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The Helsinki Declaration, 2000, and ethics of human research in developing countries
Bashir Mamdani

Lie RK, Emanuel E, Grady C, Wendler D.

The standard of care debate: the Declaration of Helsinki versus the international consensus opinion.

J Med Ethics 2004;30:190-3.

The revised Declaration of Helsinki, 2000 mandates that controls in a research trial receive the best care available anywhere and that participants get ongoing care after the conclusion of the study.

Lie et al. argue in favour of an alternative international consensus position which considers that it is ethically justifiable to conduct a trial in a developing country without providing the best worldwide standard of care, as long as: (i) there is a valid scientific reason and the treatment being evaluated is less costly or simpler; (ii) there is a clear social benefit for the developing country, and (iii) benefits outweigh the risks for the individual.

After stating that 'moral questions are not decided by which view gets the most votes', the authors do exactly that—they argue that the alternative position is better because it was arrived at independently by many international organisations such as the Council for International Organisations of Medical Sciences (CIOMS), National Bioethics Advisory Commission (NBAC) and the United Nations Programme on HIV/AIDS (UNAIDS), etc. Furthermore, all organisations included some representation from the developing world. Authors posit that the absence of any justification accompanying the Helsinki rules and the lack of transparency in how the rules were derived has robbed the Declaration of any moral authority and created controversy. They conclude with the statement, '...ethical guidelines should prohibit behaviours and practices that are clearly and incontrovertibly unethical, while recognising that there may be more than one ethically acceptable approach to a difficult issue. The fact that many...came to the same view, suggests that even if the position is not the optimal ethical standard, it is at least not clearly unethical.'

Schüklenk U. The standard of care debate: against the myth of an 'international consensus opinion'. *J Med Ethics 2004;30:194-7.*

Professor Schüklenk debunks the myth of a consensus opinion. He shows that the lower standards of care proposed by the consensus, mix economic with scientific reasons and are not necessarily accepted by the developing world.

Schüklenk characterises Lie's argument as a procedural matter: different groups in different countries reached the same conclusion, which is not the same as different groups together agreeing on a common position; the latter comes closer to an international consensus. He demonstrates that the consensus finding processes of these organisations were flawed in lack of '...transparent method of selection of participants, discussions and the utilisation of the input provided by professionals, representation from the target group and interested public.' In his opinion, these organisations do not constitute a real-world representation and only the World Health Organization (WHO) can satisfactorily play the role of an international organisation with sufficient standing to develop and promulgate ethical guidelines for research.

Commentary

In 1964, the World Medical Association (WMA) developed guidelines for ethical conduct of human research in what came to be known as the Helsinki Declaration (1). The declaration was modified in 1975, 1983, 1989 and 2000. Two areas of the 2000 Declaration evoked significant controversy: prohibition of placebo-controls and a requirement that controls receive the best care available anywhere. The concerns involving use of placebo were addressed in 2002 by modifying the language to provide for placebo-controlled arms in selected situations. Reservations persist about the need to provide the best available care anywhere to all participants.

The quality of care debate affects the patients who volunteer for studies, physicians who carry out research as well as the Government of India who must vet the protocols.

Applying the basic principles of medical ethics (autonomy, beneficence, non-maleficence and distributive justice) to this controversy, only distributive justice may be invoked to argue for the best care available for patients volunteering for an international trial. This raises several questions.

What do we mean by standard of care? It is assumed to mean drugs, investigations, doctors and hospitals. However, care is more than that-clean water, adequate food, sanitary living space, and an infrastructure that allows people to travel in a timely manner to get the care that they need. How are we going to assure equality between USA and Uganda in all aspects of care? It will be hard to assure the same 'care' even within one country, let alone across the world.

The next question is: Should distributive justice be invoked across international borders or should it apply only within the borders of the country where the research is to be carried out? Some may argue that if the organisation initiating research is in one country and the research is carried out in another country, then the principle of distributive justice should consider the populations of the two countries as one and insist that whatever is being offered to the research participants in the initiating country should be offered to the participants in the other country. Even in this scenario, if one limits care merely to provision of drugs, there are problems. Many of the drugs, such as drugs against HIV, require sophisticated laboratory tests that may be expensive and technically beyond the ability of the recipient country; in addition, well-staffed hospitals are needed to deal with the side-effects or complications of treatment. Should the research organisation be then required to staff and maintain a laboratory and hospital permanently in that country? Distributive justice also requires that patients in a given country get similar care; by setting up special centres where participants in a research trial get far superior care to that afforded to patients with the same disease elsewhere, are we not compromising that principle?

In the US, research participants are assured that all expenses of the trial (travel expense, office visits, investigations, drugs, etc.) are borne by the research organisation and if the drug being tested proves beneficial, it is provided free to the participants as long as they need it. In reality this free period has proven to be of short duration as once the drug receives approval by the Food and Drug Administration (FDA), medical insurance and government programmes pick up the tab. The situation is different in most third world countries which do not have either medical insurance or government-sponsored health care for its population. In this case, either the research organisation commits to providing lifelong treatment to the participants or the government of the country defrays the costs.

The philosophy and moral underpinning of the Helsinki Declaration, 2000 are obvious. The intent is clearly to protect vulnerable populations, be it against the predatory practices of multinational pharmaceutical corporations or the corrupt governments of developing countries. Yet, medical care in most African countries is so poor that there is no dearth of volunteers for drug trials in sub-Saharan Africa because, for most, that is the only mechanism to get any treatment. This abject vulnerability can be and will be exploited unless strong international measures are in place to protect the subjects.

The debate pits idealism against pragmatism. Economic considerations should not be paramount but neither can one proceed as if they do not exist. If the research requirements are made too stringent and economically unattractive, then few will conduct research trials in the Third world, particularly for diseases that do not affect a large segment of the western population. This will hurt the people of the third world more than those in western countries as Third world governments have neither the financial resources nor the will to pursue vigorous scientific research even for problems unique to their environment. The Helsinki Declaration sets a level of care, Schüklenk argues for the spirit of Helsinki: that research participants are protected from exploitation.

It is more important to address the shortcomings in WMA as well as the consensus approach as detailed by Lie et al. and Schüklenk. The World Medical Association is made up of representatives from national medical associations of 82 countries with eight million physicians. While the participation of physicians in developing international guidelines for human research is crucial, it leaves out large segments of international society with a major stake in research ethics. What is needed is an international body with broad representation to develop internationally applicable guidelines, a mechanism for ongoing review of multinational research (particularly when such research is being conducted in a developing country without adequate intellectual and material resources to monitor such research), and a mechanism to implement corrective measures where needed. As both Lie and Schüklenk have pointed out, WMA cannot provide the necessary structure and oversight. Only WHO fits the bill.

Reference

1. Available from URL:<http://www.wma.net/e/policy/b3.htm>(accessed on June 18, 2004).

BASHIR MAMDANI, 811, N. Oak Park Avenue, Oak Park, Illinois 60302, USA. e-mail:bmamdani@comcast.net