clinical equipoise requires that treatments in a study are consistent with competent medical care.

When is research risk is acceptable?

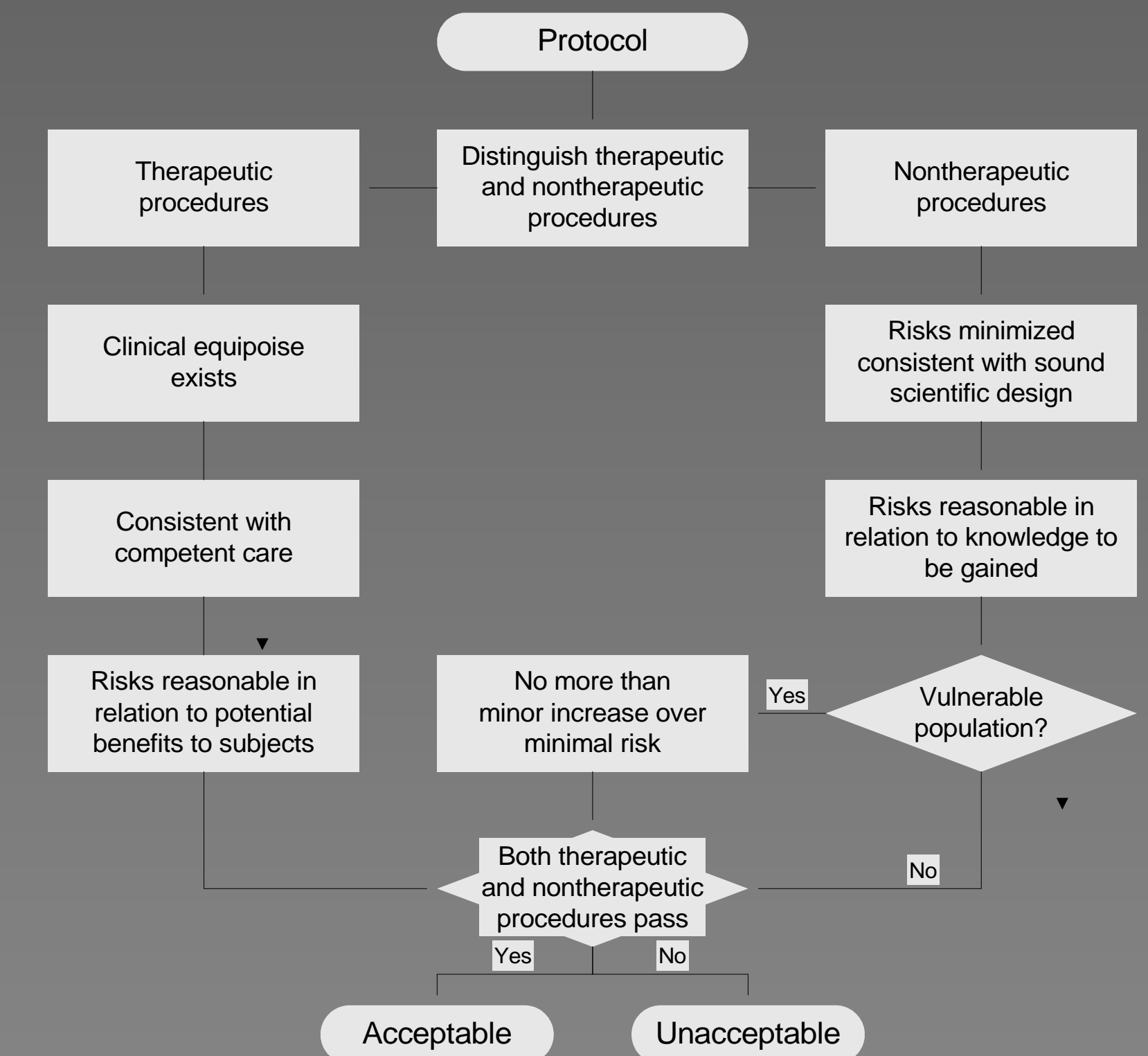
Component analysis is the only systematic approach to the ethical analysis of research benefits and harms.

Clinical research often contains a mixture of therapeutic and nontherapeutic procedures and these must be separated.

Therapeutic procedures must satisfy clinical equipoise.

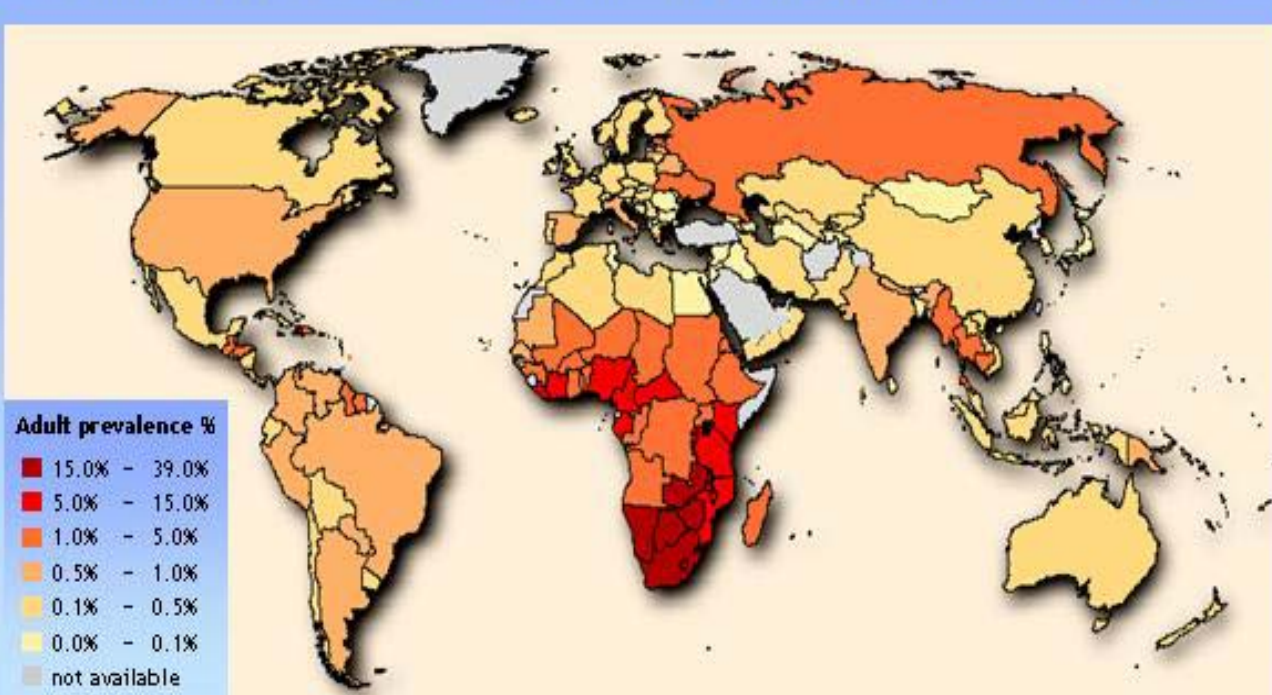
Nontherapeutic procedures must have risks (1) minimized consistent with sound scientific design and (2) that stand in reasonable relation to knowledge.

With a vulnerable population (children), nontherapeutic risks are limited to a minor increase above minimal risk.



HIV prevalence in adults, end 2003

38 million people [range: 35-42 million] living with HIV as of end 2003



How should we conduct research in developing countries?

Global health care resources are distributed unjustly.

Research must be responsive to local health needs and offer the prospect of improving local care.

To what should we compare new treatments? The best care available internationally or locally?

Clinical equipoise is consistent with the local care standard, even if this means no treatment or placebo.

Medical care of subjects is not disadvantaged by study participation, and such research is more responsive to the relevant health policy question.

How should we conduct research involving communities?

Protections focus on the individual research subject, but research may target an entire community.

Respect for communities requires that researchers take seriously the values and choices of the community and protect it from harm.

Calls for a community-researcher partnership with:

- Respect for community values and priorities
- Community consultation and consent
- Community involvement in the conduct of the research
- Negotiation regarding fate of data and samples
- Plan for disseminating research findings

