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Use of Blood Glucose Test Strips for the Management of Diabetes Mellitus – PROJECT PROTOCOL

Supporting Informed Decisions

À l'appui des décisions éclairées

This report has been prepared by the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), a service of the Canadian Agency for Drugs and Technologies in Health (CADTH). It 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 conclusions [statements] were provided by experts. The authors have also considered input from other stakeholders.

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. The information in this report should not be used as a substitute for the application of clinical judgment with respect to the care of a particular patient or other professional judgment in any decision making process nor is it intended to replace professional medical advice. While CADTH has taken care in the preparation of the report to ensure that its contents are accurate, complete, and up-to-date, CADTH does not make any guarantee to that effect. CADTH is not responsible for any errors or omissions or injury, loss, or damage arising from or as a result of the use (or misuse) of any information contained in or implied by the information in this report.

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TABLE OF CONTENTS

ABBREVIATIONS

A1C	glycosylated hemoglobin
CAC	COMPUS Advisory Committee
CADC	Canadian Academic Detailing Collaboration
CDA	Canadian Diabetes Association
EQ-5D	EuroQol 5-dimension index
GRADE	Grades of Recommendations Assessment, Development and Evaluation
NIHB	Non-Insured Health Benefits
RCT	randomized controlled trial
SIGN	Scottish Intercollegiate Guidelines Network
SMBG	self-monitoring of blood glucose
UKPDS	United Kingdom Prospective Diabetes Study

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 range from 0 to 11 points. A score of 6 or more indicates good quality, and a score lower than 6 indicates poor quality.

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

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

Case series: A descriptive observational study that 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.

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 conference 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.

Cross-over 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.

Diabetic ketoacidosis: An acute complication of diabetes caused by increased fatty acid metabolism and the accumulation of keto acids. 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 glucose-lowering agents (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 a randomized controlled trial).

Fasting plasma glucose: Plasma glucose level measured when there has been no caloric intake for at least eight hours.

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. It is 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 with respect to either specific health conditions or life as a whole from the individual perspective.

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. The prototypical patient with hyperglycemic hyperosmolar state 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 and defined by 1) the development of autonomic or neuroglycopenic symptoms, 2) a low plasma glucose level of 4.0 mmol/L for patients with insulin or an insulin secretagogue, and 3) symptoms responding to the administration of carbohydrate (Canadian Diabetes Association 2003).

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

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.

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

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 24:00 h to 6:00 h.

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 below 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; for example, 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: 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: An class of insulin analogue, produced by introducing alterations in the amino acid sequence of human insulin, which more closely mimics the short duration of action of meal-induced endogenous insulin in non-diabetic patients than does regular human insulin.

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.

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.

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

Severe hypoglycemia: An event with characteristic hypoglycemic symptoms requiring 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.

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.
The current definition of duration is less than 24 hours, but the average duration is about 12 minutes.

Type 1 diabetes mellitus: Diabetes that is primarily the result of pancreatic beta cell destruction due to an autoimmune process or for which the etiology of beta cell destruction is unknown.

Type 2 diabetes mellitus: Diabetes that may range from predominant insulin resistance with relative insulin deficiency to a predominant secretory defect with insulin resistance.

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

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 in clinical practice, then proposing evidence-based interventions to address these gaps, and
- 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) members are listed on page ii of this document. The mandate of CERC is advisory in nature and is to provide recommendations and advice to the COMPUS Directorate at CADTH on assigned topics that relate to the identification, evaluation, and promotion of best practices in the prescribing and use of drugs across Canada.
- Stakeholder feedback.

1.1 CERC

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, the four people appointed as Specialist Experts are endocrinologists or diabetes specialists. Two of the Core Members are Public Members who bring a lay perspective. 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, institutional or community clinical pharmacy, pharmacoeconomics, clinical epidemiology, drug utilization expertise, methodology, effecting 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 is to provide recommendations and advice to the COMPUS Directorate at CADTH on assigned topics that relate to the identification, evaluation, and promotion of best 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

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
- benefit to multiple jurisdictions
- measurable outcomes
- potential to effect change in prescribing and use.

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] and the optimum frequency of testing has not been defined.[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 steadily due to the increasing prevalence of diabetes in Canada and higher rates of self-monitoring.[7] In 2005/2006, the Nova Scotia Senior 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.[11] 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).[12,13]

The global prevalence of diabetes is estimated to be 177 million and is projected to increase to 300 million by 2025. In 2004/2005 approximately 1.8 million (5.5%) Canadians aged 20 years and older had diagnosed diabetes.[14] However, it is estimated that 2.7% of the general adult population has undiagnosed type 2 diabetes mellitus,[5] and the true prevalence of diabetes may approach 1.9 million.[15]

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 antidiabetic 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.[7,16] SMBG requires that patients prick their finger with a lancet device to obtain a small blood sample (0.3 µL to 5 µL).[7,16] 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.[7] Results, based on an automated reading, are available from the photometer within 5 to 30 seconds.[7] The results can be stored in the glucose meter's electronic memory or recorded in the patient's logbook. There are multiple meters available in Canada each with their own unique test strips[7,16].

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.[7,16] The Canadian Diabetes Association (CDA) 2008 Clinical Practice Guidelines[5] recommend patients with type 1 diabetes mellitus undertake SMBG at least three times daily. For patients with type 2 diabetes mellitus who are treated with insulin or oral antidiabetic drugs, the CDA recommends SMBG at least once daily.

3 OBJECTIVE

The objective of this protocol is to outline the methods to be used for identification of clinical and economic evidence supporting SMBG in patients with type 2 diabetes mellitus and identification of optimal frequency of SMBG in patients with type 1 diabetes mellitus and gestational diabetes mellitus.

Steps include:

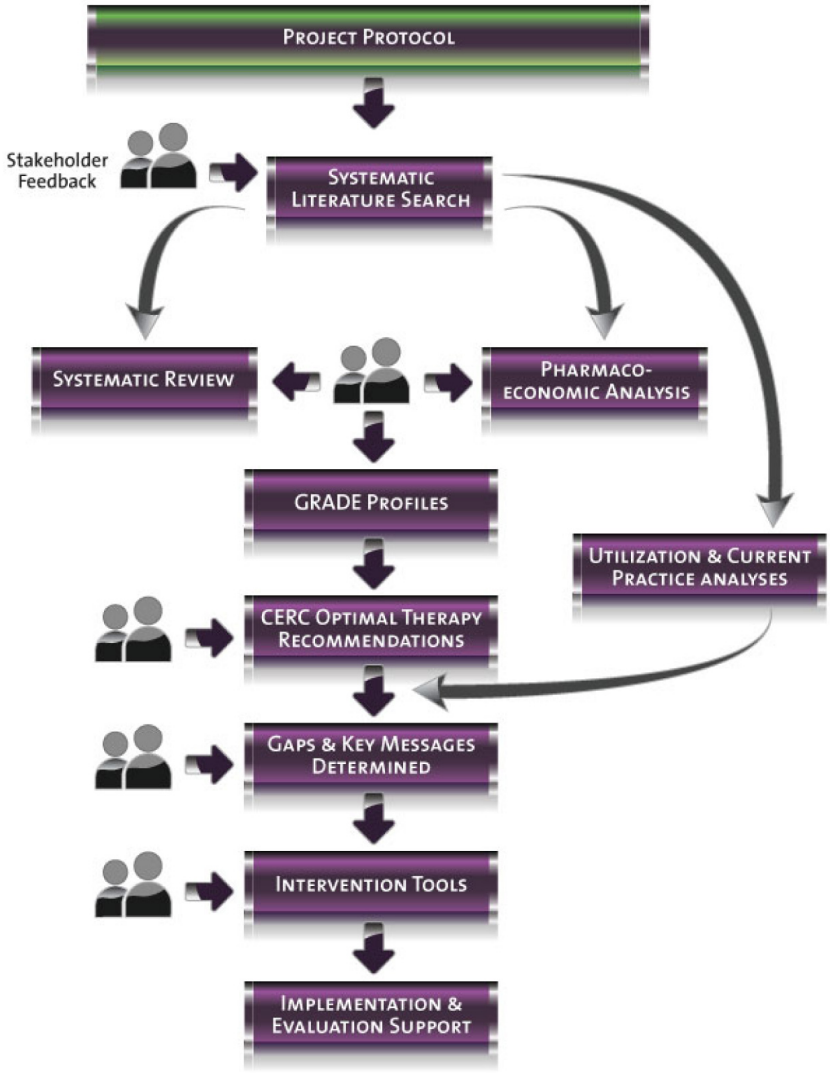
1. Identify evidence-based optimal practices, taking into consideration cost-effectiveness information when available, for the optimal prescribing and use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada
2. Identify current utilization with respect to the use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada
3. Identify current practice with respect to the use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada
4. Identify differences (the gap) between optimal prescribing and use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada (as supported by the evidence) and actual current utilization and practice
5. Identify potential barriers to optimal use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada
6. Identify key messages in order to encourage optimal prescribing and use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada
7. Identify effective activities and strategies (interventions), which could be directed towards a variety of audiences such as health and allied health professionals, patients, or government decision makers, in order to encourage optimal practices in the use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada
8. Develop intervention tools (evidence-based recommendations, menu of tools to support interventions, and support for implementing, monitoring and evaluating the tools and resulting interventions) to support optimal prescribing and use of blood glucose test strips for SMBG in the management of diabetes mellitus in Canada
9. Develop appropriate evaluation mechanisms
10. Support implementation of tools and evaluation.

4 PROJECT OVERVIEW

Once a topic is selected, COMPUS undertakes activities related to key areas in the COMPUS procedure. CAC provides advice and guidance throughout the process, from topic identification through to feedback and approval of recommendations and supporting interventions. 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 health technologies. 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 initial step (green box) toward the development of optimal therapy recommendations for the prescribing and use of blood glucose test strips. The protocol document is reviewed and approved by CAC and CERC.



5 RESEARCH QUESTIONS

The research questions to be answered are divided into six sections: 1) clinical, 2) economic, 3) current utilization, 4) current practice, 5) gap analysis, and 6) barriers to optimal use.

5.1 Clinical

5.1.1 Populations of interest

For each research question in this section, the following patient groups will be examined:

- Patients with type 1 diabetes mellitus — including adults, adolescents, pre-adolescents, and pregnant women
- Patients with type 2 diabetes mellitus — including adults, adolescents, pre-adolescents, and pregnant women using:
  - Insulin (with or without oral antidiabetic drugs)
  - Oral antidiabetic drugs only
  - No pharmacotherapy for diabetes mellitus
- Women with gestational diabetes mellitus
- Subgroups: If data are available, the research questions will be addressed for children, elderly people, First Nations people, ethnic minorities, and subgroups for whom hypoglycemia may pose occupational risks (e.g., professional drivers, pilots, and construction workers).

5.1.2 Research questions

- What effect does the practice of SMBG, compared with no SMBG, have on the important and critical outcomes shown in Table 1 (as well as fetal and maternal outcomes in pregnant women with diabetes mellitus)?
- What is the relationship between the frequency of SMBG and the important and critical outcomes shown in Table 1 (as well as fetal and maternal outcomes in pregnant women with diabetes mellitus)? What is the optimal frequency of testing?

5.2 Economic

5.2.1 Populations of interest

For each research question in this section, the following patient groups will be examined:

- Adults with type 1 diabetes mellitus
- Adults with type 2 diabetes mellitus using:
  - Insulin (with or without oral antidiabetic drugs)
  - Oral antidiabetic drugs only
  - No pharmacotherapy for diabetes mellitus.

5.2.2 Research questions

- What is the cost-effectiveness of SMBG compared with no SMBG?
- What is the relationship between frequency of SMBG and cost-effectiveness?

Table 1: Summary of outcomes as ranked by members of CERC, by median score and type of diabetes mellitus

Outcome	Median		
	Type 1	Type 2	Pediatrics
Mortality	9	9*	9*
HRQL — Diabetes-specific	8	8	8
Hyperglycemia DKA	8	8*	8
Hypoglycemia — Severe	8	8*	8
Hypoglycemia — Nocturnal	8	8*	8
Hospitalization	8	6*	8
Patient self-management	8	8	8
Blood glucose — Fasting	7	7	7
Cost of treatment	7	7	7
A1C	7	7	7*
HRQL — Generic	7	7	7
Hypoglycemia — Overall	7	7	7
Neuropathy	7*	7*	5*
Retinopathy	7*	7*	7*
Nephropathy	7*	7*	6*
Patient satisfaction with diabetes care	7	7	7
ER visits	7	7	7
Hyperosmolar hyperglycemic non-ketotic coma	7*	7*	7*
Patient satisfaction with diabetes treatment	6.5	6	7
Blood glucose — post-prandial	6*	5*	7*
Specialist visits	6*	5*	4*
Ischemic heart disease	5*	5*	4*
Peripheral vascular disease	5*	5*	4*
Stroke/TIA	5*	6*	6*
Congestive heart failure	5*	6*	6*
Primary care visits	6*	6*	7*
Weight/weight gain/BMI	5*	5*	5*
Blood pressure — Systolic	1	1	1
Blood pressure — Diastolic	1	1	1
Cholesterol — LDL-C	1	1	1
Cholesterol — TC-HDL-C ratio	1	1	1

Critical = 9, 8, 7 | Important = 6, 5, 4 | Not important = 3, 2, 1

*At least two CERC members ranked the outcome between 1 and 4.
A1C=glycosylated hemoglobin; BMI=body mass index; CERC=COMPUS Expert Review Committee; DKA=diabetic ketoacidosis; ER=emergency room; HRQL=health-related quality of life; LDL-C=low density lipoprotein cholesterol; TC-HDL-C=total cholesterol / high density lipoprotein cholesterol; TIA=transient ischemic attack.

5.3 Current Utilization

5.3.1 Populations of interest

For each research question in this section, the following patient groups will be examined:

- Patients using insulin only
- Patients using insulin and oral antidiabetic drugs
- Patients using oral antidiabetic drugs only, by class of agent
- Patients not using pharmacotherapy for diabetes mellitus.

5.3.2 Research questions

- For Canada, and for each jurisdiction, what is the average number of blood glucose test strips claimed per person per day, by gender, age group (<15 years, 15 to 24 years, 25 to 44 years, 45 to 64 years, and ≥65 years), and type of drug plan [private, public, and Non-Insured Health Benefits (NIHB)]?
- For Canada, and for each jurisdiction, what is the estimated total expenditure for the use of blood glucose test strips per year, by gender, age group (<15 years, 15 to 24 years, 25 to 44 years, 45 to 64 years, and ≥65 years), and type of drug plan (private, public, and NIHB)?
- For Canada, and for each jurisdiction, what is the estimated annual per person expenditure on blood glucose test strips, by gender, age group (<15 years, 15 to 24 years, 25 to 44 years, 45 to 64 years, and ≥65 years), and type of drug plan (private, public, and NIHB)?

The variables to be analyzed in the current utilization analysis will be:

- Number of patients
- Number of prescriptions
- Units (strips) dispensed
- Drug cost (ingredient cost and mark-up)
- Number of strips per patient.

5.4 Current Practice

5.4.1 Populations of interest

For each research question in this section, the following patient groups will be examined:

- Adult patients with type 1 diabetes mellitus
- Adult patients with type 2 diabetes mellitus
- Health care professionals including family physicians, diabetes educators, and pharmacists.

5.4.2 Research questions

There are three overarching questions to be answered:

- What are the views and experiences of health care professionals, who provide care for patients with type 1 and type 2 diabetes mellitus, on the practice of SMBG?
- What are the views and experiences of patients with type 1 and type 2 diabetes mellitus relating to the practice of SMBG including their response to high and low readings, reasons for increasing or decreasing frequency of self-monitoring, and their views on the advice and feedback from health care professionals?
- How do patients, or caregivers, modify their behaviour in response to the results obtained from SMBG in terms of:
  - Medication use
  - Diet

- Exercise
- Contact with health care professional?

- What advice do health care professionals provide in this regard?

5.5 Gap Analysis

5.5.1 Research questions

- What are the differences between optimal prescribing and use of blood glucose test strips for the management of type 1 diabetes mellitus, type 2 diabetes mellitus, and gestational diabetes mellitus (as supported by the clinical and economic evidence) and current utilization and practice?

5.6 Potential Barriers to Optimal Use

5.6.1 Research questions

- What are the barriers to the implementation of optimal prescribing and use of blood glucose test strips for the management of diabetes mellitus?
- What action is needed to address those barriers?

6 METHODS

6.1 Clinical

Where possible, COMPUS builds on existing applicable Canadian and international initiatives and research. Therefore, the first stage in our research process will be to conduct a literature review to identify existing systematic reviews that have examined the practice of SMBG in diabetes mellitus.

Should recently published, high quality systematic review(s) of randomized controlled trials (RCTs) and observational studies that address the interventions, populations, and outcomes of interest be identified, they will be used, as described in Section 6.3, to produce the COMPUS optimal therapy recommendations. If necessary, the literature search used in existing systematic review(s) will be updated, and eligible studies published after the review cut-off date will be summarized along with the findings of the systematic review(s). If no systematic reviews are identified, COMPUS will conduct its own systematic review. Further, if a comprehensive systematic review of high quality is identified, but a substantial number of studies or studies considered pivotal to determining the effectiveness of an intervention have been published since the systematic review was performed, COMPUS will conduct its own systematic review.

In the event that COMPUS performs its own systematic review, a comprehensive search of the literature, based on predefined inclusion and exclusion criteria, to identify primary studies (RCTs and observational studies) that examine the practice of SMBG in diabetes mellitus will be undertaken. Where appropriate, studies will be pooled and meta-analyses performed. The meta-analytic methods to be used are described in detail in Section 6.1.2. Where quantitative synthesis of the data is not appropriate, results will be summarized and presented in narrative form.

6.1.1 Identification of existing systematic reviews

a) Literature search

Several major databases (MEDLINE, CINAHL, EMBASE, BIOSIS, and, PsycINFO) will be searched for existing systematic reviews, health technology assessments, and meta-analyses that examine the practice of SMBG

in diabetes mellitus. The search will be broad, using general key words ("self-monitoring," "blood glucose," "test strips," "self-care," "self-management," and others) to capture studies related to SMBG for all types of diabetes published in English between the years 2000 and 2008 (Appendix 1). The Internet will be searched to identify unpublished (grey) literature from websites and databases of health care associations and related agencies.

b) Population and outcomes

The population and outcomes of interest are described in Section 5.1 and Table 1, respectively.

c) Systematic review selection

Existing systematic reviews will be selected for generating optimal therapy recommendations based on two main criteria: relevance and quality. In the event that a systematic review is reported in more than one publication, the most recent or informative systematic review will be selected for inclusion.

Two researchers will independently select systematic reviews for consideration based on predefined inclusion and exclusion criteria (Appendix 2). Each reviewer will perform an initial screening of the systematic reviews identified through the literature search by examining titles and abstracts for relevance to the review topic. Abstracts of articles will be assessed and categorized as "included" or "excluded." If the relevance of an article is uncertain, it will be retained in the included list. Full text papers of included systematic reviews will be ordered. The selection process will be repeated until all articles are categorized as included or excluded. Reasons for exclusion of systematic reviews will be recorded and compared. Discrepancies between reviewers will be discussed until consensus is reached; the judgment of a third reviewer will be considered final for disputes that cannot be resolved by the first two reviewers.

d) Assessment of systematic review quality

AMSTAR,[17] an instrument developed specifically to quantify the methodological quality of systematic reviews (see Appendix 3), will be used by two researchers to independently assess the quality of systematic reviews that have been selected for inclusion. Systematic reviews that score 6 or more (out of a maximum of 11) will be considered to be of good quality and will be retained for use as the basis for generating optimal therapy recommendations. Systematic reviews that score lower than 6 will be considered to be of poor quality and will be excluded. Researchers will compare their individual ratings, discuss discrepancies, and reach agreement before assigning a final quality rating to each systematic review. Unresolved discrepancies will be resolved by a third reviewer.

e) Updating of systematic review literature search

A literature search will be conducted to identify relevant primary studies published after the search cut-off date of included systematic reviews. The same inclusion and exclusion criteria applied by the authors of the included systematic reviews will be used. Identified studies will be evaluated for quality and data abstracted as described in Section 6.1.2 under "Assessment of study quality" and "Data extraction," respectively.

f) Data handling

Results will be summarized in narrative form and will be used to augment the results of the selected systematic review(s).

6.1.2 Meta-analysis of primary studies

As noted in Section 6.1, if no suitable systematic reviews are identified, COMPUS will conduct its own systematic review of primary studies (i.e., parallel and cross-over RCTs, non-randomized controlled clinical trials, cohort and case-control studies, and time series analyses).

a) Literature search

Detailed search strategies will be developed and applied to several major electronic databases with no language restriction. These searches will be supplemented by hand searching of bibliographies from selected articles, conference proceedings, and clinical trial registries. The Internet will be searched to identify unpublished (grey) literature from websites and databases of health professional associations, health technology assessment agencies, and related entities. Regular alerts will be established in the electronic databases to capture the most recent studies. Searches to update the grey literature will be performed regularly.

b) Outcomes

The population and outcomes of interest are described in Section 5.1 and Table 1, respectively.

c) Study selection

Two researchers, working independently, will select articles for inclusion in the review based on inclusion criteria established a priori. The presence of any exclusion criteria will result in rejection of the article. The inclusion and exclusion criteria are provided in Appendix 2. The process of study selection will be as described in Section 6.1.1 under "Systematic Review Selection." A flow chart (based on the QUOROM statement) will be generated to illustrate the study selection process.

Caution will be exercised to ensure that duplicate publications of the same study are not included. Where duplicates exist, the most recent or informative article will be selected. As well, subgroup or single centre results will be excluded if the corresponding main analyses are included in the review, unless they provide data on additional outcomes.

The list of included studies will be posted on the CADTH website to elicit stakeholder feedback. Stakeholder feedback will be collated by COMPUS staff and will be considered for inclusion based on previously stated selection criteria.

d) Assessment of study quality

The methodological quality of RCTs and observational studies will be assessed using modified versions of the SIGN 50 methodology checklists[18-20] as developed by the Scottish Intercollegiate Guidelines Network (SIGN) (see Appendix 4, Appendix 5, and Appendix 6). Using the checklists, two reviewers will independently judge the study design and assign a rating of "very good," "good," or "poor" to each study. Researchers will compare their ratings and discuss discrepancies, as described in Section 6.1.1 under "Assessment of systematic review quality."

e) Data extraction

Data extraction forms designed a priori will be used to document and tabulate all relevant information in studies selected for inclusion in the systematic review (see Appendix 7 and Appendix 8 for samples of RCT and observational study data extraction forms, respectively). Two reviewers will independently extract data from studies using these forms. Discrepancies between reviewers will be identified and resolved by consensus; the judgment of a third reviewer will be considered final if consensus cannot be reached.

f) Handling of conference abstracts

In an effort to include the most recent research findings — that is, those not yet available in peer-reviewed journals — authors of conference abstracts published after 2004 will be contacted to determine the publication status of their abstract. Data from those abstracts will be included in primary analyses if the following conditions are met:

- A full text article of the abstract has been accepted for publication in a peer-reviewed journal.

- Authors provide sufficient methodological data to enable quality assessment of the study.
- Authors give permission for the data to be included in the COMPUS report.

It is estimated that only half of all abstracts presented at conferences are later published as full text articles and that publication is positively associated with the reporting of positive trial results.[21] If this is the case, excluding abstracts from analyses would lead to results that overstate the estimate of effect. To determine the impact, if any, of excluding unpublished evidence, data from all conference abstracts will be included in sensitivity analyses (see "Sensitivity and subgroup analyses" later in this section).

g) Data synthesis and analysis

Where quantitative pooling of results from included studies is appropriate, meta-analysis will be used to estimate treatment efficacy. Meta-analysis is a statistical procedure that can be used to pool data from independent studies that address a related set of research questions.[22] It is particularly useful when combining results of individual studies that are too small or limited in scope to derive a conclusion that is valid or one that is generalizable.[22] Combining the results of similar studies using meta-analytic techniques increases the precision of the estimated outcome variables and adjusts for biases that would be created by simply summing raw data across studies, or averaging success rates.[22] A brief description of the meta-analytic method is provided in Appendix 9.

Results of individual studies will be pooled only if the populations, interventions, comparators, and outcome measures across studies are sufficiently similar to produce a clinically meaningful result. Otherwise, results will be summarized qualitatively.

Individual meta-analyses will be conducted by outcome for each type of diabetes mellitus and for individual patient populations (children and adults). Only results from peer-reviewed studies will be meta-analyzed in the primary analyses. The results of observational studies will be pooled separately from those of RCTs and other controlled clinical studies. Where data are available, the following meta-analyses will be performed for each outcome listed in Table 1:

Type 1 and gestational diabetes mellitus:
- SMBG (any frequency) versus no testing
- ≥3 tests per day versus 1 or 2 tests per day
- ≥4 tests per day versus:
  - 3 tests per day
  - <3 tests per day.

Type 2 diabetes mellitus (insulin users):
- SMBG (any frequency) versus no testing
- ≥1 test per day versus <1 test per day
- ≥3 tests per day versus 1 or 2 tests per day
- ≥4 tests per day versus:
  - 3 tests per day
  - <3 tests per day.

Type 2 diabetes mellitus (using oral antidiabetic drugs or no pharmacotherapy):
- SMBG (any frequency) versus no testing
- ≥1 test per day versus <1 test per day
- ≥2 tests per day versus:
  - 1 test per day
  - <1 test per day.

Data permitting, separate meta-analyses will be conducted for users of oral antidiabetic drugs and no pharmacotherapy.

Continuous outcomes:

For continuous outcomes such as glycosylated hemoglobin (A1C) and body weight, the difference between treatment groups in mean change from baseline will be meta-analyzed. If estimates of variability (such as standard error) for mean change from baseline are not reported, they will be imputed based on standard errors from similar studies. In instances when imputation is not possible, or when a study reports only mean values at endpoint, study authors will be contacted for the required data. Mean values at endpoint will be meta-analyzed only when efforts to obtain adequate change from baseline data have failed.

Quality-of-life and patient satisfaction will be recorded based on the measures reported in primary studies. It is expected that most studies will report mean change from baseline, allowing for meta-analysis as a continuous outcome. If quality-of-life or patient satisfaction is reported using other instruments, results will be summarized qualitatively.

Dichotomous outcomes and recurring events:

Dichotomous outcomes, such as diabetes-related complications or mortality, will be analyzed using relative risk. Recurring events, such as episodes of hypoglycemia and hospitalization, will be analyzed using relative risk, in which dichotomous categories will be defined as "no event" or "one or more events." Hypoglycemia (severe, nocturnal, and overall) will further be measured using the rate ratio; that is, the ratio of the number of events per patient per unit time observed in each treatment arm.[23-25]

Handling of crossover randomized controlled trials:

Data from crossover RCTs will be included in the same meta-analyses as parallel trials using the results of paired analyses. If paired analyses are not reported, study authors will be contacted for the necessary data. If the necessary information is not provided, a correlation coefficient between comparator arms will be calculated from similar studies reporting complete summary data (i.e., means and standard deviations for each treatment arm, as well as the mean and standard deviation of the paired difference between arms), as described by Elbourne et al.[26] For crossover trials reporting a significant carryover effect, only the data from the pre-crossover phase will be included in meta-analyses.

Heterogeneity:

Heterogeneity, or inconsistency, refers to the extent of variability in a meta-analysis that is not due to chance. Heterogeneity may be due to differences across studies in the population studied, interventions tested, or methods by which outcomes are measured. The I^2 statistic will be used in this analysis to estimate the degree of inconsistency in meta-analyses. This parameter provides an estimate of the proportion of total variation in a meta-analysis that is due to heterogeneity across study results than would be expected due to chance alone.[27] I^2 values of ≤25% are considered to represent a low level of heterogeneity, >25% to ≤50% a moderate level of heterogeneity, and >50% to ≤75% a high level of heterogeneity.[27] Pooled results will not be reported for meta-analyses demonstrating I^2 values of more than 75%. Instead, individual study results will be summarized qualitatively.

For meta-analyses demonstrating a moderate level of heterogeneity, possible explanatory factors will be explored. Differences across included studies in population characteristics (e.g., demographics, disease characteristics), interventions and comparators (e.g., SMBG testing frequency or duration, co-interventions such as diet or lifestyle education, and glycemic targets), and measurement of outcomes will be examined.

Sensitivity and subgroup analyses:
To determine robustness of the results, sensitivity analyses will be performed. In a sensitivity analysis, the effect of including studies with a particular characteristic in a meta-analysis is assessed by determining the impact of removing such studies from the analysis. That is, key decisions and assumptions that were made in the process of conducting the meta-analysis are altered. If the results of the sensitivity analyses do not substantially alter the results, then the results of the analyses can be interpreted with increased confidence.[23]

Four sensitivity analyses to explore methodological or reporting differences across individual studies are planned. The primary analysis will exclude results from abstracts and other literature that is not peer-reviewed. Abstracts will, however, be included in meta-analyses as part of the first sensitivity analysis. In a second sensitivity analysis, crossover studies will be removed. Finally, studies assessed as being of low quality (i.e., a SIGN 50[18-20] rating of "-") will be removed in a third sensitivity analysis.

As A1C is a long-term measure of glycemia that reflects plasma glucose levels over the past 90 days,[28] a fourth sensitivity analysis will be conducted for this outcome in which studies of less than three months' duration will be removed.

Subgroup analyses will be conducted based on intervention characteristics. For instance, studies that implemented SMBG alone would be analyzed separately from those that implemented SMBG in conjunction with diet or lifestyle education. Treatment differences may also be used to subgroup analyses. For example, studies in which patients were on a regimen of intensive glycemic control would be grouped separately from studies implementing a non-intensive regimen. As well, studies that report the effect of SMBG in patients with type 2 diabetes mellitus treated with sulfonylureas and/or meglitinides will be analyzed as a subgroup for hypoglycemia outcomes.

h) Publication bias
Publication bias occurs when studies are withheld from publication, by the authors or by journal editors, based on the results of the study itself. This may happen when a study fails to find an expected difference in outcomes; that is, when null or non-significant results are reported.[29] A serious consequence of publication bias in the technique of meta-analysis, which often relies solely upon the inclusion of published research studies, would be the overestimation of the treatment effect. Therefore, publication bias will be assessed through the use of funnel plots (plot of effect size versus standard error of effect).

i) Stakeholder feedback
The results of the analysis will be presented in the form of a draft systematic review report that will be posted on the CADTH website to elicit stakeholder feedback. Relevant stakeholder feedback will be incorporated into the final version of the systematic review. Input from CERC will be sought for feedback related to judgment.

6.2 Economic

A cost-utility analysis will be conducted using the United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model®.[30]

6.2.1 Model structure and validation

The UKPDS Outcomes Model[30] is a computer simulation model that can be used to forecast long-term health outcomes and cost consequences of diabetes-related complications. The UKPDS Outcomes Model[30] was developed by the University of Oxford Diabetes Trial Unit. Progression of diabetes complications are

modelled by mathematical algorithms that take into account patient characteristics, risk factors, and complication history using data derived from the UKPDS. Validation analyses have been performed to compare UKPDS Outcomes Model[30] predictions to results observed in published clinical and epidemiological studies.[31]

6.2.2 Target population

The target populations for these analyses will include:

- Adults with type 1 diabetes mellitus
- Adults with type 2 diabetes mellitus requiring insulin therapy
- Adults with type 2 diabetes mellitus using oral antidiabetic drugs
- Adults with type 2 diabetes mellitus managing with diet and/or lifestyle.

Demographic characteristics for each cohort will be obtained from published RCTs[4,32-41] and cross-referenced with epidemiological studies[42,43] to ensure that they are reflective of the clinical context.[42,43]

6.2.3 Treatment comparators

SMBG will be compared with no SMBG. Patient-relevant and clinical outcomes will be derived from meta-analyses, RCTs, and observational studies. The primary outcome measure will be quality-adjusted life years. When possible, the effect of frequency of SMBG on patient relevant and clinical outcomes will be examined.

6.2.4 Audience and perspective

The target audience for this economic evaluation is decision makers in public drug benefit programs, health professionals, and patients with diabetes mellitus. The economic evaluation takes the perspective of a third-party provincial payer.[44]

6.2.5 Time horizon

The model will forecast the occurrence of diabetes-related complications over a patient's lifetime.[44,45]

6.2.6 Valuing outcomes

Health-related quality-of-life scores will be obtained from a US catalogue of EuroQol 5-dimension index (EQ-5D) scores for chronic conditions.[46,47] The EQ-5D[48] is a widely used preference-based instrument for the measurement of health status.[49] The US catalogue,[46,47] which was generated using nationally representative data from the Medical Expenditure Panel Survey[50] is recommended for use in pharmacoeconomic analyses by the Washington Panel on Cost-Effectiveness in Health and Medicine.[46,47] Preference scores in the US catalogue were generated from an American sample and should be generalizable to Canadians, as instrument scores travel well and are applicable in other countries.[44,51] Where disutility estimates are not available from the US catalogue, they will be obtained from other sources that utilize the EQ-5D instrument.[52-55]

Disutilities for chronic health states experienced within the first year will be based upon EQ-5D scores for relevant International Classification of Diseases, 9th revision[56] codes or clinical classification category.[47,56] For subsequent years, disutilities will be based on quality priority conditions estimates,[46,47] where individuals were asked if they had *ever been diagnosed with the condition in the past* (e.g., Did you ever have a stroke before?). In instances where quality priority conditions estimates[46,47] are unavailable, it will be assumed that the disutility for the chronic condition will remain constant over time.

6.2.7 Resource use and costs

a) Prescription drug costs

Only direct costs to the publicly funded health care system will be considered. Unit costs for prescription drugs will be obtained from the PPS® Pharma Buyers Guide, Ontario Edition, January 2008.[57] When unit costs are not available from the PPS Pharma Buyers Guide, Ontario Edition,[57] costs will be obtained from the Ontario Drug Benefits Formulary / Comparative Drug Index.[58]

b) Costs of managing diabetes complications

Resource utilization and costs associated with diabetes-related complications will be obtained from the Ontario Diabetes Economic Model.[59] Inpatient and outpatient costs, cost of emergency room visits, subsequent prescription drugs claims, and long-term care and home care costs for managing diabetes-related complications will be included.[59] If resource use and costs for a health state are not available from the Ontario Diabetes Economic Model,[59] data will be obtained from published costing studies[60-63] or recent CADTH publications.[55,64] Costs will be inflated to 2008 Canadian dollars using the health component of the Consumer Price Index.[65]

6.2.8 Discount rate

Both costs and quality-adjusted life years will be discounted at a rate of 5%.[44]

6.2.9 Analysis of uncertainty

Univariate sensitivity analyses[66] will be performed to explore uncertainty of results. The effect of changing the value for acquisition costs of test strips, discount rate, effect size, and time horizon will be examined.[44] Incremental cost-effectiveness scatter plots[66] and cost-effectiveness acceptability curves[67,68] will be generated to illustrate uncertainty of results.

6.2.10 Stakeholder feedback

Economic conclusions for blood glucose test strips will be presented in a draft report that will be posted on the CADTH website to elicit stakeholder feedback. Relevant stakeholder feedback will be incorporated into the final version of the economic report.

6.3 Development of Optimal Therapy Recommendations

COMPUS will apply the Grades of Recommendation Assessment, Development and Evaluation (GRADE) approach to summarize the available evidence and facilitate the generation of optimal therapy recommendations by CERC. The GRADE Working Group, an international collaboration of methodologists and others with an interest in grading quality of evidence and strength of recommendations, developed the GRADE methodology to provide committees charged with formulating recommendations a framework for evaluating evidence. GRADE provides a systematic and transparent approach to judge quality of evidence, weigh the balance of benefits versus harms, identify underlying values and preferences, and rate the overall strength of generated recommendations.[69] The GRADE methodology is used by a number of organizations around the world to generate recommendations, such as the World Health Organization[70] and the American Thoracic Society.[71] Evidence for consideration by the panel will be presented as GRADE profiles, which consist of summaries of findings and evidence quality assessments. A sample GRADE profile form is presented in Appendix 10.

All GRADE profiles related to SMBG will be presented in a report that will be posted on the CADTH website for stakeholder feedback. Stakeholder feedback will be collated by COMPUS staff and provided to CERC. Relevant stakeholder feedback will be incorporated into the final version of the GRADE profiles.

6.3.1 Formulating recommendations

When formulating recommendations, CERC considers both clinical effectiveness regarding benefits, harms, and burdens as well as cost-effectiveness. Members of the committee bring their individual expertise and experience to bear (as experts, general practitioners, interventionists, and members of the public) and draw upon their own values and preferences to discuss the evidence and reach conclusions. The process by which recommendations are formulated by CERC consists of two main stages. First, the committee considers the clinical evidence regarding safety and effectiveness and draws conclusions regarding clinically important differences (if any) among the interventions in question. The committee then reviews the pharmacoeconomic evidence and considers the cost-effectiveness of the clinical conclusions. This sequential consideration of the evidence allows for clear delineation of the impact that cost-effectiveness considerations may have on the final recommendations. Thus, optimal therapy recommendations are formulated based on efficacy, safety, and pharmacoeconomic data.

When formulating the recommendations, CERC will take the perspective of health care policy makers pursuing maximal health outcomes for the Canadian population given finite health care system resources. Where possible, the recommendations developed by CERC will provide guidance regarding specific patient subgroups that may benefit from alternate treatment approaches.

Context statements related, but not limited to, quality and quantity of evidence, cost-effectiveness, directness of evidence, and clinical issues will be developed by CERC for inclusion in the recommendations to augment knowledge transfer to the intended audiences.

The process by which CERC used the GRADE evidence profiles and economic data on SMBG to generate optimal therapy recommendations will consist of six main steps:

- Feedback on GRADE profiles
- Discussion of clinical effectiveness evidence and feedback
- Generating statements based on clinical evidence of effectiveness and safety
- Generating draft recommendations based on clinical conclusions as well as cost and cost-effectiveness information
- Identification of underlying values and preferences for each recommendation
- Grading of the strength of recommendations.

Each of these steps is described in further detail in the following sections.

a) Feedback on GRADE profiles

CERC members will be provided with the GRADE evidence profiles and a feedback form for each profile. Committee members will complete a feedback form for each GRADE evidence profile. Feedback will be collated into a summary document for each profile and provided to members in advance of the subsequent committee meeting.

b) CERC discussion of clinical effectiveness evidence and feedback

CERC members will discuss the evidence presented in the GRADE evidence profiles and the associated feedback form. Context and clinical issues raised during the discussion will be recorded for each evidence

profile. GRADE Summary of Findings tables will be generated to reflect the body of generated information. Each Summary of Findings table will contain:

- Key results from the GRADE evidence profiles
- Draft clinical findings
- Summary of values and preferences expressed by CERC members
- Summary of feedback on the criteria used to assess strength of recommendations.

c) Generating clinical findings

Each member of CERC participating in the meeting will vote for one of the clinical findings, the single most important value or preference that guided their choice, and the overall quality of the available evidence.[1] Points of discussion related to the clinical findings statements will be documented as context.

d) Generating draft recommendations

Where one intervention appears to be more effective and more costly than another, CERC will determine whether the intervention represents reasonable "value for money" over the alternative. There is no empirical basis for assigning a particular value (or values) to the cut-off between cost-effectiveness and cost-ineffectiveness.

Once the clinical findings have been voted upon, CERC will review and discuss the results from the pharmacoeconomic analyses. Conclusions from the pharmacoeconomic analyses will be added to the GRADE Summary of Findings tables. Costing data will be supplied where cost-effectiveness results are not available. Draft recommendations, reflecting both clinical as well as cost and cost-effectiveness results, will be proposed for CERC's deliberation and voting.

e) Underlying values and preferences

An important component of each draft optimal therapy recommendation will be a clear statement regarding the underlying values and preferences that support the choice of one alternative over another. These will reflect the values expressed by CERC over the course of the assessment of both the clinical effectiveness as well as the cost and cost-effectiveness evidence. In situations where the clinical effectiveness and the cost and cost-effectiveness evidence fail to demonstrate important differences between treatments, the recommendations will be formulated to reflect that either treatment is appropriate. Associated values and preferences for each treatment option will be clearly outlined to help guide patients, clinicians, and decision makers in selecting the most appropriate treatment alternative.

6.3.2 Strength of recommendations

The final step in the GRADE methodology is assigning the strength of each recommendation as either "strong" or "weak." This rating is intended to convey the degree of confidence the committee has that adherence to the recommendation will result in the desired outcome.[71]

A proposed rating of strength (i.e., either "strong" or "weak") will be assigned to each recommendation, and feedback will be elicited from CERC members regarding the level of agreement with the ratings. To facilitate this process, a summary of all prior CERC deliberations for each recommendation will be distributed to members. This summary will contain the recommendation (with vote results), a rating of overall quality of evidence (with vote results), a listing of values and preferences (with vote results), a statement regarding

[*] All 12 CERC members were not present at all meetings. The quorum for all CERC matters that relate to a recommendation is five of the Core Members plus 66% of the Specialist Experts appointed in relation to the topic under consideration. Every voting member participating in a meeting was required to vote (i.e., a member could not abstain from voting).

the weight given by the committee to the economic evidence, a summary of pertinent contextual information, and a proposed strength of recommendation. The proposed strength of recommendation will be based on four questions put forward by the GRADE Working Group as points of consideration when evaluating recommendation strength:

- Is the available evidence of lower quality?
- Is there uncertainty regarding the balance of benefits versus harms and burdens?
- Is there uncertainty or are there differences in values and preferences?
- Is there uncertainty about whether the net benefits are worth the costs?

An affirmative answer to one or more of these questions may result in downgrading of a recommendation to "weak." As stipulated by the GRADE process, strength of recommendations is reflected by the use of the word "suggests" or "recommends" for weak and strong recommendations, respectively (i.e., "CERC suggests that..." versus "CERC recommends that..."). Where recommendations are graded as weak, the rationale supporting CERC's decision will be provided.

6.3.3 Identification of research gaps

CERC will identify instances where there is insufficient information upon which to produce optimal therapy recommendations as gaps in research or knowledge. These will consist primarily of comparisons and populations for which no peer-reviewed reports of RCTs are identified. Research gaps will be identified also when there is a paucity of comparative data on outcomes of interest for particular comparisons or populations.

6.3.4 Stakeholder feedback

A report containing the draft optimal therapy recommendations for blood glucose test strips, supporting evidence in the form of GRADE tables, and contextual material identified by CERC will be posted on the CADTH website to elicit stakeholder feedback. Stakeholder feedback will be collated by COMPUS staff and will be considered by CERC as the final optimal therapy recommendations are developed.

6.4 Current Utilization

Utilization and expenditure on blood glucose test strips in Canada will be examined by conducting a retrospective database analysis of administrative claims data from federal, provincial, and private drug plans. Analyses of aggregate and claims-level data from public and private drug plans will be conducted to estimate the frequency of blood glucose test strips claimed per person per day, and health care expenditures (total and per person) for blood glucose test strips.

6.4.1 Data sources

Data will be obtained from Brogan Inc. The Brogan Inc., database is the largest source of drug payment information (i.e., claims data) in Canada.[72] Brogan Inc. databases comply with federal and provincial privacy legislation.[72] Claims-level data provided by Brogan Inc. are protected by means of anonymous identifiers to ensure patient confidentiality. Data not available from Brogan Inc. will be sought from the National Prescription Drug Utilization Information System.[73]

a) Claims-level data

Claims-level data for test strip use will be available for the Ontario Drug Benefits Program and 65% of Canada's privately funded drug plans.[72] It is estimated that the Brogan Inc. dataset includes claims-level data for 34% of all prescriptions in Canada (i.e., the Ontario Drug Benefits Program and private drug plan

claims represent 25% and 9% of all prescription claims, respectively) *(Nevzeta Bosnic, Brogan Inc., Ottawa, ON: personal communication, May 8, 2008)*.

b) Aggregate-level data

Aggregate-level data from public drug plans in Canada will be available for seven of the 10 provinces in Canada (i.e., British Columbia, Saskatchewan, Manitoba, Ontario, Québec, Nova Scotia, and Newfoundland) as well as the Non-Insured Health Benefits (NIHB) program. In Nova Scotia, test strips are provided through the Nova Scotia Pharmacare program and Nova Scotia Diabetes Assistance Program; however, data will be available from the former program. Aggregate-level data for test strip claims will not be available for publicly funded programs in Prince Edward Island and New Brunswick, since test strips are not available as benefits in these jurisdictions.[72] Data will not be available for Alberta, because test strips are provided through the Alberta Monitoring for Health program; data from this program are not provided to Brogan Inc.[72]

6.4.2 Data analysis

a) Claims-level data

Diabetes medications and test strips claimed by beneficiaries will be determined for 2006-2007. Beneficiaries will be classified, by type of drug plan, into four treatment groups based upon their pharmacy claims history (i.e., had at least one claim corresponding to the treatment group during the period January 1, 2006, to December 31, 2006):

- Patients using insulin only
- Patients using insulin plus oral antidiabetic drugs
- Patients using oral antidiabetic drugs only
- Patients not using pharmacotherapy for diabetes.

Utilization and expenditure on test strips, by treatment group, will be reported for the most recent 12-month follow-up period. The following parameters will be calculated by treatment group and type of drug plan: total number of patients, total claims for test strips, total number of test strips claimed, and total expenditure on test strips. As well, the average daily number of test strips claimed and average daily expenditure per person will be calculated by treatment group and age (i.e., <15 years, 15 to 24 years, 25 to 44 years, 45 to 64 years, ≥65 years).

b) Aggregate-level data

Where claims-level data are not available, total utilization (i.e., number of test strips claimed), expenditures, and average cost per test strip claimed will be determined for publicly funded drug plans.

6.5 Current Practice

To understand why and how blood glucose test strips are currently prescribed and used in the management of diabetes mellitus in Canada, a qualitative approach will be employed. Specifically, data derived from focus groups of health care providers and patients will be used to identify and highlight current practice and perceptions surrounding the use of SMBG in the management of type 1 and type 2 diabetes mellitus.

This portion of the project will be outsourced to Vision Research Inc. Copies of the moderator guides for health professionals and patients are provided in Appendix 11 and Appendix 12, respectively. Development of interview questions was guided by the results of a comprehensive literature review and consultation with members of COMPUS, CERC, CAC, and staff at Vision Research Inc.

Vision Research Inc. will use a thematic analysis approach to analyze the findings. Data from the focus groups will be sorted manually based on the overall direction of each response. A team of experienced analysts at

Vision Research Inc. will review the notes and audio tapes of all groups and summarize the results, noting any areas of consensus or directionality. Themes will be identified based on prevalence among the responses of all participants and organized around the structure of the moderator's guide. In analyzing the data, the focus will be not only on prevalence but also on range, indicating where participants diverged and noting the variety of responses. Questions around which a strong majority of respondents agree, questions that prompt a split response (noting the two or three themes most prevalent), and questions that generate no consensus whatsoever (though these are rare, given the professional homogeneity of the group) will be identified and described. This analysis can be characterized as inductive and realistic. In keeping with the objectives of the study, no attempt will be made to fit the data into any prevailing theory nor to interpret the responses of participants in an effort to find latent meanings. Rather, the words of the participants (excerpts of which will accompany the findings) will speak for themselves. Representative responses from the focus group participants will be used to support the findings of the analysis.

6.6 Identification of Gaps and Key Messages

The processes related to identification of gaps, development of key messages to close those gaps through development of intervention tools, and the implementation of the tools are part of the knowledge exchange planning process. A generic Knowledge Exchange Plan is available that guides the process for each individual COMPUS project, in this case Blood Glucose Test Strips. The generic plan identifies the types of interventions, related audiences, and potential tools that would be considered and adapted for each topic. The relative effectiveness of the interventions is well documented in the *Rx for Change* interventions database. *Rx for Change* is a publicly accessible database (www.rxforchange.ca) for health care policy makers and health care professionals. It provides easy access to current research evidence about the effectiveness of strategies and programs to improve drug prescribing and use.

6.6.1 Gaps in practice

Knowledge and practice gaps related to the use of blood glucose test strips will be identified by CERC members and COMPUS staff through comparison of the Current Practice and Current Utilization analyses with the Optimal Therapy Recommendations developed by CERC. This analysis will focus on identifying the following:

- Discrepancies between the recommendations and actual practice, as indicated by the utilization data and responses in the Current Practice analysis. Quantitative utilization patterns from the utilization analysis will be compared with the recommendations to identify evidence of suboptimal use.
- Discrepancies between the recommendations and perceptions regarding blood glucose test strips, as indicated by the Current Practice analysis. Prevalent views regarding the advantages or benefits of blood glucose testing, and the clinical situations or patient groups for whom they might be useful, will be compared with the recommendations to identify perceptions that are not supported by the available evidence.
- Knowledge deficits with respect to the optimal use of blood glucose test strips (e.g., the patient groups and clinical situations in which they are most likely to confer benefit) identified in the Current Practice analysis.

6.6.2 Key messages

The identified gaps in practice and knowledge related to SMBG will be scrutinized to determine relevancy to the optimal prescribing and use of blood glucose test strips. Issues to be considered include the following:

- Are interventions and tools designed to address the gap likely to have significant impact, or is the gap unlikely to be amenable to change?

- Does the gap lend itself to the development and implementation of interventions, or is it difficult to address in a meaningful way?
- Would addressing the gap make a discernable difference in the prescribing and use of blood glucose test strips?

If multiple gaps are identified, they will be prioritized as to which most urgently require attention; that is, those that are most relevant to the optimal prescribing and use of blood glucose test strips. This will enable a focused approach to addressing gaps in practice and knowledge related to the use of test strips.

For gaps identified as being of highest priority, key messages related to the gaps will be developed based on the optimal therapy recommendations. When developing key messages, consideration will be given to barriers to change and how those barriers could potentially be overcome as well as factors favouring change (i.e., enablers). In addition, key messages are formulated as intended behaviour change statements where possible, rather than solely knowledge acquisition / reinforcement statements, and they are crafted in such a way that, where possible, behaviour change targets are measurable.

a) Feedback from stakeholders

A draft report outlining the identified gaps and key messages will be posted on the CADTH website to elicit stakeholder feedback. Feedback will also be sought from target audiences (ideally through focus groups); for example, physicians, pharmacists, diabetes educators, and patients with diabetes. Stakeholder and target audience feedback will be collated by COMPUS staff and considered by CERC as the final key messages are developed.

6.6.3 Intervention tools

In conjunction with CERC and CAC, COMPUS will identify and explore barriers to the realization of the key messages and develop a collection of evidence-based intervention tools and materials to address those barriers. Based on input from the Canadian Academic Detailing Collaboration (CADC), CADTH Liaison Officers, and advisory committees, the approach to development of intervention tools has been to start with the suite of tools developed for previous projects and augment those offerings with additional interventions specific to the new topic and target audiences.

These interventions may include presentations, newsletters, prescribing aids, and academic detailing support materials. CADTH does not implement these interventions, since delivery of health care is a jurisdictional responsibility. For this reason, a suite of intervention tools is developed to meet a variety of needs from simple to complex interventions and to meet health care professional and policy maker needs.

The following steps describe the process for development of the intervention tools:

- Target audiences are identified and confirmed.
- Types and variety of tools required for the different audiences are identified and confirmed.
  - Current suite of tools is validated as the starting point.
  - Input is sought from CAC, CERC, CADC, Liaison Officers, and focus groups regarding additional intervention tools.
  - A combination of external contractors and internal KT resources are utilized to develop intervention tools.
- Content of the tools is adapted and presented at levels appropriate for each of the targeted audiences and to meet the needs of multiple users and interventionists.
- The accuracy of the information contained in all tools is validated by the COMPUS Project Team.

Draft versions of all tools will be provided to CERC and CAC for input prior to circulation for stakeholder input. Stakeholder feedback may be elicited through posting on the CADTH website, depending upon tool content. Stakeholder feedback will be collated by COMPUS staff and considered by CERC and CAC as appropriate.

6.6.4 Evaluation of tools

A Generic Evaluation Framework is available on the CADTH website (www.cadth.ca) to guide COMPUS and users of COMPUS products in evaluation activities, from simple survey tools to more complex impact evaluations. The framework considers a variety of parameters that can be evaluated, recognizing that each of the parameters may not be applicable for each of the groups — such as the interventionists, jurisdictions, or COMPUS — and thus, not each needs to be evaluated by each group. Some of the parameters that are considered include:

- Scope, usage, and reach: extent of dissemination and uptake of tools
- Awareness
- Perceived value and quality of the tools and interventions
- Enablers and barriers to implementation
- Sustainability: the cost-effectiveness of implementing the interventions
- Changes in attitudes, skills, and knowledge
- Changes in behaviour: prescriber and patient
- Changes in health outcomes (may not be feasible in all jurisdictions; may not be measurable in short term)
- Changes in economic outcomes
- Changes in jurisdictional drug plan policies.

6.6.5 Implementation of tools

Implementation of these tools by jurisdictions, health care providers, and educators will serve to promote the optimal use of blood glucose test strips in the management of diabetes in Canada.

6.6.6 Tool adaptation

COMPUS offers a tool adaptation service. In this way, the core suite of intervention tools can be modified to meet specific jurisdictional needs. Presentations for physicians and pharmacists are the most common tools adapted; however, newsletters and prescribing aids are other examples where adaptation has been requested.

All adapted tools are subject to a scientific validation by COMPUS to ensure the content is an accurate representation of the evidence.

7 EXECUTION OF THE PROJECT

In order to promote timely execution of the blood glucose test strips phase of the diabetes mellitus project, roles and responsibilities for individual project members have been formulated and the structure of the project has been drafted.

8 DELIVERABLES

At the completion of the blood glucose test strips phase of the diabetes mellitus project, reports and intervention tools will be made available on the CADTH website at http://www.cadth.ca/index.php/en/compus.

The reports will include:

- Systematic review report on clinical evidence surrounding the use of blood glucose test strips by patients with type 1 diabetes mellitus and gestational diabetes mellitus
- Systematic review report on clinical evidence surrounding the use of blood glucose test strips by patients with type 2 diabetes mellitus
- Pharmacoeconomic analyses report — use of blood glucose test strips by patients with diabetes mellitus
- Current utilization — use of blood glucose test strips in Canada
- Current practice on the use of blood glucose test strips in Canada
- Optimal therapy recommendations on the use of SMBG in Canada
- Gap analysis and key messages report
- Project Summary Reports (Overview and Project in Brief; with an Executive Summary if warranted).

The final selection of intervention tools to be developed may include:

- Physician education sessions — didactic and interactive
- Physician education materials — newsletters, alternative prescription pad, quick reference prescribing aid
- Pharmacist education sessions — didactic and interactive
- Patient education materials — patient information brochure
- Academic detailing tools
- Others as directed.

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APPENDIX 1: SCOPING SEARCH STRATEGY FOR SYSTEMATIC REVIEWS AND META-ANALYSES

Guide to Search Syntax (Ovid)

exp	Explode the search term. Retrieve the search concept plus all narrower terms.
$	Truncation symbol. Retrieve plural and variant ending of search terms.
?	Wildcard symbol. Replaces 0 or 1 character(s).
" "	Search phrases.
adj	Proximity operator. Words must be adjacent.
ab	Search in article abstract.
sh	Subject heading (a controlled thesaurus term).
pt	Publication type.
ti	Search in titles.
tw	Text word.
hw	Heading word; that is, the subject heading (a controlled thesaurus term).

Limits:

- 2000 to January 2008
- English
- Literature type filter: Systematic Review / Meta Analysis

Search Logic:

1. Self Monitoring Blood Glucose
2. (Test Strips and Blood Glucose)
3. (Test Strips and Diabetes)
4. systematic review / MA Filter

(1 OR 2 OR 3) AND 4

MEDLINE, MEDLINE in Process, MEDLINE Daily Update, BIOSIS (Ovid)
Self-Monitoring Blood Glucose

1. Blood glucose self-monitoring/
2. (Self or patient or home or personal) adj3 (monitor$ or measure$ or measuring or management or managed or managing or test or testing or tested or tests or care or evaluation)).ti,ab,hw.
3. (Test strip$ or SMBG or testing supplies or test supplies). 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

Systematic Review / Meta Analysis Filter

1. Meta-Analysis.pt.
2. Meta-Analysis.sh. or exp Technology Assessment, Biomedical/
3. ((systematic$ adj (literature review$ or review$ or overview$)) or (methodologic$ adj (literature review$ or review$ or overview$))).ti,ab,hw
4. ((quantitative adj (review$ or overview$ or synthes$)) or (research adj (integration$ or overview$))).ti,ab,hw
5. ((integrative adj2 (review$ or overview$)) or (collaborative adj (review$ or overview$)) or pool$ analy$).ti,ab,hw
6. (data synthes$ or data extraction$ or data abstraction$).ti,ab,hw
7. (handsearch$ or hand search$).ti,ab,hw
8. (mantel haenszel or peto or der simonian or dersimonian or fixed effect$ or latin square$).ti,ab,hw
9. (meta analy$ or metaanaly$ or met analy$ or metanaly$ or health technology assessment$ or HTA or HTAs or biomedical technology assessment$ or bio-medical technology assessment$).ti,ab,hw
10. (meta regression$ or metaregression$ or mega regression$).ti,ab,hw
11. or/1-10

EMBASE (Ovid)

Self-Monitoring Blood Glucose

1. blood glucose monitoring/
2. ((Self or patient or home or personal) adj3 (monitor$ or measure$ or measuring or management or managed or managing or test or testing or tested or care or evaluation)).ti,ab.
3. test strip/
4. (Test strip$ or SMBG or test$ suppl$).ti,ab.
5. self monitoring/
6. or/1-5
7. Glucose Blood Level/
8. Blood sugar.ti,ab.
9. glucose.ti,ab.
10. or/7-9
11. 6 and 10
12. exp Diabetes Mellitus/
13. diabet$.ti,ab.
14. (Mody or niddm or iddm).ti,ab.
15. or/12-14
16. 6 and 15
17. 11 or 16

Systematic Review / Meta Analysis Filter

1. (Meta Analysis or Systematic Review or Biomedical Technology Assessment).mp.
2. (meta analy$ or metaanaly$ or met analy$ or metanaly$ or health technology assessment$ or HTA or HTAs or biomedical technology assessment$ or bio-medical technology assessment$).ti,ab.
3. (meta regression$ or metaregression$ or mega regression$).ti,ab.
4. ((systematic$ adj (literature review$ or review$ or overview$)) or (methodologic$ adj (literature review$ or review$ or overview$))).ti,ab.
5. ((quantitative adj (review$ or overview$ or synthes$)) or (research adj (integration$ or overview$))).ti,ab.

6. ((integrative adj2 (review$ or overview$)) or (collaborative adj (review$ or overview$)) or (pool$ adj analy$)).ti,ab.
7. (data synthes$ or data extraction$ or data abstraction$).ti,ab.
8. (handsearch$ or hand search$).ti,ab.
9. (mantel haenszel or peto or der simonian or dersimonian or fixed effect$ or latin square$).ti,ab.
10. or/1-9

CINAHL (Ovid)

Self-Monitoring Blood Glucose

1. Blood Glucose Self-Monitoring/
2. ((Self or patient or home or personal) adj3 (monitor$ or measure$ or measuring or management or managed or managing or test or testing or tested or care or evaluation)).ti,ab.
3. (Test strip$ or SMBG or test$ suppl$).ti,ab.
4. (abbott diabetes freestyle or arkray advance or hypoguard or arkray quicktek or bayer ascensia or precision xtra or one touch ultra or accu-chek or uni-check or fasttake or glucometer elite or precision qid or prestige smart system or surestep or ascensia).ti,ab.
5. or/2-4
6. Blood Glucose/
7. Blood sugar.ti,ab.
8. glucose.ti,ab.
9. or/6-8
10. 5 and 9
11. 1 or 10
12. exp Diabetes Mellitus/
13. diabet$.ti,ab.
14. (Mody or niddm or iddm).ti,ab.
15. or/12-14
16. 5 and 15
17. 11 or 16

Systematic Review / Meta Analysis Filter

1. meta-analysis/
2. literature review/
3. exp literature searching/
4. systematic review.pt.
5. practice guidelines.pt.
6. nursing interventions.pt.
7. (care plan or critical path or protocol).pt.
8. (metaanaly$ or meta analy$).tw.
9. metanaly$.tw.
10. ((systematic or quantitative or methodologic$) adj (overview$ or review$)).tw.
11. integrative research review$.tw.
12. research integration.tw.
13. (handsearch$ or ((hand or manual) adj search$).tw.
14. mantel haenszel.tw.
15. peto.tw.
16. fixed effect$.tw.
17. (medline or cinahl or psyc?info or psyc?lit or embase).tw.

18. (scisearch or science citation or isi citation or web of science).tw.
19. (dersimonian or der simonian).tw.
20. (pooled adj data).tw.
21. or/1-20

PsycINFO (Ovid)

Self-Monitoring Blood Glucose

1. self monitoring/
2. ((Self or patient or home or personal) adj3 (monitor$ or measure$ or measuring or management or managed or managing or test or testing or tested or care or evaluation)).ti,ab.
3. (Test strip$ or SMBG or test$ suppl$).ti,ab.
4. (abbott diabetes freestyle or arkray advance or hypoguard or arkray quicktek or bayer ascensia or precision xtra or one touch ultra or accu-chek or uni-check or fasttake or glucometer elite or precision qid or prestige smart system or surestep or ascensia).ti,ab.
5. or/1-4
6. blood sugar/ or glucose/
7. Blood sugar.ti,ab.
8. glucose.ti,ab.
9. or/6-8
10. 5 and 9
11. exp diabetes/
12. diabet$.ti,ab.
13. (Mody or niddm or iddm).ti,ab.
14. or/11-13
15. 5 and 14
16. 10 or 15

Systematic Review and Meta Analysis Filter

Database limits:
("0830 systematic review" or 1200 meta analysis)

APPENDIX 2: COMPUS STUDY SELECTION CRITERIA

Literature search for existing systematic reviews, meta-analyses, and Health Technology Assessment (HTA) reports

Inclusion criteria

- Study design — Systematic reviews and meta-analyses and health technology reports
- Population — Patients with type 1 or type 2 or gestational diabetes mellitus
- Intervention — The use of blood glucose test strips for SMBG
- Comparator — No SMBG or SMBG at a different frequency than in the intervention group
- Outcomes — See Table 1 (Section 5.1).

Exclusion criteria:

- Outcomes not reported by type of diabetes mellitus
- Outcomes not reported by type of therapy (only for type 2 diabetes mellitus)
- Mixed interventions of SMBG and self-monitoring of urine glucose
- Inclusion of trials less than four weeks in duration
- Non-English publications.

Literature search to identify primary studies to update selected "foundation documents" and/or to conduct a new systematic review

Inclusion criteria

- Study design — RCTs, non-RCTs, observational studies (case control, cohort, time series)
- Population — Patients with type 1 or type 2 or gestational diabetes mellitus
- Intervention — The use of blood glucose test strips for SMBG
- Comparator — No SMBG or SMBG at a different frequency than in the intervention group
- Outcomes — See Table 1 (Section 5.1).

Exclusion criteria

- Outcomes not reported by type of diabetes mellitus
- Outcomes not reported by type of therapy (i.e., insulin users versus non-users) (only for type 2 diabetes mellitus)
- Mixed interventions of SMBG and self-monitoring of urine glucose
- Apart from SMBG-related practices, substantial differences exist in how the intervention and comparator groups are managed
- Study duration less than four weeks.

APPENDIX 3: AMSTAR* — SYSTEMATIC REVIEW QUALITY ASSESSMENT TOOL

Project: Test Strips	Statement:	Author:
Title:		
Reviewer:		Date:
RefMan #:		**Total Score: /11**

1. Was an 'a priori' design provided? The research question and inclusion criteria should be established before the conduct of the review.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
3. Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms should be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language, etc.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
7. Was the scientific quality of the included studies assessed and documented? 'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**
11. Was the conflict of interest stated? Potential sources of support should be clearly acknowledged in both terms of the systematic review and the included studies.	☐ **Yes** ☐ **No** ☐ **Can't answer** ☐ **Not applicable**

* Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews.[17]

APPENDIX 4: SIGN 50* — RANDOMIZED CONTROLLED TRIAL QUALITY ASSESSMENT TOOL

Project: Test Strips	Statement #:	Author:
Title:		
Reviewer:	Date:	**RefMan #:**

SECTION 1: Internal validity				
	In a well conducted RCT study…	In this study this criterion is:		
1.1	The study addresses an appropriate and clearly focused question.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.2	The assignment of subjects to treatment groups is randomised	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.3	An adequate concealment method is used	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.5	The treatment and control groups are similar at the start of the trial	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.6	The only difference between groups is the treatment under investigation	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.7	All relevant outcomes are measured in a standard, valid and reliable way	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?			
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.10	Where the study is carried out at more than one site, results are comparable for all sites	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
Section 2: OVERALL ASSESSMENT OF THE STUDY				
2.1	How well was the study done to minimise bias? Code ++, +, or –		-	
SECTION 3: OTHERS				
3.1	How was this study funded? *List all sources of funding quoted in the article, whether government, voluntary sector, or industry.*			

** SIGN 50: A guideline developers' handbook.*[18]

APPENDIX 5: SIGN 50* — COHORT STUDY QUALITY ASSESSMENT TOOL

Project: Test Strips	Statement #:	Author:
Title:		
Reviewer:	Date:	**RefMan #:**

SECTION 1: Internal validity				
In a well conducted cohort study…		In this study this criterion is:		
1.1	The study addresses an appropriate and clearly focused question.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
SELECTION OF SUBJECTS				
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.			
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
ASSESSMENT				
1.7	The outcomes are clearly defined.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.8	The assessment of outcome is made blind to exposure status.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.10	The measure of assessment of exposure is reliable.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.12	Exposure level or prognostic factor is assessed more than once.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed

CONFOUNDING				
1.13	The main potential confounders are identified and taken into account in the design and analysis.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
STATISTICAL ANALYSIS				
1.14	Have confidence intervals been provided?			
SECTION 2: OVERALL ASSESSMENT OF THE STUDY				
2.1	How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? **Code ++, +, or –**		-	
Section 3: OTHERS				
3.1	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*			

* *SIGN 50: A guideline developers' handbook*.[19]

APPENDIX 6: SIGN 50* — CASE-CONTROL STUDY QUALITY ASSESSMENT TOOL

Project: Test Strips	Statement #:	Author:
Title:		
Reviewer:	Date:	**RefMan #:**

SECTION 1: Internal validity				
In a well conducted case-control study…		In this study this criterion is:		
1.1	The study addresses an appropriate and clearly focused question.	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
SELECTION OF SUBJECTS				
1.2	The cases and controls are taken from comparable populations	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.3	The same exclusion criteria are used for both cases and controls	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.4	What percentage of each group (cases and controls) participated in the study?		Cases: Controls:	
1.5	Comparison is made between participants and non-participants to establish their similarities or differences	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.6	Cases are clearly defined and differentiated from controls	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.7	It is clearly established that controls are non-cases	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
ASSESSMENT				
1.8	Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
1.9	Exposure status is measured in a standard, valid and reliable way	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
CONFOUNDING				
1.10	The main potential confounders are identified and taken into account in the design and analysis	☐ Well covered ☐ Adequately addressed	☐ Poorly addressed ☐ Not reported	☐ Not applicable ☐ Not addressed
STATISTICAL ANALYSIS				
1.11	Have confidence intervals been provided?			
SECTION 2: OVERALL ASSESSMENT OF THE STUDY				
2.1	How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? **Code ++, +, or –**		-	
SECTION 3: OTHERS				
3.1	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*			

* *SIGN 50: A guideline developers' handbook*.[19]

APPENDIX 7: CLINICAL DATA EXTRACTION FORM FOR RANDOMIZED CONTROLLED TRIALS

RefID:	**Year Published**:	**Primary Author**:
Title:		
Date Extracted:	**Pub Status**:	**Reviewer**:

Trial Characteristics:

Study Design: RCT	**Detail:**
Country(s):	**# of centres**:
Setting:	
Duration — Treatment: **Follow-up(s):**	
Type of Diabetes Included: Type 1: ☐ Type 2: ☐ GDM: ☐	
Disease Classification:	If other, specify:
DM Meds: Insulin: ☐ OAD: ☐ None: ☐ **Specify therapy**:	
Glycaemic control targets: A1C: FPG: Other (specify):	
Population(s) Included: Adults ☐ Adolescent: ☐ Pre-adolescent: ☐ Senior: ☐ **Age Cut-offs (e.g. 18-64):**	
Subpopulation (pregnant women, veterans, etc.):	
Patient inclusion criteria:	
Patient exclusion criteria:	
Analysis:	

If study reports on more than one type of diabetes, please fill out a separate extraction form for each type.

Description of Trial Arms:

Comparator 1:
Comparator 2:
Comparator 3:
Comparator 4:

Please include description and frequency of SMBG/other, as well as *other treatments or interventions* present in each arm. Change comparator 3 and/or 4 to N/A when study has fewer than four treatment arms.

Patient Characteristics:

Category	Unit	Comp 1	Comp 2	Comp 3	Comp 4	All arms
Age						
Randomised Sample Size						
% Male						
Duration of diabetes mellitus						
Race/Ethnicity						
Withdrawal/Lost to follow-up						

Please include Std Errors (SE) or Deviations (SD) where appropriate and available and specify which it is. Comp 4 can be changed to p-value if needed; specify which comparison(s) p-value is applicable to if more than two arms.

Outcomes:

Copy the following tables (within group and between group comparisons) for each outcome reported in the study.

Within Group Comparisons

Outcome: HbA1c				Unit of measurement:				
Author's Definition and/or Specifics:								
Study Arm	**Analysed N**	**Baseline**		**Endpoint- Treatment**		**• from Baseline**		**p-value**
		Mean	**SE**	**Mean**	**SE**	**Mean**	**SE**	
Comp 1								
Comp 2								
Comp 3								
Comp 4								

Author's definition of the outcome or event must be included if available. Specifics include cutoff point if a proportion is the outcome.

Between Group Comparisons

Outcome	Comparators		Diff b/w groups at Endpoint	SE	p-value
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			

Other notes about the trial:

Include any questions/issues about the trial.

APPENDIX 8: CLINICAL DATA EXTRACTION FORM FOR OBSERVATIONAL STUDIES

RefID:	**Year Published**:	**Primary Author**:
Title:		
Date Extracted:	**Pub Status:**	**Reviewer:**

Study Characteristics:

Study Design:	Prospective: ☐ Retrospective: ☐
Admin Database? Yes: ☐ No: ☐ **Specify:**	
Country(s):	**# of centres**:
Setting:	
Duration — Treatment: **Follow-ups(s):**	
Type(s) of Diabetes Included: Type 1: ☐ Type 2: ☐ GDM: ☐	
Disease Classification:	If other, specify:
DM Meds: Insulin: ☐ OAD: ☐ None: ☐ **Specify therapy:**	
Glycaemic control targets: A1C: FPG: Other (specify):	
Population(s) Included: Adults ☐ Adolescent: ☐ Pre-adolescent: ☐ Senior: ☐ **Age Cut-offs (e.g. 18-64):**	
Subpopulation (pregnant women, veterans, etc.):	
Patient inclusion criteria :	
Patient exclusion criteria:	

If study reports on more than one type of diabetes, please fill out a separate extraction form for each type.

Description of Study Arms:

Comparator 1:
Comparator 2:
Comparator 3:
Comparator 4:

Please include description and frequency of SMBG/other, as well as *other treatments or interventions* present in each arm. Change comparator 3 and/or 4 to N/A when study has fewer than four treatment arms.

Patient Characteristics:

Category	Unit	Comp 1	Comp 2	Comp 3	Comp 4	All arms
Age						
Starting Sample Size						
% Male						
Duration of diabetes mellitus						
Race/Ethnicity						
Withdrawal/Lost to follow-up						

Please include Std Errors (SE) or Deviations (SD) where appropriate and available and specify which it is. Comp 4 can be changed to p-value if needed; specify which comparison(s) p-value is applicable to if more than two arms.

Outcomes:

Copy the following tables (within group and between group comparisons) for each outcome reported in the study.

Within Group Comparisons

Outcome: HbA1c				Unknown		Unit of measurement:		
Author's Definition and/or Specifics:								
Study Arm	**Analysed N**	**Baseline**		**Endpoint- Treatment**		**• from Baseline**		**p-value**
		Mean	**SE**	**Mean**	**SE**	**Mean**	**SE**	
Comp 1								
Comp 2								
Comp 3								
Comp 4								
Regression Coefficient:								

Author's definition of the outcome or event must be included if available. Specifics include cutoff point if a proportion is the outcome.

Between Group Comparisons

Outcome	**Comparators**		**Diff b/w groups at Endpoint**	**SE**	**p-value**
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			
HbA1c	Comp:	Comp:			

Confounder Adjustments:

Please list or explain any confounder adjustments the study made.

Other notes about the study:

Include any questions/issues about the study.

APPENDIX 9: META-ANALYTIC METHODS

The meta-analytic methods most commonly used to investigate the effectiveness of health care interventions are those presented by Cochran[74,75] and DerSimonian and Laird.[76] Those methods involve combining results of individual RCTs to provide a comparison of success rates between two comparators and an estimation of the effect size.[77,78]

There are two statistical models available for meta-analytic studies: the fixed effects model and the random effects model. To determine the appropriate model for the meta-analysis, it will be necessary to make assumptions about the data that are to be combined. The fixed effects model is based on the mathematical assumption that all the studies to be included in the meta-analysis use identical methods, patients, and methods and are evaluating the same effect. That is, the effect is the same in all studies, and the results of the studies vary randomly around the true common fixed effect. The diversity around the true common fixed effect is called the *within-study* variance.[76,79] Thus, fixed effect models consider only *within-study* variability.

The random effects model does not make the same assumptions as the fixed effect model. It deals with the lack of knowledge about why real, or apparent, treatment effects differ by considering the differences as if they were random. The model assumes that 1) the studies included in the meta-analysis are a random sample from all possible studies, 2) the true effects observed in each study may be different from each other, and 3) those differences are normally distributed. The differences are called random effects and describe the *between-study* variation.[23,79,80] Thus, random effects models consider both *between-study* and *within-study* variability. This method of combining results weights by sample size and adjusts for between-study variance, serving to reduce the impact of between-study differences.[78] The underlying assumption of this model is that the true effect (outcome) of each study is different; that is, not all studies are measuring the same effect. The model assumes that there may be differences between studies due to study aspects including different populations and different methods of outcome assessment. Despite the differences between studies, it is assumed that the degree of difference is so great as to make the estimated common effect meaningless.[75]

Forest plots will be generated wherever appropriate to determine if heterogeneity exists between the results of individual studies included in the review. If significant heterogeneity does exist, the reasons for heterogeneity (e.g., study design, population characteristics, and study quality) will be explored. Should significant variation between studies be observed, analysis of subgroups based on factors potentially responsible for heterogeneity will be attempted and the influence of these factors will be assessed. If outliers are present, then results will be pooled with and without the outliers to investigate their impact on the overall result. If necessary, sensitivity analysis will be performed to investigate the robustness of the results of statistical synthesis by estimating and comparing the effects of the intervention in different trial categories (e.g., grouped by publication status, quality, and publication year).

APPENDIX 10: SAMPLE GRADE EVIDENCE PROFILE

Number of Studies	Quality Assessment						Summary of Findings					Importance of Outcome
							No. of Patients		Effect		Quality of Evidence	
	Design	Limitations	Consistency	Directness	Imprecision	Other	Intervention	Comparator	Relative (95% CI)	Absolute		
Outcome 1												
Outcome 2												
Outcome 3												

APPENDIX 11: MODERATOR'S GUIDE FOR FOCUS GROUPS — HEALTH PROFESSIONALS

1.0 Introduction — 5 minutes

1.1 Before we start, I would like to explain a few things about this study and today's focus group.

- The group will last 60 to 90 minutes.
- The group will be audio-recorded to allow for a more detailed report; audio files will remain the property of the research firm and will be erased after 12 months.
- Participation in the group is strictly voluntary and participants need not answer any question that makes them feel uncomfortable.
- The identity of participants will be kept confidential in all aspects of the study and in the final report.
- The study is being undertaken by the Canadian Agency for Drugs and Technology in Health (CADTH) — a not-for-profit agency funded by the federal and provincial governments and mandated by them to provide credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies.
- The study in which you have agreed to participate is part of a research project undertaken by CADTH, through its Canadian Optimal Medication Prescribing & Utilization Service (COMPUS) directorate. COMPUS works to identify and promote evidence-based, clinical and cost-effectiveness information on optimal drug prescribing and use. COMPUS then develops strategies, tools, and services to encourage the use of this information in decision making among health care providers and consumers.
- COMPUS is currently focusing on diabetes management as one of two priority areas where the adoption of optimal drug therapy is likely to have an impact on a large number of Canadians [the other being proton pump inhibitors (PPIs) for the treatment of gastrointestinal problems].
- There may be staff from CADTH observing the focus group from behind the mirror. This is so that they can see and hear your comments first-hand and learn as much as possible from the study.

1.2 Are there any questions or concerns related to this study?

2.0 Blood Glucose Testing — Current Practices — 25 minutes

2.1 Under what circumstances do you currently prescribe or recommend the use of blood glucose test strips for self-monitoring of blood glucose — or SMBG — as a teaching tool for patients with "pre-diabetes" or as part of managing a patient's diabetes? Does your current practice vary between patients with type 1 and type 2 diabetes?

2.2 Does your current practice related to the use of blood glucose test strips vary according to the way diabetes is managed?

- For patients that manage their diabetes by diet alone?
- For patients that manage through diet and oral agents?
- For patients taking different types of oral agents?
- For patients using insulin agents?

2.3 Do you think there are particular times or circumstances when prescribing or recommending blood glucose test strips is more useful?

- After the initial diagnosis of pre-diabetes?
- After the initial diagnosis of diabetes?
- While medications and diet are being adjusted?
- During illness?

- During pregnancy?
- For athletes?
- For very young patients?

2.4 Generally speaking, what action, if any, do you advise your patients to take when they have abnormal blood glucose test results?

2.5 Do you review your patient's self-monitoring blood glucose results? Why or why not, and, if so, how do you use this information?

2.6 Who are the main drivers for recommending blood glucose test strips? (*i.e., Who is convincing MDs to recommend BGTS and who is convincing patients to use BGTS?)*

3.0 Advantages and Disadvantages of SMBG 25 minutes

3.1 Generally speaking, how convinced are you about the appropriateness of prescribing or recommending self-monitoring of blood glucose using blood glucose test strips? Does your conviction vary by type of diabetes?

3.2 What, in your opinion, are the notable advantages of prescribing or recommending SMBG using blood glucose test strips for patients with pre-diabetes?

3.3 What, in your opinion, are the advantages of prescribing or recommending self-monitoring of blood glucose for patients with type 1 diabetes? What might encourage you to prescribe or recommend SMBG?

3.4 What, in your opinion, are the advantages of prescribing or recommending self-monitoring of blood glucose for patients with type 2 diabetes? What might encourage you to prescribe or recommend SMBG?

3.5 Overall, what do you see are the disadvantages of SMBG for patients with pre-diabetes, type 1 or type 2 diabetes? What might discourage you from prescribing or recommending this approach? *(Probe for cost, patient lifestyle or comfort, health professional's time, likelihood of patient following the advice.)*

4.0 Evidence 40 minutes

4.1 In your opinion, is there convincing clinical evidence to support recommending self-monitoring of blood glucose using blood glucose test strips for patients with pre-diabetes?

4.2 Currently, what information do you rely upon when making a decision on whether or not to prescribe or recommend self-monitoring of blood glucose using blood glucose test strips? (*Probe for: Experience, CDA Guidelines, peer-reviewed journals, client's preferences, pharmaceutical company resources, meter makers, policy, etc.)*

4.3 How would you most like to receive and access information on self-monitoring of blood glucose using blood glucose test strips? (*Probe for didactic sessions, print materials, interactive sessions, online info/sessions, academic detailing, drug reps, specialists, colleagues, etc.)*

4.4 In your opinion, is there convincing clinical evidence to support recommending self-monitoring of blood glucose for patients with type 1 diabetes? If yes, how do you access this information?

4.5 In your opinion, is there convincing clinical evidence to support recommending self-monitoring of blood glucose for patients with type 2 diabetes? If yes, how do you access this information?

4.6 In your opinion, is there convincing evidence about the cost-effectiveness of self-monitoring of blood glucose with blood glucose test strips for patients with type 1 diabetes? If yes, how do you access this information?

4.7 In your opinion, is there convincing evidence about the cost-effectiveness of self-monitoring of blood glucose with blood glucose test strips for patients with type 2 diabetes? If yes, how do you access this information?

4.8 In your opinion, is self-monitoring of blood glucose being prescribed/used appropriately (in accordance with the clinical and economic evidence) in patients with type 1 and type 2 diabetes? (*probing for gaps in current practice*)

4.9 What other evidence would you like to see related to self-monitoring of blood glucose using blood glucose test strips? What questions remain to be answered in your view?

5.0 Conclusion 5 minutes

5.1 Does anyone have any final thoughts or comments relating to the practice of SMBG, and the use of blood glucose test strips, that we have not covered today?

5.2 Does anyone have any final thoughts or comments on the efforts by CADTH to research the clinical and cost-effectiveness of self-monitoring of blood glucose using blood glucose test strips and then to communicate its findings to health professionals, policy makers, and patients to help them all make informed decisions?

Thanks very much for your participation today. I appreciate your time and your thoughts and remind you to see the receptionist on your way out to pick up your incentive.

APPENDIX 12: MODERATOR'S GUIDE FOR FOCUS GROUPS — PATIENTS

1.0 Introduction — 5 minutes

1.1 Before we start, I would like to explain a few things about this study and today's focus group.

- The group will last 60 to 90 minutes.
- The group will be audio-recorded to allow for a more detailed report; audio files will remain the property of the research firm and will be erased after 12 months.
- Participation in the group is strictly voluntary and participants need not answer any question that makes them feel uncomfortable.
- The identity of participants will be kept confidential in all aspects of the study and in the final report.
- The study is being undertaken by the Canadian Agency for Drugs and Technologies in Health (CADTH) — a not-for-profit agency funded by the federal and provincial governments and mandated by them to provide credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies.
- The study in which you have agreed to participate is part of the Agency's Canadian Optimal Medication Prescribing & Utilization Service (COMPUS). COMPUS works to identify and promote evidence-based, clinical and cost-effectiveness information on optimal drug prescribing and use. COMPUS then develops strategies, tools, and services to encourage the use of this information in decision making among health care providers and consumers.
- This study is part of the COMPUS's effort to research and identify the optimal ways to prescribe and use drugs — the ways that are most cost-effective and most effective for people's health. COMPUS then shares the results of their research to encourage governments, health professionals, and patients to adopt these optimal practices.
- COMPUS is currently focusing on diabetes management as a priority area that could have an impact on a large number of Canadians. In particular, we will talk today about using blood glucose test strips to monitor your own blood glucose levels.
- There may be staff from CADTH observing the focus group from behind the mirror. This is so that they can see and hear your comments first-hand and learn as much as possible from the study.

1.2 Are there any questions or concerns related to this study?

2.0 Blood Glucose Testing — Current Attitudes — 25 minutes

2.1 As someone who lives with diabetes, do you currently self-monitor your blood glucose levels using a blood glucose test strip? If no, have you ever done so?

2.2 Two questions for you now: First, what type of diabetes do you have (1 or 2) and, secondly, if you do or have self-monitored your blood glucose levels, how often and for how long? If you never have self-monitored, why not? *(Probe for whether the frequency is as prescribed by a professional or not.)*

2.3 What do you do with the results of your blood glucose test strips? If the reading is too high? If the reading is too low?

2.4 In your opinion, what are the advantages of self-monitoring your blood glucose? *[Probe for education (i.e., to learn how diet and exercise can improve glycemia), curiosity, reassurance, fear of hypoglycemia.]*

2.5 What are the disadvantages? *(Probe for cost, time, discomfort, self-chastisement.)*

3.0 BGTS and the Health Professional 30 minutes

3.1 If you do or have self-monitored your blood glucose, what led you to do that? Did someone recommend it to you? Did you see or read some information and decide on your own?

3.2 Has someone (a doctor, pharmacist, or diabetes educator) explained to you how to perform the test using the test trip? If yes, who provided you with that information and do you feel they did a good enough job to allow you to perform the test with confidence?

3.3 What else, if anything could that person have told you that would have given you more confidence about deciding whether or not to monitor your blood glucose levels or about actually performing the test?

3.4 Has your health care provider ever asked to see the results of your blood glucose monitoring? If yes, which health care provider was that (e.g., family physician, diabetes educator)? What action did that person take after seeing the blood test readings? What did they advise you to do based on seeing the blood test readings?

3.5 Some blood glucose monitors can be used by patients to upload their blood test results to the computer in order to analyze the results. Does your monitor have this function? If yes, how often do you upload your data (if at all)? Does your doctor or other health care provider look at this analysis?

3.6 Did you ever experience a higher than normal reading and what did you do about it?

4.0 Information 15 minutes

4.1 If you were looking for information on self-monitoring of blood glucose using blood glucose test strips, where would you be most likely to look? *(Probe for health professional, Internet, family and friends, literature, and ads from manufacturer.)*

4.2 In your opinion, is there enough information available to patients on the topic of self-monitoring of blood glucose using blood glucose test strips?

4.3 Who would be the best person or organization to provide education for Canadians on self-monitoring of blood glucose using blood glucose test strips? *(Probe for health professionals, professional associations, CDA, governments, manufacturers.)*

5.0 Conclusion 10 minutes

5.1 Does anyone have any final thoughts or comments relating to the practice of SMBG, and the use of blood glucose test strips, that we have not covered today?

Thanks very much for your participation today. I appreciate your time and your thoughts and remind you to see the receptionist on your way out to pick up your incentive.