Self-monitoring of blood glucose in type 2 diabetes: systematic review

C Clar, K Barnard, E Cummins, P Royle and N Waugh for the Aberdeen Health Technology Assessment Group

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Self-monitoring of blood glucose in type 2 diabetes: systematic review

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The research reported in this issue of the journal was commissioned by the HTA programme on behalf of the Department of Health as project number 09/19/01. The contractual start date was in February 2009. The draft report began editorial review in August 2009 and was accepted for publication in December 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Self-monitoring of blood glucose in type 2 diabetes: systematic review

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*Corresponding author

Objectives: To examine whether or not self-monitoring of blood glucose (SMBG) is worthwhile, in terms of glycaemic control, hypoglycaemia, quality of life (QoL) and cost per quality-adjusted life-year (QALY), in people with type 2 diabetes (T2DM) who were not treated with insulin or who were on basal insulin in combination with oral agents.

Data sources: Literature searched included systematic reviews published since 1996, and a systematic review and meta-analyses of randomised controlled trials (RCTs) identified from the reviews, and from searches for more recent trials, along with review of qualitative and economic studies. Search strategies were limited to the English language and to articles published since 1996, and included: databases searched from 1996 to April 2009 – The Cochrane Library, MEDLINE, EMBASE, PsycINFO, Web of Science – limited to meeting abstracts; and websites.

Review methods: The intervention was self-testing of blood glucose with a meter and test strips. Studies included adult patients with T2DM on any oral treatment or combination of regimens, including lifestyle, oral agents or once-daily basal insulin. Existing systematic reviews of SMBG were summarised and results compared. Evidence synthesis of all of the studies meeting the inclusion criteria was carried out using a narrative review. Data were analysed by outcome and subgroups. HbA1c data from RCTs were summarised using a meta-analysis. Heterogeneity was calculated using the chi-squared and I² methods. The following analyses were carried out: SMBG compared to self-monitoring of urine glucose, SMBG versus no SMBG, more intensive SMBG versus less intensive SMBG, and more intensive SMBG versus no SMBG. Available qualitative data gained from in-depth interview studies, repeated interviews, and questionnaire and survey data were summarised.

Results: The review identified 30 RCTs, although few were of high quality. Ten trials comparing SMBG with no SMBG showed statistically significant reduction in HbA1c of 0.21%, which may not be considered clinically significant. A similar, though not statistically significant difference, was shown where SMBG with education was compared to SMBG without education or feedback. RCTs showed no consistent effect on hypoglycaemic episodes and no impact on medication changes. Review of cost-effectiveness studies showed that costs of SMBG per annum vary considerably (£10–259). Although some studies assert that SMBG may lead to savings in health-care costs which may offset the costs of testing, the best analysis to date (DiGEM – Diabetes Glycaemic Education and Monitoring) concluded that SMBG was not cost-effective. Qualitative studies revealed that there was a lack of education in how to interpret and use the data from SMBG, and that failure to act on the results was common.

Conclusions: The evidence suggested that SMBG is of limited clinical effectiveness in improving glycaemic control in people with T2DM on oral agents, or diet alone, and is therefore unlikely to be cost-effective. SMBG may lead to improved glycaemic control only in the context of appropriate education – both for patients and health-care professionals – on how to respond to the data, in terms of lifestyle and treatment adjustment. Also, SMBG may be more effective if patients are able to self-adjust drug treatment. Further
research is required on the type of education and feedback that are most helpful, characteristics of patients benefiting most from SMBG, optimal timing and frequency of SMBG, and the circumstances under which SMBG causes anxiety and/or depression.
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### List of abbreviations

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<td>ADA</td>
<td>American Diabetes Association</td>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>BG</td>
<td>blood glucose</td>
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<tr>
<td>BMI</td>
<td>body mass index</td>
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<tr>
<td>CHF</td>
<td>Swiss franc</td>
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<tr>
<td>DiGEM</td>
<td>Diabetes Glycaemic Education and Monitoring</td>
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<tr>
<td>DTSQ</td>
<td>Diabetes Treatment Satisfaction Questionnaire</td>
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<tr>
<td>EASD</td>
<td>European Association for the Study of Diabetes</td>
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<tr>
<td>ESMON</td>
<td>Efficacy of Self-MONitoring of blood glucose in newly diagnosed type 2 diabetes trial</td>
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<tr>
<td>EQ-5D</td>
<td>EuroQol-5D questionnaire</td>
</tr>
<tr>
<td>FBG</td>
<td>fasting blood glucose</td>
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<tr>
<td>FDA</td>
<td>US Food and Drug Administration</td>
</tr>
<tr>
<td>FPG</td>
<td>fasting plasma glucose</td>
</tr>
<tr>
<td>GPs</td>
<td>general practitioners</td>
</tr>
<tr>
<td>HbA1c</td>
<td>glycosylated/glycated haemoglobin</td>
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<tr>
<td>HCPs</td>
<td>health-care professionals</td>
</tr>
<tr>
<td>HDL</td>
<td>high-density lipoprotein</td>
</tr>
<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>ICER</td>
<td>incremental cost-effectiveness ratio</td>
</tr>
<tr>
<td>IQWiG</td>
<td>Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen</td>
</tr>
<tr>
<td>LDL</td>
<td>low-density lipoprotein</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Products Regulatory Agency</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>NR</td>
<td>not reported</td>
</tr>
<tr>
<td>NS</td>
<td>not significant</td>
</tr>
<tr>
<td>OHA</td>
<td>oral hypoglycaemic agent</td>
</tr>
<tr>
<td>PTC</td>
<td>Pathways To Change</td>
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<tr>
<td>QALY</td>
<td>quality-adjusted life-year</td>
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<tr>
<td>QoL</td>
<td>quality of life</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
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<tr>
<td>SF-36</td>
<td>Short Form-36</td>
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<tr>
<td>SMBG</td>
<td>self-monitoring of blood glucose</td>
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<tr>
<td>SMUG</td>
<td>self-monitoring of urine glucose</td>
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<tr>
<td>T1DM</td>
<td>type 1 diabetes</td>
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<tr>
<td>T2DM</td>
<td>type 2 diabetes</td>
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<tr>
<td>UKPDS</td>
<td>UK Prospective Diabetes Study</td>
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All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.
Background

The prevalence of type 2 diabetes (T2DM) has been rising in the UK, and around 4% of the population now have the condition.

Good control of blood glucose level is important in preventing or delaying the complications of T2DM, such as heart disease, peripheral vascular disease, visual loss and renal failure.

However, many people with T2DM do not have good control of their blood glucose.

The usual method for monitoring glycaemic control is by measuring glycated haemoglobin, or HbA$_1c$, which gives an average of the blood glucose over 3 months. If it is high then control needs to be improved. The National Institute for Health and Clinical Excellence (NICE) recommends that most people with T2DM should aim to keep their HbA$_1c$ level at 6.5% or under, though targets should be tailored to the individual.

However, HbA$_1c$ level does not tell patients what their blood glucose is doing on a day-to-day basis. Self-monitoring by testing for urinary glucose is one way of checking when blood glucose is high, but is only a rough guide. A more accurate measure can be obtained by blood testing, which is done by pricking the skin to get a drop of blood, putting that blood on a testing strip, and reading the result with a small meter. This can be done at different times of day, before or after meals, or before or after physical activity.

Meters are cheap (about £14), and the NHS requires manufacturers to provide them free of charge if needed, so the main cost is the test strips, at about £14 for a pack of 50.

Main question

Is self-monitoring of blood glucose worthwhile in people with T2DM who are not treated with insulin or who are on only basal insulin in combination with oral agents, in terms of glycaemic control, hypoglycaemia, quality of life (QoL) and other relevant outcomes, and cost per quality-adjusted life-year (QALY)?

Methods

Review of systematic reviews published since 1996, and a systematic review and meta-analyses of randomised controlled trials (RCTs) identified from the reviews, and from searches for more recent trials. Review of qualitative and economic studies.

Search strategy

- Websites of the European Association for the Study of Diabetes (EASD), the American Diabetes Association (ADA) and Diabetes UK searched for meeting abstracts in April 2009.
- Websites of the US Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA), Self-Monitoring of Blood Glucose (SMBG) International Working Group, Current Controlled Trials, and ClinicalTrials.gov
- Contact with experts in the field.
- Scrutiny of bibliographies of retrieved papers.

The searches were limited to the English language and to articles published since 1996, due to the number of recent good quality systematic reviews and in order to reflect current meter technologies. The search strategy did not include limits for study design, as all types of studies were screened manually for potential inclusion.

Results

Systematic reviews

We found 11 systematic reviews published in the last 10 years, most in the last few years. Most were of good quality. They contained from three to 13 RCTs out of a total of 20. Their conclusions on
glycaemic control varied, with some saying there was no benefit, others saying there was benefit, and some saying that there was no conclusive evidence of benefit. Much of the apparent disagreement may arise from the level of HbA1c that was considered to prove benefit, since the differences in meta-analysis were often of the order of 0.2%, which can be statistically significant, but not clinically important. There was some evidence that studies in which patients were given feedback in response to SMBG values and/or in which SMBG results were used to modify therapeutic regimens were more effective than those without feedback or use of SMBG for therapy modification. Effects also tended to be larger for patients with higher baseline HbA1c values.

**Randomised controlled trials**

We found 26 RCTs, ranging in size from under 30 to over 800 patients, and in duration from 12 weeks to 30 months. Only four trials scored highly on quality assessment. Components of the SMBG interventions were not well described in many cases. Half of the trials reported a reduction in HbA1c level, and all those that did find favourable results included an educational component and/or feedback.

Ten trials compared ‘simple’ SMBG with no SMBG, and found a reduction in HbA1c level of 0.21%, which was statistically significant but of doubtful clinical significance. Four trials of ‘enhanced’ SMBG (for example with education, feedback, etc.) showed a bigger reduction in HbA1c level – 0.52% compared with no-SMBG. When SMBG enhanced with an educational or feedback component was compared to simple SMBG (five trials), there was an HbA1c reduction of 0.2%, however, this was not statistically significant.

Three RCTs showed no difference between SMBG and urine testing.

Differences in the frequency of hypoglycaemic episodes were inconsistent. There was no difference in weight or body mass index (BMI). There was no increase in medication changes with SMBG versus no SMBG, which may explain why HbA1c is not improved. Few studies examined quality of life (QoL), but the two best ones for this outcome [both from the UK, DiGEM (Diabetes Glycaemic Education and Monitoring) and ESMON (Efficacy of Self MONitoring of blood glucose in newly diagnosed type 2 diabetes trial)] reported a net adverse effect on anxiety and/or depression. Results from other studies were less clear cut.

**Observational studies**

There were 36 relevant observational studies. These are more prone to bias, from confounding factors, and association does not necessarily mean cause. Eighteen showed no difference in HbA1c level, 12 showed a reduction (but often very small), and some showed an increase in HbA1c level on SMBG, which may be because SMBG was started as a result of poor glycaemic control.

**Qualitative studies**

The qualitative studies had some fairly consistent messages:

- There was a lack of education in how to interpret and use the data from SMBG.
- In some patients, SMBG caused adverse psychological effects, including depression and self-chastisement, whereas others found it a useful tool for reassurance, assessing effects of behaviour and empowerment.
- There was a lack of education in how to interpret and use the data from SMBG.
- There was a lack of interest in the results from health-care professionals (HCPs).
- Failure to act on the results was common.

**The cost-effectiveness literature**

There was a mixture of studies: some just about costs, some looking at possible savings and others at cost-effectiveness. Some were funded by the manufacturers of testing strips and meters; these tended to be more favourable by making more generous assumptions on the effect on HbA1c level.

The cost of SMBG in people with T2DM in England is uncertain, but probably around £30M per year, of which at least half could be saved by adhering to previous guidelines and by applying the findings of DiGEM in the sulphonylurea-only group.

The reported costs per annum of SMBG vary amongst studies from £10 to £259, the lowest being an estimate about £10 per year for infrequent testers on diet alone.

Several studies asserted that SMBG can lead to savings that offset testing costs, and some estimated
that SMBG could lead to savings from reduced costs in other health care. These studies tended to have more optimistic assumptions.

However, most of these studies failed to allow for the potentially negative impact of SMBG on aspects of QoL.

The cost-effectiveness analyses vary in their assumptions, with those funded by industry producing lower incremental cost-effectiveness ratios (ICERs). The best analysis to date was that from the DiGEM trial (funded by the UK Health Technology Assessment programme), which, after taking into account all costs, gains and disutilities, concluded that SMBG was not cost-effective.

**Conclusions**

The current evidence suggests that SMBG is of limited clinical effectiveness in improving glycaemic control in people with T2DM on oral agents, or diet alone, and is therefore unlikely to be cost-effective. There were insufficient data for those on a single basal insulin to reach any conclusion. No data are available on the possible benefits of SMBG in selected patient subgroups. SMBG can be expected to lead to improved glycaemic control only in the context of appropriate education – both for patients and HCPs – on how to respond to the readings, in terms of lifestyle and treatment adjustment. It may be more effective if patients are able to self-adjust drug treatment.

In the authors’ opinion, at a time when funds are scarce, the case for investment in blood glucose monitoring in T2DM, in patients who are not treated with insulin, is not proven. Further research is required on the type of education and feedback that are most helpful, characteristics of patients benefiting most from SMBG, optimal timing and frequency of SMBG, and the circumstances under which SMBG causes anxiety and/or depression.
Chapter 1

Introduction

Background

Type 2 diabetes and its treatment

Type 2 diabetes (T2DM) is usually seen in people who are overweight or obese, and the prevalence is increasing. In most patients it is a progressive disease, in the sense that treatment starts with diet and other lifestyle measures, such as physical activity, but that tablet therapy is soon required, and progression to needing insulin is common as time passes. This is not invariable, in that some people manage to lose weight and be physically active and may not progress to needing intensified treatment.

The problems underlying progression of disease are twofold. Firstly, overweight and obesity make the body less sensitive to insulin (‘insulin resistance’), so that the pancreas needs to produce more to keep blood glucose levels normal. Secondly, there is progressive failure of the function of the beta cells in the pancreas, so that insulin production cannot be maintained. By the time someone is diagnosed with T2DM, they have usually lost about half of their beta-cell capacity.

Progression may mean that patients go through the following treatment stages:

- Diet and physical activity, aiming to achieve weight loss and reduce insulin needs and resistance.
- Treatment with a single oral drug, usually metformin.
- Treatment with two oral drugs, usually by adding a sulphonylurea to the metformin.
- Treatment with three oral drugs.
- The addition of insulin, usually with a once-daily long-acting (‘basal’) insulin, taken along with metformin and a perhaps reduced dose of sulphonylurea.
- When that fails, moving to more complex insulin regimens, such as adding short-acting insulin at mealtimes, or twice-daily mixed insulins, with the sulphonylurea being discontinued.

Each step in the treatment pathway is triggered by rising blood glucose levels. The National Institute for Health and Clinical Excellence (NICE) guideline CG661 recommends that the target should usually be a glycated haemoglobin (HbA1c) level of 6.5% or less. HbA1c is a blood test, taken by a doctor or nurse, and measured in a laboratory, and gives average blood glucose levels over the past 2–3 months. The HbA1c test measures the amount of glucose attached to the haemoglobin molecule.

If not well controlled, diabetes will increase the risk of heart disease, blindness, renal failure, amputation and other complications, so patients need to keep their blood glucose under as good control as possible. To do so, they need to know what it is. They will usually have their HbA1c level measured at intervals, which will let them know if control is poor. However, HbA1c level, being an average, will not explain why control is poor. Blood glucose can fluctuate from hour to hour, and blood glucose testing with meters and strips can identify the times when blood glucose is too high. It can also be used to check on when the level might be going too low – hypoglycaemia or hypoglycaemic episodes.

Self-monitoring of blood glucose

Nowadays, patients can measure their blood glucose level by putting a drop of blood on to a test strip, and using a meter to read colour changes in that. This is painful as patients are required to prick their finger with a lancet to obtain a blood sample. The strips are cumulatively expensive, with the average cost being £14.57 for a 50-strip pack. The meters are inexpensive at an average cost of £14.68 (2009 price) [and the NHS requires manufacturers to provide them free of charge for distribution to patients as considered appropriate by health-care professionals (HCPs)]. Knowledge of high blood glucose levels may cause anxiety, and fear of the long-term complications. However, it can also give patients information that they can use to improve control of their blood glucose. They can also measure the amount of glucose in their urine, which is a guide to blood glucose level. Urine
glucose tests only detect glucose in the urine once blood levels are above the renal threshold (around 10 mmol/l), so hypoglycaemia cannot be detected. Similarly, urine tests cannot detect the degree of hyperglycaemia.

A number of assumptions are made when proposing self-monitoring of blood glucose (SMBG) as an effective tool for blood glucose control, as outlined by McAndrew et al. (2007). The authors suggest that the efficacy of SMBG would depend on whether the interventions created a patient-centred behavioural control system that would address the patient’s skills in:

- taking a blood glucose reading
- interpreting the reading as a target for action
- perceiving linkages between specific behaviours (diet, exercise) and the reading (i.e. which behaviours lower an above-target reading and which raise a below-target reading) – ideally, the linkage would also act as a motivator to change behaviour
- implementing action plans (i.e. behavioural and treatment adjustments) in response to SMBG
- giving less weight to subjective symptoms that are the basis for commonsense decisions that one is sick or well, as these cues are invalid guides for the regulation of blood glucose levels
- incorporating the behavioural system into the patient’s ongoing daily behavioural patterns to eventually become automatic
- viewing difficulties in achieving control as issues of adjusting the behavioural treatment, not deficits in personal motivation or competence for self-management.

Table 1 suggests possible facilitators and barriers to SMBG as an effective diabetes management tool.

The volume and costs of prescriptions for blood glucose monitoring in England has risen steadily over the last 6 years. The last figures available are for the quarter July–September 2008, when the cost was £34M, which gives a projected annual cost of almost £140M. This compares with £107M in 2002. However, one would expect that much of this will be for people with type 1 diabetes (T1DM).

The SMBG controversy

There have been several recent trials and systematic reviews to evaluate the clinical effectiveness and cost-effectiveness of SMBG, but it still remains a controversial area. So, the first question may be – why is there still a question?

There are (at least) five possible answers to that.

Firstly, the evidence is to some extent conflicting, with different types of study design giving different results. There is also the issue of what harm it may do. Studies have shown that SMBG can increase anxiety.

Secondly, as with other diagnostic interventions, there is a hierarchy of questions:

- The technical level – does it accurately measure what it is supposed to?
- The treatment level – does SMBG lead to changes in treatment?
- The outcomes level – does SMBG reduce the risk of heart disease, visual loss, etc.?

Thirdly, SMBG is not an end in itself, but only an aid to management, and another question is ‘who uses the results?’. Do the patients record the results and bring them to the clinic or surgery to discuss the implications, so that the doctor or nurse can adjust treatment accordingly? Or do the patients use the information themselves and self-adjust diet, or doses of oral drugs or insulin?

Fourthly, if patients are going to self-adjust management, are they given sufficient education with which to do that?

Fifthly, knowledge alone does not always lead to action. Education might have two strands – knowledge of how to adjust treatment, but also ‘motivational knowledge’ that makes people understand the importance of good control.

Also, is there a relationship between adherence to medication, and likelihood of SMBG improving HbA1c level? If people are not adhering to a diet, exercise regimen or oral medication as prescribed (one study reported that only 35% of people adhere to any medication regimen on average) then what effect will SMBG have on patient perception of disease severity and/or importance of adherence generally? Some patients report in the qualitative studies that low SMBG readings give them the impression that they are fine. What impact does this have on adherence to therapy, diet and exercise? It is also not clear whether patients are instructed to monitor because they were in poor control initially or because they are given a tool to assist self-management.
TABLE 1 Facilitators and barriers to SMBG

<table>
<thead>
<tr>
<th>Facilitators</th>
<th>Barriers</th>
<th>Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruction in SMBG use</td>
<td>Negative message: internal (failure of self)</td>
<td>Direct feedback of effects of certain lifestyle behaviours on glucose values</td>
</tr>
<tr>
<td>Accuracy checks and adherence checks</td>
<td>or external</td>
<td>– learning effects of physiological consequences of, for example, eating</td>
</tr>
<tr>
<td>Integrated into patient education so that patients can understand and use SMBG information in a wider context</td>
<td>Lack of instruction/education – lack of understanding</td>
<td>certain foods</td>
</tr>
<tr>
<td>Positive messages</td>
<td>Lack of integration into management</td>
<td>Improved short- and long-term clinical outcomes if readings are adequately</td>
</tr>
<tr>
<td>Made easy for patient – ease of access and convenient regimen</td>
<td>People don’t like pricking fingers – and ‘dose’ of SMBG may be inappropriate cost</td>
<td>acted upon</td>
</tr>
<tr>
<td>Feedback on self-monitoring and clear messages regarding treatment/behaviour changes as a consequence of readings</td>
<td></td>
<td>Improved control/empowerment – patients have more possibilities to make</td>
</tr>
<tr>
<td></td>
<td></td>
<td>changes to influence disease positively</td>
</tr>
</tbody>
</table>

Readings facilitate individualised treatment of patient/treatment adjustments

The NICE clinical guideline on the management of T2DM, which was written before the two recent trials [DiGEM10–12 (Diabetes Glycaemic Education and Monitoring) and ESMON13 (Efficacy of Self MONitoring of blood glucose in newly diagnosed type 2 diabetes trial)] had reported, supported SMBG in certain circumstances. It recommended that SMBG should be available to newly diagnosed patients (recommendation 22), and to those on insulin and oral agents (recommendation 23).

The evidence base for these recommendations was based mainly on two observational studies, from the Kaiser Permanente14 study and the ROSSO (RetroOlective Study: Self-monitoring of blood glucose and Outcome in patients with type 2 diabetes) study.15 Two other observational studies by Wen et al.16 and Davis et al.17–19 were also mentioned, as were two randomised controlled trials (RCTs).20,21 The evidence cut-off date was before the DiGEM study was published, and well before the ESMON one. However, the NICE Guideline Development Group was clearly aware of the DiGEM study, and discounted it because ‘a study which viewed self-monitoring as a stand-alone intervention, and not as an element of a full educational programme, could not properly inform the appropriate use of self-monitoring’. This seems curious, as the third arm of the DiGEM study included patient education and motivation.

The NICE evidence review mentions only one economic study of SMBG – that by Palmer et al.22 – but did not mention that it was funded by the manufacturers of meters. As discussed in Chapter 3, it may be unduly favourable to SMBG. The cost-effectiveness results from the DiGEM trial came out too late to be included in the NICE review. It is not clear why other economics studies were not included.

The guideline commented that past research had failed ‘to address the complicated issue of its integration into patient education and self-management behaviours’.

Questions for this review

Primary question

Is SMBG worthwhile in patients, or selected patients, with T2DM:

- on diet alone
- on metformin monotherapy
- on combination oral therapy
- on combinations of oral therapy and basal insulin?

By ‘worthwhile’, we mean whether it provides clinical benefits, such as improved glycaemic control, fewer hypoglycaemic episodes or quality of life (QoL), at a cost that makes it cost-effective.

For the purposes of this review, we have assumed that, in line with NICE guidance, SMBG is
worthwhile in those on more complicated insulin regimens, such as basal + mealtimes or twice-daily mixed insulin, and the evidence on that was not examined.

**Additional questions**

- Which sub-groups of patients benefit most from SMBG?
- Which are harmed?
- What education is required to enable the patients, and their HCPs, to use the SMBG results to improve their diabetes control?
- How do we motivate those groups of patients that could benefit from SMBG to use it to improve their diabetes control?
- For those patients for whom SMBG is shown to be worthwhile, a subsidiary question might be how to best deliver SMBG (in terms of frequency and quality of testing, education, use of results, costs)?
Chapter 2
Clinical effectiveness of self-blood glucose monitoring

Methods
A protocol was produced and approved by the Health Technology Assessment (HTA) programme before the start of this review. It is available on the HTA programme website (www.ncchta.org/protocols/200900190001).

Criteria considered for synthesis of evidence of clinical effectiveness

Intervention
Self-testing of blood glucose with a meter and test strips.

Relevant comparators
The comparators were:

- self-monitoring of urine glucose (SMUG)
- monitoring with HbA\(_1c\)
- a combination of the above
- comparisons of SMBG of different intensities (either in terms of frequency or additional education, feedback or similar).

A review of the evidence for clinical effectiveness was undertaken systematically following the general principles recommended in the QUOROM (Quality of Reporting of Meta-analyses) statement.\(^{23}\)

Population
• Inclusion criteria:
  - studies including adult patients with T2DM on any oral treatment or combination of regimens, including lifestyle, oral agents or once-daily basal insulin
  - minimum duration of study was 12 weeks (as it may take longer for people using SMBG to assess the effects of changes and fine tune their treatment, a trial giving a positive result at 12 weeks would give useful information. However, a negative result at 12 weeks would not be regarded as proof that SMBG was ineffective)

- Exclusion criteria:
  - pregnant women with diabetes
  - studies in which some patients had T1DM and results were not given separately
  - studies in people on complex insulin regimens.

Place of self-monitoring of blood glucose
Evidence from existing reviews suggests that not all groups of patients benefit.

Patients could be grouped by:

- type of treatment, i.e. diet alone, metformin monotherapy, dual therapy (metformin + sulphonylurea), triple oral therapy, the combination of once-daily basal insulin + oral therapy
- baseline HbA\(_1c\) level
- duration of diabetes
- age
- patient preference (patients who feel that SMBG will benefit and empower them might do better than patients who are reluctant to use SMBG – determined by patient self-report)
- previous use of SMBG
- levels of education
- motivation for self-care (e.g. as determined using instruments related to an information-motivation-behavioural skills model of diabetes self-care).

Outcomes
• HbA\(_1c\) level.
• Hypoglycaemia.
• Quality of life, anxiety, depression.
• Costs.
• Treatment satisfaction.
• Weight.
• Treatment change in response to measurement (insulin dose, oral drug use, diet, exercise).
• Lipids (patients who adjust their diet in order to control hyperglycaemia may improve cholesterol levels as a by-product).
• Blood pressure.
In theory, complications such as retinopathy would be reported, but, realistically, very few studies would be long enough.

Technical issues related to SMBG were considered, but based only on reports in existing systematic reviews.

**Study type**

- **Inclusion criteria:**
  - For the review of clinical effectiveness, only systematic reviews and RCTs were included.
  - Large observational studies (500 participants or more) of adequate duration and published as full text articles were included for information on adverse events, longer-term outcomes (e.g. cardiovascular events, retinopathy) and qualitative issues (motivation, adherence and QoL, patient preferences).
  - Editorials, letters in journals, and small observational studies would be discussed if they threw light on the reasons for controversy.
  - Titles and abstracts were examined for inclusion by two reviewers independently. Disagreement was resolved by consensus.

- **Exclusion criteria:**
  - non-English language papers
  - papers published pre-1996
  - reports published as meeting abstracts only, where insufficient methodological details were reported to allow critical appraisal of study quality.

**Search strategy**

The search strategy comprised the following searches:

- websites of the European Association for the Study of Diabetes (EASD), American Diabetes Association (ADA) and Diabetes UK searched for meeting abstracts in April 2009.
- websites of the US Food and Drug Administration (FDA), Medicines and Healthcare Products Regulatory Agency (MHRA), SMBG International Working Group, Current Controlled Trials, ClinicalTrials.gov
- contact with experts in the field

- scrutiny of bibliographies of retrieved papers.

The searches were limited to the English language and to articles published since 1996 (due to the number of recent good quality systematic reviews) and in order to reflect current meter technologies.

The search strategy did not include limits for study design, as all types of studies were screened manually for potential inclusion. Selection was carried out independently by two reviewers.


Appendix 1 gives details of the search strategies and flow of studies.

**Quality assessment strategy**

Consideration of study quality for systematic reviews and trials included the following factors [based on key criteria of the QUOROM and CONSORT (Consolidated Standards of Reporting Trials) statements].

**Systematic reviews**

- Were inclusion/exclusion criteria that addressed the review question reported?
- Were details of the literature search given?
- Was study selection described and study flow shown?
- Was data extraction described?
- Was the validity of the included studies assessed?
- Were sufficient details about the individual included studies presented (characteristics, quality and results)?
- Was the statistical analysis appropriate?

Quality was rated as ‘high’ if no more than one of the quality criteria was not clearly fulfilled. Quality was rated as ‘moderate’ if two of the quality criteria were not clearly fulfilled (or three including study flow), and as ‘poor’ if more than two quality criteria were not fulfilled.

**Randomised controlled trials**

- Adequate description of trial design and participants.
- Method of randomisation.
• Allocation concealment.
• Blinding of outcome assessment.
• Adequate power.
• Numbers of participants randomised, excluded and lost to follow-up reported.
• Intent-to-treat analysis performed, methods for handling missing data given.
• Appropriateness of statistical analysis.
• Baseline characteristics similar.
• Funding of study.

Quality was rated as ‘high’ if no more than one of the quality criteria was not clearly fulfilled. Quality was rated as ‘moderate’ if two or three of the quality criteria were not clearly fulfilled, and as ‘poor’ if more than three quality criteria were not fulfilled.

**Methods of analysis/synthesis**

Initially, existing systematic reviews of SMBG were summarised and results compared. Reasons for differences between the reviews were investigated and possible reasons for conflicting results were investigated in a narrative review. Any RCTs and observational studies that were not included in the existing systematic reviews were data extracted and included. Details of any RCTs and observational studies included in the reviews were tabulated as far as reported in the reviews. Where there were doubts regarding the accuracy of the information in the reviews or where there was missing information, data were verified using the original papers.

Evidence synthesis of all of the studies meeting our inclusion criteria was carried out using a narrative review. Data were to be analysed by outcome and subgroups as outlined above. HbA1c data from RCTs were summarised using a meta-analysis (weighted mean differences, random effects model, inverse variance method). Heterogeneity was calculated using the chi-squared and I² methods.

The following analyses were carried out: SMBG compared to SMUG, SMBG versus no SMBG (in studies, where different intensities of SMBG were compared to no SMBG, this comparison included the less intensive SMBG intervention), more intensive SMBG (e.g. more frequent, enhanced by special education elements, etc.) versus less intensive SMBG, and more intensive SMBG versus no SMBG.

Relevant studies were examined with respect to the following aspects:

• Did patients receive education about SMBG:
  – about how to do SMBG (use of equipment, etc.)
  – about how to interpret results and how to respond
  – who carried out the education?
• Were the accuracy and frequency of monitoring (i.e. adherence) checked? (and by whom?)
• How the monitoring results were used:
  – for behaviour change by the patient
  – for treatment (medication) adjustment by the patient
  – for treatment (medication) adjustment by a doctor (or nurse)
  – was feedback on monitoring results given? (if so, what kind?)
• What message did the patients receive?
  – For example, that monitoring helped people gain control of their disease and that there was no reason to feel guilty about off-range values or that off-range values were a bad thing
  – Did patients get the impression that their doctor/nurse thought monitoring was a good thing and took note of the values?
• How does benefit of SMBG vary by:
  – starting HbA1c level (or stable/well controlled versus poor control)
  – frequency of monitoring
  – (type of) education
  – susceptibility to (unnoticed) hypoglycaemia
  – treatment (sulphonylureas versus other)
  – age
  – time point during the course of the disease (e.g. after diagnosis, during treatment change, at other times)?

**Results**

**Functionality issues**

Technical issues were discussed in the HTA report by Coster et al.:24

• They evaluated a sample of studies on device validation, which suggested that issues of observer training, interdevice variability, effects of long-term use and patient acceptability were not usually addressed.
• Some evidence (Brunner et al. (1998)) suggests that meter performance may be less satisfactory in the low glycaemic range and that there is some variation in the size and direction of measurement bias in different parts of the glycaemic range.
Development of memory meters showed that patients often make incomplete and incorrect recordings of blood glucose values in their diary records; sources of inaccurate readings include rounding values to the nearest whole number, omission of outlying values, reporting results when no test was recorded by the meter; over- and under-reporting often occurred together and was associated with higher HbA1c values and poor testing technique; occurrence of hypo- and hyperglycaemia was often obscured; informing patients of memory function of the meter led to correct readings.26

In some patients readings may be inaccurate because wide variations in blood glucose values between readings go unnoticed.

Evidence that more accurate blood glucose readings may be obtained if patients are given sufficient training – need for formal training and updating of skills in the use of meters, especially in people with special needs.

Further work should be done to develop standard packages to train patients in the use of self-monitoring devices and to provide them with the information needed to adjust their therapy in accordance with self-monitoring results.

No more recent systematic reviews were found. There is some indication that devices are becoming more reliable.27

Systematic reviews and included RCTs

There were 112,24,28–38 mostly high-quality reviews. The number of RCTs included ranged from 3 to 13 out of a total of 20 referenced RCTs (of which two were not strictly RCTs), as shown in Table 2. Our searches identified six additional RCTs (also shown in Table 2), of which two were published as abstracts only.42,51

Four of the reviews also included a range of 6–18 non-randomised/observational studies. [Agency for Healthcare Research and Quality (AHRQ; 2007),28 McAndrew et al. (2007),2 McGeoch et al. (2007)32 and St John et al. (2009)38]. Appendix 2 gives the characteristics of the systematic reviews.

Table 3 shows 31 observational or pseudoexperimental studies included in four of the systematic reviews,2,28,32,39 and another five relevant studies67,82,88,92,94 were identified which were not included in any of the reviews (three published as abstracts only). Table 4 shows the conclusions of the reviews, and Table 5 shows the results of any meta-analyses reported in the reviews.

Only two reviews were not of high or moderate quality.28,30 Six reviews24,29,31,34,36,38 included a meta-analysis of RCTs, of which several performed subgroup analyses, for example based on trial duration of whether patients received feedback on their SMBG results or not. Most reviews focused on T2DM, with some excluding trials in insulin-treated patients. The trials included mostly compared SMBG with no SMBG. Three trials40,47,56 compared SMBG with SMUG (urine monitoring), and nine trials10,11,42–44,46,50,55,59–61 compared a more intensive SMBG intervention with a less intensive one.

The systematic reviews provided evidence both in support of the benefits of SMBG and evidence that it can be associated with increased anxiety and levels of depression in users. However, the size of benefit was often very small and below the change in HbA1c level that is usually considered clinically significant (0.5% – although this is a somewhat arbitrary figure). There is a lack of evidence on why SMBG clearly does not work for some patients, and on which patients are most likely to benefit from the technology. Results are presented addressing outcome measures such as HbA1c level, rather than exploring issues predicting success or failure, and there is little exploration of either accuracy of results or whether behaviour/therapy changes are made based on those results. Furthermore, there is little evidence in the literature regarding the way in which HCPs collaborate with patients regarding how to interpret and act on readings.

Mixed results were reported among systematic reviews in terms of improvements in HbA1c level with SMBG compared to no monitoring. Five reviews include a meta-analysis,24,29,31,34,37 with the newer ones all showing some significant reduction of HbA1c level in the SMBG groups versus control (between –0.21% and –0.42%). Towfigh et al. (2008),35 however, found only a short-term significant reduction of HbA1c at 6 months but this was not sustained after a year or more. The Bayesian meta-analysis (including indirect comparisons) by Jansen et al. (2006)31 found a reduction of –1.13% with SMBG plus feedback given to patients versus no self-monitoring. This difference is much larger than those from other reviews, and may be due to the use of indirect comparisons. Poolsup et al. (2008)33 found a significant difference in HbA1c level overall (–0.24% SMBG versus no SMBG), but, when comparing trials where SMBG results were used to modify
### TABLE 2  
Randomised controlled trials (RCTs) – included in reviews (plus additional RCTs not included in previous reviews)

<table>
<thead>
<tr>
<th>RCTs</th>
<th>Systematic reviews</th>
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<tbody>
<tr>
<td>Allen (1990)</td>
<td>Yes</td>
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<tr>
<td>Barnett (2008)</td>
<td>Yes</td>
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<tr>
<td>Bonomo (2006) (abstract)</td>
<td>Yes</td>
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<tr>
<td>Brown (2002)</td>
<td>Yes</td>
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<td>Cho (2006)</td>
<td>Yes</td>
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<td>Davidson (2005)</td>
<td>Yes</td>
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<td>Estey (1990)</td>
<td>Yes</td>
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<td>Farmer (2007)</td>
<td>Yes</td>
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<td>Fontbonne (1989)</td>
<td>Yes</td>
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<td>Gallichan (1994)</td>
<td>Yes</td>
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<td>Guerci (2003)</td>
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<td>Jaber (1996)</td>
<td>Yes</td>
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<td>Johnson (2006)</td>
<td>Yes</td>
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<td>Jones (2003)</td>
<td>Yes</td>
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<td>Joy (2003) (abstract)</td>
<td>Yes</td>
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<tr>
<td>Kibiya (1999)</td>
<td>Yes</td>
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<td>Kwon (2004)</td>
<td>Yes</td>
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<td>Miles (1997)</td>
<td>Yes</td>
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<td>Moreland (2006)</td>
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<td>Muchmore (1994)</td>
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<td>O’Kane (2008)</td>
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<td>Rutten (1990)</td>
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<td>Scherbaum (2008)</td>
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<td>Seaton (1996)</td>
<td>Yes</td>
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<td>Wing (1986)</td>
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AHRQ, Agency for Healthcare Research and Quality.
<table>
<thead>
<tr>
<th>Observational study</th>
<th>Systematic reviews</th>
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<tbody>
<tr>
<td>Bajakowska-Fiedziukiewicz (2008)</td>
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<td>Banister (2004)</td>
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<td>Blonde (2002)</td>
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<td>Capelson (2006)</td>
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<td>Chan (2000)</td>
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<td>Davis (2006)</td>
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<td>Franciosi (2001)</td>
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<td>Hanninen (2001)</td>
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<td>Wen (2004)</td>
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<td>Wieland (1997)</td>
<td>Yes</td>
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</table>

AHRQ, Agency for Healthcare Research and Quality.

a Classified two of the RCTs as non-randomised and included one study not relevant to this review, so only three out of six studies are shown in the table.
therapeutic regimens with those that did not, only the results for the former were statistically significant and the difference (–0.27%) was not clinically significant. There was no significant difference between SMBG and urine monitoring. Some of the reviews reported results on weight and showed that there was no significant effect of SMBG versus no monitoring on weight.

Reviews tended to focus on comparisons between SMBG and no SMBG and on trials reporting HbA1c level as an outcome. There was less consideration of studies looking at different modes of using SMBG, for example frequency, duration of monitoring, purpose, etc. This could potentially highlight why some of the important components of a successful SMBG intervention are not fully explored. Features predicting success/failure include:

- The SMBG regimens used in the trials were very different, ranging from 6 times per day for 6 days per week, to less frequent regimens or no fixed regimen, i.e. at patient’s discretion.
- Most trials did not give any details on changes made to therapy or lifestyle based on SMBG results; in some trials, therapy changes were made by physician/nurse but the patient was not allowed to change anything. No trials reported patients being actively encouraged to make behaviour/lifestyle changes based on SMBG results.
- No feedback on results was given to patients. There appears to be difference in expectation between HCPs and patients, in that patients expect HCPs to make decisions based on the readings they provide, whereas HCPs see SMBG as a tool for patients to make behaviour/lifestyle changes.
- SMBG readings were taken at inappropriate times and so it was impossible to gain meaningful results.
- Efficacy of SMBG may be lower when baseline HbA1c level is higher, i.e. SMBG may be least effective for those who need it most. This could be because at higher levels they have little scope to alter treatment or perhaps because those with higher levels are less willing to self manage.
- While several trials included an educational/counselling component, this was not widespread across all trials and the detail of education was not provided. In some cases, interventions were incomparable between cohorts, thus contributing to possible confounding variables.
- SMBG accuracy checks were not carried out in the majority of trials therefore it cannot be known whether readings represented an accurate reflection of blood glucose. Furthermore, McGeoch et al. (2007) raises questions about whether some participants are sufficiently literate and numerate to be able to take advantage of the intervention.
- Only a very limited range of outcomes was reported – mainly HbA1c level, with few reviews reporting weight, hypoglycaemia, QoL or adverse effects. Behaviour change was acknowledged; however, the extent to which behaviour was adjusted or specific adjustments remains unclear.
- Many included trials were of poor quality, i.e. sample sizes were often small and many trials had short follow-up times. Randomisation techniques were not described in many studies. The study by Worth et al. suggests that the main benefit of self-monitoring was an educational modality, leading to increased contact time with diabetes care staff and greater motivation. Any effects were short-lived and future research should focus on long-term results.
<table>
<thead>
<tr>
<th>Study</th>
<th>Conclusions (medical effectiveness)</th>
<th>Recommendations for research</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faas (1997)&lt;sup&gt;30&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: efficacy of SMBG in non-insulin dependent patients with T2DM is questionable</td>
<td>SMBG intervention should be comprehensive, stimulating patients not only to perform SMBG, but also combine it with a programme of lifestyle changes</td>
<td>• Attention of doctors and nurses and patient education could have contributed to positive results</td>
</tr>
<tr>
<td></td>
<td>Hypoglycaemia (frequency and severity): not reported</td>
<td>SMBG should have protocols, preferably with a semi-fixed regimen</td>
<td>• Effective coping of patients and physicians with lifestyle changes in combination with SMBG is most promising strategy</td>
</tr>
<tr>
<td></td>
<td>QoL/measure of empowerment – self-efficacy? not reported</td>
<td>Caregiver should give feedback on the patient's self-measured glucose levels</td>
<td>• Recommendation for practice is that SMBG should be used in patients with poor glycaemia control despite optimal treatment</td>
</tr>
<tr>
<td></td>
<td>Treatment change in response to measurements (insulin dose, oral drug dose, etc.): not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Behaviour change in response to measurements (diet, exercise etc.): not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Weight: limited evidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospital admissions: not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Costs: not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coster (2000) (NHS HTA)&lt;sup&gt;29&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: there is no evidence to show that SMBG or SMUG improves glucose control measured using GHB or FPG; there is no evidence that glucose monitoring is more effective than urine glucose monitoring in improving glucose control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hypoglycaemia (frequency and severity): not reported by trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>QoL/measure of empowerment – self-efficacy? patients' perceptions of monitoring were neither completely nor rigorously studied and further work is need in this area; urine testing is preferred by some patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment change in response to measurements (insulin dose, oral drug dose, etc.): not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Behaviour change in response to measurements (diet, exercise, etc.): not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Weight: no significant effect of SMBG vs control or SMUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospital admissions: not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Costs: urine testing is less costly than blood testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>General: the studies reviewed had low statistical power and were poorly reported and conducted; small but clinically relevant changes might not have been detectable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sarol (2005)&lt;sup&gt;34,39&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: in the short term and when integrated with educational advice, SMBG as an adjunct to standard therapy may contribute to improving glycaemic control among non-insulin-requiring patients with T2DM; SMBG does not improve glycaemic control in isolation; proper use of SMBG data can guide clinical decisions and improve control only if SMBG results are used to modify behaviour, diet, exercise and medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Research required to identify subset of patients willing and able to effectively carry out treatment adjustments</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Optimal testing frequencies, cost–benefit of SMBG and QoL as an outcome should also be explored</td>
<td></td>
<td>Factors influencing SMBG regimen include: current level of glycaemic control, medication regimen, risk of hypoglycaemia, patient motivation and attitudes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Ideal testing regimens range from four or more tests daily on insulin to a few times per week (not specified)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Conclusions (medical effectiveness)</td>
<td>Recommendations for research</td>
<td>Comments</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Welschen (2005) | HbA1c: SMGB might be effective in improving glycaemic control in patients with T2DM not using insulin; meta-analysis resulted in a statistically significant and clinically relevant reduction of HbA1c (−0.39%) | • More trial evidence needed in a large group of patients performing SMBG according to standard testing frequency instructions; both intervention and control group should receive the same standard treatment programme to change diet, lifestyle and medication, preferably with dietitian; diabetes nurse with responsibility for SMBG instruction should supervise the SMBG group; long-term FU needed; a range of outcomes should be investigated, including patient satisfaction and QoL. Hypoglycaemia; subgroups based on patient age, diabetes duration and baseline HbA1c values should be evaluated | • Studies with higher baseline HbA1c level showed a greater final reduction in HbA1c level  
• Diabetes duration at start of studies was different, which may have contributed to differences in results, i.e. short duration of diabetes was associated with higher likelihood of HbA1c level improvement  
• No standard instructions were given to the patients to adjust their behaviour and medication to adjust their glucose values |
| Jansen (2006) | HbA1c: SMBG is effective in reducing HbA1c in T2DM – regular feedback is important; SMBG is likely to be more effective than SMUG | • Studies with final end points (e.g. cardiovascular events) and patient QoL/satisfaction required | Only assesses HbA1c level through direct and indirect comparisons (Bayesian meta-analysis)  
• Further FU and feedback from nurses or physicians regarding results of SMBG use important for compliance and to improve glycaemic control |
| AHRQ (2007) | HbA1c: the studies may suggest small but possibly clinically non-significant reductions in HbA1c with SMBG, but overall studies are inconclusive; uncontrolled and cohort studies agreed with RCTs in finding small reductions in HbA1c; no conclusions regarding the frequency of SMBG and HbA1c | • Studies very different in how frequently and on which days SMBG was performed  
• As studies did not report how patients or clinicians changed their behaviour or treatments, results do not explain how use of SMBG resulted in improved HbA1c level  
• Generalisability: patients were generally younger than the typical patient population and comorbidities were not reported |  

continued
### TABLE 4  Conclusions and recommendations of systematic reviews (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Conclusions (medical effectiveness)</th>
<th>Recommendations for research</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>McAndrew (2007)²</td>
<td><strong>HbA₁c</strong>: SMBG may be effective in controlling glucose for patients with T2DM</td>
<td><strong>Concur with the view that larger, long-duration trials with patient-centred outcomes are needed but analysis should be carried out based on initial HbA₁c level or better at the level of the individual patient</strong></td>
<td>Steps required for SMBG to be effective – patients must:</td>
</tr>
<tr>
<td></td>
<td>Hypoglycaemia: not reported</td>
<td>• know how to take a reading</td>
<td>• know how to take a reading</td>
</tr>
<tr>
<td></td>
<td>QoL/make of empowerment – self-efficacy? One study found SMBG to be associated with higher depression but QoL unchanged in another two studies and improved in the SMBG group in one trial</td>
<td>• understand when reading is above/below target</td>
<td>• understand when reading is above/below target</td>
</tr>
<tr>
<td></td>
<td>Treatment change in response to measurements: not reported</td>
<td>• see the connection between deviant readings and prior behaviour</td>
<td>• see the connection between deviant readings and prior behaviour</td>
</tr>
<tr>
<td></td>
<td>Weight: not reported</td>
<td>• have and implement an action plan to control glucose levels</td>
<td>• have and implement an action plan to control glucose levels</td>
</tr>
<tr>
<td></td>
<td>Hospital admissions: not reported</td>
<td>• rely more heavily on SMBG readings and give less weight to subjective feelings of well-being</td>
<td>• rely more heavily on SMBG readings and give less weight to subjective feelings of well-being</td>
</tr>
<tr>
<td></td>
<td>Costs: not reported</td>
<td>• create simple action plans that will allow the patient to integrate them into his/her ongoing life patterns</td>
<td>• create simple action plans that will allow the patient to integrate them into his/her ongoing life patterns</td>
</tr>
<tr>
<td></td>
<td>SMBG use: data suggests that fewer than 60% of patients with T2DM using diet and/or hypoglycaemic agents practice SMBG on a regular basis</td>
<td>• evaluate glucose readings in a non-judgemental framework</td>
<td>• evaluate glucose readings in a non-judgemental framework</td>
</tr>
<tr>
<td>McGeoch (2007)³</td>
<td><strong>HbA₁c</strong>: neither RCTs nor observational studies provided conclusive evidence for or against SMBG; larger observational studies showed better results in patients with higher initial HbA₁c levels</td>
<td><strong>None of the studies examined how SMBG is used to modify patients’ lifestyles (which is also dependent on context of carrying out SMBG and incentives provided, e.g., free strips/monitors); none of the evidence addresses SMBG in terms of consistent guidance relating to when and how to monitor, and how to interpret and act on the results; frequent monitoring is meaningless unless the results are acted upon to prevent long-term diabetes complications</strong></td>
<td>None of the studies examined how SMBG is used to modify patients’ lifestyles (which is also dependent on context of carrying out SMBG and incentives provided, e.g., free strips/monitors); none of the evidence addresses SMBG in terms of consistent guidance relating to when and how to monitor, and how to interpret and act on the results; frequent monitoring is meaningless unless the results are acted upon to prevent long-term diabetes complications</td>
</tr>
<tr>
<td></td>
<td>Hypoglycaemia: not reported</td>
<td><strong>Question may not be whether SMBG confers benefits on average, but for which particular patients, and how can they be identified?</strong></td>
<td>Question may not be whether SMBG confers benefits on average, but for which particular patients, and how can they be identified?</td>
</tr>
<tr>
<td></td>
<td>QoL/make of empowerment – self-efficacy? not reported</td>
<td><strong>SMBG may not be helpful or economically justified in all cases, but it seems likely that individuals would benefit if:</strong></td>
<td><strong>SMBG may not be helpful or economically justified in all cases, but it seems likely that individuals would benefit if:</strong></td>
</tr>
<tr>
<td></td>
<td>Treatment change in response to measurements: not reported</td>
<td>• their baseline HbA₁c level is above 8%</td>
<td>• their baseline HbA₁c level is above 8%</td>
</tr>
<tr>
<td></td>
<td>Weight: not reported</td>
<td>• they are properly educated in the use of SMBG and how to take appropriate action based on the results</td>
<td>• they are properly educated in the use of SMBG and how to take appropriate action based on the results</td>
</tr>
<tr>
<td></td>
<td>Hospital admissions: not reported</td>
<td>• they are sufficiently literate and numerate to take advantage of the intervention</td>
<td>• they are sufficiently literate and numerate to take advantage of the intervention</td>
</tr>
<tr>
<td></td>
<td>Costs: not reported</td>
<td>• they are receptive to the need for better metabolic control and are motivated to make the necessary changes</td>
<td>• they are receptive to the need for better metabolic control and are motivated to make the necessary changes</td>
</tr>
<tr>
<td></td>
<td>SMBG use: data suggests that fewer than 60% of patients with T2DM using diet and/or hypoglycaemic agents practice SMBG on a regular basis</td>
<td>• there are special circumstances, such as new diagnosis, initiation or change in medication, illness, gestational diabetes, lack of awareness of hypoglycaemia</td>
<td>• there are special circumstances, such as new diagnosis, initiation or change in medication, illness, gestational diabetes, lack of awareness of hypoglycaemia</td>
</tr>
</tbody>
</table>

Other: observational study with the longest FU (6.5 years) had significantly lower mortality and morbidity in SMBG group than in non-SMBG group
Clinical effectiveness of self-blood glucose monitoring

Steps required for SMBG to be effective – patients must:

- understand when reading is above/below target
- see the connection between deviant readings and quality of life/measure of empowerment – self-efficacy?
- have and implement an action plan to control glucose levels
- treatment change in response to measurements: not reported
- weight: not reported
- hospital admissions: not reported
- costs: not reported

*HbA\(_1c\)*: neither RCTs nor observational studies provided conclusive evidence for or against SMBG; larger observational studies showed better results in patients with higher initial *HbA\(_1c\)* levels, but it seems likely that individuals would benefit if: the *HbA\(_1c\)* level is higher – meaning that SMBG may be least effective for the patients who need it most.

**Comments on potential modifiers:**
- no feedback on results
- not taught self-management skills needed to lower BG values
- measured BG at wrong times
- not results per se, rather what patient does with results that influences outcome (hard to measure in an RCT)

**Study** | **Conclusions (medical effectiveness)** | **Recommendations for research** | **Comments**
--- | --- | --- | ---
**Poolsup (2008)**\(^{15}\) | *HbA\(_1c\)*: The evidence suggests that SMBG is beneficial in improving *HbA\(_1c\)*, especially when used to adjust therapeutic regimens - hypoglycaemia: not reported
- QoL/measure of empowerment – self-efficacy? not reported
- Treatment change in response to measurements: not reported
- Weight: not reported
- Hospital admissions: not reported
- Costs: not reported | - Large, high-quality RCTs in patients with non-insulin-dependent T2DM are warranted, including standard protocols for use and frequency of SMBG testing, assessment of accuracy of the glucose meter and user technique, patient education of how to self-monitor glucose, how to interpret the SMBG results, and how to use the SMBG results to adjust lifestyle, diet, and/or medications to improve diabetes control; effect of SMBG should also be evaluated in subgroups of patients with various levels of *HbA\(_1c\)* at baseline; goal of glycaemic control should be defined; effect in new vs ongoing users should be evaluated | - Periodic checking of glucose meter user’s technique is important
- Problems of trials included low adherence in some studies; lack of standard training or use of a protocol to guide the proper use of SMBG techniques

**Towfish (2008)**\(^{15}\) | *HbA\(_1c\)*: modest but statistically significant improvement in *HbA\(_1c\)* at 6 months in patients with T2DM not requiring insulin when SMBG and education were added to management (-0.21%, 95% CI -0.38 to -0.04); 12-month result not significant; meta-regression suggested that effects may be lower with higher baseline *HbA\(_1c\)*
- Hypoglycaemia: limited evidence of three trials suggests that SMBG may increase the frequency of recognised hypoglycaemia
- QoL/measure of empowerment – self-efficacy? not reported
- Treatment change in response to measurements: not reported
- Weight: not reported
- Hospital admissions: not reported
- Costs: not reported | - Further studies needed that could determine where in the process, from performance and interpretation of SMBG and application of the result to self-management, improved education and motivation would produce the greatest gains | - Efficacy of SMBG may be lower as the baseline *HbA\(_1c\)* level is higher – meaning that SMBG may be least effective for the patients who need it most
- At best, SMBG is an intervention of modest efficacy in patients not taking insulin

**St John (2009)**\(^{15}\) | *HbA\(_1c\)*: modest but statistically significant improvement in *HbA\(_1c\)* in patients with T2DM not requiring insulin when using SMBG for up to 12 months (seven RCTs, -0.22% (95% CI -0.34 to -0.11)); finding consistent with most observational studies of similarly treated patients
- Hypoglycaemia: not reported
- QoL/measure of empowerment – self-efficacy? not reported
- Treatment change in response to measurements: not reported
- Weight: not reported
- Hospital admissions: not reported
- Costs: not reported | - Further studies needed that could determine where in the process, from performance and interpretation of SMBG and application of the result to self-management, improved education and motivation would produce the greatest gains | Comments on potential modifiers:
- no feedback on results
- not taught self-management skills needed to lower BG values
- measured BG at wrong times
- not results per se, rather what patient does with results that influences outcome (hard to measure in an RCT)
- Comments on education provided:
- large variation in education package provided

BG, blood glucose; FPG, fasting plasma glucose; FU, follow-up; GHb, glycosylated haemoglobin.
### Table 5: Results of meta-analyses in the reviews

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Results of meta-analysis (for SBMG minus comparator, so negative value = better on SMBG)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coster (2000)</strong>&lt;sup&gt;29&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>Effect of blood or urine monitoring on GHb vs control</td>
<td>$-0.25%$ (95% CI $-0.61$ to $0.10$; $p = \text{NS}$) (four studies)</td>
</tr>
<tr>
<td>SMBG vs SMUG</td>
<td>$-0.03%$ (95% CI $-0.52$ to $0.47$; $p = \text{NS}$)</td>
</tr>
<tr>
<td>Weight</td>
<td></td>
</tr>
<tr>
<td>Effect of blood or urine monitoring on weight vs control</td>
<td>$-0.28$ kg (95% CI $-1.48$ to $0.98$; $p = \text{NS}$) (four studies)</td>
</tr>
<tr>
<td>SMBG vs SMUG</td>
<td>$0.36$ kg (95% CI $-1.93$ to $2.65$; $p = \text{NS}$)</td>
</tr>
<tr>
<td><strong>Sarol (2005)</strong>&lt;sup&gt;34,39&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>SMBG vs non-SMBG (random effects)</td>
<td>$-0.42%$ (95% CI $-0.63$ to $-0.21$; $p &lt; 0.05$) (eight studies)</td>
</tr>
<tr>
<td><strong>Welschen (2005)</strong>&lt;sup&gt;36,37&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>SMBG vs control</td>
<td>$-0.39%$ (95% CI $-0.56$ to $-0.21$; $p &lt; 0.05$) (five studies)</td>
</tr>
<tr>
<td>SMBG vs SMUG</td>
<td>$-0.17%$ (95% CI $-0.96$ to $0.61$; $p = \text{NS}$) (two studies)</td>
</tr>
<tr>
<td><strong>Jansen (2006)</strong>&lt;sup&gt;31&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt; (adjusted for baseline HbA&lt;sub&gt;1c&lt;/sub&gt; to all T2DM patients)</td>
<td></td>
</tr>
<tr>
<td>No self-monitoring</td>
<td>$-0.47%$ (95% CrI: $-0.66$ to $-0.28$)</td>
</tr>
<tr>
<td>SMUG</td>
<td>$-0.61%$ (95% CrI: $-1.20$ to $-0.05$)</td>
</tr>
<tr>
<td>SMBG</td>
<td>$-0.87%$ (95% CrI: $-1.14$ to $-0.58$)</td>
</tr>
<tr>
<td>SMBG vs control</td>
<td>$-0.19%$ (95% CrI: $-0.80$ to $0.44$; $Pr = 74%$)</td>
</tr>
<tr>
<td>SMBG vs control</td>
<td>$-0.41%$ (95% CrI: $-0.72$ to $-0.06$; $Pr = 98%$)</td>
</tr>
<tr>
<td>SMBG + FB vs control</td>
<td>$-1.13%$ (95% CrI: $-1.87$ to $-0.35$; $Pr = 99%$)</td>
</tr>
<tr>
<td>SMBG vs SMUG</td>
<td>$-0.21%$ (95% CrI: $-0.82$ to $0.39$; $Pr = 78%$)</td>
</tr>
<tr>
<td>SMBG + FB vs SMUG</td>
<td>$-0.95%$ (95% CrI: $-1.78$ to $-0.09$; $Pr = 98%$)</td>
</tr>
<tr>
<td>SMBG + FB vs SMBG</td>
<td>$-0.73%$ (95% CrI: $-1.41$ to $-0.04$; $Pr = 98%$)</td>
</tr>
<tr>
<td><strong>Subgroups</strong></td>
<td><strong>Results similar for non-insulin-requiring patients with T2DM</strong></td>
</tr>
<tr>
<td><strong>Poolsup (2008)</strong>&lt;sup&gt;33&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>SMBG vs no SMBG</td>
<td>$-0.24%$ (95% CI $-0.37$ to $-0.12$; $p = 0.0002$) (seven trials)</td>
</tr>
<tr>
<td>SMBG vs no SMBG – SMBG results used to modify therapy</td>
<td>$-0.27%$ (95% CI $-0.41$ to $-0.14$; $p = 0.0001$) (six trials)</td>
</tr>
<tr>
<td>SMBG vs no SMBG – SMBG results not used to modify therapy</td>
<td>$-0.12%$ (95% CI $-0.32$ to $0.08$; $p = \text{NS}$) (six trials)</td>
</tr>
<tr>
<td><strong>Towfigh (2008)</strong>&lt;sup&gt;35&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>SMBG vs no SMBG ≥ 1 year</td>
<td>$-0.16%$ (95% CI $-0.38$ to $0.05$; $p = \text{NS}$) (five trials)</td>
</tr>
<tr>
<td>SMBG vs no SMBG 6 months</td>
<td>$-0.21%$ (95% CI $-0.38$ to $-0.04$; $p &lt; 0.05$) (six trials)</td>
</tr>
<tr>
<td><strong>St John (2009)</strong>&lt;sup&gt;38&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>SMBG vs no SMBG</td>
<td>$-0.22%$ (95% CI $-0.34$ to $-0.11$; $p &lt; 0.05$) (seven trials)</td>
</tr>
<tr>
<td>SMBG vs no SMBG to duration &lt; 1 year</td>
<td>$-0.26%$ (95% CI $-0.40$ to $-0.11$; $p = 0.001$) (five trials)</td>
</tr>
<tr>
<td>SMBG vs no SMBG to duration ≥ 1 year</td>
<td>$-0.17%$ (95% CI $-0.36$ to $0.02$; $p = 0.072$) (two trials – DiGEM to ESMON)</td>
</tr>
</tbody>
</table>

CI, confidence interval; CrI, credible interval; FB, feedback; GHb, glycosylated haemoglobin; NS, not significant; Pr, probability that first intervention results in greater reductions than second intervention.
specific questions? One could suggest that testing 6 days per week before and after meals places an unnecessary burden on patients who are treated using diet and exercise alone.

**Randomised controlled trials**

Appendix 3 shows details of the 26 relevant RCTs identified from the reviews and from our additional searches.

Trial duration/follow-up ranged from 12 weeks to 30 months. Participant numbers varied from less than 30 to over 800, with over 100 participants in the majority of trials. Some trials included only non-insulin-treated patients, whereas others specified no medication restrictions. Trials generally provided no details of oral anti-hyperglycaemic treatment received and no details of subgroups of patients (e.g., those taking sulphonylureas or those susceptible to hypoglycaemia), therefore separate assessments by treatment type could not be carried out. A few trials included small numbers of patients also taking insulin, but no details were provided of subgroups taking insulin. Primary outcome measures were mainly HbA1c level, but trials also assessed a range of additional outcomes such as HbA1c level fluctuations, fasting plasma glucose (FPG), fructosamine, episodes of hypoglycaemia, weight/body mass index (BMI), diabetes self-care activities, adverse effects, frequency of SMBG, QoL, medication use, health-care utilisation and lipid parameters.

No adequate data for meta-analysis were available for outcomes other than HbA1c level, and no data on relevant subgroups could be identified (neither for narrative nor for statistical analysis).

Due to the limitations of the data, most of the original questions of this review could not be answered, as not enough data on relevant subgroups by treatment or patient characteristics were presented.

Most trials had serious quality deficits (see Appendix 3). Only four of the trials [Barnett et al. (2008), Farmer et al. (2007) (DiGEM), O’Kane et al. (2008) (ESMON) and Scherbaum et al. (2008)] could clearly be classified as high quality, while more than half of the studies were classified as clearly being of poor quality. Randomisation and allocation concealment was often not described, sample sizes were often small, and some trials had substantial losses to follow-up. Additionally, important aspects of the SMBG intervention were not clearly described by many of the trials (e.g. what kind of instructions and education was received, how and if feedback was given, whether SMBG technique was checked, whether monitoring frequency was checked (and how frequently people were monitored, etc.).

Two of the high-quality trials, O’Kane et al. (2008 – ESMON) and Barnett et al. (2008 – DINAMIC; Diamicron MR in NIDDM: assessing management and improving control), have been criticised on the grounds that they were both in recently diagnosed patients whose control was poor, and was going to improve with treatment and intensive education whether SMBG was used or not. In the control groups, HbA1c level improved from 8.6% to 6.9% (ESMON) and from 8.1% to 7.2% (DINAMIC), hence leaving little scope to show benefit from SMBG.

The DiGEM trial has been criticised on similar grounds because control was quite good at baseline (mean HbA1c level = 7.5%), making further improvements difficult.

Table 6 presents an attempt to classify the studies by the moderators we identified as being potentially important. Overall, less than half the studies found better HbA1c values in the intervention group than in the control group. All the studies that did find more favourable results for the intervention included an education component and/or feedback on SMBG results.

The following figures (Figures 1–4) show the results of our meta-analyses. In total, 10 RCTs were included in the meta-analysis of ‘simple’ SMBG versus no SMBG. Overall, there was a small but significant reduction of HbA1c level with SMBG of –0.21% (95% CI –0.31 to –0.10, p < 0.0001, no significant heterogeneity). None of the studies comparing SMBG with SMUG (three RCTs) found a significant difference, and there was no significant difference overall (–0.06%, 95% CI –0.69 to 0.56, no significant heterogeneity).

For the meta-analysis of ‘enhanced’ SMBG versus ‘simple’ SMBG, ‘enhanced’ SMBG was subdivided into those studies with a component of education and/or feedback and those using other methods (higher versus lower frequency of monitoring, free provision of strips versus no free provisions of strips). HbA1c level reduction when comparing
<table>
<thead>
<tr>
<th>Study</th>
<th>Comparison</th>
<th>SMBG instruction</th>
<th>Education/counselling</th>
<th>Feedback given</th>
<th>Treatment adjustment</th>
<th>SMBG regimen</th>
<th>Starting HbA1c level</th>
<th>Age</th>
<th>Treatment</th>
<th>Diabetes duration</th>
<th>Hba1c results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen (1990)</td>
<td>SMBG vs SMUG</td>
<td>Yes</td>
<td>Yes (both)</td>
<td>Yes</td>
<td>Doctor</td>
<td>Moderate</td>
<td>12</td>
<td>58</td>
<td>Diet, oral</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Barnett (2008)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>Yes (both)</td>
<td>Unclear</td>
<td>No</td>
<td>Moderate</td>
<td>8</td>
<td>56</td>
<td>Diet, MET/ SU</td>
<td>3</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Bonomo (2006)</td>
<td>SMBG profile once per month vs more detailed SMBG profile every 2 weeks</td>
<td>No</td>
<td>Yes</td>
<td>Unclear</td>
<td>Yes</td>
<td>Infrequent</td>
<td>8</td>
<td>65</td>
<td>Diet, oral</td>
<td>11</td>
<td>More frequent better</td>
</tr>
<tr>
<td>Brown (2002)</td>
<td>SMBG plus education vs no SMBG</td>
<td>Yes</td>
<td>Yes (only intervention)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>12</td>
<td>NR</td>
<td>Oral</td>
<td>NR</td>
<td>Unclear</td>
</tr>
<tr>
<td>Cho (2006)</td>
<td>Internet vs non-internet SMBG</td>
<td>Unclear</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Unclear</td>
<td>7.6</td>
<td>53</td>
<td>Diet, oral, insulin</td>
<td>7</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Davidson (2005)</td>
<td>SMBG vs no SMBG</td>
<td>Unclear</td>
<td>Yes (both)</td>
<td>Unclear</td>
<td>Doctor/nurse</td>
<td>Frequent</td>
<td>8.5</td>
<td>50</td>
<td>MET/SU</td>
<td>6</td>
<td>NS</td>
</tr>
<tr>
<td>Estey (1990)</td>
<td>SMBG +feedback vs SMBG no feedback</td>
<td>Yes</td>
<td>Yes (both)</td>
<td>Yes</td>
<td>Unclear</td>
<td>Unclear</td>
<td>6.2</td>
<td>55</td>
<td>Diet, oral</td>
<td>NR</td>
<td>NS</td>
</tr>
<tr>
<td>Farmer (2007)</td>
<td>SMBG intensive vs SMBG less intensive vs no SMBG</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Patient (intensive)</td>
<td>Moderate</td>
<td>7.5</td>
<td>66</td>
<td>Diet, oral</td>
<td>3</td>
<td>NS</td>
</tr>
<tr>
<td>Fontbonne (1989)</td>
<td>SMBG vs SMUG vs no SMBG</td>
<td>Yes</td>
<td>Limited</td>
<td>Yes</td>
<td>Doctor</td>
<td>Moderate</td>
<td>8.3</td>
<td>55</td>
<td>Diet, oral</td>
<td>12.5</td>
<td>NS</td>
</tr>
<tr>
<td>Gallichan (1994)</td>
<td>SMBG vs SMUG</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Unclear</td>
<td>Unclear</td>
<td>NR</td>
<td>64</td>
<td>Diet, oral</td>
<td>NR</td>
<td>NS</td>
</tr>
<tr>
<td>Guerci (2003)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>No</td>
<td>Unclear</td>
<td>Doctor</td>
<td>Frequent</td>
<td>9</td>
<td>62</td>
<td>MET/SU</td>
<td>8</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Jaber (1996)</td>
<td>SMBG plus education vs no SMBG</td>
<td>Yes</td>
<td>Yes (only intervention)</td>
<td>Unclear</td>
<td>Doctor?</td>
<td>Moderate</td>
<td>9.5</td>
<td>62</td>
<td>Unclear</td>
<td>6.8</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Johnson (2006)</td>
<td>Free blood glucose meter plus testing strips vs free blood glucose meter</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Frequent</td>
<td>7.4</td>
<td>68</td>
<td>Diet, oral</td>
<td>8</td>
<td>NS</td>
</tr>
<tr>
<td>Study</td>
<td>Comparison</td>
<td>SMBG instruction</td>
<td>Education/counselling</td>
<td>Feedback given</td>
<td>Treatment adjustment</td>
<td>SMBG regimen</td>
<td>Starting HbA(_1c) level</td>
<td>Age</td>
<td>Treatment</td>
<td>Diabetes duration</td>
<td>HbA(_1c) results</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------------</td>
<td>------------------</td>
<td>-----------------------</td>
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<td>----------------------</td>
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<td>---------------------------</td>
<td>------</td>
<td>----------------</td>
<td>-------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Jones (2003)</td>
<td>PTC plus SMBG vs PTC vs SMBG vs control</td>
<td>No</td>
<td>Yes</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>8.5</td>
<td>55</td>
<td>Oral, insulin</td>
<td>10.5</td>
<td>NS</td>
</tr>
<tr>
<td>Joy (2003)</td>
<td>Preprandial SMBG vs postprandial SMBG</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>Doctor</td>
<td>Frequent</td>
<td>8.4</td>
<td>NR</td>
<td>Oral, insulin</td>
<td>NR</td>
<td>NS</td>
</tr>
<tr>
<td>Kibriya (1999)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>Yes (both)</td>
<td>Unclear</td>
<td>Patient</td>
<td>Infrequent</td>
<td>NR</td>
<td>50</td>
<td>Oral, insulin</td>
<td>NR</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Kwon (2004)</td>
<td>Internet vs non-internet SMBG</td>
<td>Unclear</td>
<td>Yes (only intervention)</td>
<td>Yes</td>
<td>Patient</td>
<td>Moderate</td>
<td>7.3</td>
<td>54</td>
<td>NR</td>
<td>5.6</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Miles (1997)</td>
<td>SMBG vs SMUG</td>
<td>Unclear</td>
<td>Yes (both)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Frequent</td>
<td>10.3</td>
<td>65</td>
<td>Oral, insulin</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Moreland (2006)</td>
<td>BG meter + manual vs BG meter vs no SMBG</td>
<td>Yes</td>
<td>Yes (all)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>NR</td>
<td>9</td>
<td>48</td>
<td>Oral, insulin</td>
<td>10</td>
<td>NS</td>
</tr>
<tr>
<td>Muchmore (1994)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>Yes (both)</td>
<td>Yes</td>
<td>Doctor</td>
<td>Frequent/moderate</td>
<td>10.4</td>
<td>59</td>
<td>NR</td>
<td>5.5</td>
<td>NS</td>
</tr>
<tr>
<td>O’Kane (2008)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>Yes (both)</td>
<td>Yes</td>
<td>Patient/doctor?</td>
<td>Moderate/frequent</td>
<td>8.7</td>
<td>60</td>
<td>Diet, oral</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Rutten (1990)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Doctor</td>
<td>Infrequent</td>
<td>9.3</td>
<td>63</td>
<td>Diet, oral</td>
<td>8.8</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Scherbaum (2008)</td>
<td>High SMBG vs low SMBG vs no SMBG</td>
<td>Unclear</td>
<td>No</td>
<td>Yes</td>
<td>Doctor</td>
<td>Moderate/infrequent</td>
<td>7.2</td>
<td>62</td>
<td>Diet, MET/SU</td>
<td>8</td>
<td>NS</td>
</tr>
<tr>
<td>Schwedes (2002)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>Yes (different in two groups)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Moderate</td>
<td>8.5</td>
<td>60</td>
<td>Diet, oral</td>
<td>5.3</td>
<td>SMBG better</td>
</tr>
<tr>
<td>Seaton (1996)</td>
<td>SMBG vs no SMBG</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>Doctor</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>Oral</td>
<td>NR</td>
<td>Unclear</td>
</tr>
<tr>
<td>Wing (1986)</td>
<td>SMBG vs no SMBG</td>
<td>Yes</td>
<td>Yes (both)</td>
<td>Yes</td>
<td>Doctor</td>
<td>Frequent</td>
<td>10.5</td>
<td>54</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>NS</td>
</tr>
</tbody>
</table>

BG, blood glucose; ‘Frequent’, each day/several times each day; ‘infrequent’, fewer than several times per week; ‘moderate’, several times per week; MET/SU, metformin/sulphonylurea; NR, not reported; NS, not significant; PTC, pathways to change.
### Table 1: Clinical effectiveness of self-blood glucose monitoring

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>SMBG Mean</th>
<th>SMBG SD</th>
<th>SMBG Total</th>
<th>No SMBG Mean</th>
<th>No SMBG SD</th>
<th>No SMBG Total</th>
<th>Mean difference IV, Random, 95% CI</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barnett (2008)</td>
<td>6.95</td>
<td>0.97</td>
<td>311</td>
<td>7.2</td>
<td>1.22</td>
<td>299</td>
<td>-0.25 (-0.43 to -0.07)</td>
<td>34.8%</td>
</tr>
<tr>
<td>Davidson (2005)</td>
<td>7.7</td>
<td>1.6</td>
<td>43</td>
<td>7.8</td>
<td>1.5</td>
<td>45</td>
<td>-0.10 (-0.75 to 0.55)</td>
<td>2.5%</td>
</tr>
<tr>
<td>Farmer (2007)</td>
<td>7.28</td>
<td>0.88</td>
<td>150</td>
<td>7.49</td>
<td>1.2</td>
<td>152</td>
<td>-0.21 (-0.45 to 0.03)</td>
<td>19.0%</td>
</tr>
<tr>
<td>Fontbonne (1989)</td>
<td>7.84</td>
<td>2.5</td>
<td>68</td>
<td>7.7</td>
<td>2.5</td>
<td>68</td>
<td>0.14 (-0.70 to 0.98)</td>
<td>15.5%</td>
</tr>
<tr>
<td>Guerci (2003)</td>
<td>8.1</td>
<td>1.6</td>
<td>345</td>
<td>8.4</td>
<td>1.4</td>
<td>344</td>
<td>-0.30 (-0.52 to -0.08)</td>
<td>21.2%</td>
</tr>
<tr>
<td>Kibriya (1999)</td>
<td>7.11</td>
<td>1.08</td>
<td>32</td>
<td>7.12</td>
<td>1.85</td>
<td>32</td>
<td>-0.01 (-0.75 to 0.73)</td>
<td>1.9%</td>
</tr>
<tr>
<td>Muchmore (1994)</td>
<td>8.75</td>
<td>1.66</td>
<td>12</td>
<td>9.6</td>
<td>2.1</td>
<td>11</td>
<td>-0.85 (-2.41 to 0.71)</td>
<td>0.4%</td>
</tr>
<tr>
<td>O’Kane (2008)</td>
<td>6.9</td>
<td>0.8</td>
<td>96</td>
<td>6.9</td>
<td>1.2</td>
<td>88</td>
<td>0.00 (-0.30 to 0.30)</td>
<td>12.1%</td>
</tr>
<tr>
<td>Rutten (1990)</td>
<td>9.2</td>
<td>1.49</td>
<td>66</td>
<td>9.4</td>
<td>1.14</td>
<td>83</td>
<td>-0.20 (-0.64 to 0.24)</td>
<td>5.7%</td>
</tr>
<tr>
<td>Wing (1986)</td>
<td>10.2</td>
<td>2.3</td>
<td>25</td>
<td>10.4</td>
<td>2.2</td>
<td>25</td>
<td>-0.20 (-1.45 to 1.05)</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

Total (95% CI): 1148 1147 100.0% -0.21 (-0.31 to -0.10)

Heterogeneity: $\tau^2 = 0.00; \chi^2 = 4.44, df = 9 (p = 0.88); I^2 = 0$

Test for overall effect: $z = 3.94 (p < 0.0001)$

---

### Figure 1: Self-monitoring of blood glucose (SMBG) versus no SMBG – HbA1c

---

### Table 2: Clinical effectiveness of self-blood glucose monitoring

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>SMBG Mean</th>
<th>SMBG SD</th>
<th>SMBG Total</th>
<th>SMUG Mean</th>
<th>SMUG SD</th>
<th>SMUG Total</th>
<th>Mean difference IV, Random, 95% CI</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen (1990)</td>
<td>10.4</td>
<td>2.9</td>
<td>27</td>
<td>9.7</td>
<td>2.6</td>
<td>27</td>
<td>0.70 (-0.77 to 2.17)</td>
<td>15.0%</td>
</tr>
<tr>
<td>Fontbonne (1989)</td>
<td>7.84</td>
<td>2.5</td>
<td>68</td>
<td>8.47</td>
<td>2.5</td>
<td>72</td>
<td>-0.63 (-1.46 to 0.20)</td>
<td>34.7%</td>
</tr>
<tr>
<td>Miles (1997)</td>
<td>8.8</td>
<td>1.9</td>
<td>68</td>
<td>8.7</td>
<td>1.7</td>
<td>82</td>
<td>0.10 (-0.48 to 0.68)</td>
<td>59.3%</td>
</tr>
</tbody>
</table>

Total (95% CI): 163 181 100.0% -0.06 (-0.69 to 0.56)

Heterogeneity: $\tau^2 = 0.11; \chi^2 = 3.14, df = 2 (p = 0.21); I^2 = 36$

Test for overall effect: $z = 0.20 (p = 0.84)$

---

### Figure 2: Self-monitoring of blood glucose (SMBG) versus SMUG – HbA1c

---
### FIGURE 3
Enhanced/more frequent SMBG versus only/less frequent SMBG – HbA1c

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>SMBG plus</th>
<th>SMBG</th>
<th>Mean difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education / feedback</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonomo (2006)</td>
<td>7.6</td>
<td>0.73</td>
<td>177</td>
</tr>
<tr>
<td>Cho (2006)</td>
<td>6.7</td>
<td>0.9</td>
<td>40</td>
</tr>
<tr>
<td>Estey (1990)</td>
<td>5.6</td>
<td>0.7</td>
<td>28</td>
</tr>
<tr>
<td>Farmer (2007)</td>
<td>7.36</td>
<td>1.05</td>
<td>151</td>
</tr>
<tr>
<td>Kwon (2004)</td>
<td>6.94</td>
<td>0.93</td>
<td>51</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>447</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Mean difference: $-0.20$ ($-0.44$ to $-0.03$)
- Heterogeneity: $\tau^2 = 0.04$; $\chi^2 = 9.62$, df = 4 ($p = 0.05$); $I^2 = 58$
- Test for overall effect: $z = 1.68$ ($p = 0.09$)

<table>
<thead>
<tr>
<th>Other (frequency / free strips)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson (2006)</td>
<td>7.3</td>
<td>1.5</td>
<td>131</td>
</tr>
<tr>
<td>Scherbaum (2008)</td>
<td>7.1</td>
<td>1</td>
<td>102</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>233</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Mean difference: $0.20$ ($-0.01$ to $0.41$)
- Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 0.00$, df = 1 ($p = 1.00$); $I^2 = 0$
- Test for overall effect: $z = 1.85$ ($p = 0.06$)

### FIGURE 4
Enhanced SMBG versus no SMBG – HbA1c

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>SMBG plus</th>
<th>Nothing</th>
<th>Mean difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown (2002)</td>
<td>10.89</td>
<td>2.56</td>
<td>126</td>
</tr>
<tr>
<td>Farmer (2007)</td>
<td>7.36</td>
<td>1.05</td>
<td>151</td>
</tr>
<tr>
<td>Jaber (1996)</td>
<td>7.6</td>
<td>1.48</td>
<td>17</td>
</tr>
<tr>
<td>Schwedes (2002)</td>
<td>7.47</td>
<td>1.27</td>
<td>113</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>407</td>
<td>409</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

- Mean difference: $-0.52$ ($-0.98$ to $-0.06$)
- Heterogeneity: $\tau^2 = 0.14$; $\chi^2 = 10.47$, df = 3 ($p = 0.01$); $I^2 = 71$
- Test for overall effect: $z = 2.20$ ($p = 0.03$)
SMBG with an educational/feedback component with ‘simple’ SMBG was in the same order of magnitude as when comparing ‘simple’ SMBG with no SMBG; however, the difference was not quite significant: –0.2% (95% CI –0.44 to 0.03; p = 0.09), with significant heterogeneity. There was no significant effect of providing free strips on HbA1c or of decreasing the frequency of monitoring. For comparisons between enhanced SMBG and no SMBG (four RCTs), there was a significant difference in favour of enhanced SMBG of –0.52% (95% CI –0.98 to –0.06; p = 0.03). All studies in this group included some education or feedback component in the SMBG group only. There was significant heterogeneity, which was clearly due to an outlier study.50

Figures 5–7 show some crude analyses of changes in HbA1c level dependent on baseline HbA1c level for all trials considered together. The graphs suggest that while both control groups and intervention groups showed a decrease in HbA1c level, which was larger with high baseline HbA1c values than with low baseline HbA1c values (Figures 6 and 7), the difference between the change in the control group and the change in the intervention group also increased with higher baseline HbA1c values (Figure 5).

Details of other outcomes reported by the RCTs are shown in Appendix 4.

Hypoglycaemic events were reported by six RCTs.10,13,41,49,54,60 Results for this outcome were inconsistent, although there was a suggestion that occurrence of (mild or moderate) hypoglycaemia was increased with more frequent self-monitoring.

Thirteen RCTs reported on weight or BMI and none found a significant difference between the intervention groups. Results on lipid parameters were reported by six RCTs and were inconsistent, with most studies finding no significant difference between groups. Similarly, no difference was found by a small number of studies reporting on blood pressure.

SMBG adherence was reported by eight RCTs. In most studies using a form of enhanced SMBG, adherence was greater in enhanced group – only the DiGEM trial10 reported reduced SMBG adherence in the more intensive group.

Data on medication changes were provided by seven RCTs.10,45,49,55,61,63 None found a significant difference between groups (which could be a reason for the limited effectiveness of SMBG). Only two studies reported on behaviour changes (diet or physical activity) and one found improved dietary adherence in the SMBG group compared to the control group.

Seven studies reported on outcomes such as QoL, well-being, treatment satisfaction and depression.10,13,20,56,57,61,63 For most measures, there was no significant difference between SMBG and no SMBG. However, both the DiGEM10 trial and the ESMON13 trial reported increased depression in the SMBG group (more intensive SMBG group for the DiGEM trial). The DiGEM trial found no significant difference between comparison groups for mobility, self-care, usual activities and pain; the ESMON trial found no significant differences for anxiety (p = 0.07), positive well-being and energy. On the other hand, two trials specifically including education/counselling components emphasising a positive attitude to SMBG20,61 found improved outcomes for negative affect with respect to SMBG and depression. In one study of SMBG versus SMUG, 70% of patients preferred SMUG to SMBG for ease of use (versus 15% preferring SMBG), 44% preferred SMUG for acceptability (versus 31% for SMBG), but 76% preferred SMBG for perceived accuracy (versus 11% SMUG) and 49% for usefulness (versus 21% SMUG).

Observational and non-randomised experimental studies

Appendix 5 shows details of the 36 observational and non-randomised studies identified (details for studies in reviews as far as provided by the reviews). Most studies only provided very limited details on SMBG methods and participants. Most studies examined the relationship between SMBG use and HbA1c level. An overview of the relevant parameters examined by the observational and non-randomised experimental studies is shown in Table 7.

Eighteen studies found no favourable changes in HbA1c level with SMBG, while 12 studies found a positive effect of SMBG on HbA1c level, whereas another six showed favourable effects of SMBG on HbA1c level, depending on treatment (especially in insulin-treated patients) or entry HbA1c level (especially with higher entry HbA1c level). Two studies reported on mortality and morbidity, with the ROSSO Study15,78,99 (Germany) finding that SMBG was associated with lower morbidity and mortality, while the Fremantle Diabetes Study17,19...
**FIGURE 5** Treatment difference as a function of mean baseline HbA₁c.

**FIGURE 6** Change from baseline as a function of baseline HbA₁c (control group).
Clinical effectiveness of self-blood glucose monitoring

(USA) found no changes in mortality in relation to SMBG, but SMBG use was associated with less retinopathy. These associations may be due to confounding factors – those who perform SMBG may be more motivated to self-manage in other ways.

**Qualitative studies**

A summary of studies including qualitative data in terms of study design, participants and brief results is presented in Appendix 6. Six qualitative studies were identified: Belsey et al. (2009), DiGEM RCT questionnaire and qualitative components, Lawton et al. (2004), Peel et al. (2004), Peel et al. (2007) and Zgibor and Simmons (2001). These reported results from in-depth interview studies, repeated interviews, questionnaire and survey data. Numbers of participants ranged from $n = 18$ to $n = 40$ for interview studies, to $n = 323$ to $n = 40,651$ patient records examined for survey and questionnaire data. Key positive results showed increased awareness of diabetes and help with establishing relationship between physical symptoms and blood glucose readings; increased empowerment to take more control over their health care; and the ability to use SMBG to assess effects of behaviour and promotion of adherence to self-management as a result of SMBG. Negative results showed increased levels of depression and anxiety compared with patients who do not self-monitor, few patients use SMBG to guide and maintain change to behaviour or lifestyle; negative impact on patients’ self-management when readings are counterintuitive and lack of education on how to interpret and act on out of target readings. A summary of messages regarding advantages of SMBG and barriers to benefit of SMBG is shown in Table 8.

Results from published qualitative studies have identified a number of reasons why SMBG may not be helping some individuals. Increased anxiety and depression have been reported, with individuals reporting feelings of obsession about results, paranoia, pain/discomfort, contradictory information, lack of knowledge/understanding of what results mean, monitoring fatigue, increased worry, distress and anxiety and self-blame and abandonment of regimen resulting in adverse effects on adherence, for example nihilistic attitudes. Peel et al. (2007) reported that reasons for discontinuation of SMBG included self-chastisement, with SMBG seen as a proxy measure for ‘good and bad’ behaviour rather than an aid to better diabetes self-management. Women
were particularly like to chastise themselves when readings were high, indicating specific gender differences.

Lack of education in how to interpret blood glucose readings and what to do with that information, for example how to respond to high readings, was reported in a number of studies. Peel et al. (2007)\(^{102}\) reported a lack of explicit and unified messages from health-care teams about if, when, and how, to self-monitor. None of the participants in this study reported receiving ongoing education about SMBG. It is unclear whether practice nurses provide sufficient (or any) training to patients, or indeed help patients to interpret results, and this is an area that requires further investigation. Anecdotal evidence suggests that practice nurses are unclear themselves about how to interpret blood glucose readings and how to use that information to direct behaviour changes. There is certainly a theme running through the qualitative literature that HCPs are disinterested in the results that patients take to them, resulting in disappointment and disinterest ultimately by patients. This may reflect a mismatch in expectations, with the professionals expecting patients to use SMBG to self-manage, and patients expecting the professionals to use the results to adjust treatment.

Individuals who simply purchase a blood glucose meter (which are widely available for sale in pharmacies, with basic instruction only on how to use the machine) will have received no education at all unless they have sought it from a HCP. There is perhaps an important role for pharmacists to ensure that anybody purchasing such a device is offered appropriate training on both how to use it and how to interpret the results. However, that assumes that the pharmacists have the necessary knowledge to do the training, or the ability to arrange for others to do it.

Failure to use SMBG to alter treatment dose or behaviour was reported.\(^{106,102,106}\) In the UK, few patients use SMBG to guide and maintain changes to their behaviour and lifestyle,\(^{106}\) and this appears to be due, in part, to lack of education about interpreting and acting upon results. Indeed, some participants reported that reasons for continuing with SMBG included curiosity and reassurance\(^{102}\) rather than to guide diabetes self-care behaviours. Some individuals found that SMBG promoted a focus on the ‘here and now’, which could be detrimental to long-term health behaviours and decision-making.\(^{102}\) Many were disappointed with HCPs’ disinterest in the results.\(^{101}\) Song and Lipman (2008)\(^{a}\) reported that a patient who uses SMBG on a regular basis may believe the number on the glucose meter reflects ‘the truth’, even though it may not be consistent with what his/her body is telling him/her. This is particularly worrying in view of the lack of checking/calibrating of meters,\(^{104}\) which may result in inappropriate reliance on inaccurate results. Alternatively, other patients may not believe the number because they feel fine. Incorrectly interpreting a lack of symptoms (incorrect because blood glucose has to be well above normal to cause symptoms) as meaning that all is well could lead to SMBG results being ignored.

There was a lack of data in the studies (qualitative, systematic review or economic) about whether SMBG benefits vary by frequency of monitoring, type of education, susceptibility to hypoglycaemia, treatment, age, starting HbA\(_1c\) level or time points during the course of diabetes, for example after diagnosis, during treatment change, etc.

What was evident was that older and less well-educated patients were most interested in HCP attitudes to readings\(^{102}\) and that longer diabetes duration was associated with less SMBG.\(^{18}\) Evans et al. (1999)\(^{100}\) reported a decreasing uptake of test strips which was associated with age, and Belsey et al. (2009)\(^{100}\) reported that participants on diet and exercise did least testing, with testing increasing as therapy intensifies. None of the studies reported monitoring results being used for treatment adjustment by the HCP, whilst Peel et al. (2007)\(^{102}\) were alone in reporting that most participants could counteract hypoglycaemia but not hyperglycaemia. Furthermore, they reported that inexplicable readings promoted nihilistic attitudes, whilst Lawton et al. (2004)\(^{6}\) reported that consistently normal results on self-monitoring of urine were interpreted as successful diabetes management/compliance. Highest SMBG frequency was reportedly conducted by participants who had attended diabetes education.\(^{18}\)

Interestingly, Peel et al. (2007)\(^{102}\) reported that participants felt they were monitoring for the benefit of their HCP, rather than their own benefit, despite the HCPs showing no interest in the readings. There is a clear incongruence between patient expectations of HCPs and vice versa. In fact, how the monitoring results were used for treatment adjustment by patients was not addressed in any of the qualitative studies. HCPs
**TABLE 7 Intervention components – observational and non-randomised studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Focus</th>
<th>SMBG method</th>
<th>Education/counselling</th>
<th>Starting HbA&lt;sub&gt;1c&lt;/sub&gt;</th>
<th>Age</th>
<th>Treatment</th>
<th>Diabetes duration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bajkowska-Fiedziukiewicz (2008)&lt;sup&gt;64&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>Reported</td>
<td>Yes</td>
<td>7.5</td>
<td>63</td>
<td>Oral, insulin</td>
<td>11</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Banister (2004)&lt;sup&gt;65&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>Reported</td>
<td>Yes</td>
<td>9.7</td>
<td>49</td>
<td>Unclear</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: reduced</td>
</tr>
<tr>
<td>Blonde (2002)&lt;sup&gt;66&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>35–65</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>Higher % with HbA&lt;sub&gt;1c&lt;/sub&gt; under 7% with more frequent SMBG</td>
</tr>
<tr>
<td>Capelson (2006)&lt;sup&gt;67&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>7.6</td>
<td>Insulin</td>
<td>21</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Chan (2000)&lt;sup&gt;68&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>53</td>
<td>NR</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: 0.7% lower with more frequent SMBG</td>
</tr>
<tr>
<td>Evans (1999)&lt;sup&gt;69&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>7.6</td>
<td>Insulin</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Franciosi (2001)&lt;sup&gt;70&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>7.3</td>
<td>63</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: higher with more SMBG, lower when insulin could be adjusted</td>
</tr>
<tr>
<td>Franciosi (2005)&lt;sup&gt;71&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>7–7.3</td>
<td>62</td>
<td>Diet, oral</td>
<td>9.1</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Fremantle Diabetes Study [Davis (2007)&lt;sup&gt;17,19&lt;/sup&gt;]</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>7.4</td>
<td>65</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Hanninen (2001)&lt;sup&gt;72&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>63</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: higher with more SMBG</td>
</tr>
<tr>
<td>Harris (2001)&lt;sup&gt;73&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>7.6</td>
<td>63</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Jaworska (2004)&lt;sup&gt;74&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>62</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Karter (2001)&lt;sup&gt;75&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>8.4</td>
<td>60</td>
<td>Diet, oral, insulin</td>
<td>0 to &gt; 10</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: 0.6% lower with more SMBG in those on oral drugs</td>
</tr>
<tr>
<td>Karter (2005)&lt;sup&gt;76&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>9.9</td>
<td>60</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>5% more under 7% HbA&lt;sub&gt;1c&lt;/sub&gt; with more SMBG</td>
</tr>
<tr>
<td>Karter (2006)&lt;sup&gt;14&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>6.4</td>
<td>60</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>Lower HbA&lt;sub&gt;1c&lt;/sub&gt; with more SMBG</td>
</tr>
<tr>
<td>Klein (1993)&lt;sup&gt;77&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>62</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Meier (2002)&lt;sup&gt;79&lt;/sup&gt;</td>
<td>Reduced access test strips</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>64</td>
<td>Diet, oral</td>
<td>NR</td>
<td>No change in HbA&lt;sub&gt;1c&lt;/sub&gt; after SMBG reduction</td>
</tr>
<tr>
<td>Mitchell (2004)&lt;sup&gt;80&lt;/sup&gt;</td>
<td>Association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>64</td>
<td>Diet, oral</td>
<td>NR</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NS</td>
</tr>
<tr>
<td>Study (Year)</td>
<td>Focus</td>
<td>SMBG method</td>
<td>Education/counselling</td>
<td>Starting HbA1c</td>
<td>Age</td>
<td>Treatment</td>
<td>Diabetes duration</td>
<td>Results</td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td>Murata (2003)</td>
<td>Intensified SMBG</td>
<td>NR</td>
<td>NR</td>
<td>8.1</td>
<td>48</td>
<td>Insulin</td>
<td>NR</td>
<td>Lower HbA1c (by 0.3%) with more SMBG (depending on entry HbA1c)</td>
</tr>
<tr>
<td>Murata (2009)</td>
<td>Association between SMBG use and HbA1c and medication change</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>59</td>
<td>Oral</td>
<td>NR</td>
<td>HbA1c: NS</td>
</tr>
<tr>
<td>Newman (1990)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>60</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA1c: NS</td>
</tr>
<tr>
<td>Oki (1997)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>56</td>
<td>Diet, oral, insulin</td>
<td>NR</td>
<td>HbA1c: NS</td>
</tr>
<tr>
<td>Ozmen (2003)</td>
<td>Association between SMBG use and HbA1c</td>
<td>Yes</td>
<td>NR</td>
<td>9.1</td>
<td>58</td>
<td>Diet, oral, insulin</td>
<td>8.6</td>
<td>HbA1c reduced by 1.9% with SMBG</td>
</tr>
<tr>
<td>Patrick (1994)</td>
<td>Association between SMBG/SMUG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>65</td>
<td>Sulphonylurea</td>
<td>NR</td>
<td>HbA1c: NS</td>
</tr>
<tr>
<td>Rindone (1997)</td>
<td>Access strips vs no access</td>
<td>NR</td>
<td>NR</td>
<td>8.1</td>
<td>68</td>
<td>Sulphonylurea</td>
<td>NR</td>
<td>HbA1c: NS</td>
</tr>
<tr>
<td>Roblin (2001)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>53</td>
<td>Diet, oral, insulin</td>
<td>12</td>
<td>Lower HbA1c with SMBG but not in non-insulin-treated patients</td>
</tr>
<tr>
<td>ROSSO study [Martin (2006)]</td>
<td>Association between SMBG use and morbidity/mortality</td>
<td>NR</td>
<td>NR</td>
<td>7.7</td>
<td>63</td>
<td>Diet, oral, insulin</td>
<td>0</td>
<td>Morbidity and mortality lower with SMBG</td>
</tr>
<tr>
<td>Rost (1990)</td>
<td>Association between SMBG use and HbA1c in insulin users and non-insulin users</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>56</td>
<td>Oral, insulin</td>
<td>0</td>
<td>Lower HbA1c with SMBG</td>
</tr>
<tr>
<td>Schiel (1999)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>Insulin</td>
<td>NR</td>
<td>Lower HbA1c with more SMBG</td>
</tr>
<tr>
<td>Schütte (2006)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>7.6</td>
<td>NR</td>
<td>Diet, oral, insulin</td>
<td>10</td>
<td>Lower HbA1c with more SMBG</td>
</tr>
<tr>
<td>Secnik (2007)</td>
<td>Access-free blood glucose monitors</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>20 to &gt;65</td>
<td>Oral, insulin</td>
<td>NR</td>
<td>Lower HbA1c with more SMBG only in insulin-treated patients, not with oral</td>
</tr>
<tr>
<td>Soumerai (2004)</td>
<td>Access-free blood glucose monitors</td>
<td>NR</td>
<td>NR</td>
<td>8.4</td>
<td>56</td>
<td>Oral, insulin</td>
<td>NR</td>
<td>Lower HbA1c with more SMBG only for those with higher initial HbA1c</td>
</tr>
<tr>
<td>Stiptzarov (2003)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>65</td>
<td>NR</td>
<td>NR</td>
<td>Lower HbA1c with more SMBG</td>
</tr>
<tr>
<td>Tengblad (2007)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>5.4–6.9</td>
<td>69</td>
<td>Diet, oral, insulin</td>
<td>87%, &gt;4</td>
<td>HbA1c: NS</td>
</tr>
<tr>
<td>Wieland (1997)</td>
<td>Association between SMBG use and HbA1c</td>
<td>NR</td>
<td>NR</td>
<td>7.9</td>
<td>39–89</td>
<td>Sulphonylurea</td>
<td>NR</td>
<td>HbA1c: NS</td>
</tr>
</tbody>
</table>

NR, not reported; NS, not significant.
TABLE 8 Summary of messages from qualitative studies

<table>
<thead>
<tr>
<th>Perceived advantages</th>
<th>Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reassurance when blood glucose levels were normal</td>
<td>People tended not to act on their SMBG results</td>
</tr>
<tr>
<td>Patients felt they could use SMBG to assess effects of behaviour</td>
<td>SMBG associated with increased levels of depression and anxiety compared with patients who do not self-monitor</td>
</tr>
<tr>
<td>Participants felt empowered to take more control over their health care and ability to contribute to physician's evaluation of their status</td>
<td>SMBG as threat – constant reminder of illness</td>
</tr>
<tr>
<td>Convenience of taking measurements</td>
<td>Feeling of failure, self-blame when blood glucose levels were abnormal</td>
</tr>
<tr>
<td></td>
<td>Health professionals were often perceived to show no interest in meter readings – lack of feedback</td>
</tr>
<tr>
<td></td>
<td>Lack of specific instructions and education received</td>
</tr>
</tbody>
</table>

have an expectation that individuals are using SMBG as an aid to improved self-management of diabetes. If this assumption is not challenged then patients are needlessly burdened with an additional (not to mention painful) diabetes-related task for apparently no benefit. With the NHS spending almost as much on blood glucose testing materials as on oral hypoglycaemic agents,105 and 69% of participants on oral hypoglycaemic agents taking no action at all if a reading was beyond their target range, it is clear that patient education needs to be improved. Furthermore, the behaviours of HCPs in relation to how they issue blood glucose meters and help patients interpret the results, should be examined.

The simple act of how and whether a blood glucose meter was issued at all to a patient was associated with whether individuals felt their HCP was taking their diabetes seriously enough.6 Failure to receive a blood glucose meter was associated with increased anxiety and undermining of confidence in HCPs.

The mode of obtaining meters or amounts of education received did not appear to differentially impact on patients’ views of glucose monitoring according to Peel et al. (2004).101 Whether a patient had well-controlled diabetes or not affected satisfaction with SMBG, that is patients with well-controlled diabetes viewed SMBG positively, whereas poorly controlled patients voiced more concerns and experienced monitoring fatigue.102

At a workshop at the Spring 2009 Diabetes UK conference (attended by two authors of this report), some patients and industry representatives said that some general practitioners (GPs) were now rationing test strips for individuals with diabetes, presumably because of rising costs and doubt about effectiveness. This can appear to be contrary to current guidelines, but these may not be sufficiently clear. For example, the NICE guideline CG669 says SMBG ‘should be available to those on oral glucose-lowering medications to provide information on hypoglycaemia’ but that is not relevant to those on metformin alone (because metformin does not cause hypoglycaemia). It also says that SMBG should be available to those on insulin treatment but does not say whether this should apply to those on a small once-daily dose of basal insulin. If individuals are not benefiting from SMBG, and indeed it is detrimental to their overall health, there is a clear need to cease SMBG. There is also a passionate argument from patient groups and the pharmaceutical industry that SMBG for individuals with T2DM should not be withdrawn. O’Kane and Pickup (2009)106 perhaps aptly declared that ‘present widespread use of SMBG in T2DM is a good example of a monitoring test that was adopted in advance of robust evidence of its clinical efficacy’. Thus identification of potential subgroups of those patients who would receive the most benefit from SMBG should be identified, perhaps by some qualitative work to identify characteristics of those most likely to benefit (which may be about patient attributes rather than treatment) followed by a RCT.

Most studies, including 18 out of the 36 observational studies, report that SMBG does not improve HbA1c level for most patients on diet and lifestyle change or oral hypoglycaemic agent (OHA) alone. There are repetitive themes throughout the literature on why SMBG is ineffective for many individuals. These include lack of education, lack of interest from HCPs in results, failure to make behaviour/lifestyle or therapy changes based on readings, failure to understand exactly what SMBG is (i.e. a tool to aid diabetes self-management), failure to calibrate or check accuracy of readings and failure to identify patients most likely to benefit from the technology.
Consideration needs to be given to identifying those patients who would benefit from SMBG both biomedically in terms of glycaemic control and psychosocially in terms of improved QoL. However, the key may be to not only identify these patients, but also have a supportive HCP who supports them in self-management and the best use of SMBG data.

Funnel and Anderson (2004)\textsuperscript{107} developed the empowerment philosophy within which approaches to education incorporate interactive teaching strategies that are designed to involve patients in problem-solving and address their cultural and psychosocial needs. Key tenets of the empowerment philosophy include:

- Empowering people with diabetes to make self-directed behaviour change.
- It is not the HCP’s job to get patients to do what they consider ‘the right thing’, rather HCPs’ responsibilities include helping patients make informed decisions about diabetes and its self-management in the context of their own lives so that they are empowered to engage more effectively in self-care behaviours.
- One of the biggest barriers to behaviour change is fear of failure, which grows each time we try unsuccessfully to achieve a goal. Being overwhelmed with information, but not given the tools to interpret it, can add to the burden, not reduce it. Emotions are important driving forces that require exploration.
- Patients are already motivated to accomplish their own goals – their behaviours are often not irrational to them and underlying health beliefs should be explored. Collaboration between patients and HCPs is required to set goals and achieve targets.
- Treatment needs to be personally meaningful to patients – i.e. what does it mean to me? What difference will doing this test make?
Chapter 3

Self-monitoring of blood glucose: economic literature review

In this literature review, a base year of 2008 has been applied for costs and prices, with sums converted being reported in square brackets: [£XX]. Where papers used an alternative base year, the Health and Community Services price index as reported within the Personal Social Services Research Unit (PSSRU) Costs of Health and Social Care has been applied. Where costs and prices were reported in a foreign currency these were converted to pounds sterling using the exchange rate prevailing on 5 April at the end of the base year of the paper, the Health and Community Services price index being subsequently applied to the resultant pounds sterling amount if required. Where the base year was not stated within the paper it was assumed to be the publication year.

Cost studies

Cost studies: full papers

Belsey et al. (2009) undertook a retrospective analysis of the IMS Disease Analyzer database of 40,651 patient records between March 2007 and February 2008. They identified those with T2DM who had received one or more prescriptions for oral glucose lowering drugs or insulin or had a clinical diagnosis of diabetes in the preceding 12 months. Among these patients 12.9% were estimated to be using diet and exercise alone, 34.1% were estimated to be on a single oral agent, 26.0% on multiple oral therapy, and 27% on oral therapy plus insulin.

Coprescription of test strips averaged 54%, but varied from a low of 2% among those on diet and exercise, between 36% and 44% among those on one oral agent, between 48% and 60% among those on multiple oral therapy, and between 87% and 89% for those receiving insulin. Given these rates of use, the annual average cost of tests strips was £9.83 [£10.16] for those on diet and exercise; between £15.95 [£16.48] and £23.50 [£24.28] for those on one oral therapy; between £23.87 [£24.67] and £37.91 [£39.18] for those on multiple oral therapy; and between £135.83 [£140.36] and £191.18 [£197.56] for those on insulin.

These costs were extrapolated to the UK as a whole by applying disease prevalence data of 3.7% to give an annual average cost per patient of £73.64 [£76.10] and a total UK cost of £165M [£171M]. The cost for England alone in 2006–7 was estimated to be £138M. The authors noted that what they describe as the UK consensus recommendations on monitoring, suggest that those using diet and exercise alone, or monotherapy metformin, monotherapy glitazone or metformin plus glitazone, should not be using SMBG. This resulted in an estimate of £13.42M [£13.87M] being spent unnecessarily on SMBG among these patients, which was only partially offset by a £610K [£630K] underspend among sulphonylurea monotherapy patients. In contrast, multiple oral agent patients were typically estimated as underutilising SMBG to the extent of £2.56M [£2.65M] per annum. Those using insulin plus an oral therapy were estimating as overutilising SMBG by £6.7M [£6.92M] per annum, to yield an estimate of the total overspend of £17.02M [£17.59M].

The authors acknowledged that individual circumstances will in some cases have correctly over-ridden the consensus guidelines and that, as a consequence, the estimated overspend will to some extent be an overestimate. However, they also note that the DiGEM trial showed no benefit to those on sulphonylurea alone, and avoiding SMBG in this group could double the potential savings.

Weber et al. (2007) used the results of the German ROSSO longitudinal observational study of SMBG versus non-SMBG between two groups of patients with T2DM: those using only oral drugs and those using oral drugs plus insulin. The ROSSO results included long-term outcomes in terms of micro- and macrovascular event rates over an average follow-up period of 6.5 years, which Weber et al. reported as being 7.2% among the SMBG group and 10.4% in the control group (p = 0.002). Similarly, fatal event rates were lower among the SMBG group at 2.7% compared with 4.6% with a p-value of 0.004. These event rates were associated with Swiss unit costs to determine the average cost per patient.
Self-monitoring of blood glucose was associated with an additional average annual direct cost for test strips and lancets of CHF90 (£39) among those using oral agents and CHF130 (£56) among those using oral agents in combination with insulin. But these additional direct costs were more than offset by the costs of reduced events with the total average annual costs of CHF5140 (£2219) among SMBG users compared with CHF5654 (£2441) for non-users among the oral agents group, and CHF8254 (£3564) among SMBG users compared with CHF11,776 (£5084) for non-users among the oral agents-plus-insulin group. However, the generalisability of the study is limited by the ROSSO source data being drawn from a longitudinal retrospective study, not a randomised trial. Tiley110 noted that SMBG could not be considered to be the sole source of the risk reduction. Other interventions would also have 'played a part in the outcome: these including regular educational input, regular screening and more regular dietary advice and medical consultation' among the SMBG group.

Meier et al. (2002)79 undertook a study of the effect of the frequency of SMBG on costs and HbA1c levels among a sample of patients with T2DM in the US Veterans Affairs study, who were being controlled on either diet or oral antidiabetic drugs. A retrospective analysis of prescription data provided the estimate of the pre-baseline frequency of SMBG, given an assumption of no wastage of test strips. A policy of reduced SMBG frequency was implemented by letter and by reducing the number of test strips per prescription.

The authors found that the frequency of SMBG among those on oral agents was 1.36 strips per day, with an average HbA1c level of 7.83%. Subsequent to implementation an average 0.74 strips were being used, with a non-statistically significant change in average HbA1c level to 7.86%. Among those being controlled on diet the average test frequency dropped from 1.07 strips per day to 0.51 strips per day, with HbA1c level again showing a non-significant change from 6.85% to 6.78%. The authors had to cope with a change of laboratory analyser between baseline and end of study, and used several methods to overcome this, which is slightly confusing. Despite these difficulties, the authors concluded that reduced SMBG could result in an average annual saving per patient of US$76.44 (£66.38) without affecting glycaemic control.

Cost studies: abstracts

Neeser et al. (2006)111 also report the results of the ROSSO15 study, but on the grounds of one group being 3.5 years older on average than the other group, they undertook a matched-pairs analysis based on age, gender, smoking status and blood glucose level at diagnosis. This resulted in 813 matched pairs being available for the comparison of SMBG with no-SMBG, with costs of 18 complications of diabetes being estimated in addition to the costs of SMBG. Among those treating their diabetes with oral antidiabetic drugs alone, Neeser et al. estimated that SMBG led a reduction of €214 (£162) per year, but this was not statistically significant. Among those using insulin in combination with oral antidiabetic drugs, SMBG was found to cause a significant reduction in costs of €1727 (£1310) per year. However, the caveats of Tiley (2002)110 still apply: the care for the SMBG group differed in other ways.

Quality of life

Quality of life: full papers

Farmer et al. (2009)11 reported the utility estimates derived from UK DiGEM10 trial. Within the trial period the QoL values, derived from the completed cases’ EuroQol-5D (EQ-5D) questionnaire data, showed no change between baseline and 12 months for the control group, the average increasing by an insignificant 0.002 (95% CI –0.034 to 0.038). There was some evidence of a fall among the less intensive SMBG group, –0.037 between baseline and 12 months, which, given a 95% CI of –0.080 to 0.005, was of borderline significance. The more intensive SMBG group recorded a larger fall of –0.056, which, given a 95% CI of –0.099 to –0.013, achieved significance. The differences between low-intensity SMBG and standardised care, and between more intensive SMBG and standardised care, exhibited a similar pattern, though neither quite reached statistical significance given respective central estimates and 95% CIs of –0.040 (–0.094 to 0.015) and –0.053 (–0.109 to 0.004), respectively. QoL values were also imputed for the full data set. These showed a similar pattern to that reported above, the main difference of note being that the difference between more intensive SMBG and standardised care was estimated to reach statistical significance given a central estimate and 95% confidence interval of –0.072 (–0.127 to –0.017). So SMBG may slightly reduce the QoL.
The 2005 Cochrane review of SMBG in patients with T2DM not using insulin found two relevant papers for assessing the QoL impacts of SMBG. Muchmore et al. (1994) was reported as finding identical results for QoL for those using SMBG compared with the control group across the dimensions assessed: satisfaction, impact and worry (social/vocational and diabetes related). Paralleling this, Schwedes et al. (2002) found that well-being and treatment satisfaction improved by the same amount across both groups. Neither study found any statistically significant difference between the two groups in terms of QoL.

Franciosi et al. (2001) reported the results of a prospective study of 3567 Italian outpatients with T2DM, among whom there were 2855 patients with data on SMBG: 17% tested more than once per day, 31% tested more than once per week, 14% tested less than once per week and 38% did not perform SMBG. Among those not using insulin, and adjusting for baseline characteristics, SMBG of at least once per day was significantly associated with higher levels of distress, worries and depressive symptoms, and SMBG of at least once per week was still significantly associated with higher levels of distress and worries. In contrast, there was no association between QoL and SMBG among patients using insulin, with the exception of stress, which was lower for those patients performing SMBG at least once per week.

Could these differences relate to ability to self-adjust medication? People on insulin are able to, and indeed are encouraged to, adjust insulin dose according to blood glucose levels. However, those on oral agents are presumably dependent on their doctors to change prescribed doses.

Cost-effectiveness

Cost-effectiveness: full papers

Farmer et al. (2009) undertook a cost-utility study using the results of the UK DiGEM trial, comparing the costs and effects among the DiGEM trial population of patients with T2DM being controlled through either diet or oral drug therapy. This was an update of the Simon et al. (2008) paper, and, in line with this, considered the three comparators of:

- more intensive SMBG, through which the average HbA1c level fall was –0.17%
- less intensive SMBG, through which the average HbA1c level fall was –0.14%
- standardised usual care, through which there was no impact on HbA1c level.

This analysis used only the results of the DiGEM trial, and the alternative of SMUG was not considered. Note that in addition to the HbA1c changes, clinical effects also were observed in terms of blood pressure and cholesterol. The direct QoL effects of SMBG are reported in the previous section.

The direct impact of SMBG on QoL was estimated through the baseline and 12-month EQ-5D responses, through the application of the standard UK tariff. Given the 12 months’ clinical results from the DiGEM trial, the risk factors for the complications of diabetes were extrapolated to lifetime costs, life expectancy and quality-adjusted life expectancy using the UK Prospective Diabetes Study (UKPDS) Outcomes Model. Future health effects and costs were discounted at 3.5%.

The modelling assumed that patients were initially controlling their diabetes through diet alone or oral drug therapy. As the disease progresses and control worsens, patients will intensify their therapy, moving from controlling their diabetes using diet alone, to oral drug therapy, to basal insulin-plus-oral drug therapy to basal/bolus insulin-plus-oral drug therapy. It is unclear if, or how, these intensifications of therapy have been incorporated within the modelling.

During the 12 months’ period of the DiGEM trial a resource use questionnaire was also administered, which, together with patients’ SMBG diaries and nurse notes, provided data on the within trial resource utilisation – including nurse visits, medications, primary care, hospital care, and auxiliary medical resource use such as podiatry, optician and dietitian services. Where information was missing on SMBG and medication use, the last value carried forward technique was used, which could be misleading because those who do not return may have altered their behaviour. SMBG was typically associated with longer nurse visits than standardised care, with the more intensive SMBG typically also being associated with longer nurse visits than less intensive SMBG.

Resource use was valued by applying unit costs reported in the NHS reference costs 2005–06; the Annual financial returns of NHS trusts 2003–2004; and the PSSRU Costs of Health and Social Care 2002, with these being inflated to 2005–6 costs using the Department of Health Pay and Prices Inflation Indices.
Within the trial period, standardised care was estimated to cost £89 [£95] compared with £181 [£193] for the less intensive SMBG and £173 [£184] for the more intensive SMBG, giving cost increases of £92 [£98] and £84 [£90] for the SMBG groups, respectively. Given parallel QoL losses of –0.008 quality-adjusted life-years (QALYs) and –0.036 QALYs from less intensive SMBG and more intensive SMBG, respectively, compared with standardised care, the within trial comparison estimated that standardised care dominated SMBG.

The above values are as per those reported in the Simon et al. (2009)12 paper, with Farmer et al. (2008)11 extending this through extrapolating the long-term effects by using the UKPDS Outcomes Model.112 This marginally improved the situation for the SMBG: for the less intensive SMBG, the lifetime patient loss was estimated to be –0.004 QALYs, while the additional lifetime cost was £59 [£63]; and, for the more intensive SMBG the lifetime patient loss was estimated as –0.020 QALYs, while the additional lifetime cost was £56 [£60]. This did not change the overall conclusion that standardised care was both more effective and less costly than SMBG, and so dominated SMBG.

Similarly, a probabilistic analysis estimated that while the probability of SMBG being cost-effective would rise as the willingness to pay increased to around £10K per QALY, any increases in the probability of SMBG being cost-effective as the willingness to pay increased further were limited. At a willingness to pay of £30K per QALY, the probability of less intensive SMBG was a little under 40% and the probability of more intensive SMBG was around 15%, these probabilities showing little change as the willingness to pay was increase to £50K per QALY.

Clinical effectiveness estimates in terms of the HbA1c effect were drawn from the large 3-year Kaiser Permanente Healthcare Group observational study among 30,000 patients, with the HbA1c changes reported above relating to a subset of around 16,000 new users of SMBG as reported in Karter et al. (2001).75

Medicare reimbursement unit costs were applied, with QoL values being drawn from the UKPDS study, but, crucially, it was assumed that there was no disutility associated with SMBG use.

For the comparison of ‘once-daily SMBG’ with ‘no SMBG’, the central estimate was that an additional 0.103 QALYs would accrue at an additional cost of US$808 [£493] to yield a cost-effectiveness estimate of US$7856 [£4789] per QALY. For the comparison of ‘three-times-daily SMBG’ with ‘no SMBG’ the central estimate was that an additional 0.327 QALYs would accrue at an additional cost of US$2161 [£1317] to yield a cost-effectiveness estimate of US$6601 [£4024] per QALY.

Results were particularly sensitive to the time horizon assumed. Reducing this to 5 years resulted in cost-effectiveness estimates for ‘once-daily SMBG’ and ‘three-times-daily SMBG’ compared with ‘no SMBG’ of $23,380 [£14,253] per QALY and $29,137 [£17,762] per QALY, respectively.

The Tunis and Minshall (2008)116 study needs to be interpreted with caution due to the clinical data being from an observational study, the observed differences in HbA1c level during the study being assumed to be maintained over the lifetime of the patient, and, most obviously, due to the assumption of SMBG not in itself being associated with any disutility. Aspinall and Glassman (2008)118 expressed additional concerns in a letter to the editors that not all patients would commence SMBG at the average HbA1c level assumed by Tunis and Minshall, and that the effect of SMBG would be, in all likelihood, different for different baseline levels of HbA1c. Note also that an abstract

Tunis and Minshall (2008),116 in a study funded by LifeScan, a major manufacturer of glucose testing material, modelled the cost-utility of SMBG among patients with T2DM using oral antidiabetic drugs within the US Medicare setting, using the CORE Diabetes Model.117 This compared:

- three-times-daily SMBG, through which average HbA1c level was assumed to fall by 1.02%,
- once daily SMBG, through which average HbA1c level fell by 0.32%,
- no SMBG, through which average HbA1c level rose by 0.13%.
of a cost-effectiveness study, undertaken by Tunis, of SMBG among patients with T2DM, using the same clinical data source as her 2008 paper, reported a considerably worse cost-effectiveness ratio than those reported above.

Palmer et al. (2006), also funded by LifeScan, modelled the cost–utility of SMBG among patients with T2DM controlling their diabetes with diet and exercise, or with oral antidiabetic drugs, or with insulin. This compared SMBG with non-SMBG among the three patient groups, with assumptions on HbA1c level as follows:

- for those on:
  - diet and exercise – SMBG resulted in a fall of 0.3%
  - oral antidiabetic drugs – SMBG resulted in a fall of 0.4%
  - insulin – SMBG resulted in a fall of 0.6%.

These clinical effectiveness estimates were drawn from the Karter et al. (2001) study, as reported above for the Tunis and Minshall (2008) paper, though within an alternative patient grouping. Palmer et al. (2006) also assumed that only 78% of patients would adhere to SMBG. The 22% not adhering to SMBG were assumed to be identical to the non-SMBG in terms of both costs and effects, and, as a consequence, the main effect of the inclusion of non-adherence is simply to dilute the SMBG arm.

The analysis was undertaken using the CORE model in the UK setting in terms of costs, with a base year of 2004. A lifetime horizon was adopted with costs and benefits being discounted at 3.5%.

In common with Tunis and Minshall (2008), Palmer et al. (2006) also assumed that the benefit in terms of improved HbA1c level would be maintained over patient lifetime and that there was no direct disutility from SMBG, although a sensitivity analysis was undertaken equalising this to the disutility from taking insulin.

The additional annual ongoing cost of SMBG varied between the patient groups, being £124 for those on diet and exercise, £247 for those on oral agents and £371 for those on insulin. The respective average lifetime patient gains were estimated as being 0.165 QALYs, 0.225 QALYs and 0.255 QALYs, respectively, while the respective additional lifetime costs were estimated to be £2564, £1013 and £1171, respectively. This resulted in cost-effectiveness estimates for SMBG compared with non-SMBG of:

- £15,515 per QALY for those on diet and exercise
- £4508 per QALY for those on oral antidiabetic drugs
- £4593 per QALY for those on insulin.

As in the Tunis and Minshall (2008) paper, Palmer et al. (2006) found results to be sensitive to a shorter time horizon. Reducing this to 10 years resulted in estimates of cost-effectiveness of £74,528 per QALY for those on diet and exercise; £33,742 per QALY for those on oral antidiabetic drugs; and £11,082 per QALY for those on insulin. An assumption of the HbA1c benefit only lasting for 5 years also worsened cost-effectiveness ratios among the three patient groups: £25,802 per QALY; £9141 per QALY; and, £9909 per QALY, respectively.

Applying the disutility of taking insulin to SMBG reduced the anticipated gains from SMBG. This particularly affected the diet and exercise group, among whom the anticipated gain fell from 0.165 to 0.077 QALYs, resulting in a cost-effectiveness estimate of £34,259 per QALY. The effect, while still large, was less dramatic for those taking oral antidiabetic drugs and those taking insulin, with the QALY gains falling from 0.225 to 0.140 QALYs and from 0.255 QALYs to 0.172 QALYs, respectively. As a consequence, their respective cost-effectiveness estimates worsened to £6985 and £6586 per QALY.

Cost-effectiveness: abstracts

Tunis (2009) reported the results of further cost-effectiveness modelling using data from the Kaiser Permanente Healthcare Group observational study as for her 2008 paper. Compared with ‘no SMBG’, the results were as follows, the first and third being roughly one-half to one-third of the estimated gains of her 2008 paper.

- Once-daily SMBG led to an additional 0.047 QALYs.
- Twice-daily SMBG led to an additional 0.116 QALYs.
- Three-times daily SMBG led to an additional 0.132 QALYs.

The difference may be because the 2008 study was of new users. As a consequence, cost-effectiveness...
estimates worsened considerably to US$26,206 (£17,706) per QALY, US$18,572 (£12,548) per QALY and US$25,436 (£17,186) per QALY, respectively.

Mataveli et al. (2008), in an abstract with few details, reported the results of a cost-effectiveness analysis of SMBG among patients with T2DM using oral glucose lowering drugs within the Brazilian setting. It was reported that daily use of SMBG was associated with a fall in HbA1c level of 0.6%, though details are sparse and other changes may have occurred. Over a 3-year period, once-daily SMBG was estimated to result in average cost savings across three Brazilian health maintenance organisations: R$3499 (Brazilian real) (£954), R$884 (£258) and R$649 (£190). The source of funds is not given, but one author is from LifeScan.

Erny-Albrecht et al. (2007) reported the outcome of modelling the cost-effectiveness of SMBG using the Kaiser Permanente Healthcare Group observational study. The estimated patient impacts of this modelling fell between those of the Tunis and Minshall (2008) full paper and the Tunis (2009) abstract above. Compared to ‘no SMBG’:

- Once-daily SMBG led to an additional 0.083 QALYs.
- Twice-daily SMBG led to an additional 0.216 QALYs.
- Three-times-daily SMBG led to an additional 0.270 QALYs.

Given these estimates, the respective cost-effectiveness estimates were US$65530 (£4324) per QALY, US$5997 (£3145) per QALY and US$7784 (£4082) per QALY, respectively. The source of funding is not given but, from the authorship, it is likely to have been industry funded.

Weber et al. (2007) also reported the outcomes of modelling using the Kaiser Permanente Healthcare Group observational study. Few details were provided but the additional cost of treatment in the SMBG group was estimated as being €1524 (£1073) for testing of between every 2 days and once daily, and as being €3273 (£2304) for testing of between 2.5 and 3-times-daily. Additional life expectancies of 0.021 years and 0.222 were estimated, resulting in cost-effectiveness ratios of €70,199 (£49,419) and €14,710 (£10,356), respectively. Further modelling estimated the cost-effectiveness of testing between once and twice daily as between €33,607 (£23,659) and €34,211 (£24,084), respectively. The authors regarded this as being cost-effective.

In an earlier abstract, Weber et al. (2006) report the outcome of a Markov model looking at the cost-effectiveness of SMBG among patients with T2DM not using insulin. The impact of SMBG was limited to the change in HbA1c level reported in the Sarol meta-analysis. Given a frequency of seven times per week, the impact on HbA1c level was reported as an improvement of 0.42%. This led to an estimate of the cost-effectiveness of SMBG alongside metformin treatment of €28,171 (£21,074) per life-year gained and alongside sulphonylurea of €27,062 (£20,245) per life-year gained. Applying the upper and lower 95% confidence limits reported in Sarol et al. resulted in cost-effectiveness estimates of €63,404 (£47,433) per life-year gained and €19,351 (£14,477) per life-year gained, respectively.

Neeser et al. (2006), in a letter, reported undertaking a Markov modelling exercise of the cost-effectiveness within the German health-care system using a 0.39% HbA1c level reduction from SMBG among non-insulin-using patients with T2DM, the reduction being derived from the Welschen et al. meta-analysis. No other details are provided as to the modelling inputs or the model used, but they report an anticipated gain estimated by Neeser et al. (2006) being only 30 days, and that the estimate of a reduction in HbA1c level was significant in only two out of the six trials within the meta-analysis.

**Summary**

Reviewing cost-effectiveness was complicated by:

- a lack of clarity as to the assumed duration of therapies and when or if intensification of therapy, such as switching to insulin, had been allowed for
- a lack of clarity as to the assumed duration of an effect upon HbA1c level, though it appears likely that this was assumed to be lifetime, regardless of any intensification of therapy
- with the exception of Farmer et al. typically assuming no direct QoL decrement from SMBG among those controlling their diabetes with diet or oral medication.
The cost of SMBG in people with T2DM in England is probably around £38M per year,\textsuperscript{100} of which about £17M could be saved by adhering to previous guidelines, and another similar amount by applying the findings of DiGEM in the sulphonylurea-only group.

The reported costs per annum of SMBG vary amongst studies, the lowest being the estimate by Belsey \textit{et al.} (2009)\textsuperscript{100} of about £10 per year for infrequent testers on diet alone, to £259 in the Palmer \textit{et al.} (2006) study.\textsuperscript{22}

Several studies assert that SMBG can lead to savings that offset testing costs, for example Weber \textit{et al.} (2007)\textsuperscript{122} estimate the additional costs to be £39 annually but that taking avoided events into account gives an average annual saving of £222.

Meier \textit{et al.} (2002)\textsuperscript{79} estimate savings to be £66 per annum.

However, most of these studies fail to allow for the negative impact of SMBG on QoL, as reported by the DiGEM\textsuperscript{10} group and Franciosi \textit{et al.} (2001).\textsuperscript{70}

The cost-effectiveness analyses vary in their assumptions, with those funded by industry being more optimistic in the size of gains in HbA\textsubscript{1c} level, and hence producing lower incremental cost-effectiveness ratios (ICERs). The best analysis to date is that of Farmer \textit{et al.} (2009)\textsuperscript{11} (funded by the UK Health Technology Assessment programme), which, after taking into account all costs, gains and disutilities, concluded that SMBG was not cost-effective.
Problems with the evidence base

Some of the reasons for the controversy around the value of SMBG in people with T2DM are apparent from the literature. They include:

- The evidence base did not allow us to answer our original primary or additional questions; the studies did not provide information on patient outcomes by treatment received (i.e. diet alone, metformin monotherapy, combination oral therapy, or combinations of oral therapy and insulin), with most studies not even providing a breakdown of the treatment patients were taking. Similarly, none of the studies provided enough information for making a judgement on any subgroups of patients that might benefit most, or that might be harmed. We also did not find any studies that investigated in detail the different aspects of education in relation to SMBG.

- Most, if not all, RCTs have treated SMBG – which, in the first instance, is a diagnostic tool – as an intervention in its own right, rather than acknowledging that in order to be able to have a benefit on patient outcomes. SMBG needs to be linked to appropriate education, feedback, treatment and behaviour adjustment, as well as to an analysis of the types of patients and situations for which SMBG might be most helpful. In some studies there appeared to be a lack of provision of education and/or feedback, and in others there was a lack of detail about what education was offered. Most other potential modifiers of SMBG benefit were not assessed at all.

- Differences in conclusions of the systematic reviews, with some reporting that results are inconclusive, while others reported that SMBG improves HbA1c level. However, it is notable that the latter usually find small differences in HbA1c level ranging from improvements of 0.16% to 0.42%. It is also noteworthy that the effects sizes are smaller in the later reviews with more trials – for example 0.24%, 0.16% and 0.22% compared with 0.42%, 0.39% and 0.41%.

- There is also lack of agreement on what is a clinically significant difference in HbA1c level. The consensus seems to be 0.5% or more but that appears to be an arbitrary number.

- Differences in the use made of the data from SMBG. In some studies, no action was taken based on the results, so no benefit was likely. In others, drug treatment could be changed by doctors but not by patients. In some studies, patients were encouraged to adjust treatment themselves. However, there was little evidence for adjustment in what was most under their control – diet and exercise. There appears to be a disconnection between SMBG and diet/exercise, in that neither patients nor HCPs are actively checking SMBG in response to specific behaviour changes, such as a diet or starting an exercise regime. It’s almost as if patients don’t regard lifestyle change as an appropriate remedy. Kempf et al. (2008) suggest that ‘appropriate use of SMBG data by the patient may be improved by practical lessons that allow the patient to recognise the impact of high versus low glycaemic meals and of moderate physical activity such as 30 minutes of brisk walking’.

- Some of the observational studies had too many confounders to provide useful data. For example, some reported higher HbA1c level in those undertaking SMBG but that may be because poor control was the reason for starting SMBG. In others, SMBG appeared to improve control but the improvements may have been in adherence to other aspects of self-care.

- Some studies reported the results of SMBG where there was no education to empower patients in altering treatment. Some implied that SMBG was carried out to inform the doctor or nurse, rather than the patient.

- The baseline HbA1c level may be relevant. It was sometimes too low to expect much improvement (but there could be improvements in other areas such as hypoglycaemic episodes). A simple regression analysis suggested that effects of SMBG were larger in patients with higher baseline HbA1c values.
Some common themes emerged. Use of SMBG in T2DM is clearly an international issue, with studies from the UK, Italy, New Zealand and Australia.

It may be that better targeted selection of patients for SMBG is required. McGeoch et al. (2007) concluded that SMBG may not be helpful or economically justified in all cases, but that individuals would benefit if:

- their baseline HbA1c level is above 8%
- they are properly educated in the use of SMBG and how to take appropriate action based on the results
- they are sufficiently literate and numerate to take advantage of the intervention
- they are receptive to the need for better metabolic control and are motivated to make the necessary changes
- there are special circumstances – such as new diagnosis, initiation or change in medication, illness, gestational diabetes and lack of awareness of hypoglycaemia.

Davidson (2005) commented that possible explanations for lack of effect of SMBG in patients include:

- patients receive little or no feedback on their results
- they are not taught the self-management skills to lower blood glucose
- (in his experience) the vast majority of patients monitor fasting or preprandial BG values, which neither serves to educate or motivate.

The type of education offered also seems to be of importance, with education emphasising a positive attitude and enhanced self-efficacy possibly being more effective than simple ‘information-based’ education. In one trial of both T1DM patients and T2DM patients, recruits in the intervention arm were given the Blood sugar monitoring owner’s manual, devised by Laffel et al. (available at US$5.25 from Joslin Diabetes Center, Boston, Massachusetts, USA), which emphasises a positive attitude. The control group was given meters, strips and instructions in use. While there was no significant difference in absolute HbA1c levels at the end of the 6-month trial (the difference was only 0.09%), significantly more patients in the intervention group managed to improve their HbA1c values (61% versus 44%) and fewer participants had a negative affect regarding SMBG than patients who were not receiving the manual (38% versus 65%).

In the trial by Schwedes et al., SMBG use in patients with T2DM (on diet and/or oral treatment) was combined with a short counselling algorithm focusing on promotion of self-perception (diary entries of eating, well-being and SMBG readings), self-reflection (what worked/did not work in experience with SMBG, what facilitated SMBG), and enhancement of self-regulation (ideas of how to use diary entries and SMBG to improve glycaemic control, assessment of probability of achieving goals). Compared with the non-SMBG control group, patients in the intervention group had a 0.46% greater reduction in HbA1c level, and depression was significantly reduced (no significant difference in treatment satisfaction, general well-being, anxiety, energy or positive well-being). This is in contrast with the results of the DiGEM and ESMON trials, which used more traditional educational strategies. It has been argued that the additional counselling strategy used in the SMBG group (but not in the control group) in the trial by Schwedes et al. meant that the effect of SMBG per se could not be distinguished from the effect of the counselling – but then as a diagnostic test rather than an intervention, SMBG cannot be expected to have a benefit without giving patients and HCPs optimal help in using the results.

Thus, education is required not only for patients, but also for professionals such as practice nurses so that they can advise on treatment changes – though this might require a change in prescription that the nurse could organise rather than provide. However, if the prescription was dietary, the nurse or the practice might not have access to sufficient dietetic help.

Another issue is that there seems to be an assumption across the literature that it is simply a case of ‘to test or not to test’, i.e. that SMBG is ongoing rather than episodic. There was little reference in the literature to suggest that HCPs are engaging patients in short bursts of targeted testing, for example to assess the effects of lifestyle changes (weight change, exercise, dietary changes, etc.). Such an episodic approach might be more effective and less costly. Testing could be at greater intensity initially, with routine testing then stopped pending HbA1c results. It is also unclear whether patients achieving ‘good’ diabetes control without SMBG might be actively discouraged from taking on the additional burden of it.

Selection might also be better if based more on patients’ personalities (some want to take control
themselves, some do not) than on treatment group. It would be useful to split the insulin-treated group into those on single basal injections per day from those on more complex regimens.

There may also be unrealistic expectations of the value of SMBG, for example stimulated by advertising to HCPs and patients. Being a diagnostic tool, SMBG is only ever going to be as good as the context in which it is used and the actions taken in response to the readings.

There are psychological disbenefits from SMBG as used in current practice – anxiety, depression and self-chastisement. Adverse effects on QoL were not only seen in clinical trials, but also in a large Italian observational study on SMBG in T2DM (2855 respondents, of whom 2254 were not on insulin). There was no association of SMBG frequency with HbA1c level in non-insulin-treated patients, but QoL (including diabetes-related distress, diabetes health distress, diabetes-related worries and depressive symptoms) was significantly decreased in those who were monitoring once or more per day (no significant difference for those monitoring less frequently). The authors suggest that the correlation with poorer psychological well-being could be related to the feeling of powerlessness caused by unsatisfactory results that patients are not able to improve, and they call for education and better guidance on how to use the results for treatment adjustment and/or behaviour change.

In a recent study from the USA of attitudes and behaviours in 253 people with T2DM the following factors were found to be significant barriers for SMBG, and were associated with higher HbA1c levels: ‘costs too much’, ‘hassle’, ‘depression interferes’, ‘don’t understand’, ‘don’t like’, ‘it hurts’ and ‘don’t know how to use the results’. The invasiveness of the SMBG procedure may also contribute to anxiety, as suggested by another American study of 339 diabetes patients (69.5% T2DM, 51.2% on diet and/or oral agents only), which showed that anxiety associated with SMBG invasiveness contributes to perceived burden and is negatively correlated with adherence to SMBG recommendations.

The question is whether the conclusion should be that because of these potential psychological disbenefits SMBG should not be used at all or whether these effects are just a warning sign that it should be used differently than used at present. There is a possibility – supported by some of the qualitative evidence – that depression and anxiety are due to the constant reminder of illness when monitoring (and this may be especially true in newly diagnosed patients, such as those in the ESMON trial, who may not yet have adapted to the disease). On the other hand, if the aim is increased self-efficacy then avoidance is probably not an appropriate strategy. In a study of 292 insulin-treated patients who had either T1DM or T2DM (48% T2DM) in the Netherlands, the coping style of diabetes avoidance was significantly associated with less frequent SMBG and perceiving SMBG as a burden. Participants with a low level of self-efficacy perceived all types of self-management activities as a burden. As also suggested by the data from the RCT by Schwedes et al. described above, increased self-efficacy may therefore lead to feeling more in control, less burdened and less depressed.

Clear, specific guidelines on who should use SMBG, and how frequently, are required – repeatedly articles cite ambiguity around current guidance for T2DM. Further research needs to address these factors, rather than just asking whether SMBG is useful per se.

The economics of SMBG

Belsey et al. (2009) estimated that in the UK SMBG varies from a low of 26% among those controlling their diabetes through diet and exercise alone, at an average annual cost of £10, rising as oral agents are added to peak at between 87% and 89% for those using insulin, at an average annual cost of between £140 and £198. Given this, the annual overall UK cost of SMBG was estimated as £171M, of which the authors estimated around £13M was unnecessary, given current guidelines. These results can be coupled with those of the US Veterans Affairs study of Meier et al. (2002), within which a policy of reducing test strip usage found that those using diet and exercise alone could approximately halve test strip usage, to one every other day with no impact upon HbA1c level. Similar results were reported for those using oral agents, though test strip usage was higher after the reduction, at around five per week.

Whether SMBG is cost-effective given its direct cost and its direct QoL impacts is not clear from the current literature. Farmer et al. undertook what appears to be the most comprehensive study of the cost-effectiveness of SMBG in the UK setting. This applied the direct QoL effects and HbA1c levels
effects of SMBG from the DiGEM study, assessing cost-effectiveness within the trial period and also extrapolating beyond this using the UKPDS Outcomes Model. Within the trial period, SMBG was estimated to result in additional costs and QALY losses and so be dominated by standard care. Extrapolation using the UKPDS Outcomes Model reduced both the additional costs and the QALY losses, due to some avoidance of downstream complications, but this did not affect the conclusion that SMBG was dominated by standard care. But the overall effects were small and subject to considerable uncertainty.

Other cost-effectiveness studies typically found minor QALY gains due to improvements in HbA$_1c$ level. This was typically at some additional cost, though some studies suggested the possibility of downstream cost savings outweighing the initial costs of SMBG. A key aspect of these studies was that SMBG was assumed not to be associated with any direct QoL loss, which appears unrealistic. There is the clear potential for the immediate direct QoL loss from SMBG to outweigh any downstream benefit in terms of reduced complications if the immediate impact of SMBG upon HbA$_1c$ level is minor or not sustained.

### Other reviews

The IQWiG preliminary report on SMUG and SMBG in T2DM.

The German equivalent of NICE, the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), produced a report (in German, and not included in our clinical effectiveness partly because of language and partly because the preliminary report was published after ours was completed) assessing the effects of SMBG or SMUG as an integral part of any management strategy aimed at lowering blood glucose, compared with a strategy without self-measurement of glucose, or the comparison of a strategy involving SMBG with one involving SMUG in patients with T2DM who were not treated with insulin, with respect to patient-related outcomes. Studies were included only if they also considered outcomes such as hypoglycaemia, QoL, mortality, diabetes-related morbidity, etc., but HbA$_1c$ level was also recorded. RCTs were considered, as well as epidemiological studies assessing mortality and morbidity. Minimum study duration was 6 months. Only full publications were included.

The findings of the IQWiG report are summarised in Box 1. The report placed most importance on assessment of hypoglycaemia. There was little emphasis on the issues of education and adjustment of therapy (other than using this as an outcome, but not in the sense of arguing that this is what should follow the SMBG measurement), and no discussion of behaviour changes.

A review by O’Kane and Pickup (2009) comes to a similar conclusion as our review and ends with the comment that ‘The widespread use of SMBG (particularly in type-2 patients) is a good example of self-monitoring that was adopted in advance of robust evidence of its clinical efficacy’. Their review provides a useful history of SMBG and the technical aspects.

One issue raised by O’Kane and Pickup (2009) is that most previous RCTs have excluded patients who are already monitoring their blood glucose, and that this may cause a bias in that the excluded people may be the most successful.

The International Diabetes Federation issued its guidelines on SMBG in non-insulin-treated diabetes at the World Diabetes Congress in October 2009. The summary noted ‘further studies are needed to better assess the benefits, optimal use and cost-effectiveness of SMBG’. The recommendations are given in Box 2.

### Research needs

The top priority for research is to determine whether SMBG is ineffective in T2DM, or whether we have just not used it effectively in appropriately selected and empowered patients. Perhaps there has been too much focus on the technology end of the technology–human interface and not enough on the human end.

Research is required to:

- determine characteristics of patients benefiting most from SMBG, in terms of psychological attributes, preferences, underlying treatment, baseline HbA$_1c$ level, duration of diabetes, age, level of education, previous use of SMBG, motivation for self-care, etc.
- determine the optimal duration and frequency of SMBG for such individuals; specific time periods may occur at diagnosis, onset of behaviour change regimen (such as diet...
The IQWiG report findings and conclusions were as follows:

The search identified 15 relevant papers describing 11 studies. However, five studies were excluded for the following reasons: three did not report relevant outcome measures other than HbA1c level (Allen 1990, Davidson 2005, Gallichan 1994) and two included relevant subgroups but the authors did not send the required data (Oria-Pino 2006, Wong 1986). The following five studies were included in the analysis: Guerci 2003, DiGEM 2007, Barnett 2008, ESMON 2008, Scherbaum 2008 and Schwedes 2002. Three studies were classified as having a low risk of bias, two as having a high risk of bias.

Data on hypoglycaemia were insufficiently reported: three studies reported data on severe hypoglycaemia but these were very rare. There was a statistically significant difference in HbA1c level in favour of SMBG (–0.23%), but this was judged not to be relevant as it was within the non-inferiority interval of 0.4%. There was no significant difference in therapy changes. Only one study reported other adverse events, and there was no significant difference between groups. There was no evidence of harm of SMBG compared with interventions without SMBG, but data were insufficient.

Four out of five studies reported on body weight and tended to show a slight reduction with SMBG, but overall the difference was non-significant.

Three studies reported on health-related QoL. The risk of bias for this measure was judged to be high for all three studies. In the DiGEM study, there was no significant difference for the W-BQ12 measure, and results on the EQ-5D were partially contradictory and could not be used. The ESMON study found increased depression in SMBG patients, whereas Schwedes 2002 found reduced depression in patients performing SMBG. Overall, there was no evidence for benefit or harm based in health-related QoL.

Three studies reported on patient satisfaction and there was no significant difference between groups. Two epidemiological studies were identified that reported on diabetes-related mortality and morbidity (ROSSO study and Fremantle diabetes study), but gave contradictory results.

Overall, there was no evidence for a benefit of self-measurement of blood or urinary glucose in patients with T2DM who were not being treated with insulin. There were no relevant and sufficiently clearly reported studies on measurement of urinary glucose. There was no evidence that measurement frequency had an influence on results. Epidemiological studies showed no evidence of an association between SMBG or SMUG and morbidity and mortality.

SMBG should be used only when individuals with diabetes and/or their health-care providers have the knowledge, skills and willingness to incorporate SMBG monitoring and therapy adjustment into their diabetes care plans in order to attain agreed treatment goals.

SMBG should be considered at the time of diagnosis to enhance the understanding of diabetes as part of individuals’ education and to facilitate timely treatment initiation and titration optimisation.

SMBG should also be considered as part of ongoing diabetes self-management education to assist people with diabetes to better understand their disease and provide a means to actively and effectively participate in its control and treatment, modifying behavioural and pharmacological interventions as needed, in consultation with their health-care provider.

SMBG protocols (intensity and frequency) should be individualised to address each individual’s specific educational/behavioural/clinical requirements (to identify/prevent/manage acute hyper- and hypoglycaemia) and provider requirements for data on glycaemic patterns and to monitor the impact of therapeutic decisions.

The purpose(s) of performing SMBG and using SMBG data should be agreed between the person with diabetes and the health-care provider.
or exercise programme) or on progression of disease, for example when \( \text{HbA}_1c \) level exceeds target on two or more consecutive measurements; there may be a particular benefit in patients on combination oral therapy who are being considered for the addition of insulin, as this is a group where intensive lifestyle intervention may avoid the need for insulin\(^{133} \) – it may be that motivation would be stronger at that stage; short, targeted bursts of SMBG may be more effective

- assess the size and duration of the \( \text{HbA}_1c \) effect in those in whom it does work
- assess the impact of structured education on how to read and interpret results of SMBG
- compare education containing empowerment techniques for patients with/without the aid of SMBG in patients treated with diet and/or oral glucose-lowering medication to determine the effective component, for example education, empowerment or SMBG
- assess the effect of feedback in response to SMBG with respect to treatment changes (by HCP or patient) and behavioural/lifestyle changes and examine the interaction/communication between HCP and patient regarding SMBG readings and resulting action; this would include assessing the impact on intensification of treatment, such as whether SMBG can prolong the time on diet alone or on oral agents prior to insulin
- assess the effects of SMBG on QoL and patient satisfaction, especially with respect to depression and anxiety and try to elicit the causes of depression/anxiety and the interaction between self-efficacy, depression/anxiety and clinical outcomes; if patients feel that SMBG can help them to improve their control, would that remove the depression and anxiety?
- determine situations in which urinary glucose monitoring may be of value and whether it causes less anxiety (a trial is under way – see below)
- assess the role pharmacists play in SMBG. If they are selling meters, are they providing education? What role could pharmacists play in delivering education? People usually have to go to the pharmacy to pick up their test strips
- check as to whether newer devices with quicker results and memory for storing results are more effective.

### Current or planned research

The Self Monitoring of Blood Glucose Trialists Collaboration is going to carry out an individual patient-based meta-analysis,\(^{134} \) which will, amongst other things, examine effectiveness amongst predefined subgroups, look for interactions with behavioural variables, assess the effect of co-intervention with psychosocial and educational interventions, and provide more detail on the interventions used in the trials.

A three-armed RCT of SMBG versus urine testing versus standard care is planned by Malanda et al.\(^{135} \) from Amsterdam, the Netherlands: 600 patients will be recruited. The primary outcomes will be changes in diabetes-specific emotional distress and efficacy. Secondary outcomes include glycaemic control, patient satisfaction, physical activity, health status, depressive status, hypoglycaemia and cost-utility.

A trial funded by Diabetes UK is comparing SMBG with SMUG.\(^{136} \) It is an extension of the DESMOND (Diabetes Education and Self-Management for On-going and Newly Diagnosed) study, and is measuring effects on glycaemic control (both \( \text{HbA}_1c \) level and hypoglycaemia) and QoL, with an 18-month follow-up. If differences between the arms are seen then there will be a full economic assessment using the Sheffield Diabetes Model. It started early in 2007.

A German study is comparing once-weekly glucose profile self-monitoring with 3-monthly \( \text{HbA}_1c \) to see which is better after 1 year. There are four arms: SMBG, \( \text{HbA}_1c \), both and neither, with all arms having urine glucose monitoring. The study duration is 5 years and it was expected to end by December 2008.\(^{137} \)

An Italian study called PRISMA (Prospective Randomised trial on Intensive Self-Monitoring Blood Glucose Management Added Value in Non-insulin treated type 2 diabetes), funded by Hoffman-La Roche, has two arms, both with SMBG: one arm has standard care and the other arm provides patients with specific glycaemic targets and suggestions on how to achieve them by changes in diet or physical activity.\(^{138} \)
Another Dutch study in people with T2DM, not on insulin, is comparing SMBG (four times per day, 2 days per week) with standard care (not defined) with glycaemic control, QoL, treatment satisfaction, weight and need to start insulin as outcomes. It was due to end in 2008. It is funded by the Medical Research Foundation.\textsuperscript{139}

In the USA, Bergenstal \textit{et al.}\textsuperscript{140} are examining the effects of different frequencies and timing (SMBG three times per day versus only once-daily fasting) but with a control arm with no SMBG. The trial is due to end in 2009. It is supported by LifeScan.

\textbf{Conclusions}

Self-monitoring of blood glucose seems to provide only slight benefit in terms of glycaemic control, and it can have psychological disbenefits. There was a lack of evidence regarding the subgroups of patients who may benefit most from SMBG, and optimal frequency and timing. But SMBG clearly can yield benefits if used appropriately. One issue is that a number of studies showed that no changes in self-management or treatment were made as a result of SMBG – there is no point in collecting data on blood glucose levels if nothing is done with the data.

The current evidence on cost-effectiveness is mixed, but the best economics paper is from the DiGEM trial in the UK, which concluded that SMBG in patients with T2DM not on insulin was not cost-effective.

It may be that the key should be to identify those patients who will most benefit and divert some of the money currently allocated to SMBG to improved education for both HCPs and patients. SMBG might be more effective if associated with appropriate self-care plans developed between HCPs and patients to best meet patient needs and fit into their own lifestyle.

The prevalence and costs of T2DM are rising steadily at a time when NHS development funds are going to be very scarce. If we fund an increase in SMBG, funding will have to be taken from other aspects of care. The case for investing in SMBG for patients with T2DM not treated with insulin has to be regarded at present as ‘not proven’.

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- Dr Mark Houliston, general practitioner and lead clinician, Grampian Diabetes Managed Clinical Network
- Dr Maurice O’Kane, Londonderry, Northern Ireland, UK.

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- Simon Heller (Chair)
- Eleanor Kennedy
- Andrew Farmer
- Adrian Griffin
- Martin Gulliford
- Julia Lawton
- Maurice O’Kane
- Mark Samuels
- Grace Sweeney
- Bridget Turner.

**Contributions of authors**

- Christine Clar led the review of clinical effectiveness, commented on other sections, and edited the report after peer review and editorial comments.
- Katharine Barnard led the review of qualitative studies and commented on other sections.
- Ewen Cummins led the review of economic studies.
- Pamela Royle did searches, quality assurance and editing, and commented on all sections.
- Norman Waugh wrote Chapters 1 and 4, and undertook final editing.

**About the Aberdeen HTA group**

The Aberdeen Health Technology Assessment Group is part of the Institute of Applied Health Sciences (IAHS), which is part of the College of Medicine and Life Sciences of the University of Aberdeen, Aberdeen, UK. The IAHS is made up of discrete but methodologically related research groups. The HTA Group is drawn mainly from the Health Services Research Unit, Public Health, and the Health Economics Research Unit.

The HTA Group produces independent health TARs for the UK HTA programme, which commissions TARs for NICE and other bodies, such as the National Screening Committee. It also carries out evidence reviews to support the NICE Single Technology Appraisal Programme.

Particular interests include evaluation of non-pharmacological technologies, screening and diabetes. Previous TARs from Aberdeen include:

- Non-pharmacological prevention of diabetes in those with impaired glucose tolerance. In preparation.

We also do Cochrane reviews on diabetic topics.
References


References


64. Bajkowska-Fiedziukiewicz A, Cypryk K, Kozdziej T, Mikolajczyk-Swatko A, Kosinski M, Jozefowska M.


Appendix 1

Search strategy and flow of studies

Search strategy for clinical effectiveness studies
The following MEDLINE search strategy was adapted as appropriate for other databases:

1. (self monitor* adj3 blood glucose).tw.
2. (home monitor* adj3 blood glucose).tw.
3. (HMBG or HBGM or SMBG or BGSM).tw.
4. exp Blood Glucose Self-Monitoring/
5. (glucose adj2 monitor* adj3 (self or home)).tw.
6. 4 or 1 or 3 or 2 or 5
7. exp Diabetes Mellitus, Type 2/
8. type 2 diabetes.tw.
9. 8 or 7
10. 6 and 9
11. ((self or home) and monitor* and glucose).m_titl.
12. 11 or 10
13. limit 12 to english language

Search strategy for a cost-effectiveness studies
The MEDLINE strategy below was used and adapted as appropriate for other databases:

1. (self monitor* adj3 blood glucose).tw.
2. (home monitor* adj3 blood glucose).tw.
3. (HMBG or HBGM or SMBG or BGSM).tw.
4. exp Blood Glucose Self-Monitoring/
5. (glucose adj2 monitor* adj3 (self or home)).tw.
6. 4 or 1 or 3 or 2 or 5
7. exp Diabetes Mellitus, Type 2/
8. type 2 diabetes.tw.
9. 8 or 7
10. 6 and 9
11. ((self or home) and monitor* and glucose).m_titl.
12. 11 or 10
13. limit 12 to english language
14. (cost* or economic or financial).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15. 13 and 14
Flow of studies for SMBG general search

2051 studies identified from all searches

1062 unique studies remaining

989 duplicate studies removed

736 studies excluded as not relevant to SMBG

255 studies retained for background reading and general references

326 studies remaining

71 studies selected for data extraction

16 references to 11 systematic reviews

18 RCTs + 8 from reference lists

32 observational studies

5 qualitative studies

255 studies retained for background reading and general references

Flow of studies for SMBG cost-effectiveness search

507 studies in searches

458 studies excluded on basis of abstracts

Full text of remaining 49 studies obtained

17 studies included in cost-effectiveness section
Appendix 2

Characteristics of systematic reviews
### Inclusion criteria and methodology

<table>
<thead>
<tr>
<th>Review</th>
<th>Inclusion criteria</th>
<th>Included studies</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faas (1997)&lt;sup&gt;30&lt;/sup&gt; Netherlands</td>
<td>Study design: unclear; non-RCTs included initially, but only RCTs investigated in more detail</td>
<td>Number of included trials: 11; 6 RCTs, 5 non-RCTs not further evaluated</td>
<td>• Inclusion criteria described: yes</td>
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<tr>
<td></td>
<td>Participants: T2DM; studies exclusively with patients using insulin excluded</td>
<td>Number of participants: 592</td>
<td>• Details of literature search given: yes (limited)</td>
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<tr>
<td></td>
<td>Interventions: SMBG; any comparison</td>
<td>TRIALS:</td>
<td>• Study selection described: no</td>
</tr>
<tr>
<td></td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;; other outcomes as reported</td>
<td>Design: only RCTs further evaluated</td>
<td>• Data extraction described: no</td>
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<tr>
<td></td>
<td><strong>Methodology</strong></td>
<td>Duration: 12–62 weeks</td>
<td>• Study quality assessment described: yes</td>
</tr>
<tr>
<td></td>
<td>Search strategy: MEDLINE (1976–1996); keywords given; bibliographies searched</td>
<td>Quality: 4 RCTs 7/7 points, rest 3/7 and 4/7</td>
<td>• Study flow shown: yes, narratively</td>
</tr>
<tr>
<td></td>
<td>Study selection: method not reported</td>
<td>PARTICIPANTS: see trial descriptions</td>
<td>• Study characteristics of individual studies described: yes (limited)</td>
</tr>
<tr>
<td></td>
<td>Quality assessment: criteria by Deyo and ter Riet</td>
<td>INTERVENTIONS: 4 only SMBG, 4 vs no SMBG, 3 vs urine testing; some interventions including education</td>
<td>• Quality of individual studies given: yes</td>
</tr>
<tr>
<td></td>
<td>Data extraction: method not reported</td>
<td>OUTCOMES: HbA&lt;sub&gt;1c&lt;/sub&gt;, weight, fasting glucose, lifestyle adherence, SMBG adherence, fructosamine</td>
<td>• Results of individual studies shown: yes</td>
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<td></td>
<td>Meta-analysis: none</td>
<td><strong>Number of included trials:</strong> 8</td>
<td>• Statistical analysis appropriate: yes</td>
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<td></td>
<td>Data analysis: text and tables</td>
<td><strong>Number of participants:</strong> 734</td>
<td>OVERALL QUALITY: moderate – limited description of methods and of study characteristics</td>
</tr>
<tr>
<td></td>
<td>Subgroups/sensitivity analyses: none</td>
<td><strong>TRIALS:</strong></td>
<td>COMMENT: investigated use of therapy decision scheme by the investigator, comparisons, nature of SMBG device; key points of patient instruction and education, self-monitoring regimen, assessment of self-monitoring frequency, feedback received from care provider</td>
</tr>
<tr>
<td>Coster (2000)&lt;sup&gt;29&lt;/sup&gt; UK – NHS HTA</td>
<td>Study design: RCTs</td>
<td><strong>Quality</strong>: mean quality score 15 of 27</td>
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<tr>
<td></td>
<td>Participants: T2DM, independent of treatment type</td>
<td><strong>PARTICIPANTS:</strong> see trial descriptions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interventions: SMBG vs SMUG or no monitoring</td>
<td><strong>INTERVENTIONS:</strong> some interventions including education – see descriptions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;, weight, any other outcomes reported</td>
<td><strong>OUTCOMES:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;, fasting blood glucose, fructosamine, body weight, QoL</td>
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<td></td>
<td><strong>Methodology</strong></td>
<td><strong>Number of included trials:</strong> 8</td>
<td>• Inclusion criteria described: yes</td>
</tr>
<tr>
<td></td>
<td>Search strategy: MEDLINE, EMBASE; Index and Bibliography of Social Science (IBSS); database of Diabetes Health Economic Study Group; search dates 1976–99 (MEDLINE); 1980–98 (EMBASE); keywords given; hand-searching Diabetic Medicine (1990–9) and Diabetes Care (1990–9); requests to British Diabetic Association and manufacturers of testing equipment (Bayer and Roche Diagnostics); reference lists; restriction to English language</td>
<td><strong>Number of participants:</strong> 734</td>
<td>• Details of literature search given: yes</td>
</tr>
<tr>
<td></td>
<td>Study selection: method not reported</td>
<td><strong>TRIALS:</strong></td>
<td>• Study selection described: no</td>
</tr>
<tr>
<td></td>
<td>Quality assessment: criteria by Deyo and ter Riet</td>
<td>Design: RCTs</td>
<td>• Data extraction described: no</td>
</tr>
<tr>
<td></td>
<td>Data extraction: method not reported</td>
<td>Duration: 3–12 months</td>
<td>• Study quality assessment described: yes</td>
</tr>
<tr>
<td></td>
<td>Meta-analysis: none</td>
<td>Quality: mean quality score 15 of 27</td>
<td>• Study flow shown: yes</td>
</tr>
<tr>
<td></td>
<td>Data analysis: text and tables</td>
<td><strong>PARTICIPANTS:</strong> see trial descriptions</td>
<td>• Study characteristics of individual studies described: yes</td>
</tr>
<tr>
<td></td>
<td>Subgroups/sensitivity analyses: none</td>
<td><strong>INTERVENTIONS:</strong> some interventions including education – see descriptions</td>
<td>• Quality of individual studies given: yes</td>
</tr>
<tr>
<td></td>
<td><strong>Included studies</strong></td>
<td><strong>OUTCOMES:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;, fasting blood glucose, fructosamine, body weight, QoL</td>
<td>• Results of individual studies shown: yes</td>
</tr>
<tr>
<td></td>
<td><strong>Quality</strong></td>
<td><strong>OVERALL QUALITY:</strong> high – but some methodology not described (but probably HTA programme standard)</td>
<td>• Statistical analysis appropriate: yes</td>
</tr>
</tbody>
</table>
### Review Inclusion criteria and methodology Included studies Quality

<table>
<thead>
<tr>
<th>Study selection: method not reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality assessment: modified quality checklist by Downs and Black (1998) applied by two reviewers independently</td>
</tr>
<tr>
<td>Data extraction: method not reported</td>
</tr>
<tr>
<td>Meta-analysis: yes</td>
</tr>
<tr>
<td>Data analysis: random effects model; heterogeneity assessed</td>
</tr>
<tr>
<td>Subgroups/sensitivity analyses: sensitivity analyses used that did not change the overall results (based on study design and comparisons)</td>
</tr>
</tbody>
</table>

#### Sarol (2005)

**Philippines**

Focus: self-monitoring of blood glucose on HbA1c in non-insulin-requiring patients with T2DM

**Funding:** Johnson & Johnson

<table>
<thead>
<tr>
<th>Study design: RCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants: T2DM without insulin treatment</td>
</tr>
<tr>
<td>Interventions: diabetes management strategy with SMBG component vs strategy without SMBG component</td>
</tr>
<tr>
<td>Outcomes: HbA1c</td>
</tr>
</tbody>
</table>

**Methodology**

Search strategy: MEDLINE, Cochrane Library, EMBASE, CRD databases, Online ADA Index Journals, personal collections (up to 2004); keywords listed; reference lists searched; English or English translation

Study selection: titles and abstracts independently assessed by two reviewers

Quality assessment: Cochrane Collaboration criteria

Data extraction: items extracted listed

Meta-analysis: yes

Data analysis: fixed and random effects; heterogeneity assessed

---

Number of included trials: 8

Number of participants: 1307

**TRIALS:**

- Design: RCTs
- Duration: 12–44 weeks
- Quality: quality B for 5 studies and C for 3 studies

**PARTICIPANTS:** see trial descriptions

**INTERVENTIONS:** some interventions including education – see descriptions

**OUTCOMES:** HbA1c

- Inclusion criteria described: yes
- Details of literature search given: yes
- Study selection described: yes
- Data extraction described: yes
- Study quality assessment described: yes
- Study flow shown: yes, narratively
- Study characteristics of individual studies described: yes
- Quality of individual studies given: yes
- Results of individual studies shown: yes
- Statistical analysis appropriate: yes

OVERALL QUALITY: high
<table>
<thead>
<tr>
<th>Review</th>
<th>Inclusion criteria and methodology</th>
<th>Included studies</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Welschen (2005)</strong></td>
<td>Inclusion criteria: Study design: RCTs, Participants: T2DM: non-insulin treated, Interventions: SMBG vs SMUG or no monitoring, Outcomes: HbA1c, FPG, QoL, patient satisfaction, hypoglycaemia, morbidity, adverse effects, costs.</td>
<td>Number of included trials: 6  Number of participants: 1285  TRIALS: RCTs  Duration: 6 months to 44 weeks  Quality: 1 trial 7/11, 1 trial 6/11, 4 trials 5/11  PARTICIPANTS: see trial descriptions  OUTCOMES: glycaemic control, HbA1c and/or fasting glucose, QoL, SF-36, well-being, patient satisfaction, DTSQ, hypoglycaemia episodes, morbidity, adverse effects, costs, weight.</td>
<td>• Inclusion criteria described: yes  • Details of literature search given: yes  • Study selection described: yes  • Data extraction described: yes  • Study quality assessment described: yes  • Study flow shown: yes, narratively  • Study characteristics of individual studies described: yes  • Quality of individual studies given: yes  • Results of individual studies shown: yes  • Statistical analysis appropriate: yes  OVERALL QUALITY: high</td>
</tr>
<tr>
<td><strong>Jansen (2006)</strong></td>
<td>Inclusion criteria: Study design: RCTs (full, published reports), Participants: T2DM; independent of treatment type, Interventions: self-monitoring of blood (SMBG) or urine glucose (SMUG), SMBG vs no SMBG, SMBG vs SMUG, SMBG with feedback vs SMBG without feedback, Outcomes: HbA1c.</td>
<td>Number of included trials: 13  Number of participants: 2092  TRIALS: all RCTs  Duration: 3 months to 62 weeks  Quality: mean quality score 8.5 of 13  PARTICIPANTS: no demographic information on participants provided; 2 studies – mixed insulin and non-insulin patients; 11 studies – patients did not use insulin or there was no information on insulin use  OUTCOMES: glycaemic control, HbA1c, and/or fasting glucose, QoL, SF-36, well-being, patient satisfaction, DTSQ, hypoglycaemia episodes, morbidity, adverse effects, costs, weight.</td>
<td>• Inclusion criteria described: yes  • Details of literature search given: yes  • Study selection described: yes  • Data extraction described: yes  • Study quality assessment described: yes  • Study flow shown: yes, narratively  • Study characteristics of individual studies described: yes  • Quality of individual studies given: yes  • Results of individual studies shown: yes  • Statistical analysis appropriate: yes  OVERALL QUALITY: high</td>
</tr>
</tbody>
</table>

**Netherlands**

**Focus:** effects of SMBG in patients with T2DM who are not using insulin  
**Funding:** non-commercial
### Review: AHRQ (2007)

**USA**  
**Focus:** effect of frequency of glucose monitoring on clinical outcomes and HbA₁c in patients with T2DM  
**Funding:** AHRQ

#### Inclusion criteria

- **Study design:** prospective studies with at least 50 patients and 6 weeks FU  
- **Participants:** T2DM of any duration; independent of treatment type; studies with more than 50% T1DM excluded  
- **Interventions:** SMBG vs no monitoring  
- **Outcomes:** HbA₁c

#### Methodology

- **Search strategy:** MEDLINE (up to April 2006); keywords given; reference lists of reviews and guidelines searched; English only  
- **Study selection:** abstracts screened by two reviewers  
- **Quality assessment:** quality not assessed  
- **Data extraction:** data extraction into evidence tables by single reviewer  
- **Data analysis:** text and tables  
- **Subgroups/sensitivity analyses:** none

#### Included studies

- **Number of included trials:** 5 RCTs, 8 non-RCTs  
- **Number of participants:** 2092

### Review Inclusion criteria and methodology

<table>
<thead>
<tr>
<th>Review</th>
<th>Inclusion criteria and methodology</th>
<th>Included studies</th>
<th>Quality</th>
</tr>
</thead>
</table>
| AHRQ (2007) | Meta-analysis: yes  
Data analysis: Bayesian random effects model (simultaneous direct and indirect comparisons)  
Subgroups/sensitivity analyses: all T2DM and non-insulin-treated T2DM only | Number of included trials: 5 RCTs, 8 non-RCTs  
Number of participants: 2092 |  
- Inclusion criteria described: yes  
- Details of literature search given: yes  
- Study selection described: no  
- Data extraction described: partly  
- Study quality assessment described: no  
- Study flow shown: no  
- Study characteristics of individual studies described: very limited  
- Quality of individual studies given: no  
- Results of individual studies shown: yes  
- Statistical analysis appropriate: yes | OVERALL QUALITY: poor – no description of study quality, English only |

<table>
<thead>
<tr>
<th>Review</th>
<th>Inclusion criteria</th>
<th>Included studies</th>
<th>Quality</th>
</tr>
</thead>
</table>
| AHRQ (2007) | Study design: prospective studies with at least 50 patients and 6 weeks FU  
Participants: T2DM of any duration; independent of treatment type; studies with more than 50% T1DM excluded  
Interventions: SMBG vs no monitoring  
Outcomes: HbA₁c | Number of included trials: 5 RCTs, 8 non-RCTs  
Number of participants: 2092 |  
- Inclusion criteria described: yes  
- Details of literature search given: yes  
- Study selection described: no  
- Data extraction described: partly  
- Study quality assessment described: no  
- Study flow shown: no  
- Study characteristics of individual studies described: very limited  
- Quality of individual studies given: no  
- Results of individual studies shown: yes  
- Statistical analysis appropriate: yes | OVERALL QUALITY: poor – no description of study quality, English only |

<table>
<thead>
<tr>
<th>Review</th>
<th>Inclusion criteria</th>
<th>Included studies</th>
<th>Quality</th>
</tr>
</thead>
</table>
| AHRQ (2007) | Search strategy: MEDLINE (up to April 2006); keywords given; reference lists of reviews and guidelines searched; English only  
Study selection: abstracts screened by two reviewers  
Quality assessment: quality not assessed  
Data extraction: data extraction into evidence tables by single reviewer  
Data analysis: text and tables  
Subgroups/sensitivity analyses: none | Number of included trials: 5 RCTs, 8 non-RCTs  
Number of participants: 2092 |  
- Inclusion criteria described: yes  
- Details of literature search given: yes  
- Study selection described: no  
- Data extraction described: partly  
- Study quality assessment described: no  
- Study flow shown: no  
- Study characteristics of individual studies described: very limited  
- Quality of individual studies given: no  
- Results of individual studies shown: yes  
- Statistical analysis appropriate: yes | OVERALL QUALITY: poor – no description of study quality, English only |
<table>
<thead>
<tr>
<th>Review</th>
<th>Inclusion criteria and methodology</th>
<th>Included studies</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>McAndrew (2007)²</td>
<td><strong>Inclusion criteria</strong>&lt;br&gt;Study design: RCT, cross-sectional and longitudinal studies&lt;br&gt;Participants: T2DM, non-insulin treated&lt;br&gt;Interventions: SMBG, comparator unclear&lt;br&gt;Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;&lt;br&gt;&lt;br&gt;<strong>Methodology</strong>&lt;br&gt;Search strategy: MEDLINE, PsycInfo, Cochrane Library, CINAHL (up to first quarter 2006); keywords given&lt;br&gt;Study selection: unclear – by one reviewer only?&lt;br&gt;Quality assessment: ADA evidence grading criteria, rated by one reviewer, if in doubt referring to other reviewers; only studies of ADA evidence grade A, B or C included&lt;br&gt;Data extraction: data extracted by one reviewer, checked by a second one&lt;br&gt;Meta-analysis: no&lt;br&gt;Data analysis: text and tables&lt;br&gt;Subgroups/sensitivity analyses: none</td>
<td>Number of included trials: 29 (30, DIGEM added in addendum)&lt;br&gt;Number of participants: 1759 RCTs, 36,091 non-RCTs&lt;br&gt;TRIALS: Design: 9 cross-sectional, 9 longitudinal, 11 RCTs&lt;br&gt;Duration: RCTs unclear, non-RCTs up to 3 years&lt;br&gt;Outcome: mean quality score 8.5 of 13&lt;br&gt;Participants: see trial descriptions&lt;br&gt;Interventions: some included education – see trial details&lt;br&gt;Outcomes: depression, HbA&lt;sub&gt;1c&lt;/sub&gt;, QoL</td>
<td>• Inclusion criteria described: yes&lt;br&gt;• Details of literature search given: yes&lt;br&gt;• Study selection described: unclear&lt;br&gt;• Data extraction described: yes&lt;br&gt;• Study quality assessment described: yes&lt;br&gt;• Study flow shown: yes&lt;br&gt;• Study characteristics of individual studies described: yes (but limited)&lt;br&gt;• Quality of individual studies given: no&lt;br&gt;• Results of individual studies shown: yes&lt;br&gt;• Statistical analysis appropriate: yes&lt;br&gt;OVERALL QUALITY: moderate</td>
</tr>
<tr>
<td>McGeoch (2007)²</td>
<td><strong>Inclusion criteria</strong>&lt;br&gt;Study design: RCTs and observational studies; at least 50 patients, FU at least 6 months&lt;br&gt;Participants: T2DM, non-insulin treated&lt;br&gt;Interventions: SMBG, comparator unclear&lt;br&gt;Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;, and diabetes-related morbidity&lt;br&gt;&lt;br&gt;<strong>Methodology</strong>&lt;br&gt;Search strategy: PubMed, EMBASE, Cochrane Library, MEDLINE; search dates: Jan 1990–Nov 2006; Google and Google Scholar; keywords given; no language restrictions&lt;br&gt;Study selection: no details of methods&lt;br&gt;Quality assessment: 1–5 score quality scale&lt;br&gt;Data extraction: two reviewers independently extracted information; items listed&lt;br&gt;Meta-analysis: no&lt;br&gt;Data analysis: text and tables&lt;br&gt;Subgroups/sensitivity analyses: none</td>
<td>Number of included trials: 16&lt;br&gt;Number of participants: 1000 in RCTs, &gt;60,000 in observational&lt;br&gt;TRIALS: Design: 3 RCTs, 13 observational&lt;br&gt;Duration: RCTs 6–12 months, observational up to 6.5 years&lt;br&gt;Quality: RCTs 1 or 2 of 5 points&lt;br&gt;Participants: see trial info&lt;br&gt;Interventions: interventions differed significantly in the amount of education given and in advised monitoring practice; control groups also received differing amounts of training in diabetes management&lt;br&gt;Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;, frequency of SMBG, weight, BMI, medication use, adverse effects (including diabetic complications)</td>
<td>• Inclusion criteria described: yes&lt;br&gt;• Details of literature search given: yes&lt;br&gt;• Study selection described: no&lt;br&gt;• Data extraction described: yes&lt;br&gt;• Study quality assessment described: yes&lt;br&gt;• Study flow shown: no&lt;br&gt;• Study characteristics of individual studies described: yes&lt;br&gt;• Quality of individual studies given: yes&lt;br&gt;• Results of individual studies shown: yes&lt;br&gt;• Statistical analysis appropriate: yes&lt;br&gt;OVERALL QUALITY: moderate/high</td>
</tr>
<tr>
<td>Review</td>
<td>Inclusion criteria and methodology</td>
<td>Included studies</td>
<td>Quality</td>
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<tr>
<td><strong>Poolsup (2008)</strong>[^1]</td>
<td><strong>Thailand</strong>&lt;br&gt;Focus: effects of SMBG on glycaemic control in non-insulin-treated patients with T2DM&lt;br&gt;Funding: not reported</td>
<td><strong>Inclusion criteria</strong>&lt;br&gt;Study design: RCTs&lt;br&gt;Participants: T2DM; non-insulin treated&lt;br&gt;Interventions: SMBG vs no SMBG&lt;br&gt;Outcomes: HbA(_1c) reported as outcome measure</td>
<td><strong>Number of included trials:</strong> 7 RCTs&lt;br&gt;<strong>Number of participants:</strong> 1625&lt;br&gt;<strong>TRIALS:</strong> Design: all RCTs&lt;br&gt;<strong>Quality:</strong> 5/7 high quality, 2/7 low quality&lt;br&gt;<strong>PARTICIPANTS:</strong> see trial details&lt;br&gt;<strong>INTERVENTIONS:</strong> some including education/counselling – see trial details&lt;br&gt;<strong>OUTCOMES:</strong> HbA(_1c), body weight, BMI, QoL score, FPG, blood pressure, serum creatinine, creatinine clearance, microalbumin–creatinine ratio, total cholesterol, triglycerides, HDL, LDL, well-being, treatment satisfaction, hypoglycaemic episodes</td>
</tr>
<tr>
<td><strong>Towfigh (2008)</strong>[^3]</td>
<td><strong>USA</strong>&lt;br&gt;Focus: effect of SMBG in patients with T2DM&lt;br&gt;Funding: non-commercial</td>
<td><strong>Inclusion criteria</strong>&lt;br&gt;Study design: RCTs and CCTs; FU at least 12 weeks&lt;br&gt;Participants: T2DM&lt;br&gt;Interventions: SMBG alone or as part of multicomponent intervention vs no SMBG&lt;br&gt;Outcomes: HbA(_1c)</td>
<td><strong>Number of included trials:</strong> 9&lt;br&gt;<strong>Number of participants:</strong> 1862&lt;br&gt;<strong>TRIALS:</strong> Design: all RCTs&lt;br&gt;<strong>Duration:</strong> 6 months to 62 weeks&lt;br&gt;<strong>Quality:</strong> quality variable, most trials scored positively on less than half of the criteria of the Delphi list&lt;br&gt;<strong>PARTICIPANTS:</strong> all patients with T2DM treated without insulin except one study&lt;br&gt;<strong>INTERVENTIONS:</strong> all patients with T2DM treated without insulin except one study&lt;br&gt;<strong>OUTCOMES:</strong> HbA(_1c), hypoglycaemia, fasting glucose, BMI/weight loss, health-related QoL</td>
</tr>
<tr>
<td>Review</td>
<td>Inclusion criteria and methodology</td>
<td>Included studies</td>
<td>Quality</td>
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</tbody>
</table>
| St John (2009)<sup>a</sup>  
Australia/UK  
Focus: reviewing literature relating to SMBG and glycaemic control in T1DM and T2DM  
Funding: not reported | **Inclusion criteria**  
Study design: experimental (RCTs or pseudo-experimental) and observational (cross-sectional or cohort studies)  
Participants: adults and children with type 1 or T2DM (excluding pregnant women)  
Interventions: SMBG alone or education programmes including SMBG and HbA<sub>1c</sub> as primary outcome measure  
Outcomes: HbA<sub>1c</sub>, SMBG use  
**Methodology**  
Search strategy: EMBASE, MEDLINE; search dates: 1996–June 2008; keywords reported, checking of reference lists  
Study selection: not reported  
Quality assessment: not reported  
Data extraction: not reported  
Meta-analysis: yes  
Data analysis: fixed and random effects models; heterogeneity assessed  
Subgroups/sensitivity analyses: in/excluding studies of doubtful eligibility, excluding largest trial, robustness to fixed vs random effects, duration <1 year or ≥1 year | Number of included trials: in T2DM: 23  
Number of participants: >75,000 in observational studies, 3941 pseudo-experimental, 2573 in RCTs  
**TRIALS:**  
Design: 13 observational, 4 pseudo-experimental, 6 RCTs  
Duration: experimental and pseudo-experimental 6 months to 4 years  
Quality: not reported  
**PARTICIPANTS:** see trial details  
**INTERVENTIONS:** some including education – see details trial description  
**OUTCOMES:** HbA<sub>1c</sub>, SMBG frequency, blood pressure, weight, cholesterol, hypoglycaemia, depression | • Inclusion criteria described: yes  
• Details of literature search given: yes  
• Study selection described: no  
• Data extraction described: no  
• Study quality assessment described: no  
• Study flow shown: yes, narratively  
• Study characteristics of individual studies described: yes  
• Quality of individual studies given: no  
• Results of individual studies given: no  
• Statistical analysis appropriate: yes  
OVERALL QUALITY: poor/moderate – limited description of methodology, no description of study quality |

ADA, American Diabetes Association; AHRQ, Agency for Healthcare Research and Quality; BMI, body mass index; CCT, controlled clinical trial; DTSQ, Diabetes Treatment Satisfaction Questionnaire; FPG, fasting plasma glucose; FU, follow-up; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NIH, National Institutes of Health; SF-36, Short Form-36.
Appendix 3

Characteristics of RCTS
<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
</table>
| **Allen (1990)**<sup>a</sup>  
USA  
Follow-up: 6 months  
Quality:  
• trial design and participants described: yes  
• randomisation described: yes  
• allocation concealment: no  
• outcome assessment blinded: unclear  
• adequate power: probably not  
• withdrawals/losses to FU described: yes (11%)  
• ITT analysis: no  
• statistical analysis appropriate: yes  
• baseline characteristics similar: ?  
• funding: ?  
OVERALL QUALITY: poor | Total number: 54 (27/27)  
Inclusion criteria: FPG > 8.8 and < 22 mmol, no history of ketoacidosis, treatment with diet and/or oral hypoglycaemic agent, no active infection or serious concurrent illness, no physical or mental handicap, no prior knowledge of monitoring; poorly controlled; diet or oral agents only  
Age: 58 years; 100% male  
BMI:  
HbA<sub>1c</sub>: I: 12.4 ± 3.3%, C: 11.7 ± 3.0%  
Diabetes duration: SMBG: 6.8 years; SMUG: 9.0 years  
Treatment: diet, oral hypoglycaemic agents (details of oral treatment unclear) | SMBG regimen: every other day SMBG before each meal  
SMBG other:  
SMBG method: Chemstrip bG, Accu-Chek 1; Tes-Tape (Eli Lilly) for urine  
Use of therapy decision scheme: yes  
SMBG instruction: yes; patients were instructed in use of prescribed testing technique, which they practised for 7–10 days  
SMBG accuracy checks: yes; were required to show proficiency in technique at initial visit; during study, physician, physician’s associate and diabetes teaching nurse reinforced proper use of the monitoring techniques  
Education: yes; instruction and exercise diary; instruction and food intake diary; diet instruction by a dietitian, based on weight and activity level; booklet with ADA’s exchange lists for food items with estimate of fibre content (both groups)  
Assessment of monitoring frequency: yes  
Feedback on SMBG: yes  
SMBG treatment adjustment/advice: patients not allowed to alter their own therapy, but encouraged to alter behavioural regimen or diet according to readings; urine and BG results and FPG were used to guide physician-initiated treatment alterations  
Control: urine glucose testing  
Adherence assessment: records submitted were complete on > 87% of visits in both groups  
Outcomes: GHb, weight, fasting glucose, lipids | • Significant reductions in HbA<sub>1c</sub> with SMBG and SMUG but no significant difference between groups in FPG, GHb or body weight  
• Trend towards younger and better educated patients improving more  
• Baseline HbA<sub>1c</sub>, weight, FPG, use of oral medications, duration of diabetes, ethnicity did not predict improved glucose control |

<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
</table>
| **Barnett (2008)**<sup>b</sup>  
DINAMIC 1 study, international  
Follow-up: 27 weeks  
Quality:  
• trial design and participants described: yes  
• randomisation described: yes | Total number: 610 patients with T2DM  
Inclusion criteria: T2DM, not insulin treated  
Age: 56 years, men and women  
BMI: 30 kg/m<sup>2</sup>  
HbA<sub>1c</sub>: 8.12%  
Diabetes duration: 2.8 years | SMBG (n = 311): patients instructed in self-monitoring their blood-glucose (approved devices listed); instruction on what to do in case of asymptomatic hypoglycaemia; appropriate use of glucose meter was checked at each visit by study investigator; patients assessed BG on 2 days per week (one working and one non-working day) before each meal and 2 hours after the main meal and before bedtime; once-a-month frequency was increased to measuring postprandial values after each meal; no specific information given to patients with respect to changing behaviour based on SMBG results | After 6 months:  
• Significantly greater reduction in HbA<sub>1c</sub> in the intervention group than in the control group (~1.15% versus ~0.91%, treatment difference 0.25% (95% CI 0.06 to 1.03; p = 0.0097).  
• Hypoglycaemia: SMBG group – 27 (8.7%) of patients had 51 hypoglycaemic events (27 symptomatic, 11 asymptomatic, 11 SMBG-confirmed, 2 non-graded); control group – 21 (7.0%) of patients had 66 hypoglycaemic events of which 64 were symptomatic and two were non-graded; none of the patients had severe hypoglycaemia (no statistics reported but difference presumably non-significant). |
### Trial – design
- **Participants**
  - Treatment: 70–74% previously treated with oral glucose lowering agent (43% biguanide, 46–50% insulin secretagogue) (the rest diet only)
- **Intervention**
  - Control (n = 299): no SMBG
  - Both groups: all patients received diet and lifestyle advice, which was reinforced at each visit; oral antidiabetic therapy was standardised for all patients – those previously on insulin secretagogue were transferred to gliclazide MR following approved dosage recommendations; for other patients, gliclazide was added to their treatment at an initial dose of 30 mg once daily then up-titrated as necessary; all patients had patient’s diary for recording symptoms of hypoglycaemia and SMBG (for intervention group)
- **Results**
  - Both groups had small decrease in weight (SMBG −0.68 ± 5.70 kg, non-SMBG −0.50 ± 4.01 kg).
  - No significant difference in number of all-cause adverse events.

### Bonomo (2006)-hook

- **Total number**: 273
- **Inclusion criteria**
  - T2DM, stable HbA1c within last 6 months, already on SMBG, not on insulin
  - Age: mean 63–66 years
  - BMI: mean 28–29 kg/m²
  - HbA1c: 8.0–8.1%
  - Diabetes duration: 10.6 years
- **SMBG regimen**
  - Group A: one BG profile (fasting, 2 hours after breakfast, 2 hours after lunch, 2 hours after dinner) per month
  - Group B1: one BG profile (fasting, 2 hours after breakfast, before lunch, 2 hours after lunch, before dinner, 2 hours after dinner) every 2 weeks
  - Group B2: as B1 but with recommendation to call diabetes clinic when BG targets were not met
- **SMBG other**
  - Stated that patients followed the same education and treatment protocol
- **SMBG method**
  - No other details given
- **Education**
  - Yes – not specified
- **SMBG treatment adjustment/advice**
  - Control: see above – three modes of SMBG compared
- **Adherence assessment**
  - SMBG carried out as recommended by 73% of group A and 44% of groups B1 and B2; very few patients of group B2 called the clinic, so groups B1 and B2 were lumped together – only compliant patients assessed
- **Outcomes**: HbA1c, BG, therapeutic changes

### Quality
- **Trial design and participants described**: yes
- **Randomisation described**: no
- **Allocation concealment**: unclear
- **Outcome assessment blinded**: unclear
- **Adequate power**: unclear
- **Withdrawals/losses to FU described**: no
- **ITT analysis**: no
- **Statistical analysis appropriate**: unclear
- **Baseline characteristics similar**: yes
- **Funding**: non-industry
- **Overall quality**: poor
Trial – design

Brown (2002)

Follow-up: 12 months
Quality:
- trial design and participants described: yes
- randomisation described: no
- allocation concealment: unclear
- outcome assessment blinded: no
- adequate power: unclear
- withdrawals/losses to FU described: no
- ITT analysis: unclear
- statistical analysis appropriate: yes
- baseline characteristics similar: yes
- funding: non-industry

OVERALL QUALITY: poor

Participants

Total number: 252
Inclusion criteria: FBG 140 mg/dl; have taken glucose lowering agents > 1 year; poorly controlled; oral agents
Age: 54 years
BMI: NR
HbA1c: I: 11.8 (SD 3.0), C: 11.8 (SD 3.0)
Diabetes duration: 7.9 years
Treatment: 7% diet only, 67% oral only, 20% insulin only, 6% oral plus insulin (no details on oral treatment)

Intervention

SMBG regimen: unclear
SMBG other: culturally competent diabetes self-management intervention with SMBG education and support sessions; focused on success, designed to provide rapid frequent feedback

Results

• HbA1c reduced significantly more in the intervention group (11.81%, SD 3.0 > 10.89%, SD 2.56) than in the control group (11.8%, SD 3.0 > 11.64%, SD 2.85), p = 0.016
• No significant difference in cholesterol levels, triglycerides or BMI

COMMENT: this was a complex multicomponent intervention including SMBG only as one element

Cho (2006)

Korea
Follow-up: 30 months
Quality:
- trial design and participants described: yes
- randomisation described: unclear
- allocation concealment: unclear
- outcome assessment blinded: unclear
- adequate power: unclear
- withdrawals/losses to FU described: yes (11%)
- ITT analysis: yes
- statistical analysis appropriate: yes
- baseline characteristics similar: yes
- funding: non-industry

OVERALL QUALITY: moderate/poor

Participants

Total number: 80 patients with T2DM
Age: 51–55 years
BMI: 23–24 kg/m² (Asian population)
HbA1c: 7.5–7.7%
Diabetes duration: 6.7–6.9 years
Treatment: 18 patients were insulin treated (7 in intervention, 11 in control) (no details on oral treatment)

Intervention

internet-based glucose monitoring system; patients logged onto a website at their convenience and uploaded their SMBG results; additional information also uploaded (current medication, blood pressure, weight, changes in lifestyle, questions patients wanted to discuss); 3 endocrinologists, a diettian and a nurse participated in the online system, and logged on daily and sent appropriate recommendations (based in the patients’ SMBG data) every 2 weeks
Control: standard SMBG; outpatient visits every 3 months; conventional note-keeping record system; usual recommendation about medications, dosage and lifestyle modification

Both groups: patients were given glucometers; diabetes education programme; method and frequency of SMBG monitoring

Outcomes: HbA1c, HbA1c fluctuation index

After 30 months:
• HbA1c level significantly lower in intervention group than in control group (6.7 ± 0.9% vs 7.4 ± 1.3%, p = 0.009)
• HbA1c fluctuation was also significantly lower in the intervention than in the control group (p = 0.03)
• Frequency of SMBG was significantly higher in the intervention than in the control group (34 ± 28 vs 22 ± 19; p = 0.024) – but no significant difference between good compliance (≥80% of SMBG measurements complied with) and poor compliance groups
• No significant difference in total or HDL cholesterol; triglycerides significantly lower in intervention group after 30 months [1.16 mmol/l (SD 0.73) vs 1.28 mmol/l (SD 0.75)]
• Significantly better adherence to SMBG measurements in the intervention group than in the control group
Trial – design

Participants

Intervention

Results

Davidson (2005)¹

USA

Inclusion criteria: patients with T2DM on oral antidiabetic treatment

SMBG regimen (n=43): SMBG 6 days per week before and after each meal (6 times per day)

• Fall in HbA₁c in both groups significant but no significant difference between groups

Follow-up: 6 months

• No significant difference in weight or BMI

Quality:

• Persons described: yes

• Funding: industry

• No significant difference in medication at study end

• USA

- randomisation described: no

- allocation concealment: unclear

- outcome assessment blinded: yes

- adequate power: unclear

- withdrawals/losses to FU described: yes (none)

OVERALL QUALITY: high/moderate

Total number: 88 (43/45)

- ITT analysis: yes

- statistical analysis appropriate: yes

- baseline characteristics similar: yes

- SMBG regimen: yes

- SMBG instruction: NR

- SMBG accuracy checks: NR

- SMBG treatment adjustment/advice: did not report training on how to respond to readings; nurse followed detailed algorithm to make therapeutic decisions (to achieve HbA₁c goal of < 7.5%)

- Control (n=45): regular HbA₁c determination every 2 months by a physician; 5 dietitian visits

- Adherence assessment: patients performed an average of 45% of required tests

- Outcomes: HbA₁c, BMI weight loss

Age: 50 years

Diabetes duration: 5.6 years

BMI: 32.2 kg/m²

HbA₁c: I: 8.4 (SD 2.1), C: 8.5 (SD 2.2)

Treatment: MET (27–28% MET alone, 51–53% in combination with SU), SU (0–9% SU alone, 51–53% in combination with MET), and/or thiazolidinedione (triple therapy with MET and SU, 7–21%)

SMBG regimen: yes

SMBG other: five dietitian visits

SMBG method: NR

Use of therapy decision scheme: yes

Feedback on SMBG:

Assessment of monitoring frequency:

- SMBG accuracy: NR

- Education: dietitian visits; dietitian used glucose values and meal descriptions in nutritional counselling to educate the patient on the effects of meal components and portion sizes on the rise of postprandial glucose values (both groups)

Adherence assessment:

- Dietitian visits: yes

- SMBG: yes

- SMBG method: NR

- Baseline characteristics similar: yes

- Funding: industry

- Overall quality: high/moderate

- Trial design and participants described: yes

- Randomisation described: no

- Allocation concealment: unclear

- Outcome assessment blinded: yes

- Adequate power: unclear

- Withdrawals/losses to FU described: yes (none)

- ITT analysis: yes

- Statistical analysis appropriate: yes

- Baseline characteristics similar: yes

- Funding: industry
### Trial – design

<table>
<thead>
<tr>
<th>Estey (1990)</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Total number: 60 (controls 25 after dropouts/intervention 28)</td>
<td>SMBG regimen: no details of protocols for SMBG</td>
<td>- No significant difference in HbA1c,</td>
</tr>
<tr>
<td>Follow-up: 4 months</td>
<td>Inclusion criteria: T2DM; treatment with diet and/or oral hypoglycaemic agents; completion of the 3-day education programme provided at the Diabetes Centre; accessibility by telephone</td>
<td>SMBG other: 3-day education plus SMBG; intense FU and feedback on SMBG testing practices was given by series of telephone calls and one home visit from a registered nurse</td>
<td>- No significant difference in body weight, but of patients who were instructed to lose weight, significantly more lost weight in the intervention than in the control group (p&lt;0.0001)</td>
</tr>
<tr>
<td>Quality:</td>
<td>Age: I 56 years, C: 54 years</td>
<td>SMBG method: no description of device, diary</td>
<td>- Intervention group performed SMBG more frequently than control group (p&lt;0.0001)</td>
</tr>
<tr>
<td>- trial design and participants described: yes</td>
<td>BMI: weight 85.6 kg; 36–46% &gt; 115% ideal body weight</td>
<td>Use of therapy decision scheme:</td>
<td>-</td>
</tr>
<tr>
<td>- randomisation described: no</td>
<td>HbA1c: I: 6.3 ± 1.1%, C: 6.1 ± 1.4%</td>
<td>SMBG instruction: yes</td>
<td></td>
</tr>
<tr>
<td>- allocation concealment: unclear</td>
<td>Diabetes duration: NR</td>
<td>SMBG accuracy checks: no</td>
<td></td>
</tr>
<tr>
<td>- outcome assessment blinded: unclear</td>
<td>Treatment: diet, oral hypoglycaemic agents (no details on oral treatment)</td>
<td>Education: yes; 3-day education (both groups)</td>
<td></td>
</tr>
<tr>
<td>- adequate power: unclear (probably not)</td>
<td></td>
<td>Assessment of monitoring frequency: yes</td>
<td></td>
</tr>
<tr>
<td>- withdrawals/losses to FU described: yes (12%)</td>
<td></td>
<td>Feedback on SMBG yes</td>
<td></td>
</tr>
<tr>
<td>ITT analysis: yes</td>
<td></td>
<td>SMBG treatment adjustment/advice: no details on changes made to therapy or lifestyle</td>
<td></td>
</tr>
<tr>
<td>- statistical analysis appropriate: yes</td>
<td></td>
<td>Control: standard 3-day education plus SMBG</td>
<td></td>
</tr>
<tr>
<td>- baseline characteristics similar: yes</td>
<td></td>
<td>Adherence assessment: patient data sheets or memory of meters consulted to compare number of tests conducted with number of tests requested</td>
<td></td>
</tr>
<tr>
<td>- funding: unclear</td>
<td></td>
<td>Outcomes: HbA1c, weight, SMBG adherence</td>
<td></td>
</tr>
<tr>
<td>OVERALL QUALITY: moderate/poor</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Farmer (2007) UK</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIGEM trial</td>
<td>Total number: 453 patients with T2DM</td>
<td>SMBG less intensive: continued to use goal setting and review techniques introduced at assessment visit; were given a glucose meter and asked to record 3 values daily on 2 days per week (one after fasting and 2 before meals or 2 ours after meals) and to aim for glucose levels of 4–6 mmol/l after fasting and before meals and levels of 6–8 mmol/l 2 hours after meals; advised by nurse to contact doctor if readings were consistently high or low (defined); given no information on how to interpret BG readings</td>
<td>- no significant difference in HbA1c for all groups,</td>
</tr>
<tr>
<td>Follow-up: 12 months</td>
<td>Inclusion criteria: T2DM, not insulin treated</td>
<td>SMBG intensive: as before, and were given training and support in timing, interpreting and using the results of SMBG to enhance motivation and to maintain adherence to diet, physical activity and drug regimens</td>
<td>- one or more grade 2 hypoglycaemic episodes experienced by 14 patients in control group, 33 in less intensive group, 43 in more intensive group (p&lt;0.0001)</td>
</tr>
<tr>
<td>Quality:</td>
<td>Age: 65.7 years</td>
<td>Control: standardised usual care, including the use of goal setting and review; asked not to use a glucose meter unless their doctor considered it essential for their clinical management</td>
<td>- significantly fewer patients in more intensive group persisted with meter use (52.3% vs 66%), but meter users in the more intensive group monitored significantly more often</td>
</tr>
<tr>
<td>- trial design and participants described: yes</td>
<td>BMI: 31–32 kg/m²</td>
<td>Outcomes: HbA1c, weight, SMBG adherence</td>
<td>- no significant difference in systolic or diastolic blood pressure, weight, BMI</td>
</tr>
<tr>
<td>- randomisation described: yes</td>
<td>Diabetes duration: median 3 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- allocation concealment: yes</td>
<td>HbA1c: 7.4–7.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- outcome assessment blinded: yes</td>
<td>Treatment: diet only 26–29%, oral monotherapy 37.5–39%; combined oral therapy 34–35% (no details on oral treatment)</td>
<td></td>
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<tr>
<td>- adequate power: yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- withdrawals/losses to FU described: yes (12.6%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ITT analysis: yes</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- statistical analysis appropriate: yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- baseline characteristics similar: yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- funding: non-industry</td>
<td></td>
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<tr>
<td>OVERALL QUALITY: high</td>
<td></td>
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</tbody>
</table>

After 12 months:
- no significant difference in HbA1c, for all groups
- one or more grade 2 hypoglycaemic episodes experienced by 14 patients in control group, 33 in less intensive group, 43 in more intensive group (p<0.0001)
- significantly fewer patients in more intensive group persisted with meter use (52.3% vs 66%), but meter users in the more intensive group monitored significantly more often
- no significant difference in systolic or diastolic blood pressure, weight, BMI
- total cholesterol significantly more reduced in the more intensive group than control
- significantly lower QoL (EQ-5D) for more intensive group vs control, mainly due to increased anxiety/depression (no significant difference in mobility, self-care, usual activities, or pain)
- neither SMBG intervention was judged to be cost-effective

COMMENT: HbA1c was already quite low at the beginning
### Trial – design

<table>
<thead>
<tr>
<th>Fontbonne (1989)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>France</strong></td>
</tr>
<tr>
<td><strong>Follow-up:</strong> 6 months</td>
</tr>
</tbody>
</table>

#### Quality:
- trial design and participants described: yes
- randomisation described: no
- allocation concealment: unclear
- outcome assessment blinded: unclear
- adequate power: unclear
- withdrawals/losses to FU described: yes (21%)
- ITT analysis: no
- statistical analysis appropriate: yes
- baseline characteristics similar: yes
- funding: ?

**OVERALL QUALITY:** poor

### Participants

- **Total number:** 208 (68/72/68)
- **Inclusion criteria:** treatment with diet and/or oral hypoglycaemic agents, FBG > 8.8 mmol/l or postprandial BG > 11 mmol/l 3 times within preceding year; at least occasional glucosuria; no rapidly progressing complications, no severe illness, DM > 3 years
- **Age:** SMBG 55; SMUG 55; C: 56
- **BMI:** 27.1 kg/m²
- **HbA₁c:** I: 8.2 (SE 0.3), C1: 8.6 (SE 0.3), C2: 8.2 (SE 0.3)
- **Diabetes duration:** 12.5 years
- **Treatment:** diet, oral hypoglycaemic agents (details of oral treatment unclear)

### Intervention

- **SMBG regimen:** SMBG twice every other day, fasting and 2 hours after the evening meal, with an extra test 2 hours after lunch on Sunday
- **SMBG other:** not reported
- **SMBG method:** Dextrostix, Glucometer (Ames), diary; Ketodiastix for urine
- **Use of therapy decision scheme:** not reported
- **SMBG instruction:** yes
- **SMBG accuracy checks:** no

### Results

- **SMBG treatment adjustment/advice:** no instructions on how to alter therapy according to SMBG readings (all changes made by physician)
- **Control 1:** urine glucose monitoring twice every other day, on the first urine voided in the morning and the first urine voided after the evening meal, with an extra test on the first urine voided after lunch on Sundays
- **Control 2:** no self-testing of urine or BG; HbA₁c was determined every 2 months at the outpatient clinic visit; the results were sent to the patient with the physician’s comment on their metabolic control

- **Adherence assessment:** number of reactive strips that should have been used – urine group had used significantly less; poorer compliance than SMBG or control group
- **Outcomes:** HbA₁c, weight, number of reactive strips reported

- **No significant difference in HbA₁c or body weight**
<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gallichan (1994)</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Total number: 27 (15/12) Inclusion criteria: on oral hypoglycaemic agents Age: 64 years (47–80) BMI: NR HbA&lt;sub&gt;1c&lt;/sub&gt;: NR Diabetes duration: NR Treatment: diet, oral hypoglycaemic agents (details of oral treatment unclear)</td>
<td>SMBG regimen: no details of protocols for blood or urine monitoring SMBG other: FBG and after meals 2 days per week SMBG method: no description Use of therapy decision scheme: not reported SMBG instruction: yes SMBG accuracy checks: no Education: no Assessment of monitoring frequency: no Feedback on SMBG: no SMBG treatment adjustment/advice: no details on changes made to therapy or lifestyle Control: SMUG Adherence assessment: not reported</td>
<td>• No significant difference in fructosamine concentration monitoring • SMBG other: FBG and after meals 2 days per week • SMBG method: no description • Use of therapy decision scheme: not reported • SMBG instruction: yes • SMBG accuracy checks: no • Education: no • Assessment of monitoring frequency: no • Feedback on SMBG: no • SMBG treatment adjustment/advice: no details on changes made to therapy or lifestyle • Control: SMUG • Adherence assessment: not reported • No significant difference in fructosamine concentration monitoring</td>
</tr>
<tr>
<td><strong>Guerci (2003)</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Total number: 689 (345/344) Inclusion criteria: T2DM &lt; 1 year, patients insufficiently controlled with oral glucose lowering treatment (HbA&lt;sub&gt;1c&lt;/sub&gt; &gt; 7.5 and &lt; 11%), age 40–75 years and not previously treated with insulin (for more than 7 consecutive days) and not requiring insulin at inclusion, patients who did not previously receive SMBG but able to carry out SMBG Age: 62 (40–75) years BMI: 30 kg/m&lt;sup&gt;2&lt;/sup&gt;</td>
<td>SMBG regimen: (n=345): patients received a conventional laboratory work-up based on laboratory measurement of HbA&lt;sub&gt;1c&lt;/sub&gt; every 12 weeks and underwent SMBG (≥ 6 times per week) SMBG other: unclear SMBG method: unclear Use of therapy decision scheme: unclear SMBG instruction: yes; initial training given by GP SMBG accuracy checks: yes Education: no; at GP visits, patients were informed of their BG values, the necessity of good diabetes control, and importance of weight loss in combination with physical activity</td>
<td>• 57.1% patients had improvement in HbA&lt;sub&gt;1c&lt;/sub&gt; at 3 months compared to 46.8% in the control group (p = 0.007) • improvement in HbA&lt;sub&gt;1c&lt;/sub&gt; predicted by HbA&lt;sub&gt;1c&lt;/sub&gt; at baseline (OR 1.749, p&lt;0.001) and SMBG group (OR 0.665, p = 0.015) • Patients doing SMBG were more likely reporting that they followed dietary advice • Predictors of improvement included SMBG group, higher initial HbA&lt;sub&gt;1c&lt;/sub&gt;, shorter duration of diabetes, lower BMI • No significant difference in blood pressure, weight, medication • Significantly more patients in the SMBG group continued following dietary instructions than in the control group; no significant difference in exercise behaviour</td>
</tr>
</tbody>
</table>

**UK**
Follow-up: 24 weeks
Quality: • trial design and participants described: unclear
• randomisation described: ?
• allocation concealment: ?
• outcome assessment blinded: ?
• adequate power: ?
• withdrawals/losses to FU described: ? (26%)
• ITT analysis: ?
• statistical analysis appropriate: yes
• baseline characteristics similar: ?
• funding: ?
OVERALL QUALITY: study not available for assessment; rated as follows by other reviews: Faas 1997<sup>20</sup> 3/7; Coster 2000<sup>29</sup> 4/11 reporting, 3/3 external validity, 3/7 bias, 3/6 confounding, 13/27 total (poor)

**France**
Follow-up: 24 weeks
Quality: • trial design and participants described: yes
• randomisation described: no
• allocation concealment: unclear
• outcome assessment blinded: unclear
• adequate power: yes
• withdrawals/losses to FU described: yes (31%)
### Jaber (1996)\(^{50}\)

**Follow-up:** 4 months  
**Quality:**  
- trial design and participants described: yes  
- randomisation described: no  
- allocation concealment: unclear  
- outcome assessment blinded: unclear  
- adequate power: probably not  
- withdrawals/losses to FU described: yes (13%)  
- ITT analysis: yes  
- statistical analysis appropriate: yes  
- baseline characteristics similar: yes  
- funding?: unclear  

**OVERALL QUALITY:** moderate/poor

<table>
<thead>
<tr>
<th><strong>Trial – design</strong></th>
<th><strong>Participants</strong></th>
<th><strong>Intervention</strong></th>
<th><strong>Results</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• ITT analysis: yes</td>
<td>HbA(_1c): I: 9.0 ± 1.3%, C: 9.0 ± 1.3%</td>
<td>Assessment of monitoring frequency: unclear</td>
<td>• HbA(_1c) significantly lower in the SMBG group after treatment (SMBG 7.6% vs control 9.65%, p &lt; 0.05) This study seems to be a bit of an outlier in effect size, but it was SMBG + education vs nothing</td>
</tr>
<tr>
<td>• statistical analysis appropriate: yes</td>
<td>Diabetes duration: 8.0 years</td>
<td>Feedback on SMBG: unclear</td>
<td></td>
</tr>
<tr>
<td>• baseline characteristics similar: yes</td>
<td>Treatment: 99.5% on oral antidiabetic agents (80.8% on SUs, 61.1% on biguanides, 30% on alpha-glucosidase inhibitors), ~80% on fibrates, ACE I or HMG-CoA reductase inhibitors</td>
<td>SMBG treatment adjustment/advice: did not report training on how to respond to readings; GP could change treatment based on HbA(_1c)</td>
<td></td>
</tr>
<tr>
<td>• funding: unclear</td>
<td>Baseline characteristics similar: yes</td>
<td>Control (n = 344): conventional laboratory work-up only</td>
<td></td>
</tr>
<tr>
<td>OVERALL QUALITY: moderate/poor</td>
<td></td>
<td>Adherence assessment: not reported</td>
<td></td>
</tr>
</tbody>
</table>

**Inclusion criteria:** urban African-American patients with T2DM who were currently attending a university-affiliated, internal medicine outpatient clinic  
**Age:** I: 59 years, C: 65 years  
**BMI:** 33 kg/m\(^2\)  
**HbA\(_1c\):** I: 9.2 (SD 2.0), C: 9.7 (SD 2.5)  
**Diabetes duration:** 6.8 years  
**Treatment:** details of treatment unclear  
**SMBG regimen:** 4 times per day for 2 days per week  
**SMBG other:** instruction on diabetes and diabetes regulation, medical counselling, exercise, SMBG  
**SMBG method:** unclear  
**Use of therapy decision scheme:** unclear  
**SMBG instruction:** yes  
**SMBG accuracy checks:** Education: yes (intervention only)  
**Assessment of monitoring frequency:** unclear  
**Feedback on SMBG:** unclear  
**SMBG treatment adjustment/advice:** yes  
**Control:** usual care  
**Adherence assessment:** unclear  
**Outcomes:** HbA\(_1c\), hypoglycaemia, HRQoL
<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Johnson (2006)</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Canada</td>
<td><strong>Total number:</strong> 262</td>
<td><strong>Intervention:</strong> free BG meter, free 6-month supply of testing strips</td>
</tr>
<tr>
<td></td>
<td>Follow-up: 6 months</td>
<td><strong>Inclusion criteria:</strong> T2DM (&gt; 1 year); not insulin treated</td>
<td><strong>Control:</strong> free BG meter</td>
</tr>
<tr>
<td></td>
<td>Quality:</td>
<td><strong>Age:</strong> 68.4 years, men and women</td>
<td><strong>Both:</strong> all participants received free meter (Glucometer Elite XL); all received training at the pharmacy; study pharmacists recommended average testing of 7 times per week for patients on oral agents, and for those on diet only, once daily or every 4 times per week; FU visits at 3 and 6 months for reinforcement of testing procedures</td>
</tr>
<tr>
<td></td>
<td>• Trial design and participants described: yes</td>
<td><strong>BMI:</strong> 29–32 kg/m&lt;sup&gt;2&lt;/sup&gt;</td>
<td><strong>No information on therapy changes in response to SMBG</strong></td>
</tr>
<tr>
<td></td>
<td>• Randomisation described: no</td>
<td><strong>HbA&lt;sub&gt;1c&lt;/sub&gt;:</strong> 7.3–7.5%</td>
<td><strong>Outcomes:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;, diabetes self-care activities [Summary of Diabetes Self-Care Activities (SDSCA)]</td>
</tr>
<tr>
<td></td>
<td>• Allocation concealment: unclear</td>
<td><strong>Diabetes duration:</strong> 7.7–8.6 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment blinded:</strong> yes (for HbA&lt;sub&gt;1c&lt;/sub&gt;)</td>
<td><strong>Treatment:</strong> 96–97% on oral agents (no details)</td>
<td></td>
</tr>
</tbody>
</table>
### Joy (2003)\(^1\)

**USA**

**Follow-up:** 4 months

**Quality:**
- trial design and participants described: yes
- randomisation described: no
- allocation concealment: unclear
- outcome assessment blinded: unclear
- adequate power: unclear (probably not)
- withdrawals/losses to FU described: yes (33%)
- ITT analysis: unclear
- statistical analysis appropriate: unclear
- baseline characteristics similar: unclear
- funding: unclear

**OVERALL QUALITY:** poor

<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>• outcome assessment blinded: unclear</td>
<td>Diabetes duration: 10–11 years</td>
<td>SMBG regimen: twice-daily, preprandial SMBG</td>
<td>• HbA(_1c) decreased by 0.8% in preprandial SMBG group and by 0.9% in postprandial SMBG group – no significant difference</td>
</tr>
<tr>
<td>• adequate power: unclear</td>
<td>Treatment: about half of the patients were insulin-treated (no details of oral treatment); patients on diet only were not included</td>
<td>SMBG other: SMBG method not reported</td>
<td></td>
</tr>
<tr>
<td>• withdrawals/losses to FU described: yes (22.3%)</td>
<td></td>
<td>SMBG method: NR</td>
<td></td>
</tr>
<tr>
<td>• ITT analysis: yes</td>
<td></td>
<td>Use of therapy decision scheme: NR</td>
<td></td>
</tr>
<tr>
<td>• statistical analysis appropriate: yes</td>
<td></td>
<td>SMBG instruction: NR</td>
<td></td>
</tr>
<tr>
<td>• baseline characteristics similar: yes</td>
<td></td>
<td>SMBG accuracy checks: NR</td>
<td></td>
</tr>
<tr>
<td>• funding industry</td>
<td></td>
<td>Education: NR</td>
<td></td>
</tr>
<tr>
<td>OVERALL QUALITY: poor</td>
<td></td>
<td>Assessment of monitoring frequency: NR</td>
<td></td>
</tr>
</tbody>
</table>

**Total number:** 57

**Inclusion criteria:** T2DM, using medication

**Age:** NR

**BMI:** NR

**HbA\(_1c\):** 8.3–8.4%

**Diabetes duration:** NR

**Treatment:** NR

**SMBG regimen:** twice-daily, preprandial SMBG

**SMBG other:** SMBG method not reported

**SMBG method:** NR

**Use of therapy decision scheme:** NR

**SMBG instruction:** NR

**SMBG accuracy checks:** NR

**Education:** NR

**Assessment of monitoring frequency:** NR

**Feedback on SMBG:** NR

**SMBG treatment adjustment/advice:** physician could give treatment advice

**Control:** twice-daily, postprandial SMBG

**Adherence assessment:** NR

**Outcomes:** HbA\(_1c\)
<table>
<thead>
<tr>
<th>Appendix 3</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
</table>
| **Kibriya (1999)**<sup>4</sup>  
Bangladesh  
Follow-up: 18 months  
Quality:  
- trial design and participants described: yes  
- randomisation described: no  
- allocation concealment: unclear  
- outcome assessment blinded: no  
- adequate power: unclear (probably not)  
- withdrawals/losses to FU described: yes (11 patients in the control group were excluded due to irregular visits and replaced by another 11!)  
- ITT analysis: no  
- statistical analysis appropriate: unclear  
- baseline characteristics similar: control group slightly lower BMI (23 vs 25 kg/m<sup>2</sup>)  
- funding: industry  
OVERALL QUALITY: poor | Total number: 64  
Inclusion criteria: T2DM, oral medication or insulin  
Age: 50 (35–65) years  
BMI: 23.9 kg/m<sup>2</sup> (Asian population)  
HbA<sub>C</sub>: 7.55–8.2%  
Diabetes duration: NR  
Treatment: oral hypoglycaemic agents or insulin (not reported how many were using insulin, no details of oral medication) | SMBG regimen: 2–3 times/day every 2 weeks (FPG and 2 hours after breakfast and/or lunch)  
SMBG other: not reported  
SMBG method: Glucostix  
Use of therapy decision scheme: unclear  
SMBG instruction: 2-day class on SMBG  
SMBG accuracy checks: yes  
Education: yes, both groups  
Assessment of monitoring frequency: unclear  
Feedback on SMBG: unclear  
SMBG treatment adjustment/advice: patients were advised how to act based on SMBG measurements; medications adjusted by patients based on SMBG, as necessary  
Control: no SMBG, monthly visits, doctor made medication changes  
Adherence assessment: unclear  
Outcomes: HbA<sub>C</sub>, costs, hypoglycaemia | • HbA<sub>C</sub> decreased 1.37% (p = 0.022) in SMBG group and 0.38% in control group (NS) – not reported if significant difference between groups  
• Significantly fewer episodes of hypoglycaemia with SMBG (0.172 vs 0.354 per patient-year; p = 0.03)  
• Intervention judged to be cost-effective |
| **Kwon (2004)**<sup>5</sup>  
Korea  
Follow-up: 12 weeks  
Quality:  
- trial design and participants described: yes  
- randomisation described: unclear (adaptive randomisation)  
- allocation concealment: unclear  
- outcome assessment blinded: unclear  
- withdrawals/losses to FU described: no  
- ITT analysis: no  
- statistical analysis appropriate: unclear  
- baseline characteristics similar: control group slightly lower BMI (23 vs 25 kg/m<sup>2</sup>)  
- funding: industry  
OVERALL QUALITY: poor | Total number: 101 (50/51)  
Inclusion criteria: men and women diagnosed with T2DM for > 1 year; age > 30 years, no medication limits reported  
Age: 54 years  
BMI: 24 kg/m<sup>2</sup> (Asian population)  
HbA<sub>C</sub>: I: 7.59% (SD 1.42), C: 7.19% (SD 1.17)  
Diabetes duration: 6.8 years  
Treatment: NR | SMBG regimen (n = 40): SMBG pre and post meals; recommended to use SMBG ≥3 days per week 1–3 times per day including after meals  
SMBG other: SMBG with internet-assisted patient consultations with outpatient management visits; included recording SMBG values online, asking questions, receiving feedback (recommendations re diet, exercise, medication)  
SMBG method: not reported  
Use of therapy decision scheme: no  
SMBG instruction: NR | • HbA<sub>C</sub> significantly lower in the internet intervention group after treatment than in the control group (–0.54% vs +0.33%; p < 0.05)  
• Differences between groups more pronounced in patients with initial HbA<sub>C</sub> ≥ 7%  
• No significant difference between groups in lipid parameters  
• Would not meet our inclusion criteria because no no-SMBG control group, but is of interest as it seems to show that extra support is needed for SMBG to work |
## Trial – design

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate power</td>
<td>Yes</td>
</tr>
<tr>
<td>Withdrawals/losses to FU described</td>
<td>Yes (8%)</td>
</tr>
<tr>
<td>ITT analysis</td>
<td>No</td>
</tr>
<tr>
<td>Statistical analysis appropriate</td>
<td>Yes</td>
</tr>
<tr>
<td>Baseline characteristics similar</td>
<td>Yes</td>
</tr>
<tr>
<td>Funding</td>
<td>Non-industry</td>
</tr>
</tbody>
</table>

**OVERALL QUALITY:** Poor

---

### Miles (1997)

- **UK**
- **Follow-up:** 24 weeks
- **Quality:**
  - Trial design and participants described: Unclear
  - Randomisation described: No (not really randomised, allocation altered from week to week)
  - Allocation concealment: No
  - Outcome assessment blinded: Unclear
  - Adequate power: Unclear
  - Withdrawals/losses to FU described: Yes (24%)
  - ITT analysis: Unclear
  - Statistical analysis appropriate: Unclear
  - Baseline characteristics similar: Unclear
  - Funding: Unclear

**OVERALL QUALITY:** Poor

---

### Participants

- **Total number:** 150
- **Inclusion criteria:** Newly diagnosed T2DM; oral agents or insulin
- **Age:** 65 (31–91) years
- **BMI:** 27.3 kg/m²
- **HbA₁c:** I: 10.3 (SD 2.6), C: 10.3 (SD 2.3)
- **Diabetes duration:** 0 (newly diagnosed)
- **Treatment:** No details of treatment

---

### Intervention

- **SMBG accuracy checks:** NR
- **Education:** Intervention patients were taught how to use the internet system
- **Assessment of monitoring frequency:** Yes
- **Feedback on SMBG:** Recommendations received via the internet
- **SMBG treatment adjustment/advice:** Internet recommendations included medication changes
- **Control:** (n = 41): SMBG and usual care involved monthly visits with two or three visits with senior staff during 12-week period; control group also recommended to use SMBG ≥ 3 days per week 1–3 times per day including after meals
- **Adherence assessment:** Yes

### Results

- **Outcomes:** HbA₁c

- **SMGB regimen:** SMBG once daily before a different meal or at bedtime, each day (target < 8 mmol/l)
- **SMGB method:** No details given
- **SMGB accuracy checks:** Yes
- **Education:** 4 education sessions (both groups)
- **NR SMBG treatment adjustment/advice:** No details on changes made to therapy or lifestyle
- **Control:** Test once daily for glucosuria, alternating before or 2 hours after different meals, or at bedtime (target = aglucosuria)
- **Adherence assessment:** NR
- **Outcomes:** GHb, QoL, weight

- **No significant difference between groups in GHb or well-being**
- **Preferences by patients based on ease of use:** 70% SMUG vs 15% SMBG; acceptability: 44% SMUG vs 31% SMBG; perceived accuracy: 11% SMUG vs 76% SMBG; usefulness: 21% SMUG vs 49% SMBG

**COMMENT:** Does not mention randomisation; crossover
<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
</table>
| **Moreland (2006)**<sup>20</sup>  
USA  
Follow-up: 6 months  
Quality:  
- trial design and participants described: yes  
- randomisation described: no  
- allocation concealment: unclear  
- outcome assessment blinded: unclear  
- adequate power: unclear  
- ITT analysis: unclear  
- statistical analysis appropriate: yes  
- baseline characteristics similar: unclear  
- funding: industry and non-industry  
OVERALL QUALITY: poor |
| Total number: 199 patients with T1DM or T2DM (26–39% in each group had T1DM)  
Inclusion criteria: T1DM or T2DM  
Age: 46–50 years  
BMI: 30 kg/m²  
Diabetes duration: 9.5–11 years  
HbA₁c: 8.9–9.3%  
Treatment: 16–18% were not insulin-treated (no details of oral therapy)  
Three comparison groups:  
BGM+ (n = 50): BG meter and received blood sugar monitoring owner’s manual – includes practical information, but also information to help people overcome barriers to monitoring (e.g. emphasis on positive emotions, not self-blame, etc.)  
MT (n = 50): BG meter  
Both groups: BG meter received and 30-minute diabetes education session focusing on BG monitoring and support from certified diabetes educator; patients received new meters but no test strips; received prescriptions for monitoring supplies (covered by health insurance)  
SC (n = 99): standard care [individual or group standard diabetes education (ADA accredited)]  
No information on recommended SMBG regimen, no information on therapy adjustments in response to SMBG; no information on accuracy checks  
*Outcomes:* SMBG monitoring, HbA₁c, affect  
After 6 months:  
- Patients in BGM+ group were checking BG levels significantly more often than patients in MT and SC groups [2.8 ± 1.5 times per day vs 2.0 ± 1.3 (p = 0.01) and 2.1 ± 1.7 (p = 0.4)]  
- Only 38% of patients in the BGM+ group reported negative affect regarding BG monitoring results compared with 65% in MT group and 57% in SC group (p = 0.03)  
- absolute HbA₁c levels not significantly different between groups at study end (BGM+: –0.13%, MT: –0.04%, SC: +0.4%); but 61% in BGM+ group improved their HbA₁c levels compared with 44% in the other groups (p = 0.05); in a multivariate model controlling for age, sex, diabetes type, baseline HbA₁c, duration of diabetes, education level and SES, assignment to BGM+ group was a significant predictor of improvement in glycaemic control at study end (no significant difference between T1DM and T2DM)  
COMMENT: not an inclusion (no clear separation of T1DM and T2DM, but some limited information on T1DM vs T2DM); interesting, as it stresses that negative emotions in response to SMBG can be changed and that this can result in behaviour change and – possibly – have a positive influence on HbA₁c  
- No significant difference in HbA₁c, body weight or QoL between groups  
- HbA₁c reduced by 1.54% in SMBG group (p < 0.05), 0.84% in control group (NS)  
- Duration of diabetes, initial HbA₁c and SMBG frequency not related to HbA₁c  
- No significant correlations between HbA₁c and duration of diabetes, initial HbA₁c, SMBG frequency |
| **Muchmore (1994)**<sup>57</sup>  
USA  
Follow-up: 44 weeks  
Quality:  
- trial design and participants described: yes  
- randomisation described: unclear (blocked groups)  
- allocation concealment: no  
- outcome assessment blinded: unclear  
- adequate power: unclear (probably not)  
- withdrawals/losses to FU described: no (21%)  
Total number: 29  
Inclusion criteria: overweight patients with T2DM, age 40–75 years, T2DM > 1 year, no SMBG within the previous 3 months, not instructed to count dietary carbohydrate, HbA₁c 9.5–13%, no serious underlying medical or psychiatric illness, drug abuse or alcoholism  
Age: I: 57 years, C: 60 years  
BMI: 34 kg/m²  
HbA₁c: I: 10.3 (SD 1.1), C: 10.5 (SD 1.5)  
Diabetes duration: I: 5.7 years, C: 5.2 years  
SMBG regimen (n = 12): initially 6 times per day before and after meals then just one set of tests before and after meals per day  
SMBG other: proprietary behavioural weight control programme, one-on-one counselling by a diabetes nurse and dietitian during a run-in period of 8 weeks; SMBG, carbohydrate counting training, using the blood monitoring  
SMBG method: One touch (LifeScan) reflectance meters  
Use of therapy decision scheme: NR  
SMBG instruction: yes  
SMBG accuracy checks: yes  
Education: counselling (both groups)  
Assessment of monitoring frequency: Feedback on SMBG NR  
After 44 weeks:  
- No significant difference in HbA₁c, body weight or QoL between groups  
- HbA₁c reduced by 1.54% in SMBG group (p < 0.05), 0.84% in control group (NS)  
- Duration of diabetes, initial HbA₁c and SMBG frequency not related to HbA₁c  
- No significant correlations between HbA₁c and duration of diabetes, initial HbA₁c, SMBG frequency |
<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ITT analysis: unclear</td>
<td>Treatment: 74% on oral agents (no details given), rest on diet</td>
<td>SMBG treatment adjustment/advice: SMBG used to support dietary intervention based on caloric counting; patients not allowed to alter their own therapy (but could be altered by GP), but encouraged to alter behavioural regimen or diet according to readings</td>
<td>No significant difference in ( \text{HbA}_1c ) at 12 months: 6.9 ± 0.8% SMBG vs 6.9 ± 1.2% control</td>
</tr>
<tr>
<td>• statistical analysis appropriate: yes</td>
<td></td>
<td></td>
<td>Psychological variables: no significant difference in anxiety, positive well-being, energy, but patients receiving SMBG were significantly more depressed (scoring 6% higher on the depression subscale of the well-being questionnaire)</td>
</tr>
<tr>
<td>• baseline characteristics similar: yes</td>
<td></td>
<td></td>
<td>• No significant difference in BMI (33.1 ± 6.4 kg/m(^2) vs 31.8 ± 6.0 kg/m(^2) control)</td>
</tr>
<tr>
<td>• funding: industry and non-industry</td>
<td></td>
<td></td>
<td>• No significant difference in hypoglycaemia but the study lacked power to detect a difference</td>
</tr>
<tr>
<td>OVERALL QUALITY: poor</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

O’Kane (2008)\(^{13}\)

UK ESMON study

Follow-up: 1 year

Quality:
• trial design and participants described: yes
• randomisation described: yes
• allocation concealment: yes
• outcome assessment blinded: yes
• adequate power: yes
• withdrawals/losses to FU described: yes (2.2%)
• ITT analysis: yes
• statistical analysis appropriate: yes
• baseline characteristics similar: yes
• funding: non-industry, meters supplied free of charge by Johnson & Johnson

OVERALL QUALITY: high

Total number: 184 (96/88)
Inclusion criteria: patients with newly diagnosed T2DM; not insulin treated
Age: 58–61 years, men and women
BMI: 32–34 kg/m\(^2\)
\( \text{HbA}_1c \): 8.6–8.8%
Diabetes duration: 0

Treatment: not reported

SMBG provided with glucose monitor (LifeScan OneTouch Ultra) and given instruction on monitoring; patients were asked to monitor 4 fasting and 4 postprandial capillary BG measurements per week; were advised on appropriate responses to high or low readings (including need for dietary review or suggestion of exercise in response to high readings); at each clinic visit, concordance with self-monitoring regimen was verified by downloading meter readings; ongoing advice and support in appropriate interpretation of and response to their BG results

Control: no monitoring

Both groups: identical structured core education programme involving diabetes nurse practitioners, dietitians, podiatrists, medical staff; all patients reviewed by doctor, diabetes nurse practitioner and dietitian at 3-monthly intervals; at each visit all aspects of diabetes care were reviewed; identical algorithm for dietary and pharmacological management of glycaemia for both groups based on \( \text{HbA}_1c \)

Outcomes: \( \text{HbA}_1c \), hypoglycaemia, BMI, use of oral hypoglycaemic drugs, well-being, treatment satisfaction, attitude
### Rutten (1990)

**Country:** Netherlands  
**Follow-up:** 12 months  
**Quality:**  
- Trial design and participants described: yes  
- Trial design and participants described: yes  
- Randomisation described: no  
- Allocation concealment: unclear  
- Outcome assessment blinded: unclear  
- Adequate power: unclear  
- Withdrawals/losses to FU described: yes (13%)  
- ITT analysis: no  
- Baseline characteristics similar: no  
- Use of therapy decision scheme: yes  
- SMBG method: Haemo-Glukotest 20–800 strips  
- SMBG accuracy checks: yes  
- SMBG instruction: yes (2–5 sessions)  
- SMBG regimen: no  
- SMBG other: patients accepting opportunity of SMBG were given instructions; patients contacted practice nurse monthly to state level of FBG; patients under GP care were informed of current BG level; for all patients in experimental group a therapeutic scheme was used with emphasis on loss of body weight  
- Educational activities: 2–3 training visits  
- Feedback on SMBG: no  
- SMBG treatment adjustment/advice: no instructions on how to alter therapy according to SMBG readings (all changes made by physician); made appointment with GP when BG high  
- Control: no fixed appointments; no instruction in SMBG  
- Adherence assessment: adherence inferred by noting low number of trial dropouts  

<table>
<thead>
<tr>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number: 49 (45/4)</td>
<td>SMBG regime: no fixed regime; patients were told to monitor BG when they did not feel well or if they had taken part in unusually strenuous activity</td>
<td>Small reduction in HbA1c in the intervention group by 0.5% (p &lt; 0.05); increase by 0.5% in control group (p &lt; 0.001); difference between groups not reported</td>
</tr>
</tbody>
</table>
- Patients with initial HbA1c > 10% were more likely to improve |
<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
</table>
| **Schwarzwald (2002)**<sup>1</sup>  
Germany  
Follow-Up: 12 months  
Quality:  
- trial design and participants described: yes  
- randomisation described: no  
- allocation concealment: unclear  
- outcome assessment: unclear  
- adequate power: yes  
- withdrawals/losses to FU described: yes (11%)  
- ITT analysis: no  
- statistical analysis appropriate: yes  
- baseline characteristics similar: yes  
- funding: non-industry, meters provided by Roche Diagnostics  
OVERALL QUALITY: high  
**Siebolds (2006)**<sup>2</sup>  
Germany  
Follow-Up: 12 months  
Quality:  
- trial design and participants described: yes  
- randomisation described: yes  
- allocation concealment: unclear  
- outcome assessment: unclear  
- adequate power: yes  
- withdrawals/losses to FU described: yes (17%)  
- ITT analysis: yes  
- statistical analysis appropriate: yes  
- baseline characteristics similar: yes  
- funding: industry  
OVERALL QUALITY: poor

Total number: 223  
Inclusion criteria: age 45–70 years, BMI > 25 kg/m²; with HbA₁c values between 7.5% and 10%; treated with diet alone or pancreas substitution and/or insulin therapy or diet in combination with SU or combination therapy; diabetes known at least 3 months; participants in a diabetes educational programme within the previous 2 years  
Age: 60 (45–70) years  
BMI: 31.4 (> 25) kg/m²  
HbA₁c: 8.5 (SD 0.9); C: 8.4 (SD 0.8)  
Diabetes duration: 5.3 years  
Treatment: diet alone, with or without SU or MET (no details given)

SMBG regimen (n = 113): patients requested to measure BG 6 times on 2 days per week (before and 1 hour after 3 meals; weekday and Sunday)

- Significantly greater HbA₁c reduction in SMBG group (−1.0 ± 1.08% vs −0.54 ± 1.41%; p = 0.0086)
- Average number of SMBG tests 24.8 ± 3.9 per week/patient
- No significant difference in body weight reduction
- Significantly less depression in the intervention group (SMBG) after 6 months
- In the SMBG group, not making behavioural changes in response to HbA₁c led to failure
- Longer diabetes duration and higher baseline HbA₁c predicted a delay in response

Outcomes: HbA₁c, adherence, change in diabetes treatment, hypoglycaemia, QoL, satisfaction, adverse events
<table>
<thead>
<tr>
<th>Trial – design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seaton (1996)</td>
<td>Total number: 10</td>
<td>SMBG regimen: NR</td>
<td>Significant reduction in HbA1c of 0.8% in the SMBG group, no change in the control group, not reported if significant difference between groups</td>
</tr>
<tr>
<td>Follow-up: NR</td>
<td>Inclusion criteria: T2DM on oral medication</td>
<td>SMBG other: NR</td>
<td></td>
</tr>
<tr>
<td>Quality:</td>
<td>Age: NR</td>
<td>SMBG method: no details reported</td>
<td></td>
</tr>
<tr>
<td>• unclear (not available for investigation)</td>
<td>BMI: NR</td>
<td>Use of therapy decision scheme: yes, standardised treatment algorithm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA1c: NR</td>
<td>Control: no SMBG</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: NR</td>
<td>Adherence assessment: NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: NR</td>
<td>Outcomes: HbA1c</td>
<td></td>
</tr>
<tr>
<td>Wing (1986)</td>
<td>Total number: 50 (25/25)</td>
<td>SMBG regimen: fasting BG on 5 days per week and 2 postprandial glucose measurements per week; after 12 weeks only FBG on 5 days per week</td>
<td>No significant difference in GHb, FPG or body weight</td>
</tr>
<tr>
<td>Follow-up: 62 weeks</td>
<td>Inclusion criteria: age 35–65 years; &gt; 20% above ideal weight for height; use of oral hypoglycaemic medication or insulin for BG control; development of diabetes after the age of 30</td>
<td>SMBG other: behavioural weight control treatment programme, SMBG and focusing on weight–BG relationship</td>
<td></td>
</tr>
<tr>
<td>Quality:</td>
<td>Age: 54 years (35–65)</td>
<td>SMBG method: Chemstrips bG, diary</td>
<td></td>
</tr>
<tr>
<td>• trial design and participants described: yes</td>
<td>BMI: weight 98 kg</td>
<td>Use of therapy decision scheme: yes</td>
<td></td>
</tr>
<tr>
<td>• randomisation described: no</td>
<td>HbA1c: I: 10.19 (SD 2.51), C: 10.86 (SD 2.00)</td>
<td>SMBG instruction: yes</td>
<td></td>
</tr>
<tr>
<td>• allocation concealment: unclear</td>
<td>Diabetes duration: NR</td>
<td>SMBG accuracy checks: yes</td>
<td></td>
</tr>
<tr>
<td>• outcome assessment blinded: unclear (probably)</td>
<td>Treatment: diet, oral hypoglycaemic agents; about half of the patients used insulin</td>
<td>Education: behavioural weight control programme (both); 3 months, FU sessions over per year</td>
<td></td>
</tr>
<tr>
<td>• adequate power: unclear (probably not)</td>
<td></td>
<td>Assessment of monitoring frequency: yes</td>
<td></td>
</tr>
<tr>
<td>• withdrawals/losses to FU described: no (10%)</td>
<td></td>
<td>Feedback on SMBG: yes</td>
<td></td>
</tr>
<tr>
<td>• ITT analysis: unclear</td>
<td></td>
<td>SMBG treatment adjustment/advice: participants required to modify diet and exercise habits according to SMBG results; patients not allowed to change therapy</td>
<td></td>
</tr>
<tr>
<td>• statistical analysis appropriate: yes</td>
<td></td>
<td>Control: behavioural weight control treatment programme</td>
<td></td>
</tr>
<tr>
<td>• baseline characteristics similar: unclear</td>
<td></td>
<td>Adherence assessment: patient data sheets or memory of meters consulted to compare number of tests conducted with number of tests requested; marked item technique</td>
<td></td>
</tr>
<tr>
<td>• funding: non-industry</td>
<td></td>
<td>Outcomes: GHb, weight, fasting glucose, lifestyle adherence, medication changes, serum lipids</td>
<td></td>
</tr>
<tr>
<td>OVERALL QUALITY: poor</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

ACE 1, angiotensin converting enzyme; ADA, American Diabetes Association; BG, blood glucose; BMI, body mass index; C, control; CI, confidence interval; DM, diabetes mellitus; FBG, fasting blood glucose; FPG, fasting plasma glucose; FU, follow-up; GHb, glycosylated haemoglobin; HDL, high-density lipoprotein; HMG-CoA, hydroxy-methyl-glutaryl-CoA reductase; HRQoL, health-related quality of life; I, intervention; ITT, intention to treat; MET, metformin; NR, not reported; OR, odds ratio; SD, standard deviation; SE, standard error; SU(s), sulphonylurea(s); TAU, treatment as usual.
Appendix 4

Results of RCTs (included in reviews and additional)
## Study Outcome Baseline End of study Difference p-value

### HbA<sub>1c</sub>/glucose control

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome</th>
<th>Baseline</th>
<th>End of study</th>
<th>Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen (1990)&lt;sup&gt;40&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG: 12.4% (SD 3.3)</td>
<td>SMBG: 10.4% (SD 2.9)</td>
<td>SMBG: –2.0% (SD 3.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Barnett (2008)&lt;sup&gt;41&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG: 8.12% (SD 0.89)</td>
<td>SMBG: 6.95% (SD 0.97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonomo (2006)&lt;sup&gt;42&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>More frequent SMBG: 8.08% (SD 0.84)</td>
<td>More frequent SMBG: 7.6% (SD 0.73)</td>
<td>Significant decrease in HbA&lt;sub&gt;1c&lt;/sub&gt; in twice monthly SMBG monitoring group, no decrease in once monthly</td>
<td>Difference between groups not reported</td>
</tr>
<tr>
<td>Cho (2006)&lt;sup&gt;44&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG internet: 7.7% (SD 1.5)</td>
<td>SMBG internet: 6.7% (SD 0.9)</td>
<td></td>
<td>p=0.029</td>
</tr>
<tr>
<td>Brown (2002)&lt;sup&gt;43&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG: 11.8% (SD 3.0)</td>
<td>SMBG: 10.89% (SD 2.56)</td>
<td></td>
<td>p=0.016</td>
</tr>
<tr>
<td>Davidson (2005)&lt;sup&gt;45&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG: 8.4% (SD 2.1)</td>
<td>SMBG: 7.53% (SE 0.236)</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Estey (1990)&lt;sup&gt;46&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG +FB: 6.3% (SD 1.1)</td>
<td>SMBG +FB: 5.6% (SD 0.7)</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Farmer (2007)&lt;sup&gt;10&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG intensive: 7.53% (SD 1.12)</td>
<td>SMBG intensive: –0.17% (SD 0.73)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fontbonne (1989)&lt;sup&gt;17&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG: 8.2% (SD 2.5)</td>
<td>SMBG: 7.84%</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Galichan (1994)&lt;sup&gt;48&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG: 324 µmol/l</td>
<td>SMBG: 333 µmol/l</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Guerci (2003)&lt;sup&gt;49&lt;/sup&gt;</td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>SMBG: 9.0% (SD 1.3)</td>
<td>SMBG: 8.1% (SD 1.6)</td>
<td></td>
<td>0.012</td>
</tr>
<tr>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt; improvement</td>
<td></td>
<td>SMBG: 57.1%</td>
<td></td>
<td>C: 46.8%</td>
<td>0.007</td>
</tr>
<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
<td>Difference</td>
<td>p-value</td>
</tr>
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</tr>
<tr>
<td>Jaber (1996)[50]</td>
<td>HbA1c</td>
<td>SMBG: 9.2% (SD 2.0)</td>
<td>SMBG: 7.6% (SD 1.48)</td>
<td>SMBG: –1.62% (SD 1.83)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 9.7% (SD 2.5)</td>
<td>C: 9.65% (SD 2.61)</td>
<td>C: –0.07% (SD 2.12)</td>
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</tr>
<tr>
<td>Johnson (2006)[51]</td>
<td>HbA1c</td>
<td>Free strips: 7.5% (SD 1.6)</td>
<td>Free strips: 7.3% (SD 1.5)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td></td>
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<td>No free strips: 7.3% (SD 1.2)</td>
<td>No free strips: 7.3% (SD 1.2)</td>
<td>NS</td>
<td></td>
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<tr>
<td>Joy (2003)[52]</td>
<td>HbA1c</td>
<td>Preprandial SMBG: 8.3%</td>
<td>Preprandial SMBG: –0.8%</td>
<td>NS</td>
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</tr>
<tr>
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<td></td>
<td>Postprandial SMBG: 8.4%</td>
<td>Postprandial SMBG: –0.9%</td>
<td>NS</td>
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<tr>
<td>Kibriya (1999)[53]</td>
<td>HbA1c</td>
<td>SMBG: 8.19% (SD 1.37)</td>
<td>SMBG: 7.11% (SD 1.0.8)</td>
<td>SMBG: –0.99%</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 7.55% (SD 1.62)</td>
<td>C: 7.12% (SD 1.85)</td>
<td>C: –0.38%</td>
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<tr>
<td>Kwon (2004)[54]</td>
<td>HbA1c</td>
<td>SMBG + FB: 7.59% (SD 1.42)</td>
<td>SMBG + FB: 6.94% (SD 0.92)</td>
<td>SMBG + FB: –0.54%</td>
<td>p &lt; 0.001</td>
</tr>
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<td></td>
<td></td>
<td>SMBG: 7.19% (SD 1.17)</td>
<td>SMBG: 7.62% (SD 0.93)</td>
<td>SMBG: +0.33%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA1c ≤ 7% at baseline</td>
<td>SMBG + FB: 6.38% (SE 0.22)</td>
<td>SMBG: 6.99% (SE 0.18)</td>
<td>SMBG: &lt; 0.001</td>
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<tr>
<td></td>
<td></td>
<td>SMBG + FB: 6.38% (SE 0.22)</td>
<td>SMBG: 6.99% (SE 0.18)</td>
<td>SMBG: &lt; 0.001</td>
<td></td>
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<tr>
<td>Miles (1997)[55]</td>
<td>HbA1c</td>
<td>SMBG: 10.3% (SD 2.6)</td>
<td>SMBG: 8.8% (SD 1.9)</td>
<td>SMBG: –1.5% (SD 2.1)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMUG: 10.3% (SD 2.3)</td>
<td>SMUG: 8.7% (SD 1.7)</td>
<td>SMUG: –1.6% (SD 1.9)</td>
<td>NS</td>
</tr>
<tr>
<td>Moreland (2006)[56]</td>
<td>HbA1c</td>
<td>BGM+: 9.3% (SD 1.2)</td>
<td>BGM+: 9.3% (SD 1.7)</td>
<td>BGM+: –0.13% (SD 1.28)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MT: 9.1% (SD 1.2)</td>
<td>MT: 9.1% (SD 1.3)</td>
<td>MT: –0.04% (SD 1.31)</td>
<td>NS</td>
</tr>
<tr>
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<td></td>
<td>SC: 8.9% (SD 0.9)</td>
<td>SC: 9.0% (SD 1.5)</td>
<td>SC: +0.04% (SD 1.1)</td>
<td>NS</td>
</tr>
<tr>
<td>Muchmore (1994)[57]</td>
<td>HbA1c</td>
<td>SMBG: 10.29% (SD 1.1)</td>
<td>SMBG: 8.75% (SD 1.66)</td>
<td>SMBG: –1.54% (SD 1.46)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
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<td>C: 10.45% (SD 1.5)</td>
<td>C: 9.6% (SD 2.1)</td>
<td>C: –0.85% (SD 1.87)</td>
<td>NS</td>
</tr>
<tr>
<td>O’Kane (2008)[58]</td>
<td>HbA1c</td>
<td>SMBG: 8.8% (SD 2.1)</td>
<td>SMBG: 6.9% (SD 0.8)</td>
<td>SMBG: –0.4% (SD 0.4)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 8.6% (SD 2.3)</td>
<td>C: 6.9% (SD 1.2)</td>
<td>C: +0.5%</td>
<td></td>
</tr>
<tr>
<td>Rutten (1990)[59]</td>
<td>HbA1c</td>
<td>SMBG: 9.7% (SD 2.1)</td>
<td>SMBG: 9.2% (SD 1.49)</td>
<td>SMBG: –0.4% (SD 0.4)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 8.9% (SD 1.9)</td>
<td>C: 9.4% (SD 1.14)</td>
<td>C: +0.5%</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
<td>Difference</td>
<td>p-value</td>
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</tr>
<tr>
<td>Scherbaum (2008)⁶⁰</td>
<td>HbA₁c</td>
<td>Low SMBG: 7.2% (SD 1.4)</td>
<td>Low SMBG: 6.9% (SD 1.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>High SMBG: 7.2% (SD 1.0)</td>
<td>High SMBG: 7.1% (SD 1.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schwedes (2002)⁶¹</td>
<td>HbA₁c</td>
<td>SMBG: 8.5% (SD 0.9)</td>
<td>SMBG: 7.47% (SD 1.27)</td>
<td>SMBG: –1.0% (SD 1.08)</td>
<td>0.009</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 8.4% (SD 0.8)</td>
<td>C: 7.81% (SD 1.52)</td>
<td>C: –0.54% (SD 1.41)</td>
<td></td>
</tr>
<tr>
<td>Wing (1986)⁶³</td>
<td>HbA₁c</td>
<td>SMBG: 10.2% (SD 2.5)</td>
<td>SMBG: 10.2% (SD 2.29)</td>
<td>SMBG: 0.0% (SD 2.16)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 10.7% (SD 2.0)</td>
<td>C: 10.4% (SD 2.16)</td>
<td>C: –0.24% (SD 1.87)</td>
<td></td>
</tr>
<tr>
<td><strong>Hypoglycaemia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barnett (2008)⁶¹</td>
<td>Hypoglycaemic events</td>
<td>SMBG: n = 27 (8.7%) with 51 hypoglycaemic events (27, symptomatic, 11 asymptomatic, 11 SMBG confirmed, 2 non-graded)</td>
<td>p-value not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: n = 21 (7%) with 66 hypoglycaemic events (64, symptomatic, 2 non-graded)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nocturnal hypoglycaemia</td>
<td>SMBG: n = 3 patients</td>
<td>C: n = 7 patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Farmer (2007)¹⁰</td>
<td>Hypoglycaemic episodes</td>
<td>SMBG more intensive: 43</td>
<td>SMBG less intensive: 33</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guerci (2003)⁴⁹</td>
<td>Hypoglycaemic episodes (capillary BG &lt; 3 mmol/l)</td>
<td>Significant difference in asymptomatic hypoglycaemia (10.4% of patients in SMBG and 5.2% of patients in control group, but based on capillary blood, which could not be determined by control group – probably invalid comparison; no serious hypoglycaemia</td>
<td>0.003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kibriya (1999)⁵⁴</td>
<td>Hypoglycaemic episodes</td>
<td>SMBG: 5 patients with 7 episodes; 0.172/patient-year</td>
<td>0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 10 patients with 17 episodes; 0.354/patient-year</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
<td>Difference</td>
<td>p-value</td>
</tr>
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</tr>
<tr>
<td>O’Kane (2008)¹³</td>
<td>Hypoglycaemic episodes</td>
<td>SMBG: 31 episodes</td>
<td>C: 36 episodes</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Scherbaum (2008)⁶⁰</td>
<td>Relevant hypoglycaemia</td>
<td>Low SMBG: 5 patients (1 with 1 event, 4 with several events)</td>
<td>High SMBG: 18 patients (9 with 1 event, 9 with several)</td>
<td>Significantly more with 1 event in high group than low group</td>
<td>0.02</td>
</tr>
<tr>
<td>Weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allen (1990)⁴⁶</td>
<td>Weight</td>
<td>SMBG: 32.33 kg/m² (SD 5.97)</td>
<td>C: 32.12 kg/m² (SD 6.35)</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Barnett (2008)⁴¹</td>
<td>Weight</td>
<td>SMBG: 32.17 kg/m² (SD 6.45)</td>
<td>C: 32.28 kg/m² (SD 6.52)</td>
<td></td>
<td>NS</td>
</tr>
<tr>
<td>Brown (2002)⁴³</td>
<td>BMI</td>
<td>SMBG: 84.2 kg (SD 15.8)</td>
<td>SMBG: 86.1 kg (SD 17.3)</td>
<td>SMBG + FB: 84.2 kg (SD 15.8)</td>
<td>NS</td>
</tr>
<tr>
<td>Estey (1990)⁴⁶</td>
<td>Weight</td>
<td>SMBG: 82.4 kg (SD 22.2)</td>
<td>SMBG: 86.1 kg (SD 17.3)</td>
<td>SMBG + FB: 82.4 kg (SD 22.2)</td>
<td>NS</td>
</tr>
<tr>
<td>Davidson (2005)⁴⁶</td>
<td>Weight</td>
<td>SMBG + FB: 86.2 kg (SD 17.3)</td>
<td>SMBG: 86.1 kg (SD 17.3)</td>
<td>SMBG + FB: 86.2 kg (SD 17.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Farmer (2007)¹⁰</td>
<td>Weight</td>
<td>SMBG more intensive: 86.9 kg (SD 16.4)</td>
<td>SMBG more intensive: 86.1 kg (SD 15.7)</td>
<td>SMBG more intensive: 86.9 kg (SD 16.4)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMBG less intensive: 90.4 kg (SD 18.9)</td>
<td>SMBG less intensive: 89.9 kg (SD 19.0)</td>
<td>SMBG less intensive: 90.4 kg (SD 18.9)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 86.7 kg (SD 18.9)</td>
<td>C: 86.4 kg (SD 19.4)</td>
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</tr>
<tr>
<td></td>
<td>BMI</td>
<td>SMBG more intensive: 31.0 kg/m² (SD 5.3)</td>
<td>SMBG more intensive: 30.7 kg/m² (SD 5.0)</td>
<td>SMBG more intensive: 31.0 kg/m² (SD 5.3)</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMBG less intensive: 31.9 kg/m² (SD 6.2)</td>
<td>SMBG less intensive: 31.8 kg/m² (SD 6.3)</td>
<td>SMBG less intensive: 31.9 kg/m² (SD 6.2)</td>
<td>NS</td>
</tr>
<tr>
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<td></td>
<td>C: 30.9 kg/m² (SD 6.1)</td>
<td>C: 30.8 kg/m² (SD 6.3)</td>
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 DOI: 10.3310/hta14120
### Study Outcome Baseline End of study Difference p-value

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<th>Study</th>
<th>Outcome</th>
<th>Baseline</th>
<th>End of study</th>
<th>Difference SMBG vs control</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>Fontbonne (1989)¹⁷</td>
<td>Weight</td>
<td>SMBG: 47.0 kg/m² (SD 8.0)</td>
<td>Control: 47.0 kg/m² (SD 6.2)</td>
<td>-0.22 kg (95% CI -1.36 to 0.93)</td>
<td>NS</td>
</tr>
<tr>
<td>Guerci (2003)⁴⁹</td>
<td>Weight</td>
<td>SMBG: -0.93 ± 4.35 kg</td>
<td>Control: -0.83 ± 4.87 kg</td>
<td>NS</td>
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<tr>
<td>Muchmore (1994)⁵⁷</td>
<td>Weight</td>
<td>SMBG: 0.10 kg/m² (SD 6.0)</td>
<td>Control: 0.10 kg/m² (SD 6.0)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>O'Kane (2008)¹³</td>
<td>BMI</td>
<td>SMBG: 34.0 kg/m² (SD 7.0)</td>
<td>Control: 32.0 kg/m² (SD 6.2; p = 0.04)</td>
<td>NS</td>
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<tr>
<td>Rutten (1990)⁵⁸</td>
<td>Weight</td>
<td>SMBG: 99.02 kg (SD 16.13)</td>
<td>Control: 96.35 kg (SD 23.57)</td>
<td>4.10 kg (95% CI -1.07 to 9.27)</td>
<td>NS</td>
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</table>

### Lipid parameters

<table>
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<th>Baseline</th>
<th>End of study</th>
<th>Difference</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>Brown (2002)³⁵</td>
<td>Cholesterol</td>
<td>No significant difference</td>
<td>No significant difference</td>
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</tr>
<tr>
<td></td>
<td>Triglycerides</td>
<td>No significant difference</td>
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<tr>
<td>Cho (2006)⁴⁴</td>
<td>Total cholesterol</td>
<td>Significantly lower in the intervention group</td>
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<tr>
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<td>HDL cholesterol</td>
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</tr>
<tr>
<td></td>
<td>Triglycerides</td>
<td>No significant difference</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Farmer (2007)¹⁰</td>
<td>Total cholesterol</td>
<td>Significantly more reduction in more intensive vs control</td>
<td>0.01</td>
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<tr>
<td></td>
<td>Total-HDL cholesterol ratio</td>
<td>Significantly more reduction in more intensive vs control</td>
<td>0.013</td>
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<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
<td>Difference</td>
<td>p-value</td>
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</tr>
<tr>
<td>Kwon (2004)55</td>
<td>Total cholesterol</td>
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<td>No significant differences reported</td>
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</tr>
<tr>
<td></td>
<td>HDL cholesterol</td>
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<td></td>
<td>Significant increase from baseline in control group, but not significant differences between groups reported</td>
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</tr>
<tr>
<td></td>
<td>LDL cholesterol</td>
<td></td>
<td></td>
<td>No significant differences reported</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Triglycerides</td>
<td></td>
<td></td>
<td>No significant differences reported</td>
<td></td>
</tr>
<tr>
<td>Schwedes (2002)61</td>
<td>Total cholesterol</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Triglycerides</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td>Wing (1986)63</td>
<td>Lipid parameters (cholesterol, triglycerides)</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
</tbody>
</table>

**Adherence**

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome</th>
<th>Baseline</th>
<th>End of study</th>
<th>Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cho (2006)44</td>
<td>SMBG frequency</td>
<td></td>
<td>SMBG + internet: 34 ± 28 times per month</td>
<td>SMBG: 22 ± 19 times per month</td>
<td>0.024</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SMBG adherence greater in SMBG + FB group (no data shown)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Estey (1990)46</td>
<td>SMBG adherence</td>
<td></td>
<td></td>
<td>SMBG more intensive: 52.3% continued to use meter at least twice weekly for 12 months</td>
<td>0.012</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SMBG less intensive: 66% continued to use meter at least twice weekly for 12 months</td>
<td></td>
</tr>
<tr>
<td>Farmer (2007)10</td>
<td>SMBG adherence</td>
<td></td>
<td></td>
<td>Number of readings in meter users</td>
<td>0.022</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Significantly more in the more intensive group</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
<td>Difference</td>
<td>p-value</td>
</tr>
<tr>
<td>-----------------------</td>
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<td>--------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Johnson (2006)&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Days of testing</td>
<td></td>
<td></td>
<td>Patients receiving free strips tested and average of 0.64 days per week more often than patients not receiving free strips</td>
<td>0.007</td>
</tr>
<tr>
<td>Kwon (2004)&lt;sup&gt;55&lt;/sup&gt;</td>
<td>Frequency of SMBG during study (3 months)</td>
<td>SMBG internet: 71.5 ± 36.2 SMBG: 38.1 ± 24.8</td>
<td></td>
<td>p-value not reported</td>
<td></td>
</tr>
<tr>
<td>Moreland (2006)&lt;sup&gt;20&lt;/sup&gt;</td>
<td>Frequency of SMBG</td>
<td>BGM+: 2.8 (SD 1.5) MT: 2.0 (SD 1.3) SC: 2.1 (SD 1.7)</td>
<td></td>
<td>&lt; 0.05 BGM+ vs the other two groups</td>
<td></td>
</tr>
<tr>
<td>Scherbaum (2008)&lt;sup&gt;40&lt;/sup&gt;</td>
<td>Adherence assessed by investigator</td>
<td></td>
<td>Low SMBG: 73% High SMBG: 83%</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adherence assessed by patient</td>
<td></td>
<td>Low SMBG: 85–88% High SMBG: 84–88%</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Wing (1986)&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Adherence with self-monitoring</td>
<td>SMBG: 89.1% of strips used during initial treatment, 70.2% during FU, 83% of patients interpreted results within 20% of actual level</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Changes in treatment**

<table>
<thead>
<tr>
<th>Study</th>
<th>Medication at end of study</th>
<th>SMBG: 19% MET, 35% MET + SU, 37% triple oral therapy, 7% insulin + oral, 2% insulin alone C: 22% MET, 38% MET + SU, 27% triple oral therapy, 1.3% insulin + oral, 0 insulin alone</th>
<th>NS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davidson (2005)&lt;sup&gt;45&lt;/sup&gt;</td>
<td>Medication increase</td>
<td>SMBG more intensive: increased in 31.8% of patients</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SMBG less intensive: increased in 28.7% of patients</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: increased in 29.6% of patients</td>
<td></td>
</tr>
<tr>
<td>Farmer (2007)&lt;sup&gt;10&lt;/sup&gt;</td>
<td>Medication change</td>
<td></td>
<td>No significant difference</td>
</tr>
<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>O’Kane (2008)</td>
<td>Medication use</td>
<td>SMBG: no drugs n=86, 1 drug n=8, 2 drugs n=0 C: no drugs n=78, 1 drug n=7, 2 drugs n=2</td>
<td>SMBG: no drugs n=34, 1 drug n=44, 2 drugs n=11 C: no drugs n=29, 1 drug n=40, 2 drugs n=6</td>
</tr>
<tr>
<td>Rutten (1990)</td>
<td>Medication change</td>
<td></td>
<td>SMBG: 64% unchanged C: 78% unchanged</td>
</tr>
<tr>
<td>Scherbaum (2008)</td>
<td>Change from oral agents to insulin</td>
<td></td>
<td>No significant difference</td>
</tr>
<tr>
<td>Wing (1986)</td>
<td>Change in medication</td>
<td></td>
<td>SMBG: decrease in oral agents 73%, decrease in insulin 83% C: decrease in oral agents 64%, decrease in insulin 64%</td>
</tr>
<tr>
<td><strong>QoL/preference</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Farmer (2007)</td>
<td>QoL (EQ-5D)</td>
<td></td>
<td>Significantly lower values on EQ-5D for more intensive group vs control, mainly due to increased anxiety/depression</td>
</tr>
<tr>
<td>Gallichan (1994)</td>
<td>Preference</td>
<td></td>
<td>71% preferred urine testing to blood testing</td>
</tr>
<tr>
<td>Miles (1997)</td>
<td>Preference</td>
<td></td>
<td>70% preferred urine testing, 15% preferred blood testing</td>
</tr>
<tr>
<td></td>
<td>Well-being questionnaire</td>
<td></td>
<td>No significant difference</td>
</tr>
<tr>
<td>Moreland (2006)</td>
<td>Negative affect with respect to SMBG</td>
<td></td>
<td>BGM+: 38% MT: 65% SC: 57%</td>
</tr>
<tr>
<td></td>
<td>Satisfaction</td>
<td></td>
<td>No significant difference</td>
</tr>
<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
</tr>
<tr>
<td>-------------------</td>
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<td>------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>O’Kane (2008)</td>
<td>Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive well-being</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Energy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schwedes (2002)</td>
<td>Well-being, treatment</td>
<td></td>
<td>Similar improvement in both groups</td>
</tr>
<tr>
<td></td>
<td>satisfaction</td>
<td></td>
<td>Depression</td>
</tr>
<tr>
<td>Wing (1986)</td>
<td>Mood</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Changes in behaviour**

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Guerci (2003)</td>
<td>Diet and exercise</td>
<td></td>
<td></td>
<td>Significantly more patients in the SMBG group</td>
<td></td>
</tr>
<tr>
<td></td>
<td>behaviour</td>
<td></td>
<td></td>
<td>continued following dietary instructions than in the control group, no significant difference in exercise behaviour</td>
<td></td>
</tr>
<tr>
<td>Wing (1986)</td>
<td>Diet and exercise</td>
<td></td>
<td>No significant difference</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>habits</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td></td>
<td></td>
<td>SMBG 12 times more in first year,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8 times more in later years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Outcome</td>
<td>Baseline</td>
<td>End of study</td>
<td>Difference</td>
<td>p-value</td>
</tr>
<tr>
<td>-----------------------</td>
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<td>--------------</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Farmer (2007)</td>
<td>Systolic blood pressure</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diastolic blood pressure</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td>Guerci (2003)</td>
<td>Systolic blood pressure</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diastolic blood pressure</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td>Scherbaum (2008)</td>
<td>Physician visits</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inpatient stay</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Incapacity to work</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td>Wing (1986)</td>
<td>Blood pressure</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse events</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barnett (2008)</td>
<td>All-cause adverse events</td>
<td>SMBG: 13.2%</td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: 15.1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scherbaum (2008)</td>
<td>Adverse events (with</td>
<td></td>
<td></td>
<td>No significant difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>details)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BGM, blood glucose monitoring; C, control; FB, feedback; HDL, high-density lipoprotein; I, intervention; LDL, low-density lipoprotein; MT, mixed treatment; NS, not significant; SC, standard care; SD, standard deviation; SE, standard error.
Appendix 5

Observational and non-randomised studies (included in reviews and new)
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Interventions</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bajkowska-Fiedziukiewicz (2008)</strong></td>
<td>Total number: 600</td>
<td>Comparison: association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>• No association between SMBG frequency and HbA&lt;sub&gt;1c&lt;/sub&gt; irrespective of diabetes treatment</td>
</tr>
<tr>
<td>Poland</td>
<td>Setting: diabetes clinic, Łódź</td>
<td>SMBG regimen: maximum and minimum glucose levels during last week plus 8-point profile on freely selected day</td>
<td>• Frequency of SMBG: 44.3% monitored 1–2 per day, 31.8% 1–2 per week</td>
</tr>
<tr>
<td>Design: cross-sectional</td>
<td><strong>Inclusion criteria:</strong> T2DM, insulin and/or oral treatment</td>
<td>SMBG method: glucometer</td>
<td>• Mean HbA&lt;sub&gt;1c&lt;/sub&gt; 7.45 ± 1.08%</td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td><strong>Age:</strong> 63.4 years</td>
<td>Education: standard diabetes education</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;, frequency of SMBG</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: 7.45%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: 11.4 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: insulin, oral glucose-lowering medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Banister (2004)</strong></td>
<td>Total number: 70</td>
<td>Comparison: association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>• HbA&lt;sub&gt;1c&lt;/sub&gt; –1.5% (9.7% reduced to 8.2%); p&lt;0.001</td>
</tr>
<tr>
<td>USA</td>
<td>Setting: community clinic</td>
<td>SMBG regimen: SMBG once per day</td>
<td></td>
</tr>
<tr>
<td>Design: cohort, before and after</td>
<td><strong>Inclusion criteria:</strong> T2DM</td>
<td>SMBG method: glucometer</td>
<td></td>
</tr>
<tr>
<td>Follow-up: 2–12 months</td>
<td><strong>Age:</strong> 49 years</td>
<td>Education: diabetes self-management training programme</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethnicity: most Hispanic or African-American</td>
<td>SMBG treatment adjustment/advice: did not report on how to respond to readings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: 34 kg/m&lt;sup&gt;2&lt;/sup&gt; (90% &gt; 25)</td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: 9.7% (range 5.2–16.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blonde (2002)</strong></td>
<td>Total number: 228</td>
<td>Comparison: association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>• Regular SMBG users: 21%; irregular SMBG users 42%; non-SMBG users 37%</td>
</tr>
<tr>
<td>USA</td>
<td>Setting: USA health clinics, chart review</td>
<td>SMBG regimen: no details of SMBG use/protocols</td>
<td></td>
</tr>
<tr>
<td>Design: cross-sectional</td>
<td><strong>Inclusion criteria:</strong> T2DM, no medication limits</td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;, frequency of SMBG</td>
<td></td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td><strong>Age:</strong> range 35–65 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: no details</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Capelson (2006)</strong></td>
<td>Total number: 808</td>
<td>Comparison: association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>• HbA&lt;sub&gt;1c&lt;/sub&gt; ≤ 8%: 70% regular users, 18% irregular users, 22% non-SMBG users</td>
</tr>
<tr>
<td>USA</td>
<td>Setting: chart review Joslin Clinic 2001–2005</td>
<td>SMBG regimen: divided into groups: (1) no SMBG; (2) SMBG 1–2 times per day; (3) SMBG 3–4 times per day; (4) SMBG &gt; 4 times per day</td>
<td></td>
</tr>
<tr>
<td>Design: cross-sectional</td>
<td><strong>Inclusion criteria:</strong> diabetes (type not specified), &gt; 75 years, insulin use</td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td><strong>Age:</strong> 80.4 ± 4.5 years</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: 7.5–7.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: 21.3 ± 14.9 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: insulin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Interventions</td>
<td>Results</td>
</tr>
<tr>
<td>------------</td>
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<td>---------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chan (2000)</td>
<td>Total number: 562</td>
<td>Comparison: association between SMBG use and HbA1c</td>
<td>SMBG associated with lower HbA1c than no SMBG (7.9% vs 8.6%; p-value not reported)</td>
</tr>
<tr>
<td>China</td>
<td>Setting: teaching hospital</td>
<td>SMBG regimen: no details of SMBG use/protocols</td>
<td></td>
</tr>
<tr>
<td>Design: cross-sectional</td>
<td>Inclusion criteria: T2DM</td>
<td>Outcomes: HbA1c</td>
<td></td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td>Age: 53 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: mean 2.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA1c: 8.4% (SD 2.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: 5 (SD 6) years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: 63% OHA, 21% diet alone, 9% insulin, rest no treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evans (1999)</td>
<td>Total number: 790 with T2DM; 807 with T1DM</td>
<td>Comparison: association between SMBG use and HbA1c</td>
<td>No association between SMBG frequency and HbA1c</td>
</tr>
<tr>
<td>UK</td>
<td>Setting: UK diabetes database</td>
<td>SMBG regimen: no details of SMBG use/protocols</td>
<td>Reagent strip uptake was influenced by age and by deprivation category. There was a direct correlation between uptake and glycaemic control for patients with T1DM, but no such relation for patients with T2DM who used insulin.</td>
</tr>
<tr>
<td>Design: cross-sectional</td>
<td>Inclusion criteria: diabetes mellitus, insulin treated</td>
<td>Outcomes: HbA1c, frequency of SMBG (no. of strips dispensed)</td>
<td></td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td>Age: unclear</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA1c: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: mean NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: all on insulin, some with OHAs in addition</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Interventions</td>
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</table>
| Franciosi (2001)<sup>1</sup>  | Total number: 2855                                                           | Comparison: association between SMBG use and HbA<sub>1c</sub>                  | • Overall, HbA<sub>1c</sub> higher in those testing more often  
• Higher frequency of SMBG associated with lower HbA<sub>1c</sub> only in patients who could adjust insulin; no relationship in non-insulin-treated patients  
• SMBG frequency > once per day significantly related to higher levels of distress, worries and depressive symptoms among non-insulin-treated patients  
• The correlation with poorer psychological well-being could be related to the feeling of powerlessness caused by unsatisfactory results that patients are not able to improve  
• Higher use of SMBG associated with: female, hypoglycaemic symptoms, use of insulin  
• Lower use of SMBG associated with: > 65 years, less well educated, treated by GP  
• Frequency of SMBG: 10.3% at least once per day, 30.5% at least once per week, 59.2% less than once per week/never  
• Patients practising SMBG regularly were significantly younger, had higher levels of school education, longer diabetes duration, higher levels of HbA<sub>1c</sub>, were more often treated with a combination of SUs and MET, had a higher frequency of hypoglycaemic episodes and were more frequently in the charge of a diabetes clinic  
• Overall, no association between SMBG monitoring frequency and HbA<sub>1c</sub> during 3-year FU; increasing SMBG frequency was associated with a slight decrease in HbA<sub>1c</sub>  
• In 40% of patients who increased SMBG frequency this was associated with major treatment changes – decrease in HbA<sub>1c</sub> over time only present in those who changed their treatment, but not in those who just changed SMBG monitoring frequency  
• Lowest likelihood for performing SMBG: no family support and on diet alone; highest likelihood of performing SMBG: family support of SMBG, followed by a diabetologist (rather than a GP), BMI < 25 kg/m<sup>2</sup> |
| Part of QuED Study | Italy Design: cross-sectional Follow-up: 3 years | SMBG regimen: no details of SMBG use/protocols  
SMBG other: SMBG method: glucometer used by 99% of patients using SMBG at least once per day; by 95.8% of patients using SMBG at least once per week; by 20.8% of the rest  
Outcomes: HbA<sub>1c</sub>, frequency of SMBG, QoL |                                                                 |                                                                 |                                                                 |                                                                 |                                                                 |
<table>
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<th>Study</th>
<th>Participants</th>
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<th>Results</th>
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</table>
| Fremantle Diabetes    | Total number: 1286 patients with T2DM at entry, 531 followed up over 5 years (longitudinal cohort significantly younger, healthier, better glycaemic control) | Comparison: association between SMBG use and HbA₁c.                           | • At baseline, 70.2% (898 out of 1280) of patients with T2DM used SMBG  
• No significant association between HbA₁c and SMBG frequency within treatment groups (oral or no medications)  
• Of those using SMBG, 79% had diabetes education; of those not using SMBG, 41% had diabetes education  
• During 12,491 patient-years of FU (mean 9.8 ± 3.5 years), 486 (38.0%) participants with T2DM died – 196 (15.3%) from cardiac causes; SMBG was significantly less prevalent in those who died during FU than in those who were still alive at the end of June 2006 (65.4 vs 73.0%; p = 0.005)  
• After adjustment for confounding and explanatory variables, SMBG was not independently associated with all-cause mortality, but was associated with a 79% increased risk of cardiovascular mortality in patients not treated with insulin  
• For the 5-year cohort, time-dependent SMBG was independently associated with a 48% reduced risk of retinopathy  
• As well as increasing the burden of self-care, SMBG contributes significantly to diabetes attributable and total direct health-care costs  
• Participant reasons for not monitoring: no education on how to do SMBG (45%); no motivation to start or to continue SMBG (31%); fear of finger pricks (9%); and physical or mental disability preventing its use (5%)  
• Patients with longer diabetes duration were less likely to self-monitor  
• General health status was worse in those self-monitoring, although DQoL measures were not associated with SMBG |
<p>| Study [Davis (2007)]  | Australia                                                                    | SMBG regimen: no details of SMBG use/protocols                                |                                                                                                                                         |
|                       | Design: cross-sectional and longitudinal                                       | Control: no use of SMBG                                                       |                                                                                                                                         |
|                       | Follow-up: 5 years                                                            | Outcomes: HbA₁c, morbidity                                                    |                                                                                                                                         |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Interventions</th>
<th>Results</th>
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</thead>
<tbody>
<tr>
<td>Hanninen (2001)</td>
<td>Total number: 260</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA1c</td>
<td>• SMBG associated with higher HbA1c (9% vs 8.5% without SMBG) (possibly because those with poorer control were asked to do SMBG)</td>
</tr>
<tr>
<td>Finland</td>
<td><strong>Setting</strong>:</td>
<td><strong>SMBG regimen</strong>: no details of SMBG use/protocols</td>
<td></td>
</tr>
<tr>
<td>Design: cross-sectional</td>
<td><strong>Inclusion criteria</strong>: T2DM, no medication limits</td>
<td><strong>Outcomes</strong>: HbA1c</td>
<td></td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td><strong>Age</strong>: 63 years</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>BMI</strong>: 30 (SEM 0.5)</td>
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<tr>
<td></td>
<td><strong>HbA1c</strong>: 8.5% (SEM 0.2)</td>
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<tr>
<td></td>
<td><strong>Diabetes duration</strong>: some newly diagnosed</td>
<td></td>
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<tr>
<td></td>
<td><strong>Treatment</strong>: OHA or insulin</td>
<td></td>
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<tr>
<td>Harris (2001)</td>
<td>Total number: 1480 people with T2DM</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA1c</td>
<td>• Frequency of SMBG: insulin: never or &lt; 1 times per month 28.7%, 1–3 times per month 11.1%, 1–6 times per week 21.1%, ≥ once per day 39.1%; oral agents: never or &lt; once per month 65.2%, 1–3 times per month 9.2%, 1–6 times per week 21.0%, ≥ once per day 4.6%; diet only: never or &lt; once per month 79.7%, 1–3 times per month 4.6%, 1–6 times per week 9.2%, ≥ 1 time per day 6.5%</td>
</tr>
<tr>
<td>USA</td>
<td><strong>Setting</strong>: NHANES III database</td>
<td><strong>SMBG regimen</strong>: no details of SMBG use/protocols</td>
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</tr>
<tr>
<td>Design: cross-sectional</td>
<td><strong>Inclusion criteria</strong>: T2DM, users and non-users of SMBG</td>
<td><strong>Outcomes</strong>: HbA1c</td>
<td></td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td><strong>Age</strong>: 62.5 years</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>BMI</strong>: NR</td>
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<tr>
<td></td>
<td><strong>HbA1c</strong>: mean 7.64%, 6.37% (diet only), 8.04% (oral agents), 8.29% (insulin)</td>
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<tr>
<td></td>
<td><strong>Diabetes duration</strong>: NR</td>
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<tr>
<td></td>
<td><strong>Treatment</strong>: diet only (27.2%), oral hypoglycaemic agents (45.5%), insulin (27.3%)</td>
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<tr>
<td>Jaworska (2001)</td>
<td>Total number: 218 people with T2DM</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA1c</td>
<td>• No association between SMBG monitoring frequency and HbA1c</td>
</tr>
<tr>
<td>Poland</td>
<td><strong>Setting</strong>: outpatient</td>
<td><strong>SMBG regimen</strong>: no details of SMBG use/protocols</td>
<td></td>
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<tr>
<td>Design: cross-sectional</td>
<td><strong>Inclusion criteria</strong>: T2DM, no medication limits reported</td>
<td><strong>Outcomes</strong>: HbA1c</td>
<td></td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td><strong>Age</strong>: 62 years</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• SMBG also not related to HbA1c in patients who could change insulin dose based on SMBG</td>
</tr>
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Note: SMBG = Self-Monitoring of Blood Glucose
<table>
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<tr>
<th>Study</th>
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<th>Interventions</th>
<th>Results</th>
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</thead>
<tbody>
<tr>
<td>Karter (2001)*</td>
<td><strong>Total number</strong>: 23,153 people with T2DM&lt;br&gt;Setting: Kaiser Permanente database&lt;br&gt;Inclusion criteria: T2DM, &gt; 19 years, pharmacy benefits, single HbA1c measured during FU; on insulin, oral agents or diet only&lt;br&gt;Age: 60 years&lt;br&gt;BMI: NR&lt;br&gt;HbA1c: ~8.4 ± 2.2%&lt;br&gt;Diabetes duration: 75% 0–9 years; 25% ≥ 10 years&lt;br&gt;Treatment: diet only (21%), oral hypoglycaemic agents (55%), insulin (24%)</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA1c&lt;br&gt;SMBG regimen: ADA recommendations&lt;br&gt;Control: no use of SMBG&lt;br&gt;Outcomes: HbA1c, frequency of SMBG</td>
<td>• Adherent patients (following ADA recommendations) were monitoring ≥ once daily (insulin/oral agents) or ≥ occasionally (diet only)&lt;br&gt;• Insulin: significantly lower HbA1c in adherent vs non-adherent [8.2% (95% CI 8.2 to 8.3) vs 8.8% (95% CI 8.8 to 8.9); p &lt; 0.0001]&lt;br&gt;• Oral agents: significantly lower HbA1c in adherent vs non-adherent [8.1% (95% CI 8.0 to 8.2) vs 8.7% (95% CI 8.7 to 8.7); p &lt; 0.0001]&lt;br&gt;• Diet only: lower levels of HbA1c in patients performing SMBG than in those who did not&lt;br&gt;• Adherent patients likely to be female, white, better educated, higher income, healthier lifestyle (adjusted for in analysis)&lt;br&gt;• Adverse events (hospital or ER visit) 41% non-insulin adherent patients vs 36% non-insulin non-adherent patients</td>
</tr>
<tr>
<td></td>
<td><strong>Total number</strong>: 4775 people with T2DM&lt;br&gt;Setting: Kaiser Permanente database&lt;br&gt;Inclusion criteria: T2DM, HbA1c &gt;8%, initiating new therapies&lt;br&gt;Age: 60 years&lt;br&gt;BMI: NR&lt;br&gt;HbA1c: 9.9 ± 1.5%&lt;br&gt;Diabetes duration: ≥ 1 year&lt;br&gt;Treatment: 74.2% not using insulin (pre-initiation)</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA1c&lt;br&gt;SMBG regimen: not reported&lt;br&gt;Outcomes: HbA1c, frequency of SMBG</td>
<td>• SMBG frequency 0.9 ± 1.0 per day&lt;br&gt;• Good control (HbA1c ≤ 7.0%): (case-mix adjustments with a wide range of covariates used)&lt;br&gt;• No SMBG: 13.4% (95% CI 11.3 to 15.8)&lt;br&gt;• Some SMBG but &lt; once daily: 15.5% (95% CI 14.0 to 17.2)&lt;br&gt;• Daily SMBG: 18.8% (95% CI 16.9 to 20.9)</td>
</tr>
<tr>
<td>Karter (2006)</td>
<td><strong>Total number</strong>: 1 6091 new users, 15 347 prevalent users with T2DM&lt;br&gt;Setting: Kaiser Permanente database&lt;br&gt;Inclusion criteria: T2DM, insulin, oral therapy or diet&lt;br&gt;Age: ~60±10 years&lt;br&gt;BMI: NR&lt;br&gt;HbA1c: 6.4 ± 0.8% to 8.6 ± 2.0% (new user cohort higher HbA1c)&lt;br&gt;Diabetes duration: NR&lt;br&gt;Treatment: new users: n = 9 264 no medication, n = 5 867 oral only; prevalent users: n = 1 622 no medication, n = 7 409 oral only</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA1c&lt;br&gt;SMBG regimen: no details of SMBG use/protocols&lt;br&gt;Outcomes: HbA1c, frequency of SMBG</td>
<td>• Frequency of SMBG inversely associated with HbA1c in new users regardless of diabetes therapy (p &lt; 0.0001) and in pharmacologically treated prevalent users (p &lt; 0.0001)</td>
</tr>
<tr>
<td>Study</td>
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<td>Interventions</td>
<td>Results</td>
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<tr>
<td><strong>Klein (1993)</strong>&lt;sup&gt;77&lt;/sup&gt; USA</td>
<td><strong>Design:</strong> chart review at Veterans Affairs medical centre&lt;br&gt;<strong>Follow-up:</strong></td>
<td><strong>Comparison:</strong> association between SMBG/SMUG use and HbA&lt;sub&gt;1c&lt;/sub&gt;&lt;br&gt;<strong>SMBG regimen:</strong> no details of SMBG use/protocols&lt;br&gt;<strong>Outcomes:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;, frequency of SMBG</td>
<td>• No significant differences between SMBG and urine monitoring&lt;br&gt;• HbA&lt;sub&gt;1c&lt;/sub&gt; did not differ based on length of time monitored or number of strips dispensed&lt;br&gt;• Seven patients reported making insulin changes in response to monitoring; this was not associated with HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
</tr>
<tr>
<td><strong>Meier (2002)</strong>&lt;sup&gt;79&lt;/sup&gt; USA</td>
<td><strong>Design:</strong> before/after chart review and before and after study&lt;br&gt;<strong>Follow-up:</strong> 6 months</td>
<td><strong>Intervention:</strong> reduced access to test strips&lt;br&gt;<strong>Outcomes:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;, strip use</td>
<td>• Chart review: SMBG associated with lower HbA&lt;sub&gt;1c&lt;/sub&gt;&lt;br&gt;• No significant difference in HbA&lt;sub&gt;1c&lt;/sub&gt; before (oral agents: 7.82 ± 1.22%) and after strip reduction (oral agents: 7.83 ± 1.21%)&lt;br&gt;• Strip use reduction: oral agents 1.35 ± 0.92 to 0.67 ± 0.44; &lt;sup&gt;p&lt;/sup&gt;&lt; 0.001; diet: 1.17 ± 1.04 to 0.61 ± 0.44; &lt;sup&gt;p&lt;/sup&gt;&lt; 0.001</td>
</tr>
<tr>
<td><strong>Mitchell (2004)</strong>&lt;sup&gt;80&lt;/sup&gt; Canada</td>
<td><strong>Design:</strong> cross-sectional&lt;br&gt;<strong>Follow-up:</strong> NA</td>
<td><strong>Comparison:</strong> association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;&lt;br&gt;<strong>Outcomes:</strong> HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>• No association between HbA&lt;sub&gt;1c&lt;/sub&gt; and SMBG</td>
</tr>
</tbody>
</table>
| **Murata (2003)**<sup>81</sup> USA | **Design:** before/after<br>**Follow-up:** 12 months | **Intervention:** intensified SMBG<br>**SMBG regimen:** SMBG using an electronic BG meter before all meals and at bedtime for 8 weeks then usual monitoring resumed<br>**Outcomes:** HbA<sub>1c</sub><br>**Quality:** 27.1% dropouts at 1 year | • Entry HbA<sub>1c</sub> 8.1 ± 1.67% (<i>n</i> = 210), decrease by 0.32 ± 1.17 at 1 year (<i>n</i> = 159)<br>• Decrease predicted by entry level HbA<sub>1c</sub> and compliance with SMBG (r = 0.862, <sup>p</sup>&lt; 0.001)
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<tbody>
<tr>
<td>Murata (2008)</td>
<td>USA</td>
<td><strong>Total number</strong>: 5862 patients with T2DM</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA₁c and medication change</td>
</tr>
<tr>
<td></td>
<td>Setting: Southwest Healthcare Network veterans</td>
<td><strong>SMBG regimen</strong>: no details of SMBG use/protocols</td>
<td><strong>SMBG use, subdivided by treatment alterations:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Inclusion criteria</strong>: T2DM, taking oral antihyperglycaemic agents</td>
<td><strong>Outcomes</strong>: HbA₁c</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age: NR</td>
<td></td>
<td><strong>Group 2</strong>: OHA dose(s) increased; 38.0% used SMBG and were monitoring a median of 2.6 times weekly (interquartile range 1.2–4.1)</td>
</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td></td>
<td><strong>Group 3</strong>: new OHA added; 39.7% used SMBG and were monitoring a median of 2.8 times weekly (interquartile range 0.9–4.1)</td>
</tr>
<tr>
<td></td>
<td>HbA₁c: NR</td>
<td></td>
<td><strong>Group 4</strong>: OHA dose(s) increased and new OHA added; 41.8% used SMBG and were monitoring a median of 2.7 times weekly (interquartile range 1.1–3.9)</td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: NR</td>
<td></td>
<td><strong>Group 5</strong>: Insulin added; 77.6% used SMBG and were monitoring a median of 3.7 times weekly (interquartile range 1.7–7.2)</td>
</tr>
<tr>
<td></td>
<td>Treatment: no details</td>
<td></td>
<td><strong>No association between SMBG monitoring frequency and HbA₁c overall; more frequent testing associated with lower HbA₁c in groups 1, 4 and 5, effect ranged from –0.22% to –0.94% for every 10 glucose test strips/week</strong></td>
</tr>
<tr>
<td>Newman (1990)</td>
<td>USA</td>
<td><strong>Total number</strong>: 38 patients with T1DM or T2DM</td>
<td><strong>No association between HbA₁c and SMBG</strong></td>
</tr>
<tr>
<td></td>
<td>Setting: Veteran Affairs chart review</td>
<td><strong>Inclusion criteria</strong>: T1DM or T2DM, no medication limits</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Age</strong>: 60 years</td>
<td><strong>Outcomes</strong>: HbA₁c</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA₁c: 8.2% (from graph)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Diabetes duration: 14 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: diet, OHA or insulin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oki (1997)</td>
<td>USA</td>
<td><strong>Total number</strong>: 98 patients with T2DM</td>
<td><strong>No association between HbA₁c and SMBG</strong></td>
</tr>
<tr>
<td></td>
<td>Setting: routine care</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA₁c</td>
<td><strong>No difference in HbA₁c between patients with SMBG &lt; 7 times per week and patients with SMBG &gt; 7 times per week</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Inclusion criteria</strong>: T2DM, no medication limits</td>
<td><strong>Outcomes</strong>: HbA₁c</td>
<td><strong>HbA₁c not associated with SMBG when analysed based on treatment group (insulin vs diet/oral)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Age</strong>: 56 years</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA₁c: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment: diet, OHAs, insulin</td>
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<tr>
<td>Study</td>
<td>Participants</td>
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<td>Results</td>
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</tr>
<tr>
<td>Ozmen (2003)</td>
<td>Total number: 267 patients with T2DM</td>
<td><strong>Comparison</strong>: association between SMBG use and HbA\textsubscript{1c}</td>
<td>- HbA\textsubscript{1c} reduced by 1.9% after 12 months (p &lt; 0.001)</td>
</tr>
<tr>
<td>Turkey</td>
<td><strong>Design</strong>: cohort</td>
<td>SMBG regimen: month 1: 2–3 per week, during the following 11 months: as</td>
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<tr>
<td></td>
<td><strong>Follow-up</strong>: 1 year</td>
<td>necessary to maintain normoglycaemia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age: 58 years</td>
<td><strong>SMBG treatment adjustment/advice</strong>: clinicians evaluated SMBG readings to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: 29.1 kg/m\textsuperscript{2}</td>
<td>adjust treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HbA\textsubscript{1c}: 9.1%</td>
<td><strong>Control</strong>: none</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: 8.6 years</td>
<td><strong>Outcomes</strong>: HbA\textsubscript{1c}</td>
<td></td>
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<tr>
<td></td>
<td><strong>Treatment</strong>: 34% using insulin; diet alone, insulin ± SUs, acarbose or MET</td>
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</table>

| Patrick (1994)        | Total number: 200                                                             | **Comparison**: association between SMBG/SMUG use and HbA\textsubscript{1c}    | - 97 (48%) patients (group 1) regularly monitored urine (n = 74), blood (n = 19) or both (n = 4); 103 (52%) patients (group 2) performed no home monitoring |
| UK                    | **Design**: cross-sectional                                                    | **SMBG regimen**: no details of SMBG use/protocols                            | - No association between HbA\textsubscript{1c} and SMBG                  |
|                       | **Follow-up**: NA                                                             | **Outcomes**: HbA\textsubscript{1c}                                           | - No difference between patients who reported they would act on monitoring results and those who reported they would not act on monitoring results |
|                       | **Setting**: hospital diabetes clinic                                          |                                                                                | - Prevalence of diabetic complications was also closely comparable and only peripheral neuropathy differed between the groups, being more common in group 1 (n = 12) than group 2 (n = 4); p < 0.05 |
|                       | **Inclusion criteria**: T2DM, no insulin                                       |                                                                                |                                                                        |
|                       | **Age**: 65 years                                                             |                                                                                |                                                                        |
|                       | BMI: NR                                                                      |                                                                                |                                                                        |
|                       | HbA\textsubscript{1c}: NR                                                     |                                                                                |                                                                        |
|                       | Diabetes duration: 6.4 years                                                  |                                                                                |                                                                        |
|                       | **Treatment**: diet oral hypoglycaemic agents                                 |                                                                                |                                                                        |

<p>| Rindone (1997)        | Total number: 115                                                            | <strong>Comparison</strong>: access to strips vs no access SMBG use/protocols               | - No significant difference in HbA\textsubscript{1c} between people      |
| USA                   | <strong>Design</strong>: retrospective chart review                                        | <strong>SMBG method</strong>: Chemstrips                                                   | with and without access to strips                                         |
|                       | <strong>Follow-up</strong>: 2 years                                                        | <strong>Outcomes</strong>: HbA\textsubscript{1c}                                           | - Few changes made to SU medication in either group (so SMBG results probably not used to change treatment) |
|                       | <strong>Setting</strong>: outpatient clinics                                               |                                                                                |                                                                        |
|                       | <strong>Inclusion criteria</strong>: T2DM, SU therapy for &gt; 2 years; no insulin or MET     |                                                                                |                                                                        |
|                       | <strong>Age</strong>: 68 years                                                             |                                                                                |                                                                        |
|                       | BMI: weight 91 ± 20 kg                                                        |                                                                                |                                                                        |
|                       | HbA\textsubscript{1c}: 8.1 ± 1.5%                                             |                                                                                |                                                                        |
|                       | Diabetes duration: NR                                                         |                                                                                |                                                                        |
|                       | <strong>Treatment</strong>: oral hypoglycaemic agents (SU)                                |                                                                                |                                                                        |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Interventions</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roblin (2001) †</td>
<td>Total number: 955</td>
<td>Comparison: association between SMBG use and HbA₁c</td>
<td>• Mean HbA₁c significantly lower in insulin-treated patients using at least daily SMBG than those using less than daily SMBG (8.8% vs 9.7%; <em>p</em> &lt; 0.05)</td>
</tr>
<tr>
<td></td>
<td>USA</td>
<td>Outcomes: HbA₁c, SMBG frequency</td>
<td>• No difference in patients not using insulin</td>
</tr>
<tr>
<td></td>
<td>Design: cross-sectional</td>
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<tr>
<td></td>
<td>Follow-up: NA</td>
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<tr>
<td></td>
<td>Setting: 3 sites of an HMO</td>
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<tr>
<td></td>
<td>Inclusion criteria: T2DM (95%), pharmacologically treated</td>
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<tr>
<td></td>
<td>Age: 53 years</td>
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<tr>
<td></td>
<td>BMI: NR</td>
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</tr>
<tr>
<td></td>
<td>HbA₁c: NR</td>
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<tr>
<td></td>
<td>Diabetes duration: 12 years</td>
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<tr>
<td></td>
<td>Treatment: 43% insulin, 52% oral agents</td>
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<tr>
<td>ROSSO Study (Martin (2006) †, Schneider (2007) †, Martin (2009) †)</td>
<td>Total number: 3268 patients with T2DM</td>
<td>Comparison: association between SMBG use and morbidity/mortality SMBG regimen: no details of SMBG use/protocols</td>
<td>• SMBG use: 45.3% began SMBG prior to an end point; an additional 64 patients started SMBG after a non-fatal end point; 32% used SMBG while being treated with diet or oral agents</td>
</tr>
<tr>
<td></td>
<td>Setting: 192 doctors’ practices</td>
<td>Outcomes: HbA₁c, diabetes-related morbidity (non-fatal myocardial infarction, stroke, foot amputation, blindness, haemodialysis), all-cause mortality</td>
<td>• At baseline, SMBG group had higher mean FPG and HbA₁c than non-SMBG group (HbA₁c 8.1% vs 7.2%) (suggestion insufficient control may have been reason for initiating SMBG)</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: T2DM, followed from diagnosis</td>
<td></td>
<td>• Total rate of non-fatal events lower in SMBG group than non-SMBG after 6.5 years (7.2% vs 10.4%; <em>p</em> = 0.002)</td>
</tr>
<tr>
<td></td>
<td>Age: 62.4 years</td>
<td></td>
<td>• Fatal events lower in SMBG group (2.7% vs 4.6%; <em>p</em> = 0.004)</td>
</tr>
<tr>
<td></td>
<td>BMI: 29.8 kg/m²</td>
<td></td>
<td>• Effects remained when analysing only patients not using insulin</td>
</tr>
<tr>
<td></td>
<td>HbA₁c: 7.7%</td>
<td></td>
<td>• No significant difference at baseline in classic cardiovascular risk factors</td>
</tr>
<tr>
<td></td>
<td>Diabetes duration: followed from diagnosis</td>
<td></td>
<td>• SMBG initiation often associated with treatment change/intensification (so confounding a problem)</td>
</tr>
<tr>
<td></td>
<td>Treatment: <em>n</em> = 2515 not using insulin</td>
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<tr>
<td></td>
<td>Follow-up: mean 6.5 years</td>
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<tr>
<td></td>
<td>Setting: inpatient</td>
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<tr>
<td></td>
<td>Inclusion criteria: T2DM, no medication limitation</td>
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<tr>
<td></td>
<td>Age: 56 years</td>
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<tr>
<td></td>
<td>Diabetes duration: followed from diagnosis</td>
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<tr>
<td></td>
<td>Treatment: insulin, oral medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rost (1990) †</td>
<td>Total number: 84 patients with T2DM</td>
<td>Comparison: association between SMBG use and HbA₁c in insulin users and non-insulin users</td>
<td>• SMBG associated with lower HbA₁c (independent of treatment)</td>
</tr>
<tr>
<td></td>
<td>USA</td>
<td>Outcomes: HbA₁c</td>
<td>• Relationship of SMBG to HbA₁c was independent of other self-care behaviours</td>
</tr>
<tr>
<td></td>
<td>Design: cross-sectional</td>
<td></td>
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<tr>
<td></td>
<td>Follow-up: NA</td>
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<tr>
<td></td>
<td>Setting: inpatient</td>
<td></td>
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</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Interventions</td>
<td>Results</td>
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</tr>
</tbody>
</table>
| **Schiel (1999)**<sup>90</sup>  
Germany  
**Design:** cross-sectional  
**Follow-up:** NA | **Total number:** 842  
**Setting:** hospital outpatient clinic  
**Inclusion criteria:** T2DM, insulin treatment > 1 year  
**Age:** 60 (SD 1.1) years  
**Diabetes duration:** 12.6 (SD 7) years  
**Treatment:** insulin | **Comparison:** association between SMBG use and HbA<sub>1c</sub>  
**SMBG regimen:** no details of SMBG use/protocols  
**Outcomes:** HbA<sub>1c</sub>, frequency of SMBG |  
• Frequency of SMBG inversely related to HbA<sub>1c</sub>  
(\(r = -0.17, p < 0.001\))  
• Most important determinants of HbA<sub>1c</sub> included frequency of SMBG |
| **Schütt (2006)**<sup>91</sup>  
Germany/Austria  
**Design:** cross-sectional  
**Follow-up:** NA | **Total number:** 5009 people with T2DM  
**Setting:** German/Austrian DPV-Wiss database, 191 centres  
**Inclusion criteria:** T2DM  
**Age:** NR  
**BMI:** NR  
**HbA<sub>1c</sub>:** mean 7.64%, 6.37% (diet only), 8.04% (oral agents), 8.29% (insulin)  
**Diabetes duration:** 10 years  
**Treatment:** insulin, oral antihyperglycaemic agents, diet  
(n = 2988 not using insulin) | **Comparison:** association between SMBG use and HbA<sub>1c</sub>  
**SMBG regimen:** no details of SMBG use/protocols  
**Outcomes:** most recent frequency of SMBG, most recent HbA<sub>1c</sub> |  
• **Insulin treated:** average SMBG frequency 2.7 times per day; increased frequency associated with lower HbA<sub>1c</sub>  
(−0.16%/one additional SMBG per day; \(p < 0.0001\))  
• **Non-insulin treated:** average SMBG frequency 2.0 times per day; increased frequency associated with higher HbA<sub>1c</sub>  
(presumably because those with poorer control were asked to test more often)  
(+0.14%/one additional SMBG per day; \(p < 0.0001\)) |
| **Secnik (2007)**<sup>92</sup>  
UK  
**Design:** database study  
**Follow-up:** 12 months | **Total number:** 2783  
**Setting:** UK General Practice Research Database  
**Inclusion criteria:** T2DM, insulin or oral agent, 12-month postinitiation data  
**Age:** 8% 20–44 years, 45% 45–64 years, 47% ≥ 65 years  
**BMI:** > 80% overweight or obese  
**HbA<sub>1c</sub>:** NR  
**Diabetes duration:** NR  
**Treatment:** \(n = 347\) insulin, \(n = 2436\) oral agents | **Intervention:** access to free BG monitors  
**Outcomes:** HbA<sub>1c</sub>, SMBG use |  
• In the insulin cohort, the total number of test strips prescribed was a predictor of HbA<sub>1c</sub>  
with a decrease of HbA<sub>1c</sub> concentration of 0.65% for every extra 180 test strips dispensed (equivalent to 1 per day)  
• No such relation found for the cohort on oral agents |
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Interventions</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Soumerai (2004)</strong></td>
<td>Total number: 3219 people with T1DM or T2DM</td>
<td>Intervention: access to free BG monitors</td>
<td>• Baseline HbA&lt;sub&gt;1c&lt;/sub&gt; in patients on SUs (n=1791) 8.4 ± 1.7%; in 90 initiators of SMBG vs 43 control subjects with HbA&lt;sub&gt;1c&lt;/sub&gt; &gt; 10%; decrease in HbA&lt;sub&gt;1c&lt;/sub&gt; of 0.63% (95% CI 1.14 to 0.12); p=0.03</td>
</tr>
<tr>
<td>USA</td>
<td>Setting: database</td>
<td>SMBG regimen: no details of SMBG use/protocols</td>
<td>No association of SMBG and HbA&lt;sub&gt;1c&lt;/sub&gt; in those with good (7.1%) or adequate (8.0%) control</td>
</tr>
<tr>
<td>Design: interrupted time series</td>
<td>Inclusion criteria: T2DM, any treatment</td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;, SMBG use, medication use</td>
<td>Adjusted (for baseline trend) initiation rate of SMBG in SU users increased by 14 (95% CI 10 to 17) patients/1000 patients per month</td>
</tr>
<tr>
<td>Follow-up: 4 years</td>
<td>Age: 56 ± 12.3 years</td>
<td></td>
<td>Initiators of SMBG showed sudden significant improvements in regularity of medication use by 6 months post initiation</td>
</tr>
<tr>
<td></td>
<td>BMI: &lt;25 kg/m² 11.8%, 25–30 kg/m² 24.6%, ≥30 kg/m² 44.5%</td>
<td></td>
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<tr>
<td></td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: 8.4 ± 1.7%</td>
<td></td>
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<tr>
<td></td>
<td>Diabetes duration: NR</td>
<td></td>
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<tr>
<td></td>
<td>Treatment: insulin, oral hypoglycaemic agents (57% on SUs)</td>
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<tr>
<td><strong>Stiptzarov (2003)</strong></td>
<td>Total number: 14329</td>
<td>Comparison: association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>• 36% received 0.75 strips or more per day (mean 1.7) with mean HbA&lt;sub&gt;1c&lt;/sub&gt; 8.13%, those who received less than 0.75 strips per day (mean 0.17) had HbA&lt;sub&gt;1c&lt;/sub&gt; 8.0%</td>
</tr>
<tr>
<td>USA</td>
<td>Setting: Veterans Affairs facilities</td>
<td>SMBG regimen: no details of SMBG use/protocols</td>
<td>SMBG was associated with reduced HbA&lt;sub&gt;1c&lt;/sub&gt; in subsequent quarter: using ≥0.75 strips per day was associated (p&lt;0.0001) with a reduction of 0.1% HbA&lt;sub&gt;1c&lt;/sub&gt; for people not receiving antihyperglycaemic medication, 0.07% for oral treatment, 0.13% for insulin only treatment, and 0.32% for oral plus insulin treatment</td>
</tr>
<tr>
<td>Design: cross-sectional, survey</td>
<td>Age: 65 years; 98% male</td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
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<tr>
<td>Follow-up: NA</td>
<td>BMI: NR</td>
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<tr>
<td></td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: NR</td>
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<tr>
<td></td>
<td>Diabetes duration: NR</td>
<td></td>
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<tr>
<td></td>
<td>Treatment: OHAs, insulin; no details given</td>
<td></td>
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<tr>
<td><strong>Tengblad (2007)</strong></td>
<td>Total number: 6495 people with T2DM, further exploration of medical records of 896, telephone interviews with 533 patients using SMBG on their opinions and SMBG habits</td>
<td>Comparison: association between SMBG use and HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td>• Frequency of SMBG 36% in diet only group, 54% in patients on oral agents, 79% in patients on insulin</td>
</tr>
<tr>
<td>Sweden</td>
<td>Setting: 18 primary care health centres in Östergötland and Jönköping, Sweden</td>
<td>SMBG regimen: no details of SMBG use/protocols</td>
<td>No significant differences in HbA&lt;sub&gt;1c&lt;/sub&gt; levels between SMBG users and non-users on insulin (6.9% vs 6.8%), or on oral agents (6.3% in both groups), in diet only group HbA&lt;sub&gt;1c&lt;/sub&gt; significantly higher [but not relevant??] in SMBG group (5.5% vs 5.3%)</td>
</tr>
<tr>
<td>Design: cross-sectional</td>
<td>Inclusion criteria: T2DM, users and non-users of SMBG</td>
<td>SMBG other:</td>
<td>COMMENT: low HbA&lt;sub&gt;1c&lt;/sub&gt; levels might preclude meaningful difference in HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
</tr>
<tr>
<td>Follow-up: NA</td>
<td>Age: 69 years</td>
<td>SMBG method:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI: NR</td>
<td>Outcomes: HbA&lt;sub&gt;1c&lt;/sub&gt;</td>
<td></td>
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<tr>
<td></td>
<td>HbA&lt;sub&gt;1c&lt;/sub&gt;: 5.4% to 6.9%</td>
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<tr>
<td></td>
<td>Diabetes duration: &lt;2 years, 4–33%; 2–4 years, 9–35%; &gt;4 years, 32–87%</td>
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<tr>
<td></td>
<td>Treatment: diet only (32%), oral hypoglycaemic agents (37%), insulin (31%)</td>
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<tr>
<td>Study</td>
<td>Participants</td>
<td>Interventions</td>
<td>Results</td>
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</tr>
<tr>
<td>Wen (2004)16 USA</td>
<td>Total number: 976 people with T2DM</td>
<td>Comparison: no SMBG vs SMBG year 3 or SMBG years 2–3 or SMBG years 1–3</td>
<td>• SMBG frequency not associated with HbA1c (but HbA1c already quite low)</td>
</tr>
<tr>
<td></td>
<td>Setting: Veteran Affairs</td>
<td>Outcomes: HbA1c</td>
<td>• Median usage of strips 4 per week</td>
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<tr>
<td></td>
<td>Inclusion criteria: T2DM, prescribed oral medication</td>
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<tr>
<td></td>
<td>Age: 63 years; 97% male</td>
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<tr>
<td></td>
<td>BMI: 31 ± 6 kg/m²</td>
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<tr>
<td></td>
<td>HbA1c: 7–7.3%</td>
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<tr>
<td></td>
<td>Diabetes duration: NR</td>
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<td></td>
<td>Treatment: OHAs only</td>
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<tr>
<td></td>
<td>Total number: 216 people with T2DM</td>
<td>Comparison: no SMBG vs SMBG once per day vs SMBG ≥ twice per day</td>
<td>• Frequency of SMBG not associated with HbA1c</td>
</tr>
<tr>
<td>Wieland (1997)96 USA</td>
<td>Setting: Veteran Affairs</td>
<td>Outcomes: HbA1c</td>
<td>• Age and glibenclamide dose were significantly associated with HbA1c</td>
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<tr>
<td></td>
<td>Inclusion criteria: T2DM, prescribed glyburide</td>
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<td></td>
<td>Age: range: 39–89 years; all male</td>
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<tr>
<td></td>
<td>BMI: NR</td>
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<tr>
<td></td>
<td>HbA1c: 7.9 ± 1.4%</td>
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<td></td>
<td>Diabetes duration: NR</td>
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<td></td>
<td>Treatment: OHAs only</td>
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</tbody>
</table>

BG, blood glucose; DPV-DISS, database for quality management and documentation of diabetes in Germany; DQoL, Diabetes Quality-of-Life Measure; ER, emergency room; FU, follow-up; HMO, health maintenance organisation; MET, metformin; NA, not available; NHANES III, Third National Health and Nutrition Examination Survey; NR, not reported; OHA, oral hypoglycaemic agent; QuED, quality of care and outcomes in type 2 diabetes; SEM, standard error of the mean; SU(s), sulphonylurea(s).
Appendix 6
Characteristics and results of qualitative studies
<table>
<thead>
<tr>
<th>Study, design</th>
<th>Participants/Issues</th>
<th>Results</th>
</tr>
</thead>
</table>
| Belsey (2009), UK<sup>10</sup> | Prevalence data assessed using Quality and Outcomes Framework | 40,651 records examined
| | | SMBG value is less clear-cut for patients unlikely to alter their treatment dose/behaviour, or if they are using treatments that lack the potential to cause hypoglycaemia
| | | British people tend not to act on their SMBG results
| | | SMBG is associated with increased levels of depression and anxiety compared with that of patients who do not self-monitor
| | | Expenditure in the UK in 2006–7 was £164,648,000; mean annual test strip cost per patient was £62.06, with those taking oral antidiabetic treatment having a mean of £2.56
| | | Patients who are on diet and exercise alone (mean 2.5 strips per week), MET/glitazones (2.6–3.3 mean per week). This group represents 22% of all patients testing, thus the absolute expenditure in these groups is high
| | | In the UK, few patients use SMBG to guide and maintain changes to their behaviour/lifestyle and this appears to be due in part to a lack of education about interpreting and acting upon result; could be considerable wastage due to inappropriate repeat prescriptions
| DIGEM RCT, UK<sup>10</sup> | Qualitative component | 40 participants
| | | Semistructured interviews to discuss experiences of having diabetes and taking part in the trial
| | | Age: 68.5 years (± 9.0)
| | | Topics of specific inquiry: understanding of the RCT; usefulness of taking part in the RCT; comparison of SMBG and clinical monitoring; usefulness of knowledge of glycaemic control; use of SMBG – ease, prompts, timing, relationship to behaviour
| | | Several patients mentioned an increased awareness of having diabetes as a consequence of SMBG
| | | Presence of elevated BG level viewed by respondents as tangible evidence of abnormality, one participant felt threatened by constant reminder of illness
| | | Some participants noted SMBG helped them establish the relationship between their physical symptoms and their blood sugar – most who reported this used SMBG to confirm suspected hypoglycaemia rather than hyperglycaemia
| | | Awareness of blood sugar levels provided reassurance for several respondents when associated with normal readings; however, readings outside parameters were associated with feelings of failure
| | | Some participants felt they could use SMBG to assess effects of behaviour, for example timing of monitoring, effect of certain foods
| | | Promotion of adherence to self-management emerged as benefit of SMBG. Respondents used feedback on general diabetes control and on specific behaviours in both monitoring groups
| | | Other incentives might be needed to encourage maintenance of behaviour change in patients who did not recognise long-term benefits of behaviour change
| | | Two participants said they timed their SMBG to ensure they only got satisfactory readings
| | | Participants felt empowered to take more control over their health care and ability to contribute to physician’s evaluation of their status
| | | Several participants said convenience was a benefit of SMBG
| | | While SMBG may have enabled some participants to feel more in control of their diabetes, only 2 respondents expressed an absolute preference for SMBG over periodic clinic visits and HbA<sub>1c</sub>
| | | SMBG thought to be more accurate than SMUG, but participants expressed reservations about its accuracy when compared with HbA<sub>1c</sub>
| DIGEM RCT, UK | Questionnaire study measuring patients’ beliefs about diabetes and self-monitoring | Standard questionnaire (revised Illness Perceptions Questionnaire)
| | | 399 patients returned completed questionnaires
| | | Concerns about the consequences of diabetes increased in both self-monitoring groups, relative to control participants
| | | Beliefs about the importance of self-testing increased in both self-monitoring groups relative to usual care
| | | Changes in psychological well-being did not differ, but control patients reported greater increases in general and specific dietary adherence than patients in either self-monitoring groups
| | | Authors concluded that despite changes in some beliefs about diabetes differing between groups there was no corresponding change in self-reported health behaviours
Lawton (2004), UK
Qualitative study using in-depth interviews, study informed by grounded theory
Participants were interviewed at 6-monthly intervals over 1 year (3 interviews)
Patients were recruited from hospital clinics (n = 3) and general practices (n = 16) in Lothian, Scotland

- 40 patients diagnosed as having T2DM within previous 6 months
- Mean age 53.5 (range 21–77), 18 women, 22 men; range of social classes
- All but one patient were white
- Treatment by diet alone or diet and MET and/or gliclazide
- Patients were asked:
  - whether they self-monitored and by what means
  - whether they had changed their method and frequency of self-monitoring
  - how they thought about and responded to (different) readings

16 patients performed urine testing post diagnosis; of these, 6 had changed to SMBG by round 2, and 2 further had changed to SMBG by round 3; 3 had stopped monitoring altogether; 3 patients did not monitor at any point (SMBG mainly initiated after visiting hospital clinic, GPs generally advised urine testing or nothing)
Patients expressed negative views about urine testing, especially when compared to subsequent use of SMBG - SMBG perceived to be more convenient, hygienic and accurate
Most patients assumed that BG meters were given to those with more advanced or serious forms of diabetes; this could have implications on how they thought about their own disease
Patients often interpreted negative urine results as indicating that they could not have diabetes

Peel (2004), UK
Qualitative study using repeat interviews; thematic analysis based in grounded theory
Two interviews over 6 months
Patients were recruited from hospital clinics (n = 3) and general practices (n = 16) in Lothian, Scotland

- 40 patients diagnosed as having T2DM within previous 6 months
- Mean age 53.5 (range 21–77), 19 women, 21 men; range of social classes
- All but one patients were white
- Treatment by diet alone or diet and MET and/or gliclazide
- (Presumably same sample as above?)
- Patients were asked:
  - Tell me about monitoring your blood sugar
  - Have there been changes in the amount of monitoring you do?
  - What do you think and do when you get high and low readings?

In round 1 interviews, 37.5% of patients used glucose meters, 7 did not self-monitor; by round 2, 52.5% used glucose meters – most reported having been provided with meters by hospital clinics and had attended structured group-based education sessions including instructions on meter use
Patients see both pros and cons in self-monitoring; can encourage self-regulation and regimen modifications; low readings can offer reassurance; glucose monitoring can heighten patients’ awareness of the impact of lifestyle, for example dietary choices, on BG levels; glucose monitoring amplifies a sense of ‘success’ or ‘failure’ about self-management, often resulting in anxiety and self-blame if glucose readings remain consistently high. Moreover, monitoring can negatively effect patients’ self-management when readings are counterintuitive

Conclusions: Analysis highlights the importance of understanding the meanings that newly diagnosed patients attach to glucose self-monitoring. To maximise the positive effects of self-monitoring, health professionals should ensure that patients understand the purpose of monitoring and should clarify with patients how readings should be interpreted
<table>
<thead>
<tr>
<th>Study, design</th>
<th>Participants/issues</th>
<th>Results</th>
</tr>
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<tbody>
<tr>
<td><strong>Peel (2007),</strong>&lt;sup&gt;102&lt;/sup&gt; UK Qualitative study as above, repeat interviews over 4 years after diagnosis&lt;br&gt;• 18 patients with T2DM repeatedly interviewed over 4 years</td>
<td>Analysis revealed three main themes – the role of health professionals, interpreting readings and managing high values, and the ongoing role of BG self-monitoring. Self-monitoring decreased over time, and health professionals’ behaviour seemed crucial in this: participants interpreted doctors’ focus on levels of HbA&lt;sub&gt;1c&lt;/sub&gt; and lack of perceived interest in meter readings, as indicating that self-monitoring was not worth continuing. Some participants saw readings as a proxy measure of good and bad behaviour – with women, especially, chastising themselves when readings were high. Some participants continued to find readings difficult to interpret, with uncertainty about how to respond to high readings. Reassurance and habit were key reasons for continuing. There was little indication that participants were using self-monitoring to effect and maintain behaviour change.</td>
<td><strong>Conclusions:</strong> Clinical uncertainty about the efficacy and role of BG self-monitoring in patients with T2DM is mirrored in patients’ own accounts. Patients tended not to act on their self-monitoring results, in part because of a lack of education about the appropriate response to readings. Health professionals should be explicit about whether and when such patients should self-monitor and how they should interpret and act upon the results, especially high readings.</td>
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<td><strong>Zgibor (2002),</strong>&lt;sup&gt;103&lt;/sup&gt; New Zealand Qualitative survey&lt;br&gt;• 323 participants from the South Auckland Diabetes project (2.2–5.5% T1DM, 9.2–12.7% insulin treated; the rest T2DM non-insulin treated)&lt;br&gt;• Age: 52–63 years, men and women&lt;br&gt;• Survey to determine barriers to diabetes care, and to SMBG</td>
<td>Patient-reported barriers to diabetes care associated with SMBG include financial, psychosocial and self-efficacy issues. Characteristics associated with SMBG greater than or twice weekly were female sex, HbA&lt;sub&gt;1c&lt;/sub&gt; &gt; 8%, higher diabetes knowledge scores, insulin use; multivariate analyses demonstrated that those reporting external physical barriers (particularly financial), external psychological barriers, internal psychological barriers were less likely to perform SMBG independent of ethnicity, insulin use, age, sex, diabetes knowledge and glycaemic control. Carriers need to be addressed to encourage increased participation in self-care. Previous studies have shown lower SMBG in ethnic minorities, lower socioeconomic status and patients with lower diabetes knowledge. Individuals reporting personal barriers to diabetes care – particularly relating to finance and access, community and family support and self-efficacy, motivation and health beliefs – were less likely to perform prescribed SMBG.</td>
<td><strong>Conclusions:</strong> Clinical uncertainty about the efficacy and role of BG self-monitoring in patients with T2DM is mirrored in patients’ own accounts. Patients tended not to act on their self-monitoring results, in part because of a lack of education about the appropriate response to readings. Health professionals should be explicit about whether and when such patients should self-monitor and how they should interpret and act upon the results, especially high readings.</td>
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BG, blood glucose; MET, metformin.
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Feedback

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*We look forward to hearing from you.*