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Protocol Adherence During Inter-Facility Transfer of Acute Ischemic Stroke Patients Treated with IV rtPA

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PROTOCOL ADHERENCE DURING INTER-FACILITY TRANSFER OF ACUTE ISCHEMIC STROKE PATIENTS TREATED WITH IV rtPA

by

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Abstract

Stroke is a common and serious health disorder, affecting approximately 795,000 people in the United States every year. Intravenous recombinant tissue plasminogen activator (IV rtPA) is the only FDA approved thrombolytic for treating acute ischemic stroke within 3 hours of symptom onset. Patients treated at rural health centers are often transported within hours to the closest primary stroke center. The purpose of this study was to evaluate the structure, process and outcomes related to the inter-facility transport of ischemic stroke patients treated with intravenous rtPA. The Quality-Caring Model© was the guiding framework.

A quantitative, retrospective, non-experimental analysis of inter-facility transport documentation was conducted. The study population included ischemic stroke patients treated with intravenous rtPA at a North Carolina hospital and were subsequently transferred to the primary stroke center. The study correlated structural and process components (type of transport, time of transport, and adherence to protocol) in relation to patient outcomes (presence of post rtPA intracerebral hemorrhage and discharge disposition).

The study sample size was considered too small to support statistical significance. However, the sample demonstrated the variation in terms of age, community and transport type. Factors associated with protocol adherence include: air medical transport, shorter transport times, and transporting with the intravenous rtPA infusing en route. Factors associated with protocol non-adherence include: night shift transport and transport times greater than or equal to 60 minutes. The research confirms the need for a state-wide guideline for inter-facility transport of ischemic stroke patients treated with intravenous rtPA.

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Chapter I

Introduction

Statement of the Problem

Stroke is a common and serious health disorder, affecting approximately 795,000 people in the United States every year. It is the fourth leading cause of death and a major cause of long term disability. It is a costly disease in excess of $73 billion annually in the United States (Alberts et al., 2011). Any intervention that could reverse or limit the effects of a stroke would have dramatic benefits.

Ischemic stroke accounts for approximately 87 percent of all strokes and it is important to understand that early intervention is associated with improved outcomes (Rosamond et al., 2008). Intravenous recombinant tissue plasminogen activator (IV rtPA) is the only FDA approved thrombolytic for treating acute ischemic stroke within the first 3 hours of symptom onset. Its main mechanism of action is to lyse a clot that is occluding a cerebral vessel, thereby reperfusing distal ischemic brain tissue and preventing or limiting the area of cell death (Alberts, Felberg, Guterman & Levine, 2008).

Background/Social Significance

The efficacy of intravenous rtPA was proven in the pivotal National Institute of Neurological Disorders and Stroke (NINDS) rtPA study, which showed improved outcomes for patients treated within three hours of stroke onset (Khatri, Levine & Jovin, 2008). Despite availability of rtPA since 1996, the use of IV rtPA has been limited to 2 percent - 5.2 percent of acute ischemic stroke patients (Arora et al, 2005; Bambauer et al, 2006; Adeoye et al, 2011). There are a number of factors that contribute to the low usage of IV rtPA. They include avoidable and unavoidable causes. Avoidable causes include a failure of the part of the public to

recognize signs and symptoms, to understand that stroke is a time-sensitive emergency and to immediately access emergency medical services. A main reason for the low usage is a lack of timely neurological coverage at small or rural hospitals (Johnson & Bakas, 2010). A 2008 North Carolina survey of hospital-based stroke services found that nearly 20 percent of the state's population resided in a county without a Primary Stroke Center and without a facility that used telephone/telemedicine support or had a standing transfer plan (Goldstein, 2010). Within the 18 county region of Western North Carolina (WNC) only one hospital is a Joint Commission certified Primary Stroke Center and has a hospitalist neurology service. In WNC over 70 percent of the hospitals are considered rural and five are Critical Access Hospitals. All WNC hospitals have given IV rtPA for ischemic stroke. The Emergency Department physicians at these rural sites administer rtPA without a neurologist on site. The neurology consultation is either by telephone or by telemedicine. Once the rtPA is given, the patient is transferred to the Joint Commission certified Primary Stroke Center for further evaluation, stabilization and specialized care. Inter-facility transport is provided by the local county emergency medical services, critical care transport or air-medical transport services.

Intracerebral hemorrhage is the principle risk factor of intravenous rtPA in ischemic stroke patients. These hemorrhages usually occur within the first 24 hours of rtPA administration, and can be fatal. The risk of a symptomatic intracerebral hemorrhage is approximately 6 percent when intravenous rtPA is given within 3 hours of stroke onset (Alberts et al, 2008). Arterial pressure during the initial 24 hours after treatment is associated with rtPA related hemorrhagic complications. For every 10 point (also known as mm Hg or millimeter of mercury) elevation in blood pressure in the post treatment period, the odds of secondary hemorrhage increased by 59 percent (Butcher et al., 2010). Following rtPA administration, blood

pressure should be closely monitored and maintained less than 180/105 mm Hg. The American Stroke Association guidelines for the management of blood pressure after treatment with rtPA include monitoring of the blood pressure (BP) every 15 minutes for the first 2 hours; then every 30 minutes for 6 hours; then hourly until 24 hours after treatment (Adams, et al., 2007). Attention to management of blood pressure is critical before, during and after the administration of rtPA (Adams, et al., 2007). Medications, such as labetelol, nicardipine, or nitroprusside, are recommended if the BP exceeds the recommended levels (Bader & Palmer, 2006). Angioedema, a swelling or localized edema beneath the skin surface, is another less common adverse reaction associated with intravenous rtPA treatment occurring in 1-2 percent of intravenous rtPA treated patients (Khatri, Levine & Jovin, 2008).

Vigilant monitoring of the rtPA treated patient is essential. Most hospitals use an intensive care unit (ICU) for monitoring the post-rtPA patient during the subsequent 24 hours (Bader & Palmer, 2006). It is imperative that all personnel caring for ischemic stroke patients treated with intravenous rtPA are knowledgeable of and adhere to evidence-based guidelines.

Purpose

Tissue plasminogen activator (rtPA) is a proven intervention for acute ischemic stroke patients, with a Class I, evidence-based recommendation from the American Heart/American Stroke Association (Adams, et al., 2007).The benefit of intravenous rtPA in acute ischemic stroke is strongly time-dependent (Fonarow, 2011). Telemedicine consults between stroke specialists and community hospital emergency physicians has increased the number of ischemic stroke patients treated with intravenous rtPA, which in turn has increased the need for inter-facility transfers (Pervez, et. al., 2009, Schwamm, et al., 2009). Intracerebral hemorrhage and angioedema are possible complications associated with intravenous rtPA that require serial

assessments and appropriate actions to prevent adverse outcomes (Khatri, Levine & Jovin, 2008). The purpose of this study is to determine the protocol adherence rate of pre-hospital personnel during transport of acute ischemic stroke patients treated with intravenous rtPA.

Theoretical Framework

The study of adherence to evidence based protocols will utilize the Quality-Caring Model© developed by Joann Duffy (Duffy & Hoskins, 2003). In the Quality-Caring Model© evidence-based practice of present-day healthcare is merged with the caring processes of nursing. Caring values, attitudes, and behaviors dominate the processes of care and establish a foundation for key relationships. Collaborative relationships include those activities and responsibilities that nurses share with other members of the healthcare team (Duffy, Baldwin & Matorovich, 2007).

The model places relationships at the core of the therapeutic process. Through caring relationships, nurses interact, connect and come to know the context of patients, families and co-workers. As a result, individuals feel "cared for" and are more willing to share, work together, change old patterns, and adhere to new regimes (Duffy, 2005).

The Quality-Caring Model© combines the evidence-based practice while simultaneously representing nursing's unique contribution to quality health care. According to Duffy and Hoskins (2003) the Quality-Caring Model© is grounded in the works of Donabedian (1992) and Watson (1985) and influenced by contributions from King (1981), Mitchell (998) and Irvine (1998). The model reflects the trend toward evidence-based nursing practice (Duffy & Hoskins, 2003). Donabedian developed a framework in the 1980's emphasizing a dynamic process of improvement cycles that look at system structure, process intervention of care and the outcome effects (Chin & Muramatsu, 2003). Structure is organizational design of how a health system runs. *Structure* relates to how the culture of health professionals are utilized in the health care

setting, the characteristics of the providers, resources, tools, and staffing ratios and patterns (Chin & Muramatsu, 2003).

The first major component, *structure*, is blended with the construct, causal past, and includes the concept, participants (Duffy & Hoskins, 2003). The *central* component refers to important factors that are present prior to the delivery of health care. Such factors are present in the participants of the model, namely for this study, the patient, the nursing staff and the inter-facility transport personnel. Structural components include, but not limited to: evidence based guidelines, organizational culture and policy, available resources, and staffing patterns. Concepts and sub-concepts included in the structure component influence the process of care and may directly or indirectly influence outcomes of care (Duffy & Hoskins, 2003). The structure for the study of protocol adherence during inter-facility transport of ischemic stroke patients treated with intravenous rtPA includes national and state guidelines and recommendations for a stroke system of care and North Carolina Emergency Medical Services policy related to inter-facility transport. Additional structural components will include the level of pre-hospital inter-facility personnel, the time of day and the distance traveled.

The second major component, *process*, involves interventions or practices that health care provider's offer and is the focus of this model (Duffy & Hoskins, 2003). Caring relationships are human interactions grounded in clinical caring processes. They incorporate physical work (doing), interaction (being with), and relationship (knowing). Collaborative relationships include: those activities and responsibilities that nurses share with other members of the health care team. Professional encounters that are relationship-centered are outcomes enhancers for the patient, the provider, and the health care system (Duffy, 2005). According to Duffy and Hoskins (2003) Donabedian relates process to "what is being done for patients" and suggests that it is composed

of two broad categories of activities: technical and interpersonal. Process outcomes is improved in cycles by analyzing an improvement intervention in patient care, studying the effect of that care and finally using that data to repeat the cycle (Chin & Muramatsu, 2003). The process is defined by the documentation by inter-facility transport personnel during the transfer of ischemic stroke patients treated with intravenous rtPA.

The third major component, *outcomes,* corresponds to the end result of health care (Duffy & Hoskins, 2003). Two forms of outcomes are apparent: intermediate and terminal Intermediate outcomes include goals on care plans and clinical pathways, but may also include feelings about the health care process. Terminal outcomes are those major concepts that affect the future, such as quality of life, costs, disease-specific variables, and satisfaction with care (Duffy & Hoskins, 2003). Outcomes are dynamic and can be continually improved. Success in outcomes is heavily dependent on the dynamic and balanced independent and collaborative relationships that comprise professional encounters. The outcomes for the study on protocol adherence during inter-facility transport of ischemic stroke patients treated with intravenous rtPA will include the reported incidence of intracerebral hemorrhage and/or angioedema and patient discharge disposition.

The measurement of quality is based on set standards of care or criteria that are scientifically evidenced based. Inherent in the Quality-Caring Model© is the continuous search for evidence that care provided does in fact benefit patients (Duffy & Hoskins, 2003). Duffy's Quality Caring Model© is applicable for this project, as outlined in Figure 1-1. The framework describes the structure, process and outcomes utilized to examine the inter-facility care of the ischemic stroke patient status post treatment with intravenous rtPA. The structure is defined by the evidence-based guidelines for post rtPA care and the personnel involved. The process is

defined by the documentation related to procedures and resources. For the purposes of this study, the outcomes will be defined as the analysis or findings of the study.

Significance to Nursing

Stroke is a complex disease that requires the efforts and skills of all members of the multidisciplinary team (Summers, et al., 2009). Nurses are often responsible for the coordination of care throughout the continuum. Optimal management of the acute ischemic stroke patient in the emergency phase of care requires an accurate and systematic evaluation that is coordinated and timely (Summers, et al., 2009). Nurses have a unique role in improving patient outcomes. Adherence to evidence-based protocols can be accomplished through comprehensive planning and preparation (Rafter & Kelly, 2011).

Theoretical assumptions

For the purposes of this study, the following assumptions will be made:

1. The structure for monitoring and evaluating the ischemic stroke patients treated with intravenous rtPA is well defined and accepted as evidence-based care.

2. The process for inter-facility transfer of the post intravenous rtPA treated stroke patient is not well defined; therefore, it is assumed there will be variation in the process.

3. The variation in process will have a correlation to the outcome.

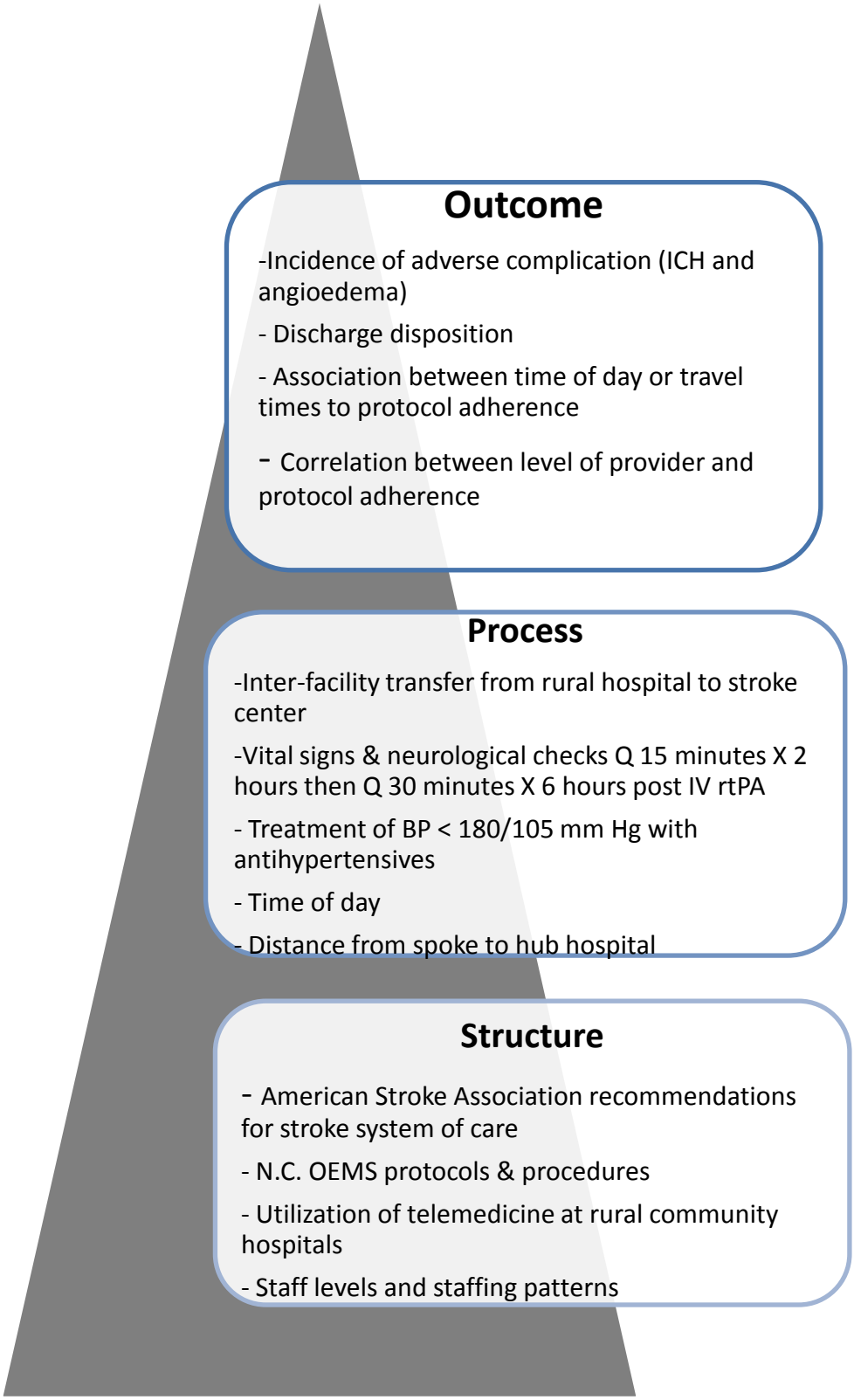


Figure 1: Theoretical Framework Describing Protocol Adherence in Acute Stroke

Research question

National guidelines recommend serial assessments and monitoring for all ischemic stroke patients treated with intravenous thrombolytics (rtPA). With the advent of telemedicine rural hospital physicians are now administering the medication and transferring the patient to the closest stroke center. The mode of transportation includes pre-hospital paramedic county Emergency Medical Services, critical care transport teams or air-medical transport teams. The purpose of this study is to evaluate the protocol adherence by transport personnel. In this study the questions to be answered are:

1. What are the demographic characteristics of the study population?
2. What is the association between travel time and adherence to protocol?
3. What is the association between time of day on adherence to protocol?
4. What is the association between type of transport agency on adherence to protocol?
5. Is there a correlation between protocol adherence and discharge disposition**?**
6. Is there a correlation between protocol adherence and time of completion of intravenous rtPA?

Definition of terms

For the purposes of this study, the following definitions were utilized.

Advanced Life Support (ALS).

An advanced level of pre-hospital and inter-facility emergency care that includes basic life support functions (including cardiopulmonary resuscitation, plus cardiac monitoring, electrocardiography, intravenous therapy, administration of medications, drugs and solutions, use of adjunctive medical devices, trauma care and other authorized techniques and procedures.,

initiated for the treatment of real or potential acute life threatening conditions under the direction of the EMS medical director (Bledsoe, Porter & Cherry, 2009).

Air medical transport.

An air medical ambulance is used for emergency medical transport of stroke patients when either a traditional ambulance cannot reach the scene easily or quickly enough, or the patient needs to be transported over a distance that makes air transportation the most practical transport (Bledsoe, Porter & Cherry, 2009).

Angioedema.

An allergic reaction to intravenous rtPA is angioedema of the tongue. The occurrence rate is less than 1 percent of all patients treated with intravenous rtPA. Practitioners should routinely inspect the tongue and oropharynx in patients 30-45 minutes after the start of the rtPA infusion. Recommended treatment includes antihistamines and corticosteroids (Khatri, Levine & Jovin, 2008).

Critical care emergency medical transport.

Critical care emergency medical transport is a certified program that utilizes paramedics and registered nurses for complicated inter-facility transports. This type of program is typically from one intensive care unit to another in specially equipped ambulances or aircraft designed to provide a higher level of care (Bledsoe, Porter & Cherry, 2009).

Emergency Medical Services (EMS).

A type of emergency services dedicated to providing out-of-hospital acute medical care and/or transport to definitive care, to patients with illnesses or injuries with the patient, or the medical practitioner, believes constitutes a medical emergency. In a stroke system of care, the

EMS also encompasses the role of moving a stroke patient from a community hospital to a stroke center (Schwamm, et al., 2005).

Intracranial hemorrhage.

Intracranial hemorrhage (ICH) occurs when a blood vessel within the brain bursts, allowing blood to leak inside the brain. The most common cause of ICH is high blood pressure (hypertension). Intracranial hemorrhage is the principal risk of intravenous rtPA in stroke patients. These hemorrhages typically occur within the first 24 hours of intravenous rtPA administration (Caplan, 2000).

Intravenous rtPA.

The only drug approved by the Food and Drug Administration (FDA) for medical therapy in acute ischemic stroke. Its main mechanism of action is to lyses a clot that is occluding a brain artery, thereby reperfusion the ischemic brain tissue and preventing or limiting the area of brain cell death (Adams, et al., 2007).

Ischemic Stroke.

Ischemic stroke occurs when an artery to the brain is blocked. The brain depends on its arteries to bring fresh blood from the heart and lungs. The blood carries oxygen and nutrients to the brain, and takes away carbon dioxide and cellular waste. If an artery is blocked, the brain cells cannot make enough energy and will eventually stop working. If the artery remains blocked for more than a few minutes, the brain cells may die. For this reason immediate medically treatment is absolutely essential (Summers, et al., 2009).

Stroke.

Stroke is defined as an acute neurologic dysfunction of vascular origin with sudden (within seconds) or at least rapid (within hours) occurrence of symptoms and signs corresponding to the

involvement of focal areas in the brain. Stroke is comprised of two major subtypes. Ischemic stroke is caused by a blockage inside an artery feeding the brain and accounts for almost 80 percent of all strokes. The remaining 20 percent of strokes are hemorrhagic caused by rupture of an artery feeding the brain (Adams, et al., 2007).

Stroke center.

In 2000, a multidisciplinary group known as the Brain Attack Coalition (BAC) identified evidence-based interventions known to improve the outcomes of patients sustaining acute stroke. The BAC recommendations assisted acute care hospitals in prioritizing care for stroke patients. The major interconnecting elements include: organized acute stroke team for rapid response to the ED, and written care protocols for the multidisciplinary team to follow integrating evidence-based literature. The BAC efforts led to the creation of Primary Stroke Center certification by The Joint Commission (Alberts, et al., 2011).

Chapter II

Review of the Literature

The review of the literature will follow Duffy's Quality-Caring Model© (2005) with a concentration on structure, process and outcome. Stroke is a common and serious disorder. Each year in the United States, approximately 795,000 people will have a new or recurrent stroke. Improved care of patients with acute stroke may reduce the high morbidity and mortality from this disorder and have significant public and financial implications (Alberts, et al., 2011). Prior studies have shown that many patients with stroke are not treated according to contemporary guidelines. One approach to improving stroke care is the development of Stroke Centers. These hospitals would act as focal points for the care of patients with acute stroke. Approximately seventy-seven percent of all US counties lack a hospital with neurological services highlights the need for more organized and centralized stroke care (Alberts, et al., 2011).

A review of the current literature was completed using PubMed, CINAHL, MEDLINE, and OVID databases using key words: stroke, emergency medical services, inter-facility transfer, telemedicine, thrombolysis, guidelines and quality. The search was limited to English studies published between 2006 and 2011. The initial search yield included forty-three position statements and peer-reviewed studies. To date there are no published studies regarding the inter-facility transport of ischemic stroke patients treated with intravenous rtPA or on the role of Emergency Medical Services in the post treatment phase of care.

Structure

The American Heart Association/American Stroke Association publishes evidence-based guidelines for the early management of adults with ischemic stroke every three to five years. The latest guidelines were published in 2007. The goal is to provide an overview of the current

evidence about components of the evaluation and treatment of adults with ischemic stroke. The intended audience is physicians and other emergency healthcare providers who treat patients within the first 48 hours after stroke. Members of the panel were appointed by the American Heart Association Stroke Council's Scientific Statement Oversight Committee and represent different areas of expertise. The panel completes a review of the current literature with an emphasis on the most current reports. After approval by the panel, the guidelines are peer-reviewed and approved by the Committee (Adams, et al., 2007).

The availability of resources to care for patients with acute stroke varies widely both among and within communities (Adams, et al., 2007). The National Institute of Health (NIH) Task Force report "Improving the Chain of Recovery for Acute Stroke in Your Community," recommends identifying hospitals capable of providing acute stroke care and creating a transport system to these centers based on patient location. Such systems require advance planning and frequent updating and should incorporate EMS representatives, community leaders, hospitals, and physicians to ensure clear guidance for EMS providers with regard to patient destination (Adams, et al., 2007). The emphasis for EMS in the 2007 guidelines was for early recognition and rapid transport to the closest stroke center. The authors did note that strategies such as telemedicine or air medical transport (helicopter) may provide access to specialized stroke care when it is not available locally, and such approaches may increase the number of patient who can be treated especially in rural or otherwise underserved areas (Adams, et al., 2007).

Intravenous thrombolytic therapy for acute stroke is now generally accepted (Adams, et al., 2007). The US Food and Drug Administration (FDA) approved the use of intravenous rtPA in 1996 on the basis of the NINDS rtPA Stroke Study, in which 624 patients with ischemic stroke were treated with placebo or rtPA (0.9mg/kg IV, maximum 90 mg) within 3 hours of symptom

onset, with approximately one half treated within 90 minutes. Favorable outcomes (defined as complete or nearly complete neurological recovery 3 months after stroke) were achieved in 31 percent to 50 percent of patients treated with rtPA, as compared with 20 percent to 35 percent of patients given placebo (Adams, et al, 2007). The major risk of treatment was symptomatic intracranial hemorrhage, which occurred in 6.4 percent patients treated with rtPA and 0.6 percent of patients given placebo. The risk of hemorrhage is proportional to the degree to which the NINDS protocol is not followed (Appendix C).

In 2011 the Brain Attack Coalition published a revision and update of the original 2000 recommendations for the establishment of Primary Stroke Centers (Alberts, et al., 2011). The update includes a new recommendation that patients with acute stroke be transported to the nearest facility that can operate as a Primary Stroke Center. The use of telemedicine and air ambulances may be efficacious for treating and transporting in a rural setting remote from a PSC, thus allowing the expertise of the PSC to be exported to a remote facility and expediting transfer of the patient to a PSC (Alberts, et al., 2011). The importance of including EMS in a PSC is supported by Class I, Level A recommendation. The BAC supports the emergent triage of patients with stroke to the nearest Stroke Center that can provide appropriate care, and the use of telemedicine/telestroke/teleradiology as useful components for PSCs that serve as support hospitals for other facilities in need of such support (Alberts, et al., 2011).

The Institute of Medicine (IOM) of the National Academy of Science has concluded that the fragmentation of the delivery of healthcare services frequently results in suboptimal treatment, safety concerns, and inefficient use of healthcare resources. To ensure that scientific knowledge is translated into practice, the IOM has recommended the establishment of coordinated systems of care that integrate preventive and treatment services and promote patient

access to evidence-based care (Schwamm, et al., 2005). The American Stroke Association's task force on development of stroke system of care found that although individual components of a stroke system may be well developed, these components often operate in isolation. The problem of access to coordinated care may be exacerbated in rural or neurologically underserved (inadequate access to neurological expertise) areas (Schwamm, et al., 2005). Acute stroke interventions may be extended to patients in rural and neurologically underserved areas by establishing consultation and patient transfer protocols. The protocols should include participation by EMS personnel who are called on to provide inter-facility transport to appropriate stroke care facilities and support the transport of patients who may receive an infusion of intravenous rtPA initiated at the referring hospital (Schwamm, et al., 2005).

Statewide assessments of stroke prevention and treatment services were performed in North Carolina in 1998 and 2003 (Goldstein, 2010). The 2003 survey found certain technologies, but not stroke-related programs, were more widely available. The survey was repeated in 2008 to determine whether there was an interval change in accessibility. A 2-page questionnaire was sent to each North Carolina hospital. Results were compared with the 1998 and 2003 surveys. Complete responses were obtained from each of the state's emergent stroke care hospitals. The use of care maps and intravenous rtPA increased between 2003 and 2008. The proportions of hospitals having a group of "basic" stroke capabilities did not change (18%, 21 % and 20% respectively, $P>0.05$). In 2008, 41 percent of North Carolina's population resided in a county with at least 1 Primary Stroke Center and an additional 40 percent in a county using telemedicine or having a transfer plan for patients with acute stroke (Goldstein, 2010). Many North Carolina hospitals without the expertise to support hyper-acute interventions used remote (telephone/telemedicine) support and/or a policy or plan to transfer patients with acute stroke to

another facility. Nearly 20 percent of the state's population, however, resided in a county without a PSC and without a facility that used telephone/telemedicine support or had a standing transfer plan. The researcher concluded that knowledge of hospitals' existing resources can help target facilities for PSC development and those without this potential to develop alternative strategies such as telemedicine to provide optimal care (Goldstein, 2010).

Process

In 1996, recombinant tissue-type plasminogen activator (rtPA) was approved by the Food and Drug Administration for ischemic stroke within 3 hours of onset of symptom onset, based on two randomized phase 3 trials jointly published as the National Institute of Neurological Disorders and Stroke (NINDS) rtPA Stroke Study(A Evidence) (NINDS, 1995). The NINDS rtPA stroke study was a double-blind, placebo-controlled study. Preventing and identifying intracerebral hemorrhage were the foci of patient management both during the rtPA infusion and in the 24 hours after administration. The original study protocol required that no anticoagulants or antiplatelet agents be given for 24 hours after treatment and that blood pressure be maintained within prespecified values (NEJM, 1995). In a special report Dr. Frankel, a principle investigator for the NINDS rtPA Stroke Study, responded to questions regarding the study protocol and monitoring regimes (Frankel, 1996). The blood pressure and neurological assessments were performed every 15 minutes for 2 hours after the infusion was started, then every 30 minutes for 6 hours, and every hour from the eighth hour until 24 hours after the infusion was stopped (Table 1). The original blood pressure treatment regime established by the NINDS rtPA Stroke Study has been amended since 1996 to include newer pharmaceutical agents (Table 2) (Adams, et al., 2007). For the purposes of this study it should be noted that in the original rtPA stroke study, patients were enrolled at one of eight centers and it is not known if any of the rtPA treated

patients were transferred from a community hospital to a stroke center after the initiation of intravenous rtPA.

Administration of tissue plasminogen activator (rtPA) for acute ischemic stroke remains controversial in community practice for a variety of reasons. Well organized hierarchic systems of acute stroke care have been proposed to link community hospitals to comprehensive stroke centers. The Maryland Brain Attack Center is a statewide communications and transport network that provides emergency staff in the state access to stroke specialists. LaMonte and colleagues (2009) reviewed all Maryland Brain Attack Center consultations for ischemic stroke from 1996 to 2005. Out of the 2,670 consultations and diagnosed 1,788 ischemic stroke patients, two hundred forty patients (9% of all consultations; and 13.4% of all ischemic stroke patients, were treated with intravenous rtPA. Patients who were potential candidates were transferred to the stroke center for care. Initiation of intravenous rtPA was begun before transfer at the community hospital Emergency Department. Inter-facility transport was provided by Emergency Medical Services either by ground or by air, depending on the patient condition (LaMonte, et al., 2008). All patients were transferred to the stroke center and admitted to the medical or neurocare ICU, where treatment continued according to the stroke protocol modeled after that used in the NINDS trial (LaMonte, et al., 2008). The percentages of patients with symptomatic intracranial hemorrhage and 3-month modified Rankin scale scores were less than or equal to 1, compared with those in the NINDS trial, were as follows: 3.3% versus 6.4% and 53% versus 43% (P=.04). Mortality rates were 13 percent (network) versus 17 percent (NINDS) (LaMonte et al., 2008). The researchers concluded the results indicate that the NINDS tPA protocol is applicable to community practice, with the support of a university-based brain attack center (LaMonte, et al., 2008).

In 2006, the North Carolina General Assembly ratified House Bill 1860, which established a stroke advisory council to provide guidance on the development of a statewide system of care, including a system for identifying primary stroke centers and disseminate information about their location (Asimos, Enright, Huston & Mettam, 2010). Quality stroke care requires expeditious treatment, but several impediments exist. The purpose this study involved a critical component in the stroke chain of survival – the potential of expeditious ground transport to hospitals capable of administering high-quality care for acute stroke (Asimos, Enright, Huston & Mettam, 2010). The study examined the impact of a statewide increase in stroke centers between 2006 and 2008. They used the drive-time proximity of the residents address to the nearest Joint Commission Primary Stroke Center (JCPSC) among people who died of stroke as the outcome. In 2006, 37 percent of geocodable residences of patients who died of stroke (3,834 of 10,469) were within a 40-minute drive from a JCPSC. By the end of 2008, the percentage increased to 56 percent (3,482 of 6,204). Inclusion of other hospitals that participated in a recognized quality-improvement program for acute stroke care increased the 40-minute drive-time coverage to 82 percent (5,095 or 6,204) (Asimos, Enright, Huston & Mettam, 2010). The researchers concluded that the stroke burden is high for many regions of North Carolina and that timely stroke care is unavailable (Asimos, Enright, Huston & Mettam, 2010). The study did not consider telestroke support or the use of field-to-hospital helicopter transport, both of which have the ability to enhance statewide access to experts in acute stroke care.

Many community hospitals do not have a stroke specialist and must rely on telemedicine or telephone consultation with a stroke neurologist before treating ischemic stroke patients with intravenous rtPA and transferring to a regional stroke center. Pervez and colleagues (2009) conducted a retrospective review of the Get with the Guidelines Stroke (GWTG-Stroke) database

from 01/2003 to 03/2008 and identified 296 patients who received intravenous rtPA within 3 hours of onset of symptom onset. They analyzed complications and outcomes of patients treated with intravenous rtPA using the "drip and ship" approach compared to those directly at the regional stroke center. Of the 296 patients, 181 (61.1%) had rtPA infusion started at an outside hospital (OSH) and 115 (38.9%) at the regional stroke center (RSC). The patients treated at OSH were younger with fewer severe strokes than RSC patients. Patients treated via telestroke were more frequently octogenarians that patients treated based on a telephone consult. Mortality, symptomatic intracranial hemorrhage, and functional outcomes were not different between OSH versus RSC and telephone versus telestroke patients (Pervez, et al., 2009). The instruction to OSH includes post rtPA care management advice. There were no apparent protocol violations in the determination of eligibility criteria for treatment with intravenous rtPA. Patients were transferred from hospitals in Massachusetts (n=27 hospitals), New Hampshire (n=5 hospitals), and Maine (n=1 hospital). The median distance from OSH to the RSC was 43.3 miles with telestroke hospitals farther away than telephone hospitals 52.2 versus 40 (P=0.005) (Pervez, et al., 2009). To control for any difference associated with hospital inpatient care processes, they only included patients treated with intravenous rtPA at an outside hospital if the patient was transferred to the stroke center. Limitations to the study include no evaluation of inter-facility transfer adherence to protocol.

Intravenous tissue plasminogen activator for acute ischemic stroke must be provided in an appropriate setting. According to researchers at the University of Pennsylvania, the best way to provide thrombolysis small community hospitals remains uncertain (Uchino, Massaro, Jovin, Hammer & Wechsler, 2010). A retrospective medical record review was conducted of ischemic stroke patients treated with intravenous rtPA at a stroke center between January 2002 and

October 2005. The stroke center provides phone consultation for acute stroke to smaller hospitals in the region. Subjects were classified into 3 groups: intravenous rtPA started at referring hospitals before transfer (treat and transfer group), intravenous rtPA started at the stroke center after transfer (transfer and treat group), and the control group of patients who presented directly to the stroke center and received intravenous rtPA. There were 133 patients in the treat and transfer group, 35 patients in the transfer and treat group, and 86 patients in the control group. Fifty-five protocol deviations occurred in 38 percent patients in the treat and transfer group, compared with 6 percent in the stroke center group ($P<.001$) (Unchino et al., 2010). The most common deviations were related to time window violations and incorrect rtPA dosing (Unchino et al., 2010). The findings indicate a need for improved protocol adherence for stroke thrombolysis in patients presenting to small community hospitals. The study did not address protocol adherence by inter-facility transport personnel.

Outcomes

The optimal blood pressure (BP) in stroke remains unclear. For ischemic stroke patients treated with intravenous thrombolysis, current guidelines suggest pharmacological intervention if systolic BP exceeds 180 mm Hg (Ahmed, et al., 2009). Researchers from the Department of Neurology in Stockholm Sweden analyzed the data from a large randomized stroke thrombolysis clinical trial to determine if there was an association of BP and antihypertensive therapy with clinical outcomes (Ahmed, et al., 2009). In multivariate analysis, high BP 2 to 24 hours after thrombolysis was a continuous variable and was associated with poor outcome ($P<0.001$) and as a categorical variable had a liner association with symptomatic intracranial hemorrhage (Ahmed, et al., 2009). Systolic BP > 140 mm Hg is generally accepted as hypertension, therefore it was categorized as systolic BP >140 mm Hg by each 10 mm Hg. Researchers concluded that the

higher the systolic BP, the higher the risk of symptomatic intracranial hemorrhage (Ahmed, et al., 2009).

Hemorrhagic transformation is the most feared and most common complication of thrombolysis for acute ischemic stroke (Butcher, et al., 2009). The Echoplanar Imaging Thrombolytic Evaluation Trial (EPITHET) was a randomized, controlled trial of tissue plasminogen activator (rtPA) or placebo in ischemic stroke patients treated 3 to 6 hours after onset and who were imaged serially with diffusion (DWI) and perfusion (PWI) weighted imaging (Butcher, et al., 2009). The aim of the study was to identify predictors of post rtPA intracranial hemorrhage. Patients were excluded when systolic blood pressure (SBP) was greater than 185 mm Hg, despite acute treatment, or when they had early ischemic changes on computerized tomography (CT) involving greater than 1/3 of the middle cerebral territory. All patients were kept on a cardiac monitor and continuous BP monitor for 24 hours after randomization. Heart rate and BP were recorded every 15 minutes for 2 hours, every 30 minutes for 4 hours, hourly for 4 hours, every 2 hours for 8 hours, and then every 4 hours thereafter (Butcher, et al., 2009). Researchers concluded that arterial pressure during the initial 24 hours after treatment is associated with rtPA related intracranial hemorrhagic complications. This finding confirmed that patients treated with intravenous rtPA must have stringent blood pressure control (Butcher, 2009).

A major concern of physicians, who treat acute ischemic stroke with intravenous rtPA, is the risk of intracerebral hemorrhage. However, other adverse reactions, including anaphylaxis and angioedema, can also occur. Angioedema is typically seen in 1 percent to 2 percent of patients treated with rtPA and may be seen in as many as 5.1 percent of patients if detailed examination is performed (Khatri, Levine & Jovin, 2008). It is more common in patients on

angiotensin-converting enzyme inhibitors and in patients with frontal and insular ischemic infarcts (Khatri, Levine & Jovin, 2008). While the course is usually benign, vigilant monitoring and treatment are recommended. A suggested protocol from the University of Cincinnati recommends examination of the tongue 20 minutes before the intravenous rtPA infusion is complete and repeat examinations several times until 20 minutes after the end of the infusion. Look for signs of unilateral or bilateral tongue enlargement. If angioedema is suspected, the algorithm proceeds with pharmacological treatment with antihistamines and corticosteroids. If angioedema continues emergent airway intubation or tracheostomy may be necessary (Khatri, Levine & Jovin, 2008). Inter-facility transport personnel should receive training and be prepared to respond to this emergency.

Ischemic stroke patients are being treated with intravenous rtPA at community hospital settings with remote consultation by neurology and then being transferred to the closest stroke center. To date there are no published studies on the inter-facility transport of acute stroke patients and the association between evidence based protocols and adherence. The purpose of this study is to measure the protocol adherence during inter-facility transport of acute ischemic stroke patients treated with intravenous rtPA.

Chapter III

Methodology

This chapter describes the methodology applied to this study. The design, setting, population/sampling plan and protection of human subjects are addressed. Additionally, data collection tools, procedure, data analysis, and analytical assumptions are discussed. The aim of this study was to measure adherence to acute stroke protocols by transport personnel during inter-facility transfer of ischemic stroke patients treated with intravenous rtPA. Adherence to protocol is imperative to reduce the risk of post thrombolysis complications such as intracranial hemorrhage (Bader & Palmer, 2006). A review of current North Carolina EMS policies, protocols and procedures was completed as part of the literature review. At present time the North Carolina Emergency Medical Service has a Suspected Stroke Medical Protocol (Appendix A), Stroke Destination Plan (Appendix B), a policy for Transport (Appendix C) and a policy for Air Transport (Appendix D). However, there is no policy or procedure for the management of stroke patients treated with intravenous rtPA requiring inter-facility transport. This study will aid in advancing the knowledge base regarding post thrombolysis monitoring and evaluation during inter-facility transport.

The purpose of the study is to measure the protocol adherence of inter-facility transport personnel during transport of acute ischemic stroke patients treated with intravenous rtPA.

Setting

The setting for this study was a not-for-profit acute care facility. This institution is a 730 bed acute care facility in western North Carolina. The institution is a Joint Commission certified primary stroke center serving more than 1.5 million people in eighteen counties of western North Carolina. The institution is located in the largest city in western North Carolina however the

service area is predominantly rural. The service area includes sixteen acute care hospitals, five of which are certified as Critical Access hospitals. The stroke center operates a 24/7/365 hospitalist neurology program with telephone/telemedicine coverage for hospitals in western North Carolina and upstate South Carolina. In 2010 the stroke patient volume for the stroke center was 1,185 with 134 stroke patients treated with intravenous rtPA.

Study population

A convenience sampling was used for this study to include all ischemic stroke patients treated with intravenous rtPA at a western North Carolina hospital and were subsequently transferred to the primary stroke center between the dates of January 1, 2009 and December 31, 2010.

Inclusion criteria.

The study population included adult subjects (age 18 years and older) that received intravenous rtPA for acute ischemic stroke at a western North Carolina community hospital and were transferred to the primary stroke center between the dates of January 1, 2009 and December 31, 2010. The study population included any subjects that developed secondary intracranial hemorrhage or angioedema post intravenous rtPA.

Exclusion criteria.

The study population excluded all subjects transferred from other states and/or subjects receiving neuro-interventional treatment at the primary stroke center. The study excluded subjects with known intracerebral hemorrhage post intravenous rtPA prior to transfer to the primary stroke center. The study excluded any subject under the age of 18. Subjects with no inter-facility transport record were excluded from the study. No one was excluded from the study based on gender or race.

Data collection and analysis

The study of protocol adherence during inter-facility transport of acute ischemic stroke patients treated with intravenous rtPA is a quantitative, retrospective, non-experimental analysis of inter-facility transport documentation. The study received approval from both Gardner-Webb University's Institutional Review Board (IRB) and the study facility's IRB prior to data collection and analysis.

The primary stroke center maintains a database of all patients transferred to the stroke center. A query was conducted to select all ischemic stroke patients treated with intravenous rtPA transferred to the stroke center between January 1, 2009 and December 31, 2010. The study subject list was validated using the principle diagnosis ICD9 codes 433 or 434 and a secondary V-code of V45.88. The secondary V-code V45.88 was created in 2008 by the Center for Medicare and Medicaid (CMS) for the purposes of tracking all patients that receive intravenous rtPA within 24 hours of transfer to a tertiary care hospital (Tonarelli, 2010).

A data abstraction tool was created to include subject characteristics (age, gender and referring institution), time of rtPA initiation, time and duration of inter-facility transport, frequency of documented blood pressure and neurological assessment during transport, 24 hour CT or MRI results and subject discharge disposition. Subject identification will be the medical record number. The medical record abstraction will include access to referring hospital records that accompanied the subject at the time of transfer and records from the inter-facility transport team (EMS, Critical Care transport or Air medical transport). The researcher contacted the transporting agency via email to secure any missing documentation to ensure adequate representation of all transferred subjects. The transporting agency was asked to fax a de-identified record to a secure fax machine located in the primary stroke center administrative

office. Subjects with no inter-facility transport documentation were excluded from the study population.

For the purposes of this study *protocol adherence* was defined as documentation of blood pressure and neurological assessment with expected intervals determined by the time of initiation of intravenous rtPA.

IBM SPSS Statistics 19 was used for analysis. Both descriptive and inferential statistics were utilized to address the following research questions.

1. What are the demographic characteristics of the study population?
2. What is the association between travel time and adherence to protocol?
3. What is the association between time of day on adherence to protocol?
4. What is the association between type of transport agency on adherence to protocol?
5. Is there a correlation between protocol adherence and discharge disposition**?**
6. Is there a correlation between protocol adherence and time of completion of intravenous rtPA?

Consent and protection of human subjects

Informed consent was not required as no subject names were recorded and there was no contact with the subjects. The data collection forms will remain secured in a locked cabinet in the researcher's office. At the end of six years research data will be destroyed.

Summary

This chapter describes the research methodology that provided the statistical framework for this study. The setting and sample were also described, as well as the protection of the human rights of the participants. Analyses and study findings are presented in Chapter 4.

Chapter IV

Results

The study of protocol adherence during inter-facility transport of acute ischemic stroke patients treated with intravenous rtPA is a quantitative, retrospective, non-experimental analysis of inter-facility transport documentation. The purpose of this chapter is to present and discuss the results of this study. To facilitate the reader's understanding, the discussion of the findings and presentations are organized in relation to the research questions and as each relates to the framework of structure, process and outcome.

Description of the sample

The sample was a convenience sample of all ischemic stroke patients treated with intravenous rtPA and transferred to the primary stroke center between the dates of January 1, 2009 and December 31, 2010. The study subjects were selected using the stroke center database and validated using the principle diagnosis ICD9 codes 433 or 434 and a secondary V-code of V45.88. The initial query yielded a potential pool of seventy-four subjects. Of these, fourteen were excluded due to transfer from facilities outside of North Carolina, one was excluded due to transfer ensued after the development of a post intravenous rtPA related intracranial hemorrhage and fourteen were excluded due to no inter-facility transport documentation available to the researcher. The final study population was forty five subjects with principle diagnosis of ischemic stroke that were treated with intravenous rtPA at a North Carolina hospital and transferred to the primary stroke center between the dates of January 1, 2009 and December 31, 2010.

Research question one evaluates the study population (structure) and was addressed descriptively. The study population was evenly distributed with slightly higher number of males.

The mean age for entire sample was 71.3 with SD 11.5. The mean age was 70 and 72 for males and females respectfully. The range was 48 with minimum age of 45 years to maximum age of 93 years. Table 1 illustrates the description of the demographic factors of the population.

Table 1
Study population demographics n=45

Gender	Frequency	Percentage	Mean Age
Male	24	53.3	70
Female	21	46.7	72

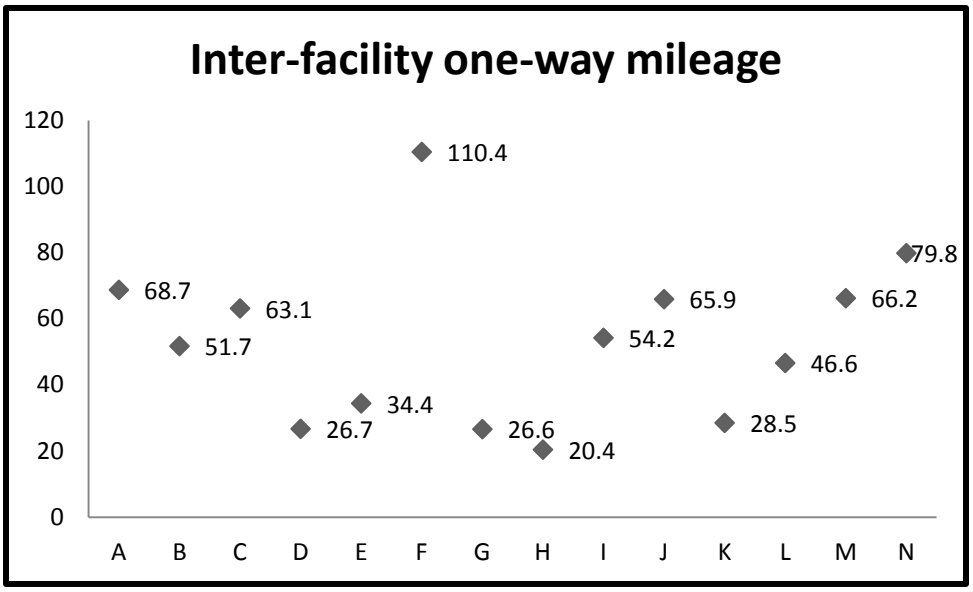
Research question two inquired of the nature of the association between distance of travel (structure) and the adherence to protocol (outcome). To answer this question descriptive statistics were utilized to describe the referral hospitals, the mode of inter-facility transport and the time to complete transportation between referral hospital and receiving hospital. Table 2 presents data pertaining to the referral hospital demographics. All referral hospitals are community based and not-for-profit. The type indicates the designation of Critical Access Hospital (CAH). The frequency and percentage volumes refer to rate of inter-facility transfers specific to the study population. The majority of transfers (44.5%) were from 3 hospitals (Referral Hospitals A, E, and K), two of these are designated CAH. The frequency range was from a minimum of 1 transfer to a maximum of 8. Table 3 outlines the transport time as “door-to-door” mean time for each type of transportation.

Figure 2 displays the distance in miles and was calculated for one-way transport between the referral hospital and the stroke center. The distance between facilities ranges from a minimum of 20.4 miles to a maximum of 110.4 miles.

Table 2
Referral hospital characteristics

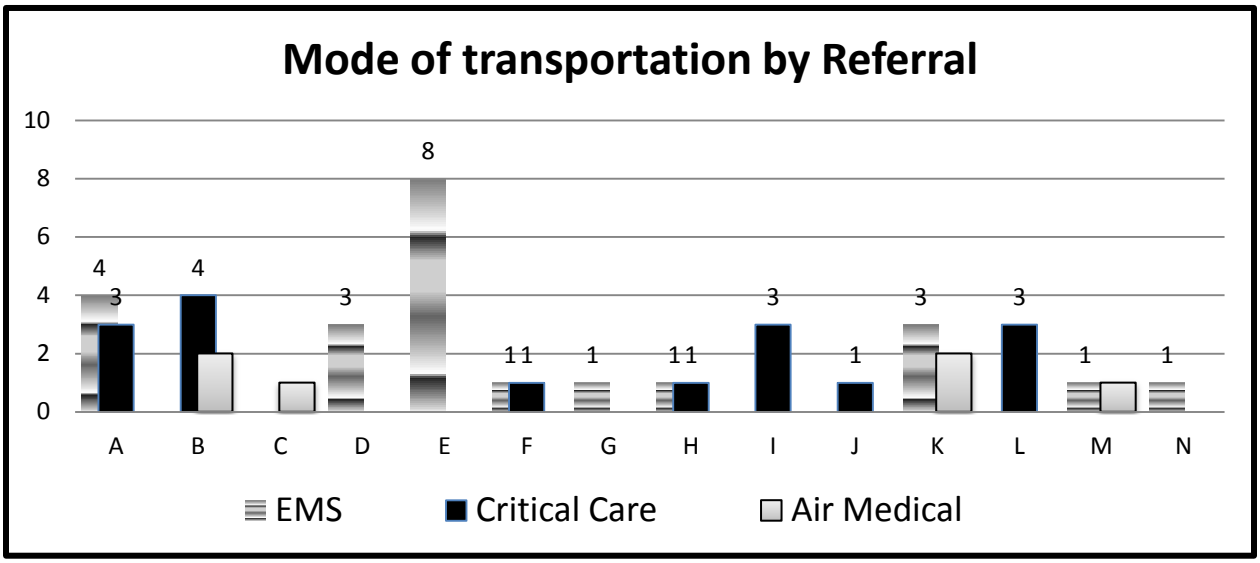
Referral Hospital	Critical Access Designation	Frequency	Percentage
A	Yes	7	15.6
B	No	6	13.3
C	No	1	2.2
D	No	3	6.7
E	No	8	17.8
F	No	2	4.4
G	No	1	2.2
H	No	2	4.4
I	No	3	6.7
J	Yes	1	2.2
K	Yes	5	11.1
L	No	3	6.7
M	Yes	2	4.4
N	No	1	2.2

Figure 2: Inter-facility one-way mileage



The mode of inter-facility transport for the study population was either by county level Emergency Medical Services (EMS), the receiving hospital-based critical care transport truck or the receiving hospital-based air medical service (helicopter). The referral hospital physician determines the most appropriate mode of transport based on both the urgency for a timely transfer and the appropriate level of monitoring required during inter-facility transport. Figure 3 presents the data regarding the mode of transport utilized by referral hospital.

Figure 3: Mode of transportation by referral hospital



The transport time was derived by calculating the time of departure from the referral hospital to the time of arrival at the receiving facility. The door-to-door time in minutes ranged from a minimum of 12 minutes to a maximum of 131 minutes. The door-to-door time was significantly shorter for the air medical transport ($P<.005$). Table 3 presents the mean and SD times for each transportation type. Drive times reflect the variation in distance between referral hospitals and the receiving facility.

Table 3
Door to Door Transport Times

Mode	Number	Mean	Minimum	Maximum	Std D
EMS	23	48.61	19	119	27.820
Critical Care	16	67.69	24	131	29.309
Air Medical	6	24.33	12	56	16.108

Door-to-door transport time was compared to protocol adherence. The findings were not significant but point to the conclusion that shorter transport times correlate with increased protocol adherence. Figure 4 and 5 compares transport time to protocol adherence. Protocol

adherence was present for transport times less than 60 minutes 65% versus protocol adherence for transport times greater than or equal to 60 minutes at 37%.

Figure 4: Protocol adherence related to transport time greater or equal to 60 minutes

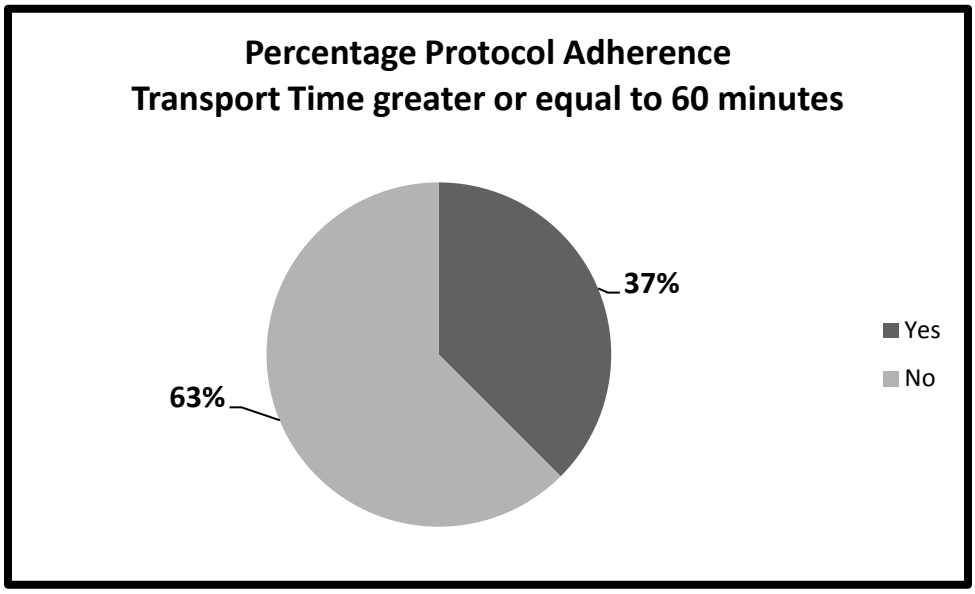
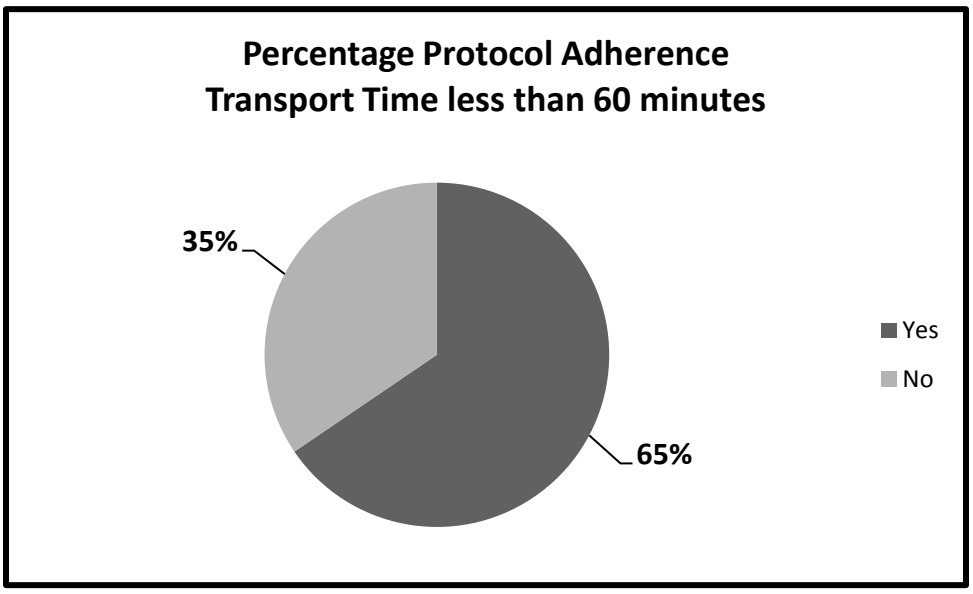


Figure 5: Protocol adherence related to transport time less than 60 minutes



Research questions three through five reflect on how structure and process affect the adherence to protocol or outcome. The descriptive analysis presents that in 55.6% of all study cases the transporting agency did adhere to the monitoring protocol.

Research question three inquired as to the effect of time of day on adherence to the protocol. To evaluate this variable the time of day was sub-divided into two separate time periods: 1) day shift (DS) from 0800 to midnight and 2) night shift (NS) from midnight to 0800. The rationale for the time selection was based on EMS and transport providers' work 24 hour shifts at a time and time of day may have a direct association with adherence to protocol. The majority of the transports occurred during the DS (91.1%) with only four cases (8.9%) transferred during the NS. No statistical significance demonstrated based on small sample size.

Table 4
Transport shift and protocol adherence

Transport Shift	Protocol adherence	Frequency	Percent
DS 0800 – midnight	Yes	24	58.5
	No	17	41.5
NS midnight - 0800	Yes	1	25
	No	3	75

Research question four inquired the association between the type of transport agency provider and protocol adherence. Correlations related to the type of transport and the components of a protocol adherence were calculated to determine if adherence differed among groups. A Chi Square statistic was conducted on the frequencies per agency type. The air medical service level demonstrated protocol adherence 83.3% of all air medical transports. However, the results were not statistically significant due to the small sample size. Table 5 compares adherence by transport type.

Table 5
Protocol adherence related to transport type

Transport type	Protocol adherence	Frequency	Percent
EMS	Yes	11	47.8
	No	12	52.2
Critical Care	Yes	9	56.3
	No	7	43.8
Air Medical	Yes	5	83.3
	No	1	16.7

Research question five inquired as to the effect of the process on discharge disposition. A cross tabulation of adherence to protocol to discharge disposition using Chi Square was not statistically significant due to the small sample size. There was a noted tendency towards significance with 100% positive adherence to protocol in the subjects discharged to a skilled nursing facility or expired. Table 6 lists the percentages based on discharge disposition.

Table 6
Percent protocol adherence for discharge disposition

Protocol adherence	Home	Home Health	Acute Rehab	Hospice	Skilled Nursing	Expired
Yes	41.2	75	57.1	40	100	100
No	58.8	25	42.9	60	0	0

An additional outcome marker to consider would be the incidence of post thrombolytic (rtPA) intracranial hemorrhage. There was one case with a documented asymptomatic intracranial hemorrhage noted on the CT scan performed at 24 hours post intravenous rtPA. This equals a 2.2% hemorrhage rate which is lower than the original NINDS reported rate of 6% (Alberts et al, 2008). Non-adherence to protocol has been associated with post thrombolytic intracranial hemorrhage and the one case in the study sample was associated with non-adherence. A cross tabulation Chi Square statistic was conducted on the frequencies of 24 hour ICH in

relation to protocol adherence. A continuity correction was computed for a 2x2 table with P=.013 and is not considered statistically significant.

There was no documented incidence of post rtPA associate angioedema or oro-lingual edema in the study population. One subject did require emergency oral intubation for respiratory distress. The intubation was completed by the EMS paramedic en route to the stroke center.

Research question six evaluated the association between the time of completion of intravenous rtPA and protocol adherence. The time of intravenous rtPA completion was derived from calculating the time of initiation as documented by the referral hospital and a standard infusion time of 60 minutes. The frequency of inter-facility transport with intravenous rtPA infusing occurred in 25 of the cases for a percentage rate of 55.6%. A Chi Square statistic was conducted on the frequency of rtPA infusing en route by transport type with P=.004. A cross tabulation Chi Square statistic was conducted on the frequencies of rtPA infusing en route and protocol adherence. The results showed a positive trend for protocol adherence when intravenous rtPA is infusing en route. The continuity correction value was computed for a 2x2 table and with P<.001 and this was considered statistically significant.

This study provided a snapshot of the demographics of a convenience sample of ischemic stroke patients from western North Carolina who were treated with intravenous rtPA at the local community hospital and were subsequently transferred to the stroke center. The constructs of structure, process and outcome were applied to the relationships between inter-facility transport personnel and protocol adherence. A statistical finding was identified between the presence of intravenous rtPA infusing during transport and protocol adherence. A discussion of factors that could have had an effect of the outcomes of this study is presented in Chapter 5.

Chapter V

Discussion

Significance of the Findings

The purpose of this study was to evaluate the structure, process and outcomes related to the inter-facility transport of ischemic stroke patients treated with intravenous rtPA. The study was conducted on a convenience sample of all ischemic stroke patients treated with intravenous rtPA in a North Carolina hospital and transferred post treatment to the stroke center within 24 hours of intravenous rtPA. The study correlated structural and process components (type of transport, time of transport, and adherence to protocol) in relation to patient outcomes (presence of post rtPA intracerebral hemorrhage and discharge disposition).

The study sample size was considered too small to support statistical significance. However, the sample demonstrated the variation in terms of age, community and transport type. Low volumes with potential high risk such as this type of patient situation support the need for a protocol or guideline to reduce the likelihood of preventable complications. The discovery that North Carolina does not have a standard policy or guideline pertaining to inter-facility transport of ischemic stroke patients treated with intravenous rtPA was the most significant finding of this study. The evidence strongly supports strict adherence to blood pressure guidelines and neurological assessment for ischemic stroke patients treated with intravenous rtPA (Bader & Palmer, 2006).

A statistical finding from the study supports that air medical transport is the fastest mode of transportation from the referring hospital to the receiving hospital. For those patients needing additional treatment intervention at the stroke center the referring facility should consider air medical transport. The study findings suggest that shorter transport times increase the likelihood

of protocol adherence by all transport types, 65.5% protocol adherence if less than 60 minutes compared to 37.5% protocol adherence if greater than or equal to 60 minutes for transport. The shorter transport times reduces the expected frequency of serial assessments.

The relationship between protocol adherence and discharge disposition was not statistically significant. The finding suggests a correlation between protocol adherence and discharge status to skilled nursing facility or expired in the hospital. This correlation may indicate that stroke severity at the time of transport prompts more frequent re-assessments.

The study findings support a direct correlation between the continuance of intravenous rtPA during transport and positive protocol adherence. This suggests that medical personnel are more aware of the risks associated with thrombolytic use (rtPA) and when present they are more diligent with performing and documenting patient assessment.

Implications for Nursing Practice

Duffy's Quality-Caring Model© combines evidence-based practice while simultaneously representing nursing's unique contribution to quality health care. . Inherent in the Quality-Caring Model© is the continuous search for evidence that care provided does in fact benefit patients. Nurses' are responsible for assuring the patient's safe transition of care from one provider to another and from one facility to another. The implications for nursing practice include the development and dissemination of a post thrombolytic monitoring and assessment protocol to be used by nursing and inter-facility transport personnel. The study highlighted the fact that this is not an everyday occurrence in most emergency departments; this infrequent occurrence necessitates the need for standardization and clearly defined monitoring parameters and protocols.

Limitations of the study

Several limitations were identified for this study. It is North Carolina EMS policy that all patient transports are documented and a copy of such is provided to the receiving hospital, however, the documentation may be limited to one-page brief description of the inter-facility transport. Fourteen potential subjects were excluded from the study because no record of inter-facility transport was accessible by the researcher. The sample size was too small to produce statistically significant correlations and these fourteen cases would have added valuable information. The ideal situation would be to have the inter-facility transport documentation at the time of transport to facilitate communication and patient transition of care.

The study findings were limited to the available data. Outcome measurements were limited to the data available such as discharge disposition and post thrombolytic complications. The documentation of the patient's baseline neurologic deficit was limited and in some cases not available. The study did not include the stroke severity.

Other statistical limitations were related to the small sample size. The sample was limited to only those patients who received intravenous rtPA and were transferred to the stroke center. Application of the data may be limited to a similarly selected population of acute stroke patients who received stroke specialty consultation.

Recommendations for future research

A subsequent study that follows the development and implementation of an inter-facility transfer guideline for EMS transport personnel should be considered in order to compare pre- and post- implementation outcomes. The patients should be evaluated at baseline using the NIH Stroke Scale and Modified Rankin Score to document baseline neurologic and functional ability.

Importance of the findings for nursing

Nurses are often responsible for the coordination of care throughout the continuum. Optimal management of the acute ischemic stroke patient in the emergency phase of care requires an accurate and systematic evaluation that is coordinated and timely. Nurses have a unique role in improving patient outcomes. Adherence to evidence-based protocols can be accomplished through comprehensive planning and preparation. Research is paramount to understanding of how structure and process impact outcomes.

To positively affect patient outcomes all stroke care providers must be knowledgeable of evidence-based guidelines. In many community and academic institutions, education of EMS providers has become a function of the nurse educator. Before beginning an EMS stroke education program, the nurse educator should verify local policies and regulations governing acceptable practice for paramedics and EMTs for the region or state. Continuing education of EMS personnel is challenging requiring frequent updates. As a part of their continuing education, EMS personnel must be provided with accurate information regarding acute stroke guidelines and protocols. Stroke education should emphasize that inter-facility transport of the stroke patient treated with intravenous rtPA requires priority status and includes serial monitoring of vital signs and neurological status.

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Appendices

Appendix A: Patient Management After rtPA Administration (Frankel, 1996)

- No anticoagulants or antiplatelets agents for 24 hours
- Blood pressure monitoring for the first 24 hours: every 15 minutes for 2 hours after starting the infusion, every 30 minutes for 6 hours, then every hour from the eighth hour until 24 hours after rtPA started
- Aggressive blood pressure management to maintain BP <185/110 mm Hg

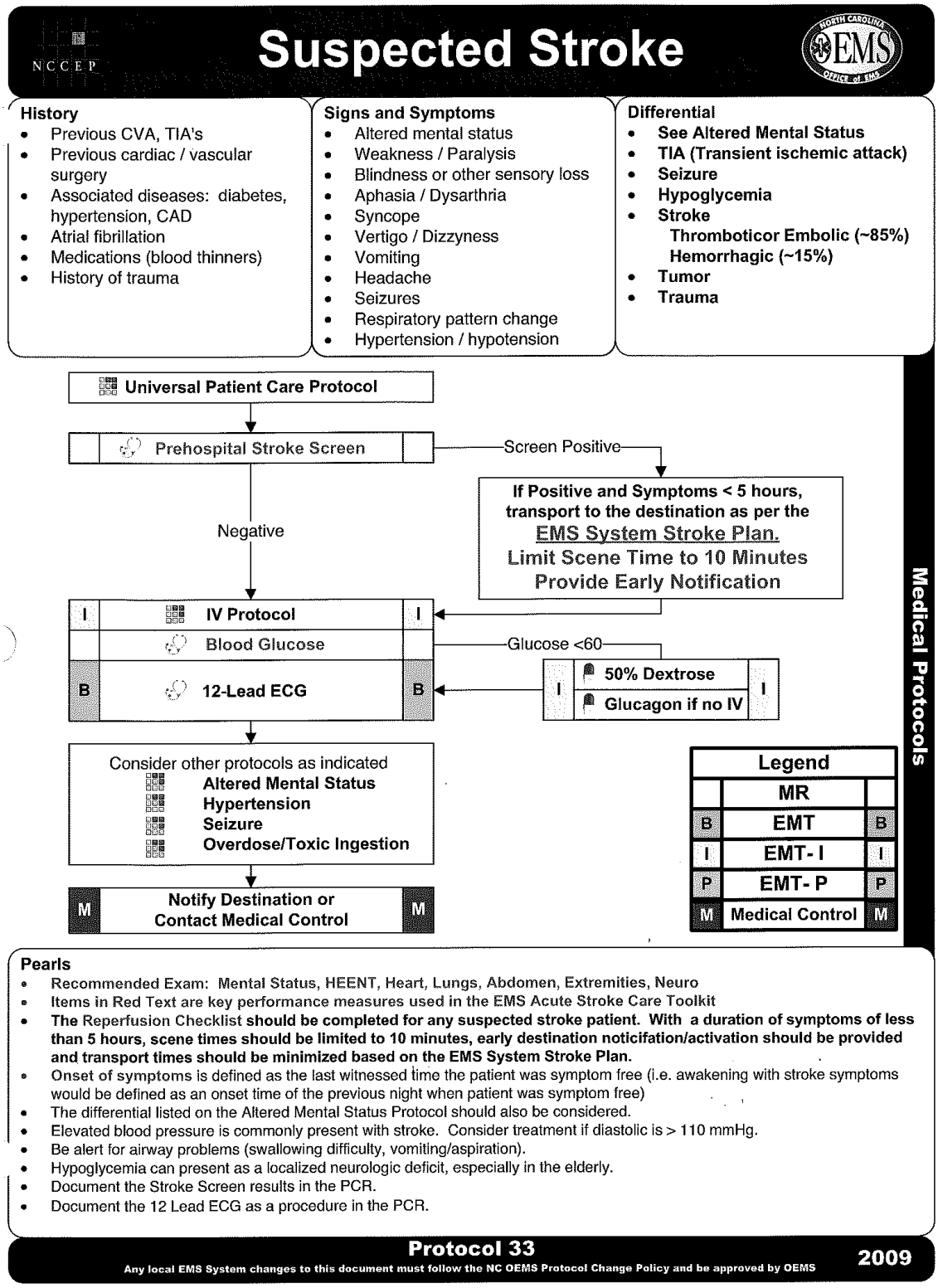
Appendix B: Approach to Hypertension in Acute Ischemic Stroke (Adams, et al., 2007)

During/after treatment

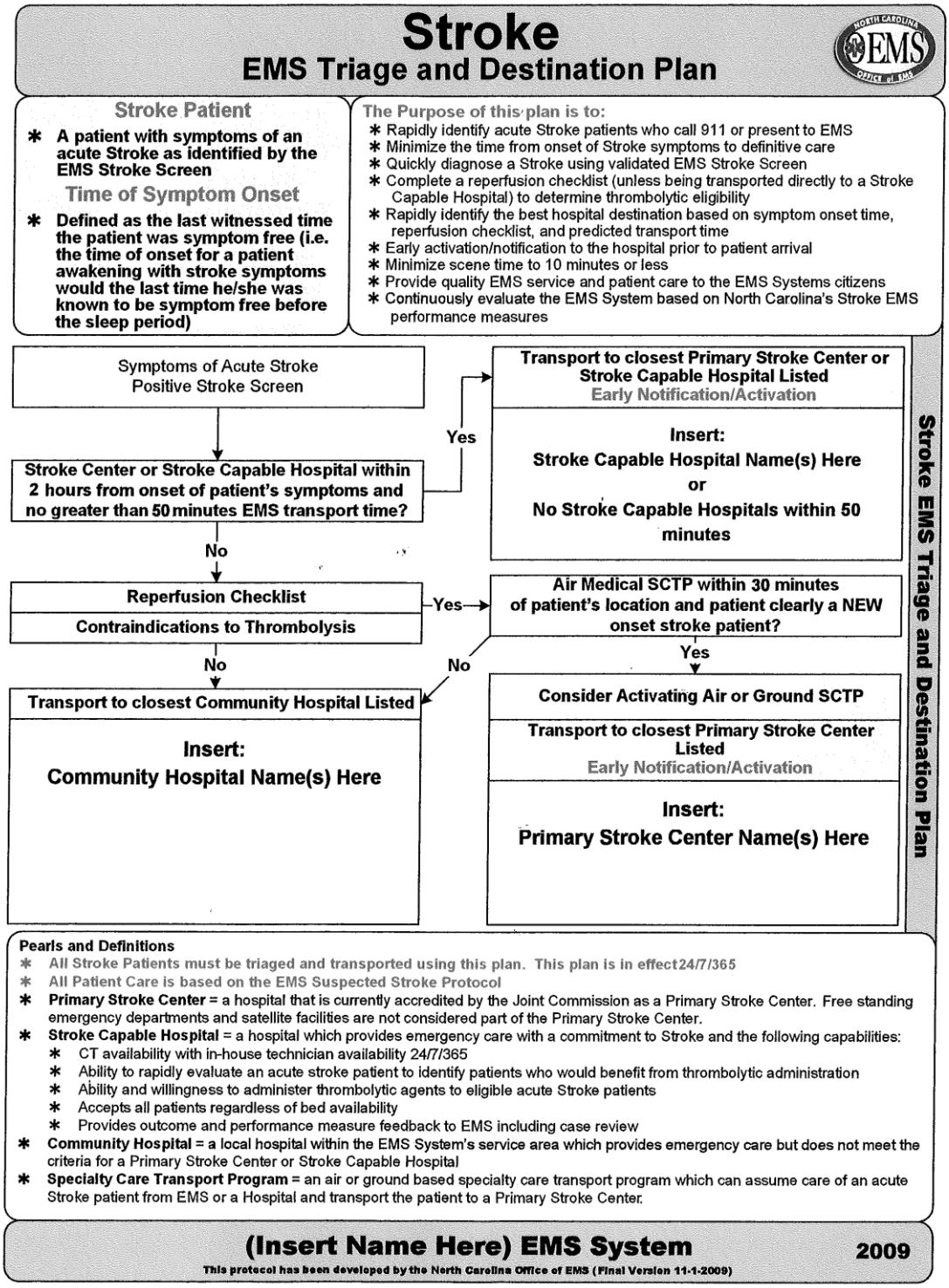
1. Monitor blood pressure
    - Check blood pressure every 15 min for 2 h, then every 30 min for 6 h, and finally every hour for 16 h
2. Diastolic greater than 140
    - Sodium nitroprusside 0.5 mcg/kg/min IV infusion as initial dose and titrate to desired blood pressure
3. Systolic greater than 230 OR diastolic 121 – 140.
    - Option 1
        - Labetalol 10 mg IV for 1 - 2 min
        - May repeat or double labetalol every 10 min to maximum dose of 300 mg, or give initial labetalol dose, then start labetalol drip at 2 - 8 mg/min
    - Option 2
        - Nicardipine 5 mg/h IV infusion as initial dose and titrate to desired effect by increasing 2.5 mg/h every 5 min to maximum of 15 mg/h; if blood pressure is not controlled by labetolol or nicardipine, consider sodium nitroprusside.
4. Systolic 180 - 230 OR diastolic 105 - 120
    - Labetalol 10 mg IV for 1 - 2 min

May repeat or double labetalol every 10 - 20 min to maximum dose of 300 mg or give initial labetalol dose, then start labetalol drip at 2 - 8 mg/min

Appendix C: North Carolina EMS Protocol for suspected stroke



Appendix D: North Carolina EMS stroke destination plan



Appendix E: North Carolina EMS transport policy

Standards Policy

Transport

Policy:

All individuals served by the EMS system will be evaluated, treated, and furnished transportation (if indicated) in the most timely and appropriate manner for each individual situation.

Purpose:

To provide:

- Rapid emergency EMS transport when needed.
- Appropriate medical stabilization and treatment at the scene when necessary
- Protection of patients, EMS personnel, and citizens from undue risk when possible.

Procedure:

1. All trauma patients with significant mechanism or history for multiple system trauma will be transported as soon as possible. The scene time should be 10 minutes or less.

2. All acute Stroke and acute ST-Elevation Myocardial Infarction patients will be transported as soon as possible. The scene time should be 10 minutes or less for acute Stroke patients and 15 minutes or less (with 12 Lead ECG) for STEMI patients

3. Other Medical patients will be transported in the most efficient manner possible considering the medical condition. Advanced life support therapy should be provided at the scene if it would positively impact patient care. Justification for scene times greater than 20 minutes should be documented.

4. No patients will be transported in initial response non-transport vehicles.

5. In unusual circumstances, transport in other vehicles may be appropriate when directed by EMS administration.

Appendix E: North Carolina Air Transport policy

Standards Policy

Air Transport

Policy:

Air transport should be utilized whenever patient care can be improved by decreasing transport time or by giving advanced care not available from ground EMS services, but available from air medical transport services (i.e. blood).

Purpose:

The purpose of this policy is to:

- Improve patient care in the prehospital setting.
- Allow for expedient transport in serious, mass casualty settings.
- Provide life-saving treatment such as blood transfusion.
- Provide more timely access to interventional care in acute Stroke and ST-elevation myocardial infarction (STEMI) patients

Procedure:

Patient transportation via ground ambulance will not be delayed to wait for helicopter transportation. If the patient is packaged and ready for transport and the helicopter is not on the ground, or within a reasonable distance, the transportation will be initiated by ground ambulance.

Air transport should be considered if any of the following criteria apply:

- Critical/unstable patient with > 20 minute transport time
- Multiple casualty incident with red/yellow tag patients
- Multi-trauma or medical patient requiring life-saving treatment not available in prehospital environment (i.e., blood transfusion, invasive procedure, operative intervention)
- Time dependent medical conditions such as acute ST-elevation myocardial infarctions (STEMI) or acute Stroke that could benefit from the resources at a specialty center as per the EMS System's Stroke and STEMI Plans.

If a potential need for air transport is anticipated, but not yet confirmed, an air medical transport service can be placed on standby.

If the scene conditions or patient situation improves after activation of the air medical transport service and air transport is determined not to be necessary, paramedic or administrative personnel may cancel the request for air transport.

Minimal Information which should be provided to the air medical transport service include:

- Number of patients
- Age of patients
- Sex of patients
- Mechanism of injury or complaint (MVC, fall, etc)