Clinical and cost-effectiveness of self-monitoring of blood glucose (SMBG) for non-insulin treated type 2 diabetes

Health technology description
Self-monitoring of blood glucose (SMBG) involves measurement of blood glucose concentration by patients with diabetes or their carers in their daily environment. This usually entails pricking a finger with a lancet device to obtain a small blood sample. A drop of blood is applied onto a reagent strip and glucose concentration is determined by inserting the strip into a meter for automated reading based on electrochemical or colour responses. SMBG can be performed at any time of the day. It measures the level of blood glucose which fluctuates with the intake of food or certain medications. It does not measure glycated haemoglobin ($\text{HbA}_1c$), which is a more stable indicator requiring analysis in laboratories. $\text{HbA}_1c$ reflects glycaemic control over the past two to three months and is used to set treatment targets and monitor longer-term control of blood glucose.

SMBG is considered part of self-management of diabetes rather than a stand-alone intervention. It is used for controlling blood glucose and to motivate changes in lifestyle, diet and physical activity. The SIGN guidelines on the management of diabetes are being updated and are expected in 2010. Current NICE guidelines on type 2 diabetes recommend that SMBG should be offered to newly diagnosed patients only as an integral part of self-management education, with the purpose discussed and agreement reached on how results should be interpreted and acted upon. For patients who require insulin, frequent SMBG is recommended as an integrated part of active dose titration. NICE guidelines do not address care for patients with advanced complications or significant illness (e.g. infections) and for diabetic women before or during pregnancy. SMBG is considered necessary in these patients for early recognition of deteriorating glycaemic control.

Epidemiology
Diabetes is a progressive disorder of glucose metabolism, which is commonly treated initially by lifestyle modification (nutrition therapy and physical activity), followed by oral drugs, and in some cases with insulin injections. The 2007 Scottish Diabetes Survey estimated that 209,706 people in Scotland (4.1% of the population) have diabetes, over 85% of which are type 2. Diabetes is more common among men than women (53.8% versus 46.1%). About half of all people with diabetes are aged 65 years or older.

Diabetes is associated with a large healthcare burden, the majority of which is attributed to the treatment of complications. Patients with type 2 diabetes have increased risk of premature death, cardiovascular disease, amputation and microvascular complications including retinopathy.
and renal failure. Observational studies suggest that each 1% reduction in HbA1c is associated with a 21% reduction in diabetes related death, 12-14% reduction of myocardial infarction and stroke and 37% reduction of microvascular complications. Intensive glycaemic control reduces microvascular complications, but its effect on cardiovascular risk is less clear than the benefits observed through modification of cigarette smoking, obesity, inactivity, hypertension and hyperlipidaemia. NICE guidelines suggest that highly intensive management to HbA1c levels of less than 6.5% should be avoided.

Clinical effectiveness

The evidence summarised in this and subsequent sections focuses on type 2 diabetes patients not treated with insulin, for whom the role of SMBG is debated. Two most recent systematic reviews specifically addressed SMBG in this population. One of the reviews combined results from seven RCTs and found a statistically significant reduction of HbA1c with SMBG compared to no SMBG (weighted mean difference (WMD) -0.24%, 95% confidence interval (CI) -0.37% to -0.12%) based on a stratified analysis, the authors suggested that SMBG is effective only when the readings were used to modify treatment regimens. However, appropriate methods for subgroup analysis were not used for this comparison.

The second review included nine RCTs and analysed results at 6 months and one year (or longer). Five trials reported outcomes at 6 months and the pooled results suggest a statistically significant decrease in HbA1c for SMBG compared to no SMBG (weighted mean difference (WMD) -0.24%, 95% CI -0.38% to -0.12%). Based on a stratified analysis, the authors suggested that SMBG is effective only when the readings were used to modify treatment regimens. However, appropriate methods for subgroup analysis were not used for this comparison.

The relationship between estimated effect of SMBG and various characteristics of the trials/patients (such as study quality and baseline HbA1c level) was explored but the findings were inconclusive.

Both systematic reviews included a relatively recent UK trial (DiGEM) which compared: (1) no SMBG; (2) SMBG with advice for patient to contact their doctor for interpretation of results; (3) SMBG with training of patients in interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle. At baseline patients were reasonably well controlled (mean HbA1c 7.5%), were not treated with insulin and had not regularly used SMBG. The study found no significant benefit for either SMBG groups compared to control, and no significant difference between the two monitoring strategies.

Two RCTs have subsequently been published. The ESMON study differs from previous trials in that newly diagnosed patients with type 2 diabetes (rather than patients with established diabetes) were recruited and that a uniform treatment algorithm based on HbA1c targets was applied to both SMBG and non-SMBG groups. At 12 months HbA1c was reduced in both groups and no significant difference between the groups was observed (mean difference 0.07%, 95% CI -0.25% to 0.38%). Patients in the SMBG group were more depressed, having a 6% higher score on the depression subscale of the well-being questionnaire (p=0.011). Another trial compared different frequencies of SMBG measurements (one per week versus four per week) in patients who were on stable oral antidiabetic drugs with HbA1c close to glycaemic control target. No significant differences between groups in HbA1c, hypoglycaemia, hyperglycaemia and adverse events were found.

Interpretation of findings from the reviews and trials is complicated by several factors. More recent trials (eg DiGEM and ESMON) which found minimal effects of SMBG compared to no SMBG are generally of higher quality. The models of care in the control arms (no SMBG) of these trials are similar to current practice in Scotland hence the results are likely to be generalisable. However there remains some debate with regard to whether the greater effects of SMBG observed in some of the older trials are attributed to various aspects of trial quality and suboptimal care in the control group, or whether they are related to differing patient characteristics, intensity of monitoring or other factors.

Safety

One review found that SMBG increases the frequency of recognised hypoglycaemia but evidence regarding more clinically significant hypoglycaemia was scant. The Medicines
Economic implications

SMBG contributes to the high management cost of implementing intensive blood glucose control\textsuperscript{16}. Approximately 80% of marketed strips are used at home by people with diabetes for self-monitoring\textsuperscript{1}. The current cost of providing SMBG in Scotland is around £14 million per annum\textsuperscript{17}.

Two economic evaluations assessed SMBG in non-insulin treated type 2 diabetes from the NHS perspective\textsuperscript{18,19}. The studies reported conflicting findings, which reflect differing estimates of the effect of SMBG compared to usual care used. One was based on the DiGEM trial\textsuperscript{18}. Total healthcare cost for each patient was calculated and the impact of SMBG on quality of life was estimated using the EuroQol EQ-5D. SMBG was significantly more expensive but resulted in lower quality of life than control group over 12 months. Potential limitations of the study include generalisability of outcomes in relation to patient selection criteria, and that EQ-5D may not capture all aspects of quality of life changes.

The second study modelled SMBG in three cohorts (type 2 diabetes patients treated by diet and exercise; oral antidiabetic agents; or insulin) over lifetime\textsuperscript{19}. Effectiveness data was obtained from published systematic reviews (which did not include DiGEM and ESMON). The reduction in HbA\textsubscript{1c} associated with SMBG compared to usual care was estimated to be 0.3% for the diet and exercise cohort and 0.4% for the oral antidiabetic cohort. The calculated incremental cost-effectiveness ratios for SMBG versus no SMBG was £15,515/QALY gained for the diet and exercise cohort and £4,508/QALY for the oral antidiabetic cohort. The latter corresponds to a 51% likelihood of being cost-effective at £30,000/QALY. Sensitivity analysis suggests the results are most sensitive to the time horizon used but assumptions related to duration of effect on HbA\textsubscript{1c} (assumed to last over a lifetime in the base case), compliance with SMBG and whether SMBG impacts on health utility also influence the results.

Equality & Diversity

NHS QIS is committed to equality and diversity in respect of the six equality groups defined by age, disability, gender, race, religion/belief and sexual orientation. The Evidence Note process has been assessed, and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.nhshealthquality.org.

About Evidence Notes

- For further information about the Evidence Note process, see www.nhshealthquality.org
- To propose a topic for an Evidence Note email evidencenotes.qis@nhs.net
- References can be accessed via the internet (where the addresses are provided), via the e-Library (www.elib.scot.nhs.uk), or by contacting your local library and information service.

Acknowledgements

NHS Quality Improvement Scotland (NHS QIS) would like to acknowledge the helpful contribution of the following, who gave advice on the content of this Evidence Note:

- Dr Donald Pearson, Consultant Diabetologist, Aberdeen Royal Infirmary
- Miss Mary Scott, Diabetes MCN Manager, NHS Lothian
- Members of the Working Group for SHTG

NHS QIS Development Team

- Dr Olalekan Uthman & Dr Yen-Fu Chen, Systematic Reviewers & Authors, University of Birmingham
- Ms Anne Fry-Smith, Senior Information Specialist & Dr David Moore, Senior Reviewer, University of Birmingham
- Ms Doreen Pedlar, Project Co-ordinator, NHS QIS
References


