■ CADTH Reports

Other Diagnostic Point-of-Care Tests: CADTH Evidence

Reports With Critical Appraisal and Key Messages

Flash Glucose Monitoring Systems in Pediatric Populations With Diabetes (April 2021)

Health Technology Review

Background and Context

Flash glucose monitoring (FGM) is a method of glucose testing where a sensor inserted into the skin continuously measures interstitial glucose levels. It can be used by people with diabetes to inform treatment decisions, such as insulin dosing, as an alternative or complement to blood glucose testing.

Evidence Identified

- Three health technology assessments (that each included a systematic review with or without meta-analysis)
- Five systematic reviews (3 with meta-analysis).
- One randomized controlled trial
- Six non-randomized studies

Key Messages and Findings

- Evidence suggests that FGM may improve quality of life, patient satisfaction, diabetes distress, self-efficacy, and frequency of glucose monitoring compared to self-monitoring blood glucose techniques in pediatric populations with type 1 diabetes.
- Findings related to other outcomes, such as hemoglobin A1C, glucose time in range metrics, and adverse events, were mixed or inconclusive.
- No studies were identified that compared the clinical effectiveness of FGM systems with hypoglycemia, hyperglycemia, or signal loss alarms (e.g., FreeStyle Libre 2) to FGM systems without these features (e.g., FreeStyle Libre) in people of any age with diabetes requiring insulin therapy.

Rapid Testing for the Diagnosis of Pulmonary Tuberculosis and Rifampicin Resistance: A Review of Cost-Effectiveness (February 2021)

Health Technology Review

Background and Context

The Xpert *M. tuberculosis* complex and resistance to rifampicin (MTB/RIF) test is a Health Canada-approved rapid diagnostic test for pulmonary tuberculosis (TB) that uses polymerase chain reaction-based nucleic acid amplification to detect *M. tuberculosis* and rifampin resistance.

This report summarizes the evidence regarding the cost-effectiveness of the Xpert MTB/RIF test compared with smear microscopy in diagnosing TB.

Evidence Identified

- Six economic evaluations

Key Messages and Findings

- Results from the included studies showed that Xpert MTB/RIF testing is a cost-effective option compared with sputum smear microscopy.
- However, the generalizability of the results to the Canadian setting are unclear because of the clinical data source populations, willingness-to-pay thresholds, and assumptions used in the analyses.
- There is a lack of evidence regarding the cost-effectiveness of Xpert MTB/RIF testing compared with mycobacterial cultures or culture-based susceptibility testing.

Rapid and Simultaneous Tuberculosis and Antibiotic Susceptibility Testing for the Diagnosis of Pulmonary Tuberculosis and Rifampicin Resistance: A Review of Diagnostic Accuracy (December 2020)

Summary With Critical Appraisal

Background and Context

The conventional diagnostic approach for individuals with presumptive pulmonary TB includes smear microscopy, followed by the culture-based method to confirm the diagnosis and for drug susceptibility testing. The culture-based method is considered the gold standard. However, it takes 2 to 6 weeks to get the culture results and an additional 3 or more weeks for conventional multi-drug resistance testing. Hence, there is potential for treatment being delayed if waiting for confirmatory culture results.

The Xpert MTB/RIF assay is a relatively new test that is rapid (takes less than 2 hours) and can simultaneously detect *M. tuberculosis* and rifampicin resistance.

Evidence Identified

- Six systematic reviews

Key Messages and Findings

- Three of the systematic reviews reported on the diagnostic accuracy of Xpert compared to smear microscopy status.
- Five of the systematic reviews reported on the diagnostic accuracy of Xpert compared with the mycobacterial culture test.
- All 6 of the systematic reviews reported on the diagnostic accuracy of Xpert for the detection of rifampicin resistance compared to culture-based drug susceptibility testing.
- Details on the comparative sensitivities and specificities can be found in the full CADTH report.

Flash Glucose Monitoring System FreeStyle Libre to Monitor Glycemia in Patients With Diabetes (September 2020)

Health Technology Review and Implementation Advice

Background and Context

The objective of this technology review is to synthesize the key findings of the 2 recent Canadian provincial (Ontario and Quebec) health technology assessment reports on flash glucose monitoring systems (FGMS), including clinical, economic, and budget impact analysis results. Recommendations from jurisdictional committees were also summarized. Members of an ad hoc implementation advice panel considered this information to develop advice on the implementation of the recent recommendations for public funding of FGMS in Canada. This is intended to help facilitate funding discussions for FGMS in jurisdictions that have not commissioned HTAs.

Evidence Identified

- Two Canadian Health Technology Assessments

Key Messages and Findings

- Based on the guidance of Ontario Health Technology Advisory Committee (OHTAC), Health Quality Ontario (HQO), now a part of Ontario Health, recommended publicly funding FGMS for the following 2 groups of patients: persons with type 1 diabetes who experience recurrent hypoglycemia despite frequent self-monitoring of blood glucose (SMBG) and efforts to optimize insulin management, and persons with type 2 diabetes requiring intensive insulin therapy (IIT) – that is, multiple daily injections of insulin or continuous subcutaneous insulin infusion for those who experience recurrent hypoglycemia despite frequent SMBG and efforts to optimize insulin management.

- Institut national d'excellence en santé et en services sociaux (INESSS) evaluated FreeStyle Libre FGMS, and Comité scientifique permanent de l'évaluation des médicaments aux fins d'inscription (CSEMI) recommended to add Freestyle Libre to the list of the prescription drug insurance plan for self-monitoring of glycemia in patients on insulin therapy, provided the economic burden is lessened. If the economic burden of funding Freestyle Libre was not reduced for the province, CSEMI recommended that this FGMS be listed as an exceptional drug product for adults aged 18 years and older who meet the following criteria: IIT, frequent or severe hypoglycemic events, and necessity for blood glucose self-monitoring at least 8 times daily.
- Additional detail, recommendations, and implementation advice is available in the full report.

Natriuretic Peptide Testing for Monitoring of Heart Failure Therapy: A Review of Clinical Effectiveness, Clinical Utility, Cost-Effectiveness, and Guidelines (August 2019)

Summary With Critical Appraisal

Background and Context

In heart failure (HF) patients, natriuretic peptide (NP) levels are elevated. Measurement of NP levels in plasma has been used for diagnosis and prognosis of HF patients, but its role in guiding therapy for patients with HF appears uncertain.

The report reviews the clinical effectiveness, cost-effectiveness, and evidence-based guidelines regarding NP testing for monitoring of HF therapy.

Evidence Identified

- Four systematic reviews
- One economic evaluation
- Two evidence-based guidelines

Key Messages and Findings

- Three of the systematic reviews showed that the between-group differences for NP-guided therapy compared with clinically guided therapy for HF patients were statistically significant with respect to HF-related hospitalization, favouring NP-guided therapy. (However, in 2 of them, the confidence intervals indicated marginal significance.)
- For the other outcomes (all-cause mortality, HF-related mortality, all-cause hospitalization, and quality of life), there were no statistically significant differences.
- Overall, the clinical effectiveness and clinical utility of NP-guided therapy for HF patients remains uncertain.
- One economic evaluation showed that NP-guided therapy appears to be cost-effective for patients who are younger than 75 years of age with reduced ejection fraction (if NP-guided therapy is considered effective).

- Two guidelines suggested that NP-guided therapy may be considered for HF patients younger than 75 years of age (with 1 stating the recommendation was weak and the other not specifying the strength of the recommendation).

Rapid Tests for the Diagnosis of Group A Streptococcal Infection: A Review of Diagnostic Test Accuracy, Clinical Utility, Safety, and Cost-Effectiveness (May 2018)

Peer-Reviewed Summary With Critical Appraisal

Background and Context

Diagnostic tests based on throat culture are generally considered the gold standard for diagnosing group A (GA) streptococcus (strep). However, these culture-based tests are associated with a lag time between sample collection and obtaining test results.

Several non-culture-based, rapid tests for diagnosing GA strep have been developed. These rapid tests are based on immunoassays and more recently on molecular assays. These rapid tests may enable faster diagnosis and hence prevent the inappropriate use of antibiotics and the use of more effective treatment strategies.

Evidence Identified

- Three systematic reviews
- One randomized controlled trial including an economic analysis
- Twenty-three observational studies

Key Messages and Findings

- One randomized controlled trial showed no clear advantage of rapid antigen test over clinical score for management of GA strep infection with respect to duration of symptoms, severity of condition, or antibiotic use. However, 1 observational study comparing antibiotic use before and after the introduction of rapid antigen detection tests showed that there was a reduction in antibiotic use following the introduction of rapid antigen detection tests.
- There was no evidence regarding adverse effects.
- The economic analysis nested in the randomized controlled trial showed that management strategies based on clinical score were more effective in reducing symptoms and less costly than management strategies based on rapid antigen detection tests. However, results of the cost-utility analysis were less clear.
- It appears that, even if throat culture assays are replaced with other assays for the detection of GA strep, it may still be necessary to maintain cultures for antimicrobial susceptibility testing.
- It appears there are no tests that distinguish between GA strep carriers or actual GA strep infection

Fetal Scalp Lactate Testing During Intrapartum Pregnancy with Abnormal Fetal Heart Rate: A Review of Clinical Effectiveness, and Guidelines (March 2018)

Summary With Critical Appraisal

Background and Context

Cardiotocography, or electronic fetal heart rate monitoring, is a non-invasive technique used as a first-line option to assess the intrapartum fetal condition. However, while cardiotocography is thought to have a relatively high negative predictive value (i.e., it provides reliable information in healthy fetuses), a non-reassuring test result may not be the most accurate predictor of fetal status due to the test's high rate of false positives (i.e., the test has a high rate of falsely identifying healthy fetuses as abnormal – as high as 60%).

A common second-line screening method is analysis of fetal scalp blood, which is retrieved by making a small incision in the fetal scalp (during the intrapartum period) and collecting blood with a capillary tube. Chemical examination of the blood is then undertaken to assess either the pH or the lactate concentration, both of which can provide insight into the oxygenation status of the fetus. While there are a wide variety of tools and meters which can be used to estimate the pH or lactate concentration in fetal blood, some clinical studies suggest that lactate meters may offer advantages as they require a smaller volume of blood and less time for analysis.

The purpose of this report was to identify, summarize, and critically appraise the available clinical evidence and guidelines regarding the effectiveness of fetal scalp lactate testing for managing intrapartum pregnancy with abnormal fetal heart rate.

Evidence Identified

- One systematic review with meta-analysis
- Three evidence-based guidelines

Key Messages and Findings

- The authors of the systematic review concluded that the available evidence indicated that fetal scalp lactate testing was more likely to be successful with fewer scalp incisions and the results were available in less time than with pH estimation.
- However, the results of the meta-analysis suggested that lactate and pH tests did not significantly differ from each other for a large number of neonatal outcomes including neonatal encephalopathy, death from congenital abnormalities, Apgar score at 5 minutes, admission to neonatal intensive care unit, umbilical cord pH or base deficit values, metabolic acidemia, number of additional tests performed per fetus to evaluate fetal well-being, mode of birth, and operative birth for non-reassuring fetal status.

- The 3 guidelines each recommended the use of fetal scalp blood sampling for women in labour when there is an abnormal or non-reassuring cardiotocography results. However, the guidelines did not specifically compare the effectiveness of the 2 tests (but 2 of them noted that lactate measurement may provide an easier and more affordable adjunct to continuous electronic fetal monitoring).

Point-of-Care D-Dimer Testing: A Review of Diagnostic Accuracy, Clinical Utility, and Safety (November 2017)

Summary With Critical Appraisal

Background and Context

In patients with low pre-test probability of pulmonary embolism (PE), D-dimer testing becomes an important clinical tool in risk stratifying patients, who require further diagnostic imaging to rule out a PE. Not all health care centres have the capability of timely processing of D-dimer tests in central laboratories. Recently, point-of-care (POC) D-dimer testing has become available.

This report focuses on evidence for the diagnostic accuracy, clinical utility, and safety of POC D-dimer testing in adult patients presenting with symptoms of PE outside of tertiary and quaternary care settings.

Evidence Identified

- One systematic review

Key Messages and Findings

- In adults presenting from the community with symptoms of PE and a low pre-test probability based on the Wells score, a negative POC D-dimer test demonstrated good diagnostic accuracy with high sensitivity and negative predictive value for PE compared to standard care.
- In elderly patients presenting from the community or a nursing home, the sensitivity and negative predictive value were slightly lower.
- There were no studies that met the inclusion criteria to address the safety of POC D-dimer testing.

Increasing Frequency of Self-Monitoring Blood Glucose Test Strips During Pregnancy: A Review of the Clinical and Cost-Effectiveness and Guidelines (April 2017)

Summary With Critical Appraisal

Background and Context

Poor glycemic control in pregestational maternal diabetes and in gestational diabetes may be associated with pregnancy complications such as preeclampsia, neonatal jaundice, and respiratory distress. Self-monitoring of blood glucose (SMBG) is an essential part in diabetes care for achieving glycemic targets and avoiding diabetes-related adverse events. The frequency of SMBG tests required to adequately monitor blood glucose levels depends on the patient circumstances and types of treatment.

Evidence Identified

- Two evidence-based guidelines

Key Messages and Findings

- Two evidence-based guidelines were identified.
- The Diabetes Canada (formerly the Canadian Diabetes Association) guideline recommended that SMBG testing times for pregnant women with diabetes, whether using insulin or not, should depend on individual circumstances and may be performed at least 4 times per day.
- The Endocrine Society guideline recommended SMBG for all pregnant women with diabetes and suggested that testing be performed before and after each meal, at bedtime, and during the night. Assuming a person has 3 meals per day, SMBG should be performed at least 8 times per day according to the Endocrine Society guideline.
- The recommendations on the frequency of SMBG from the included guidelines; however, should be interpreted with caution, as they were derived mainly from low-quality evidence.

CADTH Reports Summarizing Available Literature Without Critical Appraisal

Flash Glucose Monitoring and Continuous Glucose Monitoring for People With Diabetes in Acute Care Settings (April 2021)

Reference List

Evidence Identified

- Three randomized controlled trials and 13 non-randomized studies on clinical effectiveness and accuracy
- One evidence-based guideline

Point-of-Care Testing of International Normalized Ratios for People on Oral Anticoagulants: A Reference List (November 2020)

Reference List

Evidence Identified

- Four primary qualitative studies on patients' perspectives and experiences
- One primary qualitative study on health care providers' perspectives and experiences

Automated versus Manual Blood Pressure and Cardiac Monitors in Prehospital Settings: Clinical Effectiveness and Guidelines (November 2020)

Summary of Abstracts

Evidence Identified

- No clinical effectiveness evidence
- Two evidence-based guidelines

International Normalized Point of Care Testing for Patients on Anticoagulant Therapies: Clinical Utility and Cost-Effectiveness (April 2020)

Summary of Abstracts

Evidence Identified

- Nine non-randomized studies on clinical utility
- No cost-effectiveness evidence

Creatinine and Urea Point of Care Testing for Patients with Suspected Renal Failure: Clinical Utility, Cost-Effectiveness, and Guidelines (April 2020)

Summary of Abstracts

Evidence Identified

- Four non-randomized studies on clinical utility
- No cost-effectiveness evidence
- One evidence-based guideline

Electrolyte Point of Care Testing for Patient with Dehydration or Electrolyte Abnormalities: Clinical Utility, Cost-Effectiveness, and Guidelines (April 2020)

Summary of Abstracts

Evidence Identified

- No clinical evidence
- One economic evaluation
- One evidence-based guideline

Natriuretic Peptide Testing for Perioperative Risk Assessment: Clinical Effectiveness, Cost-Effectiveness, and Guidelines (July 2019)

Summary of Abstracts

Evidence Identified

- One systematic review (with meta-analysis) and 1 non-randomized study
- No cost-effectiveness evidence
- One evidence-based guideline

Infrared Tympanic Thermometers for Measurement of Temperature in Adults and Children: Clinical Effectiveness, Diagnostic Accuracy, and Guidelines (April 2019)

Summary of Abstracts

Evidence Identified

- Two non-randomized studies on clinical effectiveness and diagnostic accuracy
- One evidence-based guideline

Urinary Dipstick Testing for Bladder Cancer Screening: Diagnostic Accuracy, Clinical Effectiveness and Guidelines (April 2019)

Summary of Abstracts

Evidence Identified

- Two non-randomized studies on diagnostic accuracy
- One evidence-based guideline

Point-of-Care Urine Dipstick Testing for Suspected Urinary Tract Infections for Adults: Diagnostic Accuracy (February 2019)

Reference List

Evidence Identified

- One systematic review and 2 non-randomized studies

High Blood Pressure Monitors: Clinical Accuracy and Guidelines (February 2019)

Summary of Abstracts

Evidence Identified

- One meta-analysis
- No evidence-based guidelines

Frequency of Prothrombin Time and International Normalized Ratio Testing: Guidelines (January 2018)

Summary of Abstracts

Evidence Identified

- Two evidence-based guidelines

Point-of-Care Urine Testing for Suspected Urinary Tract Infections in the Emergency Department: Diagnostic Accuracy, Clinical Utility, and Guidelines (December 2017)

Summary of Abstracts

Evidence Identified

- Two systematic reviews (1 with meta-analysis) and 4 non-randomized studies on diagnostic accuracy or clinical utility
- No evidence-based guidelines

Point-of-Care Urine Pregnancy Screening in the Emergency Department: Diagnostic Accuracy, Clinical Utility, and Guidelines (December 2017)

Summary of Abstracts

Evidence Identified

- Three non-randomized studies on diagnostic accuracy or clinical utility
- No evidence-based guidelines

Transcutaneous Bilirubin Measurements in Newborns: Clinical and Cost-Effectiveness, and Guidelines (November 2017)

Summary of Abstracts

Evidence Identified

- One health technology assessment, 1 systematic review with meta-analysis, 1 randomized controlled trial, and 21 non-randomized studies on clinical effectiveness or diagnostic accuracy
- One economic evaluation
- Three evidence-based guidelines

Multiplex Testing for Sexually Transmitted Infections: Diagnostic Accuracy, Clinical Utility, and Cost-Effectiveness (May 2017)

Summary of Abstracts

Evidence Identified

- One systematic review and 38 non-randomized studies

Reports Summarizing the Evidence on Emerging Technologies

Self-Collection of Nose and Throat Swab Samples for SARS-CoV-2 Antigen Testing (June 2022)

Background and Context

The emergence of new variants of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has raised questions about the accuracy of currently available rapid antigen detection tests (RADTs) for the detection of these variants using the currently authorized sampling methods.

Six Canadian provinces and 2 international jurisdictions have formally recommended people swab both their throat and nose when performing a RADT in response to the emergence of the Omicron variant. The evidence used to support these decisions was not clearly reported.

Evidence Identified

- Three preprint, non–peer-reviewed publications on non-randomized studies were identified regarding the diagnostic accuracy and clinical utility of RADTs using dual nasal and throat self-collected sample for suspected COVID-19
- No studies were identified regarding the diagnostic accuracy and clinical utility of RADTs using dual nasal and throat sample collection for suspected COVID-19 in children younger than 16 years

Key Messages and Findings

- Findings from these publications indicate that using self-collected combined nasal plus throat samples, instead of self-collected nasal samples only for RADTs, resulted in greater detection rates without having an impact on true negative rates. Furthermore, combined nasal plus throat sampling is associated with high participant accessibility and tolerability, ease of use, and low incidence of harms (when reported). However, the limitations of these publications (e.g., no–peer-reviewed preprints; dual nasal and throat sampling with swabs approved for nasal sampling only) should be taken into consideration when interpreting these findings.
- As new variants emerge and real-world clinical evaluations are published, regulatory bodies and/or RADT manufacturers could consider reassessing sampling methods, suitable swab types, and testing instructions.

Biomarker-Based Point-of-Care Tests for the Evaluation of Mild Traumatic Brain Injury (September 2021)

Background and Context

Mild traumatic brain injury can have subtle signs and symptoms, yet the underlying neuropathology is complex and involves several neurochemical, structural, and functional changes in the brain. Currently, in patients who present with mild signs and symptoms, neurologic assessment and mental status testing guide the triage decision for an imaging investigation of potential brain lesions.

Ideally, a portable biomarker-based POC test would contribute information to help health care professionals determine the need for imaging in those suspected of having a mild traumatic brain injury and would safely avoid unnecessary radiation exposure in others, while also saving health care resources.

Evidence Identified

- Four studies identified for the BrainScope One device
- One study identified for the i-STAT Alinity device

Key Messages and Findings

- Several biomarker-based POC devices are currently in development; however, the identification of a single optimal biomarker has proven to be quite difficult, and it is likely that a composite of several biomarkers will be required for optimal assessment results.

A Rapid Point-of-Care Test to Differentiate Bacterial From Viral Acute Upper Respiratory Infections (August 2018)

Background and Context

While lab-based testing is the current standard of care, there is currently no gold standard test for differentiating between bacterial and viral respiratory infections.

A POC blood test, FebriDx, may help health care providers identify clinically significant infections, distinguish bacterial from viral infections during the initial primary care office visit, and prescribe antibiotics more judiciously. Note that FebriDx is an add-on test and is not intended to be used as a stand-alone diagnostic test, or to replace other tests.

Evidence Identified

Four studies: 3 looked at diagnostic test accuracy and 1 was a retrospective chart review examining the impact of using FebriDx on patient treatment and antibiotic prescribing

Key Messages and Findings

- Using POC tests to differentiate between bacterial and viral respiratory infections may improve the appropriate prescribing of antibiotics in primary care and contribute to antibiotic stewardship.
- No adverse events were reported in the studies of FebriDx.
- Most of the evidence to date has been in adult populations; more studies are needed in children.
- A recent US study found that the majority of patients with respiratory tract infections in 6 primary care clinics would be willing to have a blood test to help determine whether antibiotic treatment could be avoided.

A Rapid Test for Microbial Identification in Patients With Suspected Sepsis (September 2017)

Background and Context

The FilmArray Blood Culture Identification (FA-BCID) panel is a multiplex polymerase chain reaction-based diagnostic test that can detect 24 sepsis-related pathogens (bacteria and yeast) and 3 antimicrobial resistance genes in patients with suspected sepsis. An initial blood culture is still required, as the FA-BCID panel must be performed on blood cultures that have tested positive (indicating initial microbial growth). The FA-BCID panel can identify specific pathogens from positive blood cultures with a turnaround of approximately 1 hour; this is significantly faster than the time required to grow a full blood culture to identify pathogens.

Evidence Identified

- 22 studies on clinical effectiveness
- No cost-effectiveness studies
- Two systematic reviews looking at rapid tests in general (not FA-BCID specifically)

Key Messages and Findings

- The sensitivity and specificity of the FA-BCID panel are well established for organisms included in the panel; however, its primary limitation from a diagnostic standpoint is an inability to detect other pathogens not included in its panel.
- Used along with antimicrobial stewardship programs, the FA-BCID panel may improve patient outcomes by, for example, reducing the time it takes to receive appropriate antimicrobial therapy and shortening hospital stays.
- No comprehensive economic evaluations were identified.

Point-of-Care Glycated Hemoglobin Testing to Diagnose Type 2 Diabetes (June 2017)

Background and Context

Glycated hemoglobin (A1C) is a blood marker used to monitor glycemic (blood glucose or blood sugar) control in people living with both type 1 diabetes and type 2 diabetes. A1C has advantages over blood glucose testing, as it indicates long-term (90-day) blood glucose control. In addition, because A1C is stable throughout the day, measuring it eliminates the need for people to fast or restrict their diets before testing, and there is low variability within an individual's test results.

Designed for use in a physician's office, a treatment room, or at a bedside, POC A1C analyzers are bench-top instruments that use a finger-prick capillary blood sample. The blood is applied to a test cartridge and the sample is analyzed within several minutes.

Evidence Identified

- One systematic review
- One non-randomized study

Key Messages and Findings

- Many POC A1C testing devices have US regulatory approval for use in monitoring glycemic control in people with diabetes, but as yet, none are cleared by the FDA for the diagnosis of type 2 diabetes.
- The evidence comparing POC A1C devices to laboratory-based testing shows that POC devices performed as well as laboratory devices.
- If point-of-care test systems are approved for diagnosing type 2 diabetes, comparative evidence will be needed to inform purchasing decisions. Quality assurance systems and cost analyses will also be needed.

CADTH offers a range of evidence products and services to meet the needs of decision-makers. These products include reimbursement reviews, health technology reviews, reference lists, horizon scans, and other tailored programs and services. We remain open to creating the products and services that will best meet decision-makers' needs.

For more information about CADTH, visit our website or contact us at

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