Management of type 2 diabetes

Less testing times?

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This well-conducted study from Northern Ireland on the efficacy of self-monitoring of blood glucose (SMBG) for people newly diagnosed with type 2 diabetes (summarised alongside), suggests SMBG is an additional burden they can be spared. For individuals initially treated with the, now standard, step-wise intensified treatment algorithm (diet, then metformin, then sulphonylurea...) there was no benefit in terms of improved glycaemic control (reduction in HbA_{1c} or reduction in hypoglycaemia rates) and a real cost – in significantly higher depression scores and a trend to greater anxiety with SMBG. This would suggest that most people newly diagnosed with type 2 diabetes should not be asked or taught to test routinely. It doesn't appear to help, and if we were to restrict SMBG in newly-diagnosed non-insulin-treated patients, the time released from hard-pressed patient and healthcare professional schedules could perhaps be used more productively on other aspects of diabetes education and enabling self-care.

But what about people with longer-standing type 2 diabetes? Well, again for those with well-controlled diabetes, the Oxford based DiGEM (Diabetes Glycaemic Education and Monitoring) trial showed that for those with relatively short diabetes duration (mean 3 years) and moderately good control (mean HbA_{1c} 7.5%) SMBG was neither clinically effective nor cost effective (Farmer et al, 2007). The key practical issue is that SMBG seems to be a burden rather than a benefit for most of these individuals with lifestyle- and tablet-treated type 2 diabetes, and does not justify the time, effort and money involved (Simon et al, 2008; summarised on page 156).

This is not to say there is never a role for SMBG in type 2 diabetes. Indeed in a non-randomised observational study of people with type 2 diabetes studied over 6.5 years, SMBG was a marker of improved clinical outcomes for those with poor HbA_{1c} at baseline, suggesting that for those with longer duration of diabetes with poor control at baseline, SMBG is associated with decreased diabetes-related morbidity and all-cause mortality, whether or not they were using insulin (Martin et al, 2006). For some patients with a particular problem or in particular personal and clinical contexts, for example, to confirm or exclude hypoglycaemia, to assess the impact of particular dietary modifications or concomitant drug therapies (such as steroids) or poorly controlled patients, SMBG may have a role. In addition, as the condition progresses with increasing beta-cell failure towards insulin requirement, with associated increased risk and rates of hypoglycaemia, SMBG is a practical and useful tool with immediate utility and greater potential benefit. This, and the contrast between the US and UK healthcare systems, may explain the apparently paradoxical results of the US study (Tunis et al, 2008; summarised on page 156).

As the authors of DiGEM suggest, the optimum use and frequency of testing for those with insulin-treated diabetes remains unanswered, and the potential role for SMBG in other people with diabetes who have particular characteristics or who are at particular stages of the condition's progression remain to be defined. In my opinion, for most people with type 2 diabetes of early or intermediate duration, SMBG is probably unnecessary. You may find that, in practice, it is easier not to start patients testing inappropriately rather than to attempt to stop those wedded to the ritual from doing so, but the future for most people with type 2 diabetes should, at least initially, be less testing.

Farmer A, Wade A, Goyder E, Yudkin P, French D, Craven A, et al (2007) Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel randomised trial. *BMJ* **335**: 132–9

Martin S, Schneider B, Heinemann L et al (2006) Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: an epidemiological cohort study. *Diabetologia* **49**: 271–8

BRITISH MEDICAL JOURNAL

SMBG efficacy in newly diagnosed type 2 diabetes

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓✓
WOW! factor	✓✓✓✓

1 The effects of self-monitoring of blood glucose (SMBG) on glycaemic control (HbA_{1c}, and incidence of hypoglycaemia) and psychological indices were assessed in patients newly diagnosed with type 2 diabetes.

2 The efficacy of SMBG in patients with newly diagnosed type 2 diabetes (ESMON) study was a randomised controlled trial in which 184 patients <70 years of age were assigned to self-monitoring (n=96) or no monitoring (control; n=88) groups.

3 Both groups underwent a core educational programme, with additional education on monitoring provided for the SMBG group, and were followed up every three months over the course of a year.

4 Depression and anxiety were measured on a 100-point scale, and regressed on the baseline measurement.

5 No statistically significant difference in HbA_{1c} levels, or in the incidence of hypoglycaemia, were observed between the study groups.

6 The depression score of patients in the SMBG group were 6% higher than those of the control group.

7 The authors conclude that SMBG in patients newly diagnosed type 2 diabetes is not associated with better glycaemic control, and may reduce patient well-being.

O'Kane M, Bunting B, Copeland M et al (2008) Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study). *BMJ* **336**: 1174–7

'SMBG, regardless of daily frequency, in patients with type 2 diabetes being treated with oral antidiabetic medications represents good value for money.'

BRITISH MEDICAL JOURNAL

Cost-effectiveness, quality of life and SMBG

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓✓
WOW! factor	✓✓✓

1 This study assessed the cost-effectiveness of self-monitoring of blood glucose (SMBG) in 453 patients with non-insulin treated type 2 diabetes in the UK.

2 From the diabetes glycaemic education and monitoring (DiGEM) trial, data were collected for a year prior to the baseline, and quarterly from the baseline for 12 months.

3 Patients were assigned to three groups: standardised usual care (control; *n*=152); use of a blood glucose meter (BGM) with health professional assistance (less intensive; *n*=150); and use of a BGM in conjunction with training in the interpretation and application of results (more intensive; *n*=151).

4 The average cost of intervention was found to increase according to the intensity of the intervention (£89, control; £181, less intensive; £173, more intensive).

5 A statistically significant difference in the cost of intervention was found between the control group and the two SMBG groups, but no significant difference in the clinical outcomes was seen between the groups.

6 The authors suggest that SMBG is unlikely to yield lifetime health benefits, or be more cost-effective than standardised usual care.

7 Reductions in quality of life scores for patients in both SMBG groups was attributed to increases in anxiety and depression during the study period.

Simon J, Gray A, Clarke P et al (2008) Cost effectiveness of self monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evalustion of data from the DiGEM trial. *BMJ* **336**: 1177–80

THE AMERICAN JOURNAL OF MANAGED CARE

Long-term cost-effectiveness of SMBG

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 This study modelled the long-term cost-effectiveness of self-monitoring of blood glucose (SMBG) in patients with type 2 diabetes being treated with oral antidiabetic medications in the USA.

2 Using baseline data from the Kaiser Permanente Diabetes Registry on mean HbA_{1c}, age and sex to simulate the cohort, the authors produced a computer-generated 40-year projection of the clinical and economic outcomes of SMBG once- or thrice-daily, or no self-monitoring.

3 An increase of 0.103 quality-adjusted life-years (QALYs) was seen for the once-daily SMBG group, and 0.327 for the thrice-daily group.

4 SMBG was associated with mean per patient lifetime direct medical cost increases for once- and thrice-daily monitoring ($808 and $2161, respectively), compared to no self-monitoring.

5 Increased QALYs partially offset the increased costs for the once daily monitoring group, and was still more cost-effective for the thrice daily (incremental cost-effective ratios of $7856/QALY and $6601/QALY, respectively).

6 SMBG, regardless of daily frequency, in patients with type 2 diabetes being treated with oral antidiabetic medications represents good value for money.

7 Further, it was found that the longer the time horizon, the greater the cost-effectiveness of SMBG.

Tunis SL, Minshall ME (2008) Self-monitoring of Blood Glucose in Type 2 Diabetes: Cost-effectiveness in the United States. *The American Journal of Managed Care* **14**: 131–40

AMERICAN HEART JOURNAL

Pioglitazone reduces risk of major adverse CV events

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 The effect of pioglitazone in the treatment of type 2 diabetes was evaluated, taking the time from randomisation to the first major adverse cardiovascular event (MACE) as the primary end point.

2 People with type 2 diabetes and a history of macrovascular disease (*n*=5238) were designated high-risk patients and randomly assigned to pioglitazone (15–45 mg/day, dose based on tolerance) and placebo groups. Normal glucose-lowering and cardiovascular medication regimes were maintained.

3 After 3 years, the pioglitazone treatment group experienced a 16% risk reduction in all-cause mortality, nonfatal myocardial infarction and nonfatal stroke, compared with the placebo group (*P*=0.027).

4 Of the pioglitazone group, 257 patients had experienced cardiovascular death, nonfatal myocardial infarction or nonfatal stroke by the time of the final visit, compared with 313 placebo patients (*P*=0.020).

5 It is clinically significant that the reduction in MACEs by approximately 20% in the pioglitazone group was achieved in addition to the ongoing treatment of these patients with standard cardiovascular management medication regimens.

6 At 9 months post-randomisation, the pioglitazone and placebo groups diverged in the rate of MACEs (*P*=0.02), indicating that the treatment is slow to become clinically apparent.

Wilcox R, Kupfer S, Erdmann E (2008) Effects of pioglitazone on major adverse cardiovascualr events in high-risk patients with type 2 diabetes: Results from PROspective pioglitAzone Clinical trial In Vascular Events (PROactive 10). *American Heart Journal* **155**: 712–7