Screening for gestational diabetes: a systematic review and economic evaluation

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Executive summary

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Background

Screening for gestational diabetes mellitus (GDM) has been controversial, with some expert bodies advising universal screening, others selective screening, and yet others advising against screening at all. This has partly been a result of debate about the definition of GDM, and partly because of the profusion of different tests available, both for screening and definite diagnosis. In the UK, there is no national policy on screening, and a variety of practices exist in different parts of the country. There have also been doubts about the treatment of GDM, and particularly about management of minor degrees of glucose elevation, which are better described as glucose intolerance rather than true diabetes.

Objectives

To provide an updated review of current knowledge, to clarify research needs, and to assist with policy making in the interim, pending future research.

Methods

A literature review was carried out, with a particular focus on screening methods and costs, and an appraisal of screening for GDM against the criteria for assessing screening programmes used by the UK National Screening Committee (NSC).

Results

There is still debate about what is meant by GDM – the threshold for diagnosis is not soundly based; the terms GDM and impaired glucose tolerance are not used in a standard fashion in pregnancy; there is almost certainly a continuum of risk to the baby, rather than there being separate normal and abnormal groups; and the key risk factor in most women may be maternal overweight, with glucose intolerance being an associate of that. In addition there are some rare genetic conditions, which affect a few women, such as glucokinase and hepatic nuclear factor disorders.

GDM is usually defined according to divergence from normal glucose levels, but glucose levels are usually raised in pregnancy, and so diagnosis by normal levels in non-pregnant women may misclassify many normal pregnant women as abnormal. This may lead to anxiety and the inconvenience of extra investigations and ‘disease’ care. The Caesarean section rate appears to be increased by the diagnosis alone.

Ideally, the condition should be defined by the incidence of adverse effects. However, the most common reported complication of GDM is ‘macrosomia’ in the baby. This is usually defined by arbitrary weight cut-offs (usually a birth weight of 4000 g, but sometimes 4500 g), but such neat thresholds fail to distinguish between larger than average healthy babies and those that have the abnormal growth patterns associated with high insulin levels in the womb.

Screening for GDM fails to meet some of the NSC criteria.

A number of screening tests have been used but some, such as glycosylated haemoglobin and fructosamine, have proved unsatisfactory and can be discarded. Others, such as urine testing or random blood glucose, are far from satisfactory, although they may be cheap to do. There is marked international variation. Risk factors such as weight, age and family history are useful for selective screening but some patients with GDM would be missed. Fasting plasma glucose (FPG) is convenient and reliable, but some pregnant women have normal fasting levels but raised levels of glucose after meals, and would be missed by screening based on FPG alone. Glucose challenge tests (GCTs) are based on glucose levels after a glucose drink, but also have shortcomings. The definitive diagnosis is usually by oral glucose tolerance test (OGTT), but the glucose load and timing vary in different countries; taking a 75 g glucose load is unnatural, makes some women sick, and the reproducibility of the test is poor. More natural methods such as test meals have been used, but not widely.
Conclusions

Interim conclusions
There are clearly some women whose glucose levels rise sufficiently in pregnancy to cause harm to their babies. However, there are also many women with lower levels of glucose intolerance whose babies are not at risk, but who may suffer anxiety and inconvenience as a result of being classed as abnormal. On balance, the present evidence suggests that we should not have universal screening, but a highly selective policy, based on age and overweight.

The best test at present, for those deemed to need testing, is probably the GCT, preferably combined with an FPG. The benefits of a follow-up OGTT are doubtful.

Recommendations for research
The main research needs appear to be:

1. There is a need to better define the ‘disease’ by documenting the frequency of adverse events, best done by population-based epidemiological surveys. These should include ethnic groups, as risks appear to vary, although this may be partly due to the prevalence of overweight. This work would relate outcomes of pregnancy to maternal blood glucose and other factors, to determine the level of glucose at which outcomes worsened significantly. Data on other factors such as overweight would be used to determine whether glucose intolerance was an independent cause, and if so at what level.

2. If such research showed that there was a continuum of risk, rather than there being distinct normal and abnormal groups, economic analysis should examine the cost-effectiveness of intervention at different levels.

3. Trials of the marginal costs and benefits of different screening tests – for example, FPG versus GCT – and whether if these are positive, a follow-up OGTT is necessary, because it is far from being a gold standard.

4. Trials of intervention in key groups, such as those with normal FPG but elevated postprandial levels.

5. After all these, further analysis of the cost-effectiveness of screening – should it be done, and if so, how selective should it be?

Some research is under way overseas, and it is recommended that the results of the two main trials, the Hyperglycaemia and Pregnancy Outcome Study (HAPO) and the ACHOIS trial (a collaborative trial of treatment for screen-detected GDM) be awaited before further research is commissioned by the Health Technology Assessment Programme.

Publication
The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 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 provide care in the NHS.

The research reported in this monograph was commissioned by the HTA Programme on behalf of the National Institute for Clinical Excellence (NICE). Technology assessment reports are completed in a limited time to inform the appraisal and guidance development processes managed by NICE. The review brings together evidence on key aspects of the use of the technology concerned. However, appraisals and guidance produced by NICE are informed by a wide range of sources.

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