Intra-Uterine Systems Containing Levonorgestrel in the Treatment of Menorraghia

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. Questions are identified and prioritised to meet the needs of the NHS and its patients. Health technology assessment forms the largest portfolio of work in the NHS Research and Development Programme and each year about forty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include primary and secondary research and cost about £10 million a year.

Question

What is the cost-effectiveness of intra-uterine systems containing levonorgestrel (Mirena) in the treatment of menorraghia?

1. ***Technology:*** Intra-uterine systems containing levonorgestrel
2. ***Design:*** Long-term randomised trial (randomisation occurs in primary care)
3. ***Patient group:*** Women experiencing Menorraghia
4. ***Setting:*** Primary care setting (before referral onto secondary care)
5. ***Control or comparator treatment:*** Standard medical treatment within general practice based upon NICE and RCOG guidelines using tranexamic acid, northisterone or, mefenamic acid
6. ***Primary outcomes:*** Patient satisfaction, safety, mortality, morbidity, rates of surgical intervention, referral rates to secondary care
7. ***Minimum duration of follow-up:*** 24 months
8. ***Is the research question concerned with a licensed or unlicensed indication for the drug in question?*** Licensed

For many of the questions posed by the HTA programme, a randomised controlled trial is likely to be the most appropriate method of providing an answer. However, there may be practical or ethical reasons why this might not be possible. Applicants proposing other research methods are invited to justify these choices.

When appropriate, applicants should take note of the Medical Research Council's Good Clinical Practice guidelines (www.mrc.ac.uk/clinical_trials/ctg.html) when planning how studies, particularly RCTs, will be supervised. Further advice specific to each topic will be given by the HTA programme at full proposal and contract stages.

Making an application

If you wish to submit an outline proposal on this topic, complete the electronic application form and return it to the Commissioning Manager at the National Coordinating Centre for Health Technology Assessment, Mailpoint 728 Boldrewood, University of Southampton, Southampton SO16 7PX by 18 July,2002. Outline applications will be considered by the HTA Commissioning Board at its meeting in October, 2002. If they are acceptable, investigators will be given a minimum of eight weeks to submit a full proposal.

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

Guidance on applications

Required expertise

HTA is a multidisciplinary enterprise. It needs to draw on the expertise and knowledge of clinicians and of those trained in health service research methodologies such as health economics, medical statistics, study design and qualitative approaches. Applicants will need to show a commitment to team working and may wish to consider a collaborative approach between several institutions. It is expected that the research will be undertaken only following a thorough literature review.

Outcomes

Wherever possible, the results of HTA should provide information about the effectiveness and cost-effectiveness of care provided in its usual clinical setting and for the diverse subjects who would be eligible for the interventions under study. The endpoints of interest will in most cases include disease specific measures, health related quality of life and costs (directly and indirectly related to patient management). Wherever possible, these measurements should be made by individuals who are unaware of the treatment allocation of the subjects they are assessing. We encourage applicants to involve consumers of health care in the preparation of their proposal, for instance in selecting patient-oriented outcomes. A period of follow up should be undertaken which is sufficient to ensure that a wider range of effects are identified other than those which are evident immediately after treatment. These factors should guide applicants in their choice of subjects, settings and measurements made.

Sample size

A formal estimate should be made of the number of subjects required to show important differences in the chosen primary outcome measure. Justification of this estimate will be expected in the application.

Communication

Communication of the results of research to decision makers in the NHS is central to the HTA Programme. Successful applicants will be required to submit a single final report for publication by the HTA programme. They are also required to seek peer-reviewed publication of their results elsewhere 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. However, there is a pressing need within the NHS for the information and so the research would normally be expected to be completed within three years, unless long-term follow-up is necessary.