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Point-of-Care Hemoglobin A_{1c} Testing: A Budget Impact Analysis

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Health Quality Ontario 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 expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policymakers.

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To conduct its comprehensive analyses, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review.

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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.

Abstract

Background

The increasing prevalence of diabetes in Ontario means that there will be growing demand for hemoglobin A_{1c} (HbA_{1c}) testing to monitor glycemic control as part of managing this chronic disease. Testing HbA_{1c} where patients receive their diabetes care may improve system efficiency if the results from point-of-care HbA_{1c} testing are comparable to those from laboratory HbA_{1c} measurements.

Objectives

To estimate the budget impact of point-of-care HbA_{1c} testing to replace laboratory HbA_{1c} measurement for monitoring glycemic control in patients with diabetes in 2013/2014.

Review Methods

This analysis compared the average testing cost of 3 point-of-care HbA_{1c} devices licensed by Health Canada and available on the market in Canada (Bayer's A1cNow+, Siemens's DCA Vantage, and Bio Rad's In2it), with that of the laboratory HbA_{1c} reference method. The cost difference between point-of-care HbA_{1c} testing and laboratory HbA_{1c} measurement was calculated. Costs and the corresponding range of net impact were estimated in sensitivity analyses.

Results

The total annual costs of laboratory HbA_{1c} measurement and point-of-care HbA_{1c} testing for 2013/2014 were $91.5 million and $86.8 million, respectively. Replacing all laboratory HbA_{1c} measurements with point-of-care HbA_{1c} testing would save approximately $4.7 million over the next year. Savings could be realized by the health care system at each level that point-of-care HbA_{1c} testing is substituted for laboratory HbA_{1c} measurement. If physician fees were excluded from the analysis, the health care system would incur a net impact from using point-of-care HbA_{1c} testing instead of laboratory A_{1c} measurement.

Limitations

Point-of-care HbA_{1c} technology is already in use in the Ontario health care system, but the current uptake is unclear. Knowing the adoption rate and market share of point-of-care HbA_{1c} technology would allow for a more accurate estimate of budget impact.

Conclusions

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

Plain Language Summary

Diabetes occurs when the body cannot use glucose normally. It happens because either the pancreas does not make enough insulin (a hormone that controls the level of glucose in the blood) or the body does not respond well to the insulin it makes. High blood glucose levels over a long time cause damage to the heart, eyes, kidneys, and nerves. Checking blood glucose levels often can help doctors choose the right treatment to help keep diabetes in control.

Hemoglobin A_{1c} (HbA_{1c}) is a test that measures the amount of glucose that has stuck to red blood cells over a 3-month period. It is directly related to a patient's average blood glucose levels. People with diabetes usually go to a laboratory to have their HbA_{1c} tested. However, testing HbA_{1c} in diabetes education centres or doctor's offices may save money for the health care system.

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HbA_{1c}	Hemoglobin A_{1c}
Lab HbA_{1c}	Laboratory hemoglobin A_{1c}
POC HbA_{1c}	Point-of-care hemoglobin A_{1c}

Background

Overuse, underuse, and misuse of interventions are important concerns in health care and lead to individuals receiving unnecessary or inappropriate care. In April 2012, under the guidance of the Ontario Health Technology Advisory Committee's Appropriateness Working Group, Health Quality Ontario (HQO) launched its Appropriateness Initiative. The objective of this initiative is to develop a systematic framework for the ongoing identification, prioritization, and assessment of health interventions in Ontario for which there is possible misuse, overuse, or underuse.

For more information on HQO's Appropriateness Initiative, visit our website at www.hqontario.ca.

The Programs for the Assessment of Technology in Health (PATH) Research Institute was commissioned by Health Quality Ontario to evaluate the budget impact and predict the costs of point-of-care testing for hemoglobin A_{1c} for the management of diabetes. The budget impact of implementing each intervention is estimated.

Health Quality Ontario conducts full evidence-based analyses, including economic analyses, of health technologies being considered for use in Ontario. These analyses are then presented to the Ontario Health Technology Advisory Committee, whose mandate it is to examine proposed health technologies in the context of available evidence and existing clinical practice, and to provide advice and recommendations to Ontario health care practitioners, the broader health care system, and the Ontario Ministry of Health and Long-Term Care.

DISCLAIMER: Health Quality Ontario uses a standardized costing method for its economic analyses. The main cost categories and associated methods of retrieval from the province's perspective are described below.

Hospital costs: Ontario Case Costing Initiative cost data are used for in-hospital stay, emergency department visit, and day procedure costs for the designated International Classification of Diseases diagnosis codes and Canadian Classification of Health Interventions procedure codes. Adjustments may be required to reflect accuracy in the estimated costs of the diagnoses and procedures under consideration. Due to difficulties in estimating indirect costs in hospitals associated with a particular diagnosis or procedure, Health Quality Ontario normally defaults to a consideration of direct treatment costs only.

Non-hospital costs: These include physician services costs obtained from the Ontario Schedule of Physician Benefits, laboratory fees from the Ontario Schedule of Laboratory Fees, drug costs from the Ontario Drug Benefit Formulary, and device costs from the perspective of local health care institutions whenever possible, or from the device manufacturer.

Discounting: For cost-effectiveness analyses, a discount rate of 5% is applied (to both costs and effects/QALYs), as recommended by economic guidelines.

Downstream costs: All reported downstream costs are based on assumptions of population trends (i.e., incidence, prevalence, and mortality rates), time horizon, resource utilization, patient compliance, health care patterns, market trends (i.e., rates of intervention uptake or trends in current programs in place in the province), and estimates of funding and prices. These may or may not be realized by the Ontario health care system or individual institutions and are often based on evidence from the medical literature, standard listing references, and educated hypotheses from expert panels. In cases where a deviation from this standard is used, an explanation is offered as to the reasons, the assumptions, and the revised approach.

The economic analysis represents ***an estimate only***, based on the assumptions and costing methods explicitly stated above. These estimates will change if different assumptions and costing methods are applied to the analysis.

NOTE: Numbers may be rounded to the nearest decimal point, as they may be reported from an Excel spreadsheet.

Objective of Analysis

The objective of this analysis was to estimate the budget impact (2013/2014) of point-of-care hemoglobin A_{1c} (POC HbA_{1c}) testing to replace laboratory hemoglobin A_{1c} (lab HbA_{1c}) measurement for monitoring glycemic control in patients with diabetes.

Clinical Need and Target Population

Description of Disease/Condition

Diabetes is a metabolic disorder resulting from defective insulin production and/or action. There are 2 major types of diabetes: type 1 and type 2. Type 1 diabetes is an autoimmune disease in which the body's defence system attacks its own insulin-producing cells; type 2 diabetes is characterized by insulin resistance and inadequate insulin production. Type 2 diabetes accounts for over 90% of the diabetes population. Left uncontrolled, the chronic hyperglycemia associated with diabetes contributes to cardiovascular disease and microvascular complications affecting the eyes, kidneys, and nerves. (1) Classic diabetes trials, including the Diabetes Control and Complications Trial for type 1 diabetes and the United Kingdom Prospective Diabetes Study for type 2 diabetes, have demonstrated that optimal glycemic control slows the onset and progression of diabetes-related complications. (2-4)

Hemoglobin A_{1c} (HbA_{1c}) is a marker of long-term glycemic control, and it has been widely used to guide treatment decisions in clinical practice. Its value reflects average blood glucose concentration over the preceding 3 months. (5) It is recommended that patients with diabetes have HbA_{1c} tested every 3 to 6 months to assess glycemic control. (6)

Ontario Prevalence

In 2012, Statistics Canada reported a prevalent diabetes population of 770,410 in Ontario. (7) This figure is expected to increase in parallel with the upward trend of obesity and the aging population.

Technology/Technique

Point-of-care testing refers to diagnostic testing at or near the site of patient care. (8) POC HbA_{1c} testing is an alternative to lab HbA_{1c} measurement, and it has several potential advantages. First, it provides rapid test results following blood collection, to expedite medical decision-making. Second, it may improve health system efficiency and be convenient for patients, because fewer visits to laboratories or physician's offices would be needed. Third, it may improve access to HbA_{1c} measurement for patients in underserved populations (e.g., rural or remote communities).

Ontario Context

The current standard of care in Ontario is that patients with diabetes go to community laboratories or hospitals for HbA_{1c} measurement, usually prior to their physician visit. POC HbA_{1c} devices are being used in selected diabetes education centres, community health centres, and doctor's offices, funded by their operating budgets.

The prevalence of POC HbA_{1c} testing in Ontario is unclear. However, considering the increasing prevalence of diabetes, there will be a growing need for HbA_{1c} testing to monitor glycemic control. POC HbA_{1c} testing may improve system efficiency if the results from point-of-care devices are comparable to those from laboratory assays. Therefore, Health Quality Ontario chose to compare the correlation between POC HbA_{1c} and lab HbA_{1c} measurement in clinical settings.

Interventions Under Evaluation

Six POC HbA1c devices are licensed by Health Canada as class-3 devices for quantitative determination of HbA_{1c} from capillary or venous whole blood. The manufacturer information for these devices is presented in Table 1.

Table 1: Manufacturer Information for POC HbA_{1c} Devices Licensed for Use in Canada

Manufacturer Information	A1c Now Self-Check at Home A_{1c} System	A1c Now+	DCA 2000 Analyzer System	DCA Vantage Analyzer	In2it (I) System	Smart Direct HbA1c Analyzer
Manufacturer	Bayer Healthcare LLC	Bayer Healthcare LLC	Siemens Healthcare Diagnostics Inc	Siemens Healthcare Diagnostics Inc	Bio-Rad Laboratories Deeside	Diazyme Laboratories
Licence number	84541	65484	1990	76034	80662	88752
Issue date	November 2010	July 2008	March 1999	January 2008	September 2009	April 2012
Remark	—	—	Unavailable in Canada	—	—	Unavailable in Canada

Abbreviation: POC HbA_{1c}, point-of-care hemoglobin A_{1c}.

The operating characteristics of the 3 POC HbA_{1c} devices that are available for use in Canada are summarized in Table 2.

Table 2: Characteristics of POC HbA_{1c} Devices Available for Use in Canada

Characteristic	A1c Now+	DCA Vantage Analyzer	In2it (I) System
Manufacturer	Bayer Healthcare LLC	Siemens Healthcare Diagnostics Inc	Bio-Rad Laboratories Deeside
Method	Immunoassay	Latex agglutination inhibition immunoassay	Boronate-affinity chromatography
Blood sample	5 µL (capillary or venous)	1 µL (capillary or venous)	10 µL (capillary or venous)
Time for results	5 minutes	6 minutes	10 minutes
Interference with abnormal hemoglobin variants (15)	HbC, HbS, HbF > 10–15%	HbC, HbE, HbF > 10–15%	HbF > 10%
NGSP-certified (16)	Yes	Yes	Yes
CLIA waived	Yes	Yes	Yes
Other characteristics	Same device as A1c Now, with more test cartridges in the kit	Successor of DCA 2000	N/A

Abbreviation: CLIA, Clinical Laboratory Improvement Amendments; HbC, hemoglobin C; HbE, hemoglobin E; HbF, hemoglobin F; HbS, hemoglobin S; NGSP, National Glycohemoglobin Standardization Program; POC HbA_{1c}, point-of-care hemoglobin A_{1c}.

Economic Analysis

Research Question

What is the estimated budget impact (2013/2014) of POC HbA_{1c} testing to replace lab HbA_{1c} measurement for monitoring glycemic control in patients with diabetes?

Budget Impact Analysis

A budget impact analysis was conducted from the perspective of the Ontario Ministry of Health and Long-Term Care to determine the estimated cost burden of replacing lab HbA_{1c} measurements performed in community laboratories with POC HbA_{1c} testing to monitor glycemic control in Ontario patients with diabetes. All costs are reported in 2013 Canadian dollars.

Research Methods

Prevalent Population

The population of Ontario was estimated using data from Statistics Canada (Table 3). (9) The overall prevalent population with diabetes was estimated using prevalence rates and constant rate projection with data from the Institute for Clinical Evaluative Sciences and the Canadian Diabetes Association. (10) However, the overall prevalence of diabetes includes both diagnosed and undiagnosed populations. Because only those *diagnosed* with diabetes receive HbA_{1c} testing, the population of those with diagnosed diabetes was also determined.

Table 3: Ontario Population and Estimated Prevalence of Diabetes

Population/Prevalence	2013/2014
Ontario population[a]	13,673,500
Prevalence of diabetes (overall)[b]	9.4%
Ontario population with diabetes (overall)[c]	1,280,000
Prevalence of diabetes (diagnosed)[d]	6.0%
Ontario population with diabetes (diagnosed)[c]	820,000

[a]Statistics Canada. (9)
[b]Institute for Clinical and Evaluative Sciences. (10)
[c]Numbers rounded to the nearest thousand.
[d]Public Health Agency of Canada. (11)

The population with diagnosed diabetes was selected for the budget impact analysis, and patients were divided into 2 groups: those with optimal glycemic control ($HbA_{1c} \leq 7.0\%$) and those with suboptimal glycemic control ($HbA_{1c} > 7.0\%$). (6) The Diabetes in Canada Evaluation study (2002/2003) reported that approximately 49% of patients with diagnosed diabetes had suboptimal glycemic control. (12) Using this estimate, the number of patients in each subgroup was projected for 2013/2014 (Table 4).

Table 4: Prevalent Population: Glycemic Control

Glycemic Control	%[a]	n
Optimal (HbA_{1c} ≤ 7.0%)	51.0%	418,409
Suboptimal (HbA_{1c} > 7.0%)	49.0%	402,001

Abbreviation: HbA_{1c}, hemoglobin A_{1c}.
[a]Diabetes in Canada Evaluation study. (12)

Resources

Patients with diabetes should have their HbA_{1c} levels tested twice yearly if their glycemic control is optimal, or 4 times yearly if their glycemic control is suboptimal (Table 5). (6) For patients with suboptimal glycemic control, an additional 2 physician visits were assumed for follow-up treatment changes after lab HbA_{1c} measurement, totalling 6 visits. According to administrative data from the Institute for Clinical Evaluative Sciences, approximately 64% of patients with diagnosed diabetes (N = 525,062) receive HbA_{1c} testing according to the guidelines. (13)

Table 5: Physician Visits per Year for Lab HbA_{1c} Measurement and POC HbA_{1c} Testing

Population	Lab HbA_{1c}		POC HbA_{1c}	
	Physician Visits per Patient per Year	Total Physician Visits	Physician Visits per Patient per Year	Total Physician Visits
Patients with optimal glycemic control (HbA_{1c} ≤ 7.0%) (n = 267,781)	2	836,818	2	836,818
Patients with suboptimal glycemic control (HbA_{1c} > 7.0%) (n = 257,281)	6	2,412,005	4	1,608,004
All patients (N = 525,062)	—	3,248,824	—	2,444,822

Abbreviation: lab HbA_{1c}, laboratory hemoglobin A_{1c}; POC HbA_{1c}, point-of-care hemoglobin A_{1c}.

Canadian Costs

The average Canadian costs for HbA_{1c} testing are presented in Table 6.

Table 6: Per Procedure Cost

Procedure	Average Cost
POC HbA_{1c} testing	$16.26[a]
Bayer A1C Now +	*$16.45[b]*
DCA Vantage	*$9.74[c]*
In2it	*$22.50[d]*
Lancets	*$0.03[e]*
Lab HbA_{1c} measurement	$8.81[f]
Physician visit (diabetes management assessment)	$39.20 (fee code K030)[g]
Additional physician visit for patients with suboptimal glycemic control	$33.70 (fee code A007)[h]

Abbreviations: lab HbA_{1c}, laboratory hemoglobin A_{1c}; POC HbA_{1c}, point-of-care hemoglobin A_{1c}.
[a]Total cost for a POC HbA_{1c} test includes the average cost of the 3 reviewed devices plus the cost of a lancet.
[b]Manufacturer list price from McKesson, based on a 10-test MD kit. Cost includes a wholesale markup.
[c]Price for DCA 2000 kit reagent 10TST/PK. Personal communication, Manthamed distributor, September 1, 2013.
[d]Personal communication, product manager, Bio-Rad Laboratories (Canada) Ltd., September 19, 2013.
[e]Manufacturer list price from McKesson, based on a 100 lancets per box (Medi+Sure Soft Twist Lancet). Cost includes a wholesale markup.
[f]Cost for a lab HbA_{1c} test is based on the Ontario Schedule of Benefits for Laboratory Services, (14) assuming that the cap per test is 77.5% (average of 75% to 80%) of the total of $11.37 (average cost of $8.81).
[g]The cost per physician visit for patients with diabetes was obtained from the Ontario Schedule of Benefits for Physician Services, using the fee code K030 for Diabetic Management Assessment, up to a maximum of 4 visits per year. (15)
[h]The cost for the 2 additional physician visits for patients with suboptimal glycemic control was applied using the fee code A007. (15)

Results of Budget Impact Analysis

The total estimated annual cost of POC HbA_{1c} testing and lab HbA_{1c} measurement in 2013/2014 is presented in Table 7. Replacing lab HbA_{1c} test with POC HbA_{1c} would result in cost savings.

Table 7: Budget Impact of POC HbA_{1c} Testing

	2013/2014
Total annual cost of lab HbA_{1c} testing	$91,482,155
Total annual cost of POC HbA_{1c} testing [a]	$86,779,673
Net budget impact	**– $4,702,481**

Abbreviations: lab HbA_{1c}, laboratory hemoglobin A_{1c}; POC HbA_{1c}, point-of-care hemoglobin A_{1c}.
[a]Total annual cost of POC HbA_{1c} testing if being used instead of lab HbA_{1c} testing in patients with diabetes.

Sensitivity Analyses

Sensitivity analyses were conducted on the prevalence of both diagnosed and undiagnosed diabetes; the rate of HbA_{1c} testing; the percentage of patients with diabetes and suboptimal glycemic control; increases in the volume of POC HbA_{1c} testing (with a corresponding decrease in lab HbA_{1c} testing); and the exclusion of physicians' visits. Table 8 outlines the results of these sensitivity analyses and their net budget impact. All but 1 of the sensitivity analyses indicated that the use of of POC HbA_{1c} testing to monitor glycemic control would result in savings in 2013/2014. If physicians' visits were excluded from the analysis, there would an increase in spending with the full-scale introduction of POC HbA_{1c} testing.

Table 8: Results of Sensitivity Analyses

	Net Budget Impact, 2013/2014
Prevalence of diagnosed diabetes in Ontario increased by 50%	– $7,053,722
HbA_{1c} testing increased by 25%	– $5,878,102
HbA_{1c} testing decreased by 25%	– $3,526,861
Percentage of patients with suboptimal glycemic control increased by 25%	– $8,315,175
Percentage of patients with suboptimal glycemic control increased by 50%	– $11,927,868
Impact of increasing POC HbA_{1c} testing by 25%	– $1,175,620
Impact of increasing POC HbA_{1c} testing by 50%	– $2,351,241
Impact of increasing POC HbA_{1c} testing by 75%	– $3,526,861
Physicians' visits excluded	$11,656,363

Abbreviations: HbA_{1c}, hemoglobin A_{1c}; POC HbA_{1c}, point-of-care hemoglobin A_{1c}.

Limitations

Although POC HbA_{1c} technology is already in use in the Ontario health care system, the current uptake is unclear. Knowing the adoption rate and market share of POC HbA_{1c} technology would allow for a more accurate estimate of budget impact.

Conclusions

Replacing lab HbA_{1c} measurement with POC HbA_{1c} testing or using POC HbA_{1c} testing in combination with lab HbA_{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.

Acknowledgements

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Expert Advisory Panel on Community-Based Care for Adult Patients With Type 2 Diabetes

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