

# Self-Monitoring Blood Glucose in Non-insulin Treated Type 2 Diabetes

A review of the literature, August 2011



This review was commissioned by the Australian Diabetes Educators Association and funded through the National Diabetes Services Scheme (NDSS). The NDSS is an initiative of the Australian Government administered by Diabetes Australia.

ADEA - Benchmarking best practice  
in diabetes education and care

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## Acknowledgements

This review was commissioned by the Australian Diabetes Educators Association. The initial systematic review of literature was undertaken by the Joanna Briggs Institute (January 2009). This report combines the initial systematic review results with the updated review (March 2011) conducted by Baker IDI Heart and Diabetes Institute.

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## **Executive Summary**

### **Objectives**

The objective of the review was to examine the effectiveness, appropriateness and meaningfulness of self-monitoring of blood glucose (SMBG). Specifically, the review sought to address the question:

‘What is the current best evidence of the effectiveness, appropriateness and meaningfulness of SMBG in people with type 2 diabetes who are not treated with insulin’?

### **Inclusion criteria**

The effectiveness component of the original and updated reviews considered systematic reviews and randomised controlled trials (RCTs) while the appropriateness and meaningfulness components of the review considered interpretive studies. All studies and papers that involved adults (aged 16 years or over) with type 2 diabetes who were not treated with insulin were included. Studies involving participants who used SMBG or educators who provided SMBG education were also included.

### **Search strategy**

Both search strategies for the original review conducted in 2009 and the updated review in 2011 were designed to find both published and unpublished studies and papers written in the English language. For the systematic reviews and qualitative evidence, studies published between 2002 and March 2011 were targeted. An additional search to identify primary studies was conducted to find any RCTs published between the years 1986 to 2011. This search sought to establish to what degree the systematic reviews had captured the relevant primary research.

### **Results**

The original review identified seven systematic reviews, 39 RCTs and 351 qualitative through the search strategies. Screening by title and abstract against the inclusion criteria resulted in the acceptance of 4 systematic reviews published between 2005-2007; 10 RCTs published between 1989 - 2008, and 10 qualitative studies published between 2003 - 2007. When these search strategies were replicated in March 2011, an additional 5 systematic reviews and 3 new RCTs on SMBG were included from the recent literature.

## **Effectiveness**

The updated evidence corroborated the view that SMBG was no more effective than other forms of monitoring of glycaemic control. In the original review, a meta-analysis at 6 months using strict criteria was not statistically significant, and was also confounded by statistical heterogeneity. The statistical benefit at 6 and 12 months in a follow up exploratory meta-analysis was also confounded by clinical heterogeneity among the included studies.

The updated evidence continues to suggest that people using SMBG identify more otherwise “silent” episodes of hypoglycaemia, had improved total serum cholesterol and may be more aware of how lifestyle, diet and exercise choices can impact on their glycaemic control. Glycaemic control was associated with frequency of SMBG, with people who using higher numbers of monitoring strips having better glycaemic control than other people on SMBG using less monitoring strips

## **Appropriateness**

In the original review, one study was detailed that examined the perspective of the care providers/educators to articulate insights into the value system and culture behind the education and practice of SMBG. The results of the original meta-synthesis derived from the subjective accounts of participants were clearly consistent with the major findings from the accounts of the care providers/educators, which suggest the existence of values and assumptions shared by people with type 2 diabetes and care providers/educators in the use of SMBG.

Several informative and valuable findings were identified in relation to the appropriate practice and education of SMBG. There is a shared belief by care providers/educators, or both, that:

1. The use of SMBG should be encouraged for the purpose of facilitating effective diabetes self-management.
2. Self-monitoring blood glucose is considered to be a superior method of monitoring glycaemic control to that of the previously more common method of urinalysis.
3. The autonomous decision-making and active involvement of people were considered to be important in the use of SMBG, as were the provision of tailored educational/supportive interventions that met the needs of the individual.

The updated literature stresses the need for culturally appropriate education related to self-management behavior, including SMBG which includes recognition that, if written health information should be targeted at literacy levels at the 6th-grade level or below, patients with low and high literacy have similar improvements in HbA1c levels when they underwent a similar education programme that had been specifically adapted for people with low literacy. There are also new tools which can measure a

patient's level of self-efficacy to determine whether further intervention is required by the diabetes educator to enable successful SMBG.

### **Meaningfulness**

Self-monitoring blood glucose was understood and experienced as an effective means to facilitate an empowering process that raises positive and active attitudes toward self-management. Negative experiences in the use of SMBG were often caused by insufficient knowledge and skills, and non-constructive coping strategies concerning diabetes management. The belief of each person concerning the use of SMBG, such as stigma and the purpose and the need of SMBG, should be assessed before the commencement of SMBG is recommended. In confronting SMBG, people are required to prioritise their life needs (such as financial cost in the use of SMBG) or individual-physical circumstances (such as poor eyesight). Individualised assessment of such factors is recommended. Despite the continued absence of evidence to support the superiority of SMBG in glycaemic control, qualitative findings support the role of individual preference for methods of monitoring glycaemic control.

### **Conclusions**

The findings from this updated review support the findings of the original review that there are some beneficial effects of SMBG on improving glycaemic control in people with non-insulin treated type 2 diabetes up to 6 months from commencement of SMBG interventions. Qualitative findings continue to suggest that the use of SMBG may be encouraged as a part of diabetes self-management in most people with non-insulin treated type 2 diabetes, provided there is adequate education, supervision and assessment. In particular, SMBG is associated with greater individual engagement with ones' own glycaemic control and lifestyle related needs.

Qualitative findings also reveal an overall patient preference for SMBG over urine testing. Determining which people might benefit most from SMBG in light of this evidence should include a detailed assessment leading to targeted interventions in order to meet each individual's various life needs such as the status of personal finance and insurance, and physical/mental status in order to make beneficial use of SMBG. Individualised and culturally appropriate educational interventions are considered important to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes provided that any written information is provided at an appropriate literacy level. It should be understood that SMBG itself is not a goal, but the learning process to actualise self-management of diabetes with the use of SMBG is important.

Investigating the effectiveness of SMBG in daily life settings presented challenges to researchers. The small number of high-quality RCTs on the effectiveness of SMBG was a limitation for both original and updated reviews. Further quantitative research is needed to determine both the statistical and the

clinical effectiveness of SMBG in achieving glycaemic control in recommended target range. It is particularly important that this research focuses on ensuring homogeneity of sample characteristics and interventions. Further investigation is also required to determine the potential variables that may affect the outcome in the use of SMBG to achieve glycaemic control, such as age, and duration since diagnosis.

This review has lead to the development of a comprehensive list of recommendations for practice as follows:

- The use of SMBG may be encouraged as a part of diabetes self-management in non-insulin treated type 2 diabetes people with adequate supervision and assessment. (Grade A)
- SMBG increases the detection of episodes of hypoglycaemia. Health professionals should make people aware of the benefits of increased detection. (Grade B)
- Individual patients indicate an overall preference for SMBG rather than urine testing. (Grade B)
- The autonomous decision making of individuals and promoting self efficacy should be supported and facilitated in the use of SMBG. (Grade B)
- Individualised educational interventions are essential in order to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes. (Grade B)
- It should be understood that SMBG itself is not a goal, but is part of the learning process to actualise self-management of diabetes including the use of SMBG. (Grade B)
- Multifactorial assessment and interventions are necessary in order to meet each person's various life needs such as the status of personal finance and insurance, and physical/mental status in order to make beneficial use of SMBG. (Grade B)
- In the absence of conclusive evidence, the frequency of SMBG should be decided depending on individual circumstance and clinical judgment. (Grade B)
- Education should include the management and prevention of hypoglycaemia as well as dietary, activity and lifestyle modifications to optimise glycaemic control. (Grade B)
- For the individual with a recent diagnosis, the introduction of SMBG should be supported with strategies to evaluate and enhance the individual's psychosocial status. (Grade B)

## **Keywords**

Self-monitoring blood glucose, self-monitoring, type 2 diabetes, glycaemic control, blood glucose, hypoglycaemia, experience, education.



## Introduction

The purpose of this review is to provide updated evidence related to the effectiveness, appropriateness and meaningfulness of SMBG in individuals with non-insulin treated type 2 diabetes. The original review published in 2009 by the ADEA employed a mixed methods approach to bring together qualitative and quantitative data, although for clarity, the results section was presented as two discrete sections. The effectiveness component was conducted according to the norms of the quantitative paradigm, including studies such as systematic reviews of RCTs and primary RCTs that had not been previously identified in such systematic reviews. The review of the appropriateness and meaningfulness of SMBG was conducted according to the norms of the interpretive paradigm, including existing interpretive studies. The design and conduct of this review was in accordance with the methods established by The Joanna Briggs Institute (JBI). The JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI) was used to assist with the review (Appendix I). This update adds to this considerable evidence base by providing new literature on the subject up until March 2011.

## Background

Self-monitoring of blood glucose has been increasingly used in the management of diabetes and has been promoted as an integral part of diabetes self-management. (1, 2) Educational and supportive programs with the use of SMBG based on principles of self-management have been advocated by clinicians and educators alike. (1, 3, 4)

Clinical use of SMBG is already accepted practice for people with type 1 diabetes (5) and people with type 2 diabetes who are treated with insulin.(4, 6) Self-monitoring of blood glucose has become an important component of diabetes self-management programs. Self-monitoring of blood glucose can provide insulin treated people with guidance on adjusting insulin dosage according to their individual needs, which can directly improve glycaemic control.(7, 8) However, in the case of people with non-insulin treated type 2 diabetes not using insulin, evidence has been conflicting.(9, 10)

The first question this review sought to address was the effectiveness of SMBG on glycaemic control, self-care, diabetes-related complications and quality of life (QOL). To answer this question, both the original review and updated review examined systematic reviews (with and without meta-analyses) and RCTs.

The second addressed appropriateness of SMBG and the third question concerned meaningfulness of SMBG.

To answer questions two and three, the original and updated reviews both examined descriptive studies that reported on the subjective accounts of diabetes educators and people in the use of, and education concerning SMBG, in order to gain a deeper understanding of the phenomena around the use of SMBG among people with non-insulin treated diabetes.

In the context of this review, the following definitions were applied:(11, 12)

**Effectiveness:** the extent to which an intervention, when used appropriately, achieves the intended effect. Clinical effectiveness is about the relationship between an intervention and clinical or health outcomes.

**Appropriateness:** the extent to which an intervention or activity fits with or is apt in a situation. Clinical appropriateness is about how an activity or intervention relates to the context in which care is given.

**Meaningfulness:** how intervention or activity is experienced by the people with diabetes or health professionals. Meaningfulness related to the personal experience, opinions, values, thoughts, beliefs and interpretations of people with diabetes.

**SMBG:** Self Monitoring Blood Glucose, also known as SBGM – self blood glucose monitoring, or CBGM – client blood glucose monitoring, or HBGM – home blood glucose monitoring. In this report, only the term SMBG has been used.

## Objective

The objective of this review was to establish the appropriateness, meaningfulness and effectiveness of SMBG with an updated review of the literature up to March 2011.

- The specific objective in examining effectiveness was to analyse the evidence across previous and new systematic reviews and RCTS that investigated the clinical effectiveness of SMBG,
- The specific objective in reviewing the appropriateness of SMBG was to identify cultural perceptions embedded in being a diabetes educator and examine the underlying assumptions and expectations related to teaching people SMBG,
- The specific objective in reviewing evidence of meaningfulness was to identify the experiences of both diabetes educators, and individuals with type 2 diabetes in relation to SMBG to uncover the meanings they attribute to the experience of education for SMBG.

Specifically, this updated review addressed the research question:

What is the current best evidence of the effectiveness, appropriateness and meaningfulness of SMBG in people with type 2 diabetes who are not treated with insulin?

## **Review Methods**

### **Inclusion criteria**

Both the original and updated reviews used a-priori inclusion criteria to assess whether papers were relevant to the review topic. Papers that met the criteria were considered to be applicable to the review topic and retrieved for further assessment of quality. The inclusion criteria for this review are outlined below.

#### ***Types of studies/papers***

To establish the effectiveness of SMBG, the reviews included systematic reviews of the effectiveness of SMBG. Additionally, as a method of testing the completeness of systematic reviews, any RCTs undertaken to investigate effectiveness of SMBG that had been published during the dates of included systematic reviews were sought and considered for inclusion. To avoid duplication of effect (i.e. RCTs which were already reported in systematic reviews, and identified in the RCT specific search), only RCTs that were subsequently identified as not being included in the identified reviews were reported.

To initially establish the appropriateness and meaningfulness of SMBG, the original review included qualitative evidence on the meaning and experience of participants who received SMBG or delivered education programs on SMBG. Therefore, research designs such as phenomenology, grounded theory and ethnography were considered. All studies were categorised according to the JBI Levels of Evidence (Appendix I).

#### ***Types of participants***

To establish the effectiveness and meaningfulness of SMBG, the participants of interest were adults (aged 16 years or over) who had non-insulin treated type 2 diabetes. No restrictions were placed on gender or co-morbidities.

To establish the appropriateness and meaningfulness, the participants were care providers/educators who had been involved in teaching/training people regarding SMBG.

### ***Types of intervention(s)***

The intervention of interest was SMBG and all forms of educational interventions of SMBG by educators. These interventions were compared to standard practice (usual diabetes care) without SMBG.

### ***Type of outcomes***

This review considered studies that include the following outcome measures:

#### *Effectiveness*

- Blood glucose control as measured by routine SMBG and, validation by HbA1c,
- Effectiveness outcomes, including diabetes self-efficacy, self-care knowledge scores and reduction of acute diabetes complications,
- Individual related outcomes including QOL and satisfaction.

#### *Meaningfulness and appropriateness*

- Individual perceptions diabetes educators associate with the provision of SMBG education to people with diabetes,
- The perceptions of individuals who have attended or are attending education provided by diabetes educators on SMBG,
- The phenomenon of being a person who has experienced education for SMBG and is practicing SMBG (including their interpretation of SMBG results).

## **Search Strategy**

The search strategy aimed to find both published and unpublished studies and papers written in the English language. For the systematic reviews and qualitative study reports, papers published between 2002 to March 2011 were targeted. The original review employed a three-step search strategy. The first step of the original review was a limited search of MEDLINE and CINAHL followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the articles to collate key words related to the topic. The second step was a search using all identified keywords and index terms specific to each database across all included databases from 1998 to February 2008. Thirdly, the reference lists of all identified reports and articles were searched for additional studies. An additional search was also conducted to find any RCTs published between the years 1986 to 2008, which had not been identified in published systematic reviews. However, the earliest published RCT

identified in the included reviews was 1989. Therefore, going back to 1986 allowed for capture of studies that may have been published during the conduct of early reviews.

The updated review omitted the first step, as detailed above, but searched all the databases listed below for any publications looking at the effectiveness, appropriateness or meaningfulness of SMBG in non-insulin treated Type 2 diabetes.

The databases searched included:

MEDLINE

CINAHL

Cochrane Library

EMBASE

Current Contents

PsycINFO

The search for unpublished studies included:

Digital Dissertations (Proquest)

For a complete list of search terms, see Appendix II

## **Assessment of Methodological Quality**

Identified papers that met the inclusion criteria were grouped into one of the following categories: systematic reviews, experimental studies and qualitative studies. The papers were then assessed by two independent reviewers for methodological quality before inclusion in the review using JBI SUMARI (Appendix III). Any disagreements that arose between the reviewers were resolved through discussion.

## **Data Collection**

Following assessment of methodological quality, papers were grouped according to study methodology. The quantitative data for both original and updated reviews were extracted using the standardized forms from JBI-Meta Analysis of Statistics Assessment and Review Instrument (JBI-MASARI) (Appendix IV), while qualitative data were extracted using the standardized forms from JBI Qualitative Assessment and Review Instrument (JBI-QARI) (Appendix V).

## **Data Synthesis**

### **Quantitative data analysis**

The systematic reviews included in the original review were analysed in narrative format. The Cochrane statistical package Review Manager (RevMan) Version 5 was used for the statistical analysis of the included RCTs. All results were double entered to confirm reliability of data extraction. Clinical heterogeneity was assessed by considering the populations, interventions and outcomes between the studies. The  $I^2$  was used in the assessment of statistical heterogeneity and if this indicated a high level of heterogeneity among the included studies in the meta-analysis, a random effects model was also performed. In meta-analysis, both fixed effects model and random effect models were used for combining study data if the trials were judged to be sufficiently similar.

For continuous data, the mean and standard deviation values were used to derive weighted mean differences and their 95% Confidence Intervals (CI). The outcomes captured from the included papers were all based on continuous data, hence methods for combining dichotomous data were not required. Where synthesis was inappropriate (including a high degree of heterogeneity between study populations, interventions and outcome measures) the analysis was presented in a narrative summary format.

The updated evidence from RCTs presented in this update was not been pooled as per the original review but is presented as summarized information.

### **Qualitative data synthesis**

In the original review, qualitative research findings were also pooled using the Qualitative Assessment and Review Instrument (JBI-QARI). The process of meta-synthesis embodied in this program involved the aggregation or synthesis of findings/conclusions made in relation to the intervention, activity or phenomenon that is the subject of the review. The aim of this process was to generate a set of statements that represent aggregation through assembling the findings or conclusions rated according to their credibility, and categorising these findings/conclusions on the basis of similarity in meaning. These categories were then subjected to a meta-synthesis in order to produce a single comprehensive set of synthesized findings that are used as a basis for evidence-based practice.(12)

In qualitative and textual evidence, findings or conclusions are not study “results”, rather they are the spoken words, themes or metaphors of persons who conducted the research based on their analysis of the experiences of the people they were conducting the research with. (12) This approach was not adopted for the update which summarized the conclusions of the authors as they appear in the publications.

## Results

### Description of studies

The original searches identified 1300 studies while 4332 articles were retrieved using the same search terms for the updated search. Following removal of duplicates, the majority were excluded based on assessment of the title and abstract of the citation against the inclusion criteria. The original review retrieved a total of 7 systematic reviews to critically appraise of which 4 subsequently met the inclusion criteria. The updated review led to the retrieval of an additional 19 systematic reviews of which 5 were included.

Forty-one primary studies (17 RCTs and 24 non-experimental studies) were identified out of the 4 original systematic reviews (Appendix VI). Of the 17 RCTs, 7 had included participants with type 1 diabetes and/or insulin treated participants and therefore did not meet the inclusion criteria of the present review. Of the remaining ten RCTs, one study was a duplicate of another article published in the following year.<sup>(13)</sup> One study was only available in abstract form and full text could not be obtained.<sup>(14)</sup> Therefore, from the included systematic reviews, eight RCTs that examined the effectiveness of SMBG in people with type 2 diabetes, were included in this review. An additional RCT specific search was conducted as directed by the Review Reference Group as a method of validating the comprehensiveness of the identified systematic review papers search strategies. From this additional database search between 1986 (three years before the oldest RCT in the included systematic reviews was published) to April 2008, a total of 31 new studies were identified and considered for inclusion. Full texts were obtained and critically appraised. Two RCTs met the inclusion criteria and 29 studies were excluded (Appendix VII). In total, 10 RCTs from the original review and 3 from the new database search) were included in the final analysis. (Appendix VIII).

From the search for qualitative studies, 351 papers were identified for possible inclusion in the original review and 592 from the updated searches (total = 943). Based on the title and abstract, 42 papers that were relevant to the review topic were retrieved for evaluation of methodological quality in the original review and 67 for the update. Thirty-two papers were excluded in the original review and 62 in the update due to incongruity with the review objectives and/or outcomes (Appendix IX) and 10 papers were included in the original review and 5 were added in the update. (Appendix X).

The four figures (Figures 1-4) below provide a schematic of the included studies for the original and updated reviews:

Figure 1: Effectiveness Search strategy: Numbers of papers identified, retrieved, included and excluded.

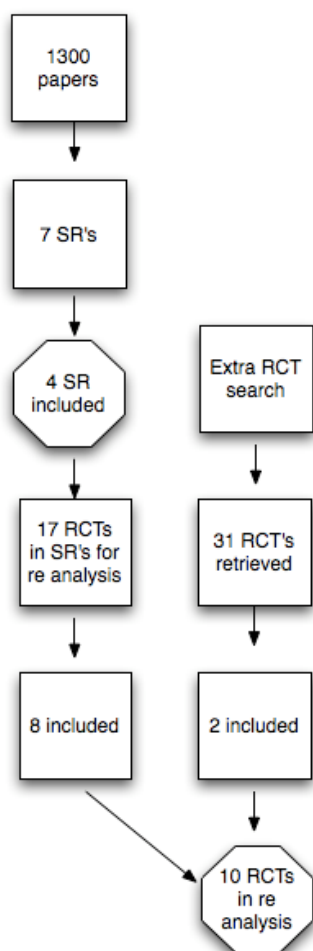


Figure 2: Appropriateness and Meaningfulness Search Strategy: Numbers of papers identified, retrieved, included and excluded.

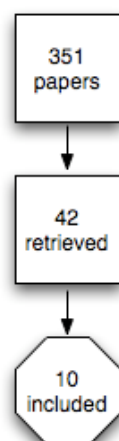


Figure 3: Updated literature (to March 2011)

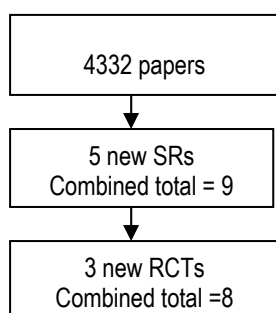
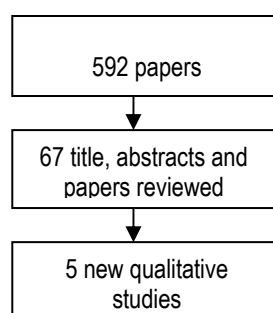


Figure 4: Updated Appropriateness and Meaningfulness





## Included Studies (combined reviews)

<p>Included quantitative systematic reviews (4):</p> <ul style="list-style-type: none"> <li>• Jansen, 2006</li> <li>• McGeoch, 2007</li> <li>• Sarol, 2005</li> <li>• Welschen, 2005</li> </ul> <ul style="list-style-type: none"> <li>• <b>NEW (5):</b></li> <li>• <b>Alleman 2009</b></li> <li>• <b>Clar 2009</b></li> <li>• <b>Lockwood 2010</b></li> <li>• <b>McIntosh 2010</b></li> <li>• <b>St John 2010</b></li> </ul> <p><b>Total = 9</b></p>	<p>Included qualitative papers (10):</p> <ul style="list-style-type: none"> <li>• Abbott <i>et al.</i> 2004</li> <li>• Benavides-Vaello <i>et al.</i>, 2004</li> <li>• Burke <i>et al.</i>, 2006</li> <li>• Davis <i>et al.</i>, 2007</li> <li>• Hill-Briggs, <i>et al.</i>, 2003</li> <li>• Holmstrom <i>et al.</i>, 2005</li> <li>• Jeanfreau, 2005</li> <li>• Lawton <i>et al.</i>, 2004</li> <li>• Peel <i>et al.</i>, 2007</li> <li>• Peel <i>et al.</i>, 2004</li> </ul> <ul style="list-style-type: none"> <li>• <b>NEW (5):</b></li> <li>• <b>Hawthorne, 2010</b></li> <li>• <b>Rothman, 2004</b></li> <li>• <b>Upchurch, 2009</b></li> <li>• <b>White, 2010</b></li> <li>• <b>Sturt, 2010</b></li> </ul> <p><b>Total = 15</b></p>
<p>Included RCTs (10):</p> <ul style="list-style-type: none"> <li>• Allen, 1990</li> <li>• Davidson, 2005</li> <li>• Estey, 1996</li> <li>• Farmer, 2007</li> <li>• Fontbonne, 1989</li> <li>• Guerri, 2003</li> <li>• Muchmore, 1994</li> <li>• O'kane, 2008</li> <li>• Rutten, 1990</li> <li>• Schwedes, 2002</li> </ul> <ul style="list-style-type: none"> <li>• <b>NEW (3):</b></li> <li>• <b>Farmer, 2009</b></li> <li>• <b>Pignone 2009</b></li> <li>• <b>Polonsky 2009</b></li> </ul> <p><b>Total = 13</b></p>	

## **Effectiveness of Self-Monitoring Blood Glucose in diabetes management**

The results regarding the clinical effectiveness of SMBG in people with type 2 diabetes are presented in two sections: findings of systematic reviews (review and update, n=9) and a further analysis of 10 RCTs from the original review and 3 newly reported trials. The analysis of trials was performed as a verification of the meta-analysis within the systematic reviews, and added a further 2 studies that were published at the time of writing the original review.

All 4 identified systematic reviews in the original review investigated the relative efficacy of SMBG versus other types of care such as urine monitoring and usual care without SMBG.(15-18) Only 3 reviews included studies of participants with type 2 diabetes who were not treated with insulin.(16-18) The review by Jansen included 5 studies that involved both insulin treated and non-insulin treated participants.(15) Sub group analysis was undertaken to separate insulin treated from non-insulin treated participants in this review. Results are presented under the primary outcomes of interest.

To this evidence base, five new systematic reviews (new references; 42-46) investigating the same topic that report glycaemic control as an outcome are added in this updated review.

## **Glycaemic control**

### ***Systematic reviews of people with non-insulin treated type 2 diabetes***

Three of the 4 systematic reviews met the inclusion criteria and are reported in this section. McGeoch (16), Welschen (18) and Sarol (17) reviewed RCTs of participants with type 2 diabetes who were not treated with insulin. Sarol conducted a meta-analysis that demonstrated a significantly positive effect of a diabetes management strategy including the use of SMBG in reduction of HbA1c values.(17) Results from the other 2 reviews also support the effectiveness of SMBG in glycaemic control in the people with type 2 diabetes (18, 19).

*McGeoch et al, 2007 (16)*

McGeoch et al conducted a systematic review of 3 RCTs to examine existing clinically relevant evidence related to the use of SMBG in people with type 2 diabetes who were not receiving insulin treatment.(16) The author did not conduct meta-analysis due to different populations and interventions. The review included 3 RCTs with a total of 1000 participants.(19-21), the larger 2 studies indicated a statistically significant reduction in HbA1c levels with SMBG.(20, 21) The smaller study also reported a trend favoring SMBG although this was not statistically significant.(19) The review concluded that SMBG was likely to be beneficial for people with type 2 diabetes who have poor glycaemic control and

are not using insulin and as an educational tool due to the ability to read results of SMBG tests and observe the impact of diet and lifestyle on blood glucose levels.(16)

The monitoring process varied across studies, but included education given in different amounts, advice on monitoring practice, nutritional counseling and diet diaries, active modification of behavior based on SMBG results and management algorithms.

**Table I: McGeogh et al - Studies interventions and results for HbA1c as reported in the included studies. [16]**

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Schwedes, 2002 (21)	type 2 diabetes, diet or oral medications. Outcome measured at 6 months	Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review	Intervention Group: 7.47±1.27 Control Group: 7.81±1.52 p=0.0086	Intervention Group: -1.0±1.27 Control Group: -0.54±1.14
Guerci, 2003 (20)	type 2 diabetes, diet or oral medications, poor glycaemic control. Outcome measured at 6 months	Intervention Group (n=345): GP training to do ≥6 readings per week Control Group (n=344): No self-monitoring training or instruction	Intervention Group : 8.1±1.6 Control Group: 8.4±1.4 p=0.012	Intervention Group: -0.9±2.1 Control Group: -0.5±1.9
Davidson, 2005 (19)	type 2 diabetes, diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months	Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary. Control Group (n=45): Nutritional advice	Intervention Group: 7.7±1.6 Control Group: 7.8±1.5 p=0.58	Intervention Group: -0.8±1.6 Control Group: -0.6±2.1

Table I shows average changes in HbA1c, with Schwedes and Guerci obtaining statistically significant results favouring self-monitoring with mean reductions of around 1% in HbA1c, however, the control group results were only marginally lower.

Welschen, 2005 (18)

Welschen *et al*, reviewed 6 RCTs to examine the effects of SMBG in HbA1c control among participants with type 2 diabetes not treated with insulin.(18) The review used narrative summary as the participant characteristics, interventions and outcomes were considered too divergent to combine in meta analysis.

Of the 6 included RCTs, four reported improvement across study groups, with a slight trend to better HbA1c values in SMBG groups than in conventional/usual care without SMBG groups(18, 19, 22, 23), while 2 studies reported statistically significant improvement in HbA1c value.(20, 21) (It should be noted that the data tables for these reviews include studies that are common across other reviews cited in this report).

**Table II: Welschen et al - Studies, interventions and results for HbA1c as reported in included studies. [18]**

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Schwedes, 2002 (21)	type 2 diabetes, diet or oral medications. Outcome measured at 6 months	Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review	Intervention Group: 7.47±1.27 Control Group: 7.81±1.52 p=0.0086	Intervention Group: -1.0±1.27 Control Group: -0.54±1.14
Guerci, 2003 (20)	type 2 diabetes, diet or oral medications, poor glycaemic control. Outcome measured at 6 months	Intervention Group (n=345): GP training to do ≥6 readings per week Control Group (n=344): No self-monitoring training or instruction	Intervention Group: 8.1±1.6 Control Group: 8.4±1.4 p=0.012	Intervention Group: -0.9±2.1 Control Group: -0.5±1.9
Davidson, 2005 (19)	type 2 diabetes, diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months	Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary. Control Group (n=45): Nutritional advice	Intervention Group: 7.7±1.6 Control Group: 7.8±1.5 p=0.58	Intervention Group: -0.8±1.6 Control Group: -0.6±2.1

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Allen 1990, (24)	type 2 diabetes, diet or oral medication. Outcome measured at 6 months	Intervention Group (n=27): SMBG, diet advice, food and fibre booklet, individual instruction Control Group (n=27): Self urine glucose monitoring, diet advice, food and fibre booklet, individual instruction	Intervention Group: 10.4±2.9 Control Group: 9.7±2.6 p>0.95	Intervention Group: 2.0±3.4% Control Group: 2.0±3.4% p<0.01
Fontbonne 1989 (22)	type 2 diabetes, diet or oral medication. Outcome measured at 6 months	Intervention A Group (n=68): GP monitoring, personal dietary advice, 2 monthly review Intervention B Group (n=72): Self Urine monitoring, personal dietary advice, 2 monthly review Intervention C Group (n=68): SMBG, personal dietary advice, 2 monthly review	Intervention A Group: HbA1c 7.7 % Intervention B Group: HbA1c 8.5 % Intervention C Group: HbA1c 7.8 % P≥0.5	Intervention A Group: HbA1c-0.5%±1.5 Intervention B Group: HbA1c-0.1%±2.2 Intervention C Group: HbA1c -0.4%±3.1
Muchmore, 1994 (23)	type 2 diabetes, overweight. Outcome measured at 12 months	Intervention Group (n=12): Group and individual teaching on carbohydrate counting and SMBG Control Group (n=11): Same time allocation but general information only	Intervention Group: HbA1c 8.8%±1.7 Control Group: HbA1c 9.6%±2.09 P≥0.05	Intervention Group: HbA1c -1.5% Control Group: HbA1c -0.9%

Table II shows end of study and average changes in HbA1c. Schwedes and Guerci found in favour of SMBG, while the results were non-significant for Davidson, Allen, Fontbonne and Muchmore. The timeframes for outcome measurement varied between six and-12 months.

This was a focused review, with tight inclusion criteria and a particular focus on study methodology. The results and discussion focus more on methodological quality and potential limitations than they do on the actual results. Tightly defined inclusion criteria limited the number of papers included, although the outcomes reported are congruent with other reviews and primary evidence. Fontbonne(22), Muchmore

(23), Allen (24) and Davidson (19) all reported an improvement in HbA1c for all trial participants regardless of group allocation. However, Schwedes(21) and Guerici(20) found a statistically significant improvement favouring SMBG.

*Sarol, 2005 (17)*

Sarol conducted a systematic review to determine if therapeutic management programs with SMBG result in greater HbA1c reduction in people with type 2 diabetes compared to programs without SMBG.(17) Heterogeneity among included studies was not statistically significant ( $p=0.19$ ).

**Table III: Sarol et al - Studies, interventions and results for HbA1c as reported in included studies. [17]**

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Schwedes, 2002 (21)	type 2 diabetes , diet or oral medications. Outcome measured at 6 months	Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review	Intervention Group: $7.47 \pm 1.27$ Control Group: $7.81 \pm 1.52$ $p=0.0086$	Intervention Group: $-1.0 \pm 1.27$ Control Group: $-0.54 \pm 1.14$
Guerici, 2003 (20)	type 2 diabetes , diet or oral medications, poor glycaemic control. Outcome measured at 6 months	Intervention Group (n=345): GP training to do $\geq 6$ readings per week Control Group (n=344): No self-monitoring training or instruction	Intervention Group: $8.1 \pm 1.6$ Control Group: $8.4 \pm 1.4$ $p=0.012$	Intervention Group: $-0.9 \pm 2.1$ Control Group: $-0.5 \pm 1.9$
Davidson, 2005 (19)	type 2 diabetes , diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months	Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary. Control Group (n=43): Nutritional advice	Intervention Group: $7.7 \pm 1.6$ Control Group: $7.8 \pm 1.5$ $p=0.58$	Intervention Group: $-0.8 \pm 1.6$ Control Group: $-0.6 \pm 2.1$

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Fontbonne, 1989 (22)	type 2 diabetes , diet or oral medication. Outcome measured at 6 months.	Intervention A Group (68): GP monitoring, personal dietary advice, 2 monthly review Intervention B Group (72): Self Urine monitoring, personal dietary advice, 2 monthly review Intervention C Group (n=68): SMBG, personal dietary advice, 2 monthly review	Intervention A Group: HbA1c 7.7 % Intervention B Group: HbA1c 8.5 % Intervention C Group: HbA1c 7.8 % p≥0.05	Intervention A Group: HbA1c-0.5%±1.5 Intervention B Group: HbA1c-0.1%±2.2 Intervention C Group: HbA1c -0.4%±3.1
**Kwon, 2004 (25)	type 2 diabetes , diet or oral medication. Outcome measured at 12 weeks,	Intervention Group (n=40): Internet information support system Control Group (n=41): Usual outpatient care	Intervention Group: 7.49±1.54 Control Group: 6.97±0.89 p≤0.05	WMD (95%CI) -0.84 (-1.35-0.33)
**Jaber, 1996 (26)	type 2 diabetes , diet or oral medication. Outcome measured at 4 months	Intervention Group (n=17): Instruction on diabetes and diet, medication counseling, exercise, SMBG Control Group (n=22): Usual care	Intervention Group: 9.23±2.08 Control Group: 9.72±2.58 p≤0.05	WMD (95%CI) -1.55(-0.78-0.31)
**Estey, 1990 (27)	type 2 diabetes , diet or oral medication. Outcome measured at 4 months.	Intervention Group (n=28): SMBG, 3 day education program, follow-up Control Group (n=25): 3 day education program, no follow-up	Intervention Group: 6.3±1.1 Control Group: 6.1±1.4 p≥0.05	WMD (95%CI) -0.40 (-0.85-0.05)

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
*Muchmore, 1994 (23)	type 2 diabetes , overweight. Outcome measured at 12 months	Intervention Group (n=12): Group and individual teaching on carbohydrate counting and SMBG Control Group (n=11): Same time allocation but general information only	Intervention Group: HbA1c 8.8%±1.7 Control Group: HbA1c 9.6%±2.09 P≥0.05	Intervention Group: HbA1c -1.5% Control Group: HbA1c -0.9%

\* HbA1c percentage and percentage change

\*\* WMD with 95% CI

Table III again shows the variability in outcomes achieved in different studies, albeit with more diverse timeframes for outcome measurement than Table I and Table II. Some studies reported in the review by Sarol were screened and excluded from this review report due to methodological issues. Interestingly, the smaller studies tended toward non-significant findings while Schwedes and Guerici, the two larger studies found in favour of SMBG.

Result of the meta-analysis of 8 RCTs demonstrated a multi-faceted management strategy that included SMBG showed a mean additional HbA1c reduction of 0.39% (95%CI: -0.54%, -0.23%) under fixed effects model and 0.42% (95%CI: -0.63%, -0.21%) under random effects model.

The new data included from recently published systematic reviews which reported glycaemic control as an outcome are detailed below.

Allemann, 2009 [42]

In the systematic review published by Allemann in 2009, MEDLINE and the Cochrane Controlled Trials Register were searched from inception to January 2009 for randomised controlled trials including non-insulin treated type 2 patients only that compared SMBG with non-SMBG or more frequent SMBG with less intensive SMBG. Fifteen trials (3270 patients) were included in the analyses. SMBG was associated with a larger reduction in HbA1c compared with non-SMBG (WMD -0.31%, 95% confidence interval -0.44 to -0.17). The beneficial effect associated with SMBG was not attenuated over longer follow-up. SMBG significantly increased the probability of detecting a hypoglycaemia (RR 2.10, 1.37 to 3.22). More frequent SMBG did not result in significant changes of HbA1c compared with less intensive SMBG (WMD -0.21%, 95% CI -0.57 to 0.15). The authors concluded that SMBG compared with non-SMBG is associated with a significantly improved glycaemic control in non-insulin



treated patients with type 2 diabetes. The added value of more frequent SMBG compared with less intensive SMBG remains uncertain.

Study	Participants	Intervention	Final HbA <sub>1c</sub>	Average HbA <sub>1c</sub> change
Fontbonne, 1989 (22)	Intervention A Group (68): Intervention B Group (72): Intervention C Group (n=68):  Type 2 diabetes, diet or oral medication. Outcome measured at 6 months.	GP monitoring, personal dietary advice, 2 monthly review Self Urine monitoring, personal dietary advice, 2 monthly review SMBG, personal dietary advice, 2 monthly review	Intervention A Group: HbA <sub>1c</sub> 7.7 % Intervention B Group: HbA <sub>1c</sub> 8.5 % Intervention C Group: HbA <sub>1c</sub> 7.8 % p≥0.05	Intervention A Group: HbA <sub>1c</sub> -0.5%±1.5 Intervention B Group: HbA <sub>1c</sub> -0.1%±2.2 Intervention C Group: HbA <sub>1c</sub> -0.4%± 3.1
Rutten, 1990 (31)	<b>Control:</b> (n=36) G.P. consultation 4/year. No SMBG instruction.  <b>Intervention:</b> (n=34)	<b>Control:</b> G.P. consultation 4/year. No SMBG instruction.  <b>Intervention:</b> -2-5 education session on SMBG -patients contacted diabetes nurses monthly to report SMBG readings. If high, made appointment with G.P. -All patients also met with G.P. after 6mths. -medication algorithms were followed by G.P.s  12mths follow up	1. Final HbA <sub>1c</sub> SMBG: decreased by 0.4% Control: increased by 0.5% (P<0.005) 2. SMBG: HbA <sub>1c</sub> decreased in two patients with an initial HbA <sub>1c</sub> <8 (14%). Control: HbA <sub>1c</sub> unchanged or increased in all patients. 3. SMBG: HbA <sub>1c</sub> decreased in 80% of the patients with an initial value of >10. Control: HbA <sub>1c</sub> decreased in 53% of the patients with an initial value of >10.	
*Muchmore, 1994 (23)	type 2 diabetes, overweight. Outcome measured at 12 months	Intervention Group (n=12): Group and individual teaching on carbohydrate counting and SMBG Control Group (n=11):	Intervention Group: HbA <sub>1c</sub> 8.8%±1.7 Control Group: HbA <sub>1c</sub> 9.6%±2.09 P≥0.05	Intervention Group: HbA <sub>1c</sub> -1.5% Control Group: HbA <sub>1c</sub> -0.9%

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
		Same time allocation but general information only		
Muchmore, 1994 [23]	n=23 Drop out 6/29 No-ITT	<p><b>Control:</b> (n=11) - conventional care - teaching individually and at group level on general principles of diabetes nutrition.</p> <p><b>Intervention:</b> (n=12) -conventional care -SMBG,6x per day (pre &amp; 2h postprandially) for 4 wks then pre and postprandially for a single meal per day for 16 wks. SMBG beyond 20weeks was at own expense and choice. -dietary CHO counting teaching individually and at group level. -results of SMBG and calorie counting was charted on a daily worksheet. -Teaching focused on postprandial increment in blood glucose of 2.2 to 3.9mMol/L.</p> <p><b>Control and Intervention:</b> -Both groups received care under their primary physician who coordinated any decision on medication adjustment. -1st 8wks run-in period formed in groups of 7-8 members and met for 90min wkly for formal proprietary behavioural weight management program (L.E.A.R.N.) + 1hr counselling by</p>	<p>1. HbA<sub>1c</sub> progressively declined in SMBG group (<math>P &lt; 0.05</math>) and no improvement in control group.</p> <p>2. HbA<sub>1c</sub> at week 44</p> <p>SMBG: 8.75%±0.63: 1.54% (1.46) reduction (<math>P &lt; 0.05</math>)</p> <p>Control: 9.6%±0.63: 0.84% (1.87) reduction (<math>P &gt; 0.3</math>)</p> <p>No significant differences between groups at study end.</p>	

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
		<p>diabetes nurse educator + individual session with dietician.</p> <p>-follow-up one-on-one sessions with the dietician (30min) at wks 1 and 3 and the nurse educator at wks 1, 3, and 24.</p> <p>-both groups were recommended a meal composition of 50% of calories from carbohydrates, 30% from fat, and 20% from protein. Total calories were individualized for a weight loss of 0.5-1kg per week.</p> <p>44 wks follow up</p>		
Jaber, 1996 (26)	<p>type 2 diabetes , diet or oral medication.</p> <p>Outcome measured at 4 months</p>	<p>Intervention Group (n=17):</p> <p>Instruction on diabetes and diet, medication counseling, exercise, SMBG</p> <p>Control Group (n=22):</p> <p>Usual care</p>	<p>Intervention Group: 9.23±2.08</p> <p>Control Group: 9.72±2.58</p> <p>p≤0.05</p>	<p>WMD (95%CI)</p> <p>-1.55(-0.78-0.31)</p>
Atsumi, 1997 [47]	<p>N=85 (intervention)</p> <p>N=86 (control)</p>	<p>Intervention :</p> <p>Education and SMBG (twice daily three times a week)</p> <p>Control:</p> <p>Education</p>	<p>Intervention:</p> <p>Hba1C at Baseline: 7.36</p> <p>At followup 7.32</p> <p>Control:</p> <p>At baseline: 7.52</p> <p>At followup 7.83</p>	NS difference
Brown, 2002 [48]	<p>N=83 (Intervention)</p> <p>N=86 (Control)</p>	<p>Intervention:</p> <p>Education plus SMBG versus</p> <p>Control:</p> <p>Usual care</p>	<p>Intervention:</p> <p>Hba1C at Baseline: 11.90 (3.20)</p> <p>At followup 10.90 (2.80)</p> <p>Control:</p> <p>At baseline: 11.60 (3.10)</p>	

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
			At followup 11.70 (3.00)	
Schwedes, 2002 (21)	Type 2 diabetes , diet or oral medications. Outcome measured at 6 months	Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review	Intervention Group: 7.47±1.27 Control Group: 7.81±1.52 p=0.0086	Intervention Group: -1.0±1.27 Control Group: -0.54±1.14
Guerci, 2003 (20)	type 2 diabetes , diet or oral medications, poor glycaemic control. Outcome measured at 6 months	Intervention Group (n=345): GP training to do ≥6 readings per week Control Group (n=344): No self-monitoring training or instruction	Intervention Group: 8.1±1.6 Control Group: 8.4±1.4 p=0.012	Intervention Group: -0.9±2.1 Control Group: -0.5±1.9
Davidson, 2005 (19)	type 2 diabetes , diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months	Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary. Control Group (n=43): Nutritional advice	Intervention Group: 7.7±1.6 Control Group: 7.8±1.5 p=0.58	Intervention Group: -0.8±1.6 Control Group: -0.6±2.1
Farmer 1, 2007 (28)	N=150 (Intervention) N=152 (Control)	Intervention: Education plus SMBG versus  Control: Usual care	Intervention: Hba1C at Baseline: 7.41 (1.02) At followup 7.28 (0.88) Control: At baseline: 7.49 (1.09) At followup 7.49 (1.20)	

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Farmer 2, 2007 [30]	N=151 (Intervention) N=152 (Control)	Intervention: Education and SMBG and interpretation of SMBG Versus Control: Usual care	Intervention: Hba1C at Baseline: 7.53 (1.12) At followup 7.36 (1.05) Control: At baseline: 7.49 (1.09) At followup 7.49 (1.20)	
O'Kane, 2008 [26]	180 participants with newly diagnosed type 2 diabetes	The study compared a control group with no monitoring and an intervention group that received an additional educational program on SMBG. Follow up was scheduled every three months until 12 months.	At the end point (month 12), HbA1c values were 6.9% ( $\pm 1.2$ ) in the control group and 6.9% ( $\pm 0.8$ ) in the SMBG group: $p=0.69$ ; (95% CI $-0.25\%$ to $0.38\%$ ). Mean HbA1c value in the SMBG group changed from 8.8% ( $\pm 2.1$ ) to 6.9% ( $\pm 0.8$ ) while the control group changed from 8.6% ( $\pm 2.3$ ) to 6.9% ( $\pm 1.2$ ). There was no statistically significant difference between the groups at any time point.	
Barnett, 2008 [50]	N=311 (Intervention) N=299 (Control)	Intervention: Education and SMBG Control Education	Intervention: Hba1C at Baseline: 8.12 (0.89) At followup 6.95 (0.97) Control: At baseline: 8.12 (0.84) At followup 7.20 (1.22)	

Clar, 2009 [43]

Clar et al., published a new systematic review in 2009 which identified 30 RCTs. Ten of these trials (detailed in the table below) directly compared SMBG with no SMBG showing a statistically significant reduction in HbA1C of 0.21%, which may not be considered clinically significant. This study concluded that SMBG is of limited clinical effectiveness in improving glycaemic control in people with type 2 diabetes treated with oral agents, or diet alone. They postulated that SMBG may lead to improved glycaemic control only in the context of appropriate education – both for patients and health-care professionals on how to respond to the data, in terms of lifestyle and treatment adjustment.

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Barnett (2008) [ 50]	N=311 (Intervention) N=299 (Control)	Intervention: Education and SMBG Control Education	SMBG Mean (SD) 6.95 (0.97) No SMBG 7.2 (1.22)	Mean difference -0.25 -0.43 to -0.07)
Davidson (2005) [19]	Type 2 diabetes, diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months	Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary. Control Group (n=43): Nutritional advice	SMBG Mean (SD) 7.7(1.6) No SMBG 7.8 (1.5)	Mean difference -0.10 (-0.75 to 0.55)
Farmer 1 (2007) [28]	N=150 (Intervention) N=152 (Control)	Intervention: Education plus SMBG versus  Control: Usual care	SMBG Mean (SD) 7.28(0.88) No SMBG 7.49 (1.2)	Mean difference -0.21 (-0.45 to 0.03)
Fontbonne (1989) [22]	Intervention A Group (68): Intervention B Group (72): Intervention C Group (n=68):  Type 2 diabetes , diet	GP monitoring, personal dietary advice, 2 monthly review Self Urine monitoring, personal dietary advice, 2 monthly review SMBG, personal	SMBG Mean (SD) 7.84 (2.5) No SMBG 7.7 (2.5)	Mean difference 0.14 (-0.70 to 0.98)

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
	or oral medication. Outcome measured at 6 months.	dietary advice, 2 monthly review		
Guerci (2003) [20]	Type 2 diabetes , diet or oral medications, poor glycaemic control. Outcome measured at 6 months	Intervention Group (n=345): GP training to do $\geq 6$ readings per week Control Group (n=344): No self-monitoring training or instruction	SMBG Mean (SD) 8.1 (1.6) No SMBG 8.4 (1.4)	Mean difference -0.30 (-0.52 to -0.08)
Kibriya (1999) [ 51]	Total number: 64 Inclusion criteria: T2DM, oral medication or insulin	Intervention: SMBG versus No SMBG	SMBG Mean (SD) 7.11 (1.08) No SMBG 7.12 (1.85)	Mean difference -0.01 (-0.75 to 0.73)
Muchmore (1994) [23]	Type 2 diabetes , overweight. Outcome measured at 12 months	Intervention Group (n=12): Group and individual teaching on carbohydrate counting and SMBG Control Group (n=11): Same time allocation but general information only	SMBG Mean (SD) 8.75 (1.66) No SMBG 9.6 (2.1)	Mean difference -0.85 (-2.41 to 0.71)
O'Kane (2008) [29]	180 participants with newly diagnosed type 2 diabetes	The study compared a control group with no monitoring and an intervention group that received an additional educational program on SMBG. Follow up was scheduled every three months until 12 months.	SMBG Mean (SD) 6.9 (0.8) No SMBG 6.9 (1.2)	Mean difference 0.00 (-0.30 to 0.30)
Rutten (1990) [31]	<b>Control:</b> (n=36) G.P. consultation 4/year. No SMBG instruction.	<b>Control:</b> G.P. consultation 4/year. No SMBG instruction.  <b>Intervention:</b> -2-5 education session on SMBG	SMBG Mean (SD) 9.2 (1.49) No SMBG 9.4 (1.14)	Mean difference -0.20 (-0.64 to 0.24)

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
	<b>Intervention:</b> (n=34)	-patients contacted diabetes nurses monthly to report SMBG readings. If high, made appointment with G.P. -All patients also met with G.P. after 6mths. -medication algorithms were followed by G.P.s  12mths follow up		
Wing (1986) [52]	<i>Total number:</i> 50 (25/25) <i>Inclusion criteria:</i> age 35–65 years; > 20% above ideal weight for height; use of oral hypoglycaemic medication or insulin for BG control; development of diabetes after the age of 30	<i>SMBG regimen:</i> fasting BG on 5 days per week and 2 postprandial glucose measurements per week; after 12 weeks only FBG on 5 days per week <i>SMBG other:</i> behavioural weight control treatment programme, SMBG and focusing on weight–BG relationship <i>SMBG method:</i> Chemstrips bG, diary <i>Use of therapy decision scheme:</i> yes <i>SMBG instruction:</i> yes <i>SMBG accuracy checks:</i> yes	SMBG Mean (SD) 10.2 (2.3) No SMBG 10.4 (2.2)	Mean difference –0.20 (–1.45 to 1.05)



McIntosh, 2010 [45]

McIntosh et al., observed a statistically significant improvement in the HbA1c concentration across 7 RCTs (see table below) which compared SMBG with no self-monitoring among patients taking oral anti-diabetes drug therapy (weighted mean difference  $-0.25\%$ , 95% confidence interval  $-0.36\%$  to  $-0.15\%$ ). In contrast to Clar, [43], their subgroup analysis indicated that results from RCTs that provided patients with education on how to interpret and apply self-monitoring test results were similar to those from RCTs that did not. Their conclusion was that SMBG was associated with a modest, statistically significant reduction in HbA1c concentrations, regardless of whether patients were provided with education on how to interpret and use the test results.

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Barnett, 2008 [50]	N=311 (Intervention) N=299 (Control)	Intervention: Education and SMBG Control Education	SMBG Mean (SD) 6.95 (0.97) No SMBG 7.2 (1.22)	Mean difference -0.25 -0.43 to -0.07)
Davidson, 2005 [19]	Type 2 diabetes, diet or oral medications, from low socioeconomic and educational backgrounds. Outcome measured at 6 months	Intervention Group (n=43): Nutrition advice plus self-monitoring plus diary. Control Group (n=43): Nutritional advice	SMBG Mean (SD) 7.7(1.6) No SMBG 7.8 (1.5)	Mean difference -0.10 (-0.75 to 0.55)
Farmer 1, 2007 (28)	N=150 (Intervention) N=152 (Control)	Intervention: Education plus SMBG versus  Control: Usual care	SMBG Mean (SD) 7.28(0.88) No SMBG 7.49 (1.2)	Mean difference -0.21 (-0.45 to 0.03)
Guerci, 2003 [20]	Type 2 diabetes, diet or oral medications, poor glycaemic control. Outcome measured at 6 months	Intervention Group (n=345): GP training to do $\geq 6$ readings per week Control Group (n=344): No self-monitoring training or instruction	SMBG Mean (SD) 8.1 (1.6) No SMBG 8.4 (1.4)	Mean difference -0.30 (-0.52 to -0.08)

Study	Participants	Intervention	Final HbA1c	Average HbA1c change
Muchmore, 1994 [23]	Type 2 diabetes , overweight. Outcome measured at 12 months	Intervention Group (n=12): Group and individual teaching on carbohydrate counting and SMBG Control Group (n=11): Same time allocation but general information only	SMBG Mean (SD) 8.75 (1.66) No SMBG 9.6 (2.1)	Mean difference -0.85 (-2.41 to 0.71)
O'Kane, 2008 [29]	180 participants with newly diagnosed type 2 diabetes	The study compared a control group with no monitoring and an intervention group that received an additional educational program on SMBG. Follow up was scheduled every three months until 12 months.	SMBG Mean (SD) 6.9 (0.8) No SMBG 6.9 (1.2)	Mean difference 0.00 (-0.30 to 0.30)
Schwedes, 2002 [21]	Type 2 diabetes , diet or oral medications. Outcome measured at 6 months	Intervention Group (n=113): Training, SMBGX6 per day for 2 days/wk, diet and wellbeing diary Control Group (n=110): Routine training on diet and lifestyle, 4 weekly review	Intervention Group: 7.47±1.27 Control Group: 7.81±1.52 p=0.0086	Intervention Group: -1.0±1.27 Control Group: -0.54±1.14

#### Poolsup, 2009 [53]

Poolsup et al., published results from 9 trials that indicated that SMBG was effective in reducing HbA1c in non-insulin-treated type 2 diabetes (pooled mean difference, -0.24%; 95% confidence interval, -0.34% to -0.14%;  $P < 0.00001$ ). Glycaemic control significantly improved among the subgroup of patients whose baseline HbA1c was greater than or equal to 8%. In contrast, no significant effect of SMBG was detected in patients who had HbA1c <8%. These results suggested that SMBG was useful in improving glycaemic control in non-insulin-treated type 2 diabetes, particularly in patients whose baseline HbA1c was greater than or equal to 8%. As individual trial results were not reported in this publication, a detailed summary table cannot be provided.

***Systematic review of RCTs on people with type 2 diabetes including both non-insulin treated and insulin treated participants***

One systematic review examined the effect of SMBG in the diabetes management of people with type 2 diabetes who were either treated with insulin or not treated with insulin.(15) The review incorporated two separate analyses, therefore, only the meta-analysis that did not include insulin treated people was included in this report.

*Jansen, 2006 (15)*

Jansen evaluated the relative effectiveness of interventions with SMBG and self-monitoring urine glucose, versus interventions without self-monitoring in terms of HbA1c reductions in type 2 diabetes. Thirteen randomised controlled trials with a total of 2080 participants were included. Five RCTs included both insulin-treated and non-insulin-treated participants with type 2 diabetes. However, two separate meta-analyses (Bayesian random effect model) of all included 13 RCTs and a meta-analysis of 8 RCTs with non-insulin treated type 2 diabetes participants were performed (only the non insulin group meta analysis is reported here).

The meta-analysis by Jansen indicated two findings in the clinical effectiveness of SMBG in glycaemic control. Firstly, interventions with SMBG were more effective than interventions without SMBG in reducing HbA1c value. [Pr=98%; 0.42% reduction] Secondly, interventions with SMBG that include regular feedback were more likely to be effective than interventions with SMBG that did not include feedback [Pr=99%; CrI-1.49; -0.13]. Additionally, interventions with SMBG were more likely to be effective than interventions with urine monitoring [Pr=80%; 0.28% reduction]; urine monitoring had similar results to interventions without self-monitoring. This meta-analysis indicates that among this group of people, SMBG was an independent variable associated with a reduction in HbA1c.

*St John, 2010 [46]*

A recently published Australian systematic review by St John et al., identified 6 trials that reported results for non-insulin treated patients separately for type 2 diabetes. The results of 5 RCTs in non-insulin-treated patients with type 2 diabetes were combined in a meta-analysis with two earlier RCTs which yielded a significant pooled SMBG-related decrease in HbA1c of -0.22 (95% CI -0.34% to -0.11%) demonstrating an SMBG-related HbA1c reduction in non-insulin-treated type 2 diabetes patients. As the individual trial results for HbA1c have not been reported in this publication, a detailed summary table cannot be provided.

### ***Results from newly identified randomised controlled trials***

The search strategy also identified primary research that had been published since the systematic reviews. Two RCTs are reported from the original review and 3 new RCTs are reported below which met the inclusion criteria.

#### *Farmer, 2007 (28)*

Farmer conducted a three-armed trial of 453 participants to examine the efficacy of SMBG in glycaemic control and efficacy of additional education of interpretation of results and behavioural modifications.(28) The results did not support the effectiveness of SMBG in the glycaemic control either with or without educational supports.

The control group received standard care that consisted of goal setting and review without SMBG unless their doctor suggested it, while the two intervention groups received either standard care plus SMBG without specific education on interpretation of the readings, or standard care plus SMBG with additional training on interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle. The follow up period was 12 months. The study did not find significant differences in HbA1c values at the end of the study period ( $p=0.12$ ). Mean difference in changes of HbA1c from baseline to 12 months were as follows: between control and SMBG without educational supports:  $-0.14\%$  (CI 95%  $-0.35$  to  $0.07\%$ ) and between control & SMBG with education:  $-0.17\%$  ( $-0.37$  to  $0.03\%$ ). No statistically significant differences were found in changes of HbA1c between the groups ( $p=0.38$ ). (28)

Additionally, a significant difference was found in changes in total cholesterol level favouring the SMBG group without education:  $-0.06\text{mmol/L}$  ( $-0.26$  to  $0.14$ ), and the SMBG group with education:  $-0.23\text{mmol/L}$  ( $-0.43$  to  $-0.04$ ). Hypoglycaemic episodes were identified more often in the SMBG group than the control group: control group: 14 episodes/152, SMBG group without education: 33/150, SMBG group with education: 43/151. The higher frequency of identification of episodes of hypoglycaemia (blood glucose level  $<4\text{mmol/L}$ ) is not surprising given the control group only monitored blood glucose levels on the specific advice of their General Practitioner (GP) while the interventions groups used routine SMBG and were hence more likely to identify hypoglycaemic events.

#### *O'Kane, 2008 (29)*

O'Kane conducted a RCT of 180 participants with newly diagnosed type 2 diabetes to examine the effect of SMBG on glycaemic control and psychological status.(29) The study compared a control group with no monitoring and an intervention group that received an additional educational program on SMBG. Follow up was scheduled every 3 months until 12 months. The study found no significant difference

between groups in HbA1c values. Concerning psychological status, a significant association was found between SMBG and higher scores on a depression subscale.

At the end point (month 12), HbA1c values were 6.9% ( $\pm 1.2$ ) in the control group and 6.9% ( $\pm 0.8$ ) in the SMBG group:  $p=0.69$ ; (95% CI  $-0.25\%$  to  $0.38\%$ ). Mean HbA1c value in the SMBG group changed from 8.8% ( $\pm 2.1$ ) to 6.9% ( $\pm 0.8$ ) while the control group changed from 8.6% ( $\pm 2.3$ ) to 6.9% ( $\pm 1.2$ ). There was no statistically significant difference between the groups at any time point. In regards to non-significant difference between the groups in the mean changes of HbA1c values, the authors noted, the rigorous use of a treatment algorithm applied equally to all participants across both groups during the study period may have over-shadowed the observable subtle benefit of SMBG.(29)

In the well-being questionnaire of the psychological indices, SMBG was associated with a 6% higher score on the depression subscale ( $p=0.01$ ). The authors concluded that the result could be due to psychological reaction to the new diagnosis of diabetes and related life changes. The participants in this study were still in the very early stage of the coping/adjusting process while other included studies had participants with long established diabetes. The authors concluded that the newly enforced discipline of regular SMBG in uncertain and unfamiliar life circumstances may have impacted on the psychological status of newly diagnosed people in the study.(29)

Farmer, 2009 [49]

The updated review identified a recently published RCT by Farmer et al., that studied patients with non-insulin-treated type 2 diabetes, aged  $\geq 25$  years and with a HbA1c  $\geq 6.2\%$ . A total of 453 patients were individually randomised to standardised usual care with 3-monthly HbA1c (control,  $n = 152$ ); SMBG with patient training focused on clinician interpretation of results in addition to usual care (less intensive self-monitoring,  $n = 150$ ) or SMBG with additional training of patients in interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle (more intensive self-monitoring,  $n = 151$ ). This RCT reported differences in 12-month HbA1c between the three groups (adjusted for baseline HbA1c) were not statistically significant ( $p = 0.12$ ). The difference in unadjusted mean change in HbA1c from baseline to 12 months between the control and less intensive self-monitoring groups was  $-0.14\%$  [95% confidence interval (CI)  $-0.35$  to  $0.07$ ] and between the control and more intensive self-monitoring groups was  $-0.17\%$  (95% CI  $-0.37$  to  $0.03$ ). There was no evidence of a significantly different impact of self-monitoring on glycaemic control when comparing subgroups of patients defined by duration of diabetes, therapy, diabetes related complications and EQ-5D score.

Pignone, 2009 [54]

In a new RCT published by Pignone in 2009, 184 adults with newly diagnosed type 2 diabetes who were not taking insulin were randomised to receive either a structured educational program alone or a structured educational program plus additional training and advice about SMBG. All participants received follow-up visits every 3 months with predefined treatment algorithms based on HbA1c level. Patients in the SMBG group were asked to complete four fasting and four postprandial measures per week and were given advice about what to do in response to high SMBG readings. No differences between groups were observed in HbA1c at 12 months (6.9% in each group; mean difference 0.07%; 95% confidence interval -0.25 to 0.38) or in the incidence of hypoglycaemia. Interestingly, those in the SMBG group had somewhat higher scores on the depression subscale of a well-being questionnaire. This study concluded that the addition of SMBG did not appear to provide additional benefit for newly diagnosed, non-insulin-using patients with type 2 diabetes who were receiving care in an organised program with a strong educational component.

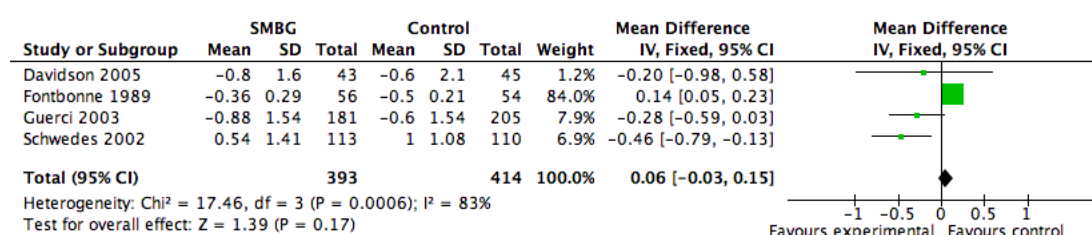
Polonsky, 2011[55]

Polonsky et al., have published results in 2011 from the Structured Testing Program (STEP) study. This 12-month, prospective, cluster randomized, multicentre study recruited 483 poorly controlled (HbA1c  $\geq 7.5\%$ ), insulin-naïve subjects with type 2 diabetes from 34 primary care practices in the U.S. Practices were randomised to an active control group (ACG) with enhanced usual care or a structured testing group (STG) with enhanced usual care and at least quarterly use of structured SMBG. STG patients and physicians were trained to use a paper tool to collect/interpret 7-point glucose profiles over 3 consecutive days. The primary end point was HbA1c level measured at 12 months. Results indicated that the 12-month intent-to-treat analysis (ACG, n = 227; STG, n = 256) showed significantly greater reductions in mean (SE) HbA1c in the STG compared with the ACG: 21.2% (0.09) vs. 20.9% (0.10); D = 20.3%; P = 0.04. Per protocol analysis (ACG, n = 161; STG, n = 130) showed even greater mean (SE) HbA1c reductions in the STG compared with the ACG: 21.3% (0.11) vs. 20.8% (0.11); D = 20.5%; P, 0.003. Significantly more STG patients received a treatment change recommendation at the month 1 visit compared with ACG patients, regardless of the patient's initial baseline HbA1c level: 179 (75.5%) vs. 61 (28.0%) P<0.0001. Both STG and ACG patients displayed significant (P<0.0001) improvements in general well-being. This trial concluded that appropriate use of structured SMBG significantly improves glycaemic control and facilitates more timely/aggressive treatment changes in non-insulin treated type 2 diabetes.

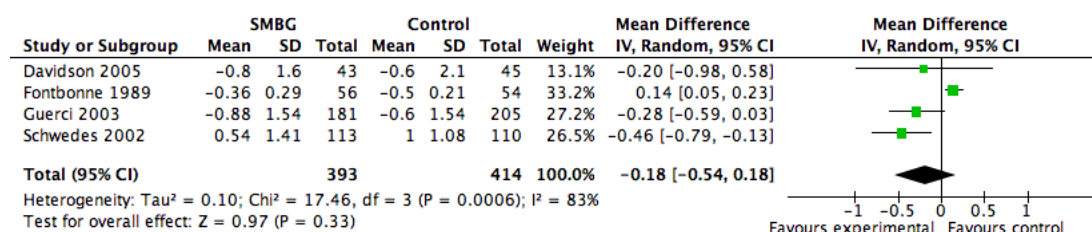
### **Meta analyses of primary Randomised Control Trials of the effects of Self-Monitoring Blood Glucose on HbA1c**

The following sections are reproduced from the original review to reproduce details of the specific meta-analyses that were run to provide additional information. This was undertaken because two relatively recent RCTs had been identified, and the review by Welschen in particular had focused more on exploring methodology through meta analysis and had used restrictive criteria.(18) even though there were already systematic reviews including meta-analyses available on the effectiveness of SMBG in diabetes management in people with type 2 diabetes in the last five years. The meta-analysis was based on clinical homogeneity using strict entry criteria, therefore, only 4 studies with outcome of HbA1c measured at 6 months were included. In this analysis, the outcome measurement is mean difference from baseline to final measurement point hence, the figures per study vary from the previous inclusive analysis. In spite of the stricter entry criteria, both fixed and random effect models demonstrated statistical heterogeneity, therefore the findings from this analysis should be considered carefully. The studies that compared control groups without SMBG (n=414) and intervention groups with SMBG (n=393) were entered for meta-analysis. All interventions were conducted over 6 months and follow-up data were collected six months after the commencement of the interventions.

**Figure 4: Meta-analysis 1: Fixed Effect Model**



**Figure 5: Meta-analysis 2: Random Effect Model**



Both fixed effect and random effect model were utilised to investigate the degree of heterogeneity between the studies. A high degree of statistical heterogeneity was observed ( $I^2=83\%$ ). Fontbonne is a statistical outlier in both analyses, and is given a very high weighting in the fixed effect model. Removing the Fontbonne study from the analysis results in an analysis that is statistically significantly in favour of SMBG, and is homogenous.[22] However, removal of studies to identify sources of heterogeneity is a test for, rather than a solution to, the problem of heterogeneity. The weighting in the

random effect model is more balanced between studies of comparable sizes and this model is probably the more reliable presentation of the data.

Statistical heterogeneity arises when there is variability in the intervention effects in the included studies (either or both of clinical and methodological diversity). Fixed-effect meta-analysis is based on the assumption that observed differences between studies are due solely to chance rather than bias (i.e. there is no statistical heterogeneity). Where there is statistical heterogeneity (as with this analysis) a random effects model is applied as it involves an assumption that the effects being estimated in the different studies are not identical.

The result of the fixed effect model indicated modest-negative effect of SMBG in the changes of HbA1c value at 6 months while the result of the random effect model found a modest positive effect (neither result is statistically significant). Possible causes of the inconsistency of these results includes: poor methodological quality; the limited number of included studies; and very stable effect of SMBG in the control of HbA1c in a 6 months period. The difference between fixed and random effects model outcomes in terms of statistical significance is explained by the underlying assumption that fixed effects models of meta analysis are calculated based on the assumption of a single effect size where as the random effects model allows for greater error in effect size by assuming that it varies (in a normal distribution) between studies.

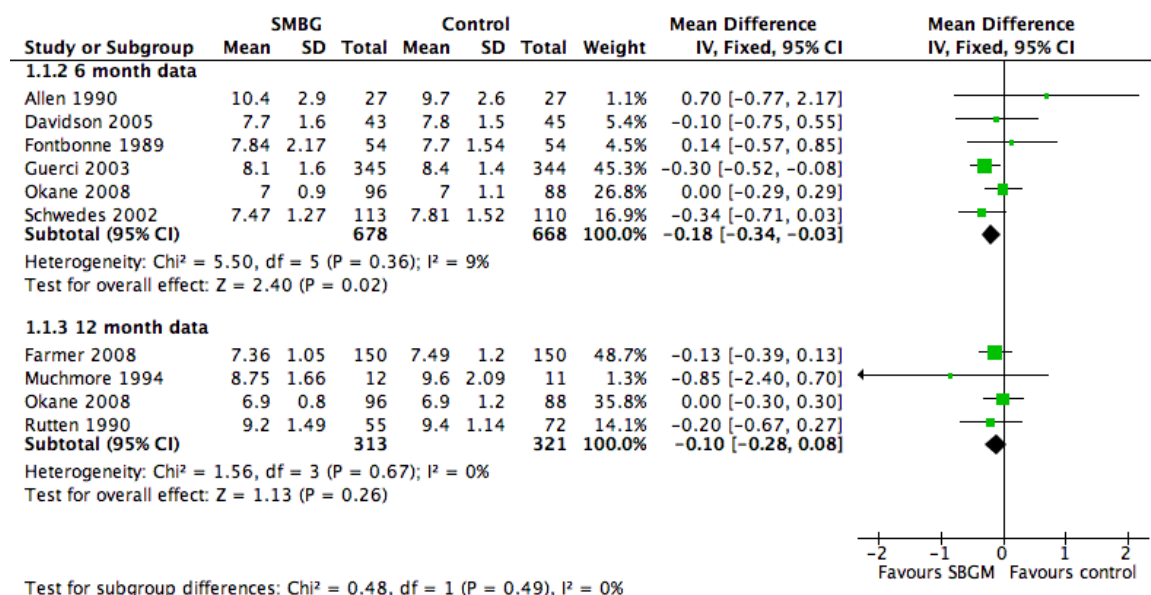
### ***Exploratory meta- analysis***

In addition, the original review contained the following meta-analysis, comprised of non-insulin treated people with type 2 diabetes controlled by diet and/or oral medication. It was a deliberately broad analysis, with open inclusion criteria covering the scope of care across 1346 participants at 6 months, and 634 participants at 12 months. Despite the inclusive approach, statistical heterogeneity was not evident for 6 or 12 month data.

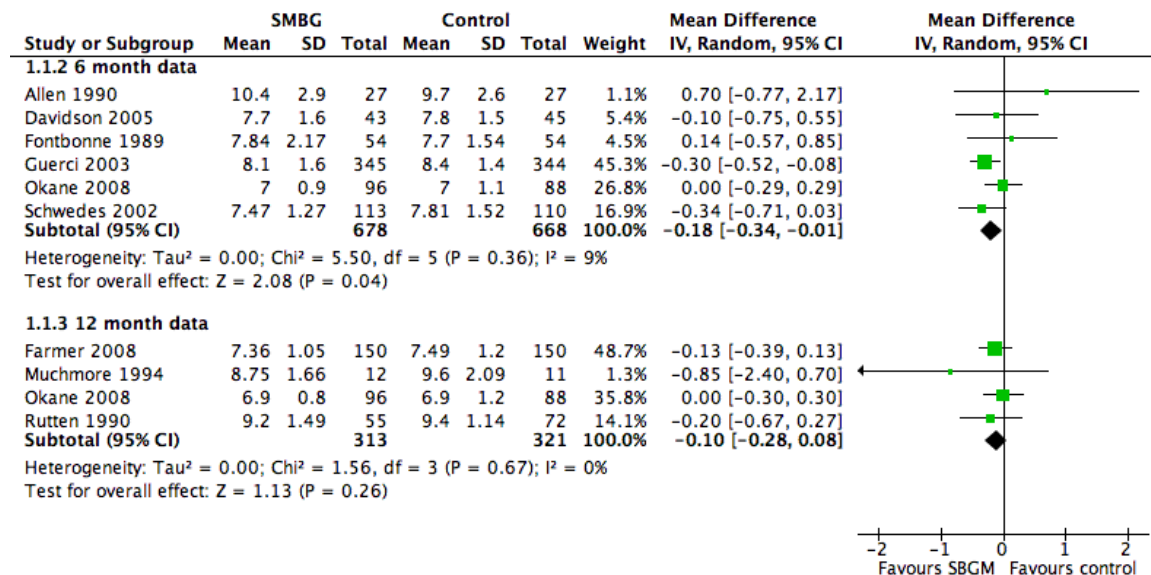
Not all primary studies reported outcome data in the same way, with some reporting the mean difference and standard error of the mean rather than the mean and standard deviation; therefore regression analysis was undertaken to standardise results and enable comparison.



**Figure 6: Fixed Effects meta-analysis of effects of interventions including Self-Monitoring Blood Glucose on HbA1c.**



**Figure 7: Random Effects meta-analysis of effects of interventions including Self-Monitoring Blood Glucose on HbA1c.**



The study by Estey was not included in this exploratory analysis (Figure 6 and 7) as it was testing a different intervention to SMBG.(27) The pooled results of the total scores were significant and favouring the intervention at 6 months. The result of both models indicated a beneficial effect of SMBG in the changes of HbA1c value at 6 months, however this effect does not continue at 12 months.

It should be noted that this meta-analysis was exploratory in nature and clinical heterogeneity was likely between studies, although statistical heterogeneity was not evident. These results should be considered carefully before application to practice or policy.

#### *Changes in HbA1c over other timeframes*

Of the included RCTs, 3 reported mean changes in HbA1c values other than at 6 months, including 3 months (27), 11 months (21) and 12 months (29). None of these studies demonstrated that SMBG inclusive methods of care were effective for any of these timeframes.

#### *Frequency of Self-Monitoring Blood Glucose and changes in HbA1c*

Fontbonne (n=164) reported that there was a significant association between the number of SMBG strips used and the decrease in HbA1c ( $P < 0.02$ ) in the SMBG group.(22) Participants in the SMBG group whose HbA1c decreased over 1% used significantly more blood strips than participants who had less reduction in HbA1c in the same SMBG group.(22)

Farmer (n=453) reported that mean frequency of SMBG use was significantly higher in the SMBG group with educational intervention compared with the SMBG group without educational intervention ( $p = 0.022$ ). (28) However, association between the frequency of the SMBG use and glycaemic control was not reported and overall no significant difference in changes in HbA1c was found between the groups.

In the updated literature, Clar [43] provides a meta-analysis of enhanced SMBG versus simple SMBG where enhanced SMBG was subdivided into those studies with a component of education and/or feedback and those using other methods (higher versus lower frequency of monitoring, free provision of strips versus no free provisions of strips). There was no significant effect of decreasing the frequency of monitoring however, these particular trials had significant heterogeneity.

Allemann [42] also reported on 4 trials that compared more frequent SMBG with less intensive SMBG on HbA1c. SMBG did not result in a significantly lower HbA1c compared with less intensive monitoring but heterogeneity was also reported to be moderate to high in these trials.

McIntosh [45] conducted a subgroup analyses to determine whether the HbA1c estimate was affected by differences across studies in the frequency or duration of SMBG, baseline HbA1c concentration, time since diabetes diagnosis and type of oral anti-diabetes drug therapy used and found that this corroborated the overall analysis, finding no difference related to the frequency of SMBG.

### *Episodes of hypoglycaemia*

Two studies reported episodes of hypoglycaemia during the study periods. Findings support the modest/moderate association between the frequency of hypoglycaemic episodes and the use of SMBG.(20, 28) In Farmer's study, an episode of hypoglycaemia was found in 9.2% of participants in the non-SMBG group, 22.0% in the less intensive SMBG group and 28.4% in the intensive SMBG group, further to this, the study found significant episodes of hypoglycaemia were highest in the SMBG group and lowest in the control group, although the authors did not discuss whether this was a feature of frequency or accuracy of monitoring.(28) Guerri also reported two times higher hypoglycaemic episodes in the SMBG group (10.4%) compared with 5.2% of participants in the non-SMBG group, although there were no serious episodes, with all identified episodes being classified as asymptomatic.(20) Without SMBG, the author suggests it is possible these episodes would have been missed.(20)

The updated evidence corroborates the finding that SMBG is more capable of identifying hypoglycaemia. Allemann et al., [42] included 7 trials which provided data on the occurrence of hypoglycaemia. One of these 7 trials recorded no episodes. However, the remaining 6 reported 268 events in both the interventional and control groups. All events were graded as mild to moderate with the exception of one serious event in the control group. This review concluded that SMBG significantly increased the probability to detect a hypoglycaemia (RR 2.10, 1.37 to 3.22, I<sup>2</sup> =59.3%).

Clar [43] reported hypoglycaemic events from 6 RCTs. Results for this outcome were inconsistent, but there was a suggestion that occurrence of (mild or moderate) hypoglycaemia was increased with more frequent self-monitoring. The new study by Farmer et al., [49] also concluded that there is an increased rate of hypoglycaemia reported among individuals using SMBG.

### *Psychological outcomes*

Three studies indicated ambivalent results regarding the impact of SMBG on the QOL or satisfaction rate of non-insulin treated participants with type 2 diabetes. O'Kane examined the impact of SMBG on the psychological status of 180 newly diagnosed participants.(29) It was reported that SMBG was associated with a 6% higher scores on the depression sub-scale of the Patient Well-Being Questionnaire at the 12 months point (p=0.01) compared with a control group without SMBG. No statistically significant between group differences were found in the sub-scale of anxiety, or positive well-being, or energy.

In contrast, Schwedes reported a positive effect of SMBG in the scores of depression and well-being.(21) The Patient Well-Being Questionnaire was used to assess the psychological well-being of 223 participants with type 2 diabetes in the control group without SMBG and the SMBG group with structured counseling. In both groups, treatment satisfaction improved to a similar extent while well-

being scores improved in the SMBG group ( $p=0.9$ ). Statistically significant improvements were found in the SMBG group in the depression score ( $p=0.032$ ) and lack of well-being ( $p=0.02$ ).

Muchmore (n=23) used The Quality-of-Life (QOL) Inventory to compare the effect of SMBG in participants QOL.(23) Differences in the scores between the control group without SMBG and the SMBG group were assessed. Identical results were found between the control group and the SMBG group in satisfaction, impact, worry-social/vocational and worry-diabetes related categories. In both groups, the satisfaction score improved between 0 to 24 weeks ( $p<0.05$ ). There were no change to scores on the impact, worry-social/vocational and worry-diabetes over time ( $p>0.3$ ).

The total duration of diabetes among the included individuals appeared to have a large impact on the results from three studies. O'Kane (29) studied individuals with newly diagnosed type 2 diabetes, while 2 studies included individuals with relatively established diabetes around 5-6 years after the initial diagnosis.(21, 23) Muchmore had a very small population size (n=23), which limits the validity of the study and interpretation of the results need to be carefully considered.(23). In terms of impact on HbA1c, the primary outcome measure used across studies to indicate glycaemic control, individuals using SMBG were no more likely to have improved control at 6 months than those who did not use SMBG in a meta analysis of four studies.

In the exploratory analysis, there was an effect at 6 months that did not continue by 12 months. However, this analysis used very open criteria and was very likely to be confounded by clinical heterogeneity.

The updated literature notes some negative impact of SMBG on a person's quality of life. The recent review by Clar [43] comments upon recent evidence that there are psychological disbenefits from SMBG as used in current practice – anxiety, depression and self-chastisement. Adverse effects on quality of life were not only seen in clinical trials, but also in a large Italian observational study on SMBG in subjects with type 2 diabetes (2855 respondents, of whom 2254 were not on insulin). [43]

Farmer et al.,[49] also suggests that there appears to be an initial negative impact of SMBG on quality of life measured on the EQ-5D, and the potential additional lifetime gains in quality-adjusted life-years were outweighed by these initial impacts for both SMBG groups compared with control. Their conclusion was that for some patients felt that SMBG was helpful, but there was evidence that those using more intensive self-monitoring perceived diabetes as having more serious consequences.

However, McIntosh et al., [45] reported that their analysis of subscales related to psychological well-being demonstrated discrepant findings across their included studies who reported on the effect of self-monitoring on anxiety and depression. This led to their conclusion that the currently available data on the effects of SMBG on quality of life and patient satisfaction is, thus far, inconclusive.

Some studies found an association between the frequency of SMBG monitoring and HbA1c, with evidence suggesting increased monitoring is associated with a decrease in HbA1c ( $P < 0.02$ ). While Farmer found an association between adherence to SMBG and educational interventions, SMBG was also associated with a higher level of detection of episodes of hypoglycaemia compared with either no SMBG, or alternate forms of SMBG.(28)

There is no clear evidence regarding the impact of SMBG on sense of well-being, energy, anxiety or depression with some studies finding an effect for particular sub scales, while other studies found no effect, or the opposite effects. Further studies are needed to determine the significance of psychological outcomes from the individual's perspective. Further detail on the trials included in this report is located in Appendix XIII.

### **Appropriateness and Meaningfulness of Self-Monitoring Blood Glucose**

Following the literature search and critical appraisal, 10 interpretive studies were included in the original review and 5 new qualitative papers on the general topic were included in the update. From the database search to the data collection of the qualitative part of the present review, particular attention to the following two issues was required.

For both reviews, maximum effort was paid to maintain consistency with the review objectives which specifically focused on the use of SMBG in the management of non-insulin treated type 2 diabetes. It was evident during both literature searches that the majority of qualitative studies had taken a broad perspective to examine the phenomenon of diabetes self-management while only a few studies narrowly examined SMBG and related issues. Judging the extent to which SMBG had been examined was often impossible unless a careful examination of the full text was conducted.

The scope for retrieving full texts was expanded in order to include a number of studies that may have addressed SMBG in a broad exploration of diabetes self-management. From the studies of diabetes self-management with a minor focus on SMBG, only the parts explicitly addressing SMBG were included in this review in order to comply with the review objectives of examining the phenomenon of SMBG.

Secondly, maximum effort was made not to distort the findings from primary studies in the process of meta-synthesis. Quantitative examination measures variables such as HbA1c and blood glucose range in order to find statistical explanations for the impact of SMBG on glycaemic control/management. In contrast, interpretative understanding is concerned with the wholeness of subjective experience, including values and cultures embedded in the historical moment of the practice shared by people.

In a practical sense, it was often impossible and inappropriate to make a clear distinction between studies on the meaningfulness of the SMBG practice (what is the experience of SMBG) and the

appropriateness of the SMBG practice (whether the practice of SMBG is appropriate to the specific context at the time or not). Interpretive representation of the meaningfulness and appropriateness of SMBG was often expressed in inter-related and inseparable forms. Therefore, the relevant data from included studies were pooled together in the original review in the JBI-QARI to make a broad synthesis and each review objective, appropriateness and meaningfulness of SMBG, is elaborated and discussed in the following section.

The list of excluded studies is presented in Appendix IX. The summary of 15 included studies is presented in Appendix X.

### ***Meta-synthesis***

The following meta-synthesis is reproduced from the original review and is based on a thematic analysis of the included papers related to the meaningfulness and appropriateness of the use of SMBG. The synthesised findings were identified by a process of iterative reading and recording of statements (narratives and conclusions) from the papers. These were then aggregated based on similarity of meaning or intent, into a smaller number of categories. The categories were then similarly reduced to a small number of synthesised findings in the tradition of thematic analysis emanating from the interpretive research paradigm. The quotations and extracts that informed the synthesis are in Appendix XII.

### Synthesised finding 1

Experience of the use of SMBG is an empowering process that can foster positive and active attitudes toward diabetes and self-management in everyday life.

Category	Finding
SMBG facilitates peoples' understanding of their own life with diabetes.	<p>SMBG helps patients to accept the diagnosis of diabetes.</p> <p>SMBG is a useful and convenient tool to assess ones' glycaemic control.</p> <p>SMBG provides people with an objective/clear status of their glycaemic control.</p>
SMBG provides people with reassurance concerning successful self-management of diabetes	<p>A low reading is perceived as an indication of successful disease management.</p> <p>SMBG provides peace of mind.</p>
SMBG raises positive consciousness towards self-management.	<p>People can modify their diet depending on the readings.</p> <p>People search for a rational cause for every reading such as food intake prior to the reading.</p> <p>Self-management of diabetes can become a part of normal life and normal self-image.</p>

A total of eight findings were grouped into three categories and derived into a synthesis related to a positive learning process toward diabetes self-management with the use of SMBG.

In the first category: *SMBG facilitates people's' understanding of their own life with diabetes*, peoples' perception toward SMBG is described as a convenient indicator of their current life with diabetes, which helps peoples to understand and to accept diabetes.

The second category: *SMBG provides people with reassurance concerning successful self-management of diabetes*, is related to the feeling of reassurance towards their appropriate diabetes management which people can receive through the use of SMBG.

The third category: *SMBG raises positive consciousness towards self-management* illuminates the individual's transition to the stage of taking initiative/control of own diabetes management in everyday life with the use of SMBG.

These three categories were synthesised into the first synthesis, *"Experience of the use of SMBG is an empowering process that can foster positive and active attitudes toward diabetes and self-management in everyday life"*. SMBG is not perceived as a mere tool but it is experienced as a powerful vehicle to facilitate the process of transcendence to a successful/active diabetes self-management.

### **Synthesised finding 2**

People using SMBG weight glycaemic control against perceived life needs.

Category	Finding
Belief impacts on adherence.	<p>Questioning the need for regular and frequent use of SMBG.</p> <p>Negative meanings attached to SMBG</p> <p>Being sceptical about the accuracy of SMBG</p> <p>Personal preference to use urine testing to SMBG.</p>
Ineffective adjusting/coping strategies	<p>Knowledge and skills deficiency</p> <p>Feelings of self-blame, disappointment, anger and other negative emotional reactions to high readings. (U)</p> <p>Lack of understanding of the value and purpose of SMBG and diabetes self-management.</p>
Prioritisation of life needs.	<p>Physical barriers</p> <p>Financial strain</p>

A total of nine findings were grouped into three categories and derived into a synthesis related to several negative or challenging attributes of the use of SMBG.



The first category: *Belief impacts on adherence* is related to negative personal beliefs or conceptions that influence the patients' adherence to SMBG. Despite advice/suggestion from health care professionals, some people were not convinced of the necessity of SMBG in their glycaemic control. For instance, SMBG was often understood as a therapeutic tool for people who required insulin treatment; therefore, non-insulin treated type 2 diabetes individuals were not *bad enough* to start SMBG. Inconsistency between the HbA1c values and everyday readings could raise questions about the accuracy of the blood glucose meter and the need for use of SMBG itself. Some people did prefer to continue using the now less common and not recommended method of urine monitoring despite its possibly inconvenient features.

The second category: *Ineffective adjusting/coping strategies* is related to various negative or unconstructive involvements with the use of SMBG. Insufficient knowledge and skills in the actual practice of SMBG and related behavioural modifications were found to hinder the beneficial outcome of SMBG. Positive attributes of SMBG as a central means of diabetes self-management were not blindly shared and understood by everyone. Many individuals perceived high readings as proof of failure in the required behavioural/dietary modification and blamed themselves without constructive solutions.

The third category: *Prioritisation of life needs* is related to peoples' experiences and individual life circumstances which arise with the use of SMBG. Physical barriers such as poor eyesight were reported to make the use of blood glucose meters very difficult. Depending on the health insurance system in each country, SMBG could be financially too demanding for everyday use for some people.

These three categories were synthesized into the first synthesis, "*People using SMBG weight glycaemic control against perceived life needs*". In contrast with the first synthesis which described the positive and empowering attributes of the use of SMBG, it is represented as a challenge or some sort of burden that people do not/cannot accept without difficulties and questions. This synthesis illuminates the need for appropriate educational and other support strategies while respecting the individuals' own belief and autonomous decision making.

### ***Summary of appropriateness and meaningfulness***

A total of 8 findings were grouped into 3 categories and derived into a synthesis related to a positive learning process toward diabetes self-management with the use of SMBG. While in the second synthesised finding, 9 primary findings were grouped into 3 categories and derived into a synthesis related to several negative or challenging attributes of the use of SMBG.

In relation to "a positive learning process toward diabetes self-management", the evidence suggests attitude toward and perception of SMBG is indicative of one's attitude toward and potential acceptance of having diabetes. SMBG was seen by participants as promoting their sense of confidence and certainty to the otherwise "invisible" nature of glycaemic control and enabled people with diabetes using

SMBG to take greater control of their lives, becoming active participants and managers of their everyday life.

The second synthesised finding established that participants may feel that using SMBG is related to perceived severity of diabetes, and that a potential disparity between HbA1c and regular SMBG was difficult to conceptualise. This highlighted the felt need for greater levels of knowledge, and coping strategies for life changes to manage higher readings without feeling a sense of failure. Participant's views and beliefs were impacted by practical experiences. In particular, they perceived the support and education they had received helped transform their perspective from one of "success" or "failure" to one of empowerment and informed decision making.

The updated literature stresses the need for culturally appropriate education related to self-management behavior, including SMBG. An American study [56] reported that of the 111 patients with follow-up data, 55% had literacy levels at the 6th-grade level or below. Lower literacy was more common among African Americans, older patients, and patients who required medication assistance. There was no significant relationship between literacy status and HbA1c prior to enrolment or at enrolment. This study found that over a 6-month study period, patients with low and high literacy had similar improvements in HbA1c when they underwent a similar education programme that had been specifically adapted for people with low literacy. Upchurch [57] defined "culturally appropriate" as education tailored to the cultural and religious beliefs (including diet) and linguistic and literacy skills of a specific community. Their systematic review (11 RCTs) in this area concluded that culturally appropriate educational interventions improved HbA1c concentrations at 3 and 6 months after the start of the intervention but not at 12 months.

A recent publication by Sturt [58] reported on the results of tests of validity and reliability for a general tool to measure a patient's level of self-efficacy. Perceived self-efficacy is a reliable predictor of behaviour initiation. It demonstrates its value as the cornerstone of effective chronic disease self-management through its increasing use as a self-management research outcome measure. The DMSES UK is available as a measure of diabetes management self-efficacy for both clinical and research use. The predictive reliability of self-efficacy means that the DMSES UK can be used to enable more effective targeting of self management interventions and clinical resources to the individual patient.

## Discussion

### Effectiveness

Nine existing systematic reviews were included in the final quantitative analysis. In the original review, two of the reviews combined types of participants, i.e.: those not treated with insulin, and those treated with insulin, hence the data from those two reviews were reported separately.

The meta-analysis of people with poor glycaemic control that was undertaken for the original review found no statistically significant benefit for SMBG at 6 months. That meta-analysis suggested no additional clinical benefit for people with type 2 diabetes not using insulin whom have not been able to obtain good glycaemic control and overall, the updated literature retrieved for this new review appears to corroborate this view. However, studies included in the original meta-analysis were statistically heterogeneous. In an attempt to explore the research further, an open, exploratory analysis for HbA1c at 6 and 12 months was conducted in the original review and reproduced in this report. The exploratory meta-analysis did not control for clinical heterogeneity, the primary criterion for inclusion being that the intervention group be the only group to use SMBG. It showed that strategies for glycaemic control inclusive of SMBG are effective. However, it was statistically confounded and clinical heterogeneity was highly likely given only the intervention was used to guide inclusion – potential variations in populations were ignored.

The initial meta-analysis of 4 RCTs contained in the original review was much tighter in design, accepting only studies where clinical heterogeneity was not evident in the inclusion criteria and methods. Interestingly, this meta-analysis was confounded by statistical heterogeneity, with the studies clearly showing disparate weightings and measures of effect that were not at all consistent. Therefore, no clear conclusions can be drawn from these meta-analyses other than that the studies included complex interventions where a specific effect attributable to SMBG was not able to be established.

The new RCTs (28, 29) discovered at the time of the original report writing from additional database searches found a range of interesting trends in relation to SMBG for glycaemic control. Farmer conducted a three-armed trial of 453 patients in order to examine the efficacy of SMBG in glycaemic control and efficacy of additional education of interpretation of results and behavioural modifications.(28) Outcomes in terms of HbA1c were similar across groups, with SMBG inclusive glycaemic control interventions providing as effective a level of control as non-SMBG interventions. However, SMBG appeared to be associated with several additional benefits that the non-SMBG group did not experience. Participants in the SMBG group experienced a statistically significant beneficial change in total serum cholesterol levels compared with the study arm that did not use SMBG, but was otherwise treated the same. SMBG itself is unlikely to be the casual factor in this difference, but it may be that people who are actively monitoring their glycaemic control may also be more likely to make healthy,

proactive choices in other areas of their lives, such as dietary control. The second benefit was that significantly more hypoglycaemic episodes were identified in the SMBG trial arm compared with the non-SMBG arm. This finding was also reported in the new updated trials. While no serious episodes of hypoglycaemia occurred in any trial included in this review, the evidence does clearly suggest that increased monitoring is associated with more accurate and reliable rates of detection of changes in glycaemic control.(28)

Participants in the Farmer study had a higher mean age - the highest among the included studies: 66.3 in the control group, 65.2 in the less intensive SMBG group, and 65.9 in the intensive SMBG group. This requires further investigation to determine whether age is an independent variable in terms of glycaemic control and adherence to interventions that include SMBG.(28)

The second RCT compared a control group without SMBG and an experimental group with SMBG of 180 newly diagnosed participants with non-insulin treated type 2 diabetes. The study found both groups glycaemic control improved, with no net negative impact from the use of SMBG in the intervention group. As the authors (29) noted, the treatment algorithm was applied in a rigorous manner during the study period, which may have produced a Hawthorne effect that negated measurable benefit of SMBG.

The participants in this study were newly diagnosed and in the early stages of adjustment and developing coping strategies. Interestingly, participants in the SMBG group study had higher scores on a depression subscale. At the end point, HbA1c value was 6.9% ( $\pm 1.2$ ) in the control group and 6.9% ( $\pm 0.8$ ) in the SMBG group:  $p=0.69$ ; (95% CI  $-0.25\%$  to  $0.38\%$ ). Mean HbA1c value in the SMBG group changed from 8.8% ( $\pm 2.1$ ) to 6.9 ( $\pm 0.8$ ) while the control group changed from 8.6% ( $\pm 2.3$ ) to 6.9 ( $\pm 1.2$ ). The authors suggest these findings could be that individuals' readiness to accept the newly found diagnosis and daily discipline of regular SMBG and related life modification.(29) The findings suggest careful assessment and consideration of peoples' degree of acceptance and readiness concerning their own diagnosis and related regular behavioural modification in daily life needs to occur. When assisting newly diagnosed individuals to commence SMBG, health care professionals should be aware of their psychological needs, facilitate access to appropriate services and encourage such people in their adjustment to life with type 2 diabetes.

Overall, the body of evidence of effectiveness related to SMBG is still accumulating, with growing numbers of trials available. Such trials are necessarily complex in design, and the multi interventional nature of management required for type 2 diabetes is a challenge for reviewers seeking to pool evidence of effects related to the impact of SMBG on clinical outcomes. However, the finding remains that current evidence suggests the use of SMBG is no more effective than not using SMBG other than the benefit of increased individual surveillance leading to higher detection rates of episodes of hypoglycaemia.

### **Summary of findings – effectiveness**

The central findings of the updated review of the effectiveness of SMBG in glycaemic control in people with type 2 diabetes are:

- There is now some evidence that SMBG improves glycaemic control in people with type 2 diabetes not requiring insulin compared with not using SMBG but it is not likely to be cost effective. (Level I)
- There is growing evidence of increased individual surveillance leading to higher detection rates of episodes of hypoglycaemia. (Level 1)

### **Appropriateness and Meaningfulness**

Included interpretive studies explored a range of issues related to the appropriateness and meaningfulness of SMBG. These studies provided synthesised evidence related to the appropriateness of certain cultural and experiential perspectives associated with SMBG and the meaningfulness of SMBG.

The experience of SMBG among people with type 2 diabetes was found to be heavily influenced by the individual's sense of self, and their life view of diabetes as being either an illness, somewhat separate from themselves (e.g. associating not requiring insulin with not having “severe diabetes”). Individuals' attitudes and responses to SMBG results were found to differ depending on their life view, and this was influenced by knowledge and exposure to specific education such as reading or interpreting results from SMBG.

Where individuals had received education and training in SMBG, they were more likely to perceive test results as informative and enabling, leading to active participation in their glycaemic control. Where the participants felt SMBG highlighted “poor” results, this could be seen as a personal failure in the absence of positive self-views, and/or inadequate education and training. This evidence highlights the value of delivering education and training that provides not only the technical and process based information required to monitor glycaemic control, but also the less technical self-actualisation knowledge that needs to be individually realized in order for people with type 2 diabetes to progress beyond seeing SMBG results as either indicative of personal success or failure.

### **Appropriateness of Self-Monitoring Blood Glucose from educators' perspectives**

In relation to the appropriateness of the use of SMBG from the perspectives of care providers/educators, one interpretive study reported the values and culture shared by community nurses in relation to recommending SMBG to people with type 2 diabetes in the community.[35] Moreover, from the meta-synthesis of included interpretive studies, both from the perspectives of care

providers/educators and people with non-insulin treated diabetes, further valuable evidence was aggregated which provides rich information concerning culture and values embedded in the use of SMBG.

In addition, several studies which examined appropriateness in the quantifiable aspects of SMBG practice were identified but they were not included in order to comply with the review objectives.

One study (30) examined the reasons why community nurses recommended the use of SMBG to their patients in UK settings. Several themes emerged from the analysis which illuminated the beliefs that formed the specific culture embedded in their everyday practice. The community nurses held the following general ideas associated with their shared values in relation to SMBG: *SMBG is a superior means of measuring glycaemic control compared with the previously more common method of urine testing and the use of SMBG should be encouraged.* Respecting the patients' autonomous decision and the choice of equipment regarding SMBG was also commonly considered important. The individuals' passive attitudes in both decision making in the use of SMBG and lifestyle modifications including diet or exercise were perceived as barriers against the beneficial use of SMBG in successful diabetes self-management. Individual life circumstances such as poor eyesight also emerged as factors to consider in terms of provision of appropriate support for the patients with diverse health and lifestyle needs.

The following figures demonstrate how such values and beliefs shared by community nurses are inter-related with each category of the meta-syntheses that were largely derived from the perspectives of participating individuals. It was evident that the experiences and perceptions of people have strongly affected how community nurses make sense of their role and develop certain views regarding the support and education of these people, and *vice versa*.

Figure 8: Relationship between the educators' belief and meta-synthesis 1

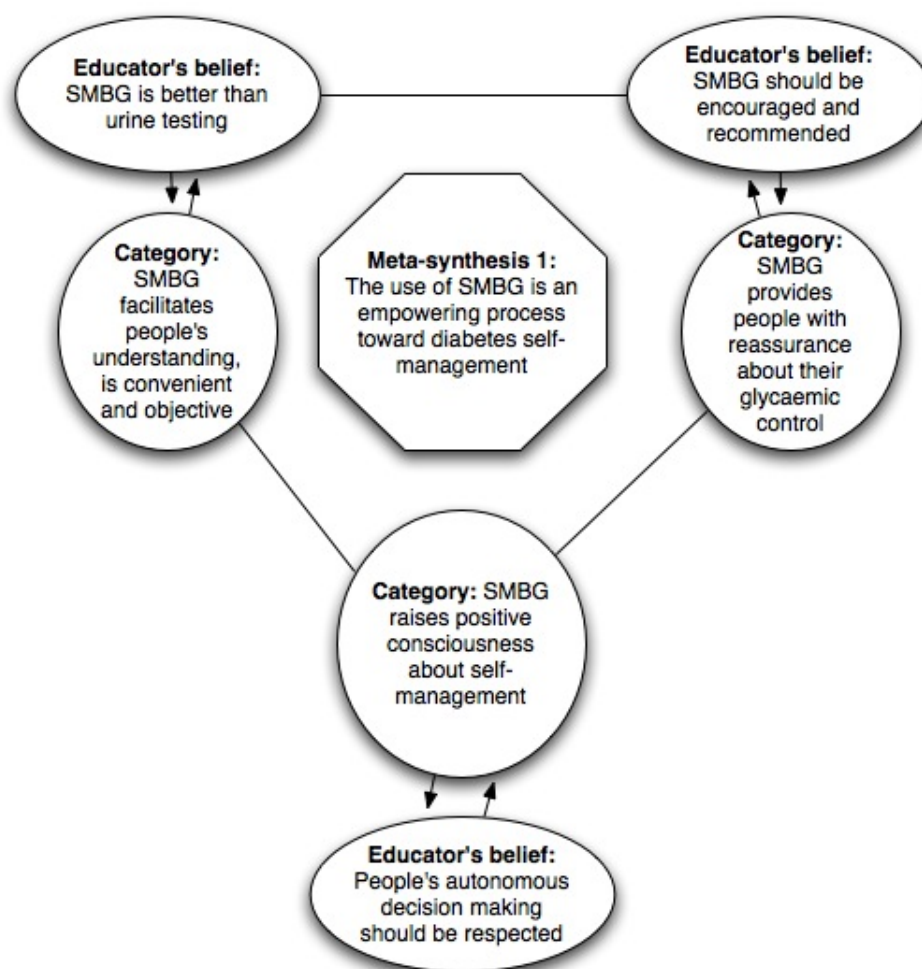


Figure 8 illustrates positive perspectives concerning the use of SMBG which are shared by community nurses and the empowering features of SMBG are reported largely from the perspectives of people with type 2 diabetes. The community nurses' belief that *SMBG is better than urine testing*. This belief is associated with the category of 'SMBG facilitates people's understanding'. SMBG was often preferred over the previously more common urine monitoring method by people with type 2 diabetes because of its ability to provide objective glycaemic status in a practical and convenient way. The use of SMBG was also reported to be useful in the self-assurance of their own diabetes, which helped people accept the diagnosis and take responsibility for diabetes self-management. From these positive effects concerning the use of SMBG, community nurses appeared to have developed the view that the use of *SMBG should be recommended and encouraged*.

As SMBG is continuously used, SMBG helps people to foster positive attitudes and consciousness towards the importance and value of diabetes self-management. This notion runs parallel with the care providers'/educators' belief that *people's autonomous decision making in the process of learning diabetes self-management should be encouraged and respected*. The popular discourse around the

self-management of diabetes which emphasises the individual taking responsibility/control over their own lifestyle and health is evident in the community nurses' account. The positive experiences of the individuals in learning to manage SMBG, clearly justifies the appropriateness of encouraging the use of SMBG in diabetes self-management, in which individuals are expected to play the leading role.

**Figure 9: Relationship between the educators' belief and meta-synthesis 2**

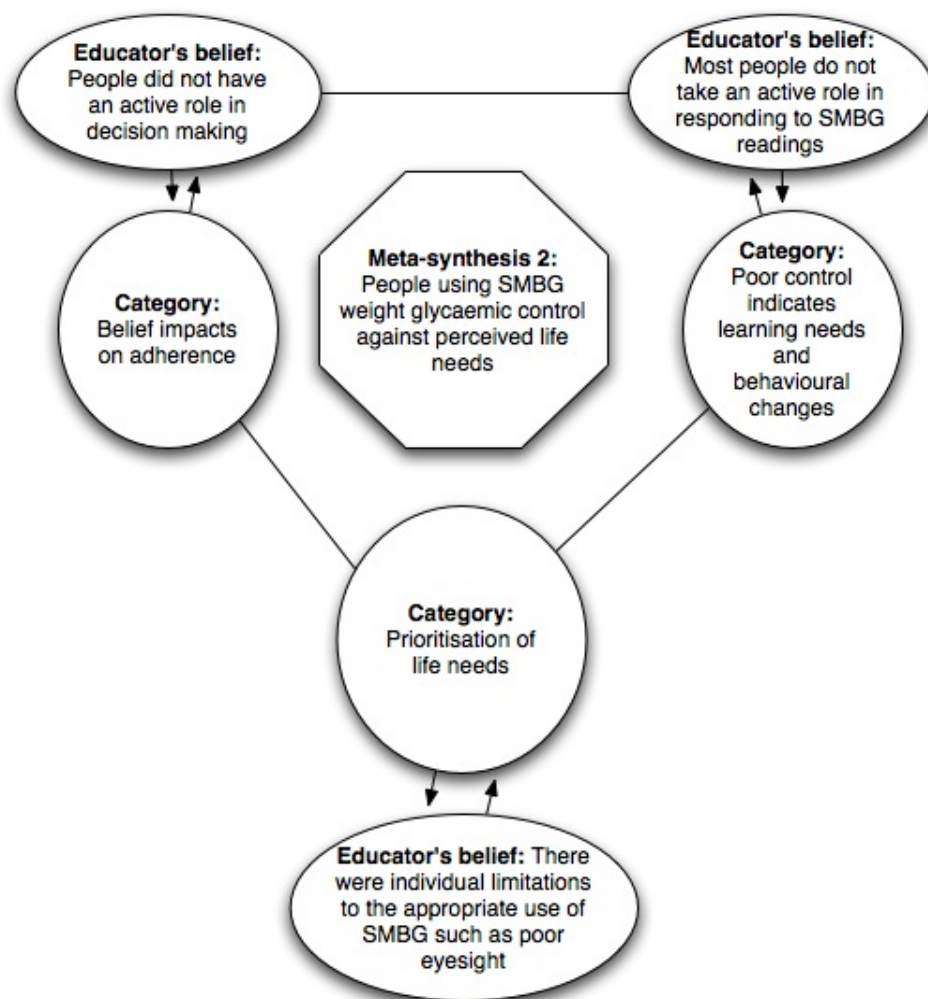


Figure 9 presents the perceptions and beliefs shared by community nurses in relation to various challenging experiences/outcomes and their direct relation with the categories from the second meta-synthesis which captured the confronting issues mainly experienced by people in the use of SMBG. These findings capture the belief shared by care providers/educators that SMBG cannot be fully used by all people depending on individual circumstances while the related categories derived from the lived experiences support this notion.

The care providers/educators held the view that *people do not often have an active role in decision-making*. The passive attitudes of not taking initiative in the use of SMBG reported by community nurses' are consistent with the category derived from the account of people with type 2 diabetes. Despite a



general consensus that the use of SMBG should be encouraged as a central means of diabetes self-management, as discussed in the previous section, some people were found to hold conflicting values and attitudes in relation to the use of SMBG in general; to the need of SMBG for their own diabetes, and to the value of SMBG including the concept of self-management itself.

The care providers'/educators' belief that *most people do not take an active role in responding to the readings in terms of modifying diet and exercise* corresponds with another category; 'poor control' indicates learning needs and behavioural changes. While the importance of respecting autonomous decision making by individuals in their self-management has been emphasized by health care professionals, a clear dilemma is also evident in that not all people can use SMBG as an effective guide for daily behavioural modifications, such as diet and exercise. Lack of knowledge and skills, unconstructive psychological reaction to high readings, such as self-blame and avoidance, not understanding the value and the need of SMBG in diabetes self-management, all hinder the appropriate use of SMBG.

The care providers'/educators' account, *there were individual limitations concerning the appropriate use of SMBG* related to the individual life circumstances that influence the persons' decision making and experience in the use of SMBG. Physical problems such as poor eyesight, physical discomfort of fingers from regular blood checks and problems of financial capacity for long-term use of SMBG, were identified as conflicting life circumstances that some people are forced to prioritise, according to their individual needs and SMBG.

### **Summary of findings - appropriateness**

Findings from one interpretive study in the original review that reported the care providers'/educators' perceptions towards SMBG and related findings from the meta-synthesis, largely concern the experiences of people with type 2 diabetes. These qualitative findings are derived from critical and interpretive paradigms which are ranked differently in terms of level of evidence to that of quantitative under the Effectiveness section in the Discussion (See Appendix I for further details. The following conclusions reflect shared values related to appropriateness:

- There is a shared value between providers of diabetes education and people with type 2 diabetes that SMBG is a superior method of self-monitoring. (Level III)
- There is a shared value that SMBG can be recommended for people with type 2 diabetes whether treated with insulin or without insulin. (Level III)
- There is a shared assumption that individual autonomy should be respected and encouraged in the decision making process. (Level III)

- There is a shared value that SMBG should be used for the purpose of facilitating effective diabetes self-management. (Level III)
- The findings suggest that some individuals remain passive or refuse to take an active role in the use of SMBG due to their conflicting beliefs concerning the needs and the use of SMBG, or lack of knowledge and skills. (Level III)
- The findings suggest that some people cannot adjust their lifestyles such as diet and exercise, in response to high readings, due to insufficient knowledge and skills and the use of inadequate coping strategies. (Level III)
- The findings suggest that introduction of SMBG for all people is not appropriate and may need individualised consideration depending on various life circumstances such as financial strain, physical discomfort associated with SMBG or physical problems such as poor eyesight. (Level III)

### Meaningfulness

Two meta-syntheses of the original 10 included interpretive studies clearly indicate the meaning that both people with type 2 diabetes and care providers/educators attribute to the experience of education and the use of SMBG.

The first synthesis, *SMBG facilitates peoples' understanding of their own life with diabetes*, is related to a positive learning process concerning diabetes self-management with the use of SMBG. In the first category: *SMBG facilitates peoples' understanding of their own life with diabetes*, states that people perceive SMBG as a convenient indicator of up-to-date glycaemic control, which helps them to comprehend and to accept their own diagnosis. The second category: *SMBG provides people with reassurance concerning successful self-management of diabetes* captures the feeling of reassurance towards their successful diabetes management that people can receive through the use of SMBG. The third category: *SMBG raises positive consciousness towards self-management* addresses the individuals' transcendental experience in the stage of taking initiative/control of own diabetes. It is evident that SMBG is not perceived as a mere tool, but it is experienced as a powerful vehicle to facilitate the learning process in successful/active diabetes self-management in which SMBG and related behavioural modification become a normal part of everyday life and self-image.

In contrast, the second synthesis, *Individuals using SMBG weight glycaemic control against perceived life needs*, captures the negative/challenging experiences in the use of SMBG. While the first synthesis described the positive and empowering attributes of SMBG, the second synthesis represents the experience of SMBG as a challenge or some sort of burden that some people do not/cannot accept without difficulties and questions. The synthesis illuminates the particular issues and need for

appropriate educational and other supportive strategies while respecting and encouraging the individual's own beliefs; autonomous decision-making is important. The first category: *Belief impacts on adherence* is related to negative personal beliefs or conceptions that influence adherence to SMBG. The second category: *Ineffective adjusting/coping strategies* is related to various negative or unconstructive involvements with the use of SMBG. The third category: *Prioritisation of life needs* is related to experiences with individual life circumstances which arise with the use of SMBG. Since some of these issues have been already discussed in relation to the appropriateness of SMBG in the previous part, the key findings in this section will have particular focus on the experience of the individual in the use of SMBG in a broad scope.

### ***Summary of findings–meaningfulness***

These qualitative findings are derived from critical and interpretive literature, which is ranked differently in terms of levels of evidence to the quantitative findings listed above (See Appendix I for further details). From 2 meta-syntheses from the original 10 interpretive studies that reported the experiences of both people with type 2 diabetes and care providers/educators of SMBG, the following conclusions relating to meaningfulness were derived:

- Qualitative meta-synthesis concluded that SMBG can be used as an effective means to facilitate an empowering process that raises positive and active attitudes to self-management. (Level I)
- People using SMBG balance glycaemic control against perceived life needs. (Level I)
- Despite absence of evidence to support the superiority of SMBG in glycaemic control, qualitative findings support the role of individual preference for methods of monitoring glycaemic control. (Level III)
- SMBG facilitates peoples' understanding of their own glycaemic control by providing objective glycaemic status in a convenient and practical manner. (Level III)
- SMBG provides individuals with reassurance concerning successful self-management of diabetes which provides peace of mind and a sense of achievement. (Level III)
- SMBG raises positive consciousness towards self-management as individuals start questioning their recent diabetes-related behaviours such as diet and exercise and ongoing readings from SMBG. (Level III)

## Conclusions

### Effectiveness

The primary finding of this updated review is that there is some evidence of the beneficial effects of SMBG as measured by HbA1c in people with non-insulin treated type 2 diabetes particularly if they have not yet achieved consistent glycaemic control. Current evidence also suggests that people with type 2 diabetes can benefit directly from SMBG in terms of greater awareness of their level of glycaemic control, and general health. The studies included in this updated review also found better general health knowledge may also lead to improvements in serum cholesterol, ability to identify how dietary, exercise and lifestyle choices impact glycaemic control, and episodes of hypoglycaemia. Further research evaluating the impact of age as a potential independent variable in acceptance and adherence to SMBG should be considered.

### Appropriateness

One study was available that examined the perspective of care provider/educators to articulate insights into the value system and culture behind the education and practice of SMBG. The results of the original meta-synthesis that was largely derived from the subjective accounts of individuals were clearly consistent with the major findings from the accounts of the care providers/educators, suggesting the existence of values and assumptions shared by people with type 2 diabetes and educators in the use of SMBG.

Several informative and valuable findings were identified in relation to the appropriate practice and education of SMBG. There is a shared belief by care providers/educators that:

1. The use of SMBG should be encouraged for the purpose of facilitating effective diabetes self-management.
2. Self-monitoring blood glucose is largely considered to be a superior method of monitoring glycaemic control to that of the previously more common method of urinalysis.
3. The autonomous decision making and active involvement of people were considered to be important in the use of SMBG, as were the provision of individually tailored educational/supportive interventions that met the needs of the individual.

## Meaningfulness

The updated review found that self-monitoring blood glucose can be used as an effective means to facilitate an empowering process that raises positive and active attitudes toward self-management. Negative experiences in the use of SMBG were often caused by insufficient knowledge and skills, and non-constructive coping strategies concerning diabetes management. The belief of each individual concerning the use of SMBG, such as stigma and misunderstanding of the purpose and the needs of SMBG, should be assessed before the commencement of SMBG is recommended. In confronting SMBG, people are required to prioritise their life needs such as financial cost in the use of SMBG, or individual-physical circumstances such as poor eyesight. Individualised assessment of such factors is recommended.

## Implications for Practice

From the overall results of this updated review, a number of recommendations are made for practice. Grades of recommendations have been assigned (See Appendix X).

- The use of SMBG may be encouraged as a part of diabetes self-management in non-insulin treated type 2 diabetes people with adequate supervision and assessment. (Grade A)
- SMBG increases the detection of episodes of hypoglycaemia. Health professionals should make people aware of the benefits of increased detection. (Grade A)
- It is recommended that health professionals need to be aware that qualitative research findings revealed the individuals' overall preference for SMBG but remain cognizant of the fact that this may not hold true for all patients for which SMBG can provoke distress and self-chastisement instead of empowering. (Grade B)
- The autonomous decision making of individuals should be supported and facilitated in the use of SMBG. (Grade B)
- Individualised, culturally and literacy appropriate educational interventions are essential in order to enhance the knowledge and skills required for the appropriate use of SMBG in the self-management of diabetes. (Grade B)
- It should be understood that SMBG itself is not a goal, but the learning process to actualise self-management of diabetes including the use of SMBG. (Grade B)

- Multi-factorial assessment and interventions are necessary in order to meet each person's various life needs such as the status of personal finance and insurance, and physical/mental status in order to make beneficial use of SMBG. (Grade B)
- In the continued absence of conclusive evidence, the frequency of SMBG should be determined by individual circumstance and clinical judgment. (Grade B)
- Education should include the management and prevention of hypoglycaemia as well as dietary, activity and lifestyle modifications to optimise glycaemic control. (Grade B)
- For the individual with a recent diagnosis, the introduction of SMBG should be supported with strategies to evaluate and enhance the individual's psychosocial status. (Grade B)

## **Implication for Research**

Investigating the effectiveness of SMBG in daily life settings still presents many challenges to researchers. Further high quality quantitative research is still needed to fully establish the clinical effectiveness of SMBG in achieving glycaemic control near recommended target and provide guidance, especially as to which sub-groups of people with non-insulin treated type 2 diabetes would most directly benefit. Further investigation is required to determine the potential variables that may affect the outcome of glycaemic control in the use of SMBG, including: demographic background, health status, treatments and other possible variables that may affect the outcome. The relationship between the frequency of SMBG and timing of SMBG also requires further investigation, with a methodologically sound approach. Timing, quality and volume of educational programs and educational interventions, frequency and nature of support by health care providers, should also be investigated. The impact of duration of diabetes prior to commencement of SMBG, the impact of age, and the role of SMBG in relation to secondary outcomes such as total serum cholesterol also warrant further investigation.

In the interpretive investigations of appropriateness and meaningfulness of SMBG, most identified papers have examined the perspectives and overall self-management of people with type 2 diabetes. This may be due to an unchallenged shared discourse around the use of SMBG among educators and care providers. Further study is needed to facilitate understanding of the values and cultures associated with SMBG for the provision of appropriate educational supports. Furthermore, most studies specifically examining the phenomena around the use of SMBG were largely targeted at the Caucasian population in Anglo and European countries although some papers were located in the updated review which examined other cultural groups with an increased predisposition to type 2 diabetes. The scope of such papers tended to be very broad, encompassing whole experiences related to diabetes self-management. Further investigation is required to understand the subjective accounts of such non-Caucasian groups to gain insights to understand their cultural values and specific experiences

associated with the use of SMBG, in order to facilitate the beneficial use of SMBG as a central part of diabetes self-management.

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## Appendix I: JBI Levels of Evidence

Level of Evidence	Feasibility, Appropriateness, Meaningfulness	Effectiveness	Economic Analysis
<b>I</b>	Metasynthesis of research with unequivocal synthesised findings	Meta-analysis (with homogeneity) of experimental studies (eg RCT with concealed randomisation)	SR (with homogeneity) of Level 1 economic studies
<b>II</b>	Metasynthesis of research with credible synthesised findings	One or more RCT, retrospective cohort studies or untreated control groups in RCTs.  Retrospective cohort study or follow-up of untreated control patients in an RCT	SR (with homogeneity) of Level 2 economic studies  Analysis comparing a limited number of alternative outcomes against appropriate cost measurement, and including a sensitivity analysis incorporating clinically sensible variations in important variables
<b>III</b>	a. Metasynthesis of text/opinion with credible synthesised findings  b. One or more single research studies of high quality	Case-series (and poor quality prognostic cohort studies)	Analysis without accurate cost measurement but including a sensitivity analysis incorporating clinically sensible variations in important variables
<b>IV</b>	Expert opinion	Expert opinion, or physiology bench research, or consensus	Expert opinion, or based on economic theory

## Appendix II: Comprehensive Search Terms

Limiters: 1998-2008; English language; adult >16

MEDLINE (OVID)

Database: Ovid MEDLINE(R) <1996 to March Week 2 2011>

Search Strategy:

- 
- 1 exp Diabetes Mellitus, Type 1/ or type 1 diabetes.mp.
  - 2 type I diabetes.mp.
  - 3 insulin pump.mp. or exp Insulin Infusion Systems/
  - 4 insulin pump therapy.mp.
  - 5 insulin dependent diabetes.mp.
  - 6 exp Blood Glucose/ or continuous subcutaneous insulin infusion.mp. or  
exp Diabetic Ketoacidosis/
  - 7 exp adolescent/ or exp adult/
  - 8 exp Patient Education as Topic/ or diabetes education.mp.
  - 9 diabetes educators.mp.
  - 10 limit 15 to (english language and humans and yr="1998 - 2011")

CINAHL (EBSCOHOST)

- 
- S1 (type 1 diabetes) or (MH "Diabetes Mellitus, Insulin-Dependent")
  - S2 insulin dependent diabetes
  - S3 type I diabetes
  - S4 S3 or S2 or S1

- S5 (adult) or (MH "Adult")
- S6 S5 and S4
- S7 (education) or (MH "Education") or (MH "Outcomes of Education") or (MH "Adult Education")
- S8 (diabetes education) or (MH "Diabetes Education") or (MH "Diabetes Educators")
- S9 training or blood glucose monitoring
- S10 diabetes training
- S11 S10 or S9 or S8 or S7
- S12 (insulin pump therapy) or (MH "Insulin Infusion Systems")
- S13 (continuous subcutaneous insulin infusion) or (MH "Insulin Infusion Systems")
- S14 S13 or S12

Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED

Database: All EBM Reviews - Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED

Search Strategy:

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- 1 type 1 diabetes.mp.
- 2 type I diabetes.mp.
- 3 insulin dependent diabetes.mp.
- 4 diabetes mellitus.mp
- 5 insulin pump therapy.mp.
- 6 education.mp.
- 7 limit to english language [Limit not valid in: CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained] (27)
- 8 limit to humans [Limit not valid in: CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained] (26)
- 11 limit 10 to yr="1998 - 2011" [Limit not valid in: DARE; records were retained]
- 12 from 11 keep 1-18 (18)

## EMBASE

Database: EMBASE <1980 to 2011 March Week 2>

Search Strategy:

- 
- 1 exp Insulin Dependent Diabetes Mellitus/ or type 1 diabetes.mp.
  - 2 type I diabetes.mp.
  - 3 insulin pump.mp. or exp Insulin Pump/
  - 4 exp Insulin Treatment/ or insulin pump therapy.mp.
  - 5 Adult/
  - 6 Adolescent/
  - 7 education.mp. or exp EDUCATION/
  - 8 diabetes education.mp. or exp Health Education/ or exp Diabetes Education/ or exp Patient Education/ or exp Education/
  - 9 diabetes educators.mp. or exp Diabetes Educator/
  - 10 self management.mp. or exp Self Care or blood glucose monitoring/
  - 11 exp EXPERIENCE/ or exp PERSONAL EXPERIENCE/ or experience.mp.
  - 12 1 or 2
  - 13 exp Subcutaneous Drug Administration/ or continuous subcutaneous insulin infusion.mp.
  - 14 limit to (human and english language and yr="1998 - 2011")

## Current Contents

- 
1. insulin pump
  2. continuous subcutaneous insulin infusion
  3. 1 OR 2
  4. educat\*
  5. 3 AND 4

PsycINFO

Database: PsycINFO <1985 to March Week 2 2011>

Search Strategy:

- 
- 1 diabetes/ or exp diabetes mellitus/
  - 2 type 1 diabetes.mp.
  - 3 type I diabetes.mp.
  - 4 insulin dependent diabetes.mp.
  - 5 exp Insulin/ or insulin pump.mp.
  - 6 insulin pump therapy.mp.
  - 7 continuous subcutaneous insulin infusion.mp.
  - 8 limit to (human and english language and yr="1998 - 2011")

Digital Dissertations (Proquest)

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Basic search strategy: 1998-2011 'insulin pump therapy'



## Appendix III: JBI-SUMARI Package Validity Checklists

### JBI Critical Appraisal Checklist for Systematic Reviews

Reviewer \_\_\_\_\_ Date \_\_\_\_\_

Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

	Yes	No	Unclear
1. Is the review question clearly and explicitly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Was the search strategy appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were the sources of studies adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the inclusion criteria appropriate for the review question?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were the criteria for appraising studies appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was critical appraisal conducted by two or more reviewers independently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were there methods used to minimise error in data extraction?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were the methods used to combine studies appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were the recommendations supported by the reported data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Were the specific directives for new research appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reasons for exclusion)

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### JBI Critical Appraisal Checklist for Experimental Studies

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Reviewer \_\_\_\_\_ Date \_\_\_\_\_

Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

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	Yes	No	Unclear
1. Was the assignment to treatment groups truly random?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were participants blinded to treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was allocation to treatment groups concealed from the allocator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were those assessing outcomes blind to the treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were the control and treatment groups comparable at entry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were groups treated identically other than for the named interventions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in the same way for all groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reasons for exclusion)

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## JBI QARI Critical Appraisal Checklist for Interpretive & Critical Research

Reviewer \_\_\_\_\_ Date \_\_\_\_\_  
 Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

	Yes	No	Unclear
1. Is there congruity between the stated philosophical perspective and the research methodology?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is there congruity between the research methodology and the research question or objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is there congruity between the research methodology and the methods used to collect data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there congruity between the research methodology and the representation and analysis of data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there congruity between the research methodology and the interpretation of results?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is there a statement locating the researcher culturally or theoretically?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is the influence of the researcher on the research, and vice-versa, addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are participants, and their voices, adequately represented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reasons for exclusion)

## Appendix IV: JBI-Meta Analysis of Statistics Assessment and Review Instrument (JBI-MASARI) Data Extraction Forms

**JBI Data Extraction Form for Systematic Review of  
Experimental/Observational Studies**

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Reviewer \_\_\_\_\_

Author \_\_\_\_\_

Journal \_\_\_\_\_

Date \_\_\_\_\_

Year \_\_\_\_\_

Record Number \_\_\_\_\_

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**Included studies**

RCT ☐

Quasi-RCT ☐

Longitudinal ☐

Retrospective ☐

Observational ☐

Other \_\_\_\_\_

**Participants**

Setting \_\_\_\_\_

Population \_\_\_\_\_

**Interventions**

Intervention 1 \_\_\_\_\_

Intervention 2 \_\_\_\_\_

Intervention 3 \_\_\_\_\_

**Clinical outcome measures**

Outcome Description	Scale/measure

**Meta-analysis results****Dichotomous data**

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number	Statistic Combined measure (CI)

**Continuous data**

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number	Statistic Combined measure (CI)

**Summary of Narrative Results**


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**Authors Conclusions**


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**Comments**


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## JBI Data Extraction Form for Experimental and Observational Studies

Reviewer:	Date:
Author:	Publication year:
Journal:	Record number:

### Study Method:

- ☐ RCT
 ☐ Quasi-RCT
 ☐ Longitudinal  
☐ Retrospective
 ☐ Observational
 ☐ Other \_\_\_\_\_

### Participants:

Setting:
Population:
Sample size:
Intervention 1:                      Intervention 2:                      Intervention 3:

### Types of Interventions:

Intervention 1:
Intervention 2:
Intervention 3:

### Clinical Outcome Measures:

<i>Outcome Description</i>	<i>Scale / Measure</i>

**Study Results:**

Dichotomous Data:

<i>Outcome</i>	<i>Intervention ( )</i> <i>number / total number</i>	<i>Intervention ( )</i> <i>number / total number</i>

Continuous Data:

<i>Outcome</i>	<i>Intervention ( )</i> <i>number / total</i>	<i>Intervention ( )</i> <i>number / total</i>

**Authors' conclusions:**


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**Comments:**


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## Appendix V: JBI QARI Data Extraction Form for Interpretive & Critical Research

Reviewer \_\_\_\_\_ Date \_\_\_\_\_  
 Author \_\_\_\_\_ Year \_\_\_\_\_  
 Journal \_\_\_\_\_ Record Number \_\_\_\_\_

### Study Description

Methodology

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Intervention

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Setting

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Geographical

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Cultural

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Participants

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Data analysis

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**Authors Conclusions**

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**Comments**

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Findings	Illustration from Publication (page number)	Evidence		
		Unequivocal	Credible	Unsupported

## Appendix VI: Included Systematic Reviews

Author	Objectives	Included studies	Included studies		Analysis	Findings	Conclusion
Jansen 2006	To evaluate the relative effectiveness of interventions with SMBG and self-monitoring urine glucose, versus interventions without self-monitoring in terms of HbA1c reductions in type 2 diabetes  5 studies included insulin treated patients	RCTs type 2 diabetes including insulin treated participants	Allen <i>et al.</i> (1990) Fontbonne <i>et al.</i> (1989) Miles, <i>et al.</i> (1997) Brown <i>et al.</i> (2002) Davidson, <i>et al.</i> (2005) Guerci <i>et al.</i> (2003) Jaber <i>et al.</i> (1996) Muchmore <i>et al.</i> (1994) Rutten <i>et al.</i> (1990) Schwedes <i>et al.</i> (2002) Wing <i>et al.</i> (1986) Estey <i>et al.</i> (1990) Kwon <i>et al.</i> (2004)	n= 54 208 150 252 89 689 39 23 149 223 50 53 101	Meta-analysis (Bayesian random effect model)  1) Analysis with all type 2 diabetes mellitus patients 2) Analysis with only non-insulin treated type 2 diabetes patients 3) Adjustment of baseline glycaemic level 4) Adjustment for study quality	<b>Including insulin treated patients</b> <ul style="list-style-type: none"> <li>Interventions with SMBG showed a reduction in HbA1c of 0.40% (95% CrI: 0.07 to 0.70%) in comparison to interventions without self-monitoring.</li> <li>Regular feedback reduced HbA1c more than two times.</li> <li>Urine monitoring and interventions without monitoring showed similar results (0.02% reduction in HbA1c: 95%CrI-0.62 to 0.70%).</li> <li>There is 88% probability that SMBG is more effective than urine testing (relative reduction in HbA1c is 0.38%, 95% CrI-0.3 to 1.00%).</li> </ul> <b>Relative efficacy among non-insulin treated patients</b> <ul style="list-style-type: none"> <li>Interventions with urine monitoring had comparable results to interventions without self-monitoring.</li> <li>Interventions with SMBG are more effective than interventions without self-monitoring [98% probability: 0.42% reduction]</li> <li>Interventions with SMBG are more likely to be effective than interventions with urine monitoring. [80%probability: 0.28% reduction]</li> <li>Interventions with SMBG + feedback are more likely to be effective than interventions without feedback [99%CrI-1.49; -0.13].</li> </ul>	Interventions with SMBG are effective in reducing HbA1c than interventions without monitoring or with urine monitoring.

Author	Objectives	Included studies	Included studies	Analysis	Findings	Conclusion	Author
McGeoch 2007	1) To examine all of the clinically relevant evidence regarding the use of SMBG in patients with type 2 diabetes not using insulin. 2) To identify how to use SMBG to the greatest effect.	RCTs  Observational studies  (type 2 diabetes patients with/without insulin treatment)	<b>RCTs</b>  Schwedes et al, (2002) Guerci et al, (2003) Davidson et al, (2005)  <b>Observational studies</b>  Rindone et al, (1997) Weiland et al, (1997) Harris (2001) Karter et al, (2001) Franciosi et al, (2001) Franciosi et al, (2005) Meier et al, (2002) Soumerai et al, (2004) Wen et al, (2004) Karter et al, (2005) Martin et al, ((2006) Davis et al, (2006) Schutt et al, (2006) Karter et al, (2006)	n= 223 689 88  115 216 1076 (non- insulin) 24312 204 2855 1952 3219 976 4775 3268 1286 5009 (type 2 diabetes) 24162 (non-insulin)	Narrative summary due to the clinical heterogeneity	<ul style="list-style-type: none"> <li>In 3 RCTs, the two larger studies (Schwedes, Guerci) had statistically significant reduction in HbA1c levels with SMBG.</li> <li>In observation studies, smaller studies had lower initial HbA1c and showed no association between SMBG and laboratory or clinical improvement.</li> <li>Larger studies tended to have higher initial HbA1c and did show an association between SMBG and laboratory or clinical improvement.</li> <li>Overall, improvement in glycaemic control with SMBG tended to be seen in studies with initial HbA1c above 8%.</li> </ul>	It is likely that SMBG is beneficial in some circumstances such as an educational tool, for patients with type 2 diabetes not using insulin who have poor glycaemic control.

Author	Objectives	Included studies	Included studies	Analysis	Findings	Conclusion	Author
Sarol 2005	To determine if therapeutic management programs with SMBG result in greater HbA1c reduction in non-insulin-requiring type 2 diabetes patients compared to programs without SMBG.	RCTs (type 2 diabetes with/without insulin treatment)	8 RCTs Fontbonne et al, (1989) Estey et al, (1990) Muchmore et al, (1994) Jaber et al, (1996) Schwedes et al, (2002) Guerci et al, (2003) Davidson et al, (2004) Kwon et al, (2004)	208 53 23 39 223 689 89 81	Meta-analysis	<i>Anti-diabetic therapies that included SMBG as part of a multi-component management strategy produced a mean additional HbA1c reduction of</i> <ul style="list-style-type: none"> <li>-0.39% (95%CI: -0.54%, -0.23%) (fixed effects model)</li> <li>-0.42% (95%CI: -0.63%, -0.21%) (random effects model)</li> <li>Without 3 studies with C rate (poor quality), summary effect estimate was -0.31% (95% CI: -0.49%, -0.14%).</li> <li>Heterogeneity among studies was not statistically significant. (chi-square test ).</li> </ul>	Multi-component diabetes management programs with SMBG result in better glycaemic control among non-insulin-using type 2 diabetes patients.
Welschen 2005	To assess the effects of SMBG in patients with type 2 diabetes not using insulin.	RCTs (type 2 diabetes non-insulin treated)	6 RCTs Allen et al, (1990) Davidson et al, (2005) Fontbonne et al, (1989) Guerci, et al, (2003) Muchmore et al, (1994) Schwedes et al, (2002)	54 89 208 689 23 223	Narrative summary due to the heterogeneity	<ul style="list-style-type: none"> <li>Four studies found more improvement in HbA1c levels in SBG groups than in usual care groups (Davidson, Guerci, Muchmore, Schwedes).</li> <li>Two studies found (Guerci, Schwedes) statistically significant improvement in HbA1c but Schwedes had a co-intervention with education on diet and lifestyle.</li> <li>There were few data on the effects of other outcomes and these effects were not statistically significant.</li> <li>There was no significant evidence available that SMBG had a beneficial effect on other outcomes as only one study reported data on hypoglycaemic episode (Guerci 2002) and only two studies reported some data on quality of life and patient satisfaction (Muchmore, Schwedes).</li> </ul>	SMBG might be effective in improving glycaemic control in patients with type 2 diabetes who are not using insulin. (Previous reviews (Faas 1997 Holmes 2002 Coster 2000) reported there was insufficient evidence).

## Included Papers: New Systematic Reviews

Author	Objectives	Included studies	Included studies	Analysis	Findings	Conclusion
Alleman 2009	Objective: To assess the effect of self-monitoring of blood glucose (SMBG) on glycaemic control in non-insulin treated patients with type 2 diabetes by means of a systematic review and meta-analysis.	To be included, studies had to be randomised controlled trials including non-insulin treated patients with type 2 diabetes and comparing a treatment strategy including self measurements of blood glucose (SMBG) with a treatment strategy without or with less frequent SMBG. In addition, trials had to report data on HbA1c. For trials including both patients treated with and without insulin separate results had to be available for non-insulin treated patients.  There were no language restrictions.	Rutten, 1990  Muchmore, 1994  Jaber, 1996  Atsumi, 1997  Brown, 2002  Schwedes, 2002  Guerci, 2003,  Davidson, 2005,  Farmer 1, 2007,  Farmer 2, 2007,  O'Kane, 2008,  Barnett, 2008,	(Int)+ (Control) n= 66+ 83  n =12 + 11 n= 17+ 22  n= 85+ 86  n= 83+ 86  n=113+110  n=345 + 344  n=43 +45  n+150 + 152  n=151 + 152  n=96 + 88  n=311 +299	Twelve trials including 2934 patients contributed to the primary analysis. Since the study of Farmer et al. contributed two comparisons to this analysis the analysis was based on a total of 13 comparisons.  Heterogeneity was low to moderate (I <sup>2</sup> /43.3%), therefore results based on the random-effects model are presented.  When combining the data from the twelve trials, SMBG was associated with a significantly lower HbA1c compared with non-SMBG (WMD _0.31%, 95%CI _0.44 to _0.17). Analysis of funnel plot asymmetry revealed little evidence for an inclusion bias (p for Egger's test 0.07).	In non-insulin treated patients with type 2 diabetes SMBG compared with non-SMBG is associated with a significant reduction of HbA1c. The effect tended to be greatest in patients with poor glycaemic control and is not attenuated over longer follow-up periods.

Clar 2009	To examine whether or not self monitoring of blood glucose (SMBG) is worthwhile, in terms of glycaemic control, hypoglycaemia, quality of life (QoL) and cost per quality-adjusted life-year (QALY), in people with type 2 diabetes (T2DM) who were not treated with insulin or who were on basal insulin in combination with oral agents.	A systematic review and meta-analyses of randomised controlled trials (RCTs) identified from the reviews, and from searches for more recent trials, along with review of qualitative and economic studies. Search strategies were limited to the English language and to articles published since 1996, and included: databases searched from 1996 to April 2009 – The Cochrane Library, MEDLINE, EMBASE, PsycINFO, Web of Science – limited to meeting abstracts; and websites.	Barnett (2008) Davidson (2005) Farmer 1,(2007) Fontbonne (1989) Guerci, 2003 Kibriya (1999) Muchmore (1994) O’Kane (2008) Rutten (1990) Wing (1986)	311 + 299 150 +152  150 +152  68+72+68 345+344  64 12+11  180  36 + 34 25+25	In total, 10 RCTs were included in the meta-analysis of ('simple') SMBG versus no SMBG. Overall, there was a small but significant reduction of HbA1c level with SMBG of $-0.21\%$ (95% CI $-0.31$ to $-0.10$ , $p < 0.0001$ , no significant heterogeneity).  None of the studies comparing SMBG with SMUG (three RCTs) found a significant difference, and there was no significant difference overall ( $-0.06\%$ , 95% CI $-0.69$ to $0.56$ , no significant heterogeneity).	The evidence suggested that SMBG is of limited clinical effectiveness in improving glycaemic control in people with T2DM on oral agents, or diet alone, and is therefore unlikely to be cost-effective. SMBG may lead to improved glycaemic control only in the context of appropriate education – both for patients and health-care professionals – on how to respond to the data, in terms of lifestyle and treatment adjustment. Also, SMBG may be more effective if patients are able to self-adjust drug treatment.
Lockwood 2010	What is the economic effectiveness of self-monitoring of blood glucose among adults with type 2 diabetes in terms of economic utility and cost effectiveness?	The review included studies where participants had type 2 diabetes and were using insulin or oral medication or diet and exercise plans for glycaemic control.	Data presented for both insulin and non –insulin treated patients and cannot be segregated for data extraction for the purposes of this review.	NR	NR	Subgroups may exist for which SMBG could be cost effective, e.g. those who adhere strictly to treatment recommendations, patients with certain characteristics

McIntosh 2010	A systematic review and meta-analysis to determine the effect of self-monitoring versus no self-monitoring, and the optimal frequency of self-monitoring, in patients with type 2 diabetes managed without insulin. This publication also assessed the effect of patient education regarding self-interpretation and application of test results on HbA1c concentrations and other clinical outcomes.	Included English-language full-text articles and conference abstracts of randomized controlled trials (RCTs) and observational studies (i.e., cohort, case-control and time series) that compared self-monitoring of blood glucose levels with no self-monitoring, or that compared different frequencies of self-monitoring, in adults or children with type 2 diabetes managed without insulin.	<p>Barnett 2008</p> <p>Davidson 2005</p> <p>Farmer 1, 2007</p> <p>Guerci, 2003</p> <p>Muchmore 2004</p> <p>O'Kane, 2008</p> <p>Schwedes 2003</p>	<p>311 + 299</p> <p>43 + 43</p> <p>150 + 152</p> <p>345+ 344</p> <p>12 + 11</p> <p>180</p> <p>113 + 110</p>	<p>The meta-analysis yielded a statistically significant difference in HbA1c in favour of self-monitoring (weighted mean difference -0.25%, 95% confidence interval [CI] -0.36% to -0.15%)</p> <p>A subgroup analysis based on whether study participants were instructed on how to interpret and apply results from self-monitoring pooled differences in HbA1c concentration were similar regardless of whether trials implemented such an educational component No statistically significant difference in HbA1c concentration was found between study groups (mean difference 0.03%, 95% CI -0.15% to 0.21%).</p> <p>A subgroup analyses to determine whether the HbA1c estimate was affected by differences across studies in the frequency or duration of self-monitoring, baseline HbA1c concentration, time since diabetes diagnosis and type of oral antidiabetes drug therapy used. No statistically significant effect of self-monitoring on HbA1c concentration in the only RCT that enrolled newly diagnosed patients (mean difference -0.40%, 95% CI -0.96% to 0.16%).</p>	Self-monitoring of blood glucose levels is associated with modest improvements in glycemic control among patients with type 2 diabetes managed without insulin. The provision of education to help patients translate results from self-monitoring into appropriate responses appeared to result in no greater benefit than self-monitoring without education, although studies may have been limited in their ability to adequately assess the effects of education.
St John 2010	To review the recent literature relating to the role of self-monitoring of blood glucose (SMBG) and glycaemic control	A systematic review of 6 trials that reported results for non insulin treated patients separately for type 2 diabetes.	As the individual trial results for Hba1c have not been reported in this publication, a detailed summary table cannot be provided.		<p>The results of the 5 RCTs in non-insulin-treated type 2 diabetic patients were combined in a meta-analysis with two earlier RCTs which yielded a significant pooled SMBG-related decrease in HbA1c of -0.22 (95% CI -0.34% to -0.11%) demonstrating an SMBG-related HbA1c reduction in non-insulin-treated type 2 diabetes patients.</p>	SMBG-related HbA1c reduction in non-insulin-treated type 2 diabetes patients that was similar to that in previous systematic reviews but in a substantially larger patient sample.

## Appendix VII: Excluded Studies - Effectiveness

### 3 Systematic Reviews

Karter AJ, Parker MM, Moffet HH, Spence MM, Chan J, Ettner SL, et al. Longitudinal study of new and prevalent use of self-monitoring of blood glucose: Role of self-monitoring of blood glucose in glycemic control. [Review] [56 refs]. Endocrine Practice. 2006;12 Suppl 1:110-7.

**Reason for Exclusion:** Literature review only, no description of methodology.

Saudek C, Derr R, Kalyani R. Assessing glycemia in diabetes using self-monitoring blood glucose and hemoglobin A1c. Journal of The American Medical Association. 2008;295(14):1688-97.

**Reason for Exclusion:** Did not meeting methodological criteria; one reviewer, limited search.

McAndrew, L, Schneider, SH, Burns, E, Leventhal, H. Does patient blood glucose monitoring improve diabetes control? A systematic review of the literature.[comment]. Diabetes Educator, 33, 6, 991-1011; discussion 1012-3

**Reason for Exclusion:** Did not distinguish between people on insulin and those not receiving insulin in the analysis.

### 9 RCTs From Systematic Reviews

Brown SA, Garcia AA, Kouzekanani K, Hanis CL. Culturally competent diabetes self-management education for Mexican Americans: the Starr County border health initiative. Diabetes Care. 2002;25(2):259-68.

**Reason for Exclusion:** Insulin users were included in the study, could not be extracted.

Davidson M. Self-monitoring of blood glucose linked to nutritional counseling in minority type 2 diabetic patients on diet and oral antidiabetes medication does not improve glycemic outcomes. Diabetes. 2004;53(Suppl):A73.

**Reason for Exclusion:** Only abstract was published.

Jaber LA, Halapy H, Fernet M, Tummalapalli S, Diwakaran H. Evaluation of a pharmaceutical care model on diabetes management.[see comment]. Annals of Pharmacotherapy. 1996;30:238-43.

**Reason for Exclusion:** No medication limits were identified.

Kibriya M, Ali L, Banik N, Azad K, AZ, . Home monitoring of blood glucose (HMBG) in Type-2 Diabetes mellitus in a developing country. Diabetes Research and Clinical Practice. 1999;46(3):253-7.

**Reason for Exclusion:** Data from insulin users were included.



Kwon H, Cho J, Kim H, Song B, Ko S, Lee J. Establishment of Blood Glucose Monitoring System Using the Internet. *Diabetes Care*. 2004;27:478-83.

**Reason for Exclusion:** No medication limits were identified.

Miles P, Everett J, Murphy J, Kerr D. Comparison of blood or urine testing by patients with newly diagnosed non-insulin dependent diabetes: patient survey after randomised crossover trial *British Medical Journal*. 1997;315(7104):348-9.

**Reason for Exclusion:** No medication limits were identified.

Moreland E, Volkening L, Lawlor M, Chalmers K, Anderson B, Laffel L. Use of a Blood Glucose Monitoring Manual to Enhance Monitoring Adherence in Adults With Diabetes: A Randomized Controlled Trial. *Arch Intern Med* 2006;166:689-695. 1996;166(6):689-95.

**Reason for Exclusion:** Type 1 and insulin treated patients were included.

Seaton T. Benefit of self-monitoring blood glucose in patients with NIDD receiving oral sulfonylureas. *Pharmacotherapy*. 1996;16:498.

**Reason for Exclusion:** We could not identify this paper.

Wing R, Epstein L, Nowalk M. Does self-monitoring of blood glucose levels improve dietary compliance for obese patients with type II diabetes? *American Journal of Medicine*. 1986;81(5):830-6.

**Reason for Exclusion:** Insulin users are included.

### **Updated Review - Excluded Systematic Reviews and RCTs for effectiveness**

Alam, R., J. Sturt, et al. (2009). "An updated meta-analysis to assess the effectiveness of psychological interventions delivered by psychological specialists and generalist clinicians on glycaemic control and on psychological status." *Patient Education and Counseling* 75(1): 25-36.

**Reason for Exclusion:** Did not meeting methodological criteria

Belsey, J. D., J. B. Pittard, et al. (2009). "Self blood glucose monitoring in type 2 diabetes. A financial impact analysis based on UK primary care." *International Journal of Clinical Practice* 63(3): 439-448.

**Reason for Exclusion:** Did not meeting methodological criteria

Bird, D., B. Oldenburg, et al. (2010). "Randomised controlled trial of an automated, interactive telephone intervention to improve type 2 diabetes self-management (Telephone-Linked Care Diabetes Project): study protocol." *BMC Public Health* 10: 599.

**Reason for Exclusion:** Did not meeting methodological criteria

Boren, S. A., K. A. Fitzner, et al. (2009). "Costs and benefits associated with diabetes education: a review of the literature." *Diabetes Educator* 35(1): 72-96.

**Reason for Exclusion:** Did not meeting methodological criteria

Braun, A. K., T. Kubiak, et al. (2009). "SGS: a structured treatment and teaching programme for older patients with diabetes mellitus--a prospective randomised controlled multi-centre trial." *Age & Ageing* 38(4): 390-396.

**Reason for Exclusion:** Did not meeting methodological criteria

Coppell, K. J., M. Kataoka, et al. (2010). "Nutritional intervention in patients with type 2 diabetes who are hyperglycaemic despite optimised drug treatment--Lifestyle Over and Above Drugs in Diabetes (LOADD) study: randomised controlled trial." *Bmj* 341: c3337.

**Reason for Exclusion:** Did not meeting methodological criteria

de Belvis, A. G., F. Pelone, et al. (2009). "Can primary care professionals' adherence to Evidence Based Medicine tools improve quality of care in type 2 diabetes mellitus? A systematic review." *Diabetes Res Clin Pract* 85(2):119-31.

**Reason for Exclusion:** Did not meeting methodological criteria

De Mattia, G., O. Laurenti, et al. (2009). "Comparison of glycaemic control in patients with Type 2 diabetes on basal insulin and fixed combination oral antidiabetic treatment: results of a pilot study." *Acta Diabetol* 46(1): 67-73.

**Reason for Exclusion:** Did not meeting methodological criteria

Duke Sally-Anne, S., S. Colagiuri, et al. (2009) "Individual patient education for people with type 2 diabetes mellitus." *Cochrane Database of Systematic Reviews* DOI: .1002/14651858.CD005268.pub2.

**Reason for Exclusion:** Did not meeting methodological criteria

Eakin, E. G., M. M. Reeves, et al. (2010). "Living Well with Diabetes: a randomized controlled trial of a telephone-delivered intervention for maintenance of weight loss, physical activity and glycaemic control in adults with type 2 diabetes." *BMC Public Health* 10: 452.

**Reason for Exclusion:** Did not meeting methodological criteria

Evans, M. M. (2010). "Evidence-based practice protocol to improve glucose control in individuals with type 2 diabetes mellitus." *MEDSURG Nursing* 19(6): 317-322.

**Reason for Exclusion:** Did not meeting methodological criteria

Farmer, A. J., C. Heneghan, et al. (2009). "Individual patient data meta-analysis of trials of self-monitoring of blood glucose in non-insulin treated type 2 diabetes: Protocol for a systematic review." *Primary Care Diabetes* 3(2): 117-121.

**Reason for Exclusion:** Did not meeting methodological criteria

Gambling, T. and A. F. Long (2010). "The realisation of patient-centred care during a 3-year proactive telephone counselling self-care intervention for diabetes." *Patient Education and Counseling* 80(2): 219-226.

**Reason for Exclusion:** Did not meeting methodological criteria

Genz, J., B. Haastert, et al. (2010). "Blood glucose testing and primary prevention of diabetes mellitus type 2--evaluation of the effect of evidence based patient information." *BMC Public Health* 10: 15.SMBG Literature Update.enl Page 2

**Reason for Exclusion:** Did not meeting methodological criteria

Gerrald, K. R., R. M. Malone, et al. (2010). "Clinical benefit of self-monitoring of blood glucose is uncertain for non-insulin-treated patients with type 2 diabetes." *Clinical Diabetes* 28(3): 121-123.

**Reason for Exclusion:** Did not meeting methodological criteria

Gillett, M., H. M. Dallosso, et al. (2010). "Delivering the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cost effectiveness analysis." *Bmj* 341: c4093.

**Reason for Exclusion:** Did not meeting methodological criteria

Greven Wendela, L., B. E. A. Hoeks Lette, et al. (2010) "Continuous glucose monitoring systems for type 2 diabetes mellitus." *Cochrane Database of Systematic Reviews* DOI: 10.1002/14651858.CD008526.

**Reason for Exclusion:** Did not meeting methodological criteria

Guldborg, T. L., T. Lauritzen, et al. (2009). "The effect of feedback to general practitioners on quality of care for people with type 2 diabetes. A systematic review of the literature." *BMC Fam Pract* 10: 30.

Heinrich, E., N. C. Schaper, et al. (2010). "Self-management interventions for type 2 diabetes: a systematic review." *European Diabetes Nursing* 7(2): 71-76.

**Reason for Exclusion:** Did not meeting methodological criteria

Hemmingsen, B., S. Lund Søren, et al. (2009) "Targeting intensive glycaemic control versus targeting conventional glycaemic control for type 2 diabetes mellitus." Cochrane Database of Systematic Reviews DOI: 10.1002/14651858.CD008143.

**Reason for Exclusion:** Did not meeting methodological criteria

Hoffmann, F. and F. Andersohn (2011). "Immortal time bias and survival in patients who self-monitor blood glucose in the Retrolective Study: Self-monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes (ROSSO)." Diabetologia 54(2): 308-311.

**Reason for Exclusion:** Did not meeting methodological criteria

Ismail-Beigi, F., T. Craven, et al. (2010). "Effect of intensive treatment of hyperglycaemia on microvascular outcomes in type 2 diabetes: an analysis of the ACCORD randomised trial." Lancet 376(9739): 419-30.

**Reason for Exclusion:** Did not meeting methodological criteria

Kelly, T. N., L. A. Bazzano, et al. (2009). "Systematic review: glucose control and cardiovascular disease in type 2 diabetes." Ann Intern Med 151(6): 394-403.

**Reason for Exclusion:** Did not meeting methodological criteria

Marso, S. P., K. F. Kennedy, et al. (2010). "The effect of intensive glucose control on all-cause and cardiovascular mortality, myocardial infarction and stroke in persons with type 2 diabetes mellitus: a systematic review and meta-analysis." Diab Vasc Dis Res 7(2): 119-30.

**Reason for Exclusion:** Did not meeting methodological criteria

Minet, L., S. Moller, et al. (2010). "Mediating the effect of self-care management intervention in type 2 diabetes: a meta-analysis of 47 randomised controlled trials." Patient Educ Couns 80(1): 29-41.

**Reason for Exclusion:** Did not meeting methodological criteria

Muthusamy, K., S. A. Smith, et al. (2009). "Minimally invasive and conventional glucose monitoring did not differ for long-term glycemic control in insulin-treated diabetes." ACP Journal Club 151(4): 4-4.

**Reason for Exclusion:** Did not meeting methodological criteria

Newman, S., D. Cooke, et al. (2009). "A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE)." Health Technology Assessment 13(28): 1-216.

**Reason for Exclusion:** Did not meeting methodological criteria

O'Keefe, J. H., M. Abuannadi, et al. (2011). "Strategies for optimizing glycemic control and cardiovascular prognosis in patients with type 2 diabetes mellitus." *Mayo Clinic Proceedings* 86(2): 128-138.

**Reason for Exclusion:** Did not meeting methodological criteria

Pal, K., V. Eastwood Sophie, et al. (2010) "Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus." *Cochrane Database of Systematic Reviews* DOI: 10.1002,14651858.CD008776.SMBG Literature Update.enl Page 3

**Reason for Exclusion:** Did not meeting methodological criteria

Ray, K. K., S. R. Seshasai, et al. (2009). "Effect of intensive control of glucose on cardiovascular outcomes and death in patients with diabetes mellitus: a meta-analysis of randomised controlled trials." *Lancet* 373(9677): 1765-1772.

**Reason for Exclusion:** Did not meeting methodological criteria

Shi, Q., S. K. Ostwald, et al. (2010). "Improving glycaemic control self-efficacy and glycaemic control behaviour in Chinese patients with Type 2 diabetes mellitus: randomised controlled trial." *Journal of Clinical Nursing* 19(3-4): 398-404.

**Reason for Exclusion:** Did not meeting methodological criteria

Spahn, J. M., R. S. Reeves, et al. (2010). "State of the Evidence Regarding Behavior Change Theories and Strategies in Nutrition Counseling to Facilitate Health and Food Behavior Change." *Journal of the American Dietetic Association* 110(6): 879-891.

**Reason for Exclusion:** Did not meeting methodological criteria

Sturt, J., H. Hearnshaw, et al. (2010). "Validity and reliability of the DMSSES UK: A measure of self-efficacy for type 2 diabetes self-management." *Primary Health Care Research and Development* 11(4): 374-381.

**Reason for Exclusion:** Did not meeting methodological criteria

Valentine, W. J., R. F. Pollock, et al. (2010). "Systematic review of the cost-effectiveness of biphasic insulin aspart 30 in type 2 diabetes." *Curr Med Res Opin* 26(6): 1399-412.

**Reason for Exclusion:** Did not meeting methodological criteria

Wu, L., A. Forbes, et al. (2010). "Telephone follow-up to improve glycaemic control in patients with Type 2 diabetes: systematic review and meta-analysis of controlled trials." *Diabet Med* 27(11): 1217-25.

**Reason for Exclusion:** Did not meeting methodological criteria

## 29 RCTs from New Search

Cho JH, Chang SA, Kwon HS, Choi YH, S.-H. K, D. MS, et al. Long-term effect of the internet-based glucose monitoring system on HbA<sub>1c</sub> reduction and glucose stability: A 30-month follow-up study for diabetes management with a ubiquitous medical care system. *Diabetes Care*. 2006;29(1):2625-31.

**Reason for Exclusion:** Insulin users are included.

Farmer A, Wade A, French DP, Goyder E, Kinmonth AL, Neil A. The DiGEM trial protocol--a 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 Family Practice*. 2005 Jun 16;6:25.

**Reason for Exclusion:** Protocol awaiting completion.

Fedele D, Corsi A, Noacco C, Prisco F, Squatrito S, Torre E. Alternative site blood glucose testing: a multicenter study. *Diabetes Technology & Therapeutics*. 2003;5(6):983-9.

**Reason for Exclusion:** The study compared glucose measurement between fingertip and forearm using the blood glucose (BG) monitoring system.

Gallegos EC, Ovalle-Berumen F, Gomez-Meza MV. Metabolic control of adults with type 2 diabetes mellitus through education and counseling. *Journal of Nursing Scholarship*. 2006;38(4):344-51.

**Reason for Exclusion:** Quasi-experimental study. No medication limits were identified.

Gallichan M. Self-monitoring by patients receiving oral hypoglycaemic agents: A survey and a comparative trial. *Practical Diabetes International*. 1994;11(1):28-30.

**Reason for Exclusion:** No a RCT.

Glasgow R, Toobert D. Computer-Assisted Diabetes Dietary Self-Management Counseling: A Technology for Addressing a Public Health Need. *Medical Care*. 2000;38(11):1059-61.

**Reason for Exclusion:** SMBG is not a main intervention.

Harno K, Kauppinen-Mäkelin R, Syrjäläinen J. Managing diabetes care using an integrated regional e-health approach *Journal of Telemedicine and Telecare*. 2006;12(Sup1):13-5.

**Reason for Exclusion:** Both intervention and control groups used SMBG.

Hawthorne K. Effect of culturally appropriate health education on glycaemic control and knowledge of diabetes in British Pakistani women with type 2 diabetes mellitus. *Health Education Research*. 2001;16(3):378-81.

**Reason for Exclusion:** SMBG was not used in intervention or control groups.

Hee-Sung K. Impact of Web-based nurse's education on glycosylated haemoglobin in type 2 diabetic patients. *Journal of Clinical Nursing*. 2007;16(7):1361-6.

**Reason for Exclusion:** SMBG is not a main intervention. Insulin users were included.

Johnson JA, Majumdar SR, Bowker SL, Toth EL, Edwards A. Self-monitoring in Type 2 diabetes: A randomized trial of reimbursement policy. *Diabetic Medicine*. 2006;23(11):1247-51.

**Reason for Exclusion:** SMBG was not used in intervention or control groups.

Keogh K, White P, Smith S, McGilloway S, O'Dowd T, Gibney J. Changing illness perceptions in patients with poorly controlled type 2 diabetes, a randomised controlled trial of a family-based intervention: protocol and pilot study. *BMC Family Practice*. 2007;8(36).

**Reason for Exclusion:** SMBG is not the main intervention.

Khunti K, Stone M, Burden A, Turner D, Raymond N, Burden M, et al. Randomised controlled trial of near-patient testing for glycated haemoglobin in people with type 2 diabetes mellitus. *British Journal of General Practice*. 2006;56(528):511-7.

**Reason for Exclusion:** No medication limits were identified.

Kim H, Jeong H. A nurse short message service by cellular phone in type-2 diabetic patients for six months. *Journal of Clinical Nursing*. 2007;6(16):1082-7.

**Reason for Exclusion:** Insulin users are included.

King AB, Wolfe GS, Armstrong DU. Evaluation of a patient education booklet (SimpleStart) effect on postprandial glucose control in type 2 diabetes. *Diabetes Technology & Therapeutics*. 2007;9(3):241-5.

**Reason for Exclusion:** SMBG is not the main intervention.

Pill R, Stott NC, Rollnick SR, Rees M. A randomized controlled trial of an intervention designed to improve the care given in general practice to Type II diabetic patients: patient outcomes and professional ability to change behaviour. *Family Practice*. 1998;15(3):229-35.

**Reason for Exclusion:** SMBG is not included.

Rachmani R, Slavacheski I, Berla M, Frommer-Shapira R, Ravid M. Treatment of high-risk patients with diabetes: motivation and teaching intervention: a randomized, prospective 8-year follow-up study. *Journal of the American Society of Nephrology*. 2005;16(1):22-6.

**Reason for Exclusion:** SMBG is not included.

Ridgeway NA, Harvill DR, Harvill LM, Falin TM, Forester GM, Gose OD. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *Southern Medical Journal*. 1999;92(7):667-72.

**Reason for Exclusion:** Insulin users are included.

Samuel-Hodge C, Headen A, Skelly A, Ingram A, Keyserling T, Jackson E. Influences on day-to-day self-management of type 2 diabetes among African-American women: spirituality, the multi-caregiver role, and other social context factors. *Diabetes Care*. 2000;23(7):928-33.

**Reason for Exclusion:** Not an RCT.

Seaton T. Benefit of self-monitoring blood glucose in patients with NIDD receiving oral sulfonylureas. *Pharmacotherapy*. 1996;16:498.

**Reason for Exclusion:** We could not identify and retrieve this paper.

Siebolds M, Siebolds M, Gaedeke. O. Self-monitoring of blood glucose – Psychological aspects relevant to changes in HbA1c in type 2 diabetic patients treated with diet or diet plus oral antidiabetic medication”. *Patient Education and Counselling*. 2006;61(1):104-10.

**Reason for Exclusion:** SMBG is not a main intervention.

Steed L, Lankester J, Barnard M, Earle K, Hurel S, Newman S. Evaluation of the UCL Diabetes Self-management Programme (UCL-DSMP): A Randomized Controlled Trial. *Journal of Health Psychology*. 2005;10(2):261-76.

**Reason for Exclusion:** SMBG is no a main intervention.

Sturt J, Whitlock S, Hearnshaw H. Complex intervention development for diabetes self-management. *Jornal of Advanced Nursing*. 2006;54(3):293-303.

**Reason for Exclusion:** SMBG is not included.

Suppakitporn S, Chindavijak B, Onsanit S. Effect of Diabetes Drug Counseling by Pharmacist, Diabetic Disease Booklet and Special Medication Containers on Glycemic Control of Type 2 Diabetes Mellitus:A Randomized Controlled Trial. *Journal of Medical Association of Thailand*. 2005;88(Sup4):S134-41.

**Reason for Exclusion:** SMBG is not included.

Tu KS, McDaniel G, Gay JT. Diabetes self-care knowledge, behaviors, and metabolic control of older adults--the effect of a posteducational follow-up program. *Diabetes Educator*. 1993;19(1):25-30.

**Reason for Exclusion:** SMBG is not a main intervention.

Tunis S, Minshall M. Self-monitoring of blood glucose in type 2 diabetes: Cost, effectiveness in the United States. *American Journal of Managed Care*. 2008;14(3):131-40.

**Reason for Exclusion:** Focus of study was on cost effectiveness of SMBG.

Varroud-Vial M, Simon D, Attali J, Durand-Zaleski I, Bera L, Attali C, et al. Improving glycaemic control of patients with Type 2 diabetes in a primary care setting: a French application of the Staged Diabetes Management programme. *Diabetes medicine*. 2004;21:592-8.

**Reason for Exclusion:** SMBG is not included. Insulin users are included.

Wangberg SC. An Internet-based diabetes self-care intervention tailored to self-efficacy. [References]. *Health Education Research* 2008;23(1):170-9.

**Reason for Exclusion:** Insulin users are included.



Wen L, Michael L. Parchman, Linn W, 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. 2005;61(22):2401-5.

**Reason for Exclusion:** Not an RCT.

Williams G, McGregor H, Zeldman A, Freedman Z, Deci E, Elder D. Promoting glycemic control through diabetes self-management: evaluating a patient activation intervention. Patients Education and Counseling. 2005;56(1): 28-34.

**Reason for Exclusion:** SMBG is not a main intervention.

## Appendix VIII: Included RCTs

Author	Methods	Population	Interventions	Outcome measures	Main Results (HbA <sub>1c</sub> , FBG)	Other findings	SRs using article
Allen 1990	<p>Randomised Control Trial (RCT)</p> <p>Randomised in groups of 10 by computer generated table</p> <p>Duration: 6 mths</p> <p>Allocation concealment: -neither patient or study physician blinded to the interventions</p>	<p>Country: USA n=54 male=100% Drop out 7/61 No ITT (Intention-to-treat analysis)</p> <p><b>Inclusion Criteria:</b> - type 2 diabetes non-insulin dependent patients -fasting glucose &gt;8.8mmol/L and &lt;22 mmol/L -no history ketoacidosis -diet controlled or diet controlled + hypoglycaemic agent -no active infection or serious concurrent infection -no physical/ mental handicap determined by cognitive-capacity screening examination &amp; physical-abilities questionnaire)</p> <p><b>Exclusion Criteria:</b> -SMBG devices used before -serum creatinine &gt;177 mmol/L</p> <p><b>Mean age (yrs):</b> SMBG: 58.2 ± 9.7 Urine testing: 57.9 ± 10.7 Diabetes duration (yrs): SMBG: 6.8± 6.5 Urine testing: 9.0 ± 10.3 Baseline HbA<sub>1c</sub> (%): SMBG: 12.4±3.3 Urine testing: 11.7±3.0</p>	<p><b>Control:</b> Urine monitoring (n=27) 36 urine glucose determinations/mth, before meal every other day</p> <p><b>Intervention:</b> SMBG (n=27) 36 blood glucose determinations/mth, before meal every other day</p> <p>Both received diet + counseling and monthly visits with treatment team, which used treatment algorithm (including medication changes) in response to monitoring results.</p> <p><b>Follow up:</b> Monthly follow up for 6mths</p>	<p>1. HbA<sub>1c</sub> at 3mths and 6mths by affinity chromatography</p> <p>2. Fasting plasma glucose,(FPG) monthly by glucose oxidase method.</p> <p>3. Total cholesterol, high density lipoprotein cholesterol, Measured by spectrophotometer with Beckman Dri-Stat reagents.</p> <p>4. Weight, monthly, patients fully clothed.</p>	<p>1. HbA<sub>1c</sub> at 6mths: SMBG : 10.4% (P&lt;.001) Urine Baseline: 9.7% (P&lt;.001)</p> <p>2. No significant difference in HbA<sub>1c</sub> was found between two groups. (P&gt;0.95)</p> <p>3. Within each group, HbA<sub>1c</sub> significantly improved.</p> <p>4. No significant difference in FBG (P&gt;0.86), Glycosylated haemoglobin (P&gt;0.95) or weight (p&gt;0.19) was found between the two groups</p> <p>5. Within each group, FPB improved significantly.</p>	<p>Medication changes</p> <p>1. Started insulin SMBG: 1 patient Urine testing: 2 patients</p> <p>2. Started oral medication: SMBG: 2 patients Urine monitoring: 4 patients</p> <p>3. Changed dosage of oral medication or switched to a new medication SMBG: 9 Urine testing:14</p> <p>4. SMBG was 8-12 times more expensive than urine testing.</p> <p>5. Younger and better educated participants improved more.</p> <p>6. Baseline HbA<sub>1c</sub>, weight, FGB, use of oral medications, duration of diabetes and race did not have association with improving glucose control.</p> <p>7. Control group used standardised urine monitoring.</p>	Jansen McAndrew Welschen

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Davidson 2005	Randomised Control Trial  -method of randomisation unclear Duration: 6 mths  Allocation Concealment: Single blind study: Blinded to study nurse	Country: USA n=88 Drop out 1/89 ITT  <b>Inclusion Criteria:</b> -Patients not on insulin - type 2 diabetes with oral medication (sulfonylurea, metformin, glitazone)  <b>Mean age: (yrs)</b> Control 49.8± 11.2 SMBG 50.9± 11.0 Diabetes duration: (yrs) Control 5.5± 4.7 SMBG 5.8± 5/8 Baseline HbA <sub>1c</sub> Control: 8.4% ± 2.1 SMBG: 8.5 ± 2.2	<b>Control:</b> (n=45) dietary counseling 5 times; at randomisation and 2,4,8 and 12 weeks later,  <b>Intervention:</b> (n=43) SMBG before and between 1 and 2 hrs post meals 6 days per week + dietary counseling 5 times; at randomisation and 2,4,8 and 12 weeks later,  Both groups had nurse follow-up with detailed algorithms to make therapeutic decisions based on laboratory determined FPG & HbA <sub>1c</sub> with oral drugs sulfonylurea, metformin and glitazone)  <b>Follow up:</b> 6mths follow up	1. HbA <sub>1c</sub> (Every 2mths for 6mths) 2. Medication changes	1. HbA <sub>1c</sub> : At 6mths: SMBG group 7.7±1.6 Control 7.8 ±1.5 Average change SMBG group -0.8±1.6 Control -0.6±2.1 Both control and SMBG group fell significantly (monitoring group p= <0.001; control group p= 0.05). The decrease was not significantly different between the SMBG group (-0.8%) and the control group (-0.6%). The 95% confidence interval of the change in HbA <sub>1c</sub> levels was -1.1 to +0.6%. 2. Weight or BMI: There was no change to weight or BMI for either group	1. Medication levels at the end of the study had similar outcomes in both groups. 2. Glucose monitoring is expensive but no definitive costs calculated 3. Overall there was no evidence that SMBG for these patients gave them a better glycaemic outcome.	Jansen McAndrew McGeoch Welschen

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Estey 1996	Randomised Control Trial  -method unclear and allocation concealment unclear, no blinding)	Country: Canada n=53 Drop out: 7/60 No-ITT  <b>Inclusion Criteria:</b> - type 2 diabetes not on insulin -referred by physician for diabetes education -diabetes controlled by either diet, and exercise, or diet, exercise, and oral hypoglycaemic agents. -completion of 3-day education at the Diabetes Centre -willingness to practice SMBG -accessibility by phone  <b>Exclusion Criteria:</b> -none specified  <b>Mean age: (yrs)</b> Control: 54.2±13.3 Intervention: 56.2±11.1 Male/Female Control: 54/46 Intervention: 39/61 Baseline HbA <sub>1c</sub> Control: 6.1±1.4 Intervention: 6.3±1.1	<b>Control:</b> 3 days diabetes education program  <b>Intervention:</b> -3 days diabetes education program -SMBG 4 follow up calls for review of learned skills and for encouragement over 10 wk period -keeping a diary of all their SMBG values 4mths follow up	1. Changes in pre- to post-study HbA <sub>1c</sub> values. 2. Weight. 3. Frequency of SMBG practice	1. Frequency of SMBG practice was significantly higher for the intervention group (P< .0001). 2. No significant differences were found in post-study HbA <sub>1c</sub> or weight changes in the two groups.	1. No information on treatment adjustments 2. Providing an intense follow-up intervention appeared to improve SMBG practices compared with an intervention that focused primarily on providing only information. 3. Telephone calls can be an effective means of reinforcing behaviour 4. Factors influencing noncompliance were job, lack of family support, knowledge deficiencies, and financial concerns. 5. Educational effect diminishes quickly subsequent to educational programs. 6. Less-frequent, but long-term reinforcement is probably required to sustain behaviours rather than intense intervention	Jansen Sarol

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Farmer 2007	Randomised Control Trial  -randomised by computer generation + partial independent minimisation procedure to adjust randomisation probabilities between groups.	Country: U.K. n=453 Drop out: 57/510 ITT  <b>Inclusion Criteria:</b> - type 2 diabetes -non-insulin treated -invited and referred by their own practitioner -≥25yrs at diagnosis -managed with diet or oralhypoglycaemic agents alone -HbA <sub>1c</sub> ≥6.2% on assessment visit -independent in daily living activities  <b>Exclusion Criteria:</b> -use of blood glucose monitor ≥2 times/wk over last three mths -serious illness -limited life expectancy making glycaemic control inappropriate -inability to follow trial procedures  <b>Mean age: (yrs)</b> Control: 66.3(±10.2) Less intensive SMBG: 65.2±10.6 Intensive SMBG: 65.9 ±9.9 Male (%): Control: 55.9 Less SMBG: 58.7 Intensive SMBG: 57.6 Duration of diabetes: (yrs) Control: 3(2-6) Less SMBG: 3 (2-7) Intensive SMBG: 3 (2-6) Baseline HbA <sub>1c</sub> Control: 7.49(±1.09) Less intensive SMBG: 7.41 (±1.02) Intensive SMBG: 7.53 (±1.12)	<b>Control:</b> (n=152) Standard care with goal setting and review. 3 mthly HbA <sub>1c</sub> No SMBG unless their doctor suggested -diary kept to record self care goals and strategies for achieving them.  <b>Interventions:</b> (n=151) Less intensive SMBG: Standard care -SMBG with advice for patients to contact their doctor for interpretation of results (If it is too high (>15mmol/L) or too low (<4 mmol/L). 3 SMBG daily readings on 2 days during the week (one after fasting, the other two before meals or two hours after meals). No specific instruction on how to interpret the readings. Diaries were kept by patient of SMBG readings  Intensive SMBG: Standard care + SMBG with additional training of patients in interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle. Personal diaries were kept of SMBG readings Blood glucose meters were calibrated to provide plasma equivalent.  12mths follow up	1. Primary outcome : HbA <sub>1c</sub> at 12mths measured using Variant II Hemoglobin Testing System (Bio-Rad Laboratories, Hercules, CA) 2. Secondary outcome: BP, weight, total cholesterol, ratio of total cholesterol to high density lipoprotein cholesterol, body mass index at 12mths 3. Hypoglycaemia, frequency of SMBG	1. No significant improvement in glycaemic control was found after 12mths in patients with non-insulin treated diabetes 2 using SMBG when compared to those not self-monitoring. 2. HbA <sub>1c</sub> at 12 mths No significant differences in HbA <sub>1c</sub> value between the 3 groups were found (p= .12). 3. Mean difference in change in HbA <sub>1c</sub> from baseline to 12mths Between Control & Less SMBG: -0.14% (CI 95% -0.35 to 0.07%) Control & Intensive SMBG: -0.17% (-0.37 to 0.03%) 4. No differences in HbA <sub>1c</sub> changes between groups (p=0.38%) 5. Significant difference in the change in total cholesterol level: Control vs. less intensive SMBG: -0.06mmol/L (-0.26 to 0.14) Control vs. Intensive SMBG: -0.23mmol/L (-0.43 to -0.04) 6. Hypoglycaemia: Control: 14. Less SMBG: 33, Intensive SMBG: 43 ( $\chi^2=18.3$ , P<0.001) 6. Less SMBG group was more likely to persist with SMBG than the intensive SMBG group. (67% vs 52%)	1. There was no difference between groups in the proportions of patients prescribed an increase in hypoglycaemic drugs between baseline and 12mths 2. There were no significant differences between subgroups of patients on the impact of SMBG 3. On glycaemic control (as defined by duration of diabetes, therapy, diabetic complications or health status) 4. There were no differences in glycaemic control between the more, or less monitored SMBG groups. 5. Patients with reasonably controlled diabetes do not need active encouragement to use a meter.	New

Author	Methods	Population	Interventions	Outcome measures	Main Results (HbA <sub>1c</sub> , FBG)	Other findings	SRs using article
Fontbonne 1989	Randomised Control Trial  Randomised procedure stratified by clinic	Country: France n=164 Drop out 44/208 No-ITT  <b>Inclusion Criteria:</b> - type 2 diabetes non-insulin treated -managed with diet and/or oralhypoglycaemic agents alone. -poorly controlled with FPG >8.8mmol/L or postprandial blood glucose >11mmol/L, 3 times within preceding yr. -presence of occasional glucosuria (renal glucose threshold <11mmol/L) to justify randomisation to self urinary glucose monitoring group. -duration of diabetes- at least 3 yrs. -a contact with the diabetic clinic 6mths previously and had attended 2 outpatient appointments since first contact.  <b>Exclusion Criteria:</b> -no rapidly progressing diabetic complications, and no severe illness.  <b>Mean age: (yrs)</b> Group A: 56.3±9.1 Group B: 54.9±10.2 Group C: 54.5±10.7 Male/Female: Group A: 40/28 Group B: 52/20 Group C: 36/32 Baseline HbA <sub>1c</sub> Group A: 8.2±0.3 Group B: 8.6±0.3 Group C: 8.2±0.3 Diabetes duration: (yrs) Group A: 12.7±0.8 Group B: 13.3±6.8 Group C: 12.2±6.6	<b>Control:</b> Group A- (n=54) HbA <sub>1c</sub> readings taken bimonthly and monitored by physician but no self-monitoring  <b>Interventions:</b> Group B- (n=54) self-urine glucose monitoring, twice every other day Group C- (n=56) SMBG, twice every other day, fasting and 2hrs after the evening meal, with an extra test 2 hours after lunch on Sunday.  Each participant assigned to a physician for bimonthly visit for modification of diet and/or hypoglycaemics according to results.  6mths follow up, seen bimonthly	1. HbA <sub>1c</sub> 2. Weight (measured every 2mths) 3. Number of reactive strips reported in a diary, recorded every 2mths.	1) Decrease of HbA <sub>1c</sub> or weight over 6mths was not significantly different between the three groups (P< .02) Mean ± SEM; Group A: -0.5 ±0.2% Group B: -0.1 ± 0.3% Group C: -0.4 ± 0.3%	1. HbA <sub>1c</sub> based treatment adjustment by physicians 2. In group C, significant association was found between the number of SMBG strips and the decrease in HbA <sub>1c</sub> . 3. Some patients motivated by SMBG may benefit from its use. 4. Methods used to reduce poor compliance may not always yield better metabolic control. 5. Comprehensive programs are yet to be designed and validated, where SMBG is to find a place of choice in routine management of type 2 diabetes without insulin treatment.	Jansen Sarol Welschen

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Guerci 2003	Randomised control trial  Open label randomised prospective trial  Randomised method unclear	Country: France n=689 303/988 Drop out No-ITT  <b>Inclusion Criteria:</b> -Poorly controlled type 2 diabetes > 1yr non- insulin treated for ≤7 consecutive days -oral antidiabetics -40 to 75yrs - HbA <sub>1c</sub> level ≥7.5 and ≤11% -no previous SMBG - able to perform own SMBG  <b>Exclusion Criteria:</b> -Type I diabetes -maturity onset diabetes of the young (MODY) -secondary diabetes -recent wt loss >3kgs over 3 mths -impending complications of diabetes -pregnant women -patient unable to read or write uncooperative or unconsented  <b>Mean age: (yrs)</b> SMBG: 60.9 ±9.4 Control: 62.2 ± 9.1 Male/Female: SMBG: 53.7/46.3 (%) Control: 56.6/43.4 (%) Diabetes duration: (yrs) SMBG 7. 7± 6.3 Control 8.4 ± 6.6 Baseline HbA <sub>1c</sub> : SMBG 9.0± 1.3, Control: 8.9±1.3	<b>Control:</b> (n=344) -conventional care -12 wkly laboratory measured HbA <sub>1c</sub>  <b>Intervention:</b> (n=345) conventional care + SMBG with initial training by G.P. -6 SMBG readings per week (on 3 different days) - including 6wkly follow-up over 6mths including 5 visits -trained to monitor their blood glucose which could give them feedback to change their lifestyle accordingly (diet & physical activity).  <b>Both Control &amp; Intervention:</b> -dietary advice from G.P. -similar management in drugs, diet and physical activity.  6mths follow up	HbA <sub>1c</sub> (baseline, 3, 6mths) weight, Systolic BP Diastolic BP at baseline, 3, 6mths At 3 mths each general practitioner (G.P.) could modify treatments of diabetic patients according to HbA <sub>1c</sub> Number of hypoglycaemia episode	1. Final HbA <sub>1c</sub> : SMBG: 8.1±1.6 Control: 8.4±1.4 (p= .012) The statistically significant difference between the two groups (P< .005) Mean change: SMBG: -0.88±1.54 Control: -0.60±1.54 There was a significant difference between the two groups. 2. There was no statistically difference in fasting blood glucose levels at endpoint between the two groups. 3. No difference was found in mean change of weight, drugs prescribed, diet or physical activity between the two groups. 4. Overall SMBG was associated with a slight but significant improvement of metabolic control. The benefit was greater in patients with higher initial HbA <sub>1c</sub> levels, lower BMI and lower duration of TII diabetes.	1. (Treatment modification unknown) 2. Hypoglycaemic episodes Control: 25 (5.2%) SMBG: 53 (10.4%) 3. Age and educational level approached statistical significance, concluding that educated patients might benefit from a program of intensive SMBG with 36 blood glucose determinations per month.	Jansen McAndrew McGeoch Sarol Welschen

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Muchmore 1994	Randomised control trial  Prospective RCT	<p>Country: USA n=23 Drop out 6/29 No-ITT</p> <p><b>Inclusion Criteria</b> -Overweight BMI 27.5-44 kg/m<sup>2</sup> -40-75 yrs - type 2 diabetes, diet and/or oral medication &gt;1yr duration -non-insulin treated - HbA<sub>1c</sub> at entry 9.5%-13.5% (normal-5.1%-7.7%) -compliance with protocol</p> <p><b>Exclusion Criteria</b> -SMBG use within last 3mths -serious underlying medical or psychiatric illness, drug abuse, or alcoholism. -received previous dietary carbohydrate counselling.</p> <p><b>Mean age: (yrs)</b> SMBG: 57.3 ± 2.3 Control: 60.1 ± 2.2 Male/Female: SMBG: 4/8 Control: 5/6 Diabetes duration: (yrs) SMBG 5.7 ± 1.4 Control 5.2 ± 1.4 Baseline HbA<sub>1c</sub> SMBG: 10.29 ± 0.33 Control 10.45 ± 0.44</p>	<p><b>Control:</b> (n=11) - conventional care - teaching individually and at group level on general principles of diabetes nutrition.</p> <p><b>Intervention:</b> (n=12) -conventional care -SMBG,6x per day (pre &amp; 2h postprandially) for 4 wks then pre and postprandially for a single meal per day for 16 wks. SMBG beyond 20weeks was at own expense and choice. -dietary CHO counting teaching individually and at group level. -results of SMBG and calorie counting was charted on a daily worksheet. -Teaching focused on postprandial increment in blood glucose of 2.2 to 3.9mMol/L.</p> <p><b>Control and Intervention:</b> -Both groups received care under their primary physician who coordinated any decision on medication adjustment. -1st 8wks run-in period formed in groups of 7-8 members and met for 90min wkly for formal proprietary behavioural weight management program (L.E.A.R.N.) + 1hr counselling by diabetes nurse educator + individual session with dietician. -follow-up one-on-one sessions with the dietician (30min) at wks 1 and 3 and the nurse educator at wks 1, 3, and 24. -both groups were recommended a meal composition of 50% of calories from carbohydrates, 30% from fat, and 20% from protein. Total calories were individualized for a weight loss of 0.5-1kg per week.</p> <p>44 wks follow up</p>	<p>1. HbA<sub>1c</sub> (-8, 0, 16, 28 and 44 weeks) 2. Weight measured at every encounter Diabetes Quality of Life (QOL) Inventory (0, 24, 44 weeks)</p>	<p>1. HbA<sub>1c</sub> progressively declined in SMBG group (P&lt;0.05) and no improvement in control group. 2. HbA<sub>1c</sub> at week 44 SMBG: 8.75%±0.63: 1.54% (1.46) reduction (P&lt;0.05) Control: 9.6%±0.63: 0.84% (1.87) reduction (P&gt;0.3) No significant differences between groups at study end.</p>	<p>1. Duration of diabetes, initial HbA<sub>1c</sub>, and number of SMBG were not related to HbA<sub>1c</sub>. 2. QOL results were identical in both groups.</p>	Jansen McAndrew Sarol Welschen



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O'Kane 2008	Randomised control trial  Randomised by randomly generated allocation code in consecutively numbered sealed envelopes.	Country: Northern Ireland (U.K.) n=180  Drop out 4/184 No-ITT  <b>Inclusion Criteria</b> - type 2 diabetes -newly diagnosed -<70yrs  <b>Exclusion Criteria</b> -secondary diabetes - insulin treatment -previous self-monitoring of diabetes -major illness within previous six months, chronic liver disease, and alcohol misuse.  <b>Mean age: (yrs)</b> Control: 60.9 ( $\pm$ 11.5) SMBG: 57.7 ( $\pm$ 11.04) Male/Female: Control: 55/41 SMBG: 56/32 Baseline HbA <sub>1c</sub> Control: 8.6 ( $\pm$ 2.3) SMBG: 8.8 ( $\pm$ 2.1)	Both groups received an identical structured core education program.  <b>Control:</b> (n=88) -no monitoring (no monitoring during the study period)  <b>Intervention:</b> (n=96) -additional educational program on SMBG -SMBG (4 times fasting and 4 posprandial SMBG per week) - education given as to responses needed for high or low readings (dietary and exercise) Every 3mths follow up for 1 year  <b>Control &amp; Intervention:</b> -both underwent identical education programs involving nurse practitioners, dieticians, podiatrists, and medical staff. -all reviewed by doctor, diabetes nurse practitioner, and dietician at 3mthly intervals for 1yr. All glycaemic indices were reviewed. -identical treatment algorithms for dietary and pharmacological glycaemic management based on HbA <sub>1c</sub> targets.	1. differences in HbA <sub>1c</sub> , psychological indices, use of oral hypoglycaemic drugs, body mass index and hypoglycaemia rates. 2. At each 3mthly visit patients completed a questionnaire survey incorporating diabetes treatment satisfaction, a diabetes attitude scale and well-being questions (depression, anxiety, energy, positive wellbeing, and general wellbeing)	1. HbA <sub>1c</sub> value (12 mths) Control: 6.9 ( $\pm$ 1.2) SMBG: 6.9 ( $\pm$ 0.8) p=0.69; (95% CI -0.25% to 0.38%) No significant differences were found between groups at any time point.	1. No significant differences were found between groups in the use of oral hypoglycaemic medicines and hypoglycaemia. 2. SMBG was associated with a 6% higher score (i.e. more depressed) on the depression subscale of the wellbeing questionnaire (p=0.01). Therefore SMBG can be associated with reduced wellbeing.	New

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Rutten 1990	Randomised control trial  Multi G.P. Centre, randomised controlled design  Patients chosen from G.P. centres randomised by care levels (not high or low care)	Country: Netherlands n=139  Drop out 10/149 No-ITT  <b>Inclusion Criteria:</b> - type 2 diabetes >6mths - under G.P. care - 40-75yrs  <b>Exclusion Criteria:</b> - insulin therapy - treatment for diseases other than obesity or hypertension  <b>Mean age</b> SMBG: 62.6±9.9 Control: 63.7±8.1 Male/Female SMBG: 34/66% Control: 36/64% Duration of diabetes: (yrs) SMBG: 10.0±7.8 Control: 6.6±4.0 Baseline HbA <sub>1c</sub> SMBG: 9.7±2.1 Control: 8.9±1.9	<b>Control:</b> (n=36) G.P. consultation 4/year. No SMBG instruction.  <b>Intervention:</b> (n=34) - 2-5 education session on SMBG - patients contacted diabetes nurses monthly to report SMBG readings. If high, made appointment with G.P. - All patients also met with G.P. after 6mths. - medication algorithms were followed by G.P.s  12mths follow up	1. HbA <sub>1c</sub> 2. weight 3. Number of SMBG strips	1. Final HbA <sub>1c</sub> SMBG: decreased by 0.4% Control: increased by 0.5% (P<0.005) 2. SMBG: HbA <sub>1c</sub> decreased in two patients with an initial HbA <sub>1c</sub> <8 (14%). Control: HbA <sub>1c</sub> unchanged or increased in all patients. 3. SMBG: HbA <sub>1c</sub> decreased in 80% of the patients with an initial value of >10. Control: HbA <sub>1c</sub> decreased in 53% of the patients with an initial value of >10.	1. Weight: SMBG: 0.4kg weight loss Control: 0.1kg weight gain No significant difference between two groups.	Jansen McAndrew

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Schwedes 2002	Randomised control trial  Multicentre, prospective, randomised controlled design (21 centres)  Randomised within blocks of 8 for treatment	Country: Germany & Austria n=223 Drop out 27/250 No-ITT <b>Inclusion Criteria:</b> - type 2 diabetes >3mths -BMI>25kg/m <sup>2</sup> - HbA <sub>1c</sub> between 7.5 & 10% -managed with diet and/or oralhypoglycaemic agents alone. -45-70yrs -participation in diabetes education within previous 2yrs <b>Exclusion Criteria:</b> -incapable of maintaining an eating diary or documenting state of wellbeing. -sensomotor disturbances -used regular SMBG during 6mths prior to study -participated in previous clinical study within 30days before study. -women who were pregnant, lactating or without safe contraceptive method. -treatment with other antidiabetic agents such as insulin, non-selective b-blockers, glucocorticoids, amphetamines, or anabolic agents. -diet reduction during course of study (<1,000 Kcal/day) -serum creatinine> 3mg/dl-serum transaminases>50 units/l -serious underlying medical or psychiatric disorders or drug or alcohol abuse. -use of acarbose <b>Mean age: (yrs)</b> SMBG: 58.7 ± 7.6 Control: 60.5 ± 6.6 Male/Female SMBG: 47.8/52.2% Control: 48.2/51.8% Diabetes duration: (mths) SMBG: 65.5 ± 57.2 Control: 62.6 ± 47.3 Baseline HbA <sub>1c</sub> SMBG: 8.47±0.86 Control: 8.35±0.75	<b>Control:</b> (n=110) - non-standardised counseling focused on diet and lifestyle  <b>Intervention:</b> (n=113) -structured counselling focused on self-perception, reflection and regulation, eating diary - SMBG 6x per day on 2 days per week. -recordings of blood glucose data, eating habits and state of wellbeing entered in diary. - blood glucose meter testing continued during follow-up period.  6mths trial with 6mths follow up	HbA <sub>1c</sub> Weight Lipid and microalbumin Well-being and treatment satisfaction, by the Patient Well-being Questionnaire and the Diabetes Treatment Satisfaction Questionnaire.	1. Final HbA <sub>1c</sub> : SMBG: 7.47±1.27. Control 7.81±1.52 (p=0.0086) 2. Average change SMBG -1.0 ± 1.08. Control -0.54±1.41 3. There was a statistically significant difference between the groups.	1. Body weight, total cholesterol and microalbumin improved in the SMBG group but no significant difference between the two groups was found. 2. All items of the Patient Well-being Questionnaire improved in SMBG group with statistically significant improvement in depression (p=. 032) and lack of well-being (p= .02)	Jansen McAndrew McGeoch Sarol Welschen

Author	Methods	Population	Interventions	Outcome measures	Main Results (HbA <sub>1c</sub> , FBG)	Other findings	SRs using article
Farmer, 2009	Design: An open, parallel group randomised controlled trial.	Setting: 24 general practices in Oxfordshire and 24 in South Yorkshire, UK. Participants: Patients with non-insulin-treated type 2 diabetes, aged $\geq 25$ years and with glycosylated haemoglobin (HbA <sub>1c</sub> ) $\geq 6.2\%$ .	Interventions: A total of 453 patients were individually randomised to one of: (1) standardised usual care with 3-monthly HbA <sub>1c</sub> (control, n = 152); (2) blood glucose self-testing with patient training focused on clinician interpretation of results in addition to usual care (less intensive self-monitoring, n = 150); (3) SMBG with additional training of patients in interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle (more intensive self-monitoring, n = 151)	The primary outcome was HbA <sub>1c</sub> at 12 months, and an intention-to-treat analysis, including all patients, was undertaken. Blood pressure, lipids, episodes of hypoglycaemia and quality of life, measured with the EuroQol 5 dimensions (EQ-5D), were secondary measures.	The differences in 12-month HbA <sub>1c</sub> between the three groups (adjusted for baseline HbA <sub>1c</sub> ) were not statistically significant ( $p = 0.12$ ).  The difference in unadjusted mean change in HbA <sub>1c</sub> from baseline to 12 months between the control and less intensive self-monitoring groups was $-0.14\%$ [95% confidence interval (CI) $-0.35$ to $0.07$ ] and between the control and more intensive self-monitoring groups was $-0.17\%$ (95% CI $-0.37$ to $0.03$ ).  There was no evidence of a significantly different impact of self-monitoring on glycaemic control when comparing subgroups of patients defined by duration of diabetes, therapy, diabetes related complications and EQ-5D score.	The economic analysis suggested that SMBG resulted in extra healthcare costs and was unlikely to be cost-effective if used routinely.  There appeared to be an initial negative impact of SMBG on quality of life measured on the EQ-5D, and the potential additional lifetime gains in quality-adjusted life-years, resulting from the lower levels of risk factors achieved at the end of trial followup, were outweighed by these initial impacts for both SMBG groups compared with control.	None

Pignone, 2009	RCT	Participants included 184 adults with newly diagnosed type 2 diabetes who were not taking insulin	<p>A structured educational program alone or a structured educational program plus additional training and advice about self-monitoring of blood glucose (SMBG).</p> <p>All participants received follow-up visits every 3 months with predefined treatment algorithms based on A1C level.</p> <p>Patients in the SMBG group were asked to complete four fasting and four postprandial measures per week and were given advice about what to do in response to high SMBG readings.</p>	<p>Adherence to SMBG</p> <p>HbA1c</p> <p>Rate of hypoglycaemia</p>	<p>Adherence to SMBG was good: 66% of participants in the SMBG group completed &gt; 80% of requested measures.</p> <p>No differences between groups were observed in A1C at 12 months (6.9% in each group; mean difference 0.07%; 95% confidence interval -0.25 to 0.38) or in the incidence of hypoglycemia.</p>	Those in the SMBG group had somewhat higher scores on the depression subscale of a well-being questionnaire.	None
Polonsky, 2010	12-month, prospective, cluster, randomized, multicenter study	483 poorly controlled (HbA1c >7.5%), insulin-naïve, type 2 diabetic subjects from 34 primary care practices in the U.S.	<p>Practices were randomized to an active control group (ACG) with enhanced usual care or a structured testing group (STG) with enhanced usual care and at least quarterly use of structured self-monitoring of blood glucose (SMBG).</p> <p>STG patients and physicians were trained to use a paper tool to collect/interpret 7-point glucose profiles over 3 consecutive days. The primary end point was HbA1c level measured at 12 months.</p>	HbA <sup>1</sup> c at 12 months	<p>The 12-month intent-to-treat analysis (ACG, n = 227; STG, n = 256) showed significantly greater reductions in mean (SE) A1C in the STG compared with the ACG: 21.2% (0.09) vs. 20.9% (0.10); D = 20.3%; P = 0.04.</p> <p>Per protocol analysis (ACG, n = 161; STG, n = 130) showed even greater mean (SE) A1C reductions in the STG compared with the ACG: 21.3% (0.11) vs. 20.8% (0.11); D = 20.5%; P = 0.003.</p>	<p>Significantly more STG patients received a treatment change recommendation at the month 1 visit compared with ACG patients, regardless of the patient's initial baseline A1C level: 179 (75.5%) vs. 61 (28.0%);,0.0001</p> <p>Both STG and ACG patients displayed significant (P , 0.0001) improvements in general well-being (GWB).</p>	None

## **Appendix IX: Excluded Qualitative Studies (appropriateness and meaningfulness)**

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## Appendix X: Included Qualitative Studies

Study	Purpose	Participants	Methods	Analysis	Findings and conclusion
Abbott <i>et al.</i> 2004	To explore the reasons why nurses working in the community recommend SMBG to their patients.	7 community nurses caring primarily for housebound patients	Semi-structured qualitative interviews by primary care nurses acting as researchers	Thematic analysis (4 researchers worked together)	<ul style="list-style-type: none"> <li>The participants believed that SMBG was superior to urine testing.</li> <li>The participants had a general assumption that SMBG should be encouraged.</li> <li>There was no indication that patients had an active role in decision-making.</li> <li>There were patient limitations to the appropriate use of SMBG such as poor eyesight.</li> <li>Most patients do not take active role in responding to the readings such as modification of diet or exercise.</li> <li>The participants felt that it was important to respect the patients' choice (SMBG or urine testing, type of glucose meters, SMBG or no-SMBG)</li> </ul>
Benavides-Vaello <i>et al.</i> , 2004	To illustrate the successful use of focus groups in evaluating diabetes education intervention for Mexican Americans in a south Texas border community.	40 individuals type 2 Mostly female Mexican Americans in a south Texas boarder community.	6 focus group sessions in 2 counties (Starr County and Hidalgo County) by the trained moderator, assistant moderator and an expert in focus group administration (the moderator and transcriber were native Spanish speaker)	Content analysis method	<p><i>Starr County</i></p> <ul style="list-style-type: none"> <li>The participants were confident with their abilities to manage their diabetes and take control of their health.</li> <li>Other emerged themes were: maintenance, barriers, familial support, self-awareness and folk remedies.</li> </ul> <p><i>Hidalgo County (lack of formal diabetes education in the area)</i></p> <ul style="list-style-type: none"> <li>The participants' knowledge and skills in self-management was limited.</li> <li>Other themes were: confusion, fear, distrust of healthcare providers, reliance on folk remedies, varying motivation, persistence of hunger, barriers to diabetes management, and the overriding theme of lack of self-confidence in managing diabetes.</li> <li>Results support the importance of diabetes educational intervention to facilitate self-management.</li> </ul>

Study	Purpose	Participants	Methods	Analysis	Findings and conclusion
Burke <i>et al</i> , 2006	To examine the patients' perspectives for medical interviews in order to determine how physicians could improve the health care outcomes of patients with diabetes.	8 participants with diabetes who were recruited from urban-suburban family practice clinic in a large city in northwest Ohio Ohio, US	2 focus group interviews (4 participants each)	Grounded theory	Six themes emerged: 1. The participants experienced many complications and comorbidities which affected their practice of self-care. 2. Time is seen as a valued resource that is inexorably consumed by having diabetes. 3. Achieving control in glycaemic or metabolic status and self-control was a major concern. 4. The need for reliable information to manage their illness was emphasised. 5. The participants most often expressed how their family supported or hindered their dietary management. 6. Physician behaviours largely influenced the patients' satisfaction with their medical appointments.
Davis <i>et al</i> , 2007	To describe ways in which community health workers (CHW) are used in various clinic and community settings to support diabetes self-management.	1859 CHWs from a US national program to improve the QOL of people with diabetes. <i>Qualitative part:</i> 47 Hispanic adults with type 2 diabetes who had received service by CHW.  Missouri, US	Quantitative and qualitative mixed method  <i>Quantitative part:</i> descriptive method using the data from CHW's worker logs semi-structured interviews	descriptive statistics and thematic analysis	1. Providing assistance and teaching or practicing skill to patients were the most common objectives of individual visit. 2. Providing encouragement/motivation to the patients was the most reported service CHW offered. 3. The participants (patients) largely shared the view that CHWs were helpful in demonstrating how to incorporate diabetes self-management into their daily lives. 4. Openness to individual problem was widely appreciated.
Hill-Briggs, <i>et al</i> , 2003	To explore and compare diabetes-related problem solving in urban African Americans in good and poor glycaemic control.	15 participants with diabetes (7 in poor control, 8 in good control)	2 focus groups (a good control group and a poor control group)	1) Focus group data analysis method by Kruger 2) Coding using QSR NUDIST Vivo 3) Review by expert panel	1. Similar type of primary problems with diabetes self-management were found in both groups. 2. A good control group expressed a positive orientation toward diabetes self-management and problem solving, a rational problem-solving process, and a positive transfer of past experience. 3. A poor control group expressed a negative orientation, careless and avoidant problem-solving processes, and negative transfer of past learning to new situations.

Study	Purpose	Participants	Methods	Analysis	Findings and conclusion
Holmstrom <i>et al</i> , 2005	To describe the misunderstandings that Swedish patients with type 2 diabetes have about their illness and treatment.	18 participants with type 2 diabetes Sweden	1. 18 authentic encounters between a patient with diabetes and physician, or a diabetes nurse were video-taped. 2. Patients' reflection	Phenomenology (thematic analysis)	Misunderstanding of diabetes and treatment were common. Five themes were emerged: 1. Type 2 diabetes was understood as not real diabetes in contrast to type 1- a real diabetes. 2. The fear of complications of diabetes was constantly threatening the participants. 3. SMBG and medication was perceived as a routine, not a learning tool. 4. Misunderstanding in diet was commonly identified. 5. Understanding of the benefit of physical exercise was superficial.
Jeanfreau 2005	To describe the basic social psychological processes experienced during 11 adults' transitions toward self-management of type 2 diabetes.	11 participants with type 2 diabetes Louisiana, US	Grounded theory	Grounded theory (constant comparison, cross-case analysis, use of time, metaphor, narrative analysis)	1. The diagnosis of type 2 diabetes strongly impacts the person's life. 2. People with type 2 diabetes undergo multiple transitions that must be processed and resolved through the establishment of a sense of renewal and the disengagement from perceived losses. 3. Development of the Diabetic self occurs. 4. People with diabetes can benefit from having contact with other people with the same diagnosis. 5. Adherence ambivalence, mixed feelings regarding the extent to which they should alter their life-style.
Lawton <i>et al</i> , 2004	To explore the respective merits of urine testing and SMBG from the perspectives of newly diagnosed patients with type 2 diabetes.	40 participants with type 2 diabetes no-insulin treated Scotland	Grounded theory (In-depth interviews)	Grounded theory (constant comparison, concurrent data collection and analysis)	1. Participants largely expressed negative views of urine testing when it was compared with SMBG. 2. It was largely assumed that SMBG meter were given to those with people with more serious diabetes. 3. Participants expressed that SMBG was easier to use. 4. For SMBG users, low reading was understood as indicating successful self-management. 5. For some urine testing users, low reading was misunderstood as cure of diabetes or misdiagnosis by their physicians.

Study	Purpose	Participants	Methods	Analysis	Findings and conclusion
Peel <i>et al</i> , 2007	To explore views of patients with type 2 diabetes about SMBG.	18 participants with type 2 diabetes Scotland	In-depth interviews	Thematic analysis	1. The relationship with GP, diabetes nurses, and diabetologists had strong impact on the participants' self-monitoring. 2. Interpreting readings was problematic for some participants. 3. Health care professionals' lack of interest in SMBG readings was a cause of discontinuity of SMBG in some cases.
Peel <i>et al</i> , 2004	To explore the pros and cons of glucose monitoring from the patients' perspectives.	40 participants with type 2 diabetes  Scotland	Qualitative repeat-interview study	Thematic analysis (Grounded theory)	1. SMBG heightened participants' awareness of the impact of lifestyle. 2. SMBG amplified a sense of success or failure about self-management. 3. High readings often resulted in anxiety and self-blame. 4. Counter-intuitive readings could have negative affect on participants' self-management.
<b>NEW STUDIES</b>					
Hawthorne, 2011	To determine if culturally appropriate health education is more effective than 'usual' health education for people with diabetes from ethnic minority groups living in high- and upper-middle-income countries.	A systematic review with meta-analysis, following the methodology of the Cochrane Collaboration. Electronic literature searches of nine databases were made, with hand searching of three journals and 16 author contacts.  The criteria for inclusion into the analysis were randomized controlled trials of a specified diabetes health education intervention, and a named ethnic minority group with type 2 diabetes.	Systematic review	Meta-analysis	Culturally appropriate health education was more effective than 'usual' health education in improving HbA1c and knowledge in the short to medium term.  Few studies fitted the selection criteria, and were heterogeneous in methodologies and outcome measures, making meta-analysis difficult. HbA1c showed an improvement at 3 months [weighted mean difference (WMD)]0.32%, 95% confidence interval (CI) )0.63, )0.01] and 6 months post intervention (WMD )0.60%, 95% CI )0.85, )0.35).  Knowledge scores also improved in the intervention groups at 6 months (standardized mean difference 0.46, 95% CI 0.27, 0.65). There was only one longer-term follow-up study, and one formal cost-effectiveness analysis.

Study	Purpose	Participants	Methods	Analysis	Findings and conclusion
Rothman, 2004	Examining the role of literacy in patients with poorly controlled diabetes who were participating in a diabetes management program that included low-literacy-oriented interventions.	159 patients with type 2 diabetes and poor glycaemic control (hemoglobin A1c [A1C] $\geq 8.0\%$ ).	A before-after analysis of a pharmacist-led diabetes management program	Literacy was measured by the Rapid Estimate of Adult Literacy in Medicine (REALM) test and dichotomized at the 6th-grade level.  The A1C values were collected prior to enrollment, at enrollment, and approximately 6 months after enrollment.	Of the 111 patients with follow-up data, 55% had literacy levels at the 6th-grade level or below.  Lower literacy was more common among African Americans, older patients, and patients who required medication assistance.
Upchurch, 2009	Does culturally appropriate health education improve outcomes in members of ethnic minority groups with type 2 diabetes mellitus?	Studies selected compared a culturally appropriate health education intervention with conventional health education in patients with type 2 diabetes who were members of an ethnic minority community living in high-income countries.	Systematic review	Outcomes: Hba1c at 3 and 6 months  Diabetes knowledge	Culturally appropriate educational interventions improved HbA1c concentrations at 3 and 6 months after the start of the intervention but not at 12 months  Patients receiving culturally appropriate interventions had better knowledge of diabetes and healthy lifestyle (7 RCTs, n=882).
White, 2010	Developing a validated numeracy measure for diabetes educators to use for people with type 2 diabetes	A narrative review of the work done to develop the DLNET numeracy tool	Not applicable	Not applicable	Significant deficits in health literacy common amongst patients with Type 2 diabetes. Instruments such as DLNET can be useful tools for diabetes educators to use for assessment of numeracy skills that are key to appropriate diabetes self management.

Study	Purpose	Participants	Methods	Analysis	Findings and conclusion
Sturt 2010	To establish UK validity and reliability of the diabetes management self-efficacy scale (DMSES).	175 participants who were adults with type 2 diabetes enrolled in a randomised controlled trial (RCT) of the diabetes manual, a self-management education intervention, with an HbA1c over 7% and who understood English.	Consultation with people with type 2 diabetes and health professionals established UK content and face validity resulting in item reduction to 15 from 20 items.	Comparison of baseline versus follow-up questionnaire scores	<p>A total of 175 participants completed all 15 items. Pearson's correlation coefficient of 20.46 (P,0.0001) between the DMSES UK and the problem areas in diabetes scale demonstrated criterion validity. Intra-class correlation between data from 67 of these participants was 0.77, demonstrating test-retest reliability.</p> <p>The correlation coefficients between item scores and total scores were .0.30. Cronbach's alpha was 0.89 over all items</p> <p>The 15 item DMSES UK is suitable for use in research and clinical settings to measure the self efficacy of people living with type 2 diabetes in managing their diabetes.</p>

## Appendix XI: JBI Grades of Recommendation

In 2007 these grades of recommendation were adopted for evidence of Feasibility, Appropriateness, Meaningfulness and Effectiveness (FAME).

Grade of Recommendation	
A	Strong support that merits application
B	Moderate support that warrants consideration of application
C	Not supported



## Appendix XII: Quotations and Extracts Informing the Original Meta-Synthesis

### Synthesised finding 1

[Experience of the use of SMBG is an empowering process that can foster positive and active attitudes toward disease and self-management in everyday life.](#)

The key findings of included studies in the meta-synthesis and illustrations to support those findings were:

#### ***Category 1. SMBG facilitates peoples' understanding of their own life with diabetes.***

##### *Finding 1. SMBG helps people to accept the diagnosis of diabetes. (C)*

It had obviously crept up from when I started taking readings. But it got to a point where I felt, y'know, it was high both in the morning and in the evening. So that's when I took it up with the doctor.(p.495) (31)

##### *Finding 2. SMBG is both a useful and convenient tool to check ones' glycaemic control.*

SMBG is really nice and quick. (p.1047) (32)

(With urine testing) you've got to go to a toilet, and if you go to a toilet, it's usually too small or too whatever you know what I mean. The little meter (blood sugar meter), you just take it out and that's you, there's no problem. (p.1047) (32)

##### *Finding 3. SMBG provides people with an objective/clear status of their glycaemic control*

....."Well, I would rather have that so's I know exactly what's going on." And I do find it reassuring that when you do your check you can see right away what's registering and that. (p.496) (31)

**Category 2. SMBG provides people with reassurance concerning successful self-management of diabetes**

*Finding 1. A low reading is perceived as an indication of successful disease management.*

(I am)....quite pleased I think if I get a low reading 'cos I'm obviously doing something right."  
(p.185) (33)

I'm obviously doing something right. (p.1047) (32)

*Finding 2. SMBG provides peace of mind.*

It's just sort of comforting to know that it's not going high and it's at the level where it won't cause any complications that's the biggest thing I think....I find it reassuring.(p,185) (31)

**Category 3. SMBG raises positive consciousness towards self-management.**

*Finding 1. People can modify their diet depending on the readings.*

I guess the first thing relevant to diabetes is I do my blood sugar before breakfast. Then I eat breakfast and I eat more or less a standard breakfast....And then, unless something awful happens, the next event is lunch.....And then I eat a sensible lunch...evening comes and I again measure my blood sugar and eat sensible (healthy) supper. (p.131) (30)

*Finding 2. People search for a rational cause for every reading such as food intake prior to the reading.*

Some mornings it would be great, other mornings it would be awful. Sometimes at lunch times it was (sigh) you'd think, "What have I had? Oh I had a digestive biscuit, maybe that was it." But they say you can eat digestive biscuits, you know. So you bla-try to think, "What on earth's caused it?.....You think, "well, I've not done that so it shouldnae be high," y'know. And then if you have eaten something and you are high you though, "Well hell bloody mend you, you shouldnae have eaten that. (p.496) (31)

*Finding 3. Self-management of diabetes can become a part of normal life and normal self-image.*

I check my blood sugar. I take seriously the need to count carbohydrates-I don't always do it, but I know it needs to be done...I don't think of diabetes as something separate that I have to deal with; it is simply the way life is.... (p.131) (30)

## Synthesised finding 2

[People using SMBG weight glycaemic control against perceived life needs.](#)

### **Category 1. Belief impacts on adherence.**

#### *Finding 1. Questioning the need for regular and frequent use of SMBG.*

I stopped about a year ago because I was getting to the stage I was getting the same sort of levels every day....it wasn't sort of fluctuating up and down. (p.496) (31)

#### *Finding 2. Negative meanings attached to SMBG*

(Blood glucose meters were given to people who were) a higher level of diabetic. (p.1047) (32)

(My diabetes is) not serious enough (to use SMBG). (p.1047) (32)

#### *Finding 3. Being sceptical about the accuracy of SMBG*

Yes, stopped totally because, whereas I thought I was doing quite well, and when he (diabetologist) said to me I wasn't, I thought, "Well, that's pointless using that machine." Maybe lulling myself into a false sense of security. (p. 495) (31)

Yes, then I thought, "Well, I've no medical knowledge so." But sometimes I did think, "That's a bit unfair, I've been really good. (p.496) (31)

#### *Finding 4. Personal preference to use urine testing rather than SMBG*

There are a few people that I have been to who have urine sticks. But that is very much their own business, and I don't get involved. (p.10) (34)

### **Category 2. Poor control indicates learning needs and behavioural changes.**

#### *Finding 1. Knowledge and skills deficiency*

(I struggle to)....work that darned thing, that machine. ( p.185) (33)

One client was documenting 'error' every time meter said error...no one had explained this meant error with machine/strip. Sometimes people stick rigidly to what they think has been said to them, but that isn't what was meant. The patient is at fault in misunderstanding information. (p.9) (34)

I didn't know how to check my blood sugar, and they (Community Health Workers) showed me. Also how to calibrate the machine. (p.214) (35)

*Finding 2. Feelings of self-blame, disappointment, anger and other negative emotional reactions to high readings*

It's telling me I'm being bad maybe or not keeping-not being strict enough-and I think, "Oh, I ain't using you today," or whatever. I think that's why I don't use it. (p.496) (31)

(I was)...letting it (SMBG) rule me. (p.186) (33)

If I feel I don't want to do it (SMBG), I just don't do it.... (p.1024) (36)

*Finding 3. Lack of understanding the value and purpose of SMBG and diabetes self-management*

I do not know the value of that...I cannot say anything about it really. What I could use it for I do not know. I do what they tell me to. (p.150) (37)

I did gather the impression that they didn't really bother too much with the day to day results.....they certainly didn't sort of, ask, for these. In fact, when I did-if I told them about it they were inclined to say, "Oh it varies very much depending on whether you've had a cup of tea or biscuit or whatever," At least, I got that impression, and it seemed to me that it---maybe wasn't worth keeping an eye on all of this." (p.494) (31)

Four checks in the week, I do. But I write it down, and that's as far as it goes. (p.495) (31)

**Category 3. Prioritisation of life needs.**

*Finding 1. Physical barriers*

They got me a glucometer....but I had so much trouble...ya gotta get the blood right down on one particular spot. And I couldn't see it good enough, and I'd always get blood all over everything. And I'd get four or five of those strips in there and still wouldn't get an answer. (p.107) (38)

I have only five fingers and they're all sort of pricked useless." (p,186) (33)

*Finding 3. Financial strain*

I check myself every now and then because the strips are expensive. (p.248)(38)

I have the bill (for lancets) to pay as soon as my cheque arrives. (p.248)(38)

## **Appendix XIII: Additional Detail on Trials Included in the Original Report**

### **Description of interventions from the existing trials**

The trials included in the meta analysis included a range of interventions, were based on populations with elevated HbA1c values and used a variety of comparator methods of monitoring. While the meta analysis did not show statistical heterogeneity, there is often a lack of detail in systematic review reports on the specific interventions that are included. These have been extracted from the included studies and are reported below and focus on describing the types of interventions that included SMBG in the experimental or interventional arm of the study. Where available, details on the control intervention and nature of follow up have also been provided, however, it should be noted that reporting of such data, particularly control group data is not always sufficiently described as to enable detailed write up.

#### **Farmer, 2007 (28)**

The objective of this three arm, open trial was to investigate the impact of SMBG among non insulin treated participants with type 2 diabetes, the primary outcome was HbA1c, measured at 12 months.(28)

Standard usual care consisted of measurement of HbA1c by a health professional every 3 months. Participants in this group used a diary to record their self-care goals and strategies and were asked to not SMBG unless specifically advised by their GP. This group had their HbA1c level taken two weeks prior to their scheduled GP review, and were given feedback on their glycaemic control.

The second arm used a blood glucose meter and was advised to contact their GP for interpretation of the results. These participants also used goal setting and review methods from their first assessment. Additionally, they conducted SMBG three times per day on two days each week for the duration of the study. These were both pre and post-prandial. Their goal setting included targets of 4-6mmol/L pre-prandial and 6-8mmol/L post-prandial. Readings outside the range of 4-15mmol/L were a trigger for contacting their GP. Follow up for participants in this arm and the third arm included review of SMBG results and feedback on their level of control.

The participants in the third arm received training on the conduct and interpretation of SMBG results, and application to self managed changes in diet, physical activity, and medication adherence. This more intensive group used goal setting as a means of increasing motivation to maintain adherence with diet, physical activity, and medication regimens. Additionally, this group was encouraged to experiment with monitoring outside prescribed times and frequencies to learn how exercise and dietary patterns could

influence their glycaemic control. Further to this information, the authors have published a separate description of the interventions offered.(39)

#### **Allen, 1990 (24)**

The objective of this dual arm, randomised trial was to compare the efficacy and cost of self-monitoring against routine urine testing for participants with type 2 diabetes not being treated with insulin over a period of six months.(24) All participants in the trial were given education and advice on diet titrated to their ideal body weight and activity level, with a focus on increased fibre intake. The urine-monitoring group were expected to conduct up to 36 episodes of monitoring per month. The test instruction was for single-voided urine samples prior to each meal every second day, with the aim of achieving negative urine checks.

The SMBG group were also required to conduct 36 checks per month, undertake monitoring as prescribed, prior to each meal every second day and aim to achieve a AMBG result of <7.7mmol/L fasting or <8.8mmol/L prior to lunch or dinner. Follow up across both groups was by the individual's GP, and adherence was tested by observation of SMBG technique and ability to identify appropriate actions based on the responses via regular monthly visits.(24)

#### **O'Kane, 2008 (29)**

This prospective trial sought to establish the effectiveness of SMBG compared with no SMBG over a 12 month timeframe.(29) Participants in the SMBG group were required to conduct four fasting and four postprandial tests per week and were advised (by who is not clear) on how to manage their diet, and exercise based on whether the results were high or low. Adherence was measured by verification of SMBG readings from the monitor at clinic visits. Participants in the control group (no SMBG) were not required to perform any monitoring for the duration of the study.

Both groups received the same structured education program conducted by diabetes nurse practitioners, dietitians, podiatrists and medical staff. The multi disciplinary team reviewed both groups at three monthly intervals. The only difference in treatment algorithm between groups was that the monitoring group also received ongoing advice and support in the interpretation and management of their regular monitoring results.(29)

#### **Rutten, 1990 (40)**

This trial explored the effectiveness of protocol based blood glucose self-monitoring within the context of general practice over a 12-month time frame.(40)

The unit of randomisation was general practice clinics rather than individual people with type 2 diabetes, those in experimental settings were given a protocol that emphasised home monitoring at self selected times of the day, and to provide monthly feedback to the clinic on their fasting blood glucose. They were also given a program that emphasised weight reduction and management of oral hypoglycaemic agents. Participants were advised to only contact their GP if blood glucose was inadequately balanced. The educational preparation for this study arm was repeated between 2-5 times.

The control group continued with their usual care pattern and consulted their regular GP or specialist at least four times per year and more frequently as required.

### **Guerci, 2003 (20)**

This 6 month trial examined changes in glycaemic control when using SMBG compared with usual care.(20) The experimental group received specific training and were required to perform six tests per week, this training was conducted by the GP at the time of study enrolment. Participants were followed up every 6 weeks throughout the 24 week study. Visits were used by the participant's GP to titrate management to keep HbA1c within a specified range and to discuss glycaemic control, weight loss and exercise

### **Schwedes, 2002 (21)**

This prospective multi centre study compared use of SMBG at meal times with usual care that did not include SMBG.(21) The experimental group was required to measure their capillary blood glucose prior to and one hour after main meals two days per week, to maintain a diary of glycaemic control and dietary habits. Participants in the experimental group were reviewed every four weeks and given counseling to evaluate their self perception, self reflection and self regulation. Blood glucose monitoring technique was also checked by the practice nurse at these visits.

The control group received non-standardised counseling with an emphasis on diet and lifestyle choices. It was not clear whether the control group were required to keep a diary of any sort.(21)

### **Fontbonne, 1989 (22)**

This three armed trial examined changes in metabolic control over 6 months across three endocrine clinics in France.(22) In Group A, participants were assigned to General Practitioner assessment of HbA1c every second month, with written feedback to the participant from their GP; in Group B, participants undertook self-urine glucose measurement twice every second day, on first morning void, and on the first void following the evening meal and an additional test on first void following Sunday

lunch, and in Group C participants undertook self blood glucose monitoring twice every second day, once fasting and two hours after the evening meal, with an additional test two hours after Sunday lunch.

On randomisation, baseline data including HbA1c was collected for each participant, additionally personal dietary recommendations were given, but no specific behavioural strategies were offered. On follow up (each two months for the duration of the trial), weight and HbA1c was again measured, and number of reactive strips used since previous visit was recorded. Dietary adjustments were also discussed between participant and GP on an individual basis, these conversations were limited to the scope of data collected during the trial to avoid contamination.(22)

### **Davidson, 2005 (19)**

This 6 month trial sought to establish the effects of self-monitoring blood glucose on HbA1c levels, with an emphasis on post prandial measurements of capillary glucose levels by participants in the experimental arm of the trial.(19) Participants in both groups met with a dietitian five times throughout the study to discuss nutritional goals and receive education and counseling related to dietary based glycaemic control. A nurse (blinded to allocation) also provided regular review and used a treatment algorithm to guide therapeutic decisions. Participants in the monitoring group were requested (and adherence was checked) to monitor their blood glucose levels prior to meals, and between 1-2 hours after meals six days per week, with equal spread across the three main meals. The study did not include any further details on either the experimental or control group interventions.(19)

### **Muchmore, 1994 (23)**

This small trial sought to establish whether the combination of carbohydrate counting and SMBG would benefit overweight people.(23) Both groups received the same intervention for the first 8 weeks, consisting of a 90 minute, facilitated weekly meeting to undertake a formal weight loss program and individual counseling by a diabetes nurse educator and a nutritionist. Following week eight, the intervention groups also received group and individual education on carbohydrate counting, while the control groups were allocated the same amount of time to general counseling related to nutritional management. The intervention groups were also taught SMBG technique by the diabetes nurse educator and were required to demonstrate competency prior to commencing testing six times daily for four weeks. After this four week period, the frequency of testing was reduced pre and post prandial once per day for 16 weeks, followed by individually determined testing frequencies up to 44 weeks. The control group received the same amount of time with health professionals, at each follow up point, but did not receive information on carbohydrate counting, although the guidance they were offered was based on current national guidelines at the time of publication.