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**CADTH RAPID RESPONSE REPORT:**
**SUMMARY WITH CRITICAL APPRAISAL**

# Increasing Frequency of Self-Monitoring Blood Glucose Test Strips During Pregnancy: A Review of the Clinical and Cost-Effectiveness and Guidelines


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## Context and Policy Issues

Diabetes is a chronic medical condition in which the body impairs to the responding to or production of insulin, leading to the abnormal metabolism of sugar and increase in blood sugar level.[1] Over the seven-year period (2004/2005 to 2010/2011), the rate of type 1 diabetes in pregnant women remained unchanged (about 2.9 per 1,000 deliveries), the rate of type 2 diabetes in pregnant women increased from 2.9 to 4.3 per 1,000 deliveries, and the rate of gestational diabetes increased from 40.8 to 54.5 per 1,000 deliveries.[2] The rate of type 2 and gestational diabetes also increased with age.[2] Pre-gestational (pre-existing type 1 or type 2) and gestational diabetes in pregnant women can have significant impact to pregnancy outcomes.[3-5] Poor glycemic control in pre-gestational maternal diabetes and in gestational diabetes may be associated with pregnancy complications, such as preeclampsia, neonatal jaundice, and respiratory distress.[3-5]

Self-monitoring blood glucose (SMBG) is an essential part in diabetes care to achieve glycemic targets and to avoid diabetes-related adverse events.[6] The frequency of SMBG tests that requires to adequately monitoring blood glucose levels depends on the patient circumstances and types of treatment.[6] The majority of patients using insulin usually performed SMBG at least three times per day.[6] For pre-gestational type 1 or type 2 diabetes, a more intense SMBG regimen may be indicated.[6] For strict glucose monitoring during pregnancy, it is suggested that SMBG should be performed before a meal, one or two hours after a meal, and during the night.[6]

The aim of this report was to review the clinical and cost-effectiveness on the increasing frequency of SMBG test strips (i.e., from three to eight or 10 times per day) in pregnant women with diabetes. A review of evidence-based guidelines on the frequency of SMBG in pregnant women with diabetes was also conducted.

## Research Questions

1. What is the clinical effectiveness of increasing the frequency of self-monitoring of blood glucose test strips in patients with pre-gestational Type I or Type II diabetes or who acquire gestational diabetes and are on insulin?

2. What is the cost-effectiveness of increasing the frequency of self-monitoring of blood glucose test strips in patients with pre-gestational Type I or Type II diabetes or who acquire gestational diabetes and are on insulin?

3. What are the evidence-based guidelines associated with the use of self-monitoring of blood glucose test strips in patients with pre-gestational Type I or Type II diabetes or who acquire gestational diabetes and are on insulin?

## Key Findings

No relevant clinical or economic studies were found. One Canadian guideline on diabetes and pregnancy recommended self-monitoring blood glucose (SMBG), to be performed at least four times per day, irrespective to the use of insulin, while a US guideline recommended SMBG for all pregnant women with diabetes and suggested that SMBG should be performed before and after each meal, at bedtime, and during the night.

## Methods

### Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2017, Issue 3), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic studies and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2012 and March 5, 2017.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

**Table 1: Selection Criteria**

| | |
|---|---|
| **Population** | Pregnant patients who have pre-gestational, Type I or Type II diabetes mellitus or acquire gestational diabetes; all patients taking insulin |
| **Intervention** | Self-monitoring blood glucose test strips (SMBG) eight to 10 times per day |
| **Comparator** | Q1 and 2: Variable testing (e.g., but not limited to, three times per day or<br>Other amounts [individualized to the patient's needs]);<br>Standard of care<br>Q3: No comparator |
| **Outcomes** | Q1: Clinical effectiveness (e.g., more effective glycemic control, less complications, etc.) and safety (e.g., outcomes specific to both fetus/neonate and mother)<br>Q2: Cost-effectiveness (e.g., cost per benefit, complication costs circumvented, etc.)<br>Q3: Guidelines |
| **Study Designs** | Health technology assessments (HTAs), systematic reviews (SRs), meta-analyses (MAs), randomized controlled trials (RCTs), economic evaluations, non-randomized studies and guidelines |

### Exclusion Criteria

Studies were excluded if they did not satisfy the selection criteria in Table 1, and if they were published prior to 2012. Conference abstracts and duplicates of publication of the same study were excluded.

### Critical Appraisal of Individual Studies

The Appraisal of Guidelines Research & Evaluation (AGREE II) instrument was used to evaluate the quality of the included guidelines.[7]

## Summary of Evidence

### Quantity of Research Available

A total of 495 citations were identified in the literature search. Following the screening of titles and abstracts, 486 citations were excluded and nine potentially relevant reports from the electronic search were retrieved for full-text review. Seven potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, 14 publications were excluded for various reasons, while two evidence-based guidelines met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

### Summary of Study Characteristics

The characteristics of the included guidelines[8,9] are summarized below and presented in Appendix 2.

#### *Country of Origin*

Two evidence-based guidelines were identified and both were published in 2013.[8,9] One guideline was from Canada (Canadian Diabetes Association [CDA])[8] and one from the US (Endocrine Society).[9]

#### *Overall Objectives*

The CDA guideline had broad objectives in providing recommendations to the prevention and management of diabetes.[8] One chapter discussed diabetes and pregnancy, and provided recommendations for the diagnosis and management of both pre-gestational and gestational diabetes. The objective of the Endocrine Society guideline was to provide a clinical practice guideline for the management of pregnant women with diabetes.[9]

#### *Target Users of the Guidelines*

Both guidelines[8,9] were targeted to physicians and healthcare professionals, who are involved in the management and treatment of diabetes in women before conception, during pregnancy, and in a postpartum setting.

#### *Methods Used to Formulate Recommendations*

The strength of the recommendations in the CDA guidelines was graded according to the level of evidence in a hierarchical manner.[8] The Endocrine Society guidelines used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the quality of evidence and the strength of the recommendation.[9]

### Summary of Critical Appraisal

The summary of the quality assessment for the guidelines was briefly described below and presented in Appendix 3.

The CDA guideline[8] was explicit in all categories of the AGREE II checklist, such as scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, and editorial independence. The Endocrine Society guideline[9] was explicit in terms of scope and purpose, clarity of presentation, and editorial independence. For stakeholder involvement, individuals from relevant profession groups were included the guideline development group and the target users of the guidelines were clearly defined, but it was unclear if the views and preferences of the target population had been sought.[9] For rigour development, it was unclear about the systematic methods used to search for evidence, the criteria for selecting the evidence and a procedure for guideline updating.[9] However, the recommendations were graded according the strengths and limitations of the evidence, and the health benefits and risks were considered in formulating the recommendations.[9] For applicability, the US guideline described facilitators and barriers to its application, and presented monitoring or auditing criteria, but did not provide advice or tools on how the recommendations can be put into practice, and did not consider the potential resource implications of applying the recommendations.[9]

## Summary of Findings

*Question 1: What is the clinical effectiveness of increasing the frequency of self-monitoring of blood glucose test strips in patients with pre-gestational Type I or Type II diabetes or who acquire gestational diabetes and are on insulin?*

No relevant clinical studies were found.

*Question 2: What is the cost-effectiveness of increasing the frequency of self-monitoring of blood glucose test strips in patients with pre-gestational Type I or Type II diabetes or who acquire gestational diabetes and are on insulin?*

No relevant economic studies were found.

*Question 3: What are the evidence-based guidelines associated with the use of self-monitoring of blood glucose test strips in patients with pre-gestational Type I or Type II diabetes or who acquire gestational diabetes and are on insulin?*

The recommendations of the included guidelines[8,9] are presented in Appendix 4.

The CDA guideline[8] recommended that pregnant women with type 1 or type 2 diabetes should use SMBG both preprandially and postprandially, and that pregnant women with gestational diabetes use SMBG both at fasting and postprandially. In the SMBG Recommendation Tool for Healthcare Providers presented in the Appendix 4 of the guideline (p. S202),[8] SMBG was recommended to be individualized and can be used at least four times per day, irrespective of the use of insulin.

The Endocrine Society guideline[9] recommended SMBG for all pregnant women with type 1, type 2 or gestational diabetes. It was suggested that SMBG be performed before each meal, one or two hours after the start of each meal, at bedtime and during the night.

### Limitations

No studies on the clinical or cost-effectiveness of increasing frequency of SMBG testing in pregnant women with diabetes were identified. Although the CDA guidelines are expected to be updated in 2018, no evidence-based guidelines on recommendations on the frequency of SMBG for pregnancy and diabetes published after 2013 were found. The SMBG recommendations of both guidelines were based on low quality evidence.

## Conclusions and Implications for Decision or Policy Making

The CDA guideline recommended that SMBG testing times for pregnant women with diabetes, whether using insulin or not, should depend on individual circumstances and may perform at least four times per day. The Endocrine Society guideline recommended SMBG for all pregnant women with diabetes and suggested that testing can be performed before and after each meal, at bedtime, and during the night. Assuming a person has three meals per day, SMBG should be performed at least eight times per day according to the Endocrine Society guideline. The recommendations on the frequency of SMBG from the included guidelines, however, should be interpreted with caution as they were derived mainly from low quality evidence. Primary studies are needed to provide direct evidence on clinical and cost-effectiveness of increasing the frequency of SMBG up to at least eight times a day in pregnant women with pre-gestational or gestational diabetes and who are on insulin.

## References


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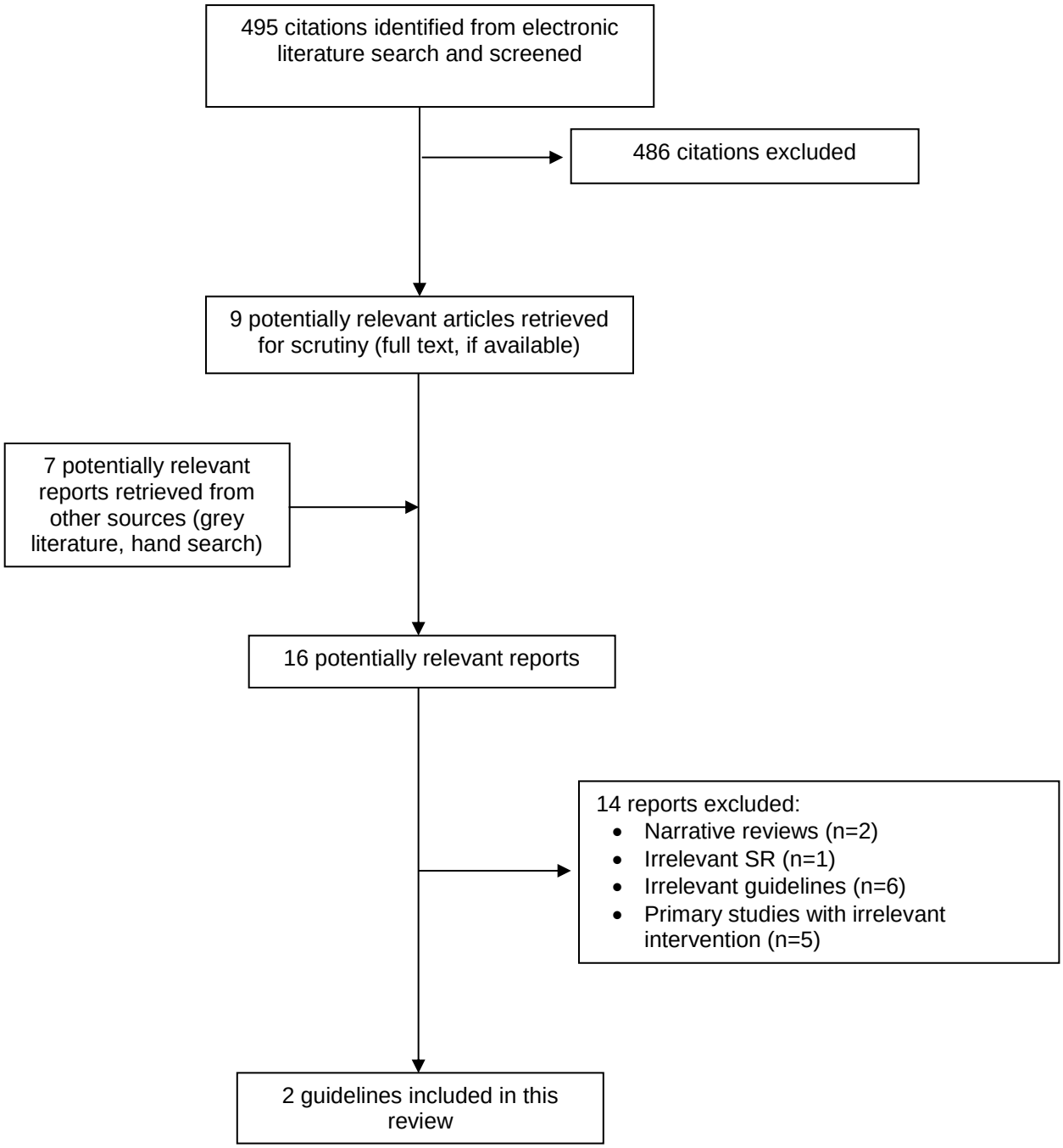
9. Blumer I, Hadar E, Hadden DR, Jovanovic L, Mestman JH, Murad MH, et al. Diabetes and pregnancy: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2013 Nov;98(11):4227-49.

## Appendix 1: Selection of Included Studies



# Appendix 2: Characteristics of Included Studies

## Table A1: Characteristics of Included Guidelines

| First Author, Society/Group Name, Publication Year, Country, Funding | Intended Users/ Target Population | Intervention and Practice Considered | Major Outcomes Considered | Evidence Collection, Selection and Synthesis | Recommendations Development and Evaluation | Guideline Validation |
|---|---|---|---|---|---|---|
| Thompson et al., Canadian Diabetes Association[8]<br><br>2013<br><br>Canada<br><br>Funding: Canadian Diabetes Association and unrestricted educational grants from Novo Nordisk Canada Inc., Eli Lilly Canada Inc., Merck Canada Inc., Bristol-Myers Squibb and AstraZeneca, and Novartis Pharmaceuticals Canada Inc. | Intended users: Primary care physicians and other healthcare professionals who care for people with diabetes or those at risk of diabetes.<br><br>Target population: Adults with diabetes including type 1, type 2 and gestational diabetes. | For Diabetes and Pregnancy: Non-pharmacological and pharmacological interventions for diagnosis and management for pregnant women with pregestational and gestational diabetes, as well as women of reproductive age with type 1 or type 2 diabetes | For Monitoring: Fasting, pre- and postprandial glycemic targets, and pregnancy outcomes | Literature search was performed expert librarian searching the relevant English-language, published, peer-reviewed literature using validated search strategies of electronic databases (MEDLINE, EMBASE, CINAHL, the Cochrane Central Registered of Trials, and PsycINFO.<br><br>The level of evidence was determined by the paper's objectives, methodological rigour, susceptibility to bias and generalizability.<br><br>Evaluation was used the national standard Appraisal of Guidelines Research and Evaluation (AGREE) II | The guideline development process involved an Executive Committee, Steering Committee and Expert Committee with broad expertise and geographic representation. People with diabetes also participated in the guideline development process. | The guideline document was circulated nationally and internationally for review by numerous stakeholders and experts in the relevant field. |

| First Author, Society/Group Name, Publication Year, Country, Funding | Intended Users/ Target Population | Intervention and Practice Considered | Major Outcomes Considered | Evidence Collection, Selection and Synthesis | Recommendations Development and Evaluation | Guideline Validation |
|---|---|---|---|---|---|---|
| | | | | instrument. Each recommendation was assigned a grade from A through D. | | |
| Blumer et al., Endocrine Society[9]<br><br>2013<br><br>USA<br><br>Funding: Not clear | Intended users: Physicians involving in the management and treatment of diabetes in women before conception, during pregnancy, and in postpartum setting<br><br>Target population: Pregnant women with gestational or pregestational diabetes | Non-pharmacological and pharmacological interventions for diagnosis and management of diabetes in women before conception, during pregnancy, and in postpartum setting. | For Monitoring: Fasting, pre- and postprandial glycemic targets | Not reported | Recommendations were developed by the Task Force composed of a chair, selected by the Clinical Guidelines Subcommittee of the Endocrine Society, five experts, a methodologist, and a medical writer | The guideline was reviewed by the Endocrine Society Clinical Guidelines Subcommittee and Clinical Affairs Core Committee, and was posted on the Society's website for additional comments and suggestions |

## Table A2: Grade of Recommendations and Level of Evidence

| Guideline Society or Institute, Year, Country | Grade of Recommendation | Level of Evidence |
|---|---|---|
| Canadian Diabetes Association[8]<br><br>2013<br><br>Canada | **A** The best evidence was at Level 1<br>**B** The best evidence was at Level 2<br>**C** The best evidence was at Level 3<br>**D** The best evidence was at Level 4 or consensus | **1A** Systematic overview of meta-analysis of high quality RCTs or appropriate designed RCT with adequate power to answer the question posed by the investigators<br>**1B** Nonrandomized clinical trial or cohort study with indisputable results<br>**2** RCT or systematic review that does not meet Level 1 criteria<br>**3** Nonrandomized clinical trial or cohort study; systematic review or meta-analysis of level 3 studies<br>**4** Other |
| Endocrine Society[9]<br><br>2013<br><br>USA | **1** Strong recommendation. Phrase used "we recommend". The Task Force has confidence that persons will derive, on average, more good than harm.<br>**2** Less strong recommendation. Phrase used "we suggest". This require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action | ⨁⨁⨁⨁ High quality[a]<br>⨁⨁⨁◯ Moderate quality[b]<br>⨁⨁◯◯ Low quality[c]<br>⨁◯◯◯ Very low quality[d]<br>Quality of evidence was judged based on risk of bias, inconsistency, indirectness, imprecision, and publication bias.<br>[a] Very confident that the true effect lies close to that of the estimate of the effect.<br>[b] Moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.<br>[c] Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.<br>[d] Very little confident in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect. |

RCT = randomized controlled trial

# Appendix 3: Quality Assessment of Included Studies

## Table A3: Quality Assessment of Guidelines

| AGREE II Checklist | Canadian Diabetes Association, 2013[8] | Endocrine Society, 2013[9] |
|---|---|---|
| **Scope and purpose** | | |
| 1. Objectives and target patients population were explicit | Yes | Yes |
| 2. The health question covered by the guidelines is specifically described | Yes | Yes |
| 3. The population to whom the guidelines is meant to apply is specifically described | Yes | Yes |
| **Stakeholder involvement** | | |
| 4. The guideline development group includes individuals from all relevant professional groups | Yes | Yes |
| 5. The views and preferences of the target population have been sought | Yes | Not clear |
| 6. The target users of the guideline are clearly defined | Yes | Yes |
| **Rigour of development** | | |
| 7. Systematic methods were used to search for evidence | Yes | Not clear |
| 8. The criteria for selecting the evidence are clearly described | Yes | Not clear |
| 9. The strengths and limitations of the body of evidence are clearly described | Yes | Yes |
| 10. The methods of formulating the recommendations are clearly described | Yes | Yes |
| 11. The health benefits, side effects, and risks have been considered in formulating the recommendations | Yes | Yes |
| 12. There is an explicit link between the recommendations and the supporting evidence | Yes | Yes |
| 13. The guideline has been externally reviewed by experts prior to its publication | Yes | Yes |
| 14. A procedure for updating the guideline is provided | Yes | Not clear |
| **Clarity of presentation** | | |
| 15. The recommendations are specific and unambiguous | Yes | Yes |
| 16. The different options for management of the condition or health issue are clearly presented | Yes | Yes |
| 17. Key recommendations are easily identified | Yes | Yes |
| **Applicability** | | |
| 18. The guideline describes facilitators and barriers to its application | Yes | Yes |
| 19. The guidelines provides advice and/or tools on how the recommendations can be put into practice | Yes | Not clear |
| 20. The potential resource (cost) implications of applying the recommendations have been considered | Yes | Not clear |
| 21. The guideline presents monitoring and/or auditing criteria | Yes | Yes |
| **Editorial independence** | | |
| 22. The views of the funding body have not influenced the content of the guideline | Yes | Yes |

| AGREE II Checklist | Canadian Diabetes Association, 2013[8] | Endocrine Society, 2013[9] |
|---|---|---|
| 23. Competing interests of guideline development group members have been recorded and addressed | Yes | Yes |

# Appendix 4: Main Study Findings and Author's Conclusions

## Table A4: Summary of Findings of Included Guidelines

| Recommendations |
|---|
| Canadian Diabetes Association, 2013[8] |
| • Recommendation: *"Pregnant women with type 1 or type 2 diabetes should perform SMBG, both pre- and postprandially, to achieve glycemic targets and improve pregnancy outcomes"* [Grade C, Level 3][8] p.S177<br>• Recommendation: *"Women with GDM should perform SMBG, both fasting and postprandially, to achieve glycemic targets and improve pregnancy outcomes"* [Grade B, Level 2][8] p.S178<br>• Recommendation from Appendix 4 of the guideline:<br>*"Situation: Pregnant (or planning a pregnancy), whether using insulin or not*<br>*SMBG recommendation: SMBG individualized and may involve SMBG ≥4 times per day"* p.S202 |
| Endocrine Society, 2013[9] |
| • Recommendation: *"We recommend self-monitoring of blood glucose in all pregnant women with gestational or overt diabetes (1/⊕⊕⊕⊕) and suggest testing before and either 1 or 2 hours after the start of each meal (choosing the post meal time when it is estimated that peak postprandial blood glucose is most likely to occur) and, as indicated, at bedtime and during the night. (2/⊕⊕◯◯)"*[9] p.4230 |

GDM = gestational diabetes mellitus; SMBG = self-monitoring of blood glucose

# Appendix 5: Additional References of Potential Interest

Kesavadev J, Sadikot S, Wangnoo S, Kannampilly J, Saboo B, Aravind SR, et al. Consensus guidelines for glycemic monitoring in type 1/type 2 & GDM. Diabetes Metab Syndr. 2014 Jul;8(3):187-95.

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