An Overview of New and Emerging Technologies for the Pre-hospital Identification of Ischemic Stroke
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Methods

Bulletins present an overview of the technology and available evidence. They are not systematic reviews and do not involve critical appraisal or include a detailed summary of study findings. Bulletins are not intended to provide recommendations for or against a particular technology.

Literature Search Strategy

A limited literature search was conducted by an information specialist on key resources including PubMed, MEDLINE and Embase via OVID, Scopus, the Cochrane Library, the University of York Centre for Reviews and Dissemination databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were early identification of stroke and the pre-hospital setting. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2014 and October 14, 2019. Regular alerts updated the search until project completion; only citations retrieved before January 1, 2020 were incorporated into the analysis.

Study Selection

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention was an emerging technology for the identification of ischemic stroke in the pre-hospital environment. Conference abstracts and grey literature were included when they provided additional information to that available in the published studies. The list of included technologies is not exhaustive.

Peer Review

A draft version of this bulletin was reviewed by a clinical expert.
Summary

• Every year in Canada, there are more than 50,000 strokes and 14,000 deaths from stroke.

• Ischemic stroke is the most common type of stroke: 85% of strokes are ischemic.

• There are effective treatments for ischemic stroke: endovascular treatment (mechanical thrombectomy) and medical thrombolysis with intravenous tissue plasminogen activator (tPA), or alteplase. These treatments are time-sensitive.

• Individuals who experience ischemic stroke caused by large vessel occlusion (LVO) and meet specific eligibility criteria are candidates for mechanical thrombectomy up to 24 hours from known or presumed stroke onset.

• Individuals who experience ischemic stroke and meet specific eligibility criteria are candidates for thrombolysis with tPA for up to 4.5 hours after known or presumed symptom onset.

• The identification of ischemic stroke in the pre-hospital setting and the transportation of individuals who experience stroke to a place where they can be assessed for and receive treatment are key in providing optimal stroke care.

• Technologies such as stroke apps and mobile stroke sensing devices may have a role in helping to identify ischemic stroke in the pre-hospital environment and transporting individuals who are eligible for treatment to stroke treatment centres quickly.

• If effective, devices and technologies that assist with earlier identification and transportation for individuals who experience ischemic stroke may have implications for how stroke care is organized in Canada.

Background

Every year in Canada, there are more than 50,000 strokes and 14,000 deaths from stroke. Stroke is a debilitating condition; there are more than 400,000 Canadians living with long-term disability from stroke. Approximately 60% of those who have experienced stroke are left with some disability and more than 40% are left with moderate to severe disability that requires intense rehabilitation and support in the community. There are two types of stroke: ischemic stroke, the more common type, which is caused by a blood clot; and hemorrhagic stroke, which occurs when a blood vessel ruptures, causing bleeding in or around the brain.

There are two main types of treatment for ischemic stroke: physically removing the clot (mechanical thrombectomy) or dissolving it (medical thrombolysis). Determining what type of stroke an individual is experiencing is crucial because mechanical thrombectomy and medical thrombolysis are contraindicated for individuals experiencing hemorrhagic stroke. Although effective in ischemic stroke, both treatments must be started within hours of symptom onset. Mechanical thrombectomy is indicated for patients with acute ischemic stroke due to a large artery occlusion in the anterior circulation and can be treated up to 24 hours of symptom onset. An estimated 10% of patients with acute ischemic stroke have a proximal large artery occlusion in the anterior circulation and present early enough to qualify for mechanical thrombectomy within six hours, while approximately 9% of patients presenting in the six- to 24-hour time window may qualify for mechanical thrombectomy. Patients are eligible for medical thrombolysis using intravenous alteplase, or tissue plasminogen activator (tPA), within 4.5 hours of known or presumed symptom onset and, as a result, tPA is applicable to a small number of patients with ischemic stroke. According to a 2014 article, approximately 6% of Canadians who experienced ischemic stroke actually received thrombolysis, while an estimated 24% of stroke patients are eligible for thrombolysis treatment if delays between the onset of symptoms and
admission to hospital are avoided.\textsuperscript{7} It is important to note that thrombolytic drugs are effective only some of the time: large proximal artery occlusions (e.g., carotid artery or middle cerebral artery stem) are opened up 10\% to 35\% of the time, and smaller more distal arteries are opened up to 60\% to 80\% of the time.\textsuperscript{8} The longer a stroke goes unrecognized and untreated, the more brain cells die and the less likely a person is to recover function. Therefore, timeliness is essential in optimal stroke treatment.\textsuperscript{4,9}

Fast and effective identification and management of ischemic stroke in the pre-hospital environment is the first step in delivering optimal stroke care. The pre-hospital environment can be anywhere a patient receives care in advance of their arrival in a treatment centre; however, it most often refers to the care provided by a member of an emergency medical services (EMS) team. There are numerous opportunities for time saving in pre-hospital stroke care: from detection to triage, to transportation, and there are technologies emerging which aim to address stroke at each of these points.

**The Pre-Hospital Environment**

A recent Canadian guideline defines the pre-hospital environment in four distinct phases: dispatch, on-scene management, transportation, and hand-off to the emergency department care team.\textsuperscript{4} Pre-hospital care starts with the EMS dispatch system (911). Ideally, the stroke can be recognized at this early stage and the call can be prioritized appropriately. Next, the paramedics arrive on the scene, where an individual is assessed in-person and prepared for transportation to a stroke treatment centre. This assessment involves a stroke evaluation tool and could also involve a physical examination.\textsuperscript{4} The guideline recommends that direct transport protocols should be in place to facilitate the transfer of patients with suspected acute stroke who are eligible for medical thrombolysis and/or mechanical thrombectomy to the most appropriate treatment centre.\textsuperscript{4} Direct transport protocols allow certain patients to bypass hospitals that are close by in favour of stroke treatment centres. The guideline delineates several criteria for transportation including determining the probability that the patient is eligible for treatment with either medical thrombolysis with tPA and/or mechanical thrombectomy.\textsuperscript{4} Portable technology that accurately and quickly identifies ischemic stroke and provides additional information about the mechanism of stroke would be useful at the transport phase. It should be noted that there is some disagreement in the literature and among experts over the best treatment and transportation strategy. The “drip and ship” strategy refers to the administration of medical thrombolysis at the nearest hospital and then transportation to a location that offers mechanical thrombectomy. The “mothership” strategy involves bypassing the nearest hospital and taking an individual directly to a comprehensive stroke centre for mechanical thrombectomy.\textsuperscript{10}

The final step in pre-hospital care of suspected acute stroke is handover from EMS to the emergency department staff.\textsuperscript{4} Technology that facilitates communication between EMS and hospital staff is of use at this phase.

A mobile stroke unit (MSU) is a pre-hospital environment in which a person experiencing a stroke can receive care; it is a modified ambulance that contains a small CT scanner and other stroke care technology to provide on-site imaging and management of patients with suspected stroke.\textsuperscript{11} Although MSUs are not available everywhere, the evidence for MSUs is well-established.\textsuperscript{12,13} A previous CADTH report reviewed MSUs for ischemic stroke.\textsuperscript{11}

**Who Might Benefit?**

The devices and technologies described in this report could result in benefits for any person who experiences stroke outside of the hospital environment, specifically individuals living in rural or remote areas and those living in communities without a stroke treatment centre. Recent information suggests that individuals treated for stroke in rural hospitals had worse outcomes than individuals treated in urban hospitals.\textsuperscript{14} This may be due in part to a lack of resources or longer transportation time to stroke treatment centres. While both primary and comprehensive stroke centres offer medical thrombolysis with tPA, mechanical thrombectomy is only available in a limited number of comprehensive stroke centres that have the necessary equipment and professional expertise.\textsuperscript{15,16} Earlier identification of ischemic stroke may make the timely transfer to a stroke treatment centre that offers intravenous tPA or mechanical thrombectomy possible.

**The Technologies**

This report describes emerging technologies for use in the pre-hospital environment. These include software technologies that facilitate the appropriate triage, transportation, and treatment of individuals who experience stroke such as stroke scale apps and other communication apps, as well as devices that facilitate the identification of stroke such as mobile stroke sensing devices, biomarkers, and point-of-care screening. In addition to communication software and devices for diagnosing stroke, technologies that facilitate the understanding of technical information in the absence of specialized clinicians such as artificial intelligence and decision support tools will be discussed.
Technology for Assessing and Communicating Stroke Status

Recent guidelines have highlighted the need to improve stroke identification in the pre-hospital setting. These guidelines recommend that when stroke is identified by EMS in the pre-hospital environment, EMS should alert the hospital so that appropriate hospital resources may be mobilized before patient arrival. Because of their ubiquity and ease of use, smartphones are well suited to assist with these functions.

Stroke Apps

Pre-hospital screening using a stroke scale is a way of rapidly assessing a patient for stroke so that treatment can be provided in a timely fashion. The use of stroke scales to identify stroke symptoms is standard practice in patient triage; however, the rise of smartphones means these tools are now available in a form that offers new capabilities. Stroke scale apps, designed for use by EMS, combine the function of a stroke scale with improved navigation to a stroke centre. JoinTriage (Allm Inc., Tokyo, Japan) — previously called FAST-ED App — is an application available for smartphones that combines a stroke assessment questionnaire with a database of regional stroke centres and uses the smartphone’s GPS to map the quickest route to the treatment destination. One validation study was identified that compared FAST-ED to the National Institutes of Health Stroke Scale, the Rapid Arterial Occlusion Evaluation, and Cincinnati Prehospital Stroke Severity scales to predict large vessel occlusion (LVO). The JoinTriage app is a resource for EMS to use in the pre-hospital environment to potentially help identify stroke due to LVO that can be treated by mechanical thrombectomy.

The Stroke Finder device (HMRI–Hunter Medical Research Institute, New Lambton Heights, New South Wales, Australia) is a portable device designed to provide a real-time assessment of brain fluid distribution for patients undergoing neurologic assessment. The Stroke Finder device uses volumetric impedance phase-shift spectroscopy to assign a bioimpedance asymmetry score to patients. One study that evaluated the ability of the Stroke Finder device to differentiate severe stroke from minor stroke was identified. Authors concluded that the visor may be useful to detect emergent LVO in the pre-hospital environment. As emergent LVO is one of the criteria for mechanical thrombectomy, the use of this device may lead to faster triage to stroke treatment. This could result in more people presenting for mechanical thrombectomy during the treatment window.

Other Smartphone Technology

In addition to the use of specific apps, smartphones offer capabilities that can be utilized by health care professionals to assist with triage and transportation such as GPS and video-teleconferencing capabilities. Furthermore, tablets and smartphones have been used by EMS to assist in rural and remote settings by connecting experts to patients using mobile telestroke assessments.

Mobile Stroke Sensing Devices

In addition to software that assists in the identification, triage, and transportation of suspected stroke, there are emerging medical devices and procedures that may help to confirm stroke diagnosis in the pre-hospital environment. This in turn would help to ensure that care is optimized once a patient reaches a treatment centre. For example, as hemorrhagic and ischemic stroke require different treatments, it is necessary to determine what type of stroke an individual is experiencing. Additionally, as mechanical thrombectomy is only indicated for patients with ischemic stroke caused by LVO, determining the mechanism of stroke is therefore useful when considering stroke treatment options. There are emerging technologies designed to help clinicians garner this information. These technologies are not a replacement for clinical expertise. Rather, the emerging pre-hospital stroke sensing devices are additional tools that may help to identify patients who are candidates for specific stroke therapies. Some emerging technologies may be of particular use in areas where certain clinical expertise is not immediately available — such as, for example, technicians to read and interpret CT scan results. Furthermore, the new technologies have a role to play in resource stewardship, as they may help rule out stroke mimics.

Electromagnetic Induction

The Cerebrotech Visor (Cerebrotech Medical, Pleasanton, CA) is a portable device designed to provide a real-time assessment of brain fluid distribution for patients undergoing neurologic assessment. The Visor uses volumetric impedance phase-shift spectroscopy to assign a bioimpedance asymmetry score to patients. One study that evaluated the ability of the Cerebrotech Visor to differentiate severe stroke from minor stroke was identified. Authors concluded that the visor may be useful to detect emergent LVO in the pre-hospital environment. As emergent LVO is one of the criteria for mechanical thrombectomy, the use of this device may lead to faster triage to stroke treatment. This could result in more people presenting for mechanical thrombectomy during the treatment window.

Microwave

The Stroke Finder device (HMRI–Hunter Medical Research Institute, New Lambton Heights, New South Wales, Australia) aims to differentiate between a bleeding stroke and a clotting stroke. The Stroke Finder device consists of three parts: a...
Studies. One feasibility study used the ALPHASTROKE device to identify LVOs in a sample of 75 individuals. Another observational study of 34 individuals reported that the ALPHASTROKE device could distinguish between ischemic and hemorrhagic stroke. The portability and ease of use of this device makes it a good candidate for aiding in assessing patients for stroke in the pre-hospital environment. Additional studies on the ability of the ALPHASTROKE device to detect LVO are warranted, as this functionality could aid in identifying individuals who are candidates for mechanical thrombectomy in the pre-hospital environment.

Another portable EEG device, BrainScope (BrainScope, Bethesda, Maryland), has been primarily studied in populations with traumatic brain injury. The BrainScope device works by taking EEG recordings and inputting them into a proprietary classification algorithm to produce an index called the structural brain injury index. One retrospective study was identified that evaluated the ability of the BrainScope device to differentiate among ischemic stroke, hemorrhagic stroke, and stroke mimic in 183 cases of individuals who had presented in a hospital emergency department. In this confirmatory study, the structural brain injury index was able to correctly identify 80% of strokes for which a CT returned negative results but a stroke diagnosis was later confirmed on MRI. This device is a candidate for use in the pre-hospital environment because of its portability and non-reliance on specialized clinicians to interpret results.

Artificial Intelligence and Decision Support Tools
Several of the devices mentioned previously — such as the Lucid Robotic ultrasound system, the Stroke Finder device, and the two EEG devices ALPHASTROKE and BrainScope — combine stroke sensing with some sort of artificial intelligence to interpret the information captured by the devices. Stroke sensors are useful only when the information they provide can be quickly and correctly interpreted. Artificial intelligence, machine learning, and decision support tools are being leveraged to ensure that clinical information can be used even in the absence of specially trained professionals such as ultrasound technicians.

e-ASPECTS
The Alberta Stroke Program Early CT Score (ASPECTS) software (Brainomix, Oxford, UK) is a standardized topographic system for scoring CT scans performed in the setting of acute ischemic stroke. The ASPECTS value is a simple and accurate predictor of functional outcome after thrombolytic treatment. Interpreting CT scans takes specialized clinical knowledge that is not always available; the e-ASPECTS software is a decision support tool designed to ensure that CT scans can be interpreted in the
absence of an individual with specialized clinical knowledge. The e-ASPECTS software itself is not specifically a pre-hospital technology; however, the search identified one study evaluating the implementation of the e-ASPECTS system in the pre-hospital environment in an MSU in order to facilitate decisions about stroke treatment and triage.\textsuperscript{64}

### Point-of-Care International Normalized Ratio Testing

**CoaguChek**

An International Normalized Ratio (INR) of 1.7 or higher is a contraindication to ischemic stroke treatments such as thrombolysis. Therefore, rapidly determining a patient’s INR is necessary in order to determine if they are a candidate for treatment. The standard of care for INR testing is laboratory measurement, which is accurate but can take hours. Point-of-care INR testing is possible with the CoaguChek device (Roche Diagnostics, Switzerland).\textsuperscript{55} The search identified several studies that evaluated the CoaguChek device.\textsuperscript{55-61} The CoaguChek device is approved in Canada as a Class III medical device.\textsuperscript{62} The use of the CoaguChek device by medical professionals would mark a change from its approved use by individuals. If approved for use by professionals to ensure that individuals who experience stroke receive care appropriate to their INR status — point-of-care INR testing could potentially be used in the pre-hospital environment because of its portability and the fact that it does not require the presence of a lab to interpret results.

### Additional Technologies in Early Stages of Development

**Biomarkers**

Because of an historical lack of portability and the need for specially trained experts to interpret the results, most imaging modalities are not very accessible in the pre-hospital setting. Blood-based biomarkers are potentially a more accessible method for distinguishing ischemic from hemorrhagic stroke in the pre-hospital environment,\textsuperscript{63} particularly if the test could be administered at the point of care and if biomarkers are found to have good clinical utility for distinguishing those individuals who are eligible for stroke treatment.\textsuperscript{63} There are several promising stroke biomarkers including: activated protein C–Protein C inhibitor complex and glial fibrillary acidic protein, which have been found to have high sensitivity and specificity for differentiating between ischemic and hemorrhagic stroke.\textsuperscript{64-66} There is presently no point-of-care biomarker device on the market. However, the search identified one in development that uses NT-proBNP and S100beta biomarkers.\textsuperscript{67}

### Positron Emission Tomography

**PET** is an imaging modality that uses radiation to produce a medical image of the distribution of the imaging agent in the human body. PET imaging has applications in brain and central nervous system conditions such as stroke.\textsuperscript{56,69} However, its use is limited, as PET scanning requires that the individual undergoing the scan remain still for long durations of time and exposes the individual to radiation. The Ambulatory Microdose PET is portable and wearable, and offers a lower radiation dose.\textsuperscript{68} This device is in the very early stages of development and no clinical trials were identified at this time.

### Artificial Neural Networks

An artificial neural network (ANN) is a method of mimicking the way the human brain learns through its connection of neurons, using a computer model.\textsuperscript{70} One study that described the development and evaluation of an ANN model for the recognition of acute cerebral ischemia was identified.\textsuperscript{71} The tool uses a supervised learning method to recognize acute cerebral ischemia quickly and to distinguish ischemic stroke from stroke mimics.\textsuperscript{71} The use of artificial intelligence to screen for stroke could help ensure the clinical threshold is met for stroke treatment such as mechanical thrombectomy and medical thrombolysis, especially in areas where access to specialized clinicians is limited.

### Implications for Stroke Care

Although medical thrombolysis with tPA and mechanical thrombectomy are both effective treatments for ischemic stroke, not everyone who experiences ischemic stroke is a candidate for these treatments. Both treatments have limited treatment windows; for example, mechanical thrombectomy can only be used in individuals with LVO. Rapid assessment of patients with suspected stroke helps determine what treatment or treatments an individual is a candidate for. Therefore, technologies that allow more patients to be assessed rapidly would aid in the identification of patients eligible for tPA and mechanical thrombectomy who would have otherwise been missed. The mobile stroke sensing technologies described could potentially serve this need.

Further complicating the picture is that medical thrombolysis with tPA and mechanical thrombectomy treatments are not currently offered at all hospitals in Canada. While tPA could be offered at most centres via telehealth, only a few have the necessary equipment and professional expertise to offer mechanical thrombectomy.\textsuperscript{15,16} Mechanical thrombectomy is offered in fewer institutions than tPA because it is a technical procedure that requires clinicians with specialized training and equipment.\textsuperscript{72}
More than 85% of Canadians live within six hours’ road access to a specialized stroke centre — i.e., emergency medical services — so an individual experiencing stroke can likely be transported in time to receive potentially life-saving treatments. For individuals living in rural and especially in remote locations, it is more difficult to access EMS for any urgent or emergent condition including stroke. A major obstacle to offering mechanical thrombectomy to all eligible patients is that the distribution of specialized clinicians and resources tend to be concentrated in urban areas. The geography and availability of specialized resources has implications for the triage and transportation of individuals with suspected stroke.

The treatment window for mechanical thrombectomy is widening, which means that more people will be candidates for this treatment. A larger treatment window will have an effect on the organization of stroke care resources in Canada. For example, a draft NICE National Institute for Health and Care Excellence guideline from 2018 found that the widening window for thrombectomy is likely to have a substantial resource impact on the National Health Service. Mechanical thrombectomy will now need to be available 24 hours a day with appropriate staffing and imaging, and in the short-term there will be costs associated with transferring patients to centres already offering this treatment. The NICE guidance does note that these increased costs are balanced against a decrease in demand for in-patient rehabilitation and other forms of intensive stroke care. Furthermore, better outcomes from mechanical thrombectomy mean a potential reduction in the need for long-term care for individuals who experience stroke.

The emerging technologies described in this report have the potential to disrupt how stroke care is delivered in Canada, particularly if they increase the number of patients eligible for mechanical thrombectomy and/or medical thrombolysis (i.e., tPA). In the event that these technologies are found be effective in the pre-hospital setting and become widely used, stroke systems may need to consider the increased number of people to screen, the distribution of specialized clinical resources, and the location of primary and comprehensive stroke centres in order to optimize functionality of the stroke care system with the goal of getting the correct person the correct treatment in a timely fashion. The screening, communication, and assessment tools detailed in this report are both hastening and facilitating the system transformation of stroke care.

### Uptake Considerations

#### Software and Infrastructure Considerations

Many of the emerging interventions for stroke are technology-reliant, which can lead to challenges with implementation. When using proprietary software, there is always a potential concern about compatibility with the existing software in use in treatment centres. Additionally, the use of these software might cause accessibility issues. Many of the technologies discussed such as apps and mobile sensors rely on an internet connection to transmit the information from the pre-hospital environment to the treatment centre. Internet coverage is a known issue in Canada, which could mean that these technologies might not be accessible in every region.

#### Privacy

In addition to the hardware and software issues, there is the issue of patient privacy. Many of the technologies collect personal health information to help facilitate diagnosis and treatment. In Canada, personal health information is governed by several provincial and territorially laws, and the federally by the Personal Information Protection and Electronic Documents Act, or PIPEDA. Some methods that have been considered to maintain patient privacy include servers with encryption, firewall-protected WiFi, and basic cellular network data encryption. The successful widespread adoption of these new technologies would require public trust in the use and dissemination of their personal health data.

#### Cost

The costs of implementing these emerging technologies is difficult to ascertain. Where available, direct costs of individual devices were noted. However, in addition to purchasing new technology, there would be costs associated with training and ensuring compatibility with existing technology.

Stroke costs the Canadian economy more than $3.6 billion a year in physician services, hospital costs, lost wages, and decreased productivity. Limiting disability from stroke could potentially lead to fewer days away from work and therefore fewer lost wages for individuals who experience stroke. Better access to effective stroke treatments might lead to better outcomes for individuals, which could mean a decrease in the cost of follow-up care for both the individual and the health care system.
Final Remarks

The pre-hospital period is a critical part of the stroke care continuum. Leveraging effective technology in this environment could prove useful in aiding more people to access treatment. The new technologies described in this report — which could facilitate the identification, triage, and transportation of an individual who experiences stroke — could disrupt stroke care in Canada. Some of the technologies described are already in use, such as the existing smartphone applications. However, many of these technologies are in the very early stages of development and are not yet available to the public. In both cases, additional research is required to link the usage of these devices and technologies to improved clinical outcomes. More information about the clinical utility and cost-effectiveness of these emerging technologies would help decision-makers understand the potential impact these technologies could have on Canada's health care system.
References


