

Justice as Equitable Power Relations: Beyond the "Standard of Care" Debate and the Declaration of Helsinki

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The proper negative aim of equalitarian justice is not to eliminate the impact of brute bad luck from human affairs, but to end oppression, which by definition is socially imposed. Its proper positive aim is not to ensure that everyone gets what they morally deserve, but to create a community in which people stand in relations of equality to others. (Anderson 1999, 288-9)

In a recent edition of *The Lancet*, Lewis et al. drew attention to section 29 of the revised Declaration of Helsinki. They pointed out that section 29 is laudable in its purpose of preventing the exploitation of research subjects in the developing world. They suggest, however, that "section 29 also seems to rule out some vital uses of placebo-controlled trials in areas of medicine in which proven prophylactic, diagnostic or therapeutic methods already exist" (Lewis et al. 2002). My purpose is not to refute the arguments put forward by Lewis et al. Rather, it is to suggest that section 29, while going some way to protect research subjects from exploitation, is not backed up with a description of the kinds of processes that might ensure that such exploitation does not in fact take place.

There has been much controversy concerning standards of treatment and the care of research subjects in the developing world. Most notably the vertical transmission trials of AZT that used placebo (Lurie and Wolfe 1997), and research into the efficacy of early intervention AZT that took place in the Rakai district of Uganda that left those with HIV untreated, provoked heated debate (Angell 2000).

Much of this discussion has revolved around whether or not local standards of care or the best-known standards should be used. This is of particular importance as HIV preventive clinical trials on negative subjects are about to begin in many third world countries. In the developed world, those who contract HIV will have recourse to combination therapy. In many countries, particularly in sub-Saharan Africa, subjects have no access to such treatment, and HIV is therefore a death sentence.

I would like to suggest, however, that the debate about standards of care has been badly formulated, and that several different accounts of justice are in conflict. Most notably, justice as reciprocity, whereby those who participate receive a share of the profits, and subject centred justice, whereby all persons are entitled to receive the best possible care based upon the concept of human rights are often in conflict. In the first case, commentators have argued that trials that use local standards of care are ethi-

cal as long as research subjects (or their communities) receive a share of the profits through affordable drugs or vaccines.

The second view is usually used to defend the use of the "best possible standard" – currently spelled out in section 29 – on the basis of justice being equated with a fair redistribution of goods. Therefore, wealthy institutions, such as drug companies must ensure that subjects are treated fairly, according to the standards that would be practiced in their home country, whereby the potential profits that they may gain are recompensed with a reasonable standard of care for those taking part in research they sponsor. While it seems undeniable that this is an improvement on relying on the "local standard" it leaves several problems untouched. Among these are issues relating to corruption and lack of transparency in many developing countries, the potential for misunderstanding of the processes that are involved that might undermine proper informed consent and the problems that occur *within* communities, where various types of discrimination may occur (Castillo 2002).

A third view of justice therefore merits careful consideration. This view is predicated upon justice not as an equal distribution of goods, but as equitable power relations through which fair and culturally appropriate agreements can be formulated. In order for this to come about, researchers would have to enter much more fully into the world of potential subjects, uncovering the kinds of unjust power relations that beset their communities and trying to negotiate with the subjects themselves. This would overturn the current practice, which relies upon negotiating with representatives who may not adequately stand for their interests.

Several recent developments reinforce the importance of rethinking the process through which negotiation of such issues as informed consent, the meaning of autonomy and recruitment of trial subjects takes place, as well as the relevance of guidelines such as those devised by UNAIDS, CIOMS and the Declaration of Helsinki. In a recent article, Ruth Chadwick and Udo Schuklenk stated that

One of us had the opportunity of asking about 120 delegates of the 2nd Asia-Pacific Bioethics Conference in Manila whether they had come across the purportedly widely known and widely distributed CIOMS draft of revisions to its ethics guidelines. Not a single delegate from developing Asian nations such as Sri Lanka, Bangladesh, Pakistan, India, the PR of China and others was

aware of this consultation. (Chadwick and Schuklenk 2002)

Apart from concerns that those most directly affected are insufficiently consulted in the drafting of international guidelines, there are other issues that cause some disquiet in relation to international clinical research. One of these is the issue of corruption that occurs on a national and local level in many developing countries. One commentator suggested recently that corruption "thrived in environments of poor governance, and were exacerbated by poverty." The same researcher also stated that people were appointed to review boards for reasons unrelated to skill or experience.¹

It seems then that the lack of political and economic rights that exist in many countries intensify the common ethical problems that beset clinical research. This is particularly important if we consider the difficult relationship between vulnerable populations – in this case those who already live in desperate circumstances – and informed consent (Zion, Gillam and Loff 2000). Apart from the concerns that arise from profound cultural differences between researchers and their subjects, there are also problems that relate to equating autonomy with rationality, rather than with having basic freedoms that underpin the possibility of making meaningful choices. It is important to note that it is not poverty alone that limits such freedoms. Douglas Wassenaar and colleagues recently suggested that in South Africa women's experiences of autonomous consent are likely to be "severely compromised," owing to cultural constraints, although it is these same women who will be candidates for HIV preventative trials (Slack et al. 2000). They rightly call for a process that relies on the "emancipatory informed and sensitive social-scientific research and action...built on the voices of women" (Slack et al. 2000).

If proper negotiation, and empowerment of research subjects took place, the advantages would go far beyond drug development, and leave ongoing social and health benefits for local communities. It would also mean those issues of exploitation and manipulation could be uncovered more easily, and persons who are easily exploitable could receive aid and assistance, rather than necessarily engage in a clinical trial (Edejer 1999).

In order to achieve these ends, investigators would have to develop a more interactive and sophisticated process of information exchange and informed consent-one that takes into account the lack of transparency, cultural diversity within communities and between researchers and subjects, and problems of corruption. Fundamental to realising this end properly funded and ongoing social research – particularly follow up studies-would have a vital part to play in clinical trials in the developing world.☺

Notes

1. This issue was raised by Donna Knapp van Bogaert and reported by Bebe Loff. See, B. Loff. 2002. Africans discuss ethics of biomedical research. *The Lancet* 359:956. See also, F. Luna. 1999. Corruption and research. *Bioethics* 13(3/4): 262-271.

References

- Anderson, E. 1999. What is the point of equality? *Ethics* 109(2): 287-337.
- Angell, M. 2000. Investigator's responsibilities for human subjects in developing countries. *New England Journal of Medicine* 342(13): 967-969.
- Castillo, F. A. 2002. Limiting factors impacting on voluntary first person informed consent in the Philippines. *Developing World Bioethics* 2(1): 21-27.
- Chadwick, R., and U. Schuklenk. 2002. The politics of ethical consensus finding. *Bioethics* 16(2): 3-5.
- Edejer, T. T. 1999. North-south research partnerships: The ethics of carrying out research in developing countries. *British Medical Journal* 319(7207): 438-441.
- Lewis, J. A., B. Jonsson, G. Kreutz et al. 2002. Placebo-controlled trials and the Declaration of Helsinki. *The Lancet* 359(9314): 1337.
- Lurie, P., and S. Wolfe. 1997. Unethical trials of interventions to reduce perinatal transmission of the Human Immunodeficiency Virus in developing countries. *New England Journal of Medicine* 337(12): 853-855.
- Slack, C., G. Lindegger, E. Vardas et al. 2000. Ethical issues in HIV vaccine trials in South Africa. *South African Journal of Science* 96:291-5.
- Zion, D., L. Gillam, and B. Loff. 2000. The Declaration of Helsinki, CIOMS and the ethics of research on vulnerable populations. *Nature Medicine* 6(6): 615-617.