Self-Monitoring of Blood Glucose Frequency for Patients with Hypoglycemia Unawareness: A Review of Clinical Effectiveness and Guidelines
SUMMARY WITH CRITICAL APPRAISAL

SMBG Frequency for Patients with Hypoglycemia Unawareness

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Context and Policy Issues

Over time, changes in the symptoms and intensity of symptoms of hypoglycemia in patients with type 1 diabetes mellitus (DM) can occur leading to unawareness or impaired awareness of the condition. Patients with type 1 DM and hypoglycemia unawareness are at a six-fold greater risk of recurrent hypoglycemia.\(^2\) Hypoglycemia is associated with significant morbidity and mortality for type 1 DM patients, and in order to improve outcomes for these patients continuous glucose monitoring systems are frequently recommended.\(^{5, 16, 18}\)

For type 1 DM patients self-monitoring blood glucose (SMBG) using test strips has been recommended prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when low blood glucose is suspected, following treatment of low blood glucose, and prior to tasks such as driving.\(^3, 5\) In 2010, CADTH identified evidence that SMBG testing frequency should be individualized to guide insulin therapy adjustments in patients with type 1 DM.\(^6\)

The clinical benefit of frequent monitoring of blood glucose appears to plateau around 5 times per day in children and adolescents with type 1 DM.\(^3, 7\) Survey studies also suggest that adult patients with type 1 DM and impaired awareness of hypoglycemia utilized SMBG more frequently on average, and more frequent testing correlated with improved glycemic control.\(^{18, 6}\)

The purpose of this report is to retrieve and review the existing clinical effectiveness evidence for various frequencies of SMBG with test strips for patients with type 1 DM and hypoglycemia unawareness. Additionally, this report aims to retrieve and review evidence-based guidelines regarding the optimal frequency of SMBG with test strips for this patient population.

Research Questions

1. What is the clinical effectiveness of various frequencies of self-monitoring of blood glucose with test strips for patients with type 1 diabetes mellitus and hypoglycemia unawareness?

2. What are the evidence-based guidelines regarding the optimal frequency of self-monitoring of blood glucose with test strips for patients with type 1 diabetes mellitus and hypoglycemia unawareness?

Key Findings

No evidence was identified that addressed clinical impacts of self-monitoring blood glucose test frequency for adult patients with type 1 diabetes with hypoglycemia unawareness. Additionally, no evidence-based guidelines were identified that had recommendations for the optimal frequency of self-monitoring of blood glucose with test strips for this patient population.
Methods

Literature Search Methods
A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. The search was limited to English language documents published between Jan 1, 2012 and Mar 19, 2017. Upon review of the titles and abstracts by one reviewer, the literature search was expanded to include documents published since Jan 1, 2009.

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

<table>
<thead>
<tr>
<th>Population</th>
<th>Adults with type 1 diabetes mellitus and hypoglycemia unawareness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>SMBG with test strips at various testing frequencies or number of tests per day (up to 20 times per day)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Q1: Different frequencies of SMBG with test strips compared with each other</td>
</tr>
<tr>
<td></td>
<td>Q2: No comparator necessary</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Q1: Clinical benefits and harms (e.g. A1C levels, hypoglycemic episodes and associated harms)</td>
</tr>
<tr>
<td></td>
<td>Q2: Recommendations for the optimal frequency of SMBG in patients with type 1 diabetes mellitus and hypoglycemia unawareness</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and non-randomized studies, and evidence-based guidelines.</td>
</tr>
</tbody>
</table>

Exclusion Criteria
Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2009.

Summary of Evidence
Quantity of Research Available
A total of 591 citations were identified in the initial literature search and an additional 179 citations upon expansion of the search to 2009. Following screening of titles and abstracts, 753 citations were excluded and 17 potentially relevant reports from the electronic search were retrieved for full-text review. Six potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, all 23 publications were excluded for various reasons; no publications met the inclusion criteria. Appendix 1 describes the PRISMA flowchart of the study selection.
Summary of Findings
No studies comparing different frequency of blood glucose self-testing for patients with type 1 diabetes and hypoglycemia unawareness were identified. Similarly, no guidelines for testing frequency in this population were identified.

Limitations
No evidence meeting the selection criteria for this review was identified. Additionally, evidence-based recommendations determined not to be relevant may have been intended to be applicable to adult type 1 diabetic patients with hypoglycemia unawareness without specific mention of this patient subpopulation.

Conclusions and Implications for Decision or Policy Making
The lack of evidence identified in this report suggests that more research is needed to assess the clinical impact of SMBG testing frequency for type 1 DM patients with hypoglycemia unawareness.
References


Appendix 1: Selection of Included Studies

770 citations identified from electronic literature search and screened

753 citations excluded

17 potentially relevant articles retrieved for scrutiny (full text, if available)

6 potentially relevant reports retrieved from other sources (grey literature, hand search)

23 potentially relevant reports

23 reports excluded:
- irrelevant population (11)
- irrelevant intervention (8)
- irrelevant outcomes (1)
- other (review articles, editorials) (3)

No reports included in review