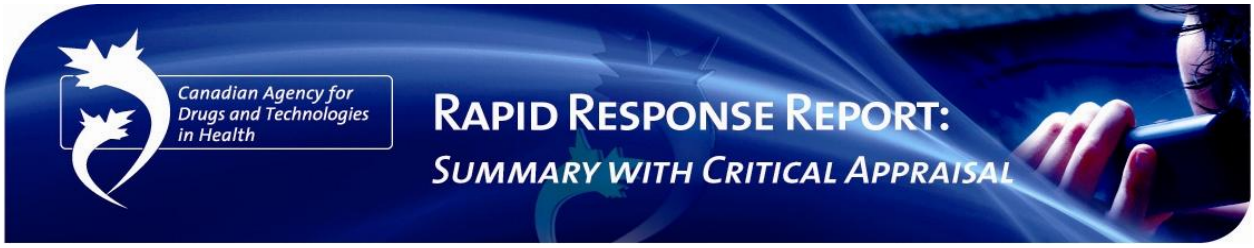

TITLE: Calibration of Blood Glucose Monitors for Diabetes: A Review of the Clinical Evidence and Guidelines

DATE: 08 June 2011

CONTEXT AND POLICY ISSUES:

In 2005, approximately 1.8 million adult Canadians had diabetes, the leading cause of blindness, end-stage renal failure and non-traumatic amputation.[1] Evidence-based clinical practice guidelines recommend regular blood glucose monitoring as a means of preventing complications and comorbidities associated with diabetes.[1,2] Self monitoring improves glycemic control in patients with insulin-treated type 2 diabetes.[3]

The concentration of glucose in blood is determined by placing a small drop of blood, obtained from a finger prick, on a disposable test strip read by a glucose meter. Test strips vary from batch to batch so glucose monitors need to be calibrated to match each new box of test strips. Depending on the meter, calibration may involve entering a code, a code chip or a bar from the vial or box of test strips into the meter. Errors in blood glucose measurements of up to 4 mmol/L can occur if meters are calibrated incorrectly.[4]

Quality control tests are performed before using a new monitor, a new box of test strips, when strips are exposed to extreme temperature, once every 24 hours of monitor use or when patients' symptoms contradict the monitor readings. Two quality control tests are usually performed, one with low and one with high control solutions provided by the manufacturer.[5]

Current Canadian practice regarding the calibration and quality testing of glucose monitors varies. This systematic review evaluates the clinical evidence and evidence-based guidelines regarding the calibration of blood glucose monitors to help standardize practice.

RESEARCH QUESTIONS:

1. What is the clinical evidence regarding the calibration of blood glucose monitors?

2. What are the guidelines on testing and calibrating blood glucose monitors?

KEY MESSAGE:

No clinical evidence or evidence-based guidelines were identified regarding the calibration of blood glucose monitors.

METHODS:

Literature search strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 4), 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 added to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2006 and May 10, 2011.

Selection criteria and method

One reviewer screened citations to identify clinical evidence and evidence-based guidelines regarding the calibration of blood glucose monitors. Potentially relevant articles were ordered based on titles and abstracts, where available. Full-text articles were considered for inclusion based on the selection criteria listed below. Two secondary reviewers confirmed excluded studies.

Table 1: Selection Criteria

Population	Patients with all stages of diabetes in any setting
Intervention	Any methods used for the calibration of blood glucose monitors
Comparator	No comparator
Outcomes	Number of uses between calibrations Length of time between calibrations Validity of capillary and venous blood for calibration Recommendations on: Testing of blood glucose monitors Calibration of blood glucose monitors Appropriate setting for calibration of blood glucose monitors Appropriate healthcare practitioner for calibrating glucose monitors
Study designs	Health technology assessments, systematic review, meta-analyses, randomized controlled trials, non-randomized studies, and evidence-based guidelines

Exclusion criteria

Articles were excluded if they did not meet the selection criteria in table 1 or if no methods were provided to describe how results or guidance was reached.

SUMMARY OF EVIDENCE:

The process of study selection is outlined in the PRISMA flowchart (Appendix 1). No health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies or evidence-based clinical practice guidelines were identified regarding the calibration of blood glucose monitors. However, a potentially relevant article on glucose monitoring training was included in Appendix 2.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

No conclusions can be drawn regarding the most appropriate frequency, setting, or practitioner for calibrating blood glucose monitors or performing quality control tests as no clinical evidence or guidelines were found.

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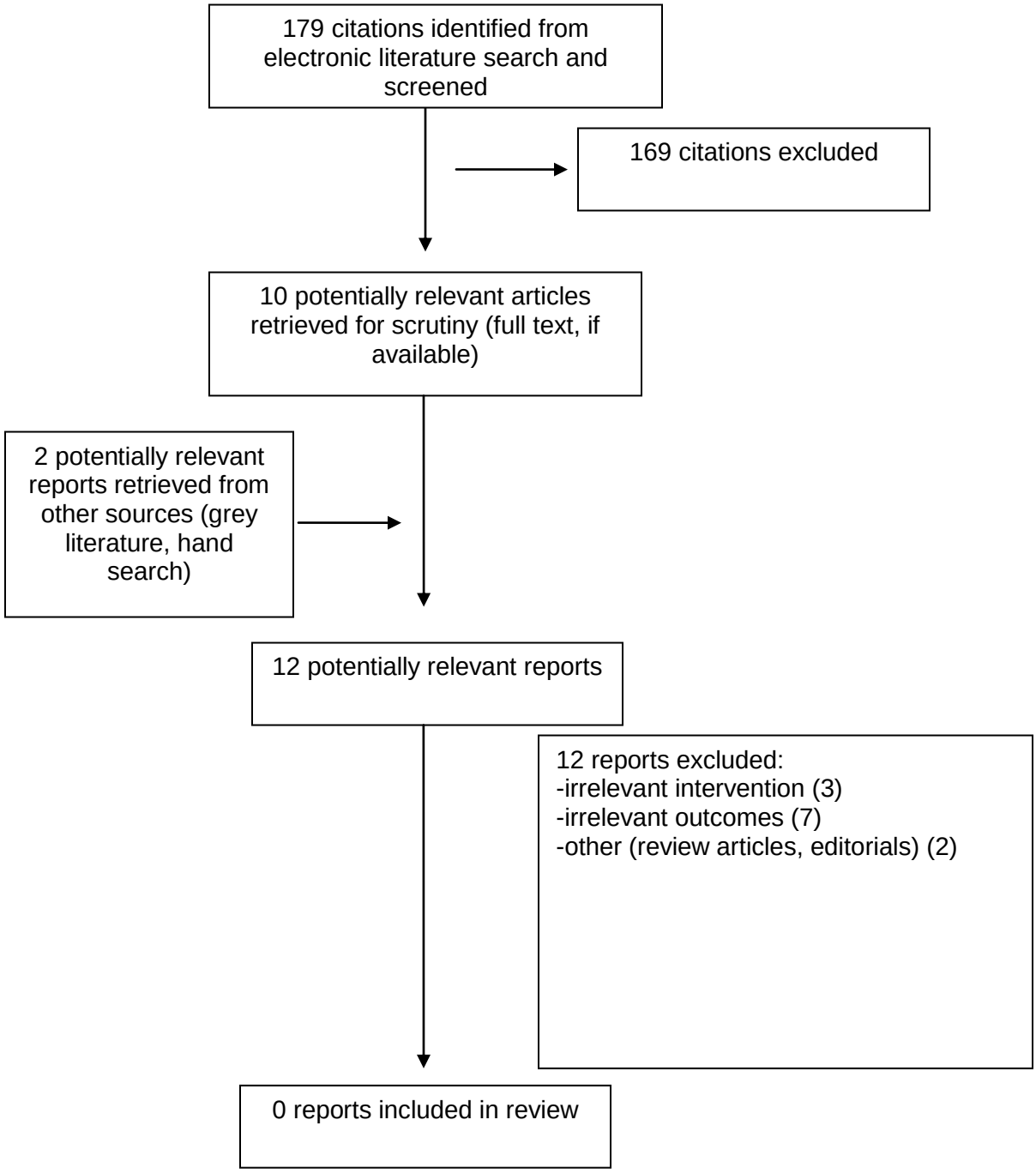
APPENDICES:

APPENDIX 1: Selection of Included Studies



APPENDIX 2: Potentially Relevant Review Articles and Recommendations

Glucose monitoring training [Internet]. Book 3. Mundelein (IL): Medline Industries, Inc.; 2009. [cited 2011 May 26]. Available from: http://www.medlineuniversity.com/DesktopModules/Documents/ViewDocument.aspx?AddToLog=1&DocumentID=783