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OPTIMAL THERAPY REPORT

COMPUS

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Gap Analysis and Key Messages for the Prescribing and Use of Blood Glucose Test Strips for the Self-Monitoring of Blood Glucose

Supporting Informed Decisions

À l'appui des décisions éclairées

This report is prepared by the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), a service of the Canadian Agency for Drugs and Technologies in Health (CADTH). This report is based on the comparison of evidence-based recommendations related to the prescribing and use of blood glucose test strips including current utilization patterns and practices. The intent of this report is to identify areas that may require interventions and information to optimize the prescribing and use of blood glucose test strips. While CADTH has taken care in the preparation of the report to ensure that its content is accurate, complete, and up to date, CADTH does not make any guarantee to that effect. The information in this report should neither be used as a substitute for the application of clinical judgment in respect to the care of a particular patient or other professional judgments in any decision-making process, nor is it intended to replace professional medical advice.

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1 INTRODUCTION

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

The goal of COMPUS is to optimize drug-related health outcomes and the 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 achieves its goal through three main approaches:

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

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

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

2 ISSUE

CAC has identified the management of diabetes mellitus as being a priority area for optimal practice initiatives, based on the following criteria:

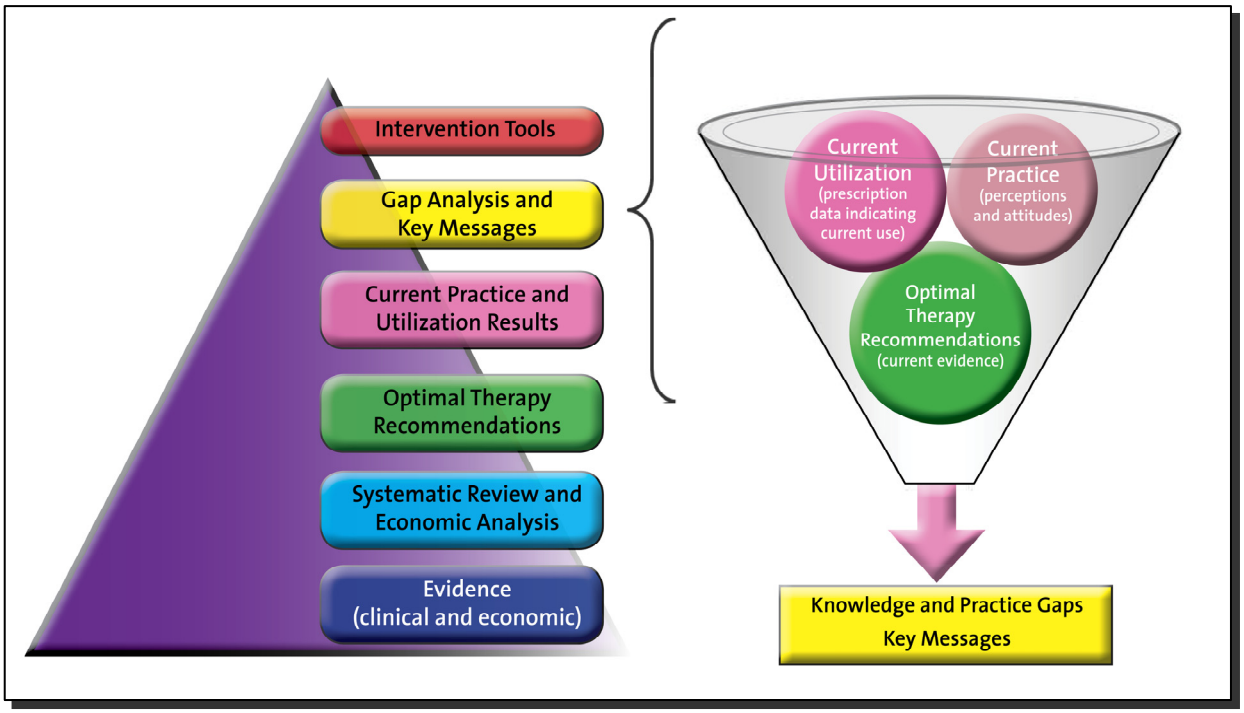
- large deviations from optimal utilization (overuse or underuse)
- size of patient populations
- impact on health outcomes and cost-effectiveness
- potential to effect change
- benefit to multiple jurisdictions
- measurable outcomes.

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

Despite widespread use, there is uncertainty regarding the benefits of self-monitoring of blood glucose (SMBG), especially in patients with type 2 diabetes mellitus who are not using insulin.[1-4] Moreover, costs associated with SMBG are high[5] and rising steadily[5-7] due to the increasing prevalence of type 2 diabetes.[8] In some Canadian publicly funded drug plans, blood glucose test strips are among the top five classes in total expenditure,[5] and more money is often spent on blood glucose test strips than for all oral antidiabetes drugs (Brogan Inc., *Utilization of oral antiglycemics in Canada*, unpublished dataset, 2008).[9] In 2006, $250 million was spent on blood glucose test strips in eight Canadian publicly funded drug plans (Newfoundland, Nova Scotia, Quebec, Ontario, Manitoba, Saskatchewan, British Columbia,

and the Non-Insured Health Benefits Program), while more than $120 million was spent in privately funded drug plans.[*9] It is estimated that greater than 50% of the total cost of blood glucose test strips is expended on patients with type 2 diabetes who are not using insulin agents.[*9]

3 OBJECTIVE



The objective of this report is to present the gaps in practice and prescriber knowledge related to SMBG that were identified through comparison of the results of the *Current Utilization of Blood Glucose Test Strips in Canada* Optimal Therapy Report and the *Current Practice Analysis of Health Care Providers and Patients on Self-Monitoring of Blood Glucose* Optimal Therapy Report with the Optimal Therapy Recommendations developed by CERC. Key messages addressing these gaps are also presented.

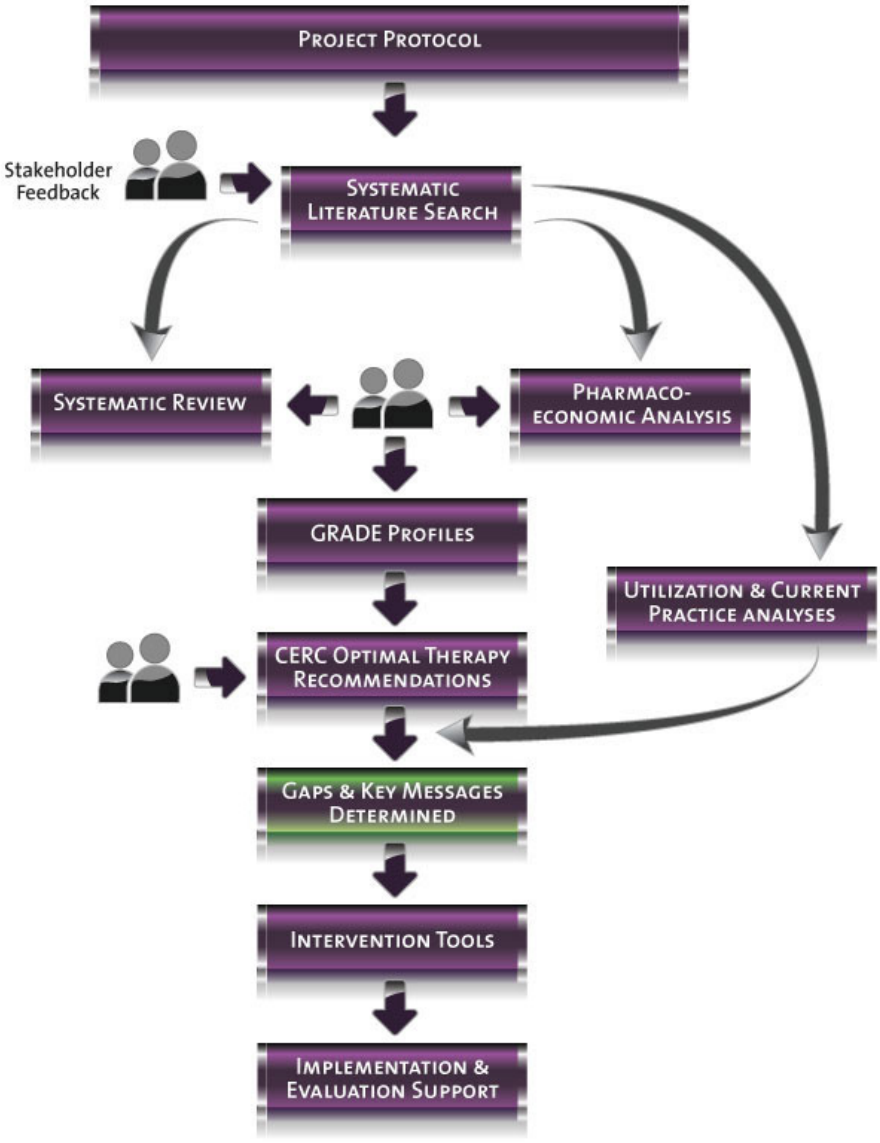
[*] Extrapolated from data reported for 67% of privately funded drug plans in Canada.

4 PROJECT OVERVIEW

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

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

This report represents the presentation of gaps and key messages (green box).



5 GAPS

Practice Gaps
• There is routine use of blood glucose test strips among patients with type 2 diabetes who are not using insulin. • There is limited use of SMBG results in therapeutic decisions by physicians. • SMBG is often seen to be synonymous with self-management of diabetes by health care professionals.
Knowledge Gaps
• There is lack of awareness among health care professionals of key evidence related to the efficacy of SMBG in patients with type 2 diabetes who are not using insulin. • There is lack of awareness of opportunity costs associated with widespread use of blood glucose testing by patients with type 2 diabetes who are not using insulin.

5.1 Identification of Gaps

The CADTH process for identifying practice and knowledge gaps focused on identifying:

- **Discrepancies between the evidence-based recommendations and actual practice, as indicated by the utilization data and responses in the Current Practice analysis:**
  - Quantitative prescribing patterns (e.g., by treatment group) from the utilization analysis were compared with the recommendations. As well, descriptions of typical situations in which SMBG was recommended from the Current Practice analysis were compared with the recommendations to identify discrepancies.

- **Discrepancies between the evidence-based recommendations and perceptions regarding the use of blood glucose test strips for SMBG, as indicated by the Current Practice analysis:**
  - Prevalent views regarding the advantages or benefits of SMBG and the clinical situations or patient groups for whom it might be useful were compared with the recommendations to identify perceptions that were not supported by the available evidence.

- **Knowledge deficits, self-reported by health care providers or patients on the optimal use of blood glucose test strips for SMBG (e.g., patient groups or clinical situations in which blood glucose test strips would provide benefit) identified in the Current Practice analysis.**

5.2 Findings

Blood glucose test strips are widely recommended and used by health care professionals as a tool for the self-management of diabetes. In practice, the SMBG strategies of patients may vary due to a number of factors. These include health care provider perceptions and beliefs, patient attitudes and beliefs about SMBG, and available health care and financial resources. Context, together with quantifiable parameters related to the management of diabetes (e.g., glycosylated hemoglobin [A1C] levels, incidence of hypoglycemia [nocturnal, severe, overall], satisfaction surveys, quality of life indices), is important when determining optimal use of blood glucose test strips for SMBG.

Three practice gaps and two knowledge gaps for the prescribing and use of blood glucose test strips for SMBG were identified through the gap analysis. The identified gaps are both qualitative (gaps in knowledge related to perceptions and beliefs) as well as quantitative (gaps in practice related to the frequency of blood glucose monitoring defined by diabetes type and treatment).

5.2.1 Practice Gaps

1. **There is routine use of blood glucose test strips among patients with type 2 diabetes who are not using insulin.**
   The Current Utilization analysis indicated that patients with diabetes who are using oral antidiabetes drugs alone (without insulin) used an average of 1.35 test strips per day, while patients using no pharmacotherapy for diabetes used an average of 0.99 test strips per day. These results suggest that routine SMBG is common in these populations. The Current Practice analysis showed that physicians and diabetes educators recommend SMBG whether patients use insulin or not. Taken together, these findings represent a practice gap since CERC recommended that routine use of blood glucose test strips for SMBG is not warranted in patients with type 2 diabetes who are not using insulin, except in specific populations.[1]

2. **There is limited use of SMBG results in therapeutic decisions by physicians.**
   Although physicians who were participating in the focus groups of the Current Practice analysis generally indicated that they routinely reviewed SMBG results, most patients reported that their physicians seemed to have little interest in their SMBG results. Instead, patients reported that treatment decisions were usually based on A1C values. This finding represents a practice gap since the rationale for continued SMBG is uncertain if the SMBG results are not used by health professionals to monitor or adjust antidiabetes therapy. This is of particular relevance to patients who are treated with oral antidiabetes agents, since the potential for self-adjustment of such medications in response to blood glucose readings is limited.

3. **SMBG is often seen to be synonymous with self-management of diabetes by health care professionals.**
   The Current Practice analysis indicated that the view among health care professionals, particularly diabetes educators, was that SMBG was an important tool for educating patients about diabetes and the effects of lifestyle and medication on glycemic levels. SMBG was seen as being a useful way to motivate patients to initiate or continue self-management practices and take charge of their diabetes. These views also indicate that the terms SMBG and diabetes self-management practices are used synonymously, in that SMBG is seen as being equivalent to self-management. These views may underlie the high rates of SMBG among patients with type 2 diabetes who are not treated with insulin.

5.2.2 Knowledge Gaps

1. **There is lack of awareness among health care professionals about key evidence related to the efficacy of SMBG in patients with type 2 diabetes who are not using insulin.**
   In the Current Practice analysis, opinions regarding the sufficiency of evidence to support SMBG varied between physicians and diabetes educators. While educators believed that there was sufficient evidence to support SMBG, physicians generally believed that the

evidence was insufficient to support SMBG and that more studies were necessary. The primary source of information on SMBG for diabetes educators was the Canadian Diabetes Association guidelines. Neither group reported an awareness of findings from large, well-designed randomized controlled trials that showed modest benefits of SMBG in patients with type 2 diabetes who were not using insulin. This represents a key knowledge gap related to Practice Gap #1 above.

2. **There is lack of awareness of opportunity costs associated with widespread blood glucose testing by patients with type 2 diabetes who are not using insulin.**
   The widespread use of blood glucose test strips for SMBG in patients who are not using insulin indicates that health professionals may be unaware of the opportunity costs involved, that is, the potential gain in health outcomes if the significant resources expended on blood glucose test strips (where such practice is not supported by the evidence) were to be redeployed in other areas. This inference is supported by the Current Practice analysis, in which issues surrounding resource use related to blood glucose test strips were rarely discussed by health professionals.

The identified Practice Gaps earlier in this document lend themselves to the development and implementation of interventions and tools that may potentially change prescribing and use behaviour related to blood glucose test strips. According to the Current Practice analysis, health care providers recognized that there are gaps in knowledge about current evidence supporting the use of blood glucose test strips for SMBG and further information and guidance is required — an enabler to the uptake of key messages aimed at these gaps. Findings from the Current Practice analysis also indicated that patients reported limited use of their SMBG results for therapeutic decisions by physicians resulting in unnecessary testing, patient inconvenience, and the associated costs. Providing information and guidance to patients on the appropriate use of blood glucose test strips for the management of diabetes will support the uptake of key messages addressing this gap. Potential barriers, such as a perception that SMBG is synonymous with the management of diabetes, diabetes educators' influence on patient SMBG practice, or pharmaceutical marketing techniques may need to be overcome. By providing evidence and information to fill the identified knowledge gaps, while considering potential enablers and barriers, the use of blood glucose test strips for people with diabetes will be optimized.

6 KEY MESSAGES

1. **For people with type 1 or type 2 diabetes who are using basal-bolus insulin regimens, SMBG should be individualized to guide adjustments in insulin therapy to achieve optimal blood glucose control.**

2. **In adults with type 2 diabetes who are using basal insulin, SMBG should be individualized, but testing of up to 14 times per week should be sufficient for most patients at most times.**

3. **Most adults with type 2 diabetes managed on oral antidiabetes drugs do not require routine SMBG. Periodic testing in selected patients** (e.g., those with unstable glucose levels, acute illness, pharmacotherapy changes, risk of hypoglycemia with insulin secretagogues like glyburide) **should be linked to specific patient actions** (e.g., prevention or management of hypoglycemia, self-directed dosage adjustment).

4. **Most adults with type 2 diabetes controlled by diet alone should not require routine SMBG.**

Notes:

- *During interviews and focus groups, health care providers identified SMBG to be an integral part of the diabetes self-management strategy. Although there was no specific evidence on the benefits of SMBG within the self-management programs identified, it is recommended that SMBG be practiced in conjunction with education and self-management strategies since the act of SMBG is, in itself, unlikely to result in improvements in diabetes management.*
- *When recommending the use of blood glucose test strips for SMBG, the COMPUS Optimal Therapy Recommendations, which include clinical and cost-effectiveness information, should be taken into account along with each patient's unique situation.*

Once gaps in practice and knowledge related to blood glucose test strips were identified, the gaps were scrutinized to determine their relevancy to the optimal prescribing and use of blood glucose test strips. For example, could addressing the gap through interventions and targeted tools potentially impact on the gap, or was the gap unlikely to be amenable to change? Did the gap lend itself to the development and implementation of interventions, or was 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 for SMBG?

After identifying the gaps most relevant to the optimal prescribing and use of blood glucose test strips, key messages related to the gaps were developed based on the associated Optimal Therapy Recommendation. In developing the key messages, consideration was given to the associated barriers to change and how those barriers could potentially be overcome, as well as to factors favouring change (i.e., enablers). Key messages 1 and 2 highlight where practice is already optimal. The dissemination of key messages 1 and 2 is not to effect behaviour change, but to validate current practice and use behaviours in relation to SMBG for patients using insulin. Positive validation of key messages 1 and 2 may also assist in overcoming

barriers to the widest gaps between recommendations and current practice on the use of blood glucose test strips for SMBG, as represented in key message 3 and 4. The usability and acceptability of these key messages were tested through focus groups composed of target audience members (those to whom the key messages are directed in an effort to effect change and optimize the prescribing and use of blood glucose test strips). Identified target audiences include endocrinologists, physicians, nurse practitioners, diabetes educators, pharmacists, and patients.

Interventions and tools will be developed based on the key messages.

7 THE EVIDENCE

7.1 Optimal Therapy Recommendations

Recommendations developed by CERC for the optimal prescribing and use of blood glucose test strips, as well as the methods used in their development, are presented in *Optimal Therapy Recommendations for the Prescribing and Use of Blood Glucose Test Strips*.[10] In brief, CADTH applied the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to summarize the available clinical and economic evidence on blood glucose test strips and facilitate the generation of Optimal Therapy Recommendations by CERC. This process resulted in seven detailed Optimal Therapy Recommendations, agreed to by CERC members through voting. Recommendations were made on the use of blood glucose test strips for SMBG in children and in adults with type 1 diabetes, adults with type 2 diabetes, and women with gestational diabetes. The overall quality of evidence and strength of recommendation were also decided through voting for each statement.

The final *Optimal Therapy Recommendations for the Prescribing and Use of Blood Glucose Test Strips* is posted on the CADTH website.

7.2 Current Utilization Analysis

A retrospective database analysis using administrative claims data from publicly and privately funded drug plans in Canada was used for the examination of current utilization of blood glucose test strips in Canada. The frequency and cost of blood glucose test strips claimed per person, per day, were calculated, as were the values for total utilization and expenditure on blood glucose test strips.

The final *Current Utilization of Blood Glucose Test Strips in Canada* Optimal Therapy Report is posted on the CADTH website.

7.3 Current Practice Analysis

The Current Practice analysis was a qualitative study designed to assess health care providers' (i.e., physicians, pharmacists, and diabetes educators) and patients' with diabetes, perceptions and beliefs regarding SMBG, as well as to determine how blood glucose test strips are typically used in the management of diabetes.[11] A total of 43 physicians, 19 pharmacists, and 18 diabetes educators participated in 14 focus groups in three different cities. A total of 40 patients with either type 1 or type 2 diabetes participated in six focus groups in three different cities. All participants were interviewed by an experienced qualitative researcher

using a structured interview guide designed either for health care providers or patients. A thematic analysis approach was used to analyze responses.

The final *Current Practice Analysis of Health Care Providers and Patients on Self-Monitoring of Blood Glucose* Optimal Therapy Report is posted on the CADTH website.

8 TARGET AUDIENCES

The Current Practice analysis revealed that nearly all participating health care providers (physicians, diabetes educators, pharmacists) recommend SMBG to the vast majority of patients with diabetes. Responses from health care professionals indicated that they had limited awareness of evidence to support the clinical and cost-effectiveness of SMBG, making these health care providers a target for the key messages. The Current Practice analysis indicated that although physicians are generally the first to encourage patients to test, it is diabetes educators who provide ongoing encouragement for patients to continue monitoring. Diabetes educators play a significant role in diabetes care, and because SMBG is an integral part of their interaction with patients, they are a primary audience to target messaging. Other prescribers such as endocrinologists and nurse practitioners also represent key target audiences, as identified during the focus group testing of the key messages. Patients play an important role in the management of their diabetes, and the importance of disseminating the key messages to this target audience should not be overlooked. The key messages will also be of interest to policy- and decision-makers who must make formulary decisions on the use and coverage of blood glucose test strips. Finally, researchers in the area of diabetes will also find important information in the key messages, indicating where further research is required.

9 NEXT STEPS

Development of interventions and tools to disseminate the messages and effect change will be based on the key messages. The interventions and tools will be selected using the best available evidence with input from experts (both clinical and educational).

APPENDIX A: ABBREVIATIONS

A1C	glycosylated hemoglobin
CAC	COMPUS Advisory Committee
CADTH	Canadian Agency for Drugs and Technologies in Health
CERC	COMPUS Expert Review Committee
COMPUS	Canadian Optimal Medication Prescribing and Utilization Service
SMBG	self-monitoring of blood glucose

APPENDIX B: 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.
Cost-effectiveness analysis: A form of economic evaluation that compares the costs and effects of two or more alternative treatments.

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

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

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

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

Thematic analysis: Thematic analysis is a method for identifying, analyzing, and reporting patterns (themes) within qualitative data. Phases of thematic analysis include familiarization with the data, generation of initial codes, a search for themes, a review of themes, definition and naming of themes, and production of report.

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

Type 2 diabetes mellitus: This refers to diabetes as characterized by insulin resistance and varying degrees of insulin deficiency, especially as the disease progresses. It may range from predominant insulin resistance with relative insulin deficiency to a predominant secretory defect with insulin resistance.

APPENDIX C: COMPUS EXPERT REVIEW COMMITTEE

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

The mandate of CERC is advisory in nature and consists of providing recommendations and advice to CADTH's COMPUS directorate on assigned topics that relate to the identification, evaluation, and promotion of optimal practices in the prescribing and use of drugs across Canada. CERC develops recommendations and advice with the aim of contributing to optimal health outcomes and fostering a sustainable health care system for Canadians. CERC considers the practical needs of policy-makers, health care providers, and consumers in implementing and using the recommendations and advice toward the promotion of optimal practices. 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.

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