# An Evaluation of Carotid Artery Ultrasound Imaging at a Testing Facility in St. John's, Newfoundland and Labrador, and Design of an Electronic Test Ordering Solution to Improve Access to Testing

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### ABSTRACT

#### Objective

To determine volume, clinical characteristics, appropriateness of, and time-to-access carotid artery ultrasound (U/S) testing; and, to describe requirements for an electronic ordering solution.

#### Background

Carotid artery disease is a cause of stroke and transient ischemic attack (TIA). Carotid imaging is urgently required in patients with recent neurological symptoms arising from the carotid territory to diagnose critical stenosis and eligibility for carotid revascularization.

#### Methods

Utilization of carotid artery U/S testing in adults at the vascular laboratory operated by Eastern Health was evaluated. In phase I, data from 2007-19 were analyzed for incidence of testing, clinical characteristics of the tested cohort, appropriateness of testing, and time-to-access testing. Phase II interventions were aimed at improving access to testing. Phase III involved documentation of learnings into requirements for an electronic testordering solution.

#### Results

22,167 adults were tested. 35% of testing was for appropriate reasons and 29% resulted in a diagnosis of critical carotid disease. Prediction of clinically significant stenosis using referral data was poor. At baseline, time-to-access testing was prolonged and 85% of incoming requisitions were defective (unable to triage). Following interventions, mean time-to-access was reduced for highest priority referrals and referral quality improved to a 23% defect rate.

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### Conclusions

Although improved access to testing and referral quality were observed with enhancements to the ordering requisition, streamlined triage and scheduling processes, and knowledge translation initiatives, time-to-access was not optimal in patients with recent neurological events. Learnings informed the design of an electronic ordering solution aimed at improving access for highest priority patients.

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# LIST OF ABBREVIATIONS AND SYMBOLS

1.	Transient Ischemic Attack	TIA
2.	Newfoundland and Labrador	NL
3.	Computed Tomography Angiogram	CTA
4.	Magnetic Resonance Angiogram	MRA
5.	Ultrasound	U/S
6.	Cumulative Index of Nursing and Allied Health Literature	CINAHL
7.	Excerpta Medica Database	EMBASE
8.	Randomized Control Trial	RCT
9.	Number Needed to Treat	NNT
10.	Quality of Stroke Care in Canada	QSCIC
11.	Face, Arm, Speech, Time	FAST
12.	Heart and Stroke Foundation	HSF
13.	Emergency Department	ED
14.	Tissue Plasminogen Activator	tPA
15.	Relative Risk	RR
16.	Confidence Interval	CI

17. Diagnostic Imaging	DI
18. Canadian Medical Protective Association	СМРА
19. Critical to Quality	СТQ
20. Electronic Test Ordering	eOrder
21. National Health Service	NHS
22. Canadian Institute of Health Information	CIHI
23. Canadian Foundation for Healthcare Improvement	CFHI
24. Regional Health Authority	RHA
25. Centre for Health Informatics and Analytics	CHIA
26. Health Research Ethics Board	HREB
27. Memorial University of Newfoundland	MUN
28. Peak Systolic Velocity	PSV
29. Odds Ratio	OR
30. United States	U.S.
31. Knowledge Translation	КТ
32. Priority 1	P1
33. Priority 2	P2
34. Priority 3	РЗ
35. Newfoundland and Labrador Centre for Health Information	NLCHI
36. Canadian Medical Association	СМА
37. Quality Improvement/Quality Assurance	QI/QA

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# **CHAPTER 1 – INTRODUCTION**

**Stroke places enormous burden on people and the healthcare system.** Worldwide, stroke is a leading cause of mortality and the number one cause of adult disability. In Canada, stroke is the third leading cause of death. Approximately 62,000 people are treated in Canadian hospitals for stroke each year, at an annual cost of more than \$3.6 billion (Heart and Stroke Foundation, 2018). Amplifying stroke's direct incidence, it is estimated that for every symptomatic stroke there are nine covert, or undetected, strokes resulting in some degree of vascular cognitive impairment (Heart and Stroke Foundation, 2018).

**Causes of stroke**. Stroke occurs when blood stops flowing to any part of the brain, damaging brain cells. There are two types, hemorrhagic and ischemic. Hemorrhagic stroke occurs when a weakened artery in the brain ruptures, interrupting blood flow within its territory, allowing bleeding and compression to surrounding tissues. Hemorrhagic stroke is less common at 13% of all cases, often resulting from aneurysms and arteriovenous malformations (Heart and Stroke Foundation, 2018). In contrast, ischemic stroke occurs when a vessel supplying blood to the brain is obstructed, most often by atherosclerotic plaque build-up. The blood clot, or thrombus, may develop within the brain (cerebral thrombosis), or travel to the brain from another site such as the heart or carotid vessels (cerebral embolism) (Heart and Stroke Foundation, 2018). Ischemic stroke is much more common, making up 87% of all events. In both hemorrhagic and ischemic stroke, the person's outcome depends upon which area of the brain was damaged and the degree of injury to the tissues (Heart and Stroke Foundation, 2018).

**Risk factors.** An individual's risk of stroke is increased by modifiable lifestyle factors such as unhealthy diet, physical inactivity, obesity, smoking, drug and alcohol abuse, and stress. These may contribute to the development of health conditions that also

increase stroke risk such as high blood pressure, high serum cholesterol, diabetes, atrial fibrillation, and vascular cognitive impairment. Non-modifiable factors including South Asian, African, and Indigenous heritage, age, and family history of cardiovascular disease also increase a person's risk of stroke.

**Burden of disease.** Each year in Newfoundland and Labrador, approximately 1500 people suffer stroke, and incur upwards of \$235 million in direct and indirect stroke-related expenses (Newfoundland and Labrador Centre for Health Information, 2019; Newfoundland and Labrador Integrated Stroke Strategy, 2013). This burden will increase with projected growth in risk factor prevalence and continued demographic shift towards 'graying' of the population. From both a financial and human perspective, stroke continues to exact its price for years after the initial event, as people cope with medical complications, mental health issues, changes in independence, and other impacts of living with stroke.

**Secondary stroke.** In an estimated 16–30% of strokes, people suffer stroke 'secondary' to a warning event (Kocaman, 2015; Hong, 2011). These heralding events are known as transient ischemic attacks (TIA), or mini-strokes, and are defined as, 'temporary focal loss of cerebral or ocular function attributed to ischemic vascular disease lasting less than 24 hours' (Easton, 2009). TIAs indicate temporary compromise to brain tissue that is salvageable, but at high risk of future infarction. The mechanism of injury most commonly linked to TIA is large artery atherosclerosis; plaques accumulating in large arteries (particularly the aortic arch, carotids, and intracranial vessels) become unstable, allowing pieces to separate and move into the cerebral circulation (Tsivgoulis, 2018). Mobile plaques temporarily disrupt perfusion, causing transient ischemia, or TIA. Permanent injury, (stroke) occurs when plaques occlude vessels that perfuse large territories of brain tissue (Bose, 2017). In keeping with this etiology, strokes occurring after TIA tend to be catastrophic i.e., severely disabling or fatal, and tend to occur within

48 hours of the warning event (Bose, 2017). The etiology of secondary stroke explains the critical importance of urgent recognition and intervention in the event of TIA. **Prevention of secondary strokes.** There have been many advances in stroke care, but prevention remains, without question, the pinnacle of 'outcomes.' Far superior to managing a completed stroke with sophisticated drugs, procedures, and rehabilitation, is identifying a person at risk and intervening to prevent the event. As Hong et al. (2011) conclude, the last 50 years of clinical trials have brought preventative therapies of proven efficacy into clinical practice including anti-hypertensive, anti-platelet, and anti-coagulant medications, and re-vascularization procedures such as carotid endarterectomy. Research, including several landmark clinical trials (EXPRESS, SOS-TIA), has demonstrated that identification and risk stratification of TIA, followed rapidly by effective medical/surgical management, can prevent 80% of secondary strokes (Giles, 2007; Lavallee, 2007). That is, by recognizing the forewarning provided by TIA, patients, clinicians, and the health care system can take preventative measures to save many lives and prevent enormous disability caused by secondary stroke. Critical to the secondary stroke prevention process is that patients with neurological symptoms arising from the carotid artery territory access carotid artery testing within 24 hours, if symptoms have occurred within the previous 48 hours, and within 14 days if symptoms have occurred within more than 48 hours. This allows the presence of critical carotid disease to be diagnosed and patient eligibility for carotid artery revascularization to be determined.

**Carotid revascularization.** Carotid endarterectomy is the revascularization procedure recommended as soon as possible and within 14 days of the onset of carotid territory ischemia caused by atherosclerotic stenosis of the carotid artery (Gocan et al., 2016; Heart and Stroke Foundation, 2018). Carotid endarterectomy involves opening the carotid artery at the site of occlusion, removing the plaque, and repairing the artery with a graft from vein elsewhere in the body, or a woven patch. When performed within target

timeframes (14 days of symptom onset), by a surgeon and/or centre that routinely audits perioperative stroke and death rates, carotid endarterectomy substantially reduces the risk of secondary stroke in patients with ipsilateral carotid stenosis of 70–99% (severe stenosis) and appropriately selected patients with 50-69 % (moderate stenosis) (Heart and Stroke Foundation, 2018). In the severe group, carotid endarterectomy has been shown to reduce the 2-year risk of stroke or death by more than 80 %, from greater than 1 in 4, to less than 1 in 10; and, in the moderate group, Carotid endarterectomy reduces the 5-year risk of stroke or death from greater than 1 in 4 to less than 1 in 7 (Barnett et al., 1991; National Institute of Neurological Disorders and Stroke, 2020; Rerkasem et al., 2017). **Care gap.** Despite well-established evidence-based recommendations to guide secondary stroke prevention, an 80% level of risk reduction for secondary stroke has been difficult to achieve in clinical practice. While improved secondary prevention outcomes are becoming more evident, epidemiological data indicates secondary stroke events remain common (Gocan et al., 2016). In some cases, upwards of one in four patients with completed stroke have had a warning event (Hong 2011; Kocaman 2015). Rothwell et al., (2007) found of 2416 patients presenting with ischemic stroke, 23% had a warning event. Data from the Quality of Stroke Care in Canada Report (2011) shows national secondary stroke rates at approximately 12% and region-specific data from the same study shows the incidence of secondary stroke in Newfoundland and Labrador to be much higher, at 19.8%.

Examining these data from a prevention perspective, if approximately 800,000 people have a stroke annually, as is the case in the United States, approximately 200,000 are recurrent, i.e., a TIA had provided clear warning that a stroke was imminent, and 80% of these or 160 000 strokes, could be prevented. In Canada, effective secondary prevention could reduce the annual incidence of stroke by 16,250, and in Newfoundland and Labrador (NL), high quality secondary prevention could translate to approximately 400 fewer strokes each year. In NL, the median acute care length of stay for stroke

is 8 days, thus 400 fewer strokes could reduce the burden on acute care resources by 3200 acute care bed days annually (Newfoundland and Labrador Centre for Health Information, 2019).

The discrepancy between the secondary prevention potential reported in academic research and the outcomes seen in clinical settings raises important considerations regarding the translation of evidence into practice. Bringing health research from bench to bedside requires an appreciation for the practicalities of health system substructure that may hinder the delivery of optimal care. In secondary stroke prevention, there is widespread acknowledgement of the gap between evidence and practice. Given the particularly high incidence of secondary stroke in NL, there is justification for an examination of its clinical components to identify opportunities for improving outcomes. This epidemiological evaluation examines local clinical processes underpinning secondary stroke prevention, specifically: access to carotid imaging.

Patients presenting acutely with symptoms of carotid artery territory occlusion require testing, or imaging, of the carotid arteries to evaluate the presence and degree of carotid stenosis. Carotid artery imaging is frequently obtained using Doppler U/S. In this non-invasive test, sound waves are used to visualize the flow of blood through the arteries and measure its velocity. Imaging of the carotid arteries can also be obtained using computed tomography angiography (CTA) or magnetic resonance angiography, where digital images are created using radio and/or magnetic waves. These methods of imaging the carotid arteries are used to determine eligibility for surgical revascularization using carotid endarterectomy to prevent stroke. Carotid endarterectomy is recommended within 48hrs of symptom onset in eligible patients, therefore rapid access to carotid imaging is critical to effective secondary stroke prevention.

**Local context.** The primary site for carotid artery testing in Eastern Health (a health authority serving a rural and urban population of about 250,000 residents) is at the

vascular laboratory at St. Clare's Hospital, using ultrasound. Carotid imaging may also be carried out at other facilities within Eastern Health and elsewhere in the province using ultrasound, CTA, or magnetic resonance angiography. The care process being evaluated is outlined in Figure 1.



**Figure 1.** The process for carotid artery imaging following the acute onset of neurological symptoms suggestive of carotid artery occlusion. Original figure.

This thesis is written in traditional style with chapters corresponding to the components of the project. The research questions addressed were:

- What are the volume, and clinical and demographic characteristics of patients referred for carotid U/S from 2007–2019 at St. Clare's Hospital, Eastern Health Authority, NL; and, how appropriate was the referral?
- What was the time-to-access carotid U/S (hours, days) in patients referred for testing at baseline (March-June, 2015) and after process improvement took place (July 2015-June, 2017)?
- 3. Could an electronic test-ordering solution be designed to improve access to U/S in symptomatic patients arising from the learnings of phases I and II and input from stakeholders?

# **CHAPTER 2 – LITERATURE REVIEW**

The following literature review examined clinical and administrative principles and processes underpinning secondary stroke prevention. Consequently, it reviewed recognition and reaction of the public to symptoms of a TIA; diagnosis and management of a TIA; access to carotid artery imaging; imaging of extra-cranial vessels; carotid endarterectomy; coordination of care; referral to dedicated secondary prevention clinics; clinical handover and paper processes; and, shift to electronic tools.

### 2.1 Search Strategy

Publications were located through searches of PubMed, CINAHL, EMBASE, and Google Scholar. A combination of the terms: *secondary stroke, transient isch(a)emic attack (TIA), minor isch(a)emic stroke, extra-cranial, imaging, carotid, access, testing, and prevention* (Figure 2.) yielded 743 articles. Most papers dealt with the broad topic of secondary stroke prevention. Additional search terms were applied including *carotid imaging pathway, efficiency, appropriateness, clinical practice guidelines, electronic, decision support, electronic order, electronic referral, barriers, facilitators, delay, errors, referral quality, and defects.* Filters were applied, limiting results from 2005 to 2019. A Cochrane Database search was carried out utilizing the same list of terms. The final yield was 53 articles, 9 of direct relevance. All 53 were reviewed and reference lists explored for additional publications. **Table 1.** Inclusion/Exclusion Criteria used in Search of Literature 2005–2019 for Articles Relevant toImproving Access to Carotid Imaging

Inclusion Criteria	Exclusion Criteria
Experimental design: randomized control trials (RCT) preferred but given the paucity of evidence, all experimental study designs were reviewed.	Non peer-reviewed publications.
Peer-reviewed publications.	Non-English
Articles written in English or English translation.	Non-experimental
Studies involving operations and processes relevant to access to carotid imaging	aesign

One particular author, Dr. Annemarei Ranta of New Zealand, has been actively working in the area of electronic decision support in access to carotid artery imaging in secondary stroke prevention, and is the only researcher identified with multiple relevant publications. She was contacted in the event she was aware of other research or gray literature pertinent to this review. Dr. Ranta responded personally but was not able to recommend any further literature. She confirmed a paucity of research on process improvement in acute secondary stroke prevention, specifically use of electronic decision support pathways and/or electronic test ordering of carotid artery investigation.





#### **2.2 Critical Appraisal Process**

Each article was assessed for methodological rigor and relevance to the research. Inclusion criteria are presented in Table 1. The objective was to determine if the evidence presented was strong and generalizable based on criteria employed by the Canadian Stroke Best Practices Writing Groups, and the Centre for Evidence Based Medicine (Heart and Stroke Foundation, 2018; Howick, 2011). Elements assessed included: research design, sample characteristics and recruitment methods, follow-up, data collection/analysis, sources of bias, and confounders. Key themes identified through the literature review relevant to accessing extra-cranial imaging are discussed below.

#### 2.3 The Secondary Stroke Prevention Process

Effective acute secondary stroke prevention encompasses a series of activities and responses by patients, practitioners, and the health care system. Broadly, these include recognition and reaction to indicators of risk and warning symptoms; initiation of investigations and medical management; analysis of findings; and, in eligible patients, surgical intervention through carotid endarterectomy (Bose et al., 2017).

Extra-cranial imaging is carried out to identify patients who may benefit from carotid endarterectomy to prevent stroke (Figure. 3). Carotid endarterectomy is a surgical revascularization procedure performed to enable blood flow to the brain via the carotid arteries. Carotid endarterectomy is effective for symptomatic patients with moderate to high-grade ipsilateral stenosis, but its effectiveness is highly time-dependent. The number needed to treat (NNT) is 5 among those undergoing carotid endarterectomy within 2 weeks of symptoms, compared with 125 among those undergoing the procedure after 12 weeks (Gocan et al., 2016). These diminishing returns over time explain why warning events suggestive of carotid territory ischemia are a medical emergency, necessitating swift access to investigation and treatment.



**Figure 3.** Key clinical milestones in the acute secondary stroke prevention process. (QSCIC Key Indicator # 36). Original figure.

Important components of the clinical timeline from symptom onset-to-carotid endarterectomy are symptom onset-to-presentation; presentation-to-carotid imaging; and, carotid imaging-to-carotid endarterectomy. According to the Quality of Stroke Care in Canada (QSCIC) (2011), these constituent times comprise an overall performance indicator of, 'time from symptom onset to carotid revascularization' (QSCIC Key Indicator # 36). Figure 3 highlights key steps in the process of acute secondary prevention. Reduced efficiency anywhere along this process may result in a missed opportunity for effective secondary stroke prevention.

#### **2.4 Public Recognition and Reaction to TIA**

The first steps in successful secondary stroke prevention encompass recognition of neurological symptoms arising from the carotid artery, and appropriate reaction by the individual. Despite widespread and coordinated public awareness efforts, recognition and reaction to the signs and symptoms of stroke by the general public is sub-optimal (Duque et al., 2015). A recent Canadian survey revealed 50% or fewer respondents could name two signs of stroke, (Heart and Stroke Foundation of Canada, 2018). Similar results from other jurisdictions confirm these findings (Gocan et al., 2016; Groschel et al., 2011).

In response to this issue, many jurisdictions have focused on public awareness campaigns designed to improve stroke symptom recognition and reaction. In North America, the acronym 'FAST' is used (Figure 4). FAST reminds people that acute onset of symptoms involving the *Face, Arm,* and *Speech* indicate it is *Time* to activate emergency medical services. FAST was recently adopted by the Heart and Stroke Foundation (HSF) of Canada as a replacement for their pre-existing approach to public awareness of stroke signs and symptoms. The new, four-item FAST strategy is also used by HSF counterparts in the United States, Europe, and other areas of the world, enabling a coordinated public awareness approach across jurisdictions.



**Figure 4.** Example of Heart and Stroke Foundation of Canada's FAST resources used to increase public recognition of stroke symptoms (Heart and Stroke Canada, 2014). Used with permission of Heart and Stroke Foundation of Canada.

Evaluation of the effectiveness of 'FAST' indicates individuals exposed to 'FAST' multimedia campaigns become better able to recognize the signs and symptoms of stroke, and show improved knowledge of appropriate action i.e., call 911 (Environics, 2009; Heart and Stroke Foundation of Canada, 2018; Jurkowski et al., 2008; Bray et al., 2013).

In light of the known limitations in awareness and appropriate reaction to the signs and symptoms of stroke by the public, it is not surprising that epidemiological data confirm people experiencing hyperacute stroke and/or TIA delay seeking treatment (Gocan et al., 2016; Groschel et al., 2011). Many go first to their general practitioner (GP), (Bose et al., 2017; Chandratheva, 2010). Even when symptom onset is outside traditional general practitioner office hours, i.e., when onset is in the evening or on the weekend, many people wait for their General practitioner to open and provide an appointment rather than go directly to an emergency department (ED), (Bose et al., 2017; Bray et al., 2013; Chandratheva, 2010; Fairhead et al., 2005). This creates an immediate delay.

Intensifying the problem, general practitioners are known to have poor accuracy in diagnosing TIA, (Bose et al., 2017; Massengo et al., 2013; Ranta 2013). Literature from multiple countries confirms this pervasive issue, also showing emergency room physicians (ERPs) and neurologists are often poor identifiers of TIA, (Bose et al., 2017; Bray et al., 2013; Chandratheva, 2010; Fairhead et al., 2005; Jeerakathil et al., 2014; Massengo et al., 2013; Ranta 2013).

#### 2.5 Diagnosis and management of TIA

While recognition of stroke symptoms, and knowledge of appropriate reaction are necessary components of secondary stroke prevention, they do not guarantee an effective response at first contact with the health system. Upon presentation, the cornerstones of evidence-informed acute secondary prevention are rapid identification and risk stratification, investigation, initiation of medical treatment, and surgical revascularization, where appropriate (summarized in Figure 3).

A TIA is defined as "temporary focal loss of cerebral or ocular function attributed to ischemic vascular disease less than 24 hours" (Easton 2009). The temporary nature of the symptoms indicate that urgent imaging is needed to diagnose critical coronary artery disease, rather than provision of tissue plasminogen activator (tPA) or other interventions to treat an established stroke.

Multiple examples of best practice recommendations for secondary stroke prevention are available to support care, including the current Canadian guidelines (Heart and Stroke Foundation, 2018). These resources provide trusted guidance on accurate identification and management of patients, but despite efforts to encourage uptake, the literature confirms non-adherent practice is a pervasive problem (Bose et al., 2017; Brownlee et al., 2014; Jarhult et al., 2017; Raposo et al, 2018).

Beyond initial identification, research shows primary providers and Emergency room physicianss have limited knowledge of up-to-date guidelines for secondary prevention, and may not follow best practices (Raposo et al, 2018; Sales et al., 2015). Amplifying these issues, within the health system the use of standardized stroke management protocols is inconsistent, and the information exchange processes used to coordinate care across sectors are often not optimized for efficiency and effectiveness. For example, standardized hyperacute stroke/TIA protocols (paper-based or electronic) are inconsistently deployed across jurisdictions. In the province of NL, efforts are underway to implement standardized operating procedures for hyperacute stroke (Code Stroke), but a TIA protocol has not yet been introduced. Figure 5 illustrates an evidence-based resource for management of TIA developed to support care providers in Newfoundland and Labrador.



**Figure 5.** CODE TIA Pocket Card produced by Quality of Care NL, adapted from Canadian best practice recommendations for secondary stroke prevention (Quality of Care NL, 2018). This resource was developed to support health care providers with risk stratification and appropriate management of individuals presenting with TIA. Used with permission of Quality of Care NL.

## 2.6 Imaging of Extra-Cranial Vessels

Where there is high clinical suspicion of TIA or stroke arising from brain territory perfused by the carotid arteries, imaging is urgently required. Imaging of extra-cranial vessels may be obtained using several methods, however CTA is the recommended modality (Heart and Stroke Foundation, 2019; Wein et al., 2017). Aside from providing exceptional image quality, CTA is widely available, even in remote areas (Kramer et al., 2015). Doppler U/S is also recognized as an acceptable modality and MRA, in some

cases (Heart and Stroke Foundation, 2019). These tend to be less accessible and in the case of Doppler U/S, testing is more time-consuming, and the accuracy of findings is highly technician-dependent (Birmpili et al., 2018; Kramer et al., 2015). Thus, to ensure inter/intra-rater reliability with the use of Doppler U/S, a consistent quality assurance process is required (Birmpili et al., 2018).

In Newfoundland and Labrador, carotid Doppler U/S is widely utilized for carotid imaging. The tertiary Vascular Surgery program based in St. John's operates an accredited Vascular Laboratory. The four vascular surgeons carrying out carotid endarterectomy in this province rely heavily upon carotid Doppler U/S to evaluate degree of stenosis in the determination of surgical eligibility for carotid revascularization. For this reason, time-to-access carotid imaging at the Vascular Lab is of critical importance to patients who undergo carotid endarterectomy in Newfoundland and Labrador. In some cases, patients referred for carotid endarterectomy have imaging completed at regional health authority sites other than the Vascular Lab. If the degree of stenosis has been evaluated elsewhere using CTA or magnetic resonance angiography, patients proceed directly to surgery. If, however, the imaging has been obtained via U/S at another (non-accredited) facility, the testing is repeated at the Vascular Lab.

#### **2.6.1 Carotid Endarterectomy**

Carotid endarterectomy has been shown to be highly beneficial in preventing stroke recurrence in patients who have experienced a minor stroke or TIA when there is high-grade/severe stenosis (70–99% narrowing) of the carotid artery supplying the affected brain tissue; and, modestly effective when there is moderate stenosis (50–69% narrowing) (Heart and Stroke Foundation, 2018). In neurologically stable individuals, carotid endarterectomy was most beneficial within 2 weeks of symptom onset and benefits decreased rapidly with increasing delay (Barnett et al., 1991; Rothwell et al.,

2007). Several large trials have been conducted comparing carotid endarterectomy for symptomatic stenosis with best medical treatment, including a 2017 Cochrane review (Rothwell et al., 2007; Rerkasem et al., 2017). The risk of stroke or operative death at 5-years in patients with severe stenosis (70–99%) was significantly reduced in patients in the carotid endarterectomy group (relative risk (RR) =0.53, 0.42–0.67, p<0.0001, NNT=6) with an associated absolute risk reduction of 16.0% (Rothwell et al., 2007; Rerkasem et al., 2017). For patients with moderate stenosis (50–69%), the risk was also reduced (RR=0.77, 0.63–0.94, p=0.001, NNT=22) and for patients with mild stenosis (<50%), there was no benefit of carotid endarterectomy. Perioperative death or stroke incidence was 7.0% (95% confidence interval (CI) 6.2 to 8.0) and the greatest benefits of carotid endarterectomy were found in men, patients aged 75 years or over, and those randomized to treatment within two weeks of symptom onset (Rothwell et al., 2007; Rerkasem et al., 2017).

Although carotid endarterectomy has been shown to significantly reduce stroke risk, its effectiveness is highly time-dependent, with a number needed to treat of five among those who undergo surgery within 2 weeks, compared with a number needed to treat of 125 among those receiving surgery after 12 weeks (Gocan et al., 2016). For optimal stroke prevention, international best practice guidelines recommend carotid endarterectomy intervention as soon as possible for appropriate candidates, with a target time of intervention in less than 2 weeks of symptom onset (Gocan et al., 2016). In keeping with these findings, the Canadian Stroke Best Practice Recommendation for management of patients with recent TIA or non-disabling stroke and 50–99% stenosis is immediate evaluation by an individual with stroke expertise and extra-cranial imaging to determine the presence, extent, and location of stenosis; and, eligible patients should be offered carotid endarterectomy as soon as possible after symptom onset and within 14 days (Heart and Stroke Foundation, 2018).

#### **2.6.2** Coordination of Care

A consideration in secondary stroke prevention is consistency in triage/management principles utilized by individual sectors of care such as EDs, general practitioners, Diagnostic Imaging (DI), and vascular surgery. A mismatch in response and triage principles between interdependent entities within secondary stroke prevention processes may result in disorganized care that falls short of performance targets. This concept is illustrated in the 2018 work published by Mofidi et al., showing improved outcomes for surgical candidates with symptomatic carotid stenosis when an integrated care pathway was utilized in comparison to usual care.

To demonstrate the above with an example: patients may present to an ED with acute onset of symptoms suggestive of carotid territory ischemia. ED and DI services are often separate, both organizationally and physically. A classic set of local events might entail a requisition being submitted to DI by the ED, requesting brain and extra-cranial (carotid) imaging. If the ED is treating the patient with a high index of suspicion for acute ischemic event and moving rapidly towards determining eligibility for time-dependent therapy such as thrombolysis or carotid endarterectomy, they may incorrectly assume DI is following the same approach (or vice versa). Simultaneously, DI's protocol may be to complete brain imaging at the time of presentation or to schedule extra-cranial imaging for 'next business day'.

In a more efficient scenario, a standardized, electronic, acute stroke and TIA protocol would ensure patients en route or arriving to ED with suspected acute carotid territory ischemia are made immediately known to DI (Jarhult et al., 2017). This enables DI to enact a 'next on table' protocol that expedites unenhanced CT head and CTA of extra-cranial vessels *during the same scan*, if clinically warranted and safe. Without such a coordinated approach, the extra-cranial vessels may not be investigated rapidly, or at all. If not specifically ordered at the time of initial presentation, CTA of carotid

vessels may require separate paperwork and a subsequent appointment. This is despite a clear opportunity to adhere to a best practice protocol and complete testing in one imaging episode at the time of initial presentation. Patients not affiliated with a general practitioner are at even greater risk that imaging of extra-cranial vessels may be delayed or missed (Raposo et al., 2018; Sales et al., 2015).

The potential impacts of mismatched service delivery models include delay and uncoordinated care. An optimized scenario would see services integrated so that each sector performs their part with unambiguous communication and clarity of roles and responsibilities, in the shortest period of time. The scenario described above is not uncommon across provincial jurisdictions, and may help explain why even comprehensive stroke centres often fail to achieve rapid access to carotid endarterectomy (Jarhult et al., 2017; Blacquiere et al., 2013).

Given known deficiencies in systemic and individual clinician ability to execute effective secondary prevention, it is not surprising that patients, even those presenting promptly, may experience ineffective management. Patients often leave the initial point of care without appropriate medications (anti-thrombotics); they may not receive brain imaging immediately; and, they frequently do not access rapid imaging of carotid vessels or carotid endarterectomy within recommended timeframes (Bose et al., 2017; Brownlee et al., 2014; Jarhult et al., 2017; Raposo et al., 2018; Sales et al., 2015). Canadian and Newfoundland and Labrador data confirm these issues exist locally. The Quality of Stroke Care in Canada 2011 report showed only 22% of patients diagnosed with ischemic stroke received brain imaging within 1 hour of emergency arrival, and only 72% of people had brain imaging within 24 hours (Heart and Stroke Foundation of Canada, 2011). Similar concerns persist at the provincial level. Data from the 2017/18 fiscal period indicate 84.7% of admitted patients with confirmed stroke in this province had brain imaging within 24 hours, and only 69.6% were discharged on antithrombotic

therapy (Newfoundland and Labrador Centre for Health Information, 2019).

Best practices for secondary prevention recommend patients receive advice on lifestyle modification as well as educational resources, appropriate monitoring, and streamlined transitions of care (Wein et al., 2017). This includes support for smoking cessation, weight loss/dietary changes, and physical activity. Studies show primary providers, emergency room physicians, and neurologists often neglect these topics, thus many patients at risk do not receive appropriate follow-up, monitoring, and supported risk factor modification (Ranta et al., 2013).

#### 2.7 Referral to Dedicated Secondary Prevention Clinics

The model of practice from the two landmark studies achieving 70–80% risk reduction in secondary stroke entails 24-hour/7-day access to secondary stroke prevention clinics (Rothwell et al., 2007; Lavallee et al., 2007). Dedicated stroke prevention clinics typically use standardized protocols for rapid intake and optimization of medical therapy to coordinate access to required investigations and interventions, and to arrange ongoing follow-up (Gocan et al., 2016; Jarhult et al., 2017; Jeerakathil et al., 2014).

Authentic duplication of the academically-described rapid access model is problematic. In many jurisdictions, specialist-driven models are infeasible, as specialist care is typically concentrated in urban areas. Canadian epidemiological data shows the initiation of secondary prevention frequently falls to general practitioners or emergency room physicians, and proceeds in a fragmented course across geographic and health sectoral boundaries (Heart and Stroke Foundation, 2011). The 2011 Quality of Stroke Care in Canada report shows over half of Canadian patients with stroke are managed by general practitioners, including in Newfoundland and Labrador.

This province provides an example of the infeasibility of replicating the dedicated models of secondary stroke prevention utilized in research settings. With a population of

approximately 500,000 people scattered heterogeneously over a challenging landmass about twice the size of the United Kingdom, rapid access to basic care can be a challenge. As of 2018, one secondary stroke prevention clinic, primarily serving the most densely populated area of the province, was resourced by a single neurologist, without the benefit of Telehealth. Access to the clinic is limited to Monday-Friday, business hours, and is restricted by the neurologist's other duties. The sole neurologist coordinates all investigations and follow-up initiated from the clinic.

Some jurisdictions with higher population density and greater access to specialty services may operate rapid access clinics without genuinely reproducing the round-theclock model employed by the EXPRESS or SOS-TIA trials (Giles, 2007; Lavallee, 2007). Paradoxically, rapid access clinics operating Monday-Friday, business hours or less, amount to 'partial rapid access' and may actually contribute to delayed care. Blacquiere et al., 2013, describe a rapid access clinic that was operational 2–3 days/week. In such designs, patients presenting outside operating hours do not have access to optimal care. Compounding the problem, after-hours patients influence the care of people presenting during operating hours because the backlog they create must be managed before new patients are seen. Ironically, Blacquiere, 2013, reported participation by neurologists in the 'partial rapid access' model was a factor contributing to slower flow. Providing specialist care only on particular days creates a logjam effect by 'batching' referrals to be processed together. The same bottleneck effect is seen at imaging facilities and within surgical services, where carotid investigations and/or carotid endarterectomy are continuously required, but services are not operational on a 24/7 basis (Shah et al., 2013).

#### **2.8** Clinical Handover and Paper-Based Processes

Care transactions between sectors within the health system typically require a request/ requisition process. These may be paper and/or fax-based, verbal/telephone, occasionally mail, and increasingly computerized/electronic. Usually a handover of referral information occurs, followed by triage, appointment booking, execution of a service, interpretation of results, documentation of findings, and dispatch of responsibility and accountability for the next step in the patient's care. As Marmor et al., (2017) discuss, these maneuvers take time and are at high risk for error and delay which may lead to patient harm. The Canadian Medical Protective Association (CMPA) describes handover as, 'the transfer of responsibility and accountability for some or all aspects of care for a patient or group of patients, on a temporary or permanent basis,' (Canadian Medical Protective Association, 2019). The large body of literature on safety in clinical handover is clear on the necessity of standardizing information transfer through the use of structured protocols (Eggins et al., 2015).

The hazards associated with use of paper in health care, including clinical handovers, are well-documented (Canada Health Infoway, 2011). Issues such as illegibility, misdirection, inability to constrain responses or make fields mandatory, and the need for manual processing are widely acknowledged as shortcomings of working in paper (Menachemi et al., 2011). Paper-based transactions entail inherent risk of delay due to the need to physically handle requisitions for scanning, faxing, or other transmission between sectors. Even when paper requests are accurately and rapidly completed and transmitted, they must be managed by the receiving service, often necessitating another handover of information between administrative and clinical staff. These known risks raise obvious concerns about use of paper processing to execute clinical handovers during time-sensitive investigations and interventions in secondary stroke prevention.

Paper-based processes also impair the ability to balance clinical resources. In their 2018 systematic review, Kruse et al., highlighted the limitations of paper-based processes in clinical productivity and resource management (Kruse et al., 2018). As discussed by Lin et al., (2018), clinical sectors such as DI or Vascular Surgery must continuously balance their demand for services against their internal capacity to complete the work. Triage of incoming requests is carried out to stratify demand according to risk, providing the earliest slots to patients whose risk is highest (Lin et al., 2018). The ability to accurately carry out risk stratification depends upon access to the clinical information required for triage. With paper processing, the receiving service is reliant upon the referrer to legibly, and unambiguously, provide the required information. Without 'critical-to-quality' (CTQ) information, triage becomes inaccurate or impossible (Tripathi et al. 2017; Wahlberg et al., 2015). This impairs the health system's ability to routinely adjust demand against capacity, and to engage in informed health resource planning. The use of structured templates and electronic tools for both transmission of critical information and to perform triage is emerging (Canada Health Infoway, 2013; Wahlberg et al., 2015). In 2017, medical researchers with Johns Hopkins published work showing equal or more accurate triage and prediction of patient outcomes using an electronic triage tool (Johns Hopkins Medicine, 2017). Ranta et al., 2013, showed an electronic decision support tool could be used to manage new TIA referrals more comprehensively than General practitioners, emergency room physicians, or even neurologists.

#### 2.9 Shift to Electronic Tools

Electronic test-ordering solutions (eOrder) provide a prime opportunity to facilitate evidence-based care and to eliminate risks inherent to paper-based communication. To date, there is minimal evidence for the use of electronic decision support tools in secondary stroke prevention, and the literature confirms a persistent reliance on fax machines and paper processes, with both in persistent and widespread use (Bodkin, 2018; Picard, 2018; Ranta et al., 2015; Toerper, 2017).

The National Health Service (NHS) in the United Kingdom is the largest buyer of fax machines in the world, however recognizing the deficiencies of fax, the UK has recently passed legislation to phase out and prohibit future fax procurement (Bodkin, 2018). Like the NHS, many organizations are moving towards electronic record-keeping and information-exchange processes, and there is a growing social movement towards elimination of faxing (Picard, 2018). Agencies such as Canada Health Infoway, the Canadian Institute of Health Information (CIHI), and the Canadian Foundation for Healthcare Improvement (CFHI) present public arguments for the use of digital strategies in health information exchange. One example is the use of the slogan, '#AxeTheFax' on Twitter and other social media platforms (Bruce, 2019). With the shift away from paper, there is growing recognition that well-designed electronic tools and processes provide sophisticated opportunities for enhanced health care and health resource management (Canada Health Infoway, 2019; Menachemi et al., 2011).

#### 2.10 Research Concept

The body of research addressing access to carotid artery imaging, to date, has focused largely on the relationship between delayed care and the risk of a secondary stroke, and on quantifying the length of delays. Less consideration has been given to dissecting *why* and *where along the process* delays in care exist, and the role of reliable and efficient ordering, triaging, and scheduling. The work outlined in this thesis evaluates local processes for accessing carotid artery imaging via Doppler U/S in the prevention of secondary stroke. It is anticipated this work will be hypothesis-generating: an examination of local processes will identify opportunities for improvement and inform the design of an electronic ordering (eOrder) solution. In future phases of research, the eOrder solution will be analyzed to determine impact on access to carotid artery imaging and clinical outcomes.

## 2.11 Objective and Hypothesis

As part of a suite of quality improvement initiatives targeting secondary stroke prevention within a regional health authority (RHA), a retrospective mixed-methods analysis of carotid U/S utilization was carried out with the following **objectives**:

- To analyze the utilization of carotid artery U/S imaging at a local adult testing facility, including:
  - Volume of testing
  - Clinical characteristics of the tested population
  - Appropriateness of testing
  - Time-to-access testing
- 2. To examine the effect of system enhancements supporting improved efficiency and appropriateness on access to testing.
- To identify the requirements for an electronic test ordering (eOrder) solution to improve access to testing.

The following hypothesis was established:

In a local testing facility, processes of care for accessing carotid artery imaging using Doppler U/S in the management of adults presenting acutely with symptoms of carotid territory ischemia can be improved to enhance access for high priority patients.

# **CHAPTER 3 – METHODOLOGY**

This analysis was carried out with the authorization and support of Eastern Health, its Vascular Surgery Program, and the Centre for Health Informatics and Analytics (CHIA) – a sub-entity of Memorial University of Newfoundland's Translational and Personalized Medicine Initiative. Ethics approval was requested of the local Health Research Ethics Board (HREB). The application (HREB # 2017.067) was categorized as quality improvement and, as such, did not require ethics approval. This is in keeping with the origin and intent of the work within Eastern Health as a continuous quality improvement initiative. Eastern Health's quality improvement work in secondary stroke prevention is ongoing, with current focus on clinical implementation of an electronic ordering (eOrder) tool.

#### 3.1 Data

**3.1.1 Interrogation of the Vascular Database** (St. Clare's Mercy Hospital Vascular Lab) 2007–2019. The database contains demographic and limited clinical information on the population of individuals investigated using carotid artery U/S at St. Clare's Vascular Lab. Table 2 lists variables contained within the Vascular Database up to May 2017. Additional data from updated software installed in the Vascular Lab from May 2017-April 2019 were available, but did not contain the entire set of variables within the original 2007–2017 dataset. The additional data were analyzed for incidence and appropriateness.

**3.1.2 Time-to-Access** Information (date referral written, date received by lab, date of U/S, and data quality e.g., legibility) was abstracted from paper-based referral forms for carotid artery U/S received at St. Clare's Vascular Lab during two discrete periods in 2015 (March-June and August-December). Follow-up was conducted in 2016 (January-March); and, 2017 (January-June) examining temporal information only.
**3.1.3 Qualitative Information Collection** from subject matter experts including referrers, Vascular Lab technical and administrative staff, vascular surgeons, vascular program and RHA leadership, information technology staff, and patients.

**Table 2.** List of variables included in the electronic database pertaining to carotid artery U/S imaging at St. Clare's Vascular Lab 2007–2019.

Variable	Example
Exam ID	46799
Birth Date	(m/d/y)
Sex	M or F
Test ID	BCSCAV (indicates 'carotid' vs 'arterial' or 'venous'
Age at Test	years
Test Date	(m/d/y)
Patient Status	Outpatient or Inpatient
Reason	See Table 3
Peak Systolic Volume per Artery Tested	RD/ICA/PSV e.g. 80 cm/s

## **3.2 Research Phases**

The three phases of research are largely in chronological order, however in some cases elements of a particular phase overlapped with the work of a phase before or after. Key methodological elements within each phase are summarized below, followed by an expanded description of the methodology for each phase.

## Phase I – Utilization of Carotid Artery U/S Imaging, St. Clare's Vascular Lab

- Analysis of the vascular database 2007–2017, including:
  - > Volume of testing
  - > Clinical characteristics of the tested population
  - > Appropriateness of testing
  - > Diagnosis of clinically significant carotid disease

- Analysis of May 2017-April 2019 vascular data (new software):
  - > Volume of testing
  - > Appropriateness of testing
  - > Diagnosis of clinically significant carotid disease

### Phase II – Improving Access to Carotid U/S

- 2014 initiation of consultation and stakeholder workshops, key informant interviews, observations, process documentation
- March-June 2015, baseline data collection on time-to-access carotid artery testing
- June 2015 redesign of the requisition used within the RHA to order carotid U/S
- 2016 Personalized audit and feedback (referrers)
- 2015–2018 Knowledge translation initiatives (referrers, internal stakeholders).
   Includes didactic education sessions, development of an online carotid imaging training module, site visits, slide deck and webinar development, dissemination of a Code TIA pocket card
- 2015–2018 Public awareness campaign: social media, radio, television, newsprint, online, and social media dissemination of information
- Follow-up sampling of requisitions received at the Vascular Lab during 2016 (January-March); and, 2017 (January-June) including analysis of referral quality and time-to-access testing

## Phase III – eOrder Solution Requirements and Design

- Documentation, design, and implementation-planning of an electronic test-ordering solution.
  - > 2017/18 eOrder requirements documentation
  - > 2018/19 Co-design of eOrder software

- > 2019 Creation of eOrder communication and training strategies
- > 2019/20 (*ongoing*) Deployment of eOrder

## **3.3 Data Preparation**

Encrypted, de-identified, data files were transferred from Eastern Health to Memorial University of Newfoundland and stored on a secure server operated by CHIA. Industrystandard security practices were employed to ensure data integrity and confidentiality, and access to the data was limited to authorized individuals.

The de-identified administrative dataset and the manually sampled data were formatted to an .xlsx format (Excel software). The master file of de-identified data included the entire population of individuals provided with carotid artery U/S at the Vascular Lab between 2008 and 2017; the truncated 2017–19 data from the newer lab software; and, the manually-collected data from baseline and follow-up sampling of time-to-access testing. The data were organized in a tidy fashion based on the Hadley Wickham definition, where each column represents a variable and each row of cells contains the recorded values for one individual or case corresponding to the variable represented by each column (Wickham, 2014).

# *Phase I Methods – Utilization of Carotid Artery U/S Imaging*3.4 Indication and Appropriateness

Age was coded into five age categories: 20–50, 51–60, 61–70, 71–80, and 81–120 years. Within the vascular database, a 'reason for test' was documented for each carotid artery U/S conducted. The 'reason' was selected from a dropdown menu by the vascular technician at the time of the test. Possible reasons selectable within the dropdown menu are listed in Table 3. 'Reason for test' was further categorized into two dichotomous groups: 'indicated cerebrovascular event' and 'not indicated.' Using this approach,

'indicated cerebrovascular event' encompassed stroke, TIA, and/or amaurosis fugax, a type of visual loss. The category 'not indicated' included carotid bruit, asymptomatic, vertigo/dizziness/syncope, and/or other.

**Table 3.** 'Reason for test' recorded by Vascular Technicians for carotid artery U/S testing requestedbetween 2007–2017 at St. Clare's Vascular Lab.

Reason for Requesting Test	Appropriateness		
Asymptomatic			
Carotid Bruit			
Other	Not indicated		
Vertigo/Dizziness/Syncope			
Stroke/TIA/Amaurosis Fugax	Indicated		

The 2017–19 data were treated separately, as this period was transitional between two software systems used within the Vascular Lab. 2017–19 data came from new software implemented in 2017. Capture of variables in the new system is not entirely congruous with the 2007–17 data, resulting in discontinuity between the original variables and those included in the 2017–19 data. For example, 'reason for test' was not captured in the new system using identical dropdown menu options. As a result, the 2017–19 data could not be combined with the 2007–17 data for a continuous analysis.

## **3.5 Diagnosis of Critical Carotid Artery Disease**

The numeric values recorded for age and Peak Systolic Velocity (PSV) were re-coded into new categorical variables. The categories used to re-code PSV values into degree of stenosis were determined in consultation with the vascular surgeons, and involved applying the same treatment to the aggregate dataset as would be used in the interpretation of an individual test. Using the PSV cut-offs shown in Table 4, each test was labelled as one of four outcomes: normal; 50–69% occluded; 70–99% occluded; and, fully occluded. Outcome was further categorized as 'normal' or 'abnormal,' where

abnormal encompassed the clinically significant outcomes of 50–99% occlusion. Stenosis greater than 50% is considered clinically significant and in the presence of recent symptoms suggestive of cerebral ischemia, will be further evaluated for surgical intervention.

Degree of Stenosis	Peak Systolic Flow	
Normal	PSV < 125 cm/s	
50–69%	PSV 125–230 cm/s	
70–99%	PSV > 230 cm/s	Abnorma
Fully Occluded	PSV 0 cm/s	

Table 4. Degree of stenosis categories derived from peak systolic flow velocity (PSV in cm/s).

## **3.6 Statistical Analysis**

Following data preparation and coding, the file was imported into SPSS statistical software, version 24.0. Clinically important variables were represented in graphical format for visual inspection. Incidence of testing and clinical characteristics of the tested population were investigated using descriptive statistics including cross-tabulation and the chi-squared test for association. Time-to-access testing during 2015 was evaluated using survival analysis including the Kaplan-Meier method. Subsequent monitoring of time-to-access in 2016 and 2017 did not involve survival analysis due to limitations in data capture. The 2016, 2017 data was collected by another individual and provided as a mean value.

Appropriateness of testing/ability to predict diagnosis of critical carotid disease were evaluated using several methods. Associations between clinically important variables such as admission status, sex, and 'reason for test' were analyzed using descriptive statistics, including the chi-squared test for association. Binomial logistic regression was used to examine the relationship between the dependent variable 'test outcome' (normal/stenosis), and the predictor variable, 'reason for test' (Table 3). Odds ratios (OR) and accompanying significance (p-values) were interpreted to determine the odds of a clinically significant outcome (abnormal) with each 'reason for test,' admission status, and sex.

## Phase II Methods – Improving Access to Testing and Referral Quality

Definitions of priority are provided in Table 5. Phase II began with abstraction of information from incoming priority 1 and 2 referrals from March to June 2015. Following interventions implemented in July 2015, incoming referrals were sampled again, from August to December, 2015. Subsequent sampling of incoming referrals was carried out in January to May, 2016 and January to June, 2017 to monitor time-to-access. At baseline, 98 P1 and 99 P2 referrals were assessed. In the period August to December 2015, 136 P1 and 128 P2 were studied, as were 99 P1, and 119 P2 from January to May, 2016, and 104 P1 and 139 P2 in January to June, 2017.

The time-to-access testing was calculated as the number of days from when the referral was signed and dated by the referrer, to the test date. If the patient was tested the day the referral was written, time-to-access was recorded as zero. Weekends and holidays were included as elapsed time. The only exception was if a person was offered an earlier appointment but refused it. In such cases, access was calculated using the date the person could have been tested rather than a later time at which they elected to be tested.

**Table 5.** Priority categories assigned to referrals at St. Clare's Vascular Lab 2015–17 with timelines for testing with onset of neurological symptoms indicating carotid territory ischemia (unilateral weakness (face/arm/leg), speech disturbance/aphasia, or amaurosis fugax.)

Priority	Clinical History and Risk	Timeline for Testing
P1	Symptom onset within previous 48 hrs	Test within 48 hrs of symptom onset
P2	Symptom onset between 48 hrs and 2 wks	Test within 14 days of symptom onset
P3	Symptom onset more than 2 wks	Elective (next available appointment)

## 3.7 Referrals: Critical to Quality (CTQ) Features and Defects

Using observation, process mapping, and facilitated stakeholder workshops, the process of accessing carotid artery U/S was deconstructed and documented. Component steps, variation(s) in process, and referral defects were analyzed to identify root causes for protracted access, and to hypothesize methods of improvement.

The key clinical features required to triage each referral and the information required to contact the patient with an appointment are the CTQ elements. According to the United States (U.S.) Department of Health and Human Services Quality Toolbox, 2011, CTQ elements are, 'those key measurable characteristics of a product or process whose performance standards or specification limits must be met in order to satisfy the customer (U.S. Department of Health, 2011). Clinical CTQ elements of carotid imaging referrals were determined based on Canadian best practice recommendations for the prevention of secondary stroke, and include type and timing of symptoms (Figure 5. Quality of Care NL Pocket Card). Additionally, the demographic information to accurately identify the patient and their referrer were deemed CTQ elements. Using this approach, a defective referral was defined as an incoming requisition where CTQ elements were missing, illegible, or ambiguous to the point of being impossible to triage. A baseline proportion of defective referrals was measured for incoming P1 requisitions. Examples of defects are illustrated in Figure 6.



**Figure 6.** Examples of defective referrals received at the Vascular Lab, June 2015. Both requests are presumably for carotid artery imaging, though it is not specified. Date of onset, and/or type of symptoms are not provided, and legibility is poor in both cases, making these referrals impossible to triage using an evidence-based method of risk stratification.

A standardized requisition (Figure 7), purposefully designed to capture CTQ elements, was deployed in June 2015. In addition, the vascular lab adopted a standard approach to triage and appointment booking, and a practice of 'spot-checking' access time for P1 and P2 referrals. Staff came to consensus on booking P1 referrals within 48 hours and P2's within 14 days. The practice of triaging incoming referrals on an ongoing basis rather than allowing them to 'batch' for triage every 2–3 days, was established.

<b>1. Carotid Exam:</b> Screening Date of most recent TIA or Stroke:	Surveillance Post Carotide	ndarectomy (CEA) Date of CEA:	
Clinical Symptoms:			
Unilateral weakness (face, arm, leg)	Aphasia	Other	·····
Unilateral sensory loss (face, arm, leg)	Amaurosis Fugax		
Duration of Symptoms:			
Seconds Minutes Hours	Days Intermittent/R	ecurring	

Figure 7. The carotid imaging portion of the enhanced requisition introduced in June, 2015.

## 3.8 Knowledge Translation Activities

In partnership with Quality of Care NL, a comprehensive multi-media education and knowledge translation (KT) campaign, customized to various stakeholder groups, was undertaken. Examples of KT initiatives include, didactic education sessions (in person and via webinar); online learning module development; facilitated workshops; printed materials such as a quarterly academic publication, posters, and pocket cards; shareable slide decks; and, media coverage (television, newspaper, radio, and social media) (Figure. 8). A panel of patient representatives was engaged to discuss the initiative and to provide advice and feedback. KT activities began in June 2015 and continued over the subsequent 24-month period. Ongoing response was sought from stakeholders using internal RHA communication channels such as email and regular stroke and vascular program meetings. In addition, feedback mechanisms managed by Quality of Care NL were utilized including a public feedback email and subsequent patient panel discussions.

# Don't order a procedure that will not change the patient's clinical course

Carotid Studies are not indicated for:

Syncope Headache Dizziness Tinnitus Carotid bruit Pain Generalized weakness

**Figure 8.** An example of educational material developed and utilized as a component of the 2015–16 Quality of Care NL secondary stroke prevention/carotid U/S utilization KT campaign. Used with permission of Quality of Care NL.

# 3.9 Academic Detailing

During 2015–16, peer-to-peer educational outreach, or academic detailing, was led by Quality of Care NL. This entailed an individualized audit and feedback initiative led by knowledgeable and experienced physicians with the objective of facilitating behavior change by referring providers for better quality referrals and more appropriate testing. Referrers within the catchment area were provided confidentially with their own Vascular Lab carotid U/S utilization history (Figure. 9). This was followed–up with a voluntary face-to-face academic detailing visit by Quality of Care physician lead(s), comprising visits with 95% of family physicians in Eastern Health. During these academic detailing visits, a physician champion with subject matter expertise reviewed referrers' personalized carotid imaging utilization history. Visits were conducted individually or in small groups, per clinic. They aimed to orient referrers to the findings of the carotid utilization review in relation to current evidence-based guidelines for test-ordering. Academic detailing visits were also used to listen to referrers about the challenges of managing the population at-risk for secondary stroke, and to gather feedback on the overall process improvement initiative.





To gauge the impact of the interventions, time-to-access carotid imaging and incoming referral quality were re-evaluated. In the period immediately following implementation of the new requisition, (June-December 2015), incoming referrals were consecutively sampled and analyzed for time-to-access and defects/data quality. Results of referral quality and time-to-access testing were shared with stakeholders. Time-to-access was subsequently monitored in 2016 (January-May) and 2017 (January-June) to determine whether improvements in time-to-access were sustained. The 2016–17 data analysis utilized the same methodology but the referrals were not collected by the writer and thus cannot be verified to be consecutive sampling.

## Phase III Methods – eOrder

The third phase of this work was the design, development, and creation of an implementation plan for an electronic ordering (eOrder) solution. This work began in 2017 as a partnership between Eastern Health, Memorial University's Quality of Care NL program, the Newfoundland and Labrador Centre for Health Information, and the Government of Newfoundland and Labrador.

A project team consisting of representatives of the partner organizations was assembled. The team began engaging with stakeholders, including booking staff, Vascular Lab technicians, referring physicians, vascular surgeons, RHA management, information technology specialists, researchers, and others. Over multiple workshop sessions 2017– 19, stakeholders were consulted on their experience ordering, triaging, coordinating and booking appointments, communicating relevant information, and other aspects of the test-ordering process. The information was documented and translated into the technical requirements for an electronic test-ordering solution.

When sufficient information was gathered to produce an early version of the eOrder tool, workshop sessions were conducted to review a prototype. This enabled stakeholders situated remotely to visualize the application, imagine the steps and clicks, and suggest necessary adjustments. In May 2019, the eOrder solution underwent final testing, and was deployed in October 2019.

# **CHAPTER 4 – RESULTS**

# Phase I – Utilization of carotid artery U/S testing

## 4.1 Volume of Testing

The volume of testing performed annually at St. Clare's Vascular Lab decreased over time with an overall 32% reduction from 2008 to 2016, after which annual testing volume stabilized. Figure 10 illustrates the volume of annual testing from 2007–2018, (2007 data represents a partial year). There was no difference between the volume of males and females tested each year.



Figure 10. Volume of carotid U/S testing at St. Clare's Vascular Lab, 2007–2018.

Figure 11 illustrates the volume of carotid testing taking place at St. Clare's Vascular Lab, along with testing taking place within Eastern Health using CTA, MRA, and carotid U/S at locations other than St. Clare's Vascular Lab. Data from Eastern Health testing sites external to St. Clare's Vascular Lab was not available prior to 2015. Although the of number carotid ultrasounds at St. Clare's fell by 224 from 2015 to 2018, the number of carotid imaging tests done elsewhere in Eastern Health increased by 395.



**Figure 11.** Incidence of carotid U/S testing at St. Clare's Vascular Lab, and imaging conducted at other sites within the RHA using CTA, MRA, and U/S from 2015–18. (\*External site data available from 2015 only).

# 4.2 Clinical Characteristics of the Tested Population

Table 6. summarizes baseline characteristics of the cohort of 19,074 adults tested with carotid artery U/S at the Vascular Lab from 2007–2017. The tested population ranged in age from 20–101 years, with average age of 65 years and no statistical difference in age between men and women. The 61–70 years category was the largest, at 6500 patients (Figure 12). Eighty seven % (87%) were outpatients (Figure. 13).

Total tested population (N=19,074)								
Sex	Males	Females	Total					
Count (% of total)	9406 (49%)	9668 (51%)	19,074					
Ave age yrs (SD)	65.5 (11.1)	65.6 (12.1)						
Admitted	1300 (54%)	1099 (46%)	2399					
Outpatient	8106 (49%)	8569 (51%)	16,675					

**Table 6.** Characteristics of the population tested with carotid U/S at the Vascular Lab, 2007–17.



**Figure 12.** Volume of individuals tested with carotid U/S at St. Clare's Vascular Lab 2007–17 by age group (years), N=19,074.



**Figure 13.** Proportion of carotid U/S testing at St. Clare's Vascular Lab 2007–17 by admission status, N=19,074. n=2399 inpatients; n=16,675 outpatients.

The risk factors documented most commonly by vascular technicians at the time of testing are shown in Figure 14. Hypertension (45%), hyperlipidemia (24%), and diabetes (20%) were recorded most frequently.



**Figure 14.** Most common risk factors documented by vascular technicians at the time of carotid U/S St. Clare's Vascular Lab, 2007–17, N=19,074.

# 4.3 Appropriateness of Testing

Within the total population, the most common 'reason for testing' recorded by vascular technicians at the time of the U/S was 'other,' recorded for 8380 people (44.0%). The next most common reason was 'cerebrovascular event' at 6574 (34.5%). When 'reason for test' was analyzed in relation to admission status, it was observed the most common 'reason for test' among inpatients was 'cerebrovascular event' (57%). Figures 15 and 16 illustrate the volume of carotid testing by 'reason for test' within the total and admitted population, respectively.



Figure 15. Volume of <u>all carotid testing</u> by 'reason for test' 2007–17 at St. Clare's Vascular Lab, N=19,074



**Figure 16.** Volume of carotid U/S testing among <u>admitted</u> patients by 'reason for test,' 2007–17 at St. Clare's Vascular Lab, n=2399.

The total volume of appropriate testing (carried out to investigate an acute



4000

2000

0

cerebrovascular event) was 7863, representing 35% of all testing 2007–2019, Figure 23.

**Figure 17.** Total volume of indicated/appropriate carotid U/S testing at St. Clare's Vascular Lab from 2007–19, N=22,167. \*Indicated testing is for investigation of Cerebrovascular Event including Stroke, TIA, and Amaurosis Fugax.

Not Appropriate

Appropriate

Figure 18 shows the annual percentage of indicated testing. A trend towards more appropriate testing was observed over time between 2007–19 and a chi-squared test for association reinforces this observation is not a random finding,  $\chi^2(10)=79.260$ , p<0.001.



**Figure 18.** Annual proportion of appropriate carotid artery U/S testing at St. Clare's Vascular Lab from 2007–19, N=22,167. \*Indicated testing is for investigation of acute Cerebrovascular Event including Stroke, TIA, and Amaurosis Fugax. \*\*2019 partial year ends April.

## 4.3.1 Carotid Ultrasound Results

The majority of the population had a normal outcome. Of 19,074 people tested, 71.4%, (n=13,621) had a normal result, and 28.6% (n=5453) had clinically significant carotid stenosis or occlusion (Figure 19).



Figure 19. % patients with abnormal carotid artery tests

Table 7 illustrates the proportion of clinically significant carotid stenosis by admission status. Abnormal findings occurred more frequently in admitted patients, and this association was statistically significant ( $\chi 2$  (1) =43.94, p<0.001). (Figure 20).

**Table 7.** Proportion of patients with normal/abnormal carotid ultrasound within the tested population atSt. Clare's Vascular Lab, 2007–17, sub-divided by admission status.

Total Tested Population (N=19,074)									
Outcome	Abnormal	Normal	Total	P-value					
Inpatient (% of Inpatients)	823 (34%)	1576 (66%)	2399						
Outpatient (% of Outpatients)	4630 (28%)	12,045 (72%)	16,675	<0.001					
Total	5453 (28.6%)	13,621 (71.4%)	19,074						



**Figure 20.** % with abnormal carotid tests within the admitted sub-group tested with U/S at St. Clare's Vascular Lab, 2007–17, n=2399.

Table 8 shows the total number of females 'vs' males tested was similar, but there was a significantly higher proportion of males with an outcome of critical stenosis, p<0.001. This is illustrated in Figure 21 below.

**Table 8.** Comparison of critical carotid disease in males and females tested with carotid U/S at St. Clare'sVascular Lab, 2007–17.

Sex	Males	Females	Total	Significance
Stenosis (% of total)	2906 (15.2%)	2547 (13.4%)	5453 (28.6%)	n <0.001
Normal (% of total)	6500 (34.1%)	7121 (37.3%)	13,621 (71.4%)	p<0.001
Count (% of total)	9406 (49.3%)	9668 (51.0%)	19,074	



**Figure 21.** Carotid U/S testing at St. Clare's Vascular Lab, 2007–17, showing differences in outcome by sex, N=19,074.

#### 4.3.2 Critical Carotid Disease by Reason for Testing

Figure 22. Illustrates, the volume of testing carried out for each 'reason for test' showing the proportion of normal and abnormal outcomes within each testing category. Within the appropriate test group (had a cerebrovascular event), rate of diagnosis of critical carotid disease was 33% and in those referred because of a carotid bruit it was 44%. In those who did not have symptoms arising from the carotid artery territory the rate was 27.1% (asymptomatic patients), 26% (other group) and 17% in those with vertigo/dizziness.



**Figure 22.** Volume of carotid U/S testing at St. Clare's Vascular Lab by reason-for-test, showing outcome of testing per reason, 2007–17, N=19,074.

## 4.3.3 Prediction of Critical Carotid Disease Using Clinical Data

The dichotomous response variable investigated using regression analysis was, 'test outcome' (normal or abnormal). Reason for test, (five mutually exclusive options), sex (male or female), and admission status (inpatient or outpatient) were entered as predictor variables. Results of the regression analysis are summarized in Table 9.

Variables in the Equation											
	_					- (-)	95% C.I.	for EXP(B)			
	В	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper			
Reason			315.017	4	p<0.001						
Carotid Bruit	0.768	0.089	73.769	1	p<0.001	2.156	1.809	2.569			
Cerebrovascular Event	0.230	0.073	9.840	1	0.002	1.259	1.090	1.454			
Other	0.054	0.072	0.563	1	0.453	0.947	0.822	1.092			
Vertigo	0.587	0.093	40.256	1	p<0.001	0.556	0.464	0.666			
Male	0.209	0.032	41.268	1	p<0.001	1.232	1.156	1.313			
Inpatient	0.236	0.048	24.578	1	p<0.001	1.266	1.153	1.390			
Constant	1.119	0.070	256.319	1	p<0.001	0.326					

**Table 9.** Results of multiple logistic regression analysis of relationship between 'reason-for-test', 'sex', and 'admission status', and 'outcome' in carotid U/S testing at St. Clare's Vascular Lab, 2007–17, N=19,074.

\*Using Asymptomatic, Outpatient, and Female as reference categories

The analysis indicates abnormal results were two times more likely when the 'reason for test' recorded was 'Carotid Bruit', (OR 2.156, p<0.001). An abnormal result was approximately half as likely when 'Vertigo' was recorded (OR 0.556, p<0.001), 26% more likely when the recorded reason was 'Cerebrovascular Event' (OR 1.259 p<0.001) and 'other' was not statistically significant. Males had a 23% increased likelihood of an abnormal outcome, (OR 1.232, p<0.001), and inpatients had 27% increased likelihood of having a clinically significant carotid stenosis (OR 1.266, p<0.001).

# Phase II Results – Interventions to Improve Access and Referral Quality 4.4 Time-to-Access Carotid Artery U/S Imaging

Measurements of access time were obtained over four sampling episodes between March 2015 and June 2017. Mean time-to-access testing by priority level is shown in Figure 23 and Figure 24 for P1 and P2 referrals during each of the four periods. For high priority patients who had recent neurological symptoms, and for whom testing was recommended within 48 hours, mean time to U/S at baseline was 9 days. Following interventions it was reduced to 3.1 days. For P2 patients who had neurological symptoms more than 48 hours ago and required testing within 48 hours to 14 days, on average, time-to-access at baseline was 41 days. After interventions the target P2 access time was achieved, at 10 days.



**Figure 23.** Average time (days) to access carotid U/S at St. Clare's Vascular Lab for Priority 1 referral over four periods of manual sampling 2015–17, n = 98, 136, 99, and 104 for each period, respectively.



**Figure 24.** Average time (days) to access carotid U/S at St. Clare's Vascular Lab for Priority 2 referrals over four periods of consecutive sampling 2015–17, n = 99, 128, 119, and 139 for each period, respectively.

Time-to-event analysis was carried out for the data collected in 2015 using a consecutive sampling process. The outputs of the time-to-event analysis using the Kaplan-Meier method are found in Table 10 and 11. Mean and median time to access carotid U/S are given for P1 and P2 referrals during the baseline data collection period (March-May 2015), in comparison to after process and referral changes (July-December 2015). The significance of the log-rank tests in both cases (p<0.001) supports rejecting the null hypothesis: that there is no difference in the time to access U/S between baseline and after the interventions. For P1 patients, no individuals were accessing carotid U/S within the target of 48 hours of symptom onset at baseline, and 14% were within the 2 day target after the interventions were implemented. Within the P2 group, at baseline no patients were receiving a test within 2 weeks and following the interventions, 9% accessed testing within the target 14 days. It was not possible to carry out time-to-event analyses on subsequent testing in 2016/17, as data from these periods were available in aggregate form, as mean values only.

		Mea		Median						
Condition	Estimate	Ctul Funan	95%		nfidence rval	Fatimate	Ctal Farman	95%	95% Confidence Interval	
		Sta. Error	Low Bour	er nd	Upper Bound	Estimate	Stu. EITOI	Low Boui	er nd	Upper Bound
Post	5.794	.298	5.2	210	6.379	5.000	.275	4.4	462	5.538
Pre	9.153	.755	7.6	573	10.633	7.000	.429	6.3	159	7.841
Overall	7.201	.376				6.000	.235	5.5	538	6.462
	Chi-Squa				df	Sig.				
	Log Rank (N	lantel-Cox)	21.9	989	1	p<0.001				
				Р	ercentiles					
Condition		25.0%		50.0%			75.0%			
Condition	Estimate	Std. E	rror	E	stimate	Std. Erro	r Estir	nate	St	td. Error
Post	7.0	00	.576		5.000	.2	75	3.000		.271
Pre	11.0	00	1.398		7.000	.4	29	4.000		.323
Overall	8.0	00	.563		6.000	.2	35	5.000		.253

**Table 10.** Time-to-event from date of referral to date of appointment for P1 patients at baseline and postintervention for carotid artery U/S referrals received at St. Clare's Vascular Lab.

		Mea		Median						
Condition	Fatimata	Std Frank	95%	6 Cor Inte	nfidence rval	Fatimata	Std Free	95% Confidence Interval		nfidence rval
	Estimate	Sta. Error	Low Boui	er nd	Upper Bound	Estimate	Sta. Error	Low Bour	er nd	Upper Bound
Post	21.898	.644	20.6	536	23.160	21.000	.707	19.6	515	22.385
Pre	41.480	1.22	39.0	388	43.871	37.000	.521	35.9	979	38.021
Overall	30.389	.911	28.0	504	32.174	29.000	1.542	1.542 25.9		32.022
	Chi-Squ			are	df	Sig.				
	Log Rank (N	lantel-Cox)	157.6	655	1	p<0.001				
				Ρ	ercentiles					
Condition		25.0%		50.0%				75.	0%	
Condition	Estimate	Std. E	rror	E	stimate	Std. Erro	r Estim	ate	St	td. Error
Post	26.0	00	.320		21.000	.7	07 1	6.000		.330
Pre	43.0	00	1.016		37.000	.5	21 3	5.000		.323
Overall	37.0	00	.546		29.000	1.5	42 2	20.000		1.106

**Table 11.** Time-to-event from date of referral to date of appointment for P2 patients at baseline and postintervention for carotid artery U/S referrals received at St. Clare's Vascular Lab.



**Figure 25.** Kaplan-Meier survival function for P1 patients at baseline (March-May 2015) and post process improvement interventions July-December 2015.



**Figure 26.** Kaplan-Meier survival function for P2 patients at baseline (March-May, 2015) and post process improvement interventions (July-December, 2015).

#### **4.4.1 Referral Quality**

Following the implementation of a standard requisition, and interventions to educate referrers on CTQ elements of incoming requisitions, referral quality was re-evaluated. The findings are summarized in Figure 27. Evaluation of incoming requisitions using the standard form indicated: onset date and time and type of symptoms were very much more likely to be provided (15% v. 88%) and twice as legible (42% v. 87%) following implementation of the standardized requisition form. It was observed that some referrers continued to submit requisitions without completing mandatory fields, and/or crossed out the form's field labels and entered their own data. Wherever data was hand-written, legibility was an issue.



**Figure 27.** Defects in P1 requisitions received at St. Clare's Vascular Lab for carotid U/S testing at baseline, and following implementation of a standard requisition, (n=98 referrals in March-May, 2015, and n=136 from July-December, 2015). *\*Some requisitions had more than one defect.* 

## Phase III Results

## 4.5 eOrder Requirements

The objective of phase III was to document system enhancements supporting improved efficiency and appropriateness of testing, including requirements for an electronic ordering solution. The results of the requirements-gathering sessions are documented and themed in Table 12, according to the priorities of each major stakeholder group. Five basic requirements were identified by point-of-care clinical and administrative stakeholders as mandatory elements for an eOrder system:

- 1. Software must be web-enabled/accessible from multiple locations.
- It must be possible to modify the electronic ordering software in response to changes in best practice recommendations and/or logistical changes in ordering processes.
- 3. The electronic ordering solution must be secure and capable of ensuring industrystandard privacy and confidentiality requirements upheld.
- 4. The solution must be sufficiently fast so as not to impose delay on usual clinical procedures.
- The solution must be capable of safely supporting prioritization of incoming referrals in real-time and on a continuous basis, therefore requiring an internal triage algorithm.

Two additional items of high importance identified by stakeholders were the capacity for immediate scheduling and notification of appointment, and the ability to access the eOrder tool through a single organizational sign-on or login process.

Aside from identifying requirements for a future eOrder tool, stakeholders were also consulted on communication and implementation plans for the new software. Their recommendations are summarized in Tables 12 and 13. **Table 12.** Themed requirements/functionality for the eOrder tool, as identified by stakeholders during requirements-gathering sessions during 2018–19.

	Stakeholder Group										
Functionality/ Requirement	Ordering Provider	Vascular Lab Technician	Vascular Surgeon	Vascular Administrative Staff	RHA	NLCHI	Patient				
Legibility		$\checkmark$	$\checkmark$	~			$\checkmark$				
Mandatory and/or Constrained Data Fields, Minimal Free Text		~	~	~			~				
Risk Stratification Embedded in Order		$\checkmark$	$\checkmark$	$\checkmark$			$\checkmark$				
Immediate Scheduling	~	~	$\checkmark$	✓	✓		$\checkmark$				
Secure and Private	~	$\checkmark$	$\checkmark$	~	✓	✓	$\checkmark$				
Modifiable	~	$\checkmark$	$\checkmark$	~	$\checkmark$	$\checkmark$	~				
Single User Sign-On	~	$\checkmark$	$\checkmark$	~	~						
Interoperable with eHealth Systems	~		$\checkmark$		~	~	$\checkmark$				
Cost-Effective					✓	$\checkmark$					
Configurable, Customizable	~	$\checkmark$	$\checkmark$	$\checkmark$		~					
Role-Based Access					✓	✓	$\checkmark$				
Rapid Performance	~				✓	✓	~				
Web-Enabled	~	$\checkmark$	$\checkmark$	~	~	$\checkmark$	$\checkmark$				
Searchable					$\checkmark$	$\checkmark$					
Mobile-Ready	~		$\checkmark$		~	$\checkmark$					
Minimum Clicks	✓				~	✓					
User-Friendly Interface	$\checkmark$										
Clean, Uncluttered Aesthetic	~										
Waitlist Management		$\checkmark$	$\checkmark$	~	$\checkmark$		$\checkmark$				
Data Visualization, Trending		~	$\checkmark$	~	~	~					
Print Worklist		$\checkmark$	$\checkmark$	$\checkmark$	~						

**Table 13.** Recommendations provided by stakeholders during eOrder consultation sessions 2018–19

 regarding future eOrder communication and implementation strategy.

Ensure software performs rapidly and accurately, (no glitches or impediments to clinical workflow) before launch takes place.
Use incoming referrals at the Vascular Lab to 'test' usability of the tool before embarking upon a live launch.
Carry out a 'soft' launch first to identify challenges and mitigate user frustration
When early users are satisfied with the eOrder tool, expand the launch to widespread access across the province.
Provide change management support at the Vascular Lab full-time for the first 2 weeks following launch of the eOrder tool
Begin communicating about eOrder prior to soft launch using one-pager fact sheet.
Have an identified "change champion" reach out personally to the soft launch group to invite and encourage their participation.
Ensure the soft launch captures a variety of ordering environments including primary care, emergency departments, and acute care.
Select a firm target date after which paper forms will no longer be accepted at the Vascular Lab.
Communicate the end of paper requisitions at the Vascular Lab extensively within the referring provider group.
Create help resources for all user groups including referrers, and the Vascular Lab administrative and technical staff.
Plan sessions for core group to share experiences and troubleshoot issues at key points post soft launch.

## 4.5.1 Electronic Requisition Form

The electronic requisition form was deployed in October 2019 using the provincial electronic health record, known as HealtheNL, as the access point. Screenshots of the eOrdering tool are provided in the appendix.

# **CHAPTER 5 – DISCUSSION**

The primary objective of this research was to analyze the utilization of carotid artery U/S imaging at the Vascular Laboratory operated by Eastern Health at St. Clare's hospital within four areas:

- 1. volume of testing;
- 2. clinical characteristics of the tested population;
- 3. appropriateness of testing; and,
- 4. time-to-access testing.

A secondary objective was to describe system enhancements supporting improved efficiency and appropriateness of testing, including requirements for an electronic testordering solution. Acknowledging this is a mixed methods analysis lacking the rigor necessary for attributing cause and effect, the findings do support the hypothesis: *In a local testing facility, processes of care for accessing carotid artery imaging using Doppler U/S in the management of adults presenting acutely with symptoms of carotid territory ischemia can be improved to enhance access for high priority patients.* 

The results are discussed below in reference to the literature and locally significant factors.

# 5.1 Utilization of testing

From 2007–2019, a substantial number of adults (N=22,167) had carotid artery U/S testing at St. Clare's Vascular Lab. This analysis indicates only 35% of all testing was for an appropriate reason: neurological symptoms arising from the carotid artery territory. Referral because of a carotid bruit (6%) and the remaining 59% (other, vertigo/ dizziness, and asymptomatic) may be considered inappropriate because no surgical intervention would be considered in an asymptomatic patient. Even in the event of diagnosis of high-grade stenosis, this 65% of testing was not associated with recent

symptoms suggestive of carotid artery stenosis or carotid territory ischemia, and therefore these patients would not be eligible for revascularization. From a clinical perspective, inappropriate testing creates a line-up/wait-list, likely to interfere with access to testing for those patients who do need it urgently.

Each U/S requires approximately 45 minutes of direct technician effort, along with usage of equipment and administrative support for booking and registration. Following the test, a vascular surgeon interprets the results, dictates a consultation report, and forwards the information to the referring provider. A conservative estimate is 60 minutes of collective time and effort per test. The additive impact of over 14,000 potentially unnecessary U/S studies, at 60 minutes each, encompasses a significant outlay of highly specialized health system resources. The published cost of an extra-cranial U/S in a Canadian facility ranges from \$55 to \$525, (Government of Ontario, 2015). At these rates, inappropriate U/S testing at the Vascular Lab between 2007–19 had direct cost of approximately \$0.8–\$7.5 M.

#### 5.1.1 Cost of Stroke

Examining cost from a preventative perspective, the primary purpose of extra-cranial imaging is to identify candidates who may require re-vascularization to prevent a secondary stroke. One prevented stroke saves approximately \$74,000 in the first twelve months after the event (Mittmann et al., 2012). If carotid testing led to 500 re-vascularization procedures over 10 years, at a NNT of 5 patients (within 14 days of symptom onset), 100 prevented strokes avoids a minimum of \$7.4M, accounting only for the cost of the first year for each event. These simple financial calculations provide even greater perspective to the well-established recommendations for timely access to carotid imaging.

While this research does not examine the local relationship between incidence of secondary events and delayed testing, the results do show substantial inappropriate testing as well as delayed access for highest priority patients. It is reasonable to assume that significant amounts of inappropriate testing 'clogs' access to imaging for those who need it rapidly to determine their need for surgical re-vascularization, thereby contributing to higher rates of secondary stroke. The low annual volume of carotid endarterectomy carried out in the province, 61 cases/year from 2013–18, reinforces this assumption, though further review is required in this area along with an examination of access to carotid testing and carotid endarterectomy, and incidence of stroke in relation to where people live within the province.

#### **5.1.2 Need for Imaging**

Given the substantial time, expertise, cost, and the importance of timely imaging to secondary stroke prevention, it is critical that health systems carefully manage access to carotid testing. Responsible stewardship of this resource ensures those who need a test can access one rapidly, and those who do not require testing are not utilizing resources unnecessarily and blocking access for those who do. In keeping with this, Choosing Wisely Canada, and its American counterpart, have released recommendations advising against carotid testing in the absence of acute carotid territory symptoms (Choosing Wisely Canada, 2018; Scott et al., 2014). Their local counterparts, Choosing Wisely NL and Quality of Care NL, are also actively pursuing appropriate care in this area (Figure 8).

The high prevalence of cardiovascular risk factors in the province, along with aging of the population, indicate substantial risk of stroke in Newfoundland and Labrador's general population. Sixty-three per cent of residents over the age of twelve has at least one chronic condition and rates of diabetes, hypertension, obesity, and smoking are among the highest across all Canadian jurisdictions (Government of Newfoundland and Labrador, 2015). Almost 70 per cent of people in the province are overweight or obese, 50 per cent are not getting the recommended amount of physical
activity, and over 20 per cent of the population smokes (Government of Newfoundland and Labrador, 2015). Newfoundland and Labrador's population is aging faster than any other jurisdiction in Canada; in 2011, 16 per cent of the province was over the age of 65, with projections of continued 'graying' of the population (Government of Newfoundland and Labrador, 2015). The incidence of hospitalized stroke in Newfoundland and Labrador is higher than the Canadian average, at 161/100,000 compared to 142/100,000 in Canada (Canadian Institute for Health Information, 2019). Secondary stroke is also more common within the province at 19%, in comparison to 12% nationally (Heart and Stroke Foundation of Canada, 2011).

#### **5.1.3 Decreased Testing at the Vascular Laboratory**

Despite an aging population at increasingly high risk for stroke, the volume of testing performed annually at St. Clare's Vascular Lab was observed to be decreasing from 2007–15 and between 2016–18, annual testing volume stabilized. In keeping with a growing burden of chronic disease in a rapidly aging population, a stable or increasing volume of annual testing would be anticipated at the vascular lab. This was not observed until 2016/17, the period immediately following the initiation of a provincial process improvement targeting secondary stroke prevention. A key component of the initiative was awareness and recognition of signs and symptoms of stroke and TIA, by both the public and health care providers. Specific emphasis was placed upon the importance of rapid initiation of investigations in the presence of acute, localizing, carotid territory symptoms. The apparent stabilization in annual volume of carotid testing at the Lab after 2016 may be cautiously interpreted as a response to the process improvement efforts. In consideration of this information, it is important to note that vascular testing also takes place at sites external to the Vascular Lab. Data on incidence of carotid imaging outside the lab is only available after 2015 and indicates an upturn in testing, particularly in usage

of CTA (Figure 11). This is an important observation in view of the considerable effort applied to improving access to carotid imaging for appropriate patients, beginning in 2015.

A possible explanation for reducing annual test volume at the Vascular Lab from 2007–15 is concurrent increase in the use of CTA testing at external sites. While the data in Figure 11 suggest this to be the case it cannot be confirmed, as CTA utilization for the complete study period is not available. An increase in CTA utilization is in keeping with the growing body of evidence recommending its use as the first line imaging modality for hyperacute investigation of TIA and non-disabling stroke (Wintermark et al., 2013). Efforts to increase awareness of appropriate TIA management, including imaging, have been ongoing both within the broad medical community, and locally. Agencies like the Canadian Heart and Stroke Foundation (*Canadian Stroke Best Practice Recommendations*), and the American Heart and Stroke Association (*Get with the Guidelines*), have undertaken substantial campaigns to disseminate evidence and tools supporting guidelines-based care (Heart and Stroke Foundation of Canada, 2018; American Stroke Association, 2019). Some uptake of knowledge from these efforts would be expected, possibly resulting in increased use of CTA, decreased use of U/S, and improved appropriateness.

In contrast to the argument that declining annual carotid U/S volumes is due to improved use of CTA, the decline may also be attributed to poor recognition of and reaction to high risk symptoms by the general public, and suboptimal practice patterns within the referring population. The latter can be neither confirmed nor refuted without the ability to reconcile the total number and timing of high-risk carotid territory presentations in primary care and/or emergency settings, against referrals for carotid testing. In other words, an answer is required to the following question: *are all people presenting with symptoms of acute carotid territory ischemia being referred for extracranial imaging (via U/S, CTA, and/or MRA)?* This question is under consideration for future quality improvement efforts within the local region.

#### **5.2** Clinical Characteristics of the Tested Population

The average age within the tested population was 65 years for both sexes. The largest age category was 60–70 years, and the next largest was 70–80 years. There was no statistical difference in the volume of men and women tested, but fewer females were tested within the two largest age categories (60–70 and 70–80 years), and in the youngest and oldest age groups there were more females tested. These findings are partially consistent with documented age and sex-related trends in stroke incidence.

Risk of stroke generally increases with age and stroke is slightly more common in women at particular stages of life. Women are at higher risk in their younger years due to reproductive physiology, and in their later years due to longer life expectancy (Benjamin et al., 2018; Harvard Health Publishing, 2014). The observation that women are underrepresented locally in the two largest volume categories is concerning, as women are expected to be at the same or higher risk for stroke at all ages. This observation suggests disparity in access to testing between males and females and raises important questions about local recognition and reaction to high-risk symptoms in women, and management of women by the local health care system. Such findings are not unique to this region. Recent reports by the Heart and Stroke Foundation of Canada and the American Stroke Association point to a gap in womens' ability to access services equitably, and differences in stroke outcomes between males and females (American Stroke Association, 2019; Heart and Stroke Foundation of Canada, 2018). In keeping with the reports, these local results demonstrate women access testing less frequently between the ages of 60–80, when stroke risk is highest for both males and females, and when the majority of testing takes place at the local facility. Future quality improvement work should explore root causes and solutions to mitigate this disparity.

#### 5.2.1 Risk Factors

Figure 11. lists the most common risk factors/co-morbid conditions recorded by vascular lab technicians at the time of carotid U/S. As this information is by self-report, it must be interpreted with caution; however, findings are in keeping with risk factors/comorbidities for stroke reported in the literature (Boehme, 2017; Madsen et al., 2018). Hypertension, the most contributing risk factor for stroke, was documented for over 40% of the tested population, followed by hyperlipidemia in 20% of those tested, diabetes in 18%, and smoking in 13%. Aside from the issue of self-report impacting data quality, an additional concern in the interpretation of this information is lack of standardization and use of strict definitions by vascular technicians during data collection. For example, smoking is anticipated to be under-estimated in this data. This is due to known issues with disagreement between self-report of smoking status and gold standard testing for exposure to nicotine, and variability in the interpretation of 'quit' by both technicians and patients (Zhang et al., 2016). When documenting risk factors, vascular technicians were not working from a standard definition of 'quit.' Many people later divulge they 'quit' smoking the day of their test. Similarly, in the data it is not possible to differentiate between Type I or Type II Diabetes, because 'type' is not documented. The impact of lack of standardization in the collection of risk factor (and other) data is reduced confidence in the validity of findings.

### **5.3 Appropriateness of Testing**

According to the Canadian Medical Association (CMA), appropriateness encompasses 'the right care, provided by the right providers, to the right patient, in the right place, at the right time, resulting in optimal quality care' (Canadian Medical Association, 2015). The CMA further describes appropriateness according to five key components, summarized in Table 12. Applying the CMA's definition, the results of this research demonstrate a substantial amount of inappropriate carotid testing stemming from testing patients without sufficient indication; and, testing patients outside recommended timeframes. It might also be argued that a lack of robust QI/QA practices to identify and address declining annual test volumes and defective incoming referrals also constitutes inappropriate service delivery, as per CMA's definition.

**Table 14.** Components of appropriate care, adapted from Canadian Medical Association, 2015.

#### **Dimensions of Appropriate Care**

- 1. Right care is based on evidence for effectiveness and efficacy in the clinical literature and covers not only use but failure to use;
- 2. Right provider is based on ensuring the provider's scope of practice adequately meets but does not far exceed the skills and knowledge to deliver the care;
- 3. Right patient acknowledges that care choices must be matched to individual patient characteristics and preferences and must recognize the potential challenge of reconciling patient and practitioner perceptions;
- 4. Right venue emphasizes that some settings are better suited in terms of safety and efficiency to delivering a specific type of care than others;
- 5. Right time indicates care is delivered in a timely manner consistent with agreed upon

Each individual tested has a 'reason for test' recorded by vascular technicians at the time of their carotid U/S. The most commonly recorded 'reason' from 2007–17 was 'other,' a highly non-specific indication for testing, recorded in 8380 encounters. For the complete dataset 2007–2019, in 65.5% of all testing, the documented 'reason for test' was for a non-indicated issue i.e., vertigo/dizziness/syncope, carotid bruit, asymptomatic, or other. This finding is consistent with Keyhani (2016), who found of 4124 carotid U/S, only 5.4% were for a clearly indicated reason and the remaining 94.6% were for uncertain, or frankly inappropriate reasons – the most common of which were carotid bruit, vascular risk factors, and dizziness/syncope. The high incidence of testing for inappropriate reasons observed in these results may be related to current and historical inconsistency between various sets of North American practice guidelines (Wintermark et al., 2013). Despite Level A evidence supporting the use of extra-cranial imaging in the presence of acute localizing carotid territory symptoms, a number of organizations continue to publically endorse the practice of broad carotid artery screening (Wein et al., 2017). According to the Radiological Society of North America (2019), "Joint guidelines issued by the American College of Cardiology Foundation, American Heart Association, American Stroke Association and other healthcare groups suggest that carotid duplex US may be considered for asymptomatic patients who have peripheral artery disease, coronary artery disease, atherosclerotic aortic aneurysm, or at least two risk factors for stroke." In contrast, current Canadian Best Practice Recommendations specify the use of extra-cranial imaging for symptomatic patients i.e., in the presence of acute, localizing, carotid territory symptoms (Wein et al., 2017; Heart and Stroke Foundation Canada, 2018). As Nguyen et al., (2018) summarize, the Canadian recommendations are concordant with international guidelines.

Given the pervasive practice of asymptomatic carotid artery screening and subsequent surgical revascularization in the U.S., a number of organizations have released public statements recommending against this low value and potentially harmful care. The U.S. Preventive Services Task Force has a recommendation against carotid screening in adult asymptomatic patients (U.S. Preventative Services, 2014). Carotid imaging in asymptomatic populations is described as a low-value test, appearing on multiple "Choosing Wisely" campaign lists (American Academy of Family Physicians, 2019; American Academy of Neurology, 2013; Choosing Wisely Canada, 2018). Keyhani et al., 2016, state, 'reducing inappropriate carotid imaging may stem a pipeline of lowvalue care because many patients who are subsequently re-vascularized received initial imaging for reasons considered inappropriate.'

In this analysis, 35.5% of testing was carried out with 'reason for test' documented as cerebrovascular event i.e., TIA or stroke. This suggests approximately one third of testing at the Vascular Lab was carried out for indicated/appropriate reasons however, without the time/date of symptom onset, it is unknown whether testing was within the recommended timeframe. Extrapolating from the small subset of manually collected data on 'time-to-access' testing, it is reasonable to assume prolonged access was an existing issue within the total population tested, regardless of 'reason for test'. This is corroborated by key informant interviews with Vascular Lab staff indicating that often patients whose referral suggested carotid territory ischemic event may have had symptom onset quite remote to the time of the test. It is suspected that a substantial proportion of the 35.5% were outside the timeline within which surgical intervention is recommended, and therefore a finding of carotid stenosis would not change their clinical course. Thus, 35.5% is anticipated to be an over-estimation of true appropriateness. In keeping with these findings, in their 2016 analysis of over 4000 carotid imaging cases, Keyhani et al., judged only 5.4% of tests as appropriate, 83% uncertain, and 11% inappropriate. Also consistent with the findings of this work, Keyhani et al., found the most common reasons for test-ordering to be: carotid bruit, multiple vascular risk factors, dizziness/syncope/ vertigo, and routine follow-up post-surgery. While these results point to a significant and possibly long-standing local issue with appropriateness and utilization of carotid imaging resources, they also highlight vast potential for improved stewardship with relatively little effort and low-cost intervention.

#### 5.3.1 Predictors of Critical Carotid Artery Disease

The independent risk factors for diagnosis of critical carotid artery disease were being male, an inpatient, having had a cerebrovascular event, or, the presence of a carotid bruit. The relatively poor predictive power of these variables suggests that asymptomatic carotid disease was quite prevalent in the tested population and the clinical description of a cerebrovascular event provided by the referring provider was questionable.

The population tested was primarily outpatient. This is in keeping with the protocol used across many jurisdictions in North America and Europe, of managing TIA and non-disabling stroke in outpatient settings except in the case of crescendo TIA (Lavallee et al., 2007; Rothwell et al., 2007). Based on this approach, one would expect the population of admitted individuals to be at higher risk, likely being comprised of patients having frequent highest risk acute carotid territory events. It follows that the probability of abnormal carotid findings would also be high in the admitted group. This outcome was observed in the descriptive data and multiple logistic regression analysis, indicating admitted patients were more likely to have abnormal carotid findings than those managed in the community (OR 1.266, p<0.001).

Within the admitted group, the most common 'reason for test' recorded was 'cerebrovascular event', (n=1377) followed by 'other' (n=813). The substantial number of people given a carotid U/S for reason 'other' suggests a mismatch between the evidence and current practice, and/or non-standard clinical documentation practices. Again, these issues are not surprising, given the absence of clear region-wide protocols for managing TIA and/or non-disabling stroke. Key informant interviews reinforce this assumption. A repeating theme was frustration with the practice of admitting patients for the purposes of arranging carotid testing, an investigation that can be readily carried out at the time of initial head CT, and/or at a later date as an outpatient. There is a wellestablished body of literature supporting the use of algorithmic tools such as CODE TIA protocols for guideline-based management of TIA (Dutta, D., 2015; Jeerakathil et al., 2014). Such algorithms create an evidence-informed care pathway that facilitates community management of most patients and admission only for highest-risk individuals. It is anticipated that local implementation of CODE TIA would lead to fewer unnecessary admissions and improved utilization of carotid imaging resources, including timely access for highest-risk individuals.

## 5.4 Time to Access Imaging

Various themes emerged within the process improvement activities hypothesized to be contributing to prolonged time-to-access testing. These included: the use of multiple sub-optimal paper requisitions; high frequency of defective referrals; reduced awareness of/reaction to stroke risk by the general public; limited adherence to evidence-based timelines by referrers; variable triage and appointment booking procedures at the Vascular Lab; and, impaired ability within the Vascular Lab to monitor and balance demand and capacity.

Prior to Phase I interventions, baseline measurement of time-to-access indicated patients categorized as P1 or P2 were accessing investigations substantially outside recommended timeframes. Somewhat ironically, P3 patients, referred for elective screening, were the only group accessing testing within recommendations. This being the case because there is no clear consensus on screening for carotid stenosis, and therefore no time guideline to follow. Time-to-access testing improved considerably in both P1 and P2 groups following Phase I interventions, and reductions in access time were sustained at follow-up testing January-June, 2017.

While time-to-access was markedly reduced, Vascular Lab staff reported frustration that the wait time for a test could not be decreased further, and acknowledged that extensive effort and vigilance is required to maintain timely access. The process of fax, manual triage, booking of appointment, and contacting the patient and/or referring provider with appointment is extremely sensitive to defects, disruption, and delayed access. One example illustrating this is the newly adopted practice of having the Vascular Surgeon on-call triage incoming referrals daily, rather than the legacy practice of allowing referrals to 'batch' for a few days. Even in the new approach, if daily triage doesn't occur until after-hours due to the on-call physician's schedule, an individual's referral may sit for an entire day before it is triaged. Similarly, referrals received on a Friday that are not triaged until after the weekend will be at least 48 hours old before the person can be booked for their test.

Findings of prolonged access times for carotid imaging are not unique to this study. Multiple published research efforts have confirmed delayed access to imaging, and delays in other components of hyperacute secondary stroke prevention, to be a widespread issue. Fairhead et al., (2005), report mean wait for carotid imaging at 33 days. McCabe et al., (2014), report mean wait of 13.4 days. While the evidence is clear that delayed access to care is a pervasive problem, the literature is less clear on *why* delays occur. In a recent Canadian review, Blacquiere et al., (2013), reported median time from symptom onset to carotid endarterectomy as 76 days and described multiple process delays, particularly in the transfer of care between specialists (e.g., Neurology to Vascular Surgery.) Based on the findings of key informant interviews and focus sessions, it would appear similar issues exist locally. Stakeholders described routine experiences with misdirected faxes; incoming referrals lacking sufficient information for triage; difficulty reaching individuals to arrange imaging appointments; and, lack of alignment in prioritization approach across various health sectors (ED, DI, Vascular Surgery, and Neurology).

In response to the well-documented problem of delayed access to carotid imaging and other components of secondary stroke prevention, the literature supports streamlining care using clinical pathways and protocols. The 2010 work of Wasserman et al., demonstrates compelling improvements in predicted stroke risk with the implementation of a guidelines-based TIA management protocol. Similarly, in their 2018 study, Jarhult et al., implemented a TIA management protocol and showed improved efficiency and reduced utilization of health care resources without compromise to patient safety.

While these examples of rapid, guidelines-based, TIA management show promise, it must be acknowledged that protocols relying on paper processing will continue to carry inherent limitations. Legibility problems, inability to constrain responses or make fields mandatory, chances of loss or misdirection, and the need for manual handling of paper cannot be avoided and almost certainly contribute to inefficiency. With a growing appreciation of the shortcomings of paper, it is not surprising that electronic recordkeeping and digital methods of exchanging health information are becoming increasingly well-established in clinical practice. In particular, the use of embedded logic, designed to prompt optimal care or, 'clinical decision support' within medical software is gaining traction in many areas of health care (Canada Health Infoway, 2019).

## 5.5 Electronic Ordering – eOrder

The *inability* to answer the previously posed question of 'what is an optimal rate of imaging in a given population' and, current challenges in the ability to evaluate practice patterns in or near real-time, underscores the importance of creating health information infrastructure and processes capable of supporting quality assurance/improvement.

In Newfoundland and Labrador, health data capture occurs using a variety of disconnected paper and electronic systems, across sectors, and across the health care continuum. There is a growing trend towards the use of electronic record-keeping and improved interoperability between systems, however legacy software components are often not compatible with each other, impeding information exchange. Taking the

example of carotid imaging, an emergency department presentation may result in a paper record (later scanned as an image), and/or presenting information may be captured within the Meditech hospital information system. For a primary care presentation, clinical history is documented on paper or within an electronic medical record. In either case, the key elements required for quality monitoring (type/timing of symptoms and date/ type of referral) are isolated, and cannot readily be reconciled against incoming imaging referrals. This reality should inform future decision-making regarding clinical tools and electronic infrastructure. In a clinical program providing a highly time-sensitive, and medically necessary service, the ability to monitor and adjust capacity and process based on real-time demand is of critical importance.

A secondary objective of this initiative was to describe system enhancements supporting improved efficiency and appropriateness of testing, including requirements for an electronic test-ordering solution. While research on the use of electronic health tools in hyperacute stroke management is limited, the work of Ranta and colleagues provides preliminary evidence for the benefits of digitized pathways and electronic clinical decision support tools in secondary stroke prevention (Ranta et al., 2015). Using guidelines-based algorithms embedded within digital practice software, Ranta et al., (2015) demonstrated improved access to care, and enhanced adherence to recommendations without reducing safety or interfering with privacy and security of information. In another example, Karlsson et al., (2018) showed improved adherence to guidelines-based care by using an electronic decision support tool to increase rates of anti-coagulation in patients with atrial fibrillation at risk of stroke.

Based on these objective results, and stakeholder requirements gathered throughout the initiative, the eOrder software for carotid imaging should be both a testordering mechanism and a clinical decision support system. The eOrder software should also provide real-time guidance to referrers on appropriateness and urgency of testing. In keeping with these requirements, in the prototype version of the eOrder tool, when clinical information is recorded, an algorithm based on Canadian stroke best practice recommendations returns a priority score (P1–3). If testing is not indicated based on the clinical information provided, the software generates a clinical decision support message to that effect. The eOrder tool will not prevent users from ordering a test if they wish to override the algorithm, but additional information will be required to submit. Following submission of the referral by ordering provider, the software interacts with the Vascular Lab's scheduling interface and immediately returns an appointment within a timeframe appropriate to the level of risk. Screenshots of the eOrder tool (in development) are included in Appendix A.

As shown in Appendix A (page 85), at the Vascular Lab incoming referrals are displayed in a digital list according to priority level. Vascular Lab staff can manually interrogate each referral for additional information, and/or manually override the automatically booked appointment to provide the necessary flexibility at the lab to adjust the schedule, if necessary. The system can also be configured to send an alert when referrals queue beyond available appointments. In this way, visual monitoring of demand vs. capacity is possible, and real-time adjustments can be made by Vascular Lab staff to ensure highest priority patients are seen first and fastest. It is anticipated that implementation of the eOrder software will contribute to improved efficiency and appropriateness of carotid testing. The capacity to utilize an algorithm to risk stratify incoming referrals and designate priority of testing, and to provide an immediate booking within 24 hours for P1 patients, makes the eOrder tool novel and highly attractive.

### **5.6 Limitations and Delimitations**

This work originated as part of a process improvement initiative within Eastern Health and evolved to include Memorial University of Newfoundland and Labrador, and the Newfoundland and Labrador Centre for Health Information. The analysis provides novel information specific to local carotid artery imaging, however a limitation of the work is reduced generalizability beyond St. Clare's Vascular Lab setting. Carotid imaging takes place at DI departments elsewhere within Eastern Health and the province. While it is anticipated that similar clinical and process characteristics would be found, care should be taken in generalizing these results to all provincial sites.

While every attempt was made to employ a consistent and thorough approach throughout the analysis, it must be acknowledged that Phase I information was collected retrospectively and was not subject to standard definitions and data capture processes. Though the dataset is large, and vascular technicians utilized a basic template to document each encounter, it is anticipated that lack of standardized data capture between testers may have contributed to variability and bias in the results. For example, some technicians may have copied the referral information verbatim, whereas others may have extracted further clinical details from the patient which may have resulted in a change in 'appropriateness.'

In entries where values were missing or defective, the entire case was eliminated. This constituted less than 50 cases in over 19,000 or less than 0.5%, but nonetheless, these cases are not represented in the analysis.

In Phase II, data collection was purposeful and took place in or near real-time. To reduce variability and support least bias within the process, a template was utilized employing standard definitions. Data capture techniques used formatted fields where possible, and/or dichotomous values. To further reduce variability, one individual, (CC) was responsible for data capture, where possible. In the case of time-to-access testing data, the 2016 measurements were manually collected per test, by CC. The follow-up information for 2016 and 2017 was collected and provided to the writer by Eastern Health's Vascular Program in aggregate form, as mean values. This made it impossible to repeat the time-to-event analysis that was conducted on the 2015 data and impacts the ability to generalize about sustainment of the changes. As a mean value for time-to-access testing can only include those who actually had a test, it is likely that the true access time in 2016/17 is underestimated.

Due to the nature of the initiative, no attempts were made to introduce blinding or randomization into the process and study design did not enable comparison to a control group. Future evaluation following the implementation of the new eOrder software may rely upon this work to act as a control against which to evaluate the new electronic process.

During Phase III stakeholder consultations, efforts were made to include a representative sample of stakeholders and to accurately document and theme their responses. Two recorders were used and their original documentation was compared to ensure similar interpretation. Where possible, a summary of findings was provided to stakeholders for their review and approval after each session. Despite efforts to maintain objectivity during requirements-gathering sessions, the participation of those with specific experience may have influenced outcomes. For example, Vascular Lab staff were particularly vocal about patient delays due to booking appointments. In response to this, the functionality for the eOrder software to generate an appointment in real-time became a prime requirement. While it is possible that a particular stakeholder(s)' views became more prominently positioned during the sessions, the final requirements define a process that is internally consistent with effective carotid artery imaging.

## **CHAPTER 6 – CONCLUSION**

The results show the annual volume of carotid artery U/S imaging at St. Clare's Vascular Lab declined 2007–2015 and stabilized between 2015 and 2019. From 2015–2019 there was growth in the volume of carotid imaging carried out via CTA/MRA at Eastern Health sites external to the Vascular Lab. Characteristics of the population tested at the Vascular Lab, including age and risk factors, are consistent with a population at risk for stroke, however documentation of 'reason for test' and incidence of normal test findings suggest high incidence of inappropriate testing. The findings also suggest disparity in access to testing between males and females, and raises important questions about local recognition and reaction to high-risk symptoms in women, and management of women by the local health care system

Baseline sampling of incoming referrals demonstrated protracted wait times across all priority groups. Current processes for referring patients for carotid imaging at the Vascular Lab are paper-based and do not guarantee transmission of CTQ information necessary for accurate triage. Sampling revealed information deficiencies in incoming paper-based referrals consistently necessitating re-work, and contributing to delays for patients needing urgent access. In the current process, there is limited opportunity for efficient monitoring for quality assurance/quality improvement purposes.

Time-to-access testing and referral quality improved in association with enhancements to the paper requisition, improvements to the lab's triage and scheduling processes, and knowledge translation initiatives customized to specific stakeholder groups. While improvements in referral quality, time-to-access, and process efficiency were observed, considerable manual effort was necessary to track wait times, queue size, and referral quality on an ongoing basis, and for sustainment of the improvements. It was noted that when attention to quality monitoring by individuals leading the Phase II QI initiative was withdrawn, there was a tendency for wait times and priority queues to creep up. The objective findings and subjective experience suggest paper-based processing for multi-step, multi-stakeholder care is sub-optimal. A more efficient system enabling real-time processing and visual management of supply/demand is recommended.

Learnings from phase I and II, as well as the findings of stakeholder consultations informed the design of an electronic ordering solution for carotid artery investigation. Key functionality for referrers includes the ability to complete referrals quickly, accurately, and without duplication; rapid and secure transmission of completed requests; and, immediate notification of risk (priority score) with appointment date/ time. Staff receiving completed referrals at the lab had identical requirements with the addition of legibility; mandatory fields with constrained formatting for CTQ clinical/ triage information; and, ability to link incoming referrals with referring provider using electronic identity authentication.

The learnings of this research may be applied to future policy development, stakeholder education, and quality improvement in secondary stroke prevention. This work may form the baseline for a future evaluation of the design and implementation of the eOrder software.

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# **APPENDIX I – eORDER TOOL (IN DEVELOPMENT)**

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Clicking on the Referrals tab at the top of the screen shows the patient's referral history.

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	Patient has other symptoms than those listed below									
	Approximate Event 2019-Feb-27									
Date of suspected Transient Ischemic Attack (TIA) or Stroke										
	Carotid symptoms Weakness *       Yes       No       Region *      Face	Arm 🗌 Leg								
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	After submitting this form, please complete appointment booking immediately to ensure the patient is seen possible.	as soon as								

Patient Details		
Patient Details		
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		Enter a different address
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Patient/Guardian Informed	○ Yes ○ No ☑ Has the patient/guar	rdian been informed of the diagnosis or reason for referral?
Providers		
Sending Provider	From on file *	Name: Dr. Danielle PORTER Address: Labrador Health Centre, 227 Hamilton River Road, P.O. Box 7000, Station C, Happy Valley-Goose Bay, Rony, A0P 1C0 Phone Number: (709) 897-2000 Fax Number: EMR Site Id:
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Family Provider	From on file	Name: Brent THISTLE Address: Western Memorial Regional Hospital, 1 Brookfield Avenue, P.O. Box 2005 , Corner Brook NL A2H 6J7 Phone Number: Fax Number: EMR Site Id:	8
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#### Medications Patient's Recent Prescriptions

NITROGLYCERIN 400 MCG/SPRAY (Qty: 1440); Prescribed by PROVIDER, EHR on 2018-May-25; Last Dispensed: 2018-May-25; Directions: USE AS DIRECTED METOPROLOL TARTRATE 50 MG (Qty: 720); Prescribed by PROVIDER, EHR on 2018-May-25; Last Dispensed: 2018-May-25; Directions: TAKE 1 TABLET TWICE A DAY CLOPIDOGREL BISULFATE 75 MG (Qty: 360); Prescribed by PROVIDER, EHR on 2018-May-25; Last Dispensed: 2018-May-25; Directions: TAKE 1 TABLET ONCE DAILY ROSUVASTATIN CALCIUM 20 MG (Qty: 360); Prescribed by PROVIDER, EHR on 2018-May-25; Last Dispensed: 2018-May-25; Directions: TAKE 1 TABLET ONCE DAILY ROSUVASTATIN CALCIUM 20 MG (Qty: 360); Prescribed by PROVIDER, EHR on 2018-May-25; Last Dispensed: 2018-May-25; Directions: TAKE 1 TABLET ONCE DAILY Patient medication records for the past 6 months.

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GING	<b>P1</b>	2019-Mar-01 10:00	SOTO, Phung_Tpchi	329571539025	1957-Jun-01 ( 61 years )	Carotid Exam - Investigation of Carotid Territory Ischemic Event	Vascular Imaging	St. Clare's Mercy Hospital Vascular Lab	Booked		2019- Feb-28 14:05	2019- Feb-28 14:07
	<b>P1</b>	2019-Feb-27 13:00	STARK, Vince_Tpchi_VI	9217268461	1975-Dec-02 ( 43 years )	Arterial Exam - Ischemic Pain at Rest	Vascular Imaging	St. Clare's Mercy Hospital Vascular Lab	Booked		2019- Feb-25 10:59	2019- Feb-26 11:00
	P1	2019-Feb-27 10:00	WEBER, Timothy_Tpchi_VI	859570332295	1957-Feb-02 ( 62 years )	Venous Exam - Suspected DVT	Vascular Imaging	St. Clare's Mercy Hospital Vascular Lab	Booked		2019- Feb-25 22:14	2019- Feb-25 22:17
	<b>P1</b>	2019-Feb-27 08:30	ROBERTSON, Hyo_Tpchi_VI	699722075024	1972-jul-25 ( 46 years )	Venous Exam - Suspected DVT	Vascular Imaging	St. Clare's Mercy Hospital Vascular Lab	Booked		2019- Feb-25 21:59	2019- Feb-25 22:03
	PI	2019-Feb-26 08:30	FUENTES, Chung_Tpchi_VI	839581847747	1958-Jul-02 ( 60 years )	Arterial Exam - Ulceration	Vascular Imaging	St. Clare's Mercy Hospital Vascular Lab	Booked		2019- Feb-21 14:45	2019- Feb-25 11:19
	P1	2019-Feb-26 13:00	ROBERTSON, Hyo_Tpchi_VI	699722075024	1972-Jul-25 ( 46 years )	Carotid Exam - Investigation of Carotid Territory Ischemic Event	Vascular Imaging	St. Clare's Mercy Hospital Vascular Lab	Booked		2019- Feb-25 10:55	2019- Feb-25 11:00
	PI	2019-Feb-26 11:00	DUARTE, Esteban_Tpchi_VI	209532380430	1953-Aug- 25 ( 65 years )	Arterial Exam - Ulceration	Vascular Imaging	St. Clare's Mercy Hospital Vascular Lab	Booked		2019- Feb-22 10:48	2019- Feb-25 10:09
	P1	2019-Feb-25 13:00	HARTMAN, Yoko_Tpchi_VI	389952078720	1995-Jul-25 ( 23 years )	Arterial Exam - Ischemic Pain at Rest	Vascular Imaging	St. Clare's Mercy Hospital Vascular	Booked		2019- Feb-24 18-02	2019- Feb-24

The Vascular Lab Clerk logs in and clicks their Referral Dashboard in the left menu to view queued exams.

# **APPENDIX II – COPYRIGHT AND PERMISSIONS**

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