THE CORRELATION BETWEEN SYMPTOMS OF STROKE AND THE LENGTH OF TIME TO SEEK MEDICAL TREATMENT

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by

Lornalyn Grace E. Jimenez

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School of Nursing
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Abstract

of

THE CORRELATION BETWEEN SYMPTOMS OF STROKE AND THE LENGTH OF TIME TO SEEK MEDICAL TREATMENT

by

Lornalyn Grace E. Jimenez

Statement of Problem
Stoke is currently the fourth leading cause of death and disability in the United States (US) (CDC, 2014). Approximately 800,000 Americans suffer a stroke every year; 8,000 of them live in Orange County (USCB, 2014). Stroke is considered a medical emergency and requires activation of the emergency medical services (EMS) because those who arrive in the emergency room within three hours of the onset of symptoms tend to have less disability three months after a stroke than those who receive delayed care. Despite the abundance of public awareness and education on stroke available in the community, Americans still face challenges in recognizing symptoms of stroke and making the decision to seek medical treatment immediately.

Sources of Data
A non-probability, consecutive sampling methodology will be used to recruit all transient ischemic attack (TIA) and ischemic stroke patients present on the Progressive Care and Stroke Unit at Mission Hospital. They will be asked about the symptom that prompted them to seek medical treatment and the estimated time it took for them to decide to seek treatment.

Conclusion
This study will determine if there is a relationship between symptoms of stroke and delay time. Those symptoms that prompt a longer delay time will be discussed.
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CHAPTER 1: INTRODUCTION

Background and Significance

Stroke is currently the fourth leading cause of death in the United States (US) (Centers for Disease Control and Infection [CDC], 2014). Every year almost 800,000 American’s suffer a stroke and approximately 130,000 of them die from a stroke. In Orange County, California there are roughly 8,000 cases of stroke each year (USCB, 2014). The incidence of stroke among adults between the ages of 20 to 54 has increased drastically in the last 12 years (Kisella et al., 2012). In 2009, 34% of those hospitalized for a stroke were less than 65 years old (CDC, 2014). It is important to study stroke because it can be debilitating and cause long-term disability. In addition, it can be very costly. In 2008 alone, the US spent over 65.5 billion dollars for stroke care (Tadros et al., 2009).

There are two types of stroke: hemorrhagic and ischemic. A hemorrhagic stroke occurs when there is a weakened blood vessel in the brain that ruptures and causes a bleed in the brain (American Stroke Association [ASA], 2013). An ischemic stroke on the other hand occurs when there is an obstruction in a blood vessel that supplies blood and oxygen to the brain (ASA, 2013). In addition, there is also what is called a transient ischemic attack (TIA). A TIA is also known as a “mini stroke” and occurs when there is a temporary obstruction of blood flow to the brain (ASA, 2013). Eighty-seven percent of all strokes are ischemic strokes (CDC, 2014), and when this occurs, individuals experience symptoms such as blurred vision, dizziness, numbness, tingling, slurred speech, dysphagia, sudden weakness to one side of the body, loss of balance, lack of coordination, and confusion (CDC, 2014).

When symptoms of stroke occur, in order to minimize permanent disability, the individual should seek medical help immediately. There is a medication called tissue
plasminogen activator (TPA) which is injected intravenously to dissolve the clot that is causing the stroke. However, this medication is only appropriate to use within three to four hours of the onset of symptoms (ASA, 2013). The problem is that many individuals who experience these symptoms do not seek medical treatment immediately. The delay in seeking medical treatment puts them outside of the administration window for TPA administration.

Understanding the causes for delayed time to seek medical care is important and may relate to the type and severity of stroke symptoms. It is important to look at the strength of the relationship between stroke symptoms and the length of time to seek care because patients who arrive in the emergency room within three hours of their first symptoms tend to have less disability three months after a stroke than those who received delayed care (CDC, 2014). In addition, those with a history of stroke have a higher risk of having another stroke or a TIA within 90 days; the greatest risk occurring during the first week. Twenty-five percent of all stroke survivors will have another stroke within five years (CDC, 2014).

The actual time of delay of each symptom will be reported. If symptoms that prompt a longer and shorter length of time to seek medical treatment can be identified, this information may be valuable in determining which symptoms need to have more focus during stroke education. Stroke education can be overwhelming especially if an ample amount of information is given at once. If the proposed study can determine which symptoms prompt a longer delay time, more education can be focused on those symptoms to help improve delay time in seeking medical treatment.
The Problem

Stroke is one of the leading causes of death and disability in the US. It is a medical emergency that requires activation of the emergency medical services (EMS) for faster transport to a designated stroke facility and to initiate medical treatment. Health care professionals and educators have emphasized the importance of seeking medical treatment immediately by presenting an ample amount of stroke information to the public. However, Americans still face challenges in recognizing stroke symptoms and making the decision to seek immediate medical treatment.

There are several research studies including the study by Zerwic et al. (2007), McSharry et al. (2014) and Hsai et al. (2011) that focus on stroke knowledge, stroke symptoms, and risk factors associated with stroke; however less is known about the actual length of time to seek medical treatment and why there is often a delay in seeking medical treatment. Time of delay is important to study and crucial for improving the chances for survival and reducing disability. It has been found in the studies reviewed that stroke knowledge, perception of the stroke symptom, barriers related to culture, and possession of healthcare insurance are all related to the time of delay in seeking medical treatment, however, despite the abundance of education individuals experiencing stroke symptoms still wait before seeking medical treatment.

Purpose of the Research

This study will determine whether there is a relationship between common symptoms of stroke and the length of time to seek medical treatment. The common sense model of illness by Howard Leventhal is the conceptual framework that will be used to explain how an individual perceives and responds to a health threat based on internal and external stimuli and past experiences.
Implications for Nursing Practice/Policy/Research

The information concluded in this study can be used to focus on education to the general public about the stroke symptoms that are identified to have a longer length of time in seeking medical treatment. If the general public is aware of the symptoms that prompt a longer length of time to seek medical treatment, perhaps focusing education on that symptom will improve the delay time in the future. In addition, a nurse practitioner (NP) is a health care professional that is trained to diagnose, treat, and improve the health of individuals and promote health maintenance. Not only can they provide detailed education about stroke in general, but they can also further discuss and interpret radiological and laboratory results so that individuals can better understand the disease and work towards prevention and treatment of stroke. The education and discussion on stroke provided by the NP will hopefully impact the general public to help improve the time to seeking medical care in the future.

Research Question

Is there a relationship between symptoms of stroke and the length of time to seek medical treatment?

Hypothesis

The hypothesis states that there is a relationship between the type of stroke symptom and the length of time to seek medical treatment.

Research Variables

There are two variables in this proposed study, the symptom variable which is the physical symptom that the patient is experiencing and the length of time variable which is also a continuous variable and is measured in minutes. The length of time variable is the time it takes
for the individual to seek medical treatment. The symptom variable is assessed by asking the question “what symptom did you experience that prompted you to seek treatment?” If the participant experienced multiple symptoms, the participant must only choose the one symptom that made them decide to seek treatment. Seeking treatment can be any form of action such as dialing 911, calling a family or friend to take them to the hospital, or driving themselves to the hospital. The length of time to seek medical treatment is a numeric variable which will be the estimated time that the individual waited prior to seeking medical treatment.

**Conceptual Framework**

This research study will be based on The Common Sense Model of Illness (CSMI) by Howard Leventhal (see Figure 1 for the Common Sense Model of Illness by Howard Leventhal). This model helps to explain an individual’s action when experiencing symptoms of illness (Zerwic, Hwang, and Tucco, 2007). Howard Leventhal proposed that a person’s response or behavior to illness is determined by their representation of that illness (Zerwic et al., 2007). There are five components to illness representation: identity, cause, timeline, consequences and controllability/cure. The identity attribute is a disease label which includes the individual’s thoughts and ideas about the somatic aspect of the disease. The cause attribute refers to the individual’s beliefs about the cause of the illness. The timeline attribute is the individual’s expected timeframe of the illness (acute vs. chronic). The consequences attribute is the individual’s anticipated outcomes of the illness. Lastly, the controllability/cure attribute refers to whether the stimulus can be controlled (Diefenbach & Leventhal, 1996).

In this model, the individual deals with two phenomena: “the perceived reality of the health threat and emotional reactions to this threat” (Diefenbach & Leventhal, 1996). The individual is the problem solver who seeks information to test the meaning of the somatic
sensations or symptoms that they are experiencing. They will determine the relevance of the symptom from the media and messages about health risks. The representations of the illness (identity, cause, timeline, consequences and controllability/cure) will guide the way they cope. The study will focus primarily on the representation of the illness and their action to control the illness and/or to control their emotion related to the illness. The individual’s representation of the illness is highly individualized and may or may not be influenced by medical facts (Diefenbach & Leventhal, 1996).

The CSMI is appropriate for this study as the time between the illness representation and the individual’s action accounts for the length in delay time to seek medical treatment. The other factors involved in the decision to seek treatment are based on internal and external stimuli but will not be a focus of this study.
Figure 1: Common Sense Model of Illness by Howard Leventhal
CHAPTER 2: LITERATURE REVIEW

Introduction

CINAHL and PubMed were the databases searched to find relevant literature for this review. The search terms used include stroke, stroke 911, stroke symptoms, stroke delay, and stroke behavior. The search was limited to peer-reviewed articles written in English and published after 2007. No studies were found that examine the relationship between actual stroke symptoms and the length of time to seek medical treatment. Stroke symptoms and time of delay have been collected individually in two studies (Zerwic et al., 2007 & Mc Sharry et al., 2014); however, the relationship of stroke symptoms and the length of time in seeking treatment was not studied. Most articles focused on factors that contribute to a delay in seeking medical treatment, many of which involved stroke knowledge about symptoms and risk factors associated with stroke.

Literature Review

Mc Sharry et al. (2014) conducted a qualitative study in England with 20 participants looking at the symptoms experienced versus the symptoms expected and the time of delay in seeking medical treatment during a transient ischemic attack (TIA). They found that the delay in seeking treatment varied from minutes to eight days and that awareness of stroke symptoms lead to urgent action if severe TIA symptoms were present. Another study in the delay in seeking treatment was conducted by Zerwic et al. (2007). This exploratory study examined the knowledge of stroke symptoms, risk factors, and the factors causing a delay in seeking treatment. Among the 38 participants in the study, 60.5% of the participants were able to identify one risk factor for stroke and 55.3% were able to identify one symptom of stroke. However, with this knowledge, the median delay time from the onset of symptoms and arrival to the emergency
department (ED) in an urban community was 16 hours. Factors related to longer delay times were African-American race and Latino ethnicity, lack in recognizing the severity of the symptom, non-motor symptoms, did not use 911, and residing in an urban area. More specifically, they found that a primary non-motor symptom (p=.05) and not using 911 (p=.03) were of most significance in the delay of greater than two hours.

Understanding the reasons for delay in seeking medical treatment has also been studied in depth. A stroke survey conducted by Hsai et al. (2011) in a predominately urban black population found that of the 253 community participants who volunteered to do the study in the Washington D.C area, 89% said they would call 911, however of the 100 in-hospital participants who actually had a stroke, only 12% called 911. Most of them (75%) called a relative or friend. In addition, they also found that 89% of those who had a stroke reported a delay in seeking medical treatment; half of them thought that the symptoms were not serious enough and that they would self-resolve. Of those who arrived at the hospital via ambulance, 25% called EMS because they thought it would be faster while 35% said that they had no other mode of transportation. Furthermore, Ekundaya et al. (2013) studied the patterns of EMS use with stroke treatment. They analyzed data from 204,591 patients nationwide and found that 63.7% arrived to the ER via ambulance. Those who were more likely to activate EMS were older patients, those with Medicare or Medicaid insurance, and those who were experiencing severe symptoms of stroke. Minorities and those living in rural communities were less likely to activate EMS. In addition, having a history of stroke or TIA did not increase the likelihood of activating EMS.

A one-year population based survey developed by the CDC’s Behavioral Risk Factor Surveillance System (BRFSS) surveyed 131,988 participants from 18 states (Alabama, Arizona, Connecticut, Florida, Georgia, Idaho, Indiana, Kentucky, Louisiana, Minnesota, Mississippi,
Missouri, Montana, North and South Carolina, Virginia, West Virginia, and Wisconsin) and the District of Colombia in 2009 and found that the majority of the participants would call 911 if they thought that someone was having a stroke (Seo, Begley, Langabeer, and DelliFraine, 2014). They found that the more stroke symptoms present, the more likely the individual will call 911. The survey examined the barriers and disparities of the participants and found that those who were men, 65 years of age and older, unmarried, family income of $25,000 or less, education level of a high school diploma or less, uninsured, no primary care provider, financial burden, fair/poor health, and history of stroke are less likely to call 911 during a stroke. Furthermore, a study with 2,975 participants by Kleindorfer et al. (2009) and conducted in the Cincinnati/Northern Kentucky region examined the symptoms that were more likely to prompt a 911 call. They found that symptoms such as weakness, dizziness/vertigo, coordination, confusions, and speech/language problems were more likely to prompt a 911 call versus symptoms such as numbness and visual changes. Kleindorfer et al. (2009) suggests that some symptoms are recognized as more of an emergency. In this study, weakness was the most powerful symptom promoting a 911 call to activate EMS.

The association between knowledge of stroke symptoms and the intent to call 911 has also been studied. A population based survey in Michigan by Fussman, Rafferty, Lyon-Callo, Morgenstern, and Reeves (2010) found no association between knowledge of stroke symptom and intent to call 911. The study presented with three stroke scenarios: trouble speaking, trouble seeing, and sudden numbness or weakness. Among the 4841 participants, between 72% and 87% said they would take them to the hospital. However, despite the number of participants with adequate knowledge about stroke symptoms, only 17.6% said they would call 911 for these symptoms (Fussman et al., 2010). It is likely that a barrier to dialing 911 may be public
unawareness of the advantages of EMS transport. Another similar study was done by Ellis and Egede (2008). They compared three ethnic groups: non-Hispanic white, non-Hispanic black, and Hispanic/other. They found that among the 2,970 adults who have a history of stroke, the non-Hispanic black and the Hispanic/other group was found to be the lowest in recognizing the symptoms of stroke and taking action to call 911. They also found that recognizing warning signs of stroke was high in individuals with a history of stroke.

Summary

The major variables defined in the literature review include symptoms experienced, perception of symptoms, knowledge of symptoms, risk factors of stroke, and time of delay. Studies have explored these variables amongst various groups of individuals across the nation who have suffered an ischemic stroke or TIA. Despite the ample amount of research studies on stroke and all the available resources on stroke education there is still a concern as to why individuals experiencing acute symptoms of stroke still wait before seeking medical treatment.
CHAPTER 3: METHODOLOGY

Introduction

Symptoms of stroke and the length of time to seek medical treatment are important to study in order to improve stroke outcome. By looking at these variables, health care providers can determine better strategies in stroke education.

Research Question

The research question for this study asks “is there a relationship between symptoms of stroke and the length of time to seek medical treatment?” This research question focuses on nine common symptoms of stroke as well as any other symptoms experienced by the patient and the length of time it took for the individual to seek medical treatment.

Hypothesis

The hypothesis states that there is a relationship between the type of stroke symptom and the length of time to seek medical treatment.

Identification of Setting

The setting for this study will be on the Progressive Care and Stroke Unit (PCSU) at Mission Hospital in Mission Viejo, California.

Research Design

A correlational design will be used with the intent to explore the relationship between symptoms of stroke and the length of time to seek medical treatment. A researcher developed questionnaire written in English at a fifth grade level will be used for data collection (see Appendix A for stroke questionnaire). Content validity of the questionnaire will be established by having two experts review the appropriateness and clarity of the questions. A Clinical Nurse
Specialist (CNS) and a hospital Neurologist at Mission Hospital will be given a copy of the questionnaire to evaluate. Feedback and additional recommendations will be requested verbally over the phone or in person to improve the face validity and content of the questionnaire. In addition, to measure internal consistency reliability, Cronbachs alpha will be reported (Plichta and Kelvin, 2013). Demographic data will also be collected for purposes of describing the sample.

**Population and Sample**

A non-probability, consecutive sampling methodology will be used to recruit all TIA and ischemic stroke patients present on PCSU every Monday, Wednesday, and Friday between the hours of eleven o’clock in the morning and seven o’clock in the evening during a six-month period. They will be assessed for inclusion and exclusion criteria prior to extending an invitation.

A sample size of 37 participants was calculated for this study using the software program (G Power). A bivariate normal model correlational statistical test was used with a priori power analysis and an effect size of 0.40, an alpha of 0.05, and a power of 0.80. An effect size of 0.4 is the common average of measures to quantify the difference between groups over time. In addition, the higher the power, the higher the probability that the study will have a statistically significant result, therefore a power of 0.8 will be used.
Measurement Methods

Each participant will be interviewed. The variables will be recorded by the research assistant (RA) on each individual questionnaire. One symptom variable will be addressed as present while the length of time to seek treatment will be measured in days, hours, and/or minutes and later converted into minutes for the analysis.

Inclusion and Exclusion Criteria

All men and women age 18 and over admitted to or transferred to PCSU at Mission Hospital with a confirmed diagnosis of ischemic stroke or TIA will be invited. Those included in the study will have no memory deficits regarding the event and no history of dementia or Alzheimer’s disease. They must be oriented to person, place, time and event (meaning they must be able to briefly explain what happened during the time when symptoms occurred). The patient must be capable of describing the onset of the event in any language that can be translated into English using the interpreter phone provided by the hospital. Those who are incomprehensible due to dysarthria and/or aphasia but are clearly alert and oriented to person, place, time, and event and able to communicate via writing will be given the questionnaire to complete by hand with the RA at the bedside for guidance and assistance. However, those who are both unable to write and are incomprehensible due to dysarthria and/or aphasia will be excluded. Other patients who will be excluded include those who reside in or admitted from a medically supervised environment such as a skilled nursing facility (SNF), rehabilitation center, or boarding care facility due to the presence of trained health care professionals in the setting. Those residing in jail will also be excluded due to the presence of health care professionals in the setting. Those whose site of onset was unknown will be excluded. In addition, women who are pregnant will also be excluded due to the low probability of them having a stroke.
Data Collection Process

Once the Institutional Review Board (IRB) from California State University, San Marcos and Mission Hospital (see Appendix B for IRB application) approve the research plan, data collection will be started. Prior to the start of the study, all nurses on PCSU who work on both day shift and night shift will be notified of the study. They will be asked to notify the primary investigator (PI) or the RA in person or by phone if they are caring for a patient positive for an ischemic stroke or TIA, including those who are newly diagnosed, newly admitted, and/or newly transferred to the unit. In addition, since the charge nurses are familiar with the patients on the unit, they will be approached more often by the PI or RA to follow up on new admissions and transfers during the day who are positive for an acute ischemic stroke or TIA.

Prior to getting consent (see Appendix C for informed consent) to participate, the bedside nurse will be asked to assist the RA to determine if the patient’s mentation is appropriate for participation. The chart for potential candidates will be reviewed for inclusion and exclusion criteria. If the patient meets the criteria for the study, the RA will extend an invitation to the patient to participate. The RA will give a copy of the consent and explain the purpose of the study and the process. Once the patient consents to the study, the RA will start asking the questions on the questionnaire. The RA will handwrite the participant’s answers on the individual questionnaire. The patient will be interviewed without the presence and influence of family or friends at the bedside.

If at any time during the completion of the individual questionnaire the RA determines ineligibility of the participant, the individual survey will be aborted and the participant will be thanked for his or her participation. Any partially completed data collection tools will be shredded to protect confidentiality. In addition, the participant may at any time during the
completion of the questionnaire withdraw from the study. All questionnaires will be anonymous therefore withdrawal from the study after submitting the questionnaire will be impossible. This is clearly written on the consent. To control for repeated participation in the study, each individual will be asked if they have participated in this study at Mission Hospital in the last six months and if they have, the RA will check the saved consents located in a 3-ring binder and filed in alphabetical order for the individual’s name and signature to confirm previous participation. If they have already participated the patient will be notified and they will not be invited to participate in the study.

**Data Coding and Scoring**

The demographic data included in the study include age, gender, and ethnicity. Age will be coded in raw number form. Gender will be coded as male=0, female =1 and 2=transgender. Ethnicity will be coded as Hispanic or Latino=0, American-Indian or Alaska Native=1, Asian=2, Black or African-American=3, Native Hawaiian or Pacific Islander=4, and White=5.

Participants will be asked if they experienced any of the ten common symptoms of stroke which include facial droop, headache, dizziness, blurred vision, numbness/tingling, slurred speech, difficulty swallowing, sudden weakness, coordination difficulty, and confusion. Each of these symptoms will be coded and grouped. Facial droop=0, headache=1, dizziness=2, blurred vision=3, numbness/tingling=4, slurred speech=5, difficulty swallowing=6, sudden weakness=7, coordination difficulty=8, confusion=9 and the last category is other which will be a symptom that must be specified by the participant and will be added as its own category and coded individually. Only one of these symptoms must be checked. The variable is also in the form of a question and asks “How long did you wait before intervening? From the time you first experienced the symptom to the time you sought medical treatment?” This question asks for an
estimated length of time from the onset of symptoms to the time they decided to seek medical treatment. This is a continuous variable therefore the participant must answer to the best of their knowledge in days, hours, and/or minutes. If they are unable to calculate the estimated time, the RA may simply ask approximately what time did you experience the symptom? And approximately what time did you seek medical treatment? The RA will record the times on the questionnaire and then calculate the time of delay based on those answer. The researcher will convert this numeric variable into minutes to conduct the analysis.

There are three other questions that are included and the frequencies will be reported. First question is “Was there anyone present at the time of onset of symptoms who influenced your decision to seek treatment, and if so who? No=0. If yes, Spouse=1, Sibling=2, Parent=3, Other Blood Relatives (Aunt, Uncle, Niece, Nephew, Cousins etc.)=4, Friend=5, Stranger=6. If there was a presence of another individual, the RA will ask “which of you made the decision to seek treatment?” This question will be important in determining the influence others have on the length of time in seeking treatment. The third question asks participants how they arrived to the hospital. Ambulance=1, Private Vehicle=2, Public Transportation=3.

Data Analysis

The program that will be used to analyze the data is SPSS version 20. The Spearman rho correlation test will be used for the statistical analysis of this study. Spearman rho measures the relationship between two variables; in this case, the variables are symptoms of stroke and the length of time to seek medical treatment. Spearman rho will test the strength and direction of two non-parametric variables (Prion & Haerling, 2014). In this analysis, a value between -1 and +1 will be calculated. A value of 0 means no relationship. The higher the value, the stronger the relationship between the variables.
When interpreting Spearman rho, the rule of thumb is as follows: “0 to +0.20 is negligible, +0.21 to +0.40 is weak, +0.41 to +0.60 is moderate, +0.61 to +0.80 is strong, and +0.81 to +1.00 is considered very strong” (Prion & Haerling, 2014). If both variables move in the same direction, it is a positive correlation. If both variables move in opposite directions, it is a negative correlation (Prion & Haerling, 2014). Frequencies will be reported for demographic variables. Measures of central tendency will be reported for the time-to-treatment delay variable.

**Bias**

There is some potential for bias in this study. Investigator bias could occur when assessing for ability to participate. Measuring the mentation of the patient to determine whether or not to include them in the study could result in over or under estimation of mentation. Furthermore, the self-reported data for the dependent variable (time of delay) may have some inaccuracy. Participants may overestimate or underestimate the time of delay in hours which may lead to inaccurate findings. In addition, social desirability may also be an issue. Social desirability is the tendency of participants to answer questions in a manner that is favorable to others which may lead to misleading research results. Although there are methods for testing social desirability such as the Crown Marlow Index, the PI decided not to administer this questionnaire because it will be assumed that the participant will answer accordingly and will be advised that there is no right or wrong answers on the stroke questionnaire.

**Ethical Considerations**

Approval from the CSUSM and Mission Hospital IRB will be obtained. The PI and RA will complete CITI training for protection of human subjects prior to submitting IRB application. Informed consent will be signed by all participants. Informed consent documents will be kept for
three years as per IRB requirements. Cognitively and developmentally disabled persons, prisoners, and children will be excluded from the study. Since pregnant women will also be excluded from the study due to low probability of them having a stroke, there will be no vulnerable groups included in the study.

During the duration of this study, all process and procedures will adhere to ethical standards. All questionnaires will be kept in a locked file and placed in the unit Educators office in a locked filing cabinet. Questionnaires will only be accessible to the researcher who will hold the key to the filing cabinet and will be destroyed/shredded 6 months upon completion of the study.

Summary

The collaboration of the PI, RA and the unit nurses will be critical in this research study. The unit nurses and the charge nurse will be the most important resource in determining the appropriateness of the participant. Since they are more familiar with the potential participant they will be able to help the PI and RA to quickly screen for inclusion and exclusion criteria. In addition, they will also be helpful to control for repeated participation.
CHAPTER 4: GRANT ELEMENTS

Potential Grant 1

The National Institute of Neurological Disorders and Stroke (NINDS) continue to fund unsolicited, investigator-initiated research projects. The Omnibus Appropriations Bill was signed by President Obama to provide more than 1.5 billion dollars in funding to national research studies which include the NINDS.

A Research Project Grant (R01) supports a focused research study conducted by a principal investigator with or without collaborators. They may include postdoctoral trainees, graduate students and/or technicians. The applicant is the research organization. The research organization must be a domestic or foreign for-profit and non-profit organization and/or public or private institutions (NIH, 2016a). For this study, California State University, San Marcos or Mission Hospital will be the research organization applying for the grant on behalf of the principal investigator. Research project grants are awarded to the institution and the research institution will be accountable for the grant funds to ensure that the study is provided with the facilities necessary to complete the research.

There is no limit to a requested budget for this application, however those exceeding $500,000 in direct costs must contact the NINDS prior to submitting their application. This grant accepts applications year round with an upcoming deadline on June 5 and October 5, 2016. The study fulfills the requirements for this grant, however getting an institute or research organization to apply on behalf of the principal investigator is of concern (DHHS, 2016a).
Potential Grant 2

NIH Small Grant Program (R03) can support small, short-term research projects that can be carried out within two years and that require limited funding. No more than $50,000 can be requested per year. This program is similar to R01, but is not expected to have the same level of detail (DHHS, 2016b).

Eligible organizations must be a domestic or foreign for-profit and non-profit organization and/or public or private institutions. Eligible individuals include anyone with the skills, knowledge and resources to conduct and complete the research study. This program recommends that individuals who are applying work with his/her organization to develop an application for support (NIH, 2016b). The study fulfills the requirements for this grant.

Potential Grant 3

The American Heart Association (AHA) and the American Stroke Association (ASA) is a national health organization dedicated to improving the health of individuals with cardiovascular disease and stroke. Together they formed the National Coalition for Heart and Stroke Research in 1995 to help fund research programs to support beginner and novice investigators who are pursuing a study in identifying new ways to prevent, detect and treat cardiovascular disease and stroke.

The requirements for this fund include applicant credentials. The applicant must hold a faculty or staff appointment or hold a post-baccalaureate doctoral degree. There is no minimum specified effort required however the principal investigator must demonstrate that the applicant holding the necessary credential invest sufficient time to ensure successful completion of the project. Another requirement is the location of the study. California is an approved state for approval of this fund. In addition, the award must be conducted at an accredited institution which
includes public and voluntary hospitals that can demonstrate the ability to conduct the proposed research.

The requirements for this grant have been met in this proposed study therefore it would be feasible to apply. The total award budget available is $154,000 for 2 years ($77,000/year). However, it will only pay 50% of the salary and fringe to the principal investigator and any other collaborating investigators including the research assistant and the faculty staff advisor (FSA). This will be a problem. They will however pay up to $3,000 for travel expenses, which is more than enough to cover the travel expense for the PI and RA. The deadline to apply is July 27, 2016.

**Selected Grant**

The NIH small grant program (R03) would be the selected grant. This program will support small studies such as this and will pay up to $50,000 which is enough as this study will require approximately $49,733 to complete. The PI and FSA will need to develop an application for either Mission Hospital or CSUSM to serve as the “applicant” in this study per the requirements for this grant.

**Budget**

The projected total for this study is $49,733. This amount will include the compensated salary and travel expense for the PI, RA, and the FSA (see Table 1 for the Total Compensation for Salary and Travel) as well as the total cost for the supplies needed for the study (see table 2 for Cost for Supplies).

The PI for this study holds a Master’s Degree in Family Nurse Practitioner from California State University, San Marcos. She has six years of experience working with stroke victims; 4 of those years on PCSU at Mission Hospital. The PI will be responsible for the overall
direction of the project. She will present the project to the Institutional Review Board (IRB), facilitate data collection by the RA, analyze the data, and manage the budget. The PI will be spending 8 hours every Monday, Wednesday, and Friday from the hours of 11am to 7pm to enter data into SPSS and conduct the analysis. That will be a total of 576 hours in 6 months. The PI will also need additional time after the collection of data to complete her analysis and conclude the study and an expected average of 200 hours will be invested for a total of 776 hours.

The RA is a Licensed Vocational Nurse (LVN) and currently a Bachelor’s Degree student at American University of Health Sciences. She will be spending a total of 24 hours a week collecting data on Monday, Wednesday, and Friday between the hours of 11am to 7pm. This will be a total of 576 hours in 6 months.

The FSA is a Professor and a part-time lecturer at California State University, San Marcos and San Diego State University. She is a Clinical Nurse Leader with a Doctorate Degree. She will be the expert for this project and will help guide the PI and oversee the progress and direction of the project. The 30 hours will be time spent during phone and in-person meetings to discuss methodological issues and statistical analysis.
Table 1: Total Compensation for Salary and Travel

<table>
<thead>
<tr>
<th>Role on the Project</th>
<th>Hours Invested</th>
<th>Salary Base</th>
<th>Travel Cost</th>
<th>Total Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Investigator</td>
<td>776 (8 months)</td>
<td>$45/hour</td>
<td>$1,296</td>
<td>$36,216</td>
</tr>
<tr>
<td>Research Assistant</td>
<td>576 (6 months)</td>
<td>$10/hour</td>
<td>$250</td>
<td>$6,010</td>
</tr>
<tr>
<td>Faculty Staff Advisor</td>
<td>30 (8 months)</td>
<td>$100/hour</td>
<td>$0</td>
<td>$3,000</td>
</tr>
</tbody>
</table>

*Table 1.* The PI will be compensated at $45/hour for a total of 776 hours in 8 months, totaling $34,920. The PI resides 30 miles from Mission Hospital therefore the total cost for gasoline round trip three days a week for 6 months is $504. In addition the PI will need to pay toll fees to get to and from Mission Hospital. The cost for toll round trip to Mission Hospital 3 days a week for 6 months is $792.00. The RA will be compensated at $10 per hour for a total of 576 hours for a total of $5,760. The RA resides 15 miles from Mission Hospital therefore the total cost for gasoline three days a week for 6 months is $250.00. The FSA will be compensated $100 per hour for 30 hours for a total of $3,000. There is no compensation for transport. The total compensation for salary and travel is $45,226.

All supplies will be purchased at Office Depot. Supplies needed for this project include a laptop computer, all-in-one printer, printer ink, Microsoft Office 2016, SPSS and stationary supplies.

A Hewlett Packard laptop computer will be needed to store and analyze the data. It will be used to create and store the final product of the research study which will include colored graphs, charts, and tables. The laptop computer will also be used to store copies of the consent forms and questionnaire. An Epson wireless ink-jet all-in-one colored printer and scanner will be used to print copies of the consent form and the questionnaire. It will be used to scan signed consent forms and individual questionnaires for electronic storage in the computer. It will also be used to print the final research study which will include colorful graphs, charts, and tables to depict differences in the study. The Microsoft Office 2016 (Word, Excel, PowerPoint, and OneNote) application will be purchased and used to create and store the original consent form.
and questionnaire. It will be used to create the final product of the research study which will include graphs, tables, and charts. The IBM SPSS Statistics Standard Pack is a statistical software application that will be downloaded on the laptop computer and will be used for data management analysis. Stationary supplies will be purchased and used for data collection, storage of questionnaires, consents and forms. A pack of ball point pens and two clipboards are materials that the RA will need to collect data in the patient’s room. Two large envelopes will be used to hold the blank consent forms and the blank questionnaires. A 2-inch ring binder will be needed to hold the hard copy of the signed consent forms and completed questionnaires. Index tabs will be used to organize the consent forms and questionnaires in the 2-inch ring binder. In addition, one case (5000 sheets) of copy paper will be needed for questionnaires, consent forms, letters, and reports.

Table 2: Cost for Supplies

<table>
<thead>
<tr>
<th>Supplies</th>
<th>Quantity</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laptop computer + 2 year protection plan</td>
<td>1</td>
<td>$1,200.00</td>
</tr>
<tr>
<td>All-in-one printer + 2 year protection plan</td>
<td>1</td>
<td>$126.00</td>
</tr>
<tr>
<td>Black ink cartridge</td>
<td>2</td>
<td>$74.00</td>
</tr>
<tr>
<td>Colored ink cartridge</td>
<td>2</td>
<td>$72.00</td>
</tr>
<tr>
<td>Microsoft Office 2016</td>
<td>1</td>
<td>$165.00</td>
</tr>
<tr>
<td>IBS SPSS Statistics Pack + 1 year license and technical support</td>
<td>1</td>
<td>$2,610.00</td>
</tr>
<tr>
<td>Stationary Supplies</td>
<td></td>
<td>$260.00</td>
</tr>
</tbody>
</table>
Timeline

The estimated timeline for this project is eight months. It will take no longer than six months to collect data from 37 participants which is the minimum sample size needed for the project. If the number of participants is reached before the six month deadline for data collection, data will still continue to be collected until the six month deadline. The PI will be inputting the data into SPSS during the course of data collection, therefore once the data collection has ended, the last two months will be used to analyze the data and complete the research study.

Plan for Dissemination of Findings

Every year the AHA and the ASA conducts the International Stroke Conference which is the world’s largest meeting dedicated to stroke. This conference features more than 1,500 presentations on clinical and community findings, research-based studies, and new treatment findings and management strategies to improve the outcome of stroke. This conference is over a two and a half day period and would be a good opportunity to present the findings of this project.

Furthermore, the AHA and the ASA is the nation’s largest and oldest organization committed to fighting stroke and heart disease. In addition to funding research, they provide multiple resources for the community to help American’s make healthy lifestyle choices and improve quality of life. The AHA and the ASA would be the best choice to publish this study. Otherwise, the Journal of Stroke and Cerebrovascular Disease (JSCD) would also be appropriate. The JSCD focuses on the prevention and repair of cerebrovascular disease.

In addition, the PI will offer a one hour presentation and a free lunch at the PCSU conference center in December, 2017 for Doctors and Nurses who are interested in learning about the findings of the study. The intent of this presentation is to ideally improve stroke education.
REFERENCES

American Heart Association (AHA), (2016) Grants@Heart. Retrieved from:
https://research.americanheart.org/ris/template.jsp?pid=ris.extlogin&_requestid=41

http://www.strokeassociation.org/STROKEORG/AboutStroke/TypesofStroke/IschemicClots/Ischemic-Strokes-Clots_UCM_310939_Article.jsp

http://www.cdc.gov/stroke/facts.htm


of association between stroke symptom knowledge and intent to call 911 a population-based survey. *Stroke, 41*, 1501-1507.


Seo, M., Begley, C., Lagabeer, J. R., & Dellifraine J. L. (2014). Barriers and disparities


Appendix A

Stroke Questionnaire

Age: __________

Gender:       Male □   Female □   Transgender □

Ethnicity:     Hispanic or Latino □
               American-Indian or Alaska Native □
               Asian □
               Black or African-American □
               Native Hawaiian or Pacific Islander □
               White □

1. What symptom did you experience that prompted you to seek treatment? If you were experiencing more than one symptom, choose the symptom that concerned you the most.

   Facial droop □
   Headache □
   Dizziness □
   Blurred Vision □
   Numbness/Tingling □
   Slurred Speech □
   Difficulty Swallowing □
   Sudden Weakness □
   Coordination Difficulty □
   Confusion □
   Other: __________ □

2. How long did you wait before intervening? From the time you first experienced the first symptom (Days, Hours, Minutes)

   D_________ H_________ M_________

3. A. Was there anyone present at the time the symptom occurred who influenced your decision to seek medical treatment? No □ If Yes, □ Who? (Spouse, Sibling, Parent, Other Blood Relative, Friend, Stranger) ________________

   B. Which of you made the decision to seek medical treatment?

4. How did you arrive in the hospital? Car □ Ambulance □ Public Transportation □
Appendix B

Submission Procedures:
1. The researcher completes application
2. If the researcher is a student, their faculty advisor must review the application and sign the application in IRBNet. Additional instructions can be found on the last page of this application. **
3. The researcher submits the application and accompanying documents to IRBNet. http://www.csusm.edu/qsr/irb/forms.html
For assistance completing this form, please review the resources located at www.csusm.edu/irb.
If you have any questions, please refer to the IRB website or contact the IRB staff at (760) 750-4029 or irb@csusm.edu.
Please answer each section completely and as concisely as possible. Use lay terms as IRB members have diverse backgrounds.

☐ Full Review  ☑ Expedited Review  Proposed Start Date 01/01/2017

Project Title
THE CORRELATION BETWEEN SYMPTOMS OF STROKE AND THE LENGTH OF TIME TO SEEK MEDICAL TREATMENT.

Faculty/Staff Investigator:

Name
Phone Number
Date CITI Completed
Department/College
E-mail

Student Investigator: (if the student is the primary investigator) **

Name LORNALYN JIMENEZ
Department/College CSU SAN MARCOS
Phone Number 707-342-8364
E-mail JIMENo87@COUGARS.CSUSM.EDU
Date Training Completed
CITI Yes IRB Workshop

Faculty Advisor Name: JOANNA DAUGHERTY
Department/College CSU SAN MARCOS - NURSING
Phone Number 760-750-7550
E-mail JDAUGHERTY@CSUSM.EDU
Date CITI Completed

Checklist: Check which of the following items are included, as applicable:

☑ Certification of Human Subjects Protection training for each researcher and the faculty advisor.

☑ Letter/email of organizational support (required if recruiting or interacting with participants at a specific site or through a specific organization outside of CSUSM.) If sent in an email, must include organization and position of the person who approved.

☐ Recruitment flier(s) or advertisements, scripts for radio or TV.

☑ Survey(s), questionnaires, or interview questions. If this is an online survey, please provide a pdf copy of the survey.

☑ Consent and/or child assent form(s) or information sheet(s).
   For online surveys, provide a pdf copy of the introduction/information screens.
   1. Provide unique forms for each population in your research.
   2. Use official letterhead or the masthead found in the samples on the IRB website
   3. Include contact information for the Researcher, faculty mentor, and IRB office.
   4. Be sure the information in your consent/information sheet MATCH your application information!

☑ Students Researchers ONLY: Faculty advisor has approved the project and has signed the application in IRB Net.

☐ Ed.D Students ONLY: Attach the required UCSD-CSUSM-JDP IRB Cover Sheet. Please be sure to sign the form, scan it, and submit it with your application as a separate document.
1. Purpose of Project and Project Background

Describe your research question, including why the question is important, and how your study will attempt to answer it. Include how your literature review supports this with at least three citations. (Do not exceed one page.-Use lay language.)

The purpose of this study is to determine if there is a relationship between symptoms of stroke and the length of time to seek medical treatment. There were no studies found that examine the relationship between actual stroke symptoms and the length of time to seek medical treatment. Many of the articles reviewed focused on factors that contribute to a delay in seeking medical treatment, many of which involve knowledge about symptoms and risk factors associated with stroke. Mc Sharry et al. (2014) found that the length of time in seeking treatment varied from minutes to eight days and that awareness of stroke symptoms lead to urgent action if severe transient ischemic attack (TIA) symptoms were present. A stroke survey conducted by Hsai et al. (2011) in a predominately urban black population found that 89% of those who had a stroke reported a delay in seeking medical treatment; half of them who thought that the symptoms were not serious enough and that it would self-resolve. In addition, Zerwic, Hwang, and Tucco (2007) found that the median length of time from the onset of symptoms and arrival to the emergency department (ED) in an urban community was 16 hours and the factors related to longer delay times were African-American and Latino ethnicity, lack in recognizing the severity of the symptom, non-motor symptoms, did not use 911, and residing in an urban area. It is important to look at the relationship between stroke symptoms and time of delay because patients who arrive in the emergency room within three hours of their first symptom tend to have less disability three months after a stroke than those who receive delayed care (CDC, 2014). In addition, stroke education can be overwhelming especially if an ample amount of information is given all at one time. If we can determine the symptoms that prompt a longer length of time in seeking medical treatment, we can focus on emphasizing stroke educating on those symptoms in order to improve future delay time in seeking treatment.

The setting for this study will be on the Progressive Care and Stroke Unit (PCSU) at Mission Hospital in Mission Viejo, California. A correlational design will be used with the intent to explore the relationship between symptoms of stroke and the length of time to seek medical treatment. A non-probability, consecutive sampling methodology will be used to recruit all TIA and ischemic stroke patients present on PCSU every Monday, Wednesday, and Friday between the hours of eleven o’clock in the morning and seven o’clock in the evening that meet the inclusion and exclusion criteria over a six month period. Data will be collected by the research assistant (RA). A researcher developed questionnaire with questions pertaining to the symptom and time of delay as well as demographics will be asked by the RA and written on each individual questionnaire. Once data collection is done, the Spearman rho will be used for the statistical analysis of this study.

2. Recruitment Procedures & Participant Population

A) List the expected number of participants for each population group included in this study. 37

B) Describe all characteristics relevant to being selection of participants. (e.g., demographics, ethnicity, vulnerabilities, etc.) Explain why you are targeting this specific population.

All men and women 18 and older admitted or transferred to PCSU at Mission Hospital with a confirmed diagnosis of ischemic stroke or TIA will be invited. To allow for better accuracy of data collection, those included in the study will have no memory deficits regarding the ischemic event and no history of dementia or Alzheimer's disease; they must be oriented to person, place, time and event (meaning they must be able to briefly explain what happened during the time when symptoms occurred.) The RA will ask each individual the questions on the questionnaire and write in their answers on the participants questionnaire. The patient must be capable of describing the onset of event in English. Family and friends will not be allowed to assist with answering the questions.
C) Indicate whether anyone might be excluded from participating and explain why.

To control for better accuracy, those who are both unable to write and are incomprehensible due to dysarthria and/or aphasia will be excluded, however, those who are incomprehensible due to dysarthria and/or aphasia but are able to write will be given the questionnaire to complete by hand as long as they are oriented to person, place, time, event. The RA will be at bedside to assist if needed. Other individuals who will be excluded include those who reside in or admitted from a medically supervised environment such as a skilled nursing facility (SNF), rehabilitation center, or boarding care facility due to the presence of trained health care professionals in the setting. Those residing in jail will also be excluded due to the presence of health care professionals in the setting. Those whose site of onset was unknown will be excluded. Pregnant women will also be excluded.

D) How will you find, recruit, or identify potential subjects? How will you select, from the volunteers, the final group of participants? Submit flyers, posters, or other oral or written invitations used to recruit potential participants.

Prior to the start of the study, all nurses on PCSU who work on both day shift and night shift will be notified of the study. On data collection days (Monday, Wednesday, Friday) the nurses will be reminded during the morning meeting prior to every shift of the study. They will be asked to notify the researcher by phone if they are caring for a patient positive for an ischemic stroke or TIA. In addition, since the charge nurses are familiar with the patients on the unit, they will be approached more often by the RA to follow up on new admissions and transfers during the day who are positive for an acute ischemic stroke or TIA.

E) Will you be offering an incentive?

☐ Yes  ☐ No

If yes, please explain procedure for any incentives that will be offered. Include how much participants must do to be eligible to receive credit.


Explain for each population participating in your research.
See the IRB web page on Informed Consent. See also Language Requirements.

A) How and when will you explain the study and the required elements of Informed Consent? Will you be doing this or will it be handled by a research assistant?

Prior to getting consent for participation, the bedside nurse will be asked to help the researcher determine if the patient's mentation is appropriate for participation. The chart for potential candidates will be reviewed for inclusion and exclusion criteria. If the patient meets the inclusion and exclusion criteria, the research assistant will enter the room, introduce herself, explain the purpose of the study and the process, and then personally extend an invitation to the patient to participate in the study. Once the patient consents to the study and they are ready to complete the questionnaire right then and there, the RA will start asking the questions.
B) How much time will participants have to consider participating between the explanation described above, the receipt of the consent document, and the beginning of study?

The participant will have until 7pm that day to decide if they would like to participate. If by then they have not decided, they will be approached during the next data collection day if they have not been discharged.

C) If there are subjects under the age of 18, how will the study be explained to them? How will parental consent and child assent be handled?

There are no subjects under the age of 18.

D) If you are requesting a Waiver of Consent or a Waiver of Documentation of Consent, explain why this waiver is needed. Outline alternative procedures for obtaining consent or providing study information (e.g., information sheet, introduction screen for web survey, etc.).

Not Requested.

E) Indicate the primary language(s) of your participants. If any participants’ is not fluent and comfortable with English, explain how you will ensure that participants’ understanding of the activity for which they are giving consent.

An interpreting agency provided by the hospital will be available for those participants who are not fluent or comfortable with English.

4. Procedures and Methodology

Provide descriptions of each distinct procedure and each population group.

A) Provide a step-by-step explanation of your research activities and methodologies that involve human subjects.

The study design that will be used is a Correlational design. A researcher developed questionnaire written in English at a fifth grade level will be used to collect data. A non-probability, consecutive sampling methodology will be used to recruit all TIA and ischemic stroke patients present on PCSU every Monday, Wednesday, and Friday between the hours of eleven o'clock in the morning and seven o’clock in the evening that meet the inclusion and exclusion criteria over a six month period. Patients who meet the criteria for participation will be approached. The RA will explain the study and ask for consent prior to participation. The data will then be collected by the RA. Upon completion of the data collection, the RA will thank them for their participation and provide them with a business card with the primary investigators (PI) name, phone number, and e-mail address. The RA or PI will input the data into the SPSS 20.
program on the laptop. Spearman rho will be used to statistically analyze the data.

B) Where will the research will be conducted? Describe any risks or confidentiality issues related to using this location.

The research will be conducted on the Progressive Care & Stroke Unit at Mission Hospital in Mission Viejo, California. Because of the location, there is a risk for confidentiality however the questionnaires are anonymous and in order to maintain confidentiality, all questionnaires will be kept in a locked box and placed in the unit Educators office in a locked filing cabinet. Questionnaires will only be accessible to the PI and the RA. The PI will hold the key to the locked box and the locked filing cabinet.

C) State the specific dates/timeframe in which you plan to conduct your research.

Data collection will be 6 months long and start on January 1, 2017 and end on June 30, 2017. An addition 2 months will be needed to complete the analysis and the conclusion. The study should be fully completed by August 31, 2017.

5. Participant Debriefing or Feedback.
   If deception is involved in your research, participants should be debriefed about the nature of the study as soon as possible.
   Participants should be given the opportunity to request a copy of the results of the study/your final report.

A) Describe any feedback or information you will offer participants.

The RA will give the participant a copy of the consent and a business card which will include the e-mail address and phone number of the RA and PI. If the participant would like a copy of the final research study, they may contact the PI via e-mail to request a copy of the final research study.

6. Risks
   List risks for each population participating in the research and for each methodology.
   Please be sure the risks listed here match the risks mentioned in your consent letter or information sheets.
   Consider all risks very carefully. For more information on risks, see Examples of Risk.

A) Explain potential risks to your participants. Risks may be physical, psychological (e.g., strong emotional reactions to research questions), or inconveniences (e.g., time required).

Psychological Risk: The participant may become emotional when recalling the event. It can be distressing when they reflect on what they could have done to prevent the event and have regrets.
Inconvenience: The participant may feel that it is too time consuming and will take up too much time out of their day when they feel the need to rest.

B) Vulnerable Subjects: Select which, if any, of the following vulnerable subjects will be involved in your research.

☐ Pregnant women, human fetuses, neonates (see Federal Guidelines, 45 CFR 26, subpart B)
Prisoners (see Federal Guidelines, 45CFR26, subpart C)
Children (see Federal Guidelines, 45CFR26, subpart D)
Other Vulnerable Populations such as persons with cognitive disabilities, economically or educationally disadvantaged persons, etc.
C) Describe and special risks to vulnerable populations or your population profile

No vulnerable subjects will be included in the study.

D) List risks related to confidentiality of data. What could happen if an unauthorized person accessed the data? For instance, participant’s identify or personal information could be known by others

If the locked box and locked filing cabinet that contain the consent forms and questionnaires is accessed by another individual, the risk for confidentiality of data is low because the data collected will be anonymous and there will be no identifying marks on the responses thus it would be impossible for an unauthorized person to determine each participants questionnaire. The unauthorized individual may have an idea of who the participants are based on the signed consent forms but that will be the extent.

E) Will any personal identifying data be recorded? If so, what information will be recorded?
(e.g., Social security number, drivers license number, student id, address, phone number, birth date, personal email address)

Other than the consent forms which will include the participants name and signature, there will be no other personal identifying data recorded on the questionnaire other than their response.

7. Safeguard Procedures to Minimize Risks.

A) Please respond to each risk that you listed in #6 above. State how you will minimize each risk and protect confidentiality.

Psychological: The PI will visit the participant after data collection to personally thank the participant. At this time, the PI will ask if they have any concerns. Any signs of psychological distress caused by the study questionnaire will not be taken lightly and will be mentioned to the attending doctor. In addition, the hospital provides spiritual care services and concierge services which can also be called to come and talk to the participant.

Inconvenience: The RA will explain that it will take no longer than 5 minutes to explain the study, get consent, and do the questionnaire.

Confidentiality: To protect confidentiality, all consent forms and questionnaires will be stored in a locked box located in a locked filing cabinet in the Educators office that is only open between the hours of 9am and 5pm Monday to Friday when the Educator is working. The office key can be retrieved from hospital security if needed however only the researcher and the research assistant will have the keys to the locked filing cabinet and box.

B) How you will safeguard data? Where/how will data be stored? Who will have access to the data? How will access be limited?

Data will be stored in a password protected laptop. Access will only be granted to the PI and RA.
C) List referrals and/or resources that may be offered if a participant has a strong emotional response or a physical injury (e.g., clinics or shelters, medical or psychological referrals).

If the participant has an emotional response to the study, the attending doctor will be notified. Spiritual care and the hospital concierge will be available for emotional support.

8. Study Benefits

A) Discuss any potential individual and/or societal benefits. Note, often there is no direct benefit for the participants. However, the study may contribute to the literature and/or future research.

There is no direct benefit to the participant; however, they will be notified that their participation in the study may be beneficial to them in the future as it will help future research on improving stroke education and length of time in seeking medical treatment.

B) Do the benefits from this study exceed the risks to participants? Please explain.

No. By explaining the benefits of the study, hopefully it will encourage the individual to participate as they will be contributing to the future of stroke education.

9. Researcher(s) qualifications and experience.

A) Briefly outline the primary researcher(s)'s qualifications and experiences relative to the subject of this research.

The PI received her Bachelor of Science Degree in Nursing at San Jose State University. She is currently in a Master's Degree Program for Family Nurse Practitioner at California State University, San Marcos. She has four years of experience working with stroke survivors at Mission Hospital. She works as a charge nurse and a bedside nurse on the Progressive Care & Stroke Unit. She has a certification from the National Institutes of Health Stroke Scale to professionally assess stroke victims. In addition, she has four years of experience providing stroke patients with educational material to help them understand and prevent stroke.
B) If this is a student project, include faculty sponsor's qualifications.

Dr. JoAnn Daugherty PhD, RN, CNL is a part-time lecturer at California State University, San Marcos and San Diego State University. She will serve as the Faculty Staff Advisor (FSA) and expert for this project.

C) If using student or research assistants, please state how you will ensure that these assistants are trained and qualified to assist. All assistants should complete the CITI training on the protection of human participants in research.

| The RA will be a student nurse from the American University of Health Sciences. She is familiar with the Progressive Care & Stroke Unit as she has done clinical rotations at this site and has been recognized by the nurses on the unit to be very competent. To ensure that she is trained and qualified to assist she will first complete the CITI training. The RA will practice her approach with the PI until she feels comfortable. She will be accompanied by the PI during the first few participants to ensure that she is competent. |
Appendix C

California State University
SAN MARCOS
School of Nursing
College of Health and Human Services
333 Twin Oaks Valley Road
San Marcos, CA 92078

Informed Consent-Symptoms of Stroke and Length of Time to Seek Medical Treatment

Lornalyn Jimenez, RN, BSN, a Master Degree student at California State University, San Marcos is conducting a study on symptoms of stroke and the length of time to seek medical treatment. You are invited to participate in this study because you presented to Mission Hospital with symptoms of stroke and diagnosed with either a transient ischemia attack (TIA) or a Stroke. The goal of this study is to determine if there is a relationship between symptoms of stroke and the length of time to seek medical treatment. The findings of this study will help determine where to focus stroke education to help improve the length of time in seeking medical treatment in the future.

Requirements of Participation: You will be asked a total of five questions which will include the symptom you experienced that prompted you to seek treatment, the estimated time it took for you to seek treatment, the presence of an individual who influenced your decision to seek treatment, your mode of arrival to the hospital, and your demographic information. In total, this study should take no longer than five minutes.

Risks and Safeguards: None of the questions are expected to cause emotional reaction, however if for any reason you need emotional support after the collection of data, please notify the research assistant and emotional support can be provided during your hospital stay.

Please be reminded that the results of the study will not be specific to you and all information collected will only be used for this research and will be kept confidential. Your responses will be documented on individual questionnaire forms which will then be placed in a locked box in a locked filing cabinet. The data will later be stored on a password protected laptop for analysis. Only group data will be included in the final report and no one will be able to trace your response back to you.

Benefits and Incentives: There will be no financial incentives available. Your participation however will be greatly appreciated as it will help determine the course for future stroke education in decreasing time of delay in seeking medical treatment when symptoms occur. This may benefit stroke sufferers in the future.

Voluntary Participation: Your participation is strictly voluntary. There are no consequences if you choose not to participate and it will not affect the care you are receiving in the hospital. You may stop participation at any time during the completion of the questionnaire. The questionnaire is anonymous, therefore once you have completed the questionnaire you will not be able to withdraw from the study.

Contact Information: If you have any questions about the study I will be happy to answer them today. If you have questions in the future, please contact the principal investigator, Lornalyn Jimenez at 707-342-8364 or you may email her at lj jimenez@yahoo.com or her faculty advisor JoAnn Daugherty RN at 760-750-7550. If you have questions about your rights as a research participant, you may contact CSUSM’s Institutional Board at 760-750-4029.

Participant’s Name
Participant’s Signature
Date

Researcher Assistant’s Signature
Date