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The South Carolina Telestroke Program:
Does County-level Telestroke Access Increase the Odds that Patients Will Receive t-PA?

BY

Steven M. DiLembo

A doctoral project submitted to the faculty of the Medical University of South Carolina in
partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

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Abstract

Abstract of Doctoral Project Presented to the
Executive Doctoral Program in Health Administration & Leadership
Medical University of South Carolina
In Partial Fulfillment of the Requirements for the
Degree of Doctor of Health Administration

THE SOUTH CAROLINA TELESTROKE PROGRAM:

DOES COUNTY-LEVEL TELESTROKE ACCESS INCREASE THE ODDS THAT
PATIENTS WILL RECEIVE T-PA?

Steven M. DiLembo

Chairperson: Dr. Annie Simpson

Committee: Dr. Jillian Harvey

Committee: Dr. Mark Persin

Stroke is a disease that is responsible for disabling more of its victims than any other disease in the United States. There are four types of stroke. However, ischemic stroke is responsible for 87% of all strokes. T-PA is a pharmaceutical that has proven an effective treatment for ischemic stroke patients since 1996. T-PA works by dissolving the thrombosis that has become lodged in a brain vessel. This pharmaceutical has its limitations; mainly it must be administered within 4.5 hours of symptom onset. Nationally, the medical field experiences low utilization rates, between 3-5%. The many variables that affect this low usage rate, however, this study focuses on patient's

residence in a county that offers telestroke services compared to counties that do not have telestroke services.

In completion, of the necessary research, archival data from the 2013 Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) for South Carolina was utilized. Hospital encounters that had a primary diagnosis code of 424.xx & 436.xx (ICD-9-CM) were identified for analysis. The analysis revealed 9,311 South Carolinians suffered a stroke in 2013 while a total of 461 patients were administered t-PA (4.95%). The study found a greater percentage of patients living in “Telestroke Access” counties received t-PA compared to those that did not, 5.11% to 4.76%, respectively. However, the county in which patients resides was not a statistically significant indicator because of the p-value = 0.36.

Keywords: Telestroke, ischemic stroke, barriers in telestroke, tissue plasminogen activase, telestroke effectiveness, benefits of telestroke, treatments of acute ischemic stroke, and utilization rates of t-pa

CHAPTER 1: INTRODUCTION

Stroke is a disease that is responsible for causing more disability to its victims than any other disease (Silva & Schwamm, 2012). In the United States alone, 780,000 strokes occur annually. In 2014, it was the cause of death in 1 in 16 people. (Kazley, Simpson, K., Simpson, A., Jauch, & Adams, 2013). Although there are many different types of stroke, the type with the highest rate of occurrence is ischemic, comprising 87% of all strokes (Demaerschalk, Hwang, & Leung, 2010). This type of stroke is responsible for a large burden on society with; 30% of those who survive become permanently disabled, and 20% require inpatient care for three-months post event. Not only is this costly for the patient, but also costly on society. In 2008, indirect and direct costs associated with stroke totaled \$65.5 billion dollars (Demaerschalk, Hwang, & Leung, 2010). The amount cited above is important, because the majority of people who suffer a stroke have their health care financed by the American taxpayer through Medicare (Bonilha et al., 2011). Obviously, something needs to be done to reduce the impact stroke has on patients and society.

In 1996, the FDA approved a revolutionary treatment for stroke a named pharmaceutical called Tissue Plasminogen Activator (t-PA), which is a thrombolytic agent—working to dissolve the clot in the patient’s vessel inside the brain. T-PA has been used with great success over the years, but due to its strict indications for use, only 3-5% of stroke patients receive t-PA in the United States. The factor most responsible for its limited utilization is the limited period in which t-PA can be administered after initial onset of stroke symptoms, which is no more than 4.5 hours. This window may seem sufficient to some, however, taking in consideration the events leading up to t-PA

administration often takes many hours (Sliva & Schwamm, 2012). Recognition of symptoms occurs by oneself, family, friends, or medical professionals. The FAST method facilitates early identification of stroke symptoms: F (Face Drooping), A (Arm Weakness), S (Speech Difficulty), T (Time to Call 911) acronym. If the patient is not already under the care of medical professionals the order of events consists of the following: alerting first responders, travel time to a medical facility, entering the Emergency Department, triage, rooming, further assessment, diagnostic tests, and eventually administering t-PA. In addition to the time constraint, other barriers exist to receiving t-PA, such as the availability of the thrombolytic agent or of trained staff in house to assess, diagnose, and treat stroke patients. If the facility does not have access to the medication, it would not be possible for the patient to receive it, even if the patient was assessed and the decision to administer t-PA was made. Additionally, the lack of specially trained neurologists or emergency medical physicians in the facility when a stroke patient arrives also prevents or lowers the likelihood of t-PA administration (Silva & Schwamm, 2012).

A potential solution to this problem is to utilize technology to improve the access to specialty stroke providers and bring the highly-specialized stroke specialists to the patient's bedside, regardless of distance. The solution is commonly referred to as telestroke. The term telestroke is a broad term and is defined differently by many agencies, some of which will be described later. However, telestroke can be used as a tool to foster greater rates of administration in this nation's stroke patient population, increasing the 3-5% national benchmark. For example, a study in South Carolina on REACH-MUSC reported a 35.7% rate of t-PA administration following telestroke care

(Lazaridis, DeSantis, Jauch, & Adams, 2013). The goal of this work is to investigate differing rates of t-PA administration based on the proximity of the patient to a medical facility prepared to treat stroke patients. If the rates are shown to increase compared to national averages in areas with greater accessibility, and stakeholder insurers, both public and private, reimburse for this type of telehealth service, more hospitals would designate the capital necessary to implement this technological solution. However, to support this argument more research must be conducted to show the utility of telemedicine or telestroke. The question this study will answer is if patients that live in counties offering telestroke services realize higher rates of t-PA administration compared to patients who live in counties that do not offer telestroke services.

To accomplish this goal, one must review the current literature available surrounding the major topics related to stroke and its effects on society and family, t-PA, telehealth, barriers to adoption, and others pertinent topics. The goal is to bring awareness to the national community of caregivers, insurers, and policy-makers with the purpose of fostering change and saving lives and financial resources.

CHAPTER 2: LITERATURE REVIEW

Impact on Society:

According to various sources, stroke is the fourth most common cause of humans and third most common killer of Americans (Joubert J. et al., 2008), behind heart disease and cancer in 2004 (Demaerschalk, Hwang, & Leung, 2010). Stroke affects 780,000 people in the United States per year (Demaerschalk, Hwang, & Leung, 2010), costing the American public roughly \$65.5 billion dollars (Demaerschalk, Hwang, & Leung, 2010). Stroke is also the leading cause of long-term disability in the United States; 30% of stroke survivors suffer from permanent disability, while 20% will require institutional care three-month post event (Demaerschalk, Hwang, & Leung, 2010). It is important to note these figures do not include individuals who succumb to this event and die.

Two types of stroke are responsible for the enormous amount of affected lives and money spent—ischemic and hemorrhagic. Ischemic stroke is the most common, comprising 78% of all strokes; hemorrhagic strokes comprise 22% (Demaerschalk, Hwang, & Leung, 2010). It is astounding the impact stroke has on society as a whole; the figures above describe this fact. However, what they do not describe is the effect on the family of those who suffer from stroke.

Impact on Family:

Families of stroke victims are affected in many ways. Those who experience a loved one dying from stroke suffer from the loss of life. At times the death alone is not the only impact. When the deceased was a source of funding for the family, such as a working mother or father, the family must adjust not only to the death of a loved one but

also the lost income. If the deceased leaves children behind, someone must raise the children, or the children will suffer from lost guidance and parenting.

As the statistics indicate not all stroke victims succumb to death. Many of the survivors face the long-term effects of the disease. The survivors often require care and assistance with activities of daily living (ADL). These activities, taken for granted before the occurrence of a stroke, include feeding, dressing, and toileting, which to be addressed as soon as the patient cannot perform independently. When the survivor suffers from aphasia, the victim may lose his or her ability to communicate effectively (Healthclop.com, 2013). Depending on the family's life situation and severity of the stroke, family members of the stroke survivor, such as the spouse, adult children, or parents of the survivor may be thrust into a new role as a caregiver. This change in role for both the caregiver and survivor often is difficult to handle for both parties. Caregivers may find themselves withdrawing from life as they knew it to care for their loved one, sacrificing social, professional, and emotional aspects of their life to provide the level of required care. Often this change of lifestyle due to the demand of providing varying degrees of care can negatively impact the caregiver, causing anxiety and depression. At the time of stroke, the family members are not entirely aware of the resulting level of care required. Some strokes may be mild while others are debilitating. It may be difficult for the stroke survivor to accept the care from a spouse, child, or family members due to previously established family roles. Beyond the potential impacts already listed, new people who find themselves in the role of the caregiver may see a worsening of their physical condition, especially when pre-existing conditions are present.

However, taking on the role of caregiver is not always viewed in a stressful manner (Gillespie & Campbell, 2011). Instead, some caregivers experience a higher level of personal importance in their lives and thrive as a result of learning new skills. One study found, 90% of caregivers developed a greater appreciation for life, 81% reported that caring for others caused them to feel good about themselves, and 67% expressed encouragement from the opportunity of learning new skills (Gillespie & Campbell, 2011). Stroke is a disease that can kill, disable, change, and enrich life, but what is a stroke? How does it affect the body leaving such a lasting impact on the sufferer and those who develop into caregivers?

Stroke:

“Stroke is a disease that affects the arteries leading to and within the brain” (ASA, 2016, “What is a Stroke?,” para. 2). From this basic definition, there are two types of stroke, hemorrhagic and ischemic. A hemorrhagic stroke occurs when an artery within the brain leaks or ruptures. The blood leaked fills areas in the brain cavity, applying pressure to the brain. This pressure applied to the brain causes brain cell death, resulting in an intracerebral hemorrhage. Also, similar to the intracerebral hemorrhage, a subarachnoid hemorrhage is similar, but the blood collects and applies pressure between the brain and the thin tissue called meninges that covers the brain (CDC, 2016).

The other type of stroke is called ischemic. Ischemic stroke accounts for 85% of strokes. Ischemic strokes occur when an occlusion occurs in a blood vessel in the brain, preventing continued blood flow to the areas of the brain beyond the blockage. That

organic barrier causes cells to starve and eventually die from suffocation or starvation, resulting in an ischemic stroke (CDC, 2016).

Not as severe as a full ischemic stroke, a Transient Ischemic Attack (TIA) is often referred to as a mini-stroke. This stroke takes on the same physiological characteristics as an ischemic stroke. However, the blood flow is only momentarily blocked for anywhere from a few minutes to a few hours, then blood flow resumes without medical intervention (CDC, 2016). TIAs are considered a warning for a much larger and threatening stroke (CDC, 2016). These mini-strokes should be treated with as much caution as a full ischemic stroke. In fact, the CDC reports greater than a third of people who suffer from a TIA will have a severe stroke within one year following a TIA if treatment is not received (CDC, 2016). If treatment is not pursued, 10-15% of these people will suffer a major stroke within three months of the TIA (CDC, 2016).

Assessment of a Stroke:

The evaluation of a stroke patient is conducted with the use of the NIH Stroke Scale. The stroke scale is a systematic quantitative neurologic assessment used to evaluate a patient's level of consciousness, ability to follow commands, facial palsy, and other post stroke features (Mitka, 2009). When a patient with signs of stroke presents to an emergency department, a neurologist needs to be consulted to determine the existence and classification of a suspected stroke. These evaluations can occur utilizing traditional workup or by using a version of telemedicine known as telestroke. Telestroke is similar to video conferencing and allows the physician to rapidly examine the patient from a remote location (Mitka, 2009).

Physiology of Ischemic Stroke:

An ischemic stroke is general defined as an obstruction in a brain vessel that prevents blood from freely flowing through, preventing oxygenated and nutrient laden blood from reaching the areas past the occlusion (ASA, 2016). There are four types of ischemic strokes: thrombotic, embolic, systemic hypoperfusion, and venous thrombosis (Deb, Sharma, & Hassan, 2010). In a thrombotic stroke, a thrombus forms in arteries that supply blood to the brain (Hopkinsmedicine.org, n.d.).

An embolic stroke is similar to a thrombotic but differs in the origin of the clot. The clot, in this case, develops outside of the brain and is carried to the brain via the blood stream. The clot could form in the lungs, heart, or other various locations in the body. Once the clot reaches a vessel, the embolus can no longer continue to flow freely and becomes lodged, creating a blockage and preventing life sustaining nutrients from passing further downstream (Mangla, Kolar, Almast, & Ekholm, 2011).

A systemic hypoperfusion or Watershed/Border Zone stroke, is grouped into two categories. The categories are determined based on the location of the lining of the brain; external are located in the cortical region while internal occur in the subcortical region (Mangla, Kolar, Almast, & Ekholm, 2011).

It is hypothesized, “that decreased perfusion in the distal regions of the vascular territories leaves them vulnerable to infarction. Internal border zone infarcts are caused mainly by hemodynamic compromise, whereas external border zone infarcts are believed to result from embolism but not always with associated hypoperfusion” (Mangla, Kolar, Almast, & Ekholm, 2011, para. 1).

Finally, venous thrombosis is similar to a thrombotic stroke except the blocked vessel is carrying blood to the heart for reoxygenation as the occlusion occurs in a vein. No matter the type of stroke, the effects are dangerous. According to the neurologist Dr. Kenneth Gaines, every minute brain cells are starved of oxygen approximately two million cells die (Morrissey, 2013).

Diagnosis of Acute Ischemic Stroke:

Diagnosis of stroke often begins far from medical professionals and facilities. In fact, the initial identification of onset is by those around the person at the time of symptom presentation. The symptoms commonly experienced or observed are facial palsy (drooping), arm weakness, or slurring of speech. The acronym usually associated with the presence of these symptoms is F.A.S.T. with the "T" signifying it is time to call 911 (ASA, 2016). Once Emergency Medical Services (EMS) is notified of a possible stroke, a crew is dispatched within 90 seconds, with the goal of reaching the patient in less than nine minutes. Upon arrival, the first responders will begin assessing the patient for the presence and type of stroke. Two of the most commonly used assessment tools are the Cincinnati Prehospital Stroke Scale (CPSS) and the Los Angeles Prehospital Spinal Stroke Scale (LAPASS) (Nentwich, 2016), which help the emergency providers assess severity and type of stroke. The information gained during this critical time can influence where the ambulance crew rushes the patient for continued care. As a result of the evaluations, the providers may be able to determine if a large vessel stroke is occurring, then divert to facilities with the resources and staff to adequately treat this type of stroke. Once the ambulance arrives at the emergency department, the patient is immediately

received for further assessment and care. It is important to note, those patients that do not arrive by ambulance may have treatment delayed due to normal Emergency Department wait times depending on number of patients already present in the department. Patient assessment in the emergency department centers around the rapid identification of those individuals having a vascular event. The assessment includes a rapid evaluation by an Emergency Medicine Physician (less than 10 minutes upon ED arrival) of anyone suspected of having a stroke. A thorough history including last known well time, age, types of symptoms, medications (specifically antiplatelet agents, warfarin, novel oral anticoagulants) and past medical history (CAD, HTN, DM, TIA/CVA, PVD, seizure, tobacco or illicit drug use) is obtained. Additionally, a detailed exam of visual fields, extraocular muscles, speech impairment, weakness or sensory deficits, incoordination, ataxia is performed.

Additionally, physical examination determines if basic life functions are satisfactory. If not, for example, a patient may require intubation secure the airway ensuring oxygen saturation. Upon reaching a state of stabilization, vital signs are assessed and neurological deficits are monitored.

The assessment tool often completed at this stage is the National Institutes of Health Stroke Scale (NIHSS). This tool looks for patient performance in areas ranging from “level of consciousness, language, neglect, visual-field loss, extraocular movements, motor strength, ataxia, dysarthria, and sensory loss” (Nentwich, 2016). Based on the clinician’s findings, the patient is rated on a scale of 0-42. A score of less than 5 equates to a minor stroke, while a score greater than 20 signifies a severe stroke.

In efforts to determine the cause of visible symptoms, medical staff rely on imaging studies. First, a noncontrast computerized tomography (NCCT) study is completed to determine if a hemorrhage exists. Identifying a possible hemorrhagic stroke is necessary because administering t-PA for an ischemic stroke during a hemorrhagic stroke can result in patient death. Often an NCCT is the only radiological study completed before a patient is treated for an ischemic stroke. However, other variants of CT scans may be used to gather greater details of the characteristics of the stroke, including both CT with angiography (CTA) and CT perfusion (CTP). A CTA helps determine intra- or extra-cranial arterial circulation for blockages or hardening of the vessels. A CTP provides information on blood volume, blood flow, and transit time for blood to perfuse throughout the brain (Nentwich, 2016). Lastly, an MRI will help determine the type of stroke and the prognosis. Determination of prognosis is based on the details provided on extent of damage and location of the brain affected (Nentwich, 2016). A diagnosis is reached based on information from multiple sources, including those with the patient at the time of the stroke, EMS, as well as hospital staff.

Treatments of Acute Ischemic Stroke:

Clinicians have known for decades reperfusion was essential to treat ischemic strokes successfully.

Initial studies in the 1950s used streptokinase and urokinase, isolated from *Streptococcus* strains and human urine, respectively. Intracerebral hemorrhage (ICH) was a leading cause of death in these early investigations, which preceded computed tomography (CT) technology. In the 1960s, Meyer and colleagues used

diagnostic angiography to perform investigations, first comparing intravenous (IV) plasmin with placebo, then combination therapy with streptokinase and heparin versus heparin alone. Although the former showed no benefit in the plasmin treated group, the latter showed greater mortality and ICH in the streptokinase-treated group. The MAST-E (Multicenter Acute Stroke Trial-Europe) and MAST-I (Multicenter Acute Stroke Trial-Italy) trials of streptokinase in the 1990s further confirmed increased risk of ICH and mortality, leading to the eventual abandonment of it as a treatment for [Acute Ischemic Stroke] AIS (Nentwich, 2016, “Reperfusion with Intravenous Thrombolysis,” para. 1).

In 1996 the FDA approved treatment for ischemic stroke using Tissue Plasminogen Activator (t-PA) for revascularization. T-PA is administered intravenously into the patient’s body. The medication’s purpose is to reach the thrombus and dissolve the clot, allowing blood to resume flow through the brain, supplying needed oxygen and nutrients to the affected areas of the brain.

While this drug has achieved great success in preventing death and disability, there are guidelines that must be met which dictate its use. The patient must have suffered from a non-hemorrhagic stroke, and this determination must have occurred within 3-4.5 hours after the first observed symptoms of stroke (Stroke Foundation, 2017).

An optional adjunctive treatment to t-PA administration is mechanical thrombectomy. In a mechanical thrombectomy, a physician will attempt to remove the blockage by use of a stent retriever. This procedure is only completed after t-PA has been administered and no more than six hours post onset of symptoms (ASA, 2016). In this

procedure, the device is threaded through vessels to reach the clot. Once the clot is reached the device will open allowing the clot to be captured, removing the thrombus from the vessel (ASA, 2016).

Barriers to t-PA Administration:

The following can prevent stroke sufferers from receiving t-PA: lack of the public's knowledge of stroke identification, lack of inadequately trained, and prepared clinicians, lack of infrastructure to support telestroke, and physician licensure requirements. Given the lifesaving and disability preventing abilities of this drug, clinicians should be more open to administer t-PA to as many Ischemic stroke sufferers that meet the guidelines. However, only 3-5% of AIS patients receive t-PA (Silva & Schwamm, 2012).

The first barrier is the lack of public awareness in identifying the symptoms of stroke. The most commonly known symptoms of stroke are facial droop, slurred speech, arm and leg weakness, but often these items while observed or experienced are not taken seriously. Many patients or family members will wait to seek medical advice for various reasons including waiting to see if the symptoms will resolve, not understanding the severity of the situation, or preferring to contacting their PCP (Eissa, Krass, & Bajorek, 2012). This lack of action leads to many patients delaying their treatment, if they seek treatment at all. In fact, less than 20% of AIS victims arrive at a hospital within three hours of symptom onset (Eissa, Krass, & Bajorek, 2012). The main reason for this missed or ignored recognition of symptoms is simply the lack of public knowledge. If the public was widely familiar with the signs of stroke onset, proper action could occur, preventing

late arrival to the ED, which reduces clinicians opportunity to treat patients with t-PA.

EMS education surrounding stroke may be a barrier for many reasons. When an ambulance is called for a potential stroke patient, first responders may not be equipped with the proper knowledge to identify a stroke, nor gauge its severity. EMS staff may not be aware of the screening tools available to assess stroke patients under their care. In fact, 28% of stroke patients are not identified while in the care of paramedics due to the lack of EMS knowledge (Eissa, Krass, & Bajorek, 2012). Additionally, first responders may transport the patient to the nearest hospital instead of a facility properly equipped for thrombolysis. As an example of this occurrence, a study in Switzerland found that 20% of stroke patients were transported to hospitals that do not administer t-PA (Eissa, Krass, & Bajorek, 2012). Patients transferred to facilities that lack thrombolysis services will only have an opportunity to receive t-PA if they are later transferred to a facility that administers t-PA, yet subsequent transfers only reduce the already short window for t-PA administration.

First responders and paramedics are not the only health care professionals that are lacking in preparedness to properly care for stroke patients. As one can imagine, not all patients will arrive via ambulance. Those patients who arrive by other methods will enter the ED and will process through triage. Previous studies have found opportunities for improvement exists during this phase of care. If the nurses are not adequately educated to identify a stroke rapidly and accurately, further delay in care can result (Eissa, Krass, & Bajorek, 2012). After triage for a suspected stroke, a protocol or code should be initiated. Some EDs do not have efficient workflows, inhibiting the execution of a stroke protocol. It is crucial these protocols be established and well rehearsed. These workflows should

ensure that necessary diagnostics and staff notification occur. As important as the protocols are, the staff caring for stroke patients need to be educated on best practices in caring for a stroke patient.

Most clinicians are knowledgeable and professional. However, institutions that may not see a high number of stroke cases will need to remain up-to-date on clinical practices. Additionally, some providers are hesitant to administer t-PA because they lack familiarity with the drug or have had unwanted results from a past case. One study investigating barriers to using thrombolysis found 40% of 2,600 emergency medical physicians are unlikely to use t-PA, even under ideal conditions (Eissa, Krass, & Bajorek, 2012). The researchers also reports the result of a survey conducted in Los Angeles, "60% recognized that thrombolysis should be administered within 3 hours, and 28% indicated that they did not even consider the use of thrombolysis in AIS" (Eissa, Krass, & Bajorek, 2012). It is important to point out that emergency medical providers create most emergency departments' policy and procedures. If these providers are uncomfortable with or knowledgeable about proper utilization of t-PA, policies will reflect this same confusion (Eissa, Krass, & Bajorek, 2012). In light of this type of preparedness/practices emergency departments moving towards nontraditional stroke treatment models. Some health care institutions are moving away from on-site clinicians for reasons stated previously. The nontraditional models being migrated to are based on technology that bridges the gaps identified in the previous paragraph. This move utilizes technology and is called telestroke, a form of telehealth.

Telehealth, however also has its barriers to functionality, installation, and implementation. Telestroke is defined as,

“Telemedicine involves the use of videoconferencing, which incorporates a dedicated, high-quality, interactive, bidirectional audiovisual system, alongside the use of teleradiology that enables the remote inspection of brain scans. This system allows the bedside and distant (expert neurologist) clinicians to clearly see and hear each other in full colour via the use of appropriate cameras and display screens” (Eissa, Krass, & Bajorek, 2012).

The barriers that often exist with telestroke include the following: lack of a reliable and fast internet connection, expensive audio/video conferencing equipment, insufficiently trained staff, and insufficient funds to implement and maintain this solution (Eissa, Krass, & Bajorek, 2012). Through telestroke a neurologist can assist the care team on-site from a remote location. There is no real limitation on distance from the remote provider to the patient and the on-site care team. However, because telestroke care allows for care remotely, from anywhere in the world, legal barriers often arise.

Because providers are often licensed to practice in one state, out-of-state consultation and referrals can be a challenge when licensure is considered. Much can be learned from teleradiology, which is responsible for 50% of all telemedicine that occurs in the United States. For example, some states are offering special telemedicine licenses for radiologists, and some physicians who practice outside of the states that allow a special license are seeking licensure in all 50 states. In addition to state licensure presenting a potential barrier, hospital credentialing is also a concern. Typically, physicians need to have credentials in the hospitals where they practice, yet this can be difficult, time-consuming, expensive, and redundant. However, in 2011 CMS made this process easier "by allowing hospitals to rely on the credentialing and the privileging

decision of the distant hospital where the consulting physician practices" (Weinstein et al., 2014). Each of the barriers that can slow or even prevent the administration of t-PA need to be resolved to increase the currently low utilization rate of t-PA.

Telestroke:

Although telestroke can present itself as a barrier, telestroke can also be used to correct gaps in stroke care to be corrected by its capability. Telemedicine, according to the American Heart Association, is "the use of telecommunication technologies to provide medical information and services" (Perednia & Allen, 1995). This definition is a vague but accurate definition of telemedicine because it does not focus on one device or technology. The history of telemedicine use ranges from telephones and fax machines to two-way video and audio conferencing between a patient and an off-site provider. As long as an electronic medium is used to transmit medical information, it is classified as telemedicine. (Demaerschalk et al., 2009). This exchange of data has existed in some form since the early 1900s. During this time the ability existed to transfer electrocardiograms and electroencephalograms through analog telephone lines. In the 1920's, medical advice and information was transferred by the use of Morse code and two-way radios. It was not until the 1960's, however, that the medical profession was able to transmit information using methods similar to those used today. Currently, with the advances in technology, personal computing devices, and the Internet, patients and providers are now able to communicate with one another on opposite sides of the globe, if needed. As one can imagine, telemedicine can be applied in many different practices. Some of the areas that this technology is used include "dermatology, oncology, out-patient burn victims follow-up, radiology, cardiology, psychiatry, emergency medical

services, rural medicine, nephrology, urology, emergency department, home health” (Duchesne et al., 2008), and stroke.

Just as there are many uses of telehealth as detailed above, there are many settings in which telestroke is utilized. One common schema of stroke telehealth is referred to as “hub and spoke.” This system is made up of a centralized location, the *hub*, and satellite facilities in areas lacking appropriate staff and resources, the *spokes*. The hubs are located in metropolitan areas while the spokes are in rural or underserved areas. (Demaerschalk et al., 2009) The components used in these systems are typically “high-resolution digital camera, microphone, speaker, a server for scan storage, and a monitor for the patient to view the telestroke practitioner” (Demaechalk et al., 2009). To better illustrate the use of telehealth in stroke, a case example is provided below.

A 75-year-old female resident of a rural community identified the sudden onset of left facial droop, slurred speech, and weakness and numbness of the left arm and leg at 3:30 PM. She presented to the local emergency department of the spoke hospital at 4:21 PM, at which time the emergency department physician examined her and initiated a stroke alert. Blood samples were drawn, CT was completed, and the spoke center activated the telestroke hub hotline. The hub center’s on-call stroke neurologist responded. After the patient had undergone CT, the telestroke camera system was placed in front of the patient and the consultation began at 5:08 PM. The patient and her family interacted with the stroke neurologist via the camera system, answered questions, and engaged in the consultation. The spoke emergency department nurse assisted the stroke neurologist with the examination and the laboratory results. The stroke

neurologist zoomed in on the cardiac monitor to observe the patient's electrocardiographic results, heart rate, blood pressure, respiratory rate, and oxygen saturations. During the AV telemedicine examination, the stroke neurologist simultaneously accessed the CT by a Digital Imaging and Communications in Medicine system. Through examination via the AV camera system, the NIH Stroke Scale score was determined to be 6. After the clinical, laboratory, and CT examinations were complete, the neurologist requested the presence of the emergency physician and the daughter at the bedside to discuss the plan for care. At 5:53 PM the stroke neurologist reviewed the observations and recommended the administration of t-PA. The spoke emergency department initiated t-PA at 6:09 PM. The hub stroke neurologist dictated a consultation and faxed it to the spoke center emergency department. (Demaerschalk et al., 2009)

In addition to telestroke practice in the above manner, delivery of care without allowing geography to act as a barrier is a possibility. Consistent with telestroke advances, health care is seeing a treatment technique for stroke called "drip and ship." This technique is utilized when a patient presents to a satellite facility, sometimes a rural hospital lacking specialized physicians, and the patient is evaluated and found to have stroke symptoms. The patient is administered t-PA (drip), and after administration and stabilization, is transferred to a medical hub for further treatment and evaluation (Pervez et al., 2009).

The Cost of Telestroke:

Although it can be a lifesaving technological enhancement when applied in the appropriate circumstance, the implementation of telestroke is not without its drawbacks.

In fact, this offering to the community is very expensive. In the hub and spoke model described above, it is not uncommon for a spoke on average to spend \$46,000 annually, while the possible figure can range from \$10,000 to \$200,000 (Demaerschalk, 2010). Factors that would affect this annual cost are the type of facility, utilization rates of the telestroke service, hardware and software selection, case complexity, and follow-up needs. Additionally, post-installation of the technology maintenance fees for hardware and software also add to the total cost. The funds required to support and sustain this technology are difficult to obtain. Many telestroke programs are dependent on public funding in the form of grants or subsidies (Demaerschalk, 2010). In recent years, telestroke and other telemedicine programs have realized more public and private insurance reimbursement, but more revenue sources are needed to enable widely-available telestroke access.

Reimbursement of Telestroke:

Medicare is the insurer that is responsible for the greatest number of stroke patients in the US, paying for an estimated 72% of strokes (Bonilha et al., 2014). Because of that overwhelming percentage, Medicare is consulted for guidance regarding future reimbursement for telehealth and telestroke services.

Currently, there are some Medicare reimbursement requirements Medicare. The main requirement is the *originating site* clause, which “is the location of an eligible Medicare beneficiary at the time the service is furnished via a telecommunication system” (DHHS, 2015). Furthermore, Medicare patients must also be at an originating site in a "rural Health Professional Shortage Area (HPSA) located either outside a

Metropolitan Statistical Area (MSA) or in a rural census tract; or a county outside of a MSA" (DHHS, 2015). The DHHS also describes the technological functionality required: the patient must receive audio and visual telecommunication that fosters real-time communication between the remote provider and the patient (DHHS, 2015). In some circumstances asynchronous or "store and forward" is permitted but only in specific programs (DHHS, 2015).

Medicaid has a greater variance in regulation than Medicare, which are largely based on the respective state's ability to define what is covered by the state's plan. In 2013, 42 states included some telemedicine services in their plans. The amount of coverage varies considerably. California, for instance, has no limiting guideline preventing telehealth services based on geographic area, while other states follow a Medicare-like approach, permitting services only in rural localities (Horton, Malcarney, & Seiler, 2014).

Other payers besides Medicare are beginning to offer reimbursement for telemedicine, but there has not been an universally recognized insurance policy to this point. Some states have required insurers to pay for these services while privately insured plans are not included in these laws. In 2013, 16 states required insurance agencies to pay for telehealth services. However, many of these state laws are not following Medicare's approach to underserved areas. In fact, Maryland prohibits any insurer from distinguishing between rural and non-rural areas (Horton, Malcarney, & Seiler, 2014).

Cost Attributable to Rehab Care:

Stroke disables more people than any other medical condition in the United States. As a result of stroke's high incidence and often-debilitating effect on its sufferers, it costs the nation greatly. In fact, the net present value per admission into a nursing home as a result of a stroke is \$29,296 (Taylor et al., 1996). Additionally, the mean lifetime cost for ischemic stroke sufferers was estimated to be \$123,565 per person (Taylor, Davis, Torner, Holmes, Meyer, & Jacobson, 1996). Two resulting disorders caused by stroke that often cause people to seek rehabilitation care are aphasia and dysphagia.

Aphasia is a speech disorder that affects around 100,000 stroke survivors annually (Ellis, Simpson, Bonilha, Mauldin, & Simpson, 2012). The disorder leaves the patient with an impaired ability to communicate. The difficulties caused by this disorder result in greater need for medical resource utilization, as well as greater morbidity and mortality. Clearly, greater resources are needed to care for these patients, otherwise increased rates of medical complications will increase the cost of caring for these patients. It has been estimated that the increase in medical expenditures is \$1,703 for stroke patients with aphasia, versus a patient who does not experience aphasia post-stroke. Further, an increase in the length of stay (LOS) has been determined to increase costs by 6.5% (Ellis, Simpson, Bonilha, Mauldin, & Simpson, 2012).

Dysphagia is also a common post-stroke condition. The difficulty of swallowing characterizes this medical condition. This condition is common for stroke patients, occurring in 37-78% of stroke patients (Bonilha et al., 2014). Dysphagia is also known to cause a need for a higher level of medical treatment and expenditures in stroke patients

that encounter this disorder compared to those that do not (Bonilha et al., 2014). The comorbidities of this disorder include dehydration, worse long-term outcomes, and increased risk of aspiration pneumonia (an infection in the lungs resulting from inhaling food or liquid into the lungs). The article titled, *The One-Year Attributable Cost of Post-Stroke Dysphagia*, reported that 64% of stroke patients that require inpatient rehabilitation care suffer from varying degrees of dysphagia. Just as aphasia has a higher financial cost to treat, so does dysphagia. This disorder is said to cost \$4,510 more to treat when present (Bonilha et al., 2014). The increased cost is associated with increased need for hospital resources utilization, discharge to a skilled nursing facility, and extra durable medical equipment. On average, dysphagia increases stroke health care costs by 23% and results in a 30% increase in length of stay (Bonilha et al., 2014).

Aphasia and Dysphagia are costly, both financially and medically. Having one or both of these conditions will cause impairment and increase the costs of care for both the insurer and the patient. It is important to note that Medicare is the insurer for 72% of all stroke patients, meaning the United States and its taxpayers fund the majority of stroke care (Bonilha et al., 2014). Knowing how impactful stroke is medically and financially to the survivors and the nation, anything that can be done to improve stroke outcomes should be pursued.

Underutilization of t-PA:

T-PA is a pharmaceutical that can have a great impact on a patient suffering from a stroke if administered within the 3-4.5 hour window. Patients who experience a better outcome are those that receive the drug with the least amount of time having elapsed

between onset of symptoms and administration of t-PA. Between these two points many factors that can contribute to delay prolonging or prevent administration. Many of these factors were discussed in the Barriers section of this work. However, additional factors are relevant and contribute to the utilization of t-PA. In the United States, there are Primary Stroke Centers (PSC) and Comprehensive Stroke Centers (CSC). These facilities possess properly trained staff, streamlined workflows, and the necessary facilities and equipment to treat stroke patients. While these types of facilities are well prepared to deal with stroke patients, they do not represent the majority of acute care medical facilities (Demaerschalk, 2010). The majority of PSCs and CSCs are located in metropolitan areas, while 40% of the United States population lives in the countryside. This disparity does not augur well for those that live outside the immediate service areas of these specially designated facilities.

In addition to lack of properly equipped facilities, many other variables contribute to the low administration rate of t-PA to acute ischemic stroke patients. These variables include the lack of timely identification of stroke symptoms, delays in reaching a medical facility, unavailability of properly prepared medical staff, misdiagnosis of stroke, and the short t-PA administration window. An investigation is needed to uncover additional information that describes low utilization. Uncovering this information will empower the medical systems to save greater lives and reduce the rates of disability.

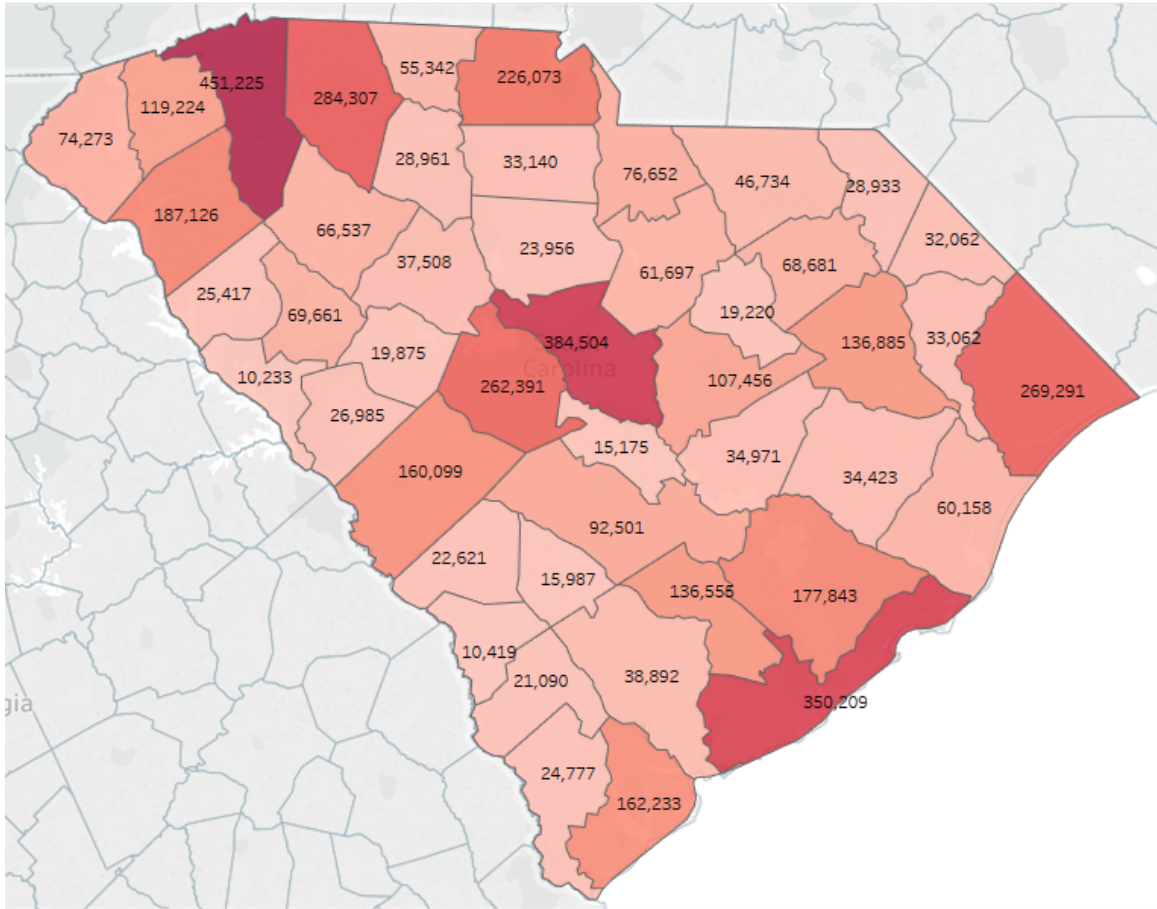
Utilization of t-PA in South Carolina:

Traditionally, states in the South and Midwest have had the lowest rates for t-PA administration (Samson, Trivedi, & Heidari, 2015). These low rates are believed to be the

result of a lack of accessibility to t-PA prepared facilities (Samson, Trivedi, & Heidari, 2015). The distance between patient residence and medical facilities causes the inaccessibility. In 2013, around one-half of South Carolina's citizens lived within 30 minutes of a stroke center, and 30% lived within 60 minutes. Increased time and distance from stroke centers further delays evaluation, diagnosis, and treatment. South Carolina and other areas that share this characteristic will see greater mortality and disability of their stroke patients. A study titled, "Telestroke Centers as an Option for Addressing Geographical Disparities in Access to Stroke Care in South Carolina, 2013", found that counties in South Carolina without a PSC within 30-60 minutes are found to have higher death rates than South Carolina counties that do have a PSC within 30-60 minutes (2015). The authors of this study also reasoned that if telestroke equipped facilities were more prevalent, the rate of mortality could decrease. The two charts below provide references of population per county in South Carolina and counties that have telestroke-equipped facilities. As reflected in the charts, many counties are without a telestroke prepared facility.

2010 Census by County

Figure 1

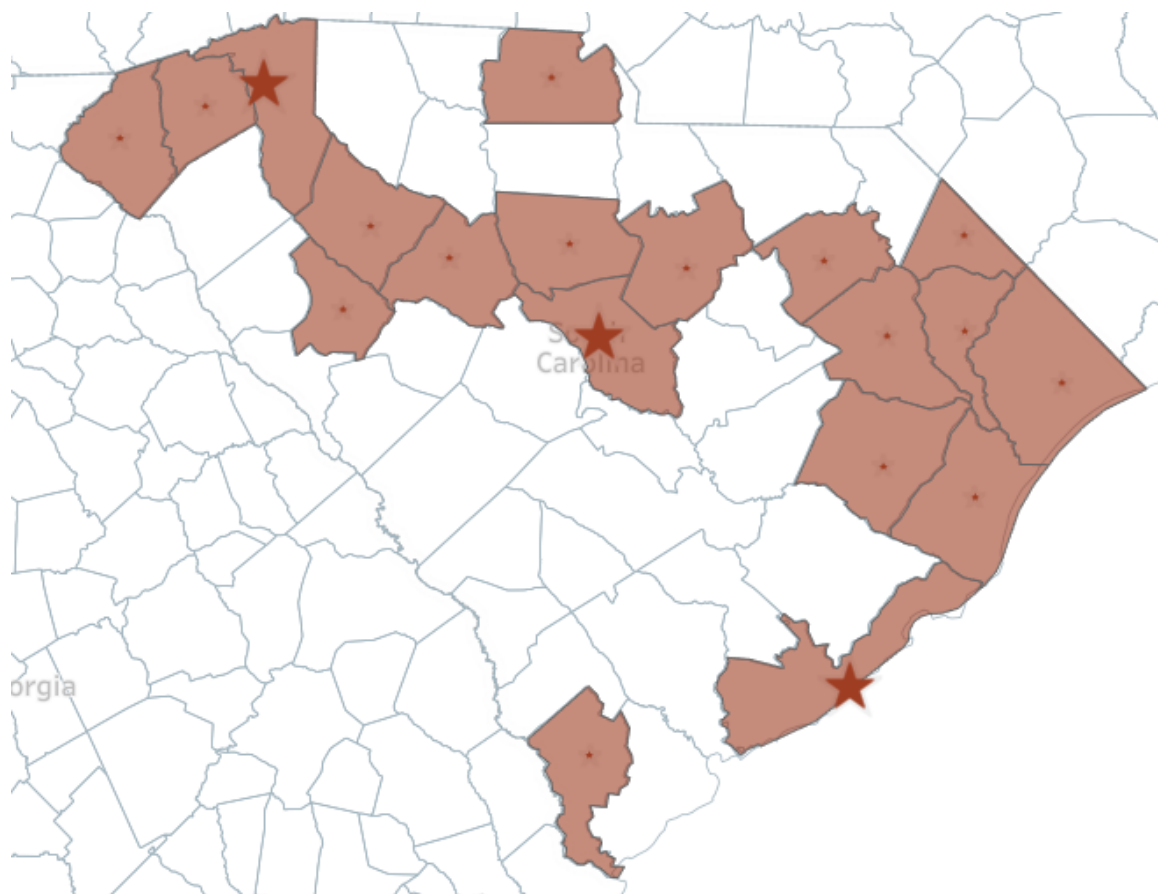


Data retrieved 19Feb2017

U.S. Census Bureau: 2010 Census

Figure 2

Telestroke Facilities by County in 2013

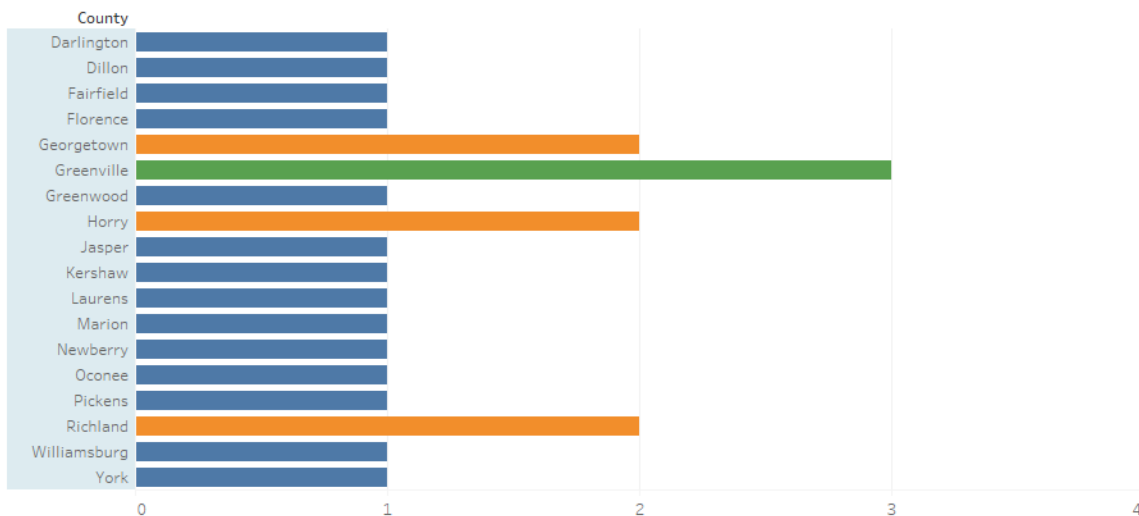


Date Retrieved 8Jan2017

<http://palmettocareconnections.org/telehealth-in-sc/telehealth-services-map/>

Figure 3

Number of Telestroke Sites per County in 2013



Date Retrieved 8Jan2017

<http://www.muschealth.org/telehealth/telestroke/index.html>

The majority of PSC facilities in South Carolina are located in the northwestern part of the state and in the coastal region near Charleston. When the telestroke facilities are factored into available destinations for stroke care, 76% of the population lives within 30 minutes, and 95% are within 60 minutes (Samson, Trivedi, & Heidari, 2015). South Carolina has a few telestroke networks that enable stroke services in more facilities than just the PCSs. One network in particular is called REACH-MUSC, which stands for remote evaluation of acute ischemic stroke at Medical University of South Carolina. REACH-MUSC is a hub and spoke model, with MUSC's main tertiary facility serving as the hub. The hub provides remote access to neurologists, emergency department physician with acute stroke experience, neurointerventionalists, neurointensivists, and neurosurgeons as members of an integrated team. MUSC's team is available 24 hours a day, seven days a week, and 365 days a year. The clinicians at MUSC's hub provide

services to 12 spoke facilities, ranging in size from 25 to 453 beds with the furthest spoke being 187 miles away (Lazaridis, DeSantis, Jauch, & Adams, 2013).

REACH-MUSC operates in the following manner. When a patient arrives at a spoke member of the network, the MUSC Emergency Communication Center (MECC) is called, and the specialists are alerted. The on-call providers enter the REACH website utilizing all connected technology to assist in the assessment and evaluation of the patient. Based on the work-up, a joint decision is made to administer t-PA or not administer the agent (Lazaridis, DeSantis, Jauch, & Adams, 2013). In the article, “Telestroke in South Carolina,” it is reported the REACH-MUSC experienced a 35.7% t-PA administration rate out of a total population of 965 consults. Out of the total population in the study, 525 members of the population had a NIHSS score greater than 3 (Lazaridis, DeSantis, Jauch, & Adams, 2013). South Carolina witnessed a much higher administration rate of the life-saving drug, t-PA when only including participants of REACH-MUSC. The main difference between investigating utilization in only PSC (single facility) compared to a hub and spoke network model is telestroke services are more available (Lazaridis, DeSantis, Jauch, & Adams, 2013).

Following Research:

The possible linkage to greater accessibility and higher rates of t-PA administration when stroke victims reside closer to facilities equipped with telestroke requires study. Using the Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) to identify patients with ICD-9-CM codes of 434.xx (AIS) and if they live in a South Carolina county offering stroke services will be conducted. The goal of

this effort is to determine if patients are more likely to receive t-PA if it is available in their home county. If higher rates of t-PA utilization in counties that offer necessary stroke services are found, this evidence can be provided to hospital administrators and legislators with the goal of increasing the number of counties offering telestroke services. Currently, many barriers that contribute to underutilization are known, but more research is necessary to determine any additional factors.

Hypothesis:

In the state of South Carolina, patients who suffer an ischemic stroke in counties that contain medical facilities offering telestroke services are more likely to receive t-PA compared to patients who live in counties that do not have telestroke services.

CHAPTER 3: METHODS

The data used to test the hypothesis originates from the Healthcare Cost and Utilization Project (HCUP) South Carolina State Inpatient Database (SID). HCUP is a data source populated from many databases ranging from various state-based organizations, hospitals, private, and Federal government databases. The data contained within HCUP consists of encounter-level, inpatient data. The SID data “encompass all patients, regardless of payer, providing a unique view of inpatient care in a defined market” (AHRQ, 2016).

Utilizing the HCUP South Carolina SID two cohorts are defined. The cohorts were defined as "Telestroke Access" and "No Telestroke Access." These cohorts shared the commonality of primary diagnosis of Acute Ischemic Stroke (AIS) and were and were not administered t-PA during an encounter. The “telestroke access” cohort was defined as patients who live in a SC county that offers telestroke services. While the “no telestroke access” cohort included patients who do not live in a county where the hospitals offer telestroke services.

The data used for this study were obtained from the South Carolina State office of Research and Statistics (ORS) and includes all hospital discharge billing records for all South Carolina hospitals in 2013. Because of the de-identifiable nature of the data, it has been deemed non-human research and does not require review by the MUSC Institutional Review Board.

Study Design and Population:

This study is a retrospective observational cross-sectional analysis using secondary data from the year 2013. The population in this study was defined as patients with a primary diagnosis of ischemic stroke, 434.x or 436.x, based on accepted coding standards using the International Classification of Diseases 9th Revision – Clinical Modification (ICD-9-CM) (Reker, Hamilton, Duncan, Yeh, & Rosen, 2001). Additionally, comorbidity and patient demographics were evaluated and controlled for in both patient populations. Comorbidity was accounted for by the use of the Deyo version of the Charlson Comorbidity Index (CCI). CCI was developed to use administrative data to establish a risk-adjusted index, measuring the probability of death within one year (Simpson, A. et al., 2015). The CCI provides researchers the ability to extrapolate the index by processing patients' ICD diagnoses data producing corresponding weighted values (Simpson, A. et al., 2015). In addition to CCI, the Stroke Severity Score (SSI) was utilized. SASI was created to predict the outcome of stroke patients based on stroke severity from data gathered from the NIHSS. Comparison groups were selected by splitting the population into cohort “Telestroke Access” and “No Telestroke Access” based on whether a hospital has submitted at least two bills for telestroke consultations in that year. These codes are provided by the Healthcare Common Procedure Coding System (HCPCS) Level II and are G0425, G0426, G0427 (DHHS, 2015). The existence of these codes designates that a patient has received telehealth consultation either in an emergency department or an inpatient setting for specified amounts of time (CMS, 2016).

Statistical Analysis:

The study's data was evaluated using multivariable regression. The control and predictor variables variable are listed below. Non-control variables are the existence of

telestroke services and administration of t-PA. There is a limited need to control for demographic variables since the data consists of all stroke encounters in South Carolina during the 2013 calendar year. However, comorbidities were controlled for using CCI and SASI. During the initial phase of statistical analysis, descriptive measures of central tendency and variability were completed. In completing these measurements, mean and standard deviation were calculated for each of the variables. When assessing the distribution of the categorical variables, percentages and frequencies were calculated for all categorical data elements. Then the comparison populations were evaluated (patients living in counties with access to telestroke hospitals and those not living in counties having telestroke). Descriptive statistics were performed to examine differences in demographic and patient characteristics between the two groups at baseline using chi-square tests for categorical data, t-tests for normally distributed continuous variables, and the Wilcoxon/Mann-Whitney U test for non-normally distributed continuous variables. Adjusted analysis was conducted using multivariable logistic regression models, giving the odds of t-PA administration between the two groups using adjusted odds ratios. All covariates listed in the descriptive statistics were assessed in the multivariable model. Traditional model-fitting procedures (log-rank tests and Akaike Information Criterion) were used to assess the value of each independent variable in the model (Hosmer & Lemeshow, 2000). Variables were removed from the model if they are not statistically significant (P -value > 0.5) and their removal does not reduce model strength until a final parsimonious best fit model was found.

CHAPTER 4: MANUSCRIPT

The South Carolina Telestroke Program:

Does County-level Telestroke Access Increase the Odds that Patients Will Receive t-PA?

Introduction:

Stroke is a disease that is responsible for causing more disability to its victims than any other disease (Silva & Schwamm, 2012). In the United States alone, 780,000 strokes occur annually. In 2014, it was the cause of death in 1 in 16 people. (Kazley, Simpson, K., Simpson, A., Jauch, & Adams, 2013). Although there are many different types of stroke, the type with the highest rate of occurrence is ischemic, comprising 87% of all strokes. (Demaerschalk, Hwang, & Leung, 2010). This type of stroke is responsible for a large burden on society with; 30% of those who survive become permanently disabled, and 20% require inpatient care for three-months post event. Not only is this costly for the patient, but also costly on society. In 2008, indirect and direct costs associated with stroke totaled \$65.5 billion dollars (Demaerschalk, Hwang, & Leung, 2010). The amount cited above is important, because the majority of people who suffer a stroke have their health care financed by the American taxpayer through Medicare (Bonilha et al., 2011).

In 1996, the FDA approved a revolutionary treatment for stroke a named pharmaceutical called Tissue Plasminogen Activator (t-PA), which works to dissolve the clot in the patient's vessel inside the brain. T-PA has been used with great success over the years, but due to its strict indications for use, only 3-5% of stroke patients receive t-PA in the United States. The stroke patients that have received t-PA have experienced

better outcomes compared to not receiving the thrombolysis. However, many stroke patients throughout the country are not realizing the benefits of this life-saving/disability preventing treatment. There are many reasons that prevent or impede administration of t-PA, however, the one of focus in this work is proximity to facilities prepared for ischemic stroke patients. It is believed, if patients experiencing an ischemic stroke live in a county having access to properly prepared clinical staff and resources to diagnosis and treat ischemic stroke, they will have a greater chance of receiving the brain cell saving drug, t-PA. In research of this hypothesis, a 2013 sample of stroke patients from South Carolina will be analyzed. The data will be reviewed to uncover if stroke patients' county ("Telestroke Access") of residence had necessary stroke treatment resources and if these patients realized greater rates of t-PA administration compared to stroke patients living in counties ("No Telestroke Access") not offering the same resources.

Background:

"Time is Brain" is a phrase used throughout the medical world in reference to stroke. The meaning of this three-word phrase is, for every minute of oxygen loss to the brain two million brain cells die (Morrissey, 2013). This fact is the result of starving brain tissue of oxygen past an occlusion in a brain vessel. When this occurs the blockage prevents the flow of oxygen carrying blood to those areas of the brain beyond the occluded vessel. The goal of treating a ischemic stroke patient is to restore blood flow as quickly as possible limiting the amount of brain cell death.

T-PA is a thrombolytic that when used dissolves the blockage and restores blood flow to the brain. The difficulty experienced with the administration of this drug is the many barriers that prevent its use. First and foremost, t-PA has a short window in which

it can be administered. As specified by the FDA it can only be administered within 3 – 4.5 hours post onset of stroke symptoms. There are many other impediments that play a role in delaying administration, these are: travel time from site of stroke onset to medical facility, preparedness of EMS staff (if their services are utilized), time between entering an emergency department lobby to triage to being seen, the readiness of emergency departments to care for ischemic stroke patients, is the staff properly trained and do they have specially trained neurologist or emergency medical physicians available, assessment of symptoms, diagnosis of ischemic stroke (making sure to rule out hemorrhagic stroke), and finally, decisions to administration t-PA. It is important to note that not all medical facilities receiving ischemic stroke patients have t-PA available for administration. The availability of having access to properly trained staff and physicians cannot be understated. It has been stated, some providers are hesitant to administer t-PA because of they lack familiarity with the drug or have had negative results from a past case. One study investigating barriers to using thrombolysis found 40% of 2,600 emergency medical physicians are unlikely to use t-PA, even under ideal conditions (Eissa, Krass, & Bajorek, 2012). The researchers also reports the result of a survey conducted in Los Angeles, "60% recognized that thrombolysis should be administered within 3 hours, and 28% indicated that they did not even consider the use of thrombolysis in AIS" (Eissa, Krass, & Bajorek, 2012). The above article describes the importance of having access to properly prepared providers in the instance of ischemic stroke patients. Furthermore, the lack of specially trained providers in a facility receiving stroke patients has been shown to lower the likelihood of t-PA administration (Silva & Schwamm, 2012). Of the barriers listed preventing administration of t-PA to qualifying stroke patients of most

importance in this research is the availability of stroke specialists. For safe and effective administration of t-PA these providers should be members of a stroke patient's care team. When they are not, as stated above, patients are less likely to be administered t-PA. Many smaller medical facilities, especially those located in less densely populated, southern and mid-western regions of the United States do not have the stroke specialist on staff or available 24/7 (Samson, Trivedi, & Heidari, 2015). In these instances methodologies can be implemented to reduce the disparities of care.

Telestroke:

Telestroke defined by the American Heart Association (AHA), is "the use of telecommunication technologies to provide medical information and services" (Perednia & Allen, 1995). In providing more detail to AHA definition, telestroke occurs when a stroke patient presents to a medical facility that does not have the needed stroke clinicians available but instead is a member of a telestroke network. One common schema is the "hub and spoke" model. This system is made up of a centralized location, the *hub*, and satellite facilities in areas lacking appropriate staff and resources, the *spokes*. The hubs are located in metropolitan areas while the spokes are in rural or underserved areas. (Demaerschalk et al., 2009). The components used in these systems are typically "high-resolution digital camera, microphone, speaker, a server for scan storage, and a monitor for the patient to view the telestroke practitioner" (Demaerschalk et al., 2009). During the telestroke encounter many gaps in care are eliminated and the specialist at the hub can assist the clinicians at the spoke in diagnosing and providing the proper level of care for the patient based on assessment, diagnostic test results, and properly informing the patient and family members of treatment methodology. Once all of the above is

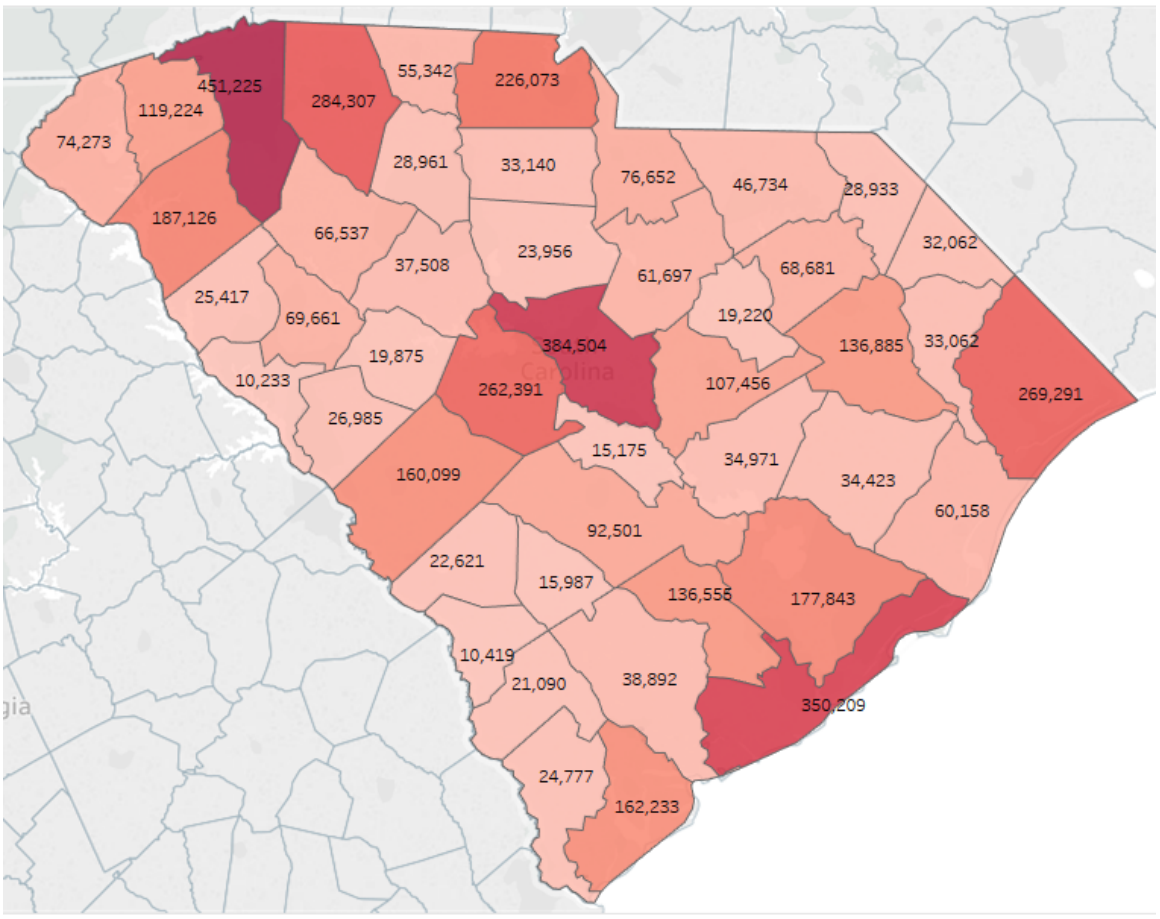
completed the stakeholders collectively proceed with administration of t-PA when warranted. The belief of this research is, patients whom live near a facility that is equipped with telestroke or these specialized providers patients will be more likely to receive t-PA.

South Carolina:

In 2013, around one-half of South Carolina's citizens lived within 30 minutes of a stroke center, and 30% lived within 60-minutes. Increased time and distance from stroke centers further delays evaluation, diagnosis, and treatment, South Carolina and other areas that share this characteristic will see greater mortality and disability of their stroke patients. A study titled, "Telestroke Centers as an Option for Addressing Geographical Disparities in Access to Stroke Care in South Carolina, 2013", found that counties in South Carolina without a PSC within 30-60 minutes are found to have higher death rates than South Carolina counties that do have a PSC with 30-60 minutes (2015). The authors of this study also reasoned that if telestroke equipped facilities were more prevalent, the rate of mortality would decrease. In this study, proximity to telestroke facility is based on if the patient resides in a county designated as "Telestroke Access". South Carolina's "Telestroke Access" counties can be referenced in Figure 1. In Figure 1 the colored counties have access to telestroke resources. The counties designated with a large star are those that possess a hub, all others are considered spokes. There are vast regions of the state do not have "Telestroke Access" and are considered "No Telestroke Access". Figure 2 displays county population data based on the 2010 U.S. Census. This figure shows the relation of population density of counties throughout the state. When one compares

2010 Census by County

Figure. 2



Data retrieved 19Feb2017

U.S. Census Bureau: 2010 Census

Methods:

Database and Study Population:

Data used in this study was obtained from the Healthcare Cost and Utilization Project (HCUP) South Carolina State Inpatient Database (SID). The data collected in this dataset originates from various state-based organizations, hospitals, private, and Federal government databases. The data contained within HCUP consists of encounter-level, inpatient data. This study was completed using data from 9,311 patients with a primary ICD-9-CM diagnosis of stroke (424.xx & 436.xx). The primary diagnosis is assigned to patients post discharge from the hospital based on clinical information gained during patients' encounter(s). ICD-9 codes are used throughout the world for the purpose of statistics gathering and tracking mortality and morbidity. ICD-9 codes are published and updated by the World Health Organization. Additionally, ICD-9 code of 99.10 was used to determine if the patient had received t-PA.

The study was then broken into two cohorts. Each cohort was defined based patients' county of residence. The counties of South Carolina are defined as either "Telestroke Access" or "No Telestroke Access." Each county was placed into this grouping based on data collected concerning if the county has a medical facility that had access to telestroke services (Palmetto Care Connections, 2017).

Statistical Design:

The data used in this research was exempt from the Medical University of South Carolina's IRB process due to being de-identified, it is thus deemed non-human research and does not require review. This study is a retrospective observational cross-sectional analysis using secondary data from the year 2013. The population in this study was

defined as patients with a primary diagnosis of ischemic stroke, 434.xx or 436.xx based on accepted coding standards. Additionally, comorbidity and patient demographics were evaluated and controlled for in both populations. The record was further analyzed for the presence of the ICD-9 code of 99.10, the code assigned when a patient is administered t-PA. Comorbidities was accounted for by using the Deyo version of the Charlson Comorbidity Index (CCI). CCI was developed to use administrative data to establish a risk-adjusted index, measuring the probability of death within one year of event (Simpson, A. et al., 2015). The CCI provides researchers the ability to extrapolate the index by processing patients' ICD diagnosis data producing corresponding weighted values (Simpson, A. et al, 2015). Additionally, severity of stroke was controlled for using the Stroke Severity Index (SSI). SSI was created to predict the outcome of stroke patients based on stroke severity from data gathered from the NIHSS (Simpson, A. et al., 2017).

Statistical Analysis:

The study data was evaluated using a multivariable regression. During the initial phase of statistical analysis, descriptive measures of central tendency and variability were completed. In completing these measurements, mean and standard deviation were calculated for each of the variables. When assessing the distribution of the categorical variables, percentages and frequencies will be calculated for all categorical data elements. Then the comparison populations will be evaluated (patients living in counties with access to telestroke hospitals and those not living in counties having telestroke). Descriptive statistics will be performed to examine differences in demographic and patient characteristics between the two groups using chi square tests for categorical data, t-test for normally distributed continuous variables, and the Wilcoxon/Mann-Whitney U

test for non-normally distributed continuous variables. Final analysis models examining the adjusted “risk” of t-PA administration between the two groups will be reported using adjusted odds ratios and multivariable logistic regression methods. All covariates listed in the descriptive statistics will be assessed in the multivariable model. Traditional model-fitting procedures (log-rank tests and Akaike Information Criterion) will be used to assess the value of each independent variable in the model (Hosmer & Lemeshow, 2000).

Variables will be removed from the model if they are not statistically significant (P-value > 0.05) and their removal does not reduce model strength until a final parsimonious best fit model was found.

The formula used to represent analysis conducted in the study is:

$$\text{Log odds (receipt of t-PA)} = \text{Intercept} + \beta_1 \text{Telestroke} + \beta_2 \text{CharlsonComorbidityScore} + \beta_3 \text{SASISStrokeSeverityScore} + \beta_{4\dots 10} \text{PatientDemographics}$$

The independent variable in this study is “Telestroke Access” vs. “No Telestroke Access”. The dependent variable is whether the patient received t-PA or not and the control variables were age, gender, race, CCI, and SASI. The data was analyzed using SAS statistical software version 9.4 (SAS Institute, Inc., Cary, NC).

Table 1. Demographics and Characteristics of "Telestroke Access" vs. "No Telestroke Access"

| | Overall (n=9,311) | Telestroke Access (n=5,132) | No Telestroke Access (n=4,179) | p-value* |
|-----------------------------|----------------------|--------------------------------|-----------------------------------|----------|
| Age 20-59 ^ | 1595 (17.13) | 853 (16.62) | 742 (17.76) | 0.34 |
| Age 60-74 ^ | 3335 (35.82) | 1844 (35.93) | 1491 (35.68) | |
| Age 75+ ^ | 4381 (47.05) | 2435 (47.45) | 1946 (46.57) | |
| Female ^ | 4739 (50.9) | 2639 (51.42) | 2100 (50.25) | 0.26 |
| Caucasian ^ | 5767 (61.94) | 3159 (61.55) | 2608 (62.41) | 0.39 |
| t-PA ^ | 461 (4.95) | 262 (5.11) | 199 (4.76) | 0.36 |
| Charlson Comorbidity Index† | 1.55 (±1.71) | 1.53 (±4.9) | 1.57 (±1.73) | 0.35 |
| Stroke Sensitivity Index† | 3.61 (±4.84) | 3.73 (±4.93) | 3.46 (±4.72) | <0.01 |

† Mean (±SD)

^ N (%)

*p-values were calculated to compare characteristic differences between the 2013 Telestroke Access Group and the No Telestroke Access Group non-parametric Mann-Whitney/Wilcoxon Scores for continuous variables[†] and Chi-square for categorical variables[^].

Table 2. Patients Seen in South Carolina's Telestroke Counties

| County | Overall N (%) | County | Overall (n =5,132) N (%) |
|------------|------------------|--------------|--------------------------------|
| Richland | 735 (14.32) | Kershaw | 170 (3.31) |
| Greenville | 711 (13.85) | Laurens | 164 (3.20) |
| Charleston | 653 (12.72) | Oconee | 146 (2.84) |
| Horry | 640 (12.47) | Dillon | 115 (2.24) |
| Florence | 399 (7.77) | Marion | 98 (1.91) |
| York | 244 (4.75) | Williamsburg | 96 (1.87) |
| Georgetown | 206 (4.01) | Newberry | 96 (1.87) |
| Pickens | 193 (3.76) | Fairfield | 67 (1.31) |
| Darlington | 181 (3.53) | Jasper | 41 (0.80) |
| Greenwood | 177 (3.45) | | |

All values are expressed in N (%)

Table 3. Patients Administered t-PA in South Carolina's Telestroke Counties

| County | Overall N (%) | County | Overall (n =5,132) N (%) |
|------------|------------------|---------------|--------------------------------|
| Greenville | 61 (8.6) | Georgetown | 4 |
| Charleston | 54 (8.3) | Newberry* | 4 |
| Richland | 46 (6.3) | Darlington | 3 |
| Horry | 19 (3.0) | Oconee | 3 |
| Florence | 16 (4.0) | Fairfield* | 3 |
| Pickens | 15 (7.8) | Williamsburg* | 2 |
| Laurens | 10 (6.1) | Dillon | 1 |
| York | 8 (3.3) | Marion* | 1 |
| Greenwood | 7 (4.0) | Jasper* | 0 |
| Kershaw | 5 (2.9) | | |

* Indicate less than 100 ischemic stroke patients in 2013; second column percentages removed due to small cell sizes.

Results

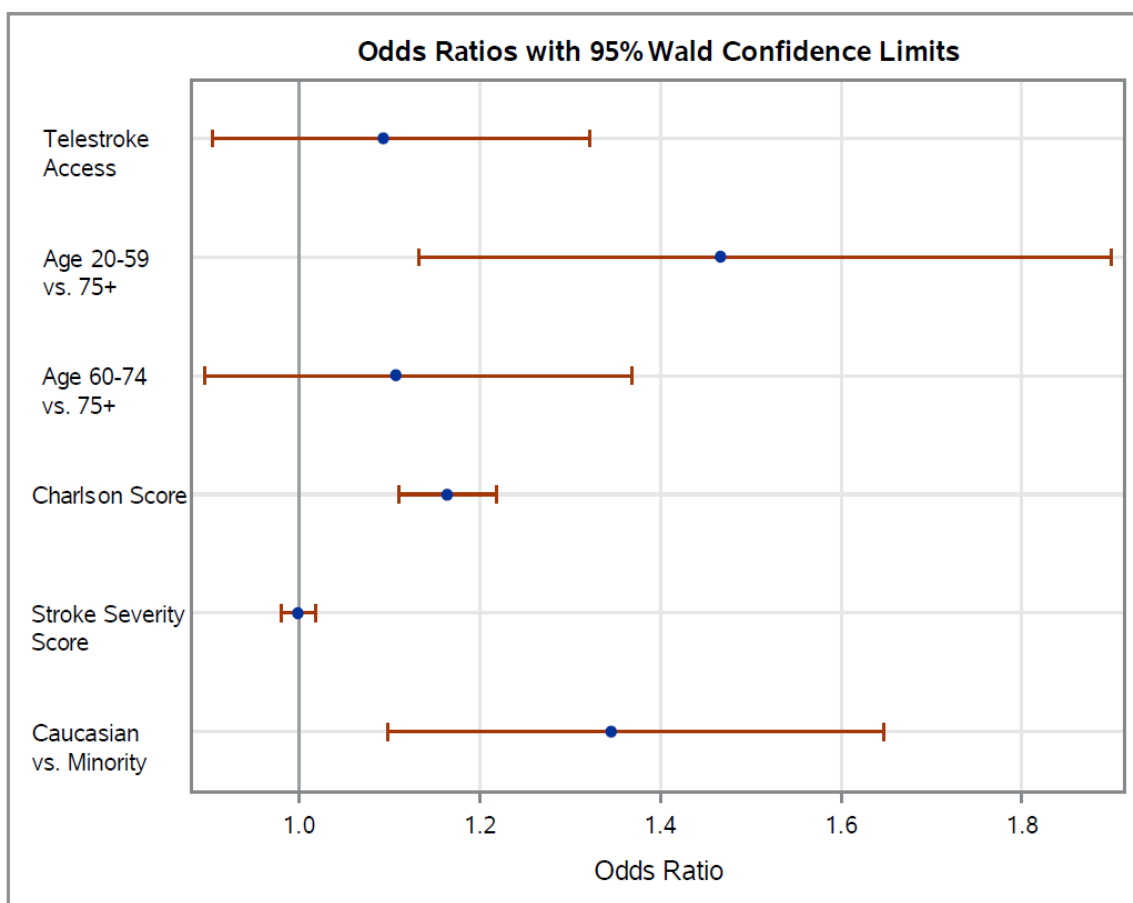
Patient Characteristics and Outcomes:

According to the data presented in Table 1, 9,311 South Carolinians suffered from an ischemic stroke in 2013. Of the 9,311 patients 55.12% (5,132) lived in counties deemed to have telestroke access while 44.88% (4,179) lived in without telestroke access counties. The age breakdown of the population consists 47.05% of patients being 75 years or older, 35.82% between the ages of 60-74, and 17.13% between 20-59. The population is roughly half males (49.1%). There was a greater proportion of females that lived in counties with telestroke access, 2,639 (51.42%) compared to 2,100 (50.25%) without telestroke access. The race of the South Carolina's population consists mainly of Caucasians (61.94%) and minorities. 61.55% of the Caucasians in the study reside in "Telestroke Access" counties. The Charlson comorbidity index scores (high scores indicate higher levels of comorbidity) were similar between the two groups, 1.53 in counties with telestroke access compared to 1.57 in counties without telestroke access (p=0.35). Stroke severity scores were also qualitatively similar 3.73 in counties with

telectroke access compared to 3.46 in counties without telestroke access, however they were statistically different between the groups ($p=0.0043$).

Out of the 9,311 stroke suffers only 461 (4.95%) were administered t-PA, which is similar to published national benchmarks. When estimating the crude rate of t-PA utilization a greater amount of patients that live in a county with “Telestroke Access” more frequently received t-PA, 262 compared to 199 in no-access counties, however this did not reach statistical significance (5.11% vs 4.76% respectively; $p=0.45$).

Figure 3. Adjusted Odds Ratio for Final Model “Odds of t-PA Use”



In adjusted analysis, stroke patients hospitalized in telestroke access counties had a 1.09 higher odds of receiving t-PA when compared to those hospitalized in counties without telestroke access (AOR 1.09, 95% CI 0.90-1.32; p-value=0.34), however this did not reach statistical significance (Figure 3). This multiple logistic regression model controlled for Charlson comorbidity, stroke severity (SSI), age, and race.

Statistics of “Telestroke Access” Counties:

South Carolina is made up of 46 counties. In 2013 only 19 counties (41.30%) provided access to telestroke and related resources. Of the 19 counties, 14 care for more than 100 stroke patients as seen in Table 2. The first 4 counties combined treated the majority of ischemic stroke patients, more than the other 15 counties combined. Three of these four counties also surpassed the average total rate of t-PA administration (Table 3).

Discussion

After examination of the 2013 state of South Carolina’s HCUP SID data a total of 9,311 subjects were diagnosed with ischemic stroke. Of these subjects, only 262 (4.95%) were administered t-PA, which is concordant with national benchmarks for t-PA administration at 3-5% (Silva & Schwamm, 2012). When comparing the cohorts of “Telestroke Access” to “No Telestroke Access” it was found that patients living in a “Telestroke Access” counties do receive t-PA more frequently than the comparison cohort, 5.11% vs. 4.76. However, after adjusted analysis these differences did not reach statistical significant ($p = 0.35$). After completing the research and statistical analysis it was determined the authors failed to reject the null hypothesis. This finding showed there is no difference in rates of t-PA administration between stroke patients living in a South

Carolina county with telestroke access vs. those living in a county without telestroke access.

Limitations:

There exist a number of limitations in this study. Telestroke is not the only variable that may influence t-PA usage, as recognition of signs and symptoms of stroke are often not recognized, travel time from residence or site of occurrence to medical facility can vary, by-passing properly prepared facilities by patient's transport, preparedness of emergency medical professional, and errors made during final coding of the medical record may influence rates. These are examples that we could not be controlled for in this study but are believed to have an impact on the amount of time it takes a stroke patient to be seen and properly assessed. It must be kept in mind that minutes matter in the course of a stroke; two million brain cells die every minute they are starved oxygen (Morrissey, 2013). As the saying goes, "Time is Brain," stroke patients have a limited window (3-4.5 hours) from symptom onset in which they are eligible to receive t-PA and anything that delays their assessment and treatment is detrimental to their surviving or suffering from the effects of the disease. Indication of non-significant trend toward greater t-PA use among patients in telestroke counties may become significant given a larger sample. This study may not have enough power to reject the null hypothesis. It is recommended that researchers should use a larger sample size of data when undertaking future studies in telestroke research.

Conclusion:

We have determined by analyzing 2013 data from South Carolina living in a county that has access to telestroke resources is not an indicator of increased likelihood of receiving t-PA among acute ischemic stroke patients—which is believed to be attributable to an insufficient sample size. Therefore, additional research on this topic with a larger sample may be warranted. While this study did find a trend toward higher rates of t-PA utilization in patients in counties with telestroke access, the finding lacked statistical significance.

In the State of South Carolina, as well as many other regions across the United States, funds may only be allocated to expand telestroke services if these services improve patient care and outcomes—particularly in the rates of t-PA administration. While this current study was not able to show a statistically-significant difference in rates of t-PA administration between counties with and without telestroke access, perhaps sufficiently powered future studies might show a difference. If a difference is found, perhaps the national benchmark rate of t-PA administration could be increased from 3-5% of all acute ischemic strokes to a much higher rate.

Increasing the rate of t-PA administration to eligible acute ischemic stroke patients would improve outcomes, and is the right thing to do for patients—as its effectiveness has been demonstrated. t-PA is a lifesaving, “clot-busting” pharmaceutical that has been proven to save stroke patients’ lives or reduce their degree or comorbidity.

In conclusion, stroke is a disease that is burdensome for the patient, the patient’s loved ones, the healthcare system, and the nation as a whole. Telestroke has the ability to

bridge many of the shortcomings realized by facilities have limited stroke professionals, due to being geographically distant from larger cities or because of a lack of funds. Or limited funds for advanced care teams. Evidence to support the benefit of telestroke programs is essential for policymakers and hospital administrators to make the best decisions given in environment of limited funding to care for their constituents or the communities they serve.

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