

Screening for hyperglycaemia in pregnancy / Gestational diabetes mellitus (GDM)

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:

In the UK, can a strategy for screening women for gestational diabetes mellitus (GDM) based on individual risk be developed that would be more cost effective than one of universal screening, and how does the level of glucose, at which treatment is commenced, effect the overall cost-effectiveness of the strategy?

- 1. Intervention:** Screening for hyperglycaemia in pregnancy
- 2. Patient group:** Pregnant women in the UK
- 3. Setting:** Primary and secondary care
- 4. Comparator:** Routine care with testing for GDM as recommended by NICE
- 5. Study design:** A modelling study using data from the HAPO study and/or other recent research to identify the cost-effectiveness of different thresholds and tests (fasting plasma glucose, HbA1c, OGTT) for diagnosing and treating GDM and investigating the importance of individual risk factors to derive risk categories. A model of cost-effectiveness is required to identify the difference in cost-effectiveness of a policy of universal screening compared to one based on selective testing of women identified as at higher risk. Applicants are expected to demonstrate that they have access to appropriate data.
- 6. Important outcomes:** Cost-effectiveness and cost per QALY of a screening strategy based on individual risk assessment compared to universal screening, incremental cost-effectiveness / cost per QALY at different thresholds for treatment, a tool to enable individual risk assessment.

Background information for potential applicants:

Hyperglycaemia in pregnancy was historically called 'gestational diabetes'. The prevalence of hyperglycaemia in pregnancy is increasing with as many as 17% of pregnant women now classified as hyperglycaemic. This is due in part to older maternal age and rising BMI. Uncertainty exists around the threshold for treatment and on the best screening strategy and there has been a divergence of views concerning appropriate testing and screening, differences in understanding about what is meant by gestational diabetes and contrasting perspectives from diabetologists, obstetricians, epidemiologists and health economists, contributing to the controversy.

Current evidence is limited and research is required to determine at what level of plasma glucose or HbA1c treatment is justified and whether a policy of selective testing or universal screening might be cost effective in the UK.

Making an application

The NIHR Health Technology Assessment programme is funded by the NIHR, with contributions from the CSO in Scotland and WORD in Wales. Researchers from Northern Ireland should contact NETSCC to discuss their eligibility to apply.

If you wish to submit an outline 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 **9th February 2012**. Applications will be considered by the HTA Commissioning Board at its meeting in April. For outline applications, if shortlisted, investigators will be given a minimum of eight weeks to submit a full proposal.

NB. Please note that for this call we are expecting applicants to fill in the outline proposal form as detailed on the website.

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/#>

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.

In evaluating diagnostic and imaging techniques, the emphasis of the HTA programme is to assess the effect on patient management and outcomes (particularly where changes in management can be shown to have patient benefits). Improvements in diagnostic accuracy, whilst relevant, are not the primary interest of this commissioned research programme. Applicants should justify where they consider improvements in diagnostic accuracy to be relevant to these objectives. Where there is poor evidence to link diagnostic improvements to patient benefits, part of the research may be to assess the effects of such changes on patient outcome.

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.