Health Technology Assessment Programme

National Institute for Health Research

HTA no 12/152

Interventions for hyperemesis gravidarum

Introduction

The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technologies is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

Research Question:

What is the clinical and cost-effectiveness of interventions for hyperemesis gravidarum?

1. **Intervention:** Any treatments relevant to the NHS for hyperemesis gravidarum.
2. **Patient group:** Pregnant women with hyperemesis gravidarum - severe and persistent nausea and vomiting (exact criteria to be defined by applicants).
3. **Setting:** Community and inpatient.
4. **Control or comparator:** Treatment as usual or other appropriate control.
5. **Study design:** An evidence synthesis by systematic review and, if primary evidence permits, economic modelling. Treatments delivered in an outpatient/community setting are of particular interest. Where possible consideration should be given to the timing of treatments in relation to symptoms, and to the severity and duration of symptoms. Researchers should consider and justify the inclusion of non-randomised studies.
6. **Important outcomes:** Severity of hyperemesis gravidarum symptoms (such as Pregnancy-Unique Quantification of Emesis questionnaire).
   Other outcomes: Health related quality of life; healthcare utilisation including admission to hospital; satisfaction; foetal outcomes; costs; cost-effectiveness; research recommendations.

Background information for potential applicants:

Hyperemesis gravidarum (HG) can lead to negative health consequences for both mother and foetus. It is accompanied by a significant reduction in quality of life for the patient and high healthcare costs. A recent systematic review and meta-analysis looking at the consequences of HG for offspring reported that babies born to women with HG were more likely to be premature, be small for gestational age and be of low birth weight.

Although at least four clinical reviews have recently been published there appears to have been no overarching systematic review of the evidence nor a measure of cost-effectiveness of the many interventions used to treat HG. An evidence synthesis is needed that examines cost-effectiveness, could inform future guidelines and that identifies areas for needs-led high quality research.

The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), based at the University of Southampton, manages evaluation research programmes and activities for the NIHR

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Making an application

The NIHR Health Technology Assessment programme is funded by the NIHR, with contributions from the CSO in Scotland, NISCHR in Wales, and the Public Health Agency in Northern Ireland. Researchers from Northern Ireland and Scotland for certain NICE related calls should contact NETSCC to discuss their eligibility to apply.

If you wish to submit a proposal on this topic, complete the on-line application form at http://www.hta.ac.uk/funding/standardcalls/index.shtml and submit it on line by **27th September 2012.** You need to send a copy of the application form with original signatures, along with a detailed project description, to the HTA Evidence Synthesis Application Manager (c/o TARS Team) at the National Coordinating Centre for Health Technology Assessment, Alpha House, Enterprise Road, Southampton Science Park, Chilworth, Southampton, SO16 7NS.

Your full proposal will be assessed by designated board members, alongside other applications submitted in the same topic area. A maximum of three proposals will be taken forward for peer review by external referees, and subsequent consideration by the HTA Evidence Synthesis Board at its meeting in **January 2013**.

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: http://transparency.number10.gov.uk/#

Applicants are recommended to seek advice from suitable methodological support services, at an appropriate stage in the development of their research idea and application. It is advisable to make contact at an early a stage as possible to allow sufficient time for discussion and a considered response.

The NIHR Research Design Service (http://www.nihr.ac.uk/infrastructure/Pages/infrastructure_research_design_services.aspx) can advise on appropriate NIHR programme choice, and developing and designing high quality research grant applications.

Clinical Trials Units are regarded as an important component of any trial application and can advise and participate throughout the process from initial idea development through to project delivery and reporting. NETSCC CTU Support Funding (http://www.netscc.ac.uk/supporting_research/CTUs) provides information on the units receiving funding from the NIHR to collaborate on research applications to NIHR programmes and funded projects. In addition UKCRC CTU (http://www.ukcrc-ctu.org.uk) provides information and searchable information resource on all registered units in the UK.

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

Please see GUIDANCE ON APPLICATIONS overleaf.

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 *Systematic Reviews: CRD's guidance for undertaking reviews in health care (third edition)* (http://www.york.ac.uk/inst/crd/systematic_reviews_book.htm). Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established. 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 a 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.

Public involvement in research

The HTA Programme recognises the benefit of increasing active involvement of members of the public in research and would like to support research projects appropriately. The HTA Programme encourages applicants to consider *how* the scientific quality, feasibility or practicality of their proposal *could* be improved by involving members of the public. Examples of how this has been done for health technology assessment projects can be found at http://www.hta.ac.uk/PPIguidance/. Research teams wishing to involve members of the public should include in their application: the aims of active involvement in this project; a description of the members of the public (to be) involved; a description of the methods of involvement; and an appropriate budget. Applications that involve members of the public will not, for that reason alone, be favoured over proposals that do not but it is hoped that the involvement of members of the public will improve the quality of the application.

Updating

It is the policy of NETSCC, HTA that all search strategies undertaken as part of evidence synthesis/secondary research projects must not be more than 12 months out of date when the draft final report is submitted. We expect that most projects will manage to bring their searches up to date prior to analysis and writing up. As research funders we are aware that exceptional circumstances can apply that would not allow this to be case but this must be the exception rather than the rule and will be assessed on a case by case basis. The expectation is that projects funded by the HTA Programme will deliver information that is both relevant and timely.

In addition, 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 on-going work known at the time the review is completed. Applicants should note that they will not be expected to carry out any future 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 NETSCC, HTA 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.