# Treatment Time-Window for Endovascular Thrombectomy:

**A position statement drafted by the Cardiovascular Health and Stroke SCN™, the Provincial Acute Stroke/TIA Expert Working Group and the Endovascular Therapy Management Subgroup**

## Preamble

Ischemic stroke treatment has rapidly advanced over the last few years; however, one fact has remained constant: for select patients, treatment with intravenous thrombolytic agents and/or endovascular thrombectomy (EVT) is life and disability saving. In the past, the threshold for treatment eligibility was highly contingent upon the 6 hour time window from stroke onset. As practices in stroke care have evolved, it is becoming clear that time is only one contributing factor to treatment eligibility and that the imaging appearance defining the physiology is actually a more critical factor.

The Canadian Stroke Best Practice Recommendations, as of 2018, recognize a **24-hour threshold** for identifying potentially treatable ischemic stroke patients (Appendix A, Section 5.1 & 5.4) and indicate that **screening and imaging** are to be rapidly completed within that timeframe to determine treatment eligibility. Currently in Alberta, varying thresholds for EVT treatment exist among urban and rural hospitals, and with Emergency Medical Services (EMS); this variation in practice has created inequitable access to treatment and both clinical and administrative challenges.

The Provincial EVT Steering Committee has asked the Cardiovascular Health & Stroke Strategic Clinical Network™ (CvHS SCN™) to craft a position statement pertaining to the 24 hour EVT treatment window. This position statement has been developed in conjunction with the Acute Stroke/TIA Expert Working Group and the EVT Management Subgroup with the intent of creating equitable access to treatment, improving outcomes for patients, and standardizing provincial practice to align with the Canadian Stroke Best Practices Recommendations.

## Position Statement from the Cardiovascular Health & Stroke SCN™

*On behalf of the clinical, operational, and stroke system experts and in alignment with Canadian Stroke Best Practice Recommendations, all patients in Alberta with disabling acute ischemic stroke presenting within **24 hours** of stroke symptom onset or last known well should be rapidly screened clinically and with neurovascular imaging for eligibility for acute Endovascular Therapy treatment.*

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## Operational Implications

The CvHS SCN™ recognizes that there are operational implications to this standard, which include but are not limited to:

1. a change to the current transportation and communication algorithms along with the corresponding communication and/ or training pertaining to the change for EMS; Referral, Access, Advice, Placement, Information, Destination (RAAPID); and Shock Trauma Air Rescue Society (STARS).
2. minimal overall increase in stroke volumes or stroke admissions provincially, a 24h threshold could change the hyper-acute stroke response (Emergency Department, Stroke Neurology, Medicine, Neuro-intervention) for all primary and comprehensive stroke centres
3. the need for hyper-acute brain and neurovascular imaging will increase; nonetheless, DI and clinical operations suspect that advances in imaging software will highly impact imaging efficiency
4. stroke admissions will need to be balanced with repatriation and discharge planning; however, with reductions in morbidity and mortality length of stay will also likely decrease

## Proposed Next Steps

The CvHS SCN™ will support clinical, operational, and system partners to develop the systems and changes required to meet this standard; understanding that change will take time, education, and compromise. Collaboratively, we will work within zones and provincially to define ways to implement this standard.

The CvHS SCN™ also recommends adopting as many common approaches across the province as is pragmatically feasible to solve the challenge of implementing this standard.

## Outcomes

-Evidence based patient care

-Equitable access

-Reduced morbidity and mortality

-Clarity/standardized care

-Improved appropriateness

-Operational effectiveness

## Summary

A provincial consensus by both operational and clinical stroke leads has been reached to formally expand and standardize the EVT treatment window to 24hours for all eligible stroke patients.

The CvHS SCN™ and the provincial stroke community appreciate the challenges faced by operations in adopting the expanded time window and will provide support in developing and implementing the required changes to meet this evidence based best practice standard.

## Contributions

This position statement was developed in consultation and collaboration with the members of the Acute Stroke/TIA Expert Working Group, the EVT Management Subgroup and the CvHS SCN™, and has been approved by the Provincial EVT Steering Committee (Appendix B).

## Appendix A

The following Stroke Best Practices Recommendations for Acute Ischemic Stroke Care were retrieved from: https://www.strokebestpractices.ca/recommendations/acute-stroke-management/acute-ischemic-stroke-treatment

December 10th, 2020.

# 5. Acute Ischemic Stroke Treatment

June 2018 - 2018 UPDATE

## 5.1 Patient Selection for Acute Ischemic Stroke Treatments

*Box 5A Criteria for Stroke Centres Providing Acute Ischemic Stroke Treatment*

*Note: treatment benefits from revascularization decreases over time as an estimated 1.9 million brain cells die every minute following stroke onset (Saver 2006); therefore, all patients with stroke* ***should be treated as fast as possible*** *to maximize potential for the best outcomes, and the new extended time windows should not be interpreted to mean that time to treatment can be slowed down in any way.*

i. All patients with *disabling* acute ischemic stroke within 24 hours of stroke symptom onset or last known well should be rapidly screened clinically and with neurovascular imaging [Evidence Level B].

ii. All patients with *disabling* acute ischemic stroke who can be treated within the indicated time windows must be screened *without delay* by a physician with stroke expertise (either on-site or by telemedicine/telestroke consultation) to determine their eligibility for both intravenous alteplase (**within 4.5 hours** from stroke symptom onset) and/or interventional treatment with endovascular thrombectomy (**within a 6 hour** window from stroke symptom onset). [Evidence Level A].

iii. Patients meeting criteria in 5.1 (i) (within 6 hours) should immediately undergo neurovascular imaging with non-contrast computed tomography (NCCT) and including CT angiography (CTA) then considered for treatment on the basis of imaging [Evidence Level A].

iv. There are randomized controlled trials which indicate that **highly selected** patients with disabling stroke symptoms may benefit from endovascular thrombectomy **up to 24 hours** from the time they were last known well, including patients with stroke on awakening, and patients should be considered for eligibility within the extended time window on a case-by-case basis [Evidence Level A]. *Note, these patients were selected using CTP or diffusion-weighted criteria (as defined in Box 5C below)* (new for 2018)

v. Highly selected patients being considered for endovascular thrombectomy beyond 6 hours will require additional advanced neurovascular imaging [Evidence Level A]. *Refer to Box 4D for additional Imaging Selection Criteria.*

*to Box 4D for additional Imaging Selection Criteria.*

**Clinical considerations:**

i. One recent multi-centre randomized double-blind placebo controlled trial compared alteplase to placebo for ischemic stroke patients with unknown time of onset, using MRI selection criteria (DWI/FLAIR mismatch). It included ischemic stroke patients who were not candidates for endovascular thrombectomy, and who would otherwise have met the criteria for acute intravenous alteplase administration [46] (*refer to Box 5B for alteplase criteria*)

- This trial demonstrates a clinical benefit of intravenous alteplase administered more than 4.5 h from the time the patient was last known well in patients where onset time is unknown (no upper time limit defined).
- If intravenous alteplase is considered after 4.5 h, a consultation with a physician with stroke expertise should be obtained. Selection of patients for intravenous alteplase in patients presenting **after 4.5 hours** on the basis of CT, CTA and CTP remains unproven at this time.
- *MRI scanning can be challenging to obtain urgently in an Emergency Department setting. This must be considered in decision-making and not delay decisions regarding endovascular thrombectomy eligibility.*

**5.2 Imaging Criteria**

*Refer to Section 4.2 for detailed recommendations and Boxes 4A, 4B, 4C and 4D for selection criteria for neuroimaging.*

i. Patients should be considered for revascularization treatment when there is no evidence of extensive early infarct changes [Evidence Level B], in consultation with physicians with stroke expertise. *Note: one possible tool to assess infarct change is the ASPECT score: www.aspectsinstroke.com*

a. Timely access to CT or MR perfusion scanning can also be used to demonstrate a perfusion mismatch and to determine the extent of the ischemic core [Evidence Level A], especially in patients beyond 6 hours from last known well, including patients with stroke on awakening.

ii. For endovascular thrombectomy, patients should have a proximal occlusion in the anterior circulation [Evidence Level A]. *Refer to Box 5C for endovascular thrombectomy inclusion and exclusion criteria.*

*inclusion and exclusion criteria.*

### 5.3 Intravenous Thrombolysis with Alteplase

i. All eligible patients with disabling ischemic stroke should be offered intravenous alteplase [Evidence Level A]. Eligible patients are those who can receive intravenous alteplase within 4.5 hours of the onset of stroke symptoms [Evidence Level A]. *Refer to Section 4.2 and Boxes 4A – 4D for detailed recommendations on neuroimaging; Refer to Box 5B for inclusion and exclusion criteria for intravenous alteplase eligibility. Refer to Section 5.1 Clinical Considerations for patients who arrive beyond the 4.5 hour time window.*

   a. When it is unclear whether or not a patient should be treated with alteplase, urgently consult with a stroke specialist within the institution or through telestroke services [Evidence Level C].

   b. If there is uncertainty regarding CT imaging interpretation, consult a radiologist in your institution [Evidence Level C].

ii. All eligible patients should receive intravenous alteplase as soon as possible after hospital arrival [Evidence Level A], with a target door-to-needle time of less than 60 minutes in 90% of treated patients, and a median door-to-needle time of 30 minutes [Evidence Level B].

   a. Treatment should be initiated as soon as possible after patient arrival and CT scan [Evidence Level B]; every effort should be made to ensure door-to-needle times are routinely monitored and improved [Evidence Level C].

   b. Alteplase should be administered using a dose of 0.9 mg/kg to a maximum of 90 mg total dose, with 10 percent (0.09 mg/kg) given as an intravenous bolus over one minute and the remaining 90 percent (0.81 mg/kg) given as an intravenous infusion over 60 minutes [Evidence Level A].
   *Caution: the dosing of alteplase for stroke is not the same as the dosing protocol for administration of alteplase for myocardial infarction.*

iii. **Hospital inpatients** who present with a sudden onset of new stroke symptoms should be rapidly evaluated by a specialist team and provided with access to appropriate acute stroke treatments (including thrombolysis and endovascular thrombectomy) [Evidence Level B]. *Note: once stroke occurs to an existing inpatient, all other sections of the Canadian Stroke Best Practice modules apply to these patients for assessment, diagnosis, management, and recovery.*

*management, and recovery.*

iv. Management of complications from alteplase administration:

   a. For patients with angio-edema, a staged response using antihistamines, glucocorticoids and standard airway management should be used as per local protocol [Evidence Level C].

   b. There is insufficient evidence to support the routine use of cryoprecipitate, fresh frozen plasma, prothrombin complex concentrates, tranexamic acid, factor VIIa, or platelet transfusions for alteplase – associated bleeding [Evidence Level C]. Use of these medications should be decided on an individual case basis.

**Clinical Considerations for Alteplase Administration:** (new for 2018)

i. Consent – Intravenous thrombolysis and endovascular therapy are considered the standard of care for acute stroke treatment. Routine procedures for emergency consent apply.

ii. Intravenous alteplase is considered the standard of care and is currently the only approved thrombolytic agent for acute ischemic stroke treatment. There are other drugs being investigated; however, at this time are not approved for use in stroke patients.

iii. Alteplase administration for patients on direct oral anticoagulants (DOACs): alteplase should **not** routinely be administered to patients on DOACs presenting with acute ischemic stroke. Endovascular thrombectomy may be considered in in these cases for eligible patients, and decisions should be based on individual patient factors and assessment of benefit and risk.

   a. In comprehensive stroke centres with access to specialized tests of DOAC levels and reversal agents, thrombolysis could be considered, and decisions should be based on individual patient characteristics, in consultation with hematology specialists, patients and their families.

iv. There remain situations in which clinical trial data to support the use of intravenous thrombolytic therapy is more limited. In these situations urgent consultation with a stroke expert is recommended alongside the clinical judgment of the treating physician and discussion with the patient or substitute decision maker.

   a. This may apply to: pediatric stroke (newborn to age 18 years); and pregnant women who experience an acute ischemic stroke. *Refer to Canadian Stroke Best Practices Management of Acute Stroke during Pregnancy Consensus Statement for further information*

*information*

### 5.4 Acute Endovascular Thrombectomy Treatment (EVT)

*Refer to Section 4.2 and Boxes 4B, 4C and 4D for detailed recommendations on neuroimaging-based selection criteria.*

i. Endovascular thrombectomy should be offered within a coordinated system of care including agreements with emergency medical services, access to rapid neurovascular (brain and vascular) imaging, coordination between emergency medical services, the Emergency Department, the stroke team and radiology, local expertise in neurointervention, and access to a stroke unit for ongoing management [Evidence Level A].

ii. Endovascular thrombectomy is indicated in patients based upon imaging selection with non-contrast CT head and CT angiography (including extracranial and intracranial arteries) [Evidence Level A]. *Refer to Box 5C for Inclusion Criteria for endovascular thrombectomy.*

iii. Endovascular thrombectomy is indicated in patients who have received intravenous alteplase and those who are not eligible for intravenous alteplase [Evidence Level A].

iv. Patients eligible for intravenous alteplase as well as endovascular thrombectomy should also be treated with intravenous alteplase, which can be initiated while simultaneously preparing the angiography suite for endovascular thrombectomy [Evidence Level A].

v. Eligible patients who can be treated with endovascular thrombectomy **within 6 hours** of symptom onset (i.e., arterial access within 6 hours of onset) should receive endovascular thrombectomy [Evidence Level A]. *Refer to Box 4B for Imaging Inclusion Criteria for endovascular thrombectomy.*

vi. **Highly selected patients** with large vessel occlusion who can be treated with endovascular thrombectomy **within 24 hours** of symptom onset (i.e., arterial access within 24 hours of onset) and those patients with stroke discovered on awakening should receive endovascular thrombectomy [Evidence Level A]. *Refer to for Imaging Inclusion Criteria for endovascular thrombectomy beyond 6 hours from onset.*

vii. For large artery occlusions in the posterior circulation (e.g. basilar artery occlusion) the decision to treat with endovascular thrombectomy should be based on the potential benefits and risks of the treatment for the individual patient, and made by a physician with stroke expertise in consultation with the patient and/or substitute decision-makers. [Evidence Level C]. *Note: randomized trials are currently ongoing and guidance will be reviewed when trial results are available.*

viii. **Sedation:** For endovascular procedures, procedural sedation is generally preferred over general anaesthesia and intubation in most patients when necessary [Evidence Level B].

a. General anaesthesia and intubation is appropriate if medically indicated (e.g. for airway compromise, respiratory distress, depressed level of consciousness, severe agitation, or any other indication determined by the treating physician) and in such cases, excessive and prolonged hypotension and time delays should be avoided [Evidence Level B].

**Clinical Considerations for Endovascular Thrombectomy** (new for 2018)

i. For patients transferred to an EVT-enabled hospital, in order to ensure patient remains a candidate for EVT, consider doing repeat NCCT immediately on arrival if most recent CT was completed more than 60 minutes prior to arrival at the EVT–enabled site.

ii. Device selection should be at the discretion of the interventionalists based on clinical and technical factors during the procedure.

iii. For patients undergoing EVT following administration of alteplase, there should not be a delay in proceeding to EVT to determine clinical effectiveness of alteplase.

*Box 5B Criteria for Acute Thrombolytic Therapy with Intravenous Alteplase*

*Box 5C Inclusion Criteria for Endovascular Thrombectomy*



## Rationale

Meta-analyses of the randomized controlled trials of intravenous alteplase for acute ischemic stroke have shown that thrombolytic treatment can reduce the risk of disability and death, despite the risk of serious bleeding. The latest time for alteplase administration after stroke onset remains imprecisely defined, but currently available data show clear evidence of benefit when given up to 4.5 hours after the onset of symptoms. The available evidence demonstrates a strong inverse relationship between treatment delay and clinical outcome; eligible patients should be treated without delay, regardless of when they present within the treatment window.

treatment window.

Endovascular treatment for large artery ischemic stroke has clearly demonstrated efficacy with numbers needed to treat (NNT) of approximately four to achieve functional independence at 90 days. Recent data from the DAWN trial (Nogueira et al. 2017) suggest the NNT may be as low as three, while pooled results from a series of older trials, indicated the number was higher, closer to five (HERMES, Goyal et al. 2016). This therapy has profound impact on patients who suffer the most devastating ischemic strokes; patients who, if left untreated, will place a more significant burden on the healthcare system, long term care and family caregivers.

(Note: to obtain mRS of 0-2 at 90 days (49% vs. 13%=NNT of 2.8); HEREMES 2016 meta-analysis to obtain mRS score of 0-2 at 90 days (46% vs. 26.5%=NNT of 5.1))

## System Implications

i. Local protocols should prioritize stroke patients for immediate access to appropriate diagnostics such as CT imaging and neurovascular imaging with CTA. This should include patients with known times of stroke symptom onset (or time last seen well), and patients who are discovered with stroke symptoms on wakening.

ii. Coordinated and integrated systems of care involving all relevant personnel in the prehospital and emergency care of stroke patients, including paramedics, Emergency Department staff, stroke teams, radiologists and neurointerventionists. Protocols should be in place in partnership with EMS agencies and treating hospitals, and between hospitals within stroke systems to ensure rapid transport to centres providing advanced stroke services within treatment time windows

iii. Considerations should be given to northern, rural, remote and Indigenous residents to ensure immediate access to appropriate diagnostics and treatment is not delayed.

iv. Health regions and stroke systems should examine and determine the possible resource impact of the EVT time window extension (up to 24 hours in highly selected cases). Demand for imaging will increase especially at comprehensive stroke and EVT-enabled centres. Staffing, service hours and capacity should be considered to ensure efficiency and effectiveness of services.

v. System planners and patient flow specialists should plan for significant challenges associated with diversion of potential EVT candidates to EVT-enabled centres. This will affect Emergency Departments, Radiology Departments and acute inpatient units, where occupancy rates are already stretched (over 100% in many hospitals).

where occupancy rates are already stretched (over 100% in many hospitals).

vi. Stroke neurology and neurointerventional expertise should be regionalized, with a system in place across regions for rapid access to physicians experienced in acute thrombolysis and endovascular therapies, including through telemedicine.Â This includes protocols for contacting physicians with stroke expertise for administration of intravenous alteplase, as well as transport to higher levels of stroke care, as needed, for intravenous alteplase or endovascular thrombectomy.

vii. Build capacity for trained neurointerventionists within health regions and academic institutions to ensure sufficient availability to meet regional and provincial EVT healthcare needs.

viii. Hyperacute protocols in place and well-communicated to all healthcare practitioners within the hospital regarding management of in-hospital stroke patients, ensuring access to CT imaging of the brain and CTA of the extracranial and intracranial vessels as soon as possible after stroke symptom onset.

ix. Access to specialized acute stroke units where staff are experienced in managing patients who have received alteplase or endovascular thrombectomy.

x. Endovascular interventional programs are in evolution across Canada; decisions around appropriate site, transfer and bypass protocols, and timelines will be determined at the provincial or regional level. Decisions about when those services are fully operational, and who should be transferred by paramedics to those facilities should be made at the provincial/regional level and communicated to all relevant stakeholders.

xi. Availability of helical CT scanners with appropriate programming for CT angiography (multiphase or dynamic CTA) and CT perfusion sequences, and appropriate post-processing software optimized for the production of high-quality imaging.

xii. A consistent, comprehensive data collection protocol for EVT across Canada should be established to monitor patient outcomes.

Performance Measures +

Implementation Resources and Knowledge Transfer Tools +

Summary of the Evidence +

# Appendix B

## Acute Stroke/TIA Expert Working Group

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