Exploring Clinical Outcomes of Acute Ischemic Stroke Following a Door-to-Needle Quality Improvement Project

by

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ABSTRACT

Background: The incidence of stroke is increasing; therefore, ongoing strategies to improve patient outcomes are needed. Timely care is an essential component of hyperacute stroke care. The earlier eligible stroke patients receive intravenous recombinant tissue plasminogen activator (rt-PA) in the narrow 4.5-hour window, the greater the likelihood of a good clinical outcome. In 2011, based on sub-optimal performance results, our centre invested in a door-to-needle (DTN) quality improvement initiative, which focused on performance feedback, stroke education, and improved workflow processes. The primary aim of this thesis study was to determine if clinical outcomes in stroke patients improved following the DTN quality improvement initiative.

Methods: Guided by the Donabedian framework, we retrospectively reviewed charts of all consecutive patients (N=324) who presented to Health Sciences Centre Adult Emergency and received rt-PA pre [January 1st, 2008 to December 31st, 2010; n= 102] and post [January 1st, 2012 to December 31st, 2014; n= 224] quality improvement initiative. The washout year was 2011. Demographic and clinical patient data, and process and outcome measures were collected. Primary study outcomes included mortality, discharge location, ambulation upon discharge, and adverse events. SPSS software was used for statistical analysis, with the level of significance of .05.

Results: Patients in the two groups were similar, except that in the post-intervention period more patients were rural (p <.001), arrived by ambulance (p <.001) and had longer onset-to-door times (p <.001). Median door-to-needle (DTN) time (49 vs. 70.5 min, p <.001), and the percentage of cases with a DTN ≤ 60 minute (77.9 vs. 31.4%, p <.001) improved dramatically post-intervention. Outcomes, including a reduction in in-hospital mortality, (p = .013) and an increase in the proportion of favorable (i.e., home, rehab, community hospital) versus unfavorable discharge locations (i.e., long term care, death), p=.005, were also significant. Mortality rates in all study patients with DTN $\leq$ 60 minutes compared to those with DTN > 60 minutes were also significantly lower (p =.004).

Conclusion: This research addressed an existing gap at our hospital regarding the impact of structural and process improvements on clinical outcomes in acute stroke. Our quality improvement initiative resulted in timelier care, and likely influenced the improved clinical outcomes. This study highlights the key role of nursing as part of the multidisciplinary team, in lessening the impact of stroke. The findings also provide institutional and governmental organizations with evidence to support investing in hyperacute stroke care. Furthermore, this study will foster increased uptake and compliance with best practice stroke care. Ultimately, all stroke patients in Manitoba may benefit, as it may increase the adherence to time-driven hyperacute stroke protocols. Thus, this study has provided valuable insights and reasons for optimism in the future of stroke care at HSC, in the Province of Manitoba, and beyond.

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I would like to dedicate this thesis project to my father, who passed away in April 2016, as he always encouraged me to believe in myself and to pursue my goals and dreams. He loved to read and write, and would be very proud of this manuscript. He was very proud of my career choice, and especially my work in the emergency room.

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LIST OF ABBREVIATIONS

AHSA	American Heart and Stroke Association
AIS	acute ischemic stroke
ASA	American Stroke Association
BP	blood pressure
CIHI	Canadian Institute of Health Information
CSBPR	Canadian Stroke Best Practice Recommendations
CT	computed axial tomographic scan
CT-T-N	CT-to-needle
DTN	door-to-needle
D-T-CT	door-to-CT
ED	Emergency Department
EMS	emergency medical services
EVT	endovascular therapy
FAST	Face Arm Speech Time
FIM	functional independence measure
GCS	Glasgow Coma Scale
GWTG	Get With The Guidelines

HSC	Health Sciences Centre
HSF	Heart and Stroke Foundation
HSFC	Heart and Stroke Foundation of Canada
INR	international normalised ratio
IV	intravenous
LOS	length of stay
LSN	last seen normal
mRs	modified Rankin score
NIHSS	National Institute of Health Stroke Scale
O-T-D	onset-to-door
O-T-N	onset-to-needle
PI	principle investigator
SICH	symptomatic or secondary intracranial hemorrhage
rt-PA	recombinant tissue plasminogen activator
TIA	transient ischemic attack
USA	United States of America
VSM	value stream map

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CHAPTER ONE: STATEMENT OF THE PROBLEM

Introduction

Stroke is the third leading cause of death and the leading cause of severe disability in Canada (Casaubon et al., 2015). An estimated 315,000 Canadians live with the effects of stroke. Furthermore, stroke admissions are responsible for one of the longest lengths of stay in our acute care hospitals. The economic burden of stroke is approximately $3.6 billion annually (Lindsay et al., 2010). In addition, population projections suggest that the Canadian population is aging (*Statistics Canada*, 2010). Hence, stroke rates are expected to increase dramatically over the next 15 years (Heart & Stroke Foundation [HSF], 2014).

Over the last 20 years, there have been significant advancements in the treatment of acute stroke. Current reperfusion therapies for acute ischemic stroke include thrombolytic therapy and mechanical clot retrieval. Both reperfusion therapies are time sensitive; hence, the earlier treatment is established within the time window, the greater the benefit. With every minute that passes, the average patient loses 1.9 million neurons, 13.8 billion synapses, and 12 kilometers of axonal fibers (Saver, 2006).

Major disabling stroke is now a very treatable disease providing that stroke victims arrive at a hospital capable of delivering hyperacute stroke care within the recommended treatment window. However, more than half of Canadian stroke victims take over six hours to arrive at hospital, which is well outside the 4.5-hour window of opportunity. Furthermore, the median Canadian door-to-needle (DTN) time of 90 minutes (Ganesh et al., 2014), suggests that when these patients arrive at hospital, the care they receive is not quick enough (Heart and Stroke Foundation [HSF], 2015). Thus, clearly barriers to optimal stroke care do exist within the prehospital setting and in the emergency department (ED).

The narrow 4.5-hour window of opportunity in which to deliver thrombolysis poses several treatment challenges for both the stroke patient and the health care provider. Public recognition campaigns and evidence based hyperacute guidelines, for both pre-hospital and ED care, have been developed to minimize barriers to care (Casaubon et al., 2015; Jauch et al., 2013). These guidelines focus on rapid assessment, diagnostics, and treatment initiation (Casaubon et al., 2015; Jauch et al., 2013). Despite evidence-based Canadian Stroke Best Practice Recommendations (CSBPR, 2015), which are internationally recognized clinical practice guidelines for stroke, treatment delays remain pervasive due to lack of public stroke recognition and calling 911, as well as in-hospital treatment delays (Grotta, 2014).

Standards of hyperacute stroke care vary between and within health regions (Heart and Stroke Foundation [HSF], 2014). Similarly, quality of care evaluation may also vary. Measuring hyperacute process indicators is important, as there is strong evidence to support that shorter time intervals from symptom onset-to-treatment and from emergency department arrival-to-treatment result in improved clinical outcomes (Casaubon et al., 2015; Fonarow et al., 2014; Lindsay et al., 2010; Saver, 2013). While several centres have managed to improve quality stroke care indicators, by focusing on improving processes of care (Ganesh et al., 2015), a gap remains in translating these process improvements into patient outcomes (Fonarow et al., 2014; Rymer et al., 2014).

The purpose of this introductory chapter is to articulate the statement of the problem related to the proposed study. The purpose and the significance of the study will be outlined. Hence this chapter will provide the foundation for the proposed thesis project.

Statement of the Problem

Stroke is the third leading cause of death and the leading cause of adult disability in Canada (Casaubon et al., 2015). Approximately 315,000 Canadians live with the effects of stroke (i.e., ischemic and hemorrhagic); furthermore, stroke accounts for 62,000 hospital visits a year and an estimated annual cost of $3.6 billion (HSF, 2014). Population projections suggest that the Canadian population is aging (*Statistics Canada*, 2010). This will result in a higher incidence of stroke, as the risk of ischemic stroke increases with age. The last decade has also shown a 24% increase of stroke among fifty-year old's and a 13% rise among sixty-year old's (HSF, 2014). According to international stroke experts, these stroke rates are expected to double in the next 15 years (Lindsay & Hill, 2014).

Over the last 20 years, there have been several advancements in both stroke prevention and acute care (Haselman, 2014; Watkins 2014). Today, major stroke is very treatable if stroke victims arrive at a hospital capable of hyperacute stroke care within the recommended treatment window. Current reperfusion therapies for acute ischemic stroke include thrombolytic therapy and mechanical clot retrieval. "Intravenous recombinant tissue plasminogen activator (rt-PA) is a treatment of proven benefit for select patients with acute ischemic stroke (AIS) as long as 4.5 hours after onset" (Saver et al., 2013, p. 2480). The benefit of rt-PA in patients with acute ischemic stroke is also strongly time-dependent (Fonarow, et al., 2014), making this time-driven therapy a challenge for health regions, hospitals, and practitioners.

Endovascular therapy (EVT) in acute stroke involves catheter based mechanical clot retrieval for proximal intracranial arterial occlusion. The 2015 CSBPR support the use of EVT in the treatment of AIS patients with proximal intracranial arterial occlusion who present within six hours of symptom onset (Casaubon et al., 2015). Recent studies (Berkhemer et al., 2015;

Goyal et al., 2015), have shown that, like rt-PA, EVT requires speed and efficient workflow processes, as shorter imaging to reperfusion and door-to-groin puncture times are linked with improved patient outcomes. Stroke systems within Canada are attempting to incorporate EVT into their organized stroke care models. However, the reality is that the capacity to perform EVT in Canada and specifically in Manitoba is currently limited.

Even though stroke mortality rates in Canada have decreased over the last decade, due to advancements ranging from stroke prevention to acute intervention (Haselman, 2014; HSF, 2014), there are still provincial variations in stroke mortality. The Manitoba stroke mortality rate is 19.9 per 100,000 people. This is above the national average of 17.9 and significantly higher than the Alberta rate of 15.9 (HSF, 2014). Moreover, the length of stay (LOS) for discharged stroke patients in Manitoba is 23.9 days, which is the longest in Canada (Lindsay & Hill, 2014).

Stroke Pathophysiology

Stroke is defined as a "sudden, rapidly evolving syndrome, with a non-epileptic neurological deficit associated with a well-circumscribed volume of infarcted brain tissue within a discrete vascular territory, caused by an insufficient supply of blood to a portion of the brain" (Williams, Perry, & Watkins, 2010, p.34). Hemorrhagic strokes, which occur as the consequence of a ruptured blood vessel, account for only 15% of all strokes. The remaining 85% are ischemic, caused by a blockage within a cerebral artery.

When a cerebral blood vessel is occluded, the lack of blood flow distal to the obstruction results in a core of dead tissue, which is surrounded by a viable ischemic penumbra. The penumbra is an area of hypo-perfusion that can survive for a short while. The ischemic penumbra can be salvaged and recover its function by rapidly dissolving the clot that is causing the obstruction and restoring blood flow (Haselman, 2014). The more quickly blood flow to the brain is restored, the more impairment is prevented; hence acute stroke is a time-sensitive medical emergency.

Stroke: A Time-Sensitive Emergency

Stroke is a time-sensitive medical emergency in which delays in access to treatment affect the extent of recovery and disability. With every minute that passes, the average patient loses 1.9 million neurons, 13.8 billion synapses, and 12 kilometers of axonal fibers (Saver, 2006). "Therapeutic yield is maximal in the first minutes after symptom onset and declines rapidly during the next 4.5 hours" (Saver, 2010, p. 1431). According to Saver (2006), human nervous tissue is rapidly and irretrievably lost as stroke progresses, which is why therapeutic interventions should be emergently pursued. Treatment delay is also associated with a higher risk of complications following a stroke, including symptomatic intracranial hemorrhage following rt-PA administration (Fonarow, et al., 2014).

Although, rt-PA has revolutionized the treatment of acute ischemic stroke over the last two decades, it must be initiated within 4.5 hours. (Ghrooda, Alcock, & Jackson, 2012). This narrow window of opportunity poses treatment challenges for health care providers who provide hyperacute stroke care in the pre-hospital and ED setting. National stroke organizations have established guidelines to encourage hospitals to adopt efficient work flow processes that follow the mantra of 'time is brain' (Casaubon et al., 2015; Jauch et al., 2013). These guidelines address the critical first steps in managing a suspected stroke victim. The guidelines commence when the patient first makes contact with the medical system, and continue through to their departure from the ED. The goal of hyperacute stroke care is reperfusion of eligible ischemic strokes and the prevention of transient ischemic attacks (TIA) from converting into disabling strokes. In clinical practice, hyperacute stroke care translates into rapid performance of numerous activities: patient stabilization if airway, breathing, or circulation are compromised; initial patient assessment, stroke assessment, and thrombolytic eligibility assessment; diagnostics, including imaging and laboratory studies; and mixing and administration of the rt-PA bolus if eligible, all within 60 minutes or less.

Sadly, in Canada, more than half of all stroke patients admitted to hospital take more than six hours to arrive at the ED (Lindsay & Hill, 2014). In Manitoba, on average, it takes stroke victims an abysmal 10.3 hours to arrive at the ED, making them ineligible for thrombolytic therapy (Lindsay & Hill, 2014). Therefore, improving public recognition of stroke as a medical emergency needs to occur. Emergency staff do not control the time interval from stroke symptom onset to hospital arrival. However, in-hospital stroke teams are responsible for the hyperacute care delivered and they do have some control over inherent delays within the ED. Regardless of when stroke patients present during the time window at the hospital, they should be assessed and treated quickly. Although current guidelines recommend that eligible stroke patients receive thrombolytic therapy within 60 minutes or less of arrival (Casaubon et al., 2015; Jauch et al., 2013), the Canadian average DTN, (i.e., time of arrival at hospital to time of rt-PA bolus administration) is 90 minutes (Ganesh et al., 2014). Manitoba data reveals a median DTN time of 113 minutes (Lindsay & Hill, 2014). These figures are well outside the recommended 2015 CSBPR guidelines.

Barriers to Optimal Thrombolytic Therapy

The proportion of AIS in Canada that received thrombolysis from April 1st, 2008 to March 31st, 2009 was 6.1% (95% CI 5.8%-6.4%; Ganesh et al., 2014). Thrombolysis rate is an important quality indicator, as it requires organized systems of care that work in collaboration with each other (Lindsay et al., 2010; Ganesh et al., 2014). These figures suggest that barriers to thrombolytic therapy do exist. Reasons for delay can be categorized as pre-hospital and in-hospital barriers.

Pre-hospital barriers. Barriers that occur between stroke symptom onset and arrival at the ED are called pre-hospital barriers. Casaubon et al. (2015) and Ganesh et al. (2014) reported that the delay in hospital arrival after symptom onset is a significant barrier to thrombolysis. Reasons for delay can be attributed to: a lack of stroke recognition by the public; stroke patients being incapable of seeking help themselves; stroke symptoms not typically portraying a sense of urgency to seek treatment; and Canada's vast geography limiting the access of hyperacute stroke care for rural residents (Ganesh et al., 2014).

To improve public awareness of stroke, the HSF launched the "FAST" (i.e., Face, Arms, Speech, and Time) campaign, in December 2014 (HSF, 2015). The goal of this campaign is to improve stroke recognition among Canadians and to educate the Canadian public that stroke is a medical emergency and that 911 should be accessed immediately. Most provincial ambulance systems have stroke protocols, which include stroke recognition, rapid transport to a stroke centre that can deliver hyperacute care, and pre-notification of the stroke centre emergency.

In-hospital barriers. The Canadian median DTN time of 90 minutes (Ganesh et al., 2014) suggests that in hospital delays unfortunately persist. This suboptimal performance has resulted in a call to action for hyperacute guidelines from the CSBPR (2015). These guidelines challenge hyperacute stroke systems in Canada to achieve median DTNs of 30 minutes, with an upper limit of 60 minutes, and to have 90% of eligible patients receive rt-PA within 60 minutes or less (Casaubon et al., 2015)

Johnson and Bakas (2010) identified non-stroke centre status, lack of training of the emergency department staff, delays with imaging, and poor understanding regarding priority stroke treatment as in-hospital delays. In-hospital delays may also be related to the staff's perception and lack of knowledge regarding the care of stroke patients (Johnson and Bakas, 2010). Ruff et al., (2014) suggest that prior literature has shown that arrival in the ED soon after symptom onset may delay rt-PA as there is a perception of having lots of time. In addition, a collaborative stroke team is essential (Fonarow et al., 2014; Ruff et al., 2014). Fonarow et al. (2014), noted lack of collaboration among stroke teams as a reason for delays. Most stroke teams are made up of the following team members: emergency medical staff (EMS), emergency room physician, nurses, support staff, stroke neurologist, imaging technologist and laboratory technologist. In order for the team to function effectively, members must understand their specific roles, which can be facilitated through stroke education. Ghrooda et al. (2012), found that monitoring stroke indicators, and providing feedback to the multidisciplinary stroke team were critical in improving team performance.

Process stroke indicators, such as DTN and door-to-CT (computed axial tomographic scan) times are relatively simple for emergency departments to collect. Many process metrics measure time intervals or simply whether or not an intervention was performed. If the stroke performance metrics suggest suboptimal performance, steps must to be taken to improve the quality of care. Such quality improvement initiatives are well documented in the literature (Rymer et al., 2014).

Local Quality Improvement Initiatives

The Health Science Centre (HSC) Adult Emergency Department is one of two designated stroke centres in Winnipeg, Manitoba, that first administered rt-PA to acute stroke patients in 1999. However, it was not until the end of 2005 that a hyperacute stroke protocol was developed (S. Alcock, personal communication, May 2009). In early 2009 it was noted that stroke performance quality metrics were not being collected. A retrospective chart review examined acute stroke protocol patients who presented to the ED between January 2008 and December 2011. A total of 158 patients treated with rt-PA were identified. The following times and time intervals were captured: (1) door time – arrival time documented on the emergency record; (2) CT time – time of uninfused CT; (3) needle time – time rt-PA bolus was administered; (4) door-to-CT time, i.e. the time interval from ED arrival to CT; (5) DTN time, i.e. the time interval from ED arrival to time of rt-PA bolus administration; (6) CT-to-needle time, calculated from DTN minus door-to-CT time. The median DTN times for 2008 (n=28), 2009 (n=33), and 2010 (n=39) were 69, 71 and 76 minutes respectively. The median door-to-CT time for 2008-2010 was 27 minutes, whereas the median CT-to-needle was 47 minutes. These time intervals were well beyond current guidelines, which recommend that eligible stroke patients receive thrombolytic therapy within 60 minutes or less of arrival (Casaubon et al., 2015; Jauch et al., 2013).

Based on these findings, feedback and education on the stroke protocol were delivered during November 2010 to January 2011 to neurologists, ED physicians, ED nurses, ED unit assistants, ED unit clerks, CT technologists and laboratory technologists. The education encompassed a review of the use of rt-PA in acute stroke, an overview of the stroke protocol, and performance feedback. Emphasis was placed on the importance of time-driven therapy. Furthermore, two goals of care for 2011 were shared with all groups: a median door to needle of 50 minutes; and 80% of eligible acute ischemic stroke patients receiving rt-PA within 60 minutes of arrival.

In January 2011, an interdisciplinary HSC stroke committee was initiated to address the delays in stroke patient treatment. Membership included representatives from the following areas: Winnipeg Fire Paramedic Service, the Adult ED (nursing and physicians), Neurology program, CT department, neuro-radiology, laboratory department, and admitting department. This committee undertook a hyperacute stroke quality improvement project in the summer of 2011. T. Strome, a qualified leader in the principles of Lean, guided the group in developing a value stream map (VSM) of an acute stroke patient's pathway through the ED during a stroke protocol. Based on the identified inefficiencies, the group then developed several key steps for improving process and workflow. The most significant process change was that on arrival in the ED, instead of stopping at triage for registration, all stroke protocol patients were subsequently sent directly to a dedicated stroke bed in the resuscitation room. Once transferred to the stroke bed, a paramedic gives a report to the entire stroke team; the emergency physician ensures that the patient's primary survey is not compromised; the neurologist does a quick stroke assessment; and one ED nurse obtains intravenous access and blood tests, while a second nurse documents the patient history. The nurse and neurologist then escort the patient to the nearby CT scanner. Thus, an effective and efficient collaborative team approach was established.

The results of the quality improvement initiatives were quite remarkable. In 2011, the median DTN for acute stroke protocol patients (N = 58) dropped significantly ($p < .001$) to 49 minutes. Furthermore, between, 2008-2010, only 31% of treated patients (N=100) received rt-PA within 60 minutes of arrival, whereas in 2011 this increased to 64% (Ghrooda, et al., 2012). In 2012 and 2013, performance feedback was again provided to the neurologists during Neurosciences Rounds. Similarly, performance feedback and review of the stroke protocol with a case study was provided to ED staff during the annual education days in May 2013. Subsequent median DTN times in 2012, 2013, and 2014 where 49, 48, and 49 minutes respectively, and the percentage of patients treated within 60 minutes of arrival increased to 77%. However, the 2012-2014 performance data has not been published.

Although the ED has achieved improved and sustained stroke process metrics over the past several years, patient outcomes remain unknown. This is, in part, because process metrics are relatively easy to measure; however patient outcomes are more difficult to obtain (Grotta, 2014; Rymer et al. 2014). Although several centres have reported improvements in quality stroke care indicators (Ganesh et al., 2014), a gap in the translation of these process improvements to stroke patient outcomes persists (Fonarow et al., 2014; Rymer et al., 2014).

Purpose of the Study

While the hyperacute care quality improvement initiatives at the HSC Adult ED resulted in dramatic improvements in stroke quality metrics, to date an evaluation of these improvements with respect to patient outcomes has not been accomplished. To address this gap, the **purpose** of this thesis research project is to determine if the structural and process quality improvements in the HSC Adult ED resulted in improved clinical outcomes for stroke patients. Based on review of current evidence to-date, we hypothesize that the significant improvement in DTN times has resulted in improved clinical outcomes. The analysis of clinical outcomes will be conducted by operationalizing the structure, process, and outcome domains of the Donabedian framework.

Specific research objectives are to determine if:

1. there is a relationship between structural factors (i.e., population characteristics), process factors (e.g., arrival time) and outcomes (e.g., in hospital mortality);
2. presenting characteristics vary based on symptom onset to-needle times or DTN times;
3. there is a relationship between structural changes (e.g. dedicated stroke bed in the resuscitation room) and improved process metrics (e.g. DTN);
4. the structural changes contribute to improvements in process.

5. there is a relationship between process (e.g., DTN times) and outcomes (e.g., in-hospital mortality).

Significance of the Study

The incidence of stroke is increasing; therefore, establishing strategies to improve stroke patient outcomes is critically important. While quality improvement process initiatives, such as improving adherence to best practice care and developing innovative ways to improve healthcare are essential, determining the outcomes of these initiatives is also imperative. This study will provide evidence related to these outcomes, while considering both the structures and processes of care.

Although this type of research has been undertaken internationally and nationally, it has not been done in the Province of Manitoba. Consequently, in Manitoba organized stroke care is in its infancy. Most Regional Health Authorities in Manitoba have adopted organized stroke care and are at various stages with implementation. The number of stroke centres in the province that are delivering hyperacute stroke care is growing. The proposed study will provide Manitoba stroke centres with insight on how to direct quality improvement efforts pertaining to hyperacute stroke care, namely reducing the time from symptom onset to treatment.

Hyperacute stroke care is most successful when delivered by a multidisciplinary team. However, nursing is the key to the success of the team, because nurses are with their patients 24/7. The primary intent of this study is to provide scientific evidence on hyperacute stroke nursing care and to pave the way for others to continue advocating for quality hyperacute stroke care in our province. Furthermore, this study will contribute to the nursing management and the neurosciences nursing literature on the importance of monitoring hyperacute stroke, structures, process, and outcomes.

This research will also provide health regions and hospital administrators with evidence supporting the need to invest in structure and processes, as they are facing growing provincial and national pressures to improve quality stroke care. Patient outcome data will strengthen the stroke care delivered by the HSC Adult Emergency program, the University of Manitoba Neurology program, the Winnipeg Fire Paramedic Service stroke program, and the Winnipeg Regional Health Authority. Furthermore, this study should foster increased uptake and compliance of the stroke best practice guidelines at all levels. Ultimately stroke patients in Manitoba will benefit from this study, because it will increase the adherence to time-driven hyperacute stroke protocols. Thus, valuable insights will be established into the future of stroke care at HSC, in the Province of Manitoba, and beyond.

Summary

The impact of stroke is devastating; moreover, the human cost is immeasurable (Lindsay 2010). With treatment advances, major stroke is now a very treatable disease. However, the incidence of ischemic stroke is rising due to an aging population. Sadly, Canadians lack knowledge in recognizing a stroke, which translates into most stroke patients arriving well outside the thrombolytic window. Many of the inherent delays within the ED are within our control as members of the hyperacute stroke team in the ED. Stroke teams need to adopt and provide time-driven processes of care. Organizations need to invest in health care quality measurement activities in order to be accountable for the care they provide. Process improvements need to be undertaken to improve processes in hyperacute stroke care. Moreover, there is a need to translate process improvements into patient outcomes.

The HSC Adult ED was able to achieve dramatic results in stroke process metrics, after performing a hyperacute stroke quality improvement project; however, translating these improvements into patient outcomes has not been accomplished. Hence the purpose of this thesis research project is to explore if these structural and process quality improvements resulted in improved clinical outcomes for stroke patients. This study will provide evidence related to these outcomes, thus establishing valuable insights into the future of stroke care at HSC, in the Province of Manitoba, and beyond.

CHAPTER TWO: CONCEPTUAL FRAMEWORK

Introduction

This chapter explores the Donabedian framework, which was chosen to conceptualize, anchor, and guide this research project. The Donabedian framework provides a systematic approach to evaluating the quality of care, and focuses on three domains: structure, process, and outcome (Donabedian, 1988). The Donabedian framework remains the dominant paradigm in health care evaluation, as it facilitates an objective and systematic assessment of health care quality. The rationale for selecting the Donabedian framework will be articulated. Furthermore, a discussion of the major concepts of structure, process, and outcome will be provided. Guided by the framework, identification of the variables or minor concepts that occur under the umbrella of each major concept will follow; however, a more thorough discussion of each variable will occur in the review of the literature. Therefore, the purpose of this chapter is to articulate why the Donabedian framework was chosen to guide and provide structure to my thesis research project.

Quality of Care Frameworks

Research is meant to build knowledge in a discipline through the generation of theory or the testing of a theory. Scientific knowledge should be developed within a theoretical structure that facilitates analysis and the interpretation of findings (McEwen & Willis, 2014). A conceptual framework provides overall structure and organization to a study by defining concepts and proposing relationships among concepts. Moreover, a conceptual framework guides and provides perspective to the literature review, methods, results, discussion, and dissemination of the study (McEwen & Willis, 2014). Therefore, a framework should be used when assessing quality of care. Although several frameworks exist in the literature to examine quality of care, most frameworks are rooted in the Donabedian framework. However, the concept of quality of care must first be explored

Health care organizations aim to provide high quality care; hence, the science of measuring quality care is of great importance. Quality of care is defined as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Hammermeister, Shroyer, Sethi, & Grover, 1995, p. OS7). The World Health Organization suggests that quality care should be effective, adhere to evidence-based practice, and improve health outcomes. Furthermore, Bengoa and Kawar (2006) suggest that care needs to be efficient, accessible, patient-centred, equitable, and safe. Gaps in care develop when expected health delivery and actual provision of health care differ. Quality assessment frameworks exist to measure the health care being provided on individuals, communities, and populations. The Donabedian framework has been used as a foundation for several other conceptual frameworks in health care (Hickey & Brosnan, 2012; Jesus & Hoenig, 2015).

The Outcomes Model for Health Care Research (Holzemer, 1994), the Quality Health Outcomes Model (Mitchell & Lang, 2004), the Effectiveness-Efficiency-Equity Framework, (Aday et al., 1999) and the Logic Models (Hickey & Brosnan, 2012) are among such frameworks that have ties to Donabedian’s work.

Outcomes Model for Health Care Research

The Outcomes Model for Health Care Research (Holzemer, 1994) is based on Donabedian’s structure-process-outcome framework. Holzemer (1994) explored each of the domains (structure, process, and outcome) from the primary health care perspective, and the context of the client, provider and setting, (see Figure 1).

	Inputs	Processes	Outcomes
Client			
Provider			
Setting			

Figure 1. Visual depiction of the Outcome Model for Health Care Research. Adapted with permission from "Variables, Variability, and Variations Research: Implications for Medical Informatics" by Holzemer, W. L. & Reilly, C. A. (1995), Journal of the American Medical Informatics Association, 2(3), p. 184.

A strength of the Outcome Model for Health Care Research is that it helps to categorize variables in each of the nine categories. Holzemer (1994) proposes that this model may help understand health-related outcomes, as each box or category addresses variances. Holzemer suggests that the client, provider, and setting should be evaluated prior to preforming outcomes research (Holzemer, 1994). Even though this model has tremendous merit, it appears more useful in the primary health setting where self-care and health behaviours may have more of an influence than in the delivery of episodic care in the setting of an emergency room.

The Quality Health Outcomes Model

The Quality Health Outcomes Model (Mitchell & Lang, 2004) is also grounded in Donabedian's structure-process-outcome framework; furthermore, it builds on Holzemer's (1994) model. Mitchell and Lang (2004), argue that the system and the individual influence the relationship between the intervention and the client outcome because of a reciprocal interaction (see Figure 2). Each of the four domains in the model can be explored from a multitude of levels: the individual, the group, the community, or the organization. Mitchell and Lang (2004) postulate that understanding these levels will foster a deeper understanding of the intervention and outcomes. Nurse-sensitive outcomes that this model explores include achievement of appropriate self-care, health promotion behaviours, health-related quality of life, perception of well-being, and symptom management criteria.

This framework allows for an alternate conceptualization of the quality of care. One could perceive that the system is the structure and the process is the intervention. Although this model also has merit, the Donabedian model is a better fit for the proposed thesis study due to the less complex linear approach.

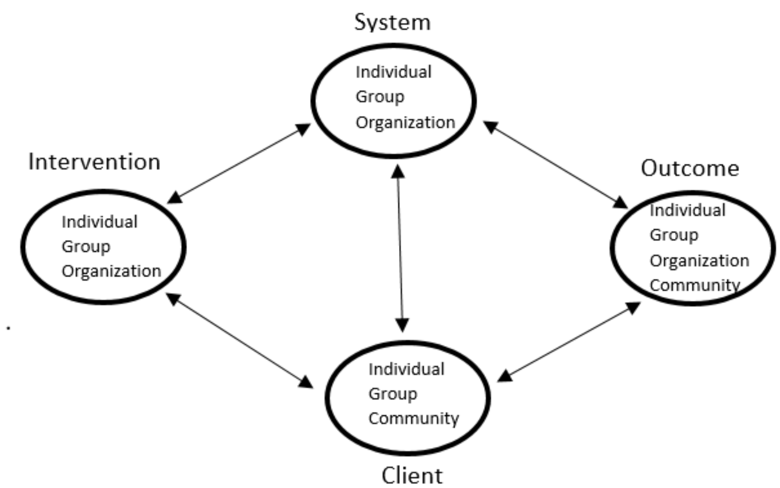

Figure 2. Visual depiction of the Quality of Health Outcomes Model. Adapted with permission from "Framing the Problem of Measuring and Improving Healthcare Quality. Has the Quality Health Outcomes Model Been Useful?" by Mitchell, P. H. & Lang, N. M. (2004), Medical Care, 42(2suppl), p. II-5.

The Effectiveness-Efficiency-Equity Framework

The Effectiveness-Efficiency-Equity Framework**,** (Aday et al., 1999) is another outcome model that is grounded in the Donabedian framework. The Effectiveness-Efficiency-Equity framework focuses on how policies affect the health status of individuals, communities, and populations, as it analyses the effectiveness of programs on changing health outcomes. This model evaluates the cost of the care, the equity, and accessibility of care, at the micro, meso, and macro levels. The Effectiveness-Efficiency-Equity framework could be effective in evaluating the delivery of a service, such as hyperacute stroke care at the micro level; however, it is too complex for the nature of the current study. If access to care was the primary outcome, this model would have been an appropriate choice for the proposed study.

Logic Models

Logic models may also be useful in the evaluation of quality improvement initiatives. Logic models provide guidance in planning, implementing, and evaluating a quality improvement initiative, as the focus is more on resources, actions, and goals of a program (Hickey & Brosnan, 2012) (see Figure 3). Logic models start with identifying the desired outcome and then tailor the interventions to meet the desired outcome. Outcomes are divided into short term, intermediate, and long-term. The use of a logic model is useful in health care, when desired outcomes are set; however, the proposed thesis study involves a retrospective analysis of care and outcomes that have already occurred. A well-known logic model used in quality improvement is the *Plan, Do, Study, Act,* model (Morelli, 2016).

<table>
<tr><td colspan="3">Process→</td><td colspan="3">Outcomes→</td></tr>
<tr><td>inputs→</td><td>activities→</td><td>outputs→</td><td>short→</td><td>intermediate→</td><td>long</td></tr>
<tr><td colspan="6">Assumptions / Contextual Factors</td></tr>
</table>

Figure 3. Layout of a general logic model. Adapted with permission from *State Heart Disease and Stroke Prevention Program*. Evaluation Guide: Developing and Using a Logic Model. Centers for Disease Control and Prevention Division for Heart Disease and Stroke Prevention, p. 2.

Thus, the Donabedian framework is the dominant paradigm in quality assessment. A plethora of literature supports the use of the Donabedian framework in various care settings as a method to evaluate the quality of health care being delivered. As demonstrated by the examples in this section, most other quality-of-care assessment models are grounded in the Donabedian framework. The following section will substantiate why the Donabedian framework was the best fit for the proposed thesis study.

The Donabedian Framework

Donabedian first introduced his framework for evaluating quality in health care in 1966 (Donabedian, 1966); this framework has since evolved to become the dominant paradigm in health service enquiry. Donabedian (1988) suggests that health care outcomes cannot be studied in isolation; rather, they must be examined within the context of the care being evaluated. The Donabedian framework provides a systematic approach to evaluate quality care; it focuses on three domains: structure, process, and outcome (Donabedian, 1988). Understanding the linkage between structure, process, and outcomes in the area being examined is critical to the Donabedian framework (Donabedian, 1988). Furthermore, the "casual links" between structure and outcomes, process and outcomes, and structure and process must also be understood.

Quality evaluation is feasible if care is taken in choosing structure and process indicators that reflect the intervention under study and demonstrate the linkages between the three domains. When choosing performance measures for monitoring structure and process, valid linkages with outcomes of care must be visible. Basing the decision on consensus alone is not recommended, as the three domains are complementary and influence each other (Hammermeister et al., 1995; Gardner, Gardner, & O'Connell, 2013). Studies also suggest that not all structural or process indicators are of equal importance (Persenius, Hall-Lord, Wilde-Larsson, & Carlson, 2015).

Donabedian (1988) poses the following practical questions: “who is being assessed and what activities are to be assessed; how are these activities supposed to be conducted; what are they to accomplish” (p. 1745). Quality of care research then examines the relationship between structure and outcome, process and outcome, and structure and process. This then provides a more accurate assessment of quality of care (Qu, Shewchuk, Chen, & Richards, 2010).

The flexibility of the Donabedian framework to evaluate care delivery has resulted in its application in a multitude of health care settings. The health evaluation literature demonstrates the use of Donabedian in the following settings: stroke rehabilitation (Jesus & Hoenig, 2015; Hoenig, Lee, & Stineman, 2010; Zorowitz, 2010), inflammatory bowel disease, (Rejler, Tholstrup, Elg, Spangeus, & Gare, (2012), spinal cord injury rehabilitation (Qu et al., 2010), infection control (Chou, Yano, McCoy, Willis, & Doebbeling, 2008), nutrition (Persenius et al., 2015), myocardial infarction (Wubker, 2007), depressed adults (Hong, Morrow-Howell, Proctor, Wentz & Rubin, 2007), staffing model (Sheild et al., 2014), nurse practitioner service (Gardner et al., 2013), stroke education, (Barrere, Delaney, Peterson & Hickey, 2010), public health, (Issel & Bekemeier, 2010) and nurse-sensitive outcomes in acute stroke (Green, Kelloway, Davies-Schinkel, Hill, & Lindsay, 2011). Relevant to the proposed study, Cornwell, Chang, Phillips, and Campbell (2003) used the Donabedian framework to evaluate the implementation of a fulltime trauma service at a Level 1 Trauma Centre in the USA. Their study objective was to evaluate the implementation of a dedicated trauma program (structure) on the process (timeliness of care in the ED) and outcomes (mortality) on trauma patients seen in their facilities.

Importantly, the Canadian Stroke Best Practice Recommendations (CSBPR) document endorses the use of the Donabedian framework in implementing and evaluating TeleStroke care in Canada (Lindsay, Taralson, McClure, Foley, & Silver, 2013). The Canadian TeleStroke

Action Collaborative Framework (Lindsay, 2010) used the Donabedian structure, process, and outcome framework to provide organization to the delivery of TeleStroke in Canada across the continuum of stroke care. Policy, advocacy, and models of TeleStroke represent structure; implementation of best practices and technology represent process; and all forms of evaluation represent outcomes (Lindsay & Taralson, 2013).

The Donabedian framework can be used as an assessment tool for health care organizations to identify gaps in the quality of care. Moreover, it can be used as the foundation for a quality improvement project. The following discussion includes an application of the Donabedian Framework structure, process, and outcome concepts to the proposed thesis study. Figure 5 illustrates the Donabedian Framework within the context of exploring clinical outcomes of acute ischemic stroke patients after a DTN quality improvement initiative at our facility.

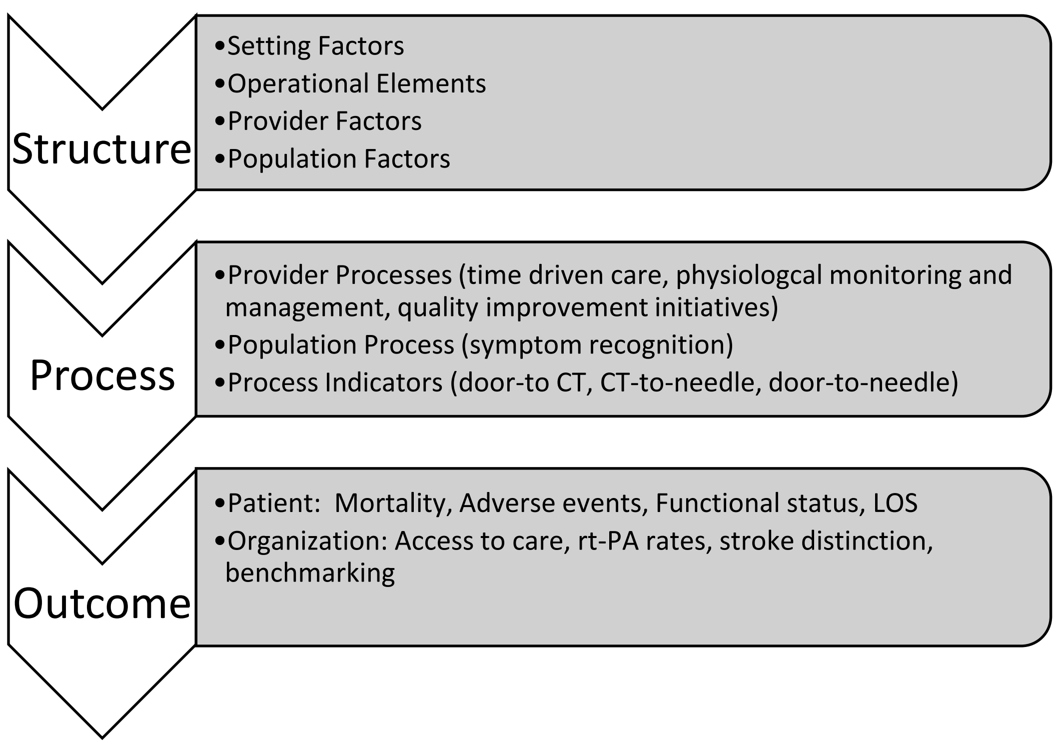

Figure 4. Adapted Framework of Structure, Process, and Outcome Variables in Hyperacute Stroke Care.

Structure

Qu et al., (2010) suggest that structures tend to be stable characteristics, which include material resources, care providers, the organization, operation programs, and personnel elements. Furthermore, structure describes the context in which the care is being delivered, to include the facilities and equipment (Hammermeister et al., 1995; Hickey & Brosnan, 2012; Qu et al., 2010; Rejler et al., 2012). Personnel elements, or human resources, describe the credentials and qualifications of the health care providers involved (Hammermeister et al., 1995). Structural components need to be safe and evidence-based in order to provide a strong foundation for quality health care (Persenius et al., 2015). Clinical practice guidelines often provide direction when establishing structural elements for providing quality care. For the proposed thesis project, structure will be further subdivided into setting factors, operational elements, provider factors, and population factors. A brief description of these structural sub-classifications follows.

Setting factors. Setting factors refer to the physical environment in which the care occurs, including the necessary equipment and proximity of the equipment in relation to the location of the patient. For example, a physical environment conducive to hyperacute stroke care would include a dedicated stroke bed, a ‘clot box’ containing all the necessary medications, intravenous supplies, and documentation forms. The proximity of the ED stroke-bed to the CT scanner would also be taken into account. Performance measures that evaluate quality pertaining to the setting within which the care takes place are descriptive in nature (e.g., does the ED have a dedicated stroke bed?).

Operational elements. Operational elements encompass organizational policies and protocols that guide a specific process of care within the organization to serve a population in need. Stroke programs, or organizations that deliver hyperacute stroke care require evidence based clinical pathways, algorithms, clinical practice guidelines, and order sets to guide the care being delivered. These stroke protocols provide guidance to the health care team providing the care. Blayney (2013) suggests that evidence-based guidelines improve care, which in turn improves outcomes. French et al. (2013) and Lindsay et al. (2010) suggest that stroke pathways, protocols, and order sets that represent efficient workflow processes need to be developed in both the pre-hospital and stroke centre ED setting. Chou et al., (2008) suggest that organizational protocols should be formal, centralized, and standardized in order to develop expert providers and utilize resources effectively. Operational elements would also be descriptively measured. For example, does the organization have a stroke protocol that is evidence-based and reflects current best practice?

Provider factors. Provider factors refer to the individuals or team delivering the care. Providers must be competent and proficient in the care they deliver. Competency can be achieved through education and experience, and is often enhanced with feedback. Tarlov et al. (1989) suggest that provider characteristics also encompass age, gender, specialty training, beliefs and attitudes, and job satisfaction. The care provider should possess the knowledge and have the resources to deliver high quality care that fosters the desired outcome of the service being delivered.

In hyperacute stroke care, the provider is a multidisciplinary, collaborative team comprising of nurses, emergency physician, stroke neurologist, CT technologist, laboratory technologist, and support staff. According to Green et al. (2011), nurses are key as they provide 24/7 patient assessment, monitoring, and symptom management. Consequently, one could argue that competent nurses are essential to delivering quality care. Provider factors can be assessed by describing the composition of the team, and by measuring experience through duration of employment on a unit, and educational qualifications.

Population factors. Population factors, such as age, gender, diagnosis, comorbid factors, health habits, and beliefs are included under structure, as variations in these patient characteristics will impact process and outcomes (Tarlov et al., 1989). For example, when evaluating hyperacute stroke care, an awareness of patient characteristics, specifically stroke risk factors, is important because they impact outcomes. In order to decrease variance between groups, an understanding of the composition of the groups is critical.

Hence it is important to establish and measure structures that support or hinder the desired health outcome. Moreover, it is important to understand the variance in structural elements that may impact processes of care and overall outcomes.

Process

The process domain builds on the structural domain. Donabedian (1988) refers to process as what is actually being done in giving and receiving the care. Donabedian (1988) goes on to explain that ideally processes of care should lead to improving the patient's health, such as survival, recovery, functional restoration, and patient satisfaction. According to Hammermeister et al. (1995), process describes the services that are provided during the episodes of care and how the patient moves into, through, and out of the health care system. Process of care would therefore describe the type or content of care, the frequency of care, the timeliness of care, and the duration of the care. For the purposes of this thesis project, ***process*** has been further subdivided into the following categories; provider processes, patient processes, and process indicators.

Provider Processes. Hickey and Brosnan (2012) and Qu et al. (2010) allude to process as the transactional practitioner/patient interaction that occurs when providing and receiving care. *Provider processes* describe how the care is being carried out by the provider during the patient provider interaction. If one looks at hyperacute stroke care as an episode of care, it should be delivered by a collaborative multidisciplinary team that understands the time-driven nature of acute stroke care. Additionally, the provider processes should adhere to current evidence-based care guidelines. Understanding the patient's physiological monitoring needs, and knowing the normal/abnormal parameters and how to manage abnormal results, are essential for a good clinical outcome. Hence, knowledge and technical proficiency are expectations of the practitioner or team providing the care. Furthermore, meeting the *standards of care* is expected of the health care provider delivering the care to the patient (*Canadian Stroke Strategy*, 2008), as standards constitute the basic requirements of quality care. Hickey and Brosnan (2012) argue that process indicators offer a direct approach to evaluating care, because care that meets practice standards in a specific time and place is quality care.

At a systems level, provider processes would also include quality improvement initiatives. Quality improvement initiatives in health care focus on process improvements. If process or outcome metrics do not align with national benchmarks, efforts to improve the care must be initiated. For example, there is a plethora of literature on system-level initiatives to improve door-to-needle times in hyperacute stroke care.

Patient Processes. The patient is the recipient of the care. Hammermeister et al. (1995), refer to patient processes as the way in which a patient moves into, through, and out of the health care system. The patient or the patient's family is ultimately responsible for seeking health care services. For example, if stroke is suspected, the patient or family member is responsible for recognizing the symptoms of a stroke and for calling 911, which initiates the move into the health care system. Once the patient is in the emergency room, the provider is responsible for moving the patient through and out of the system. Therefore, indicators of patient processes focus on the timing of seeking and receiving care.

Process Indicators. *Process indicators* are quantitative measurements of the care being delivered by the provider. Since providers are required to demonstrate professional accountability, technical care is often well documented in a patient's chart. Therefore, process indicators are easier to collect than outcome indicators, as the data is readily accessible in the patient's chart. Process indicators are usually time intervals; however, they also measure whether or not the intervention or care occurred and how well it was done. Time intervals, such as patient arrival to physician assessment or the time interval from ordering of a diagnostic test to completion are commonly collected in emergency rooms to monitor processes of care in general. Time intervals are easy to calculate if operational definitions exist to standardize the approach. Processes indicators also include the intervention itself; for example, whether an appropriate patient assessment was done, the correct diagnostic tests were done, a timely test interpretation occurred, a correct diagnosis was made, abnormal physiological parameters were managed appropriately, and if the patient and family received education.

Measuring processes of care can identify gaps between expected and actual care and can also shed light on whether or not the standard of care was delivered. However, as standards of practice change to reflect new scientific knowledge, process indicators must also change. For example: recent scientific evidence has led to practice changes related to rapid treatment in acute stroke. Accordingly, there is a new process indicator that reflects the percentage of eligible patients who receive rt-PA within 30 minutes of arrival. Current hyperacute stroke process indicators will be discussed in the review of the literature in Chapter 3.

Much of the work of the CSBPR has focused on providing evidence-based guidelines that support the delivery of quality stroke care, as well as establishing reliable and valid measurement tools to assess the quality of stroke care delivered. To this end, the CSBPR has developed a performance measurement manual data dictionary, which includes the standardized performance measures or indicators across the stroke continuum, (*Canadian Stroke Strategy*, 2008).

Outcomes

Outcomes evaluate the combined effects of structure and process (Donabedian, 1988). According to Donabedian (1988), outcomes reflect the effects of care on the health status of the individual patient, and also the population. Optimal patient outcomes are recovery, restoration of function, and survival (Donabedian, 1988). Furthermore, Donabedian (1988) emphasized that outcomes are the ultimate validation of the effectiveness and quality of medical care. For the purposes of the proposed study, most measured outcomes will be at the patient level; however, access to care, an organizational level outcome will also be captured as it impacts overall population outcomes.

Patient Outcomes. Processes of care delivery represent the occurrence of recommended care, whereas outcomes, either positive or negative, reflect the changes in the patient's health status that occur as a consequence of the care. According to Hammermeister et al. (1995), a wide range of outcomes, including mortality, symptoms, functional status, social functioning, emotional status, health perceptions, and satisfaction may be included in outcomes research. Furthermore, outcome measures may be generic or disease-specific and may be measured by the practitioner or reported by the patient (e.g., satisfaction). Many outcomes occur after the patient leaves the care setting in which the care was delivered, making the collection of outcome measures challenging.

Donabedian (1988) suggests that clinical practice outcomes demand measures that are easy, precise, and complete. Rymer et al, (2014) recommend a combination of hospital-based and post-discharge outcome indicators. Hickey & Brosnan (2012) suggest that outcomes can be standardized across a care setting. For example, outcome measures germane to hyperacute stroke care include, mortality, secondary hemorrhage, functional status, and discharge location. Quality outcomes would suggest a reduction in mortality and secondary hemorrhage, less impairment or disability, and more stroke patients discharged home or to active rehabilitation centres.

Organizational Outcomes. Access to care is a commonly measured organizational outcome, as it demonstrates how accessible the health care services are to the population. An example in hyperacute stroke care would be the number of patients who arrive within the thrombolytic window and the proportion of ischemic stroke patients that receive thrombolytic therapy.

Performance measures, which are quantitative assessments of health care processes, are divided into four levels; national, regional, organizational, and clinical levels. National organizations, such as the Heart and Stroke Foundation of Canada (HSFC) and the American Heart and Stroke Association (AHSA) have established standards, which act as benchmarks for stroke program evaluation. A standard of excellence for a specific process of care or outcome is used for comparison of groups and is called a benchmark, whereas a target is the level of performance that an organization aims to achieve within a specified period of time (*Canadian Stroke Strategy*, 2008). In Canada, the CSBPR provides clearly defined performance measures, as well as stroke quality care benchmarks, which help programs achieve and sustain best practice care (Casaubon et al, 2015; Lindsay et al., 2010). Hospitals and stroke programs can then take these national benchmarks and create their own targets; for example, a reduction in mortality by 10% or an increase in the number of stroke patients discharged home by 20%.

Structure- Process- Outcome Linkage

Structure of care primarily affects the processes of care. Processes of care rely on structural elements to provide the necessary resources for quality care. Structure can facilitate care or become a barrier in the delivery of care. According to Hoenig et al. (2010), addressing structural barriers and implementing structural improvements can help to motivate staff to provide better care. For example, implementing structural elements that facilitate faster processes of care will result in earlier rt-PA administration and improved outcomes, whereas structural barriers, such as inefficient processes, will result in loss of time and worse outcomes. Furthermore, if high-quality care is provided, the chance of a good outcome will increase as fewer complications will occur and the patient's ability to deal with complications will improve. Importantly, Donabedian (2003) suggests that a comprehensive evaluation of quality care is established when the triad of structure, process, and outcomes are considered as a whole.

Summary

The Donabedian structure-process-outcome quality framework was determined to be the most appropriate framework for this study for the following reasons. First, the Donabedian framework has become the dominant paradigm in health service enquiry, due to its simplicity and flexibility. This framework has been used to evaluate the quality of care provided in a multitude of settings. Second, the Donabedian framework is endorsed by the CSBPR and is specifically recommended for use in the implementation, delivery, and evaluation of all forms of

TeleStroke. Third, since our study is exploring clinical outcomes following a quality improvement initiative, the Donabedian framework is a good fit because it assumes that if evidence-based structures of care are in place, they will translate into improved processes of care, which in turn will lead to improved outcomes. However, contextual variance in each domain needs to be taken into account when describing the quality of care. Fourth, applying the Donabedian framework helps to identify and understand structural and process gaps, which can lead to future research. Last, and most importantly, the Donabedian framework facilitates an examination of the linkage between structure and process and between process and outcomes. Specific to the proposed thesis research, assessing the implementation, delivery, and outcomes of hyperacute stroke care based on the Donabedian quality framework will ultimately have a positive impact on our individual patient outcomes and overall stroke program outcomes.

CHAPTER THREE: REVIEW OF THE LITERATURE

Introduction

The purpose of the following literature review was to establish sound rationale for the proposed thesis research. A review of the literature on quality hyperacute stroke care was explored as it applies to the proposed study. The overall goal of hyperacute stroke care is to decrease mortality and to improve clinical outcomes by limiting disability. Scientific evidence that guides hyperacute stroke care strongly suggests that it is time sensitive, as the window in which to deliver rt-PA is narrow and the benefit of rt-PA is strongly time dependent (Fonarow, et al., 2014; Lansberg, M. G., Schrooten, M., Bluhmki, E., Thijs, V. N. & Saver, J. L., 2009; Lees et al., 2010; National Institute of Neurological Disorders and Stroke t-PA Study Group, 1995; Wardlaw et al., 2012). This requires clinical structures and processes of care that are time driven. Evidence-based guidelines, such as the Canadian Stroke Best Practice Recommendations (CSBPR; Casaubon, et al., 2015) and the American Stroke Practice Guidelines (ASPG; Jauch et al., 2013) suggest that adhering to stroke best practice guidelines will improve overall stroke outcomes. Stroke guidelines, which are supported by scientific evidence, inform our practice with standards of care and benchmarks, and also offer a wide variety of quality performance measures to evaluate the care provided. Unfortunately, despite evidence-based guidelines that are directed at clinical practice, rt-PA rates in patients with acute stroke remain low (Fonarow et al., 2014; Ganesh et al., 2014; Lindsay & Hill, 2014).

The Donabedian structure-process-outcome framework guided the literature review, as it is a useful method to organize the key concepts of quality hyperacute stroke care. Moreover, the Donabedian framework helped to facilitate an understanding of the linkage between the three domains of structure, process, and outcomes. Literature that is relevant to the study has been synthesised; moreover, gaps have been identified, with the goal to shed light on why this study was important.

Structure

Structures tend to be stable characteristics, which include material resources, care providers, the organization, operation programs, and personnel elements; thus, structure describes the context in which the care is being delivered (Hammermeister et al., 1995; Hickey & Brosnan, 2012; Qu et al., 2010; Rejler et al., 2012). In hyperacute stroke care there is a need for structures that support time-driven care and avoid treatment delays (Casaubon et al., 2015; Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011; Fonarow et al., 2014; Jauch et al., 2013; Saver et al., 2010). These structural factors can be explored within the context of the pre-hospital and in-hospital phases; however, for the purpose of this thesis research, only the in-hospital structures have been examined. These in-hospital structures can be further subdivided into four factors: *setting*, which encompass the facilities and equipment required; *operational elements*, such as written stroke protocols and evidence based practice guidelines; *provider*, such as the manpower available to deliver the care, education, staff knowledge, and qualifications; and *population*, such as patient age, comorbidities, and stroke severity.

Setting Factors

The physical environment in which the care takes place influences the process of delivering quality stroke care. Guidelines recommend general systems and protocols that support efficient workflow processes (Casaubon, et al., 2015: Jauch et al., 2013). However, the specific physical environmental factors are not clearly outlined in the guidelines, nor are they established in the research literature.

The physical environment in which hyperacute stroke care takes place should contribute to efficient workflow processes. Principles of the Lean Transformation Model (Varkey, Reller, & Resar, (2007) or value stream mapping (VSM) are often undertaken to evaluate workflow processes. The Lean Transformation model was founded by Taiichi Ohno, in the 1950s. Ohno was responsible for revolutionizing the Toyota production system by removing 'waste'. The principles of Lean identify the customer's needs and improve processes by removing non-value activities, which then results in increased customer satisfaction. Value stream mapping (VSM) is a management method that analyses the current state of a process of care and then designs a future state that is more efficient. Value stream mapping eliminates 'waste,' such as time and unnecessary steps in process, which in turn results in a more efficient workflow. These principles can be applied to healthcare.

In a prospective observational study in the USA, Ford et al. (2012) applied the principles of Lean and VSM when comparing a pre-VSM cohort (n=132) and a post-VSM cohort (n=87). The pre-VSM cohort patients arrived in the ED and were taken to the trauma bay for a physician assessment and a blood test draw, and then sent to CT. Upon returning from CT the patient was assessed by a neurologist. The post-VSM cohort patients went directly to CT. Upon return from CT the patients were assessed by the ED physician and neurologist, and blood tests were drawn, all at the same time. The authors found a significant reduction in DTN times from 60 minutes to 39 minutes ($p< 0.000$) and an increase in the number of patients that received treatment within 60 minutes from 52% to 78% ($p< 0.0001$). Door-to-CT was also significantly improved with re-routing ($p< 0.0001$). Although structural changes resulted in improved process metrics, Ford et al. (2012) reported that there were no differences in symptomatic intracerebral hemorrhage, discharge location, modified Rankin score at 90 days, or length of stay (LOS) between the two groups.

In a Winnipeg ED based DTN improvement initiative, Ghrooda, Alcock, and Jackson (2012) also applied the principles of Lean and VSM to improve the acute stroke patient's pathway through the ED during a stroke protocol. Identified inefficiencies were noted and key steps for improving process and workflow were undertaken. For example, a dedicated stroke bed, with monitoring capabilities and equipment at the bedside was established. A primary nurse was assigned to the dedicated stroke bed and all stroke team members now knew exactly where to present when they got the 'stroke 25' call. This prevented time being lost looking for the patient within the ED and avoided confusion. A new stroke package at the bedside included imaging and lab requisitions, as well as all stroke protocol charting documents. While proximity of a CT scanner to the ED is also important in DTN times, we were fortunate that this was a consideration in the planning of our relatively new ED, as the CT scanner is adjacent to the resuscitation room.

Thus, an efficient work flow process, as well as a collaborative team approach within the ED setting, was established. Our results also showed a significant drop in median DTN times from 72 minutes in the pre-intervention group (n=100) to 49 minutes in the post- intervention group (n = 58; p< 0.00005). Furthermore, only 31% of patients in the pre-intervention group received rt-PA within 60 minutes of arrival versus 64% in the post-intervention group (Ghrooda, et al., 2012). Although this quality improvement study provided convincing evidence regarding structure and process, we did not explore clinical outcomes of this initiative.

Operational Elements

Operational elements that support efficient processes in the delivery of hyperacute stroke care include supportive leadership, and well -written evidence-based *stroke-protocols*. When exploring the literature on leadership in nursing, Hutchinson and Jackson (2013) found that leaders who support and value their workforce have a more productive team. Consequently, a poor-quality work environment and suboptimal outcomes are often the result of an inadequate leader. Secondly, *stroke protocols*, which are formal written documents that address roles and responsibilities of team members, and describe the standard of care required to deliver hyperacute stroke care are associated with improved DTN times (Ruff et al., 2014; Song et al, 2016; Xian et al., 2016). Examples of stroke-protocol documents are policies, clinical pathways, clinical practice guidelines, and order sets or algorithms. Furthermore, Song et al. (2016), demonstrated improved DTN times as well as improved outcomes after implementing a stroke protocol. This recent observational study (N = 88,854) evaluated the difference in patient outcomes between hospitals in the USA that implemented the GWTG protocols and those that did not. Song et al. (2016) found an increase in the proportion of patients discharged home, and a reduction in 30-day and 1-year mortality rates in the hospitals that had implemented the guidelines.

An important systematic review identified structural operational elements that were associated with DTN ≤ 60 minutes. A multidisciplinary working group of stroke experts (Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011) identified practices associated with DTN ≤ 60 minutes that were feasible and relevant in the clinical area. Moreover, this study spearheaded the AHA/ASA national “Target: Stroke” initiative. Ten key evidence-based best practices were identified in this initiative, including advanced hospital notification by EMS, rapid triage and stroke team notification, single call activation system, rapid acquisition and interpretation of imaging, rapid laboratory testing, mixing the rt-PA ahead of time, rapid access to rt-PA, team based approach and prompt data feedback. These best practices were then launched as the “Target: Stroke” initiative, a national American stroke quality improvement program in 2010. Structural resources in the form of stroke protocols, order sets, and educational materials were given to participating hospitals. The primary goal of Target: Stroke was for at least 50 % of rt-PA eligible AIS patients to receive treatment within 60 minutes of hospital arrival (Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011). This initiative has been evaluated in several subsequent quantitative studies. For example, based on a study that explored the impact of EMS pre-notifying the stroke centre, it was found that timelier care resulted in an increase in patients that were potentially eligible for rt-PA (Lin et al., 2012).

Evidence also suggests that EDs utilizing stroke protocols, which address pre-notification of the stroke team, urgent triage, and patient flow achieve shorter DTN times (Blayney, 2013; Casaubon et al., 2015; Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011; Fonarow et al., 2014; French et al., 2013; Jauch et al., 2013; Lindsay et al., 2010; Saver et al., 2010). Moreover, in a qualitative study with semi-structured interviews, Olson et al., (2011) found having an established stroke protocol that addressed the patterns of care and roles of the team was an emerging theme in practices associated with shorten DTN times. Thus, operational elements must include supportive leadership as well as an evidence-based stroke protocol.

Provider Factors

Not only does structure address material resources and organizational protocols, it also includes the provider delivering the care. The literature suggests that since acute stroke is a time sensitive emergency, it is important to have a collaborative, experienced, and well-educated multidisciplinary team.

The multidisciplinary team is made up of EMS, the emergency room physician, the neurologist, nurses, the CT technologist, the laboratory technologist, the radiologist, and administration personnel (Summers et al., 2013). Clear boundaries between team members do not generally exist, making the contribution of each member of the team difficult to evaluate. Attributes of an effective team include: knowledge of roles and responsibilities of members, effective communication between members, strong leadership, and a coordinated effort (Olson et al., 2011). Good communication and achieving shared goals that are clearly identified in the structure domain will result in coordinated care. Experts suggest that a collaborative, well-organized team that works in parallel, is key to delivering timely hyperacute stroke care and/or improving existing workflow processes to improve DTN times (Busby et al., 2015; Casaubon et al., 2015; Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011; Koennecke, Nohr, Leistner & Marx, 2001; Ruff et al., 2014; Saver et al., 2010). Furthermore, working collaboratively reportedly results in higher use of rt-PA (Ganesh et al., 2014).

The multidisciplinary stroke team requires education (Casaubon et al., 2015). Education includes: providing information about the physiological changes that occur in the initial hours following stroke symptom onset; physiological monitoring, in particular the importance of adhering to blood pressure parameters; written stroke protocol and or order sets; and, most importantly, why stroke is a time-driven emergency. Ongoing education is also important due to staff turnover and protocol drift, where staff tend to forget the importance of the protocol, which leads to lack of adherence/compliance. This is very evident in sites with low hyperacute stroke volumes (Lindsay & Taralson, et al., 2013) and was also a contributing factor in the suboptimal performance of the HSC stroke team prior to the DTN quality improvement program (Ghrooda et al, 2012). A proficient stroke team has been linked to providing improved process in care and improved outcomes (Ruff et al., 2014). Busby et al. (2016), also found reduced DTN times when ED physicians were educated on the stroke protocol.

Timely performance feedback is also critical to the success of the stroke program (Casaubon, et al., 2015; Fonarow et al., 2014; Ruff et al., 2014; Saver, 2010). Performance feedback was considered essential to the success of the Target: Stroke quality improvement initiative (Fonarow, et al., 2014), which demonstrated a significant improvement in process measures, as well as clinical outcomes. Our quality improvement initiative (Ghrooda et al., 2012), also demonstrated that education and performance feedback to the multidisciplinary team resulted in dramatic improvements in DTN times, door-to-CT times, and CT-to-needle times, as well as the percentage of patients that were treated within 60 minutes of arrival.

In summary, structures of quality stroke care are complex and work best in tandem (Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011; Saver et al., 2010). Key attributes in the structural domain that have been identified in the research literature as central to achieving quality hyperacute stroke care are summarized in Table 1.

Evaluating structural variables in hyperacute stroke care has been mostly descriptive (Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011). However, investing in the key structural attributes of hyperacute stroke care should result in improved processes of care, which are captured by measuring process indicators. This will be discussed in the process section. Understanding structural variables will help identify gaps in care and strengthen the delivery or process of care, and in turn improve patient outcomes.

Table 1. *Key Structural Attributes of Hyperacute Stroke Care*

Setting Factors	Operational Elements	Provider Factors
• Dedicated stroke bed • Equipment at bedside: ○ Cardiac monitor ○ rt-PA ○ BP lowering medication ○ IV supplies ○ Lab supplies ○ IV pump • "Stroke Package" ○ Imaging requisition ○ Lab requisition ○ Charting forms • Close proximity to CT scanner	• Supportive leadership • Formal "Stroke Protocol" addressing: ○ Pre-notification of stroke centre by EMS ○ Stroke team pre-notification ○ Urgent triage ○ Rapid assessment ○ Rapid acquisition and interpretation of imaging and laboratory tests ○ Rapid access to rt-PA ○ Team approach • Evidence based resources	• Multidisciplinary team: ○ Collaborative ○ Works in parallel ○ Communicates effectively • Stroke Education ○ Stroke recognition ○ Pathophysiology of stroke ○ Management of acute stroke ○ Physiological monitoring ○ Complications post stroke • Knowledge of Roles and Responsibilities • Performance feedback ○ Timely ○ Entire team

Population Factors

Population factors are included under the structural domain, as patient characteristics impact both process of care and clinical outcomes. Population factors encompass the following variables; stroke recognition by the patient, patient comorbidities, and stroke severity.

According to a poll conducted by the Heart and Stroke Foundation, of Canada (HSFC), only one third of Canadians are able to describe what a stroke is (HSFC, 2015). In light of this finding, in December 2014 the HSFC launched the "FAST" (i.e., Face, Arms, Speech, and Time) campaign (HSF, 2015). The goal of this campaign is to improve stroke recognition among Canadians, to educate the Canadian public that stroke is a medical emergency, and that 911 should be accessed immediately if symptoms are suspected. Not recognizing stroke symptoms and not seeking immediate medical attention decreases the likelihood of a good outcome. Unfortunately, awareness campaigns do not reach everyone; moreover, they rely on the public paying attention to what they see and read.

Patient factors impact who receives timely care and clinical outcomes. In a large observational study, Fonarow et al. (2014) included the following patient level variables when using risk-adjusting models: "age, ethnicity, sex, medical history [atrial fibrillation, prosthetic heart valve, previous stroke or transient ischemic attack, coronary artery disease or prior myocardial infarction, carotid stenosis, peripheral vascular disease, hypertension, dyslipidemia and current smoking], NIHSS score and arrival time during regular hours [7am to 6pm Monday through Friday], and arrival mode [emergency medical services, private vehicle]" (Fonarow et al., 2014, p.1634). The patient characteristics used by Fonarow et al (2014) are commonly collected throughout the stroke literature. However, some factors are greater predictors of outcomes than others.

Patient factors, such as age, gender, comorbidities (i.e., diabetes, peripheral vascular disease, atrial fibrillation and a previous history of stroke), and stroke severity, influence who receives timely care. Experts agree that patients who suffer a severe stroke (i.e., those with a high NIHSS), are more likely to arrive at hospital soon after stroke onset, and therefore receive timely care (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011; Saposnik et al., 2008; Saver et al., 2013). Fonarow, Smith, Saver, Reeves, Bhatt, et al. (2011), Johnson and Bakas, (2010) and Saver et al., (2013) found that being female was associated with longer DTN times. Similarly, older age is also associated with not receiving timely care (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011; Johnson & Bakas, 2010). Understanding which patient groups have DTN ≤ 60 minutes, and DTN > 60 minutes may provide valuable insight into health care provider practices. Hence this data was collected and analyzed in the proposed thesis study.

Understanding patient factors is also important as they influence clinical outcomes. Saver (2011) suggests that age and stroke severity, as measured by the NIHSS are two of the strongest clinical prognostic factors in outcomes. Furthermore, Saposnik et al. (2008) suggest stroke severity, or a high NIHSS score, is associated with mortality. Interestingly, Chee et al. (2014) and Johnson and Bakas (2010) found that ethnicity played a role in clinical outcomes.

Thus, it is important to understand the population that is receiving the intervention or care. In order to evaluate if a treatment is effective, it is important to account for confounding variables and to minimize variance among the pre-intervention and post-intervention groups. Therefore, since hyperacute stroke care is a time-sensitive medical emergency and the sooner that eligible stroke patients receive reperfusion therapy, the better their potential for a good outcome. It is essential to understand who receives timely care, as well as the individual patient prognostic factors of a good outcome.

In summary, the structural factors that are central to high quality hyperacute stroke care are: physical settings that are supportive of efficient workflow processes; operational elements that address evidence-based, hyperacute stroke care; collaborative, educated stroke teams that work in parallel; and population factors. Overall the proportion of stroke patients that receive timely thrombolytic therapy treatment remains low. In order to increase this statistic, it is important to understand the structural factors associated with care delivery and the patient characteristics. Although many studies from the United States and Europe have explored the association between patient characteristics, arrival time in hospital and DTN times, to our knowledge few have been conducted in Canada and none have been done in Manitoba.

Process

Donabedian (1988) refers to process as what is actually being done in giving and receiving the care. Donabedian (1988) also contends that processes of care should lead to improving outcomes, such as overall patient health, survival, recovery, functional restoration, and patient satisfaction. Processes of care describe the services available and either measure time intervals or simply identify whether or not an intervention was performed. There is clear evidence from randomized control trials (RCTs); Lansberg et al., 2009; Lees et al., 2010; National Institute of Neurological Disorders and Stroke t-PA Study Group, 1995; Wardlaw et al., 2012) that hyperacute stroke care that utilizes time-driven structural elements will result in efficient processes of care. In turn, these processes should translate into a reduction in hospital mortality and improved functional outcomes. Stroke guidelines (Casaubon et al., 2015; Jauch et al., 2013), which are supported by different levels of scientific evidence, recommend clinical practices that promote the highest standard of care for our patients. For the purpose of this thesis study, *process* was examined within the following three categories: 1) provider processes, which include time driven processes of care, physiological monitoring, and quality improvement initiatives; 2) population processes, which relate to symptom recognition; and 3) process indicators, which include, onset-to-needle, door-to-needle, CT-to-needle etc. The existing process literature will be synthesized; research gaps will also be identified to establish sound rationale for this study.

Provider Processes

Time driven care. The benefits of early treatment with rt-PA are well established in the literature (Casaubon et al., 2015; Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011; Fonarow et al., 2014; Jauch et al., 2013; Saver et al., 2010). Several RCTs and pooled analyses have confirmed that earlier treatment with rt-PA decreases disability; however, the benefits are strongly time dependent (Lansberg et al., 2009; Lees et al., 2010; National Institute of Neurological Disorders and Stroke t-PA Study Group, 1995; Wardlaw et al., 2012). Furthermore, according to Saver (2006), as the stroke progresses in the early hours after onset, brain cells are rapidly and irretrievably lost. The reality is that patient assessment, diagnostics, and therapeutic interventions should be emergently pursued. Providing the *standard of care* is expected of the health care provider delivering the care to the patient (*Canadian Stroke Strategy*, 2008), as these standards constitute the basic requirements of quality care. If one views hyperacute stroke care as an episode of care, it should be delivered by a collaborative, multidisciplinary team that understands the time-driven nature of acute stroke care. Additionally, the provider processes should adhere to current evidence-based care guidelines. Fonarow, Smith, Saver, Reeves, Bhatt, et al. (2011) explored patient characteristics, hospital factors, and outcomes associated with DTN times within 60 minutes and found a significant reduction in in-hospital mortality (p= 0.0003) for ischemic stroke patients treated with rt-PA within 60 minutes of arrival compared to DTN times > 60 minutes, thus strengthening the argument for time-driven care.

Physiological monitoring. Nurses play a critical role in physiological monitoring as they are with their patients 24/7. Nurses caring for acute stroke patients require stroke education, which includes gaining insight into the patient's physiological monitoring needs, and knowledge of the normal/abnormal parameters, and why managing abnormal results is essential for a good clinical outcome. Hence, knowledge and technical proficiency are expectations of the practitioner or team providing the care.

Scientific evidence regarding the importance of physiological monitoring can be seen in the work by Middleton et al. (2011). In a RCT (N=1696), Middleton et al. (2011) demonstrated that good nursing care was responsible for a reduction in death and disability related to stroke. In this study, an evidence-based protocol/intervention was established to address the management of fever, hyperglycemia and swallowing was. Stroke patients in the post-intervention group were significantly more likely to be alive ($p = 0.002$) and independent ($p=0.002$) at 90 days after admission. This study illustrates that evidence-based physiological monitoring, specifically temperature and glucose management by nursing, contributes to improved clinical outcomes. Furthermore, in a discussion paper that reviewed evidence-related to acute stroke nursing in the ED, McGillivray and Considine (2009) concluded that ED nurses play a critical role in physiological surveillance, which includes vital signs and blood glucose. They also suggest that early triage of stroke patients, fluid and risk management, and early referral of this population to a specialist, are key ED nursing responsibilities. In a subsequent prospective study (N= 105), McGillivray and Considine (2010) examined if implementing an ED nursing evidence-based guideline improved nursing care and patient outcomes. They concluded that increased physiological surveillance, and management of abnormal parameters and clinical risks, resulted in improved clinical outcomes post stroke. Patients were triaged more urgently (*p*= 0.009), and vital sign frequency was increased, including respiratory rate (*p*= 0.009), heart rate (*p*= 0.002), blood pressure (BP); *p*= 0.032), and oxygen saturation (*p*= 0.001). Increasing the frequency of swallowing assessments prior to oral intake and increasing the frequency of pressure sore assessment and interventions also helped with decreasing complications post-stroke.

Most would agree that this component of process in acute stroke care is very likely associated with clinical outcomes. Although physiological monitoring of the acute stroke patient includes many parameters, the two central components in hyperacute stroke care are BP monitoring and measuring stroke severity.

Measuring stroke severity. The NIHSS is the gold standard for quantifying stroke severity. However, not all hospitals consistently gather the NIHSS score on their patients. Saver (2011) suggests that using more than one scale, such as the NIHSS, the Glasgow Coma Scale (GCS), or the modified Rankin score (mRs) may be beneficial when measuring baseline and discharge impairments.

Although Nurses at the HSC consistently use the GCS, the GCS is not a validated stroke deficit tool for assessing stroke patients. Furthermore, the neurologists do not consistently utilize or document the NIHSS in the patients' charts. Even though the GCS is a head injury tool, it is a useful functional outcome tool, even in the setting of stroke where more sophisticated tools exist (Saver, 2011).

Blood pressure monitoring and management. Blood pressure is an important predicator of outcomes, as an elevated BP is directly associated with an increased risk of an intracranial hemorrhage during and post rt-PA administration. Clearly, nurses play a central role in ongoing

BP monitoring in the acute stroke patient; however, BP management remains controversial in the stroke literature. In the retrospective SITS-ISTR study (N = 11,080), Ahmed et al. (2009) found that high systolic BP in the first 24 hours post thrombolysis was associated with a worse outcome ($p < 0.001$). Blood pressure above suggested parameters, before, during, and 24 hours post rt-PA administration is associated with an increased risk of a symptomatic intracranial hemorrhage (SICH). Casaubon et al. (2015) recommend treating a systolic BP above 180 and a diastolic BP above 105 with rt-PA administration in order to reduce the risk of an intracranial hemorrhage associate. Prior guidelines (Lindsay et al., 2013) utilized slightly a higher parameter of 185 systolic and 110 diastolic. The current study gathered baseline BP as part of the patient characteristic data, with the intent to see if systolic and diastolic BP correlated with SICH rates.

Quality improvement initiatives. *Quality improvement initiatives* are aimed at addressing a need for improving service delivery, or process, based on performance analysis. Quality improvement initiatives usually involve both the efforts of health care providers and organizational leadership (Varkey, Reller, & Resar, 2007). The ultimate goal of quality improvement projects is to improve the health status of the patients being treated. Process metrics, as opposed to clinical outcome metrics, are often the focus of quality improvement projects, as process metrics provide feedback on whether a benchmark or target has been met. Moreover, an intervention or system change causes a direct response upon the process metric (Song et al., 2016).

Several observational studies have concluded that quality improvement initiatives result in dramatic improvements in the processes of care, such as reducing DTN times (Busby et al., 2016; Fonarow et al., 2015; Ford et al., 2012, Gropen et al., 2006; Hill et al., 2000; Mehdiratta et al., 2006; Schaik et al., 2015); however, clinical outcomes or end points, such as mortality, or secondary intracranial hemorrhage only occur in some of the patients and therefore are less responsive to the system change. As well, they require a well-validated risk adjustment model (Song et al., 2016).

Fonarow et al. (2014) published findings on a national quality improvement initiative, which built on the earlier work of Fonarow, Smith, Saver, Reeves, Bhatt, et al. (2011) that examined patient characteristics, hospital factors, and outcomes associated with DTN times within 60 minutes, and a systematic review by Fonarow, Smith, Saver, Reeves, Hernandez et al. (2011), which recommended ten evidence based best practices for improving DTN times. Fonarow et al. (2014) collected before and after data from AIS patients (N = 71,169) in 1030 US hospitals who had participated in the Target: Stroke quality improvement initiative between 2003-2013 and had received rt-PA within 3 hours, and Fonarow et al. (2014) demonstrated that after implementing the recommended ten key best practices, which focused on efficient structural changes, there was a significant reduction in DTN times ($p< 0.001$), which translated into improved clinical outcomes, namely a reduction in all-cause in-hospital mortality ($p< 0.001$), a reduction in secondary intracranial hemorrhage rate ($p< 0.001$), and an increase in the number of patients being discharged home ($p< 0.001$). Consequently, the study clearly illustrates that when structural improvements are undertaken, they lead to improved processes of care, which in turn translate to improved patient outcomes.

Improving in-hospital processes at single centres are also feasible when undertaking quality improvement projects. For example, in a Helsinki study, which is well-known because of its dramatic results and time span, Meretoja et al. (2012) reported convincing evidence that very short door-to-needle times can be achieved and sustained. This single centre retrospective cohort study (N=1860) spanned over 10 years (1998- 2011). Meretoja et al. (2012) published a median

DTN time of 20 minutes post quality improvement initiative. They attributed their success to a well-written and executed stroke protocol, which included direct transfer of the patient from the ambulance stretcher to the CT table and rt-PA delivery in the CT suite. Meretoja et al. (2012) concluded that a single intervention is never solely responsible for improved process metrics, rather continuous analysis and entire system improvement is needed. Similarly, in a prospective cohort study (N=334), Schaik et al. (2015) also achieved a median DTN time of 25 minutes in 71% of cases after an intravenous thrombolysis protocol was implemented. A recent study by Busby et al. (2016), (N=93) found a substantial reduction in median DTN times from 62 minutes to 25 minutes ($p < 0.0001$) after they implemented a code stroke protocol at their hospital. The existing evidence on outcomes of DTN quality improvement projects is likely underrepresented in the literature. Hence, it is important for single centres to continue implementing, evaluating, and publishing their findings.

Population Processes

Population processes are the ways in which patients move into, through, and out of the health care system (Hammermeister et al., 1995). The patient or the patient's family is ultimately responsible for initially seeking health care services. For example, if stroke is suspected, the patient or family member is responsible for recognizing the symptoms of a stroke and calling 911, which initiates the move into the health care system. Once the patient arrives in the ED, the provider is responsible for moving the patient through and out of the system. Although the patient/family knowledge and ability to recognize symptoms of stroke are essential, how they act upon these symptoms is even more important. Therefore, indicators of patient processes focus on the timing of seeking and receiving care.

Process Indicators

Process indicators analyse the delivery of care by the stroke team. Guidelines (Casaubon et al., 2015; Jauch et al., 2013) and stroke experts (Fonarow et al., 2014) agree that measuring the process indicators is essential. Process metrics are often easier to measure and require fewer resources than outcome indicators. The following key time intervals that are evidence-based indicators of process and therefore require collection will be discussed: onset-to-door (OTD), onset-to-needle (OTN), door-to-needle (DTN), door-to-CT (D-T-CT) and CT-to-needle (CT-T-N). How these process metrics link with outcomes will be explored and the current evidence regarding each metric will also be discussed.

Onset-To-Door (OTD). Although the onset-to-door (OTD) time metric is not controlled by the in-hospital stroke team, it is a crucial component of the hyperacute stroke care continuum. Saver (2010) suggests that due to the rapid loss of brain tissue, early presentation in hospital is key to timely initiation of reperfusion therapy. To this end, the HSFC has invested in the FAST-public awareness campaign, with the goal to increase the proportion of patients that arrive early in the thrombolytic window (Casaubon et al., 2015). Research is required to examine if this awareness campaign has made a difference in OTD times of acute stroke patients at the national, provincial and organizational level.

Studies also suggest that when a stroke patient arrives after regular hours (i.e., between 1900 and 0700) they are less likely to receive timely care (Busby et al., 2015; Johnson & Bakas, 2010; Miluluk et al., 2012). Moreover, time of arrival in the ED after symptom onset affects who receives timely care. Arriving in the ED soon after symptom onset has been shown to lengthen DTN times, as there is a false perception of having time (Meretoja et al., 2012; Mikulik et al., 2012; Saver, 2010). Furthermore, in a prospective observational study, which compared

OTD times with outcomes, Chee et al. (2014) found that OTD was not a significant predictor of outcomes when using the 90-day mRs. They concluded that expedited care processes in the primary stroke centre may have compensated for the differences in outcomes. Therefore, further OTD research is needed to verify these findings.

Onset-To-Needle (OTN). The patient or public's ability to recognize a stroke and call 911, as well as the processes of care delivered by paramedics and the stroke centre ED staff, affect the OTN time interval. Public and provider stroke education is a key factor in this process indicator. In a pooled analysis of eight RCTs evaluating rt-PA in acute stroke (N= 3670), Lees et al. (2010) reported that OTN was an important determinant of in-hospital clinical outcomes, as well as 90-day and 1-year functional outcomes in patients with AIS. The earlier that rt-PA was given to eligible AIS patients, the greater the benefit (Lees et al., 2010). If rt-PA was given after 4.5 hours the harm outweighed the benefit, as mortality increased (Lees et al., 2010).

Similarly, Saver et al. (2013) examined the association of OTN time interval with outcomes among AIS patients in the GWTG-stroke registry treated with rt-PA within 4.5 hours of symptom onset between 2003 and 2012 (N =58353). Clinical outcomes of patients with OTN times between 0-90, 91-180, and 181-270 minutes were compared. "Faster OTN times, in 15-minute increments was associated with a reduction in in-hospital mortality ($p < 0.001$), less symptomatic intracranial hemorrhages ($p < 0.001$), higher rates of independent ambulation upon discharge ($p < 0.001$) and more discharges home ($p < 0.001$; Saver et al., 2013, p. 2480). This study supports the need to deliver time-driven therapy. Hence, guidelines endorse an onset-to-treatment benchmark within 90 minutes of symptom onset (Casaubon et al., 2015; Jauch et al., 2013).

Our centre's quality improvement project did not explore OTN times. Shedding light on this process time metric could provide valuable information to the in-hospital team, paramedics and the public, as it may influence the allocation of resources.

Door-To-Needle (DTN). The multidisciplinary hospital-based stroke team, which is made up of nurses, physicians, technologists, and support staff, is directly responsible for the DTN interval time. However, there are instances where delays may be inevitable, such as a compromised airway or BP exceeding acceptable parameters for rt-PA administration. Evidence from RCTs and pooled analysis on rt-PA therapy in acute ischemic stroke agree that the benefits are strongly time-dependent, and a strong inverse relationship exists between treatment delay and worse clinical outcomes (Marler et al., 2000 Lansberg et al., 2009; Lees et al., 2010; National Institute of Neurological Disorders and Stroke t-PA Study Group, 1995; Wardlaw et al., 2012). Numerous studies have demonstrated that achievement of DTN benchmark times of ≤ 60 minutes translates into improved outcomes.

In a large observational study (N = 25,504) conducted in the USA, Fonarow, Smith, Saver, Reeves, Bhatt, et al. (2011) demonstrated that shorter DTN times were associated with improved clinical outcomes when comparing patients with DTN times < 60 minutes and patients with DTN times > 60 minutes; a lower in-hospital mortality ($p < 0.0003$) and a lower symptomatic intracranial hemorrhage rate ($p < 0.0017$) were present in patients with a DTN < 60 minutes as compared to patients with DTN >60 minutes. Using a multivariate model, which analyzed the relationship between DTN and in-hospital mortality, Fonarow, Smith, Saver, Reeves, Bhatt, et al. (2011) concluded that for "every 15-minute reduction in DTN time, there was a 5% lower odds of risk adjusted in-hospital mortality" ($p = 0.0007$)" (p. 752).

In a subsequent observational study (N = 71,169), Fonarow et al. (2014) compared DTN times with clinical outcomes before and after a national quality improvement program. Based on the findings, Fonarow and colleagues concluded that substantial improvement in short term clinical outcomes in the post intervention group occurred due to the significant reduction in DTN times. Fonarow et al. (2014) found that reduced DTN times resulted in a significant reduction of in-hospital mortality, less secondary intracranial hemorrhages, and more patients discharged home ($p < 0.001$). The reduction in DTN times also resulted in more patients receiving treatment within 60 minutes of arrival (Fonarow et al., 2014).

Numerous smaller, single centres have demonstrated that it is possible to reduce DTN times after initiating a quality improvement initiative and improve patient outcomes (Busby et al., 2016; Ford et al., 2012, Gropen et al., 2006; Hill et al., 2000; Mehdiratta et al., 2006; Schaik et al., 2015). However, Canadian single centre studies are dated and limited (Hill et al., 2000; Mehdiratta et al., 2006). Therefore, more studies are needed to show how DTN quality improvement projects improve clinical outcomes within the context of the Canadian healthcare system.

In addition, despite valiant efforts of single centres to improve DTN times, a gap remains in consistently evaluating DTN quality improvement projects within the context of clinical outcomes. Secondly, although stroke centres should be accountable for the care they provide, process and outcome metrics are not consistently evaluated. Thus, more rigorous data collection and analysis could result in changes to the allocation of resources to sustain or improve patient outcomes.

However, the most Recent literature (Casaubon et al., Kamal et al., 2014; Musuka, Wilton, Traboulsi, & Hill, 2015) suggests the need for even faster DTN benchmark times. The

Canadian guidelines (Casaubon et al., 2015) challenge hyperacute stroke systems in Canada to achieve a median DTN of 30 minutes, with an upper limit of 60 minutes, and to have 90% of eligible patients receive rt-PA within 60 minutes or less. Since speed is critical in the delivery of hyperacute stroke care, we must all search for innovative ways to further reduce DTN times (Kamal et al., 2014; Musuka, Wilton, Traboulsi, & Hill, 2015; Smith & von Kummer, 2012). "The question now is not whether we can extend the window of treatment, rather how do we get everyone treated faster" (Hill & Coutts, 2014, p. 1905). These latest targets demonstrate the even greater need for studies illustrating efficient workflow processes that result in time-driven care and improved clinical outcomes.

In light of these new benchmarks, completing and disseminating the findings of this thesis study will be even more important as it may pave the way to reducing DTN times even further in the Province of Manitoba. Reducing DTN times would enable more stroke victims to get treated within the 4.5-hour time window and more could be treated within the first 60 minutes of arrival, which translate into improved clinical outcomes. Earlier treatment after stroke onset also means earlier BP control, which may reduce the SICH rates with rt-PA administration and result in more candidates being chosen for endovascular therapy (Grotta, 2014). Furthermore, the current study gathered data on median DTN times and explored if we are reaching the 2016 HSFC targets: median (50th percentile) of 30 minutes and a 90th percentile of 60 minutes (*Heart and Stroke Foundation*, 2016).

Percentage of Patients Treated within 60 Minutes of Arrival. International stroke guidelines recommend that eligible stroke patients receive thrombolytic therapy within 60 minutes or less of arrival (Casaubon et al., 2015; Jauch et al., 2013). Canadian guidelines recommend that 90% of eligible patients receive rt-PA within 60 minutes or less (Casaubon et al., 2015), whereas the American guidelines recommend 80% of eligible patients receive rt-PA within 60 minutes of arrival (Jauch et al., 2013). This indicator is affected by the performance of the in-hospital stroke team.

The 'DTN' and 'the percentage of patients treated within 60-minutes of arrival' performance measures have an inverse relationship. As DTN times decrease, the percentage of patients that receive rt-PA within 60 minutes will rise. Structural initiatives that reduce DTN times result in an increased number of patients treated within 60 minutes of arrival (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011; Fonarow et al., 2014). Hence, overall, a greater number of patients benefiting from rapid stroke diagnostics and management will be possible. Experts suggest that ongoing hospital level quality improvement projects are needed to shorten DTN times so that more patients may benefit from treatment within 60 minutes of arrival (Saver et al., 2010).

In light of the new scientific evidence that supports even faster care, our study analysed if we are meeting the new HSFC benchmarks of median (50%) within 30 minutes and 90th percentile within 60 minutes (*Heart and Stroke Foundation*, 2016).

Door-To-CT (D-T-CT). D-T-CT times are dependent on several factors including the stroke team, and in particular the availability of the CT technologist, as well as the proximity of the CT scanner to the ED. Expert consensus is that imaging should be timely (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011; Fonarow et al., 2014; Lees et al., 2010; Saver et al., 2012). This consensus is based on research evidence of a link between rapid brain imaging and reduced DTN times (Lees et al., 2010; Kelly, Hellkamp, Olson, Smith & Schwamm, 2012; Sauser, Levine, Nickles & Reeves, 2014; Saver et al., 2010). After a patient's initial assessment, which includes airway, breathing, and circulation is cleared, brain imaging is the next most important step in the rt-PA inclusion/exclusion decision-making process, in order to rule out a hemorrhagic stroke. International stroke guidelines recommend imaging within 25 minutes of arrival (Jauch et al., 2013) and more recent Canadian guidelines (Casaubon et al., 2015) recommend imaging as soon as possible after arriving in the ED (i.e., immediately after the initial assessment is cleared and completed).

The findings of a recent Canadian retrospective study (N=13250) suggest that only a minority of stroke patients receive timely imaging (Burton et al., 2016). Using Ontario data between April 2010 and March 2011, Burton et al. (2016) found that only 27.3% of acute stroke patients who arrived in the ED within 4 hours of symptom onset received timely imaging. Factors independently associated with timely neuroimaging included: shorter onset-to-door time, increased stroke severity, being male, and no history of stroke (Burton et al., 2015). This suggests that specific populations may be more prone to imaging delays. As well, delays in imaging that result in longer DTN times may lead to worse outcomes

Our quality improvement study (Ghrooda et al., 2012) demonstrated a reduction in D-T-CT times post intervention. In part, this was probably attributed to educating the CT technologists, because after the intervention, there were fewer CT department delays. However, the population that is at risk for delays in imaging is unknown at our site; therefore, further research is important.

CT-To-Needle (CT-T-N). The time interval from the completion of the CT scan to administration of the rt-PA bolus is not well discussed in the literature. However, this is an important phase in the rt-PA decision-making process. In our centre’s quality improvement project (Ghrooda et al., 2012), we analysed this time interval. It was felt that the performance of the neurologist in particular in the rt-PA delivery process would greatly affect this time interval.

Following performance feedback, our CT-T-N decreased significantly ($p < 0.005$). Linking these structural and process improvements to clinical outcomes will contribute to this body of literature.

Sauser et al. (2014), explored how the D-T-CT time interval and the CT-T-N time interval contributed to time delays in DTN time. A retrospective analysis of a representative sample of 25 Michigan hospitals between January 2009 and December 2012 that entered data into the GWTG stroke registry (N= 1193) was used. Sauser et al. (2012) found that the CT-T-N time contributed more to delays in rt-PA delivery and was a greater source of variability than D-T-CT. According to Sauser et al. (2014), this was the first study that examined how D-T-CT and CT-T-N affected DTN times. The current thesis study provided additional evidence related to this important process factor.

Endovascular Therapy (EVT). Similar to rt-PA in the 1990s, endovascular therapy has transformed the treatment of acute stroke. Current recommendations, based on evidence from five recent randomized control trials, including ESCAPE (Goyal et al., 2015), MRCLEAN (Berkhemer et al., 2015), EXTEND-IA (Campbell et al., 2015), SWIFT PRIME (Saver, Goyal et al., 2015), and REVASCAT (Jovin et al., 2015), include the use of endovascular therapy with mechanical thrombectomy in patients with ischemic stroke and proximal intracranial arterial occlusion (Casaubon et al., 2015). Evidence suggests that endovascular therapy for the treatment of acute stroke is beneficial up to six hours post symptom onset (Berkhemer et al., 2015; Goyal et al., 2015). Therefore, like rt-PA, endovascular therapy requires speed and efficient workflow processes that promote rapid clinical diagnosis, and rapid imaging acquisition and image interpretation, as shorter imaging to reperfusion and door-to-groin puncture times are linked with improved patient outcomes (Berkhemer et al., 2015; Goyal et al., 2015).

In summary, clear evidence exists in hyperacute stroke care that time-driven processes of care improve outcomes. ED nursing plays a critical role in physiological surveillance and in the management of abnormal parameters, with a particular emphasis on BP control in the hyperacute stage. Many single centre DTN quality improvement initiatives can be found in the literature, however as scientific evidence grows, and benchmarks change to reflect current evidence, it remains of critically important to disseminate findings of such initiatives. Furthermore, it is essential that stroke programs are accountable for the care they deliver, making process and outcome monitoring essential. Gathering key stroke indicators is the first step towards achieving evidence-based targets (*Heart and Stroke Foundation*, 2016). Although achieving these benchmarks will reflect quality hyperacute processes of care, outcome measures are equally important as they are the true measure of the care delivered.

Outcomes

Outcomes reflect the combined effects of structure and process (Donabedian, 1988). Outcomes can be measured as patient outcomes, such as mortality, functional disability, length of stay, and organizational outcomes, such as rt-PA rates, meeting organizational benchmarks, and stroke distinction.

Patient Outcomes

Patient outcomes are a central concept to the Donabedian framework since they are directly linked to the structures utilized and the processes undertaken to deliver the care. Patient outcomes can be either positive or negative; moreover, they are the ultimate validators of care provided (Donabedian, 1988). Reeves, Parker, Fonarow, Smith, and Schwamm (2010) argue that since stroke may result in disability, outcome measures such as functional status and quality of life are important; however, most stroke performance measures are process-based. As a rule, indicators demand measures that are easy, precise, and complete, resulting in outcome evaluation often being overlooked, because b/c process indicators are more easily evaluated. While stroke care focus has been on measuring process, the importance of outcomes as the ultimate validators of patient care have provided the ultimate rationale for the proposed study.

Rymer et al. (2014) presented the findings from a global stroke forum that explored improving and measuring outcomes for stroke patients. Core metrics for measuring access to care and patient outcomes in acute stroke were based on consensus recommendations from a group of global stroke experts. The core measurements comprised both hospital-based and post-discharge outcome indicators. The outcome metrics recommended for stroke centres were as follows: "neurological status at 24 hours and discharge, compared with baseline, measured by NIHSS score or another validated scale, discharge disposition, ambulatory status at discharge, communication status at discharge, mRs score at 30 and/or 90 days and quality of life metric [country specific]" (Rymer et al., 2014, p. 76). Since most quality measures in stroke are process-based, Rymer et al. (2014) suggest there remains a need for assessing how process improvements translate into patient outcomes, namely "evidence is lacking in demonstrating how adherence to process measures result in improved patient outcomes" (Rymer et al., 2014, p. 75). Rymer et al. (2014) argue that it is critical that stroke centres continually collect and analyze stroke outcome data. However, Mant (2001) cautions the use of outcome indicators and suggests they should only be used if a health service has a major effect on outcomes and recommends the use of standardized data collection and case mix adjustment. Thus, outcome indicators that reflect hyperacute stroke management and treatment are, mortality, adverse events, functional outcomes, and length of stay.

Mortality. Mortality is a very common outcome indicator; however, the method in which it is reported differs between studies and organizations. Mortality can be described as in-hospital mortality, 7-day mortality, 30-day mortality, and 1-year mortality, as well as terms like ‘all-cause’ or ‘risk adjusted’ or ‘standardized in-hospital are also used.

7-day / in-hospital mortality. Several studies have used 7-day/ in hospital mortality as an outcome variable for stroke (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011; Fonarow et al., 2014; Wardlaw et al., 2012). In addition, in a cross-sectional survey of all report cards within the American Agency for Healthcare Research and Quality Report Card Compendium, from 2003 to 2006, Kelly, Thompson, Tuttle, Benesch, and Holloway (2008) found the most common stroke outcome measure was risk-adjusted in-hospital mortality. Nevertheless, there is considerable controversy regarding which mortality time line to choose and whether 7-day mortality accurately reflects processes of care.

Kelly et al. (2008) suggest that short-term mortality correlates poorly with process measures, and is likely to be related to unsafe care in less than 10% of cases. Despite this argument, there is convincing evidence that early in-hospital mortality remains a feasible indicator in measuring clinical outcomes of stroke care. For example, based on a large retrospective data set (N= 71,169) Fonarow and associates reported a reduction in all-cause in-hospital mortality ($p < 0.001$) when median DTN was reduced post national quality improvement initiative (Fonarow et al., 2014). Similarly, stroke experts (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011), demonstrated that when rt-PA is given within three hours of symptom onset, there is a 5% lower odds of risk-adjusted in-hospital mortality ($p = 0.0007$) (p. 753).

In a Canadian study, Saposnik et al. (2008) explored the association between stroke and several mortality periods. They examined variables associated with 7-day, 30-day, and 1-year fatality after ischemic stroke and found that 7-day mortality was primarily associated with stroke severity and early neurological deterioration, which is consistent with other studies. Saposnik et al. (2008) concluded from their data that many of the factors associated with 7-day mortality were the same for 1-year mortality, making 7-day mortality an acceptable indicator for mortality. Hence, at the national level, the proportion of acute stroke patients who die in-hospital within 7-days of admission is used as an outcome indicator (HSF, 2016).

Locally, the Manitoba technical stroke report (Lindsay & Hill, 2014) also claims that 7-day in-hospital stroke mortality is directly related to the stroke event. Early mortality or 7-day mortality is easier to collect as patients are usually still in hospital since the average length of an acute care stay for ischemic stroke is 5-7 days, whereas 30-day or 1- year mortality is more challenging as the patient has usually been discharged making data more difficult to capture. Thus, our study measured 7-day/in-hospital stroke mortality.

***30-day mortality*.** Overall, hospital performance may be more accurately reflected by 30-day mortality, as it reflects both mortality from the stroke itself and complications secondary to the effects of the stroke, such as pneumonia. In a study (N=119 hospitals) that compared in-hospital versus 30-day mortality rates among six medical conditions, of which stroke was one, Borzecki, Christiansen, Chew, Loveland, and Rosen (2010) found that 30-day mortality was more accurate than in-hospital mortality in reflecting hospital performance, because in-hospital mortality is more dependent on hospital discharge practices. However, Borzecki et al. (2010), concluded that in-hospital mortality is a reliable substitute when 30-day mortality data is not obtainable.

In Canada, the Canadian Stroke Best Practice Recommendations use 30-day in-hospital mortality; moreover, when analyzing mortality, they suggest grouping 30-day mortality into those that receive rt-PA and those who do not (Casaubon & Boulanger, 2015). Similarly, CIHI and the annual stroke reports by HSFC both use the 30-day risk-adjusted in-hospital mortality. For example, in their Manitoba Stroke Report, Lindsay and Hill (2014) qualify that the 30-day mortality may be caused by the stroke itself; however, complications post stroke, such as pneumonia, could also be responsible for the death. In light of this evidence, and due to feasibility, it appears reasonable to use 7-day/in-hospital mortality as an outcome indicator.

1-year mortality. Although more difficult to collect, some studies do use 1-year mortality as a clinical outcome. For example, when assessing the difference in patient outcomes between hospitals practicing, versus those not participating, in the GWTG quality improvement initiative, Song et al. (2016) used 1-year mortality as a clinical outcome indicator. They found that there was a reduction in 30-day and 1-year mortality rates with those hospitals participating in the quality improvement initiative (Song et al., 2016). However, there was a greater reduction in the 1-year mortality than the 30-day mortality. Song et al. (2016) also demonstrated that, as time passed, participating centres showed a decrease in mortality, for both 30-day and 1-year mortality. This may be of significance when evaluating a quality improvement initiative.

In summary, mortality is commonly used as an outcome measure for stroke. Additionally, 7-day/in-hospital mortality is a common outcome indicator gathered in post DTN quality improvement projects. While the rationale for selecting a particular mortality time interval is often unclear in many studies, experts agree that all-cause mortality should be used as a universal endpoint for all stroke trials (Saver, 2011). However, there are important considerations related to the various time frames for mortality measurement, such as what part of the continuum of care is being evaluated. Although using in-hospital mortality alone is perhaps not the best outcome indicator to directly reflect our DTN quality improvements, it is the most feasible and used in isolation as an indicator in the literature. Therefore 7-day in-hospital mortality was used in the current study.

Adverse Events. Complications may occur during the acute care phase of a stroke patient's recovery. These adverse events can occur because of the stroke itself, such as stroke evolution, seizures, cerebral edema, or hemorrhagic transformation, or due to the secondary effects of the stroke, which may include dysphagia, deep vein thrombosis, falls, incontinence, pneumonia, or other secondary infections. However, many secondary effects of stroke result from a lack of mobility. Therefore, when choosing clinical outcomes associated with rt-PA therapy, it is important to demonstrate a linkage to the treatment being delivered. Complications that are linked to thrombolytic therapy result in life threatening bleeding or intracranial hemorrhage.

Life-threatening bleeding. Life-threatening hemorrhage within 36 hours of rt-PA administration is linked to rt-PA administration (Fonarow et al., 2014). An uncontrolled epistaxis, a gastrointestinal bleed, or a vaginal bleed are examples of serious hemorrhages related to the rt-PA. Life threatening bleeding due to rt-PA administration itself is very rare (Fonarow et al., 2014).

Symptomatic or secondary intracranial hemorrhage (SICH). SICH within 36 hours of rt-PA administration is often identified as an adverse clinical outcome, with a direct link between the therapy and this complication. Fonarow et al. (2014) describe a SICH as a "neurological worsening within 36 hours of rt-PA administration that is attributed to intracranial hemorrhage by physician documentation and verified by brain imaging" (p.1634). The Canadian stroke best practices define SICH as a subarachnoid or intracerebral hemorrhage following rt-PA administration with a four point or more worsening on the NIHSS within 24 hours (Casaubon &

Boulanger, 2015). Treatment delay in rt-PA administration is associated with a higher risk of symptomatic intracranial hemorrhage following rt-PA administration (Fonarow, Smith, Saver, Reeves, Bhatt, et al, 2011; Saver et al., 2013). Mortality is an consequence of a SICH; the larger the SICH, the greater the risk of mortality.

Thus, any type of bleeding following a stroke can impact on longer term morbidity and mortality, with potentially significant implications for the patient, the family, and the healthcare system. Therefore, SICH and life-threatening bleeding were used as outcome indicators in the current study.

Functional Outcomes. Stroke is the number one cause of adult disability (Casaubon et al., 2015). Evidence suggests that the earlier rt-PA is given within the 4.5-hour window, the less the permanent disability (Lansberg et al., 2009; Lees et al., 2010; National Institute of Neurological Disorders and Stroke t-PA Study Group, 1995; Wardlaw et al., 2012). In addition, Lees et al. (2010) reported that O-T-N was an important determinant of in-hospital clinical outcomes, as well as 90-day and 1-year functional outcomes. Hence, it is important to measure the degree of functional impairment, in order to assess if the care provided was effective. Functional outcomes are most commonly measured by patient discharge location, ambulation status on discharge, and functional ordinal scales.

Discharge Location. Numerous studies use *discharge location* as a functional outcome measure post stroke (Busby et al., 2015; Ford et al, 2012; Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011; Fonarow et al., 2014; Gropen et al., 2006; Lindsay & Hill, 2014; Saver et al., 2013; Song et al., 2016). Discharge location can be described as home, acute rehabilitation, a skilled nursing facility, such as a long-term care facility, or death. With each location comes a certain level of independence or dependence. For example, to be discharged home one would be independent, as opposed to being discharged to a long-term care facility, where one would be care-dependent.

The global consensus forum on stroke recommends the use of discharge location as an outcome indicator (Rymer et al., 2014). In a large retrospective study which sought to measure clinical outcomes post DTN quality improvement initiative (N= 71,169), Fonarow et al. (2014) used discharge location as one of the outcome indicators. Discharge status was described as home, acute rehabilitation, a skilled nursing facility, hospice, or death (Fonarow et al., 2014). Fonarow et al., (2014) found a significant increase in being *discharged home* [$p < 0.001$] post DTN quality improvement program. Busby et al. (2015) strengthened the existing literature by demonstrating that a reduction in DTN time was associated with a higher number of patients discharged home. When a binary logistic regression model was used, younger age and lower NIHSS score were associated with discharge home (Busby et al., 2015). Discharge location is relatively easy data to gather during a chart audit; hence, it was used in our study as an outcome indicator.

Ambulation Upon Discharge. Functional outcomes can also be described by *ambulation upon discharge*, which measures functional independence; furthermore, collection of this measure is relatively easy. *Ambulation upon discharge* can categorized as independent, ambulatory with assistance or non-ambulatory. The global consensus forum on stroke also recommended the use of *ambulation upon discharge* as an outcome metric for stroke centres (Rymer et al., 2014). Many American stroke experts have used *ambulation upon discharge* as a measure of functional outcome in their studies (Fonarow et al., 2014; Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011; Saver, 2013). In Canada, the HSFC uses this metric when evaluating outcomes post stroke (HSF, 2016; Lindsay & Hill, 2014). Therefore, ambulation status at discharge was used as an outcome indicator in our study.

Functional Scales. Reliable and valid functional status measurement scales are important as they help to standardize measurements in health care. There are several commonly used ordinal scales to measure functional outcomes post-stroke, including: the NIHSS (Harding & Semonin-Holleran, 2010), which is the gold standard, for measuring neurological deficit; the Barthel Index (*Heart and Stroke Foundation Canadian Partnership for Stroke Recovery*, 2016), which measures activities of daily living; the mRs, (*Heart and Stroke Foundation Canadian Partnership for Stroke Recovery*, 2016), which measures functional status; and the GCS (Rush, 1997), a head injury tool, which measures global disability. In a systematic review, Geyh et al. (2014) examined standardized health status measures. The most frequently used outcome measures in 160 randomized control trials in descending order were: Barthel index, Rankin scale, NIHSS, and the functional independence measure (FIM); the GCS was in eighth place (Geyh et al., 2004). Many clinical trials also use mRs to measure functional status at 90 days (Rymer et al., 2014).

Although there are several reliable and valid scales to measure stroke recovery, all functional status measurement scales are subject to issues with inter-rater reliability (Saver, 2011). Therefore, Saver (2011) suggests using several similar scales and statistically combining them using an estimating equation, as this would increase confidence. In addition, certified training before using a tool, limiting the number of users, and preforming repeated measures can all increase the confidence of the inter-rater reliability (Saver, 2011).

In the current retrospective thesis study, the key determinant for selecting a hospital-based functional outcome scale was data availability. Although the NIHSS is not consistently collected at our facility, it is important to gather this data at baseline and at discharge. Therefore, baseline and discharge GCS scores, which are routinely done by nurses, was collected as a proxy for the NIHSS. Our study will hopefully establish research-based evidence regarding the importance of routinely collecting the NIHSS and bring about a change in practice. Collecting and documenting the NIHSS will improve patient assessments and will add strength to stroke research data at our facility. The FIM score is a hospital based functional independence measurement and is routinely done by allied health at our facility prior to discharge. The FIM measures disability and helps to indicate how much assistance is required to carry out activities of daily living. Our study was unable to collect the discharge FIM score, as it was not documented.

Length of Stay (LOS). Acute care LOS has been frequently utilized as a clinical outcome indicator in the stroke literature. Lindsay et al. (2010, 2013) suggest that rt-PA administration in stroke decreases the overall burden of stroke by decreasing LOS; however, many other factors can also affect LOS. While a direct link between LOS and rt-PA administration is difficult to verify, LOS is important to hospital administrators, especially in today’s health care climate, and the existing bed shortages. Therefore, it was important to collect LOS in our study.

In summary, even though clinical outcome indicators are more difficult to collect, they are the ultimate validators of the care provided. Outcome indicators need to be reliable, valid, feasible, and purposefully linked to the treatment or intervention (Donabedian, 1988). Locally, a gap exists in translating our centre’s DTN process improvements into patient outcomes. Hence, the following in-hospital outcomes were gathered: 7-day in-hospital mortality; SICH with 36 hours of rt-PA administration; life threatening or other serious systemic hemorrhage within 36 hours of rt-PA administration; discharge location; ambulation upon discharge; baseline and discharge NIHSS; baseline and discharge GCS; FIM score upon discharge and acute care LOS.

Organizational Outcomes

Most outcomes reflect the health status of the patient; however organizational outcomes capture elements that describe the performance of the system as a whole. Of importance to the health care consumer and organizational leadership are access to care and achieving organizational benchmarks. Organizational outcomes that best reflect hyperacute stroke care are rt-PA rates, which reflect access to care and achieving organizational benchmarks for stroke.

Access to Care / rt-PA rates. Thrombolysis rate is an important quality indicator, as it requires organized systems of care that work in collaboration with each other (Ganesh et al., 2014; Lindsay et al., 2010); moreover, it reflects access to care. When stroke systems, organizations, and EDs have efficient, time driven workflow processes, more stroke patients will be evaluated and receive reperfusion therapy. Hence, rt-PA rates will improve. Using a retrospective cohort design (N=9588), Ganesh et al. (2014) examined the quality of stroke care in Canada by using rt-PA rates as the key indicator. Their study found that only 6.1% of ischemic strokes received rt-PA. Interestingly, comprehensive stroke centres, which are large stroke centres that offer speciality services such as stroke unit care, neurosurgery and endovascular therapy, used rt-PA in about one third of cases. This was double the rate seen in primary stroke centres, which are smaller centres that offer thrombolytic therapy. This is an important observation when setting up provincial stroke systems and may suggest a lack experience or comfort with administering rt-PA in the primary stroke centres.

Experts suggest that thrombolysis rates in acute stroke centres are too low in the USA (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011) and in Canada (Lindsay, 2011). The

Quality of Stroke Care in Canada (Lindsay, 2011) reported that rt-PA rates for eligible stroke patients (i.e. arriving within the thrombolytic window) is 22%. Several studies have shown that the overall number of patients treated with rt-PA increases when structural changes are made to improve the processes of care (Busby et al., 2015; Fonarow et al., 2014; Ghrooda et al., 2012; Ruff et al., 2014). Hence it is important for organizations to continually monitor rt-PA rates as a marker or measure of access to stroke care.

Benchmarking. As a performance measurement tool, *benchmarking* is used to compare the delivery of a specific type of care at the local institutional level, provincial level, and national level (Hall et al., 2013). Benchmarks are important in developing realistic goals for quality improvement projects. Benchmarking is also a useful method to assess service accountability. The Quality of Stroke Care in Canada (HSF, 2016) is a program that provides ongoing monitoring and reporting of core stroke indicators. Just recently released in Canada, the “Quality of Stroke Care in Canada. Stroke Key Quality Indicators and Stroke Case Definitions” (HSF, 2016) offers standardization on core stroke indicators at all levels of monitoring (i.e., local, provincial, and national). “Key quality indicators are representative of the highest levels of evidence and are the drivers for improvement in processes of care and patient outcomes” (HSF, 2016, p. 3). Key quality indicators that pertain to this literature review are provided in Appendix A. Targets are provided for each key indicator.

Stroke distinction. Stroke distinction is the ultimate validator of quality stroke care within an organization. This is a voluntary process in Canada; participating hospitals are evaluated by Accreditation Canada. Specific criteria addressing stroke excellence must be met in order to obtain Stroke Distinction. Importantly, one study has shown that patient outcomes improve after a centre obtains stroke distinction. In a retrospective study completed in the US

Gropen, Gagliano, and Blake (2006) aimed to determine if stroke centre designation and selective triage of acute stroke patients improved the quality of care. A between-group design was used to compare 14 newly designated stroke centre hospitals to 18 non-designated hospitals. The newly designated hospitals received education on stroke, written stroke care protocols, and timely feedback. Stroke process metrics and clinical outcome measures were then gathered. The results demonstrated that a structured system emphasizing quality improvement, written care-protocols, and stroke teams can result in better outcomes, fewer protocol deviations, and increased use of rt-PA (Gropen et al., 2006). Gropen et al. (2006) did however acknowledge that a risk adjustment was not done, which was a study limitation, thus requiring further research.

Summary

This literature review explored the existing evidence supporting quality hyperacute stroke care in the ED setting. Through the use of the Donabedian framework, evidence was reviewed in the structural, process, and outcome domains. Subsequently, gaps in the literature were identified.

Evidence within the structural domain supported the use of stroke protocols that adhere to best practice guidelines. However, some variation exists with which guideline to use, or the number of guidelines to use. There is agreement in the literature that provider factors should include a multidisciplinary team that is educated, collaborative in nature, and receives performance feedback. The literature on what constitutes quality physical attributes of the in-hospital setting was very limited. Lastly, when exploring population factors, there is agreement that in order to accurately evaluate outcomes, population characteristics need to be explored. A noticeable gap in the literature was that Canadian studies that link specific structures of hyperacute stroke care with processes of care and outcomes are limited; moreover, no Manitoba studies exist. In a time where the incidence of ischemic stroke is rising, there is also a need to understand the characteristics of the stroke population who receive timely thrombolytic therapy at our institution.

Within the process and outcome domains, there is a plethora of evidence on time-driven hyperacute stroke care. The evidence is clear that DTN times $\leq$ 60 minutes are associated with improved clinical outcomes. However, most studies use only a medical lens. Observing the processes of hyperacute stroke care from a nursing lens will hopefully generate new insights into clinical practice and ultimately improve patient outcomes. Secondly, Canadian single centre outcome data following quality improvement projects are limited or outdated. Moreover, no such studies exist in Manitoba.

This thesis study will provide observations in the field of hyperacute stroke care that are presently unknown to our leadership, healthcare providers, and the public; it will impact clinical practice, as well as generate additional research questions in hyperacute stroke care at the local level. Furthermore, it is hoped that this study will provide insight into strategies on how our stroke centre can meet the new Canadian DTN benchmark of 30 minutes and improve overall quality of stroke care in Manitoba.

CHAPTER FOUR: METHODOLOGY

Introduction

This chapter will describe the methods and procedures used to address the study's primary research question, which was to determine if the structural and process quality improvements in the HSC Adult ED resulted in improved clinical outcomes for stroke patients. Based on a review of current evidence to-date, we hypothesized that the significant improvement in DTN times resulted in improved clinical outcomes. The research question was explored within the context of the Donabedian Framework and each of the three domains: structure, process, and outcome. This chapter will describe the proposed design, setting, and sample, outline the data collection procedures and data analysis plan, describe the operational definitions of the study variables, and present the ethical considerations.

Research Design

This thesis study used a quantitative, retrospective design, which built on prior work that demonstrated improved DTN times after a quality improvement initiative at the HSC, in Winnipeg, Canada (Ghrooda et al., 2012). We hypothesized that the significant improvement in DTN times resulted in improved clinical outcomes. The methodology explored between-group differences (before and after), as well as within-group differences (DTN ≤ 60 vs. DTN > 60). Since this was a quality improvement project which had already occurred, this seemed to be a suitable study design.

While there are limitations to retrospective studies, there are several advantages, which are relevant to this study. The reason a retrospective study design was used to explore the relationships among study variables follows. First, even though evidence about the effectiveness of an intervention is strongest when it is explained with experimental research, it often is not ethical to use in the patient-care environment, as one can neither deny someone the standard of care, nor always manipulate the independent variable in the patient-care setting. For this reason, observational correlation research is often used to study the relationship among variables of interest (Polit & Beck, 2012). Second, and most important, this study builds on a previous quality improvement project (Ghrooda et al., 2012), where the quality improvement intervention had already taken place and outcome data that had already occurred was gathered. Exploring if the shorter DTN times in the post-intervention period resulted in improved clinical outcomes was of primary interest. Third, a retrospective design allows for a large amount of observational data to be gathered on numerous variables of interest (Polit & Beck, 2012). Hence, in our study we were able to generate a large amount of observational data on acute ischemic stroke patients who received rt-PA during the study period. These observations may lead to further research, increased scientific knowledge on acute ischemic stroke patient outcomes post quality improvement program, and improvements in clinical practice. Fourth, compared to other types of research this design had a relatively low overhead cost and had no impact on day-to-day operations of care in the clinical area. This is important to health care providers, as it does not increase their workload. Finally, data collection delays, which can occur because of recruitment issues and waiting for subjects to enrol, is not a problem with a retrospective study.

Although there are inherent limitations with a retrospective study design, since our study examined the quality of hyperacute stroke care and specifically explored if there was a correlation between improvements in the processes of care and clinical outcomes, a retrospective design was well suited for this type of research. Observational studies that are either retrospective or prospective are well suited in examining the effectiveness of health care interventions when the researcher is unable to manipulate the independent variable due to ethical or other reasons. Furthermore, retrospective studies, which are often simpler to undertake due to limited cost and fewer time constraints, offer rich, real world observations that help improve the care we provide our patients.

The Setting

This thesis study took place at the Health Sciences Centre (HSC) Adult Emergency Department (ED) in Winnipeg, Canada. The HSC is one of two designated hyperacute stroke centres in Winnipeg that offers rt-PA as a treatment option in the management of acute ischemic stroke. The HSC is a 759-bed teaching hospital, which is in Winnipeg's inner city and the provincial trauma, neurosurgery, and burn centre. The Adult ED saw 99,954 visits in fiscal year 2013-2014 (Winnipeg Regional Health Authority, 2014). The Adult ED treated approximately 250 hyperacute stroke protocols per year during the pre-intervention study period (Ghrooda et al., 2012).

The Sample

The study population of interest was acute ischemic stroke patients. The sample included all consecutive acute ischemic stroke patients who received intravenous rt-PA within the thrombolytic treatment window at the HSC Adult ED between January 1st, 2008 to December 31st, 2014. The year 2011 was not included as this was considered the washout year. Based on these criteria, the sample size included 330 patients. All study patients were identified on admission as a "stroke-25", and urgently evaluated by the stroke team in the HSC Adult ED. Each patient was screened by the on-call neurologist, including a review of CT results. The decision to give rt-PA was determined by using evidence based inclusion/exclusion criteria and the Canadian Stroke Best Practice Recommendations (Casaubon et al., 2015).

To glean information regarding the rural versus urban residential status of our study sample, the first three digits of the patients' postal codes were captured. Postal codes within the city of Winnipeg were coded as urban and those outside of Winnipeg were coded as rural (see Table 2). The six out-of-province postal codes were coded as rural, as it was difficult to determine where the stroke occurred based on chart reviews. A total of 232 cases were coded as urban and 92 cases where coded as rural.

Table 2
Postal Codes: Urban Versus Rural

Location	Postal code	Urban	Rural
Winnipeg	R2C, R2E, R2G, R2J, R2K, R2L, R2M, R2O, R2R, R2V, R2W, R2X, R2Y, R3A, R3B, R3C, R3E, R3G, R3J, R3K, R3L, R3N, R3P, R3R, R3T, R3Y	232	
South Eastern Manitoba	ROA		2
Northern Manitoba	R0B		2
Interlake (Ashern, Arborg)	R0C		23
Eastern Manitoba	R0E		12
South Central Manitoba	R0G		3
Southern Interlake	R0H		4
Southwestern Manitoba	R0W		1
Selkirk	R1A		14
Portage	R1N		16
West St. Paul	R4A		4
Steinbach, St. Anne	R5G, R5H		2
Winkler	R6W		2
The Pas	R9A		1
Out of Province	J0X, N2A, N8Y, P9N, T0E, USA		6
Total	324	232	92

Instrumentation

The data collected for the thesis study was based on the study purpose and objectives. Operational definitions for each of the study variables were established. These definitions were used to develop the clinical data abstraction form (see Appendix A,) which was utilized to perform the chart reviews. Stroke severity was measured using reliable and validated stroke deficit tools, the NIHSS and the GCS.

Operational Definitions. Variables of interest to a study must be operationalized to be accurately measured. Therefore, each of the structure, process, and outcome study variables were operationalized, as outlined in Table 4.2. *Structure* variables are mostly descriptive in nature; however, patient characteristics, which are included under structure, as well as stroke centre rt-PA volumes, can also be operationalized. *Process* of care variables in acute stroke are mainly measured by time intervals, and are described in Table 4.2. Finally, operational definitions of study outcomes are also provided in Table 3.

Table 3
Operational Definitions of Hyperacute Stroke Variables

Category	Variable	Operational Definition
STRUCTURE		
Stroke Centre	rt-PA rates	Number of rt-PA cases per year
Patient Characteristics -Demographics	Age Gender Urban	Age of patient at time of visit Male or female (Yes/No) Urban versus Rural. See Table 4.1 for postal code allocation
Patient Characteristics -Comorbidities	Hypertension Diabetes Dyslipidemia Current smoker Atrial fibrillation Prior stroke or Transient Ischemic Attack (TIA) Coronary Artery Disease/Myocardial Infarction (CAD/ MI) Peripheral Vascular Disease (PVD)	(Yes/No) (Yes/No) (Yes/No) (Yes/No) (Yes/No) (Yes/No) (Yes/No) (Yes/No)

Patient Characteristics -Presenting symptoms on arrival to hospital	Weakness Sensory symptoms Balance issue Visual disturbance Speech problem	(Yes/No) (Yes/No) (Yes/No) (Yes/No) (Yes/No)
Patient Arrival -Mode	Arrival by Ambulance (EMS)	(Yes)Transportation by ambulance (No) all other forms of transport such as walk-in or private transportation
Patient Arrival -Time	Day Shift between 0730-1700	(Yes) arrival at hospital between 0730 and 1700 (No) arrival at hospital between 1701 and 0729
Patient Evaluation -Stroke severity	Baseline National Institute of Health Stroke Score (NIHSS) Glasgow Coma Scale (GCS) Score	Numeric value (0-42) Numeric value (0-15)
Patient Evaluation -Blood Pressure (BP)	Baseline Systolic BP Systolic BP > 180	Numeric value (Yes/No)
Patient Evaluation -Blood pressure	Baseline Diastolic BP Diastolic BP > 105	Numeric value (Yes/No)
Patient Evaluation -Blood glucose	Baseline Glucose	Numeric value
PROCESS		
Process of Care -time metrics	Onset to Door (OTD) Onset to Needle (OTN) Door to Needle (DTN) Door to CT (DTCT)	Time interval in minutes from stroke symptom onset to hospital arrival, as documented on the triage sheet Time interval in minutes from symptom onset or Last seen normal to administration of rt-PA bolus Time interval in minutes from hospital arrival to administration of rt-PA bolus Time interval in minutes from arrival in hospital too initial non-contrast CT scan

	CT to Needle (CTTN) DTN ≤ 60 minutes DTN ≤ 30 minutes D-T-CT ≤25 minutes DTCT ≤ 15 minutes OTN ≤ 90 minutes	Time interval from completion of initial non-contrast CT scan to rt-PA bolus administration Proportion of patients that receive rt-PA bolus within 60 minutes of arrival in hospital. Proportion of patients that receive rt-PA bolus within 30 minutes of arrival in hospital. Proportion of patients that receive a non-contrast CT scan within 25 minutes of arrival in hospital Proportion of patients that receive a non-contrast CT scan within 15 minutes of arrival in hospital Proportion of patients that receive rt-PA bolus within 90 minutes of symptom onset
Process of Care - Thrombectomy	Endovascular Therapy (EVT)	(Yes) mechanical clot retrieval procedure done. (No) no mechanical clot retrieval procedure under taken
OUTCOMES (Patient)		
Mortality -In-Hospital Mortality -7 day In-Hospital Mortality 5 day In-Hospital Mortality	 In-hospital Mortality 7 day In-Hospital Mortality 5 day In-Hospital Mortality	 (Yes) death within the hospital (No) no in-hospital death (Yes) death within 7 days of admission to hospital (No) no in-hospital death (Yes) death within 5 days of admission to hospital (No) no in-hospital death
Adverse Event	Symptomatic Intracranial Hemorrhage (SICH)	Neurological worsening within 36 hours of rt-PA administration that is attributed to intracranial hemorrhage by physician

	Life-threatening Bleed	documentation and verified by brain imaging Life-threatening hemorrhage within 36 hours of rt-PA administration and is linked to rt-PA administration
Functional Outcome -Discharge Location -Discharged Home Favorable vs unfavorable discharge location	Discharge Location Discharged Home Favorable vs. unfavorable discharge	Home Acute Rehabilitation Community Hospital Long Term Care (LTC) Facility Death (Yes) discharged home (No) not discharged home (Favorable) = home, rehab, community hospital (unfavorable) = LTC, death,
Functional Outcome -Ambulation at Discharge Independent Ambulatory status at discharge	Ambulation upon discharge Independent at Discharge Ambulatory vs. non - ambulatory	Independent (ambulatory without another's assistance or device) Ambulatory with assistance Non-ambulatory Death (Yes) independent at discharge without any form of aid. (No) all other categories: ambulatory with assistance, non-ambulatory and death (Yes) independent and ambulatory with assistance categories (No) non-ambulatory and death categories
Functional Ordinal Scale	Discharge NIHSS FIM on discharge mRs on discharge	Numeric value Numeric value Numeric value
Organizational Outcomes		
rt-PA rates	Number of cases	Numeric Value

Triage Practices - Canadian Triage Acuity Score (CTAS) score on arrival -CTAS 1	CTAS score CTAS 1	1-5 (Yes) recorded as level 1 (No) recorded as level, 2,3,4 or 5
-Length of stay	Length of Stay (LOS)	Number of days from admission to the emergency department to hospital discharge
-Length of Stay	LOS excluding Community Hospital repatriations	Number of days from admission to the emergency department to hospital discharge (All cases minus the community hospital repatriations)

Data Collection Procedures

Data collection was initiated after ethical approval was received from the Health Research Ethics Board (HREB), University of Manitoba and the Health Sciences Centre Research Department. Data collection adhered to the Tri-Council Policy Statement regarding "Ethical Conduct for Research Involving Humans" (Canadian Institute of Health Research, 2010).

The original Stroke-25 database identified 334 cases that met the study criteria. The PI completed all data collection. Data collection commenced with a secondary analysis of previously collected chart review data, initially collected to guide a hyperacute stroke care quality improvement project at HSC (Ghrooda et al., 2012). Data was collected during the months of February, March, and April 2017, by performing chart audits at the HSC medical records department, using a chart abstraction tool (see Appendix A). Existing stroke-25 data and the new clinical outcome data were then entered into an Excel database. Data cleaning revealed the following data entry errors in the original Stroke-25 database: seven double entries, two entries of patients that did not receive rt-PA, and one chart that was not located by medical records. This resulted in a total of 324 cases for our study. A total of 102 patients were in the pre-intervention group (2008-2010) and 222 were in the post-intervention group (2012-2014). As mentioned earlier, 2011 was considered the washout year as this is the year the intervention took place. Data was then transferred into the SPSS statistical program by Trevor Strome, Director, Analytics & Business Intelligence, WRHA and external thesis committee member. Data cleaning was done with the assistance of James Pholman at the MCNHR. Dr. Lori Mitchell, WRHA Home Care Program, was also consulted to answer questions regarding data analysis.

Data Analysis Procedures

The data parameters including demographic data, patient evaluation data, comorbidities, process metrics and outcome metrics. Demographic data was analyzed by using descriptive summary statistics. Discrete variables, such as gender and the presence/absence of comorbidities (e.g., hypertension; diabetes mellitus), were reported with frequency distributions and percentages. Continuous data, such as age and patient treatment time intervals, was reported with mean, standard deviations, medians, and interquartile ranges. Histograms were used to further visualize the unique distributions of these data sets. The student *t* test was used to compare pre- and post-intervention performance for continuous variables, such as DTN times and onset-to-needle times, and to examine how structural changes affected process and outcomes. Performance data, such as interval times, were plotted on run charts on a month-by-month basis and run chart analysis rules will be applied to determine if trending and shifts in performance occurred during the study period.

To answer the study's research question, which compared clinical outcomes between the pre-intervention cohort (2008-2010) with the post-intervention cohort (2012-2014), various parametric and nonparametric statistical tests were used, bearing in mind that parametric tests are more powerful than nonparametric tests (Polit & Beck, 2012). Upon reviewing histograms generated through the SPSS program, and comparing means and medians of continuous study variables, it was felt that the variables were normally distributed, and sample size was adequate, thereby supporting the use of parametric tests. Furthermore, the pre-and post-cohorts were independent of each other. The student *t* test was used to analyze interval and ratio variables. Chi Square, which is a nonparametric test, was used to analyze the differences between two groups for all nominal and ordinal scale variables. For variables with small sample sizes (i.e., < 5), such as SICH < 36 hours, the Fisher's Exact Test was used to determine if a difference existed between groups.

The primary outcome for this thesis study is a good clinical outcome, which will be measured by lower mortality, lower SICH rates, more patients *discharged home* and more patients *ambulatory at discharge*. The level of statistical significance chosen for all analyses was set at alpha 0.05.

Ethical Considerations

The study adhered to the Tri-Council Policy Statement regarding "Ethical Conduct for Research Involving Humans" (Canadian Institute of Health Research, 2010). Anonymity of the study participants was addressed by using case numbers and the patients' names were not included on any of the data collection instruments. A record of the patient's ID numbers and case numbers is being kept in a separate secure password-protected file, accessible only by the PI and advisement team. Concurrently, confidentiality is being maintained. All data in the form of paper audit tool is kept in a secure filing cabinet in a locked office of the PI. All electronic copies are password protected on a USB stick and on the password protected computer of the PI. All data including hard copies and electronic copies will be kept for a maximum of 10 years and then destroyed by using confidential waste procedures.

Summary

In summary, this thesis study used a quantitative retrospective cohort design to explore if clinical outcomes improved post DTN quality improvement program. The review of the literature guided the selection of the key study variables and the data analysis plan. In addition, ethical considerations have been addressed. Therefore, this thesis study has sound methodology.

CHAPTER 5: RESULTS

Introduction

This chapter presents findings from the thesis study, *Exploring Clinical Outcomes in Acute Ischemic Stroke Post Quality Improvement Project*. The Donabedian quality framework was used to provide context for the results of the thesis study. Variables were allocated to the appropriate structure, process, and outcome domains; this provided structure in answering the study's primary question: *did the structural changes and dramatic process improvements result in improved clinical outcomes for acute stroke patients?* Furthermore, the hypothesis, which postulated that the significant improvement in DTN times resulted in improved clinical outcomes, was evaluated.

The specific research objectives were to determine if:

1. there is a relationship between structural factors, process factors, and outcomes;
2. the structural changes contributed to improvements in process;
3. there is a relationship between process and outcomes;
4. structural factors and outcomes vary based on process (i.e., OTN or DTN times)

The following is a summary of the study results, which are described within the context of the three domains of the Donabedian framework and the research objectives. The linkage between the domains was addressed within each specific research objective.

Structure

Within the context of this study, structure, including the baseline demographic and clinical characteristics of the study sample, will be described in this section. The data extraction process identified 334 cases that met the study criteria; data cleaning resulted in a total of 324 study participants (see Figure 5).

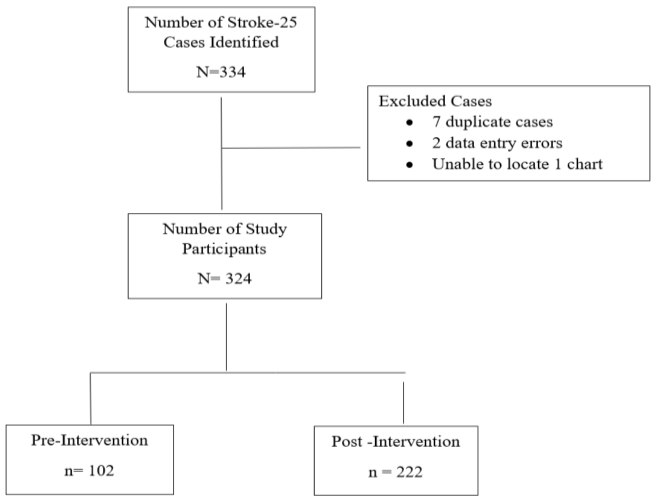

Figure 5. Selection of Study Participants

A total of 102 patients were in the pre-intervention group (2008-2010) and 222 were in the post-intervention group (2012-2014). The baseline demographic characteristics of the pre-intervention (n=102) and post-intervention (n=222) cohorts are presented in Table 4.

Table 4
Demographics of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency During the Pre-Intervention Period (2008-2010) as Compared to the Post Intervention Period (2012-2014)

	Pre-intervention (n=102)	Post-intervention (n=222)	*P* Value*
Age[a], years	76 (63-84)	73 (64-83)	.786
Male n (%)	55 (53.9)	111 (50)	.512
Urban n (%)	90 (88.2)	142 (64)	**< .001**
Arrival by EMS, n (%)	88 (86.3)	215 (96.8)	**< .001**
Day Shift Arrival[c], n (%)	59 (57.8)	121 (54.5)	.574

EMS = Emergency Medical Services; [a] median (interquartile range); [c] arrival during the hours of 0730- 1700; groups compared by χ^2 test for categorical variables & *t* test for continuous variables; *statistical significance defined as $p \leq .05$

There were no significant differences in the age or gender distribution between the two groups: the median ages of the pre- and post-intervention groups were 76 and 73 years respectively. Males comprised approximately 50% of both groups. Significantly more of the pre-intervention group (88.2%) were considered urban, compared to the post-intervention group (64.4%). Patients in the post-intervention group were significantly more likely to arrive by ambulance (i.e., EMS). Although not statistically significant, slightly more stroke patients arrived during regular day-time hours (0730-1700) as opposed to off hours, (57.8% vs. 54.5%). Most patient risk factor characteristics between the pre-intervention and the post-intervention periods were similar, except for dyslipidemia, which was marginally significant (see Table 5).

Table 5
Risk Factors of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency During the Pre-Intervention Period (2008-2010) as Compared to the Post-Intervention Period (2012-2014)

	Pre-intervention (n=102)	Post-intervention (n=222)	*P* Value*
Hypertension n (%)	64 (62.7)	148 (66.7)	.491
Diabetes n (%)	22 (21.6)	67 (30.3)	.102
Atrial fibrillation n (%)	37 (36.3)	67 (30.2)	.275
Current smoker n (%)	15 (14.7)	31 (14)	.859
Dyslipidemia n (%)	25 (24.5)	80 (36)	**.04**
CAD / MI n (%)	32 (31.4)	59 (26.6)	.372
Prior stroke or TIA n (%)	33 (32.4)	68 (30.6)	.756
PVD n (%)	1 (1)	5 (2.3)	.669 €
Carotid stenosis n (%)	7 (6.9)	8 (3.6)	.195

CAD = coronary artery disease, MI = myocardial infarction, TIA = transient ischemic attack, PVD = peripheral vascular disease; groups compared by χ^2 test for categorical variables; € = groups compared by Fisher Exact test for categorical variables; *statistical significance defined as $p \leq .05$

Patients presenting stroke symptoms on arrival were compared (see Table 6). Between group differences with all five symptom variables were not significant. As expected, most patients in both the pre- and post-intervention groups presented with weakness or speech-related symptoms.

Table 6

Presenting Symptoms of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency During the Pre-Intervention Period (2008-2010) as Compared to the Post-Intervention Period (2012-2014)

	Pre-intervention (n=102)	Post-intervention (n=222)	*P* Value
Weakness, n (%)	100 (98)	207 (93.2)	.072
Sensory Deficit, n (%)	15 (14.7)	23 (10.4)	.259
Balance Issue, n (%)	9 (8.8)	13 (5.9)	.324
Visual Disturbance n (%)	8 (7.8)	8 (3.6)	.102
Speech Problem, n (%)	78 (76.5)	170 (76.6)	.983

Groups compared by χ^2 test for categorical variables; *statistical significance defined as $p \leq .05$

Patient evaluation parameters were collected and appear in Table 7. NIHSS scores in the patients' charts were very poorly documented. NIHSS documentation was found in only 2% of cases in the pre-intervention group, and in 28% of the post-intervention group. GCS scores demonstrated no statistical difference between groups. There was also no significant difference between groups for baseline systolic BP, diastolic BP, and blood glucose on arrival. The proportion of patients in each group with systolic and diastolic BPs above best-practice guideline parameters (i.e., a systolic value above 180, or a diastolic value above 105) was also not significant.

Table 7

Patient Evaluation Characteristics of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency During the Pre-Intervention Period (2008-2010) as Compared to the Post-Intervention Period (2012-2014)

	Pre-intervention (n=102)	Post-intervention (n=222)	*P* Value*
Admission NIHSS score [a]		14 (8-20)	
NIHSS not documented, n (%)	100 (98)	160 (72)	
Admission GCS [a]	15 (12-15)	14 (11-15)	.555
Baseline SBP [a]	152 (135-170)	153 (136-172)	.684
SBP > 180, n (%)	11 (10.8)	26 (11.8)	.797
Baseline DBP [a]	82 (76-93)	84 (72 97)	.587
DBP > 105, n (%)	7 (6.9)	24 (10.9)	.257
Baseline Glucose [a]	7 (5.7-8.1)	7.1 (6-8.8)	.218

NIHSS= National Institutes of Health Score, ranging from 0-42, with higher scores indicating more severe stroke; GCS = Glasgow Coma Scale; SBP= systolic blood pressure; DPB = diastolic blood pressure; [a] median (interquartile range); groups compared by χ^2 test for categorical variables & *t* test for continuous variables; *statistical significance defined as $p \leq .05$

In summary, demographic and clinical patient characteristics did not differ significantly between the pre-and post-intervention cohorts, except for an increased number of rural patients and patients arriving by EMS in the post-intervention period.

Process

Process describes the care delivered at the time of the patient encounter, and either measures time intervals or whether or not an intervention was performed. The following hyperacute stroke process metrics were analysed: OTD, OTN, DTN, DTCT, and CTTN. To evaluate if Canadian Stroke Best Practice Guidelines were being met, we also elicited data related to the proportion of patients who received a CT Scan within 25 minutes of arrival and within 15 minutes of arrival, as well as the proportion of patients who received rt-PA within 60 minutes of arrival (DTN ≤ 60 minutes) and within 30 minutes of arrival (DTN ≤ 30 minutes). As well, we captured data on whether or not the acute stroke patient had endovascular therapy, as this reflects the 2015 Canadian Stroke Best Practice Recommendations (Casaubon et al., 2015). This section specifically describes process factors and addresses research question #2; *did the structural changes contribute to improvements in process*? Table 8 highlights the pre-post intervention analysis of all process variables.

Table 8
Process Metrics of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency During the Pre-Intervention Period (2008-2010) as Compared to the Post-Intervention Period (2012-2014)

	Pre-intervention (n=102)	Post-intervention (n=222)	*P* Value
Onset to Door time [a]	64 (44.5-101.5)	84 (54.75-137)	< **.001**
Onset to Needle time [a]	144.5 (115-180.5)	140 (107.8-193.5)	.697
Door to Needle time [a]	70.5 (57-88.5)	49 (39-58)	< **.001**
Door to CT time [a]	23 (19-32)	16 (13-22)	< **.001**
CT to Needle time [a]	46.5 (30-60.8)	32 (24-41)	< **.001**
Door to CT time ≤ 25 min	59 %	86.7 %	< **.001**
Door to CT time ≤ 15 mins	12 %	46 %	< **.001**
Door to Needle time ≤ 60 min	31.4 %	77.9 %	< **.001**
Door to Needle time ≤ 30 min	0 %	9 %	< **.001**
Endovascular treatment	2 %	7.2 %	.068

CT= uninfused brain computed axial tomographic scan; [a] Median time in min (interquartile range); groups compared by χ^2 test for categorical variables & *t* test for continuous variables; *statistical significance defined as $p \leq .05$

The time interval from symptom onset to arrival at hospital or ‘door time’, which is known as OTD, reflects pre-hospital care and not process improvements within the Adult ED. However, it was worthwhile to gather this data, as it describes our patient population. Notably, the median OTD increased significantly between the pre-intervention and the post-intervention period.

Differences in OTN (i.e., sum of OTD and DTN), which reflects at what time in the thrombolytic window treatment with rt-PA was initiated, demonstrated no statistical differences between pre- and post-intervention. Pearson’s correlation coefficient was performed to determine the relationship between the OTN, OTD, and DTN variables. The correlation was significant for OTN and DTN (r= .223; p < .001), which indicates a modest positive tendency; that is, as OTN increases, DTN increases. The correlation was also statistically significant for OTD and DTN (r= -.227; p < .001), which indicates a statistically significant modest negative tendency; that is, as OTD increases, DTN decreases.

Scatter plots help to show how much one variable is affected by another and may show trends in data. Scatter plots appear in Figure 6 to provide a visual depiction of the relationship between OTN and DTN, and OTD and DTN, supporting the correlation analysis results. As OTN increases DTN increases, and as OTD increases DTN decreases.

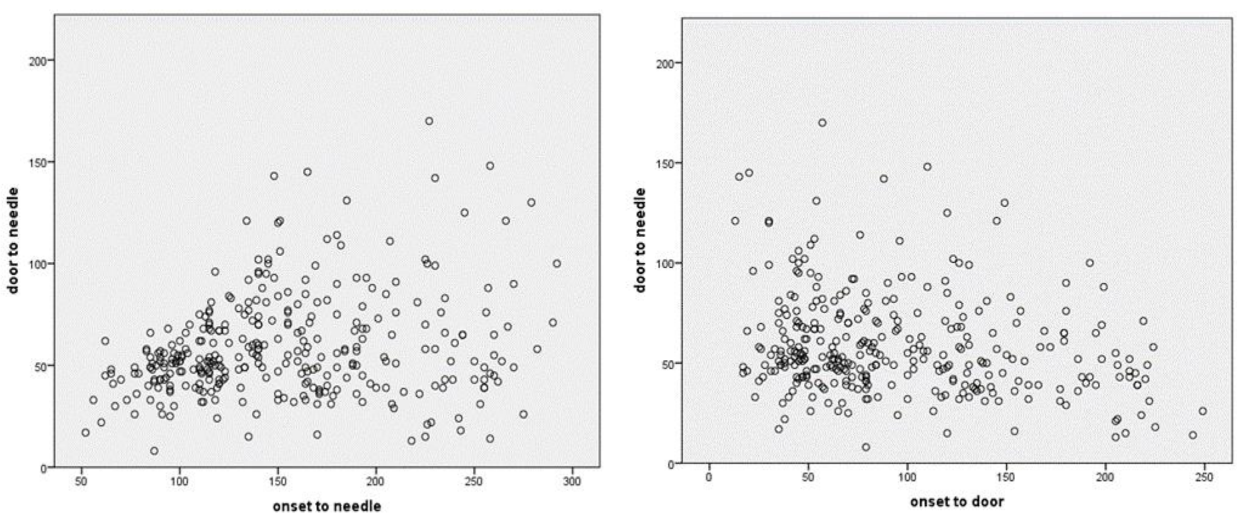

Figure 6. Scatter Plots for Onset to Needle (OTN) and Door to Needle (DTN), and Onset to Door (OTD) and Door to Needle (DTN).

The median DTN for rt-PA administration decreased significantly between the pre-intervention and the post-intervention period (70.5 vs. 49 min, p < .001). DTN time trends are illustrated in a run-chart (see Figure 7). This clearly demonstrates the significant improvement of DTN times following the quality improvement initiative, which occurred in 2011. The red line represents the DTN national benchmark of 60 minutes. On examining all study cases, there was a higher number of cases with a median DTN below 60 minutes post-intervention.

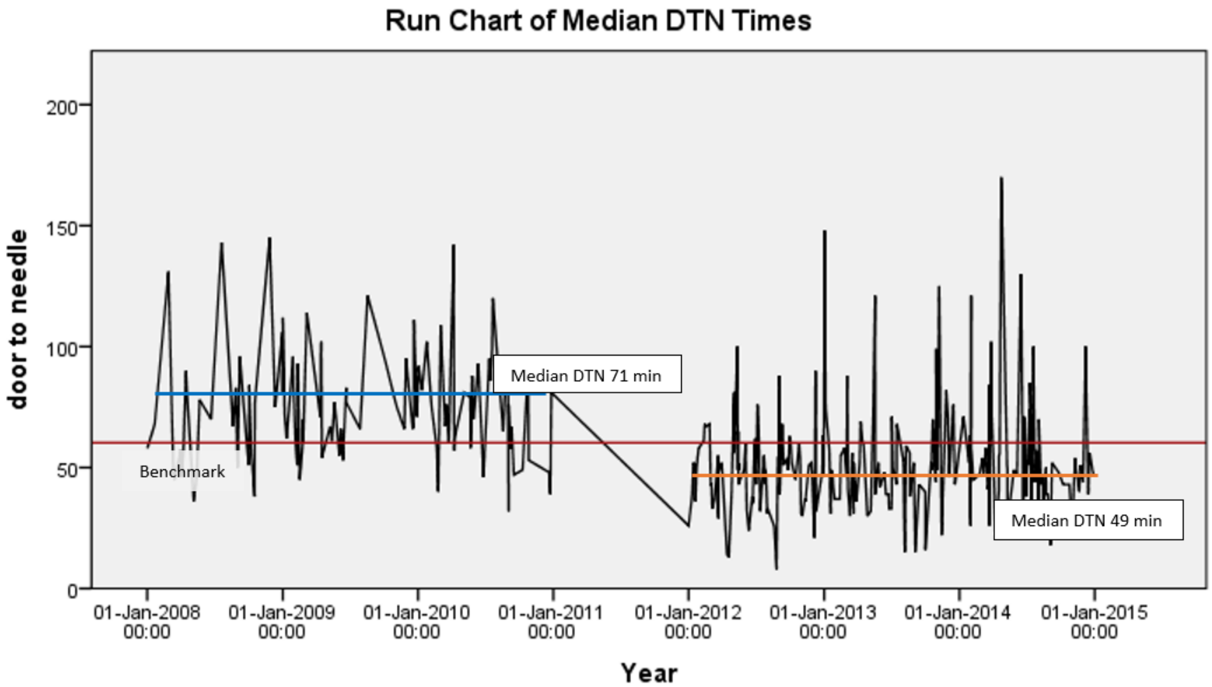

Figure 7. Run Time Chart of Median DTN Times of All Study Cases. Note: 2011 was considered the wash out year, as the intervention took place in 2011; red horizontal line = DTN national bench mark of ≤ 60 minutes.

To further demonstrate the significant decrease in mean DTN over time, the mean DTNs per yearly quartiles were examined (see Figure 8). Each year was subdivided into the following quartiles; January-March, April- June, July –September, and October-December. The red line represents the DTN national bench mark of 60 minutes. The year 2011 was excluded, as this was the washout year. Mean DTN quartiles were significantly lower in the post-intervention period.

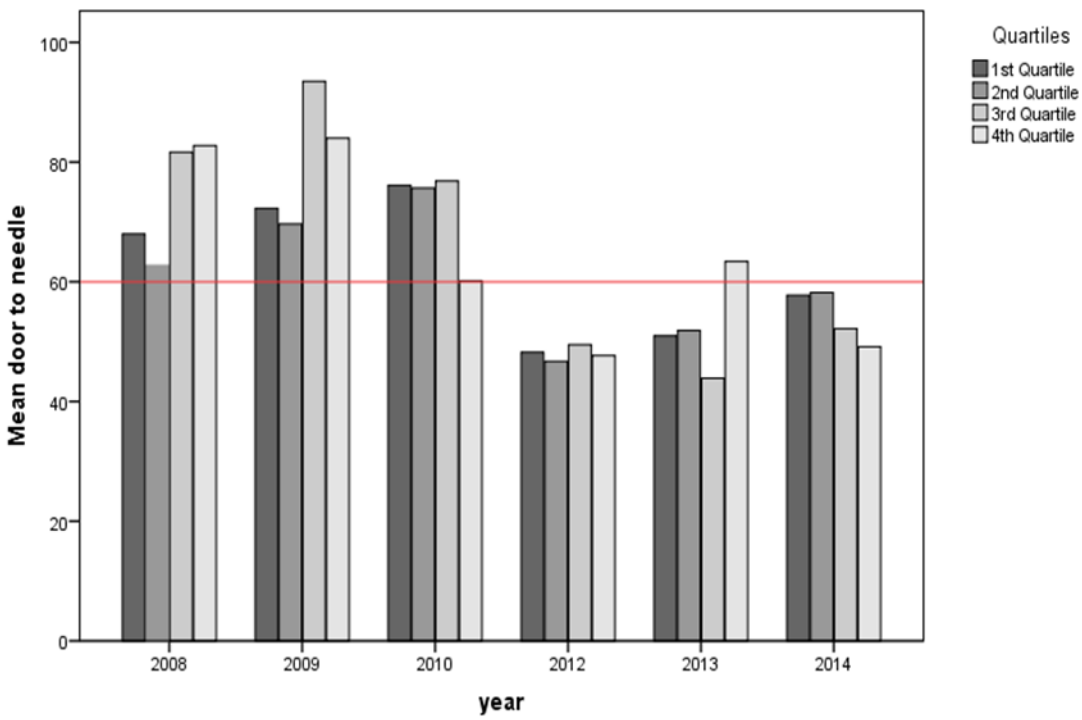

Figure 8. Time Trend in Mean Door to Needle (DTN) Times by Years in Quartiles; red horizontal line = DTN national bench mark of ≤ 60 minutes.

In our analysis, median DTCT also exhibited a significant difference between the pre-intervention (23 min) versus the post-intervention (16 min) groups ($p < .001$). Lastly, the median CTTN for the pre-intervention period was significantly longer (46.5 min) versus the post-intervention period (32 min; $p < .001$), see Table 5.5.

Since DTN, DTCT, and CTTN are interdependent, the relationship between these variables was examined using the Pearson's correlation coefficient. The Pearson correlation coefficient demonstrated a statistically significant modest positive correlation between DTN and DTCT ($r = .516$; $p < .001$) and a statistically significant strongly positive correlation between DTN and CTTN ($r = .886$; $p < .001$). This suggests that as DTN increases so does DTCT and CTTN. Figure 9 provides a visual depiction using a Scatter Plot of the relationship between DTN and DTCT as well as DTN and CTTN.

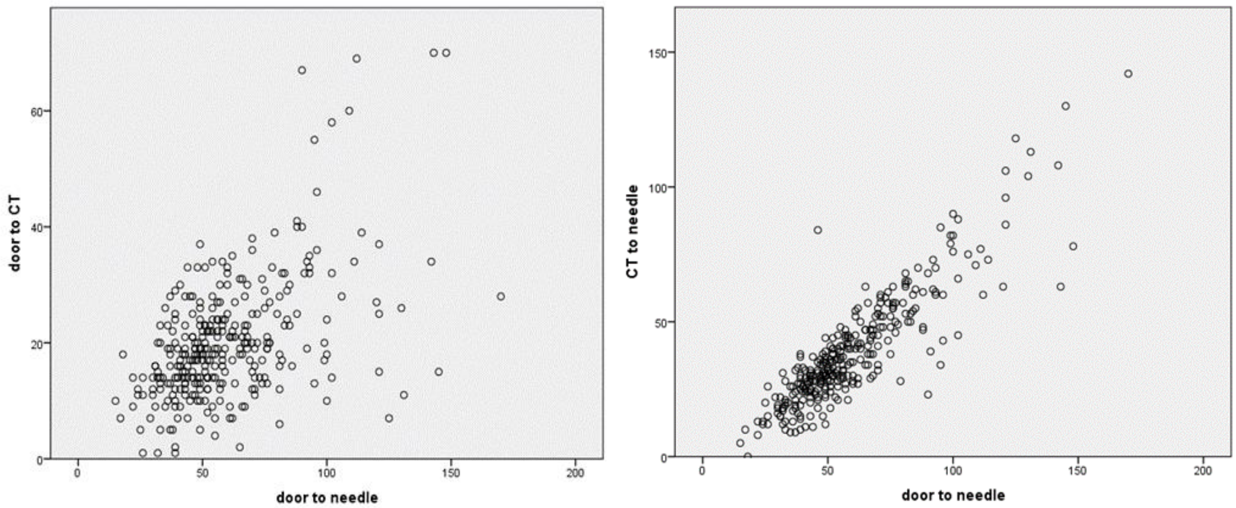

Figure 9. Scatter Plots for Door to Needle (DTN) and Door to CT (DTCT), and Door to Needle (DTN) and CT to Needle (CTTN)

To determine if our clinical practice reflects best practice, several key national indicators were also assessed. National guidelines suggest that eligible acute stroke patients should receive rt-PA within 30-60 minutes of arrival. Therefore, the percentage of patients who received rt-PA within 60 minutes of arrival (DTN ≤ 60) and within the new Canadian benchmark, 30 minutes of arrival (DTN ≤ 30), was captured (see Table 8). A significantly higher percentage of patients in the post-intervention group had a DTN time ≤ 60 ($p < .001$). Figure 10 provides a visual depiction of the percentage of patients who received rt-PA within 60 minutes of arrival by year. Based on a Chi-Square analysis, the proportion of stroke patients receiving rt-PA within 30 minutes of arrival (DTN ≤ 30) was also found to be significantly higher post-intervention ($p < .001$). National CT benchmarks were also gathered, which demonstrated statistical significance in all areas between the pre- and post-intervention period, including DTCT ≤ 25 ($p < .001$) and DTCT ≤ 15 minutes ($p < .001$; see Table 5.5).

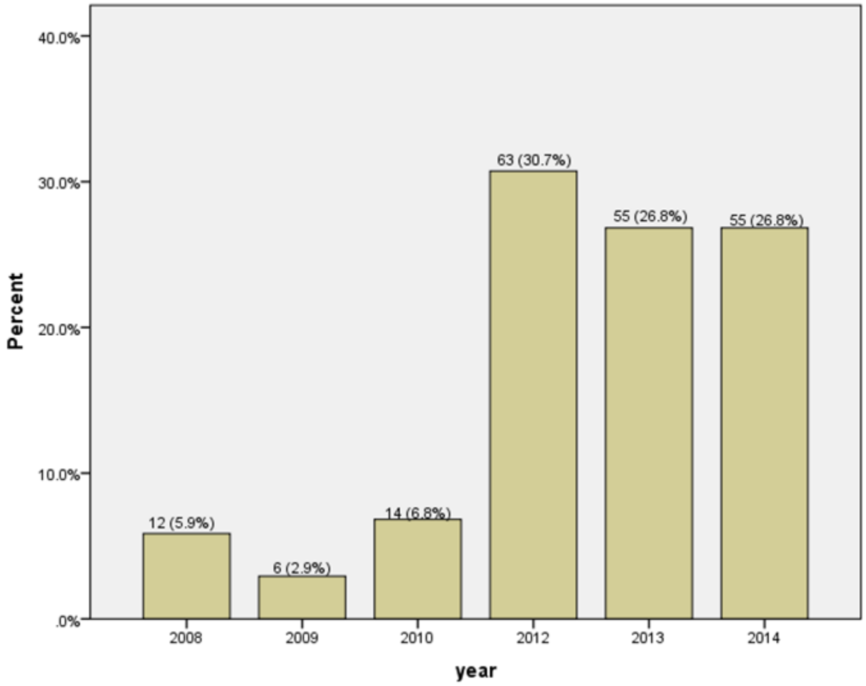

Figure 10. Percentage of Patients Receiving rt-PA Within 60 Minutes of Arrival by Year

Whether or not the patient had an endovascular therapy (EVT) procedure was also captured in the data analysis. In the pre-intervention group, the proportion of patients who had EVT was 2% (n=2) and in the post-intervention group the proportion was 7.2 % (n=16). Due to the small sample size, the Fisher Exact test was used to determine if there was a statistical difference between the groups. Although the results of the analysis were not significant (p= .068), this is a clinically significant finding, as it is likely related to a change in practice in the treatment of acute stroke following the intervention.

Overall, process indicators demonstrated a significant difference in all Canadian stroke key quality indicators between the pre-and- post-intervention group. This clearly validated a link between the structural changes, which addressed patient flow, provider education, provider feedback, and process metrics, as the process metrics improved dramatically.

Outcomes

Outcomes evaluate the combined effects of structure and process (Donabedian, 1988), and reflect the effects of care on the health status of the individual patient. Patient level outcomes in the context of hyperacute stroke care include mortality, adverse events, functional disability, and LOS. Outcomes that evaluate structural and process changes at the organizational level are: rt-PA rates, LOS, and CTAS scores**.** This section will address the primary research question: *Did the structural changes and dramatic process improvements result in improved clinical outcomes for acute stroke patients?* As well, more specifically, research question #3 will be addressed: *Is there a relationship between process and outcomes?*

Patient Outcomes

The analyses of patient outcomes pre- versus post-intervention are illustrated in Table 9. Mortality was captured as overall *in-hospital mortality*, *7-day mortality*, and *5-day mortality*. There was a significant difference between groups in *in-hospital mortality*: pre-intervention 18.6% versus post-intervention 9% (p= .013). Clinical outcomes and LOS were also analysed while excluding those repatriated to community hospitals, to account for the organizational culture change, which included early repatriation of patients to community hospitals during the post-intervention period.

Adverse events, captured as SICH within 36 hours and life-threatening bleed, operationally defined patient safety. Based on this operational definition, our quality improvement project did not appear to affect patient safety, as adverse events remained similar pre- and post-intervention (see Table 9).

Table 9
Clinical Outcomes of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency During the Pre-Intervention Period (2008-2010) as Compared to the Post-Intervention Period (2012-2014)

Outcome	Pre-intervention (n=102)	Post-intervention (n=222)	*P* Value*****
LOS, days [a]	10 (5-22)	5 (2-10)	**.004**
Mortality			
In-hospital mortality n (%)	19 (18.6)	20 (9)	**.013**
7 Day In-hospital mortality n (%)	10 (9.8)	14 (6.3)	.264
5 Day In-hospital mortality n (%)	7 (5.9)	13 (5.9)	.992
Discharge Location			
Home n (%)	30 (29.4)	74 (33.3)	.483
Favorable vs unfavorable discharge location n (%)	77 (75.5)	195 (87.8)	**.005**
Ambulatory Status at Discharge			
Independent at discharge n (%)	33 (32.4)	75 (33.8)	.845
Ambulatory at discharge vs. non-ambulatory n (%)	63 (62.4)	140 (63.1)	.902
SICH ≤ 36 hours n (%)	5 (5)	19 (8.6)	.360 €
Life-threatening hemorrhage n (%)	0	4 (1.8)	.314 €

LOS= length of stay; SICH= secondary intracranial hemorrhage; [a] Median (interquartile range); groups compared by χ^2 test for categorical variables & *t* test for continuous variables; €= groups compared by Fisher Exact test for categorical variables; *statistical significance defined as $p \leq .05$

Chart audits revealed disappointing results regarding the use of a functional ordinal scale within our institution; that is, the discharge NIHSS scores were rarely documented. However, proxy measures for functional outcomes (i.e., discharge location and ambulation upon discharge) were captured.

Discharge location was recorded as either, *home, acute rehabilitation, community hospital, long term care facility (LTC), or death.* Figure 11 provides a visual depiction of all discharge locations. Of note, post-intervention fewer patients went to a LTC facility (3.2% vs.

5.9%) and there were fewer in-hospital deaths (9% vs. 18.6%). Due to organizational changes that resulted in repatriation of patients to their catchment hospital more quickly after receiving rt-PA, significantly less patients went directly to acute rehabilitation (8.1% vs. 32.4%) and more patients went to community hospitals (46.4% vs. 13.7%) post-intervention (Figure 11).

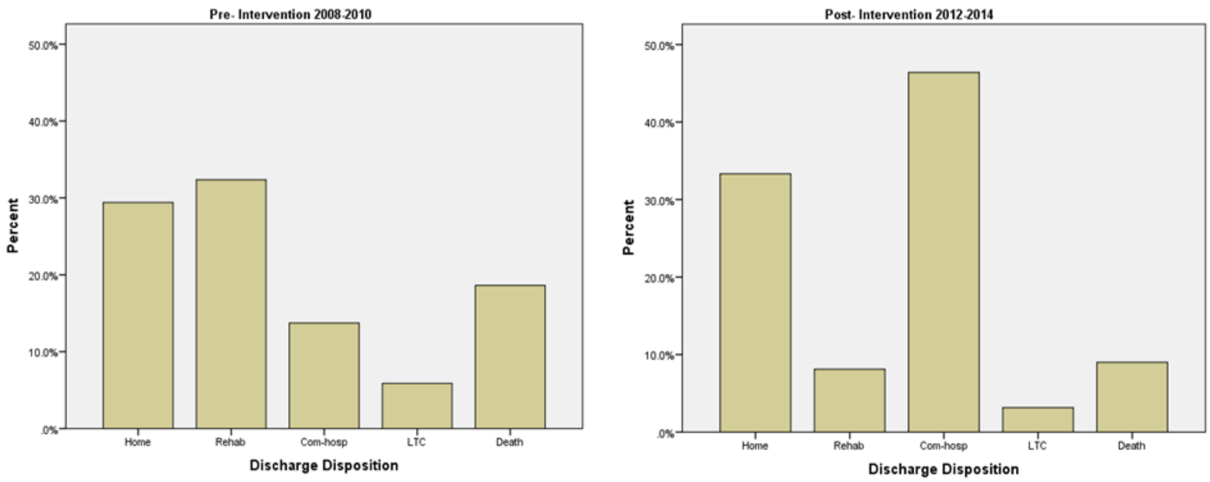

Figure 11. Discharge Location: Pre-versus Post Intervention

Discharge location was also analyzed as the percentage of patients '*discharged home'* versus discharge to other locations. Since stroke tends to cause disability, discharge home is an important indicator of recovery. Discharge was also analyzed in the categories of favorable (i.e., home, acute rehabilitation, and community hospital) versus unfavorable (i.e., LTC and death). This analysis revealed significantly more discharges to favorable locations in the post-intervention group, p= .005 (see Table 9).

Ambulatory status upon discharge was also analyzed pre- and post-intervention. Categories included; *independent*, which represented those who did not require any form of aid; *with assistance*, which included patients who required physical assistance; *non-ambulatory*, which represented those who could not ambulate; and *death*. Figure 12 shows the percentage of patients in each category pre- and post-intervention. A between group analysis of *independent* versus all other categories resulted in nonsignificant findings. Similarly, the analysis of ambulatory status at discharge, as ambulatory (i.e., independent and ambulatory with assistance) versus non-ambulatory (i.e., non-ambulatory and death) was also non-significant (see Table 9).

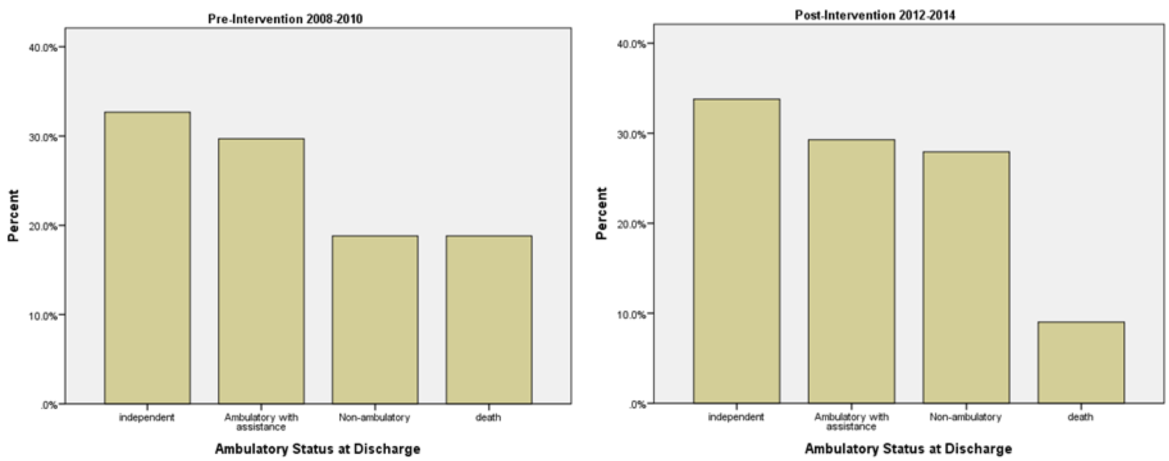

Figure 12. Ambulatory Status Upon Discharge: Pre- and Post Intervention.

To account for the organizational culture change that occurred during the study period, which was to repatriate stroke patients early, and which may have skewed the results in the full analysis because patients were repatriated much earlier to their catchment hospital, we completed an analysis that excluded all patients who had been repatriated to community hospitals in the pre- and post-intervention periods (see Table 10). This analysis revealed that a much higher percentage of patients were repatriated to community hospitals in the post-intervention period (46.4% vs. 13.7%); however, no difference was found in median LOS when comparing results to the full analysis. While differences in in-hospital mortality were significant in the original analysis, they were not significant in the reduced model.

Table 10
Clinical Outcomes of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency, Excluding Those Repatriated to Community Hospitals During the Pre-Intervention Period (2008-2010) as Compared to the Post-Intervention Period (2012-2014)

Outcome	Pre-intervention (n=88)	Post-intervention (n=119)	*P* Value*
Community hospital repartitions n (%)	14 (13.7)	103 (46.4)	
LOS, days [a]	11.5 (5-24)	5 (2-10)	**.003**
Mortality			
In-hospital mortality	19 (21.6)	20 (16.8)	.384
7 Day In-hospital mortality n (%)	10 (11.4)	14 (11.8)	.929
5 Day In-hospital mortality n (%)	6 (6.8)	13 (10.9)	.312
Discharge Location			
Home n (%)	30 (34.1)	74 (62.2)	**< .001**
Favorable vs unfavorable discharge location n (%)	63 (71.6)	92 (77.3)	.348
Ambulatory status at Discharge			
Independent at discharge n (%)	32 (36.4)	67 (56.3)	**.005**
Ambulatory at discharge vs. non-ambulatory n (%)	57 (64.8)	91 (76.5)	.065
SICH [d] ≤ 36 hours n (%)	4 (4.7)	11 (9.2)	.281 €
Life-threatening hemorrhage n (%)	0	4 (3.4)	.140 €

LOS= length of stay; SICH= secondary intracranial hemorrhage; [a] Median (interquartile range); groups compared by χ^2 test for categorical variables & *t* test for continuous variables; €= groups compared by Fisher Exact test for categorical variables; *statistical significance defined as $p \leq .05$

However, there was a significant difference between the proportion of patients *discharged home* versus other categories when community hospital repatriations were excluded (pre-intervention 34.1% vs. post-intervention 62.2%, $p < .001$). Similarly, in the analysis of independent versus all other categories at time of discharge, a significantly higher proportion of post-intervention patients were independent at discharge (56.3% vs. 36.4%; $p = .005$) (see Table 10).

In summary, in this thesis study we found a significantly shorter median LOS, significantly less in-hospital mortality, and significantly more favorable discharge locations post-intervention. When accounting for early repatriations to community hospitals, discharge home and being independent at discharge were found to be significantly higher in the post-intervention group.

Organizational Outcomes

Significant improvements were also seen in the organizational outcomes analyzed in this study (i.e., rt-PA rates, CTAS scores, & LOS). Access to care, which was captured by overall rt-PA rates, demonstrated significant improvement, as there was a dramatic increase from 102 patients in the pre-intervention period to 222 patients in the post-intervention period who received rt-PA (see Table 11). Figure 13 provides a visual depiction on the number of patients receiving rt-PA by year.

Table 11
Organizational Outcomes of Patients with Acute Ischemic Stroke Who Received rt-PA at HSC Adult Emergency During the Pre-Intervention Period (2008-2010) as Compared to the Post-Intervention Period (2012-2014)

	Pre-intervention	Post-intervention	*P* Value*
rt-PA cases, n (%)	102 (31.5)	222 (68.5)	
LOS, days [a]	10 (5-22)	5 (2-10)	**.004**
LOS, days (while, excluding Community Hospital Repatriations), days [a]	11.5 (5-24)	5 (2-10)	**.003**
CTAS score of 1 n (%)	47 (46.1)	210 (94.6)	< **.001**

LOS= length of stay; CTAS= Canadian triage acuity score; [a] Median (interquartile range); groups compared by χ^2 test for categorical variables & *t* test for continuous variables; *statistical significance defined as $p \leq .05$

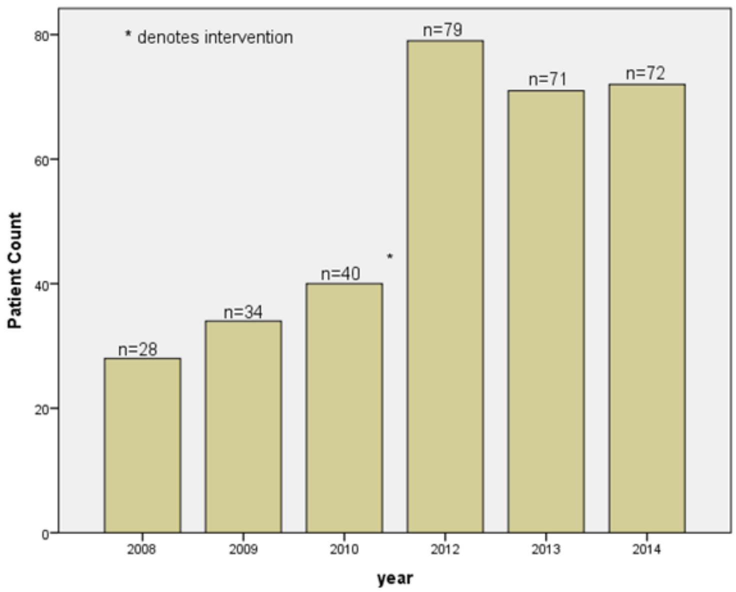

Figure 13. Access to Care: rt-PA cases by year

The proportion of patients triaged as CTAS level one versus all other scores was analyzed, as a quantitative measure, to identify whether the education sessions had resulted in a practice change when triaging acute stroke patients. There was a significant difference in the proportion of patients that were triaged as a CTAS level one score between the pre- and post-intervention groups (p < .001).

The between group difference in LOS was also significant. The median LOS pre-intervention was 10 days versus 5 days post-intervention (p= .004). This statistically significant result may have been due to our quality improvement project, but was more likely due to a culture change within our institution during the post-intervention period. Therefore, the LOS was also analysed excluding those who had been repatriated to community hospitals. This analysis revealed similar findings: pre-intervention 11.5 days versus post-intervention 5 days (p=.003).

In summary, structural changes and dramatic process improvements resulted in improved clinical outcomes for acute stroke patients, as well as significant improvements in organizational outcomes following the intervention. Clinical outcomes revealed less in-hospital mortality and an increase in favorable discharge location. When controlling for early repatriation of patients to community hospitals, a greater proportion of patients were discharged home, and were independent at discharge. Organizational outcomes improved as well, as access to thrombolytic therapy increased and LOS decreased post-intervention.

Structure, Process & Outcomes

In this section, both the primary research question and the 4th research question will be addressed: *Do structural factors (i.e., patients presenting characteristics) and outcomes vary based on process (i.e., OTN times or DTN times)?* While the statistical analysis of *OTN* times provides insight into the presenting characteristics of acute ischemic stroke patients who are treated early versus late in the thrombolytic window, the statistical analysis of *DTN* times helps us to understand who receives timely care when in the ED.

Presenting Characteristics and Outcomes of Patients and OTN Times

This analysis compared study patients based on OTN time (see Table 12). Patients treated early in the thrombolytic window were defined as OTN ≤ 90 minutes (n=38), as guidelines recommend an OTN benchmark within 90 minutes (Casaubon et al., 2015). Patients treated late in the 4.5-hour window were defined as OTN times > 90 minutes (n=286). Structural factors, including, patient demographics, risk factors, presenting symptoms, baseline evaluation parameters, and the ‘OTD time’ process factor, were included in this analysis. Lastly, clinical outcomes between the two groups were also analyzed.

The median age in both groups was similar at 73 and 74 years for OTN ≤ 90 and OTN > 90 respectively. Although not significant, the OTN > 90 group had a higher proportion of males (52.8% vs. 39.5%). A significantly higher proportion of patients in the OTN ≤ 90 group resided within the Winnipeg city limits versus rural communities (p = .003). Arrival by EMS was similar in both groups. Although not statistically significant, a higher proportion of patients in the OTN ≤ 90 group arrived during regular hours, (65.8 %), versus (54.2 %) in the OTN > 90 group (see Table 12).

Table 12

Patient Characteristics for Study Patients with OTN Times ≤ 90 Minutes Versus Patients with OTN Times > 90 Minutes (N=324)

	OTN ≤ 90 n=38	OTN > 90 n=286	*P* Value*
Age[a], years	73 (59-83)	74 (65-83)	.648
Male n (%)	15 (39.5)	151 (52.8)	.123
Urban n (%)	35 (92.1)	197 (68.9)	**.003**
Arrival by EMS n (%)	36 (94.7)	267 (93.4)	.745
Day Shift Arrival[c] n (%)	25 (65.8)	155 (54.2)	.177
Risk Factors			
Hypertension n (%)	19 (50)	193 (67.5)	**.033**
Diabetes n (%)	7 (18.4)	82 (28.8)	.180
Atrial fibrillation n (%)	12 (31.6)	92 (32.2)	.942
Current smoker n (%)	4 (10.5)	42 (14.7)	.490
Dyslipidemia n (%)	11 (28.9)	94 (32.9)	.628
CAD / MI n (%)	9 (23.7)	82 (28.7)	.520
Prior stroke or TIA n (%)	9 (23.7)	92 (32.2)	.289
PVD n (%)	0	6 (2.1)	1.0 €
Carotid Stenosis n (%)	2 (5.3)	13 (4.5)	.691
Presenting Symptoms			
Weakness n (%)	37 (97.4)	270 (94.4)	.442
Sensory n (%)	4 (10.5)	34 (11.9)	.806
Balance n (%)	3 (7.9)	19 (6.6)	.773
Visual n (%)	2 (5.3)	14 (4.9)	1.000
Speech n (%)	34 (89.5)	214 (74.8)	**.045**
Patient Evaluation			
Admission NIHSS score[a] n (%)	8 (6-21) 6 (15.8)	15 (9-20) 58 (20.3)	.307
Admission GCS score[a]	14 (12-15)	14 (12-15)	.615
Baseline SBP[a]	156 (137-174)	153 (135-170)	.592
SBP > 180 n (%)	6 (15.8)	31 (10.9)	.372
Baseline DBP[a]	81 (70-93)	83 (73-96)	.256
DBP > 105 n (%)	2 (5.3)	29 (10.2)	.556
Baseline Glucose[a]	7.2 (6.4-9.1)	7 (5.9-8.4)	.272
Onset to Door time[d]	36 (28-44)	86 (58-136)	**< .001**

EMS= Emergency Medical Services; CAD= coronary artery disease, MI= myocardial infarction, TIA= transient ischemic attack, PVD= peripheral vascular disease; NIHSS= National Institutes of Health Score, ranging from 0-42, with higher scores indicating more severe stroke; GCS= Glasgow Coma Scale; SBP= systolic blood pressure; DPB= diastolic blood pressure; [a] median (interquartile range); [c] arrival during the hours of 0730- 1700; [d] median time in minutes (interquartile range); groups compared by χ^2 test for categorical variables & *t* test for continuous variables; €= groups compared by Fisher Exact test for categorical variables; *statistical significance defined as $p \leq .05$

Risk factors for patients within OTN ≤ 90 group compared to the OTN > 90 group were also analyzed (see Table 12). Hypertension was the only risk factor that was significantly different in the two groups, as patients in the OTN > 90 group were significantly more likely to have hypertension as a risk factor (p=.033). Interestingly, with regards to presenting symptoms, the only symptom that was statistically significant was speech, suggesting that patients who are treated early in the window were more likely to have a speech problem on presentation. Lastly, OTD time intervals were analyzed. As expected, the OTN ≤ 90 cohort had a significantly shorter median OTD time ($p < .001$).

Table 13

Clinical Outcomes for Study Patients with OTN Times ≤ 90 Minutes Versus Patients with OTN Times > 90 Minutes (N=324)

	OTN ≤ 90 n=38	OTN > 90 n=286	*P* Value*
In-hospital mortality, n (%)	4 (10.5)	35 (12.2)	0.761
7-Day mortality, n (%)	2 (5.3)	22 (7.7)	1.000 €
5-Day mortality, n (%)	2 (5.3)	17 (5.9)	1.000 €
SICH < 36 hours' n (%)	6 (15.8)	18 (6.4)	0.049 €
Life threatening bleed, n (%)	2 (5.3)	2 (0.7)	0.070 €
Discharge home, n (%)	13 (34.2)	91 (31.8)	0.767
Favorable vs unfavorable discharge location, n (%)	31 (81.6)	241 (84.3)	0.672
Independent at discharge, n (%)	13 (34.2)	95 (33.3)	0.914
Ambulatory at discharge, n (%)	22 (57.9)	181 (63.5)	0.501

SICH= Secondary Intracranial Hemorrhage; Groups compared by χ^2 test for categorical variables; € = groups compared by Fisher Exact test for categorical variables
*statistical significance defined as $p \leq .05$

No significant differences were observed in clinical outcomes, between patients treated within 90 minutes of symptom onset (OTN ≤ 90) versus patients treated later than 90 minutes after symptom onset (OTN > 90); see Table 13. This is likely due to the very small cell sizes.

Interestingly, when examining adverse events, the OTN ≤ 90 minutes had significantly more SICH.

In summary, patients who were treated early in the thrombolytic window had significantly shorter OTD times, were more likely to live within the city limits of Winnipeg, have lower rates of the hypertension risk factor, and were more likely to present with a speech deficit. No significant differences were observed in clinical outcomes, between the two groups.

Presenting Characteristics and Outcomes of Patients Based on DTN Times

This analysis addressed study objective # 4: *Do structural factors and outcomes vary based on DTN times?* Importantly, it answers the question: who receives timely care? Patients who received timely care are represented by DTN times ≤ 60 minutes (n=205). Patients who did not receive timely care are represented by DTN times > 60 minutes (n=119). Table 14 provides a summary of all patient characteristics in the DTN ≤ 60-minute group and the DTN > 60-minute group.

The median age in both the DTN ≤ 60 and the DTN > 60 minutes group was 72. Males comprised a similar proportion in both groups. Interestingly, significantly less urban patients had DTN ≤ 60 minutes versus DTN > 60 minutes. As well, significantly more patients with DTN ≤ 60 were brought to hospital by EMS. Risk factors of patients in the two groups did not show any statistical difference, except for dyslipidemia, where there was a higher proportion in the DTN ≤ 60 versus the DTN > 60-minute group (see Table 14). No significant differences were found between presenting symptoms and patient evaluation parameters (see Table 14). Notably, patients in the DTN ≤ 60 group were more likely to arrive significantly later, as reflected in the results that the median OTD for the DTN ≤ 60 group was 80 minutes, versus 72.5 minutes for the DTN > 60-minute group (p=.019).

Table 14

Patient Characteristics for Study Patients with DTN Times ≤ 60 Minutes Versus DTN Times > 60 Minutes (N=324)

	DTN ≤ 60	DTN > 60	*P* Value*
# of cases	205 (63.3)	119 (36.7)	**< .001**
Age [a] year	74 (64-82)	74 (63-85)	.901
Male n (%)	106 (51.7)	60 (50.4)	.823
Urban n (%)	137 (66.8)	95 (79.8)	**.012**
Arrival by EMS n (%)	200 (97.6)	103 (86.6)	**< .001**
Day Shift Arrival, [c] n (%)	117 (57.1)	63 (52.9)	.471
Risk Factors			
Hypertension n (%)	136 (66.3)	76 (63.9)	.651
Diabetes n (%)	62 (30.4)	27 (22.7)	.135
Atrial fibrillation n (%)	61 (29.8)	43 (36.1)	.236
Current smoker n (%)	30 (14.6)	16 (13.4)	.768
Dyslipidemia n (%)	75 (36.6)	30 (25.2)	**.035**
CAD / MI n (%)	59 (28.8)	32 (26.9)	.715
Prior stroke or TIA n (%)	58 (28.3)	43 (36.1)	.142
PVD n (%)	2 (1)	4 (3.4)	.197 €
Carotid Stenosis n (%)	8 (3.9)	7 (5.9)	.414
Presenting Symptoms			
Weakness n (%)	197 (96.1)	110 (92.4)	.154
Sensory n (%)	26 (12.7)	12 (10.1)	.483
Balance n (%)	14 (6.8)	8 (6.7)	.971
Visual n (%)	9 (4.4)	7 (5.9)	.550
Speech n (%)	160 (78)	88 (73.9)	.401
Patient Evaluation			
Admission NIHSS score [a]	14 (8.5-19.5)	15 (6-20)	.911
n (%)	49 (23.9)	15 (12.6)	
Admission GCS score [a]	14 (12-15)	14 (11-15)	.211
Baseline SBP [a]	154 (136-170)	152 (135-171)	.812
SBP > 180 n (%)	22 (10.8)	15 (12.6)	.620
Baseline DBP [a]	83 (72-96)	84 (75-95)	.667
DBP > 105 n (%)	15 (7.4)	16 (13.4)	.073
Baseline Glucose [a]	7.1 (6-8.9)	6.9 (5.7-8.2)	.163
Endovascular treatment n (%)	16 (7.8)	2 (1.7)	**.022**
Onset to Door time [d]	80 (50.5-137.5)	72.5 (48-120)	**.019**

EMS= Emergency Medical Services; CAD= coronary artery disease, MI= myocardial infarction, TIA= transient ischemic attack, PVD= peripheral vascular disease; NIHSS= National Institutes of Health Score, ranging from 0-42, with higher scores indicating more severe stroke; GCS= Glasgow Coma Scale; SBP= systolic blood pressure; DPB= diastolic blood pressure; [a] median (interquartile range); [c] arrival during the hours of 0730- 1700; [d] median time in minutes (interquartile range); groups compared by χ^2 test for categorical variables & t test for continuous variables; €= groups compared by Fisher Exact test for categorical variables; *statistical significance defined as $p \leq .05$

As expected, improved clinical outcomes were observed for patients with DTN times ≤ 60 minutes. A significantly lower rate of in-hospital mortality was observed in this cohort (see Table 15).

Table 15
Clinical Outcomes for Study Patients with DTN Times ≤ 60 Minutes Versus DTN > 60 Minutes. (N=324)

	DTN ≤ 60 n= 205	DTN > 60 n= 119	*P* Value*
In-hospital mortality, n (%)	19 (9.3)	20 (16.8)	**.044**
7- Day In-hospital mortality, n (%)	12 (5.9)	12 (10.1)	.161
5- Day In-hospital mortality, n (%)	10 (4.9)	9 (7.6)	.321
SICH < 36 hours' n (%)	16 (7.9)	8 (6.8)	.717
Life threatening bleed, n (%)	4 (2)	0	.301 €
Discharge home, n (%)	68 (33.2)	36 (30.3)	.587
Independent at discharge, n (%)	72 (35.1)	36 (30.5)	.397
Ambulatory at discharge, n (%)	132 (64.4)	71 (60.2)	.450
Favorable vs. unfavorable discharge location, n (%)	178 (86.8)	94 (79.0)	.064

SICH= Secondary Intracranial Hemorrhage; groups compared by χ^2 test for categorical variables; € = groups compared by Fisher Exact test for categorical variables; *statistical significance defined as $p \leq .05$

Patients with DTN times ≤ 60 minutes were significantly less likely to die in-hospital compared to those with DTN times > 60 (p= .044). Adverse events (i.e., SICH and life-threatening bleeds), discharge home, and independence upon discharge were, however, were found not to be significant. A trend towards more favourable discharge locations occurred in the DTN ≤ 60 group (86.8%) as compared to the DTN > 60 group (79%), p= .064.

In summary, patients presenting in the HSC Adult ED during the study period who received timely care, (i.e., DTN ≤ 60 minutes) had characteristics that were significantly different to those who did not receive timely care (i.e., DTN > 60 minutes). They were more likely to live outside the Winnipeg city limits, arrive by EMS, and have dyslipidemia as a risk factor. OTD times were significantly longer for patients treated within 60 minutes of arrival. Finally, timely care was associated with less in-hospital mortality.

Summary

This chapter presented the findings specific to the research questions, which were developed to explore if acute stroke patient clinical outcomes improved post structural and process quality improvements in the HSC Adult ED during the study period (see Summary of Results: Figure 14). The data analysis presented clearly supports the hypothesis that the structural changes (i.e., improved patient flow, stroke education, feedback, and the emphasis on a collaborative team approach) resulted in dramatic improvements in process metrics. Furthermore, these process improvements may have translated into the significant improvements in clinical outcomes for acute ischemic stroke patients who received rt-PA during the post-intervention study period. Improved clinical outcomes included reduced in-hospital mortality and an increase in the proportion of favorable discharge locations. Secondary analysis of patients with DTN $\leq$ 60 minutes also supports the contention that earlier care results in improved clinical outcomes; as there was less in-hospital mortality for patients who received timely care.

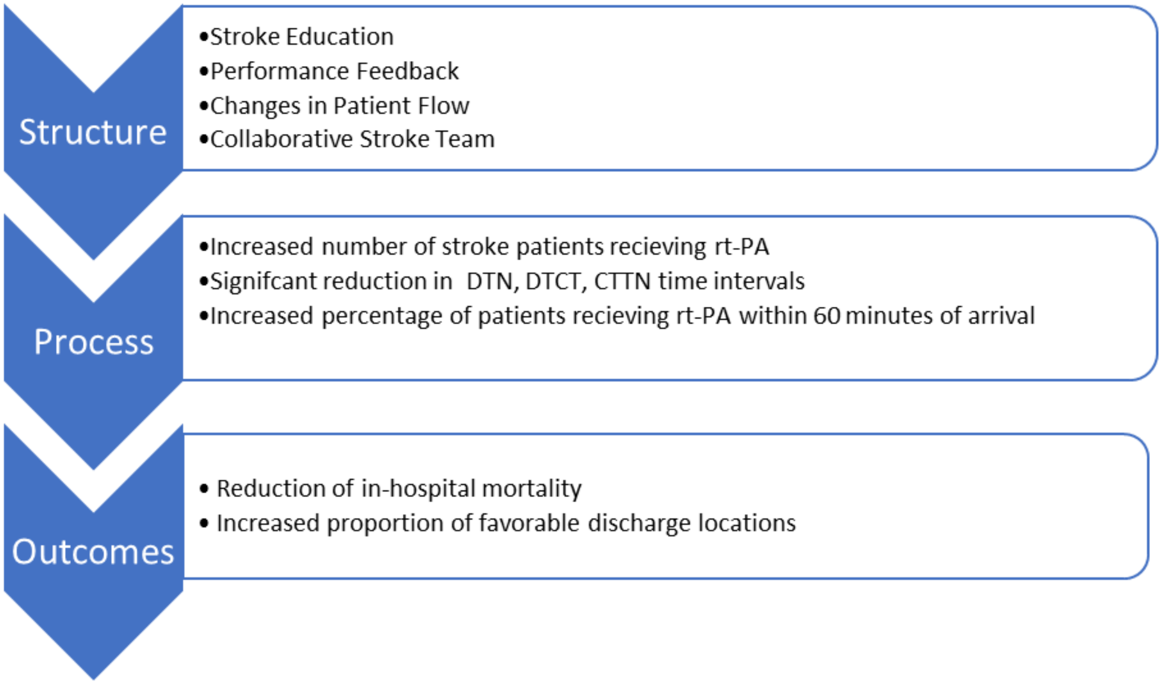

Figure 14. Summary of Results: Structural Changes that Led to Significant Improvements in the Processes of Care, Which in Turn Led to Significantly Improved Clinical Outcomes for Acute Stroke Patients at the HSC Adult ED.

CHAPTER 6: DISCUSSION

This chapter encompasses a discussion of the research study: *Exploring Clinical Outcomes in Acute Ischemic Stroke Following a Door-to-Needle Quality Improvement Project*, based on the findings presented in the previous chapter. The Donabedian Framework will be used to conceptualize the discussion of the study findings as they relate to the current literature. Study limitations are also addressed, and the study's framework is revisited. Finally, implications and recommendations for nursing practice, nurse leaders, education, and future research are presented.

Structure

Structure describes the context in which the care is being delivered. Moreover, structure tends to be stable characteristics, such as patients, material resources, care providers, operational programs and the organization systems (Qu et al., 2010). This section focuses on a discussion of study findings revealed in the Donabedian structural domain within the context of the associated research literature. The structural changes responsible for improving processes of care in the current study included: improved patient flow, as the stroke patient went directly to a dedicated bed in the resuscitation room upon arrival; acute stroke education for ED nurses, ED nurse practitioners, ED unit assistants, laboratory technicians, and CT technologists; and performance feedback for the entire stroke team, including the neurologists. These changes also fostered the growth of a collaborative stroke team. Several themes emerged in the post-intervention structural domain period, including a more collaborative team, improved access to stroke care for rural Manitobans, increased number of patients arriving by ambulance, and the importance of education.

Structure Themes

The first theme identified post intervention was a more efficient, collaborative team with a common goal: to deliver optimal stroke care. As part of the intervention, all team members were provided stroke education, which focused on roles and responsibilities and specifically stressed working together as a team. When a stroke patient arrived in the post-intervention period, a 'buzz in the air' could be felt, as everyone pulled together. Several studies have reported similar findings, suggesting that single or multiple structural improvements result in improved processes of care and are associated with improved clinical outcomes (Busby et al., 2016; Casaubon et al., 2015; Fonarow et al., 2011; Fonarow et al., 2014; Ford et al., 2012; Gropen et al., 2006; Hill et al., 2000; Mehdiratta et al., 2006; Ruff et al., 2014; Saver et al., 2010; Van Schaik et al., 2015). Furthermore, stroke education, which was part of our intervention likely fostered a collaborative stroke team that works in parallel to achieve a common goal. Others have also suggested a collaborative stroke team is key to delivering quality hyperacute stoke care (Busby et al., 2015; Casaubon et al., 2015; Fonarow, Smith, Saver, Reeves, Hernandez et al., 2011; Koennecke, Nohr, Leistner, & Marx, 2001; Ruff et al., 2014; Saver et al., 2010).

The second theme emerging in the post-intervention period was the access to thrombolytic therapy for rural patients. In August 2011, the HSC Adult ED began accepting stroke protocol patients from surrounding Regional Health Authorities (S. Alcock, personal communication, January 2012). Consequently, a longer median OTD time was observed, as the distance required to reach HSC was greater.

A third theme that emerged was that significantly more stroke patients arrived by ambulance. This is welcoming news; it is likely due to the increase in rural patients, but may also be related to increased public awareness of stroke. Experts (HSF, 2014) suggest that patients who arrive at hospital with EMS are treated more quickly. Arriving by EMS may also influence DTN time, as EMS pre-notifies the stroke team of the incoming suspected stroke patient, thereby allowing the stroke team to be ready for the patient on arrival. The 2015 HSF Stroke Report (HSF, 2015) reported that 65% of Manitobans who were admitted to hospital with a diagnosis of stroke from 2003-2014 arrived by EMS. Our study found a much higher rate of arrival by EMS, (86.3% in the pre-intervention period and 96.8 % in the post-intervention period). Our numbers are likely higher because our sample only included those who received rt-PA. Stroke patients who receive rt-PA are more likely to be severely disabled and therefore more likely to access 911.

The fourth theme addresses two issues revealed by the current study in the structural domain. Unfortunately, we were unable to capture stroke severity (see Table 7), which is used to describe the stroke population in numerous studies (Busby et al., 2015; Fonarow et al., 2011; Fonarow et al., 2014; Ford et al., 2012; Meretoja et al., 2012; Saver et al., 2013; Van Schaik et al., 2015). Only a minority of neurologists in our centre recorded the NIHSS score in the patient chart. However, nursing did consistently document the baseline GCS score on patient arrival, which demonstrated non-significant between group differences. As expected, the GCS is not sensitive enough to pick up on stroke deficits, which supports the need for baseline and ongoing NIHSS documentation.

The second issue, even though not statistically significant, was that slightly more patients arrived during the hours of 0730-1700, as compared to 1701-0729 (see Table 4). Moreover, we found that more patients (57.1%) had a DTN ≤ 60 min between the hours of 0730-1700 as compared to 42.9 % after hours. One possible reason for these findings is that the on-call neurologist is usually in-house during the hours of 0730 to 1700 hours, allowing for a quicker initial assessment. Previous studies (Busby et al., 2015; Johnson & Bakas, 2010; Miluluk et al., 2012) have shown that patients arriving after regular hours are less likely to receive timely care. Future research is needed to examine why this discrepancy exists at our hospital. Moreover, this feedback must be shared with our stroke team.

The last emerging theme is the importance of education, both in educating the public and the health care providers. As expected, the current study found that the most common patient presenting symptoms throughout the entire study were weakness and speech (Table 6). These findings support the FAST campaign, which was launched by HSFC in December 2014 to increase public recognition of stroke (HSF, 2015). Consequently, Manitoba should continue to invest in the FAST campaign (HSF, 2015), which helps people recognize the signs of stroke and call 911. The FAST messaging would also benefit all health care providers with stroke recognition, regardless of their practice setting. Hence, FAST messaging should continue to be directed at both the public and health care providers.

Stroke education, which was one of the three structural changes undertaken by this quality improvement project, was likely instrumental in the success of this initiative. However, further education is needed, in that health care providers need to be reminded of the importance of good documentation, and that education surrounding blood pressure management is vital. The current study did not uncover any significant differences in median baseline systolic and diastolic blood pressures between the pre-and post-groups. This is encouraging, as high blood pressure in the first 24 hours could be a confounding variable, as it may increase the risk of a SICH (Ahmed et al., 2009). The current study also measured the proportion of patients in the pre-and post-intervention groups that had baseline systolic or diastolic blood pressure readings above the recommended Canadian guidelines (Casaubon et al., 2015). To our knowledge this has not been reported before in Canada. However, results were not significant. The incidence of readings above suggested guidelines (Casaubon et al., 2015) was approximately 10%.

Nursing plays a central role in ongoing blood pressure monitoring and management in acute stroke to prevent complications associated with abnormal readings. Guidelines (Casaubon et al., 2015; Jauch et al., 2013) and studies (Ahmed et al., 2009) report that there is an increased risk of a SICH with blood pressure readings above the suggested parameters in the first twenty-four hours post-stroke. Of note, the percentage of patients with hypertension as a risk factor was 62.7% pre-intervention and 66.7% post-intervention. This is significantly higher than 49.7%, which was reported by Lindsay and Hill (2014), who recorded all patients presenting with stroke in Manitoba between 2003 and 2013 (N=15,760). Our sample only looked at stroke patients that received rt-PA, whereas Lindsay and Hill (2014) analyzed all patients admitted with a stroke diagnosis, which makes one wonder if patients presenting with disabling strokes that receive rt-PA have higher incidence of hypertension as a risk factor. However, this finding requires further investigation, as hypertension is the most common modifiable risk factor for acute stroke (Casaubon et al., 2015; HSF, 2015; Lindsay & Hill, 2014) and requires immediate action on the part of primary care providers.

Ongoing education should also include glucose management. Although the current study found no differences between the groups in the baseline glucose reading, glucose could be a confounding variable, as high glucose values worsen stroke outcomes (Casaubon et al., 2015). Information regarding guidelines (Casaubon et al., 2015; Jauch et al., 2013) that address early management of glucose in the hyperacute phase of stroke care should be included in all future ED stroke care education.

In summary, several themes emerged in the structural domain. The post intervention period saw the growth of an effective, collaborative stroke team. Rural Manitobans gained access to thrombolytic therapy, due to policy changes regarding the stroke protocol catchment area. More patients arrived by EMS, which most likely contributed to timely stroke care. Not using a validated stroke deficit tool is an identified gap. Understanding how time of arrival impacts timely care requires further research, and lastly ongoing education to both the public and health care providers is paramount.

Process

Donabedian (1998) refers to process as what is being done in giving and receiving the care, and should lead to improving the patient's health. The current study demonstrated that process metrics can be significantly improved and maintained by implementing structural changes, which focus on stroke education, feedback, and workflow improvements. This finding was consistent with the stroke literature. Several single centre studies (Busby et al., 2015; Ford et al., 2012; Meretoja et al., 2012; Ruff et al., 2014), as well as multicentre studies (Fonarow et al., 2014; Song et al., 2016) have demonstrated dramatic improvements in process and outcome measures following a quality improvement initiative. Additionally, this study intended to validate the initial findings published by Ghrooda et al. (2012), and to build on these findings by adding process metric data from 2012, 2013, and 2014. A discussion on how the current study's structural changes translated into dramatic process improvements will follow.

Process Indicators

Stroke process indicators reflect the type of care delivered. Process indicators are easy to measure and require fewer resources than outcome indicators. Furthermore, they are more sensitive to system changes and interventions (Song et al., 2016). The following process metrics findings will be discussed within the context of the associated research literature: median OTD time, median OTN time, median DTN time, median DTCT time, median CTTN time, the percentage of patients treated within 60 minutes and 30 minutes of arrival, the percentage of patients receiving a CT scan within 25 minutes and 15 minutes of arrival, and the proportion of patients that had endovascular therapy.

Onset-To-Door (OTD). In the current study we found that significantly more rural patients were treated with rt-PA in the post-intervention period, which may account for the longer post-intervention OTD times, as the distance to get to the stroke centre is much longer for rural patients. These findings clearly support Manitoba Health's initiative to establish TeleStroke sites in rural Manitoba, as TeleStroke sites improve access to treatment with rt-PA by decreasing the travel time (OTD) to a stroke centre. Educating rural EMS on the importance of timely hyperacute stroke care is central to reducing OTD, as the care EMS provides also impacts outcomes.

The current study also revealed that longer OTD times correlated with shorter DTN times (see Table 8). Likewise, when analyzing all study patients who had DTN ≤ 60 minutes, the median OTD was 80 minutes versus 72.5 minutes in the DTN > 60 minutes group. Similarly, several previous studies have shown a longer median OTD time in patients with DTN times less than 60 minutes (Fonarow et al., 2011; Meretoja et al., 2012; Mildluk et al., 2012; Saver et al., 2010). These findings suggest that when a patient arrives early in the thrombolytic window there is a false perception of having time to spare. Consequently, when a patient arrives late in the window, there is the perception of less time and therefore care is initiated faster (Fonarow et al., 2011; Meretoja et al., 2012; Mildluk et al., 2012; Saver et al., 2010). This highlights the need to educate ED staff about more than just the 4.5-hour window of opportunity.

Onset-To-Needle (OTN). OTN is essentially the sum of OTD and DTN. The study results did not show significant variation in OTN between the pre-and post-intervention groups. Chee et al. (2014) reported similar findings, and suggested that expedited care processes may have compensated for longer OTD times. It is likely that patients with longer OTD times were treated more quickly in the ED, which again suggests a need for further education to the ED staff about the importance of timely care for all stroke patients.

The benefits of early treatment are well established in the literature (Casaubon et al., 2015; Fonarow, Smith, Saver Reeves, Hernandez et al., 2011; Fonarow et al., 2014; Jauch et al., 2013; Saver et al., 2013). For this reason, additional data was gathered on patient characteristics as they relate to OTN time. Furthermore, it answers one of the study's secondary questions: to determine if patient characteristics varied based on OTN times. In the current study we found that patients treated early in the thrombolytic window (i.e., OTN ≤ 90 min) were more likely to live within the city of Winnipeg, have hypertension as a risk factor, present with a speech deficit, and have a shorter OTD time. A large observational study by Saver et al. (2013), that used similar variables to our study, found that patients with OTN times ≤ 90 minutes, were more likely to have a high NIHSS score, arrive by EMS, arrive during regular hours, and be male. Saver et al., (2013) did not explore corresponding OTD times or presenting symptoms. Despite not using the more comprehensive NIHSS stroke deficit tool, the current study finding which indicates a significantly higher rate of dysarthria in the OTN ≤ 90 minutes group could support Saver's finding of a high NIHSS score, as the NIHSS assessment has a speech component. However, as using the NIHSS would provide a much more comprehensive evaluation of a patient's stroke symptoms, a recommendation would be to consistently assess each stroke patient with the NIHSS tool. Further research, with larger cohorts, is also important to determine if gender differences are significant.

Door-To-Needle (DTN). Our median DTN dropped significantly from 70.5 minutes pre-intervention to 49 minutes post-intervention (p= < .001). Additionally, the variability of treatment times also decreased, as noted in the interquartile ranges (i.e., pre- IQR = 57- 88.5 vs. post-IQR = 39-58). When compared to the average Canadian DTN time of 90 minutes (Ganesh et al., 2014) or the previously reported Manitoba median DTN time of 113 minutes for 2009-2012, (Lindsay & Hill, 2014), our post quality improvement median DTN of 49 minutes is truly impressive. Since our quality improvement initiative included stroke education, performance feedback, and improved patient flow, it is likely that the combination of all three components was responsible for the improvement. This echoes the conclusions based on the study by Meretoja et al. (2012), who suggested the reduction in DTN is never solely based on one improvement, but likely the combination of multiple factors, which lends support to multi-component interventions, rather than addressing isolated issues. However, ideally a systems approach, including all disciplines should be undertaken.

Our study contributes to the existing literature on what strategies to use to achieve reduced DTN times, and suggests that dramatic reductions in median DTN time can occur after implementing a quality improvement initiative (Busby et al., 2016; Fonarow et al., 2011; Fonarow et al., 2014; Ford et al., 2012; Gropen et al., 2006; Mehdiratta et al., 2006; Ruff et al., 2014; Saver et al., 2010; Van Schaik et al., 2015). Our study will add to the Canadian stroke literature, but even more important, it will provide insight for the delivery of hyperacute stroke care within Manitoba, particularly regarding the importance of ongoing monitoring of stroke process metrics and intervening if results are poor.

Patients Treated Within 60 Minutes of Arrival. The percentage of patients treated within 60 minutes of arrival in hospital increased significantly post-intervention (from 31.4% to 77.9 %, $p < .001$). This impressive improvement was likely due to the structural changes that resulted in a collaborative stroke team. Similar findings have been reported in several other quality improvement studies (Busby et al., 2016; Fonarow et al., 2011; Fonarow et al., 2014; Ford et al., 2012; Gropen et al., 2006; Mehdiratta et al., 2006; Ruff et al., 2014; Saver et al., 2010; Van Schaik et al., 2015). However, Ganesh et al. (2014) reported that the proportion of stroke patients in Canada that are threated within 60 minutes is still low. The current study provides insight into structural changes that are effective in achieving benchmark goals for stroke patients. Because these changes are relatively easy to implement, cost effective, and are not associated with any patient risk, the recommendation would be for all stroke centres in Canada to undertake a similar quality improvement project such as ours.

The current study also revealed an inverse relationship between the DTN variable and the percentage of patients that were treated within 60 minutes of arrival. Pre-intervention, the DTN times were longer and less stroke patients were treated, whereas post-intervention DTN times were shorter and more patients received treatment with rt-PA. This relationship is likely because the collaborative stroke team worked faster and more efficiently and effectively, resulting in more patients being treated within the thrombolytic window.

To gain further insight into those who received timely care, we completed an additional analysis of patient characteristics with DTN times within 60 minutes of arrival. This also answers the secondary study question which was to determine if presenting characteristics varied based on DTN times. In the current study, we found that patients who receive timely care were more likely to live within the city of Winnipeg, arrive by EMS, and have a significantly longer

OTD time. Larger studies (Fonarow et al., 2011; Saver et al., 2013) suggest that older patients and female patients are less likely to receive timely care, whereas patients who suffer a severe stroke (i.e., high NIHSS) are more likely to arrive at hospital sooner and receive more timely care. Age and gender were not significant factors in timely care in our study, which is likely due to a small sample size. Unfortunately, NIHSS scores were not consistently documented in our study and therefore cannot be used to infer conclusions about stroke severity.

In the current study we also measured the percentage of patients that were treated within 30 minutes of arrival. Several researchers (Casaubon et al., 2015; Kamal et al., 2014) suggest that more aggressive DTN targets are needed, as the current DTN time of 60 minutes is no longer a sufficiently ambitious goal target. Hence, it was important to understand how the current study process metrics compared in relation to the new DTN target of within 30 minutes of arrival. Determining these results will further improve stroke care in Manitoba. This analysis suggested that a significant amount of additional work is required to meet the new target of a DTN within 30 minutes, as the pre-intervention cohort found no cases with a DTN ≤ 30 minute and only 9% in the post-intervention cohort. Echoing the words of Hill & Coutts (2014), "we must find ways to treat everyone even faster" (p. 1905).

Door-To-CT (DTCT). The current study showed that there were dramatic improvements in median DTCT times (i.e., pre-intervention = 23 minutes vs. post-intervention =16 minutes). Several factors were likely responsible for this improvement. Firstly, stroke education was provided to the CT technologists. This education focused on the time-sensitive nature of acute stroke and basic stroke protocol awareness. The CT technologists were also given performance feedback and were made aware of the national benchmarks that should be achieved. Anecdotally, this educational intervention translated into the CT scanner table more often being ready on patient arrival. Secondly, as part of the intervention, on arrival all stroke protocol patients went directly to a dedicated stroke bed, which is adjacent to the CT scanner, thus reducing the transport distance. Our study findings, which illustrate DTCT improvements, align with the findings of Meretoja et al. (2012) and Ford et al. (2012). Meretoja et al. (2012), who achieved an outstanding median DTN of 20 minutes, reported that the success was in part because the patient went directly to the CT scanner from the EMS bay. Ford et al. (2012), also found a significant reduction in median DTCT after applying the principles of Lean and value stream mapping (VSM) in their study, which suggested transporting the stroke patient directly to CT on arrival. The current study affirms the importance of including the CT department as a member of the stroke team, and providing this team with ongoing stroke education and performance feedback.

CT-To-Needle (CTTN). In the current study, we observed a significant reduction in median CTTN, from 46.5 minutes, pre-intervention to 32 minutes, post-intervention. One could argue that the neurologists had the biggest impact on reducing the CTTN time interval in the post-intervention period. Our neurologists and neurology residents were naïve prior to performance feedback; therefore, a presentation was given to this group at a Neurology Rounds session demonstrating our suboptimal performance on key quality stroke indicators. *Time is Brain*, was also emphasized. Arguably, this resulted in patient assessments regarding rt-PA eligibility occurring much more quickly. Sauser et al. (2014) explored how DTCT time and CTTN time contributed to time delays in DTN, and found that the CTTN time interval contributed more to rt-PA delays and was a greater source of variance. Similarly, we found that the CTTN time interval contributed more to time delays. Thus, ongoing education to the medical stroke team on reducing this time interval is critically important, as it is associated with greater variance than DTCT.

Door-to-CT Within 25 Minutes and 15 Minutes of Arrival. To ensure that stroke care is time driven, national stroke guidelines (Casaubon et al., 2015) provide benchmarks that stroke programs should strive to achieve. At the time of the current study, (i.e., 2008-2014), the national benchmark for brain imaging was within 25 minutes of arrival. In 2016, Quality of Stroke Care in Canada, Stroke Key Quality Indicators and Stroke Case Definitions (HSF, 2016) was published and suggested that initial brain imaging should ideally be achieved within 15 minutes of arrival. In our study, we found significant improvement with both brain imaging indicators (i.e., DTCT within 25 minutes, $p < .001$; DTCT within 15 minutes, $p < .001$). However, there is certainly room for improvement in meeting and sustaining the new key quality indicator of a DTCT ≤ 15 minutes.

Endovascular Therapy. Endovascular therapy (EVT) is now the standard of care for large proximal vessel occlusions (Casaubon et al., 2015). The current study found clinically significant differences in EVT rates, as only two patients received this type of therapy pre-intervention and 16 patients benefited from this therapy in the post-intervention period. In 2016, the HSFC recommend a developmental target of > 10 % (HSF, 2016), suggesting that our program should strive for approximately 30 cases per year. HSC is the provincial referral centre for endovascular procedures in acute stroke; however, this therapy is in its infancy in Manitoba and significant resources are required to bring it up to national standards. The current study only captured whether the procedure was done or not, which is a study limitation. Future studies should include an assessment of the level of EVT success, as this is important in stroke outcome evaluation. Recent studies (Berkhemer et al., 2015; Goyal et al., 2015) have shown that, like rt-

PA, EVT requires speed and efficient workflow processes, as shorter imaging to reperfusion and door-to-groin puncture times are linked with improved patient outcomes.

In summary, we found that there was a strong link between structural changes and processes of care, which are demonstrated by the statistically significant differences in process metrics. Implementing structural changes, which included stroke education, performance feedback, and workflow improvements, resulted in significant improvements in stroke process metrics. However, the increased percentage of EMS arrivals in the post intervention period may also have had some influence on these results. The data on OTD times clearly supports the need to establish TeleStroke sites in rural Manitoba.

The finding that shorter DTN times were associated with longer OTD times, and longer DTN times were associated with shorter OTD times, underpins the concept that *all* acute stroke patients need to receive timely care on presentation to the ED, no matter what time they present to the ED. Median DTN time was drastically reduced, likely due to our quality improvement initiative, which fostered a collaborative team atmosphere. The impact of educating the CT technologists was demonstrated in the reduced DTCT time interval and informing the performance naïve neurologists about their role in improving patient outcomes impacted our CTTN times. While our centre is quite new in EVT for acute stroke, we do need to strive to build a high-quality program for Manitobans. Given the new national benchmarks, it is clear that we have plenty of work ahead of us.

Outcomes

Clinical trials (Lansberg et al., 2009; Lees et al., 2010; National Institute of Neurological Disorders and Stroke t-PA Study Group, 1995; Wardlaw et al., 2012) have provided ample scientific evidence that timely care is associated with improved outcomes. The current study revealed improvements in clinical and organizational outcomes that are most likely associated with structural and process improvements that resulted in timely care, but may have been influenced by other variables. A discussion pertaining to patient and organizational outcomes follows.

Patient Outcomes

Patient outcomes are a central concept in the Donabedian framework, since they are directly linked to the structures utilized and the processes undertaken to deliver the care. Furthermore, patient outcomes validate the care provided (Donabedian, 1988). The focus of this study was to explore if clinical outcomes of acute stroke patients who received rt-PA improved post DTN quality improvement project.

Mortality. The current study revealed a significant decrease in *in-hospital* mortality post intervention (pre= 18.6% vs. post= 9%, p=.013). However, our *7-day* mortality rate was similar between the pre-and post-intervention groups. This non-significant finding is likely related to a corresponding significant decrease in median LOS, from 10 days to 5 days (p =.004), which most likely occurred due to the organizational cultural change, which saw early repatriation of stroke patients to their catchment hospitals. To account for this change in practice, and a potentially confounding variable, *in-hospital* and *7-day* mortality rates were also analyzed by excluding patients repatriated to community hospitals. In this analysis we found that both the *in-hospital* and *7-day* mortality rates were non-significant. Interestingly, when excluding patients repatriated early to community hospitals, the overall percentage of in-hospital mortality remained quite high (i.e., pre-intervention = 21.5 %; post-intervention = 16.8 %), which is likely due to critically ill patients staying at HSC and not being repatriated. Additionally, patients who had a complete recovery from the rt-PA treatment would likely have been discharged directly from

HSC. Unfortunately, we did not have access to any outcome measures for the patients who were repatriated early to community hospitals post rt-PA.

In the hallmark study by Fonarow et al. (2014), results included a significant reduction in all cause in-hospital mortality post DTN quality improvement project. Lindsay & Hill (2014) suggest that 7-day mortality is more directly related to the stroke event and the data is easier to collect. Our significant decrease in in-hospital mortality is likely due to an overall improvement of hyperacute stroke care in the post-intervention period. Furthermore, our 7-day mortality rate of 6.3 % post-intervention is comparable to the national Canadian average of 7.2 % reported by Ganesh et al. (2014) for patients receiving rt-PA at comprehensive stroke centres.

Lastly, we also analyzed mortality rates of patients who received rt-PA within 60 minutes of arrival (DTN $\leq$ 60) and found a significantly lower *in-hospital* mortality compared to patients with DTN > 60 minutes (p =.044). Others (Fonarow, Smith, Saver, Reeves, Bhatt, et al., 2011) have reported similar findings, when exploring mortality associated with timely care, suggesting that timely care does impact mortality.

In summary, despite a relatively small sample size, and the potentially confounding variable of early repatriation of stroke patients to their catchment hospital, this study did reveal a significant reduction in *in-hospital* mortality post-intervention. Furthermore, our 7-day mortality is comparable to the national average. When analyzing all study patients with DTN $\leq$ 60 minutes, in-hospital mortality also was significantly lower, suggesting that timely care did decrease mortality in our study cohort.

Adverse Events. Significant adverse events that are linked to thrombolytic therapy include life-threatening bleed and symptomatic intracranial hemorrhage (SICH).

The incidence of life-threatening bleeding in our study was very low (i.e., pre-intervention = 0 vs. 1.8 % post-intervention), which is consistent with other studies (Fonarow et al., 2014). A major reason for these favorable findings is likely because of the thorough screening done by the neurologists when assessing a potential rt-PA candidate. Furthermore, it suggests that patient safety is not jeopardized by faster care.

Similarly, there was no significant increase in SICH within 36 hours of rt-PA (i.e., 5% pre-intervention vs. 8.6% post-intervention). The incidence of SICH post rt-PA in the current study was comparable to existing stroke literature (Fonarow et al., 2014; Ganesh et al., 2014). One possible explanation for the slight increase in SICH may be the overall increase in the number of cases in the post-intervention period. However, it is important to note that the CSBPR stroke key quality indicators suggest a target of < 6% for SICH within 36 hours (HSF, 2016). Treating patients late in the thrombolytic window is associated with an increased risk of SICH (Fonarow, Smith, Saver, Reeves, Bhatt et al., 2011; Saver et al., 2013); therefore, every effort must be made to treat eligible patients early in the thrombolytic window and caution must be taken to do a thorough assessment with regards to rt-PA inclusion and exclusion criteria. However, since our sample size for adverse events was very low, this data must be interpreted with caution.

Functional Outcomes. Numerous studies report discharge location (Busby et al., 2016; Fonarow et al., 2011; Fonarow et al., 2014; Ford et al., 2012; Saver et al., 2013; Song et al., 2016) and ambulation upon discharge (Fonarow et al., 2011; Fonarow et al., 2014; Saver et al., 2013) as functional outcomes. Since discharge location and ambulation at discharge are relatively easy to collect, and since the lack of routine use of a functional ordinal scale such as the NIHSS was identified as a gap, the current study evaluated the following functional outcomes: discharge home versus other locations; favorable versus unfavorable discharge location; independent at discharge versus other categories; and being ambulatory versus non-ambulatory at discharge.

Discharge Location. Large studies, such as Song et al. (2016) and Fonarow et al. (2014) reported an increase in the proportion of patients being discharged home post quality improvement project. The current study included similar categories as discharge locations: *home; acute rehabilitation; community hospital; long term care facility (LTC); and death*. Each of these locations is associated with a certain level of independence or dependence. When examining each category independently, less discharge dispositions to LTC and death occurred post-intervention, which is very encouraging. This is likely due to the overall improvement in hyperacute stroke care.

Upon comparing the category of *discharge home* versus all other categories, the findings were not significant. This is probably due to the study's small sample size. Being discharged home adds to a patient's quality of life, therefore even though our findings were non-significant one could argue that they are clinically significant, as more patients went home in the post-intervention period (post-intervention 74 patients vs. pre-intervention 30 patients). Discharge location was also analyzed by excluding patients repatriated early to community hospitals, to account for the organizational culture change. This analysis demonstrated significantly more patients were discharged home ($p < .001$), which may in part be due to more patients having excellent results from the rt-PA treatment and therefore not requiring a long hospital stay. Therefore, it is important for future studies to include a large sample size to verify these findings.

Our study also categorized discharge locations into favorable versus unfavorable locations. We categorized home, acute rehabilitation and community hospital as a favorable discharge location, whereas discharge to a LTC facility and death were classified as an unfavorable discharge location. Our results support Ford et al.'s (2012) findings that significantly more patients were discharged to a favorable discharge location post quality improvement initiative. Our study findings are encouraging for two reasons: less transfers to LTC will result in cost reduction; and since the brain recovers for a long-time post stroke, it is vital that patients access rehabilitation at either acute rehabilitation facilities or community hospitals to maximize their recovery.

In summary, the post intervention period revealed a significantly higher number of favorable discharges, with less LTC admissions, which would suggest a cost reduction to the health care system and an increased quality of life for patients and their families.

Ambulation Upon Discharge. Larger studies (Fonarow et al., 2014; Saver et al., 2013) have demonstrated a significant increase in the number of stroke patients being independent at discharge post DTN quality improvement project. Hence, ambulation upon discharge was also captured by the current study as: *independent, ambulatory with assistance, non-ambulatory,* and *death*. Unlike the previous larger studies, the currents study's findings were nonsignificant. Results of the analysis of ambulatory status at discharge categorized as ambulatory (i.e., independent and ambulatory with assistance) versus non-ambulatory (i.e., non-ambulatory and death), were also non-significant. These findings may be explained by our small sample size.

Due to the organizational cultural change, ambulation upon discharge was also analyzed, while excluding those patients repatriated early to community hospitals. Based on this analysis, the percentage of patients who were independent at discharge was significantly higher post-intervention (p= .005). One possible explanation is that patients who responded well to rt-PA were likely independent within days of their treatment and did not require further hospitalization or rehabilitation.

Overall, the quality improvement initiative had a negligible impact on independence at discharge, except in the analysis that excluded the community hospital repatriations. This is likely due to the current study's small sample. However, every case where a good functional prevails, is a personal victory for patients and their families.

Summary. The current study revealed that structural changes, which improved the processes of care, were most likely associated with improved patient outcomes, including less *in-hospital* mortality and more discharges to favorable locations. Although many factors can influence outcomes, we are confident that patients received better hyperacute stroke care post-intervention.

Organizational Outcomes

Organizational outcomes capture elements that describe the performance of the system or program. Organizational outcomes that best reflect hyperacute stroke care are rt-PA rates, which reflect access to care and LOS. The current study also used CTAS scores to reflect triaging practices of triage nurses in the Adult ED during the study period.

Access to care improved dramatically in the post-intervention period, as the number of patients in our study doubled (pre-intervention 102 vs. post-intervention 222). These findings concur with the results from Meretoja et al's. (2012) study, which suggested that more ischemic stroke patients can be treated with thrombolytic therapy when DTN times are reduced. Ideally, other single stroke centres will adopt structural changes to increase the rt-PA rates in Canada.

There was a significant decrease in the median LOS between the pre-and post-intervention groups (pre-intervention= 10 days vs. post-intervention= 5 days, p =.004). The sharp decline in LOS is likely due to two factors: 1) the organizational cultural change of repatriating patients early, resulted in many patients continuing their acute care stay at a local community hospital once they were clinically stable and their 24-hour post CT was clear; and 2) more patients had timely care, which likely resulted in an excellent response to the rt-PA. Consequently, these patients were discharged from HSC earlier, provided their 24-hour post CT was clear and no rehabilitation services were needed.

The current study revealed that there was a significant change post-intervention in how stroke patients were triaged. Even though this could be a process variable, we chose to use it as an outcome measure to quantify the impact of nursing stroke education in the ED. The use of the CTAS level one category increased from 46.1% to 94.6% (p < .001), supporting the contention that triage nurses now had a better understanding that stroke is a time-sensitive medical emergency. Our study supports the findings of McGillivray and Considine (2009) who suggested that an increase in the use of a more urgent triage category was viewed as an increased perception of urgency of stroke care by nurses. McGillivray and Considine (2009) alluded to the triage decision as being the first step to towards facilitating timely stroke care in the ED.

In summary, organizational outcomes improved post-intervention. These results suggest that more Manitobans benefitted from best practice hyperacute stroke care. The decrease in LOS suggests that there is a cost reduction for the hospital, as less inpatient bed days are used. Lastly the increased use of the CTAS level one triage category suggests that triage nurses are doing a better job in triaging stroke patients, so they receive timely care, as a stroke patient's hospital stay starts with the triage decision.

Conceptual Framework Revisited

The conceptual framework selected for this study was the Donabedian Framework. A conceptual framework is meant to guide a study though the entire research process. Moreover, it helps to categorise variables within concepts and helps to explain relationships between variables. The Donabedian framework was an excellent fit, as it provided a systematic approach to evaluating the care being delivered. In this study, the structural domain represented setting factors, operational elements, provider factors, and population factors. The process domain evaluated the various processes of hyperacute stroke care, such as DTN time. The outcome domain represented patient and organizational outcomes that were related to hyperacute stroke care. The framework also guided the analysis and the interpretation of the results. Thus, the Donabedian framework was a suitable framework for this study.

Study Limitations

This study had several limitations. These limitations will be addressed within the general context of the study design, methods, and results. As this was a retrospective observational study, which is a type of non-experimental study, it began with an existing phenomenon in the present and looked for a potential relationship that existed in the past. This type of design lacks control, as participants are not randomized, and inherent in this type of design is the inability to address causal relationships. As well, the retrospective nature of the study, based on data from 2008 to 2014, may be viewed as out of date. A prospective study would have allowed for more rigor as the implementation of the intervention could have been controlled and the study measures could have been more carefully selected. However, despite the limitations, the retrospective design was cost effective and an efficient means to address important research questions.

Second, the current study was a single-centre study, with a relatively small sample size, and therefore the generalizability of the study is not optimal. However, our sample was similar to the larger population reported by Ganesh et al. (2014). The small sample may explain why some of the clinical outcome measures were not statistically significant. However, it is important to note that, our study revealed dramatic improvements in most process metrics and some of the outcome measures.

Third, the current study involved three very distinct structural changes: 1) stroke education was provided for all ED staff, laboratory technologists, and CT technologists; 2) performance feedback was provided to the entire stroke team including the neurologists; and 3) a value stream map suggested that sending the stroke protocol patient to a dedicated stroke bed in the resuscitation room would improve patient flow. Having three distinct interventions could be a limitation, as we cannot isolate the impact of each of these changes on the processes of care. Although a single intervention would be easier to measure, the multiple changes had already been implemented prior to initiating this study. That the three components of the intervention in our study could be relatively easily replicated in future studies was also important.

Fourth, there were several limiting factors related to instrumentation. The current study did not measure stroke impairment with a reliable, validated, stroke deficit tool, such as the NIHSS, which has been consistently used in other similar studies (Busby et al., 2015; Fonarow et al., 2011; Fonarow et al., 2014; Ford et al., 2012; Meretoja et al., 2012; Saver et al., 2013; Van Schaik et al., 2015). Moreover, measuring the 30-day or 90-day mortality rates, as reported in other studies (Chee et al., 2014; Ford et al., 2012; Meretoja et al., 2012) would have added depth to our study. However, discharge home and ambulation at discharge, which have been used in previous studies as measures of functional outcomes (Fonarow et al., 2011; Fonarow et al., 2014;

Ford et al., 2012; Saver et al., 2013) were included. Furthermore, since this was a retrospective chart audit, the quality of documentation by the nurses and physicians was critical, and at times, less than optimal. Data quality was dependent on the documentation practices of the emergency nurses, physicians, and neurologists. However, the principal investigator (PI) had worked for several years in emergency and has observed that documentation practices under-represent the nursing care delivered. As well, the PI, who has a strong working knowledge of the ED and the stroke patient population, was the only abstractor retrieving the data from the charts in medical records, which added strength in the data collection procedures.

Fifth, although mortality data was collected as all cause *in-hospital* mortality and *7-day* mortality, there are limitations with these measures. For example, *in-hospital* mortality may have been caused by other factors, such as pneumonia or a urinary tract infection; however, the current study did not capture the cause of death. Although we were unable to measure stroke severity because the NIHSS was not consistently documented, 7-day mortality is associated with stroke severity and early neurological deterioration (Saposnik et al., 2008). While 7-day mortality may also have been influenced by the organizational culture change, collecting data on the mortality of patients who are repatriated, as well as 30-day mortality of all study patients, should be considered in future studies.

Finally**,** several possible confounding variables were identified. To our knowledge there were no concurrent stroke initiatives taking place on the inpatient units, although inpatient nursing or allied health stroke care may also have impacted outcomes. In addition, the current study did not capture the success or failure of the EVT procedure. Patients who had a successful EVT procedure would have likely had significantly better outcomes than if they only had rt-PA or an unsuccessful EVT procedure. However, the total number of cases that had an EVT procedure during the study was very low. Other unidentified confounding variables may also have influenced the clinical outcomes of patients in the current study.

In summary, although this study had several significant limitations, there are also numerous strengths. This time-efficient and cost-effective study generated a large amount of unique observational data on acute ischemic stroke patients who received rt-PA, which will guide the organization in developing further strategies to provide optimal stroke care.

Implications and Recommendations

This study has important implications and recommendations for nursing on many levels, including clinical practice, nursing management and administration, education, and future research.

Nursing Practice

The main implications of this study for nursing practice focus on measuring stroke severity, delivering timely stroke care, blood pressure management, and clinical practice guidelines. Each of these points will be addressed in turn.

Measuring stroke severity. There is an urgent need for all health care providers in Manitoba (i.e., physicians, nurses, and allied health professionals) who assess and care for stroke patients to utilize a stroke deficit tool. Using the NIHSS stroke deficit tool, which is a reliable and validated tool would allow for an objective measurement of stroke impairment. The NIHSS could also be used as an ongoing assessment tool to monitor effectiveness of rt-PA treatment. The recommendation would be to complete a baseline NIHSS score, one at 24 hours post rt-PA, and one upon discharge. Implementing the NIHSS stroke deficit tool at the provincial level would also be beneficial when stroke patients are repatriated to their catchment hospitals, or transferred to HSC for comprehensive stroke care, because all health care providers would be speaking the same language when assessing stroke impairment. Utilizing the NIHSS score would also add rigor to future stroke research and facilitate comparisons with the work of others, as the NIHSS is commonly used in the stroke literature studies.

Timely stroke care. One coincidental area of practice change identified in the current study was in the nurses' triaging of acute stroke patients. Triage nurses were significantly more likely to score patients as a CTAS level one in the post-intervention period. Arguably, this practice change was due to stroke education, as the HSC ED triage nurses understood the urgency of acute stroke. Triage is the critical entry point and first step within the hospital system that can facilitate or impede timely care. Therefore, nurses are in a unique and vital position to advocate for timely stroke care.

Since *time is brain*, front line nurses need to champion timely stroke care for the following four reasons. First, the current study revealed that patients with shorter OTD times were treated more slowly than patients with longer OTD times, suggesting that there is a discrepancy in the timeliness of care when a patient arrives in hospital. During the initial phase of a stroke protocol, nursing provides one-to-one care, making nurses the ideal advocates for ensuring that timely care occurs.

Second, the 2015 CSBPR suggests that a median DTN goal of ≤ 60 min is no longer ambitious enough; stroke programs should be achieving a median (50th percentile) DTN ≤ 30 min (Casaubon et al., 2015; HSF, 2016). It is nursing's role to remind the members of the stroke team that the clock is ticking! Turning on a timer, such as a resuscitation clock, when the patient arrives, and assigning a nurse the task to remind the stroke team of the time would help the stroke team achieve these new goals.

Third, although not significant, the current study revealed that stroke patients arriving after hours received less timely care than patients arriving during regular daytime hours, demonstrating that a discrepancy does exist with timeliness of care. Since nurses are with the patients 24/7, we become the perfect advocates for ensuring that timely care happens.

Fourth, time is brain and timely care also involves arriving at the hospital as quickly as possible after the onset of stroke symptoms. All nurses - community hospital and public health nurses in particular - can make a difference by advocating for the FAST campaign. Our study suggests that most stroke patients arrived with a motor or speech deficit, supporting the use of the FAST stroke recognition campaign. The ED stroke team, does not have direct control over the OTD time interval, however, indirectly through educating our patients and families on FAST, we can make a difference on getting patients to hospital more quickly.

Blood pressure management. Front line nursing plays a critical role in physiological monitoring of stroke patients, particularly with blood pressure monitoring. Blood pressure is an important predictor of outcomes, as elevated readings during and post rt-PA administration are associated with an increased risk of an intracranial hemorrhage. Therefore, vigilant monitoring is required. Knowledge of normal/abnormal parameters, and how to manage abnormal results is essential for an optimal clinical outcome.

Clinical practice guidelines. Clinical practice guidelines, such as the Canadian Stroke Best Practice Recommendations: Hyperacute Stroke Care Guidelines, Update 2015 (Casaubon, et al, 2015) are current practice guidelines that help to guide hyperacute stroke care. Stroke protocol documents, such as institutional policies, clinical pathways, algorithms, and order sets, should reflect these guidelines. Institutional policies, which address all stroke team members' roles and responsibilities, should reflect 'standard of care.' Although Stroke algorithms do exist for the HSC Adult ED, inpatient units, and the WRHA, outlining the pathway of a stroke protocol patient, these documents are outdated. Hyperacute order sets, which have already been written, need to move through the approval processes quickly and be disseminated. And, although a regional clinical practice guideline does exist to guide *acute inpatient* nursing stroke care, guidelines for hyperacute stroke nursing care must also be established.

Nursing Administration

The current study lends support for several important recommendations for nursing leadership. These recommendations are related to stroke unit care, Tele-Stroke sites, quality of care, NIHSS implementation, and EVT.

Stroke unit care. Despite the positive outcomes from this quality improvement project, WRHA nurse leaders need to continue to advocate for best practice stroke care across the stroke continuum, especially regarding the acquisition of an acute stroke unit. Clinical outcomes are influenced by the care received during the acute inpatient stay, after they leave the ED, which is usually five to seven days in length. Evidence (Casaubon et al., 2016) suggests that patients treated on a stroke unit are more likely to survive, be independent, and return home, compared to stroke patients who do not receive care on a stroke unit. Stroke unit care is provided by a multidisciplinary team (i.e., nurses, physiotherapists, occupational therapists, physicians, and speech language pathologists) that is experienced in stroke care (Casaubon et al., 2016). This type of unit is usually at a geographic location, such as the HSC, that clusters stroke patients. Our province is currently the only province in Canada without an acute stroke unit. Clinical outcomes for all types of stroke would improve with stroke unit care. Therefore, there is an urgent need to lobby senior leadership and stakeholders for a stroke unit.

Tele-Stroke sites. The current study's' finding that OTD times were considerably longer for rural patients strongly supports the need for TeleStroke sites that deliver best practice hyperacute stroke care. These longer OTD times also translated into longer OTN times. Not only will TeleStroke sites decrease OTD and OTN times, they will also improve access to hyperacute stroke care for all Manitobans. Nursing leaders need to advocate for the ongoing implementation of TeleStroke–Hyperacute sites in Manitoba, as well as a framework to sustain TeleStroke care. A framework for TeleStroke–Hyperacute accountability and sustainability is a good fit within the new Shared Health Services Manitoba model (Peachey, Tait, Adams, & Croson, 2017), which is currently being implemented as part of the provincial health care reform initiative.

Quality care. Concerns regarding quality care are universal in health care; therefore, investing in stroke quality metrics monitoring would be prudent. Stroke quality metrics are relatively easy to collect, and provide valuable insight into the performance of the stroke team; however, they are currently not consistently collected. Data could be collected through periodic audits or ongoing quality indicator data collection. Based on the current study findings, as well as those of others (Casaubon et al., 2015; Fonarow et al., 2014; Ruff et al., 2014; Saver, 2010), providing performance feedback improves the quality of care a stroke team delivers. Hence, to sustain quality hyperacute stroke care it is vital that stroke quality metrics are monitored, and performance measures are disseminated to the stroke team. Furthermore, since the Donabedian framework provided excellent structure for evaluating hyperacute stroke care, nursing administration should learn from this research project and consider applying the principles of the Donabedian framework when planning, implementing, and evaluating other quality improvement initiatives. For example, the Donabedian framework could be used to evaluate care in settings such as trauma care or cardiac care, or any quality improvement initiative at the unit level.

NIHSS. Nurse leaders are in a unique position to successfully implement the NIHSS stroke deficit tool, as they are the consistent point of care for ongoing patient assessments. Investing in NIHSS education and implementation strategies would benefit all stroke patients, improve overall stroke care, and be cost effective. Therefore, it is strongly recommended that regional and provincial nursing leaders endorse the use of the NIHSS scale as the standard stroke deficit assessment tool. Furthermore, implementing the NIHSS would facilitate more seamless and smoother transitions in stroke patient transfer and repatriation processes. Similarly, allied health leadership should consider implementing a standardized functional assessment tool for their practitioners, such as the FIM or mRs. The use of such functional assessment tools would standardize care across the province and streamline the process of acquiring a rehabilitation bed.

Endovascular therapy (EVT). EVT for acute stroke is now the standard of care for acute stroke with large vessel occlusion. EVT, which is only offered in Manitoba at HSC, is still in its infancy. To the best of our knowledge, no performance monitoring has been done with respect to this new therapy. Consequently, investing in a performance-monitoring strategy for EVT would be worthwhile, as currently there is no information on how this new program is performing in terms of process and outcomes. Processes of care for EVT also should be documented, to standardize care; in time the service should be offered provincially. Even more important, performance monitoring would provide evidence and the rationale for requesting future resources for EVT therapy.

Education

Two types of ongoing education are needed: public education and health care provider education. Educating the public about stroke recognition is of utmost importance, because seeking ***immediate*** medical treatment increases the likelihood of a positive outcome. To this end, the “FAST” campaign was launched in 2014 (HSF, 2015). The aim of this simple messaging was to improve public stroke recognition and to educate the Canadian public that stroke is a medical emergency. Ongoing public education should focus on groups such as, schools, seniors’ organizations, and large businesses. This type of education will increase access to timely hyperacute stroke care and therefore increase the chances of a positive outcome following a disabling stroke.

The FAST message should also be disseminated to all health care providers, regardless of practice setting. The importance of being able to recognize the signs of stroke, and rapidly transport the patient to the closest hospital that delivers hyperacute stroke care, is critical for an optimal outcome. For example, a nurse working in a community health setting, home care setting, rural acute care hospital, remote nursing station, busy triage desk at tertiary care centre, or an inpatient unit, must know how to recognize stroke, and what action to take, and be ready to act quickly. Knowing the process of where and how to mobilize the suspected stroke patient to the appropriate hyperacute care setting is critical, because prompt recognition and rapid intervention by nursing staff will save lives and impact post-stroke outcomes.

Incorporating the FAST messaging in all nursing education programs, and medical and allied health programs is essential to the future of stroke care. Similarly, paramedics also play a critical role in the stroke chain of survival. Provincial and urban paramedics already follow stroke protocols; however, a reminder of the critical importance of timely care would be valuable, especially in relation to the findings of this study and the new national benchmarks.

The importance of ongoing hyperacute stroke education in the stroke centre EDs cannot be over-emphasized. Hyperacute stroke nursing is much more than just starting an IV! Knowledge and understanding the stroke protocol will impact outcomes. Furthermore, being technically proficient at hyperacute stroke nursing, such as assisting with stabilization of airway, breathing or circulation if compromised, performing initial patient assessment, facilitating diagnostics, and preparing and administering rt-PA, will reduce DTN times. Hyperacute stroke education is important for all members of the stroke team. Clear messaging that addresses the roles of the various team members during the stroke protocol, the importance of adhering to national benchmarks, and ultimately that stroke is a time-driven emergency, needs to be provided at regular intervals, due to high staff turnover rates in this area.

Since the incidence of stroke will likely soar in the next few decades, as the population ages and stroke victims are becoming younger, investing in education at all levels of the stroke continuum is critical. Two distinct areas of education are needed: public education and provider education that impacts the OTD time interval; and hyperacute stroke education that affects the DTN time interval at stroke centres. Together we can make a difference.

Future Research.

The current retrospective observational study provided a rich source of data for future research. Several additional studies could be undertaken, building on the current data: 1) Exploring the state of pre-hospital stroke care would provide insight into the early part of the stroke continuum in Manitoba. Current study data could provide insight as to who arrives early versus late and if there is an association between OTD and clinical outcomes. 2) Exploring whether there is a difference in the type of care provided, and clinical outcomes, for rural versus urban patients; this may lend support for additional TeleStroke sites in Manitoba, and answer the question: “is geography a barrier to optimal stroke care in Manitoba?” 3) Study the effect of arrival times as “on” hours (0730-1700) versus “off” hours (1701-0729). This may provide valuable information related to clinical practice, possible barriers to optimal stroke care, and rationale for increased availability of staff and resources after hours.

Although the current study has answered several questions pertaining to OTN times, such as the characteristics of patients arriving early in the window, exploring OTN further would also provide insight on how clinical outcomes are associated with arrival time within the thrombolytic window. Researchers (Saver et al., 2013) have explored clinical outcomes of patients with OTN times in the following categories: 0-90 minutes; 91-180 minutes; and 181-270 minutes. As OTN is the sum of OTD and DTN, this research could be of value to the public and pre-hospital care providers.

The current study framework, and specifically the SPSS database that was established as part of the thesis project, could provide the bases for ongoing data collection for patients who receive rt-PA at HSC Adult ED. Since the framework to collect data already exists, it would be simple to expand this study sample by including data from 2015, 2016, and 2017. This would likely double the sample size, which would add rigor to the data analysis and perhaps impact some of the non-significant clinical outcomes found in this study. This extended study could also answer the question: “Are we sustaining and or improving our performance in providing timely hyperacute stroke care?”

Implementing Hyperacute–TeleStroke sites in rural Manitoba is a provincial initiative that will improve access to best practice hyperacute stroke care for all Manitobans. To date, the implementation process has not been completed. Using the framework from the current study would be useful when evaluating the impact of the new Hyperacute-TeleStroke sites. Furthermore, comparing the processes of care and clinical outcomes at TeleStroke sites versus urban stroke centres would provide important data both towards sustaining the TeleStroke program and about rural/remote access to stroke care in general.

Since EVT is now the new standard of care for acute strokes with large vessel occlusion (Casaubon et al., 2015), the processes of care and the outcomes from EVT need to be explored, as they remain unknown at HSC. This is important research, which would determine if our organization is meeting the national benchmarks associated with endovascular therapy. Answering these questions would provide insight into the direction our institution and the Province needs to take to build this critically important program.

Future studies should also explore 30-day mortality as an outcome indicator, since early repatriation of stroke patients to their catchment hospital is now part of our organizational culture. Gathering data on stroke patients who did not receive rt-PA during the study period would also be of value. Comparing patients who received rt-PA versus patients who did not receive rt-PA, pre-and post- quality improvement initiative, would add an element of control and rigor to the current study data, as well as future research.

Qualitative research questions have also been generated from the current study. Manitoba has a large population of First Nations people. Exploring how the experiences of First Nations people compare to other ethnicities may provide insights into possible disparities in care. Additionally, the lived experiences of stroke victims and their families who have received care at HSC Adult ED and the perceived barriers to timely stroke care, from the perspectives of the patients and staff in the HSC Adult ED could be useful for informing nursing practice, as well as organizational structure and processes of care.

This study has revealed several important implications for nursing within the areas of clinical practice, administration, education, and future research. Furthermore, this study has revealed the key role the public plays in the stroke chain of survival, as optimal outcomes start with early recognition. While the impact of stroke will likely worsen in the coming decades, nurses can make a difference by doing their part in lessening the impact and improving the outcomes of stroke.

Knowledge Translation.

The results of this study will be shared within the organization, specifically with the staff of the HSC Adult Emergency Department, Neurology Program, and leadership team. This will be done by formal presentations. The intent is also to share the findings within the Winnipeg Regional Health Authority, especially with Saint Boniface Emergency Department as it also provides hyperacute stroke care within the region.

The principal investigator is also involved in developing rural stroke centres within the province; therefore, the study findings will be disseminated at the provincial level. For example, the research findings will be presented at the College of Nursing Seminar Series, which uses Manitoba Telehealth videoconferencing technology to disseminate research findings across the province. Upon project completion, the findings will be disseminated more broadly through abstract submissions to national conferences, such as the Canadian Stroke Congress, the Canadian National Emergency Nursing Association Conference, and/or the Canadian Council of Cardiovascular Nurses Conference. Also on the local level, the intent is to share the findings with Heart and Stroke Manitoba, and the ambulance service. As well, a manuscript will be submitted to a scholarly neuroscience journal.

Chapter Summary

A discussion of the study results has been presented in this chapter. Structural results, process metrics, clinical outcomes, and organizational outcomes were reviewed within the context of the existing literature and the study setting. The Donabedian framework was revisited, and found to be an excellent fit to guide this study. Study limitations were described and recommendations for nursing practice, administration, education, and future research were discussed.

Our DTN quality improvement project was a success on several levels. First, there were no costs incurred by the health care system. Second, the post intervention period saw the development of an effective, efficient collaborative team. Third, there were dramatic process improvements in the post-intervention period. Finally, clinical outcomes for acute ischemic stroke patients who received rt-PA improved; organization performance also improved.

This study provides strong evidence for organizations to invest in monitoring the quality of stroke care being delivered. In order to provide the consumer quality care, organizations first need to know how they are performing. If the quality of care is suboptimal, an initiative to improve the quality of care should be undertaken and performance should be remeasured. Additionally, the type of quality improvement initiative that is implemented should be evidence based. The current study has also shown the value of using the Donabedian framework in assessing, implementing and evaluating quality care

Conclusion

This thesis project accomplished the primary research objective to apply the Donabedian structure, process, outcome framework and explore if the structural and process improvements in the HSC Adult ED resulted in improved clinical outcomes for stroke patients. Through a nursing lens, and while using the Donabedian framework as a guide, the current study found that there was a reduction in *in-hospital* mortality and an increase in favorable discharge locations, which were likely associated with our DTN quality improvement initiative. Furthermore, the Donabedian framework helped illustrate the linkage between the three domains. The initial findings by Ghrooda et al. (2012), which suggested that significant process improvements resulted from the DTN quality improvement initiative, were verified by this study. Despite being a relatively small, retrospective study, this thesis research will contribute to the existing stroke literature. Moreover, valuable insight into hyperacute stroke care in Manitoba has been achieved.

Although hyperacute stroke care is dependent on the performance of a multidisciplinary team, nursing is key to the success of this team, because nurses are with their patients 24/7, making stroke recognition and advocating for timely care critical components of nursing care. Therefore, nursing leaders must seize this opportunity to promote nursing's role in optimal stroke care.

Furthermore, this study provides a framework for Manitoba stroke centres or TeleStroke sites to evaluate and/or improve hyperacute stroke process metrics and clinical outcomes. However, despite the overall advancements in stroke care our hospital has achieved, there continues to be room for improvement. We need to look for ways to deliver care faster, and strive to achieve the new national benchmarks. Echoing the words of stroke experts, "The question now is not whether we can extend the window of treatment, rather how do we get everyone treated faster” (Hill & Coutts, 2014, p. 1905).

Our stroke centre needs to celebrate this achievement! However, it is a very small piece of a large puzzle, and we cannot lose site of the bigger picture of best practice stroke care to further reduce the current and impending impact of stroke. Hence, all parts of the stroke continuum need to be addressed, including stroke prevention, stroke recognition, pre-hospital care, acute inpatient care, rehabilitation, and stroke reintegration. Since the Canadian landscape is showing that the population is aging, and since stroke victims are becoming younger, this thesis research project is timely, as it provides local context and highlights the importance of best practice hyperacute stroke care and its impact on patient outcomes. Thus, the goal to establish the foundation for health care leaders and decision makers to make informed decisions related to stroke care has been accomplished.

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APPENDIX A

Quality of Stroke Care in Canada, Key Quality Indicators

#	Key Quality Indicator	Rationale and Target
1	Proportion of population aware of 2 or more signs of stroke, based on FAST (face, arm, speech, Time)	HSF FAST impact outcome measure Target: 10% improvement over previous year.
2	Median time rom patient arrival to hospital (recorded triage time to first brain imaging scan (first slice time) in minutes	Measure of ED/hospital system efficiency, process Target ≤ 15 minutes
3	Proportion of all ischemic stroke patients who receive treatment with rt-PA	Measure of access, appropriateness, process Target: >21% at 25th percentile and 28% at 10th percentile of top performing hospitals for patients arriving within 4.5 hours at advanced and comprehensive stroke centres; (based on Canadian Stroke Audit)
4	Median time from patient arrival in the emergency department (recorded triage time) to administration of rt-PA (start of bolus) (in minutes).	Measure of efficiency, process. Target: median (50th percentile) of 30 minutes; 90th percentile 60 minutes
5	Median time from stroke symptom onset (and/or last seen normal [LSN] time) to administration rt-PA (start of bolus) (in minutes).	Measure of efficiency, process. SBP: less than 4.5 hours Target: TBD
6	Proportion of all thrombolyzed ischemic stroke patients who receive acute thrombolytic therapy within 30 minutes and within one hour of hospital arrival.	Measure of efficiency, process. Target: median (50%) within 30 minutes; 90th percentile within 60 minutes. 13
7	Proportion of patients with symptomatic intracranial hemorrhage within 24 hours of receiving rt-PA (includes ICH, SAH, IVH, SDH).	Measure of effectiveness, outcome. Target is less than 6% for IV alteplase
8	Proportion of all ischemic stroke patients who receive acute endovascular treatment.	Measure of access, appropriateness, process. * Targets TBD and will be dependent on regional and institutional characteristics and system organization

		for stroke. (Developmental target is >10% of cases) 15
9	Median time from arrival at a comprehensive stroke centre to arterial puncture (groin or other access point) for patients undergoing acute endovascular treatment (minutes)	Measure of efficiency, process. Target: Target: median (50th percentile) of 60 minutes; 90th percentile 90 minutes
10	Median time from stroke symptom onset (and/or last seen normal [LSN] time) to arterial puncture (groin or other access point) for patients undergoing acute endovascular treatment (minutes)	Measure of efficiency, process. SBP: less than 6 hours, with select cases < 12 hours. Target: TBD

APPENDIX B

Clinical Data Abstraction Form

Stroke-25 Quality Assurance Project: Secondary data

AGE: _______

GENDER: Male / Female

Arrived by EMS: Yes
No
Unknown

ED ARRIVAL TIME: year ________ month______ day ______ time______

Symptom onset/last seen normal: year_____ month______ day______ time______

TYPE OF SYMPTOMS: weakness
Sensory issue
Balance problem
Visual disturbance
Speech disturbance

NIHSS score: __________ not documented ☐

CT Time: year _____ month _______ day _______ time _______

rt-PA needle time: year_____ month ______ day ______ time ______

If delay reason why: __________________________

Onset to Door time interval: _____ minutes

Onset to Needle time interval: _____ minutes

Door to Needle time interval: ______ minutes

Door to CT time interval: ______ minutes

CT to Needle time interval: ______ minutes

Primary Data required from chart review

Presence or absences of Co-morbidities as documented on patient history:

Hypertension:	Yes	No
Diabetes:	Yes	No
Current smoker:	Yes	No
CAD/MI:	Yes	No
Atrial Fibrillation:	Yes	No

Peripheral Vascular Disease: Yes No
Carotid stenosis: Yes No
Dyslipidemia: Yes No
Prior Stroke or TIA: Yes No

Charlson Comorbidity Index: ________

Postal code: ________ (first 3 digits):

CTAS score: _________

GCS score: ___________

Baseline Blood Pressure: Systolic ______ Diastolic _______

Baseline Glucose: ________

Outcomes

In-hospital mortality: YES NO
Date: year_____ month ______ day ______

Secondary intracranial hemorrhage within 36 hours of rt-PA: YES NO

Life threatening bleed: YES NO

Ambulatory status at discharge: Ambulatory without another's assistance (independent)
Ambulatory with assistance
Non-ambulatory

Discharge disposition: Home
Acute rehabilitation
Long term care facility
Death

Discharge FIM score: _____

Discharge mRs: ________

Discharge NIHSS score: ________ not documented □

Discharge date: year _______ month______ day ______