

DISCUSSION

Universality of care: a response

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Dr Asad Jamil Raja's essay (1) on the amendments to the Helsinki Declaration raises many significant issues. While I agree with the essence of his comments, I differ on certain issues.

Quoting three amended clauses in the revised Helsinki Declaration, Dr Raja indicates that they are problematic; they neither provide protection to participants nor enable essential research into affordable treatments for the poor. I believe that these amendments are not ambiguous, and that their straight-forward interpretation is protective of participants. Nor do they in any way impede serious research into affordable treatments; what they may do is discourage research which is not meant for application in the participants' community.

It is clear that there are great inequities in health care and health care delivery in the world. Therefore it is imperative that people are not exploited in the name of research. So, research in developing countries should not commence unless the researchers have ensured the availability of health systems to implement its findings, and have put in place guidelines for treatment for any given disease.

Clause 19 of the Helsinki Declaration states: "Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research." (2) I take Clause 19 to mean exactly what it states. Therefore I believe that if the results of a research project are unlikely to be implemented because the local community does not have the necessary systems with resources in place, the research itself should not be carried out; it should be deferred till those systems and finances are made available.

For example, 10 years of published and unpublished research in reproductive health in two provinces of Pakistan were reviewed recently. The studies used five different methods to look at indicators of well-being such as maternal mortality ratios. The study population's lifetime risk of maternal death was calculated. Both hospital- and community-based information was gathered. At the end of all this, the review concluded that despite a steady increase in research activities, there is no direct evidence that interventions such as improved treatment protocols, equipment, or training of personnel, were either developed or tested - or made any impact on maternal morbidity or mortality. (3) So what was all this research in aid of?

Clause 29 states: "The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists."

In the light of Clause 29, each developing nation needs to develop its own guidelines of what ought to be the treatment of any given disease. Even though this treatment may not be available in any or all institutions within the country, it should be the standard of care that researchers provide their research subjects. This would hold regardless of whether the research was funded locally or internationally. Unfortunately, such guidelines do not exist in most developing nations. Our priority should be to channel funds so that these guidelines are developed. The responsibility for this could be given to individual professional societies. Ethics Review Boards can seek the help of such societies for individual research grant applications where the standard of care is a major ethical concern. (4)

Clause 30 states that at the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study. To me, it is clear that assured access means exactly that: if a person cannot afford the treatment, it should be provided free. If treatment is to be given life long, then life long it is.

References:

1. Raja Asad Jamil. *Universality of care: slogan or reality? Issues in Medical Ethics* 2001; 9: 114-116.
2. World Medical Association Declaration of Helsinki: *Ethical principles for medical research involving human subjects*. Edinburgh, Scotland, October 2000.
3. Comment made by Ms Kausar S Khan at the Asia Pacific Conference on Reproductive Health, February 2001, quoting personal communication by the reviewers.
4. I would like to acknowledge the comments here of Dr. Adnan Ali Hyder Assistant Professor. Johns Hopkins University, USA.

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