

Endovascular Stroke Treatment Centre Service Delivery Requirements

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Introduction

Ontario Health (CorHealth)

On December 1, 2021, CorHealth Ontario became part of Ontario Health (OH). Our mandate covers cardiac, stroke, and vascular throughout the entire course of care treatment, including secondary prevention, rehabilitation, and recovery. Ontario Health (CorHealth) works closely with the Ministry of Health (MOH), Ontario Health Regions, hospitals, and care providers to improve the quality, efficiency, accessibility, and equity of cardiac, stroke, and vascular services for patients across the province.

Endovascular Treatment for Stroke

Endovascular Thrombectomy (EVT) is an intra-arterial procedure designed to mechanically remove a clot from the brain, offering life- and disability- saving intervention for patients with acute ischemic stroke caused by large vessel occlusions (LVOs). In 2015, following the pivotal results of five major randomized controlled trials, EVT became the standard of care for patients presenting within 6 hours of stroke symptom onset with LVOs in the anterior circulation. These landmark trials demonstrated that EVT significantly reduces disability and death in select patients with acute ischemic stroke due to LVOs.^{1,2,3,4,5} Since then, the indications for EVT have expanded, with treatment now offered up to 24 hours^{6,7} of last known well for proximal occlusions in both the anterior and posterior circulation. Despite these expanded indications, rapid triage, timely assessment, and imaging to identify patients who may benefit from EVT remains essential for optimal outcomes.

EVT is a highly specialized procedure that is performed at a limited number of sites (11) in Ontario. To support regional and cross-regional access, a provincial process has been established. This process builds on existing systems for accessing thrombolysis and considers time, distance, clinical presentation, and imaging.

About this Document

In alignment with the Canadian Stroke Best Practice Recommendations, the Ontario Health (CorHealth) Hyperacute Stroke Care Steering Committee, developed and endorsed the EVT service delivery criteria contained in this document. As per the annual Hospital Funding Allocation letter, hospitals that receive EVT funding are required to comply with service delivery requirements set out by Ontario Health (CorHealth). As such, Ontario Health (CorHealth), in collaboration with the MOH, communicates these requirements and facilitates a review and attestation process (Appendix B: EVT Requirement Attestation Form) to ensure EVT Centres compliance with the requirements.

This document is not intended to determine readiness or appropriateness for expanding stroke EVT services at new hospitals in Ontario. Decisions to expand current services are multifaceted and require a regional and/or provincial planning approach that takes into consideration population

¹ O. Berkhemer, P. Fransen, et. al. A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke. N Engl J Med 2015; 372:11-20. (Mr. CLEAN)

² M. Goyal, A. Demchuk, et. al. Randomized Assessment of Rapid Endovascular treatment of Ischemic Stroke. N Engl J Med 2015; 372:1019-30 (ESCAPE)

³ B.C.V Campbell, P.J Mitchell et. al. Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection. N Engl J Med 2015; 372:1009-18 (EXTEND-IA).

⁴ J. Saver, M. Goyal et. al Stent-Retriever Thrombectomy After Intravenous t-PA vs. t-PA Alone in Stroke. N Engl J Med 2015; 372:2285-2295 (SWIFT PRIME)

⁵ T. Jovin, A. Chamorro, et. al. Thrombectomy within 8 hours after Symptom Onset in Ischemic Stroke. N Engl J Med 2015; 372:2296-2306 (REVASCAT)

⁶ R.G. Nogueira, A.P. Jadhav et. al Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct. N Engl J Med 2018; 378:11-21 (DAWN)

⁷ G.W. Albers, M.P. Marks et. al. Thrombectomy for Stroke at 6 to 16 Hours with Selection by Perfusion Imaging. N Engl J Med 2018;378:708-18. (DEFUSE 3)

need, resource availability, sustainability of current specialized stroke services within the system, and timely access to best practice care.

Hospitals interested in expanding services to include EVT should refer to Ontario Health (CorHealth)'s Specialized Acute Stroke Service Framework. This framework provides an overview of the different levels of clinical service provision within the Ontario stroke system, as well as the process hospitals are required to follow when seeking to expand existing stroke services.

Endovascular Treatment Centre Requirements

Volume Criteria

CRITERION 1- MINIMUM VOLUMES

EVT Treatment centres are required to provide a minimum of 30 cases per year⁸ to ensure both program sustainability and clinical expertise. All centres, especially those with lower case volumes (i.e., 30 cases/year), should implement a quality assurance and improvement program that includes monitoring of key processes, outcomes, and safety measures.

Infrastructure & Equipment Criteria

CRITERION 2- STROKE IMAGING

EVT treatment centres must have on-site imaging capabilities with 24-hour access, seven days a week, including a computed tomography (CT) scanner (3rd generation or higher helical scanner) with programming for CT angiography (CTA) (multiphase or dynamic CTA),⁹ and CT perfusion imaging with automated post-processing software.¹⁰

CRITERION 3- ANGIOGRAPHY SUITE

EVT treatment centres must have an adequately staffed angiography suite, ideally equipped with a biplane system; however, the use of a single-plane system is also acceptable.¹¹

CRITERION 4- ON-SITE NEUROSURGERY AND CRITICAL CARE UNIT FACILITIES

EVT treatment centres must have on-site neurosurgical support, and a critical care unit (Level 2 Basic, with the ability to escalate to Level 3 Basic on-site, as defined by Critical Care Services Ontario¹²), supported by a stroke physician with expertise in post procedure care, and with appropriate monitoring

⁸ Recommendation from the Ontario Health (CorHealth) Hyperacute Stroke Care Steering Committee

⁹ Heran, M., Lindsay, P., Gubitz, G., Yu, A., Ganesh, A., Lund, R., . . . Shamy, M. (2022). Canadian Stroke Best Practice Recommendations: Acute Stroke Management Module, 7th Edition Practice Guidelines Update, 2022. Heart and Stroke Canadian Stroke Best Practices website, 1-162

¹⁰ Recommendation from the Ontario Health (CorHealth) Hyperacute Stroke Care Steering Committee

¹¹ Recommendation from the Ontario Health (CorHealth) Hyperacute Stroke Care Steering Committee

¹² Critical Care Services Ontario. (2020). Adult Critical Care Levels of Care Guidance Document. Retrieved from <https://criticalcareontario.ca/wp-content/uploads/2020/11/Adult-LoC-Guidance-Documents-Final.pdf>

capabilities and protocols in place that follow current evidence-based stroke best practice recommendations.¹³

CRITERION 5- LINKAGES WITH REGIONAL OR DISTRICT STROKE PROGRAM

EVT treatment centres must ensure established linkages between the EVT clinical program and the Regional and/or District Stroke Network teams.

The EVT site is required to collaborate with stroke system partners to develop and implement protocols and processes that enable access to EVT.

CRITERION 6- ACUTE STROKE CARE FACILITIES

EVT treatment centres must have a stroke unit that meets Ontario Health (CorHealth)'s Ontario Stroke Unit Definition,¹⁴ have protocols and processes in place to support best practice care delivery, and be actively working towards implementing the core components outlined in [*The Ontario Stroke Unit Definition – A Best Practice Standard for Stroke Units in Ontario*](#).

EVT treatment centre must have established referral pathways to access Stroke Prevention Clinic services.

CRITERION 7- THROMBECTOMY DEVICES

EVT treatment centres must maintain an adequate inventory of required devices necessary to perform the procedure, including retrievable stents (with or without additional aspiration) or direct aspiration alone with either a distal access catheter or a balloon guided catheter. Use will be based on operator preference and expertise.

Clinical Service Criteria

CRITERION 8- INTRAVENOUS THROMBOLYSIS

EVT treatment centres must ensure that the clinical team is capable and experienced in the administration of intravenous thrombolysis, targeting a door-to-needle times of less than 60 minutes in 90% of treated patients, and a median door to needle time of 30 minutes.¹⁵

CRITERION 9- STROKE ENDOVASCULAR TEAM

EVT treatment centres must have a locally designated Stroke Endovascular Team that is available 24 hours a day, seven days a week. The team must include specialists with neuro-intervention expertise (e.g. neuroradiologists, neurosurgeons and neurologists), as well as stroke specialists with fellowship training or equivalent experience to support the identification of thrombolysis and/or EVT eligible patients, and post procedure management.

¹³ Heran, M., Lindsay, P., Gubitz, G., Yu, A., Ganesh, A., Lund, R., . . . Shamy, M. (2022). Canadian Stroke Best Practice Recommendations: Acute Stroke Management Module, 7th Edition Practice Guidelines Update, 2022. Heart and Stroke Canadian Stroke Best Practices website, 1-162

¹⁴ A stroke unit is a specialized unit dedicated to the care of persons with stroke and staffed by an experienced, interprofessional stroke team. The unit has designated stroke unit beds that are co-located and in physical proximity to each other. These beds are used to provide care for stroke patients most of the time.

¹⁵ Heran, M., Lindsay, P., Gubitz, G., Yu, A., Ganesh, A., Lund, R., . . . Shamy, M. (2022). Canadian Stroke Best Practice Recommendations: Acute Stroke Management Module, 7th Edition Practice Guidelines Update, 2022. Heart and Stroke Canadian Stroke Best Practices website, 1-162

CRITERION 10- EXPANDED TIME WINDOW

EVT Treatment centres must ensure that the clinical team is capable and experienced in selecting patients for EVT up to 24 hours from stroke symptom onset including those with stroke symptoms on awakening.

CRITERION 11-NEURO-INTERVENTIONAL TRAINING AND EXPERTISE

EVT treatment centres must ensure that specialists performing Stroke Endovascular Thrombectomy meet the training requirements outlined by The Joint Commission, Canadian Interventional Neuro Group (CING), Society of Neurointerventional Surgery (SNIS), Society of Vascular and Interventional Neurology (SVIN), and World Federation of Interventional and Therapeutic Neuroradiology (WFITN).

CRITERION 12- UTILIZATION OF “SAFE PUNCTURE” PRACTICES

EVT treatment centres must ensure that interventionalists adhere to best practices for vascular arterial access (refer to Appendix A: Safe Puncture Practices), and that the equipment necessary to support these practices is readily available.

CRITERION 13- PERFORMANCE MEASUREMENT AND QUALITY IMPROVEMENT

EVT treatment centres are required to participate in an established process for the collection and analysis of process and outcome data (locally and provincially), establishing plans for quality improvement in compliance with [Ontario Health \(CorHealth\)’s Quality Performance Measurement and Monitoring Cycle](#).

Appendix A: Safe Puncture Practices for Stroke EVT

Exact artery to be punctured should be left to the discretion of the proceduralist. However, similar principles in terms of safe puncture should be followed.

- Prior to the intervention, baseline arterial examination of the limb is recommended to allow for post intervention comparison. This should include review of any available imaging, clinical arterial examination and assessment of any known peripheral arterial disease or previous vascular intervention that may play a role in decision making.
- Ultrasound guided puncture to visualize the common femoral artery, landmarks such as the femoral artery bifurcation and femoral head, identification, and avoidance of significant arterial disease.
- At all times, avoiding a high puncture (above the inguinal ligament, above the inferior epigastric vessel or above the proximal 1/3 of the femoral head) should be the goal. Identifying a high puncture during or immediately at the end of the procedure may warrant further imaging or vascular consultation.
- The ideal puncture should occur a) in the anterior wall of the common femoral artery b) below the epigastric vessels c) above the femoral bifurcation d) below the inguinal ligament e) over the proximal 1/3 of the femoral head and f) in a healthy portion of the artery.
- If available, micropuncture needles are recommended and techniques that avoid more than one puncture of the artery. The technique, number of attempts and location of the puncture on the femoral artery should be included in the procedure dictation.
- Initial femoral puncture and final dedicated angiograms to confirm arterial puncture anatomy and identification of high arterial puncture, patency of the access site and any other puncture related complications.
- If indicated, use of appropriate closure devices to assist with hemostasis and reduce bleeding complications.
- Post intervention assessment of the femoral puncture site, with serial post intervention monitoring to assess for any post intervention complications. Should any pulse deficit or change or concern of bleeding (e.g. arterial ischemia, signs of active groin or retroperitoneal bleeding) be realized after intervention, further imaging to assess for puncture related complications is recommended. If required, vascular consultation should be considered.

Appendix B: EVT Requirement Attestation Form

As per the annual Hospital Funding Allocation letter, hospitals receiving EVT funding are required to comply with service delivery requirements set out by Ontario Health. The purpose of this attestation is to confirm the Stroke Endovascular Centre's compliance with these requirements. It is the responsibility of the undersigned Hospital CEO or Delegate to complete this Attestation.

You may keep a copy of this Confirmation and Attestation for your files and future reference, with the original to be provided to Ontario Health (CorHealth)

Name of Hospital (Corporation and Site, if applicable):

Hospital Address:

Date:

EVT REQUIREMENT ATTESTATION
<p>CRITERION 1- MINIMUM VOLUMES</p> <p>EVT treatment centres are required to provide a minimum of 30 cases per year to ensure both program sustainability and clinical expertise. All centres, especially those with lower case volumes (i.e., 30 cases/year), should implement a quality assurance program that includes monitoring of key process, outcome, and safety measures.</p> <p>Hospital to provide:</p> <p>Attestation to an annual EVT volumes of 30 cases/year/centre, at minimum</p> <p>Attestation to the presence of a quality assurance and improvement program that includes monitoring of key process, outcome, and safety measures.</p>
<p>ADDITIONAL COMMENTS</p>
<p>CRITERION 2- STROKE IMAGING</p> <p>EVT treatment centres must have on-site imaging capabilities with 24-hour access, seven days a week, including a computed tomography (CT) scanner (3rd generation or higher helical scanner) with programming for CT angiography (CTA) (multiphase or dynamic CTA), and CT perfusion imaging</p>

<p>with automated post-processing software.</p> <p>Hospital to provide:</p> <ul style="list-style-type: none"> Attestation to the presence of CT with programming for CT angiography (CTA) (multiphase or dynamic CTA) on-site and accessible 24 hours a day, seven days a week. <p>Attestation that CT perfusion imaging with automated post-processing software is available on-site and accessible 24 hours a day, seven days a week.</p>
<p>ADDITIONAL COMMENTS</p>
<p>CRITERION 3- ANGIOGRAPHY SUITE</p> <p>EVT treatment centres must have an adequately staffed angiography suite, ideally equipped with a biplane system; however, the use of a single-plane system is also acceptable.</p> <p>Hospital to provide:</p> <p>Attestation of availability of biplane angiography suite</p> <p>Attestation of availability of single plane (monoplane) angiography suite</p>
<p>ADDITIONAL COMMENTS</p>
<p>CRITERION 4- ON-SITE NEUROSURGERY AND CRITICAL CARE UNIT FACILITIES</p> <p>EVT treatment centres must have on-site neurosurgical support, and a critical care unit (Level 2 Basic, with the ability to escalate to Level 3 Basic on-site, as defined by Critical Care Services Ontario), supported by a stroke physician with expertise in post procedure care, and with appropriate monitoring capabilities and protocols in place that follow current evidence-based stroke best practice recommendations.</p> <p>Hospital to provide:</p> <ul style="list-style-type: none"> Attestation that neurosurgery is available on-site.

- Attestation of the availability of level 2 basic critical care beds for post procedure care.
- Attestation of the ability to escalate to level 3 basic critical care beds on-site, as required.
- Attestation that standardized post procedural care processes are available to critical care staff, such as pre-printed order sets, patient care pathways, and standard care algorithms.

ADDITIONAL COMMENTS

CRITERION 5- LINKAGES WITH REGIONAL OR DISTRICT STROKE PROGRAM

EVT treatment centres must ensure established linkages between the EVT clinical program and the Regional and/or District Stroke Network teams.

The EVT site is required to collaborate with stroke system partners to develop and implement protocols and processes that enable access to EVT.

Hospital to provide:

Name and contact information of Regional and/or District Stroke Coordinator:

Attestation of regional access protocols and processes to support access to EVT up to 24 hours of time last known well.

ADDITIONAL COMMENTS

CRITERION 6- ACUTE STROKE CARE FACILITIES

EVT treatment centres must have a stroke unit that meets Ontario Health (CorHealth)'s Ontario Stroke Unit Definition,¹⁶ have protocols and processes in place to support best practice care delivery, and be actively working towards implementing the core components outlined in [*The Ontario Stroke Unit Definition – A Best Practice Standard for Stroke Units in Ontario*](#).

¹⁶ A stroke unit is a specialized unit dedicated to the care of persons with stroke and staffed by an experienced, interprofessional stroke team. The unit has designated stroke unit beds that are co-located and in physical proximity to each other. These beds are used to provide care for stroke patients most of the time.

EVT treatment centre must have established referral pathways to access Stroke Prevention Clinic services.

Hospital to provide:

- Attestation to the availability of a stroke unit that meets the Ontario definition.

Attestation to actively working towards meeting the core components outlined in the Ontario Stroke Unit Definition-A Best Practice Standard for Stroke Units in Ontario

Attestation that standardized care processes for stroke EVT patients are available to stroke unit staff, such as pre- printed order sets, patient care pathways, and standard care algorithms.

Attestation to having an established referral pathway to access Stroke Prevention Clinic services.

ADDITIONAL COMMENTS

CRITERION 7- THROMBECTOMY DEVICES

EVT treatment centres must maintain an adequate inventory of required devices necessary to perform the procedure, including retrievable stents (with or without additional aspiration) or direct aspiration alone with either a distal access catheter or a balloon guided catheter. Use will be based on operator preference and expertise.

Hospitals to provide:

A description of the in-house stock of stents, catheters, guidewires, and thrombo-aspiration devices:

ADDITIONAL COMMENTS

CRITERION 8- INTRAVENOUS THROMBOLYSIS

EVT treatment centres must ensure that the clinical team is capable and experienced in the administration of intravenous thrombolysis, targeting a door-to-needle times of less than 60 minutes

in 90% of treated patients, and a median door to needle time of 30 minutes.

Hospitals to provide:

- Attestation that standardized care processes for treatment of stroke patients eligible for thrombolysis are available to ED staff, such as pre-printed order sets, patient care pathways, and standard care algorithms.

Attestation to achieving target door-to-needle times of less than 60 minutes in 90% of treated patients, and a median door to needle time of 30 minutes.

Attestation that Executed Memorandums of Understanding (MOUs) are in place if access to thrombolysis is provided in cooperation with other hospitals.

ADDITIONAL COMMENTS

CRITERION 9- STROKE ENDOVASCULAR TEAM

EVT treatment centres must have a locally designated Stroke Endovascular Team that is available 24 hours a day, seven days a week. The team must include specialists with neuro-intervention expertise (e.g. neuroradiologists, neurosurgeons and neurologists), as well as stroke specialists with fellowship training or equivalent experience to support the identification of thrombolysis and/or EVT eligible patients, and post procedure management.

Hospitals to provide:

A description of the health human resources that are mobilized to support 24/7 call services:

If not available 24/7, include a description and timelines of planning to support moving to 24/7:

ADDITIONAL COMMENTS

CRITERION 10- EXPANDED TIME WINDOW

EVT Treatment centres must ensure that the clinical team is capable and experienced in selecting patients for EVT up to 24 hours from stroke symptom onset including those with stroke symptoms on awakening.

Hospital to provide:

- Attestation of selecting and administering EVT up to 24 hours of stroke symptom onset including those with symptoms on awakening.

ADDITIONAL COMMENTS

CRITERION 11-NEURO-INTERVENTIONAL TRAINING AND EXPERTISE

EVT Treatment centres must ensure that specialists performing Stroke Endovascular Thrombectomy meet the training requirements outlined by The Joint Commission, Canadian Interventional Neuro Group (CING), Society of Neurointerventional Surgery (SNIS), Society of Vascular and Interventional Neurology (SVIN), and World Federation of Interventional and Therapeutic Neuroradiology (WFITN)

Hospitals to provide:

Attestation to ensuring interventionalists meet training requirements of the above listed organizations.

Attestation to processes to support maintenance of qualifications.

ADDITIONAL COMMENTS

CRITERION 12- UTILIZATION OF “SAFE PUNCTURE” PRACTICES

EVT Treatment centres must ensure that interventionalists adhere to best practices for vascular arterial access (refer to Appendix A: Safe Puncture Practices), and that the necessary equipment to support these practices is available.

Hospital to provide:

- Attestation to the utilization of “safe puncture” practices for stroke EVT

ADDITIONAL COMMENTS

CRITERION 13- PERFORMANCE MEASUREMENT AND QUALITY IMPROVEMENT

EVT Treatment centres is required to participate in an established process for the collection and analysis of process and outcome data (locally and provincially), establishing plans for quality improvement in compliance with [Ontario Health \(CorHealth\)'s Quality Performance Measurement and Monitoring Cycle](#).

Hospitals to provide:

Attestation to commitment to participating in local and provincial data collection and analysis processes.

Attestation to implementation of quality improvement initiatives where performance warrants (include examples below, as appropriate).

ADDITIONAL COMMENTS

I, the undersigned, hereby attest that the information contained within this EVT Requirement Attestation Form submission is accurate to the best of my knowledge.

Signature of Hospital CEO/Delegate:

Printed Name of Hospital CEO/Delegate:

Date:

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, info@ontariohealth.ca.
Document disponible en français en contactant info@ontariohealth.ca