CORRESPONDENCE

Research in the developing world

There is a growing concern about the potentially exploitative nature of research in developing countries, conducted by researchers from the developed world (1). Some of this research would not be possible in developed countries.

Externally funded research in developing countries has been justified on the grounds that it will benefit the health of people in these countries, changing global inequities in health. At present, there is only one physician for every 100,000 people in Burundi compared to 607 in Italy (2). More than 90 per cent of one-year-olds are immunized against measles in Australia, Sweden and the USA compared to 49%, 67% and 77% in Sudan, India and Bangladesh respectively (2) Research can change this, it is argued.

However, what are the real reasons for global inequalities in access to education, employment, clean water and health care? There is a need to address the underlying reasons for the ever-widening gap between those who have and those who don't. Just 10% of annual health research expenses address 90% of the global burden of disease, mostly in developing countries (3). This needs correction with more money going for research on health problems of the developing world. Is this happening through externally funded research?

Some ethical issues

Some argue for different standards of care for research subjects in the developing and the developed world (4) They suggest that in any case there are low standards of care in developing countries, and these countries do not have the resources to provide international standards of care. They also justify lower standards of care with the argument that the research will have indirect benefits for the subjects.

Researchers from the developed world can help improve the health of deprived populations in other ways. The standard of care for research subjects must be the same in the developing and the developed world. Permitting the 'best local care' gives an incentive for research to be conducted in developing countries in order to save costs. Further, interventions found effective should be made available to research subjects after the trial is completed.

In Nigeria, a multinational company tested an antibiotic in the middle of a meningitis epidemic without participants' informed consent (5). One might argue that subjects are protected from exploitation as research projects will undergo ethical review by local Institutional Review Boards (IRB). However, there are many instances of ethical review boards permitting unethical research. For example, in Kerala, India, an experimental anti-cancer drug was tested illegally but with the approval of the local IRB (6). IRBs must be made accountable. The appointment of IRB members and functioning of IRBs must be transparent, credible and fair.

'Informed consent' is often obtained in an unsatisfactory manner during research in the developing world (7). Informed consent should be obtained by an independent third party, in order to ensure that it is informed and free from coercion. Potential subjects should be given all the relevant information, in a clear manner and in their own language. There is no reason to assume that non-literate research subjects in developing countries are unable to understand the elements of informed consent.

Researchers must inform the IRB of any conflicts of interest. These should also be explained to research subjects who should be aware that they are free to refuse participation in the study. Finally, it should be mandatory to consider conflicts of interest of IRB members who may have a vested interest in the research project.

Research in developing countries should be based on core ethical principles of equality and respect for the rights of research subjects.

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Who participates in clinical trials?

It has been more than 70 years since the US Public Health Service started documenting the effects of syphilis on 399 human test subjects -- all of them black, all of them poor and most of them illiterate. None of them were informed that they were infected with syphilis, nor were they told the real purpose behind the experiment (1). The world has been aware of the horrible truth of Tuskegee since 1972. Since then we have come a long way in terms of monitoring of clinical trials and observing ethical guidelines for experiments on human subjects.

Still, innumerable trials are done, especially by pharmaceutical industries and commercial research organisations that do not follow ethical norms. Often, participants are not fully informed of the risks involved, while the benefits are over-stated. These are examples of ethical misconduct.