Do preferences act as an effect modifier?

Introduction

The aim of the 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. Health technology assessment forms the single largest portfolio of work within the NHS Research and Development Programme and each year some 40 new studies are funded to help answer questions of direct importance to the NHS. These studies, which include both primary and secondary research, cost about £5 million a year.

Within the HTA programme, it is extremely important that resources are applied to areas where the returns will be of greatest benefit to both patients and the NHS. The process of identifying and prioritising research questions is therefore crucial and one of the key roles of the Standing Group on Health Technology is to advise on national priorities for health technology assessment. "Do preferences act as an effect modifier" has been identified as such a priority for assessment and outline project proposals are now invited. These will be considered by the HTA Commissioning Board at its meeting in **April 1999**. If they are acceptable, investigators will be given a minimum of eight weeks to submit a full proposal.

Title

Do patients' and practitioners' preferences act as an effect modifier in clinical trials?

The topic

A better understanding of preference is fundamental to accurate interpretation of effect size in evaluative research.

The impact of preference on the design and conduct of randomised controlled trials is clearest where strong patient preferences make it impossible to obtain consent for randomisation. Where preferences are less strong, randomisation may go ahead despite the lack of complete equipoise, and the potential for interaction between preference and treatment effects arises. As there is evidence that slightly more people participate in RCTs out of self interest than for altruistic reasons, it is possible that preference may have had an effect in many RCTs. Furthermore, patient preference is bound together with practitioner preference in ways that are not yet clear. It is therefore necessary to investigate the nature and size of subtle preference effects, including the interactions between patients and practitioners, and to consider the value of methodological approaches to controlling for them.

Methods

Methodological research is required, using a variety of complementary methods. Researchers are invited to justify the methods they propose to use to:

- Explore the meaning of "preference" as it applies to different stakeholders in research (patient, practitioner, researcher), how such preferences arise and how they can best be measured. This will require conceptual and qualitative research.
- Investigate the effects of patient preference bias in different circumstances which may influence the nature and importance of preference effects. For example, where the technology is/is not

widely diffused, or where blinding is not feasible (making the evaluation more prone to preference effects).

The HTA Programme has already commissioned research in related areas: *Comparing the use of randomised controlled trial designs with quasi-experimental studies for assessing health technologies* (93/45)*; Methods to assess and use the non-specific aspects of care ("placebo effects")* (94/34)*; Factors that limit the quality, number and progress of RCTs* (93/43); *Systematic reviews of randomised controlled trials and observational methods* (93/45) and *Implications of socio-cultural contexts for the ethics of randomised controlled trials* (93/41). Applicants should build on the conclusions of this once it has reported. (Up-to-date information on progress with all HTA reports can be obtained from the HTA programme's web site at www.soton.ac.uk/~hta).

Applicants should demonstrate knowledge of both current research in the field as well as systematic review methods where these would apply to the question posed. Valid and reliable methods should be proposed for identifying and selecting relevant material, for assessing its quality and synthesising the results. Guidance on choice of appropriate methods is contained in NHS CRD Report 4 "*Undertaking systematic reviews of research or effectiveness*" (which can be accessed from their website: http://www.york.ac.uk/inst/crd/report4.htm). If applicants consider these methods inappropriate for this piece of research, they should justify their opinion. Reviews should summarise the evidence and highlight areas for further research. Where policy implications are considered, the emphasis should be on assessing the likely effects of a range of policy options open to decision makers rather than a judgement on any single strategy.

In order to inform decisions on whether and when to update this work, researchers will be expected to give some indication of how fast the evidence base is changing in the field concerned, based on the nature and volume of ongoing work known at the time the review is completed. Applicants should note that they will not be expected to carry out updating as part of the contract to complete the review.

Communication of the results of research to decision makers in the NHS is central to the HTA Programme. Applicants will be required to communicate their work through peer reviewed journals and may also be asked to support the NCCHTA in further efforts to ensure that results are readily available to all relevant parties in the NHS. Where findings demonstrate continuing uncertainty, these should be highlighted as areas for further research.

Timescale

There are no fixed limits on the duration of projects or funding and proposals should be tailored to fully address the problem. At the same time, there is a pressing need within the NHS for the information and so the research would normally be expected to be completed within 2 years.

What to do now

Submit an outline proposal to the Commissioning Manager at the National Coordinating Centre for Health Technology Assessment, Mailpoint 728 Boldrewood, University of Southampton, SOUTHAMPTON SO16 7PX by **12th February 1999**.

Applications received after 1700 hours on the due date will not be considered.