Implications of socio-cultural contexts for the ethics of clinical trials.
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Abstract

Health technology assessment (HTA) requires scientifically rigorous experimentation involving patients as subjects. HTA itself is required so that treatment given to patients will be both effective and efficient; this requirement is itself ethical in nature. At the same time it is essential that the methods used in HTA are ethically sound. Most healthcare researchers agree that the most effective
This occurs precisely because the implications of these measures are context-dependent. Research in a number of settings has shown that improved education and employment cannot be assumed to lead to greater empowerment for women. For instance, when male unemployment is high, working to increase female employment may elicit reactions of anger and violence against women. In fact, in many of the societies where such practices are performed, people live in disastrous conditions of poverty and socio-economic deprivation. We actually have little experience with the process of eliciting priorities from groups of people whose voices have traditionally been muted. In their absence, local community and cultural contexts may influence consent processes.

Ethical considerations for clinical trials on medicinal products conducted with minors: Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. Revision 1, 18 September 2017. European Commission.

The methods used were adapted from systematic reviews in medicine. Systematic searches of Medline, Psychlit and Sociofile CD-ROM databases; hand-searches of the major journals in general medicine and surgery, medical ethics and philosophy; and searches of books were carried out. The literature survey was restricted to articles published or abstracted in English. A database of the most relevant and useful materials was compiled, and is accessible on the Internet (http://www.liv.ac.uk/sdthomps/page1.html).

The randomised controlled trial (RCT) is the key to the ethics of medical research, both in most theories and in all codes of research conduct. Many RCTs therefore risk being unethical in practice, even if ethical in principle. To survey the main objections to the RCT and its alternatives. To assess the philosophical and methodological basis of these objections, and of the methods recommended for addressing them. To identify areas where objections are founded in social or cultural factors normally overlooked in ethical argument about the RCT methodology. To identify alternative arguments or methods which might resolve ethical conflicts in this area.

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