



TITLE: Point-of-Care Testing: A Review of Systematic Reviews on Testing Accuracy and Cost-Effectiveness

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CONTEXT AND POLICY ISSUES

Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care, without sending the sample to a laboratory setting.¹ POCT has grown substantially both in volume and in terms of the types of available tests in recent years.² The possible sites for POCT can be in hospital, such as intensive care units, emergency departments and neonatal units, or outside of hospital, such as ambulances, the workplace, pharmacies and the homes of patients in primary care.^{1,3} POCT can be used in a number of areas including blood glucose testing, coagulation testing, blood gas analysis, cardiac testing, complete blood count, and electrolytes analysis.³

Point-of-care tests are conveniently brought to the patient, so that shorter turnaround time is required to obtain the results from POCT. In this way, clinicians are provided with timely information to make immediate decisions about patient management.² POCT approaches may be less invasive since a smaller sample is usually required compared with a laboratory setting. In addition, the introduction of POCT has been reported to reduce costs and total emergency department length of stay.⁴ On the other hand, the potential disadvantages related to POCT may be poor quality of analysis, lack of result interpretation, and failure to detect erroneous results.³

The purpose of this report is to review the evidence for the clinical and cost-effectiveness of POCT compared to conventional laboratory testing for a range of conditions.

RESEARCH QUESTIONS

1. What is the testing accuracy of point of care testing for international normalized ratio (INR), blood glucose, electrolytes, blood gases, troponin, complete blood count and liver function?
2. What is the cost-effectiveness of point of care testing for INR, blood glucose, electrolytes, blood gases, troponin, complete blood count and liver function?

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KEY MESSAGE

Evidence which is limited in quantity as well as quality suggests comparable testing accuracy of point-of-care testing in monitoring patients needing anticoagulation therapy or glycemic control, when compared with conventional laboratory testing. Point-of-care testing is more cost-effective than standard of care in anticoagulation therapy, while the results should be interpreted with caution in a Canadian context.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2012, issue 3), Canadian and abbreviated list of 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, and meta-analyses. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2007 and March 13, 2012.

Selection Criteria and Methods

One reviewer screened the titles and abstracts of the retrieved publications, and evaluated the full-text publications for the final article selection, according to the selection criteria present in Table 1.

Table 1: Selection Criteria

Population	Patients that require medical tests (INR blood glucose, electrolytes, blood gases, troponin, complete blood count or liver function tests)
Intervention	Point-of-care testing
Comparator	Laboratory testing
Outcomes	Testing accuracy Cost-effectiveness
Study Designs	Health technology assessments, systematic reviews and meta-analyses

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria, were duplicate publications, were abstracts or conference proceedings, were included in a selected systematic review, were superseded by a more recent systematic review, or were published prior to 2007. Studies comparing POCT with usual care without specifying the definition of “usual care”, or where laboratory work-up was not part of the usual care were excluded.

Critical Appraisal of Individual Studies

The quality of the included systematic reviews (SRs) and meta-analyses (MAs) were assessed using the Assessment of Multiple Systematic Reviews (AMSTAR) tool.⁵ Economic evaluation in

health technology assessments (HTAs) was assessed using a 35-item Drummond checklist.^{6,7} A numeric score was not calculated for each study. Instead, the strengths and weakness of each study were summarized and described.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search yielded 234 citations. Upon screening titles and abstracts, 204 citations were excluded, and 30 potentially relevant articles were retrieved for full-text review. Of the 30 potentially relevant reports, 26 did not meet the inclusion criteria, and thus four publications were included in this review.⁸⁻¹¹ The study selection process is outlined in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (Appendix 1). Two HTAs^{10,11} and two SRs or MAs^{8,9} met the inclusion criteria.

Summary of Study Characteristics

Two of the HTAs^{10,11} were conducted in Canada, one SR in Denmark⁸ and one SR/MA⁹ in Saudi Arabia. The study designs reviewed included RCTs and economic evaluations. In one SR,⁸ the author did not specify the study designs for their included studies.

The characteristics of the selected HTAs, SRs, and MAs are outlined in Appendix 2.

POCT for INR in adult patients on anticoagulants

Three studies examined the effects of POCT in patients on anticoagulants.

Christensen and coworkers performed an SR to assess the precision and accuracy of several POCT coagulometers on INR for oral anticoagulation therapy (OAT).⁸ Literature search for relevant English-language studies published from the start of 1951 to September 2011 was conducted. The authors did not specify what study designs they were interested in for study selection, although we believe, based on data presented, that all included trials were non-randomized comparative studies comparing the performance of POCT with a laboratory test, according to the data presented in this article. Precision was the degree of reproducibility measured by standard deviation or coefficient of variation (CV) of the variability. A result with CV of <3% was considered precise. Accuracy reflected the level of agreement between the result of one measurement and the true value. It was expressed by correlation coefficient (CC) or concordance in this SR. The investigated devices in this SR were *CoaguChek XS*, *INRatio*, *ProTime/ProTime 3*, and *SmartCheck INR System*. A drop of capillary whole blood was needed to be applied to a test strip and then inserted into the POCT coagulometer. The quality of the included studies was determined using these criteria: number of INR measurements > 100; use of an INR comparator, such as a laboratory using certified plasma/external quality control; or use of mean/median difference and not merely linear interpolation for testing accuracy. In total, 22 studies met the selection criteria (14 examined *CoaguChek XS* and eight examined *INRatio*, *ProTime/ProTime 3*, and *SmartCheck INR System*). Four of them were classified as high-quality studies.

The Medical Advisory Secretariat of The Ministry of Health and Long-Term Care (MOHLTC) of Ontario conducted an HTA in 2009, to examine the safety and effectiveness of POCT in INR monitoring devices for patients on long-term (longer than three months) OAT.¹⁰ The standard of

care in Ontario for the target population is laboratory-based INR determination with management carried out by primary care physicians or anticoagulation clinics. There was a section of economic analysis in this report. English-language full economic evaluations published between 1996 to November 2008 were examined. In total, six economic evaluations were included in this HTA. In addition, the authors used a 5-year Markov model, from the perspective of MOHLTC, to evaluate the cost-effectiveness of four different anticoagulation management approaches: standard care, healthcare staff testing using POCT in a medical clinic, patient self-testing using POCT and phoning in results to health care provider (PST), and patient self-managing using POCT and self-adjustment of OAT according to a standardized protocol (PSM). The clinical review section of this report examined relevant English-language RCTs, SRs and MAs. The clinical review excluded studies where the POCT was compared to laboratory testing to assess test accuracy. Therefore, only results from the economic analysis are presented in the current report.

In an HTA conducted by Brown et al.,¹¹ clinical and cost-effectiveness of POCT were compared with standard laboratory tests in long-term (longer than three months) OAT. It was included in the aforementioned Medical Advisory Secretariat HTA. Relevant literature was searched for in multiple databases from 1966 through August 2006, without year or language restrictions. In the review of economic literature, full or partial economic evaluations were included in economic review. The primary outcome was an incremental measure of the implication of moving from the comparator to the intervention. Quality of the full economic studies was assessed using a checklist developed for the British Medical Journal. A primary economic evaluation was conducted using a decision analytic approach on patients on long-term oral coagulants. A Markov model was presented from the perspective of a health care provider and from a societal perspective. The time horizon of the model was five years. A total of six studies (four American studies, one Spanish study and one German study) were eligible for the economic review. In the clinical review, RCTs were included. The outcomes of interest in clinical review were rates of major hemorrhage, rates of major thromboembolic events, mortality and percentage of time the patient's blood was in the normal therapeutic INR range. Test accuracy was not reported.

POCT for blood glucose in adult patients

One study compared the results of glycated hemoglobin (HbA1c) from POCT with that from laboratory testing in adult patients with diabetes.

An SR and MA was conducted by Al-Ansary et al. to compare the performance of POCT in patients with diabetes with conventional laboratory-based testing.⁹ Relevant RCTs were searched for in multiple databases from 1980 to August 2010. The authors did not indicate if there was a restriction on language during study selection. The primary outcome was change in HbA1c. Methodologic quality for the included RCTs was assessed using the Cochrane guidance on preparing systematic reviews of interventions from the following specific criteria: sequence generation, allocation concealment, incomplete outcome data addressed, and selective outcome reporting. Seven RCTs that enrolled patients with type 1 or type 2 diabetes were included in this SR. The sample size of these studies varied between 201 and 3,953. The study period of the selected RCTs ranged from one to 18 months.

POCT for electrolytes

No studies were identified from the literature search.

POCT for blood gases

No studies were identified from the literature search.

POCT for troponin in adult patients with chest pain

No studies were identified from the literature search.

POCT for complete blood count

No studies were identified from the literature search.

POCT for liver function in adult patients

No studies were identified from the literature search.

Summary of Critical Appraisal

The details on the critical appraisal of individual included studies are presented in Appendix 3.

Overall, the included HTA, SRs and MAs described clear research questions and selection criteria. Multiple databases were searched in all reviews. One SR⁹ indicated that independent reviewers conducted study selection and data extraction. In most HTAs/SRs (n=3), the quality of the primary studies was appraised using predefined quality assessment instruments. The results were not reported in sufficient detail in some reviews. For instance, a description of the trial characteristics was not provided in one SR.⁸

Both of the HTAs that reported cost-effectiveness of POCT were conducted by Canadian researchers. When developing the economic models, the key parameters and assumptions such as resource utilization data for portable coagulometers and standard laboratory test, medical visit costs, drug costs, laboratory fees and rehabilitation costs were obtained from Canadian sources. This effort may help us get a better understanding of the potential benefits of the investigated interventions in a Canadian setting. In addition, sensitivity analyses were carried out in these HTAs to address variability and uncertainty.^{10,11} Neither reports received financial support from POCT manufacturers.

Conflicts of interest and funding sources were recorded in all studies.

Summary of Findings

The results of clinical effectiveness of POCT versus conventional laboratory testing are presented in Appendix 4.

*Testing Accuracy*POCT for INR

In the SR by Christensen et al.,⁸ the precision of *CoaguChek XS* varied from a CV of 1.4% to 5.9%, based on data from 14 studies; the precision of *INRatio*, *ProTime/ProTime 3* and *SmartCheck INR System* varied from a CV of 3.7% to 8.4%, based on data from eight studies. In terms of accuracy, CC for *CoaguChek XS* varied from 0.81 to 0.98, while CC for the other three devices varied from 0.73 to 0.95.

There was no direct comparison between *CoaguChek XS* and *INRatio*, *ProTime/ProTime 3* and *SmartCheck INR System*.

POCT for blood glucose

In the MA by Al-Ansary et al.,⁹ there was a nonsignificant reduction of 0.09% in HbA1c in the POCT group compared with the control group (95% confidence interval [CI] -0.21 to 0.02).

Cost-effectiveness

POCT for INR

In the HTA conducted by the Medical Advisory Secretariat of MOHLTC,¹⁰ six full economic evaluations including two Canadian studies were selected in the economic review. Inconsistent results were reported for the cost-effectiveness of POCT approaches compared with usual care. Results from the primary economic analysis indicated that use of POCT was associated with lower costs but higher QALY gain in the study population, and patient self-managing approach was deemed to be the most cost-effective method.

In the HTA by Brown et al.,¹¹ six full or partial economic evaluations, mostly from the United States, were included in the economic review. The results were generally favourable to POCT and indicated that POCT was associated with cost saving compared with standard lab testing. In the primary economic analysis, from a publicly funded health care perspective, using POCT in anticoagulation clinics was cost-effective compared to conventional therapy; but when self-testing by patients using POCT was compared with conventional therapy, the cost per additional quality-adjusted life-year (QALY) gained was C\$57,595. When a societal perspective was adopted, self-testing by patients using POCT was cost effective.

Limitations

Rapid reviews are based on a limited literature search and may not identify all potential relevant studies. Given its broad scope, this review was limited to evidence from health technology assessments and systematic reviews. Few systematic reviews were found for the performance of POCT in analyzing INR and blood glucose. No studies were retrieved for the use of POCT in electrolytes, blood gases, troponin, complete blood count and liver function. This does not necessarily reflect a lack of research in these areas, but rather a lack of reviewing of the collective evidence.

Quality of the included SRs was compromised by lack of sufficient details reporting, and restrictions in literature search.⁸ The comparison of HbA1c in a meta-analysis was based on three out of seven studies in Al-Ansary's review.⁹ The three studies enrolled approximately 20% of the patients in Al-Ansary's review.

In the economic evaluations, one¹⁰ included two Canadian economic studies when reviewing the existing economic literature, while another¹¹ did not include any Canadian studies. This may limit the generalizability of the study results. Even though the key parameters used in the economic models were retrieved from Canadian sources, the results should be interpreted with caution in a Canadian context.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Point-of-care testing has been applied in clinical practice in a range of areas in recent years. However, a limited number of systematic reviews were identified regarding their testing accuracy and cost-effectiveness (evidence from studies other than systematic reviews were not required for this report). Results from four HTAs, SRs and MAs are presented in our report. The patient populations under investigation include those undergoing oral anticoagulation therapy and needing glycemic control for diabetes. Systematic reviews of the evidence regarding the use of POCT in analyzing electrolytes, blood gases, troponin, complete blood count and liver function was not identified. It is unclear whether this is due to a lack of primary literature in these areas, but indicates a gap in compiling that evidence.

In summary, precision and accuracy of certain POCT devices in oral anticoagulants therapy is considered acceptable compared with conventional laboratory-based testing in an SR. One systematic review found no statistically significant difference between POCT and laboratory testing with respect to the change of HbA1c in diabetic patients.

Cost-effectiveness of POCT in monitoring treatment effects of anticoagulants in a Canadian setting has been demonstrated in two HTAs when comparing with the current standard care.

More studies with better study design, particularly enrolling Canadian patients, are warranted to provide more compelling evidence on the testing accuracy of POCT approaches in the target populations, before they are widely introduced into clinical practice.

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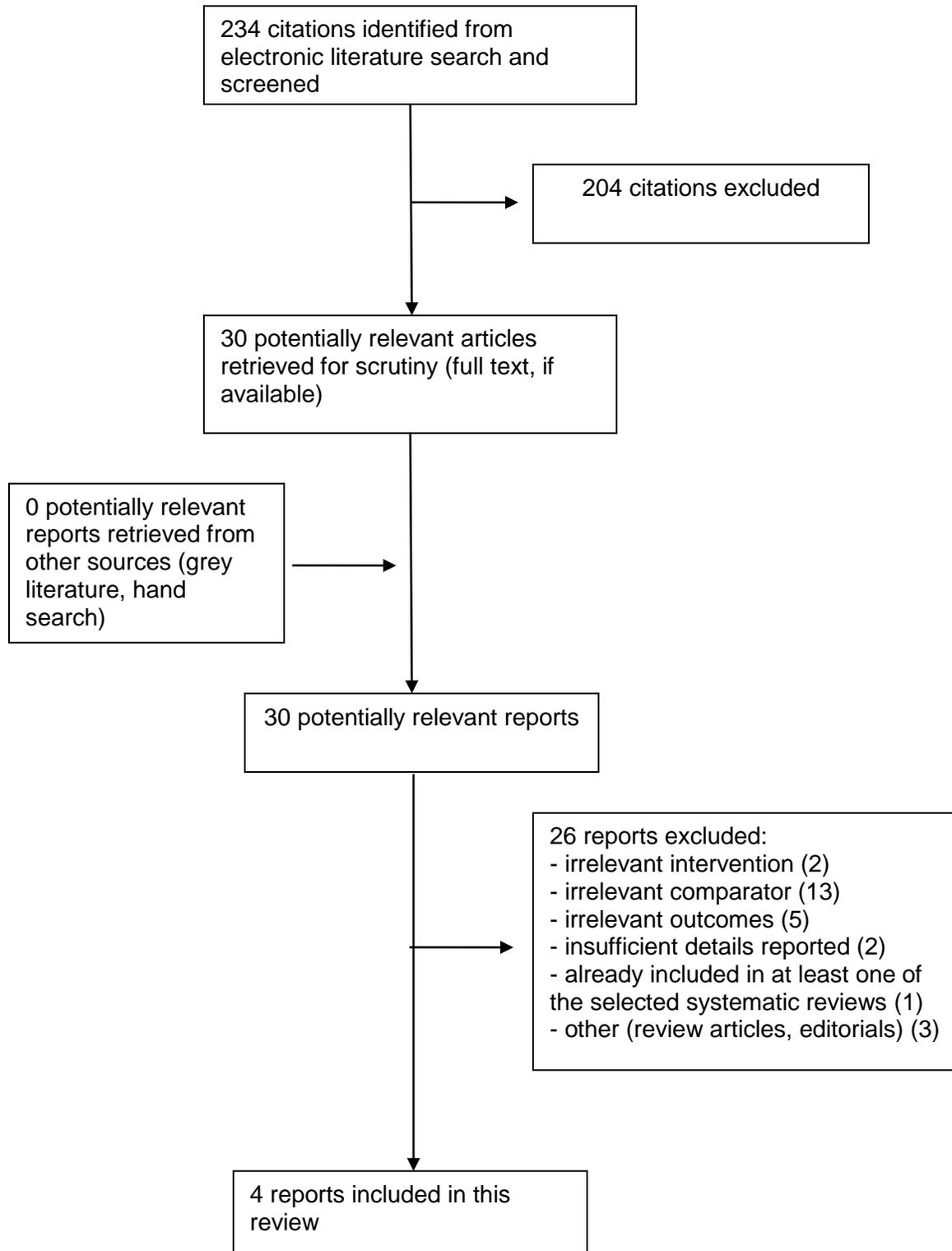
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APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Studies

First Author, Publication Year, Country	Study Design	Patient Characteristics	Intervention	Comparator(s)	Main Outcomes
Christensen, 2012, Denmark ⁸	SR (study designs of the included studies were unclear)	Patients undergoing OAT	POCT	Lab testing, or a reference POCT coagulometer	Precision Accuracy
Al-Ansary, 2011, Saudi Arabia ⁹	SR and MA (included RCTs)	Adult patients with diabetes	POCT	Lab testing	Change in HbA1c
The Medical Advisory Secretariat of MOHLTC, 2009, Canada ¹⁰	HTA (full economic evaluations included in the economic review)	Patients undergoing long-term OAT	POCT (healthcare staff testing, PST, PSM)	Standard lab testing	Cost-effectiveness
Brown, 2007, Canada ¹¹	HTA (full or partial economic evaluations included in the economic review)	Patients undergoing long-term OAT	POCT	Standard lab testing	Incremental measure of the implication of moving from the comparator to the intervention

HTA=health technology assessment; MA=meta-analysis; MOHLTC=Ministry of Health and Long-Term Care (Ontario); OAT=oral anticoagulation therapy; POCT=point-of-care testing; PSM=patient self-managing; PST=patient self-testing; RCT=randomized controlled trial; SR=systematic review; UK=United Kingdom; USA=United States of America

APPENDIX 3: Critical Appraisal of Included Studies

First Author, Publication Year	Strengths	Limitations
Christensen, 2012 ⁸	<ul style="list-style-type: none"> • Research questions and selection criteria were defined and presented • Comprehensive literature search based on pre-defined criteria • Quality assessment on the included studies • Conflict of interest declared 	<ul style="list-style-type: none"> • Only English-language studies were included • Not clear if 2 reviewers performed study selection and data extraction • Lack of list of excluded studies • Insufficient details such as study design and trial characteristics
Al-Ansary, 2011 ⁹	<ul style="list-style-type: none"> • Research questions and selection criteria were defined and presented • 3 independent investigators performed study selection and data collection • Quality assessment on the included studies • Appropriate methods for data synthesis • Conflict of interests declared 	<ul style="list-style-type: none"> • Not clear if there is a limit on language in literature search • Lack of list of excluded studies • Results from meta-analysis were based on 3 studies only, even though 7 were included in this SR
The Medical Advisory Secretariat of MOHLTC, 2009 ¹⁰	<ul style="list-style-type: none"> • Research questions and selection criteria were defined and presented • Sources of effectiveness estimates used were stated • Choice of model used and the key parameters on which it was based were justified • Sensitivity analyses performed • Conflict of interests declared 	<ul style="list-style-type: none"> • Only English-language studies were included • Not clear if two reviewers performed study selection and data extraction • Not clear if quality assessment on the selected studies were conducted
Brown, 2007 ¹¹	<ul style="list-style-type: none"> • Research questions and selection criteria were defined and presented • Comprehensive literature search based on pre-defined criteria without restriction on language • Quality assessment on the included studies • Sources of effectiveness estimated used were stated • Choice of model used and the key parameters on which it was based were justified • Societal perspective was adopted in economic modeling • Sensitivity analyses performed • Conflict of interests declared 	<ul style="list-style-type: none"> • Study selection was conducted by one reviewer • Data extraction was conducted by one reviewer and checked by a second reviewer

MOHLTC=Ministry of Health and Long-Term Care (Ontario)

APPENDIX 4: Main Study Findings and Authors' Conclusions

First Author, Publication Year	Main Study Findings	Authors' Conclusions
Christensen, 2012 ⁸	<p><u>Precision</u> <i>CoaguChek XS</i>: CV 1.4%-5.9% <i>CoaguChek XS</i> (high-quality studies): CV 2.3%-4.0%</p> <p><i>INRatio, ProTime/ProTime 3 and SmartCheck INR System</i>: CV 3.7%-8.4% <i>INRatio, ProTime/ProTime 3 and SmartCheck INR System</i> (high-quality studies): CV not reported</p> <p><u>Accuracy</u> <i>CoaguChek XS</i>: CC 0.81-0.98 <i>CoaguChek XS</i> (high-quality studies): CC 0.94-0.98</p> <p><i>INRatio, ProTime/ProTime 3 and SmartCheck INR System</i>: CC 0.73-0.95 <i>INRatio, ProTime/ProTime 3 and SmartCheck INR System</i> (high-quality studies): CC not reported</p>	<p>“The accuracy of POCT coagulometers seems to be generally acceptable, and they can be used in a clinical setting” (page 251)</p>
Al-Ansary, 2011 ⁹	<p><u>Change in mean HbA1c</u> POCT vs. lab testing: MD -0.09, 95% CI (-0.21, 0.02)</p>	<p>Nonsignificant reduction in HbA1c between POCT and the control group was observed.</p>
The Medical Advisory Secretariat of MOHLTC, 2009 ¹⁰	<p><u>Review of economic literature</u> PST was reported as a cost-saving approach in 2 out of 6 studies; PSM was reported as a cost-saving approach in 2 out of 6 studies; PSM was reported as not cost-effective as usual care in 2 out of 6 studies.</p> <p><u>Primary economic study</u> Total cost per patient (C\$) Standard care: 24k Healthcare staff testing: 19k PST: 20k PSM: 15k</p> <p>Total QALYs per patient Standard care: 3.96 Healthcare staff testing: 4.04 PST: 4.18</p>	<p>“POCT strategies are cost-effective compared to traditional INR laboratory testing; the PSM strategy appears to be the most cost-effective method” (page 68)</p>

First Author, Publication Year	Main Study Findings	Authors' Conclusions
	PSM: 4.59	
Brown, 2007 ¹¹	<p><u>Review of economic literature</u> 6 studies indicated cost-saving that was associated with POCT</p> <p><u>Primary economic study</u> From a publicly funded health care perspective: POCT conducted in anticoagulation clinics vs. conventional lab testing: cost-effective; Self-testing with POCT by patients vs. conventional lab testing: cost per additional QALY gained was C\$57,595</p> <p>From a societal perspective: Self-testing with POCT by patients vs. conventional lab testing: cost-effective</p>	<p>“Compared to lab testing, using PCOT in anticoagulation clinics is cost-saving compared with conventional testing for health care payers. It is also cost effective if society is willing to pay C\$50,000 for a QALY. Self-testing by patients compared to lab testing does not seem to be cost effective from a publicly funded health care perspective.” (page iii)</p>

CC=correlation coefficient; CI=confidence interval; CV=coefficient of variation; MD=mean difference; MOHLTC=Ministry of Health and Long-Term Care (Ontario); POCT=point-of-care testing; PSM=patient self-managing; PST=patient self-testing; QALY=quality-adjusted life-year