

Evidence Tables

SM1: Is self-monitoring effective in assisting in the management of people with with type 2 diabetes?

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect size	Source of funding
Welschen LMC, Bloemendal E, Nijpels G, Dekker JM, Heine RJJ, Stalman WAB, Bouter LM. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin. The Cochrane Database of Systematic Reviews 2005, Issue 2.	Cochrane SR 1++	Patients were from 6 RCTs: Allen 1990 (USA, N=54), Davidson 2005 (USA, N=89), Fontbonne 1989 (France, N=208), Guerci 2003 (France, N=689), Muchmore 1994 (USA, N=23), Schwedes 2002 (Germany/Austria, N=250).	Patients were diagnosed with type 2 diabetes mellitus and were not using insulin.	Self-monitoring of blood glucose (SMBG)	Usual care or urine glucose monitoring.	All studies 6 mths duration except Muchmore 1994 which was 28 weeks with follow-up to 44 weeks and Schwedes 2002 which was 6 months duration with 6 months follow-up).	Glycaemic control (HbA1c and or fasting plasma glucose level). Quality of life Patient satisfaction Hypoglycaemic episodes Morbidity Adverse events Costs.	There were differences in patient baseline data and type of intervention in the studies so no meta-analysis was performed. 2 studies were considered to be high quality studies (Allen 1990 & Davidson 2005) whilst the remainder were considered to be low quality. 3 studies found no statistically significant differences in the decrease in HbA1c (Fontbonne 1989, Muchmore 1994 & Davidson 2005). 2 studies found a statistically significant difference in favour of SMBG for decreasing HbA1c (Schwedes 2002 and Guerci 2003). Allen 1990 compared SMBG with self monitoring of urine glucose and found that both groups had a 2% HbA1c decrease at the end of he study. Fasting plasma glucose was assessed in 2 studies and showed a non-significant decrease as a result of SMBG (Allen 1990 & Guerci 2003). One study found identical results in the SMBG and control group for improvement in quality of life scales (Muchmore 1994). Another found that well-being and treatment satisfaction improved to the same extent in both groups (Schwedes 2002). A study investigating the effect of	None

								SMBG on the frequency of hypoglycaemia found a significant difference in number of patients who reported at least one episode of asymptomatic hypoglycaemia (Guerci 2003). The review authors however, note that this is an invalid result as it was not possible for the control group to measure this type of hypoglycaemia.	
Welschen LMC, Bloemendal E, Nijpels G, Dekker JM, Heine RJJ, Stalman WAB, Bouter LM. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin. <i>Diabetes Care</i> 28:1510-1517 2005.	SR 1++	Patients were from 6 RCTs: Allen 1990 (USA, N=54), Davidson 2005 (USA, N=89), Fontbonne 1989 (France, N=208), Guerci 2003 (France, N=689), Muchmore 1994 (USA, N=23), Schwedes 2002 (Germany/Austria, N=250).	Patients were diagnosed with type 2 diabetes mellitus and were not using insulin.	Self-monitoring of blood glucose	Usual care or urine glucose monitoring	All studies 6 mths duration except Muchmore 1994 which was 28 weeks with follow-up to 44 weeks and Schwedes 2002 which was 6 months duration with 6 months follow-up).	Glycaemic control (HbA1c and or fasting plasma glucose level). Quality of life Patient satisfaction Hypoglycaemic episodes Morbidity Adverse events	In the meta analysis the overall effect was a statistically significant decrease of 0.39% in HbA1c (95%CI -0.56 to -0.21) in favour of SMBG compared with the control group. The comparison between SMBG and SM urine glucose showed a nonsignificant decrease of 0.17% (-0.96 to 0.61) in HbA1c in favour of SMBG. There was no statistical heterogeneity. Other results the same as the Cochrane review (above).	None
Sarol JN, Nicodemus NA, Tan KM, Grava MB. 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) <i>Current Medical</i>	SR 1++	Patients were from 8 RCTs: Davidson 2005 (N=89), Estey 1990 (N=53), Fontbonne 1989 (N=208), Guerci 2003 (N=689), Jaber 1996 (N=39), Kwon 2004 (N=81), Muchmore 1994 (N=23), Schwedes 2002	Adult patients (18 years or over) with type 2 diabetes not employing insulin treatment. Baseline HbA1c ranged from 6.3% to	A diabetes management strategy with a self-monitoring component	A diabetes management strategy with no self-monitoring component	Study duration varied from 12 weeks to 44 weeks.	Glycaemic control (HbA1c and or fasting plasma glucose level).	Three studies (Estey 1990, Jaber 1996 & Kwon 2004) were judged to have a high risk of bias during quality appraisal whilst the other 5 were judged to be of moderate risk of bias. Interventions with SMBG produced an additional -0.39% (95%CI -0.54 to -0.23) reduction in HbA1c compared to non-self-monitoring groups using a fixed effects model and -0.42% (95%CI -	First author receives an educational grant from Johnson and

Research and Opinion. 2005; 21,173-183		(N=250).	10.29% for the SMBG group and 6.1% to 10.45% for the non-SMBG group.					0.63 to -0.21%) using a random effects model. Testing for heterogeneity did not yield significant results.	Johnson
Wen L, Parchman ML, Linn WD, Lee S. Association between self-monitoring of blood glucose and glycemic control in patients with type 2 diabetes mellitus. American Journal of Health-System Pharmacy 2004; 61(22):2401-2405. Ref ID: 26	Retrospective cohort study 2+	N=976 patients with type 2 diabetes identified from a clinical database. All patients received care at a single Texas VA (Veterans Affairs) facility between Oct 1999 and September 2002. Only those who were taking oral medications for all three years were included. Patients who did not have a prescription for diabetes medication (oral medication or insulin in 2000) were excluded.	Patients were predominantly male (97.4%) with a mean age of 62.7 ± 10.7 years with mean BMI 30.8 ± 5.6 mg/m2. Casemix score (to account for the presence of co-morbidities) was 2.7 ± 1.24 suggesting this population was more ill than the Medicaid population on which national weights are based (mean score of 1). 48.1% of the sample were Hispanic.	Group 2 N=75 Received blood glucose monitoring strips in 2002 only Group 3 N=138 Received monitoring strips in 2001 and 2002 Group 4 N=602 Received strips during all three years.	Group 1 N=161 (control group) Did not receive monitoring strips during the study period.	Monitoring duration varied from 0 to 3 years.	Glycaemic control (HbA1c)	Duration of monitoring (including no monitoring at all) was not a significant predictor of recorded HbA1c values for the year 2002. The authors note a number of study limitations including the assumption that receipt of strips by patients implied usage and no information was available on compliance with medications.	Not stated
Martin S, Schneider B, Heinemann L, Lodwig V, Kurth HJ, Kolb H et al. Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: an	Retrospective cohort study 2+	N=3268 A German multicentre study (N=192 practices), the "ROSSO" study. Based on medical records, data were collected	Sex distribution of the complete cohort was balanced (49% male) with a mean age of	N=1479 The Self-monitoring blood glucose group (SMBG).	N=1789 Without SMBG	Mean follow-up of 6.5 years.	Morbidity (non-fatal endpoints), defined as myocardial infarction, stroke	At baseline, the SMBG cohort had higher mean fasting blood glucose levels than the non-SMBG cohort (HbA1c 7.2 ± 1.7% vs. 8.1 ± 2.4%, p<0.001), suggesting that insufficient metabolic control was one reason for initiating SMBG. This was associated	Ministry of Science and Research of the State

<p>epidemiological cohort study. Diabetologia 2006; 49(2):271-278. Ref ID: 1129</p>		<p>from all patients who were initially diagnosed with type 2 diabetes between 1 January 1995 and 31st December 1999. Only those patients were included for whom information was available on age, sex, diabetes therapy and SMBG, both for the time of diabetes diagnosis and at least one subsequent year, were included.</p>	<p>62.4 ± 9.6 years. Mean BMI was 29.8 ± 5.1. Mean HbA1c was 7.7 ± 2.1%. 77% were not treated with insulin (this was 55% in the SMBG group and 95% in the without SMBG group.</p>	<p>SMBG was documented in the medical records for at least 1 year during the observation period and prior to a non-fatal endpoint.</p>			<p>(macrovascular), foot amputation, blindness or end-stage renal failure requiring haemodialysis (microvascular), and all cause mortality (fatal endpoints).</p>	<p>with a higher rate of microvascular endpoints (2.5% vs. 1.5%, p<0.03) . However, the total rate of non-fatal events, micro and macrovascular, was lower in the SMBG group than in the non-SMBG group (7.2% vs. 10.4%, p=0.002). A similar difference was found for the rate of fatal events (2.7 vs 4.6%). A better outcome for both endpoints was also observed in the SMBG cohort when only those patients who were not receiving insulin were analysed (6.7% vs. 10.4%, p=0.002, for non-fatal events and 2.5% vs 4.3%, p=0.026 for fatal events). After adjustment for potential confounders, hazard ratios indicated that SMBG was associated with a 32% reduction in combined non-fatal endpoints (HR=0.68, 95%CI 0.51 to 0.91, p=0.009), despite an increase of microvascular events, and a 51% reduction in mortality over the observation period (HR=0.49, 95%CI 0.31 to 0.78, p=0.003). In the subgroup of patients who did not receive insulin, SMBG was associated with a 28% reduction in combined non-fatal endpoints (HR=0.72, 95%CI 0.52 to 0.99, p=0.0496) and a 42% reduction in mortality over the observation period (HR=0.58, 95%CI 0.35 to 0.96, p=0.035).</p> <p>The authors note a number of study limitations including insufficient information on the frequency of blood glucose measurements available to</p>	<p>North Rhine-Westphalia and a grant from Roche diagnostics.</p>
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								analyse the impact of the frequency of SMBG on outcome and no information provided on how the decision to start SMBG was made.	
Karter A, Chan P, Parker M, Ettner S, Moffet H, Selby J, Spence MM. Longitudinal Study of New and Prevalent Use of Self-monitoring of Blood Glucose. Diabetes Care, Volume 29, No 8, August 2006	Retrospective cohort study 2+	N=16,091 patients initiating SMBG (new user cohort) and N=15,347 ongoing users of SMBG (prevalent-user cohort). Patients were drawn from a diabetes registry maintained by Kaiser Permanente Northern California Medical Programme. Eligibility was restricted to members with continuous membership and full pharmacy benefits. Subjects lacking sufficient HbA1c data were excluded as were those who modified their diabetes pharmacy regimen (discontinued, switched or added a therapeutic class).	It is unclear whether all those included had type 2 diabetes (in the prevalent user cohort 41% were on insulin only and may have been T1D patients but this is only 6% in the new user cohort). Patient characteristics varied by treatment strata. Compared with non-users and prevalent users, new users had higher HbA1c levels and were more likely to be smokers. Persistent non-users were older than new or prevalent users and had	N=9328 New user cohort-future new users N=15,347 ongoing users of SMBG (prevalent-user cohort).	N= 6763 New user cohort-persistent non-users No comparison	4 year follow-up	Association between SMBG frequency and glycaemic control (HbA1c). Average daily SMBG testing frequency based on test strip use pharmacy prescription and refill records.	<p>New User Cohort Greater SMBG practice frequency among new users was associated with a graded decrease in HbA1c (relative to non users) regardless of diabetes therapy. Initiating once daily monitoring resulted in an 0.35, 0.42 and 0.23 point lowering of HbA1c among no medication, OHA and insulin treated groups respectively (p<0.001). This benefit showed a dose-responsive relationship with frequency of testing in each group, although with diminishing returns after approximately three strips per day for OHA-only and insulin treated patients.</p> <p>Prevalent User Cohort Changes in SMBG frequency among prevalent users were associated with an inverse graded change in HbA1c only among pharmacologically treated patients (p<0.0001). Among subjects on no medications, changes in SMBG were not associated with significant changes in glycaemic control.</p>	National Institute of Health and the American Diabetes Association.

			higher comorbidity scores than new or prevalent users,						
Lawton J, Peel E, Douglas M, Parry O. 'Urine testing is a waste of time': newly diagnosed Type 2 diabetes patients' perceptions of self-monitoring. Diabetic Medicine 2004; 21(9):1045-1048. Ref ID: 27	Qualitative (informed by grounded theory) +	N=40 Study aim: To explore the respective merits of urine testing and self-blood glucose monitoring (SBGM) from the perspectives of newly diagnosed patients with Type 2 diabetes.	People clinically diagnosed with type 2 diabetes and recruited by health care professionals from 16 practices and 3 hospitals in Lothian, Scotland. 19 participants were female and 21 male. Age ranged from 21 to 77 years with a mean of 53.4 years. All participants were white except for one Pakistani woman and all were treated by diet alone or by diet and metformin and/or glicazide. Participants were evenly	Three one hour interviews carried out 6 months apart. An interview topic guide was used to elicit discussion of the same topics across interviews.	N/A	18 months	Identification of recurrent themes and consensus regarding these themes.	16 patients performed urine testing post diagnosis. Of these, 6 had changed to SBGM by the second interview. By third interview two further patients had changed to SBGM and 3 had stopped monitoring altogether. Key issues identified were: Usability of equipment: While some patients described initial difficulties with using SMBG equipment, most regarded it as easier than urine testing and less messy. Patients also perceived it as a more versatile method as it could be done in any location Meanings attached to equipment allocation: Patients described blood glucose meters as more accurate and technologically more sophisticated than urine testing equipment. Many assumed that blood glucose meters were given to patients who had a more severe form of diabetes. Conversely, where patients expressed concern about their diabetes and its threat to their future health, not having received a blood glucose meter could be a contentious issue. This prompted accusations that some health	Chief Scientist Office

			spread across socio-economic groups. 23 participants were recruited in general practice and 17 in hospitals.					professionals were not taking their disease seriously enough or that other patients were receiving preferential treatment. Understanding monitoring results: Most patients who performed urine tests reported recording negative results most or all the time. All but 2 described negative readings as bemusing or confusing. In some instances this prompted patients to ask if they were doing it right. Further negative readings caused these patients to feel increasingly frustrated and disillusioned, often leading them to decrease or abandon self-monitoring. In most cases, patients mistakenly interpreted negative readings as indicating that they no longer had diabetes. None of the patients who performed SBMG reported interpreting low readings in this way,	
Peel E, Parry O, Douglas M, Lawton J. Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a qualitative study of patients' perspectives. British Journal of General Practice 2004; 54(500):183-188. Ref ID: 37	Qualitative (informed by grounded theory) +	N=40 Study aim: To explore the pros and cons of self-monitoring of blood glucose from the patients perspective	People clinically diagnosed with type 2 diabetes and recruited by health care professionals from 16 practices and 3 hospitals in Lothian, Scotland. 19 participants were female and 21 male.	Two one hour interviews carried out 6 months apart. An interview topic guide was used to elicit discussion of the same topics across interviews.	N/A	12 months	Identification of recurrent themes and consensus regarding these themes.	During the first interviews 50% were using blood glucose meters, 32% urine testing only and 18% were not self-monitoring. During the second round of interviews this was 68%, 18% and 13% respectively. Most patients reported having been provided with meters from hospital diabetic clinics and had experienced (usually 3) structured group-based education sessions which included instructions on meter use. Pros of self-monitoring: For many asymptomatic patients the	Chief Scientist Office

			<p>Age ranged from 21 to 77 years with a mean of 53.4 years. All participants were white except for one Pakistani woman and all were treated by diet alone or by diet and metformin and/or glicazide. Participants were evenly spread across socio-economic groups. 23 participants were recruited in general practice and 17 in hospitals.</p>				<p>monitors provided patients with a heightened awareness of, and evidence of their condition. When patients glucose readings were within the advised guidelines and fluctuations in readings were easily interpretable, they emphasised the positive role that monitoring had in their diabetes management. They described low readings as a high point which often gave them personal gratification. Some patients felt that self-monitoring cultivated independence from health services and enhanced self-regulation.</p> <p>Cons of self-monitoring: Some patients' felt that they became obsessed and others paranoid about their readings (although excessive monitoring seemed to be temporary and was less apparent by the second interview). Blood glucose parameters were described as problematic by patients where they felt they were receiving contradictory information about upper thresholds or no guidance about ideal parameters. Although most patients were clear as to how to counteract hypoglycaemia, many appeared to lack awareness of how to manage hyperglycaemia. Increased self-responsibility was often accompanied by increased self-blame and negative emotional reactions to high glucose readings. Counter-intuitive readings were reported as sources of distress and anxiety, in some cases adversely</p>	
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								<p>effecting adherence to diabetic regimens by promoting nihilistic attitudes.</p> <p>Some patients felt health care professionals were not interested in their readings (perhaps implying that contrary to principles of empowerment, some patients are self monitoring for its perceived benefit to doctors).</p>	
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