CADTH Evidence Driven.

Point-of-Care Testing: **Summary of Evidence** January 2019 Update

Point-of-care testing (POCT) refers to diagnostic tests performed at or near the patient's location by a health care professional or other qualified personnel. This can include tests conducted by patients themselves in the home or other locations (i.e., patient self-testing). POCT may be performed in a variety of settings, such as hospitals, clinics, physician's offices, pharmacies, ambulances, nursing and long-term care facilities, or the patient's residence.

POCT may be advantageous compared with conventional testing because it allows increased staff and patient mobility, portability across community and rural settings, and rapid turnaround time for test results. These factors may expedite decision-making and patient management, and increase efficiency of care.

Environmental Scan

In October 2017, CADTH undertook an Environmental Scan survey to assess POCT in Canada. The primary goal of the project was to identify and analyze evidence and information that could inform how POCT is implemented and managed in jurisdictions across Canada.

Title	*Point-of-Care Testing: An Environmental Scan*
Date	October 2017
Supporting Files	Environmental Scan report

Background

The use of POCT in health care has been growing in recent years and this trend is expected to persist in the future.

Standard of Care

This includes :

- centralized laboratory-based tests
- hospital radiology department transfers (e.g., fixed X-ray, computed tomography, magnetic resonance imaging).

Technology

Questions remain on various issues, such as the reliability, safety, quality, and cost-effectiveness of POCT, and the implications for the health care system of wider POCT adoption. POCT crosses over many different aspects of health care and the technology varies depending on the particular test utilized or studied.

Little is known about current POCT practices and policies implemented across Canadian institutions. The scope of this report includes POCT performed in urgent and emergency care settings (such as in hospitals and ambulances), in primary care settings, and by patients (self-testing).

Evidence Available for Review

One Canadian study was identified that examined POCT practices in a large, tertiary care, academic health care centre in Eastern Ontario (The Ottawa Hospital). Other information presented in the report was gathered from the survey responses received and from consultations with stakeholders.

Key Messages

- Based on feedback from the 16 survey respondents (13 complete responses and three incomplete responses), POCT in Canada is often performed by nurses, which was consistent with the information reported by a Canadian study on POCT implementation in hospital settings.
- POCT is most often performed in emergency and urgent care settings, as well as in the hospital in-patient care settings, and is frequently performed with the intent to reduce turnaround time, increase patient convenience, and provide access to testing in remote or rural areas.
- POCT training and certification appear to vary across institutions, with many designing and implementing their own training programs. The variability in training and certification methods is also supported by the fact that many of the provincial accreditation standards identified designate training as the responsibility of each individual laboratory.
- Canada does not have national standards and guidelines pertaining to laboratory accreditation and POCT; however, most jurisdictions (except for Nunavut, the Northwest Territories, and the Yukon, which

do not have publicly available provincial accreditation standards) have their own clinical laboratory accreditation standards that often encompass POCT.

- Regarding barriers to POCT implementation, survey respondents noted challenges stemming from their institutions' organizational structures, particularly related to authority and accountability for POCT, as well as the lack of departmental buy-in and financial support for POCT connectivity.
- Respondents also identified challenges pertaining to the quality of POCT, such as operators not adhering to proper POCT procedures, and their institutions' lack of resources to carry out quality control and monitor operator proficiency.
- There appears to be jurisdictional interest in expanding and improving support for POCT in Canada but uncertainty remains about the status of these technologies.

CADTH is committed to the ongoing review of the evidence related to POCT. This *January 2019 Update* aims to provide an overview of published CADTH reports on the topic of POCT in the following three categories:

- drug therapy and patient self-monitoring
- diagnostics (lab-based)
- diagnostics (medical imaging).

CADTH evidence bundles on optimizing the use of lab tests and diabetes management provide more evidence-based information, as well.

Drug Therapy and Patient Self-Monitoring

Title	*Point-of-Care Testing of the International Normalized Ratio (INR) for Patients Taking Warfarin or Other Vitamin K Antagonists*
Date	July 2014
Supporting Files	Systematic review, economic analysis, guidance, summary tool

Background

When prescribed oral anticoagulation therapy with warfarin or other vitamin K antagonists to prevent blood clots, patients must be monitored to ensure they are getting the right amount of the medication and are not at risk for bleeding or blood clots.

Standard of Care

The standard method for monitoring this drug therapy is laboratory testing of blood obtained by venipuncture to measure the international normalized ratio (INR).

Technology

The point of care (POC) device used to measure a person's INR is called a coagulometer and it involves putting a sample of whole blood, usually capillary blood from a finger stick, onto a test strip. The results from POC testing are available within three minutes, compared with laboratory testing that ranges from one hour (best-case scenario in an emergency department) to 24 hours (this time frame may not include the transit time required in all cases, especially remote settings). There are three main applications for POC testing:

- patient self-management, which involves self-testing the INR using a POC device and also self-adjusting the dose of anticoagulant medication based on the results, using a predetermined algorithm or protocol
- patient self-testing, with a clinician adjusting the dose of anticoagulant medication based on the results

- clinic-based POC INR testing, in which POC testing is performed in a clinical setting such as a physician's office or anticoagulation clinic.

Evidence Available for Review

CADTH assessed relevant evidence found in six randomized controlled trials (RCTs) and 41 diagnostic accuracy evaluation studies. A cost-utility analysis was conducted using resource utilization related to various INR testing strategies and effectiveness measured in quality-adjusted life-years.

Key Messages

- Point-of-care INR testing with a POC INR device is an accurate alternative to lab INR testing.
- Patient self-management is the most cost-effective option, when feasible.
- Patient self-testing with health care provider dose adjustment may be an option when lab INR testing is difficult.
- Clinic-based POC INR testing requires careful consideration of context and costs.
- Limited data on patient satisfaction suggest a preference for finger stick by POC metres as compared with venous collection by central laboratory methods.

Title	*Optimal Self-Monitoring of Blood Glucose*
Date	2009 and 2016
Supporting Files	Current practice and recommendations report and tools

Background

Self-monitoring of blood glucose (SMBG) is used to collect information about glucose levels. This information can be used to inform appropriate action should levels be outside of the desired range.

Technology

SMBG requires obtaining a small blood sample. The blood sample is applied to a reagent (or blood glucose test strip), and glucose concentration is determined by an electronic blood glucose monitor.

Evidence Available for Review

CADTH assessed relevant evidence found in 12 RCTs, one non-randomized trial, and 18 observational studies. The economic evaluation focused on cost-effectiveness, cost-utility, and cost consequence analysis.

Key Messages

- For people with type 1 or type 2 diabetes using basal-bolus insulin regimens, SMBG should be individualized to guide adjustments in insulin therapy to achieve optimal blood glucose control.
- In adults with type 2 diabetes using basal insulin, SMBG should be individualized, but testing of up to 14 times per week should be sufficient for most patients, at most times.
- Most adults with type 2 diabetes managed on oral antidiabetes drugs do not require routine SMBG. Periodic testing in selected patients (e.g., those with unstable glucose levels, acute illness, pharmacotherapy changes, risk of hypoglycemia with insulin secretagogues like Glyburide) should be linked to specific patient actions (e.g., prevention or management of hypoglycemia, self-directed dosage adjustment).
- Most adults with type 2 diabetes controlled by diet alone should not require routine SMBG.

Title	*Blood Glucose Monitors and Test Strips: An Update*
Date	2013 and 2011
Supporting Files	Summary with critical appraisal and an update of the 2011 report

Background

Diabetes mellitus is a chronic disease characterized by the body's inability to produce enough insulin or to use it properly. Untreated, diabetes results in high levels of glucose in the blood. Over the long term, this can lead to complications including cardiovascular disease, chronic renal failure, peripheral neuropathy, and retinopathy. SMBG is recognized as one approach to improving glycemic control.

Technology

SMBG requires obtaining a small blood sample — usually capillary blood from a finger puncture. The blood sample is applied to a reagent strip (or blood glucose test strip), and the glucose concentration is determined by an electronic monitor. A variety of blood glucose monitors and test strips are available in Canada.

Evidence Available for Review

CADTH assessed relevant evidence found in two diagnostic accuracy studies.

Key Messages

For SMBG in patients with diabetes:

- Five blood glucose monitors available in Canada were reviewed and are clinically accurate.
- No evidence was found on the cost-effectiveness of blood glucose monitors and test strips for patients with diabetes.
- No evidence on glucose monitors or test strip features related to better patient outcomes was found.

Title	*Increasing Frequency of Self-Monitoring Blood Glucose Test Strips During Pregnancy: A Review of the Clinical and Cost-Effectiveness and Guidelines*
Date	April 2017
Supporting Files	Summary with critical appraisal

Background

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.

Technology

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 Available for Review

Two evidence-based guidelines met the inclusion criteria and were included in this report.

Key Messages

- 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 four 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 three meals per day, SMBG should be performed at least eight 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.
- Primary studies are needed to provide direct evidence on the clinical and cost-effectiveness of increasing the frequency of SMBG up to at least eight times a day in pregnant women with pregestational or gestational diabetes and who are on insulin.

Diagnostics (Lab-Based)

Title	*Point of Care Testing Compared to Laboratory Testing for the Assessment of White Blood Cell Counts and Differentials*
Date	October 2013
Supporting Files	Summary with critical appraisal

Background

White blood cell counts and differential counts, or "differentials," are tests that are typically used to diagnose and monitor a variety of conditions such as bacterial or viral infections, inflammation, leukemia, or immune system deficiency (which is a common side effect of chemotherapy). A white blood cell count measures the concentration of white blood cells, while a differential measures the percentage of each of the five types of white blood cells. Both are frequently part of a complete blood cell count workup during a routine health checkup.

Standard of Care

After drawing a blood sample from a patient, white blood cell counts and differentials are performed in central laboratories using blood analyzers.

Technology

POCT technologies are currently being developed with the aim of reducing the turnaround time for receiving blood cell count results and, therefore, allowing for more timely medical decisions to be made in remote sites or in outpatient settings.

Evidence Available for Review

CADTH assessed relevant evidence found in four observational studies and one guideline.

Key Messages

- In general, POCT technologies are as accurate and precise as analyzers in centralized laboratories.
- No studies comparing the clinical or cost-effectiveness of POCT with that of standard laboratory testing were found.

Title	*Three- versus Five-Part Differential Complete Blood Count Testing for Patients in the Emergency Department*
Date	August 2016
Supporting Files	Summary with critical appraisal

Background

White blood cell counts and differential counts, or "differentials," are tests that are typically used to diagnose and monitor a variety of conditions such as bacterial or viral infections, inflammation, leukemia, or immune system deficiency (which is a common side effect of chemotherapy). A white blood cell count measures the concentration of white blood cells, while a differential measures the percentage of each of the five types of white blood cells. Both are frequently part of a complete blood cell count workup during a routine health checkup.

Standard of Care

White blood cell counts and their five subgroups of cell types (often called "differentials") are common clinical measurements. The five-part differentials usually performed in central laboratories are neutrophils, lymphocytes, monocytes, eosinophils and basophils.

Three-part differentials consider granulocytes (neutrophils, eosinophils and basophils together as one group), lymphocytes, and monocytes.

Technology

POC blood analyzers reduce turnaround time (e.g., for patients presenting to the emergency department). More timely medical decisions can be made in remote sites or in outpatient settings with blood taken from a finger stick.

Evidence Available for Review

CADTH assessed relevant evidence found in one diagnostic accuracy study.

Key Messages

- The use of Chempaq XBC in the emergency room setting showed good agreement with laboratory-based analyzer results for the granulocyte and the lymphocyte counts but not for the monocytes.
- There is a potential risk of misdiagnosis for conditions where monocyte counts may be high or low.
- There were no evidence-based guidelines found regarding the use of three-part differentials of complete blood cell count tests for patients presenting to emergency departments.

Title	*Point-of-Care Troponin Testing in Patients with Symptoms Suggestive of Acute Coronary Syndrome*
Date	March 2016
Supporting Files	Systematic review and economic analysis

Background

Cardiac troponin levels in the blood increase when an insufficient blood supply leads to the death of heart cells. Measuring these levels is a sensitive test for the detection of heart muscle damage and is recommended when patients present with symptoms that suggest they may be experiencing a heart attack. However, cardiac troponin levels can be elevated in other non-cardiac conditions, so the results must be taken together with a clinical assessment and electrocardiogram findings before a diagnosis can be made.

Standard of Care

Troponin is typically measured by central laboratory testing; however, central laboratories are not always available — particularly in rural hospitals and remote settings.

Technology

POC cardiac troponin testing has the potential to improve patient care in rural and remote settings, reducing unnecessary and often expensive transfers to hospitals if patients are unlikely to be experiencing acute coronary syndrome, and allowing them to receive care in their community.

POC cardiac troponin tests offer short turnaround times for biomarker detection, typically providing results within 10 to 20 minutes compared with the recommended turnaround time of an hour for central laboratory testing. As a result, POC troponin testing could potentially expedite care in the emergency department, improving patient flow and reducing emergency room congestion.

These POC cardiac troponin test devices can be hand-held, or they can be desktop devices, and some measure an array of biomarkers, including troponin.

Evidence Available for Review

CADTH assessed relevant evidence found in 41 diagnostic accuracy studies (plus five companion reports) and two evidence-based guidelines. The economic evaluation investigated the cost-effectiveness of POC troponin compared with central laboratory testing.

Key Messages

- Use POCT for patients with suspected acute coronary syndrome, myocardial infarction, or unstable angina if immediate access to a central laboratory is not possible.
- Use laboratory troponin testing if a central laboratory is immediately available.

The 2013 CADTH report on high-sensitivity troponin for acute coronary syndrome may also be of interest: *High-Sensitivity Cardiac Troponin for the Rapid Diagnosis of Acute Coronary Syndrome in the Emergency Department* [systematic review, economic analysis and guidance, 2013]

Title	*Frequency of Prothrombin Time and International Normalized Ratio Testing: Guidelines*
Date	January 2018
Supporting Files	Summary of abstracts [not critically appraised]

Background

The research question asked in this assessment was: What are the evidence-based guidelines on testing frequency for prothrombin time and international normalized ratio (PT/INR) testing?

Standard of Care

No standard of care for PT/INR testing was identified as a comparator in this assessment. Frequencies of PT/INR testing vary in clinical practice.

Technology

Prothrombrin time and international normalized ratio (PT/INR) testing, point-of-care or laboratory-based, is the technology under review.

Evidence Available for Review

Two evidence-based guidelines were identified regarding the testing frequency for PT/INR testing. (Note: The information for this summary was taken from the published abstracts and not from a full-text review of the articles.)

Key Messages

- The first guidance document published by NICE National Institute for Health and Care Excellence provided recommendations on two point-of-care coagulometers for patients with atrial fibrillation and heart valve disease. This guideline recommends daily (or every other day) measuring of INR status until it is within the therapeutic range on two consecutive occasions. Once this target is met, the recommendation changes to measuring INR twice weekly for one to two weeks. If INR values remain stable, the guideline states that the testing frequency could be reduced to as little as once every 12 weeks.
- Importantly, the guideline also suggests that INR testing should be done more frequently for patients at risk of overcoagulation or bleeding, or in patients who have problems adhering to treatment.
- The second guideline contains recommendations for the management of outpatient anticoagulation. The recommendations made in this publication were mostly based on the American College of Chest Physicians' evidence-based, clinical practice guidelines, which were published in 2012. For patients on warfarin, this guideline recommends INR measurement at baseline, followed by measurement after two or three doses. Twice weekly testing is then recommended until INR is within the therapeutic range. Once a therapeutic range is reached, the guideline states that INR testing can be reduced to weekly, every other week, and then monthly (if a therapeutic range value is maintained).
- Finally, the guideline suggests that clinicians can consider moving INR testing up to every 12 weeks in patients who are stable and that the frequency of INR monitoring should be increased if a value outside of the therapeutic range is observed.

Title	*Point-of-care versus Central Laboratory Troponin Testing for Diagnosis of Acute Coronary Syndrome in Acute Care Settings*
Date	October 2012
Supporting Files	Summary with critical appraisal

Background

Cardiac troponin levels in the blood increase when an insufficient blood supply leads to the death of heart cells. Measuring these levels is a sensitive test for the detection of heart muscle damage and is recommended when patients present with symptoms that suggest they may be experiencing a heart attack. However, cardiac troponin levels can be elevated in other non-cardiac conditions, so the results must be taken together with a clinical assessment and electrocardiogram findings before a diagnosis can be made.

Standard of Care

Troponin is typically measured by central laboratory testing; however, central laboratories are not always available — particularly in rural hospitals and remote settings.

Technology

POC tests can be administered immediately in the emergency department, shortening turnaround time and allowing for early stage detection of myocardial infarction using troponin assays.

Evidence Available for Review

CADTH assessed relevant evidence found in one randomized control trial, two retrospective studies, and two prospective observational studies.

Key Messages

- The use of POC troponin I testing was found to increase the number of patients with a less than eight-hour length of stay in the emergency department compared with central laboratory testing.
- POC troponin I assays were inferior to central laboratory troponin I assays at predicting acute myocardial infarction, especially when blood samples were taken several hours after hospital admission.
- Central laboratory troponin I assays had better sensitivity and diagnostic accuracy than conventional POC troponin I assays in predicting death by cardiovascular disease.
- POCT may be a useful tool to rule out negative cases in the emergency setting. No evidence was identified regarding the cost-effectiveness of central laboratory troponin testing versus POCT.

Title	*Point-Of-Care D-Dimer Testing: A Review of Diagnostic Accuracy, Clinical Utility, and Safety*
Date	November 2017
Supporting Files	Summary with critical appraisal

Background

Pulmonary embolism (PE) is a common and potentially fatal diagnosis. Most PE results from the development of a blood clot in the deep venous system that travels through the heart and into the pulmonary vasculature.

D-dimers are fibrin degradation products that appear in the blood when the coagulation cascade is active, such as when a clot is present, and may be measured in a qualitative or quantitative manner. As part of a clinical decision-making pathway, D-dimer testing is an important tool in risk stratifying patients. If the D-dimer is elevated (500ng/mL or greater), then diagnostic imaging should be undertaken.

Standard of Care

The most commonly used D-dimer assays are enzyme-linked immunosorbent assays performed on whole blood in a laboratory.

Technology

Not all health care centres have the capability of timely processing D-dimer tests in central laboratories. Recently, POC D-dimer testing has become available.

Evidence Available for Review

CADTH assessed relevant evidence found in one systematic review, which included two prospective cohort studies evaluating the diagnostic accuracy and clinical utility of POC D-dimer testing for adults who presented to primary care from either the community or nursing homes with symptoms suggestive of PE. There were no studies that met the inclusion criteria to address the safety of POC D-dimer testing.

Key Messages

- The findings suggest that POC D-dimer testing may be a reasonable approach to assist clinicians in determining which community-dwelling patients do not require further diagnostic testing in the form of imaging (i.e., ventilation/perfusion lung scan or computed tomography pulmonary angiography) as part of the workup for diagnosing PE when they present to primary care with symptoms suggestive of PE.

POC D-dimer testing provided good diagnostic accuracy with high sensitivity and high negative predictive value for PE compared to standard care.

- Failures were defined as the subsequent diagnosis of PE within three months' follow-up in participants who had a negative POC D-dimer test result. Failure rates (i.e., false-negative) in participants with a Wells score of 4 or less was 1.5% in one study and 5.9% in the second study.
- In centres where a central laboratory or diagnostic imaging services are unavailable, POC D-dimer testing has the potential to prevent unnecessary patient transfers between centres and unnecessary exposure to radiation associated with diagnostic imaging. The POC D-dimer test used provided a qualitative result based on a single break point value. As D-dimer cut-off values may change with age, older individuals may require the use of either a quantitative POC D-dimer assay or a qualitative POC test with age-dependent results. POC D-dimer testing may not be appropriate in an older patient population, especially those who reside in nursing homes.

Title	*Rapid Tests for the Diagnosis of Group A Streptococcal Infection: A Review of Diagnostic Test Accuracy, Clinical Utility, Safety, and Cost-Effectiveness*
Date	May 2018
Supporting Files	Peer-reviewed summary with critical appraisal

Background

Accurate and rapid diagnosis of group A (GA) streptococcus (strep) is important, as there is a possibility that throat and skin infections could lead to severe life-threatening, invasive conditions, as well as post infection immune-mediated complications if left untreated.

It is difficult to distinguish between GA strep infections and viral infections. Antibiotics are useful to treat pharyngitis from bacterial infection but not viral infection.

Standard of Care

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

Technology

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.

Molecular assays are based on methods such as DNA probes, polymerase chain reaction, and fluorescence in situ hybridization. There is a perception that the use of these rapid tests may enable faster diagnosis and hence prevent the inappropriate use of antibiotics and the use of more effective treatment strategies.

Evidence Available for Review

CADTH assessed relevant evidence found in three systematic reviews, one RCT including an economic analysis, and 23 observational studies, which covered a mixed population of both adults and children.

Key Messages

- One pragmatic, adaptive RCT 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, one 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.

- No evidence regarding any adverse effects associated with the tests was identified.
- One economic analysis that was nested in the RCT showed that management strategies based on clinical score was 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 should be noted that the success of a test is dependent on several factors. Some factors that may affect rapid antigen detection tests results include the type of test kit used, the expertise of the personnel performing the test, the method of specimen collection, the severity of the patient's disease, and the prevalence of GA strep. Careful sampling, which is crucial for the tests to produce accurate results, is often overlooked in the clinical units.
- It appears that, even if throat culture assays are replaced with other assays for detecting GA strep, it may still be necessary to maintain cultures for antimicrobial susceptibility testing.
- It appears there are no tests to distinguish between GA strep carriers or actual GA strep infection.

Title	*Point-of-Care Testing for Influenza*
Date	November 2016
Supporting Files	CADTH Issues in Emerging Health Technologies; Issue 149

Background

Influenza is a highly contagious respiratory infection caused, in most cases, by the influenza A or influenza B viruses. The US Centers for Disease Control and Prevention, or CDC, suggest that the rapid diagnosis of influenza may help clinicians decide whether to prescribe antiviral therapy to patients. It could also help to determine the cause of respiratory outbreaks in institutions, particularly in settings such as nursing homes, hospitals, or schools.

Standard of Care

The conventional method of testing for influenza, such as the reverse transcription-polymerase chain reaction (RT-PCR) technique, is a nucleic acid amplification method that detects the virus's ribonucleic acid. This is a laboratory-based test requiring viral cultural results that can take one to 14 days.

Technology

Because of the considerable time, equipment, and facilities required to test for influenza, a market has emerged for quick (results in less than 30 minutes) POC tests. Many of these rapid tests use viral antigen detection with antibodies to determine the presence of influenza infection, but this rapid testing method is not as sensitive as RT-PCR. As well, negative results cannot rule out influenza infection and should not be used to withhold appropriate treatment. Now, newer rapid RT-PCR tests, which aim to address some of the limitations of existing tests, are becoming available. One of these tests is the cobas Liat System.

The cobas Liat System (Roche Diagnostics, Laval, Quebec) is a rapid POC, RT-PCR test device that can be used to diagnose influenza infection. The system consists of a small, bench-top analyzer and a pencil-sized assay tube. It was originally developed by iQuum and acquired by Roche in 2014.

A nasopharyngeal swab is used to collect a respiratory secretion sample from patients with suspected influenza. The sample is then transferred by pipette into the single-use assay tube and loaded into the analyzer, where it is compressed at different points and times, releasing reagents (or blood glucose test strips) and moving the sample from one segment of the tube to another. The presence or absence of influenza A and influenza B is determined using an established nucleic acid assay that detects viral ribonucleic acid using RT-PCR. Results are reported in approximately 20 minutes.

Evidence Available for Review

CADTH assessed relevant evidence found in seven studies evaluating the cobas Liat System's ability to detect influenza A and influenza B. Four of these studies were available only as a conference abstract or poster presentation. Two studies were funded by the manufacturer, one was independently initiated, and four did not state a source of funding. The studies included a mixture of fresh, prospectively analyzed samples, and frozen, retrospectively analyzed samples. All seven studies compared the cobas Liat System to commercial RT-PCR test kits or conventional laboratory RT-PCR tests, and two studies also compared the cobas Liat System to viral culture. One study included a comparison to a rapid antigen test and one study compared the cobas Liat System to another rapid RT-PCR test, the Alere i. An additional study begun by the previous manufacturer of the cobas Liat System was also identified but data from this study have not been published.

CADTH found no published evidence on the clinical effectiveness of POCT for infectious diseases by pharmacists; however, this collaboration between physicians and pharmacists may result in a more appropriate use of antivirals and reduce the number of patients who seek care from a physician when they only require symptom relief.

Key Messages

- The cobas Liat System is one of a new kind of rapid RT-PCR test for influenza that may provide greater diagnostic performance than existing rapid antigen tests and other rapid RT-PCR tests. It may be as effective as gold standard (lab-based) methods.
- The available evidence on current rapid antigen tests suggests that these kinds of tests may reduce health care costs and improve patient care through a more appropriate use of antibiotic and antiviral medications. These tests may also improve access to testing outside of traditional laboratory settings. However, further studies and Canadian cost- effectiveness studies of the cobas Liat System are needed to determine how this test may affect patient care and health care costs.
- There is limited evidence comparing the cobas Liat System with other rapid influenza detection tests.
- There is limited evidence for using rapid RT-PCR tests outside a laboratory setting.

Title	*Point-of-Care Urine Pregnancy Screening in the Emergency Department: Diagnostic Accuracy, Clinical Utility, and Guidelines*
Date	December 2017
Supporting Files	Summary of abstracts [not critically appraised]

Background

The appearance of human chorionic gonadotropin (hCG) in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

Standard of Care

The tests generally used are blood serum pregnancy tests (human chorionic gonadotropin laboratory results) and urine pregnancy tests (human chorionic gonadotropin laboratory results).

Technology

POC urine hCG screening devices for the detection of pregnancy is the technology of interest.

Evidence Available for Review

Three non-randomized studies were identified regarding the diagnostic accuracy or clinical utility of POC urine pregnancy screens for patients presenting to the emergency department. (Note: The information for this summary was taken from the published abstracts and not from a full-text review of the articles.)

Key Messages

- The authors of one study determined that false-negative results were observed in many of the currently available devices and this represents a larger public health issue that needs to be addressed.
- Investigators of another study were unable to confirm the accuracy of the test for the detection or exclusion of abnormal first-trimester pregnancies.
- The authors of the last study included in this summary concluded that their institution's false-negative rate was unacceptably high using the OSOM hCG Combo Test.

Title	*Multiplex Testing for Sexually Transmitted Infections: Diagnostic Accuracy, Clinical Utility, and Cost-Effectiveness*
Date	May 2017
Supporting Files	Summary of abstracts [not critically appraised]

Background

The consequences of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* can be serious.

Standard of Care

This is generally a reference standard and can be nucleic amplification acid or PCR testing.

Technology

Multiplexed POCT is the simultaneous on-site quantification of various analytes from a single sample (e.g., blood, plasma, or urine).

Evidence Available for Review

One systematic review and 38 non-randomized studies were identified regarding multiplex testing for sexually transmitted infections. (Note: The information for this summary was taken from the published abstracts and not from a full-text review of the articles.)

Key Messages

- Twelve studies used Anyplex systems (either HPV or STI-7) for multiplex testing of clinical samples. One study used BD Max CT/GC/TV, one study used FilmArray, two studies used Bio-Rad Dx, two studies used AmpliSens systems, and one study used the cobas 4800 System.
- The majority of studies tested for common sexually transmitted diseases such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. HPV (high-7risk and other genotypes), HIV, and hepatitis were also commonly tested for using multiplex testing and assays.
- Sensitivities and specificities of multiplex testing commonly exceeded 90%.
- The majority of the authors of studies concluded that multiplex testing has a comparable performance level to their chosen comparator and describe multiplex testing as a feasible and appropriate alternative to currently used testing methods for sexually transmitted diseases.

Title	*Point-of-Care Urine Testing for Suspected Urinary Tract Infections in the Emergency Department: Diagnostic Accuracy, Clinical Utility, and Guidelines*
Date	December 2017
Supporting Files	Summary of abstracts [not critically appraised]

Background

Urinary tract infections (UTIs) are common emergency department diagnoses. Because a urine culture, part of the gold standard for diagnosing a UTI, is usually not available for 24 to 48 hours after an emergency department visit, diagnosis and treatment decisions are based on symptoms, physical findings, and other laboratory results, potentially leading to overutilization of antibiotics, antibiotic resistance, and delayed treatment.

Standard of Care

Urine cultures from laboratory-based testing are the gold standard.

Technology

Point-of-care urine dipstick testing is commonly used.

Evidence Available for Review

Two systematic reviews (one with meta-analysis) and four non-randomized studies were identified regarding the diagnostic accuracy or clinical utility of POC urine testing for patients presenting to the emergency department with suspected UTIs. (Note: The information for this summary was taken from the published abstracts and not from a full-text review of the articles.)

Key Messages

- Among the publications identified, there were varied conclusions on the diagnostic accuracy or clinical utility of POC urine testing in the emergency department.
- One systematic review suggested that POC urinalysis can provide sufficient accuracy in ruling out UTIs in low-risk adult females.
- A second systematic review with meta-analysis concluded that rapid urine tests, including dipstick tests, were not sufficiently sensitive to identify all children with UTIs and cannot replace laboratory urine cultures. However, the authors did suggest that a positive dipstick test should be considered accurate if leucocyte esterase or nitrite was positive.
- Three of the four non-randomized studies concluded that POC urine dipstick tests provide high sensitivity and showed promising results.

Title	*Transcutaneous Bilirubin Measurements in Newborns: Clinical and Cost-Effectiveness, and Guidelines*
Date	November 2017
Supporting Files	Summary of abstracts [not critically appraised]

Background

Hyperbilirubinemia, an elevated level of bilirubin in the blood, and the jaundice, or yellowing of the skin, that almost always accompanies it, are common in the first week of life, occurring in almost 60% of term newborns. Left unchecked, elevated bilirubin levels can progress to critical hyperbilirubinemia, a condition that, although uncommon, can cause long-term, irreversible, debilitating, and sometimes devastating, neurological impairment and, in rare cases, death.

The goal of screening for hyperbilirubinemia is to promote earlier identification and treatment to avoid severe or critical hyperbilirubinemia and kernicterus, while at the same time preventing the overtreatment of newborns whose bilirubin levels will never reach a critical level and will resolve without treatment.

Standard of Care

The standard of care is serum bilirubin measurements.

Technology

Transcutaneous bilirubin measurement is a non-invasive method for the estimation of serum bilirubin using a hand-held electronic device that measures the amount of bilirubin in the skin and subcutaneous tissues. The transcutaneous bilirubin (TcB) measurements and gestational age are used by the physician or nurse to assign a risk of clinically significant hyperbilirubinemia and to determine the need for a confirmatory serum bilirubin test.

Evidence Available for Review

One health technology assessment report, one systematic review with meta-analysis, one RCT, 21 non-randomized studies, and one economic evaluation were identified regarding the clinical effectiveness, diagnostic accuracy, or cost-effectiveness of TcB measurements in well newborns. Additionally, three evidence-based guidelines were identified. The information for this summary was taken from the published abstracts and not from a full-text review of the articles.

Key Messages

- The health technology assessment concluded that TcB was a safe screening tool for the detection of hyperbilirubinemia but could not be considered as a replacement for serum bilirubin determinations.
- The systematic review revealed no significant differences between TcB and total serum bilirubin nomograms, suggesting either can be used to identify subsequent significant hyperbilirubinemia.
- The conclusions made by the authors of the individual studies varied greatly, as 15 suggested TcB measurements were well-correlated to serum bilirubin measurements or provided clinical benefit, while seven studies concluded TcB tended to over- or underestimate serum bilirubin.
- Three evidence-based guidelines address the use of TcB measurements in well newborns. Nice National Institute for Health and Care Excellence recommends TcB for infants older than 24 hours, with a gestational age of 35 weeks or more, and specifies that the bilirubin level should be checked by serum bilirubin if the TcB result is greater than 250 μmol/L.
- The second guideline states that TcB may be used in the assessment of neonatal jaundice, as well as providing information on the treatment and prevention of neonatal jaundice.

- The third guideline made a weak recommendation to support screening for hyperbilirubinemia in newborn infants using TcB measurement, early serum bilirubin measurements, or a combination of these methods to prevent severe complications.

Title	*Channels for the Diagnosis of Obstructive Sleep Apnea: Validity, Diagnostic Accuracy, and Guidelines*
Date	September 2015
Supporting Files	Summary of abstracts [not critically appraised]

Background

Obstructive sleep apnea (OSA) is a common disorder in which the upper airway is partially or fully obstructed by soft tissue during sleep. OSA interferes with breathing, resulting in disrupted sleep.

Standard of Care

Lab-based sleep studies are the standard of care.

Technology

Portable testing devices that use three or four channels are used.

Evidence Available for Review

One evidence-based guideline was identified regarding the appropriate channels and appropriate number of channels for the diagnosis of sleep apnea. (Note: The information for this summary was taken from the published abstracts and not from a full-text review of the articles.)

Key Messages

- The Portable Monitoring Task Force of the American Academy of Sleep Medicine published a guideline in 2007 regarding the use of unattended portable monitors for the diagnosis of OSA in adults.
- The guideline recommends that portable monitoring devices must record three channels (airflow, respiratory effort, and blood oxygenation), at a minimum, for the diagnosis of OSA.
- No relevant evidence was identified regarding the validity and diagnostic accuracy of portable testing devices that use three channels versus four channels, or any combination of oxygenation, nasal pressure, heart rate, pulmonary effort, or body position, as measured by portable three-channel or four-channel devices for the diagnosis of sleep apnea; therefore, no summary can be provided.

Title	*Urgent, Non-Screening Fecal Occult Blood Testing for Patients with Suspected Gastrointestinal Bleeding: A Review of Clinical Effectiveness and Guidelines*
Date	January 2017
Supporting Files	Summary with critical appraisal

Background

Gastrointestinal (GI) bleeding can be a common cause of hospitalization, particularly in elderly patients. GI bleeding can be overt (where the patient and physician can detect the presence of blood without testing), occult (where there are symptoms of bleeding such as anemia but a test is needed to confirm bleeding), or obscure (where the bleeding or source of bleeding is not identified despite invasive testing). Occult bleeding is often caused by colorectal cancer (CRC) lesions, whereas other bleeding could be caused by small bowel diseases or upper GI conditions.

Standard of Care

One commonly accepted method to screen for CRC is the fecal occult blood test (FOBT). FOBT may be guaiac-based (gFOBT) or immunochemical (iFOBT or FIT).

Technology

Immunochemical FOBT is used and can be performed as a point of care test or in the lab.

Evidence Available for Review

Four cohort studies were included (three were retrospective cohorts and in one study it was not clear if the study was retrospective or prospective).

Key Messages

- Three of the four included studies found that patients with a positive FOBT were more likely to be referred for further GI follow-up, and one study found a decrease in the number of endoscopic procedures following the discontinuation of FOBT.
- None of the studies measured patient health outcomes and it is therefore unknown if the testing had any impact on health status.
- The authors of the included studies came to the conclusions that FOBT may not influence further diagnosis or clinical decision-making, may not have a positive impact on clinical management, and seems to be used inappropriately in some hospitals — particularly with pediatric patients.
- Despite being hospitalized and having diet and medication regimens more likely to be restricted, FOBT preparation protocols may still not be followed, making FOBT results potentially unreliable.
- No clinical evidence regarding immunochemical-based FOBT was identified and no relevant evidence-based guidelines regarding the use of urgent, non-screening FOBT were identified.

Title	*Point-of-Care Glycated Hemoglobin Testing to Diagnose Type 2 Diabetes*
Date	June 2017
Supporting Files	CADTH Issues in Emerging Health Technologies; Issue 156

Background

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.

Standard of Care

Lab-based A1C testing, the most widely accepted tests for the diagnosis of type 2 diabetes, are fasting plasma glucose and the oral glucose tolerance test, although the oral glucose tolerance test has fallen out of favour because of its inconvenience, high cost, and poor reproducibility.

Technology

Designed for use in a physician's office, a treatment room, or at a bedside, point-of-care 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 Available for Review

The evidence on use of the Alere Afinion system for the diagnosis of diabetes comes from two studies: a UK systematic review from the University of Oxford, and an observational study from Norway.

Key Messages

- Many POC A1C testing devices have US regulatory approval for use in monitoring glycemic control in people with diabetes, but, as yet, none have been 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 A1C 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.

Title	*Viscoelastometric Point-of-Care Testing for Vascular Surgery and Obstetrics*
Date	January 2016
Supporting Files	Summary with critical appraisal

Background

High blood losses are associated with a marked rise in mortality. Bleeding is a potential complication of all invasive medical procedures, such as surgery, and the risk of bleeding is proportional to the size and complexity of the procedure being performed. For example, in complex vascular surgery, such as that of the aortic arch, bleeding complications are still one of the leading causes of death.

In addition, obstetric hemorrhage remains a potentially preventable leading cause of maternal death throughout the world and has been estimated to cause 13% to 34% of all cases of maternal death, particularly in low-resource countries. An increasing trend in the incidence of postpartum hemorrhage (i.e., excessive blood losses after childbirth) has also been noted in high-resource countries.

Standard of Care

Centrally-conducted standard laboratory tests, which usually take between 40 minutes and 90 minutes to provide results, are standard of care.

Technology

Viscoelastometric POC testing is used to determine whether bleeding is a result of coagulopathy (i.e., an impairment of the blood's ability to clot) or other factors (e.g., surgical bleeds) — mainly in people undergoing major surgery or in need of emergency control of bleeding caused by postpartum hemorrhage.

Rotational thromboelastometry (ROTEM) and thromboelastography (TEG) are two viscoelastometric POCT devices that, through global tests of hemostasis on whole blood, assess platelet function and coagulation. Abnormal ROTEM or TEG test results indicate coagulopathy.

Evidence Available for Review

CADTH assessed relevant evidence found in one RCT and two non-randomized controlled studies.

Key Messages

- Compared with centrally-conducted standard laboratory tests, the use of the ROTEM- or TEG-guided protocol resulted in significant reductions in the transfusion of some blood products, and the administration of some coagulation factors were reported for patients undergoing aortic surgery.
- No significant differences between the ROTEM and standard care groups were reported in the proportions of patients needing massive transfusion or re-exploration for bleeding or blood losses in the first 12 and 24 post-operative hours.
- It is uncertain whether the study sample sizes had sufficient ability to detect a real difference in outcomes and if their findings are generalizable to Canadian patients and settings.

Title	*Point of Care Tests for Infectious Diseases*
Date	March 2016
Supporting Files	Summary with critical appraisal

Background

With nearly 50,000 new HIV infections and 12 million clinical centre visits for acute pharyngitis in the US each year, 1% of the total Canadian population is antibody-positive for hepatitis. More than 7,700 hospitalizations with 591 deaths in Canada were due to influenza in 2014-2015. With these kinds of statistics, community pharmacies — with their relative accessibility and affordability — can be practical and appealing venues for screening for global infectious diseases.

Standard of Care

Lab-based testing is the standard of care.

Technology

Included are over-the-counter POC testing for patients self-testing or pharmacists testing for HIV, hepatitis C, influenza, and streptococcal infections. To identify antibodies for HIV and hepatitis C infections, a rapid antibody test (e.g., OraQuick) is available for POCT. For influenza A and B infections, and streptococcal infection, a rapid antigen diagnostic test (e.g., QuickVue) can be used as a POC diagnostic test.

Evidence Available for Review

CADTH assessed relevant evidence found in two systematic reviews with meta-analysis, one diagnostic accuracy study, and one cost study.

Key Messages

- POC tests provide a reliable diagnostic strategy for hepatitis C virus and group A streptococcal pharyngitis infections, but performance may vary among different POC tests.
- Findings from one trial showed that POCT can be a useful tool for influenza A and B infections, but its low sensitivity suggests that a negative POC test needs confirmation.
- For patient self-testing or pharmacist testing for HIV, hepatitis C, influenza, or streptococcal infections, there was no evidence found on the clinical effectiveness, or evidence-based guidelines compared with conventional testing in a laboratory.
- The costs — per test, per person — were similar between POC tests and laboratory-based assays.

Title	*Serum IgM and Molecular Tests for Mycoplasma pneumoniae Detection*
Date	November 2015
Supporting Files	Summary with critical appraisal

Background

Mycoplasma pneumoniae (*M. pneumoniae*) is a bacterium responsible for lower respiratory tract infections, including community-acquired pneumonia.

Standard of Care

Serum IgM testing and molecular tests such as polymerase chain reaction are two of the available laboratory methods for the diagnosis of acute *M. pneumoniae* infection.

Technology

LAMP assay is a single, point-of-care molecular test for *M. pneumoniae*.

Evidence Available for Review

CADTH assessed relevant evidence found in six diagnostic test accuracy studies and one evidence-based guideline.

Key Messages

- Variable results for the diagnostic accuracy of serum IgM tests and molecular tests were reported.
- The evidence-based guideline produced by the British Thoracic Society recommends acute and convalescent serology for the diagnosis of *M. pneumoniae*, based on some clinical trial evidence; however, IgM tests are not discussed in more detail.
- No evidence was identified regarding the clinical utility or cost-effectiveness of serum IgM tests compared with molecular tests for the diagnosis of *M. pneumoniae*.
- It is unclear whether the preferential use of an IgM or molecular test for the detection of *M. pneumoniae* in particular clinical situations (including in an adult population) would directly lead to improved patient or cost outcomes.
- A conservative approach may be to use both serology and molecular tests to maximize diagnostic accuracy.

Title	*A Rapid Point-of-Care Test to Differentiate Bacterial From Viral Acute Upper Respiratory Infections*
Date	August 2018
Supporting Files	Health Technology Update; Issue 21

Background

Acute upper respiratory infections — which include the common cold, rhinosinusitis, pharyngitis, and bronchitis — are a common reason for primary care visits. Patients with bacterial and viral upper respiratory infections may have similar symptoms (e.g., fever, sore throat, or cough), making clinical diagnosis and management difficult.

Most upper respiratory infections are caused by viruses, and most will resolve without treatment. But for some patients with bacterial infections, such as group A ***Streptococcus***, antibiotics may be needed. Antibiotics are not recommended for viral infections yet these are often prescribed for respiratory infections for various reasons, including the difficulty in making a diagnosis based on clinical symptoms alone and the delay in getting the results of more definitive laboratory tests.

Standard of Care

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.

Technology

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. FebriDx is an add-on test and is not intended to be used as a stand-alone diagnostic test, or to replace other tests. Rather, it is to be used in combination with clinical assessments and other diagnostic assessments, as needed. FebriDx is a single-use, finger stick blood test that provides results in 10 minutes. The immunoassay identifies two proteins (biomarkers) in the blood that are elevated as part of the body's immune response to infection.

Evidence Available for Review

Four studies of the FebriDx test were identified. This includes three US diagnostic test accuracy studies that looked at the agreement between FebriDx and various reference standard tests, as well as test sensitivity, specificity, and positive and negative predictive value.

One UK retrospective chart review studied the impact of using FebriDx on patient management and antibiotic prescribing.

In addition, a July 2017 briefing by NICE in the UK concluded that "… there was very limited evidence in terms of quantity and quality to assess the FebriDx test." This brief was published before the 2018 US, and the 2017 US and UK, study results were available.

Key Messages

- No clinical adverse events were reported in the studies of FebriDx.
- Most of the evidence to date has been in adult populations; more studies in children are needed.
- 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.
- A recent US study found that the majority of patients with respiratory tract infections in six primary care clinics would be willing to have a blood test to help determine whether antibiotic treatment could be avoided.

Diagnostics (Medical Imaging)

Title	*Portable Ultrasound Devices in the Pre-Hospital Setting*
Date	May 2015
Supporting Files	Summary with critical appraisal

Background

Portable ultrasound can assist in treating patients in critical conditions.

Standard of Care

Fixed ultrasound is the standard of care.

Technology

Portable ultrasound devices — also referred to as POC ultrasound (POCUS) — mobile ultrasound, bedside ultrasound, and encompassing specific procedures such as focused assessment with sonography for trauma, comprise a range of technologies including hand-held devices, conventional mobile bedside devices, and other devices with mobility.

Evidence Available for Review

CADTH assessed relevant evidence found in two systematic reviews and one non-randomized study (retrospective chart review).

Key Messages

- Pre-hospital portable ultrasound use for a variety of clinical applications may improve the patient care process.
- There was insufficient evidence directly evaluating the clinical benefits of portable ultrasound regarding direct patient outcomes.

Title	*Computed Tomography Imaging for the Diagnosis of Renal Colic*
Date	November 2014
Supporting Files	Summary with critical appraisal

Background

The term renal colic is used to describe the severe pain caused when kidney stones have moved from the kidneys into the ureter (a tube that goes from the kidney to the bladder). This pain is often felt in the side and back. But when a patient visits the emergency department with severe side and back pain, renal colic is only one possible diagnosis.

Standard of Care

Computed tomography (CT) is considered the standard of care.

Technology

There are alternatives to CT that can minimize or avoid radiation. For example, portable ultrasound uses high-frequency sound waves to produce images of structures inside the body. These technologies may not be as accurate as standard CT when kidney stones are small.

Evidence Available for Review

CADTH assessed relevant evidence found from one RCT.

Key Messages

- Patients undergoing CT and portable ultrasound experience similar complication rates from delayed or missed diagnoses of renal colic.
- No evidence was found on the cost-effectiveness of using CT compared with portable ultrasound to diagnose renal colic in an emergency setting.

Title	*Mobile Stroke Units for Prehospital Care of Ischemic Stroke*
Date	June 2017
Supporting Files	Issues in Emerging Health Technologies

Background

Stroke is a condition caused when blood vessels in the brain become blocked or rupture, preventing oxygen and nutrient-rich blood from reaching brain cells. Stroke is a leading cause of death and disability in Canada, and early diagnosis and treatment are essential to improving patient outcomes.

Standard of Care

This includes paramedics to transport people with suspected stroke to hospital, with a handover to emergency department. Neuroimaging with non-contrast CT must be done for any patient with suspected stroke.

Technology

Mobile stroke units are similar to ambulances but are equipped with a portable CT scanner and specially trained staff for the rapid diagnosis and treatment of ischemic stroke. Other features of mobile stroke units vary from region to region and include telestroke equipment, POC laboratories, thrombolytic drugs, and standard emergency response equipment, as in a regular ambulance.

Evidence Available for Review

Two RCTs of mobile stroke unit models in Germany (cities of Saarland and Berlin) were reported in the literature. Also found were additional observational studies, case studies, and cost studies from Europe and the US.

Key Messages

- Currently, there is no published evidence on the use of mobile stroke units in Canada, but research from other countries indicates that these units may allow earlier treatment with thrombolytic medicines for people with acute ischemic stroke.
- Mobile stroke units do not pose additional safety risks to patients.
- There is limited evidence that mobile stroke units can improve functional outcomes, and further research is underway.
- There is also limited evidence about how staffing models and the distances that mobile stroke units must travel to provide care impact patient outcomes.
- Additional research is needed to determine if mobile stroke units will be cost-effective in Canadian health care settings and how they might impact care in locations where patients are separated by large distances from centres that provide specialty stroke care.

Title	*Portable Ultrasound Devices Use by Non-Radiologists: Clinical Evidence and Guidelines*
Date	March 2016
Supporting Files	Summary of abstracts [not critically appraised]

Background

The patient population studied was those with musculoskeletal conditions, such as rotator cuff and ligament injury, and other soft tissue injuries.

Standard of Care

Magnetic resonance imaging or fixed ultrasound is the standard of care.

Technology

Portable ultrasound devices was the technology studied.

Evidence Available for Review

Two non-randomized studies were identified regarding the use of portable ultrasound by non-radiologists for the assessment and management of patients with musculoskeletal conditions. (Note: The information for this summary was taken from the published abstracts and not from a full-text review of the articles.)

Key Messages

- One non-randomized study examined the use of bedside ultrasound by emergency room physicians to evaluate suspected anterior talofibular ligament injuries. The findings of the bedside ultrasound were compared with magnetic resonance imaging. The sensitivity of the bedside ultrasound was 93.8% and the specificity was 100%. The authors concluded that emergency room physicians were able to accurately use bedside ultrasound to diagnose ligament injury.
- A second non-randomized study evaluated the ability of non-physicians to operate portable ultrasound on their own after a short training session versus the ability of other non-physicians to image under the guidance of a specialist via satellite. Diagnostic quality was obtained in 85.1% of the independent training session images and in 86.2% of the specialist-guided images. There was no significant difference observed between the two groups.

Title	*Portable Ultrasound Devices for Musculoskeletal Conditions: Clinical Effectiveness, Cost-Effectiveness and Guidelines*
Date	March 2016
Supporting Files	Summary of abstracts [not critically appraised]

Background

The patient population studied was those with musculoskeletal conditions, such as rotator cuff and ligament injury, and other soft tissue injuries.

Standard of Care

The standard of care is magnetic resonance imaging or fixed ultrasound.

Technology

Portable ultrasound devices is the technology being considered.

Evidence Available for Review

Six non-randomized studies were identified regarding the clinical effectiveness and accuracy of portable ultrasound devices for the assessment and management of patients with musculoskeletal conditions; no economic evaluations were identified regarding the cost-effectiveness of these devices for patients with musculoskeletal conditions. (Note: The information for this summary was taken from the published abstracts and not from a full-text review of the articles.)

Key Messages

- One study focused on hand and wrist joints in patients with rheumatoid arthritis, two studies focused on feet and ankles, one study included imaging of various extremity tendons, one focused on shoulders, and another study focused on patients with soft tissue and degenerative musculoskeletal conditions.
- All studies concluded that portable ultrasound devices were generally clinically effective and accurate for the assessment and management of patients with musculoskeletal conditions.

Title	*Portable versus Fixed X-ray Equipment: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines*
Date	February 2016
Supporting Files	Summary with critical appraisal

Background

Portable X-ray has been a useful tool for the diagnosis and monitoring of patients in intensive care units, in nursing homes, in prisons, and in shelters for the homeless.

Standard of Care

Transferring the patient to the hospital radiology department (fixed X-ray) for imaging would be the standard of care.

Technology

The technology considered is portable X-ray.

Evidence Available for Review

There was no evidence found from the literature search comparing the clinical or cost-effectiveness of portable X-ray to fixed X-ray. No guidelines on the use of portable X-ray were identified from the literature search.

Key Messages

- From the literature search from 2006 to 2016, the evidence on the clinical and cost-effectiveness of portable X-ray compared to fixed X-ray is lacking.
- There were no evidence-based guidelines found for the use of portable X-ray equipment.

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