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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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Abstract

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

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for the Aberdeen Health Technology Assessment Group

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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. HbA_{1c} data from RCTs were summarised using a meta-analysis. Heterogeneity was calculated using the chi-squared and I^2 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 HbA_{1C} 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.

Contents

List of abbreviations

ADA	American Diabetes Association
AHRQ	Agency for Healthcare Research and Quality
BG	blood glucose
BMI	body mass index
CHF	Swiss franc
DiGEM	Diabetes Glycaemic Education and Monitoring
DTSQ	Diabetes Treatment Satisfaction Questionnaire
EASD	European Association for the Study of Diabetes
ESMON	Efficacy of Self-MONitoring of blood glucose in newly diagnosed type 2 diabetes trial
EQ-5D	EuroQol-5D questionnaire
FBG	fasting blood glucose
FDA	US Food and Drug Administration
FPG	fasting plasma glucose
GPs	general practitioners
HbA_{1c}	glycosylated/glycated haemoglobin
HCPs	health-care professionals
HDL	high-density lipoprotein
HTA	Health Technology Assessment
ICER	incremental cost-effectiveness ratio
IQWiG	Institut für Qualität und Wirtschaftlickeit im Gesundheitswesen
LDL	low-density lipoprotein
MHRA	Medicines and Healthcare Products Regulatory Agency
NICE	National Institute for Health and Clinical Excellence
NIH	National Institutes of Health
NR	not reported
NS	not significant
OHA	oral hypoglycaemic agent
PTC	Pathways To Change
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
SF-36	Short Form-36
SMBG	self-monitoring of blood glucose
SMUG	self-monitoring of urine glucose
T1DM	type 1 diabetes
T2DM	type 2 diabetes
UKPDS	UK Prospective Diabetes Study

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.

Executive summary

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

- Electronic databases: including The Cochrane Library [all sections] (Issue 2, 2009), MEDLINE (1996–April 2009), EMBASE (1996–April 2009), PsycINFO (1996–April 2009), Web of Science – limited to meeting abstracts (1996–April 2009).
- 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} level, 12 showed a reduction (but often very small), and some showed an increase in HbA_{1c} 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 HbA_{1c} 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 CG66[1] recommends that the target should usually be a glycated haemoglobin (HbA_{1c}) level of 6.5% or less. HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} level measured at intervals, which will let them know if control is poor. However, HbA_{1c} 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[2] 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).[3] 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[4] 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.[5] 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 HbA_{1c} 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[6]) 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[7–9] 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*

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

The NICE clinical guideline[1] on the management of T2DM, which was written before the two recent trials [DiGEM[10–12] (Diabetes Glycaemic Education and Monitoring) and ESMON[13] (Efficacy of Self MONitoring of blood glucose in newly diagnosed type 2 diabetes trial)] had reported, supported SMBG in certain circumstances. It recommended that SMGB 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 Permanente[14] study and the ROSSO (RetrOlective 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,[9] 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:

- electronic databases: including The Cochrane Library (all sections) (Issue 2, 2009), MEDLINE (1996–April 2009), EMBASE (1996–April 2009), PsycINFO (1996–April 2009), Web of Science – limited to meeting abstracts (1996–April 2009)
- 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.

A separate search strategy for cost-effectiveness studies was performed and comprised searches of the following electronic databases: MEDLINE (1996–June 2009), EMBASE (1996–June 2009), Web of Science with Conference Proceedings – limited to meeting abstracts (1996–June 2009), Cochrane Library (Issue 2, 2009).

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.
- Intention-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. HbA_{1c} 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 I^2 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 HbA_{1c} 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)][25] 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 HbA_{1c} 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 11[2,24,28–38] 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.[42,53]

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,[2,28,32,38] and another five relevant studies[67,82,88,92,94] 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 reviews[24,29,31,34,36,38] 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 trials[40,47,56] compared SMBG with SMUG (urine monitoring), and nine trials[10,11,42–44,46,50,55,59–61] 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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)*

	Systematic reviews											
RCTs	**AHRQ (2007)[28]**	**Faas (1997)[30]**	**Coster (2000) (NHS HTA)[24,29]**	**Sarol (2005)[34,39]**	**Welschen (2005)[36,37]**	**Jansen (2006)[31]**	**McAndrew (2007)[2]**	**McGeoch (2007)[32]**	**Poolsup (2008)[33]**	**Towfigh (2008)[35]**	**St John (2009)[38]**	**Additional**
Allen (1990)[40]		Yes	Yes		Yes	Yes	Yes					
Barnett (2008)[41]											Yes	
Bonomo (2006)[42] (abstract)												Yes
Brown (2002)[43]						Yes						
Cho (2006)[44]												Yes
Davidson (2005)[45]	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Estey (1990)[46]		Yes	Yes	Yes		Yes						
Farmer (2007)[10,11]							Yes		Yes	Yes	Yes	
Fontbonne (1989)[47]	Yes	Yes	Yes	Yes	Yes	Yes			Yes	Yes		
Gallichan (1994)[48]		Yes	Yes									
Guerci (2003)[49]	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Jaber (1996)[50]				Yes		Yes			Yes	Yes		
Johnson (2006)[51]												Yes
Jones (2003)[52]												Yes
Joy (2003)[53] (abstract)												Yes
Kibriya (1999)[54]	Yes						Yes					
Kwon (2004)[55]				Yes		Yes	Yes				Yes	
Miles (1997)[56]	Yes (but judged to be non-randomised)		Yes			Yes	Yes					
Moreland (2006)[20]							Yes					
Muchmore (1994)[57]			Yes	Yes	Yes	Yes	Yes		Yes	Yes		
O'Kane (2008)[13]											Yes	
Rutten (1990)[58]	Yes (but judged to be non-randomised)	Yes	Yes			Yes	Yes			Yes		
Scherbaum (2008)[59,60]												Yes
Schwedes (2002)[61]	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Seaton (1996)[62]							Yes					
Wing (1986)[63]		Yes	Yes			Yes				Yes		

AHRQ, Agency for Healthcare Research and Quality.

TABLE 3 *Observational/pseudoexperimental studies included in reviews in T2DM*

	Systematic reviews				
Observational study	**AHRQ (2007)[a,28]**	**McGeoch (2007)[32]**	**McAndrew (2007)[2]**	**St John (2009)[38]**	**Additional**
Bajakowska-Fiedziukiewicz (2008)[64]				Yes	
Banister (2004)[65]	Yes				
Blonde (2002)[66]			Yes	Yes	
Capelson (2006)[67] (abstract)					Yes
Chan (2000)[68]			Yes		
Davis (2006)[18,19]		Yes		Yes	
Evans (1999)[69]				Yes	
Franciosi (2001)[70]			Yes	Yes	
Franciosi (2005)[71]	Yes	Yes		Yes	
Hanninen (2001)[72]			Yes		
Harris (2001)[73]		Yes	Yes	Yes	
Jaworska (2004)[74]			Yes		
Karter (2001)[75]		Yes	Yes	Yes	
Karter (2005)[76]		Yes			
Karter (2006)[14]		Yes		Yes	
Klein (1993)[77]			Yes		
Martin (2006)[15,78]		Yes			
Meier (2002)[79]		Yes	Yes	Yes	
Mitchell (2004)[80]			Yes		
Murata (2003)[81]				Yes	
Murata (2009)[82]					Yes
Newman (1990)[83]			Yes		
Oki (1997)[84]			Yes		
Ozmen (2003)[85]	Yes				
Patrick (1994)[86]			Yes		
Rindone (1997)[87]		Yes	Yes	Yes	
Roblin (2001)[88] (abstract)					Yes
Rost (1990)[89]			Yes		
Schiel (1999)[90]				Yes	
Schütt (2006)[91]		Yes		Yes	
Secnik (2007)[92]					Yes
Soumerai (2004)[93]		Yes	Yes	Yes	
Stiptzarov (2003)[94] (abstract)					Yes
Tengblad (2007)[95]				Yes	
Wen (2004)[16]		Yes	Yes		
Wieland (1997)[96]		Yes	Yes		

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 HbA_{1c} 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;[32] 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 results of SMBG.
- 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.[38]
- Efficacy of SMBG may be lower when baseline HbA_{1c} level is higher, i.e. SMBG may be least effective for those who need it most.[35] 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)[32] 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 HbA_{1c} 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.[24,29,34] The study by Worth *et al.*,[97] as reported in a review by Coster *et al.*,[24,29] 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.

None of the systematic reviews addressed variations in benefit from SMBG 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.). One review noted that SMBG had no clear benefit on HbA_{1c} level in a number of observational studies but did have some in RCTs.[2] Furthermore, in one study,[40] reported in a review by McAndrew *et al.*,[2] there was a trend towards younger and better-educated participants improving more with SMBG. The prevalence of T2DM in ever younger patients needs to be explored in terms of use and effectiveness of SMBG because if there are no apparent benefits, yet individuals are encouraged to continue testing, the long-term financial costs are going to be enormous.

Self-monitoring of blood glucose does not improve glycaemic control in isolation,[34] but proper use of SMBG data can guide clinical decisions and improve control if results are used only to modify behaviour, diet, exercise and medications. Optimal and realistic testing frequencies need to be explored, i.e. is it achievable by patients, do patients need to perform SBMG indefinitely or would time-limited periods be sufficient to address

TABLE 4 *Conclusions and recommendations of the systematic reviews*

Study	Conclusions (medical effectiveness)	Recommendations for research	Comments
Faas (1997)[30]	*HbA_{1c}*: efficacy of SMBG in non-insulin dependent patients with T2DM is questionable *Hypoglycaemia (frequency and severity)*: not reported *QoL/measure of empowerment – self-efficacy?* not reported *Treatment change in response to measurements* (insulin dose, oral drug dose, etc.): not reported *Behaviour change in response to measurements* (diet, exercise etc.): not reported *Weight:* limited evidence *Hospital admissions*: not reported *Costs*: not reported	• SMBG intervention should be comprehensive, stimulating patients not only to perform SMBG, but also combine it with a programme of lifestyle changes • SMBG should have protocols, preferably with a semi-fixed regimen • Caregiver should give feedback on the patient's self-measured glucose levels	• Attention of doctors and nurses and patient education could have contributed to positive results • Effective coping of patients and physicians with lifestyle changes in combination with SMBG is most promising strategy • Recommendation for practice is that SMBG should be used in patients with poor glycaemia control despite optimal treatment
Coster (2000) (NHS HTA)[29]	*HbA_{1c}*: 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 *Hypoglycaemia* (frequency and severity): not reported by trials *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 *Treatment change in response to measurements* (insulin dose, oral drug dose, etc.): not reported *Behaviour change in response to measurements* (diet, exercise, etc.): not reported *Weight:* no significant effect of SMBG vs control or SMUG *Hospital admissions*: not reported *Costs*: urine testing is less costly than blood testing *General*: the studies reviewed had low statistical power and were poorly reported and conducted; small but clinically relevant changes might not have been detectable	• RCT needed to assess issues of patient training, adherence with recommendations, use of protocols for modification of therapy; trial should have sufficient power after stratifying for important risk groups (including age, type of treatment); range of outcomes should be evaluated, including symptom severity, satisfaction with care, changes in therapy and clinical outcomes, hypoglycaemia • RCT needed to study discontinuing SMBG in well-defined groups of patients (e.g. patients with stable T2DM)	• Studies reviewed a limited range of outcomes – issues of QoL and patient satisfaction were not fully evaluated; there may be psychological benefits not evaluated • Self-monitoring may be beneficial in some groups of patients or under certain conditions of use • A failure to standardise interventions, monitor adherence and provide protocols for utilisation of self-monitoring data might have contributed to the negative findings of the trials reviewed • Main benefit may be educational modality, leading to increased contact time
Sarol (2005)[34,39]	*HbA_{1c}*: 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	• Research required to identify subset of patients willing and able to effectively carry out treatment adjustments • Optimal testing frequencies, cost–benefit of SMBG and QoL as an outcome should also be explored	• Factors influencing SMBG regimen include: current level of glycaemic control, medication regimen, risk of hypoglycaemia, patient motivation and attitudes • Ideal testing regimens range from four or more tests daily on insulin to a few times per week (not specified)

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Study	Conclusions (medical effectiveness)	Recommendations for research	Comments
Welschen (2005)[36,37]	*HbA_{1c}*: 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 HbA_{1c} (–0.39%) *Hypoglycaemia* (frequency and severity): not reported *QoL/measure of empowerment – self-efficacy?* not enough information in trials for conclusive results *Behaviour change in response to measurements* (diet, exercise, etc.): not reported *Weight*: not reported *Hospital admissions*: not reported *Costs*: not reported	• 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 HbA_{1c} values should be evaluated	• Studies with higher baseline HbA_{1c} level showed a greater final reduction in HbA_{1c} 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 HbA_{1c} level improvement • No standard instructions were given to the patients to adjust their behaviour and medication to adjust their glucose values
Jansen (2006)[31]	*HbA_{1c}*: SMBG is effective in reducing HbA_{1c} in T2DM – regular feedback is important; SMBG is likely to be more effective than SMUG *Hypoglycaemia* (frequency and severity): not reported *QoL/measure of empowerment – self-efficacy?* not reported *Treatment change in response to measurements* (insulin dose, oral drug dose, etc.): not reported *Behaviour change in response to measurements* (diet, exercise, etc.): not reported *Weight*: not reported *Hospital admissions*: not reported *Costs*: not reported	• Studies with final end points (e.g. cardiovascular events) and patient QoL/ satisfaction required	• Only assesses HbA_{1c} 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)[28]	*HbA_{1c}*: the studies may suggest small but possibly clinically non-significant reductions in HbA_{1c} with SMBG; but overall studies are inconclusive; uncontrolled and cohort studies agreed with RCTs in finding small reductions in HbA_{1c}; no conclusions regarding the frequency of SMBG and HbA_{1c} *Hypoglycaemia*: considered three cohort studies investigating SMBG and hypoglycaemia, but all patients were insulin treated and large proportions were patients with T1DM – effect of SMBG on hypoglycaemia unclear *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		• 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 HbA_{1c} 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)*

Study	Conclusions (medical effectiveness)	Recommendations for research	Comments
McAndrew (2007)[2]	*HbA_{1c}*: SMBG may be effective in controlling glucose for patients with T2DM *Hypoglycaemia*: not reported *QoL/measure 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 *Treatment change in response to measurements*: not reported *Weight*: not reported *Hospital admissions*: not reported *Costs*: not reported		Steps required for SMBG to be effective – patients must: • know how to take a reading • understand when reading is above/below target • see the connection between deviant readings and prior behaviour • have and implement an action plan to control glucose levels • rely more heavily on SMBG readings and give less weight to subjective feelings of well-being • create simple action plans that will allow the patient to integrate them into his/her ongoing life patterns • evaluate glucose readings in a non-judgemental framework
McGeoch (2007)[32]	*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 *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 *SMBG use*: data suggests that fewer than 60% of patients with T2DM using diet and/or hypoglycaemic agents practice SMBG on a regular basis *Other*: observational study with the longest FU (6.5 years) had significantly lower mortality and morbidity in SMBG group than in non-SMBG group	• Concur with the view that larger, long-duration trials with patient-centred outcomes are needed but analysis should be carried out based on initial HbA_{1c} level or better at the level of the individual patient • Trials should qualitatively and quantitatively record how SMBG is taught to individuals and used to modify behaviour	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 Question may not be whether SMBG confers benefits on average, but for which particular patients, and how can they be identified? SMBG may not be helpful or economically justified in all cases, but it seems likely that individuals would benefit if: • their baseline Hba_{1c} 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, lack of awareness of hypoglycaemia

Study	Conclusions (medical effectiveness)	Recommendations for research	Comments
Poolsup (2008)[33]	*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
Towfigh (2008)[35]	*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		• 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)[38]	*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*

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

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 HbA_{1c} level, but trials also assessed a range of additional outcomes such as HbA_{1c} 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 HbA_{1c} 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),[41] Farmer *et al*. (2007)[10] (DiGEM), O'Kane *et al*. (2008)[13] (ESMON) and Scherbaum *et al*. (2008)[60]] 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)[13] and Barnett *et al.* (2008 – DINAMIC; Diamicron MR in NIDDM: assessing management and improving control),[41] 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.[98] In the control groups, HbA_{1c} 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 HbA_{1c} level = 7.5%), making further improvements difficult.[98]

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 HbA_{1c} 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 HbA_{1c} 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). HbA_{1c} level reduction when comparing

TABLE 6 *Intervention components – RCTs*

Study	Comparison	SMBG instruction	Education/ counselling	Feedback given	Treatment adjustment	SMBG regimen	Starting HbA_{1c} level	Age	Treatment	Diabetes duration	Hba_{1c} results
Allen (1990)[40]	SMBG vs SMUG	Yes	Yes (both)	Yes	Doctor	Moderate	12	58	Diet, oral	8	NS
Barnett (2008)[41]	SMBG vs no SMBG	Yes	Yes (both)	Unclear	No	Moderate	8	56	Diet, MET/ SU	3	SMBG better
Bonomo (2006)[42]	SMBG profile once per month vs more detailed SMBG profile every 2 weeks	No	Yes	Unclear	Yes	Infrequent	8	65	Diet, oral	11	More frequent better
Brown (2002)[43]	SMBG plus education vs no SMBG	Yes	Yes (only intervention)	Unclear	Unclear	Unclear	12	NR	Oral	NR	Unclear
Cho (2006)[44]	Internet vs non-internet SMBG	Unclear	Yes	Yes	Yes	Unclear	7.6	53	Diet, oral, insulin	7	SMBG better
Davidson (2005)[45]	SMBG vs no SMBG	Unclear	Yes (both)	Unclear	Doctor/nurse	Frequent	8.5	50	MET/SU	6	NS
Estey (1990)[46]	SMBG + feedback vs SMBG no feedback	Yes	Yes (both)	Yes	Unclear	Unclear	6.2	55	Diet, oral	NR	NS
Farmer (2007)[10]	SMBG intensive vs SMBG less intensive vs no SMBG	No	Yes	Yes	Patient (intensive)	Moderate	7.5	66	Diet, oral	3	NS
Fontbonne (1989)[47]	SMBG vs SMUG vs no SMBG	Yes	Limited	Yes	Doctor	Moderate	8.3	55	Diet, oral	12.5	NS
Gallichan (1994)[48]	SMBG vs SMUG	Yes	No	No	Unclear	Unclear	NR	64	Diet, oral	NR	NS
Guerci (2003)[49]	SMBG vs no SMBG	Yes	No	Unclear	Doctor	Frequent	9	62	MET/SU	8	SMBG better
Jaber (1996)[50]	SMBG plus education vs no SMBG	Yes	Yes (only intervention)	Unclear	Doctor?	Moderate	9.5	62	Unclear	6.8	SMBG better
Johnson (2006)[51]	Free blood glucose meter plus testing strips vs free blood glucose meter	Yes	No	No	No	Frequent	7.4	68	Diet, oral	8	NS

Study	Comparison	SMBG instruction	Education/ counselling	Feedback given	Treatment adjustment	SMBG regimen	Starting HbA_{1c} level	Age	Treatment	Diabetes duration	Hba_{1c} results
Jones (2003)[52]	PTC plus SMBG vs PTC vs SMBG vs control	No	Yes	Unclear	Unclear	Unclear	8.5	55	Oral, insulin	10.5	NS
Joy (2003)[53]	Preprandial SMBG vs postprandial SMBG	NR	NR	NR	Doctor	Frequent	8.4	NR	Oral, insulin (?)	NR	NS
Kibriya (1999)[54]	SMBG vs no SMBG	Yes	Yes (both)	Unclear	Patient	Infrequent	NR	50	Oral, insulin	NR	SMBG better (?)
Kwon (2004)[55]	Internet vs non-internet SMBG	Unclear	Yes (only intervention)	Yes	Patient	Moderate	7.3	54	NR	5.6	SMBG better
Miles (1997)[56]	SMBG vs SMUG	Unclear	Yes (both)	Unclear	Unclear	Frequent	10.3	65	Oral, insulin	0	NS
Moreland (2006)[20]	BG meter + manual vs BG meter vs no SMBG	Yes	Yes (all)	Unclear	Unclear	NR	9	48	Oral, insulin	10	NS
Muchmore (1994)[57]	SMBG vs no SMBG	Yes	Yes (both)	Yes	Doctor	Frequent/moderate	10.4	59	NR	5.5	NS
O'Kane (2008)[13]	SMBG vs no SMBG	Yes	Yes (both)	Yes	Patient/doctor?	Moderate/frequent	8.7	60	Diet, oral	0	NS
Rutten (1990)[58]	SMBG vs no SMBG	Yes	No	Yes	Doctor	Infrequent	9.3	63	Diet, oral	8.8	SMBG better
Scherbaum (2008)[60]	High SMBG vs low SMBG vs no SMBG	Unclear	No	Yes	Doctor	Moderate/ infrequent	7.2	62	Diet, MET/ SU	8	NS
Schwedes (2002)[61]	SMBG vs no SMBG	Yes	Yes (different in two groups)	Unclear	Unclear	Moderate	8.5	60	Diet, oral	5.3	SMBG better
Seaton (1996)[62]	SMBG vs no SMBG	NR	NR	NR	Doctor	NR	NR	NR	Oral	NR	Unclear
Wing (1986)[63]	SMBG vs no SMBG	Yes	Yes (both)	Yes	Doctor	Frequent	10.5	54	Diet, oral, insulin	NR	NS

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.

Study or subgroup	SMBG Mean	SMBG SD	SMBG Total	No SMBG Mean	No SMBG SD	No SMBG Total	Weight	Mean difference IV, Random, 95% CI
Barnett (2008)[41]	6.95	0.97	311	7.2	1.22	299	34.8%	−0.25 (−0.43 to −0.07)
Davidson (2005)[45]	7.7	1.6	43	7.8	1.5	45	2.5%	−0.10 (−0.75 to 0.55)
Farmer (2007)[10,11]	7.28	0.88	150	7.49	1.2	152	19.0%	−0.21 (−0.45 to 0.03)
Fontbonne (1989)[47]	7.84	2.5	68	7.7	2.5	68	1.5%	0.14 (−0.70 to 0.98)
Guerci (2003)[49]	8.1	1.6	345	8.4	1.4	344	21.2%	−0.30 (−0.52 to −0.08)
Kibriya (1999)[54]	7.11	1.08	32	7.12	1.85	32	1.9%	−0.01 (−0.75 to 0.73)
Muchmore (1994)[57]	8.75	1.66	12	9.6	2.1	11	0.4%	−0.85 (−2.41 to 0.71)
O'Kane (2008)[13]	6.9	0.8	96	6.9	1.2	88	12.1%	0.00 (−0.30 to 0.30)
Rutten (1990)[58]	9.2	1.49	66	9.4	1.14	83	5.7%	−0.20 (−0.64 to 0.24)
Wing (1986)[63]	10.2	2.3	25	10.4	2.2	25	0.7%	−0.20 (−1.45 to 1.05)
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: $z = 3.94$ ($p < 0.0001$)

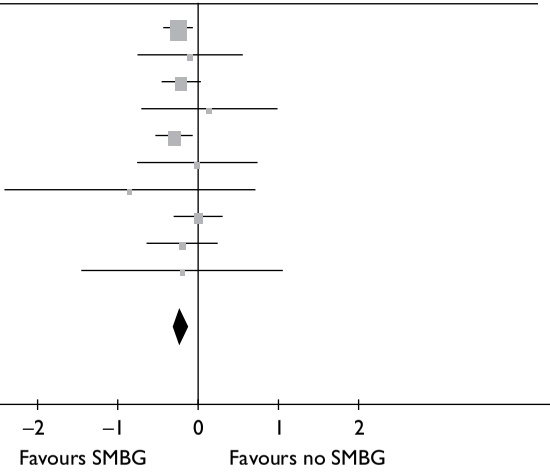

FIGURE 1 *Self-monitoring of blood glucose (SMBG) versus no SMBG – HbA_{1c}.*

Study or subgroup	SMBG Mean	SMBG SD	SMBG Total	SMUG Mean	SMUG SD	SMUG Total	Weight	Mean difference IV, Random, 95% CI
Allen (1990)[40]	10.4	2.9	27	9.7	2.6	27	15.0%	0.70 (−0.77 to 2.17)
Fontbonne (1989)[47]	7.84	2.5	68	8.47	2.5	72	34.7%	−0.63 (−1.46 to 0.20)
Miles (1997)[56]	8.8	1.9	68	8.7	1.7	82	50.3%	0.10 (−0.48 to 0.68)
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: $z = 0.20$ ($p = 0.84$)

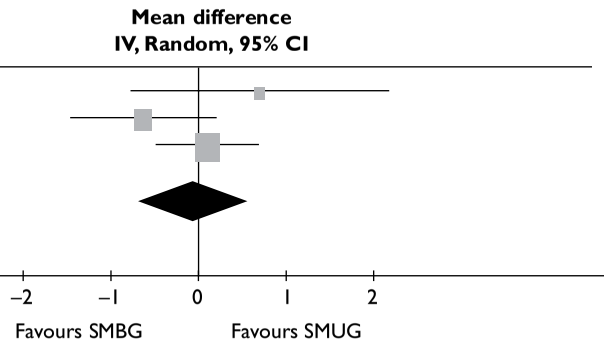

FIGURE 2 *Self-monitoring of blood glucose (SMBG) versus SMUG – HbA_{1c}.*

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Study or subgroup	SMBG plus Mean	SD	Total	SMBG Mean	SD	Total	Weight	Mean difference IV, Random, 95% CI
Education / feedback								
Bonomo (2006)[42]	7.6	0.73	177	7.78	1.05	96	27.3%	−0.18 (−0.42 to 0.06)
Cho (2006)[44]	6.7	0.9	40	7.4	1.3	40	14.4%	−0.70 (−1.19 to −0.21)
Estey (1990)[46]	5.6	0.7	28	5.8	1.5	25	10.0%	−0.20 (−0.84 to 0.44)
Farmer (2007)[10,11]	7.36	1.05	151	7.28	0.88	150	28.3%	0.08 (−0.14 to 0.30)
Kwon (2004)[55]	6.94	0.93	51	7.22	0.92	50	20.0%	−0.28 (−0.64 to 0.08)
Subtotal (95% CI)			**447**			**361**	**100.0%**	**−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: $z = 1.68$ ($p = 0.09$)								
Other (frequency / free strips)								
Johnson (2006)[51]	7.3	1.5	131	7.1	1.2	131	41.3%	0.20 (−0.13 to 0.53)
Scherbaum (2008)[59,60]	7.1	1	102	6.9	1	100	58.7%	0.20 (−0.08 to 0.48)
Subtotal (95% CI)			**233**			**231**	**100.0%**	**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: $z = 1.85$ ($p = 0.06$)								

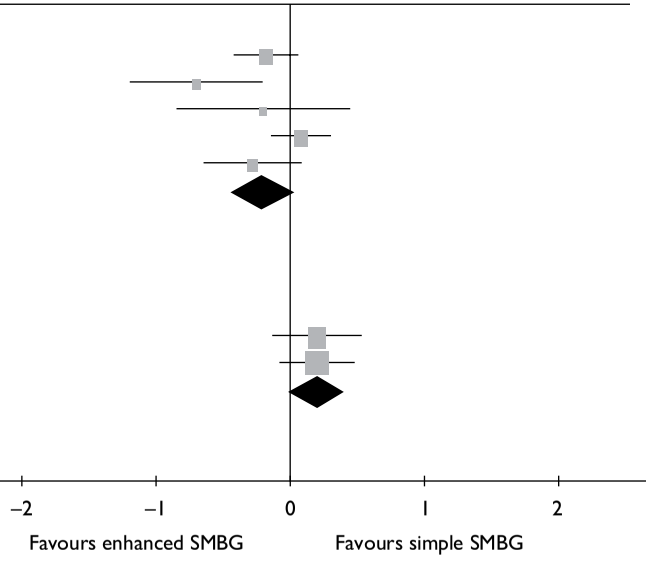

FIGURE 3 *Enhanced/more frequent SMBG versus only/less frequent SMBG – HbA_{1c}.*

Study or subgroup	SMBG plus Mean	SD	Total	Nothing Mean	SD	Total	Weight	Mean difference IV, Random, 95% CI
Brown (2002)[43]	10.89	2.56	126	11.64	2.85	125	21.9%	−0.75 (−1.42 to −0.08)
Farmer (2007)[10,11]	7.36	1.05	151	7.49	1.2	152	36.1%	−0.13 (−0.38 to 0.12)
Jaber (1996)[50]	7.6	1.48	17	9.65	2.61	22	9.7%	−2.05 (−3.35 to −0.75)
Schwedes (2002)[61]	7.47	1.27	113	7.81	1.52	110	32.3%	−0.34 (−0.71 to 0.03)
Total (95% CI)			**407**			**409**	**100.0%**	**−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: $z = 2.20$ ($p = 0.03$)								

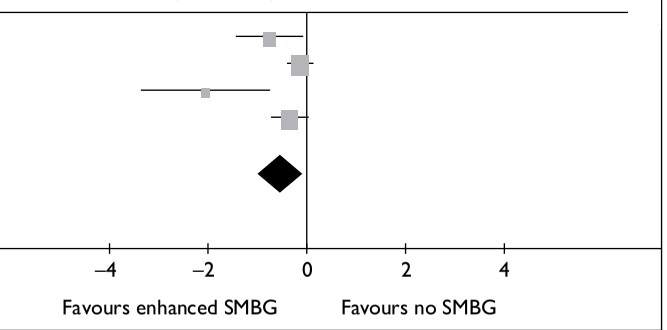

FIGURE 4 *Enhanced SMBG versus no SMBG – HbA_{1c}.*

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 HbA_{1c}, 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 HbA_{1c} level dependent on baseline HbA_{1c} level for all trials considered together. The graphs suggest that while both control groups and intervention groups showed a decrease in HbA_{1c} level, which was larger with high baseline HbA_{1c} values than with low baseline HbA_{1c} 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 HbA_{1c} 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 trial[10] 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 DiGEM[10] trial and the ESMON[13] 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 SMBG[20,61] 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 HbA_{1c} 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 HbA_{1c} level with SMBG, while 12 studies found a positive effect of SMBG on HbA_{1c} level, whereas another six showed favourable effects of SMBG on HbA_{1c} level, depending on treatment (especially in insulin-treated patients) or entry HbA_{1c} level (especially with higher entry HbA_{1c} level). Two studies reported on mortality and morbidity, with the ROSSO Study[15,78,99] (Germany) finding that SMBG was associated with lower morbidity and mortality, while the Fremantle Diabetes Study[17,19]

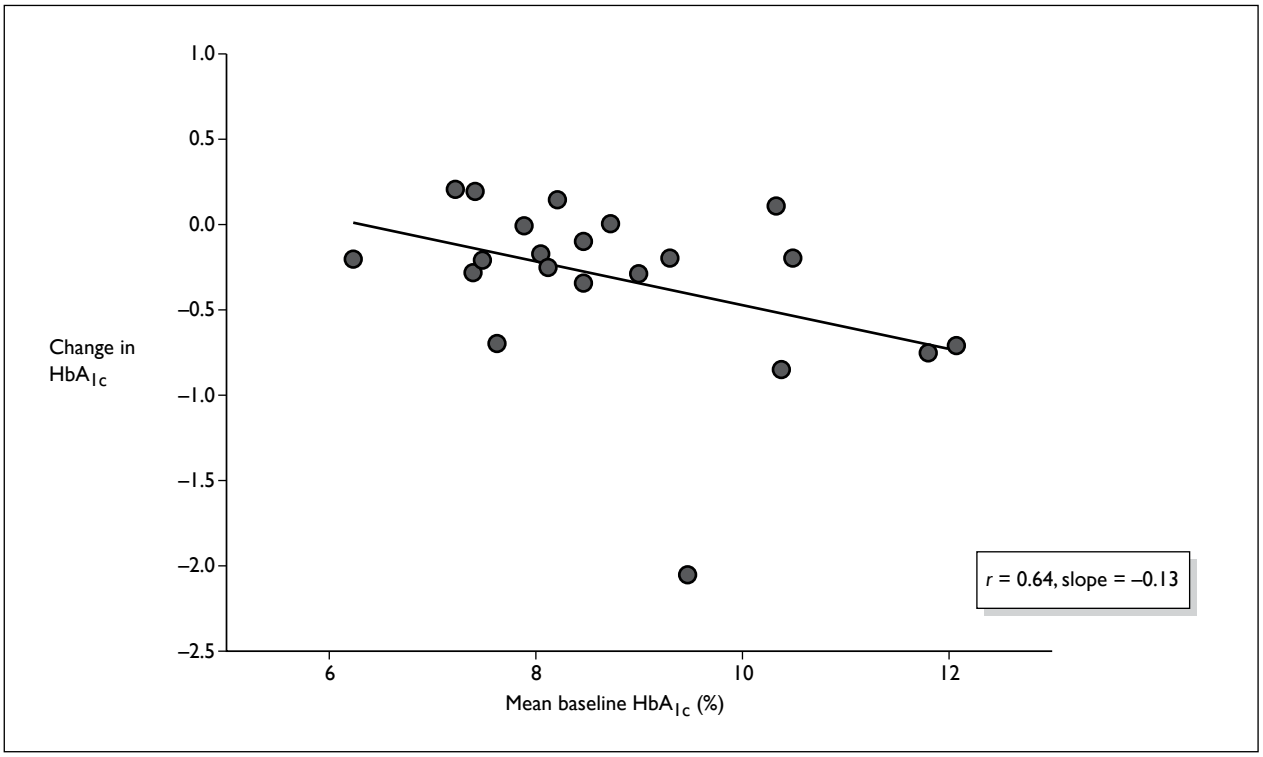

FIGURE 5 *Treatment difference as a function of mean baseline HbA_{1c}.*

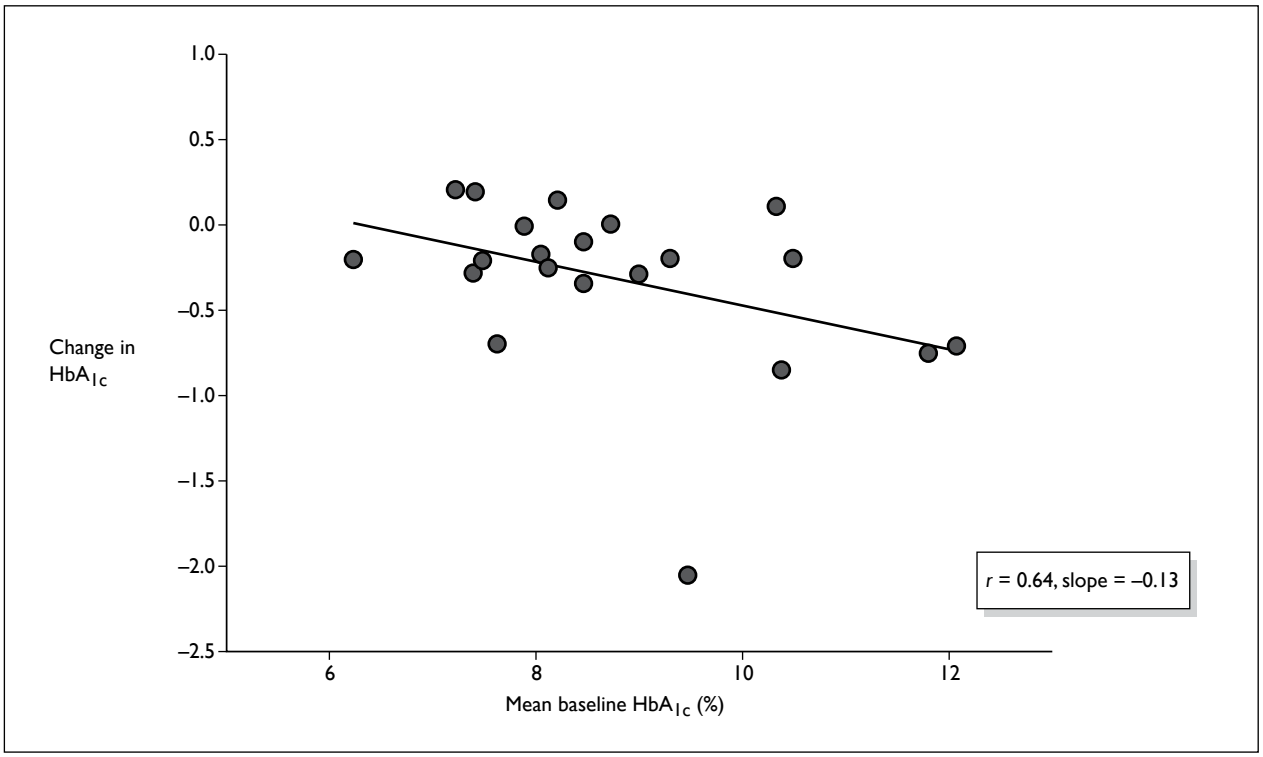

FIGURE 6 *Change from baseline as a function of baseline HbA_{1c} (control group).*

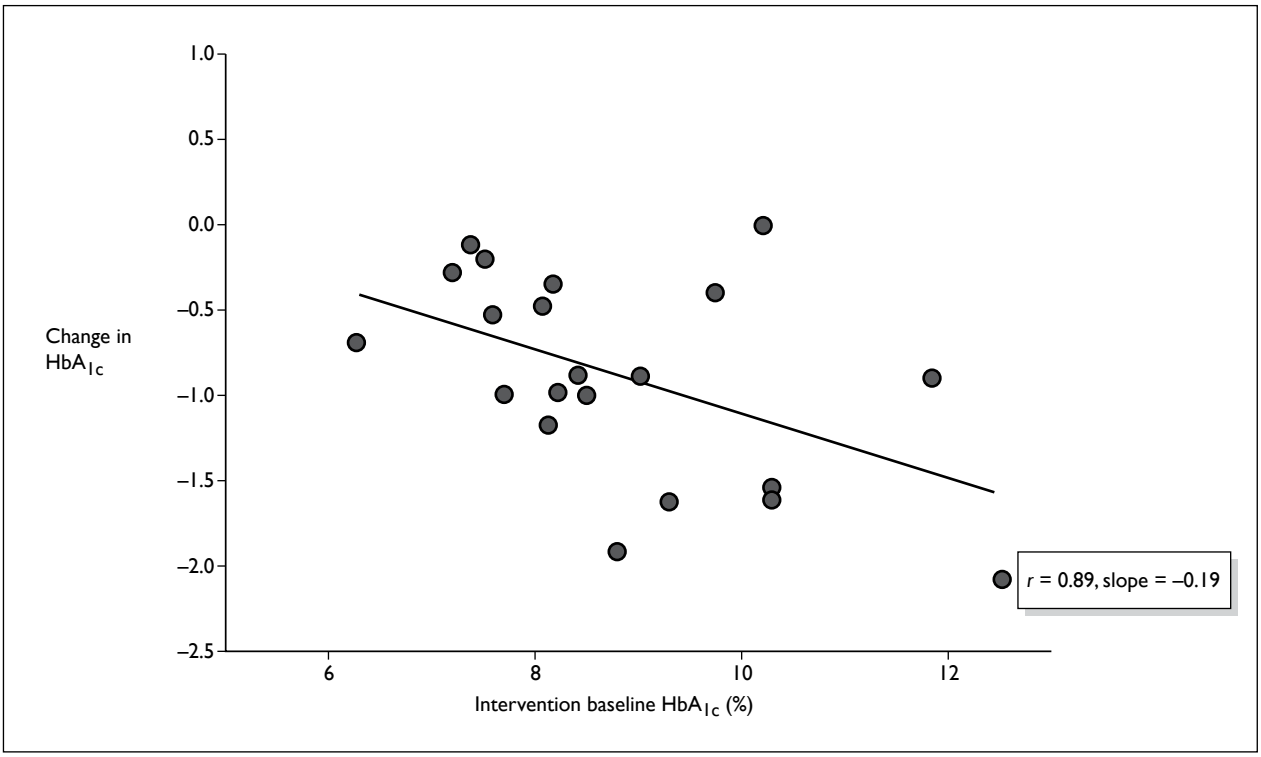

FIGURE 7 *Change from baseline as a function of baseline HbA_{1c} (intervention group).*

(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),[100] DiGEM RCT questionnaire and qualitative components,[10,11] Lawton *et al*. (2004),[6] Peel *et al*. (2004),[101] Peel *et al*. (2007)[102] and Zgibor and Simmons (2001).[103] 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,[71,100] 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.[101] Peel *et al.* (2007)[102] reported that reasons for discontinuation of SBMG 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 results and what to do with that information, for example how to respond to high readings, was reported in a number of studies.[18,100,102,104] 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.[100,102,104] In the UK, few patients use SMBG to guide and maintain changes to their behaviour and lifestyle,[100] 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)[8] reported that a patient who uses SMBG on a regular basis may believe the number on the glucose meter reflects 'the truth', even although 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)[69] 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*

Study	Focus	SMBG method	Education/ counselling	Starting HbA_{1c}	Age	Treatment	Diabetes duration	Results
Bajkowska-Fiedziukiewicz (2008)[64]	Association between SMBG use and HbA_{1c}	Reported	Yes	7.5	63	Oral, insulin	11	HbA_{1c}: NS
Banister (2004)[65]	Association between SMBG use and HbA_{1c}	Reported	Yes	9.7	49	Unclear	NR	HbA_{1c}: reduced
Blonde (2002)[66]	Association between SMBG use and HbA_{1c}	NR	NR	NR	35–65	Diet, oral, insulin	NR	Higher % with HbA_{1c} under 7% with more frequent SMBG
Capelson (2006)[67]	Association between SMBG use and HbA_{1c}	NR	NR	7.6	80	Insulin	21	HbA_{1c}: NS
Chan (2000)[68]	Association between SMBG use and HbA_{1c}	NR	NR	NR	53	NR	NR	HbA_{1c} 0.7% lower with more frequent SMBG
Evans (1999)[69]	Association between SMBG use and HbA_{1c}	NR	NR	NR	NR	Insulin	NR	HbA_{1c}: NS
Franciosi (2001)[70]	Association between SMBG use and HbA_{1c}	NR	NR	7.3	63	Diet, oral, insulin	NR	HbA_{1c} higher with more SMBG, lower when insulin could be adjusted
Franciosi (2005)[71]	Association between SMBG use and HbA_{1c}	NR	NR	7–7.3	62	Diet, oral	9.1	HbA_{1c}: NS
Fremantle Diabetes Study [Davis (2007)[17,19]]	Association between SMBG use and HbA_{1c}	NR	NR	7.4	65	Diet, oral, insulin	NR	HbA_{1c}: NS Mortality: NS SMBG: less retinopathy
Hanninen (2001)[72]	Association between SMBG use and HbA_{1c}	NR	NR	NR	63	Diet, oral, insulin	NR	HbA_{1c} higher with more SMBG
Harris (2001)[73]	Association between SMBG use and HbA_{1c}	NR	NR	7.6	63	Diet, oral, insulin	NR	HbA_{1c}: NS
Jaworska (2004)[74]	Association between SMBG use and HbA_{1c}	NR	NR	NR	62	Diet, oral, insulin	NR	HbA_{1c}: NS
Karter (2001)[75]	Association between SMBG use and HbA_{1c}	NR	NR	8.4	60	Diet, oral, insulin	0 to > 10	HbA_{1c} 0.6% lower with more SMBG in those on oral drugs
Karter (2005)[76]	Association between SMBG use and HbA_{1c}	NR	NR	9.9	60	Diet, oral, insulin	NR	5% more under 7% HbA_{1c} with more SMBG
Karter (2006)[14]	Association between SMBG use and HbA_{1c}	NR	NR	6.4	60	Diet, oral, insulin	NR	Lower HbA_{1c} with more SMBG
Klein (1993)[77]	Association between SMBG use and HbA_{1c}	NR	NR	NR	62	Diet, oral, insulin	NR	HbA_{1c}: NS
Meier (2002)[79]	Reduced access test strips	NR	NR	NR	64	Diet, oral	NR	No change in HbA_{1c} after SMBG reduction
Mitchell (2004)[80]	Association between SMBG use and HbA_{1c}	NR	NR	NR	64	Diet, oral	NR	HbA_{1c}: NS

Study	Focus	SMBG method	Education/ counselling	Starting HbA_{1c}	Age	Treatment	Diabetes duration	Results
Murata (2003)[81]	Intensified SMBG	NR	NR	8.1	48	Insulin	NR	Lower HbA_{1c} (by 0.3%) with more SMBG (depending on entry HbA_{1c})
Murata (2009)[82]	Association between SMBG use and HbA_{1c} and medication change	NR	NR	NR	59	Oral	NR	HbA_{1c} NS overall, lower HbA_{1c} with more SMBG in specified treatment groups
Newman (1990)[83]	Association between SMBG use and HbA_{1c}	NR	NR	NR	60	Diet, oral, insulin	NR	HbA_{1c}: NS
Oki (1997)[84]	Association between SMBG use and HbA_{1c}	NR	NR	NR	56	Diet, oral, insulin	NR	HbA_{1c}: NS
Ozmen (2003)[85]	Association between SMBG use and HbA_{1c}	Yes	NR	9.1	58	Diet, oral, insulin	8.6	HbA_{1c} reduced by 1.9% with SMBG
Patrick (1994)[86]	Association between SMBG/ SMUG use and HbA_{1c}	NR	NR	NR	65	Sulphonylurea	NR	HbA_{1c}: NS
Rindone (1997)[87]	Access strips vs no access	NR	NR	8.1	68	Sulphonylurea	NR	HbA_{1c}: NS
Roblin (2001)[88]	Association between SMBG use and HbA_{1c}	NR	NR	NR	53	Diet, oral, insulin	12	Lower HbA_{1c} with SMBG in insulin-treated but not non-insulin treated
ROSSO study [Martin (2006)[15]]	Association between SMBG use and morbidity/mortality	NR	NR	7.7	63	Diet, oral, insulin	0	Morbidity and mortality lower with SMBG
Rost (1990)[89]	Association between SMBG use and HbA_{1c} in insulin users and non-insulin users	NR	NR	NR	56	Oral, insulin	0	Lower HbA_{1c} with SMBG
Schiel (1999)[90]	Association between SMBG use and HbA_{1c}	NR	NR	NR	NR	Insulin	NR	Lower HbA_{1c} with more SMBG
Schütt (2006)[91]	Association between SMBG use and HbA_{1c}	NR	NR	7.6	NR	Diet, oral, insulin	10	Lower HbA_{1c} with more SMBG
Secnik (2007)[92]	Access-free blood glucose monitors	NR	NR	NR	20 to >65	Oral, insulin	NR	Lower HbA_{1c} with more SMBG only in insulin-treated patients, not with oral
Soumerai (2004)[93]	Access-free blood glucose monitors	NR	NR	8.4	56	Oral, insulin	NR	Lower HbA_{1c} with more SMBG only for those with higher initial HbA_{1c}
Stiptzarov (2003)[94]	Association between SMBG use and HbA_{1c}	NR	NR	NR	65	NR	NR	Lower HbA_{1c} with more SMBG
Tengblad (2007)[95]	Association between SMBG use and HbA_{1c}	NR	NR	5.4–6.9	69	Diet, oral, insulin	87%, >4	HbA_{1c}: NS
Wen (2004)[16]	Association between SMBG use and HbA_{1c}	NR	NR	7.2	63	Oral	NR	HbA_{1c}: NS
Wieland (1997)[96]	Association between SMBG use and HbA_{1c}	NR	NR	7.9	39–89	Sulphonylurea	NR	HbA_{1c}: NS

NR, not reported; NS, not significant.

TABLE 8 *Summary of messages from qualitative studies*

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

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 CG66[9] 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 HbA_{1c} 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)[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[108] 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)[100] 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 26% 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)[109] used the results of the German ROSSO[15] 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 (90 Swiss francs) [£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. Tiley[110] 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 HbA_{1c} 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 HbA_{1c} level of 7.83%. Subsequent to implementation an average 0.74 strips were being used, with a non-statistically significant change in average HbA_{1c} 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 HbA_{1c} 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 ROSSO[15] 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 DiGEM[10] 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[37] in patients with T2DM not using insulin found two relevant papers[57,61] for assessing the QoL impacts of SMBG. Muchmore *et al.* (1994)[57] 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)[61] 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)[70] 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)[11] undertook a cost–utility study using the results of the UK DiGEM trial, comparing the costs and effects among the DiGEM[10] 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)[12] paper, and, in line with this, considered the three comparators of:

- more intensive SMBG, through which the average HbA_{1c} level fall was –0.17%
- less intensive SMBG, through which the average HbA_{1c} level fall was –0.14%
- standardised usual care, through which there was no impact on HbA_{1c} 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 HbA_{1c} 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.[112] 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*;[113] the *Annual financial returns of NHS trusts 2003–2004*;[114] and the PSSRU *Costs of Health and Social Care 2002*,[115] with these being inflated to 2005–6 costs using the Department of Health Pay and Prices Inflation Indices.[113]

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.

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 HbA_{1c} level was assumed to fall by 1.02%
- once daily SMBG, through which average HbA_{1c} level fell by 0.32%
- no SMBG, through which average HbA_{1c} level rose by 0.13%.

Clinical effectiveness estimates in terms of the HbA_{1c} effect were drawn from the large 3-year Kaiser Permanente Healthcare Group observational study among 30,000 patients, with the HbA_{1c} 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.

The changes in HbA_{1c} level were assumed to be maintained for the duration of the modelling. Patients had an average age of 63 years, with the model time horizon of 40 years consequently, and effectively, being a lifetime horizon. Costs were inflated to 2006 prices, with costs and benefits being discounted at 3%. It was assumed that after 5 years patients would switch to insulin.

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 HbA_{1c} 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 HbA_{1c} value assumed by Tunis and Minshall, and that the effect of SMBG would be, in all likelihood, different for different baseline levels of HbA_{1c}. Note also that an abstract

of a cost-effectiveness study, undertaken by Tunis,[119] of SMBG among patients with T2DM, using the same clinical data source as her 2008[116] paper, reported a considerably worse cost-effectiveness ratio than those reported above.

Palmer *et al.* (2006),[22] 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 HbA_{1c} 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)[75] study, as reported above for the Tunis and Minshall (2008) paper,[116] though within an alternative patient grouping. Palmer *et al.* (2006)[22] 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),[116] Palmer *et al.* (2006)[22] also assumed that the benefit in terms of improved HbA_{1c} 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 [£142] for those on diet and exercise, £247 [£283] for those on oral agents and £371 [£425] 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 [£2934], £1013 [£1160] and £1171 [£1340], respectively. This resulted in cost-effectiveness estimates for SMBG compared with non-SMBG of:

- £15,515 [£17,760] per QALY for those on diet and exercise
- £4508 [£5160] per QALY for those on oral antidiabetic drugs
- £4593 [£5257] per QALY for those on insulin.

As in the Tunis and Minshall (2008) paper,[116] Palmer *et al.* (2006)[22] found results to be sensitive to a shorter time horizon. Reducing this to 10 years resulted in estimates of cost-effectiveness of £74,528 [£85,311] per QALY for those on diet and exercise; £33,742 [£38,624] per QALY for those on oral antidiabetic drugs; and £11,082 [£12,685] per QALY for those on insulin. An assumption of the HbA_{1c} benefit only lasting for 5 years also worsened cost-effectiveness ratios among the three patient groups: £25,802 [£29,535] per QALY; £9141 [£10,464] per QALY; and, £9909 [£11,342] 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 [£39,216] 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 [£7996] and £6586 [£7539] per QALY.

Cost-effectiveness: abstracts

Tunis (2009)[119] reported the results of further cost-effectiveness modelling using data from the Kaiser Permanente Healthcare Group observational study as for her 2008 paper.[116] 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.[116]

- 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),[120] 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 HbA_{1c} 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)[121] reported the outcome of modelling of 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)[116] full paper and the Tunis (2009)[119] 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$6530 [£3424] 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)[122] 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)[123] 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 HbA_{1c} level reported in the Sarol meta-analysis.[34] Given a frequency of seven times per week, the impact on HbA_{1c} 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.*[34,39] 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),[124] in a letter, reported undertaking a Markov modelling exercise of the cost-effectiveness within the German health-care system using a 0.39% HbA_{1c} level reduction from SMBG among non-insulin-using patients with T2DM, the reduction being derived from the Welschen *et al.* (2005)[36] meta-analysis. No other details are provided as to the modelling inputs or the model used, but they report an anticipated 0.083 years' additional life expectancy and a cost per life-year of ~€31,000 [£23,191]. Davidson (2006),[125] in a response to this, highlighted the anticipated gain estimated by Neeser *et al.* (2006)[124] being only 30 days, and that the estimate of a reduction in HbA_{1c} 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 HbA_{1c} 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.*,[10,11] 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,[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 *et al.* (2009)[100] of about £10 per year for infrequent testers on diet alone, to £259 in the Palmer *et al*. (2006) study.[22]

Several studies assert that SMBG can lead to savings that offset testing costs, for example Weber *et al.* (2007)[122] estimate the additional costs to be £39 annually but that taking avoided events into account gives an average annual saving of £222. Meier *et al.* (2002)[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[10] group and Franciosi *et al*. (2001).[70]

The cost-effectiveness analyses vary in their assumptions, with those funded by industry being more optimistic in the size of gains in HbA_{1c} level, and hence producing lower incremental cost-effectiveness ratios (ICERs). The best analysis to date is that of Farmer *et al.* (2009)[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.

Chapter 4
Discussion

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 HbA_{1c} level. However, it is notable that the latter usually find small differences in HbA_{1c} level ranging from improvements of 0.16%[35]–0.42%.[34] It is also noteworthy that the effects sizes are smaller in the later reviews with more trials – for example 0.24%,[33] 0.16%[35] and 0.22%[38] compared with 0.42%,[34] 0.39%[37] and 0.41%.[31]
- There is also lack of agreement on what is a clinically significant difference in HbA_{1c} 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)[126] 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 HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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)[32] concluded that SMBG may not be helpful or economically justified in all cases, but that individuals would benefit if:

- their baseline HbA_{1c} 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)[127] 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,[20] 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),[128] which emphasises a positive attitude. The control group was given meters, strips and instructions in use. While there was no significant difference in absolute HbA_{1c} 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 HbA_{1c} 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.*,[21,61] 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 HbA_{1c} 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 HbA_{1c} 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).[70] There was no association of SMBG frequency with HbA_{1c} 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 HbA_{1c} levels: 'costs too much', 'hassle', 'depression interferes', 'don't understand', 'don't like', 'it hurts' and 'don't know how to use the results'.[129]

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.[130]

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,[21,61] increased self-efficacy may therefore lead to feeling more in control, less burdened and less depressed.[131]

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)[100] 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),[79] 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 HbA_{1c} 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.*[10,11] 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 HbA_{1c} 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.[132] 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)[106] 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 it clinical efficacy'. Their review provides a useful history of SMBG and the technical aspects.

One issue raised by O'Kane and Pickup (2009)[106] 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.[98] 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

BOX 1 *The IQWiG report*

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 HbA_{1c} 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 HbA_{1c} 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.

BOX 2 *International Diabetes Federation recommendations (abbreviated)*

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 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 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 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 HbA_{1c} to see which is better after 1 year. There are four arms: SMBG, 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.[139]

In the USA, Bergenstal *et al.*[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.

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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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:

- The clinical effectiveness and cost-effectiveness of inhaled insulin in diabetes mellitus: a systematic review and economic evaluation. *Health Technol Assess* 2007;**11**(33).
- Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation. *Health Technol Assess* 2009; in press.
- Screening for type 2 diabetes: literature review and economic modelling. *Health Technol Assess* 2007;**11**(17).
- Non-pharmacological prevention of diabetes in those with impaired glucose tolerance. In preparation.
- Newer agents for blood glucose control in type 2 diabetes. *Health Technol Assess* 2010; in press.

We also do Cochrane reviews on diabetic topics.

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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:

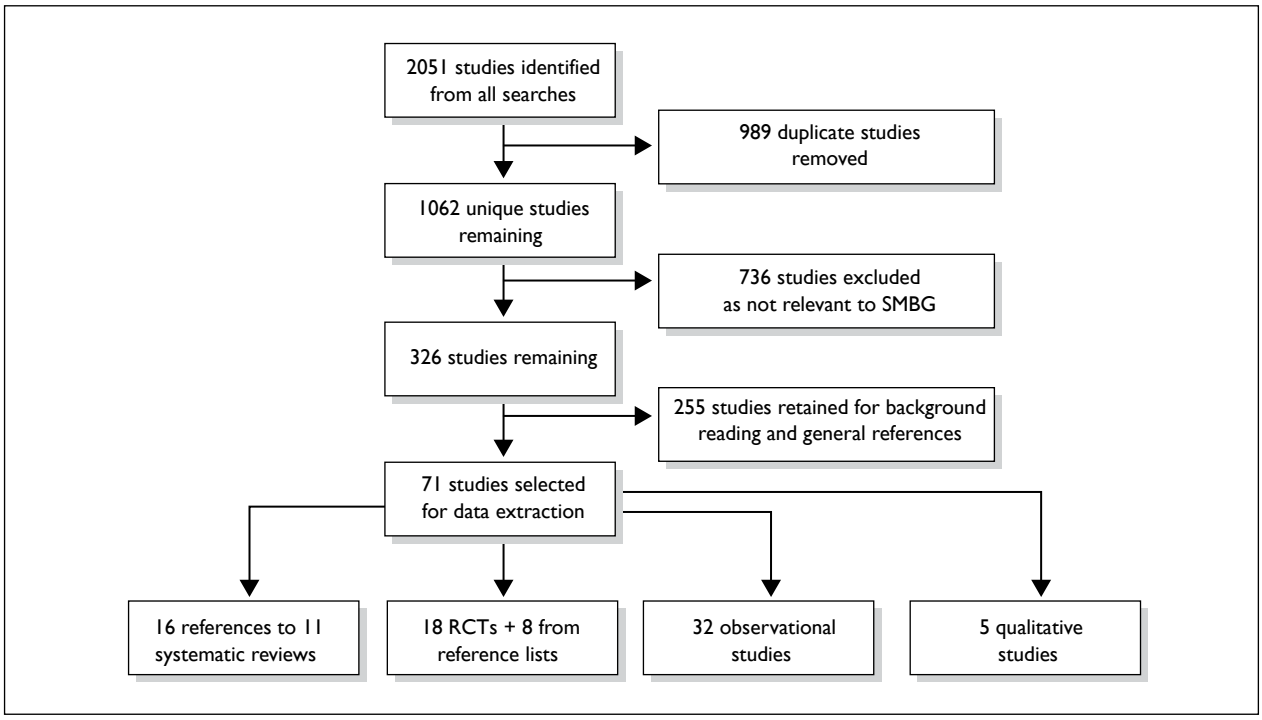
1. (self monitor* adj3 blood glucose).tw.
2. (home monitor* adj3 blood glucose).tw.
3. (HMBG or HBGM or SMBG or BGSM).tw.
4. exp Blood Glucose Self-Monitoring/
5. (glucose adj2 monitor* adj3 (self or home)).tw.
6. 4 or 1 or 3 or 2 or 5
7. exp Diabetes Mellitus, Type 2/
8. type 2 diabetes.tw.
9. 8 or 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

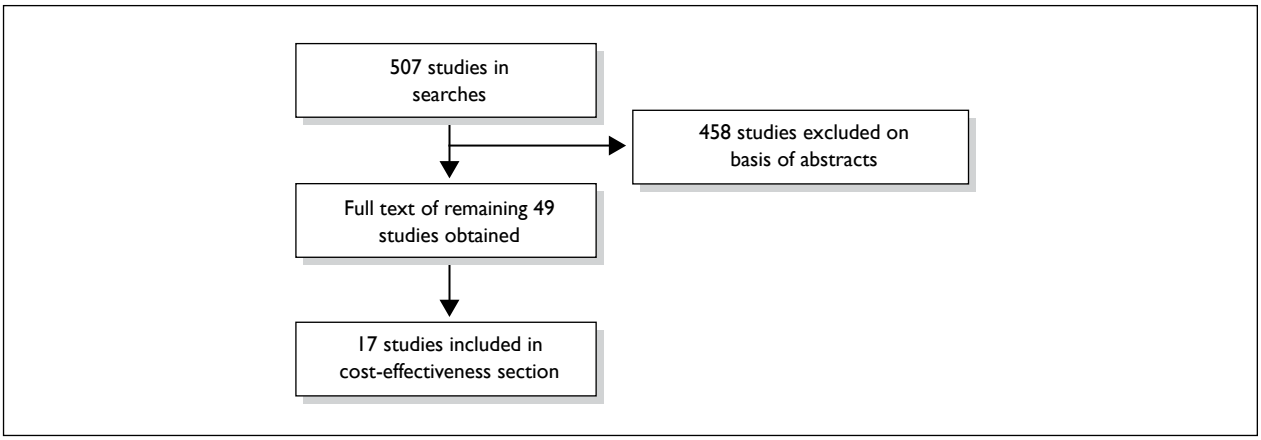
The MEDLINE strategy below was used and adapted as appropriate for other databases:

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



Flow of studies for SMBG cost-effectiveness search



Appendix 2

Characteristics of systematic reviews

Review	Inclusion criteria and methodology	Included studies	Quality
Faas (1997)[30] Netherlands *Focus*: efficacy of self-monitoring of blood glucose in patients with non insulin-dependent diabetes mellitus *Funding*: not reported	**Inclusion criteria** *Study design*: unclear; non-RCTs included initially, but only RCTs investigated in more detail *Participants*: T2DM; studies exclusively with patients using insulin excluded *Interventions*: SMBG; any comparison *Outcomes*: HbA_{1c}; other outcomes as reported **Methodology** *Search strategy*: MEDLINE (1976–1996); keywords given; bibliographies searched *Study selection*: method not reported *Quality assessment*: criteria by Deyo and ter Riet *Data extraction*: method not reported *Meta-analysis*: no *Data analysis*: text and tables *Subgroups/sensitivity analyses*: none	*Number of included trials*: 11; 6 RCTs, 5 non-RCTs not further evaluated *Number of participants*: 592 TRIALS: *Design*: only RCTs further evaluated *Duration*: 12–62 weeks *Quality*: 4 RCTs 7/7 points, rest 3/7 and 4/7 PARTICIPANTS: see trial descriptions INTERVENTIONS: 4 only SMBG, 4 vs no SMBG, 3 vs urine testing; some interventions including education OUTCOMES: HbA_{1c}, weight, fasting glucose, lifestyle adherence, SMBG adherence, fructosamine	• *Inclusion criteria described*: yes • *Details of literature search given*: yes (limited) • *Study selection described*: no • *Data extraction described*: no • *Study quality assessment described*: yes • *Study flow shown*: yes, narratively • *Study characteristics of individual studies described*: yes (limited) • *Quality of individual studies given*: yes • *Results of individual studies shown*: yes • *Statistical analysis appropriate*: yes OVERALL QUALITY: moderate – limited description of methods and of study characteristics 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
Coster (2000)[29] UK – NHS HTA *Focus*: effectiveness of blood or urine glucose self-monitoring in T2DM *Funding*: NHS R&D HTA programme	**Inclusion criteria** *Study design*: RCTs *Participants*: T2DM; independent of treatment type *Interventions*: SMBG vs SMUG or no monitoring *Outcomes*: HbA_{1c}, weight, any other outcomes reported **Methodology** 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	*Number of included trials*: 8 *Number of participants*: 734 TRIALS: *Design*: RCTs *Duration*: 3–12 months *Quality*: mean quality score 15 of 27 PARTICIPANTS: see trial descriptions INTERVENTIONS: some interventions including education – see descriptions OUTCOMES: HbA_{1c}, fasting blood glucose, fructosamine, body weight, QoL	• *Inclusion criteria described*: yes • *Details of literature search given*: yes • *Study selection described*: no • *Data extraction described*: no • *Study quality assessment described*: yes • *Study flow shown*: yes • *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 – but some methodology not described (but probably HTA programme standard)

Review	Inclusion criteria and methodology	Included studies	Quality
	Study selection: method not reported *Quality assessment*: modified quality checklist by Downs and Black (1998);[141] applied by two reviewers independently *Data extraction*: method not reported *Meta-analysis*: yes *Data analysis*: random effects model; heterogeneity assessed *Subgroups/sensitivity analyses*: sensitivity analyses used that did not change the overall results (based on study design and comparisons)		
Sarol (2005)[34,39] Philippines *Focus*: self-monitoring of blood glucose on HbA_{1c} in non-insulin-requiring patients with T2DM *Funding*: Johnson & Johnson	**Inclusion criteria** *Study design*: RCTs *Participants*: T2DM without insulin treatment *Interventions*: diabetes management strategy with SMBG component vs strategy without SMBG component *Outcomes*: HbA_{1c} **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: HbA_{1c}	• *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

Review	Inclusion criteria and methodology	Included studies	Quality
Welschen (2005)[37] Netherlands *Focus*: effects of SMBG in patients with T2DM who are not using insulin *Funding*: non-commercial	**Inclusion criteria** Study design: RCTs Participants: T2DM; non-insulin treated Interventions: SMBG vs SMUG or no monitoring Outcomes: HbA_{1c}, FPG, QoL, patient satisfaction, hypoglycaemia, morbidity, adverse effects, costs **Methodology** *Search strategy*: MEDLINE, Cochrane Library, NHS Economic Evaluation database, EMBASE, ongoing trials, reference lists; search dates up to September 2004; electronic search strategy given; no language restriction *Study selection*: titles and abstracts independently assessed by two reviewers *Quality assessment*: Maastricht–Amsterdam score; assessed independently by two reviewers *Data extraction*: data extraction form; data extracted independently by two reviewers *Meta-analysis*: no for Cochrane review/yes for published paper *Data analysis*: random effects model, heterogeneity assessed *Subgroups/sensitivity analyses*: planned but not carried out	*Number of included trials*: 6 *Number of participants*: 1285 TRIALS: *Design*: RCTs *Duration*: 6 months to 44 weeks *Quality*: 1 trial 7/11, 1 trial 6/11, 4 trials 5/11 PARTICIPANTS: see trial descriptions INTERVENTIONS: education on diet and lifestyle reported by one study OUTCOMES: glycaemic control – HbA_{1c} and/or fasting glucose, QoL – SF-36, well-being, patient satisfaction – DTSQ, hypoglycaemic episodes, morbidity, adverse effects, costs, weight	• *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
Jansen (2006)[31] Netherlands *Focus*: relative effectiveness of interventions with SMBG and SMUG vs interventions without self-monitoring in terms of HbA_{1c} reductions in T2DM *Funding*: Roche Diagnostics	**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*: HbA_{1c} **Methodology** *Search strategy*: MEDLINE, EMBASE, Cochrane Library (1966–2005); keywords given; previous systematic reviews searched; English, German, French, Dutch *Study selection*: two reviewers independently checked identified studies against inclusion criteria *Quality assessment*: checklist by Downs and Black (1998);[141] assessed independently by two reviewers *Data extraction*: data extraction sheet; data extracted by two reviewers independently	*Number of included trials*: 13 *Number of participants*: 2092 TRIALS: *Design*: 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 INTERVENTIONS: some, but not all, studies used education component OUTCOMES: HbA_{1c}	• *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 COMMENT: compares SMBG with feedback with SMBG without feedback; outcomes only HbA_{1c}

Review	Inclusion criteria and methodology	Included studies	Quality
	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		
AHRQ (2007)[28] USA *Focus*: effect of frequency of glucose monitoring on clinical outcomes and HbA_{1c} 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*: HbA_{1c} **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 *Meta-analysis*: no *Data analysis*: text and tables *Subgroups/sensitivity analyses*: none	*Number of included trials*: 5 RCTs, 8 non-RCTs *Number of participants*: 2092 TRIALS: *Design*: RCTs and cohort studies (but some probably rather chart reviews etc.) *Duration*: RCTs 6–18 months, cohort up to 3 years *Quality*: not reported PARTICIPANTS: see trial details INTERVENTIONS: 1 out of 5 RCTs did not report on training on how to respond to readings OUTCOMES: HbA_{1c}	• *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

Review	Inclusion criteria and methodology	Included studies	Quality
McAndrew (2007)[2] USA *Focus*: to perform a comprehensive review of relevant studies of SMBG on HbA_{1c} levels in patients with T2DM and to explore mediators and moderators *Funding*: NIH	**Inclusion criteria** *Study design*: RCT, cross-sectional and longitudinal studies *Participants*: T2DM; non-insulin treated *Interventions*: SMBG, comparator unclear *Outcomes*: HbA_{1c} **Methodology** *Search strategy*: MEDLINE, PsycInfo, Cochrane Library, CINAHL (up to first quarter 2006); keywords given *Study selection*: unclear – by one reviewer only? *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 *Data extraction*: data extracted by one reviewer, checked by a second one *Meta-analysis*: no *Data analysis*: text and tables *Subgroups/sensitivity analyses*: none	*Number of included trials*: 29 (30, DiGEM added in addendum) *Number of participants*: 1759 RCTs, 36,091 non-RCTs TRIALS: *Design*: 9 cross-sectional, 9 longitudinal, 11 RCTs *Duration*: RCTs unclear, non-RCTs up to 3 years *Quality*: mean quality score 8.5 of 13 PARTICIPANTS: see trial descriptions INTERVENTIONS: some included education – see trial details OUTCOMES: depression, HbA_{1c}, QoL	• *Inclusion criteria described*: yes • *Details of literature search given*: yes • *Study selection described*: unclear • *Data extraction described*: yes • *Study quality assessment described*: yes • *Study flow shown*: yes • *Study characteristics of individual studies described*: yes (but limited) • *Quality of individual studies given*: no • *Results of individual studies shown*: yes • *Statistical analysis appropriate*: yes OVERALL QUALITY: moderate
McGeoch (2007)[32] UK *Focus*: effect of SMBG on HbA_{1c} *Funding*: non-commercial	**Inclusion criteria** *Study design*: RCTs and observational studies; at least 50 patients, FU at least 6 months *Participants*: T2DM; non-insulin treated *Interventions*: SMBG, comparator unclear *Outcomes*: HbA_{1c} and diabetes-related morbidity **Methodology** *Search strategy*: PubMed, EMBASE, Cochrane Library, MEDLINE; search dates: Jan 1990–Nov 2006; Google and Google Scholar; keywords given; no language restrictions *Study selection*: no details of methods *Quality assessment*: 1–5 score quality scale *Data extraction*: two reviewers independently extracted information; items listed *Meta-analysis*: no *Data analysis*: text and tables *Subgroups/sensitivity analyses*: none	*Number of included trials*: 16 *Number of participants*: 1000 in RCTs, >60,000 in observational TRIALS: *Design*: 3 RCTs, 13 observational *Duration*: RCTs 6–12 months, observational up to 6.5 years *Quality*: RCTs 1 or 2 of 5 points PARTICIPANTS: see trial info 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 OUTCOMES: HbA_{1c}, frequency of SMBG, weight, BMI, medication use, adverse effects (including diabetic complications)	• *Inclusion criteria described*: yes • *Details of literature search given*: yes • *Study selection described*: no • *Data extraction described*: yes • *Study quality assessment described*: yes • *Study flow shown*: no • *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: moderate/high

Review	Inclusion criteria and methodology	Included studies	Quality
Poolsup (2008)[33] Thailand *Focus*: effects of SMBG on glycaemic control in non-insulin-treated patients with T2DM *Funding*: not reported	**Inclusion criteria** *Study design*: RCTs *Participants*: T2DM; non-insulin treated *Interventions*: SMBG vs no SMBG *Outcomes*: HbA_{1c} reported as outcome measure **Methodology** *Search strategy*: MEDLINE, EMBASE, Cochrane Library; search dates: inception to September 2007; keywords given; reference lists of reviews and trials searched; no language restriction *Study selection*: studies selected by two reviewers, differences settled by consensus *Quality assessment*: quality assessed using Maastricht–Amsterdam score and the Delphi list; done independently by two reviewers *Data extraction*: items listed, extracted independently by two reviewers *Meta-analysis*: yes *Data analysis*: random and fixed-effects model; heterogeneity assessed, funnel plot *Subgroups/sensitivity analyses*: use of SMBG to modify treatment vs no use of SMBG to modify treatment	*Number of included trials*: 7 RCTs *Number of participants*: 1625 TRIALS: *Design*: all RCTs *Duration*: 4–12 months *Quality*: 5/7 high quality, 2/7 low quality PARTICIPANTS: see trial details INTERVENTIONS: some including education/counselling – see trial details OUTCOMES: 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	• *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
Towfigh (2008)[35] USA *Focus*: effect of SMBG in patients withT2DM *Funding*: non-commercial	**Inclusion criteria** *Study design*: RCTs and CCTs; FU at least 12 weeks *Participants*: T2DM *Interventions*: SMBG alone or as part of multicomponent intervention vs no SMBG Outcomes: HbA_{1c} **Methodology** *Search strategy*: PubMed; Welschen search strategy updated to July 2007; keywords given; bibliographies/systematic reviews searched *Study selection*: titles independently assessed by two reviewers *Quality assessment*: Delphi list *Data extraction*: data extraction form; data extracted independently by two reviewers *Meta-analysis*: yes *Data analysis*: random effects mode; baseline HbA_{1c}; heterogeneity assessed *Subgroups/sensitivity analyses*: meta-regression on treatment frequency, quality score	*Number of included trials*: 9 *Number of participants*: 1862 TRIALS: *Design*: all RCTs *Duration*: 6 months to 62 weeks *Quality*: quality variable, most trials scored positively on less than half of the criteria of the Delphi list PARTICIPANTS: see trial details INTERVENTIONS: all patients with T2DM treated without insulin except one study OUTCOMES: HbA_{1c}, hypoglycaemia, fasting glucose, BMI/weight loss, health-related QoL	• *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 • *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/moderate – criteria fulfilled, but some information somewhat limited

Review	Inclusion criteria and methodology	Included studies	Quality
St John (2009)[38] 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_{1c} as primary outcome measure *Outcomes*: HbA_{1c}, 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_{1c}, 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 shown*: yes • *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

Trial – design	Participants	Intervention	Results
Allen (1990)[40] 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_{1c}*: 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*: Chemstrips 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_{1c} 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_{1c}, weight, FPG, use of oral medications, duration of diabetes, ethnicity did not predict improved glucose control
Barnett (2008)[41] 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^2 *HbA_{1c}*: 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 meals 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_{1c} 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	Intervention	Results
• *allocation concealment*: yes • *outcome assessment blinded*: unclear • *adequate power*: yes • *withdrawals/losses to FU described*: yes (14%) • *ITT analysis*: yes • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: industry OVERALL QUALITY: high	*Treatment*: 70–74% previously treated with oral glucose lowering agent (43% biguanide, 46–50% insulin secretagogue) (the rest diet only)	*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) *Outcomes*: HbA_{1c}, hypoglycaemia, FPG, adverse events, weight	• 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. COMMENT: study tried to ensure that treatment of the two groups apart from SMBG was identical (i.e. identical counselling, identical medication, no therapy adjustment based on SMBG results, either requested by the patient or initiated by the care provider); while the usefulness of this in practice is debatable, it argues that the fact that, nevertheless, a reduction in HbA_{1c} was observed demonstrates that the use of meal-based SMBG may enable patients to observe the effects of their food choices and motivate them to avoid problem foods, increase physical activity to manage hyperglycaemic excursions or evaluate and adjusted doses of antidiabetic agents (however, these behaviours were not reported)
Bonomo (2006)[42] Italy (abstract) Follow-up: 6 months 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	*Total number*: 273 *Inclusion criteria*: T2DM, stable HbA_{1c} within last 6 months, already on SMBG, not on insulin *Age*: mean 63–66 years *BMI*: mean 28–29 kg/m^2 *HbA_{1c}*: 8.0–8.1% *Diabetes duration*: 10.6 years *Treatment*: not reported	*SMBG regimen*: group A – one BG profile (fasting, 2 hours after breakfast, 2 hours after lunch, 2 hours after dinner) per month vs 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 vs 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*: HbA_{1c}, BG, therapeutic changes	• No change in HbA_{1c} in group A (baseline 7.97% vs 7.78% at 6 months) but significant decrease in HbA_{1c} in group B (baseline 8.1% vs 7.6% at 6 months; $p = 0.001$) • Therapeutic changes at 3-month visit were more frequent in group B (44.9%) than group A (32.8%)

Trial – design	Participants	Intervention	Results
Brown (2002)[43] *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	*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 *HbA_{1c}*: 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)	*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 *SMBG method*: no further details on SMBG given *Education*: yes (intervention only) *Control*: waiting list with usual care *Adherence assessment*: not reported *Outcomes*: HbA_{1c}	• HbA_{1c} 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)[44] 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	*Total number*: 80 patients with T2DM *Age*: 51–55 years *BMI*: 23–24 kg/m^2 (Asian population!) *HbA_{1c}*: 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 dietitian 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: HbA_{1c}, HbA_{1c} fluctuation index	*After 30 months*: • HbA_{1c} level significantly lower in intervention group than in control group (6.7 ± 0.9% vs 7.4 ± 1.3%, $p = 0.009$) • HbA_{1c} 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)[45] USA *Follow-up*: 6 months *Quality*: • *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 OVERALL QUALITY: high/moderate	*Total number*: 88 (43/45) *Inclusion criteria*: patients with T2DM on oral antidiabetic treatment *Age*: 50 years *BMI*: 32.2 kg/m^2 *HbA$_{1c}$*: I: 8.4 (SD 2.1), C: 8.5 (SD 2.2) *Diabetes duration*: 5.6 years *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* ($n = 43$): SMBG 6 days per week before and after each meal (6 times per day) *SMBG other*: five dietitian visits *SMBG method*: NR *Use of therapy decision scheme*: yes *SMBG instruction*: NR *SMBG accuracy checks*: 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) *Assessment of monitoring frequency*: *Feedback on SMBG*: *SMBG treatment adjustment/advice*: did not report training on how to respond to readings; nurse followed detailed algorithm to make therapeutic decisions (to achieve HbA$_{1c}$ goal of < 7.5%) *Control* ($n = 45$): regular HbA$_{1c}$ determination every 2 months by a physician; 5 dietitian visits *Adherence assessment*: patients performed an average of 45% of required tests *Outcomes*: HbA$_{1c}$, BMI/weight loss	• Fall in HbA$_{1c}$ in both groups significant but no significant difference between groups • No significant difference in weight or BMI • No significant difference in medication at study end

Trial – design	Participants	Intervention	Results
Estey (1990)[46] Canada *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 (12%) • *ITT analysis*: yes • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: unclear OVERALL QUALITY: moderate/poor	*Total number*: 60 (controls 25 after dropouts/intervention 28) *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 *Age*: I: 56 years, C: 54 years *BMI*: weight 85.6 kg; 36–46% >115% ideal body weight *HbA_{1c}*: I: 6.3 ± 1.1%, C: 6.1 ± 1.4% *Diabetes duration*: NR *Treatment*: diet, oral hypoglycaemic agents (no details on oral treatment)	*SMBG regimen*: no details of protocols for SMBG *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 *SMBG method*: no description of device, diary *Use of therapy decision scheme*: *SMBG instruction*: yes *SMBG accuracy checks*: no *Education*: yes; 3-day education (both groups) *Assessment of monitoring frequency*: yes *Feedback on SMBG*: yes *SMBG treatment adjustment/advice*: no details on changes made to therapy or lifestyle *Control*: standard 3-day education plus SMBG *Adherence assessment*: patient data sheets or memory of meters consulted to compare number of tests conducted with number of tests requested *Outcomes*: HbA_{1c}, weight, SMBG adherence	• No significant difference in HbA_{1c} • 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 • Intervention group performed SMBG more frequently than control group ($p < 0.0001$)
Farmer (2007) UK[10,11] DiGEM trial *Follow-up*: 12 months *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 (12.6%) • *ITT analysis*: yes • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: non-industry OVERALL QUALITY: high	*Total number*: 453 patients with T2DM *Inclusion criteria*: T2DM, not insulin treated *Age*: 65.7 years *BMI*: 31–32 kg/m^2 *Diabetes duration*: median 3 years *HbA_{1c}*: 7.4–7.5% *Treatment*: diet only 26–29%, oral monotherapy 37.5–39%; combined oral therapy 34–35% (no details on oral treatment)	*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 *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 *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 *Outcomes*: HbA_{1c}, hypoglycaemia, lipids, BMI, blood pressure	*After 12 months*: • no significant difference in HbA_{1c} 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 ($p < 0.001$) • 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: HbA_{1c} was already quite low at the beginning

Trial – design	Participants	Intervention	Results
Fontbonne (1989)[47] France *Follow-up*: 6 months *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	*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/m^2 *HbA$_{1c}$*: 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)	*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 *Education*: no; patients received individualised dietary recommendations, but no specific algorithms or predetermined strategy for behavioural changes *Assessment of monitoring frequency*: yes *Feedback on SMBG*: yes *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; HbA$_{1c}$ 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*: HbA$_{1c}$, weight, number of reactive strips reported	• No significant difference in HbA$_{1c}$ or body weight

Trial – design	Participants	Intervention	Results
Gallichan (1994)[48] 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:[30] 3/7; Coster 2000[29] 4/11 reporting, 3/3 external validity, 3/7 bias, 3/6 confounding, 13/27 total (poor)	*Total number*: 27 (15/12) *Inclusion criteria*: on oral hypoglycaemic agents *Age*: 64 years (47–80) *BMI*: NR *HbA_{1c}*: NR *Diabetes duration*: NR *Treatment*: diet, oral hypoglycaemic agents (details of oral treatment unclear)	*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 *Outcomes*: fructosamine	• No significant difference in fructosamine concentration
Guerci (2003)[49] 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%)	*Total number*: 689 (345/344) *Inclusion criteria*: T2DM < 1 year, patients insufficiently controlled with oral glucose lowering treatment (HbA_{1c} > 7.5 and < 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^2	*SMBG regimen:* (n = 345): patients received a conventional laboratory work-up based on laboratory measurement of HbA_{1c} 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	• 57.1% patients had improvement in HbA_{1c} at 3 months compared to 46.8% in the control group (p = 0.007) • improvement in HbA_{1c} predicted by HbA_{1c} at baseline (OR 1.749, p < 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_{1c}, 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

Trial – design	Participants	Intervention	Results
• *ITT analysis*: yes • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: unclear OVERALL QUALITY: moderate/poor	*HbA_{1c}*: I: 9.0 ± 1.3%, C: 9.0 ± 1.3% *Diabetes duration*: 8.0 years *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	*Assessment of monitoring frequency*: unclear *Feedback on SMBG*: unclear *SMBG treatment adjustment/advice*: did not report training on how to respond to readings; GP could change treatment based on HbA_{1c} *Control* ($n = 344$): conventional laboratory work-up only *Adherence assessment*: not reported *Outcomes*: HbA_{1c}, hypoglycaemia, weight, blood pressure	
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*: ? OVERALL QUALITY: moderate/poor	*Total number*: 39 (17/22) *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	• HbA_{1c} significantly lower in the SMBG group after treatment (SMBG 7.6% vs control 9.65%, $p < 0.05$) This study seems to be a bit of an outlier in effect size, but it was SMBG + education vs nothing

Trial – design	Participants	Intervention	Results
Johnson (2006)[51] Canada *Follow-up*: 6 months *Quality*: • *Trial design and participants described*: yes • *Randomisation described*: no • *Allocation concealment*: unclear • *Outcome assessment blinded*: yes (for HbA_{1c}) • *Adequate power*: yes • *Withdrawals/losses to FU described*: yes (45% withdrawals/losses to FU in control group, 36% in intervention group) • *ITT analysis*: yes • *Statistical analysis appropriate*: yes • *Baseline characteristics similar*: control group slightly younger (67 vs 70 years) and slightly higher BMI 31.7 vs 29.1 kg/m^2) • *Funding*: non-industry OVERALL QUALITY: moderate	*Total number*: 262 *Inclusion criteria*: T2DM (> 1 year); not insulin treated *Age*: 68.4 years, men and women *BMI*: 29–32 kg/m^2 *HbA_{1c}*: 7.3–7.5% *Diabetes duration*: 7.7–8.6 years *Treatment*: 96–97% on oral agents (no details)	*Intervention*: free BG meter, free 6-month supply of testing strips *Control*: free BG meter *Both*: 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 3 or 4 times per week; FU visits at 3 and 6 months for reinforcement of testing procedures No information on therapy changes in response to SMBG *Outcomes*: HbA_{1c}, diabetes self-care activities [Summary of Diabetes Self-Care Activities (SDSCA)]	• *No significant difference in HbA_{1c} levels at 6 months* (intervention 7.3 ± 1.5% vs control 7.1 ± 1.2%, adjusted difference 0.02% (95% CI –0.16 to 0.22) • Summary of Diabetes Self-Care Activities significantly better results in intervention group (4.1 ± 2.5 vs 3.5 ± 2.5, adjusted difference 0.64 (95% CI 0.18 to 1.10; $p = 0.007$), i.e. patients receiving free strips monitored on average 0.64 days more than patients who did not; frequency of monitoring was not associated with HbA_{1c} COMMENT: no information on SMBG messages and diabetes education patients received or how readings were used to adjust treatment, or what feedback was given to patients; patients were relatively well controlled at the beginning of the study already; study aimed to show that merely reducing financial barriers to testing (by providing free strips) will not necessarily improve outcomes if it is not linked to appropriate education, and this seemed to be the case
Jones (2003)[52] Diabetes Stages of Change Study (DiSC), Canada RCT stratified by diabetes treatment but no detailed separate reporting for T1DM and T2DM and insulin vs non-insulin *Follow-up*: 12 months *Quality*: • *trial design and participants described*: yes • *randomisation described*: no • *allocation concealment*: unclear	*Total number*: 860 *Inclusion criteria*: patients with T1DM or T2DM for SMBG intervention (all in pre-action stage for SMBG (i.e. using less than recommended) (of a total of 1029 patients, 58.2% were enrolled for 2 behaviours, 89% of those for SMBG and healthy eating) *Age*: 55 years, men and women *BMI*: 32 kg/m^2 *HbA_{1c}*: 8.4–8.6%	*Four comparison groups*: PTC + SMBG: Pathways to Change (based on Transtheoretical Model of Change) plus free strips; PTC: multicomponent intervention programme; monthly mail or telephone contact for 12 months; focus on SMBG, and/or healthy eating, or smoking PTC: Pathways to Change, no free strips TAU (treatment as usual) + SMBG: treatment as usual plus free strips TAU: treatment as usual, no free strips Outcomes: stage of change, HbA_{1c}, weight, behaviour (SMBG monitoring – and healthy eating, smoking for other parts of the study)	• For SMBG intervention, 43.4% of those receiving PTC plus strips moved to an action stage vs 30.5% receiving PTC alone vs 27.0% receiving TAU plus strips and 18.4% receiving TAU alone ($p < 0.001$) • For SMBG intervention, PTC resulted in greater decrease of HbA_{1c} than TAU, but not statistically significant; however, for those who moved to an action stage, HbA_{1c} was significantly reduced ($p < 0.001$) • Weight loss for those enrolled in both SMBG and healthy eating interventions and who increased SMBG as recommended was significantly greater than for those who remained in the pre-action stage (–1.78 kg vs –0.26 kg; $p < 0.01$)

Trial – design	Participants	Intervention	Results
• *outcome assessment blinded*: unclear • *adequate power*: unclear • *withdrawals/losses to FU described*: yes (22.3%) • *ITT analysis*: yes • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: industry OVERALL QUALITY: poor	*Diabetes duration*: 10–11 years *Treatment*: about half of the patients were insulin-treated (no details of oral treatment); patients on diet only were not included		COMMENT: does not meet our inclusion criteria (cannot separate T1DM/T2DM, insulin/non-insulin), but interesting as it demonstrates the interaction between SMBG behaviour and appropriate education/counselling and other outcomes
Joy (2003)[53] USA (abstract) *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	*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$_{1c}$	• HbA$_{1c}$ decreased by 0.8% in preprandial SMBG group and by 0.9% in postprandial SMBG group – no significant difference

Trial – design	Participants	Intervention	Results
Kibriya (1999)[54] 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^2) • *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^2 (Asian population!) *HbA$_{1c}$*: 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$_{1c}$, costs, hypoglycaemia	• HbA$_{1c}$ 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)[55] Korea *Follow-up*: 12 weeks *Quality*: • *trial design and participants described*: yes • *randomisation described*: unclear (adaptive randomisation) • *allocation concealment*: unclear • *outcome assessment blinded*: unclear	*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^2 (Asian population!) *HbA$_{1c}$*: 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 without 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$_{1c}$ 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$_{1c}$ ≥ 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	Participants	Intervention	Results
• *adequate power*: yes • *withdrawals/losses to FU described*: yes (8%) • *ITT analysis*: no • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: non-industry OVERALL QUALITY: poor		*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 *Outcomes*: HbA_{1c}	
Miles (1997)[56] 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	*Total number*: 150 *Inclusion criteria*: newly diagnosed T2DM; oral agents or insulin *Age*: 65 (31–91) years *BMI*: 27.3 kg/m^2 HbA_{1c}: I: 10.3 (SD 2.6), C: 10.3 (SD 2.3) *Diabetes duration*: 0 (newly diagnosed) *Treatment*: no details of treatment	*SMBG regimen*: SMBG once daily before a different meal or at bedtime, each day (target < 8 mmol/l) *SMBG method*: no details given *SMBG 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

Trial – design	Participants	Intervention	Results
Moreland (2006)[20] 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 • *withdrawals/losses to FU described*: no (none?) • *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/m^2 *Diabetes duration*: 9.5–11 years *HbA$_{1c}$*: 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, HbA$_{1c}$, 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 HbA$_{1c}$ 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 HbA$_{1c}$ levels compared with 44% in the other groups ($p = 0.05$); in a multivariate model controlling for age, sex, diabetes type, baseline HbA$_{1c}$, 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 HbA$_{1c}$
Muchmore (1994)[57] 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, HbA$_{1c}$ 9.5–13%, no serious underlying medical or psychiatric illness, drug abuse or alcoholism *Age*: I: 57 years, C: 60 years *BMI*: 34 kg/m^2 *HbA$_{1c}$*: 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	• No significant difference in HbA$_{1c}$, body weight or QoL between groups • HbA$_{1c}$ reduced by 1.54% in SMBG group ($p < 0.05$), 0.84% in control group (NS) • Duration of diabetes, initial HbA$_{1c}$ and SMBG frequency not related to HbA$_{1c}$ • No significant correlations between HbA$_{1c}$ and duration of diabetes, initial HbA$_{1c}$, SMBG frequency

Trial – design	Participants	Intervention	Results
• *ITT analysis*: unclear • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: industry and non-industry OVERALL QUALITY: poor	*Treatment*: 74% on oral agents (no details given), rest on diet	*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 *Control* ($n = 11$): proprietary behavioural weight control programme, one-on-one counselling by a diabetes nurse and dietitian during a run-in period of 8 weeks *Adherence assessment:* average SMBG frequency 4.67 times/week *Outcomes*: HbA_{1c}, QoL, weight	
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 *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 HbA_{1c} *Outcomes*: HbA_{1c}, hypoglycaemia, BMI, use of oral hypoglycaemic drugs, well-being, treatment satisfaction, attitude	*No significant difference in HbA_{1c} at 12 months*: 6.9 ± 0.8% SMBG vs 6.9 ± 1.2% control *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) • No significant difference in BMI (33.1 ± 6.4 kg/m^2 vs 31.8 ± 6.0 kg/m^2 control) • No significant difference in hypoglycaemia but the study lacked power to detect a difference

Trial – design	Participants	Intervention	Results
Rutten (1990)[58] Netherlands *Follow-up*: 12 months *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 (13%) • *ITT analysis*: no • *statistical analysis appropriate*: yes • *baseline characteristics similar*: control group shorter duration of diabetes (6.6 vs 10 years) and lower HbA_{1c} (8.9% vs 9.7%) • *funding*: unclear OVERALL QUALITY: poor; SMBG confounded with further interventions	*Total number*: 149 (66/83) *Inclusion criteria*: T2DM > 6 months, age 40–75 years, no insulin, no treatment by internist for diseases other than diabetes, obesity or hypertension *Age*: 63 (40–75) years *BMI*: 51% < 27 kg/m^2, 21% 27–30 kg/m^2, 27% > 30 kg/m^2 *HbA_{1c}*: I: 9.7 (SD 2.1), C: 8.9 (SD 1.9) *Diabetes duration*: 8.8 years *Treatment*: diet, oral hypoglycaemic agents (not details given)	*SMBG regimen*: no fixed regimen; patients were told to monitor BG when they did not feel well or if they had taken part in unusually strenuous activity *SMBG other*: patients accepting opportunity of SMBG were given instructions; patients contacted practice nurse monthly to state level of FBG; patients under GP care (not practising SMBG) consulted their doctors at least 4 times per year, during which patients was informed of current BG level; for all patients in experimental group a therapeutic scheme was used with fixed targets for weight and regulation and with emphasis on loss of body weight *SMBG method*: Haemo-Glukotest 20–800 strips *Use of therapy decision scheme*: yes *SMBG instruction*: yes (2–5 sessions) *SMBG accuracy checks*: yes *Education*: 2–3 training visits *Assessment of monitoring frequency*: no *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 *Outcomes*: HbA_{1c}, weight, FPG	• Small reduction in HbA_{1c} in the intervention group by 0.5% ($p < 0.05$), increase by 0.5% in control group ($p < 0.001$); difference between groups not reported • Patients with initial HbA_{1c} > 10% were more likely to improve
Scherbaum (2008)[59,60] Germany *Follow-up*: 12 months *Quality*: • *trial design and participants described*: yes • *randomisation described*: yes • *allocation concealment*: yes • *outcome assessment blinded*: unclear	*Total number*: 202 *Inclusion criteria*: patients with T2DM; not insulin-treated *Age*: 61–62 years, men and women *BMI*: not reported *HbA_{1c}*: 7.2% *Diabetes duration*: 7.8–8.2 years *Treatment*: 71–75% MET, ~50% SUs, and various others	*Low SMBG* ($n = 100$): SMBG with one measurement per week and additional measurement in the event of suspected hypoglycaemia or severe hyperglycaemia *High SMBG* ($n = 102$): SMBG with four measurements per week on Tuesdays, Thursdays and one day of the weekend before dinner and one additional measurement before lunch – also additional measurement in the event of suspected hypoglycaemia or severe hyperglycaemia *Both groups*: case-management approach, all patients asked to report back to their doctor in the event of inappropriate diabetes control, based on the targets set between the patient and their doctor	• Non-inferiority demonstrated for HbA_{1c} in the low group ($p = 0.0022$); no significant difference in HbA_{1c} values at 3, 6 or 12 months (6.9 ± 1.0% in low group vs 7.1 ± 1.0% in high group at 12 months) • No significant difference in healthcare utilisation (including hospital stays) between groups • No significant difference in changes in diabetes treatment • (QoL and satisfaction data to be published separately.) *Conclusion*: 1 SMBG per week is as sufficient and safe as 4 SMBG per week to maintain HbA_{1c}

Trial – design	Participants	Intervention	Results
• *adequate power*: yes • *withdrawals/losses to FU described*: yes (17%) • *ITT analysis*: yes • *statistical analysis appropriate*: yes • *baseline characteristics similar*: yes • *funding*: non-industry, meters provided by Roche Diagnostics OVERALL QUALITY: high		*Outcomes*: HbA_{1c}, adherence, change in diabetes treatment, hypoglycaemia, QoL, satisfaction, adverse events	
Schwedes (2002)[61] / **Siebolds (2006)**[21] Germany *Follow-up*: 12 months *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 (11%) • *ITT analysis*: no • *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/m^2; with HbA_{1c} values between 7.5% and 10%; treated either with diet alone or diet in combination with SUs or MET; 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/m^2 *HbA_{1c}*: I: 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) *SMBG other*: patients undergoing SMBG were given instructions in use of BG device; patients requested to record values obtained in a diary where documentation of eating and state of well-being was also recorded; counselling designed to discuss problems/issues related to SMBG *Use of therapy decision scheme*: yes, SMBG counselling algorithm used by nurse *SMBG instruction*: yes *SMBG accuracy checks*: nurses assessed correct use of the monitoring device in the intervention group *Education*: SMBG instruction and standardised counselling vs non standardised counselling *Assessment of monitoring frequency*: checks by nurses at regular visits *Feedback on SMBG*: not applicable *SMBG treatment adjustment/advice*: did not report training on how to respond to readings *Control* (n = 110): non-standardised counselling with focus on diet and lifestyle *Adherence assessment*: after 6 months' intervention, 87% of patients still monitored their BG *Outcomes*: HbA_{1c}, QoL, BMI	• Significantly greater HbA_{1c} 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 HbA_{1c} led to failure • Longer diabetes duration and higher baseline HbA_{1c} predicted a delay in response

Trial – design	Participants	Intervention	Results
Seaton (1996)[62] USA (abstract) *Follow-up*: NR *Quality*: • unclear (not available for investigation)	*Total number*: 10 *Inclusion criteria*: T2DM on oral medication *Age*: NR *BMI*: NR *HbA_{1c}*: NR *Diabetes duration*: NR *Treatment*: NR	*SMBG regimen*: NR *SMBG other*: NR *SMBG method*: no details reported *Use of therapy decision scheme*: yes, standardised treatment algorithm *Control*: no SMBG *Adherence assessment*: NR *Outcomes*: HbA_{1c}	• Significant reduction in HbA_{1c} of 0.8% in the SMBG group, no change in the control group; not reported if significant difference between groups
Wing (1986)[63] USA *Follow-up*: 62 weeks *Quality*: • *trial design and participants described*: yes • randomisation described: no • allocation concealment: unclear • outcome assessment blinded: unclear (probably) • adequate power: unclear (probably not) • withdrawals/losses to FU described: no (10%) • ITT analysis: unclear • statistical analysis appropriate: yes • baseline characteristics similar: unclear • funding: non-industry OVERALL QUALITY: poor	*Total number*: 50 (25/25) *Inclusion criteria*: age 35–65 years; >20% above ideal weight for height; use of oral hypoglycaemic medication or insulin for BG control; development of diabetes after the age of 30 *Age*: 54 years (35–65) *BMI*: weight 98 kg *HbA_{1c}*: I: 10.19 (SD 2.51), C: 10.86 (SD 2.00) *Diabetes duration*: NR *Treatment*: diet, oral hypoglycaemic agents; about half of the patients used insulin	*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 *SMBG other*: behavioural weight control treatment programme, SMBG and focusing on weight–BG relationship *SMBG method*: Chemstrips bG, diary *Use of therapy decision scheme*: yes *SMBG instruction*: yes *SMBG accuracy checks*: yes *Education*: behavioural weight control programme (both); 3 months, FU sessions over per year *Assessment of monitoring frequency*: yes *Feedback on SMBG*: yes *SMBG treatment adjustment/advice*: participants required to modify diet and exercise habits according to SMBG results; patients not allowed to change therapy *Control*: behavioural weight control treatment programme *Adherence assessment*: patient data sheets or memory of meters consulted to compare number of tests conducted with number of tests requested; marked item technique *Outcomes*: GHb, weight, fasting glucose, lifestyle adherence, medication changes, serum lipids	• No significant difference in GHb, FPG or body weight

ACE I, 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_{1c}/glucose control					
Allen (1990)[40]	HbA_{1c}	SMBG: 12.4% (SD 3.3) SMUG: 11.7% (SD 3.0)	SMBG: 10.4% (SD 2.9) SMUG: 9.7% (SD 2.6)	SMBG: –2.0% (SD 3.4) SMUG: –2.0% (SD 2.4)	NS
Barnett (2008)[41]	HbA_{1c}	SMBG: 8.12% (SD 0.89) C: 8.12% (SD 0.84)	SMBG: 6.95% (SD 0.97) C: 7.2% (SD 1.22)		
Bonomo (2006)[42]	HbA_{1c}	More frequent SMBG: 8.08% (SD 0.84) Less frequent SMBG: 7.97% (SD 0.72)	More frequent SMBG: 7.6% (SD 0.73) Less frequent SMBG: 7.78% (SD 1.05)	Significant decrease in HbA_{1c} in twice monthly SMBG monitoring group, no decrease in once monthly	Difference between groups not reported
Cho (2006)[44]	HbA_{1c}	SMBG internet: 7.7% (SD 1.5) SMBG: 7.5% (SD 1.3)	SMBG internet: 6.7% (SD 0.9) SMBG: 7.4% (SD 1.3)		$p = 0.029$
Brown (2002)[43]	HbA_{1c}	SMBG: 11.8% (SD 3.0) C: 11.8% (SD 3.0)	SMBG: 10.89% (SD 2.56) C: 11.64% (SD 2.85)		$p = 0.016$
Davidson (2005)[45]	HbA_{1c}	SMBG: 8.4% (SD 2.1) C: 8.5% (SD 2.2)	SMBG: 7.53% (SE 0.236) C: 7.88% (SE 0.221)	SMBG: –0.8% (SD 1.6) C: –0.6% (SD 2.1)	NS
Estey (1990)[46]	HbA_{1c}	SMBG + FB: 6.3% (SD 1.1) SMBG: 6.1% (SD 1.4)	SMBG + FB: 5.6% (SD 0.7) SMBG: 5.8% (SD 1.5)	SMBG + FB: –0.7% (SD 0.9) SMBG: –0.3% (SD 0.7)	NS
Farmer (2007)[10]	HbA_{1c}	SMBG intensive: 7.53% (SD 1.12) SMBG simple: 7.41% (SD 1.02) C: 7.49% (SD 1.09)		SMBG intensive: –0.17% (SD 0.73) SMBG simple: –0.14% (SD 0.82) C: –0% (SD 1.02)	
Fontbonne (1989)[47]	HbA_{1c}	SMBG: 8.2% (SD 2.5) SMUG: 8.6% (SD 2.5) C: 8.2% (SD 2.5)	SMBG: 7.84% SMUG: 8.47% C: 7.7%	SMBG: –0.36% (SD 3.14) SMUG: –0.13% (SD 2.20) C: –0.5% (SD 1.54)	NS
Gallichan (1994)[48]	Fructosamine	SMBG: 324 µmol/l SMUG: 343 µmol/l	SMBG: 333 µmol/l SMUG:322 µmol/l		NS
Guerci (2003)[49]	HbA_{1c}	SMBG: 9.0% (SD 1.3) C: 9.0% (SD 1.3)	SMBG: 8.1% (SD 1.6) C: 8.4% (SD 1.4)	SMBG: –0.88% (SD 1.54) C: –0.6% (SD 1.54)	0.012
	HbA_{1c} improvement		SMBG: 57.1% C: 46.8%		0.007

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Study	Outcome	Baseline	End of study	Difference	*p*-value
Jaber (1996)[50]	HbA_{1c}	SMBG: 9.2% (SD 2.0) C: 9.7% (SD 2.5)	SMBG: 7.6% (SD 1.48) C: 9.65% (SD 2.61)	SMBG: –1.62% (SD 1.83) C: –0.07% (SD 2.12)	
Johnson (2006)[51]	HbA_{1c}	Free strips: 7.5% (SD 1.6) No free strips: 7.3% (SD 1.2)	Free strips: 7.3% (SD 1.5) No free strips: 7.3% (SD 1.2)		NS
Joy (2003)[53]	HbA_{1c}	Preprandial SMBG: 8.3% Postprandial SMBG: 8.4%		Preprandial SMBG: –0.8% Postprandial SMBG: –0.9%	NS
Kibriya (1999)[54]	HbA_{1c}	SMBG: 8.19% (SD 1.37) C: 7.55% (SD 1.62)	SMBG: 7.11% (SD 1.0.8) C: 7.12% (SD 1.85)	SMBG: –0.99% C: –0.38%	NS
Kwon (2004)[55]	HbA_{1c}	SMBG + FB: 7.59% (SD 1.42) SMBG: 7.19% (SD 1.17)	SMBG + FB: 6.94% (SD 0.92) SMBG: 7.62% (SD 0.93)	SMBG + FB: –0.54% SMBG: +0.33%	$p < 0.001$
	HbA_{1c} < 7% at baseline		SMBG + FB: 6.38% (SE 0.22) SMBG: 6.99% (SE 0.18)		0.046
	$HbA_{1c} \geq 7\%$ at baseline		SMBG + FB: 7.38% (SE 0.16) SMBG: 8.12% (SE 0.19)		< 0.001
Miles (1997)[56]	HbA_{1c}	SMBG: 10.3% (SD 2.6) SMUG: 10.3% (SD 2.3	SMBG: 8.8% (SD 1.9) SMUG: 8.7% (SD 1.7)	SMBG: –1.5% (SD 2.1) SMUG: –1.6% (SD 1.9)	NS
Moreland (2006)[20]	HbA_{1c}	BGM+: 9.3% (SD 1.2)	BGM+: 9.3% (SD 1.7)	BGM+: –0.13% (SD 1.28)	NS; no significant difference between T1DM and T2DM
		MT: 9.1% (SD 1.2)	MT: 9.1% (SD 1.3)	MT: –0.04% (SD 1.31)	
		SC: 8.9% (SD 0.9)	SC: 9.0% (SD 1.5)	SC: +0.04% (SD 1.1)	
Muchmore (1994)[57]	HbA_{1c}	SMBG: 10.29% (SD 1.1) C: 10.45% (SD 1.5	SMBG: 8.75% (SD 1.66) C: 9.6% (SD 2.1)	SMBG: –1.54% (SD 1.46) C: –0.85% (SD 1.87	NS
O'Kane (2008)[13]	HbA_{1c}	SMBG: 8.8% (SD 2.1) C: 8.6% (SD 2.3)	SMBG: 6.9% (SD 0.8) C: 6.9% (SD 1.2)		NS
Rutten (1990)[58]	HbA_{1c}	SMBG: 9.7% (SD 2.1) C: 8.9% (SD 1.9)	SMBG: 9.2% (SD 1.49) C: 9.4% (SD 1.14)	SMBG: –0.4%) C: +0.5%	< 0.05

Study	Outcome	Baseline	End of study	Difference	*p*-value
Scherbaum (2008)[60]	HbA_{1c}	Low SMBG: 7.2% (SD 1.4) High SMBG: 7.2% (SD 1.0)	Low SMBG: 6.9% (SD 1.0) High SMBG: 7.1% (SD 1.0)		
Schwedes (2002)[61]	HbA_{1c}	SMBG: 8.5% (SD 0.9) C: 8.4% (SD 0.8)	SMBG: 7.47% (SD 1.27) C: 7.81% (SD 1.52)	SMBG: –1.0% (SD 1.08) C: –0.54% (SD 1.41)	0.009
Wing (1986)[63]	HbA_{1c}	SMBG: 10.2% (SD 2.5) C: 10.7% (SD 2.0)	SMBG: 10.2% (SD 2.29) C: 10.4% (SD 2.16)	SMBG: 0.0% (SD 2.16) C: –0.24% (SD 1.87)	NS
Hypoglycaemia					
Barnett (2008)[41]	Hypoglycaemic events		SMBG: *n* = 27 (8.7%) with 51 hypoglycaemic events (27, symptomatic, 11 asymptomatic, 11 SMBG confirmed, 2 non-graded) C: *n* = 21 (7%) with 66 hypoglycaemic events (64, symptomatic, 2 non-graded)		*p*-value not reported
	Nocturnal hypoglycaemia		SMBG: *n* = 3 patients C: *n* = 7 patients		
Farmer (2007)[10]	Hypoglycaemic episodes		SMBG more intensive: 43 SMBG less intensive: 33 C: 14		
Guerci (2003)[49]	Hypoglycaemic episodes (capillary BG < 3 mmol/l)			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	0.003
Kibriya (1999)[54]	Hypoglycaemic episodes			SMBG: 5 patients with 7 episodes; 0.172/patient-year C: 10 patients with 17 episodes; 0.354/patient-year	0.03

Study	Outcome	Baseline	End of study	Difference	*p*-value
O'Kane (2008)[13]	Hypoglycaemic episodes		SMBG: 31 episodes C: 36 episodes		NS
Scherbaum (2008)[60]	Relevant hypoglycaemia		Low SMBG: 5 patients (1 with 1 event, 4 with several events) High SMBG: 18 patients (9 with 1 event, 9 with several)	Significantly more with 1 event in high group than low group	0.02
Weight					
Allen (1990)[40]	Weight			SMBG: –2 kg SMUG: +0 kg	NS
Barnett (2008)[41]	Weight			SMBG: –0.68 kg (SD 5.70) C: –0.50 kg (SD 4.01)	NS
Brown (2002)[43]	BMI	SMBG: 32.33 kg/m^2 (SD 5.97) C: 32.12 kg/m^2 (SD 6.35)	SMBG: 32.17 kg/m^2 (SD 6.45) C: 32.28 kg/m^2 (SD 6.52)		NS
Estey (1990)[46]	Weight	SMBG + FB: 84.2 kg (SD 15.8) SMBG: 86.1 kg (SD 17.3)	SMBG + FB: 82.4 kg (SD 22.2) SMBG: 86.1 kg (SD 17.3)	Difference SMBG vs control –1.10 kg (95% CI –2.95 to 0.75)	NS
Davidson (2005)[45]	Weight			SMBG: –0.7 kg (SD 6.3) C: –0.1 kg (SD 2.9)	NS
	BMI			SMBG: –0.3 kg/m^2 (SD 2.3) C: –0.1 kg/m^2 (SD 1.6)	NS
Farmer (2007)[10]	Weight	SMBG more intensive: 86.9 kg (SD 16.4) SMBG less intensive: 90.4 kg (SD 18.9) C: 86.7 kg (SD 18.9)	SMBG more intensive: 86.1 kg (SD 15.7) SMBG less intensive: 89.9 kg (SD 19.0) C: 86.4 kg (SD 19.4)	SMBG more intensive: –0.8 kg (SD 3.3) SMBG less intensive: –0.5 kg (SD 2.6) C: –0.3 kg (SD 2.7)	NS
	BMI	SMBG more intensive: 31.0 kg/m^2 (SD 5.3) SMBG less intensive: 31.9 kg/m^2 (SD 6.2) C: 30.9 kg/m^2 (SD 6.1)	SMBG more intensive: 30.7 kg/m^2 (SD 5.0) SMBG less intensive: 31.8 kg/m^2 (SD 6.3) C: 30.8 kg/m^2 (SD 6.3)	SMBG more intensive: –0.3 kg/m^2 (SD 1.2) SMBG less intensive: –0.2 kg/m^2 (SD 0.9) C: –0.1 kg/m^2 (SD 1.0)	NS

Study	Outcome	Baseline	End of study	Difference	*p*-value
Fontbonne (1989)[47]	Weight			Difference SMBG/SMUG vs control –0.22 kg (95% CI –1.36 to 0.93)	NS
Guerci (2003)[49]	Weight			SMBG: –0.93 ± 4.35 kg C: –0.83 ± 4.87 kg	NS
Muchmore (1994)[57]	Weight			Difference SMBG vs control –0.10 kg (95% CI –12.28 to 12.08)	NS
O'Kane (2008)[13]	BMI	SMBG: 34.0 kg/m^2 (SD 7.0) C: 32.0 kg/m^2 (SD 6.2; $p = 0.04$)	SMBG: 33.1 kg/m^2 (SD 6.4) C: 31.8 kg/m^2 (SD 6.0)		NS
Rutten (1990)[58]	Weight			SMBG: –0.4 kg C: +0.1 kg	NS
Schwedes (2002)[61]	Weight			SMBG: –1.96 ± 2.99 kg C: –1.62 ± 3.54 kg	*p*-value not reported
Wing (1986)[63]	Weight	SMBG: 99.02 kg (SD 16.13) C: 96.35 kg (SD 23.57)	SMBG: 94.92 kg (SD 16.50) C: 88.11 kg (SD 17.79)	Difference SMBG vs control 4.10 kg (95% CI –1.07 to 9.27)	NS
Lipid parameters					
Brown (2002)[43]	Cholesterol			No significant difference	
	Triglycerides			No significant difference	
Cho (2006)[44]	Total cholesterol			Significantly lower in the intervention group	
	HDL cholesterol			No significant difference	
	Triglycerides			No significant difference	
Farmer (2007)[10]	Total cholesterol			Significantly more reduction in more intensive vs control	0.01
	Total–HDL cholesterol ratio			Significantly more reduction in more intensive vs control	0.013

Study	Outcome	Baseline	End of study	Difference	*p*-value
Kwon (2004)[55]	Total cholesterol			No significant differences reported	
	HDL cholesterol			Significant increase from baseline in control group, but not significant differences between groups reported	
	LDL cholesterol			No significant differences reported	
	Triglycerides			No significant differences reported	
Schwedes (2002)[61]	Total cholesterol			No significant difference	
	Triglycerides			No significant difference	
Wing (1986)[63]	Lipid parameters (cholesterol, triglycerides)			No significant difference	
Adherence					
Cho (2006)[44]	SMBG frequency		SMBG + internet: 34 ± 28 times per month SMBG: 22 ± 19 times per month		0.024
Estey (1990)[46]	SMBG adherence			SMBG adherence greater in SMGB + FB group (no data shown)	< 0.0001
Farmer (2007)[10]	SMBG adherence		SMBG more intensive: 52.3% continued to use meter at least twice weekly for 12 months SMBG less intensive: 66% continued to use meter at least twice weekly for 12 months		0.012
	Number of readings in meter users			Significantly more in the more intensive group	0.022

Study	Outcome	Baseline	End of study	Difference	*p*-value
Johnson (2006)[51]	Days of testing			Patients receiving free strips tested and average of 0.64 days per week more often than patients not receiving free strips	0.007
Kwon (2004)[55]	Frequency of SMBG during study (3 months)		SMBG internet: 71.5 ± 36.2 SMBG: 38.1 ± 24.8		*p*-value not reported
Moreland (2006)[20]	Frequency of SMBG		BGM+: 2.8 (SD 1.5) MT: 2.0 (SD 1.3) SC: 2.1 (SD 1.7)		< 0.05 BGM+ vs the other two groups
Scherbaum (2008)[60]	Adherence assessed by investigator		(at 6 months) Low SMBG: 73% High SMBG: 83%		NS
	Adherence assessed by patient		(at 6 months) Low SMBG: 85–88% High SMBG: 84–88%		
Wing (1986)[63]	Adherence with self-monitoring		SMBG: 89.1% of strips used during initial treatment, 70.2% during FU; 83% of patients interpreted results within 20% of actual level		
Changes in treatment					
Davidson (2005)[45]	Medication at end of study		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, 13% insulin + oral, 0 insulin alone		NS
Farmer (2007)[10]	Medication increase		SMBG more intensive: increased in 31.8% of patients SMBG less intensive: increased in 28.7% of patients C: increased in 29.6% of patients		NS
Guerci (2003)[49]	Medication change			No significant difference	

Study	Outcome	Baseline	End of study	Difference	*p*-value
O'Kane (2008)[13]	Medication use	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	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		NS
Rutten (1990)[58]	Medication change		SMBG: 64% unchanged C: 78% unchanged		NS
Scherbaum (2008)[60]	Change from oral agents to insulin			No significant difference	
Wing (1986)[63]	Change in medication		SMBG: decrease in oral agents 73%, decrease in insulin 83% C: decrease in oral agents 64%, decrease in insulin 64%		NS
QoL/preference					
Farmer (2007)[10]	QoL (EQ-5D)		Significantly lower values on EQ-5D for more intensive group vs control, mainly due to increased anxiety/depression		
Gallichan (1994)[48]	Preference		71% preferred urine testing to blood testing		
Miles (1997)[56]	Preference		70% preferred urine testing, 15% preferred blood testing		
	Well-being questionnaire		No significant difference		
Moreland (2006)[20]	Negative affect with respect to SMBG		BGM+: 38% MT: 65% SC: 57%		0.03
	Satisfaction		No significant difference		
Muchmore (1994)[57]	Quality-of-life inventory (satisfaction, impact, worry – social/vocational, worry –diabetes related)		No significant difference		

Study	Outcome	Baseline	End of study	Difference	*p*-value
O'Kane (2008)[13]	Depression			Significantly worse in the SMBG group	0.011
	Anxiety			Marginally worse in the SMBG group	0.07
	Positive well-being				NS
	Energy				NS
Schwedes (2002)[61]	Well-being, treatment satisfaction			Similar improvement in both groups	
	Depression			Significantly less in the SMBG group	0.032
Wing (1986)[63]	Mood			Significantly improved in both groups, no significant difference	
Changes in behaviour					
Guerci (2003)[49]	Diet and exercise behaviour			Significantly more patients in the SMBG group continued following dietary instructions than in the control group; no significant difference in exercise behaviour	
Wing (1986)[63]	Diet and exercise habits			No significant difference	
Cost					
Allen (1990)[40]	Cost		SMBG 12 times more in first year, 8 times more in later years		

Study	Outcome	Baseline	End of study	Difference	*p*-value
Other					
Farmer (2007)[10]	Systolic blood pressure			No significant difference	
	Diastolic blood pressure			No significant difference	
Guerci (2003)[49]	Systolic blood pressure			No significant difference	
	Diastolic blood pressure			No significant difference	
Scherbaum (2008)[60]	Physician visits			No significant difference	
	Inpatient stay			No significant difference	
	Incapacity to work			No significant difference	
Wing (1986)[63]	Blood pressure			No significant difference	
Adverse events					
Barnett (2008)[41]	All-cause adverse events		SMBG: 13.2% C: 15.1%		
Scherbaum (2008)[60]	Adverse events (with details)			No significant difference	

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)

Study	Participants	Interventions	Results
Bajkowska-Fiedziukiewicz (2008)[64] Poland *Design*: cross-sectional *Follow-up*: NA	*Total number*: 600 *Setting*: diabetes clinic, Lódź *Inclusion criteria*: T2DM, insulin and/or oral treatment *Age*: 63.4 years *BMI*: NR *HbA_{1c}*: 7.45% *Diabetes duration*: 11.4 years *Treatment*: insulin, oral glucose-lowering medication	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: maximum and minimum glucose levels during last week plus 8-point profile on freely selected day *SMBG method*: glucometer *Education*: standard diabetes education *Outcomes*: HbA_{1c}, frequency of SMBG	• No association between SMBG frequency and HbA_{1c} irrespective of diabetes treatment • Frequency of SMBG: 44.3% monitored 1–2 per day, 31.8% 1–2 per week • Mean HbA_{1c} 7.45 ± 1.08%
Banister (2004)[65] USA *Design*: cohort, before and after *Follow-up*: 2–12 months	*Total number*: 70 *Setting*: community clinic *Inclusion criteria*: T2DM *Age*: 49 years *Ethnicity*: most Hispanic or African-American *BMI*: 34 kg/m^2 (90% > 25) *HbA_{1c}*: 9.7% (range 5.2–16.2%) *Diabetes duration*: NR	*SMBG regimen*: SMBG once per day *SMBG method*: glucometer *Education*: diabetes self-management training programme *SMBG treatment adjustment/advice*: did not report on how to respond to readings *Outcomes*: HbA_{1c}	• HbA_{1c} –1.5% (9.7% reduced to 8.2%); $p < 0.001$ • Cost US$185 for each point reduction in HbA_{1c}
Blonde (2002)[66] USA *Design*: cross-sectional *Follow-up*: NA	*Total number*: 228 *Setting*: USA health clinics, chart review *Inclusion criteria*: T2DM, no medication limits *Age*: range 35–65 years *BMI*: NR *HbA_{1c}*: NR *Diabetes duration*: NR *Treatment*: no details	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}, frequency of SMBG	• Regular SMBG users: 21%; irregular SMBG users 42%; non-SMBG users 37% • $HbA_{1c} \leq 8\%$: 70% regular users, 18% irregular users, 22% non-SMBG users
Capelson (2006)[67] USA *Design*: cross-sectional *Follow-up*: NA	*Total number*: 808 *Setting*: chart review Joslin Clinic 2001–2005 *Inclusion criteria*: diabetes (type not specified), > 75 years, insulin use *Age*: 80.4 ± 4.5 years *BMI*: NR *HbA_{1c}*: 7.5–7.7% *Diabetes duration*: 21.3 ± 14.9 years *Treatment*: insulin	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: divided into groups: (1) no SMBG; (2) SMBG 1–2 times per day; (3) SMBG 3–4 times per day; (4) SMBG > 4 times per day *Outcomes*: HbA_{1c}	• No association between HbA_{1c} and SMBG frequency

Study	Participants	Interventions	Results
Chan (2000)[68] China *Design*: cross-sectional *Follow-up*: NA	*Total number*: 562 *Setting*: teaching hospital *Inclusion criteria*: T2DM *Age*: 53 years *BMI*: mean 2.4 *HbA_{1c}*: 8.4% (SD 2.3%) *Diabetes duration*: 5 (SD 6) years *Treatment*: 63% OHA, 21% diet alone, 9% insulin, rest no treatment	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}	• SMBG associated with lower HbA_{1c} than no SMBG (7.9% vs 8.6%; *p*-value not reported)
Evans (1999)[69] UK *Design*: cross-sectional *Follow-up*: NA	*Total number*: 790 with T2DM; 807 with T1DM *Setting*: UK diabetes database *Inclusion criteria*: diabetes mellitus, insulin treated *Age*: unclear *BMI*: NR *HbA_{1c}*: NR *Diabetes duration*: mean NR *Treatment*: all on insulin, some with OHAs in addition	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}, frequency of SMBG (no. of strips dispensed)	• No association between SMBG frequency and HbA_{1c} • 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. • In those with T2DM, 162 (21%) obtained no strips; 628 participants obtained between 50 and 10,100 strips, i.e. between 0.05 and 9.2 strips per day with 131 participants (17%) obtaining more than 1095 strips • A pattern of decreasing uptake with increasing age was evident among patients with T2DM; a trend of increasing uptake with increasing deprivation was evident, particularly among patients with T2DM • The 6381 prescriptions for reagent strips dispensed to patients with T2DM who used insulin cost £134,907 (£56.92 per patient per year). • There was a direct association between strip uptake in the previous 6 months and glycaemic control in patients with T1DM, but not in those with T2DM

Study	Participants	Interventions	Results
Franciosi (2001)[70,142] Part of QuED Study Italy *Design*: cross-sectional *Follow-up*: 3 years	*Total number*: 2855 *Setting*: Italian diabetes clinics and GP practices *Inclusion criteria*: T2DM *Age*: 63 years *BMI*: NR *HbA_{1c}*: ~7.3 ± 1.7% *Diabetes duration*: NR *Treatment*: diet only, oral antihyperglycaemic agents, insulin	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}, frequency of SMBG, QoL	• Overall, HbA_{1c} higher in those testing more often • Higher frequency of SMBG associated with lower HbA_{1c} 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
Franciosi (2005)[71] Part of QuED Study Italy *Design*: longitudinal *Follow-up*: 3 years	*Total number*: 1896 people with T2DM *Setting*: outpatient diabetes clinics *Inclusion criteria*: T2DM, users and non-users of SMBG; no insulin use *Age*: 62.4 years *BMI*: males 27, females 28 *HbA_{1c}*: 7.0% (testing < once per week), 7.2% (testing ≥ once per week), 7.3% (testing ≥ once per day) *Diabetes duration*: 9.1 years *Treatment*: diet only (14.4–28.7%), SUs (23.6–27.9%), MET (6.6–9.3%), SU + MET (35.3–55.4%)	*Comparison*: association between SMBG use and HbA_{1c} *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_{1c}	• 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_{1c}, 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_{1c} during 3-year FU; increasing SMBG frequency was associated with a slight decrease in HbA_{1c} • In 40% of patients who increased SMBG frequency this was associated with major treatment changes – decrease in HbA_{1c} 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^2

Study	Participants	Interventions	Results
Fremantle Diabetes Study [Davis (2007)[17,19]] Australia *Design*: cross-sectional and longitudinal *Follow-up*: 5 years	*Total number*: 1286 patients with T2DM at entry, 531 followed up over 5 years (longitudinal cohort significantly younger, healthier, better glycaemic control) *Setting*: community-based *Inclusion criteria*: T2DM *Age*: 64 ± 11 years *BMI*: 29.6 ± 5.5 kg/m^2 *HbA$_{1c}$*: 7.4% (6.4–8.9) *Diabetes duration*: NR *Treatment*: NR	*Comparison*: association between SMBG use and HbA$_{1c}$ *SMBG regimen*: no details of SMBG use/ protocols *Control*: no use of SMBG *Outcomes*: HbA$_{1c}$, morbidity	• At baseline, 70.2% (898 out of 1280) of patients with T2DM used SMBG • No significant association between HbA$_{1c}$ 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

Study	Participants	Interventions	Results
Hanninen (2001)[72] Finland *Design*: cross-sectional *Follow-up*: NA	*Total number*: 260 *Setting*: *Inclusion criteria*: T2DM, no medication limits *Age*: 63 years *BMI*: 30 (SEM 0.5) *HbA_{1c}*: 8.5% (SEM 0.2) *Diabetes duration*: some newly diagnosed *Treatment*: OHA or insulin	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}	• SMBG associated with higher HbA_{1c} (9% vs 8.5% without SMBG) (possibly because those with poorer control were asked to do SMBG)
Harris (2001)[73] USA *Design*: cross-sectional *Follow-up*: NA	*Total number*: 1480 people with T2DM *Setting*: NHANES III database *Inclusion criteria*: T2DM, users and non-users of SMBG *Age*: 62.5 years *BMI*: NR *HbA_{1c}*: mean 7.64%, 6.37% (diet only), 8.04% (oral agents), 8.29% (insulin) *Diabetes duration*: NR *Treatment*: diet only (27.2%), oral hypoglycaemic agents (45.5%), insulin (27.3%)	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}	• Frequency of SMBG: *insulin*: never or < 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 < 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 < 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% • No association between SMBG monitoring frequency and HbA_{1c}
Jaworska (2001)[74] Poland *Design*: cross-sectional *Follow-up*: NA	*Total number*: 218 people with T2DM *Setting*: outpatient *Inclusion criteria*: T2DM, no medication limits reported *Age*: 62 years	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}	• 59.2% of patients tested their BG levels at home ≥ once per day, 21.4% of them tested their BG ≥ once per week, whereas 8.7% of patients tested glucose ≤ once per week; 10.7% of patients never practised SMBG • No association between SMBG and HbA_{1c} • SMBG also not related to HbA_{1c} in patients who could change insulin dose based on SMBG

Study	Participants	Interventions	Results
Karter (2001)[75] (Kaiser Permanente) USA *Design*: cross-sectional *Follow-up*: NA	*Total number*: 23,153 people with T2DM *Setting*: Kaiser Permanente database *Inclusion criteria*: T2DM, > 19 years, pharmacy benefits, single HbA_{1c} measured during FU; on insulin, oral agents or diet only *Age*: 60 years *BMI*: NR *HbA_{1c}*: ~8.4 ± 2.2% *Diabetes duration*: 75% 0–9 years; 25% ≥ 10 years *Treatment*: diet only (21%), oral hypoglycaemic agents (55%), insulin (24%)	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: ADA recommendations *Control*: no use of SMBG *Outcomes*: HbA_{1c}, frequency of SMBG	• Adherent patients (following ADA recommendations) were monitoring ≥ once daily (insulin/oral agents) or ≥ occasionally (diet only) • Insulin: significantly lower HbA_{1c} in adherent vs non-adherent [8.2% (95% CI 8.2 to 8.3) vs 8.8% (95% CI 8.8 to 8.9); $p < 0.0001$] • Oral agents: significantly lower HbA_{1c} in adherent vs non-adherent [8.1% (95% CI 8.0 to 8.2) vs 8.7% (95% CI 8.7 to 8.7); $p < 0.0001$] • Diet only: lower levels of HbA_{1c} in patients performing SMBG than in those who did not • Adherent patients likely to be female, white, better educated, higher income, healthier lifestyle (adjusted for in analysis) • Adverse events (hospital or ER visit) 41% non-insulin adherent patients vs 36% non-insulin non-adherent patients
Karter (2005)[76] (Kaiser Permanente) USA *Design*: retrospective database *Follow-up*: 1 year	*Total number*: 4775 people with T2DM *Setting*: Kaiser Permanente database *Inclusion criteria*: T2DM, HbA_{1c} >8%, initiating new therapies *Age*: 60 years *BMI*: NR *HbA_{1c}*: 9.9 ± 1.5% *Diabetes duration*: ≥ 1 year *Treatment*: 74.2% not using insulin (pre-initiation)	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: not reported *Outcomes*: HbA_{1c}, frequency of SMBG	• SMBG frequency 0.9 ± 1.0 per day • Good control (HbA_{1c} ≤ 7.0%): (case-mix adjustments with a wide range of covariates used) • No SMBG: 13.4% (95% CI 11.3 to 15.8) • Some SMBG but < once daily: 15.5% (95% CI 14.0 to 17.2) • Daily SMBG: 18.8% (95% CI 16.9 to 20.9)
Karter (2006)[14] (Kaiser Permanente) USA *Design*: longitudinal *Follow-up*: 3.5 years	*Total number*: 16091 new users, 15347 prevalent users with T2DM *Setting*: Kaiser Permanente database *Inclusion criteria*: T2DM, insulin, oral therapy or diet *Age*: ~60 ± 10 years *BMI*: NR *HbA_{1c}*: 6.4 ± 0.8% to 8.6 ± 2.0% (new user cohort higher HbA_{1c}) *Diabetes duration*: NR Treatment: new users: $n = 9264$ no medication, $n = 5867$ oral only; prevalent users: $n = 1622$ no medication, $n = 7409$ oral only	*Comparison*: association between SMBG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}, frequency of SMBG	• Frequency of SMBG inversely associated with HbA_{1c} in new users regardless of diabetes therapy ($p < 0.0001$) and in pharmacologically treated prevalent users ($p < 0.0001$)

Study	Participants	Interventions	Results
Klein (1993)[77] USA *Design*: chart review *Follow-up*:	Total number: 229 *Setting*: chart review at Veterans Affairs medical centre *Inclusion criteria*: T2DM, no medication limits; patients who received blood or urine monitoring supplies *Age*: 62 years; 97% male	*Comparison*: association between SMBG/SMUG use and HbA_{1c} *SMBG regimen*: no details of SMBG use/protocols *Outcomes*: HbA_{1c}, frequency of SMBG	• No significant differences between SMBG and urine monitoring • HbA_{1c} did not differ based on length of time monitored or number of strips dispensed • Seven patients reported making insulin changes in response to monitoring; this was not associated with HbA_{1c}
Meier (2002)[79] USA *Design*: before/after *Follow-up*: 6 months	*Total number*: 471 patients with T2DM; chart review of 1467 patients *Setting*: Veterans Affairs chart review and before and after study *Inclusion criteria*: T2DM, no insulin *Age*: 64 years; 98% male BMI: NR HbA_{1c}: NR *Diabetes duration*: NR *Treatment*: oral antihyperglycaemic agents (89%, most on SU), diet (11%)	*Intervention*: reduced access to test strips *Outcomes*: HbA_{1c}, strip use	• Chart review: SMBG associated with lower HbA_{1c} • No significant difference in HbA_{1c} before (oral agents: 7.82 ± 1.22%) and after strip reduction (oral agents: 7.83 ± 1.21%) • Strip use reduction: oral agents 1.35 ± 0.92 to 0.67 ± 0.44; $p < 0.001$; diet: 1.17 ± 1.04 to 0.61 ± 0.44; $p < 0.001$
Mitchell (2004)[80] Canada *Design*: cross-sectional *Follow-up*: NA	*Total number*: 434 patients with T2DM *Setting*: community pharmacies *Inclusion criteria*: T2DM, no insulin *Age*: 64 years *BMI*: 30.7 (SD 6) *HbA_{1c}*: 7.3% (SD 1.3%) *Diabetes duration*: 7.8 (SD 6.5) years *Treatment*: diet and OHA only	*Comparison*: association between SMBG use and HbA_{1c} *Outcomes*: HbA_{1c}	• No association between HbA_{1c} and SMBG
Murata (2003)[81] USA *Design*: before/after *Follow-up*: 12 months	*Total number*: 218 *Setting*: veterans' administration *Inclusion criteria*: T2DM, stable *Age*: mean 65 years *BMI*: mean 31 (SD 5.7) *HbA_{1c}*: 8.1% (SD 1.7%) *Diabetes duration*: NR *Treatment:* insulin, 35% on OHAs as well	*Intervention*: intensified SMBG *SMBG regimen*: SMBG using an electronic BG meter before all meals and at bedtime for 8 weeks then usual monitoring resumed *Outcomes*: HbA_{1c} *Quality*: 27.1% dropouts at 1 year	• Entry HbA_{1c} 8.1 ± 1.67% ($n = 210$), decrease by 0.32 ± 1.17 at 1 year ($n = 159$) • Decrease predicted by entry level HbA_{1c} and compliance with SMBG ($r = 0.862$, $p < 0.001$)

Study	Participants	Interventions	Results
Murata (2008)[82] USA *Design*: database study *Follow-up*: 24 months	Total number: 5862 patients with T2DM Setting: Southwest Healthcare Network veterans *Inclusion criteria*: T2DM, taking oral antihyperglycaemic agents *Age*: NR *BMI*: NR *HbA_{1c}*: NR *Diabetes duration*: NR *Treatment*: no details	*Comparison*: association between SMBG use and HbA_{1c} and medication change *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}	• SMBG use, subdivided by treatment alterations: • *Group 1*: OHA dose(s) unchanged: 36.3% used SMBG and were monitoring a median of 2.5 times weekly (interquartile range 1.2–4.0) • *Group 2*: OHA dose(s) increased: 38.0% used SMBG and were monitoring a median of 2.6 times weekly (interquartile range 1.2–4.1) • *Group 3*: new OHA added: 39.7% used SMBG and were monitoring a median of 2.8 times weekly (interquartile range 0.9–4.1) • *Group 4*: 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) • *Group 5*: Insulin added: 77.6% used SMBG and were monitoring a median of 3.7 times weekly (interquartile range 1.7–7.2) • No association between SMBG monitoring frequency and HbA_{1c} overall; more frequent testing associated with lower HbA_{1c} in groups 1, 4 and 5, effect ranged from –0.22% to –0.94% for every 10 glucose test strips/week
Newman (1990)[83] USA *Design*: cross-sectional *Follow-up*: 3 years	*Total number*: 38 patients with T1DM or T2DM *Setting*: Veteran Affairs chart review *Inclusion criteria*: T1DM or T2DM, no medication limits *Age*: 60 years *BMI*: NR *HbA_{1c}*: 8.2% (from graph) *Diabetes duration*: 14 years *Treatment*: diet, OHA or insulin	*Comparison*: association between SMBG use and HbA_{1c} *Outcomes*: HbA_{1c}	• No association between HbA_{1c} and SMBG
Oki (1997)[84] USA *Design*: cross-sectional *Follow-up*: NA	*Total number*: 98 patients with T2DM *Setting*: routine care *Inclusion criteria*: T2DM, no medication limits *Age*: 56 years *BMI*: NR *HbA_{1c}*: NR *Diabetes duration*: NR *Treatment*: diet, OHAs, insulin	*Comparison*: association between SMBG use and HbA_{1c} *Outcomes*: HbA_{1c}	• No association between HbA_{1c} and SMBG • No difference in HbA_{1c} between patients with SMBG <7 times per week and patients with SMBG >7 times per week • HbA_{1c} not associated with SMBG when analysed based on treatment group (insulin vs diet/oral)

Study	Participants	Interventions	Results
Ozmen (2003)[85] Turkey *Design*: cohort *Follow-up*: 1 year	*Total number*: 267 patients with T2DM *Age*: 58 years *BMI*: 29.1 kg/m^2 *HbA$_{1c}$*: 9.1% *Diabetes duration*: 8.6 years *Treatment*: 34% using insulin; diet alone, insulin ± SUs, acarbose or MET	*Comparison*: association between SMBG use and HbA$_{1c}$ *SMBG regimen*: month 1: 2–3 per week, during the following 11 months: as necessary to maintain normoglycaemia *SMBG treatment adjustment/advice*: clinicians evaluated SMBG readings to adjust treatment *Control*: none *Outcomes*: HbA$_{1c}$	• HbA$_{1c}$ reduced by 1.9% after 12 months ($p < 0.001$)
Patrick (1994)[86] UK *Design*: cross-sectional *Follow-up*: NA	*Total number*: 200 *Setting*: hospital diabetes clinic *Inclusion criteria*: T2DM, no insulin *Age*: 65 years *BMI*: NR *HbA$_{1c}$*: NR *Diabetes duration*: 6.4 years *Treatment*: diet oral hypoglycaemic agents	*Comparison*: association between SMBG/SMUG use and HbA$_{1c}$ *SMBG regimen*: no details of SMBG use/protocols *Outcomes*: HbA$_{1c}$	• 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 • No association between HbA$_{1c}$ and SMBG • No difference between patients who reported they would act on monitoring results and those who reported they would not act on monitoring results • 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 ($n = 4$); $p < 0.05$
Rindone (1997)[87] USA *Design*: retrospective chart review *Follow-up*: 2 years	*Total number*: 115 *Setting*: outpatient clinics *Inclusion criteria*: T2DM, SU therapy for > 2 years; no insulin or MET *Age*: 68 years *BMI*: weight 91 ± 20 kg *HbA$_{1c}$*: 8.1 ± 1.5% *Diabetes duration*: NR *Treatment*: oral hypoglycaemic agents (SU)	*Comparison*: access to strips vs no access *SMBG regimen*: no details of SMBG use/protocols *SMBG method*: Chemstrips *Outcomes*: HbA$_{1c}$	• No significant difference in HbA$_{1c}$ between people with and without access to strips • Few changes made to SU medication in either group (so SMBG results probably not used to change treatment)

Study	Participants	Interventions	Results
Roblin (2001)[88] (abstract) USA *Design*: cross-sectional *Follow-up*: NA	*Total number*: 955 *Setting*: 3 sites of an HMO *Inclusion criteria*: T2DM (95%), pharmacologically treated *Age*: 53 years *BMI*: NR *HbA_{1c}*: NR *Diabetes duration*: 12 years *Treatment*: 43% insulin, 52% oral agents	*Comparison*: association between SMBG use and HbA_{1c} *Outcomes*: HbA_{1c}, SMBG frequency	• Mean HbA_{1c} significantly lower in insulin-treated patients using at least daily SMBG than those using less than daily SMBG (8.8% vs 9.7%; $p < 0.05$) • No difference in patients not using insulin
ROSSO Study (Martin (2006)[15]**/ Schneider (2007)**[99]**/ Martin (2009)**[78]**)** Germany *Design*: longitudinal study *Follow-up*: mean 6.5 years	*Total number*: 3268 patients with T2DM *Setting*: 192 doctors' practices *Inclusion criteria*: T2DM, followed from diagnosis *Age*: 62.4 years *BMI*: 29.8 kg/m^2 *HbA_{1c}*: 7.7% *Diabetes duration*: followed from diagnosis *Treatment*: $n = 2515$ not using insulin	*Comparison*: association between SMBG use and morbidity/mortality *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}, diabetes-related morbidity (non-fatal myocardial infarction, stroke, foot amputation, blindness, haemodialysis), all-cause mortality	• *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 • At baseline, SMBG group had higher mean FPG and HbA_{1c} than non-SMBG group (HbA_{1c} 8.1% vs 7.2%) (suggestion insufficient control may have been reason for initiating SMBG) • Total rate of non-fatal events lower in SMBG group than non-SMBG after 6.5 years (7.2% vs 10.4%; $p = 0.002$) • Fatal events lower in SMBG group (2.7% vs 4.6%; $p = 0.004$) • Effects remained when analysing only patients not using insulin • No significant difference at baseline in classic cardiovascular risk factors • SMBG initiation often associated with treatment change/intensification (so confounding a problem)
Rost (1990)[89] USA *Design*: cross-sectional *Follow-up*: NA	*Total number*: 84 patients with T2DM *Setting*: inpatient *Inclusion criteria*: T2DM, no medication limitation *Age*: 56 years *Diabetes duration*: followed from diagnosis *Treatment:* insulin, oral medication	*Comparison*: association between SMBG use and HbA_{1c} in insulin users and non-insulin users *Outcomes*: HbA_{1c}	• SMBG associated with lower HbA_{1c} (independent of treatment) • Relationship of SMBG to HbA_{1c} was independent of other self-care behaviours

Study	Participants	Interventions	Results
Schiel (1999)[90] 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_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA_{1c}, frequency of SMBG	• Frequency of SMBG inversely related to HbA_{1c} ($r = -0.17$, $p < 0.001$) • Most important determinants of HbA_{1c} included frequency of SMBG
Schütt (2006)[91] 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_{1c}*: 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_{1c} *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: most recent frequency of SMBG, most recent HbA_{1c}	• *Insulin treated*: average SMBG frequency 2.7 times per day; increased frequency associated with lower HbA_{1c} (–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_{1c} (presumably because those with poorer control were asked to test more often) (+0.14%/one additional SMBG per day; $p < 0.0001$)
Secnik (2007)[92] 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_{1c}*: NR *Diabetes duration*: NR *Treatment*: $n = 347$ insulin, $n = 2436$ oral agents	Intervention: access to free BG monitors Outcomes: HbA_{1c}, SMBG use	• In the insulin cohort, the total number of test strips prescribed was a predictor of HbA_{1c}, with a decrease of HbA_{1c} 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

Study	Participants	Interventions	Results
Soumerai (2004)[93] USA *Design*: interrupted time series *Follow-up*: 4 years	*Total number*: 3219 people with T1DM or T2DM *Setting*: database *Inclusion criteria*: T2DM, any treatment *Age*: 56 ± 12.3 years *BMI*: <25 kg/m^2 11.8%, 25–30 kg/m^2 24.6%, ≥ 30 kg/m^2 44.5% *HbA$_{1c}$*: 8.4 ± 1.7% *Diabetes duration*: NR *Treatment*: insulin, oral hypoglycaemic agents (57% on SUs)	*Intervention*: access to free BG monitors *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA$_{1c}$, SMBG use, medication use	• Baseline HbA$_{1c}$ in patients on SUs (n = 1791) 8.4 ± 1.7%; in 90 initiators of SMBG vs 43 control subjects with HbA$_{1c}$ > 10%, decrease in HbA$_{1c}$ of 0.63% (95% CI 1.14 to 0.12); p = 0.03 • No association of SMBG and HbA$_{1c}$ in those with good (7.1%) or adequate (8.0%) control • Adjusted (for baseline trend) initiation rate of SMBG in SU users increased by 14 (95% CI 10 to 17) patients/1000 patients per month • Initiators of SMBG showed sudden significant improvements in regularity of medication use by 6 months post initiation
Stiptzarov (2003)[94] USA *Design*: cross-sectional, survey *Follow-up*: NA	*Total number*: 14329 *Setting*: Veterans Affairs facilities *Age*: 65 years; 98% male *BMI*: NR *HbA$_{1c}$*: NR *Diabetes duration*: NR *Treatment*: OHAs, insulin; no details given	*Comparison*: association between SMBG use and HbA$_{1c}$ *SMBG regimen*: no details of SMBG use/ protocols *Outcomes*: HbA$_{1c}$	• 36% received 0.75 strips or more per day (mean 1.7) with mean HbA$_{1c}$ 8.13%, those who received less than 0.75 strips per day (mean 0.17) had HbA$_{1c}$ 8.0% • SMBG was associated with reduced HbA$_{1c}$ in subsequent quarter: using ≥ 0.75 strips per day was associated (p < 0.0001) with a reduction of 0.1% HbA$_{1c}$ 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
Tengblad (2007)[95] Sweden *Design*: cross-sectional *Follow-up*: NA	*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 *Setting*: 18 primary care health centres in Östergötland and Jönköping, Sweden *Inclusion criteria*: T2DM, users and non-users of SMBG *Age*: 69 years *BMI*: NR *HbA$_{1c}$*: 5.4% to 6.9% *Diabetes duration*: < 2 years, 4–33%; 2–4 years, 9–35%; > 4 years, 32–87% *Treatment*: diet only (32%), oral hypoglycaemic agents (37%), insulin (31%)	*Comparison*: association between SMBG use and HbA$_{1c}$ *SMBG regimen*: no details of SMBG use/ protocols *SMBG other*: *SMBG method*: *Outcomes*: HbA$_{1c}$	• Frequency of SMBG 36% in diet only group, 54% in patients on oral agents, 79% in patients on insulin • No significant differences in HbA$_{1c}$ 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$_{1c}$ significantly higher [but not relevant??] in SMBG group (5.5% vs 5.3%) • COMMENT: low HbA$_{1c}$ levels might preclude meaningful difference in HbA$_{1c}$

Study	Participants	Interventions	Results
Wen (2004)[16] USA *Design*: chart review *Follow-up*: 3 years	*Total number*: 976 people with T2DM *Setting*: Veteran Affairs *Inclusion criteria*: T2DM, prescribed oral medication *Age*: 63 years; 97% male *BMI*: 31 ± 6 kg/m^2 *HbA$_{1c}$*: 7–7.3% *Diabetes duration*: NR *Treatment*: OHAs only	*Comparison*: no SMBG vs SMBG year 3 or SMBG years 2–3 or SMBG years 1–3 *Outcomes*: HbA$_{1c}$	• SMBG frequency not associated with HbA$_{1c}$ (but HbA$_{1c}$ already quite low) • Median usage of strips 4 per week
Wieland (1997)[96] USA *Design*: retrospective chart review *Follow-up*: NA	*Total number*: 216 people with T2DM *Setting*: Veteran Affairs *Inclusion criteria*: T2DM, prescribed glyburide *Age*: range 39–89 years; all male *BMI*: NR *HbA$_{1c}$*: 7.9 ± 1.4% *Diabetes duration*: NR *Treatment*: OHAs only	*Comparison*: no SMBG vs SMBG once per day vs SMBG ≥ twice per day *Outcomes*: HbA$_{1c}$	• Frequency of SMBG not associated with HbA$_{1c}$ • Age and glibenclamide dose were significantly associated with HbA$_{1c}$

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

Study, design	Participants/issues	Results
Belsey (2009),[100] UK 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 £21.56 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[10] 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_{1c} SMBG thought to be more accurate than SMUG, but participants expressed reservations about its accuracy when compared with HbA_{1c}
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

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Study, design	Participants/issues	Results
Lawton (2004),[6] UK Qualitative study using in-depth interviews, study informed by grounded theory Patients 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 diagnoses: 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),[101] 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

Study, design	Participants/issues	Results
Peel (2007),[102] UK Qualitative study as above, repeat interviews over 4 years after diagnosis	• 18 patients with T2DM repeatedly interviewed over 4 years	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_{1c}, 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 *Conclusions*: 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
Zgibor (2002),[103] New Zealand Qualitative survey	• 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) • Age: 52–63 years, men and women • Survey to determine barriers to diabetes care, and to SMBG	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_{1c} > 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

BG, blood glucose; MET, metformin.

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By Campbell MK, Skea ZC, Sutherland AG, Cuthbertson BH, Entwistle VA, McDonald AM, *et al.*

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A randomised 2 × 2 trial of community versus hospital pulmonary rehabilitation for chronic obstructive pulmonary disease followed by telephone or conventional follow-up.
By Waterhouse JC, Walters SJ, Oluboyede Y, Lawson RA.

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The effectiveness and cost-effectiveness of behavioural interventions for the prevention of sexually transmitted infections in young people aged 13–19: a systematic review and economic evaluation.
By Shepherd J, Kavanagh J, Picot J, Cooper K, Harden A, Barnett-Page E, *et al.*

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By Song F, Parekh S, Hooper L, Loke YK, Ryder J, Sutton AJ, *et al.*

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By Hemingway H, Henriksson M, Chen R, Damant J, Fitzpatrick N, Abrams K, *et al.*

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By Cummins E, Royle P, Snaith A, Greene A, Robertson L, McIntyre L, *et al.*

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We look forward to hearing from you.

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