BLOOD GLUCOSE SELF MONITORING IN TYPE TWO DIABETES MELLITUS

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

Is blood glucose self-monitoring worthwhile in patients with type 2 diabetes mellitus?

The topic

Diabetes mellitus currently affects approximately 2-4% of the UK population and numbers affected are increasing, mainly due to the increased prevalence of obesity and the ageing population. Type 2 diabetes, (formerly non-insulin dependent diabetes) accounts for approximately 85 – 90% of diabetes. Many of these patients may initially be managed by dietary change alone or with oral hypoglycaemic drugs. Following the results of the UKPDS increasing numbers of these patients are being started on insulin therapy. Up to 50% of people with type 2 diabetes show some sign of complications by the time they are diagnosed. Diabetes is a progressive condition and more than one type of treatment is likely to be needed during a life-time.

Good blood glucose control is one of the main treatment objectives in diabetes mellitus. Improved glucose control may be associated with a reduction of complications of diabetes, thereby potentially improving quality of life and reducing health service resource use. The results of the United Kingdom Prospective Diabetes Study (UKPDS) clearly demonstrated that intensive blood glucose control in type 2 Diabetes Mellitus reduces the incidence of chronic complications. The European guidance on management of patients with type 2 diabetes recommends blood glucose self-monitoring, however, this is not currently routine in the UK and further work is needed to assess the benefits in terms of clinical effectiveness and cost effectiveness.

Methods

Primary research in the form of a randomised control trial should be carried out to provide a rigorous assessment of the effectiveness of self monitoring of blood glucose in patients with type 2 diabetes, or sub-groups thereof. Outcome measures should include glycaemic control as measured by glycated haemoglobin (GHb), short–term complications such as hypoglycaemia and patients' quality of life. Sub group analysis should be carried out to try to identify those patients most likely to benefit from self-monitoring. Variables such as patient education and adherence with treatment recommendations should also be addressed.

On this topic, a randomised controlled trial of self monitoring versus no self monitoring is likely to be the most appropriate design. 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.

Applicants are required to comply with the Medical Research Council's Good Clinical Practice guidelines (www.mrc.ac.uk/clinical_trials/ctg.html).

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 19th October 2001. Outline applications will be considered by the HTA Commissioning Board at its meeting in December 2001. 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.

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 primary research may be to assess the effects of such changes on patient outcome.

An assessment should also be made of changes in other resources (particularly other subsequent therapies) used as a result of changes in diagnostic methods.