

Executive summary

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

Richard E Ashcroft¹
David W Chadwick²
Stephen RL Clark³
Richard HT Edwards⁴
Lucy Frith⁵
Jane L Hutton⁶

¹ Centre for Ethics in Medicine, University of Bristol

² Department of Neurology, University of Liverpool

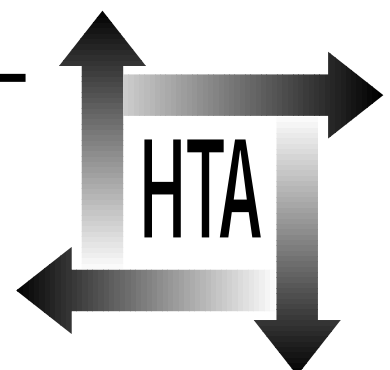
³ Department of Philosophy, University of Liverpool

⁴ Department of Medicine, University of Liverpool

⁵ Department of Primary Care, University of Liverpool

⁶ Department of Statistics, University of Newcastle, Newcastle-upon-Tyne

Health Technology Assessment
NHS R&D HTA Programme





Executive summary

Background

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 and soundest method for assessing treatments is the randomised controlled trial (RCT). However, some researchers believe that the RCT is unethical, either in essence, or for use in some forms of medical research and HTA. Furthermore, many patients seem unable to understand the principles and purposes of the RCT, a factor which is highly detrimental for the validity of informed consent. Informed consent 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.

Aim of report

- 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.

How the research was conducted

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>).

Research findings

Understanding RCTs and their alternatives

There is some evidence of difficulty in understanding the aims and methods of RCTs, and some disquiet about elements of the RCT methodologies. These objections are well known and much discussed, and concern the use of placebo, the continuation of trials after significant differentials in benefit or harm are apparent, and randomisation.

Cultural or religious objections

There was an absence of evidence of cultural or religious objections to randomisation, placebo or other kinds of controlled prospective trials. This most likely reflects an absence of research rather than absence of objections.

Informed consent

No group had explicit objections to personal informed consent. However, there is evidence for cultural variation in the desire for information in the consent process, the degree of paternalism or authority vested in the doctor by different groups, and the role of family and others in the consent process particularly when proxy consent is required.

Ethical framework of the RCT

The ethical frameworks used for discussing the ethics of the RCT are almost exclusively the liberal-individualist rights-based approach and the related so-called "principlist" approach (based on the four principles of beneficence, non-maleficence, autonomy and justice). Alternative constructions of the foundations of the RCT ethics are possible. In most cases the practical conclusions remain the same, except in two main ways. It is possible to argue for

a collective and duty-based ethics of the RCT. This risks paternalism and worse, but has the advantage of amplifying the role played by membership of a family, or a community or society, in individual autonomy. It is also possible to expand on the liberalism of the current approach, and argue that while values may be so diverse that consensus is impossible, socially we may all agree that the RCT satisfies most people's preferences most of the time, and so is just, if imperfect. Consequently, cases where this broad principle of preference-satisfaction fails should command particular research and discussion in future. This is of special relevance to the functioning of Local (and other) Research Ethics Committees.

Conclusion

The RCT is in most respects the most effective and fairest method in HTA.

Recommendations

Each recommendation is relevant especially to some group in the healthcare sector: after each recommendation the target group is given in parentheses.

- Attention should be paid by research ethics committees to the needs and values of the major religious traditions active in their area, preferably by direct representation, or at least by recognising representatives of these traditions as experts from whom advice may be sought. (Research ethics committees, area health authorities.)
- Where possible, research programmes involving clinical trials should avoid focusing on certain socio-economic groups, unless there is a clear

rationale for doing so. (Funders, trialists, ethics committees.)

- Experimental methodology should be well suited to the nature of the scientific question under consideration, rather than chosen on "philosophical" grounds. (Funders, trialists, ethics committees.)
- Further qualitative research is needed into the medical ethics of particular religious traditions, in particular Islam and other religious traditions of the Indian subcontinent. (Funders, sociologists.)
- A shift in research emphasis away from ethics from the professional viewpoint and towards lay points of view is needed. (Ethicists.)
- The connection between RCTs (and HTA) and resource allocation and justice in health care requires further research. This is already important in the USA and will become increasingly important in the UK as Health Service reform continues, and as evidence-based medicine becomes more widespread. (Ethicists, policy makers.)
- Ethical issues in non-RCT research and HTA should be addressed. This is important in areas where either the RCT is widely criticised (e.g. surgery, vaccines trials) or where the ethical utility of the consent test is generally unsatisfactory (e.g. perinatology, emergency medicine). (Ethicists, methodologists.)

Publication

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NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health.

Series Editors: Andrew Stevens, Ruairidh Milne and Ken Stein
Assistant Editor: Jane Robertson

Copies of this report can be obtained from:

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 1703 595 639 Email: hta@soton.ac.uk
<http://www.soton.ac.uk/~hta>

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