New treatments for men with benign prostatic enlargement

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 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. Questions are identified and prioritised to meet the needs of the NHS and its patients.

Question

- **What is the clinical- and cost-effectiveness of each of the main alternatives to transurethral resection of the prostate?**

1 **Design:** Secondary research is required in the form of a systematic review of the main treatments for benign prostatic enlargement. The research should include economic modelling. The following information is a guide for the minimum inclusion criteria of the review. Applicants may consider/justify other ways of doing the research.

2 **Technology:** New alternatives to transurethral resection of the prostate, including but not restricted to: transurethral electrovaporisation of the prostate (TUVP); transurethral radiofrequency needle ablation (TUNA); holmium laser resection (HoLRP); KTP laser (60-80 W) vaporisation. Applicants should specify, with justification, others they wish to include.

3 **Patient group:** Men with benign prostatic hyperplasia/enlargement requiring surgery

4 **Setting:** Inpatient/outpatient depending on procedure

5 **Control or comparator treatment:** Any, but especially transurethral resection of the prostate (TURP)

6 **Primary outcomes:** Subjective symptom improvement score (e.g. AUA/IPSS/Madsen/ "bother" assessment question); objective symptom improvement measure, such as peak urinary flow rate and post-void residual urine volume; post-operative morbidity, such as irritative urinary symptoms, retrograde ejaculation, erectile dysfunction, incontinence, recurrent urinary tract infections, blood loss; reoperation rates; length of hospital stay and length of catheterisation. If data are available, an analysis of patient preference should be included, to clarify whether men would prefer to have a simpler procedure that lasted for a year or a more complex procedure involving a longer hospital stay but with more permanent results. A measure of patient satisfaction would be appropriate.

7 **Study design:** A systematic review of randomised controlled trials or other high quality primary research.

8 **Minimum duration of follow-up:** An important consideration in the economic assessment of prostate surgery is the percentage of patients who later require surgery. Follow-up time of at least three to five years was recommended by a Swedish HTA report to take account of the additional costs of such patients.

Summary of research need: *Relatively high morbidity associated with transurethral resection of the prostate (TURP) has led to the development of a range of minimally invasive techniques. Of the four discussed here, holmium laser resection of the prostate appears to be a promising alternative to TURP. Transurethral needle ablation has the advantage of being suitable for an out-patient setting, and may be preferred by some men. Transurethral electrovaporisation appears to be effective, but may be more applicable to smaller prostates. A systematic review would provide a more comprehensive overview of these procedures and identify the best alternative to TURP, which may then be compared in a randomised trial.*

Making an application

If you wish to submit a 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 *Wednesday 17 November 2004.* Applications will be reviewed by the HTA Commissioning Board at its meeting in *February 2005*.

Applications received after 1300 hours on the due date will not be considered.

Guidance on applications

Methods

Applicants should demonstrate knowledge of current research in the field and of systematic review methods and state how these would apply to the question posed. Valid and reliable methods should be proposed for identifying and selecting relevant material, 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 on effectiveness* (www.york.ac.uk/inst/crd/report4.htm). 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. Where epidemiological modelling or economic evaluation is required, the range of uncertainty associated with the results should be assessed. In the assessment of cost-effectiveness, further data collection may be required to estimate resource use and costs. If there is evidence that the ratio of costs and benefits may differ between readily identifiable groups, applicants are encouraged to state how they will identify these differences.

Cochrane

Applicants wishing to produce and maintain a Cochrane systematic review from this HTA commissioned systematic review should make the case in their proposal. This will need to include the approval of the relevant Cochrane Review Group (www.cochrane.org). Any additional costs associated with the initial preparation of a Cochrane review should be included in your project proposal. Maintenance costs cannot be met.

Consumer involvement in research

The HTA programme recognises the increasing active involvement of consumers in research and would like to support research projects appropriately. The HTA programme encourages applicants to consider whether the scientific quality, feasibility or practicality of their proposal can be improved by involving consumers. Research teams wishing to involve consumers should include in their application: the aims of active involvement in this project; a description of the consumers (to be) involved; a description of the methods of involvement; a budget for consumer involvement. Applications that involve consumers will not, for that reason alone, be favoured over proposals that do not but it is hoped that the involvement of consumers will improve the quality of the application.

Updating

In order to inform decisions on whether and when to update the review, 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

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 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. However, there is a pressing need within the NHS for the information and so the research would normally be expected to be completed as soon as possible – however it is for applicants to justify the duration and costs proposed.