

Business Case Revision

Mechanical Thrombectomy
in Hyperacute Stroke Care:

an opportunity to improve outcomes for those with severe stroke
across Southeastern Ontario

DATE: March 21, 2017

Revised/updated from original of Dec 10 2015

Sponsor(s):

Richard Jewitt, Medicine Program

Dr. Albert Yongwon Jin, Stroke Neurologist and Medical Lead, Stroke Network of SEO

Karen Pearson, Diagnostic Imaging Services

Dr Annette McCallum, Head, Radiology

Cally Martin, Stroke Network of Southeastern Ontario (SEO)

On behalf of the KGH Endovascular Workgroup - membership list in Appendix A

KGH Executive Sponsor(s): **Silvie Crawford, VP Patient Care and CNE**
Dr David Zelt, Chief of Staff

Strategic Drivers

Role in Acute Specialty Care:

This work aligns with KGH's strategy in the delivery of **acute specialty care** to the region. KGH is one of Ontario's nine designated Regional Stroke Centres (RSCs), the only acute tertiary care centre between Toronto and Ottawa. The hospital was one of the first two acute stroke centres in Canada to receive the Accreditation Canada Stroke Distinction Award recognizing excellence in stroke care delivery. The region of Southeastern Ontario was identified as having exemplary performance in regional access to hyperacute thrombolysis in the Ontario Stroke Report Card released June 2015.

Access to Evidence-based Care:

Five landmark trials supporting strong evidence for endovascular mechanical clot retrieval (thrombectomy) in hyperacute stroke care were released in the past year. These trials have led to the identification of this treatment as a new standard of hyperacute stroke care in the July 2015 update of the [Canadian Best Practice Recommendations for Stroke Care](#) (Heart and Stroke Canada). Given the strength of the evidence, The Ontario Stroke Network distributed a Briefing Note outlining their position in June 2015 highlighting the formation of a provincial Endovascular Treatment Working Group. This fall, an [evidence-based analysis](#) and recommendation for public funding has been made by the Ontario Health Technology Advisory Committee (OHTAC) of Health Quality Ontario to the MOHLTC. There are regional implications for KGH as one of Ontario's designated Regional Stroke Centres (RSCs) due to the time sensitive nature of this treatment and the geography of the region.

Cost Centers / Departments Impacted

- Diagnostic Imaging
- Interventional Radiology
- Stroke Network of SEO – Regional Integrated Stroke Strategy RISS- thrombolysis call
- Critical Care- Kidd 2 ICU and Davies 4 ICU
- Medicine, Kidd 7 Acute Stroke Unit

Note: Impact on ED/all above cost centres in relation to possible added thrombolysis candidates could be offset by developing a tele-stroke IV thrombolysis centre in Brockville as successfully implemented in Belleville.

Background

This treatment consists of arterial catheterization and mechanical removal of large clots occluding brain vessels using a micro-catheter and retrieval stent thus promoting reperfusion of the circulation by recanalization of the artery. The evidence supports significant improvement in functional outcomes for select patients with large proximal clots that tend to respond poorly to IV thrombolysis. There are adequate volumes at KGH to warrant consideration of mechanical thrombectomy for these individuals. Some risks and challenges that need consideration have been outlined. The initial recommended action by the executive sponsors was to form a working group to develop a business case to pilot the treatment within specific parameters and to use that experience to ascertain feasibility, capacity and implications for providing regional access to the treatment. The working group (appendix A) met from August to November 2015 to create a value stream map of the anticipated care process and to jointly develop an initial business case presented to the KGH Performance and Planning Committee Dec 2015. A weekday pilot of 10 cases was approved. Now that the successful pilot is nearing completion, plans are underway to develop the service 24/7 as this is a condition for provincial EVT QBP funding. The updated 24/7 business case is included on pages 4 and 5. The risk assessment has also been updated based on the experience of the pilot and in anticipation of 24/7 funding.



Brief Description of Initiative

The evidence: In 2015, five randomized controlled trials demonstrated that mechanical thrombectomy compared to intravenous thrombolysis is clearly superior both in achieving recanalization of proximal intracranial arterial occlusion and in effecting a favorable stroke outcome at 90 days. Patients with proximal occlusion involving either the distal internal carotid artery or the proximal middle cerebral artery generally do not respond well to intravenous thrombolysis with only 20% or less achieving a

favorable outcome at 90 days. The nature of this type of stroke is that it leaves the person with significant disability. This treatment has the potential to save significant cost both to the patient and the health care system. The [MR CLEAN¹](#) trial published in January 2015 demonstrated that at even prolonged times after stroke onset, thrombectomy using a retrievable stent (also called “stent retriever”) doubled the percentage of patients who recovered to independent function. Subsequent trials including [EXTEND-IA²](#), [REVASCAT³](#) and [SWIFT-PRIME⁴](#) confirmed this result, showing that good clinical outcome was a consequence of the high successful arterial recanalization rate achieved with the stent retriever technology. The [ESCAPE Trial⁵](#) demonstrated that the success of mechanical thrombectomy can be augmented greatly by optimizing patient flow from the Emergency Department to the Interventional Angiography Suite, with 59% of mechanical thrombectomy patients regaining functional independence, compared to 30% treated with intravenous thrombolysis. A key finding in the ESCAPE trial was the importance of moving patients quickly towards the angiography suite once the patient had been identified as a suitable candidate. The time elapsed between the study CT scan and groin puncture (ie, the start of the mechanical thrombectomy procedure) was 51 minutes. The time needed to achieve reperfusion following groin puncture was on average 30 minutes, and the total time from study CT to first reperfusion was targeted at 90 minutes or less.

Time Window and Clinical Process: Time is brain. A stroke deprives the neurons and other brain cells of glucose and oxygen, which leads to cell death. The longer the brain is deprived of oxygen and nutrients, the higher the likelihood of permanent damage to the brain; 1.9 million brain cells die every minute after stroke. The potential to save brain tissue is highly time dependent necessitating a coordinated response with an extremely well designed process. Although the trials enrolled patients within anywhere from 6 to 12 hours after stroke onset, this does not mean that they had 6 to 12 hours to treat the patient. Once the patient arrives in the ED on stroke protocol, a CT scan and CT angiogram are completed. A decision is then made by the neurologist to consult interventional radiology regarding candidacy for mechanical thrombectomy. If the team agree that this approach is indicated, the goal is to achieve reperfusion within 90 minutes from the moment the scan is completed; the clock is reset to 90 minutes to achieve a good outcome. This is not enough time to then transport the patient outside the region. A value stream map has been created outlining the clinical pathway from arrival in the ED on acute stroke protocol via EMS through the ED, Diagnostic Imaging, Interventional Radiology, Critical Care to the Kidd 7 Acute Stroke Unit (see Appendix B).

The benefits if approved are:

1. Significantly improved outcomes for stroke patients, particularly for those with severe stroke:
 - a. decreased mortality
 - b. decreased morbidity/disability: improved level of functional recovery
 - c. improved quality of life
2. Decreased length of stay in acute care
3. Decreased long term costs of stroke care:
 - a. reduced inpatient rehabilitation stay
 - b. reduced need for community rehabilitation and reintegration supports
 - c. decreased long term care requirements
4. Information from the pilot can be used to assess feasibility for regional access and delivery
5. Ministry mandated role sustained as Reginal Stroke Centre providing leadership and oversight in delivery of organized protocols for access to hyperacute stroke thrombolysis.

The impacts if not approved are:

1. Cost to the patient and family:
 - a. greater mortality
 - b. greater long term disability and dependence; decreased level of functional recovery
 - c. decreased quality of life
2. Increased length of stay in acute care
3. Increased long term costs of stroke care
 - a. increased inpatient rehabilitation stay
 - b. increased need for community rehabilitation and reintegration supports
 - c. increased long term care requirements
4. No information on feasibility or mechanisms to develop access to this evidence based approach for the citizens of Southeastern Ontario; given the limited time window most eligible SE residents would not be able to access this treatment elsewhere.
5. Risk of losing the ministry designation as Reginal Stroke Centre with associated regional funding on behalf of the region
6. Risk of losing Accreditation Canada Stroke Distinction Status

Current Practice:

Current Status of Hyperacute Stroke Services:

KGH is the designated Regional Stroke Centre (RSC) for Southeastern Ontario. MOHLTC designation criteria for RSCs include the provision of leadership and oversight in delivery of organized protocols for access to hyperacute stroke thrombolysis. Our regional stroke bypass protocol has successfully improved access to stroke thrombolysis since 1999. In 2010, Quinte Health Care - Belleville site (QHC), a designated District Stroke Centre, added to this success by implementing thrombolysis for the counties of Hastings and Prince Edward using a provincial telemedicine consultation service, "telestroke". Thrombolysis is administered intravenously within a 4.5 hour time window. The [Ontario Stroke Report Card](#) has consistently shown the South East region to be a strong performer in hyperacute stroke management in both the proportion of ischemic stroke patients receiving acute IV thrombolytic therapy and in door-to-needle times. Even with the assistance from QHC there is ongoing growth in stroke protocols at KGH. Over the past three years the KGH ED and stroke team responded to 267 (FY13-4), 297 (FY14-15) and 330 (FY15-16) stroke protocols, administering thrombolysis in 72, 64 and 72 cases per respective year. A further 150-220 stroke protocols were received by QHC per year with 25 to 30 district thrombolysis cases annually. We have a positive track record to uphold.

In 2001-02, KGH was a participant in an IMS Bridging trial that tested delivery of intra-arterial delivery of tPA as an adjunct to IV thrombolysis with arterial catheterization in the interventional radiology suite and the support of neuro-interventionalists. The trial was not successful, however, KGH participation necessitated the development of guidelines and protocols for stroke patients proceeding to the interventional suite. KGH has two interventional suites operated by three interventional radiologists. The suites are both fully booked for interventional procedures for many conditions including cerebral angiography. The interventional radiologists have successfully performed intra-arterial stroke thrombolysis four times in the past 10 years for very specific cases of basilar artery occlusion. KGH did not participate in mechanical thrombectomy trials.

Five RSCs in Ontario participated in the mechanical thrombectomy trials: University Health Network – Toronto Western (50-60 cases/year); St. Michael's Hospital (24 cases/year), The Ottawa Hospital (40-50 cases/year); London Health Sciences (40-50 cases/year) and Trillium Health Centre: (18 cases/year). Hamilton and Sunnybrook Health Sciences centres also now deliver the treatment as a standard of care. Given the evidence, this treatment has become an expected standard of care for RSCs. Volumes of cases at each centre have been steadily growing. These centres now deliver the treatment on a 24/7 basis and as such, will be funded through QBP incremental funding in FY 2017-18. Thunder Bay and Windsor also deliver the treatment but, like Kingston, not yet on a 24/7 basis.

KGH launched its weekday EVT pilot in May 2016 and has performed about one case a month since that time. An interim report on the first 8 pilot cases has been prepared and will be completed once the full 10 cases have been evaluated. The Pilot has been successful with positive outcomes clearly demonstrating that this service is safe, feasible and effective at KGH. KGH has been working with the Ontario Stroke Network Endovascular Treatment Working Group on system planning issues such as revised paramedic protocols, treating centre criteria, imaging and transport protocols for referring telestroke sites such as QHC-Belleville. A "drip and ship" transfer algorithm and protocol was implemented with Belleville Dec 2016. Patients from across the region have been given access to this service at KGH and have been successfully treated. However, due to the limits to weekday hours, the numbers of missed cases are growing. For this reason, the experience of the first year is now being used to actively plan for 24/7 delivery. The business case has been revised based on Pilot learning.

2015 KGH Chart Review: Estimated Potential Volumes and Outcomes:

Dr AY Jin, stroke neurologist, performed a chart audit in 2015 of 143 stroke thrombolysis cases from March 2012 to Sept 2014 (2.5 years). Using the selection criteria of the ESCAPE trial as a guide, his review indicated that 58 of these cases could have been candidates for mechanical thrombectomy. 84% of these selected cases had a door to needle times of less than 60 minutes. Of the 58 cases, 35% percent required continuing rehabilitation or LTC; 15.5% died; 34.5% were discharged home; and median LOS was 11 days. This contrasts with the 85 tPA cases that would not have been candidates for mechanical thrombectomy as follows: 28% required continuing rehabilitation or LTC; 15.3% died; 52% were discharged home; and median LOS was 7 days. The chart review indicated that the 58 "ESCAPE trial candidates" had poor outcomes with longer lengths of stay. The ESCAPE trial evidence suggests that these candidates with more severe stroke might have responded well to mechanical thrombectomy, with outcomes and care trajectories that would be comparable to the 85 standard tPA "non-ESCAPE" cases (or possibly even better). Summary of the chart review:

- Given the KGH door to needle times, it would be possible to make timely decisions to proceed to stent retriever therapy.
- If mechanical thrombectomy were performed 24/7 estimated volumes would be 23 cases annually.

- If performed only between 7 am and 5 pm, weekdays, estimated annual volumes based on chart review would be 10-14.
- Mechanical clot retrieval has the potential to reduce median LOS and result in greater numbers discharged home rather than to LTC or to inpatient rehabilitation.
- The volume estimates from this review have proved to be accurate through the pilot period, with 10 cases being treated over the first year. 15 “missed cases” (outside the weekday service hours) have also been tracked.

The Burden of Ischemic Stroke [BURST](#) trial⁶ (Mittmann et al, 2012) indicated the cost of a disabling stroke to be \$107,883 versus \$48,330 for a non-disabling stroke. Cost-benefit analyses have strongly supported the cost effectiveness of mechanical thrombectomy.^{7,8} A recommendation was made in 2015 to the MOHLTC by the Ontario Health Technology Advisory Committee (OHTAC) of Health Quality Ontario⁹ for “publicly funding stent retrievers and thromboaspiration devices for mechanical thrombectomy in patients with acute ischemic stroke”. Key findings of the OHTAC review included “a high quality of evidence for improved functional independence with an incremental cost effectiveness ratio of \$11,990 per quality-adjusted life-year gained.” QBP funding at a price of 29K per EVT case was announced in Dec 2016 for the 7 centres that now deliver EVT 24/7.

What is the decision you would like?

The Endovascular Workgroup now seeks funding approval for a revised plan for 24/7 delivery of Endovascular Mechanical Thrombectomy based on the learning from the FY 2016-17 weekday pilot trial on 10 patients. The 24/7 approach would continue to use evidence-based selection criteria and would continue to improve upon care processes established in FY 2016-7. As the Pilot approaches completion, the business case for 24/7 service delivery has been revisited. Added costs for RN and MRT coverage have been added in order to build the human resource pool to call upon 24/7. The costs per case for weekday service have been updated (although actual equipment costs per stent retrieval were very close to estimated costs, the estimate of 50% requiring two stents was not observed and costs have been adjusted to 10% of cases. The Workgroup now seeks approval for 24/7 implementation and associated funding based on the Pilot experience. The timeline for 24/7 implementation is dependent on building human resource capacity but is expected to begin between July and Sept 2017 – the best estimate is July 5th 2017.

Financial and Cost Analysis: Cost and Benefit Projections

The chart review indicates an expected volume of 58 of 143 cases in 30 months; or 23 cases annually including 10 annual cases presenting during weekday hours (M-F, 800 hrs to 1700 hrs). Annual costing is based on 25 cases per year. Given there may be some growth due to the expansion of the treatment time window from 4.5 to 6 hours, and to access across the region, a volume “buffer” of 20% is added. The costs outlined are for the added costs of mechanical thrombectomy over and above the current delivery of IV thrombolysis. The costs for 24/7 delivery have been updated on the basis of the Pilot experience and include provision for two part time Medical Radiation Technologists (MRTs) and two part time RNs to add to the pool available for call. Scenarios:

- A. Ten pilot weekday cases (0800-1700hrs, M-F) - shown in blue
 B. Annual 24/7 service delivery – shown in orange and based on 25 cases per annum

Costs

ADDED Thrombectomy Costs for PILOT 10 cases Weekdays			ADDED Thrombectomy Cost - Delivery 24/7x1yr	Explanatory Notes		
Number of cases	One case	Ten cases	25 cases			
A. Interventional equipment costs			Expected volumes if delivering 24/7 = 25/yr 10 x daytime cases 15 x weekends/evenings	If carotid stent added		
Stent retriever + procedure						
Angio tray	473.76					
5fr Vert	24.91					
Glide wire	40.00				Spider	1750.00
J wire	17.17				Wallstent	1700.00
Exchange rosen	47.70				Carotid stent	3450.00
Progreat	650.00				retriever + carotid stent \$12803	
Fathom wire	650.00				(Frequency of 1/10 at highest)	
Cello Balloon catheter	950.00				One stent retriever is expected to be needed in 90% of the cases with an additional stent retriever for 10% of cases. ESCAPE trial methodology will continue to be adhered to. Approaches of many stent retrievals per case will not be entertained.	
Solitaire Stent	5000.00					
Total for 1 stent retrieval	\$7853.54	\$78,535.40	25 retrievals= \$196,338.50			
Add Carotid Stent x 10% cases	\$3450	1/10 cases \$3450	2 Carotid stents = \$6900			
Second Solitaire Stent x 10% cases	\$5000	1/10 cases \$5000	3 additional stents = \$15,000			
Total IVR Equipment		\$86,985.40	\$218,238.50/year			
Total including 8% PST		\$93,944.23	\$235,697.58/year			

B. Interventional HR costs			1 added MRT Stand-by x1yr	1 MRT (no longer a 2nd stand-by RN) 17:30-7:30=14 hrsX5days M-F=70 hrs plus 48 hrs on W/E = total 118 hours 118hrs x \$3.30/hr x 1 = \$389.40/wk
2 FT RNs @ \$54/hour x 2 hours	\$216	\$2160	\$389.40 x 52wks	
2 FT RN Overtime @1.5 rate x2hrs	\$324	3 cases \$972	= \$20,248.80	
2 FT MRTs @ \$49/hour x 2 hours	\$196	\$1600	RN+MRT Call-Back x15 cases	1 PT RN call-back: 1x1.5x \$56 x 4hrs = \$336
2 FT MRT Overtime@1.5ratex2hrs	\$294	3 cases \$882	Total for 15 call-backs	2 FT MRT call-back: 2x1.5x \$49 x4hrs = \$588
(rates include 21% benefits for FT and 34% benefits for PT)			= \$914.10/case x 15 cases	Minus stand-by x3 hrs x1=\$9.90
			= \$13,711.50	
			2RN+2MRT x 10 weekday cases including 5 overtime = \$9270.00	\$3240RN+\$1620 OT+\$2940MRT+\$1470 OT
			Call and overtime costs \$43,230.30/year	
			Add 2x 0.5 FTE RN Salary \$109,827 (includes benefits)	To add to RN pool available for call
			Add 2x 0.5 FTE MRT Salary \$96,412 (includes benefits)	To add to MRT pool available for call
Total IVR HR costs		\$5,644	\$249,469.30/year	Ongoing training costs not included - covered through operational budgets
Total IVR Costs (HR + equip't)		\$99,588.23	\$485, 166.88/year	Outpt CT Imaging = OHIP billing
C. OTHER costs:				
Anesthesiology call: 1/10 cases	\$800 per case	1/10 cases \$800	2/25 cases - \$1600	
Critical care added cost/bed day, K2 ICU vs D4ICU x 2days	\$1241 (\$620.50 x 2)	\$12,410	25 cases -\$31,025.00	Bed costs per patient day (includes 20% for indirect admin costs): K2 ICU: \$1804.90 D4 ICU: \$1184.40 K7 stroke unit: \$560.00
Total OTHER		\$13,210.00	\$32,625.00/year	
Subtotal	\$11,279.82/case	\$112,798.23	\$517, 791.88/year	
Add 20% Buffer for unanticipated	+20%	\$135,357.88	\$621,350.26/year	Buffer for unexpected costs & growth*
TOTAL ALL COSTS	\$13,535.79 per case weekdays	\$135,357.88 for 10 cases weekdays	\$621,350.26/year for 25 cases annually 24/7 service	
			= \$24,854.01 per case for 24/7 service	

Benefits

Anticipated costs savings for the acute stay have been estimated. NOTE: based on Pilot experience, these savings are likely underestimated as many of the Pilot EVT patients were discharged, fully independent, within a week of stroke onset. The significant longer-range cost savings to the health care system are estimated based on the strong evidence for improved functional independence in those receiving this treatment. These significant savings are also underestimated based on Pilot findings matching ESCAPE trial outcomes: 70% of candidates experienced improved functional level to non-disabling stroke.

Thrombectomy SAVINGS for PILOT 10 cases Weekdays			Thrombectomy SAVINGS- 24/7 x 1 yr	Explanatory Notes
Number of cases	One case	Ten cases	25 cases	
LOS – Acute Bed days saved				
Per chart audit – tPA cases – estimate a 4 day savings in K7 median LOS (from 11 down to 7 days) x cost of \$560/day due to reduced stroke severity	\$2,240.00	\$22,400.00	\$56,000	Bed costs per patient day (includes 20% for indirect admin costs): K2 ICU: \$1804.90 D4 ICU: \$1184.40 K7 stroke unit: \$560.00
10% of cases: LOS saved by LTC ALC avoidance; 91 days per LTC case @ \$560/day		1/10 cases x 91days x \$560 \$50,960.00	2/25 cases x 91 days x \$560 \$101,920.00	Review of all CIHI 340 stroke ALC cases destined to LTC, Home for the Aged and CC in last 18 mos at KGH = average ALC LOS of 91 days/ALC pt.
Total Acute Care Savings	\$7,336.00	\$73,360.00	\$157,920.00/yr = \$6316.80 savings/case	
Net cost to acute care	(\$6199.78) Net cost/case weekdays	(\$61,997.88) Net cost/10 cases weekdays	(\$463,430.26) 25 cases (\$18,537.21) = net cost/case Delivering 24/7	
Longterm Health System Savings:				
50% greater chance of outcome of non-disabling stroke at cost of \$48,330 versus disabling stroke at cost of \$107,883 (\$59,553 difference)	\$29,776.50	5/10 x \$59,553 = \$297,765.00	12/25 cases x \$59,553= \$714,636.00	ESCAPE trial showed 70% experienced improved functional level to non-disabling stroke – 50% chosen as a conservative estimate. Longer term health system savings based on BURST [®] economic analysis.

Acute + Long Term Savings	\$37,112.50 saving/case weekdays	\$371,125.00	\$872,556.00 25 cases \$34,902.24 per case	*Added Costs estimated in the 20% buffer for volumes: ➤ Growth in volumes in relation to the anticipated increased EMS time window from 4.5 to 6 hours ➤ Growth in volume from QHC District centre “drip and ship” NB: Not included is potential revenue related to: ➤ QBP pricing – anticipated pricing of \$29,600 per case
NET HEALTH SYSTEM SAVINGS over long term	\$37,112.50 -\$13,535.79 \$23,576.71 saving/case weekdays	\$371,125.00 -\$135,357.88 \$235,767.21 saving/10 case pilot weekdays	\$872,556.00 -\$621,350.26 \$251,205.74 Savings from annual rate of 25 cases serviced 24/7 Savings per case over the long run = \$10,048.22	

Cost-Benefit Summary:

Service provided weekdays:

- Acute Cost /Thrombectomy Case: (\$13,535.79)
- Acute Savings /Thrombectomy case: \$7,336
- **Net Acute Care Cost /Thrombectomy Case: (\$6199.78)**
- Net Long term Health System Savings per Case: \$23,576.71

Service provided 24/7 for 25 cases per year:

- Acute Cost /Thrombectomy Case: (\$24,854.01)
- Acute Savings /Thrombectomy case: \$6316.80
- **Net Acute Care Cost /Thrombectomy Case: (\$18,537,21)**
- Net Long term Health System Savings per Case: \$10,048.22

Given the longer term health system benefit and the savings in decreased acute and alternate level of care days, the cost per case to acute care would be worthwhile, not only for the patient but for the health system. Given the ministry has announced its QBP plan to fund 24/7 EVT centres at **\$29,633** per case, hospitals and the health system could ultimately save significant costs if delivering the service 24/7.

Anticipated EVT procedure cost and revenue

2017-18 (year one)

Anticipate starting EVT 24/7 beginning Q2 (July 5 2017).

Q1: 3 weekday cases (1/month) - 3 x \$13,535.79 (weekday rate) = \$40,607.37

Q2-4: 3 quarters x 25 = 19 cases - 19 x \$24,854.01 (24/7 rate) = \$472,226.19

Total anticipated costs for 2017-18 = \$512,834

Offsetting these costs:

Anticipated remaining funds from 2016/17 pilot fund = \$75,000

Funding set aside for 2017/18 = \$455,343

Total funding required = \$530,343

2018-19 (year two)

Costs: 25 cases x \$24,854 (24/7 rate) = \$621,350

QBP Revenue: 25 x \$29,633 per case = \$740,825

Risk Assessment

The following risks have been identified and addressed through the pilot. All but the first have mitigation plans:

- **Sustained Physician Reimbursement:** There are, as yet, no OHIP billing codes for EVT. Further, even if billing codes were established, given the low expected volumes, the amount of call that will be required for interventional radiologists would not be recompensed by OHIP billing. The Interventional Radiologists are requesting a call stipend of \$500 per day. There is no budget for this stipend. This poses a risk to 24/7 service delivery and therefore to KGH funding given 24/7 is a condition for EVT funding. This has been discussed with the Chief of Staff. No risk mitigation has yet been identified.
- **Financial:** Provincial funding for this service is dependent on 24/7 service delivery. Funding for the 10 pilot cases was reallocated from a previous F2010 \$175,000 pilot project in stroke care that remained unspent by April 2016. With support of hospital senior leadership, the pilot project proceeded. Further KGH funding has been identified for the service to continue in 2017-18. This will support progression to 24/7 service delivery, when KGH will qualify for QBP funding of \$29K per case.

- **Engagement:** The provision of this service involves a complex interaction of services including neurology, neuroradiology, interventional radiology and the IVR suite, ED, anesthesiology / procedural sedation, Critical Care, Kidd 7 stroke unit, stroke team. Risk mitigation: All stakeholders have been engaged in the workgroup and have provided oversight to the pilot implementation and evaluation. The workgroup has continued to meet to respond to learning and improve the service.
- **Training, credentials and competency:**
 - Mechanical thrombectomy requires significant interventional expertise. Although KGH interventional radiologists do not have formal training in neurological intervention they do have some experience. KGH neurosurgeons do not have formal interventional training. Risk mitigation: Site visits, added training, neurology and interventional radiology participation in a Calgary Knowledge Translation conference in 2016 and 2017. Mentorship model including tele-mentorship/tele-fluoroscopy via OTN has been successfully used during the pilot with Dr Brian Van Adel from Hamilton. The IVR team is now comfortable with EVT delivery without the tele-fluoroscopy link.
 - Procedural Sedation is sometimes be required for the intervention. Risk mitigation: KGH procedural sedation policy has been followed with the support of intensivists and anesthesiologists to build qualified capacity as needed. Deep sedation has not been required for Pilot cases. Ramsay scores of 2 to 3 i.e. mild to moderate at most have been used. Requirement for intubation has been an exclusion from thrombectomy in Pilot anterior circulation cases. There has not been a need for anesthesiology consultation during these Pilot cases.
 - Training was required for IVR techs and nurses, Kidd 2 ICU and Kidd 7 nurses. Risk mitigation: training was and continues to be delivered by Stroke Specialist Case Manager, Learning Specialists and Clinical Educators. Participation of interventional radiology staff in site visits and Calgary conference is noted above.
- **Neuroradiology Services:** neuroradiology is not on call 24/7 and the stroke neuroimaging protocols were not well established when the pilot was being planned. Risk Mitigation: The imaging protocol at KGH has been altered to include multiphase CTA on suitable patients. The imaging protocol from Calgary has been followed throughout the Pilot. With extension to 24/7, there will need to be a change in access to neuroradiology. This is also required for more than stroke care and is already under consideration by the radiology division.
- **Interventional Radiology Suite Capacity:** the suites are already fully booked and IVR budget is stretched. The nature of hyperacute stroke care is that it is not predictable though more calls do occur during daytime and evenings than at night. The implications for the IVR resources are significant and include a) physician, nursing and technologist capacity and b) impact on other services accessing the suite. There is currently only one RN and one MRT on call at night. The frequency of call for some is already a major burden with staff leaving the IVR for that reason. Increasing the call burden could introduce added staffing risks in terms of retention of expert staff. For 24/7 delivery, one RN and two MRTs will be needed for call back at night. This will create call burden. Risk Mitigation: The Pilot has been delivered 8am to 4 pm, weekdays using two interventionalists for the early cases. The intervention time has been successfully limited to 45 minutes; procedural sedation has been followed using KGH policy; evidence-based selection protocols have been used and cases were excluded that required intubation given the evidence that these patients did not have good outcomes. During trial period, it was determined that one RN and 2 MRTs will be needed provided neurology takes a hands-on approach to assisting in the suite. This added role of neurology has been MOCKED and processes documented. The costing for 24/7 has included provision for hiring two additional PT RNs and two additional PT MRTs allowing for an increased staffing pool to call from thus decreasing the risk of RN and MRT burn-out. The concern related to physician call remuneration is noted above and has not yet been addressed.
- **Thrombolysis Protocols and Stroke Care Plans:** these have been modified to include process flow algorithms, evidence based decision making protocols and selection criteria with clear consent procedures. Risk Mitigation: assistance is being provided by the Regional Stroke Director, Best Practice Coordinator and Stroke Specialist Case Manager to assist KGH Workgroup to sustain/update process algorithms, protocols, selection criteria, checklists and to continue to learn from other Ontario sites.
- **Evaluation and Continuous Improvement:** Given the risk and complexity of the service a focus has been placed on Continuous Improvement. Risk Mitigation: each Pilot case has been debriefed with a problem solving approach to facilitate learning, safety and continuous improvement of the service. An evaluation plan has been put in place and continues to be followed. A sustainable embedded evaluation plan using provincial indicators is being discussed by the Workgroup.
- **Sustainability and Spread:** Ethical consideration has been given to the limited capacity to safely support 24/7 regional access. Regional access has introduced some increase in volumes and some impact on EMS and regional protocols. Given regional volumes, there is always a risk of overcapacity in ED, critical care and neurosciences. Risk Mitigation: The Pilot has provided added understanding of regional implications. A protocol for Belleville transfers was added in Dec 2016. The reduced LOS associated with improved outcomes very much helped to outweigh the risks. Brockville General is not yet delivering thrombolysis. This could be a balancing step to reduce regional thrombolysis volumes at KGH and is part of the Regional Stroke Workplan for 2017-19.

References:

Landmark Endovascular trials

1. Berkhemer, O.A., Fransen, P.S.S., Beumer, D., van den Berg, L.A., Lingsma, H.F., Yoo, A.J., et al. for the [MR CLEAN](#) Investigators. A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke. *N Engl J Med*. 2015 Jan; 372(1):11–20.
2. Campbell, B.C.V., Mitchell, P.J., Kleinig, T.J., Dewey, H.M., Churilov, L., Yassi, N., et al. for the [EXTEND-IA](#) Investigators. Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection. *N Engl J Med*. 2015 Feb 11; 372 (2):1009-18.
3. Jovin T.G., Chamorro A., Cobo E. et al for the [REVASCAT](#) Trial Investigators. “Randomized Trial of Revascularization with Solitaire FR Device versus Best Medical Therapy in the Treatment of Acute Stroke due to Anterior Circulation Large Vessel Occlusion presenting within 8 Hours of Symptom Onset”. *N Engl J Med* 2015; April 17
4. Saver J., M. Goyal, A. Bonafé, H. Diener, E. Levy, V. Mendes-Pereira, G. Albers, C. Cognard, D. Cohen, W. Hacke, O. Jansen, T. Jovin, H. Mattle, R. Nogueira, A. Siddiqui, D. Yavagal, T. Devlin, D. Lopes, V. Reddy, R. du Mesnil de Rochemont and R. Jahan for the [SWIFT PRIME](#) Investigators, “Solitaire with the Intention for Thrombectomy as Primary Endovascular Treatment for Acute Ischemic Stroke Trial: Protocol for a Randomized Controlled, Multicentre Study Comparing the Solitaire Revascularization Device with IV tPA alone in Acute Ischemic Stroke” *Int J. Stroke* 2015; 10; 439
5. Goyal, M., Demchuk, A.M., Menon, B.K., Eesa, M., Rempel, J.L., Thornton, J., Hill, M. et al. for the [ESCAPE Trial](#) Investigators. Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke. *N Engl J Med* 2015; 372:1019-1030 March 12, 2015

Economic analyses

6. Mittmann, N., Seung, S.J., Hill, M.D., Phillips, S. J., Hachinski, V., Cote, R., Buck, B.H., MacKey, A., Gladstone, D. J., Howse, D. C., Shuaib, A., Sharma M. BURST study: Impact of Disability Status on Ischemic Stroke Costs in Canada in the First Year. *The Canadian Journal of Neurological Sciences* 2012; 39:6: 793 - 800.
7. Leppert, MH; Campbell JD; Simpson JR; Burke, JF; cost effectiveness of Intra-arterial Treatment as an Adjunct to Intravenous Tissue-Type Plasminogen Activator for Acute ischemic Stroke. *Stroke* 2015; 46: 1-7 July 2015
8. Gandesalingam, J; Pizzo, E; Morris, S et al; Cost Utility Analysis of Mechanical Thrombectomy using Stent Retrievers in Acute Ischemic Stroke. *Stroke* 2015; 46: 2591-2598 Sept 2015
9. Health Quality Ontario; Mechanical Thrombectomy in Patients with Acute Ischemic Stroke: A Health Technology Assessment; Ontario Health Technology Assessment Series; Vol 15; Sept 2015

EMS/ Hospital Protocols/Process

10. McTaggart RA; Ansari SA; Goyal M et al; Initial Hospital Management of Patients with Emergent Large Vessel Occlusion: report of the standards and guidelines committee of the Society of NeuroInterventional Surgery; *J Neurointervent. Surg* 2015; 0:1-9, Oct 2015
11. ESCAPE trial website - for clinical guidelines, protocols and resources: <http://www.ucalgary.ca/dcns/ESCAPE>

Decision of Planning and Performance Committee

Approved _____ Date of planned implementation _____

Not approved _____

Comments (if any)

Once approved, the proponents are expected to work with Financial Services to incorporate impacts into the current applicable year(s) operating budget. Copies of approved document are to be sent by the Administrative support of the Planning and Performance Committee to proponents and Financial Services.

APPENDIX A

KGH Stroke Endovascular Workgroup 2015-17

Medicine (Neurology, Neurosciences, Stroke Network of SEO)
Dr. Ramana Appireddy, Stroke Neurologist
Darlene Bowman, Stroke Specialist/Case Manager
Sharen Chapman, Program Manager, Neurosciences
Richard Jewitt, Program Operational Director, Medicine, Mental Health, Renal
Dr. Al Jin, Stroke Neurologist, Medical Leader, Stroke Network SEO (Co-Chair)
Cally Martin, Regional Director, Stroke Network SEO (Co-Chair)
Colleen Murphy, Regional Stroke Best Practice Coordinator, Stroke Network SEO
Jennifer Rogers, Clinical Learning Specialist
Emergency Department
Jacque Donaldson & Julie Fournier, Program Managers
Katherine Dowker and Krista Brisbin, Clinical Learning Specialists
Dr. Terry O'Brien and Dr Karen Graham, Program Medical Directors, Emergency
Cynthia Phillips, Acting Program Director, ED (and past Director, Julie Caffin) - corresponding member
Diagnostic Imaging Services and Interventional Radiology (IVR)
Brenda Beattie, Charge RN, IVR
Kelly Bodie, Program Manager, IVR
Barb Delaney, Senior CT Technologist, Diagnostic Imaging Services
Dr. Omar Islam, Neuroradiologist
Dr. Annette McCallum, Head, Radiology - corresponding member
Dr. Alex Menard, Interventional Radiologist
Dr. Ben Mussari, Interventional Radiologist
Karen Pearson, Director, Imaging Services
Lesa Thom, Imaging Services Senior IVR Technologist
Dr. Douglas Walker, Interventional Radiologist – IVR Department Chair
Anesthesiology
Dr. Imelda Galvin, Anesthesiologist and Intensivist (cross appointed to critical care)
Critical Care
Dr. Gord Boyd, Neurologist and Intensivist (cross appointed to neurology)
Kellie Kitchen, Acting Program Operational Director, Critical Care (and past Director, Julie Caffin) - corresponding member
Rebecca Gill, Clinical Learning Specialist
Christina Panopoulos-Rowe, Program Manager, D4ICU
Nicole Valade, Program Manager, K2ICU
Clinical Laboratories
Anne Vincent, Senior MLT, Point of Care Testing
Information Analysis & Distribution (IAD)
Rod Albrough, Senior Data Management Coordinator
Patient Safety, Quality & Risk
Dana MacPhail, Patient Experience Specialist