

## ***Executive summary***

# **Monitoring blood glucose control in diabetes mellitus: a systematic review**

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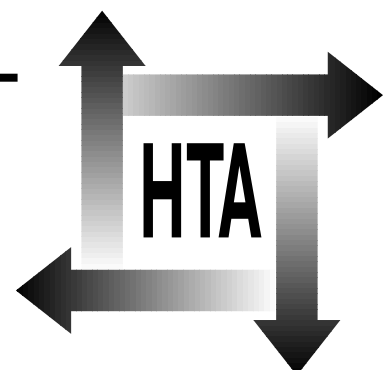
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## Executive summary

### Objectives

The aim of this review was to evaluate evidence for the clinical- and cost-effectiveness of different methods for monitoring blood glucose control in diabetes mellitus (DM). Self-monitoring by patients and near-patient or laboratory testing in healthcare settings were considered.

### Methods

- The authors' personal collections, *Diabetes Care* and *Diabetic Medicine* (1990–99), the electronic databases MEDLINE, EMBASE, and the Index and Bibliography of Social Sciences were searched.
- Citations from papers retrieved were screened.
- Letters were sent to the British Diabetic Association and leading manufacturers.
- Retrieved papers were evaluated for quality by two independent reviewers.
- Data were abstracted and synthesised using meta-analysis where possible.

### Results

#### Evaluation of blood glucose monitoring devices

There is no standard protocol for evaluating blood glucose monitoring devices. Published evaluations have often only evaluated a limited number of aspects of meter performance and have not always used appropriate methods to analyse the reliability of measurements.

#### Self-monitoring in type 2 DM

Eighteen papers were retrieved, including eight randomised controlled trials (RCTs) and ten non-randomised studies. The eight RCTs included comparisons of blood testing, urine testing and no testing in subjects with type 2 DM. Interventions were not standardised, patient training and adherence were not addressed systematically and no trial required subjects to modify their drug therapy in accordance with self-monitoring results. On a scale ranging from 0 to 28 the mean quality rating was 15.0 (standard deviation (SD) 1.69). Three studies had sufficient power to detect differences in

glycated haemoglobin (GHb) of 0.5–1.0% but none had sufficient power to detect differences  $\leq 0.5\%$ .

After excluding two RCTs, six studies were included in meta-analyses. A random-effects meta-analysis, using data from four studies, showed that the mean difference in GHb between groups of patients performing blood or urine self-monitoring and those not was  $-0.25\%$  (95% confidence interval (CI),  $-0.61$  to  $0.10$ ). Meta-analysis of data from three studies showed that the difference in GHb for those performing self-monitoring of blood glucose compared with those performing urine testing was  $-0.03\%$  (95% CI,  $-0.52$  to  $0.47$ ). Published information on patient outcomes and the avoidance of hypoglycaemia was extremely limited. Blood testing was noted to be more costly than urine testing.

#### Self-monitoring in type 1 DM

Twenty-four papers were retrieved, including eight controlled trials and 16 non-controlled studies. The RCTs included either children or adults and compared different testing frequencies, blood or urine testing, or blood testing and no testing. The mean quality rating was 14.4 (SD 1.6) and only one study had sufficient power to detect differences in GHb of  $\leq 1.0\%$ .

Among the controlled trials, only one suggested a benefit of blood testing for GHb. The remaining studies showed no difference between blood or urine testing or different frequencies of blood testing. Three studies found that the frequency of hypoglycaemia was low and not different between blood monitoring and control groups. One study reported that blood glucose monitoring revealed asymptomatic hypoglycaemia in 11 of 16 children. A meta-analysis of data from studies that compared blood monitoring with urine monitoring in children or adults with type 1 DM suggested a mean difference in GHb of approximately  $-0.567\%$  (95% CI,  $-1.073$  to  $-0.061$ ). This result, of borderline significance, was sensitive to two assumptions made in interpreting and analysing the data. Blood testing was noted to be more costly than urine testing but was preferred by patients, possibly because it provided better information.

### **Self-monitoring in diabetes mellitus in pregnancy**

Eleven papers were retrieved, including five RCTs. Six studies included women with type 1 DM, one study included women with either type 1 or type 2 DM, three studies included women with gestational DM (GDM), and one included women with either type 1 DM or GDM. The studies generally included small numbers of subjects and the mean quality rating was 11.4 (SD 3.3). The studies showed that pregnant women with type 1 DM may be managed at home by self-monitoring blood glucose rather than be admitted to hospital. This approach resulted in a reduced level of hospital utilisation. Maternal and fetal outcomes appeared to be as good with home self-monitoring as with hospital inpatient admission in late pregnancy, but the studies did not have sufficient power to give conclusive results. Firm evidence for the best approach to managing GDM is lacking and the best strategy may depend on the severity of glucose intolerance. One RCT suggested that post-prandial testing was associated with better outcomes than preprandial testing in women with GDM requiring insulin treatment.

### **Laboratory and near-patient testing**

Results from the Diabetes Control and Complications Trial (DCCT) in type 1 DM and the UK Prospective Diabetes Study in type 2 DM have demonstrated the clinical effectiveness of using GHb estimations to monitor blood glucose control. Data from the DCCT suggest that the overall package of intervention employed would have acceptable cost-effectiveness. No unconfounded studies have addressed the optimal testing frequency for GHb, but current guidelines suggest from four tests per year in subjects with type 1 DM to two tests per year in subjects with stable type 2 DM. Standardisation of GHb assays between and within laboratories is an important objective being addressed by current work. Near-patient testing for GHb is being developed, but it is too early to judge its value.

Fructosamine estimations, which measure glycaemic control over shorter intervals than GHb, may be useful in diabetic pregnancy, but have not been shown to be better than GHb at this time. Fructosamine assays are less costly than GHb.

### **Conclusions**

A standard protocol should be drawn up for conducting and reporting evaluations of blood glucose monitoring devices.

Blood glucose self-monitoring is well established in clinical practice but the optimal use of the technique has not been established. Present evidence suggests that it may not be essential for all patients.

### **Recommendations for research**

- Randomised studies should be carried out to provide decisive evidence on the clinical- and cost-effectiveness of blood glucose self-monitoring in type 2 DM and GDM.
- Observational studies should be carried out in samples of subjects with type 1 DM to identify groups of patients in whom blood glucose self-monitoring is of benefit and groups in whom it is not.
- Studies should include not just assessment of GHb, but also the occurrence of hypoglycaemia, patients' satisfaction with care and health-related quality of life.

### **Publication**

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# NHS R&D HTA Programme

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The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

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The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

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