Glucose self-monitoring: Think twice for type 2 patients. *J Fam Pract*. 2008;57:731-734.	
Potential PURL Review Form: Randomized controlled trials	
SECTION 1: IDENTIFYING INFORMATION	
1.0 Citation	O'Kane MJ, Bunting B, Copeland M, Coates VE; ESMON study group. Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial. *BMJ*. 2008;336:1174-1177.
1.1 Editor's classification of nominated study	Potential PURL Review Date: 6/19/08
1.2 Editor's reason for classification	
1.3 Hypertext link to PDF of full article	http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3051&itool=Abstract-def&uid=18420662&db=pubmed&url=http://bmj.com/cgi/pmidlookup?view=long&pmid=18420662
1.4 First date published study available to readers	5/24/08
1.5 PubMed ID	18420662
1.6 Nominated By	Sarah-Anne Schumann
1.7 Institutional Affiliation of Nominator	University of Chicago
1.8 Date Nominated	5/30/08
1.9 Identified Through	BMJ Updates Online
1.10 PURLS Editor	Bernard Ewigman
1.11 Nomination Decision Date	6/2/08
1.12 Potential PURL Review Form (PPRF) type	RCTs
1.13 Other comments, materials or discussion	
1.14 Assigned Potential PURL Reviewer	Sarah-Anne Schumann
1.15 Reviewer Affiliation	University of Chicago
1.16 Date Review Due	6/19/08

1.17 Abstract	OBJECTIVES: To assess the effect of self-monitoring of blood glucose concentrations on glycaemic control and psychological indices in patients with newly diagnosed type 2 diabetes mellitus. DESIGN: Prospective randomised controlled trial of self-monitoring versus no monitoring (control). SETTING: Hospital diabetes clinics. PARTICIPANTS: 184 (111 men) people aged <70 with newly diagnosed type 2 diabetes referred to the participating diabetes clinics. Major exclusion criteria were secondary diabetes, insulin treatment, previous self-monitoring of blood glucose. INTERVENTIONS: Participants were randomised to self-monitoring or no monitoring (control) groups for one year with follow-up at three monthly intervals. Both groups underwent an identical structured core education programme. The self-monitoring group received additional education on monitoring. MAIN OUTCOME MEASURES: Between-group differences in HbA(1c), psychological indices, use of oral hypoglycaemic drugs, body mass index (BMI), and reported hypoglycaemia rates. RESULTS: 96 patients (55 men) were randomised to monitoring and 88 (56 men) to control. There were no baseline differences in mean (SD) age (57.7 (11.0) in monitoring group v 60.9 (11.5) in control group) or HbA(1c) (8.8 (2.1)% v 8.6 (2.3)%, respectively). Those in the monitoring group had a higher baseline BMI (34 (7) v 32 (6.2)). There were no significant differences between groups at any time point (12 months values given) in HbA(1c) (6.9 (0.8)% v 6.9 (1.2)%, *P*=0.69; 95% confidence interval for difference -0.25% to 0.38%), BMI (33.1 (6.4) v 31.8 (6.0); adjusted for baseline BMI, *P*=0.32), use of oral hypoglycaemic drugs, or reported incidence of hypoglycaemia. Monitoring was associated with a 6% higher score on the depression subscale of the well-being questionnaire (*P*=0.01). CONCLUSIONS: In patients with newly diagnosed type 2 diabetes self-monitoring of blood glucose concentration has no effect on glycaemic control, but is associated with higher scores on a depression subscale. TRIAL REGISTRATION: ISRCTN 49814766.
SECTION 2: DETAILED STUDY DESCRIPTION	
2.1 Number of patients starting each arm of the study?	96 monitoring, 88 control
2.2 Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)?	Age <70 with newly diagnosed diabetes referred to a diabetes clinic in Northern Ireland; exclusions: secondary diabetes, insulin treatment, previous self-monitoring of glucose, chronic kidney or liver disease; mean age 58-61, mean HgbA1c at baseline 8.6-8.8, higher baseline BMI in monitoring group (34 vs 32)
2.3 Intervention(s) being investigated?	Self-monitoring (4 fasting and 4 postprandial weekly) vs no monitoring
2.4 Comparison treatment(s), placebo, or nothing?	Comparison of monitoring vs control (no monitoring)
2.5 Length of follow up? Note specified	1 year (doctor/NP/dietician visits every 3 months)

end points e.g. death, cure, etc.	
2.6 What outcome measures are used? List all that assess effectiveness.	Primary outcomes: Between group differences in HgbA1c, psychological indices, incidence of hypoglycemia. Secondary outcomes: difference between groups in use of oral hypoglycemics, BMI
2.7 What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, *P*-values, etc.	No significant differences between groups in HgbA1c at any time (both groups 6.9% after 12 months), BMI, use of oral hypoglycemics, or reported incidence of hypoglycemia; monitoring group had 6% higher (6 points on a 100-point scale) score in depression subscale of well-being questionnaire (*P*=0.01) at 12 months
SECTION 3: INTERNAL VALIDITY	
3.1 Study addresses an appropriate and clearly focused question	Well addressed
3.2 Random allocation to comparison groups	Well addressed
3.3 Concealed allocation to comparison groups	Well addressed
3.4 Subjects and investigators kept "blind" to comparison group allocation	Not applicable (couldn't be blinded as subjects knew whether or not they were monitoring and doctors knew because they used the monitoring results to guide treatment).
3.5 Comparison groups are similar at the start of the trial	Well addressed
3.6 Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias.	Well addressed
3.7 Were all relevant outcomes measured in a standardized, valid, and reliable way?	Well addressed
3.8 Are patient oriented outcomes	Psychological indices and hypoglycemia.

included? If yes, what are they?	
3.9 What percent dropped out, and were lost to follow up? Could this bias the results? How?	2%: 2 in each group failed to complete the study; 63/96 participants in self-monitoring group completed >80% of the requested monitoring.
3.10 Was there an intention-to-treat analysis? If not, could this bias the results? How?	Yes
3.11 If a multi-site study, are results comparable for all sites?	Not addressed
3.12 Is the funding for the trial a potential source of bias? If yes, what measures were taken to ensure scientific integrity?	Funded by Northern Ireland research and development office; Johnson and Johnson supplied blood glucose meters free of charge.
SECTION 4: EXTERNAL VALIDITY	
4.1 To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized.	Newly diagnosed type 2 diabetics and possibly all type 2 diabetics on oral agents.
4.2 In what care settings might the findings apply, or not apply?	Primary care, endocrine.
4.3 To which clinicians or policy makers might the findings be relevant?	As mentioned in section 4.2 above, and also those who make decisions about funding monitoring in patients with diabetes who are not on insulin.
SECTION 5: REVIEW OF SECONDARY LITERATURE	
5.1 DynaMed excerpts	DynaMed suggests that self-monitoring of blood glucose (SMBG) may improve glycemic control in patients with type 2 diabetes mellitus, citing a Cochrane review of 6 RCTs (level 3 [lacking direct] evidence).
5.2 DynaMed citation/access date	Accessed 6/18/08; Glucose monitoring Updated June 13, 2008
5.3 UpToDate excerpts	UpToDate recommends SMBG in all patients who use insulin and others taking medicine that can cause hypoglycemia.

5.4 UpToDate citation/access date	http://www.uptodateonline.com/online/content/author.do?topicKey=diabetes/2081 Accessed 6/18/08; This topic last updated: September 26, 2007
5.5 PEPID PCP excerpts	None found
5.6 PEPID citation/access data	
5.7 Other excerpts (USPSTF; other guidelines; etc.)	
5.8 Citations for other excerpts	
SECTION 6: CONCLUSIONS	
6.1 How well does the study minimize sources of internal bias and maximize internal validity? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)	2
6.2 If 6.1 was coded as 4 or greater, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?	
6.3 Are the results of this study relevant to the health care needs of patients cared for by "full scope" family physicians, general internists, general pediatricians, or general OB/GYNs? Are they applicable without significant change in programs or policies such as the organization or financing of practice? Give one number on a scale of 1 to 7 (1=absolutely relevant; 4=neutral; 7=not at all relevant)	1; no significant changes needed in order to implement.
6.4 Please explain your response to item 6.3.	If providers adopt this evidence, they would stop recommending monitoring to most patients with newly diagnosed type 2 diabetes who are not on insulin.
6.5 What is the main recommendation for change in practice, if any? Include a	Stop recommending self-monitoring to patients with newly diagnosed type 2 diabetes who are not on insulin; while the treatment algorithm in the study included metformin, followed by a

description of the change in practice, the indications, and the target population.	sulfonylurea, Table 5 on p. 4 shows that only 17 patients total (11 monitoring and 6 control) were on sulfonylureas, so this study may not answer the question of whether it makes sense to monitor patients who are on oral agents that can cause hypoglycemia (most were on either no meds or only metformin).
SECTION 7: EDITORIAL DECISIONS	
7.1 FPIN PURLs editorial decision	Pending PURL for Review
7.2 FPIN PURLS Editor	Bernard Ewigman
7.3 Date of decision	June 19, 2008
7.4 Brief summary of decision	The findings of this RCT are consistent with a prior meta-analysis of 8 randomized trials of SMBG in type 2 diabetes that concluded that SMBG has no definitive benefit. An issue is whether this applies only to patients with type 2 diabetes not on insulin or hypoglycemic agents, or to all patients with type 2 diabetes, and whether SMBG is routine or used for specific purposes. We think a practice change recommendation could be crafted specifically enough that it would be supported by the evidence; however, we are unclear about current practice. We will post this as a question on Sermo and see what we learn. Schumann addendum 7.2.08: A Sermo poll in April 2008 asking if people have their diabetic patients monitor blood glucose showed that a large majority of providers have patients self-monitor; this is evidence that this would be a practice changer for most health care providers.