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**Comment to: 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* 49:271–278**

Received: 22 February 2006 / Accepted: 28 February 2006  
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If causally interpreted, self-monitoring of blood glucose (SMBG) in type 2 diabetes reduces mortality by about 50% [1]. The benefit emerges swiftly, as suggested by the Kaplan–Meier survival curves. We wonder whether pricking fingers might be the most effective intervention ever reported in type 2 diabetes.

Unfortunately, the study in question is an example of observational research fallacies. The study lacks internal validity. The design is uncontrolled. Patients were not examined personally. Instead, routine medical records of a self-selected group of primary care physicians without experience in performing clinical research were used to extract patient data for analysis. Important bias and confounders are likely. Differences in the nature and severity of diabetes have not been ruled out. Heterogeneity among groups is likely. Assessments of variables such as blood pressure measurements have not been standardised. In particular, social class and indicators of social support were not documented. Socioeconomic status is a most important prognostic factor for morbidity and mortality in diabetes [2, 3]. This is of particular importance for the present analysis, since for most patients with type 2 diabetes in Germany SMBG is not reimbursed. Therefore, the study could be seen as measuring the hidden effect of social class and social capital among individuals with type 2 diabetes rather than the effect of SMBG. Even the few characteristics available from the medical records indicate some important differences between patients using SMBG and those who do not. The SMBG group is younger and has lower systolic blood pressure. Other unknown differences are conceivable. The huge number of missing

baseline data indicates how unreliable physicians' routine documentation can be. For example, HbA<sub>1c</sub> values were recorded for only 45% of the study population. Since study endpoints are not verified through additional systematic attempts, their reliability is of major concern. It is highly likely that a healthy survivor effect exists, which means that those who are still alive, fit and with social support continue to be registered in the study and to use SMBG.

To our surprise, Martin and colleagues point out that SMBG in type 2 diabetes patients would be difficult to investigate in a randomised controlled trial. Certainly, we cannot blind strips, lancets and meters. However, this is not necessary. Randomised controlled trials of heterogeneous methodological quality investigating the effects of SMBG on HbA<sub>1c</sub> in type 2 diabetes have been published [4–6]. Follow-up was up to 1 year. Long-term compliance with SMBG remains unknown. Outcomes like hypoglycaemic episodes and health-related quality of life have rarely been investigated [4]. Although recent meta-analyses suggest that SMBG may result in better glycaemic control among patients with type 2 diabetes [4, 5], any conclusion on the long-term clinical relevance of this finding is speculative. In addition, evidence on the superiority of blood glucose over urine glucose monitoring in type 2 diabetes is lacking. A Health Technology Assessment report concluded that SMBG is not of additional benefit [6]. There have been increasing requests for evidence-based data from large and carefully designed randomised controlled trials investigating important clinical endpoints and cost-effectiveness of SMBG compared with best available standard care [4–7]. Until results of such studies are available, the benefit of this invasive and expensive procedure remains uncertain [8].

In conclusion, the study by Martin et al. does not enlarge the body of knowledge on the effectiveness of SMBG, since the study lacks internal validity. In contrast, it is a most impressive example of the need for high-quality randomised controlled trials for the evaluation of interventions on clinical outcomes, whether pharmacological or non-pharmacological.

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**Duality of interest** The authors declare that they have no duality of interest.

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## References

1. 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: 271–278
2. Mühlhauser I, Overmann H, Bender R et al (1998) Social status and the quality of care for adult people with type I (insulin-dependent) diabetes mellitus—a population-based study. *Diabetologia* 41:1139–1150
3. Braveman PA, Cubbin C, Egerter S et al (2005) Socioeconomic status in health research. *JAMA* 294:2879–2888
4. 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: a systematic review. *Diabetes Care* 28:1510–1517
5. Sarol JN Jr, Nicodemus NA Jr, Tan KM, Grava MB (2005) Self-monitoring of blood glucose as part of a multi-component therapy among non-insulin requiring type 2 diabetes patients: a meta-analysis (1966–2004). *Curr Med Res Opin* 21:173–183
6. Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R (2000) Monitoring blood glucose control in diabetes mellitus: a systematic review. *Health Technol Assess* 4:1–93 (also in: *Diabet Med* 2000; 17:755–761)
7. Ipp E, Aquino RL, Christenson P (2005) Point: self-monitoring of blood glucose in type 2 diabetic patients not receiving insulin: the sanguine approach. *Diabetes Care* 28:1528–1530
8. Davidson MB (2005) Counterpoint: self-monitoring of blood glucose in type 2 diabetic patients not receiving insulin: a waste of money. *Diabetes Care* 28:1531–1533