Comment on: Davidson MB (2007) The dilemma of self-monitoring of blood glucose. *Diabetologia* 50:497–499

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To the Editor In his Commentary entitled ‘The dilemma of self-monitoring of blood glucose’ [1], M. B. Davidson acknowledges observational studies conducted by us that found benefits associated with self-monitoring of blood glucose (SMBG) in non-insulin-treated patients with type 2 diabetes. However, he concludes that there is a lack of evidence for SMBG and that ‘resources might be better spent in other areas of diabetes care’. This view dismisses observational findings, relies on select randomised controlled trials (RCTs), and ignores the positive findings from the two most up-to-date meta-analyses to systematically review existing RCTs [2, 3].

Historically, RCTs have been viewed as the best evidence of the efficacy of a therapy. However, the efficacy observed in select RCT populations often fails to translate in real-world practice in terms of clinical effectiveness. A new generation of epidemiologists feels that evaluation of behavioural interventions, particularly those that cannot be blinded and may reflect strong patient preferences, such as SMBG, require multiple types of evidence, a greater focus on real-world settings, contextual information and cost data and must address translational issues [4].

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The focus of past discussions has been on the benefit of SMBG, but this may be somewhat off-target. We must keep in mind that SMBG is a diagnostic measure, not an intervention. That is, knowing one’s actual blood glucose level does not directly affect glycaemic control. SMBG is analogous to measuring one’s body weight before breakfast—there is no direct effect on body weight, but it could lead to healthy choices at the breakfast table. The benefit of diagnostic procedures such as SMBG depends on appropriate behavioural changes in response to blood glucose readings, and potentially on modifying glucose-lowering therapy. Trials on SMBG in non-insulin-treated type 2 diabetes will fail to show a benefit if the study protocol does not link the practice to promotion of the desired behavioural changes, e.g. daily lifestyle and self-adjustment of glucose-lowering therapy. There is an implicit theory that SMBG provides feedback to patients about their glucose status, but any benefit will depend on the ability of patients to understand and incorporate the information and to respond appropriately. Clearly, SMBG may not be useful to patients who lack the necessary skills and motivation. However, several studies that have tested randomised interventions in patients already using SMBG [5, 6] found that training to improve their ability to make appropriate behavioural decisions in response to blood glucose readings resulted in better glycaemic control.

M. B. Davidson’s own research [7] serves as another illustration of the issues surrounding translatability. Glycaemic effects should not be expected if there are co-interventions with known efficacy that may overwhelm any potential clinical benefits associated with SMBG. In the trial conducted by M. B. Davidson and colleagues, the SMBG treatment arm and the non-SMBG control arm received intensive nurse case management with frequent visits (biweekly initially) and a treat-to-target protocol, with

immediate medication intensification if patients were not achieving their glycaemic target. Such intensive care shifts the bulk of the responsibility of care away from the patient and back onto the healthcare system, understandably leaving little or no opportunity for SMBG to provide any additional benefit. We accept M. B. Davidson's findings that SMBG provides little added value in non-insulin-treated patients (who are at low risk of hypoglycaemia) receiving such intensive nurse care management. However, the model of care used in this research is vastly different from that used in typical practice. Such frequent nurse case management entails expensive and specialised care, and therefore findings have limited generalisability.

In a talk at the recent meeting of the International Diabetes Federation in Cape Town (South Africa), R. Bergenstal described a patient who diligently performed SMBG and documented the results. When seeing his doctor the patient offered his SMBG log book and said, 'Here are your numbers!' Dr Bergenstal responded with, 'Oh no, these are YOUR numbers.' This is the critical message: without appropriate education and counselling of the patient, and without using SMBG results to adapt the daily lifestyle and glucose-lowering therapy regimen, SMBG is unlikely to provide a benefit.

The growing group of researchers involved in studies of SMBG in type 2 diabetes have recently formed an international SMBG working group as a platform for the exchange of information, discussion and consideration of trial protocols (for further information, please contact H. Kolb). Members include M. B. Davidson and the authors of this letter. It is encouraging to see that planned and ongoing trials of SMBG in type 2 diabetes consider patient empowerment to be the central element. The results of one such trial will become available later this year [8]. We suggest that future research needs to move beyond the question: does SMBG have an effect? There is little doubt that self-monitoring works insofar as it informs patients of their blood glucose levels. The important question is: to what extent can patients be trained to use it to their advantage? There is evidence that the clinical benefit of

this practice will increase if patients are trained to understand the readings and are motivated to adjust lifestyle and glucose-lowering therapy when appropriate. We feel it is premature to draw broad-sweeping conclusions regarding effect size, and suggest that future research needs to focus on how to make the best use of SMBG, in which patients and under what conditions.

Duality of interest S. Martin and H. Kolb received honoraria from Roche Diagnostics, a manufacturer of glucometers and glucose test strips, for speaking on SMBG. A. J. Karter has no duality of interest to report.

References

1. Davidson MB (2007) The dilemma of self-monitoring of blood glucose. *Diabetologia* 50:497–499
2. Welschen LM, Bloemendal E, Nijpels G et al (2005) Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin. *Cochrane Database Syst Rev* 18:CD005060
3. Sarol JN Jr, Nicodemus NA Jr, Tan KM et al (2005) Self-monitoring of blood glucose as part of a multi-component therapy among non-insulin requiring type 2 diabetes patients: a metaanalysis (1966–2004). *Curr Med Res Opin* 21:173–184
4. Glasgow RE, Lichtenstein E, Marcus AC (2003) Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *Am J Public Health* 93:1261–1267
5. Moreland EC, Volkening LK, Lawlor MT et al (2006) Use of a blood glucose monitoring manual to enhance monitoring adherence in adults with diabetes: a randomized controlled trial. *Arch Intern Med* 166:689–695
6. Cho JH, Chang SA, Kwon HS et al (2006) Long-term effect of the Internet-based glucose monitoring system on HbA_{1c} reduction and glucose stability: a 30-month follow-up study for diabetes management with a ubiquitous medical care system. *Diabetes Care* 29:2625–2631
7. Davidson MB, Castellanos M, Kain D et al (2005) The effect of self monitoring of blood glucose concentrations on glycated hemoglobin levels in diabetic patients not taking insulin: a blinded, randomized trial. *Am J Med* 118:422–425
8. Farmer A, Wade A, French DP et al (2005) The DiGEM trial protocols randomised controlled trial to determine the effect on glycaemic control of different strategies of blood glucose self-monitoring in people with type 2 diabetes. *BMC Fam Pract* 6:25–32