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OPTIMAL THERAPY REPORT

COMPUS
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Systematic Review of Use of Blood Glucose Test Strips for the Management of Diabetes Mellitus

Supporting Informed Decisions

À l'appui des décisions éclairées

This report is prepared by the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), a service of the Canadian Agency for Drugs and Technologies in Health (CADTH). This report contains a comprehensive review of existing public literature, studies, materials, and other information and documentation (collectively the "source documentation") available to CADTH at the time it was prepared, and it was guided by expert input and advice throughout its preparation.

The information in this report is intended to help health care decision-makers, patients, health care professionals, health systems leaders and policy-makers make well-informed decisions and thereby improve the quality of health care services.

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Conflicts of Interest

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EXECUTIVE SUMMARY

The Issue

Despite widespread use, there is controversy regarding the benefits of self-monitoring of blood glucose (SMBG), especially in patients with type 2 diabetes who are not using insulin.[1-4] The optimum frequency of SMBG has not been defined for patients with either insulin-treated or non–insulin-treated diabetes.[5,6] Thus, a need exists for the identification of clinical evidence relating to the optimal use of SMBG in the management of patients with diabetes.

Objective

To identify and synthesize the available clinical evidence on the efficacy, safety, and optimal frequency of SMBG in patients with type 1, type 2, and gestational diabetes.

Methods

A systematic review of randomized controlled trials (RCTs) and observational studies comparing SMBG with no SMBG, or comparing different SMBG frequencies, was performed. Studies were identified through electronic databases, grey literature, reference lists, and stakeholder consultation. Meta-analyses were conducted to pool trial results, when appropriate.

Results

Patients with diabetes using insulin: In general, the COMPUS systematic review identified few studies that explored the optimal frequency of SMBG in patients with either type 1 diabetes, or insulin-treated type 2 diabetes. Moreover, the studies that were identified reported mixed results, and were of low quality. In patients with insulin-treated type 2 diabetes, low-quality evidence suggests that use of SMBG was associated with improvements in glycemic control.

Patients with diabetes not using insulin: The COMPUS systematic review elicited more robust studies for patients with non–insulin-treated type 2 diabetes, including several RCTs. Pooling of results from seven RCTs demonstrated that SMBG is associated with a statistically significant improvement in glycemic control (WMD in A1C [95% CI] =-0.25% [-0.36, -0.15]. Results were similar for the subset of RCTs that were of good quality, those in which all patients enrolled used oral antidiabetes drugs, and those that used intensive education. Performing SMBG was shown to be beneficial in reducing the number of symptomatic hypoglycemic events in patients using sulfonylureas in one RCT. For patients with type 2 diabetes not using diabetes pharmacotherapy, improvements in glycemic control were less pronounced and statistically non-significant (WMD in A1C [95% CI] = -0.05% [-0.33, 0.23]). In general, effect estimates for A1C improvement with SMBG reported in observational studies were higher than those reported in RCTs.

Gestational diabetes

The COMPUS systematic review identified two RCTs that compared the effects of SMBG versus no SMBG on various clinical outcomes in women with gestational diabetes. These data did not demonstrate statistically significant effects of SMBG on maternal, pregnancy, fetal, or neonatal outcomes. However, in women with gestational diabetes who had a one hour post-standardized breakfast blood glucose of ≥ 7.8 mmol/L, the incidence of babies born large for gestational age was significantly lower in patients using SMBG as compared to those not using SMBG (RR [95% CI] = 0.43 [0.2, 0.92]). The incidence of hyperbilirubinemia

(during the first three days of life) was also found to be significantly reduced in the SMBG group (RR [95% CI] = 0.51 [0.26, 0.99]).

Conclusion

Overall, the quality of the available evidence regarding SMBG varied, depending on the patient population. For patients using insulin or for those with gestational diabetes, this CADTH report did not identify any high-quality clinical evidence; consequently, results should be interpreted with caution. The available evidence for patients with non–insulin-treated diabetes was more robust.

Within the limitations of available evidence, this report concludes:

- Use of SMBG appears to be associated with improvements in glycemic control among patients with insulin-treated type 2 diabetes.
- Few studies compared different frequencies of SMBG for patients with either type 1 or insulin-treated type 2 diabetes, and the evidence from these studies was of low quality. Well-designed studies may prove beneficial in optimizing SMBG frequency for these individuals.
- Use of SMBG in patients with type 2 diabetes who are not using insulin is associated with a statistically significant, albeit clinically modest, improvement in glycemic control. Performing SMBG may reduce the number of symptomatic hypoglycemic events in patients using sulfonylureas. There was little or no evidence that SMBG provides other benefits, such as improved quality of life, or greater patient satisfaction. Longer-term studies are needed to determine whether or not SMBG reduces diabetes-related clinical endpoints (e.g., blindness, reduction in myocardial infarctions, end-stage renal disease) or mortality. Studies of specific subgroups within this population who may be more likely to benefit from SMBG are also warranted.
- The effect of using SMBG in women with gestational diabetes requires further investigation.

ABBREVIATIONS

A1C	glycosylated hemoglobin
ADOPT	A Diabetes Outcome Progression Trial
AMSTAR	a meaSurement tool to assess reviews
BMI	body mass index
CAC	COMPUS Advisory Committee
CADTH	Canadian Agency for Drugs and Technologies in Health
CI	confidence interval
COMPUS	Canadian Optimal Medication Prescribing and Utilization Service
DiGEM	Diabetes Glycaemic Education and Monitoring trial
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HRQoL	health-related quality of life
ICD-9	International Classification of Diseases, Ninth Revision
ICUR	incremental cost-utility ratio
NNT	number needed to treat
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomized controlled trial
RR	relative risk
SIGN	Scottish Intercollegiate Guidelines Network
SMBG	self-monitoring of blood glucose
WMD	weighted mean difference

GLOSSARY

A1C: A glycosylated form of hemoglobin, formed by the attachment of sugars to the hemoglobin molecule when glucose levels are elevated. A1C levels increase with the average concentration of glucose in the blood.

Absolute risk reduction: The difference in event rates between treatment and control groups. It is the inverse of the number needed to treat

AMSTAR: An instrument developed specifically to quantify the methodological quality of systematic reviews. AMSTAR scores ranges from 0 to 11 points. A score of 6 or more indicates good quality, and a score lower than 6 indicates poor quality.

Carry-over effect: The residual effect that occurs when the treatment given in the first period of a crossover clinical trial confounds the interpretation of results in the second period.

Case series: A descriptive observational study which reports the characteristics of a group or cluster of individuals with the same disease or symptoms. The aim is to quantify various aspects of the group and present a relatively complete profile of the disease or symptoms.

Case-control study: A retrospective observational study in which participants are selected according to outcome status before exposure status is determined.

Cohort study: A longitudinal observational study (prospective or retrospective) in which participants are selected according to exposure status (before the outcome is determined), followed over time, and the outcomes for each group compared.

Confidence interval: The interval in which a population parameter lies, based on a random sample of the population. The most commonly reported confidence interval is the 95% confidence interval.

Congestive heart failure: A condition in which abnormal cardiac structure or function is responsible for the inability of the heart to fill with or eject blood at a rate to meet the requirements of the metabolizing tissues.

Crossover trial: A type of randomized controlled trial in which the intervention is applied at different times to each subject; that is, after a specified period of time, the original experiment group becomes the control group, and the original control group becomes the experimental group.

Diabetes mellitus: A group of common metabolic disorders characterized by hyperglycemia and caused by insufficient insulin secretion, reduced insulin sensitivity of target tissues, or both.

Diabetic ketoacidosis: An acute complication of diabetes caused by increased fatty acid metabolism and the accumulation of ketoacids. It was formerly considered a hallmark of type 1 diabetes mellitus, but it also occurs in individuals who lack the immunologic features of type 1 diabetes mellitus and who can subsequently be treated with oral antidiabetes drugs (in type 2 diabetes mellitus).

Effectiveness: The extent to which an intervention, procedure, regimen, or service produces the intended outcomes when deployed under routine ("real world") circumstances.

Efficacy: The extent to which an intervention, procedure, regimen, or service produces a beneficial outcome under ideal circumstances (e.g., in an RCT).

Fasting plasma glucose: Plasma glucose level measured at least eight hours after caloric intake.

Funnel plots: A graphical method used to detect publication bias. Funnel plots are simple scatter plots where treatment effects estimated from individual studies are plotted on the horizontal axis against some measure of study size on the vertical axis.

Gestational diabetes mellitus: Defined as glucose intolerance with first onset during pregnancy; usually a temporary condition.

Health-related quality of life: A broad theoretical construct developed to explain and organize measures concerned with the evaluation of health status, attitudes, values, and perceived levels of satisfaction and general well-being regarding either specific health conditions or life as a whole from the perspective of the individual.

Heterogeneity (I^2): This statistic describes the degree of variation, as a percentage, between the results of individual studies within a meta-analysis.

Hyperglycemia: A qualitative term used to describe blood glucose that is above the normal range.

Hyperosmolar, hyperglycemic, non-ketotic coma: A syndrome consisting of extreme hyperglycemia, serum hyperosmolarity and dehydration in the absence of ketoacidosis. The American Diabetes Association suggests that this disorder be renamed hyperglycemic hyperosmolar state (HHS). The prototypical patient with HHS is an elderly individual with type 2 diabetes mellitus, with a several-week history of polyuria, weight loss, and diminished oral intake that culminates in mental confusion, lethargy, or coma.

Hypoglycemia: A qualitative term used to describe blood glucose that is below the normal range. Definitions vary across studies, although one or more of the following is usually required to define a hypoglycemic event: autonomic or neuroglycopenic symptoms characteristic of low blood glucose (e.g., trembling, sweating, hunger, confusion, weakness) that respond to carbohydrate intake, and/or a plasma glucose level below a specific value (threshold is usually between 3.4 mmol/L to 4.0 mmol/L).

Ischemic heart disease: Heart disease, due to inadequate blood perfusion of the myocardium, which causes an imbalance between oxygen supply and demand.

Large for gestational age: Birth weights equal to or greater than the 90th percentile for a given gestational age.

Less intensive education: Patients were trained on using a blood-glucose meter, but were not provided with instructions regarding self-interpretation and application of their SMBG results, or the educational components of the trial were not specified.

Long-acting insulin analogues: A class of insulin analogue produced by introducing alterations in the amino acid sequence of human insulin. They do not mimic basal endogenous insulin secretion; rather, they promote a prolonged, non-fluctuating basal level of insulin activity.

Macrosomia: Usually defined as a birth weight greater than 4.0 kg or 4.5 kg.

Meta-analysis: Statistical synthesis of the results of individual studies that examine the same question to produce a single estimate of effect.

More intensive education: Patients were provided with training in the self-interpretation and application of their SMBG results to facilitate dietary and lifestyle modifications.

Myocardial infarction: The death of a portion of heart muscle resulting from a sudden loss of blood supply due to occlusive coronary artery thrombus, atherosclerotic plaque, vasospasm, inadequate myocardial blood flow (e.g., hypotension), or excessive metabolic demand. Also called heart attack.

Nocturnal hypoglycemia: Hypoglycemic events that occur at night, usually from midnight to 6:00 a.m.

Number needed to treat: The number of patients who need to be treated with a new treatment rather than the standard (control) treatment in order for one additional patient to benefit. It is calculated as the inverse of the absolute risk reduction.

Overall hypoglycemia: Overall hypoglycemia is defined by either symptoms or signs of hypoglycemia and/or blood glucose less than 4 mmol/L.

Publication bias: Unrepresentative publication of research reports that is not due to the scientific quality of the research, but to other characteristics; e.g., tendencies of investigators to submit, and publishers to accept, positive research reports (i.e., ones with results showing a beneficial treatment effect of a new intervention) over negative research reports.

Quality-adjusted life-year (QALY): A health outcome measure that combines both quantity (mortality) and quality of life (morbidity). This measure enables comparisons across diseases and programs.

Randomized controlled trial: A prospective experimental study designed to test the efficacy of an intervention in which patients are randomly allocated to either a treatment group or the control group.

Rapid-acting insulin analogue: A class of insulin analogues produced by introducing alterations in the amino acid sequence of human insulin, which more closely mimics the short duration of the action of meal-induced endogenous insulin in non-diabetic patients than does regular human insulin.

Rate ratio: The ratio of the person-time incidence rate in the exposed group to the person-time incidence rate in the unexposed group in an epidemiological study.

Relative risk: The ratio of the absolute risk of a disease among the exposed group to the absolute risk of the disease among the unexposed group in an epidemiological study.

Severe hypoglycemia: An event with characteristic hypoglycemic symptoms requiring the assistance of another person.

SIGN 50: A quality assessment tool developed for the assessment of the methodological quality of randomized control trials and observational studies.

Small for gestational age: Generally defined as the birth weight less than the 90th percentile for a given gestational age.

Standard deviation: A measure of the variability or spread of the data.

Systematic review: A summary of the medical literature that uses explicit methods to identify, select, appraise, and analyze studies relevant to a particular clinical question.

Transient ischemic attack: Episodes of stroke symptoms that last only briefly.

Type 1 diabetes mellitus: Diabetes characterized by a lack of insulin secretion caused by pancreatic beta cell destruction. This form includes cases due to an autoimmune process and those for which the etiology of beta cell destruction is unknown.

Type 2 diabetes mellitus: Diabetes characterized by insulin resistance and varying degrees of insulin deficiency, especially as the diabetes progresses.

Utility: A quantitative expression of an individual's preference for a particular health state.

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1 INTRODUCTION

In March 2004, the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) was launched by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) — now the Canadian Agency for Drugs and Technologies in Health (CADTH) — as a service to federal, provincial, and territorial jurisdictions and other stakeholders. COMPUS is a nationally coordinated program, funded by Health Canada.

The goal of COMPUS is to optimize drug-related health outcomes and cost-effective use of drugs by identifying and promoting optimal drug prescribing and use. Where possible, COMPUS builds on existing applicable Canadian and international initiatives and research. COMPUS goals are achieved through three main approaches:

- identifying evidence-based optimal therapy in prescribing and use of specific drugs
- identifying gaps between evidence-based optimal therapy and clinical practice, then proposing evidence-based interventions to address these gaps
- supporting the implementation of these interventions.

Direction and advice are provided to COMPUS through various channels, including the following:

- the COMPUS Advisory Committee (CAC): includes representatives from the federal, provincial, and territorial health ministries and related health organizations
- the COMPUS Expert Review Committee (CERC): an advisory body that makes recommendations related to the identification, evaluation, and promotion of optimal drug prescribing and use in Canada
- stakeholder feedback.

1.1 COMPUS Expert Review Committee

The COMPUS Expert Review Committee (CERC) consists of eight Core Members appointed to serve for all topics under consideration during their term of office, and three or more Specialist Experts appointed to provide their expertise in recommending optimal therapy for one or more specific topics. For the insulin analogues and blood glucose test strips, four endocrinologists/diabetes specialists were appointed as Specialist Experts. Two of the Core Members are Public Members who bring a lay perspective to the committee. The remaining six Core Members hold qualifications as physicians, pharmacists, or health economists, or have other relevant qualifications, with expertise in one or more areas such as, but not limited to, family practice, internal medicine, institutional or community clinical pharmacy, pharmacoeconomics, clinical epidemiology, drug utilization expertise, methodology, affecting behaviour change (through health professional and/or patient and/or policy interventions), and critical appraisal. The Core Members, including Public Members, are appointed by the CADTH Board of Directors.

The mandate of CERC is advisory in nature and consists of providing recommendations and advice to CADTH's COMPUS Directorate on assigned topics that relate to the identification, evaluation, and promotion of optimal practices in the prescribing and use of drugs across Canada. The overall perspective used by CERC members in producing recommendations is that of public health care policy makers in pursuit of optimizing the health of Canadians within available health care system resources.

2 ISSUE

The COMPUS Advisory Committee (CAC) has identified management of diabetes mellitus as being a priority area for optimal practice initiatives, based on the following criteria:

- large deviations from optimal utilization (overuse or underuse)
- size of patient populations
- impact on health outcomes and cost-effectiveness
- potential to effect change
- benefit to multiple jurisdictions
- measurable outcomes.

Within diabetes mellitus management, optimal use of blood glucose test strips in patients with type 1, type 2, and gestational diabetes mellitus was identified by CAC as a priority topic.

Despite widespread use, there is controversy regarding the benefits of self-monitoring of blood glucose (SMBG), especially in patients with type 2 diabetes mellitus not using insulin.[1-4] Moreover, the optimum frequency of testing has not been defined in any population.[5,6] A need exists for the identification of clinical and economic evidence relating to the optimal prescribing and use of SMBG. Costs associated with SMBG are rising due to the increasing prevalence of diabetes in Canada and higher rates of self-monitoring.[7] In 2005/2006, the Nova Scotia Seniors' Pharmacare Program spent $4 million on blood glucose test strips, approximately 60% of which was spent on beneficiaries who were not using insulin agents.[8] In Saskatchewan, of the $6.5 million spent on diabetic testing supplies in 2001 (most of it on blood glucose test strips), approximately half was for people who were not using insulin agents.[9] Evidence relating to the optimal prescribing and use of SMBG may assist policy decision makers, consumers, and health care providers in making informed decisions for patients with type 1, type 2, and gestational diabetes mellitus.

2.1 Diabetes Mellitus

Diabetes mellitus is a chronic disease characterized by the body's inability to produce sufficient insulin and/or properly use insulin.[10] Type 1 diabetes mellitus occurs in approximately 10% of patients with diabetes, and it results when little or no insulin is produced by the body.[11] Type 2 diabetes mellitus is a metabolic disorder caused by varying degrees of insulin resistance; the body usually produces insulin, but is unable to use it properly.[12] When inadequately managed, diabetes is likely to result in poor glycemic control.[10] Impaired glycemic control, if prolonged, may result in diabetes-related complications (e.g., ischemic heart disease, stroke, blindness, end-stage renal disease, lower limb amputation).[13,14]

The global prevalence of diabetes is estimated to be 246 million and is projected to increase to 380 million by 2025.[15] In 2004/2005, approximately 1.8 million (5.5%) Canadians aged 20 years and older had diagnosed diabetes.[16] However, it is estimated that 2.8% of the general adult population has undiagnosed type 2 diabetes mellitus,[5] and the true prevalence of diabetes may approach 2.0 million.[17]

2.1.1 Management of blood glucose levels in diabetes mellitus

One goal of diabetes mellitus management is to maintain control of blood glucose levels in order to reduce the patient's risk of developing long-term diabetes-related complications. Lifestyle modifications (i.e., weight control, proper nutrition, and adequate exercise), the use of medications (e.g., insulin and oral antidiabetes drugs), and SMBG are recommended approaches in improving glycemic control.[5] This project focuses on the use and frequency of blood glucose testing by patients with diabetes.

2.1.2 Technology description — self-monitoring of blood glucose

The purpose of SMBG is to collect detailed information about glucose levels across various time points each day and take appropriate action should those levels be outside the desired range.[7,18] SMBG requires that patients prick their finger with a lancet device to obtain a small blood sample (0.3 µL to 5 µL).[7,18] The blood is applied to a reagent strip or blood glucose test strip, and glucose concentration is determined by inserting the blood-laden strip into a reflectance photometer, or an electrochemical sensor.[7] Results, based on an automated reading, are available from the photometer within five to 30 seconds.[7] The results can be stored in the glucose meter's electronic memory or recorded in the patient's logbook. It has been suggested that patients can adjust food intake, physical activity, and pharmacotherapy in response to their blood glucose readings and, thus, are better able to maintain optimal glycemic control on a day-to-day basis.[7,18]

3 OBJECTIVES

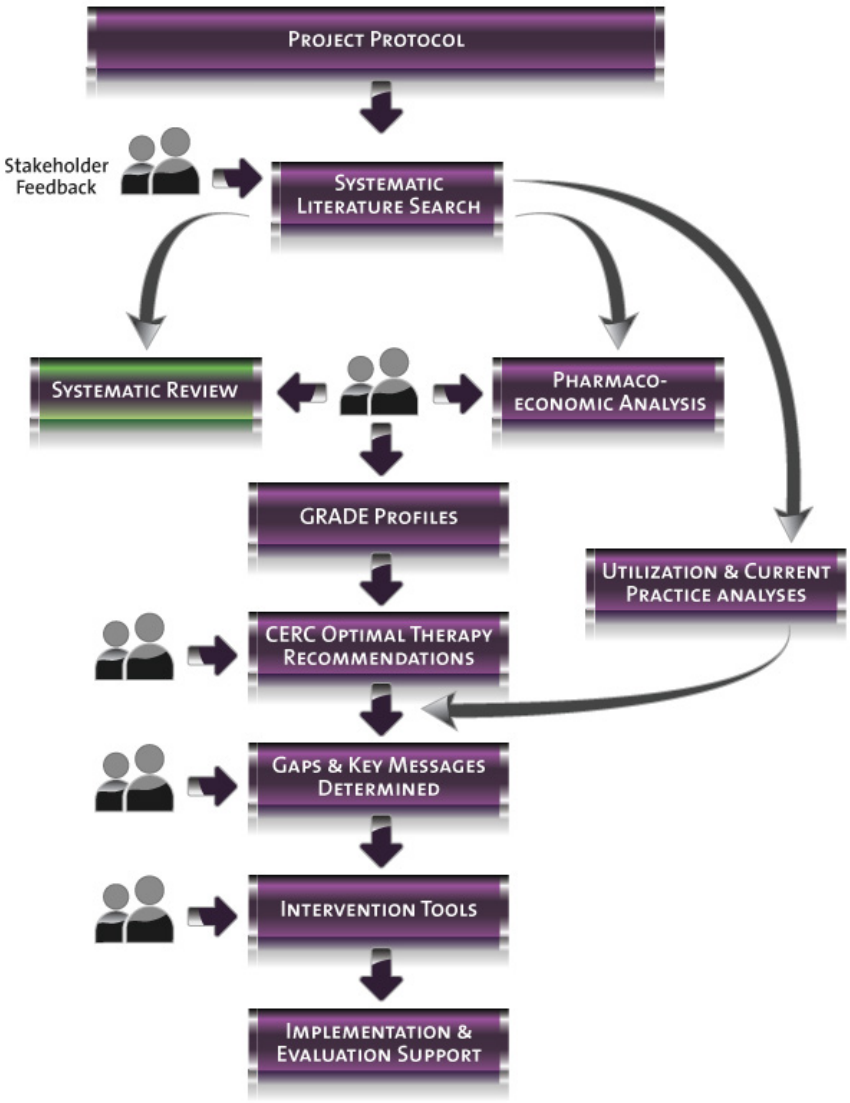
The objective of this study was to conduct a systematic review and meta-analysis of the clinical efficacy and safety of SMBG using blood glucose test strips in the treatment of type 1, type 2, and gestational diabetes.

4 PROJECT OVERVIEW

Once a topic is selected, COMPUS undertakes activities related to key areas in the COMPUS procedure. The CAC provides advice and guidance throughout the process, from topic identification through to supporting intervention and evaluation tools. CERC, as described in Section 1.1, provides expert advice and recommendations on the topic area relating to the identification, evaluation, and promotion of optimal prescribing and use of drugs. A broad range of stakeholders are invited to provide feedback at various stages in the COMPUS process.

To identify and promote the implementation of evidence-based and cost-effective optimal therapy in the use of blood glucose test strips, COMPUS follows the process outlined in the flow chart to the right.

This report represents the draft systematic review for stakeholder feedback (green box) toward the development of optimal therapy recommendations for the prescribing and use of blood glucose test strips.



5 RESEARCH QUESTIONS

5.1 Clinical

1. What effect does the practice of SMBG, compared to no SMBG, have on the outcomes listed in Section 5.2?
2. What is the relationship between the frequency of SMBG and the outcomes listed in Section 5.2?
3. What is the optimal frequency of testing?

For each research question, the following patient groups were examined:

- Patients with type 1 diabetes mellitus — including adults, adolescents, pre-adolescents, pregnant women
- Patients with type 2 diabetes mellitus —including adults, adolescents, pre-adolescents, pregnant women using:
  - insulin (with or without oral antidiabetes drugs)
  - oral antidiabetes drugs only
  - no pharmacotherapy for diabetes mellitus
- Women with gestational diabetes
- Subgroups of interest included the elderly, First Nations, ethnic minorities, and individuals for whom hypoglycemia may pose occupational risks (e.g., professional drivers, pilots, construction workers).

All research questions were developed with input from CERC.

5.2 Outcomes of Interest

Outcomes of interest for type 1 and type 2 diabetes were glycemic control (i.e., A1C, fasting plasma glucose, post-prandial plasma glucose); hypoglycemia (i.e., severe, nocturnal, and overall hypoglycemia); body weight; body mass index (BMI); diabetic ketoacidosis (in type 1 diabetes) or hyperosmolar, hyperglycemic, non-ketotic coma (in type 2 diabetes); generic and diabetes-specific health-related quality of life (HRQoL); patient satisfaction with diabetes care and treatment; patient self-management efficacy; resource utilization (i.e., number of visits to emergency room, primary care, specialists; hospitalizations); cost of treatment; and long-term diabetes complications (i.e., ischemic heart disease, congestive heart failure, stroke/transient-ischemic attack, nephropathy, retinopathy, neuropathy, peripheral vascular disease, mortality).

Outcomes of interest for gestational diabetes were glycemic control (A1C, fasting, and postprandial blood glucose), hypoglycemia (severe, nocturnal, and overall), quality of life and patient satisfaction, and maternal, pregnancy, fetal, and neonatal outcomes.

6 METHODS

Prior to initiating a systematic review of primary studies of SMBG, existing systematic reviews of this topic were identified through a literature search and appraised. Since none of the existing systematic reviews adequately met COMPUS' requirements regarding the populations, comparators, and outcomes of interest (Appendix 1), COMPUS conducted a systematic review of primary studies comparing either SMBG with no SMBG, or different frequencies of SMBG. This systematic review was conducted according to a protocol prepared a priori.[19]

6.1 Literature Search Strategy

The following bibliographic databases were searched through the Ovid interface: MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, BIOSIS Previews, CINAHL, and PsycINFO. Parallel searches were also run in The Cochrane Library and the Centre for Reviews and Dissemination (CRD) databases. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were blood glucose test strips and type 1 diabetes mellitus, type 2 diabetes mellitus or gestational diabetes mellitus. Methodological filters were applied to limit retrieval to clinical trials and observational studies. See Appendix 2 for the detailed search strategies.

The searches were not restricted by language; however, non-English language articles were excluded due to limited resources for translation. The literature searches were also limited to studies published from 1990 to February 2008. Monthly OVID AutoAlerts were active from March 2008 to March 2009 to identify any literature published after February 2008.

Grey literature (literature that is not commercially published) was identified by searching the websites of health technology assessment and related agencies, professional associations, and other specialized databases. Google and other Internet search engines were used to search for additional web-based materials and information. These searches were supplemented by hand searching the bibliographies and abstracts of key papers and conference proceedings, and through the posting of a preliminary reference list for stakeholder feedback.

Two reviewers independently selected articles for inclusion, based on criteria established a priori. RCTs (parallel and crossover), non-randomized controlled trials, and observational studies (cohort, case-control, and time series) — which examined the effect of SMBG versus no SMBG on diabetes-related outcomes, or the relationship between SMBG frequency and outcomes in type 1, type 2, and gestational diabetes mellitus — were eligible for inclusion. Studies were excluded if substantial differences existed (apart from SMBG) in the management of intervention and comparator groups. For included studies, two reviewers independently extracted study data using forms designed a priori, and assessed the methodological quality of RCTs, case-control, and cohort studies using modified versions of the SIGN 50 methodology checklists.[20-22] Any disagreements with study selection and data extraction were resolved through consensus, or a third reviewer if agreement could not be reached. Results of individual studies were pooled only if the populations, interventions, comparators, and outcomes measured across studies were sufficiently similar to produce a clinically meaningful result. Meta-analyses were performed using a random effects model in Review Manager 4.3.2. Heterogeneity in meta-analyses was assessed using the I^2 statistic; an attempt was made to identify possible moderator variables where I^2 values were between 25% and 75%. Pooled results were not presented for analyses in which the I^2 value was greater than 75%. To determine robustness of meta-analytic results, sensitivity analyses were performed by removing studies of poor methodological quality. Subgroup analyses were conducted based on clinically relevant differences across studies in terms of intervention and population characteristics.

Details regarding study selection, quality assessment, and data extraction are described in COMPUS's *Use of Blood Glucose Test Strips for the Management of Diabetes Mellitus — Project Protocol*.[19]

7 RESULTS

7.1 Selection of Primary Studies

Figures 1 to 3 show the selection process used to identify primary studies of SMBG in patients with type 1, type 2, and gestational diabetes, respectively. A total of 3,530 citations were identified in the literature search. Of these, 2,940 citations were excluded, based on titles and/or abstracts. These consisted mainly of reviews, study designs other than controlled clinical trials, or observational studies, and studies in which comparators were not of interest. Full-text articles of the remaining 590 citations were assessed, and 33 were included in the systematic review.[4,23-54] Two articles contributed data for both type 1 and type 2 diabetes.[24,25] Reasons for exclusion are reported in Appendices 3 to 5.

Figure 1: Study Selection Process for Type 1 Diabetes Mellitus

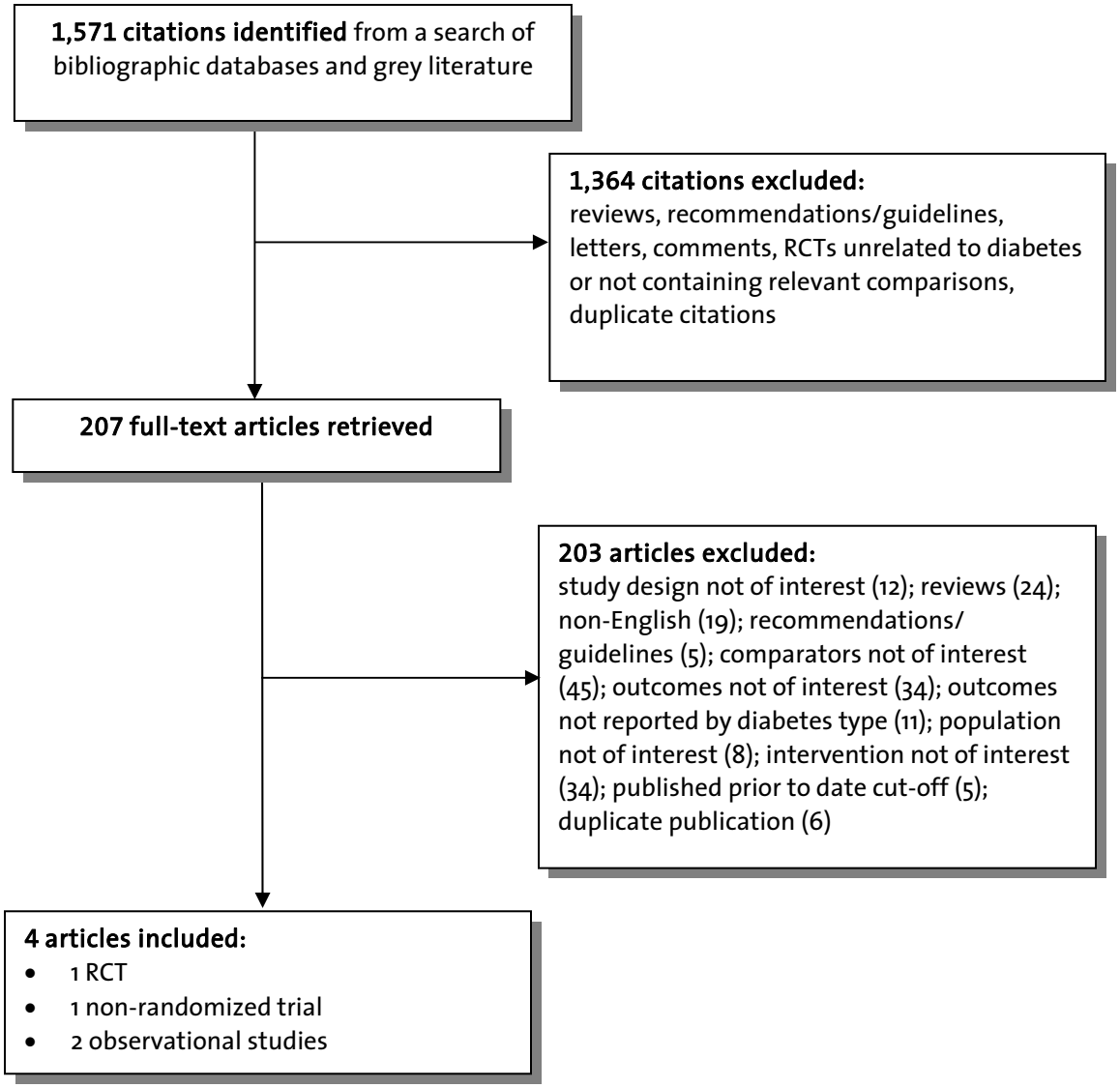


Figure 2: Study Selection Process for Type 2 Diabetes Mellitus

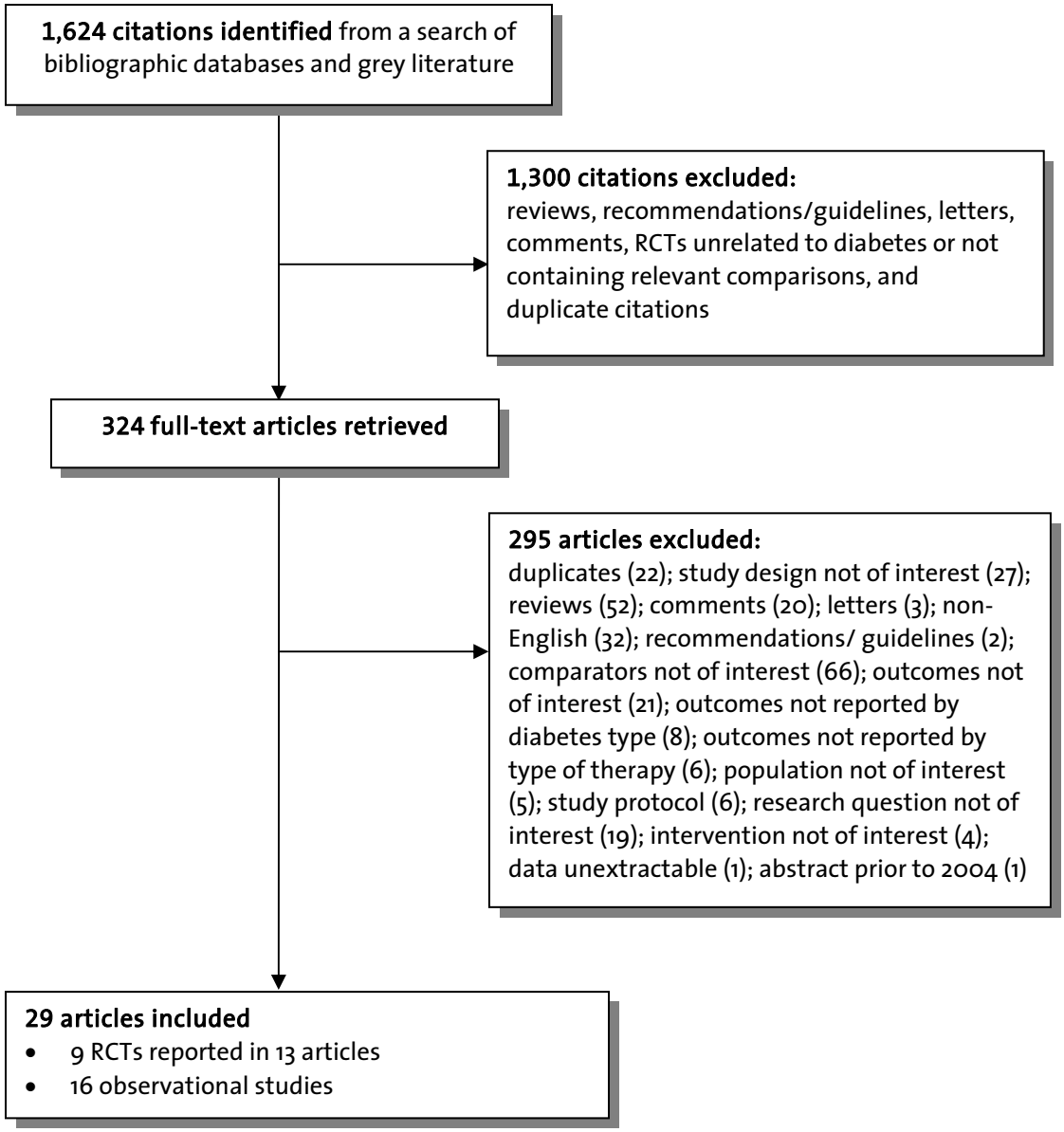
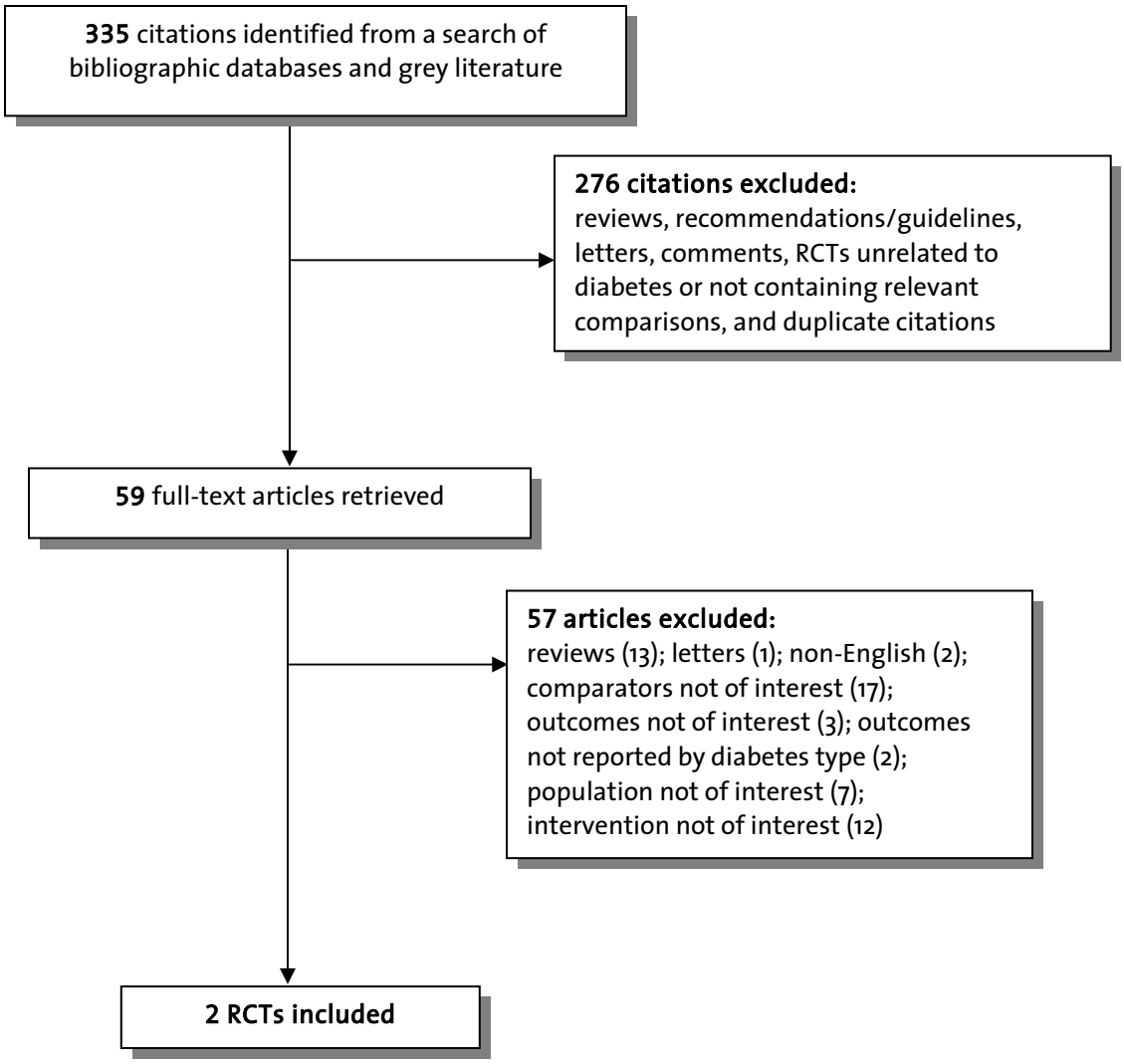


Figure 3: Study Selection Process for Gestational Diabetes Mellitus



7.2 Study Characteristics

Of the 33 studies selected for inclusion, four studied patients with type 1 diabetes,[24-27] 29 involved patients with type 2 diabetes[4,23-25,28-50,53,54] and two involved women with gestational diabetes.[51,52] Among the 33 studies, two articles reported data for both type 1 and type 2 diabetes.[24,25] Study-level details regarding study design, population characteristics, and comparators are presented in Appendices 6 to 8.

7.2.1 Studies of type 1 diabetes

a) Pediatric population

One non-randomized study of SMBG in 60 individuals (42 were under the age of 18) with type 1 diabetes was identified.[27] This study, conducted in Thailand, investigated the effect of two different SMBG frequencies (three to four per day versus less than three per day) following participation in a diabetes self-management education camp. All patients performed SMBG more than four times per day during the five-day camp, and were subsequently divided into two groups based on their willingness to perform SMBG during a six-month follow-up period. The mean age of participants was 16 years, and the age range was 10 to 46 years.

b) Adult population

Three studies investigating SMBG in adults with type 1 diabetes were identified: a crossover RCT[26] and two retrospective cohort studies.[24,25] The studies were conducted in the United Kingdom[25,26] and the United States,[24] and were published as full-text articles in peer-reviewed journals. Sample sizes ranged from 25 in the crossover RCT[26] to 1,129 in one of the retrospective cohort studies.[24] The mean age of participants ranged from 31[26] to 43[24] years; one study did not report the age of the subjects.[25] The proportion of male participants varied from 48%[24] to 64%.[26] All three studies involved comparisons of different SMBG testing frequencies.

No studies of SMBG in pregnant women with type 1 diabetes were identified.

7.2.2 Studies of type 2 diabetes

In total, 29[4,23-25,28-50,53,54] articles pertaining to SMBG in adults with type 2 diabetes were identified. Thirteen of these reported the results of RCTs,[4,23,28,29,32,34,37,39,43,44,48,50,53] one was a non-randomized trial,[31] two were prospective cohort studies,[33,49] ten were retrospective cohort studies,[24,25,35,36,40-42,46,47,54] and three were time series studies.[30,38,45] Twenty-eight studies were published as full-text articles and one as an abstract.[32]

No studies of SMBG in children or pregnant women with type 2 diabetes were identified.

a) Patients using insulin

Six studies investigated the use of SMBG in patients with type 2 diabetes who used insulin (with or without oral antidiabetes drugs).[24,25,31,33,42,49] A non-randomized trial from Turkey, by Aydin et al., encouraged subjects to self-monitor as frequently as possible, and then divided the subjects into four categories, based on their actual SMBG frequency.[31] The remaining studies consisted of two prospective cohort studies[33,49] from Australia and Poland, and three retrospective cohort studies from the United States and the United Kingdom.[24,25,42] The comparators under investigation were unique to each study, although A1C was reported as the primary outcome in four[24,25,31,42] of the five studies. Aydin et al. (2005) compared three frequencies of SMBG (one per week, one every two weeks, and one per month) against no SMBG.[31] Karter et al. (2001) used data from a large managed care organization in the United States, and grouped patients into categories of average daily SMBG frequency, based on the number of test strips dispensed.[24] Similarly, both Evans et al. (1999) and Secnik et al. (2007) used prescription data for blood glucose test strips to study the relationship

between SMBG frequency and glycemic control.[25,42] Davis et al. (2007) reported an analysis of longitudinal data obtained from the Fremantle Diabetes Study to assess the effect of SMBG on diabetes-related morbidity, cardiac death, and all-cause mortality.[33] Sample sizes varied across studies, ranging from 118[31] to 5,521.[24] Three studies[24,31,33] reported the mean age of participants, which was approximately 62 years in each study. The proportion of male participants varied from 47%[24] to 75%.[31]

b) Patients using oral antidiabetes drugs

For patients with type 2 diabetes using oral antidiabetes drugs (and no insulin), 11 articles reporting results from seven RCTs were identified that compared the use of SMBG with no SMBG.[4,23,28,29,34,37,39,43,44,50,53] Two studies enrolled patients taking oral antidiabetes drugs alone,[28,50] while the remaining included patients treated with either oral antidiabetes drugs or no pharmacotherapy.[4,23,29,34,37,39,43,44,50,53] In the latter subgroup, the proportion of patients on oral antidiabetes drugs at baseline ranged from 9.4%[39] to 97.7%,[4] although two studies[29,43] did not report this information. In the O'Kane et al. (2008) study, the proportion of patients on oral antidiabetes drugs increased substantially over the 12-month course of the trial, from 9.4% to 61.6%.[39] Farmer et al. (2007) was the only study that reported subgroup analyses based on type of therapy.[34]

In two instances, data from the same clinical trial were presented in multiple full-text articles: Farmer et al. (2007),[34] Simon et al. (2008),[44] French et al. (2008),[23] and Farmer et al. (2009)[53] reported results from the Diabetes Glycaemic Education and Monitoring (DiGEM) trial, while Siebolds et al .(2006)[43] is an extension of the trial initially reported by Schwedes et al. (2002).[29] The included studies ranged in duration from six to 12 months. The frequency of SMBG varied from a low of one strip per week[32,48] to a high of six strips per day, six days per week.[4]

Two RCTs compared the use of different frequencies of SMBG, one of which was published as a full-text article,[48] and the second as an abstract.[32] Scherbaum et al. (2008)[48] compared a SMBG frequency of one per week versus four per week (n = 202), and Bonomo et al. (2006)[32] compared four versus eight strips per month (n = 273). In both studies, primary outcomes were measured at baseline and six months.

Among the most important and commonly cited differences between RCTs investigating SMBG is whether or not patients were given instructions to translate their SMBG results into dietary and lifestyle changes.[55] For this review, studies that enabled and encouraged patients to use their SMBG results to facilitate lifestyle modification were classified as providing "more intensive" education.[29,39] RCTs that did not include a protocol for patients to interpret and act upon SMBG readings were classified as having "less intensive" education.[4,28,37,50] The DiGEM trial was the only RCT that directly compared both SMBG with either "less intensive" or "more intensive" education with no SMBG.[23,34,44,53]

The mean age of participants across the included RCTs ranged from 50[4] to 66 years,[32] the proportion of male participants varied from 21%[4] to 66%,[48] and the duration of diabetes spanned from approximately three years[34,44,50] to 11 years.[32]

A total of 14 observational studies investigating the use of SMBG in patients with type 2 diabetes using oral antidiabetes drugs were identified.[24,30,33,35,36,38,40-42,45-47,49,54] There was substantial heterogeneity in study design, populations, and comparators across studies. Six studies compared patients using SMBG with non-users of SMBG.[33,36,40,41,45,46] These included one prospective cohort study,[33] four retrospective cohort studies,[36,40,41,46] and one time series analysis.[45] Eight observational studies provided information regarding the frequency of SMBG and glycemic control, including five retrospective cohort studies,[24,35,42,47,54] and two time series,[30,38] and one prospective cohort study (data unextractable).[49] The duration of follow-up in the observational studies ranged from three months[47] to 6.5 years.[36,41]

c) Patients not using diabetes pharmacotherapy

Three studies investigated the use of SMBG in patients with type 2 diabetes treated with dietary and lifestyle advice alone. These included the DiGEM trial from the United Kingdom,[34] and two retrospective cohort studies[24,35] from the United States. In the DiGEM trial, Farmer et al. (2007) compared the effects of "less intensive" or "more intensive" SMBG education with no SMBG.[34] The randomization process for the DiGEM trial balanced several covariates, including initial diabetes therapy, allowing for a sub-group analysis of subjects (124/343) who were not treated with antidiabetes pharmacotherapy.[34]

In the retrospective cohort studies Karter et al. (2001) and Karter et al. (2006), administrative data from a large health maintenance organization in the United States was used to relate average test strips dispensed per day to glycemic control.[24,35] Karter et al. (2001) also reported comparative data regarding glycemic control in SMBG users versus non-users.[24]

7.2.3 Studies of gestational diabetes

Two RCTs studying SMBG in patients with gestational diabetes were identified.[51,52] Both Homko et al. (2002)[51] and Rey (1997)[52] compared women using SMBG with a periodic monitoring strategy in which patients did not conduct SMBG. All patients in both studies received fasting and one hour post-prandial glycemic monitoring at prenatal clinic visits. The frequency of SMBG was four per day on four days per week in Homko et al. (2002),[51] and three to four per day on seven days per week in Rey (1997).[52] Sample sizes were 58 and 115 patients in the Homko et al. (2002)[51] and Rey (1997)[52] trials, respectively. The mean age of participants was 30[51] and 31[52] years, and the duration of gestation at enrolment was 26 to 33[51] weeks and 22 to 36 weeks.[52] A wide range of fetal, neonatal, pregnancy, and maternal outcomes were reported in these studies.

7.3 Study Quality

Quality assessment was perfomed for 14 articles reporting the results of RCTs[4,23,26,28,29,34,37,39,43,44,48,50-52] and 14 observational studies.[24,25,27,31,33,35,36,40-42,46,47,49,54] The three time-series studies[30,38,45] and the RCT abstract[32] were not assessed for study quality. Details of quality assessment for studies of type 1, type 2, and gestational diabetes are presented in appendices 12 to 14, respectively.

For type 1 diabetes in adults, the single RCT and both observational studies were rated as being of poor quality.[24-26] For the RCT,[26] key shortcomings were failure to provide adequate descriptions of randomization and allocation concealment, inadequate descriptions of blinding procedures, and failure to conduct intention-to-treat analysis. Poor ratings in the observational studies were primarily attributable to failure to provide baseline values for outcomes, inadequate comparison of baseline characterisitics between patient groups, and imprecise measurements of SMBG frequency. The non-randomized trial in children with type 1 diabetes was also given a rating of poor for reasons similar to the adult studies.[27]

For type 2 diabetes, six of the RCTs were found to be of good methodological quality[23,34,39,44,48,50] and five were considered poor.[28,29,37,43,56,57] The most common reasons for judging these RCTs as being of poor quality were inadequate descriptions of randomization and allocation concealment procedures, high dropout rates, and failure to conduct an intention-to-treat analysis. The RCT reported by Bonomo et al. (2006) could not be assessed for quality because it was published as an abstract.[32] All observational studies of patients with type 2 diabetes received an overall rating of poor, primarily due to inadequate adjustment for important confounders, imprecise measurement of SMBG frequency, failure to provide baseline values for outcomes, and inadequate presentation and/or significant differences in baseline characteristics of treatment groups.

In gestational diabetes, one RCT received an overall rating of good,[52] while the other was rated as poor.[51] In the latter study,[51] the randomization procedure was poorly described, there was significant loss to follow-up, and a per-protocol analysis was used.

7.4 Results from Studies

7.4.1 Patients with diabetes treated with insulin

a) Children with type 1 diabetes

The single study of SMBG in children with type 1 diabetes was a non-randomized trial conducted in Thailand. Participants were divided into two groups, based on self-determined SMBG frequency, following participation in a diabetes self-management education camp.[27] At three months after the camp, SMBG performed at least three times per day resulted in a statistically significant A1C reduction compared with SMBG performed less than three times per day. The mean difference (95% CI) in A1C was -0.6% (-1.13, -0.02) in favour of SMBG performed at least three times per day. A similar magnitude of effect was maintained at six months, although the difference between treatment arms was not statistically significant (Table 1). There were no additional outcomes of interest reported in this study.

Table 1: Mean A1C Differences at Three and Six Months (Adjusted for Baseline) Between SMBG Performed ≥ 3 Times Per Day Compared With < 3 Times Per Day in Children With Type 1 Diabetes[27]

Follow-up Duration	Mean Difference in A1C (%) (95% CI)
3 months*	-0.6 (-1.13, -0.02)
6 months†	-0.5 (-1.35, 0.34)

A1C=glycolsylated hemoglobin; CI=confidence interval; SMBG=self-monitoring of blood glucose

* 42 of 60 patients were under 18 years of age.

† The number of patients over 18 years of age among the 40 patients included in the analysis at six months was not reported.

b) Adults with type 1 diabetes

Three studies investigating the effect of different frequencies of SMBG use in adults with type 1 diabetes were identified.[24-26] One study[26] was a crossover RCT and two[24,25] were retrospective cohort studies (i.e., analyses of administrative databases). Results for A1C, the only outcome of interest reported in all three studies, are presented in Table 2.

In the crossover RCT, there was no significant difference in mean A1C between SMBG performed twice daily on seven days per week versus four times daily on any two non-consecutive days per week.[26] In contrast, the retrospective cohort study by Karter et al.[24] showed that mean A1C was statistically significantly decreased in patients who were dispensed an average of at least three blood glucose test strips per day compared with those who were dispensed an average of one strip per day. The mean difference (95% CI) in A1C was -0.78% (-1.01, -0.55). The authors adjusted this analysis for a number of demographic, socioeconomic, lifestyle, health, self-care, and health care utilization variables, although they did not adjust for possible differences between groups in terms of baseline A1C. The retrospective analysis by Evans et al[25] involved 258 patients and dispensed an average of 0.05 to 5.68 blood glucose test strips per day. Regression analysis indicated that A1C decreased by 0.66% for each increment of 180 test strips dispensed per six-month period, after adjustment for age, sex, duration of diabetes, and socioeconomic status ($p<0.001$). There were no data reported in these studies for any other outcomes of interest.

Table 2: Mean A1c Difference Between Various Frequencies of SMBG Use in Adults With Type 1 Diabetes		
Comparison	**Number of Studies (sample size)**	**Mean Difference in A1C (%) (95% CI)**
2 times daily versus 4 times daily once a week	1 RCT[26] (n = 25)	0.10 (-1.04, 1.24)
2 times daily versus 4 times daily on 2 non-consecutive days per week	1 RCT[26] (n = 25)	0.10 (-1.01, 1.21)
≥ 3 strips per day versus one per day	1 R. cohort[24] (n = 780)	-0.78 (-1.01, -0.55)
Regressional coefficient for an average of one additional BGTS/day; i.e., 180 BGTS/6months)	1 R. cohort[25] (n = 258)	Regression coefficient : -0.661 (P < 0.001)

A1C=hemoglobin A1C; BGTS=blood glucose test strip; CI =confidence interval; RCT=randomized controlled trial; R. cohort=retrospective cohort

Type 1 diabetes in special populations

No evidence pertaining to the effect of SMBG in elderly patients with type 1 diabetes was identified. There were also no studies of patients with type 1 diabetes belonging to groups such as First Nations, ethnic minorities, or occupations in which abnormal blood glucose levels may pose special risks (e.g., professional drivers, pilots, construction workers, and athletes).

c) Adults with type 2 diabetes using insulin A1C

Three studies evaluated the effect of SMBG on A1C in patients with type 2 diabetes using insulin.[24,31,38] Aydin et al.,[31] enrolled 71 patients with type 2 diabetes managed with insulin alone in a non-randomized trial. At 12 weeks, A1C was significantly lower among subjects performing SMBG four times daily once every week, compared with no SMBG. The mean difference (95% CI) in A1C was -1.00% (-1.68, -0.32). SMBG performed four times daily once every two weeks tended to lower mean A1C compared to no SMBG (P = 0.05); however, A1C differences did not reach statistical significance for other SMBG frequencies (Table 3). There were significant differences between treatment groups at baseline for gender, disease duration, rates of hypoglycemia, and diabetes complications. A1C results at end point were not adjusted for such differences.

In a retrospective cohort analysis by Karter et al., data were analyzed for 4,061 patients with type 2 diabetes using insulin with or without oral antidiabetes drugs.[24] A statistically significant decrease in A1C was reported in patients who were dispensed an average of at least one blood glucose test strip per day over 12 months compared with those who were not dispensed test strips (mean difference [95% CI] -0.69% [-0.84, -0.54]). No significant difference was observed between the cohort dispensed an average of less than one strip per day versus no SMBG (mean difference [95% CI] = -0.13% [-0.30, 0.04]). These results were adjusted for demographic, socioeconomic, lifestyle, health, self-care, and health care utilization variables, but not for differences in baseline A1C.

A time series study by Murata et al.[38] involved 201 patients with type 2 diabetes managed with insulin alone or in combination with oral antidiabetes agents. They reported a statistically significant decrease in A1C with SMBG four times daily at eight weeks (mean difference [95% CI] = -0.36% [-0.24, -0.48]).

There was no significant difference in mean A1C at three months between subjects performing SMBG four times daily on one day per week versus four times daily once every two weeks (mean difference A1C [95% CI] = -0.30% [-0.82, 0.22])[31] (Table 3). There were significant differences in baseline characteristics between the two groups and no adjustment was made in the analysis to account for these differences.

Two retrospective cohort studies investigated the relationship between A1C and the number of strips dispensed over six months by regression coefficient[25,42] (Table 3). Secnik et al.[42] reported a statistically significant decrease of A1C by 0.65% for every 180 test strips dispensed over a six-month period (equivalent to an average of one strip per day) (P = 0.0236). In contrast, Evans et al.[25] reported that an increment of 180 test strips over six months was not an independent predictor of A1C (Table 3).

Fasting blood glucose

Schneider et al.[41] evaluated the role of SMBG in patients with type 2 diabetes managed with either insulin alone or in combination with oral antidiabetes drugs in a retrospective study based on chart reviews. At 6.5 years, there were no statistically significant differences in mean fasting blood glucose at end point versus baseline in eight patients with type 2 diabetes managed with insulin alone (9.05 mmol/L versus 9.68 mmol/L, P = 0.324), or five patients with type 2 diabetes managed with insulin and oral antidiabetes drugs (10.21 mmol/L versus 8.80 mmol/L, P = 0.129).

Hypoglycemia

Aydin et al. reported the effects on SMBG on hypoglycemia (Table 3).[31] There were also no statistically significant differences between the three SMBG frequencies, and no SMBG in the event rate and relative risk of overall hypoglycemia. There was a statistically significant difference in the relative risk or rate ratio of overall hypoglycemia between SMBG performed four times daily, once per week, versus four times daily once every two weeks (Table 3).

Mortality

A prospective cohort study in 531 patients with insulin-dependent type 2 diabetes reported no statistically significant difference in mortality between SMBG and no SMBG over a period of 5.5 years (hazard ratio [95% CI] = 0.73 [0.43, 1.26]).

Table 3: A1C, Overall Hypoglycemia, and Mortality Results in Adults With Type 2 Diabetes Using Insulin (With or Without Oral Antidiabetes Drugs)						
Therapy	Comparison	Number of Studies (sample size)	Mean Difference in A1C (%) (95% CI)	Overall Hypoglycemia RR (95%CI)	Overall Hypoglycemia Rate Ratio (95%CI)	Mortality HR (95%CI)
Insulin Alone	SMBG 4 per day x 1 day per week versus no SMBG	1 nRT[31] (n = 71)	-1.00%* (-1.68,-0.32)	0.45* (0.03, 6.86)	4.04* (0.94, 17.42)	NR
	SMBG 4 per day x once every 2 weeks versus no SMBG	1 nRT[31] (n = 55)	-0.70%* (-1.41, 0.01)	0.67* (0.04, 10.11)	2.67* (0.57, 12.56)	NR
	SMBG 4 per day x 1 day per month versus no SMBG	1 nRT[31] (n = 36)	-0.20%* (-1.08, 0.68)	0.51* (0.02, 11.74)	NR	NR
	SMBG 4 per day x 1 day per week versus SMBG 4 per day x 1 day every 2 weeks	1 nRT[31] (n = 82)	-0.30%* (-0.82, 0.22)	0.67* (0.04, 10.39)	1.52* (0.66, 3.48)	NR
	SMBG increased by 1 strip per day	1 R. cohort[42] (n = 245)	-0.65% (P = 0.0236)	NR	NR	NR
		1 R. cohort[25] (n = 290)	-0.108% (P = 0.357)	NR	NR	NR
Insulin and OADs	SMBG ≥ 1 per day versus no SMBG	1 R. cohort[24] (n = 4061)	-0.69%† (-0.84,-0.54)	NR	NR	NR
	SMBG < 1 per day versus no SMBG	1 R. cohort[24] (n = 2,541)	-0.13%† (-0.30, 0.04)	NR	NR	NR
	SMBG versus no SMBG	1 P. cohort[33] (n = 153)	NR	NR	NR	0.73‡ (0.43, 1.26)

A1C=glycosylated hemoglobin; CI=confidence interval; HR=hazard ratio; MD=mean difference; NR=not reported; nRT=non-randomized trial; OADs=oral antidiabetes drugs; P. cohort=prospective cohort; R. cohort=retrospective cohort; RR=relative risk; SMBG=self-monitoring of blood glucose

* Baseline patient characteristics including age, sex, disease duration, duration of insulin treatment, hypoglycemia, rate of complications of retinopathy, nephropathy, and neuropathy were significantly different between comparator groups. Unadjusted results were reported. (Dr. Hasan Aydin, Department of Endocrinology and Metabolism, Yeditepe University Hospital, Istanbul, TR: unpublished data, 2008 Nov 11)

† Adjusted for age, sex, ethnicity, educational attainment, annual income and occupational class, years since diabetes diagnosis, diabetes therapy refill adherence, number of daily insulin injections, clinic appointment "no show" rate, annual eye exam attendance, self-reported exercise and diet as diabetes treatment, smoking status, alcohol consumption, and hospitalization and emergency room visits during baseline year.

‡ Adjusted for age, sex, duration of diabetes, prior myocardial infarction, angina, coronary revascularization, diabetes education, A1C, ethnicity (Australian aboriginal).

7.4.2 Patients with diabetes not treated with insulin

a) Adults with type 2 diabetes using oral antidiabetes drugs

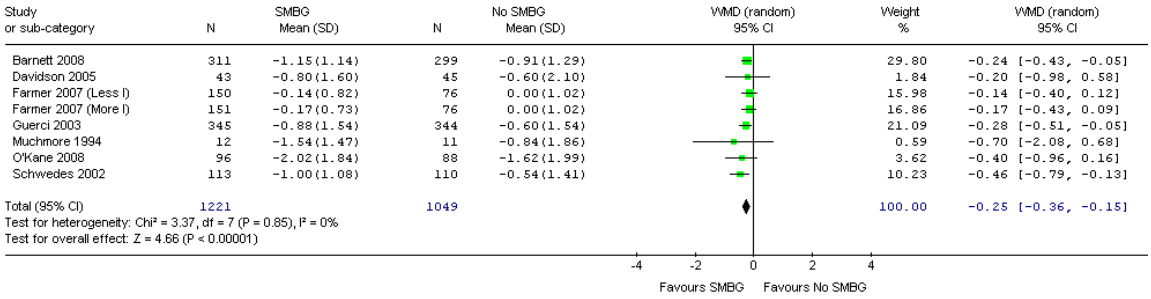
The objective of this section was to investigate the effect of SMBG on patients with type 2 diabetes using oral antidiabetes drugs. The majority of studies identified for this section contain a mixed population (i.e., patients with type 2 diabetes using oral antidiabetes drugs or not taking diabetes pharmacotherapy — see 7.2.2 (b)). The effect of BGTS on the various outcomes are presented for the total body of evidence and, where possible, for the RCTs where only patients treated with oral antidiabetes drugs were included (n = 1,299).[28,50] Five RCTs enrolled patients whose treatment consisted of either oral antidiabetes drugs or no pharmacotherapy (n = 971),[4,29,34,37,39] only one of which[34] reported results for the subgroup of patients who were treated exclusively with oral antidiabetes drugs (n = 329).

b) SMBG versus no SMBG

A1C — Evidence from RCTs

Seven RCTs[4,28,29,34,37,39,50] involving a total of 2,270 patients investigated the effect of SMBG versus no SMBG on change in A1C from baseline. SMBG was performed for a median of six months in the seven studies, at frequencies ranging from less than one per day, up to two per day, in combination with education of varying intensity. The pooled difference in A1C across the seven studies was statistically significant in favour of SMBG (WMD [95% CI] = -0.25% [-0.36, -0.15]) (Figure 4 and Table 4). There was no statistical heterogeneity between studies (I^2 = 0%). Publication bias, however, was indicated by the asymmetrical nature of the funnel plot (Figure not shown).

Figure 4: Forest Plot of RCTs that Compared the Effect of SMBG Versus No SMBG on A1C (Change From Baseline) (%) in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy*



CI=confidence intervals; Less I=less intensive education arm; More I=more intensive education arm; RCTs=randomized controlled trials; SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

*Guerci et al. (2003)[28] and Barnett et al. (2008)[50] only included patients using oral antidiabetes drugs, the remaining studies included both patients using oral antidiabetes drugs and those using no pharmacotherapy

Sensitivity analyses for good quality studies[34,39,50] and for studies where all patients used oral antidiabetes drugs[28,34,50] produced A1C differences that were similar to the overall analysis (Table 4).

A number of subgroup analyses were conducted to determine whether the A1C estimate was affected by differences across studies in SMBG frequency, duration of SMBG use, and intensity of education provided in conjunction with SMBG time from diabetes diagnosis and baseline glycemic control (Table 4). Regarding SMBG frequency, pooled differences in A1C between SMBG and no SMBG were similar to the overall analysis in the subgroup of studies implementing a testing frequency of less than once daily,[4,28,34] or one to two times daily.[39,50] However, SMBG conducted more than twice daily resulted in a somewhat larger decrease in A1C as compared to lower frequencies (WMD [95% CI] = -0.47% [-0.79, -0.15]).[29,37] The duration of SMBG use

appeared to have little impact on the pooled difference in A1C. There was no statistically significant difference in A1C (mean difference [95% CI] = 0.03% [-0.15, 0.21]) in the DiGEM trial, the only RCT[34] that directly compared the effect of SMBG with less intensive education versus SMBG with more intensive education. Similarly, the pooled difference in A1C across RCTs providing less intensive or unspecified education[4,28,34,37,50] was similar to the estimate across trials that implemented more intensive education.[29,34,39]

In the study by Barnett et al., all subjects were treated with gliclazide, either alone or in combination with oral antidiabetes drugs.[50] This was the only study in which oral antidiabetes drug treatment consisted of an insulin secretagogue for all patients. The mean difference in A1C between SMBG and no SMBG arms in this study was similar to the overall analysis (mean difference [95% CI] = -0.24% [-0.43, -0.05]). Various agents were employed in the remaining studies in which all subjects were treated with oral antidiabetes drugs;[28,34] the pooled effect across these studies was also similar to the overall analysis (WMD [95% CI] = -0.24 [-0.36, -0.11]).

The Efficacy of Self-Monitoring of Blood Glucose in Patients With Newly Diagnosed Type 2 Diabetes (ESMON) study[39] was the only RCT that enrolled newly-diagnosed patients. There was no statistically significant effect of SMBG on A1C in the ESMON study, while the pooled effect across the six studies of previously-diagnosed patients was statistically significant and of a similar magnitude as in the overall analysis. The DiGEM[34] — the only study that included patients with a mean baseline of A1C < 8.0% — reported no statistically significant effect of SMBG on A1C, regardless of the intensity of education provided, while the A1C effect across the remaining six RCTs was similar to the overall analysis.

Table 4: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses for Mean A1C (%) (Change From Baseline)

Analysis		Number of Studies (sample size)	WMD (95% CI) in A1C (%)	I^2 (%)
Overall		7 RCTs[4,28,29,34,37,39,50] (n = 2,270)	-0.25 (-0.36, -0.15)	0
Sensitivity analyses				
Good quality RCTs only		3 RCTs[34,39,50] (n = 1,247)	-0.21 (-0.34, -0.08)	0
RCTs in which all subjects used OADs		3 RCTs[28,34,50] (n = 1,628)*	-0.24 (-0.36, -0.11)	0
Subgroup analyses				
Daily SMBG frequency	SMBG < 1 per day†	3 RCTs[4,28,34] (n = 1,230)	-0.20 (-0.35, -0.06)	0
	SMBG 1-2 per day†	2 RCT[39,50] (n = 794)	-0.26 (-0.44, -0.07)	0
	SMBG > 2 per day†	2 RCTs[29,37] (n = 246)	-0.47 (-0.79, -0.15)	0
Duration of SMBG use	SMBG for 6 months	5 RCTs[4,28,29,39,50] (n = 1,794)	-0.28 (-0.41, -0.15)	0
	SMBG for > 6 months	3 RCTs[34,37,39] (n=660)	-0.19 (-0.36, -0.01)	0
Intensity of education provided with SMBG	More intensive‡	3 RCT[29,34,39] (n = 710)	-0.28 (-0.47, -0.08)	17.8
	Less intensive or unspecified§	5 RCTs[4,28,34,37,50] (n = 1,712)	-0.22 (-0.34, -0.10)	0
Type of OAD	All subjects treated with insulin secretagogue	1 RCT[50] (n = 610)	-0.24 (-0.43, -0.05)	NA
	All subjects treated with various OADs	2 RCTs[28,34] (n = 1,018)	-0.24 (-0.40, -0.07)	0

Table 4: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses for Mean A1C (%) (Change From Baseline)				
Analysis		**Number of Studies (sample size)**	**WMD (95% CI) in A1C (%)**	**I^2 (%)**
Time of diabetes diagnosis in relation to study	Previously diagnosed	6 RCTs[4,28,29,34,37,50] (n = 2,086)	-0.25 (-0.35, -0.14)	0
	Newly diagnosed	1 RCT[39] (n = 184)	-0.40 (-0.96, 0.16)**	NA
Baseline glycemic control	A1C < 8.0%	1 RCT[34] (n = 453)	-0.16 (-0.34, 0.03)**	NA
	A1C = 8.0-10.5%	6 RCTs[4,28,29,37,39,50] (n = 1,817)	-0.30 (-0.43, -0.17)	0

A1C=glycosylated hemoglobin A1C; CI=confidence interval; NA=not applicable; OADs=oral antidiabetes drugs; RCT=randomized controlled trial; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

* Farmer *et al.* (2007)[34] presented data for a subgroup of patients treated with oral antidiabetes drugs.

† The number of SMBG tests per day was estimated from the frequency data provided in each study. Specific frequencies are available in the study characteristics tables (Appendix 7)

‡ More intensive education: patients were provided with training in the self-interpretation and application of their SMBG results to facilitate dietary and lifestyle modifications.

§ Less intensive education: patients were trained on using a blood-glucose meter, but were not provided with instructions regarding self-interpretation and application of their SMBG results, or the educational components of the trial were not specified.

** Mean difference (95% CI)

A1C — Evidence from observational studies

Three retrospective cohort studies[24,40,46] were identified that examined SMBG versus no SMBG in patients with type 2 diabetes treated with oral antidiabetes drugs (Table 5). A large retrospective cohort study[24] demonstrated a statistically significant difference in A1C for subjects using at least one blood glucose test strip per day (n = 8,735) or using less than one strip per day (n = 10,243), compared to no SMBG. Two smaller retrospective cohort studies failed to demonstrate a statistically significant improvement in A1C for patients who were prescribed blood glucose test strips (two strips per week, n = 115[40] and 0.56 strips per day, n = 299[46]), compared with patients who were not prescribed test strips.

Table 5: Mean Differences in A1C Between SMBG and No SMBG in Adults With Type 2 Diabetes Using Oral Antidiabetes		
Comparison	**Number of Studies (sample size)**	**Mean Difference in A1C (%) (95% CI)**
≥ 1 per strip per day versus no SMBG	1 R. cohort[24] (n = 8,735)	-0.68 (-0.77, -0.59)*
< 1 per strip per day versus no SMBG	1 R. cohort[24] (n = 10,243)	-0.21 (-0.30, -0.12)*
Prescription of 2 to 4 strips per week versus no prescription of strips	1 R. cohort[40] (n = 115)	-0.20 (-0.77, 0.37)†
Prescription of 0.56 strips per day versus no prescription of strips	1 R. cohort[46] (n = 299)	-0.13 (-0.28, 0.02)‡

* Data were adjusted for age, sex, ethnicity, educational attainment, annual income and occupational class, years since diabetes diagnosis, diabetes therapy refill adherence, number of daily insulin injections, (insulin users only), clinic appointment "no show" rate, annual eye exam attendance, self-reported exercise and diet as diabetes treatment, smoking status, alcohol consumption, and hospitalization and emergency-room visits during the baseline year.

† Data were not adjusted for any confounder, and baseline A1C was not reported; however, age, weight, dose of glyburide and serum creatinine and proteinuria were similar between the two groups.

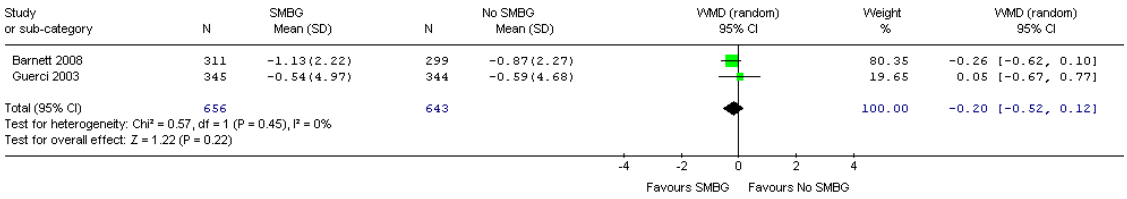
‡ Data were not adjusted for any possible confounders, although baseline A1C, BMI, chronic illness, and disability payment system and ethnicity were similar between the two groups.

A time series study by Soumerai et al.,[45] which examined the effects of SMBG in patients with type 2 diabetes managed with sulfonylureas over a two-year period, reported a statistically significant mean decrease in A1C (95%CI) of -0.63% (-1.14, -0.12) in 133 patients with baseline A1C > 10.0%. A statistically significant reduction in mean A1C was not observed in 350 patients with A1C < 8.0% or in 232 patients with A1C between 8.0% and 10.0%.

Fasting blood glucose — Evidence from RCTs

Guerci et al.[28] and Barnett et al.[50] compared the effect of SMBG versus no SMBG on lab-measured fasting blood glucose measurements over a period of six months in a total of 1,299 patients with type 2 diabetes managed with oral antidiabetes drugs. In both studies, subjects had baseline A1C > 8.0%, and less intensive education was provided in conjunction with SMBG. There was no statistically significant difference in fasting blood glucose levels between treatments (WMD [95%CI] = -0.20 mmol/L [-0.52, 0.12]) (Figure 5); there was no evidence of statistical heterogeneity (I^2 = 0%). The study by Barnett et al.[50] was the only good- quality RCT, and the only RCT in which all patients were treated with an insulin secretagogue. The mean difference in fasting blood glucose in this study was statistically non-significant and similar to the pooled estimate.

Figure 5: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Fasting Blood Glucose (mmol/L) in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs



CI=confidence intervals; SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

Fasting blood glucose — Evidence from observational studies

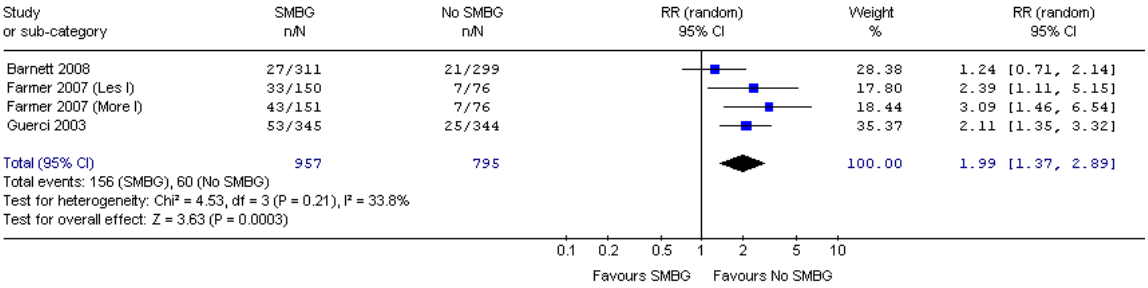
In an observational study, Rindone et al.[40] reported no difference in lab-measured fasting blood glucose (mean difference [95% CI] = -0.05 mmol/L [-1.04, 0.94]) between SMBG and no SMBG in 115 patients with type 2 diabetes managed with sulfonylureas. No adjustments were made for confounders or baseline A1C in this study, although baseline characteristics were similar between groups. A before-and-after study conducted by Schneider et al.[41] reported a statistically significant decrease in lab-measured fasting blood glucose (-0.39 mmol/L, P = 0.003) in 319 adults with type 2 diabetes, managed with oral antidiabetes drugs, who were followed over 6.5 years.

Hypoglycemia

Four RCTs[28,34,39,50] reported on the effect of SMBG versus no SMBG on overall hypoglycemia in patients with type 2 diabetes managed with oral antidiabetes drugs or no pharmacotherapy (Table 6). The pooled relative risk of overall hypoglycemia was significantly higher with SMBG compared with no SMBG across three RCTs[28,34,50] involving a total of 1,752 patients (RR [95% CI] = 1.99 [1.37, 2.89]) (Figure 6). However, the rate of overall hypoglycemia was significantly lower in the SMBG arm (rate ratio [95% CI] = 0.73 [0.55, 0.98]) (Figure 7). There was no significant statistical heterogeneity in these analyses. Based on the results of the RCT by Barnett et al. (2008), the risk and rate of overall hypoglycemia between SMBG and no SMBG in patients managed with an insulin secretagogue were similar to the overall analysis (RR [95% CI] = 2.35 [1.66, 3.32]; rate ratio [95% CI] = 0.74 [0.52, 1.07]) (Table 6).[50] However, there was a statistically significant reduction in the number of symptomatic hypoglycemic events reported by patients who were performing SMBG in this trial (rate ratio [95% CI] = 0.57 [0.38, 0.85]).

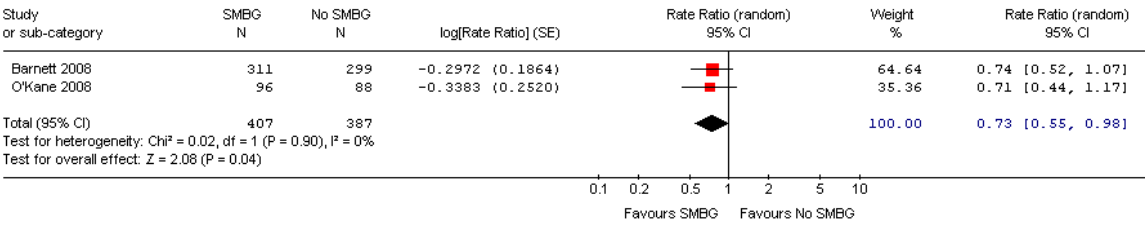
There were no statistically significant differences between SMBG and no SMBG for severe hypoglycemia (Figure 8 and Table 6). There were no events of severe hypoglycemia in the RCTs reported by Guerci et al. (2003) and Barnett et al. (2008).[28,50] There was also no statistically significant difference between SMBG and no SMBG in the risk of nocturnal hypoglycemia in the RCT by Barnett et al., the only RCT to report this outcome (Table 6).[50]

Figure 6: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Risk of Overall Hypoglycemia in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy



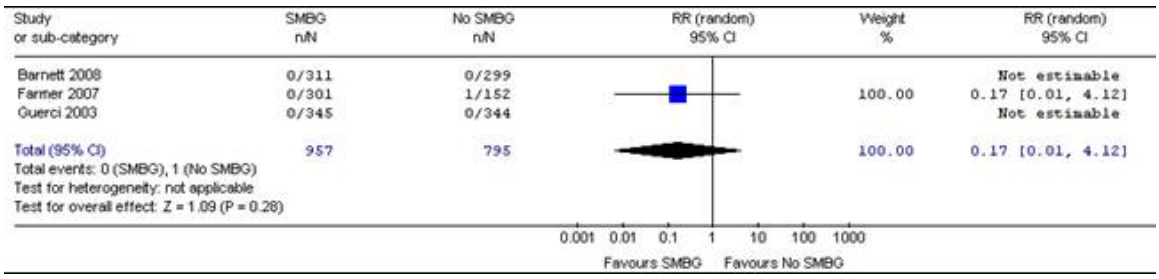
CI=confidence intervals; n=number of patients having events; N=sample size; RR=relative risk;SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

Figure 7: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Rate of Overall Hypoglycemia in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy



CI=confidence intervals; n=number of patients having events; N=sample size; RR=relative risk; SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

Figure 8: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Risk of Severe Hypoglycemia in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy



CI=confidence intervals; n=number of patients having events; N=sample size; RR=relative risk; SMBG=self-monitoring of blood glucose

Sensitivity analyses for good quality studies and for studies enrolling only patients treated with oral antidiabetes drugs and subgroup analyses for frequency of SMBG; SMBG duration; intensity of education provided in conjunction with SMBG; time of diabetes diagnosis in relation to the study; and degree of glycemic

control, relative risk, and rate ratio estimates for overall hypoglycemia were generally similar to the combined estimate (Table 6). The relative risk for overall hypoglycemia represents previously-diagnosed patients.

Table 6: Summary of Meta-analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses for Overall, Severe, and Nocturnal Hypoglycemia

Analysis			Number of Studies (sample size)	Effect Estimate (95% CI)	I^2 (%)
Overall hypoglycemia					
Overall		Relative risk	3 RCTs[28,34,50] (n = 1,752)	1.99 (1.37, 2.89)	33.8
		Rate ratio	2 RCTs[39,50] (n = 794)	0.73 (0.55, 0.98)	0
Sensitivity analyses					
Good quality RCTs only		Relative risk	2 RCTs[34,50] (n = 1,063)	1.99 (1.11, 3.56)	54.2
		Rate ratio	1 RCT[50] (n = 610)	0.74 (0.52, 1.07)	NA
RCTs in which all subjects used OADs		Relative risk	2 RCTs[28,50] (n = 1,299)	1.65 (0.98, 2.79)	54.5
		Rate ratio	1 RCT[50] (n = 610)	0.74 (0.52, 1.07)	NA
Subgroup analyses					
Duration of SMBG use (months)	6	Relative risk	2 RCTs[28,50] (n = 1,299)	1.65 (0.98, 2.79)	54.5
		Rate ratio	2 RCTs[39,50] (n = 794)	0.73 (0.55, 0.98)	NA
	12	Relative risk	1 RCT[34] (n = 453)	2.73 (1.59, 4.66)	NA
		Rate ratio	1 RCT[39] (184)	0.71 (0.44, 1.17)	NA
Daily SMBG frequency	< 1	Relative risk	2 RCTs[28,34] (n = 1,142)	2.35 (1.66, 3.32)	0
	1 to 2	Relative risk	1 RCT[50] (n = 610)	1.24 (0.71, 2.14)	NA
		Rate ratio	2 RCTs[39,50] (n = 794)	0.73 (0.55, 0.98)	0
Intensity of education provided with SMBG	Less intensive* or not specified	Relative risk	3 RCTs[28,34,50] (n = 1,601)	1.85 (1.27, 2.70)	36.6
		Rate ratio	1 RCT[50] (n = 610)	0.74 (0.52, 1.07)	NA
	More intensive†	Relative risk	1 RCT[34] (n = 303)	3.09 (1.77, 5.41)	NA
		Rate ratio	1 RCT[39] (n = 184)	0.71 (0.44, 1.17)	NA
Type of OAD	All subjects treated with insulin secretagogue	Relative risk	1 RCT[50] (n = 610)	1.24 (0.71, 2.14)	NA
		Rate ratio	1 RCT[50] (n = 610)	0.74 (0.52, 1.07)	NA
	All subjects treated with various OADs	Relative risk	2 RCTs[28,34] (n = 1,142)	2.35 (1.66, 3.32)	0
Time of diabetes diagnosis in relation to study	Newly diagnosed	Rate ratio	1 RCT[39] (n = 184)	0.71 (0.44, 1.17)	NA
	Previously diagnosed	Rate ratio	1 RCT[50] (n = 610)	0.74 (0.52, 1.07)	NA
		Relative risk	3 RCTs[28,34,50] (n = 1,752)	1.99 (1.37, 2.89)	33.8
Baseline glycemic	A1C < 8.0%	Relative risk	1 RCT[34] (n = 453)	2.73 (1.59, 4.66)	NA
	A1C = 8.0-10.5%	Relative risk	2 RCTs[28,50] (n = 1,299)	1.65 (0.98, 2.79)	54.5

Table 6: Summary of Meta-analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses for Overall, Severe, and Nocturnal Hypoglycemia

Analysis			Number of Studies (sample size)	Effect Estimate (95% CI)	I^2 (%)
control	A1C = 8.0-10.5%	Rate ratio	2 RCTs[39,50] (n = 794)	0.73 (0.55, 0.98)	0
Severe hypoglycemia					
Overall		Relative risk	3 RCTs[29,34,50] (n = 1,752)	0.17‡ (0.01, 4.12)	NA
Nocturnal hypoglycemia					
Overall **(all patients used sulfonylureas)**		Relative risk	1 RCT[50] (n = 610)	0.41 (0.11, 1.58)	NA

A1C=glycosylated hemoglobin; CI=confidence intervals; NA=not applicable; OADs=oral antidiabetes drugs; RCT=randomized controlled trial; SMBG=self-monitoring of blood glucose

* Less intensive education: patients were trained on using a blood-glucose meter but were not provided with instructions regarding self-interpretation and application of their SMBG results, or the educational components of the trial were not specified.

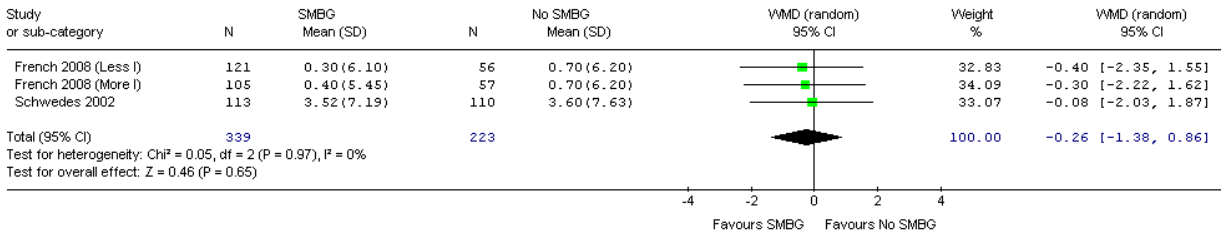
† More intensive education: patients were provided with training in the self-interpretation and application of their SMBG results to facilitate dietary and lifestyle modifications.

‡ Since no events occurred in Guerci *et al* (2003) or Barnett *et al* (2008), only the RR from Farmer *et al* (2007) contributed to the pooled estimate.

Health-related quality of life and patient satisfaction

There were no statistically significant differences between SMBG, and no SMBG regarding patient well-being[23,43] (as measured by the Well-Being Questionnaire). Furthermore, evaluation of well-being questionnaire sub-scales revealed conflicting results, with one study reporting a significant increase in the level of depression (P = 0.011)[39] and another reporting statistically significant improvements in depression scores.[43] There were no statistically significant differences between SMBG and no SMBG for patient satisfaction[23,29] (as measured by the Diabetes Treatment Satisfaction Questionnaire, Figure 9), or the EuroQol-5D utility score (Table 7). However, Simon et al.[44] reported that patients in the SMBG and intensive education arm of the DiGEM trial demonstrated significantly poorer quality of life compared with no SMBG, as measured by a lower mean EuroQol-5D utility score (WMD [95% CI] = -0.072 [-0.127, -0.017]).

Figure 9: Forest plot of RCTs that compared the effect of SMBG versus no SMBG on satisfaction with diabetes treatment (measured by the Diabetes Treatment Satisfaction Questionnaire) in adults with type 2 diabetes treated with oral antidiabetes drugs or no pharmacotherapy



CI=confidence interval; Less I=less intensive education arm; More I=more intensive education arm; OADs=oral antidiabetes drugs; RCT=randomized controlled trial; SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

Table 7: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses for Health-Related Quality of Life and Patient Satisfaction

Analysis		Number of Studies (sample size)	WMD (95% CI)	I^2 (%)
Well-being questionnaires (change from baseline)				
WBQ - 12		1 RCT[23] (n = 339)	-0.85 (-2.27, 0.56)	NA
WBQ - 22		1 RCT[43] (n = 223)	1.83 (-0.05, 3.71)	NA
Well-being questionnaires sub-scales (coefficient [SE; p-value])*				
WBQ-22		1 RCT[39] (n = 184)		NA
Depression			6.05 (2.37; P=0.011)	
Anxiety			5.86 (3.19; P=0.07)	
Positive well-being			4.16 (2.88; P=0.15)	
Energy			-0.84 (2.83; P=0.77)	
Health-related quality of life — EuroQol — 5D (change from baseline)				
Overall		1 RCT[44] (n = 453)	-0.06 (-0.13, 0.02)	NA
Subgroup analyses				
Intensity of education provided with SMBG	Less intensive†	1 RCT[44] (n = 302)	-0.029 (-0.084, 0.025)	NA
	More intensive‡	1 RCT[44] (n = 301)	-0.072 (-0.127,-0.017)	NA
Patient satisfaction with diabetes treatment (change from baseline)				
Overall		2 RCTs[23,28] (n = 562)	-0.26 (-1.38, 0.86)	0
Sensitivity analyses				
Good quality RCTs only		1 RCT[23] (n = 339)	-0.35 (-1.72, 1.02)	0

CI=confidence interval; NA=not applicable; RCT=randomized controlled trial; SMBG=self-monitoring of blood glucose; WBQ=well-being questionnaire; WMD=weighted mean difference

* All variables scored on 100-point scale, so β coefficient corresponds to % change associated with SMBG.

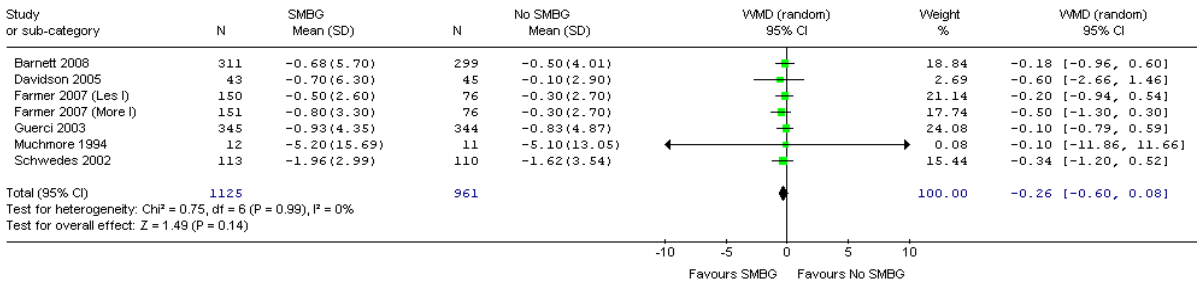
† Less intensive education: patients were trained on using a blood-glucose meter, but were not provided with instructions regarding self-interpretation and application of their SMBG results, or the educational components of the trial were not specified.

‡ More intensive education: patients were provided with training in the self-interpretation and application of their SMBG results to facilitate dietary and lifestyle modifications.

Weight

Six RCTs[4,28,29,37,50,58] enrolling a total of 2,086 patients with type 2 diabetes, managed with oral antidiabetes drugs or no pharmacotherapy, compared the effect of SMBG with no SMBG on change in body weight from baseline. Pooling across all six studies showed no statistically significant difference between treatment groups (Figure 10 and Table 8). Similar results were obtained in sensitivity and subgroup analyses. Publication bias was considered unlikely, based on inspection of the funnel plot (figure not shown).

Figure 10: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Change in Body Weight From Baseline (Kg) in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy



CI=confidence interval; Less I=less intensive education arm; More I=more intensive education arm; OADs=oral antidiabetes drugs; RCT=randomized controlled trial; SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

Table 8: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses for Change in Body Weight From Baseline (Kg)

Analysis		Number of Studies (sample size)	WMD in Body Weight (change from baseline) (kg) (95% CI)	I^2 (%)
Overall		6 RCTs[4,28,29,34,37,50] (n = 2,086)	-0.26 (-0.60, 0.08)	0
Sensitivity analyses				
Good quality RCTs only		2 RCTs[34,50] (n = 1,063)	-0.29 (-0.73, 0.16)	0
RCTs in which all subjects used OADs		2 RCTs[28,50] (n = 1,299)	-0.14 (-0.65, 0.38)	0
Subgroup analyses				
SMBG frequency (< 1/day)		3 RCTs[4,28,34] (n = 1,230)	-0.26 (-0.68, 0.16)	0
SMBG frequency (1-2/day)		1 RCT[50] (n = 610)	-0.18 (-0.96, 0.60)*	NA
SMBG frequency (> 2/day)		2 RCTs[29,37] (n = 246)	-0.34 (-1.20, 0.52)	0
Duration of SMBG (6 months)		4 RCTs[4,28,29,50] (n = 1,610)	-0.21 (-0.64, 0.23)	0
Duration of SMBG (9 months)		2 RCTs[34,37] (n = 476)	-0.34 (-0.88, 0.21)	0
Intensity of education provided with SMBG	Less intensive† or unspecified	5 RCTs[4,28,34,37,50] (n = 1,712)	-0.18 (-0.56, 0.21)	0
	More intensive‡	2 RCTs[29,34] (n = 526)	-0.44 (-0.97, 0.09)	0
Type of OAD	All subjects treated with insulin secretagogue	1 RCT[50] (n = 610)	-0.18 (-0.96, 0.60)	NA

Table 8: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses for Change in Body Weight From Baseline (Kg)

Analysis		Number of Studies (sample size)	WMD in Body Weight (change from baseline) (kg) (95% CI)	I^2 (%)
	All subjects treated with various OADs	2 RCTs[28,50] (n = 689)	-0.10 (-0.79, 0.59)	NA
Baseline glycemic control	A1C < 8.0%	1 RCT[34] (n = 453)	-0.34 (-0.88, 0.21)*	NA
	A1C = 8.0-10.5%	5 RCTs[4,28,29,37,50] (n = 1,633)	-0.21 (-0.64, 0.23)	0

A1C=glycosylated hemoglobin; CI=confidence interval; MD=mean difference; NA=not applicable; OADs=oral antidiabetes drugs; RCT= randomized controlled trial; WMD=weighted mean difference

* Mean difference (95% CI)

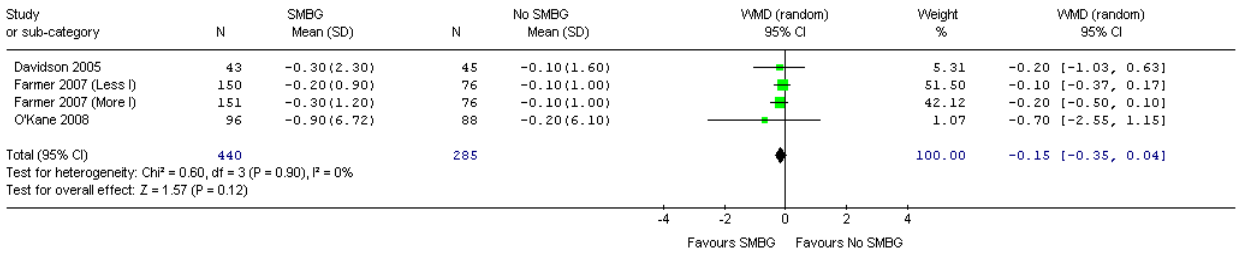
† Less intensive education: patients were trained on using a blood-glucose meter, but were not provided with instructions regarding self-interpretation and application of their SMBG results, or the educational components of the trial were not specified.

‡ More intensive education: patients were provided with training in the self-interpretation and application of their SMBG results to facilitate dietary and lifestyle modifications.

Body mass index

Three RCTs[4,34,39] consisting of a total of 725 patients with type 2 diabetes managed with oral antidiabetes drugs or no pharmacotherapy compared the effect of SMBG with no SMBG on change from baseline in body mass index (BMI) (Table 9). There was no statistically significant difference between treatments (Figure 11). Similar results were obtained in sensitivity and subgroup analyses (Table 9).

Figure 11: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Change in BMI (Kg/M^2) From Baseline in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy



BMI=body mass index; CI=confidence interval; Less I=less intensive education arm; More I=more intensive education arm; OADs=oral antidiabetes drugs; RCT=randomized controlled trial; SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

Table 9: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs or No Pharmacotherapy — Overall Results, Sensitivity Analyses, and Subgroup Analyses For Change in BMI (Kg/M²) From Baseline				
Analysis		**Number of Studies (sample size)**	**WMD in BMI (kg/m²) (95% CI)**	**I² (%)**
Overall		3 RCTs[4,34,39] (n = 725)	-0.15 (-0.35, 0.04)	0
Sensitivity analyses				
Good quality RCTs only		2 RCTs[34,39] (n = 637)	-0.15 (-0.35, 0.05)	0
Subgroup analyses				
Daily SMBG frequency	< 1	2 RCTs[4,34] (n = 541)	-0.15 (-0.34, 0.04)	0
	1-2	1 RCT[39] (n = 184)	-0.70 (-2.55, 1.15)*	NA
Duration of SMBG (months)	6	2 RCTs[4,39] (n = 272)	-0.23 (-0.99, 0.53)	0
	12	1 RCT[34,39] (n = 637)	-0.15 (-0.35, 0.05)*	NA
Intensity of education provided with SMBG	Less intensive† or unspecified	2 RCTs[4,34] (n= 390)	-0.11 (-0.31, 0.10)	0
	More intensive‡	2 RCTs[34,39] (n = 487)	-0.21 (-0.46, 0.04)	0
Time of diabetes diagnosis in relation to study	Newly diagnosed	1 RCT[39] (n = 184)	-0.70 (-2.55, 1.55)*	NA
	Previously diagnosed	2 RCTs[4,34]	-0.15 (-0.34, 0.04)	0
Baseline glycemic control	A1C < 8.0%	1 RCT[34] (n = 453)	-0.14 (-0.34, 0.05)*	NA
	A1C = 8.0-10.5%	2 RCTs[4,39](n = 272)	-0.28 (-1.04, 0.47)	0

A1C=glycosylated hemoglobin; BMI=body mass index; CI=confidence interval; NA=not applicable; RCT=randomized controlled trial; SD=standard deviation; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

* mean difference (95% CI)

† Less intensive education: patients were trained on using a blood-glucose meter, but were not provided with instructions regarding self-interpretation and application of their SMBG results, or the educational components of the trial were not specified.

‡ More intensive education: patients were provided with training in the self-interpretation and application of their SMBG results to facilitate dietary and lifestyle modifications.

Additional clinical outcomes reported in studies

Martin et al. (2006)[36] reported that SMBG use was associated with a significantly decreased risk of all-cause mortality and non-fatal events related to long-term diabetes complications at 6.5 years in a retrospective cohort study of newly diagnosed patients. Conversely, Davis et al. (2007)[33] conducted a prospective cohort study of previously diagnosed patients and reported no change in all-cause mortality with SMBG compared with no SMBG at 10 years (Table 10).

In a retrospective cohort study involving 103 patients managed with glyburide, Rindone et al.(1997)[40] reported no difference between SMBG and no SMBG in the number of patients hospitalized, the number of primary care visits, or the number of patients who visited ophthalmologists (Table 10).

Table 10: Summary of Additional Clinical Outcomes Reported in Studies Comparing SMBG With No SMBG in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs		
Outcome	**Number of Studies (sample size)**	**Effect Estimate (95% CI)**
All-cause mortality (newly diagnosed patients)	1 R. cohort[36] (n = 2,515)	HR: 0.58* (0.35, 0.96)
All-cause mortality (previously diagnosed patients)	1 P. cohort[33] (n = 1,127)	HR:1.20† (0.94, 1.52)
Non-fatal events‡	1 R. cohort[36] (n = 2,515)	HR: 0.72* (0.52, 0.999)
Hospitalization	1 R. cohort[40] (n = 115)	RR: 0.80 (0.40, 1.61)
Primary care visits	1 R. cohort[40] (n = 115)	MD: -1.10 (-2.42, 0.22)
Ophthalmologist visits	1 R. cohort[40] (n = 115)	RR: 0.85 (0.40, 1.80)

CI=confidence interval; HR=hazard ratio; MD=mean difference; R. cohort=retrospective cohort; RR=relative risk; P. cohort=prospective cohort

* Results adjusted for age, sex, concomitant disease at diabetes diagnosis (hypertension, coronary heart disease, history of stroke), laboratory values (fasting blood glucose, triglycerides), treatment, qualification of the treating physician (general practitioner, internist), centre size (number of newly diagnosed patients with type 2 diabetes during 1995-1999), centre location (small town, city), patient's habitation (small town, city), and patient's health insurance (public, private).

† Results adjusted for age, sex, duration of diabetes, prior coronary heart disease, cardiovascular disease, peripheral arterial disease, neuropathy, retinopathy, albumin/creatinine ratio (ln[ACR]), abdominal obesity (negative), use of lipid-lowering medications (negative), Australian Aboriginal, and current smoker status.

‡ Myocardial infarction, stroke, foot amputation, blindness in one or both eyes, or end-stage renal disease requiring dialysis.

c) Comparison of different SMBG frequencies

One RCT compared different SMBG frequencies in patients with type 2 diabetes using oral antidiabetes drugs and[48] reported no significant difference in A1C at six months between SMBG conducted once per week versus four times per week (Table 11).

Karter et al. (2006) reported that mean A1C was significantly lower in patients dispensed an average of one test strip per day versus those dispensed less than one strip per day in their 12-month retrospective cohort study[24] (mean difference [95% CI] = -0.47% [-0.57, -0.37]). Wieland et al. (1997) conducted a retrospective cohort study[47] comparing the effect of SMBG once per day with twice per day in patients treated with glyburide. In contrast to the results of Karter et al, no significant relationship between the frequency of SMBG and A1C was observed after adjusting for demographic and clinical characteristics (Table 11). Similar results were reported in a retrospective cohort study by Secnik et al.(2007).[42] Another retrospective cohort study[54] reported no significant relationship between A1C and an increase of 10 test strips per week in a cohort of 5,862 patients with type 2 diabetes managed with oral antidiabetes drugs alone or in combination with insulin. However, statistically significant reductions in A1C ranging from -0.22% to -0.94% were reported for the following subgroups of patients: those whose doses of oral antidiabetes drugs were unchanged; those whose doses were increased and had another oral antidiabetes drug added to their regimen; and those who began to use insulin. Finally, a before-and-after study[30] in veterans reported no statistically significant change in A1C at one year (7.82% ± 1.22% to 7.83% ± 1.21%) when the use of blood glucose test strips was decreased from an average of 1.35 to 0.67 per day.

In a retrospective cohort study, Karter et al. (2006)[35] reported that new users of SMBG (no strip utilization for 24 months prior to the patients' first dispensing of strips) demonstrated a 0.42% ($P < 0.0001$) reduction in mean A1C at three to 12 months for every additional test strip dispensed per day. This study also reported that prevalent users (i.e., patients performing SMBG for at least 3.5 years) demonstrated a 0.16% ($P < 0.0001$) decrease in A1C for every additional test strip dispensed per day during the four-year study period (Table 11).

Table 11: Summary of A1C Results From Studies Comparing Different SMBG Frequencies in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs

SMBG Frequency		Number of Studies (sample size)	Effect size (95% CI or P–value)
Evidence from RCTs			
SMBG once per week versus 4 times per week		1[48] (n = 178)	MD in A1C: -0.08% (-0.41, 0.25)
Evidence from retrospective cohort studies			
Average daily SMBG: 1 per day versus less than 1 per day		1[24] (n =6,594)	MD in A1C: -0.47% (-0.57, -0.37)[*]
SMBG increased by one strip per day	Patients using OADs	1[42] (n =1,795)	0.09% (P = 0.5392)[†]
	Patients using sulfonylureas	1[47] (n =216)	0.02% (P > 0.50)[‡]
	New users of SMBG	1[35] (n = 5,546)	-0.42% (P < 0.0001)[§]
	Prevalent users of SMBG	1[35] (n = 7,409)	-0.16% (P < 0.0001)[**]
SMBG increased by 10 test strips per week	All subjects	1[54] (n = 5,862)	-0.06% (0.01)[††] (P = 0.38)
	Subgroups		
	OAD dose(s) unchanged	1[54] (n = 2,739)	-0.22% (0.01)[††] (P = 0.04)
	OAD dose(s) increased	1[54] (n = 1,214)	-0.09% (0.02)[††] (P = 0.63)
	New OAD added	1[54] (n = 519)	-0.04% (0.03)[††](P = 0.21)
	OAD dose(s) increased and new OAD added	1[54] (n = 924)	-0.94% (0.03)[††](P = 0.002)
	Insulin added	1[54] (n = 466)	-0.5% (0.01)[††] (P < 0.001)

A1C=glycosylated hemoglobin; CI=confidence interval; MD=mean difference; OADs=oral antidiabetes drugs; RCT=randomized controlled trial; SMBG=self-monitoring of blood glucose

[*] Data adjusted for age, sex, ethnicity, educational attainment, block group attainment, block group annual income and occupation class, years since diabetes diagnosis, diabetes therapy refill adherence, clinic appointment "no show" rate, annual eye exam attendance, self-reported exercise and diet as diabetes therapy, smoking status, alcohol consumption, and hospitalization and emergency room visits during the baseline year.

[†] Adjusted for age, sex, region, body mass index, months since initiation of OAD and A1C test, number of oral medications received in six months prior to A1C test.

[‡] Adjusted for age, daily glyburide dose, serum creatinine concentration, urine protein content, hospital admissions, number of providers, number of ophthalmology visits, number of diabetes clinic visits.

[§] Data adjusted for pre-baseline A1C (last A1C prior to baseline); sex, age, inpatient comorbidity score, diabetes refill medication adherence, diabetes therapies, appointment "no show" rate, performance of annual ophthalmology exams; pre-baseline rates of hospital, emergency room, primary care and specialty visits; primary care provider type, smoking status, neighbourhood level, median family income; residence in a poorly educated neighbourhood, residence in a predominately working-class neighbourhood; and the length of time between pre and post-A1C tests.

[**] Data adjusted as in footnote "[§]" , but also for: SMBG, daily insulin injection frequency, appointment "no show" rate, inpatient comorbidity score, and inpatient/outpatient utilization.

[††] Coefficient (SE) represents change in A1c for every ten blood glucose test strips used each week. Coefficients are derived for each outcome stratum using separate multivariate linear regression models adjusting for initial doses of glyburide and metformin and the number of oral antidiabetes drugs.

An abstract[32] reported a statistically significant decrease in A1C with an SMBG frequency of six per day every two weeks compared with four per day every month (WMD [95% CI] = -0.29% [-0.57, -0.01]) at six months. The per-protocol analysis was restricted to the 44% and 73% of subjects who were compliant in the higher and lower frequency arms, respectively.

Fasting and post-prandial blood glucose

Bonomo et al. (2006)[32] reported, as an abstract, the results of an RCT comparing two different frequencies of SMBG in patients with type 2 diabetes who did not use insulin. Patients performed either a four-point blood glucose profile once per month (n = 70) or a six-point blood glucose profile once every 15 days (n = 78). For patients using the higher frequency, significant reductions from baseline were reported for the following SMBG readings: fasting (P = 0.013), two hours after breakfast (P = 0.004), before lunch (P = 0.003), before dinner (P = 0.037), and two hours after dinner (P = 0.002). There were no significant changes in any baseline blood glucose readings in patients randomized to the lower frequency arm.

Additional outcomes

Scherbaum et al. (2008)[48] compared an SMBG frequency of once-weekly with four times per week in a RCT with 202 patients with type 2 diabetes. The number of patients with overall hypoglycemia was significantly lower in the once per week arm (RR [95% CI] = 0.28 [0.11, 0.73]). There were no significant differences in all-cause mortality, hospitalization, primary care visits, or rates of hyperglycemia, nor were there any events of severe hypoglycemia or hyperosmolar coma (Table 12).

Table 12: Summary of Additional Clinical Outcomes Reported in the Scherbaum et al. RCT[48] Comparing SMBG Once Per Week Versus Four Times Per Week in Adults With Type 2 Diabetes Treated With Oral Antidiabetes Drugs

Outcome		Relative Risk (95%CI)
Overall hypoglycemia		0.28 (0.11, 0.73)
Severe hypoglycemia		No events
Hyperglycemia		1.02 (0.06, 16.08)
All-cause mortality		1.02 (0.06, 16.08)
Hospitalization*		1.38 (0.74, 2.61)
Primary care visits	0 to 3 months	0.99 (0.83, 1.18)
	4 to 6 months	1.18 (0.98, 1.41)

CI=confidence interval; SMBG=self-monitoring of blood glucose
*Inpatient stay for serious adverse events, not specific to diabetes.

d) Patients with type 2 diabetes not using diabetes pharmacotherapy

The randomization process for the DiGEM trial balanced several covariates, including initial diabetes therapy, allowing for a sub-group analysis of subjects who were not treated with any antidiabetes pharmacotherapy.[34] In this subgroup, there were no significant differences in mean A1C between SMBG users and non-users, regardless of the intensity of education provided (Table 13).

Conversely, Karter et al. (2001)[24] reported statistically significant differences in A1C favouring SMBG frequencies of one per day, and less than one per day, versus no SMBG. This study also reported a significant difference in favour of one per day versus less than one per day (Table 13). A second retrospective cohort study, Karter et al. (2006),[35] reported a 0.35% reduction (p<0.0001) in A1C at three to 12 months for every additional test strip dispensed per day in new SMBG users. However, the number of test strips dispensed was not significantly associated with A1C in prevalent SMBG users (patients performing SMBG for at least 3.5 years) over the four year study period (Table 13).

Table 13: Summary of A1C Results for Adults With Type 2 Diabetes Not Treated With Antidiabetes Drugs			
Comparison		**Sample size**	**Mean Difference in A1C (%) (95% CI)**
Evidence from Diabetes Glycemic Education and Monitoring Study[34]			
SMBG versus no SMBG		124	-0.05 (-0.33, 0.23)
SMBG with less intensive education versus no SMBG		83	0.01 (-0.30, 0.32)
SMBG with more intensive education versus no SMBG		85	-0.12 (-0.44, 0.20)
Evidence from retrospective cohort studies			
≥ 1 per day SMBG versus no SMBG[24]		3,445	-0.64 (-0.81, -0.47)*
< 1 per day SMBG versus no SMBG[24]		4,198	-0.34 (-0.47, -0.21)*
≥ 1 per day SMBG versus < 1 per day SMBG[24]		1,987	-0.30 (-0.47, -0.13)*
SMBG increased by 1 strip per day[35]	New SMBG users	7,872	-0.35% (p<0.0001)†
	Prevalent SMBG users	1,622	NS†; coefficient not reported

A1C=glycosylated haemoglobin; CI=confidence interval; NS=non-significant; RCT=randomized controlled trial; SMBG-self-monitoring of blood glucose

* Adjusted for age, sex, ethnicity, educational attainment, block group annual income and occupational class, years since diabetes diagnosis, diabetes therapy refill adherence, number of daily insulin injections (insulin users only), clinic appointment "no show" rate, annual eye exam attendance, self-reported exercise and diet as diabetes treatment, smoking status, alcohol consumption, and hospitalization and emergency room visits during the baseline year.

† Data adjusted for pre-baseline A1C (last A1C prior to baseline), sex, age, inpatient comorbidity score; diabetes refill medication adherence, diabetes therapies(therapeutic class), appointment "no show" rate, performance of annual ophthalmology exams; pre-baseline rates of hospital, emergency room, primary care and specialist visits; primary care provider type, smoking status, neighbourhood level, median family income; residence in a poorly educated neighbourhood, residence in a predominately working-class neighbourhood; and the length of time between pre and post-A1C tests.

7.4.3 Gestational diabetes

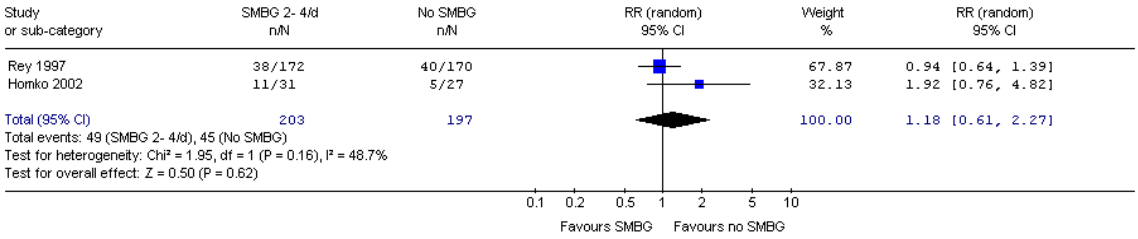
Two RCTs evaluated the impact of SMBG versus no SMBG in patients with gestational diabetes not using diabetes pharmacotherapy. Homko et al. (2002) examined the effect of SMBG on self-efficacy and pregnancy outcomes.[51] Patients within the SMBG group measured their blood glucose levels four times a day on four days a week, for a total of 16 times per week. Apart from SMBG, the management protocol was identical for both study arms. Rey (1997)[52] assessed the usefulness of a standardized breakfast test in identifying women with gestational diabetes who may not benefit from SMBG. In the SMBG arm, blood glucose was measured one hour post-prandially, three times a day, alternating with four times per day (before each meal and at bedtime). In both trials, participants' blood glucose was monitored at regular prenatal visits every two weeks, and subjects were advised to initiate insulin usage if their glycemic control target levels were not achieved. In the Homko et al. study,[51] one woman in each arm used insulin (3.2% in the SMBG arm and 3.7% in the control arm). In the RCT by Rey (1997),[52] among the women with one-hour post-breakfast blood glucose < 7.8 mmol/L, there were four (3.6%) insulin users in the SMBG arm and none in the control arm. In women with one-hour post-breakfast blood glucose ≥ 7.8 mmol/L, 25% of women used insulin in both treatment arms.

Neither of the studies examined the effect of SMBG use on A1C. The maternal, pregnancy, fetal, and neonatal outcomes from the two studies previously mentioned were analyzed and are subsequently reported.

a) Maternal and pregnancy outcomes

There were no statistically significant differences between the SMBG and no SMBG study arms for the following outcomes: fasting blood glucose, one-hour post-prandial blood glucose, body weight gain at the time of delivery, self-efficacy scores on the Diabetes Empowerment Scale, birth trauma, and Cesarean sections (Figure 12). Pooled results for all maternal and pregnancy outcomes are summarized in Table 14.

Figure 12: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Risk of Caesarean Section in Women With Gestational Diabetes



CI=confidence interval; n=number of events; N=sample size; RCTs=randomized controlled trials; RR=relative risk; SMBG-self-monitoring of blood glucose

Table 14: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Women With Gestational Diabetes — Maternal and Pregnancy Outcomes

Outcome	Number of Studies (sample size)	Effect Estimate (95%CI)	I^2 (%)
FPG (mmol/l)	1 RCT[51] (n = 58)	MD: -0.22 (-0.55, 0.11)	NA
1 hour-PPBG (mmol/l)	1 RCT[51] (n = 58)	MD: 0.47 (-0.12, 1.06)	NA
Body weight gain at delivery (kg)	1 RCT[51] (n = 58)	MD: -2.50 (-6.16, 1.16)	NA
Self efficacy score*	1 RCT[51] (n = 58)	MD: 3.70(-1.56, 8.96)	NA
Cesarean section rate	2 RCTs[51,52] (n = 400)	RR: 1.18 (0.61, 2.27)	48.7
Birth trauma	1 RCT[51] (n = 58)	RR: 0.87 (0.06, 13.27)	NA

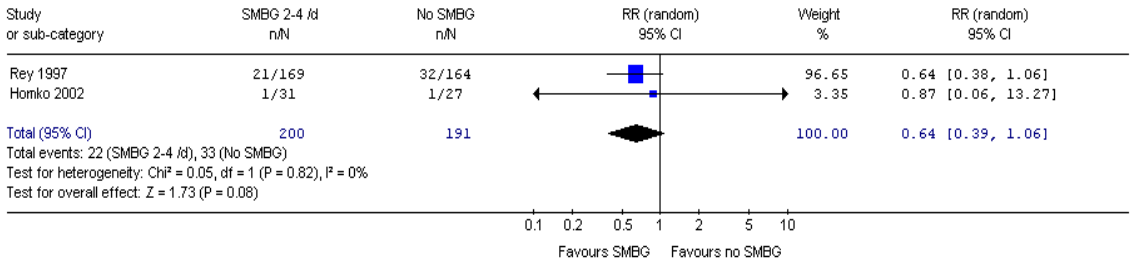
CI=confidence interval; FPG=fasting plasma glucose; MD=mean difference; NA=not applicable; PPBG=one-hour post-prandial blood glucose; RCT=randomized controlled trial; RR=relative risk

* Self-efficacy score: Diabetes Empowerment Scale. Lower scores indicate greater feelings of self-efficacy.

b) Fetal and neonatal outcomes

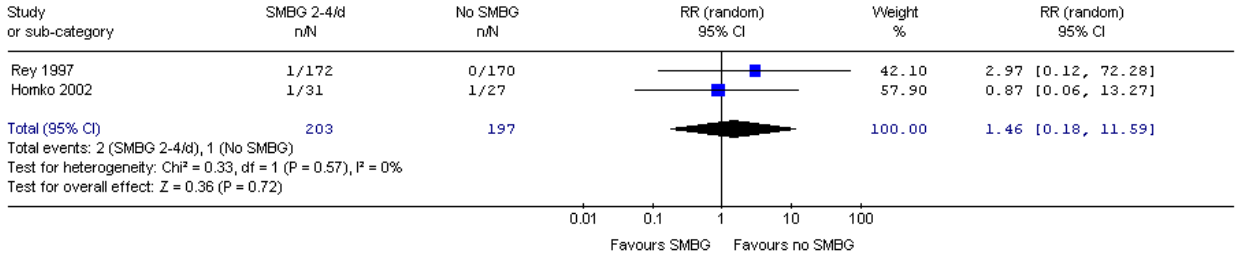
No statistically significant differences were found between SMBG and no SMBG in neonatal hypoglycemia, all-cause fetal mortality, neonatal intensive care unit admission, small for gestational age (weight < 10th percentile), large for gestational age (weight > 90th percentile), macrosomia, hyperbilirubinemia, respiratory complications, Apgar score (1 and 5 min), and gestational age at delivery (weeks) (Figures 13 to 17 andTable 15).

Figure 13: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Risk of Neonatal Hypoglycemia in Infants Born to Women With Gestational Diabetes



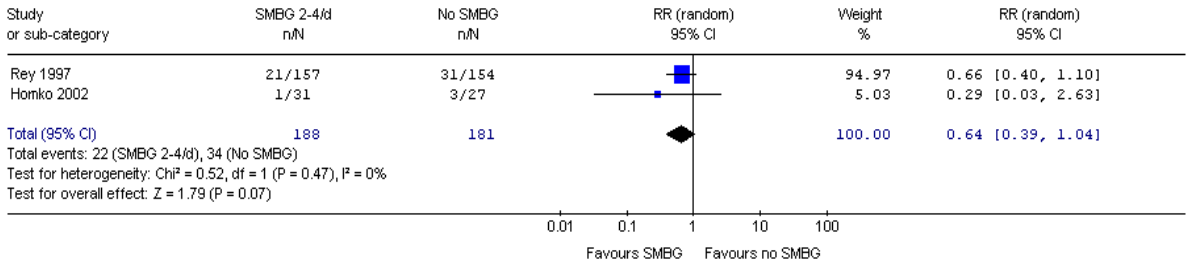
CI=confidence interval; n=number of events; N=sample size; RCTs=randomized controlled trials; RR=relative risk; SMBG-self-monitoring of blood glucose

Figure 14: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Risk of All-Cause Fetal Mortality in Infants Born to Women With Gestational Diabetes



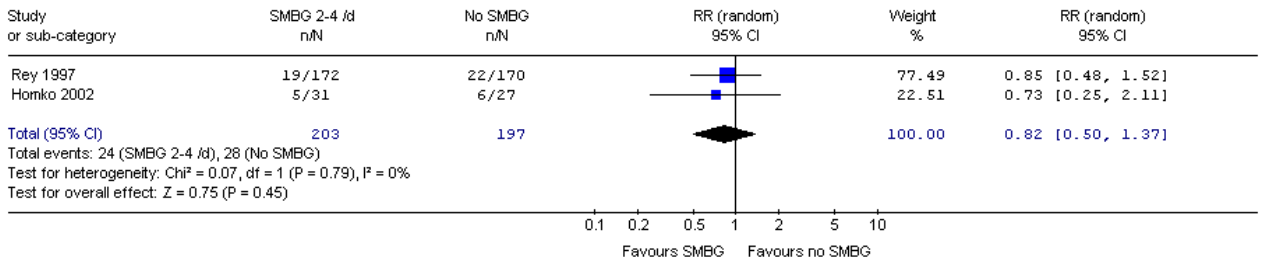
CI=confidence interval; n=number of events; N=sample size; RCTs=randomized controlled trials; RR=relative risk; SMBG-self-monitoring of blood glucose

Figure 15: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Risk of Neonatal Hyperbilirubinemia in Infants Born to Women With Gestational Diabetes



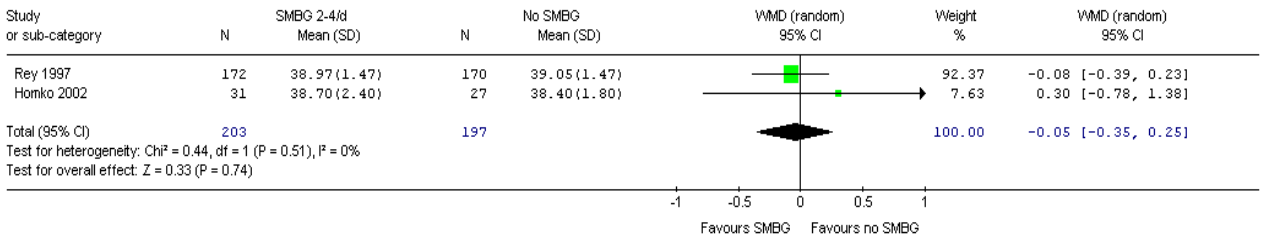
CI=confidence interval; n=number of events; N=sample size; RCTs=randomized controlled trials; RR=relative risk; SMBG-self-monitoring of blood glucose

Figure 16: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Risk of Large for Gestational Age (Weight >90th Percentile) in Infants Born to Women With Gestational Diabetes



CI=confidence interval; n=number of events; N=sample size; RCTs=randomized controlled trials; RR=relative risk; SMBG-self-monitoring of blood glucose

Figure 17: Forest Plot of RCTs That Compared the Effect of SMBG Versus No SMBG on Gestational Age at Delivery in Women With Gestational Diabetes



CI=confidence interval; n=number of events; N=sample size; RCTs=randomized controlled trials; RR=relative risk; SMBG-self-monitoring of blood glucose

Table 15: Summary of Meta-Analytic Results Across RCTs Comparing SMBG Versus No SMBG in Women With Gestational Diabetes — Fetal and Neonatal Outcomes

Outcome	Number of Studies (sample size)	Effect Estimate (95%CI)	I²
Neonatal hypoglycemia	2 RCTs[51,52] (n = 391)	RR: 0.64 (0.39, 1.06)	0
All-cause fetal mortality	2 RCTs[51,52] (n = 400)	RR: 1.46 (0.18, 11.59)	0
Neonatal ICU admission	1 RCT[51] (n = 58)	RR: 0.87 (0.13, 5.77)	NA
Small for gestational age (birth weight < 10th percentile)	1 RCT[52] (n = 342)	RR: 1.19 (0.53, 2.67)	NA
Large for gestational age (birth weight > 90th percentile)	2 RCTs[51,52] (n = 400)	RR: 0.82 (0.50, 1.37)	0
Macrosomia (birth weight > 4.00 kg)	1 RCT[52] (n = 342)	RR: 0.94 (0.53, 1.67)	NA
Hyperbilirubinemia	2 RCTs[51,52] (369)	RR: 0.64 (0.39, 1.04)	0
Respiratory complications	1 RCT[51] (n = 58)	RR: 0.87 (0.06, 13.27)	NA
Apgar score (1 min)	1 RCT[51] (n = 58)	MD: -0.40 (-1.51, 0.71)	NA
Apgar score (5 min)	1 RCT[51] (n = 58)	MD: -0.20 (-1.13, 0.73)	NA
Gestational age at delivery (weeks)	2 RCT[51,52] (n = 400)	RR: -0.05 (-0.35, 0.25)	0

CI=confidence interval; ICU=intensive care unit; MD=mean difference; NA=not applicable; RCTs=randomized controlled trials; RR=relative risk; SMBG-self-monitoring of blood glucose

Rey (1997)[52] stratified patients based on whether or not they had a one-hour standardized post-breakfast blood glucose level greater than or less than 7.8 mmol/L. For subjects with one-hour standardized post-breakfast blood glucose ≥ 7.8 mmol/L, the number of large-for-gestational age babies (birth weight > 90th percentile) was significantly lower in the SMBG group compared with no SMBG (RR [95% CI] = 0.43 [0.2, 0.92]). The incidence of hyperbilirubinemia (during the first three days of life) was also found to be significantly reduced in the SMBG arm compared with no SMBG (RR [95% CI] = 0.51 [0.26, 0.99]). No statistically significant differences were shown for hypoglycemia, macrosomia (birth weight > 4.00 kg), small for gestational age, gestational age at delivery (weeks), or all-cause fetal mortality in the ≥ 7.8 mmol/L subgroup (Table 16).

Table 16: Effects of SMBG Versus No SMBG on Fetal and Neonatal Outcomes in Women With Gestational Diabetes and a One-Hour Standardized Post-Breakfast Blood Glucose of ≥7.8 mmol/L — Results From the Rey RCT[52]

Outcome	Effect Estimate (95%CI)
Neonatal hypoglycaemia* (first 24 hours of life)	RR: 0.52,(0.26, 1.02)
Macrosomia (birth weight > 4.00 kg)	RR: 0.75 (0.34, 1.67)
Large for gestational age (birth weight > 90th percentile)	RR: 0.43 (0.20, 0.92) ARR: -0.176 (-0.24,-0.024) NNT: 6 (4, 40)
Small for gestational age (birth weight < 10th percentile)	RR: 0.61 (0.11, 3.52)
Hyperbilirubinemia† (during the first 3 days of life)	RR: 0.51(0.26, 0.99) ARR: -0.176(-0.27, -0.004) NNT: 6(4, 278)
Gestational age at delivery (weeks)	MD: -0.20 (-0.31, 0.71)
All-cause fetal mortality	Not estimable‡

ARR =absolute risk reduction; CI=confidence interval; MD=mean difference; NNT=number needed to treat; RCT=randomized controlled trial; RR=relative risk; SMBG=self-monitoring of blood glucose

* Defined as lab-measured blood glucose concentration < 1.7 mmol/L in full-term neonates and < 1.1 mmol/L in pre-term neonates.

† Defined as total serum bilirubin level > 170 mmol/L in the first 24 hours of life, > 205 mmol/L in the second day of life, or > 240mmol/L in the third day of life.

‡ No fetal deaths were reported in either study arm.

No evidence was identified for women with gestational diabetes treated with oral antidiabetes drugs.

8 DISCUSSION

8.1 Summary of Main Findings

8.1.1 Use of SMBG in patients treated with insulin

After a systematic review of the available literature, COMPUS identified seven studies[24-27,31,33,42] that examined the use of SMBG in patients with insulin-treated diabetes. These studies were all classified as being of poor quality, and reported findings were inconsistent. Due to significant heterogeneity between studies, meta-analyses were not performed.

One non-randomized trial involving children[27] and two observational studies in adults[24,25] reported that more frequent SMBG was associated with improvements in glycemic control for patients with type 1 diabetes. However, in adults with type 1 diabetes, a small crossover RCT[26] reported that increasing SMBG frequency is not associated with improvements in glycemic control. No data were reported for other outcomes of interest.

For patients with type 2 diabetes using insulin, one non-randomized trial[31] and a retrospective cohort study[24] reported a statistically significant decrease in A1C in patients using SMBG. A time series analysis[33] reported similar findings for patients with A1C > 8.0%. However, for patients with A1C ≤ 8.0%, no significant decrease in A1C was observed. There were no significant differences in fasting blood glucose, overall hypoglycemia, or mortality.[31,33,41] Comparisons of SMBG frequency for patients with type 2 diabetes using insulin were performed in three studies.[25,31,42] Aydin et al.[31] reported no statistically significant difference in A1C between SMBG frequencies of four per day once-weekly and four per day every two weeks. Secnik et al.[42] and Evans et al.[25] reported significant and non-significant decreases in A1C, respectively, for each additional test strip dispensed per day in regression analyses of observational data. The frequency of SMBG had no effect on the number of patients with hypoglycemia or in incidences of hypoglycemic events.[31]

No systematic reviews or meta-analyses were identified that examined the effect of different SMBG frequencies in patients treated with insulin. Our systematic review uncovered few studies that directly examined the optimal frequency of SMBG, and those that were available reported mixed findings of low quality. Regardless of the evidence, or lack thereof, decisions regarding SMBG frequency have to be made in clinical practice. Despite the lack of high-quality studies, SMBG is still considered a "standard of care" for patients who use insulin because it may enable:

- detection of hypoglycemia and hyperglycemia
- patients to assess real-time glucose measurements and adjust insulin doses accordingly.[5]

8.1.2 Use of SMBG in adults with non—insulin-treated diabetes

The CADTH systematic review identified eleven articles that reported results from seven RCTs which compared SMBG with no SMBG.[4,28,29,34,37,39,43,44,50,53,59] Pooling of results from these studies demonstrated that SMBG is associated with a statistically significant, albeit clinically modest,[60] improvement in glycemic control (WMD in A1C [95% CI] = -0.25% [-0.36 to -0.15]). Overall, this finding is consistent with those reported in recently published systematic reviews.[61-65]

The results from the three observational studies comparing SMBG with no SMBG in adults using oral antidiabetes drugs were inconsistent. Due to variations in study design, patient characteristics, and adjustment for potential confounding variables, the data from observational studies were not pooled. In general, effect estimates reported in observational studies may differ from those reported in RCTs. This is due to the lack of control for confounding variables and the greater likelihood of selection bias, making it difficult to isolate the effect of SMBG on glycemic control.[66]

There was some heterogeneity across the RCTs included in the meta-analyses regarding study and patient characteristics. As such, we conducted detailed sensitivity and sub-group analyses. The sensitivity analysis for good-quality RCTs and sub-group analyses for frequency of SMBG, duration of SMBG use, and for studies where all patients received oral antidiabetes drugs were consistent with the overall pooled estimate. For patients who were not using diabetes pharmacotherapy, improvements in glycemic control were less pronounced and statistically non-significant. Sub-group analysis based on baseline A1C demonstrated more pronounced improvements in glycemic control with SMBG use in patients with baseline A1C values greater than 8.0%.

It is commonly accepted that SMBG cannot improve glycemic control in isolation, meaning that SMBG should be effective when coupled with adequate education and training.[62,67,68] COMPUS conducted sub-group analyses based on whether or not patients who received training in the self-interpretation and application of their SMBG results demonstrated greater A1C improvement. Similar to the findings from the DiGEM trial,[34] COMPUS analyses showed that the effect of SMBG on A1C was similar, regardless of the intensity of patient education. It is possible that the failure to observe a difference between these two educational approaches to self-monitoring could be related to other factors, including poor compliance with the study protocol. Assessment of patient compliance was limited to monitoring frequency, with no studies reporting compliance regarding the self-interpretation requirements of the protocol. To properly assess this form of compliance, it would be necessary to document and evaluate specifications that were taken in response to abnormal readings. Such an approach could also facilitate the identification of highly-motivated subgroups that may benefit from SMBG.

Findings from studies comparing different frequencies of SMBG were mixed. Results from a well-designed RCT[48] found no statistically significant difference in A1C between subjects with non—insulin-treated diabetes who performed SMBG once-daily compared with those who performed SMBG four times a day. Results from observational studies were variable. A large retrospective cohort study found a statistically significant difference in A1C between patients who performed greater than one test per day compared with those who performed less than one test per day.[24] However, another study[47] reported no significant difference between SMBG performed either once- or twice-daily. One retrospective cohort study[35] reported statistically significant improvement in A1C with increasing SMBG frequency, whereas other studies[42,47] reported no significant association between SMBG frequency and A1C.

There was no statistically significant effect of SMBG on relative risk[28,50] or rate ratio[50] of overall hypoglycemia in patients with diabetes managed with oral antidiabetes drugs alone. However, there was a significant increase in the number of symptomatic hypoglycemic events occurring in patients using sulfonylureas who were not performing SMBG.[50] This finding suggests that SMBG may be beneficial in reducing progression of asymptomatic hypoglycemia in patients using insulin secretagogues. However, this is a subjective outcome which was not clearly defined a priori by the authors; hence, further studies employing more rigorous methods to measure symptomatic hypoglycemia are required.

The relative risk of severe or nocturnal hypoglycemia was not significantly affected with SMBG, but the risk of overall hypoglycemia was significantly higher with SMBG compared with no SMBG. It is not clear if SMBG actually increases overall hypoglycemia, or if this increase is due to greater awareness of asymptomatic hypoglycemia[28,50,61,65] that would have otherwise gone undetected. Contrary to the increase in the number of patients with overall hypoglycemia with SMBG, the number of events of overall hypoglycemia was significantly less with SMBG. The reason for this discrepancy is unclear, although it may be that increased detection of hypoglycemia with SMBG soon after SMBG initiation (which results in a higher risk of overall hypoglycemia) ultimately produces behaviour changes that reduce future hypoglycemic events (resulting in a lower rate ratio for overall hypoglycemia). There was no statistically significant effect of SMBG on relative risk[28,50] or rate ratio[50] of overall hypoglycemia in patients with diabetes managed with oral antidiabetes drugs alone.

Data from RCTs showed no statistically significant effect of SMBG on body weight,[4,28,29,34,37,50] BMI,[4,34,39] hospitalization,[48] primary care visits,[48] patient satisfaction,[23,48] or patient well-being.[23,43] With respect to mortality, findings from observational studies were conflicting. One study in newly-diagnosed patients reported a significant decrease in mortality with SMBG;[36] however, another study in previously-diagnosed patients reported no change in mortality.[33] Given the many possible confounders and likelihood of selection

bias in observational studies, the relationship between SMBG and long-term complications of diabetes remains uncertain in adults with non–insulin-treated diabetes.

8.1.3 Gestational diabetes

This systematic review identified two low-quality RCTs[51,52] investigating the use of SMBG in women with gestational diabetes. The results of these studies suggest that SMBG may produce small reductions in the number of newborns who are diagnosed as large for gestational age, and in the incidence of neonatal hyperbilirubinemia in neonates born to women with a one-hour post-standardized breakfast blood glucose greater than 7.8 mmol/L. There was no significant effect on other maternal, pregnancy, neonatal, or fetal outcomes.

8.2 Strengths and Weaknesses of Review

In terms of strengths, this systematic review has followed a transparent and accepted methodology. A protocol outlining the scope and methods was developed prior to initiating the work. As compared to previous systematic reviews on the subject of SMBG, this report included several more studies, as well as four large, good quality randomized controlled trials published after 2006.[34,39,48,50] Furthermore, unlike earlier reviews that only reported results for patients with type 2 diabetes, the CADTH review includes data for patients with type 1 diabetes, type 2 diabetes, and gestational diabetes.[61-65] Many systematic reviews have only examined the effect of SMBG on A1C, whereas this review meta-analyzed numerous outcomes. Finally, this review conducted more detailed sensitivity and sub-group analyses to examine the robustness of results, as compared to previous reviews.

COMPUS results and the strength of the conclusions are limited by the available clinical evidence. COMPUS encountered a lack of methodologically robust studies, particularly for patients with insulin-treated and gestational diabetes. Ethical considerations may prevent studies of complete abstention from SMBG in patients with insulin-treated diabetes. Given the increasing prevalence of diabetes, the paucity of studies comparing alternative SMBG testing frequencies is noteworthy.

Limitations pertaining to the RCTs included in the analysis of SMBG for patients with type 2 diabetes using insulin warrant mention. First, patient compliance with the trial protocol was either poor or not reported for nearly all RCTs.[4,23,28,34,39,44,50] There was also inconsistency regarding the type of primary analysis used in the trials, with three trials reporting per-protocol analysis[28,29,37,43] and the remaining using intention-to-treat analysis.[4,23,34,39,44,50] Use of intention-to-treat analysis may have underestimated the efficacy of SMBG in trials where compliance was poor. However, it could also be argued that such an analysis more closely reflects the actual benefit that can be expected from SMBG in clinical practice, where non-compliance rates are likely to be even higher than in the controlled setting of a clinical trial. Second, the trials reported by Muchmore et al. (1994)[37] (n = 28) and Davidson et al. (2005)[4] (n = 89) had very small sample sizes and both exhibited wide confidence intervals for their estimates of effect on A1C. It is possible that these studies were inadequately powered to detect the effects of SMBG. A third limitation of the included studies is the heterogeneity in the design and application of treatment algorithms for patients. Two high-quality studies[39,50] used well-defined treatment algorithms, two other studies did not specify an algorithm and allowed individual physicians to make therapeutic decisions based on treatment guidelines,[23,28,34,44] and the remaining studies did not report this information. Furthermore, the protocol for Barnett et al. (2008)[50] instructed patients to increase their dosage of gliclazide modified release if their fasting blood glucose exceeded > 7.0 mmol (or 7.8 mmol for patients > 65 years of age), whereas in the remaining RCTs, health care professionals either adjusted the dosage of oral antidiabetes medications based on A1c results,[4,23,28,34,39,44] or the basis for adjusting therapy was not specified.[29,37,43] It is uncertain whether or not implementation of strict treatment algorithms may

negate any possible benefits of SMBG. However, one could speculate that having patients and health care professionals adjust treatments based on a number of clinical parameters, including results from SMBG, is more reflective of current clinical practice. Hence, the generalizability of trials in which treatment decision-making processes were not reflective of clinical practice may be limited.

A limitation of existing systematic reviews investigating SMBG is the lack of a clear definition. Trials can generally be placed into two categories: those in which patients measured blood glucose values, and those in which patients measured blood glucose values and were instructed on the use of results to facilitate a lifestyle intervention. A major strength of this review is the subgroup analysis that explored the effects of whether or not patients were given specific instructions in the self-interpretation and application of SMBG results. Unfortunately, no studies attempted to measure the degree to which subjects actually implemented the advice given on appropriate implementation of SMBG results. This should be an area explored in future studies.

The observational studies identified posed a number of limitations. In most, SMBG frequency was indirectly assessed based upon pharmacy refills or patient self-report. Since the compliance of SMBG may be lower than the number of test strips dispensed, the benefit of SMBG may be underestimated, while the usage of strips may be overestimated. Also, although most studies adjusted for a variety of possible confounding factors, it is possible that results were still biased due to unadjusted factors. In particular, A1C at baseline was not reported or adjusted for in some analyses. Finally, the CADTH reviewers were unable to determine whether the glycemic benefits observed in some observational studies are attributable to SMBG, or to the underlying differences in patient characteristics. Patients who perform SMBG, in general, may have a healthier lifestyle than those who do not perform SMBG.[69]

Non–English-language articles were excluded from this review. Articles of potential relevance may have been overlooked as a result of this language restriction; however, many studies have suggested that the exclusion of non-English trials has minimal impact on the results of systematic reviews and meta-analyses.[70-72]

8.3 Generalizability of Findings

The generalizability of COMPUS findings regarding patients with insulin-treated diabetes is uncertain for a number of reasons. First, some of the studies[27,31] were conducted in countries that may differ substantially from Canada in their clinical practice (i.e., Turkey, Thailand). Second, there was a lack of methodologically rigorous clinical evidence. These two factors make it difficult to apply the findings of this review to the Canadian population. Third, several studies[26,31] used SMBG testing frequencies that may not be clinically relevant. If the frequency of SMBG tested in a particular study is lower than that recommended in usual practice, the effects of SMBG may be underestimated.

Results for patients with non–insulin-treated type 2 diabetes are more likely to be generalizable to the Canadian clinical setting. Evidence was available from a number of RCTs, most of which were conducted in countries where clinical practice patterns are similar to those in Canada (e.g., United States, United Kingdom). Also, the effect sizes were consistent across these RCTs,[4,28,29,34,37,39,50] and results were consistent with those reported in other recently published systematic reviews and meta-analyses.[61-65] It is noteworthy, however, that six of the seven RCTs included in the meta-analysis restricted enrolment to patients with mean baseline A1C ranging from 8.1% to 10.5%; therefore, COMPUS results may be more generalizable to patients with poorly controlled diabetes. The Diabetes in Canada Evaluation (DICE) study found that the average A1C of patients with type 2 diabetes in Canada is 7.5%, and that only 20% of patients have an A1C

> 8.5%.[73] The only RCT that included subjects with a baseline A1C < 8.0%[34] reported a statistically non-significant A1C benefit of SMBG of 0.16%.

The study conducted by Guerci et al. (2003)[28] specified that patients with impending complications of diabetes were ineligible for inclusion, while four other trials, including the DiGEM trial and the Efficacy of Self-Monitoring Of blood glucose in patients with Newly diagnosed type 2 diabetes (ESMON) trial,[23,29,34,37,39,43,44] excluded patients with serious underlying medical conditions. It is possible that such requirements could limit the generalizability of our findings to healthier patients with diabetes. However, it is unlikely that the exclusion criteria employed in the included studies were so restrictive that the results cannot be applied to typical patients with type 2 diabetes in Canada.

8.4 Knowledge Gaps

There is a scarcity of high-quality studies comparing different frequencies of SMBG in patients with type 1 diabetes, insulin-treated type 2 diabetes, and gestational diabetes. No studies were identified investigating SMBG in patients newly initiated on insulin, patients whose insulin dose or regimen has recently changed, children with type 2 diabetes, or pregnant women with type 1 or type 2 diabetes. Future well-designed RCTs may prove beneficial in determining the optimal use of SMBG in these populations, and assessing the impact of SMBG on clinically important complications of diabetes. There were also no studies comparing SMBG frequencies during acute illness, a situatation where more frequent testing may be required.

For patients with type 2 diabetes who were not using insulin, several high-quality studies found statistically significant improvements in glycemic control with SMBG use. However, it is uncertain how these improvements may translate into reductions in clinically important outcomes (e.g., blindness, myocardial infarctions, end-stage renal disease). The length of follow-up for most included studies was less than one year. Data from longer-term studies would help establish if the effect of SMBG on glycemic control is maintained, and whether or not this translates into reductions in diabetes-related complications. Furthermore, although the A1C benefit of SMBG appeared to be modest overall, further studies are needed to determine if specific subgroups of patients with type 2 diabetes who do not use insulin would benefit from SMBG to a greater extent (for example, patients newly initiating or undergoing changes in oral antidiabetes pharmacotherapy warrants further study). Future trials reporting patient compliance with self-interpretation and application of SMBG results could provide valuable information for optimizing the use of blood glucose test strips.

There was no evidence identified that examined the effect of SMBG in special populations such as First Nations, ethnic minorities, populations for whom abnormal blood glucose levels (especially, hypoglycemia) may pose occupational risks (e.g., professional drivers, pilots, construction workers, and athletes).

9 CONCLUSION

Based on low-quality clinical data, SMBG appears to be associated with improvements in glycemic control among patients with either type 1 or insulin-treated type 2 diabetes. For patients with non–insulin-treated type 2 diabetes, pooling of RCTs demonstrated that SMBG is associated with a statistically significant, albeit clinically modest, improvement in glycemic control. A similar degree of improvement in glycemic control was also observed in studies in which all subjects used oral antidiabetes drugs. There were no significant differences between SMBG and no SMBG arms for severe, nocturnal, or overall hypoglycemia, although a single trial demonstrated that SMBG may be beneficial in reducing symptomatic hypoglycemia in patients using sulfonylureas. There was little or no evidence to suggest that SMBG confers benefits regarding other outcomes, such as quality-of-life, patient satisfaction, body weight, long-term complications of diabetes, or

mortality. These findings were consistent with those reported in other systematic reviews and meta-analyses.[62,64,65,67,68,74,75] The effect of SMBG in women with gestational diabetes could not be clearly established from the available evidence. Given the increasing prevalence of diabetes, future methodologically rigorous RCTs of sufficient size and duration may prove beneficial in optimizing SMBG frequency in patients with type 1 and insulin-treated type 2 diabetes, and in women with gestational diabetes. Future RCTs may also help identify specific subgroups of patients with type 2 diabetes who do not use insulin and who are most likely to benefit from SMBG.

SMBG itself does not have a direct effect on either glycemic control or clinical outcomes in diabetes management. Its clinical effect can only be obtained when patients adjust their lifestyle, diet, exercise, or diabetes pharmacotherapy based on SMBG results. SMBG can only be effective, therefore, when used as part of a broader management strategy incorporating patient education on the interpretation of results and appropriate responses.

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APPENDIX 1: SUMMARY OF EXISTING SYSTEMATIC REVIEWS

Where possible, COMPUS builds on existing applicable Canadian and international initiatives and research. Therefore, the first stage in the research process was to conduct a literature search for existing systematic reviews that have examined the effect of SMBG in diabetes mellitus.

Several major databases (MEDLINE, CINAHL, EMBASE, BIOSIS, and PsycINFO) were searched to identify systematic reviews, health technology assessments, and meta-analyses that have examined the effect of SMBG in diabetes mellitus and were published in English between 2000 and January 2008. Two reviewers independently selected systematic reviews for consideration based on pre-defined inclusion and exclusion criteria. The methodological quality of selected systematic reviews was assessed independently by two reviewers using the AMSTAR instrument.[76] Based on the scope and quality of each review, two reviewers determined whether the selected publications could be used as a basis for COMPUS to develop recommendations for the optimal prescribing and use of blood glucose test strips. Details regarding the search strategy, selection process, and quality assessment are provided in the COMPUS SMBG Project Protocol.[19]

Summary of Seven Identified Systematic Reviews Regarding the Use of SMBG in the Management of Type 2 Diabetes

Author and Year of Publication	Population	Studies Included	Key Results (SMBG Versus No SMBG)
Balk et al., 2007[75]	Type 2 diabetes (regardless of therapy)	5 RCTs and 1 non-RCT	**A1C (%) difference in change from baseline:** No meta-analysis was performed; The result of 5 RCTs were inconclusive about whether or not use of SMBG resulted in clinically significant reduction in A1C. Statistically significant improvement in A1C was found in SMBG arm in the non-RCT. *Correlation of SMBG frequency with A1C*: Two studies (one cross-sectional and one RCT) were included. It was inconclusive regarding the correlation of frequency of SMBG with A1C.
Coster et al., 2000[2,77]	Type 2 diabetes (regardless of therapy) Type 1 diabetes	Type 2: 4 RCTs Type 1: 1 RCT	**A1C (%) difference:** Type 2: WMD (95%CI): -0.25% (-0.61, 0.10) (mixed RCTs of SMBG or urine monitoring versus no monitoring). Type 1: No significant change after SMBG (different frequency) was found.
McAndrew et al., 2007[67]	Type 2 diabetes not using insulin	11 RCTs, 9 longitudinal studies, and 9 cross-sectional	**A1C (%) difference at endpoint:** No meta-analysis was performed; evidence from RCTs suggests that SMBG may lead to improvements in glucose control; evidence

Author and Year of Publication	Population	Studies Included	Key Results (SMBG Versus No SMBG)
		studies	from the cross-sectional and longitudinal studies was inconclusive.
McGeoch et al., 2007[68]	Type 2 diabetes not using insulin	3 RCTs and 13 observational studies	**A1C(%)difference in change from baseline:** No meta-analysis was performed; the two larger RCTs had statistically significantly lower A1C levels with SMBG; the larger observational studies tended to have higher initial A1C and did show an association between SMBG and A1C or other clinical improvement, while the smaller observational studies, which had lower initial A1C, did not; overall, the improvement in glycemic control with SMBG tended to be seen in studies with initial A1C above 8%. **Body weight:** No significant body weight reduction was found with SMBG.
Welschen et al., 2005[65,74]	Type 2 diabetes not using insulin	5 RCTs	**A1C (%) difference in change from baseline:** WMD (95%CI): -0.39 (-0.56, -0.21). **Other outcomes:** No meta-analysis was performed; there were few data on the effects of FPG, hypoglycemia, quality of life, patient satisfaction; these effects were not statistically significant; no data was reported for morbidity and adverse effects.
Jansen, 2006[64]	Type 2 diabetes not using insulin	12 RCTs	**A1C(%) difference in change from baseline:** WMD (95%CI): -0.42 (-0.76, -0.03) (adjusted for baseline A1C and weighted for internal validity)
Sarol et al., 2005[62]	Type 2 diabetes not using insulin	8 RCTs	**A1C (%) difference in change from baseline:** WMD (95%CI): -0.39 (-0.54, -0.23) under the fixed effects model and -0.42 (-0.63, -0.21) under the random effects model.

A1C=glycosylated hemoglobin; CI=confidence interval; RCT=randomized controlled trial; RR=relative risk; SMBG=self-monitoring of blood glucose; WMD=weighted mean difference

Among the seven systematic reviews selected, none of them addressed all the populations and outcomes of interest; only one provided the limited information about the comparison between different SMBG frequencies. As a result, none of these seven systematic reviews was adopted.

APPENDIX 2: LITERATURE SEARCH STRATEGY — PRIMARY STUDIES

OVERVIEW	
Interface:	OVID
Databases:	BIOSIS Previews <1989 to 2008 Week 9>; CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to February Week 4 2008>; EMBASE <1996 to 2008 Week 9>; Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <February 28, 2008>; Ovid MEDLINE(R) <1966 to February Week 4 2008> * Note: Subject headings have been customized for each database.
Date of Search:	February 28, 2008
Alerts:	Monthly search updates began March 2008 and ran to February 2009.
Study Types:	Randomized controlled trials; controlled clinical trials; cohort studies; cross-over studies; case control studies; comparative studies; observational studies.
Limits:	Publication years 1990-present
SYNTAX GUIDE	
/	At the end of a phrase, searches the phrase as a subject heading
.sh	At the end of a phrase, searches the phrase as a subject heading
MeSH	Medical Subject Heading
fs	Floating subheading
exp	Explode a subject heading
$	Truncation symbol, or wildcard: retrieves plural or variations of a word
*	Indicates that the marked subject heading is a primary topic
?	Truncation symbol for one or no characters only
ADJ	Requires words are adjacent to each other (in any order)
ADJ#	Adjacency within # number of words (in any order)
.ti	Title
.ab	Abstract
.hw	Heading Word; usually includes subject headings and controlled vocabulary
.pt	Publication type
.rn	CAS registry number

SEARCH SYNTAX:

1. BGTS and DM1 and (clinical trial filter OR observational filter)
2. BGTS and DM2 and (clinical trial filter OR observational filter)
3. BGTS and Gestational DM and (clinical trial filter OR observational filter)

SEARCH STRATEGY

BGTS Search Strategies

Line #	Search
	MEDLINE / BIOSIS / CINAHL
1	Blood glucose self-monitoring/
2	(Self adj2 (monitor$ or measur$ or test or testing or tested or tests or evaluat$)).ti,ab,hw.
3	(Test strip$ or SMBG or testing supplies or test supplies or monitoring equipment).ti,ab,hw.
4	reagent strip/
5	(abbott diabetes freestyle or arkray advance or hypoguard or arkray quicktek or bayer ascensia or precision xtra or one touch ultra or accu-chek or uni-check or fasttake or glucometer elite or precision qid or prestige smart system or surestep or ascensia).ti,ab,hw.
6	or/2-5
7	Blood glucose/
8	Blood sugar.ti,ab,hw.
9	glucose.ti,ab,hw.
10	or/7-9
11	6 and 10
12	exp Diabetes Mellitus/
13	diabet$.ti,ab,hw.
14	(Mody or niddm or iddm).ti,ab,hw.
15	or/12-14
16	6 and 15
17	1 or 11 or 16
	EMBASE
1	blood glucose monitoring/
2	(Self adj2 (monitor$ or measur$ or test or testing or tested or tests or evaluat$)).ti,ab.
3	test strip/
4	(Test strip$ or SMBG or test supplies or testing supplies or monitoring equipment).ti,ab.
5	self monitoring/
6	or/2-5
7	Glucose Blood Level/
8	Blood sugar.ti,ab.
9	glucose.ti,ab.
10	or/7-9
11	exp Diabetes Mellitus/
12	diabet$.ti,ab.
13	(Mody or niddm or iddm).ti,ab.
14	or/11-13
15	1 and 6

Line #	Search
16	6 and 10
17	6 and 14
18	15 or 16 or 17
	PsycINFO
1	self monitoring/
2	(Self adj2 (monitor$ or measur$ or test or testing or tested or tests or evaluat$)).ti,ab.
3	(Test strip$ or SMBG or testing supplies or test supplies or monitoring equipment).ti,ab.
4	(abbott diabetes freestyle or arkray advance or hypoguard or arkray quicktek or bayer ascensia or precision xtra or one touch ultra or accu-chek or uni-check or fasttake or glucometer elite or precision qid or prestige smart system or surestep or ascensia).ti,ab.
5	or/1-4
6	blood sugar/ or glucose/
7	Blood sugar.ti,ab.
8	glucose.ti,ab.
9	or/6-8
10	exp diabetes/
11	diabet$.ti,ab.
12	(Mody or niddm or iddm).ti,ab.
13	or/10-12
14	5 and 9
15	5 and 13
16	14 or 15

Diabetes Mellitus Type 1 Search Strategies

Line #	Search
	MEDLINE / BIOSIS
1	diabetes mellitus/
2	exp diabetes mellitus, type 1/
3	((brittle or insulin dependent or juvenile or childhood or ketosis prone or sudden onset or autoimmune or type 1 or type I) adj2 diabet$).ti,ab,hw.
4	((brittle or insulin dependent or juvenile or childhood or ketosis prone or sudden onset or autoimmune or type 1 or type I) adj2 diabet$).ti,ab,hw.
5	(iddm adj4 diabet$).ti,ab,hw.
6	or/1-5
	CINAHL
1	diabetes mellitus, insulin-dependent/
2	diabetic ketoacidosis/
3	Diabetes Mellitus/
4	((brittle or insulin dependent or juvenile or childhood or ketosis prone or sudden onset or autoimmune or type 1 or type I) adj2 diabet$).ti,ab.
5	(iddm adj4 diabet$).ti,ab.
6	or/1-5
	EMBASE
1	Insulin dependent diabetes mellitus/
2	diabetes mellitus/
3	juvenile diabetes mellitus/

Line #	Search
4	diabetic ketoacidosis/
5	((brittle or insulin dependent or juvenile or childhood or ketosis prone or sudden onset or autoimmune or type 1 or type I) adj2 diabet$).ti,ab.
6	(iddm adj4 diabet$).ti,ab.
7	or/1-6

Diabetes Mellitus Type 2 Search Strategies

Line #	Search
	MEDLINE / BIOSIS
1	exp Diabetes Mellitus, Type 2/
2	Diabetes Mellitus/
3	((adult onset or ketosis resistant or maturity onset or late life or non-insulin dependent or slow onset or stable or type 2 or type II or lipoatrophic) adj2 diabet$).ti,ab,hw.
4	((niddm or mody) adj4 diabet$).ti,ab,hw.
5	or/1-4
	CINAHL
1	diabetes mellitus/ or diabetes mellitus, non-insulin-dependent/
2	((adult onset or ketosis resistant or maturity onset or late life or non-insulin dependent or slow onset or stable or type 2 or type II or lipoatrophic) adj2 diabet$).ti,ab,hw.
3	((niddm or mody) adj4 diabet$).ti,ab,hw.
4	or/1-3
	EMBASE
1	diabetes mellitus/ or lipoatrophic diabetes mellitus/ or maturity onset diabetes mellitus/ or non insulin dependent diabetes mellitus/
2	((adult onset or ketosis resistant or maturity onset or late life or non-insulin dependent or slow onset or stable or type 2 or type II or lipoatrophic) adj2 diabet$).ti,ab,hw.
3	((niddm or mody) adj4 diabet$).ti,ab,hw.
4	or/1-3
	PsycINFO
1	((adult onset or ketosis resistant or maturity onset or late life or non-insulin dependent or slow onset or stable or type 2 or type II or lipoatrophic) adj2 diabet$).ti,ab,hw.
2	(iddm adj4 diabet$).ti,ab,hw.
3	or/1-2

Gestational Diabetes Mellitus Search Strategies

Line #	Search
	MEDLINE / BIOSIS
1	GDM.ti,ab.
2	(gestation$ adj2 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab,hw.
3	(pregnan$ adj3 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab,hw.
4	or/1-3
	CINAHL
1	Diabetes Mellitus, Gestational/
2	GDM.ti,ab.
3	(gestation$ adj2 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab.
4	(pregnan$ adj3 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab.

Line #	Search
5	or/1-4
	EMBASE
1	Pregnancy Diabetes Mellitus/
2	GDM.ti,ab.
3	(gestation$ adj2 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab.
4	(pregnan$ adj3 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab.
5	or/1-4
	PsycINFO
1	(gestation$ adj2 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab.
2	(pregnan$ adj3 (diabet$ or DM or glucose intolerance or insulin resistance)).ti,ab.
3	GDM.ti,ab.
4	or/1-3

Clinical Trial Filters

Line #	Search
	MEDLINE / BIOSIS
1	randomized controlled trial.pt.
2	randomized controlled trials as topic/
3	randomized controlled trial/
4	(random$ or sham$ or placebo$ or (singl$ adj (blind$ or dumm$ or mask$)) or (doubl$ adj (blind$ or dumm$ or mask$))).ti,ab,hw.
5	((tripl$ adj (blind$ or dumm$ or mask$)) or (treb$ adj (blind$ or summ$ or mask$))).ti,ab,hw.
6	(randomi?ed control$ trial? or rct?).ti,ab,hw.
7	(Multicenter Study or Controlled Clinical Trial or Clinical Trial).pt.
8	exp clinical trial/
9	exp clinical trial as topic/
10	double-blind method.sh.
11	single-blind method.sh.
12	random allocation.sh.
13	multicenter studies.sh.
14	cross-over studies.sh.
15	cohort studies.sh.
16	(contol$ adj (study or studies or trial$)).ti,ab,hw.
17	(control$ adj clinical adj (study or studies or trial$)).ti,ab,hw.
18	((multicent$ or multi-cent$) adj (study or studies or trial$)).ti,ab,hw.
19	((crossover or cross-over) adj (study or studies or trial$)).ti,ab,hw.
20	((case control$ or case comparison$) adj (study or studies or trial$)).ti,ab,hw.
21	(cohort adj1 (study or studies or design or trial$ or analysis or analyses)).ti,ab,hw.
22	or/1-21
	EMBASE
1	exp clinical trial/
2	exp controlled study/
3	double blind procedure.sh.
4	single blind procedure.sh.
5	multicenter study.sh.

Line #	Search
6	crossover procedure.sh.
7	cohort analysis.sh.
8	(random$ or sham$ or placebo$ or (singl$ adj (blind$ or dumm$ or mask$)) or (doubl$ adj (blind$ or dumm$ or mask$))).ti,ab.
9	((trip$ adj (blind$ or dumm$ or mask$)) or (treb$ adj (blind$ or dumm$ or mask$))).ti,ab.
10	(randomi?ed control$ trial? or rct?).ti,ab.
11	(major clinical study or multicenter study).ti,ab.
12	(control$ adj (study or studies or trial$)).ti,ab.
13	(control$ adj clinical adj (study or studies or trial$)).ti,ab.
14	((multicent$ or multi-cent$) adj (study or studies or trial$)).ti,ab.
15	((crossover or cross-over) adj (study or studies or trial$)).ti,ab.
16	((case control$ or case comparison$) adj (study or studies or trial$)).ti,ab.
17	(cohort adj1 (study or studies or design or trial$ or analysis or analyses)).ti,ab.
18	or/1-17
	CINAHL
1	exp clinical trials/
2	clinical trial.pt.
3	(clinic$ adj trial$).tw.
4	((singl$ or doub$ or trebl$ or tripl$) adj (blind$ or mask$)).tw.
5	randomi?ed control$ trial$.tw.
6	random assignment/
7	random$ allocat$.tw.
8	placebo$.tw.
9	placebos/
10	quantitative studies/
11	allocat$ random$.tw.
12	or/1-11
	PsycINFO
	Database limits - or "2000 treatment outcome/randomized clinical trial"

Observational Filters

Line #	Search
	MEDLINE / BIOSIS
1	Observational stud$.ti,ab,hw.
2	Cohort studies/
3	(cohort stud$ or cohort analys?s or cohort design).ti,ab,hw.
4	Longitudinal studies/ or longitudinal stud$.ti,ab,hw.
5	Prospective studies/ or prospective stud$.ti,ab,hw.
6	Follow-up studies/ or follow-up stud$.ti,ab,hw.
7	Retrospective studies/ or restrospective stud$.ti,ab,hw.
8	Comparative Study/ or comparative stud$.ti,ab,hw.
9	Case-control studies/
10	Evaluation Study/ or evaluation stud$.ti,ab,hw.
11	(case control$ stud$ or case control$ analys?s).ti,ab,hw.
12	Population-based stud$.ti,ab,hw.
13	Population-based case control stud$.ti,ab,hw.

Line #	Search
14	or/1-13
	EMBASE
1	Observational study/
2	Observational stud$.ti,ab.
3	Cohort analysis/
4	(cohort stud$ or cohort analys?s).ti,ab.
5	Longitudinal study/ or longitudinal stud$.ti,ab.
6	Comparative Study/ or comparative stud$.ti,ab.
7	Prospective study/ or prospective stud$.ti,ab.
8	Retrospective study/ or retrospective stud$.ti,ab.
9	follow-up stud$.ti,ab.
10	Case control study/
11	(case control$ stud$ or case control$ analys?s).ti,ab.
12	Case study/
13	case series.ti,ab.
14	Population-based case control study/
15	population-based stud$.ti,ab.
16	Population-based case control study.ti,ab.
17	or/1-16
	CINAHL
1	prospective studies/
2	exp case control studies/
3	correlational studies/
4	nonconcurrent prospective studies/
5	Comparative Study/ or comparative stud$.ti,ab.
6	cross sectional studies/
7	(cohort adj (study or studies or design)).tw.
	PsycINFO
	Database Limits - ("0400 empirical study" or "0430 followup study" or "0450 longitudinal study" or "0451 prospective study" or "0452 retrospective study" or 1800 quantitative study)

OTHER DATABASES	
PubMed	Same MeSH, keywords, limits, and study types used as per MEDLINE search, with appropriate syntax used.
The Cochrane Library Issues 1, 2008	Same MeSH, keywords, and date limits used as per MEDLINE search, excluding study types. Syntax adjusted for Cochrane Library databases.

GREY LITERATURE	
Dates for Search:	February 2008 – March 2008
Keywords:	blood glucose, blood sugar, test strips, diabetes, self monitoring blood glucose
Limits:	Publication years 1990-March 2008

This section lists the main agencies, organizations, and websites searched; it is not a complete list.

Health Technology Assessment Agencies

Agence d'evaluation des technologies et des modes d'intervention en santé (AETMIS), Quebec
http://www.aetmis.gouv.qc.ca

Alberta Heritage Foundation for Medical Research (AHFMR), Alberta
http://www.ahfmr.ab.ca

Canadian Agency for Drugs and Technologies in Health (CADTH), Ontario
http://www.cadth.ca

Centre for Evaluation of Medicines (Father Sean O'Sullivan Research Centre, St.Joseph's Healthcare,Hamilton, and McMaster University, Faculty of Health Sciences, Hamilton), Ontario
http://www.thecem.net/

(UBC) Centre for Health Services and Policy Research, British Columbia.
http://www.chspr.ubc.ca/cgi-bin/pub

Health Quality Council of Alberta (HQCA), Alberta
http://www.hqca.ca

Health Quality Council, Saskatchewan
http://www.hqc.sk.ca/

Institute for Clinical Evaluative Sciences (ICES), Ontario
http://www.ices.on.ca/

Institute of Health Economics (IHE), Alberta
http://www.ihe.ca/

Manitoba Centre for Health Policy (MCHP), University of Manitoba, Manitoba
http://www.umanitoba.ca/centres/mchp/

Ontario Ministry of Health and Long-Term Care, Ontario Health Technology Assessment Series, Ontario
http://www.health.gov.on.ca/english/providers/program/mas/tech/tech_mn.html

Technology Assessment Unit of the McGill University Health Centre, Quebec
http://www.mcgill.ca/tau/

Therapeutics Initiative (Department of Pharmacology and Therapeutics, University of British Columbia), British Columbia
http://www.ti.ubc.ca

(WHO) Health Evidence Network (HEN), Denmark
http://www.euro.who.int/HEN

Health Technology Assessment International (HTAi), Alberta
http://www.htai.org

ITA — Institute of Technology Assessment, Austria
http://www.oeaw.ac.at/ita/index.htm

Swiss Network for Health Technology Assessment, Switzerland
http://www.snhta.ch/about/index.php

Australia
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)
http://www.surgeons.org/Content/NavigationMenu/Research/ASERNIPS/default.htm

Centre for Clinical Effectiveness (Monash University), Australia
http://www.med.monash.edu.au/healthservices/cce/
Medicare Services Advisory Committee (Australian Government Department of Health and Ageing)
http://www.msac.gov.au/

NPS RADAR (National Prescribing Service Limited Australian Government Department of Health and Ageing)
http://www.npsradar.org.au/site.php?page=1&content=/npsradar%2Fcontent%2Farchive_alpha.html

Sweden
CMT – The Center for Medical Technology Assessment (Linköping University), Sweden
http://www.cmt.liu.se/pub/jsp/polopoly.jsp?d=6199&l=en

International Network for Agencies for Health Technology Assessment (INAHTA), Sweden
http://www.inahta.org

Swedish Council on Technology Assessment in Health Care (SBU)
http://www.sbu.se/en

United Kingdom
Centre for Reviews and Dissemination (National Institute for Health Research, University of York)
http://www.york.ac.uk/inst/crd

European Information Network on New and Changing Health Technologies (EUROSCAN). University of Birmingham. National Horizon Scanning Centre
http://www.euroscan.bham.ac.uk

National Horizon Scanning Centre (NHSC)
http://www.pcpoh.bham.ac.uk/publichealth/horizon

NHS Health Technology Assessment /National Coordinating Centre for Health Technology Assessment (NCCHTA). Department of Health R&D Division.
http://www.ncchta.org/

NHS National Institute for Health and Clinical Excellence (NICE)
http://www.nice.org.uk

NHS Quality Improvement Scotland
http://www.nhshealthquality.org

Wessex Institute, University of Southampton
http://www.wihrd.soton.ac.uk/

West Midlands Health Technology Assessment Collaboration (WMHTAC)
http://www.wmhtac.bham.ac.uk/

United States
Agency for Healthcare Research and Quality (AHRQ), US Department of Health & Human Services
http://www.ahrq.gov/

ECRI
http://www.ecri.org/

Institute for Clinical Systems Improvement
http://www.icsi.org/index.asp

Technology Evaluation Center (Blue Cross and Blue Shield Association)
http://www.bluecares.com/tec/index.html

United States Department of Veterans Affairs
http://www.research.va.gov

VA Technology Assessment Program (VATAP)
http://www.va.gov/vatap/

Conferences/Societies/Organizations/Associations

American Association of Clinical Endocrinologists
http://www.aace.com/org/

American Diabetes Association
http://www.diabetes.org/home.jsp

Association of British Clinical Diabetologists
http://www.diabetologists-abcd.org.uk/

Canadian Diabetes Association
www.diabetes.ca/

Children with Diabetes
http://www.childrenwithdiabetes.com/

Diabetes Technology Society
http://www.diabetestechnology.org/

Diabetes UK
http://www.diabetes.org.uk/

European Association for the Study of Diabetes
http://www.easd.org/

European Society for Paediatric Endocrinology
http://www.eurospe.org/

European Society of Endocrinology
http://www.euro-endo.org/

International Diabetes Federation (IDF)
http://www.idf.org/

Primary Care Diabetes Europe (PCDE)
http://www.pcdeurope.org/

Society for Endocrinology
http://www.endocrinology.org/

The Endocrine Society
http://www.endo-society.org/

Search Engines

Google
http://www.google.ca/

Yahoo
http://www.yahoo.ca

APPENDIX 3: REASONS FOR TYPE 1 DIABETES STUDY EXCLUSION

Study	Reason for Exclusion
Abdelgadir et al.[78]	Study design not of interest
Akutsu et al.[79]	Comparators not of interest
Albertson et al.[80]	Review
Allen et al.[81]	Outcomes not of interest
Allen et al.[82]	Outcomes not of interest
American diabetes association[83]	Recommendations/guidelines
Anderson et al.[84]	Study design not of interest
Anderson et al.[85]	Intervention not of interest
Anderson et al.[86]	Study design not of interest
Austin et al.[87]	Recommendations/guidelines
Beaser[88]	Review
Ben ahmed[89]	Non-English
Billiard et al.[90]	Comparators not of interest
Blonde et al.[91]	Review
Bonomo et al.[32]	Population not of interest
Bragd et al.[92]	Comparators not of interest
Brink[93]	Review
Buckingham et al.[94]	Intervention not of interest
Buckley and Buckley[95]	Review
Bühling et al.[96]	Comparators not of interest
Burrill[97]	Review
Carter et al.[98]	Comparators not of interest
Cava et al.[99]	Non-English
Chase et al.[100]	Comparators not of interest
Clarke et al.[101]	Intervention not of interest
Conget et al.[102]	Comparators not of interest
Cook et al.[103]	Intervention not of interest
Cox et al.[104]	Comparators not of interest
Cox et al.[105]	Outcomes not of interest
Cox et al.[106]	Intervention not of interest
Craig et al.[107]	Study design not of interest
Cranor et al.[108]	Intervention not of interest
Davidson et al.[109]	Outcomes not of interest
DCCT Research Group [110]	Intervention not of interest
Deiss et al.[111]	Intervention not of interest
Deiss et al.[112]	Comparators not of interest
DeVries et al.[113]	Review
Dinneen[114]	Review
Dorchy et al.[115]	Non-English
Dorchy et al.[116]	Study design not of interest
Dorchy[117]	Non-English
Edelman[118]	Review

Study	Reason for Exclusion
El Aziz[119]	Non-English
Ellis et al.[120]	Comparators not of interest
Erny-Albrecht et al.[121]	Outcomes not of interest
Espersen and Klebe[122]	Predate search criteria
Farmer et al.[123]	Comparators not of interest
Farmer et al.[124]	Comparators not of interest
Faro[125]	Review
Fiallo-Scharer et al.[126]	Comparators not of interest
Fink et al.[127]	Intervention not of interest
Frankum et al.[128]	Outcomes not of interest
Gagliardino et al.[129]	Outcomes not of interest
Gallegos-Macias et al.[130]	Outcomes not of interest
Gautier et al.[131]	Intervention not of interest
Gebhart et al.[132]	Outcomes not reported by diabetes mellitus type
Gilden et al.[133]	Outcomes not reported by diabetes mellitus type
Glowinska-Olszewska et al.[134]	Non-English
Goldstein et al.[135]	Review
Goldstein et al.[136]	Pre-date search criteria
Grady et al.[137]	Outcomes not of interest
Grossi et al.[138]	Non-English
Grossi et al.[139]	Non-English
Guillod et al.[140]	Intervention not of interest
Halimi et al.[141]	Comparators not of interest
Halimi[142]	Non-English
Haller et al.[143]	Study design not of interest
Halvorson et al.[144]	Outcomes not of interest
Hansen et al.[145]	Outcomes not of interest
Harris et al.[146]	Comparators not of interest
Harris et al.[147]	Outcomes not of interest
Haupt et al.[148]	Intervention not of interest
Haupt et al.[149]	Intervention not of interest
Heinemann et al.[150]	Outcomes not reported by diabetes mellitus type
Hempe et al.[151]	Intervention not of interest
Hershey et al.[152]	Intervention not of interest
Hjelm et al.[153]	Outcomes not of interest
Hjelm et al.[154]	Outcomes not of interest
Hoi-Hansen et al.[155]	Comparators not of interest
Holl et al.[156]	Duplicate
Hollahan[157]	Comparators not of interest
Ikeda and Tsuruoka[158]	Review
Jeha et al.[159]	Comparators not of interest
Jones et al.[160]	Outcomes not reported by diabetes mellitus type
Kalergis et al.[161]	Outcomes not of interest
Karter et al.[35]	Outcomes not reported by diabetes mellitus type
Kasatkina et al.[162]	Non-English
Kerssen et al.[163]	Comparators not of interest

Study	Reason for Exclusion
Kim et al.[164]	Comparators not of interest
Kitis and Emiroglu[165]	Intervention not of interest
Koch[166]	Review
Kolb et al.[167]	Population not of interest
Kolb et al.[168]	Population not of interest
Kovatchev et al.[169]	Outcomes not of interest
Kovatchev et al.[170]	Intervention not of interest
Kovatchev et al.[171]	Comparators not of interest
Laffel et al.[172]	Comparators not of interest
Lagarde et al.[173]	Comparators not of interest
Lankisch et al.[174]	Duplicate
Latalski et al.[175]	Non-English
Lecomte et al.[176]	Outcomes not of interest
LeRoith and Smith[177]	Review
Levine et al.[178]	Study design not of interest
Li et al.[179]	Outcomes not of interest
Linn et al.[180]	Non-English
Litwak et al.[181]	Non-English
López et al.[182]	Comparators not of interest
Magni and Bellazzi[183]	Outcomes not of interest
Maluf[184]	Outcomes not of interest
Manderson et al.[185]	Comparators not of interest
Mann et al. [186]	Pre-date search criteria
Marre et al.[187]	Non-English
Martin et al.[188]	Population not of interest
Martin et al.[189]	Duplicate
Martin et al.[190]	Population not of interest
McLachlan et al.[191]	Intervention not of interest
Meltzer[192]	Review
Meneghini and Arce[193]	Outcomes not of interest
Miller and Elasy[194]	Outcomes not of interest
Minshall et al.[195]	Study design not of interest
Moberg et al.[196]	Intervention not of interest
Moir and Feher[197]	Outcomes not of interest
Moreland et al.[198]	Outcomes not reported by diabetes mellitus type
Müller et al.[199]	Non-English
Murata et al.[200]	Duplicate
Nansel et al.[201]	Intervention not of interest
Nathan et al.[202]	Intervention not of interest
Nathan et al.[203]	Comparators not of interest
Nathan[204]	Review
National Health Service[205]	Review
Neeser et al.[206]	Outcomes not of interest
Newman et al.[207]	Outcomes not reported by diabetes mellitus type
Nielsen et al.[208]	Comparators not of interest
Nordfeldt and Ludvigsson[209]	Intervention not of interest

Study	Reason for Exclusion
Nyomba et al.[210]	Outcomes not reported by diabetes mellitus type
Oden et al.[211]	Population not of interest
Ogawa et al.[212]	Non-English
Özmen and Boyvada[213]	Comparators not of interest
Pan et al.[214]	Outcomes not of interest
Park et al.[215]	Comparators not of interest
Pek et al.[216]	Intervention not of interest
Piatt et al.[217]	Intervention not of interest
Pickup et al.[218]	Intervention not of interest
Polonsky and Wagner[219]	Outcomes not of interest
Radman et al.[220]	Intervention not of interest
Reynolds and Karounos[221]	Review
Richardson et al.[222]	Comparators not of interest
Rodrigues et al.[223]	Comparators not of interest
ROSSO Study Group[224]	Duplicate
Sachon et al.[225]	Review
Sanyal et al.[226]	Comparators not of interest
Scherbaum et al.[227]	Duplicate
Schiel et al.[228]	Non-English
Schiel et al.[229]	Comparators not of interest
Schiel et al.[230]	Outcomes not of interest
Schütt et al.[1]	Study design not of interest
Scorpiglione et al.[231]	Outcomes not of interest
Sebo et al.[232]	Intervention not of interest
Sheppard et al.[233]	Outcomes not reported by diabetes mellitus type
Skeie et al.[234]	Comparators not of interest
Slama and Selam[235]	Non-English
Soni et al.[236]	Outcomes not of interest
Soumerai et al.[45]	Outcomes not reported by diabetes mellitus type
Soumerai et al.[237]	Population not of interest
State of Florida Agency for Health Care Administration[238]	Recommendations/guidelines
Stewart et al.[239]	Comparators not of interest
Strowig and Raskin[240]	Study design not of interest
Svensson et al.[241]	Intervention not of interest
Svoren et al.[242]	Comparators not of interest
Svoren et al.[242]	Intervention not of interest
Tacker et al.[243]	Comparators not of interest
Takata et al.[69]	Outcomes not reported by diabetes mellitus type
Tanenberg et al.[244]	Comparators not of interest
TEC bulletin[245]	Review
Tengblad et al.[246]	Population not of interest
Tercyak et al.[247]	Intervention not of interest
Terent et al.[248]	Pre-date search criteria
Tildesley et al.[249]	Comparators not of interest
Tillmann et al.[250]	Study design not of interest

Study	Reason for Exclusion
Tubiana-Rufi et al.[251]	Review
Tunis et al.[252]	Study design not of interest
Uchigata et al.[253]	Outcomes not of interest
Unspecified[254]	Recommendations/guidelines
Unspecified[255]	Recommendations/guidelines
Varner[256]	Pre-date search criteria
Walker[257]	Review
Walsh et al.[258]	Intervention not of interest
Weber et al.[259]	Outcomes not of interest
Weber et al.[260]	Outcomes not of interest
Weijman et al.[261]	Comparators not of interest
Weitgasser et al.[262]	Comparators not of interest
Weitgasser et al.[263]	Non-English
Willey et al.[264]	Comparators not of interest
Williams et al.[265]	Intervention not of interest
Wolever et al.[266]	Intervention not of interest
Wood and Laffel[267]	Review
Yates et al.[268]	Comparators not of interest
Zayfert and Goetsch[269]	Review
Ziegher et al.[270]	Intervention not of interest

APPENDIX 4: REASONS FOR TYPE 2 DIABETES STUDY EXCLUSION

Study	Reason for Exclusion
Abdelgadir et al.[78]	Study design not of interest
Adams et al.[271]	Outcomes not of interest
Akutsu et al.[79]	Comparators not of interest
Allen et al.[272]	Comparators not of interest
Alper[273]	Comments
Aschner et al.[129]	Outcomes not of interest
Austin et al.[87]	Recommendations/Guidelines
Bajkowska-Fiedziukiewicz et al.[49]	Data unextractable
Balas et al.[274]	Review
Bandolier[275]	Review
Bandolier[276]	Review
Banister et al.[277]	Comparators not of interest
Beaser[88]	Review
Ben Ahmed[89]	Non-English
Bergenstal[278]	Study protocol
Bernbaum et al.[279]	Research question not of interest
Bernbaum et al.[280]	Duplicate
Bilo[281]	Study Protocol
Bjorsness et al.[282]	Comments
Blonde and Karter[91]	Review
Blonde et al.[283]	Comments
Bowker et al.[284]	Comparators not of interest
Boyko [285]	Study protocol
Bradshaw et al.[286]	Comparators not of interest
Brewen et al.[287]	Population not of interest
Brown et al.[288]	Comparators not of interest
Brown et al.[289]	Research question not of interest
Brown and Hanis[290]	Comparators not of interest
Buckley and Buckley[95]	Review
Burge[291]	Comments
Burrill[97]	Review
Cava et al.[292]	Non-English
Chan[293]	Outcomes not reported by therapy
Chantelau and Nowicki[294]	Comments
Chen et al.[295]	Comparators not of interest
Chlebowy and Garvin[296]	Research question not of interest
Cho et al.[297]	Comparators not of interest
Choe and Edelman[298]	Review
Chyun[299]	Review
Clement[300]	Review
Clua Espuny et al.[301]	Non-English
Clua Espuny et al.[302]	Non-English

Study	Reason for Exclusion
Clua Espuny et al.[303]	Non-English
Coates[304]	Study protocol
Coster and Gulliford[305]	Comments
Coster et al.[77]	Review
Coster et al.[2]	Review
Cox et al.[106]	Comparators not of interest
Cox et al.[306]	Research question not of interest
Cranor and Christenson[108]	Outcomes not reported by diabetes mellitus type
D'agostino et al.[307]	Study design not of interest
Davidson et al.[308]	Review
Davidson et al.[109]	Study design not of interest
Davis et al.[309]	Study design not of interest
de Galan et al.[310]	Review
Derr et al.[311]	Comparators not of interest
Dunne et al.[312]	Review
Eaton et al.[313]	Research question not of interest
Edelman[118]	Review
Einecke[314]	Non-English, Duplicate
El Aziz[119]	Non-English
Ellis et al.[120]	Comparators not of interest
Erny-Albrecht et al.[121]	Study design not of interest
Estey et al.[315]	Comparators not of interest
Faas[316]	Review
Farmer et al.[317]	Duplicate
Farmer et al.[124]	Comparators not of interest
Farmer et al.[318]	Duplicate
Fransciosi et al.[319]	Study design not of interest
Gabriely et al.[320]	Review
Gagliardino et al.[129]	Outcomes not of interest
Gallichan[321]	Comparators not of interest
Gallichan[322]	Review
Gallo and Tiengo[323]	Non-English
Garcia et al.[324]	Research question not of interest
Gerich et al.[325]	Review
Gilden et al.[133]	Comparators not of interest
Gimeno Orna et al.[326]	Non-English
Goldstein et al.[135]	Review
Goldstein et al.[327]	Review
Goldstein[328]	Comments
Gosse[329]	Study design not of interest
Grady et al.[137]	Outcomes not of interest
Grimaldi and Sachon[330]	Non-English
Grossi et al.[331]	Non-English
Gulliford[332]	Comments
Haidar[333]	Study design not of interest
Halimi et al.[334]	Non-English

Study	Reason for Exclusion
Halimi[335]	Non-English
Haller et al.[143]	Population not of interest
Hanninen et al.[336]	Study design not of interest
Hansen et al.[145]	Outcomes not of interest
Harno et al.[337]	Comparators not of interest
Harris and Cracknell[338]	Comparators not of interest
Harris[339]	Study design not of interest
Hee-Sung[340]	Comparators not of interest
Heinemann et al.[150]	Outcomes not reported by diabetes mellitus type
Heisler[341]	Comparators not of interest
Herndon et al.[342]	Research question not of interest
Hjelm et al.[153]	Outcomes not reported by DM type
Hoffman et al.[343]	Comparators not of interest
Hoi-Hansen et al.[155]	Comparators not of interest
Holl et al.[156]	Duplicate
Hollahan[157]	Comparators not of interest
Holmes and Griffiths[344]	Review
Holmstrom and Rosenqvist[345]	Study design not of interest
Ibanez et al.[346]	Non-English
Ikeda and Tsuruoka[158]	Review
Ingleby et al.[347]	Comparators not of interest
Jansen[64]	Review
Jaworska et al.[348]	Study design not of interest
Jones et al.[160]	Data unextractable
Kalergis et al.[161]	Outcomes not of interest
Karter et al.[349]	Outcomes not reported by therapy
Karter[350]	Review
Kempf et al.[55]	Review
Kennedy[351]	Comments
Kibriya et al.[352]	Outcomes not reported by therapy
Kim et al.[164]	Comparators not of interest
Kitis and Emiroglu[165]	Comparators not of interest
Kleefstra et al.[353]	Comments
Klein et al.[354]	Outcomes not reported by therapy
Koch[166]	Review
Kolb et al.[355]	Comments
Kolb et al.[167]	Duplicate
Kolb et al.[168]	Duplicate
Kovatchev et al.[356]	Comparators not of interest
Kovatchev et al.[169]	Study design not of interest
Kwon et al.[357]	Comparators not of interest
Lankisch et al.[174]	Duplicate
Larsen et al.[358]	Population not of interest
Latalski et al.[175]	Non-English
Lawton et al.[359]	Study design not of interest
Lecomte et al.[176]	Outcomes not of interest

Study	Reason for Exclusion
Leese[360]	Study design not of interest
Lehmann and Tatti[361]	Research question not of interest
Lerman-Garber et al.[362]	Research question not of interest
LeRoith and Smith[177]	Review
LeRoith and Rayfield[363]	Review
Levenson[364]	Review
Lin et al.[365]	Comparators not of interest
Lister[366]	Letter
Litwak et al.[181]	Non-English
Llamas et al.[367]	Non-English
Lozano et al.[368]	Non-English
Lüddeke[369]	Non-English
Magni and Bellazzi[183]	Study design not of interest
Malanda[370]	Study Protocol
Maluf[184]	Comparators not of interest
Martin et al.[188]	Outcomes not reported by therapy
Martin et al.[189]	Duplicate
Martin et al.[190]	Duplicate
mau Llorca et al.[371]	Non-English
McAndrew et al.[67]	Review
McGeoch et al.[68]	Review
Mehuys et al.[372]	Comparators not of interest
Meneghini et al.[193]	Outcomes not of interest
Miao et al.[373]	Non-English
Miles[374]	Comparators not of interest
Miller and Elasy[194]	Outcomes not of interest
Minshall et al.[195]	Study design not of interest
Mitchell et al.[375]	Comparators not of interest
Moir and Feher[197]	Research question not of interest
Monami et al.[376]	Comparators not of interest
Montori and Bjornsen[377]	Comments
Moore et al.[378]	Letter
Moreland et al.[198]	Comparators not of interest
Muggeo et al.[379]	Recommendations/Guidelines
Murata et al.[38]	Duplicate
Murata et al.[380]	Comparators not of interest
Murata et al.[381]	Study design not of interest
Murata et al.[382]	Comparators not of interest
Murata et al.[382]	Duplicate
Murata et al.[383]	Comparators not of interest
Murata et al.[384]	Study protocol
Murata et al.[385]	Review
Murata et al.[200]	Data unextractable, Duplicate
Murff[386]	Comments
Nathan et al.[203]	Research question not of interest
Nathan[204]	Review

Study	Reason for Exclusion
National Health Service[205]	Review
Nau and Kumar[387]	Outcomes not reported by diabetes mellitus type
Neeser et al.[206]	Outcomes not of interest
Newman et al.[207]	Outcomes not reported by diabetes mellitus type
Norris et al.[388]	Review
Nuovo et al.[389]	Review
Nyomba et al.[210]	Outcomes not reported by diabetes mellitus type
Oden et al.[211]	Intervention not of interest
Ogawa et al.[212]	Non-English
Oh et al.[390]	Comparators not of interest
Ohba et al.[391]	Non-English
Oki et al.[392]	Study design not of interest
Oria-Pino et al.[393]	Non-English
Ömen and Boyvada[394]	Comparators not of interest
Ozmen and Boyvada[395]	Comparators not of interest
Page and Peacock[396]	Review
Palmer et al.[397]	Study design not of interest
Pan et al.[214]	Outcomes not of interest
Park et al.[398]	Outcomes not of interest
Park et al.[215]	Comparators not of interest
Patel et al.[399]	Comparators not of interest
Patrick et al.[400]	Comparators not of interest
Peel et al.[401]	Outcomes not of interest
Peel et al.[402]	Outcomes not of interest
Peters[403]	Comments
Petitti et al.[404]	Comparators not of interest
Peyrot and Rubin[405]	Comparators not of interest
Phillips et al.[406]	Review
Piatt et al.[217]	Outcomes not reported by diabetes mellitus type
Pitale et al.[407]	Comparators not of interest
Polonsky and Wagner[219]	Outcomes not of interest
Poolsup et al.[63]	Review
Puder et al.[408]	Research question not of interest
Rabi and Ghali[409]	Comments
Rachmani et al.[410]	Comparators not of interest
Rachmani et al.[411]	Comparators not of interest
Rayman[412]	Comments
Reynaert et al.[413]	Research question not of interest
Richardson et al.[222]	Comparators not of interest
Rodrigues et al.[223]	Comparators not of interest
Rosso[224]	Duplicate
Rost et al.[414]	Outcomes not reported by therapy
Rutten et al.[415]	Intervention not of interest
Sarkadi and Rosenqvist[416]	Comparators not of interest
Sarmiento et al.[417]	Non-English
Sarol et al.[62]	Review

Study	Reason for Exclusion
Saudek et al.[418]	Review
Scherbaum et al.[227]	Duplicate
Schiel et al.[228]	Non-English
Schiel et al.[419]	Comparators not of interest
Schiel and Müller[420]	Non-English
Schiel et al.[421]	Comparators not of interest
Schiel et al.[230]	Outcomes not of interest
Schütt et al.[1]	Study design not of interest
Sedlak et al.[422]	Comparators not of interest
Senez et al.[423]	Non-English
Sheppard et al.[233]	Comparators not of interest
Singh and Press[424]	Study design not of interest
Skeie et al.[234]	Comparators not of interest
Skelly et al.[425]	Outcomes not of interest
Skelly et al.[426]	Comparators not of interest
Slack[427]	Comments
Smide et al.[428]	Comparators not of interest
Soni et al.[236]	Outcomes not of interest
Soumerai et al.[237]	Duplicate
Sussman[429]	Comments
Tacker et al.[243]	Comparators not of interest
Takata et al.[69]	Population not of interest
Tattersall[430]	Review
Tengblad et al.[431]	Study design not of interest
Tengblad et al.[246]	Study design not of interest
Towfigh et al.[61]	Review
Trovati et al.[432]	Research question not of interest
Tunis et al.[252]	Study design not of interest
U.K. Prospective Diabetes Study Group[433]	Comparators not of interest
UKPDS[13]	Comparators not of interest
Unspecified[434]	Review
Varroud-Vial et al.[435]	Comparators not of interest
Vincent et al.[436]	Comparators not of interest
von Goeler et al.[437]	Outcomes not of interest
Wagner[438]	Non-English
Wakefield et al.[439]	Comparators not of interest
Waldron-Lynch et al.[440]	Comments
Walker[257]	Review
Watkins et al.[441]	Comparators not of interest
Weber et al.[259]	Research question not of interest
Weber et al.[260]	Research question not of interest
Weber et al.[442]	Non-English
Weijman et al.[261]	Study design not of interest
Welschen et al.[443]	Duplicate
Welschen et al.[65]	Review
Welschen et al.[444]	Non-English

Study	Reason for Exclusion
Welschen et al.[445]	Review
Wolanski et al.[446]	Population not of interest
Wolffenbuttel et al.[447]	Research question not of interest

APPENDIX 5: REASONS FOR GESTATIONAL DIABETES MELLITUS STUDY EXCLUSION

Study	Consensus Exclusion
Langer et al.[448]	Comparators not of interest
Garner et al.[449]	Comparators not of interest
Wechter et al.[450]	Comparators not of interest
Goldberg et al.[451]	Comparators not of interest
Buchanan et al.[452]	Comparators not of interest
Langer and Mazze[453]	Outcomes not reported by diabetes mellitus type
Peacock et al.[454]	Outcomes not reported by diabetes mellitus type
Stubbs et al.[455]	Population not of interest
Hanson et al.[456]	Population not of interest
Jovanovic et al.[457]	Population not of interest
Jovanovic et al.[458]	Population not of interest
Reece and Homko[459]	Review
Blonde and Karter[91]	Review
Kruger et al.[460]	Comparators not of interest
Bühling et al.[96]	Comparators not of interest
Sachon et al.[225]	Review
Meltzer[192]	Review
Zayfert and Goetsch[269]	Review
Homko et al.[461]	Comparators not of interest
McLachlan et al.[191]	Intervention not of interest
Fassett et al.[462]	Population not of interest
Kestilä et al.[463]	Comparators not of interest
Ladyzynski et al.[464]	Comparators not of interest
Gin et al.[465]	Intervention not of interest
Cypryk et al.[466]	Comparators not of interest
Ross[467]	Review
Feig et al.[468]	Intervention not of interest
Kendrick et al.[469]	Outcomes not of interest
Jensen et al.[470]	Intervention not of interest
Kerssen et al.[471]	Intervention not of interest
Bonomo et al.[472]	Intervention not of interest
Chen et al.[473]	Comparators not of interest
Yogev et al.[474]	Comparators not of interest
Henry et al.[475]	Outcomes not of interest
Jovanovic[476]	Review
Gross and Ter[477]	Intervention not of interest
Coster et al.[2]	Review
Bevier et al.[478]	Population not of interest
Langer[479]	Review
Persily[480]	Intervention not of interest
de Veciana et al.[481]	Comparators not of interest

Study	Consensus Exclusion
Langer et al.[482]	Outcomes not of interest
Thai et al.[483]	Intervention not of interest
Omori and Shimizu[484]	Non-English
Kek et al.[485]	Comparators not of interest
Elnour et al.[486]	Comparators not of interest
Yogev and Langer[487]	Intervention not of interest
Yogev and Hod[488]	Review
Montori et al.[489]	Letter
Simmons[490]	Intervention not of interest
Marciniak et al.[491]	Non-English
Fallucca et al.[492]	Comparators not of interest
Coustan[493]	Review
Spirito et al.[494]	Intervention not of interest
Homko and Reese[495]	Review
Soumerai et al.[237]	Population not of interest
Jovanovic[496]	Review

APPENDIX 6: STUDY CHARACTERISTICS OF RANDOMIZED CONTROLLED TRIALS IN TYPE 1 DIABETES

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Sponsor(s)	Country	Trial Duration (Months)	Age, Years (Mean ± SD)	% Male	Average Duration of DM (Years)	Prior SMBG Experience	
Randomized Controlled Trials									
Gordon et al., 1991[26]	RCT (crossover) (n = 25)	CP Pharmaceu-ticals	UK	3	31 ± 10	64	10.9 ± 7.7	Experienced users	SMBG 4 times/day X 2 days/week SMBG 4 times/day X 1 day/week SMBG 2 times/day X 7 days/week
Cohort Studies									
Evans et al., 1999[25]	R. cohort (n = 807)	Wellcome Trust Training Fellowship	Scotland	6	0-14: 9% 15-24: 17% 25-44: 51% 45-64: 20% ≥ 65: 3%	56	NR	NR	SMBG 0.05-5.68 strips/day SMBG one strip/day SMBG ≥ 4 strips/day no SMBG
Karter et al., 2001[24]	R. cohort (n = 780)	ADA, NIH, and Kaiser Research Foundation Institute	USA	12	43.2 (adherent) 40.4 (non-adherent)	52	≥ 10 (85%) < 10 (15%)	New users + experienced users	SMBG ≥ 3/day SMBG < 3/day
Santiprabhob et al., 2008[27]	P. cohort (n = 60)	SRRMF, Roche, Johnson & Johnson, Abbott, Terumo, B. Braun	Thailand	6	16 ± 7 (range: 10-46, 8 patients were over 18 years old)	32	6 ± 5	3%: none 17%: occasional 52%: 1-2/day 28%: 3-4/day	SMBG 3-4/day for six months after education camp (Patients performed SMBG 3-4/day at least 70% of time) versus SMBG < 3/day for six months after camp)

ADA=American Diabetes Association; Avg.=average; DM=diabetes mellitus; NIH=National Institutes of Health; NR=not reported; nRCT=non-randomized controlled trial; P. cohort=prospective cohort; R. cohort=retrospective cohort; RCT=randomized controlled trial; SD=standard deviation; SMBG=self-monitoring of blood glucose; SRRMF=Siriraj Routine to Research Management Fund

APPENDIX 7: STUDY CHARACTERISTICS OF RANDOMIZED CONTROLLED TRIALS AND OBSERVATIONAL STUDIES IN TYPE 2 DIABETES

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Study Period (Months)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	% Male	Duration of DM (Years)	Prior SMBG Experience	
Characteristics of Randomized Controlled Trials									
Barnett et al., 2008[50]	RCT (n = 610)	7	Unrestricted grant from Servier	Czech-Republic, Hungary, Iran, Malaysia, Poland, Slovakia, Turkey	55.9 ± 9.3 (SMBG) 56.1 ± 9.1 (control)	48 (SMBG) 52 (control)	2.8 ± 4.5 (SMBG) 2.8 ± 3.7 (control)	New users	SMBG (5/day x 2 days/week) versus no SMBG Diet and lifestyle advice, reinforced at each clinic visit
Bonomo et al., 2006[32]	RCT (n = 273)	6	NR	Italy	63 ± 9 (Group A) 66 ± 9 (Group B)	58 (Group A) 60 (Group B)	11 ± 9 (Group A) 10 ± 9 (Group B)	NR	SMBG 6/day x 1 day/15 days versus SMBG 4/day x 1 day/month
Davidson et al., 2005[4]	RCT (n = 89)	6	Eli Lilly and Company, NIH	USA	51 ± 11 (SMBG) 50 ± 11 (control)	21 (SMBG) 33 (control)	5.8 ± 5.8 (SMBG) 5.5 ± 4.7 (control)	NR	SMBG 6/day x 6 days/week versus no SMBG All recieved counselling & education
Farmer et al., 2007[34]	RCT (n = 453)	12	NHS and NIHR; Abbott provided meters	UK	65 ± 10 (SMBG) 60 ± 10 (control)	59 (SMBG) 56 (control)	3 (SMBG) 3 (control)	NR	More intensive: SMBG 3/day x 2 days/week (with additional training) Less intensive: SMBG 3/day x 2 days/week

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Study Period (Months)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	% Male	Duration of DM (Years)	Prior SMBG Experience	
									No SMBG All received standard care
Guerci et al., 2003[28]	RCT (n = 689)	6	Ascensia Esprit Discmeter, Bayer	France	61 ± 9 (SMBG) 62 ± 9 (control)	53 (SMBG) 57 (control)	7.7 ± 6.3 (SMBG) 8.4 ± 6.7 (control)	New users	SMBG 2/day x 3 days/week versus no SMBG All received counselling & education
Much-more et al., 1994[37]	RCT (n = 28)	7	Department of Academic Affairs, Clinic and Research Foundation. Meter supplied by LifeScan, Inc.	USA	57 ± 2 (SMBG) 60 ± 2 (no SMBG)	33 (SMBG) 45 (no SMBG)	5.7 (SMBG) 5.2 (no SMBG)	No SMBG in the previous 3 months	SMBG: 6/day for weeks 1-4; 2/day for weeks 5-20 (pre- and post-prandially) with carbohydrate counting, versus no SMBG with general strategies of diabetes management
Murata et al., 2003[38]	Time Series (n = 91)	8 weeks	Department of Veterans Affairs	USA	65 ± 10	94	NR	Experienced users	SMBG 4 times/day (before meals and at bedtime) for 8 wks; after 8 wks, the patients returned to their usual BG monitoring for 44 weeks

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Study Period (Months)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	% Male	Duration of DM (Years)	Prior SMBG Experience	
O'Kane et al., 2008[39]	RCT (n = 184)	12	Northern Ireland research and develop-ment office, Meters from Johnson & Johnson	Northern Ireland	58 ± 11 (SMBG) 61 ± 12 (control)	57 (SMBG) 64 (control)	New patients	New users	SMBG 4 fasting and 4 post-prandial measurements per week, with additional education on monitoring versus no SMBG All received education
Scher-baum et al., 2008[48]	RCT (n = 202)	6	Strips and meters from Roche, German Ministry of Education and Research, Association of Compulsory Health Insurance	Germany	62 ± 12 (1/week) 61 ± 9 (4/week)	60 (1/week) 64 (4/week)	7.8 ± 6.4 (1/week) 8.2 ± 6.5 (4/week)	Patients received instructions on SMBG prior to the start of the study	SMBG 1/week versus SMBG 4/week No additional education on DM or SMBG to the two intervention groups, and both groups had the same intensity of DM management
Schwedes et al., 2002[29]	RCT (n = 250)	6	Bayer Vital Inc.	Germany, Austria	59 ± 8 (SMBG) 61 ± 7 (control)	52 (SMBG) 52 (control)	5.5 ± 4.8 (SMBG) 5.3 ± 3.9 (control)	NR	SMBG 6/day x 2 days/week with training, diary, and standardized counselling versus no SMBG with non-standardized counselling on diet and lifestyle

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Study Period (Months)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	% Male	Duration of DM (Years)	Prior SMBG Experience	
Siebolds et al., 2006[43]	RCT (n = 250)	6	Bayer Vital Inc.	Germany, Austria	59 ± 8 (SMBG) 61 ± 7 (control)	52 (SMBG) 52 (control)	5.5 ± 4.8 (SMBG) 5.3 ± 3.9 (control)	NR	SMBG 6/day x 2 days/week with training, diary, and standardized counselling versus no SMBG with non-standardized counselling on diet and lifestyle
Simon et al., 2008[44]	RCT (n = 453)	12	NHS and NIHR; Abbott provided meters	UK	65 ± 10 (SMBG) 60 ± 10 (control)	59 (SMBG) 56 (control)	3 (SMBG) 3 (control)	NR	See Farmer et al., 2007[34]
Characteristics of Non-RCTs									
Aydin et al., 2005[31]	QExp (n = 82)	3	NR	Turkey	1/wk: 64 ± 9 0.5/wk: 62±10 1/mon: 66±10 no SMBG: 70±10	75	1/wk: 13 ± 7 0.5/wk: 9 ± 6 1/mon: 15±7 no SMBG: 10±7	experienced users	SMBG (4/day x 1 day/week or 4/day x once every 2 weeks) versus no SMBG
Davis et al., 2007[33]	P. cohort (n = 1,280)	65 ± 6	Raine Medical Research Foundation, The University of Western Australia	Australia	62 ± 9	54	NR	NR	SMBG (patients reported SMBG status at entry of FDS; unspecified frequency) versus no SMBG
Evans et al., 1999[25]	R. Cohort (n = 290)	6	Wellcome Trust Training Fellowship	Scotland	25-44: 5% 45-64: 40% ≥ 65: 55%	48	NR	NR	Blood glucose test strips dispensed

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Study Period (Months)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	% Male	Duration of DM (Years)	Prior SMBG Experience	
Karter et al., 2001[24]	R. cohort (insulin group) (n = 5,552)	12	ADA, NIH, and the Kaiser Research Foundation	USA	63 ± 10 adherent 61 ± 11 non-adherent	47 adherent 49 non-adherent	≥10 (60%) <10 (40%)	NR	Adherent (≥ 0.75 strips/day) versus non-adherent (< 0.75 strips/day)
Karter et al., 2001[24]	R. cohort (OAD group) (n = 12,786)	12	ADA, NIH, and the Kaiser Research Foundation	USA	62 ± 11 adherent 61 ± 12 non-adherent	49 adherent 55 non-adherent	≥10 (60%) <10 (40%)	NR	Adherent (≥ 0.75 strips/day) versus non-adherent (< 0.75 strips/day)
Karter et al., 2006[35]	R. cohort (OAD group (n = 13,276)	48	American Diabetes Association, NIH	USA	63 ± 12 new users 61 ± 11 prevalent 67 ± 12 persistent non-user	58 new users 55 prevalent 58 persistent non-users	NR	New and experienced users	Prevalent users: Avg. daily SMBG estimated from annual test strip usage for the 4 years during the study period New users: Avg. daily SMBG estimated from strips dispensed
Karter et al., 2006[35]	R. cohort (diet group) (n = 10,886)	48	American Diabetes Association, NIH	USA	59 ± 13 new users 61 ± 12 prevalent 67 ± 12 persistent non-users	53 new users 55 prevalent 53 persistent non-users	NR	New and experienced users	Prevalent users: Avg. daily SMBG estimated from annual test strip usage for the 4 years during the study period New users: Avg. daily SMBG estimated from strips dispensed

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Study Period (Months)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	% Male	Duration of DM (Years)	Prior SMBG Experience	
Martin et al., 2006[36]	R. cohort (n =3,268)	78 ± 19	MSRNRW, Federal Ministry of Health, unrestricted grant from Roche Diagnostics	Germany	62 ± 10	49.2	NR	NR	SMBG (documented in medical records at time of diabetes diagnosis and for at least 1 subsequent year during observational period; frequency not specified) versus no SMBG
Meier et al., 2002[30]	Time series (n =471)	6	Department of Veterans Affairs	USA	NR	NR	NR	NR	SMBG frequency 1.35 ± 0.92/day versus SMBG frequency 0.67 ± 0.44/day
Murata et al., 2009[54]	R. cohort (n = 5,862)	24	Department of Veterans Affairs	USA	NR	NR	NR	NR	Blood glucose test strips dispensed
Rindone et al., 1997[40]	R. cohort (n = 115)	24	NR	USA	66 ± 10 (BGTS) 69 ± 7 (no BGTS)	NR	NR	NR	Prescription of BGTS versus no prescription of BGTS
Schneider et al., 2007[41]	R. cohort (n = 3,268)	78	NR	Germany	60 ± 9 (SMBG) 64 ± 10 (control)	52.6 (SMBG) 46.5 (control)	NR	NR	SMBG for at least one year before an end point or until end of observation period versus no SMBG
Secnik et al., 2007[42]	R. cohort (n = 1,795)	12	Eli Lilly and Amylin Pharmaceu-ticals	UK	46.7% ≥ 65 (insulin) 47.2% ≥ 65 (OAD)	56 (insulin) 53 (OAD)	NR	NR	Blood glucose test strips prescribed
Soumerai et al., 2004[45]	Time series (n = 715)	24	Agency for Healthcare Research	USA	56 ± 12.3	56	NR	New users	Initiators of SMBG (no prior experience of monitoring for at

Study	Trial Characteristics				Patient Characteristics				Interventions/ Comparators
	Study Type (Sample Size)	Study Period (Months)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	% Male	Duration of DM (Years)	Prior SMBG Experience	
			and Quality, Harvard Pilgrim Health Care Foundation						least 12 months) versus non-initiators of SMBG (no record of SMBG over the 4-year period)
Wen et al., 2004[46]	R. cohort (n = 299)	36	Department of Veterans Affairs	USA	63 ± 11 (all)	97.4	NR	NR	Prescription of BGTS versus no prescription of BGTS
Wieland et al., 1997[47]	R. cohort (n = 216)	3	LifeScan, Inc., Abbott Labs, SAS Institute Inc.	USA	65 ± 10 (control)	100 (all)	NR	NR	3 months of strip use, frequency not reported

A1C=glycosylated hemoglobin; ADA=American Diabetes Association; Avg.=average; BGTS=blood glucose test strips; DM=diabetes mellitus; exp.=experimental group; mon=month; FDS=Fremantle Diabetes Study; MSRNW=Ministry of Science and Research of the State of North Rhine-Westphalia; NHS=National Health Service; NIH=National Institutes of Health; NIHR=National Institute for Health Research; NR=not reported; nRCT=non-randomized controlled trial; OAD=oral antidiabetes drugs; P. cohort=prospective cohort; QExp=quasi-experiment; R. cohort=retrospective cohort; RCT=randomized controlled trial; SD=standard deviation; SMBG=self-monitoring of blood glucose; wk=week

APPENDIX 8: CHARACTERISTICS OF RANDOMIZED CONTROLLED TRIALS IN GESTATIONAL DIABETES

Study	Trial Characteristics			Patient Characterisitcs		Interventions
	Study Type (Sample Size)	Sponsor(s)	Countries	Age, Years (Mean ± SD)	Weeks of Pregnancy at Enrollment	
Homko et al., 2002[51]	RCT (n = 58)	General Clinical Research Center branch of the National Center for Research Resources, LifeScan Inc.	USA	30.3 ± 5.4 (SMBG) 29.0 ± 6.4 (control)	26-33	SMBG (4/day on 4 days/week) versus no SMBG (FBG and 1-hour post-prandial glucose measured at each prenatal visit or more frequently if clinically indicated) All recieved individualized counselling for gestational diabetes
Rey, 1997[52]	RCT (n = 342)	Eli Lilly Canada	Canada	1-hr PPBG* < 7.8: 30.9 ± 5.6 (SMBG) 30.8 ± 5.1 (control) 1-hr PPBG* > 7.8: 32.1 ± 4.6 (SMBG) 30.6 ± 5.3 (control)	22-36	SMBG (3/day alternating with 4/day) versus no SMBG (blood glucose monitoring was performed by nurse educator every two weeks at prenatal clinical follow-up) All received specialized diet instructions

Avg.= average; FBG=fasting blood glucose; RCT=randomized controlled trial; SD=standard deviation; SMBG=self-monitoring of blood glucose

*1-hour post-breakfast test

APPENDIX 9: INCLUSION AND EXCLUSION CRITERIA FOR SELECTING PATIENTS IN THE STUDIES FOR TYPE 1 DIABETES

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Evans et al., 1999[25]	Type 1 DM; registered in the diabetes database, Tayside, Scotland before Jan. 1993; had at least one A1C concentration recorded between July 1993 and Dec. 1995	NR	1,2
Gordon et al., 1991[26]	Type 1 DM for ≥ 12 months; age 18 to 50 years; male or female; at least two insulin injections per day; performing SMBG ≥ 6 months	Pregnant or planning pregnancy; significant intercurrent illness (hepatic, renal, or life- threatening disease or other systemic illness); hospitalization for diabetic ketoacidosis in the previous 12 months	1
Karter et al., 2001[24]	Type 1 DM; age ≥ 19 years; continuous membership in the Northern California Kaiser Permanente Diabetes Registry from Jan.1,1996, to Dec.31,1997; full pharmacy benefits; at least one A1C level measured during the follow-up period	Unclear type of DM; no response to the survey providing potential confounders	1,2
Santiprabhob et al., 2008[27]	Type 1 DM; age ≥ 10 years; consent provided by patients ≥ 18 years and permission from a parent or guardian for patients <18 years	NR	1

A1C=glycosylated hemoglobin; DM=diabetes mellitus; NR=not reported; SMBG=self-monitoring of blood glucose

APPENDIX 10: INCLUSION AND EXCLUSION CRITERIA FOR SELECTING PATIENTS IN THE STUDIES FOR TYPE 2 DIABETES

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Aydin et al., 2005[31]	Type 2 DM for > 1 year; insulin treatment for at least 6 months; already applying SMBG	Unable to continue SMBG for any reason; on OAD; preganant or lactating women; with any chronic illness; drugs or alcohol abuse; use of drugs interferering with glucose metabolism	2
Barnett et al., 2008[50]	Type 2 DM; diet alone for 3 months; diet and biguanide or alpha-glucosidase inhibitor or diet plus any insulin secretagogue for < 12 months; A1C 7%-10%	Current management with SMBG; lifestyle or concurrent condition that could interfere with end point or ability to comply with study procedures, including SMBG and diary- keeping; abnormalities on laboratory screening, including creatinine clearance < 20 ml/min and/or serum creatinine > 140 mM and alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than three times the upper limit of the normal range; therapy with systemic glucocorticoids; known contraindication to gliclazide; known drug or alcohol dependence and pregnancy, lactation or planned pregnancy	2
Bonomo et al., 2006[32] (abstract)	Type 2 DM; not on insulin; already on SMBG; A1C stable in the last 6 months	Use of insulin	2
Davidson et al., 2005[4]	Type 2 DM; not on insulin; currently enrolled or on entrance into the DMCP	On insulin; not referred to DMCP	2
Davis et al., 2007[33]	Type 2 DM; recruited between 1993-1996; reported SMBG status at FDS entry; with complete diabetes treatment and mortality data	NR	2

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Evans et al., 1999[25]	Type 2 DM; use of insulin during the first 6 months of 1993; registered in the diabetes database, Tayside, Scotland before Jan. 1993; had at least one A1C concentration recorded between July 1993 and Dec. 1995	NR	1,2
Farmer et al., 2007[34]; (French et al., 2008[23] and Simon et al., 2008[44] [extension of publication of Farmer, 2007[34]])	Type 2 DM; ≥ 25 years at time of diagnosis; diet or OAD alone; A1C ≥ 6.2% at assessment visit; independent in activities of daily living	Use of a blood glucose monitor twice a week or more over the previous 3 months; serious disease or limited life expectancy that would make intensive glucose control inappropriate; inability to follow trial procedures	2
Guerci et al., 2003[28]	Type 2 DM for >1 year; age 40 to 75 years; insufficiently controlled on OAD treatement (A1C ≥ 7.5% and ≤11 %); not previously treated with insulin for > 7 consecutive days; not requiring insulin at inclusion; no prior SMBG, but able to carry out	Type 1 DM; maturity onset diabetes of the young (MODY) and secondary DM; weight loss > 3kg during last 3 months; impending complications of diabetes; pregnant women; unable to read or write; uncooperative; no consent to participate	2
Karter et al., 2001[24]	Type 2 DM; age ≥ 19 years; continuous membership in the Northern California Kaiser Permanente Diabetes Registry from Jan.1, 1996, to Dec.31, 1997; full pharmacy benefits; at least one A1C level measured during the follow-up period	Unclear type of DM; no response to the survey providing potential confounders	1,2
Karter et al., 2006[35]	DM; on insulin, OAD or no drugs; continuous membership in the Northern California Kaiser Permanente Diabetes Registry; full pharmacy benefits during the observation windows	No A1C data; modified diabetes pharmacy regimen (discontinued, switched, or added a therapeutic class) or unable to identify the changes in dose during the follow up; end-stage renal disease or substantially elevated serum creatinine	2
Martin et al., 2006[36]	Type 2 DM diagnosed between Jan. 1, 1995 and Dec. 31, 1999; information on age, sex, diabetes therapy, and SMBG available at the time of diagnosis and for at least 1 subsequent year	Age < 45 year	2

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Meier et al., 2002[30]	Type 2 DM; on diet or oral hypoglycemic agents; receiving SMBG strip prescription fills between July 1 and Dec. 31, 1997, (for the baseline period) and between July 1 and Dec. 31, 1998 (for the post-implementation period); documented in the local installation of the Veterans Health Information System and Technology Architecture (VistA) database	Use of insulin during, or within 3 months before, or 2 months after the study period	2
Muchmore et al., 1994[37]	Type 2 DM; age 40 to 75 years with at least 1 year of non—insulin-requiring diabetes; diet alone or diet plus sulfonylurea (SFU); BMI 27.5kg/m to 44 kg/m^2; A1C 9.5% to 13.5%; ability to comply with the protocol	Performed SMBG within the previous 3 months; previously instructed in dietary carbohydrate-counting; serious underlying medical or psychiatric illness; drug abuse; alcoholism	2
Murata et al., 2009[54]	Type 2 DM using acarbose, glipizide, glyburide, metformin, pioglitazone, rosiglitazone, and/or tolazamide, but not insulin in 1st, 2nd, or 3rd quarter of 2002; still receiving antidiabetic medications during last quarter of 2004; A1C measured within 90 days of end of study (Dec. 31, 2004). The criteria assured that all subjects were followed for at least 2 years	Patients on insulin in 1st to 3rd quarter of 2002 or given insulin in subsequent quarter; receiving chlorpropamide, glimiperide,miglitol, nateglinide, repaglinide, or tolbutamide at entry; receiving a qualifying OAD at a dose above the recommended range as defined by chlorpropamide, glimiperide,miglitol, nateglinide, repaglinide, or tolbutamide, the standard on-line drug reference for the Department of Veterans Affairs	2
O'Kane et al., 2008[39]	Type 2 DM newly diagnosed; aged < 70 years	Secondary diabetes; use of insulin; previous use of SMBG; major illness within previous 6 months; chronic kidney or liver disease; alcohol misuse	2
Rindone et al., 1997[40]	Type 2 DM; use of sulfonylurea (glipizide, glyburide) for 2 years	Use of sulfonylurea < 2 years; use of insulin and/or metformin at the beginning of the review period	2

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Scherbaum et al., 2008[48]	Type 2 DM; use of one or more OAD (not combined with insulin therapy and stable oral medication for the last 3 months); age 35 to 80 years; informed consent	Type 1 DM; advanced renal insufficiency (creatinine ≥ 2.5 mg/dL); at least 2 episodes of hypoglycemia with necessary outside help within the last 3 months, one or more severe metabolic events (hypoglycemic shock, hyperosmolaric coma, inpatient stay due to severe hyperglcemic events) within the last 3 months; pregnancy; severe impaired vision; communication problems due to language	2
Schneider et al., 2007[41]	Type 2 DM diagnosed between Jan.1, 1995 to Dec.31, 1999; age ≥ 45 years at time of diagnosis; information available on age, sex, diabetes treatment, and SMBG for the time at diagnosis until at least one subsequent year	NR	2
Schwedes et al., 2002[29]; Siebolds et al., 2006[43] (part of[29])	Type 2 DM for at least 3 months; age 45 to 70 years; treated with either diet alone, or diet in combination with sulfonylureas or metformin; participation in a diabetes educational program within the previous 2 years; BMI > 25 kg/m^2; A1C 7.5% to 10%	Incapability of maintaining an eating diary and of documenting their state of well-being (relative or complete illiteracy); sensomotor disturbances that might impair unassisted SMBG; regular (trained, systematically used) SMBG during the 6 months before the start of study; participation in another clinical trial within 30 days before the start of study; females in pregnancy or lactation or without a safe contraception method; concurrent treatment with other antidiabetes agents (e.g., insulin); treatment with nonselective B-blockers, glucocorticoids, amphetamines, or anabolic agents; treatment related to acarbose; diet reduction during the course of the study (< 1,000 kcal/day); serum creatinine > 3 mg/dL; serum transaminases > 50 units/L; serious underlying medical or psychiatric conditions; drug or alcohol abuse	2

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Secnik et al., 2007[42]	Type 2 DM (ICD-10 code of E11); age ≥ 20 years; received either insulin or an OAD medication between Jan. 1, 2001, and Nov. 4, 2003 (with first such use identified as the index date); enrolled in the General Practice Research Database (GPRD) of UK during the 12-month post-index date period; type 2 DM identified during the 12-month post-index date period Alternatively, general diabetes (ICD-10 code of E12, E13, or E14) diagnosed over the 12-month post-index date period; age ≥ 20 years at the time of diagnosis; received at least 2 prescriptions for an OAD	Type 1 DM (ICD-10 code of E10) OAD cohort: no insulin during the 12-month period	2
Soumerai et al., 2004[45]	OAD cohort: Type 2 DM; age ≥ 18 years; received at least 1 prescription for an oral sulfonylurea during the 2 years before the change in coverage policy Initiators of SMBG of OAD cohort: no prior recorded experience of monitoring for at least 12 months Non-initiators of SMBG of OAD cohort: no recorded SMBG during 4 years of observation	OAD cohort: pediatric patients; women with gestational diabetes; use of insulin	2
Wen et al., 2004[46]	Type 2 DM; use of oral medications for all 3 years between Oct. 1, 1999 and Sept. 30, 2002; eligible for Veterans Affairs (VA) benefits from Oct.1 ,1999 with ICD-9-CM codes for diabetes (250.00 to 250.XO); having an assigned primary care provider; at least two outpatient visits at the primary care clinic and at least one A1C value recorded during each of 3 consecutive fiscal years	NR	2

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Wieland et al., 1997[47]	Patients identified through the Veterans Affairs (VA) Decentralized Hospital Computer Program (DHCP) database; male; A1C measurement between Sept. 1, 1994 and Sept. 30, 1995; an active prescription of glyburide (the most widely used formulary item) at a constant dosage for at least 3 months before the most recent (index) A1C	Refill of insulin, other OADs, or corticosteroids in the 12 months preceding the index A1C	2

A1C=glycosylated hemoglobin; BMI=body mass index; DM=diabetes mellitus; DMCP=diabetes managed care program; FDS=Freemantle Diabetes Study; NR=not reported; OAD=oral antidiabetes drugs; SMBG=self-monitoring of blood glucose

APPENDIX 11: INCLUSION AND EXCLUSION CRITERIA FOR SELECTING PATIENTS IN THE STUDIES FOR GESTATIONAL DIABETES

Study	Inclusion Criteria	Exclusion Criteria	DM Type
Homko et al., 2002[51]	GDM; gestational age ≤ 33 wks; fasting blood glucose level ≤ 95 mg/dL on oral glucose tolerance test; followed in the Diabetes-in-Pregnancy Program at Temple University Hospital and/or one of its satellite hospitals	NR	GDM
Rey, 1997[52]	GDM (the institution criteria); followed in Sainte-Justine Hospital between June 1,1993 and May 31,1994	Current diet or insulin therapy; pregnancy earlier than 22 weeks; pregnancy later than 36 weeks; multiple pregnancy; fetus with congenital malformation; delivery within 2 weeks of randomization; delivery in another center or steroid therapy after randomization	GDM

DM=diabetes mellitus; GDM=gestational diabetes

APPENDIX 12: RESULTS OF QUALITY ASSESSMENT OF STUDIES FOR TYPE 1 DIABETES

Type 1 DM Quality Assessment Summary — Modified SIGN 50 Checklist for Randomized Controlled Trials											
Study	1	2	3	4	5	6	7	8	9	10	Overall QA
	Appropriate and clearly focused question	Randomized assignment	Adequate concealment	Blinding of subjects and investigators	Groups are similar at baseline	The only difference between groups is treatment under investigation	Standard, valid, and reliable measurement of outcome(s)	Percentage of dropouts	ITT analysis performed	Comparable results for multiple study sites	
Gordon, 1991[26]	AA	NR	NAd	NAd	NAd	AA	AA	16	NAd	NAp	poor

AA=adequately addressed; DM=diabetes mellitus; NAd=not addressed; Nap=not applicable; NR=not reported; PA=poorly addressed; QA=quality assessment; WC=well-covered

Type 1 DM Quality Assessment Summary – Modified SIGN 50 Checklist for Cohort Studies														
Study	1	2	3	4	5	6	7	8	9	10	11	12	13	
	Appropriate and clearly focused question	Groups are comparable other than the factor under investigation	Indication of how people asked to take part did so	Likelihood that subjects have the outcome at the time of enrolment is assessed	Percentage of dropout in each treatment arm	Comparison is made between full participants and those lost to follow-up, by exposure status	Outcomes are clearly defined	Assessment of outcome is made blind to exposure status	Recognition that knowledge of exposure status could have influenced the assessment	The measure of assessment of exposure is reliable	Evidence used to show the method of outcome assessment is valid and reliable	Exposure level or prognostic factor is assessed more than once	Main confounders are taken into account	Overall QA
Evans, 1999[25]	AA	AA	NAd	NAd	68	NAd	PA	NAd	NAp	PA	PA	NAd	PA	poor
Karter, 2001[24]	WC	AA	PA	NAd	NR	NAd	PA	NAd	NAp	PA	PA	NAd	AA	poor
Santiprabhob, 2008[27]	AA	PA	AA	AA	13% at 3 mo. Post camp	NAd	AA	NAd	NAd	AA	PA	AA	PA	poor

AA=adequately addressed; DM=diabetes mellitus; ITT=intention to treat; NAd=not addressed; Nap=not applicable; NR=not reported; PA=poorly addressed; QA=quality assessment; WC=well-covered

APPENDIX 13: RESULTS OF QUALITY ASSESSMENT OF STUDIES FOR TYPE 2 DIABETES

Type 2 DM Quality Assessment Summary — Modified SIGN 50 Checklist for Randomized Controlled Trials											
Study	1 Appropriate and clearly focused question	2 Randomized assignment	3 Adequate concealment	4 Blinding of subjects and investigators	5 Groups are similar at baseline	6 The only difference between groups is treatment under investigation	7 Standard, valid, and reliable measurement of outcome(s)	8 The drop-out rate is acceptable and is comparable between the groups	9 ITT analysis performed	10 Comparable results for multiple study sites	Overall QA
Barnett, et al., 2008[50]	AA	AA	NAd	NAd	AA	AA	AA	13% SMBG 17% no SMBG	AA	NAd	good
Davidson, et al., 2005[4]	AA	NR	NAd	AA	AA	PA	PA	1	AA	NAp	poor
Farmer, et al., 2007[34]	AA	WC	WC	NAd	AA	AA	AA	7.3 SMBG 11.2 control	AA	AA	good
Guerci, et al., 2003[28]	AA	NR	NAd	NAd	AA	AA	AA	32.2 SMBG 29.1 control	PA	AA	poor
Muchmore, et al., 1994[37]	AA	PA	NAd	NAd	PA	PA	NR	~ 10%	NAd	NAp	poor
O'Kane, et al., 2008[39]	WC	WC	PA	PA	PA	AA	PA	2.0 SMBG 2.2 control	WC	NAp	good
Scherbaum, et al., 2008[48]	WC	AA	AA	NAd	AA	WC	NAd	12% 1/week 11% 4/week	PA	NAd	good
Schwedes, et al., 2002[29]	AA	PA	NAd	PA	AA	PA	WC	10.8	PA	PA	poor
Siebolds, et al., 2006[43]	AA	PA	NAd	NAd	AA	PA	AA	10.8	PA	PA	poor

Type 2 DM Quality Assessment Summary — Adapted SIGN 50 Checklist for Cohort Studies						
Study	1	2	3	4	5	6
	Appropriate and clearly focused question	Groups are comparable other than the factor under investigation	Recruitment rate reported	Likelihood that subjects have the outcome at the time of enrollment is assessed	The dropout rate is acceptable and is comparable between the groups	Comparison is made between full participants and those lost to follow-up, by exposure status
Aydin et al., 2005[31]	AA	AA	NAd	AA	NR	NAp
Bajkowska-Fiedziukiewicz et al., 2008[49]	AA	PA	PA	NAd	NR	NAd
Davis et al., 2007[33]	AA	AA	NAd	AA	1.08	NAd
Evans et al., 1999[25]	AA	AA	NAd	NAd	63	NAd
Karter et al., 2001[24]	WC	AA	AA	NAd	NR	NAd
Karter et al., 2006[35]	AA	AA	NAd	PA	NR	NAd
Martin et al., 2006[36]	WC	AA	NR	PA	0.2	NAd
Murata et al., 2009[54]	AA	AA	NAp	NAd	NR	NAp
Rindone et al., 1997[40]	AA	AA	NAd	NAd	0	NAp
Schneider et al., 2007[41]	WC	AA	NR	AA	0.52	NAd
Secnik et al., 2007[42]	AA	AA	NAd	NAd	29 insulin 26 OAD	PA
Wen et al., 2004[46]	AA	AA	NAp	AA	NAp	NAp
Wieland et al., 1997[47]	AA	AA	NAp	NAd	NR	NAp

Type 2 DM Quality Assessment Summary — Adapted SIGN 50 Checklist for Cohort Studies								
Study	7	8	9	10	11	12	13	Overall QA
	Outcomes are clearly defined	Assessment of outcome is made blind to exposure status	Recognition that knowledge of exposure status could have influenced the assessment	The measure of assessment of exposure is reliable	Evidence used to show the method of outcome assessment is valid and reliable	Exposure level or prognostic factor is assessed more than once	Main confounders are taken into account	
Aydin et al., 2005[31]	AA	NAd	NAd	PA	NAd	NAd	PA	poor
Bajkowska-Fiedziukiewicz, et al., 2008[49]	AA	NAd	NAd	PA	AA	NAd	NAd	poor
Davis et al., 2007[33]	AA	NAd	NAp	NAd	NAd	NAd	AA	poor
Evans et al., 1999[25]	PA	NAd	NAp	PA	PA	NAd	AA	poor
Karter et al., 2001[24]	PA	WC	NAp	PA	PA	AA	AA	poor
Karter et al., 2006[35]	AA	NAd	NAp	AA	NAd	PA	AA	poor
Martin et al., 2006[36]	AA	NAp	NAp	PA	AA	NAd	AA	poor
Murata et al., 2009[54]	AA	NAd	NAp	PA	NAd	NAd	PA	poor
Rindone et al., 1997[40]	AA	NAd	NAp	AA	NAd	PA	PA	poor
Schneider et al., 2007[41]	AA	NAp	NAp	PA	AA	NAd	AA	poor
Secnik et al., 2007[42]	AA	NAd	NAp	AA	AA	PA	AA	poor
Wen et al., 2004[46]	AA	NAd	NAp	PA	NAd	PA	AA	poor
Wieland et al., 1997[47]	AA	NAd	NAp	PA	AA	NAd	NR	poor

AA=adequately addressed; DM=diabetes mellitus; ITT=intention to treat; NAd=not addressed; Nap=not applicable; PA=poorly addressed; QA=quality assessment; WC=well-covered

APPENDIX 14: RESULTS OF QUALITY ASSESSMENT OF TRIALS FOR GESTATIONAL DM

Gestational Diabetes Mellitus Quality Assessment Summary — Modified SIGN 50 Checklist for Randomized Controlled Trials											
Study	1	2	3	4	5	6	7	8	9	10	Overall QA
	Appropriate and clearly focused question	Randomized assignment	Adequate concealment	Blinding of participants and investigators	Groups are similar at baseline	The only difference between groups is treatment under investigation	Standard, valid, and reliable measurement of outcome(s)	Percentage of dropouts	ITT analysis performed	Comparable results for multiple study sites	
Homko et al. , 2002[51]	WC	NR	NAd	NAd	AA	AA	AA	10 (control) 0 (SMBG)	PA	NAd	poor
Rey, 1997[52]	AA	AA	NAd	NAd	AA	AA	AA	0	AA	NAp	good

AA=adequately addressed; DM=diabetes mellitus; ITT=intention to treat; NAd=not addressed; Nap=not applicable; PA=poorly addressed; QA=quality assessment; WC=well-covered

APPENDIX 15: DEFINITION AND MEASUREMENT OF HYPOGLYCEMIA IN TYPE 2 DIABETES STUDIES

Study	Definition and Measurement of Hypoglycemia
Aydin et al., 2005[31]	Measured symptomatic and asymptomatic hypoglycemia Overall hypoglycemia: Any value below 70 mg/dL with or without symptoms attributed to hypoglycemia, or any symptomatic period attributed to hypoglycemia if measurement was not possible
Barnett et al., 2008[50]	Reported both symptomatic and asymptomatic hypoglycemic events Overall hypoglycemia: Suspected mild to moderate hypoglycemia Severe hypoglycemia: Any hypoglycemic events that require third-party assistance or need of medical assistance Nocturnal hypoglycemia: Symptoms suggestive of hypoglycemia; time interval not defined
Farmer et al., 2007[34]	Overall hypoglycemia: Mild symptoms requiring minor intervention Severe hypoglycemia: a) Moderate symptoms requiring immediate third-party intervention; b) Patient is unconscious
Guerci et al., 2003[28]	Overall hypoglycemia: Reporting of symptomatic or asymptomatic hypoglycemia (blood glucose level < 3 mmol/L) Severe hypoglycemia: not defined
O'Kane et al., 2008[39]	Overall hypoglycemia: Hypoglycemic events reported by the patients (specific type of measurement was not reported)
Scherbaum et al., 2008[48]	Overall hypoglycemia: Reporting of asymptomatic or symptomatic hypoglycemia with a SMBG value < 3.2 mol/L Severe hypoglycemia: Any hypoglycemia with the need for assistance by another person

APPENDIX 16: DEFINITION AND MEASUREMENT OF NEONATAL HYPOGLYCEMIA IN GESTATIONAL DIABETES MELLITUS STUDIES

Study	Definition and Measurement of Hypoglycemia
Homko et al., 2002[51]	NR
Rey, 1997[52]	Newborn hypoglycemia was defined as a heel capillary blood glucose concentration (measured by the laboratory) less than 1.7 mmol/L in full-term neonates and less than 1.1 mmol/L in pre-term ones (first 24 hours of life).

NR=not reported

APPENDIX 17: A1C AND FASTING BLOOD GLUCOSE DATA IN PATIENTS WITH TYPE 1 DIABETES

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	P-Value Between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (Mean ± SD)	P-Value Between Treatments
Evans et al., 1999[25]	A1C change as 1 strip/day increased	NR	NR	NR	r = -0.661 (P < 0.001)	NR	NR	NR	NR	NR	NR
Gordon et al., 1991[26]	SMBG 4 times/day, 2 days/week	NR	9.6 ± 2.0	NR	NR	NS (between any measurements)	NR	NR	NR	NR	NR
	SMBG 4 times/day, 1 day/week	NR	9.6 ± 2.1	NR	NR		NR	NR	NR	NR	
	SMBG 2 times/day, 7 days/week	NR	9.7 ± 2.0	NR	NR		NR	NR	NR	NR	
Karter et al., 2001[24]	SMBG ≥ 3 times/day	NR	7.71*	NR	NR	NR	NR	NR	NR	NR	NR
	SMBG once daily	NR	8.49*	NR	NR		NR	NR	NR	NR	
	SMBG < daily	NR	8.93*	NR	NR		NR	NR	NR	NR	
	No SMBG	NR	9.12*	NR	NR		NR	NR	NR	NR	
Santiprabhob et al., 2008[27]	SMBG < 3 times/day	9.1 ± 1.5	8.7 ± 1.4 (at 3 months); 9.4 ± 1.9 (at 6 months)	NR	NR	0.04 (at 3 months); 0.24 (at 6 months)	NR	NR	NR	NR	NR
	SMBG 3-4 times/day	8.9 ± 2.0	8.0 ± 1.8 (at 3 months); 8.8 ± 2.6 (at 6 months)	NR	NR		NR	NR	NR	NR	

A1C=glycosylated hemoglobin; DM=diabetes mellitus; NR=not reported; SD=standard deviation; SMBG=self-monitoring of blood glucose
* Data is provided by the author.

APPENDIX 18: HYPOGLYCEMIA IN PATIENTS WITH TYPE 2 DIABETES

Study	Type of Hypoglycemia	Comparators	Sample Size	Number of Events	Number of Patients With Events	P-Value Between Treatments
Aydin et al., 2005[31]	Overall	No SMBG	22	18	1	NR
		SMBG 4/day x once a week	49	8	1	
		SMBG 4/day x once every 2 weeks	33	0	1	
		SMBG 4/day x once every month	14	2	0	
Barnett et al., 2008[50]	Overall	SMBG	311	51	27	NR
		No SMBG	299	66	21	
	Nocturnal	SMBG	311	NR	3	
		No SMBG	299	NR	7	
	Severe	SMBG	311	0	0	
		No SMBG	299	0	0	
Farmer et al., 2007[34]	Overall	No SMBG	152	NR	15	NR
		SMBG (less intensive)	150	NR	33	
		SMBG (more intensive)	151	NR	43	
	Grade 2	No SMBG	152	NR	14	P < 0.001
		SMBG (less intensive)	150	NR	33	
		SMBG (more intensive)	151	NR	43	
	Grade 3 or 4	No SMBG	152	NR	0	NR
		SMBG (less intensive)	150	NR	0	
		SMBG (more intensive)	151	NR	0	
Guerci et al., 2003[28]	Overall	SMBG	345	NR	53	P = 0.003
		No SMBG	344	NR	25	
	Severe	SMBG	345	0	0	NR
		No SMBG	344	0	0	
O'Kane et al., 2008[39]	Overall	SMBG	96	NR	28	NS
		No SMBG	88	NR	36	

Study	Type of Hypoglycemia	Comparators	Sample Size	Number of Events	Number of Patients With Events	P-Value Between Treatments
Scherbaum et al., 2008 [48]	Overall (one event)	SMBG 1/week	100	NR	1	p = 0.02
		SMBG 4/week	102	NR	9	
	Overall (several events)	SMBG 1/week	100	NR	4	p = 0.25
		SMBG 4/week	102	NR	9	
	Severe	SMBG 1/week	100	0	0	p = 1.00
		SMBG 4/week	102	0	0	

NR=not reported; NS=not significant; SMBG=self-monitoring of blood glucose

APPENDIX 19: A1C AND FASTING BLOOD GLUCOSE DATA IN PATIENTS WITH TYPE 2 DIABETES

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	P-Value Between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (Mean ± SD)	P-Value Between Treat-ments
Aydin et al., 2005[31]	SMBG 4 times/day, once 1 week	7.3 ± 1.4	6.5 ± 0.6	NR	<0.005	NR	NR	NR	NR	NR	NR
	SMBG 4 times/day, once 2 weeks	7.4 ± 1.3	6.9 ± 0.7	NR	<0.05		NR	NR	NR	NR	
	SMBG 4 times/day, once 1 month	7.8 ± 1.2	7.8 ± 1.3	NR	NS		NR	NR	NR	NR	
	No SMBG	7.5 ± 1.1	7.7 ± 1.6	NR	NS		NR	NR	NR	NR	
Barnett et al., 2008[50]	SMBG 5 times/day, 2 days/week	8.12 ± 0.89	6.95 ± 0.97	-1.15 ± 1.14	NR	0.0265 (change from baseline); 0.0097 (end point)	-1.26 ± 2.49 (FPG, change from baseline)	NR	NR	NR	NR
	No SMBG	8.12 ± 0.84	7.20 ± 1.22	-0.91 ± 1.29	NR		-0.97 ± 2.54 (FPG, change from baseline)	NR	NR	NR	
Bonomo et al., 2006[32] (abstract)	SMBG 4 times/day, once 1 month	7.97 ± 0.72	7.78 ± 1.05	NR	NS	NR	NR	NR	NR	NR	NR
	SMBG 6 times/day, once 2 weeks	8.08 ± 0.84	7.6 ± 0.73	NR	0.001		7.20 ± 1.52	6.92 ± 1.43 (lunch); 6.68 ± 1.50 (dinner)	NR	8.20 ± 1.63 (breakfast); 8.74 ± 1.55 (lunch); 8.51 ± 1.63 (dinner)	
Davidson et al., 2005[4]	SMBG 6 times/day, 6 days/week	8.5 ± 2.2	7.7 ± 1.6	-0.8 ± 1.6	<0.001	0.58 (change from baseline)	NR	NR	NR	NR	NR
	No SMBG	8.4 ± 2.1	7.8 ± 1.5	-0.6 ± 2.1	0.05		NR	NR	NR	NR	

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	P-Value Between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (Mean ± SD)	P-Value Between Treat-ments
Evans et al., 1999[25]	A1C change as 1 strip/day increased	NR	NR	NR	r = -0.108 (P = 0.357)		NR	NR	NR	NR	NR
Farmer et al., 2007[34]	SMBG 3 times/day, 2 days/week (less intensive)	7.41 ± 1.02	7.28 ± 0.88	-0.14 ±0.82	NR	0.12 for difference between groups (end point)	NR	NR	NR	NR	NR
	SMBG 3 times/day, 2 days/week + training and support (more intensive)	7.53 ± 1.12	7.36 ± 1.05	-0.17 ± 0.73	NR		NR	NR	NR	NR	
	No SMBG + usual care	7.49 ± 1.09	7.49 ± 1.2	0 ± 1.02	NR		NR	NR	NR	NR	
Farmer et al., 2007[34] (OADs)	SMBG 3 times/day, 2 days/week (less intensive)	7.61 ± 1.05	7.41 ± 0.91	-0.20 ± 0.87	NR	NR (0.90 for interaction between intervention and pre-specified subgroup treatment)	NR	NR	NR	NR	NR
	SMBG 3 times/day, 2 days/week + training and support (more intensive)	7.66 ± 1.10	7.46 ± 1.07	-0.20 ± 0.73	NR		NR	NR	NR	NR	
	No SMBG + usual care	7.61 ± 1.11	7.61 ± 1.24	-0.01 ± 1.10	NR		NR	NR	NR	NR	
Farmer et al., 2007[34] (diet only)	SMBG 3 times/day, 2 days/week (less intensive)	6.85 ± 0.66	6.9 ± 0.70	0.04 ± 0.64	NR	NR (0.90 for interaction between intervention	NR	NR	NR	NR	NR

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	P-Value Between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (Mean ± SD)	P-Value Between Treat-ments
	SMBG 3 times/day, 2 days/week + training and support (more intensive)	7.18 ± 1.11	7.09 ± 0.94	-0.09 ± 0.72	NR	and pre-specified subgroup treatment)	NR	NR	NR	NR	
	No SMBG + usual care	7.18 ± 0.98	7.21 ± 1.05	0.03 ± 0.80	NR		NR	NR	NR	NR	
Guerci , 2003[28] et al.	SMBG 6 times/week, on 3 different days	9.0± 1.3	8.1 ±1.6	-0.88 ± 1.54	NR	0.009 (change from baseline); 0.012 (end point)	7.2 ± 5.1	6.66 ± 4.83	NR	NR	NS
	No SMBG	8.9 ±1.3	8.4 ± 1.4	-0.60 ± 1.54	NR		7.5 ± 4.8	6.91 ± 4.56	NR	NR	
Karter et al., 2001[24] (insulin)	SMBG daily	NR	8.227 ± 1.7*	NR	NR	<0.0001 (daily versus other two groups)	NR	NR	NR	NR	NR
	SMBG < daily	NR	8.792*	NR	NR		NR	NR	NR	NR	
	No SMBG	NR	8.916*	NR	NR		NR	NR	NR	NR	
Karter, 2001[24] (OAD)	SMBG daily	NR	8.098 ± 1.8*	NR	NR	<0.0001 (daily versus other two groups)	NR	NR	NR	NR	NR
	SMBG < daily	NR	8.574*	NR	NR		NR	NR	NR	NR	
	No SMBG	NR	8.78*	NR	NR		NR	NR	NR	NR	
Karter et al., 2001[24] (diet)	SMBG daily	NR	7.459*	NR	NR	<0.0001 (daily versus < daily; < daily versus no SMBG)	NR	NR	NR	NR	NR
	SMBG < daily	NR	7.762*	NR	NR		NR	NR	NR	NR	
	No SMBG	NR	8.104 ± 2.3*	NR	NR		NR	NR	NR	NR	
Karter et al., 2006[35] (new users — OAD)	A1C change as 1 strip/day increased	8.6 ± 2.0	7.9 ± 1.7*	NR	r = -0.42 (P < 0.0001)		NR	NR	NR	NR	NR
Karter et al., 2006[35] (new users — diet)	A1C change as 1 strip/day increased	8.2 ± 2.0	6.9 ± 1.4*	NR	r = -0.35 (P < 0.0001)		NR	NR	NR	NR	NR
Karter et al., 2006[35] (prevalent users — OAD)	A1C change as 1 strip/day increased	7.6 ± 1.4	7.8 ± 1.5*	NR	r = -0.16 (P < 0.0001)		NR	NR	NR	NR	NR

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	P-Value Between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (Mean ± SD)	P-Value Between Treat-ments
Karter et al., 2006[35] (prevalent users — diet)	A1C change as 1 strip/day increased	6.4 ± 0.8	6.7 ± 0.9*	NR	SMBG frequency was not associated with significant changes in A1C (regression coefficient not provided)		NR	NR	NR	NR	NR
Meier et al., 2002[30] (OAD)	SMBG 1.35 ± 0.92/day (before frequency decreased)	NR	7.82 ± 1.22	NR	NR	NS	NR	NR	NR	NR	NR
	SMBG 0.67 ± 0.44/day (after frequency decreased)	NR	7.83 ± 1.21	NR	NR		NR	NR	NR	NR	
Meier et al., 2002[30] (diet only)	SMBG 1.17 ± 1.04/day (before frequency decreased)	NR	NR	NR	NR	NS	NR	NR	NR	NR	NS
	SMBG 0.61 ± 0.44/day (after frequency decreased)	NR	NR	NR	NR		NR	NR	NR	NR	
Muchmore et al.,1994[37]	SMBG 6 times/day for 4 weeks; 2 times/day for 16 weeks; individual selection after 20 weeks	10.29 ± 0.33 (SE)	8.75 ± 0.48 (SE)	-1.54	< 0.05	NS	NR	NR	NR	NR	NR
	No SMBG	10.45 ± 0.44 (SE)	9.6 ± 0.63 (SE)	-0.84	> 0.3		NR	NR	NR	NR	

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	P-Value Between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (Mean ± SD)	P-Value Between Treat-ments
Murata et al., 2009[54]	A1C change as SMBG increased 10 test strips per week	NR	NR	NR	OADs dose(s) unchanged, coefficient = - 0.2 (P = 0.04) OADs dose(s) increased, coefficient = -0.09 (P = 0.63) New OAD added, coefficient = -0.4 (P = 0.21) OADs dose(s) increased and new OAD added, coefficient = -0.9 (P = 0.002) Insulin added, coefficient = -0.05 (P < 0.001) All patients, coefficient = -0.06 (P = 0.38)		NR	NR	NR	NR	NR
O'Kane et al., 2008[39]	SMBG 8 times/week	8.8 ± 2.1	6.9 ± 0.8	NR	NR	0.69 (end point)	NR	NR	NR	NR	NR
	No SMBG	8.6 ± 2.3	6.9 ± 1.2	NR	NR		NR	NR	NR	NR	
Rindone et al., 1997[40]	SMBG	NR	8.0 ± 1.3 (over 2nd yr)	NR	NR	0.66	176 ± 37 (over 2nd yr)	NR	NR	NR	0.62
	No SMBG	NR	8.2 ± 1.8 (over 2nd yr)	NR	NR		177 ± 58 (over 2nd yr)	NR	NR	NR	
Scherbaum et al., 2008[48]	SMBG once a week	7.2 ± 1.4	6.9 ± 1.2	-0.24	NR	0.0022 (change from baseline); 0.53 (end point)	NR	NR	NR	NR	NR
	SMBG 4 times/week	7.2 ± 1.0	7.0 ± 0.8	-0.16	NR		NR	NR	NR	NR	
Schneider et al., 2007[41] (insulin+ OAD)	After SMBG	NR	NR	NR	NR	NR	8.80	NR	NR	NR	0.129
	Before SMBG	NR	NR	NR	NR		10.21	NR	NR	NR	
Schneider et al., 2007[41] (insulin)	After SMBG	NR	NR	NR	NR	NR	9.68	NR	NR	NR	0.324
	Before SMBG	NR	NR	NR	NR		9.05	NR	NR	NR	
Schneider et al., 2007[41] (OAD)	After SMBG	NR	NR	NR	NR	NR	8.64	NR	NR	NR	0.003
	Before SMBG	NR	NR	NR	NR		9.03	NR	NR	NR	
Schneider	After SMBG	NR	NR	NR	NR	NR	7.24	NR	NR	NR	0.978

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	P-Value Between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (Mean ± SD)	P-Value Between Treat-ments
et al., 2007[41] (diet)	Before SMBG	NR	NR	NR	NR		7.24	NR	NR	NR	
Schwedes et al., 2002[29]	SMBG 6 times/day, 2 days/week	8.47 ± 0.86	7.47 ± 1.27	-1.0 ± 1.08	NR	0.0086 (end point)	NR	NR	NR	NR	NR
	No SMBG	8.35 ± 0.75	7.81 ±1.52	-0.54 ± 1.41	NR		NR	NR	NR	NR	
Secnik et al., 2007[42] (Insulin)	A1C change as 1 strip/day increased	NR	NR	NR	r = -0.65 (P = 0.0236)		NR	NR	NR	NR	NR
Secnik et al., 2007[42] (OAD)	A1C change as 1 strip/day increased	NR	NR	NR	r = 0.09 (P = 0.5392)		NR	NR	NR	NR	
Soumerai et al., 2004[45] (SFU-good baseline A1C)	Initiators of SMBG	NR	NR	NR	NR	NS	NR	NR	NR	NR	NR
	Non-initiators of SMBG	NR	NR	NR	NR		NR	NR	NR	NR	
Soumerai, 2004[45] (SFU — adequate baseline A1C)	Initiators of SMBG	NR	NR	NR	NR	NS	NR	NR	NR	NR	NR
	Non-initiators of SMBG	NR	NR	NR	NR		NR	NR	NR	NR	
Soumerai et al., 2004[45] (SFU— poor baseline A1C)	Initiators of SMBG	NR	-0.63 (initiators versus non-initiators)	NR	NR	0.03	NR	NR	NR	NR	NR
	Non-initiators of SMBG	NR		NR	NR		NR	NR	NR	NR	
Wen et al., 2004[46]	SMBG	7.03	6.60	NR	NR	NR	NR	NR	NR	NR	NR
	No SMBG	7.10	6.80	NR	NR		NR	NR	NR	NR	
Wieland et al., 1997[47]	A1C change as 1 strip/day increased	NR	NR	NR	r = 0.02 (P > 0.5)		NR	NR	NR	NR	NR

A1C=glycosylated hemoglobin; NR=not reported; NS=non-significant; OAD=oral anridiabetes drug; SD=standard deviation; SMBG=self-monitoring of blood glucose
* Data is provided by the author.

APPENDIX 20: A1C AND FASTING BLOOD GLUCOSE IN PATIENTS WITH GESTATIONAL DIABETES MELLITUS

Study	Comparators	A1C (%)					Blood Glucose (mmol/L) at End Point				
		A1C at Baseline (Mean ± SD)	A1C at End Point (Mean ± SD)	A1C Change From Baseline (Mean ± SD)	P-Value End Point Versus Baseline	p-value between Treatments	Fasting (Mean ± SD)	Pre-prandial (Mean ± SD)	1-Hour Post-prandial (Mean ± SD)	2- Hour Post-prandial (mean±SD)	P-Value Between Treatments
Homko et al., 2002[51]	SMBG 4 times/day, 4 days/week	NR	NR	NR	NR	NR	4.75 ± 0.41	NR	6.14 ± 0.53	NR	0.29 (FBG); 0.11 (1-hr post-prandial)
	No SMBG (monitoring BG at each prenatal visit)	NR	NR	NR	NR		4.97 ± 0.78	NR	5.67 ± 1.47	NR	
Rey, 1997[52]	SMBG 3 times/day, alternating with 4 times/day	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	No SMBG (monitoring BG in outpatient clinic every 2 weeks)	NR	NR	NR	NR		NR	NR	NR	NR	

A1C=glycosylated hemoglobin; FBG=fasting blood glucose; NR=not reported; SD=standard deviation; SMBG=self-monitoring of blood

APPENDIX 21: STUDY-LEVEL BODY WEIGHT AND BMI DATA IN PATIENTS WITH TYPE 2 DIABETES

Study	Comparators	Body Weight (kg)					BMI (kg/m²)				
		Weight at Baseline (kg)	Weight at End Point (kg)	Weight Change From Baseline (kg)	Weight P-Value End Point Versus Baseline	Weight P-Value Between Treatments	BMI at Baseline	BMI at End Point	BMI Change From Baseline	BMI P-Value End Point Versus Baseline	BMI P-Value Between Treat-ments
Barnet et al. , 2008[50]	SMBG 5 times/day, 2 days/week	84±15.6	NR	-0.68 ± 5.7	NR	NR	30.5 ± 5.3	NR	NR	NR	NR
	No SMBG	83.8±16.7	NR	-0.50 ± 4.01	NR		30.3 ± 5.0	NR	NR	NR	
Davidson et al., 2005[4]	SMBG 6 times/day, 6 days/week	83.9±23.3	NR	-0.7 ± 6.3	NS	0.56	33.4 ± 7.0	NR	-0.37 ± 2.3	NS	0.42
	No SMBG	80.7±17.0	NR	-0.1 ± 2.9	NS		31.7 ± 6.7	NR	-0.1 ± 1.6	NS	
Farmer et al., 2007[34]	SMBG 3 times/day, 2 days/week (less intensive)	86.7 ± 18.9	86.4 ± 19.4	-0.3 ± 2.7	NR	0.37 for difference between groups	31.9 ± 6.2	31.8 ± 6.3	-0.2 ± 0.9	NR	0.41 for difference between groups
	SMBG 3 times/day, 2 days/week + training and support (more intensive)	90.4 ± 18.9	89.9 ± 19	-0.50 ± 2.6	NR		31.0 ± 5.3	30.7 ± 5.0	-0.3 ± 1.2	NR	
	No SMBG + usual care	86.9 ± 16.4	86.1 ± 15.7	-0.8 ± 3.3	NR		30.9 ± 6.1	30.8 ± 6.3	-0.1 ± 1.0	NR	
Guerci et al., 2003[28]	SMBG 6 times /week, on 3 different days	83.3 ± 15.7	NR	-0.93 ± 4.35	NR	NR	30.4 ± 6.1	NR	NR	NR	NR

Study	Comparators	Body Weight (kg)					BMI (kg/m²)				
		Weight at Baseline (kg)	Weight at End Point (kg)	Weight Change From Baseline (kg)	Weight P-Value End Point Versus Baseline	Weight P-Value Between Treatments	BMI at Baseline	BMI at End Point	BMI Change From Baseline	BMI P-Value End Point Versus Baseline	BMI P-Value Between Treat-ments
	No SMBG	82.0 ± 15.3	NR	-0.83 ± 4.87	NR		29.7 ± 4.8	NR	NR	NR	
Muchmore et al., 1994[37]	SMBG 6 times/day for 4 weeks; 2 times/day for 16 weeks; individual selection after 20 weeks	99.1 ± 4.8 (SE)	93.9 ± 4.2 (SE)	5.2 ± 15.69 (SE)	NR	NR	NR	NR	NR	NR	NR
	No SMBG	99.1 ± 3.6 (SE)	94.0 ± 4.2 (SE)	5.1 ± 13.05 (SE)	NR		NR	NR	NR	NR	
O'Kane et al., 2008[39]	SMBG 8 times/week	NR	NR	NR	NR	NR	34 ± 7	3 months: 33.0 ± 6.5 6 months: 33.0 ± 6.3 9 months: 33.1 ± 6.3 12 months: 33.1 ± 6.4	NR	NR	0 months: 0.04 3 months: 0.56 6 months: 0.75 9 months:

Study	Comparators	Body Weight (kg)					BMI (kg/m²)				
		Weight at Baseline (kg)	Weight at End Point (kg)	Weight Change From Baseline (kg)	Weight P-Value End Point Versus Baseline	Weight P-Value Between Treatments	BMI at Baseline	BMI at End Point	BMI Change From Baseline	BMI P-Value End Point Versus Baseline	BMI P-Value Between Treat-ments
	No SMBG	NR	NR	NR	NR		32 ± 6.2	3 months: 31.5 ± 6.1 6 months: 31.4 ± 6.1 9 months: 31.7 ± 6.1 12 months: 31.8 ± 6.0	NR	NR	0.49 12 months: 0.32
Schwedes et al. 2002[29]	SMBG 6 times/day, 2 days/week	88.2 ± 15.4	NR	-1.96 ± 2.99	NR	0.332 for difference from baseline between groups	31.0 ± 4.6	NR	NR	NR	NR
	No SMBG	89.6 ± 16.5	NR	-1.62 ± 3.54	NR		31.9 ± 5.5	NR	NR	NR	

BMI=body mass index; NR=not reported; NS=non-significant; SE=standard error; SMBG=self-monitoring of blood gucose
* Data is provided by the author.

APPENDIX 22: STUDY-LEVEL BODY WEIGHT AND BMI DATA IN PATIENTS WITH GESTATIONAL DIABETES MELLITUS

Study	Comparators	Body Weight (kg)					BMI (kg/m²)				
		Weight at Baseline (kg)	Weight at End Point (kg)	Weight Change From Baseline (kg)	Weight P-Value End Point Versus Baseline	Weight P-Value Between Treatments at End Point	BMI at Baseline	BMI at End Point	BMI Change From Baseline	BMI P-Value End Point Versus Baseline	BMI P-Value Between Treatments
Homko et al., 2002[51]	SMBG 4 times/day, 4 days/week	NR	NR	28.6 ± 13.8	NR	0.229	NR	NR	NR	NR	NR
	No SMBG (monitoring BG at each prenatal visit)	NR	NR	34.1 ± 17.1	NR		NR	NR	NR	NR	

BMI=body mass index; NR=not reported; SMBG=self-monitoring of blood glucose

APPENDIX 23: EDUCATIONAL COMPONENTS OF TYPE 1 DIABETES STUDY IN ADULTS

Study	Interventions	Educational Component of Intervention
Gordon et al., 1991[26]	Intervention 1: SMBG 2 times/day X 7 days/week	All patients were had pre-trial visit to be educated in insulin dose adjustment relative to exercise, diet, and blood glucose levels. Given instructions on completing SMBG diaries, insulin adjustments, frequency & severity of hypoglycemia. All patients reviewed at 6-week intervals for A1C & blood glucose. Patients were encouraged to review SMBG results between visits & make changes to insulin dose.
	Intervention 2: SMBG 4 times/day X 2 days/week	
	Intervention 3: SMBG 4 times/day X 1 day/week	

A1C=glycosylated hemoglobin; SMBG=self-monitoring of blood glucose

APPENDIX 24: EDUCATIONAL COMPONENTS OF TYPE 1 DIABETES STUDY IN CHILDREN

Study	Interventions	Educational Component of Intervention
Santiprabhob et al., 2008[27]	All study arms: All patients did SMBG ≥ 4 times/day during a 5-day diabetes self-management education camp. Then, patients were divided into two groups based on patients' willingness to perform SMBG during a 6-month follow-up period	The education camp consists of lectures, activities, or games, and small group discussion on diabetes etiology and symptoms, insulin therapy and injection techniques, the importance of diabetes control, blood glucose monitoring, exercise and diabetes, diabetes nutrition, diabetic complications, recognition and management of hypo/hyperglycemia and ketosis, insulin dosage adjustment, and the handling of unusual events and activities (e.g., sick days)
	Intervention 1: SMBG 3-4 times/day for six months after education camp (patients performed SMBG 3-4 times/day at least 70% of time)	
	Intervention 2: SMBG < 3 times/day for six months after camp	

SMBG=self-monitoring of blood glucose

APPENDIX 25: EDUCATIONAL COMPONENTS OF TYPE 2 DIABETES STUDIES

Study	Interventions	Educational Component of Intervention
Davidson et al., 2005[4]	Intervention: SMBG 6 times/day (before and 1-2 hour after meals) x 6 days/week (+ counselling); patients also recorded what they ate during those meals; nurse (blinded to treatment allocation) followed a treatment algorithm to make therapeutic decisions with the goal of lowering fasting glucose concentrations to achieve an A1C < 7.5%	Dietician counselling: dietician utilized the glucose values to educate patients on the effects of meal components and portion sizes on the rise of post-prandial glucose concentrations
	Control: No SMBG (+ counselling); nurse (blinded to treatment allocation) followed a treatment algorithm to make therapeutic decisions with the goal of lowering fasting glucose concentrations to achieve an A1C < 7.5%	Dietician counselling: education of patients on the effects of meal components and portion sizes on the rise of post-prandial glucose concentrations
Farmer et al., 2007[34]	All study arms: Assessment visit included a discussion about diabetes beliefs and a standard approach was used to help patients understand how diabetes might present a threat to their health. The roles of diet, physical activity, and drugs were discussed in association with feedback on glucose levels to change behavior by goal-setting and review. Goal-setting and review was continued in all treatment arms during follow-up visits. The patient's doctor was notified of all A1C results and asked to consider changes in drugs by following the National Institute for Clinical Excellence diabetes guidelines for all patients.	
	Less intensive self-monitoring: SMBG 3 times per day x 2 days per week (+standard care, including A1C every 3 months, separate diaries were used to record identified goals and activity, and to record SMBG results)	Use of a blood glucose meter with advice for participants to contact their doctor for interpretation of results
	More intensive self-monitoring: SMBG 3 times per day x 2 days per week with encouragement to experiment with monitoring (+standard care, including A1C every 3 months, a single diary used to record goals, activities, and SMBG results + training in self-interpretation and application of results to maintain adherence to diet, physical activity, and drug regimens)	Use of a blood glucose meter with training in self-interpretation and application of results. Educated in the timing of SMBG and using the results to enhance motivation and maintain adherence to diet, physical activity, and drug regimens. Patients were encouraged to experiment with monitoring and to explore the effects of activities such as exercise on their test results. Patients were also taught to reflect on any abnormal values to try and indentify what might have contributed to them.

Study	Interventions	Educational Component of Intervention
	Control: No SMBG (+standard care, including A1C every 3 months, diary to record self-care goals and strategies to achieve them)	Standardized usual care, including the use of goal-setting and review
Guerci et al., 2003[28]	Intervention: SMBG 2 times per day x 3 days per week (+ counselling) At the 3-month visit, practitioners could modify their treatments, based on the A1C value measured at the time	Counselling on diet and exercise from general practitioners during 5 visits and initial training in SMBG by general practitioners (no standard rules for adjusting behavior to the results of SMBG were given to patients)
	Control: No SMBG (+ counselling) At the 3-month visit, practitioners could modify their treatments, based on the A1C value measured at the time	Counselling on diet and exercise from general practitioners during 5 visits
Muchmore et al., 1994[37]	Intervention: SMBG; week 1-4: 6 times per day (before and after 3 meals); week 5-20: 2 times per day (before and after a single meal); several patients continued monitoring after 20 weeks (+ carbohydrate-counting) *Medication adjustment was not included in the study protocol, but it was done for similar amounts of patients in both groups*	Intervention: 28-week behavioral weight loss program with emphasis on glycemic response to carbohydrate intake and exercise (individual and group training on carbohydrate counting); SMBG taught by nurse educator
	Control: No SMBG (+ general strategies of diabetes control, exercise, etc.) *Medication adjustment was not included in the study protocol, but it was done for similar amounts of patients in both groups*	Control: 28-week behavioral weight loss program with focus on general principles of diabetes nutrition, diabetes control, and exercise
O'Kane et al., 2008[39]	All study arms: Structured core education program involving diabetes nurse practitioners, dieticians, podiatrists, and medical staff. All aspects of diabetes care were reviewed at each visit, including the A1C and SMBG results. Identical treatment algorithm for dietary and pharmacological management of glycemia was used, based on A1C targets for both groups.	

Study	Interventions	Educational Component of Intervention
	Intervention: SMBG; 4 fasting and 4 post-prandial measurements per week (structured education program + additional education on monitoring)	Intervention: Structure core education program plus education on monitoring Received meter training, and ongoing and appropriate advice and support in the appropriate interpretation of and response to the SMBG results. Specifically, patients were advised on appropriate responses to high or low readings, such as the need for dietary review or exercise in response to high readings
	Control: No SMBG (structured education program)	Control: Structured core education program
Scherbaum et al., 2008[48]	Intervention 1: SMBG (one test/week)	All patients had received a structured education on diabetes and instructions on SMBG in practice before the start of the study and were not specifically re-educated. All patients included in study had been stabilized on their OAD medication for at least 3 months and considered to be under stable metabolic control (no necessity to change antidiabetes medication). Patients were asked to report back to doctor in the event of inappropriate diabetes control
	Intervention 2: SMBG (four tests/week)	
Schwedes et al., 2002[29]	All study arms: Patients had to have participated in a diabetes education within the previous 2 years to be included in the study. Information on medication adjustment was not provided in the study.	
	Intervention: SMBG; 6 times/day (before and 1 hour after meals) x 2 days/week (1 weekday and Sunday) (+ structured training, diary, standardized counselling)	Intervention: Patients were instructed on the use of the SMBG device and to record values in a combined diary for blood glucose data, eating habits, and state of well-being. They were told to use the information from the SMBG results with their diary to make appropriate adjustments to their diet and lifestyle. Patients received a defined counselling algorithm which contained questions on self-perception, self-reflection, and self-regulation
	Control: No SMBG (non-standardized counselling on diet + lifestyle)	Control: Non-standardized counselling with a focus on diet and lifestyle during their visits
Siebolds et al., 2006[43]	Refer to Schwedes et al., 2002[29] for description	
Simon et al., 2008[44]	Refer to Farmer et al., 2007[34] for description	

Study	Interventions	Educational Component of Intervention
Aydin et al., 2005[31]	Intervention: SMBG (4/day x 1 day/week, 4/day x once every 2 weeks, 4/day x once per month)	All patients included in the study had experience with self-monitoring of blood glucose. Blood glucose meter training was conducted during a one week run-in period. Self-regulation of blood glucose and testing technique was discussed at each visit.
	Control: No SMBG	
Barnett et al., 2008[50] RCT	Intervention: SMBG (5/day x 2 days/ week)	Intervention: Education on using glucometer, how to check it is working, how to take the measurement, how to record in patient diary, and what to do in the event of asymptomatic hypoglycemia (glucose < 3.0 mmol/L on SMBG without symptoms/signs of hypoglycemia). In the event of suspected hypoglycemia, patients were instructed to take a blood glucose reading and to follow the instruction on management of hypoglycemia in the patient diary. The diary also provided the record of the SMBG results. Diet and lifestyle advice, reinforced at each clinic visit. Kept a diary to record symptoms suggestive of hypoglycemia, information on last meal, temporal association with OAD and action taken, e.g., resolved after eating and third-party assistance. Information on symptoms, avoidance and management of hypoglycemia with their patient diary
	Control: No SMBG	Control: Diet and lifestyle advice, reinforced at each clinic visit. Kept a diary to record symptoms suggestive of hypoglycemia, information on last meal, temporal association with OAD and action taken, e.g., resolved after eating and third-party assistance. Information on symptoms, avoidance and management of hypoglycemia with their patient diary.

A1C =glycosylated hemoglobin; SMBG=self-monitoring of blood glucose
NOTE: The educational component of the Type 2 diabetes mellitus observational studies[24,25,33,35,36,40,42,46,47] could not be determined and were not included in the above table.