Point-of-Care Hemoglobin $A_{1c}$ Testing: OHTAC Recommendation

Ontario Health Technology Advisory Committee

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Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.
About Health Quality Ontario

Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario’s health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

To conduct its systematic reviews of health interventions, the Evidence Development and Standards branch examines the available scientific literature, making every effort to consider all relevant national and international research. If there is insufficient evidence on the safety, effectiveness, and/or cost-effectiveness of a health intervention, HQO may request that its scientific collaborators conduct economic evaluations and field evaluations related to the reviews. Field evaluation partners are research institutes focused on multicentred clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies.

About the Ontario Health Technology Advisory Committee

The Ontario Health Technology Advisory Committee (OHTAC) is a standing advisory subcommittee of the Board of Directors of Health Quality Ontario. Based on the evidence provided by Evidence Development and Standards and its partners, OTHAC makes recommendations about the uptake, diffusion, distribution, or removal of health interventions within the provincial health system. When making its recommendations, OHTAC applies a unique decision-determinants framework that takes into account overall clinical benefit, value for money, societal and ethical considerations, and the economic and organizational feasibility of the health care intervention in Ontario.

Publishing Health Quality Ontario Research

When the evidence development process is nearly completed, draft reviews, reports, and OHTAC recommendations are posted on HQO’s website for 21 days for public and professional comment. For more information, please visit: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/professional-and-public-engagement-and-consultation.

Once finalized and approved by the Board of Directors of Health Quality Ontario, the research is published as part of the Ontario Health Technology Assessment Series, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding OHTAC recommendations and associated reports are also published on the HQO website. Visit http://www.hqontario.ca for more information.

When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

Disclaimer

This report was prepared by the Evidence Development and Standards branch at Health Quality Ontario or one of its research partners for the Ontario Health Technology Advisory Committee and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to HQO. The analysis may not have captured every relevant publication and relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.
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Background

The Evidence Development and Standards branch at Health Quality Ontario conducted an evidence-based analysis (1) to answer the following research question:

- What is the correlation between point-of-care hemoglobin A<sub>1c</sub> testing and laboratory hemoglobin A<sub>1c</sub> measurements in patients with diabetes in clinical settings?

In addition, HQO commissioned the Programs for Assessment of Technology in Health (PATH) Research Institute to estimate the budget impact (2013/2014) of point-of-care hemoglobin A<sub>1c</sub> testing to replace laboratory hemoglobin A<sub>1c</sub> measurement for monitoring glycemic control in patients with diabetes. (2)
Conclusions

Conclusions of the evidence-based analysis:

- Moderate quality evidence showed a positive correlation between point-of-care hemoglobin A\textsubscript{1c} testing and laboratory hemoglobin A\textsubscript{1c} measurement. Five observational studies compared 3 point-of-care hemoglobin A\textsubscript{1c} devices with laboratory hemoglobin A\textsubscript{1c} assays, and all reported strong correlation between the 2 tests.

Conclusions of the budget impact analysis:

- Replacing laboratory hemoglobin A\textsubscript{1c} measurement with point-of-care hemoglobin A\textsubscript{1c} testing or using point-of-care hemoglobin A\textsubscript{1c} testing in combination with laboratory hemoglobin A\textsubscript{1c} measurement to monitor glycemic control in patients with diabetes could have saved the province between $1,175,620 and $4,702,481 in 2013/2014.
Decision Determinants

OHTAC has developed a decision-making framework that consists of 7 guiding principles for decision-making and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into the health system. For more information on the decision-making framework, please refer to the Decision Determinants Guidance Document available at: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework.

Appendix 1 provides a summary of the decision determinants for this recommendation.

On the basis of the decision determinants and OHTAC deliberation, OHTAC favoured continued use of laboratory hemoglobin A₁c until the Ontario Laboratory Information System is fully implemented to share hemoglobin A₁c between various health care providers involved in patient care.
OHTAC Recommendations

Based on the available evidence:

- OHTAC affirms the accuracy of point-of-care testing of hemoglobin A₁c levels.
- However, recognizing that the need for quality-controlled, readily shared, non-duplicated information on hemoglobin A₁c levels is the real issue regarding access to the test, OHTAC recommends continuing laboratory-based testing. Furthermore, OHTAC urges that the Ontario Laboratory Information System reach full implementation as soon as possible to allow for sharing of hemoglobin A₁c and other laboratory information between various health care providers involved in patient care.
Appendices

Appendix 1: Decision Determinants

Table A1: Decision Determinants for Point-of-Care Hemoglobin A\textsubscript{1c} Testing

<table>
<thead>
<tr>
<th>Decision Criteria</th>
<th>Subcriteria</th>
<th>Decision Determinants Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall clinical benefit</td>
<td>Effectiveness</td>
<td>The objective of this analysis was to review the correlation between POC HbA\textsubscript{1c} testing and lab HbA\textsubscript{1c} measurement in patients with diabetes in clinical settings. The clinical effectiveness of POC HbA\textsubscript{1c} was beyond the scope of this analysis.</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>POC HbA\textsubscript{1c} testing requires a modest amount of blood from a finger prick, which is not as invasive as venipuncture for lab HbA\textsubscript{1c} measurement.</td>
</tr>
<tr>
<td></td>
<td>Burden of illness</td>
<td>In 2012, over 770,000 people had diabetes in Ontario. Each person with diabetes should undergo HbA\textsubscript{1c} testing 2–4 times yearly, depending on their glycemic control.</td>
</tr>
<tr>
<td></td>
<td>Need</td>
<td>The demand for HbA\textsubscript{1c} testing will increase in parallel to increases in diabetes prevalence.</td>
</tr>
<tr>
<td>Consistency with expected societal and</td>
<td>Societal values</td>
<td>Uncertain</td>
</tr>
<tr>
<td>ethical values</td>
<td>Ethical values</td>
<td>Uncertain</td>
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<td></td>
<td>Value for money</td>
<td>Economic evaluation</td>
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<tr>
<td></td>
<td>Feasibility of adoption into health system</td>
<td>Economic feasibility</td>
</tr>
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<td></td>
<td></td>
<td>Organizational feasibility</td>
</tr>
</tbody>
</table>

Abbreviations: HbA\textsubscript{1c}, hemoglobin A\textsubscript{1c}; lab HbA\textsubscript{1c}, laboratory hemoglobin A\textsubscript{1c}; POC HbA\textsubscript{1c}, point-of-care hemoglobin A\textsubscript{1c}.

*The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.
References

