Guest editorial

Imperialism, research ethics and global health

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The ongoing debate on the ethics of studies involving rich and poor countries¹⁻⁴ is to be welcomed, for several overlapping reasons: first, to develop a deeper understanding of the complexity of the issues under consideration; second to examine more broadly the concept of imperialism in this context, and third, to seek to improve global health through processes that go beyond simplistic band-aid or self-serving approaches.

It is widely recognised (although perhaps less openly acknowledged than is desirable) that research, even under the best of circumstances, is potentially exploitative.⁵ Because “powerful researchers” (individuals and corporations) usually have more to gain than any single research participant, much effort over recent decades has gone into designing protection for research subjects. That most of this protection lies at the level of requirements for the design and review of research protocols and very little at the level of what actually happens in the conduct of research reflects some or all of the following: (i) acceptance that researchers will do what they say they will do; (ii) a willingness to believe that informed consent in practice meets up to its moral rather than its legal requirements, or to ignore that it does not; (iii) confidence that conflicts of interest can be eliminated, and (iv) that the desire to achieve protection may have a lower priority than the pursuit of knowledge. These shortcomings of the protection process allow potentially exploitative research to continue even within perfectly designed and ethically approved studies. Seen against this background Angell’s powerfully expressed concern for preventing exploitation is admirable.²

However, her critique of the HIV transmission studies under question is diminished in at least two ways, first by stating that the Declaration of Helsinki “requires [my italics] control groups to receive the ‘best’ current treatment...”. The precise wording of the declaration is: “The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best proven diagnostic and therapeutic

method,” and: “In any medical study, every patient - including those of a control group, if any - should be assured of the *best proven* diagnostic and therapeutic method” [my italics]. For the studies referred to, the requirement to weigh benefits and hazards demands that attention be given to whether the AZT regimen was necessarily the *best proven method* for a population of women and infants differing from those studied in France and the US, and living in a context where, for economic and logistic reasons the goals of treatment may have to be less ambitious. In particular it is necessary to question whether preventing breast feeding as part of the research protocol is justifiable in Africa, given the direct risks for infants in such an environment and the indirect risks from the possibility of an early next pregnancy. It seems somewhat imperialistic to presume that a *drug regimen* shown to be of value in some of the wealthiest countries in the world is necessarily the *best proven regimen* for some of the poorest. While it may be, it may also not be. Reasons provided for designing studies to produce most efficiently results more directly relevant to the local situation⁴ indicate that a greater degree of complexity in planning and executing such research is required than is acknowledged by Angell.

Second, by drawing an analogy with the Tuskegee experiments, Angell minimises the deception, maleficence, paternalism, lack of accountability, racism, and crass exploitation demonstrated by the researchers and those colleagues who knew, but remained silent, about the study. Lurie and Wolfe also draw some implausible analogies.¹ The syphilis experiment in the US, following in the wake of the Nuremberg trials and promulgation of the Nuremberg Code, surely cannot be trivialised by comparing it with a study that had been discussed, reviewed and accepted by national and international groups (which included thoughtful bioethicists) or with attempts to diminish exploitation by involving in-country health workers in the design of studies. While these procedures may not totally eliminate exploitation, they are nevertheless

aspects that have been underplayed by Angell. Ethical dilemmas, by their very nature, are often not amenable to solutions which can be shown to be unequivocally substantively correct, hence the importance of appropriate and accountable procedural mechanisms for making ethical decisions. The Tuskegee study did not remotely approach the level of ethical awareness or procedural probity associated with the HIV transmission studies.

It is also necessary to be critical of simple assertions about what is ethical, especially when these are inconsistent with the actions of the protagonist. For example a recent *Lancet* editorial took a strong and somewhat dogmatic stand against the placebo-controlled HIV transmission studies,⁶ having two weeks previously published a randomised placebo control trial on elderly patients with isolated systolic hypertension⁷ - despite the fact that by 1991 it had been established that the standard treatment for such patients was diuretics.⁸ Such inconsistency undermines credibility.

However, much more important issues are at stake. A recent publication from the Institute of Medicine stated that: "America has a *vital and direct* stake in the health of people *around the globe*, and this interest derives from both America's long and enduring tradition of humanitarian concern and compelling reasons of enlightened self-interest" [my italics].⁹ The balance of these concerns is reflected in the priorities given to expenditure in the US: 15% of Gross National Product (GNP) on health care in the US (\$3,500 per American per year), 4% of GNP on the military (more than any other nation) and 0.1% of GNP on foreign assistance (less than all OECD countries - of which Denmark is the largest donor at 0.97% of GNP and Italy the second smallest at 0.14% of GNP). In a poll conducted in January 1995 by the Program on International Policy Attitudes at Maryland University, the median level of proposed foreign aid by those polled was 15 times greater than the amount actually spent.⁹ This reveals the gap between concern expressed for the wellbeing of distant others and its translation into practice. The clear need for new approaches to foreign aid and global health is emphasised by the fact that 50% of the world's population live on less than \$350 per person per year, for reasons not insignificantly related to the exploitative economic and political policies of powerful nations.^{10 11}

Seen in this context Angell's concern about exploitation is thus of great importance. It draws attention to the need for concern about exploitation in medical research to be seen in the context of the exploitative milieu in which modern medicine is practised.⁵ Careful examination of the powerful

economic and political forces which increasingly polarise people into poor and rich, within and between nations, reveals (i) the extent to which privileged people worldwide take their standard of life and their desire for continuous economic growth for granted (regardless of the cost to others) and (ii) how they are unwittingly co-opted into exploitative and often imperialistic processes.¹³ While such imperialism differs markedly from imperialism in the age of empire it retains a supremacist component.¹¹ In a globalising world understanding these issues is crucial to addressing the concept of national and global health - regardless of location or wealth. Because much of the record of aid to poor countries is tainted by exploitation, as powerfully illustrated by Hancock and others,¹⁴ Angell is lauded for expressing great concern for patients in distant and poor countries, and for striving to prevent even benevolent aid efforts in medical research from becoming thinly disguised forms of exploitation. Her concern, if redirected to broader efforts to reshape public opinion and political will in rich nations, could have profoundly beneficial effects on global health.

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