

A NURSE PRACTITIONER-LED TIA/STROKE PROGRAM TO SERVE
RURAL NORTHWEST MONTANA

by

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SIGNED: Elizabeth Louise King

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DEDICATION

Charlotte, Rowan, Isla and Luciana

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ABSTRACT

Cerebrovascular accidents (CVAs) are identified as the principal cause of long-term severe disability in the United States (American Heart Association, 2012). Cerebrovascular accidents (CVAs) are the fourth leading cause of mortality in the United States (Minino, Murphy, Xu & Kochanek, 2011). Small towns and rural areas are currently in a health care crisis. With most subspecialty services located in metropolitan areas, distance and lack of accessibility creates disparity in evidence-based practice implementation. The growing gap between the health of rural and urban Americans is evident and will widen without proper interjection (Alkadry, Wilson, & Nicholas, 2006; Brown, Lisabeth, Roychoudhury, Ye, & Morgenstern, 2005; Sacco et. al, 2006).

While there have been significant recent advances to support patients during the acute phase of a stroke in Montana, guidance for primary care providers and patients is currently limited for secondary stroke prevention services in the state, including Northwest Montana. Current morbidity and mortality data due to stroke in rural northwestern Montana may reflect a gap between existing guidelines for secondary risk reduction and the current practice of instituting those prevention guidelines. Effective secondary stroke prevention strategies are those that are based on a model of care that is evidenced based, feasible, and meets the unique needs of the population

A qualitative descriptive design was used to achieve the AIMS of this study. A critical analysis of the literature was used (AIM 1) to identify previously published information related to TIA/stroke clinics and programs. Focus groups were used (AIM 2) to elicit information from

health care professionals in northwestern Montana about the need for and preferences for an advanced practice nurse-run stroke/TIA clinic.

We found that like other reports from rural sectors, Primary Care Providers and Neurology providers in Northwest rural Montana identified challenges in access to care and cultural influences on patient adherence. It was evident that Primary Care and Neurology providers were in favor of instituting a Nurse Practitioner-led secondary prevention program for stroke and TIA. We propose a stroke/TIA program to serve Northwest rural Montana that includes Nurse Practitioner-led transitional care services, care coordination, and education and program evaluation services.

CHAPTER I

INTRODUCTION

This chapter introduces the clinical significance of stroke and transient ischemic attack (TIA) in the United States, in rural areas of the nation and most specifically, in rural Montana. The concept of TIA/Stroke clinics serving rural areas is introduced as well as the idea that a Nurse Practitioner is perfectly poised to lead the development of such clinics. The DNP project purpose, specific aims and significance to the doctor of nursing practice will be described.

Stroke and Transient Ischemic Attack

Cerebrovascular accidents (CVA) are the principal cause of long-term severe disability in the United States and the fourth leading cause of mortality in the United States (American Heart Association, 2012 & Minino, Murphy, Xu & Kochanek, 2011). Approximately 795,000 individuals experience a CVA annually in the United States (Mukherjee & Pail, 2011). Nearly 185,000 CVAs are the result of subsequent attacks, indicating approximately 1 in 4 CVAs occur after an initial event (Mukherjee & Pail, 2011).

Americans spend approximately \$73 billion on CVA related care and disability funding annually (Reynolds, Panagos, Zipfel, Lee & Derdeyn, 2012). Current estimates suggest approximately ()% of our population is over the age of...Faced with an aging population, our attention should focus on decreasing the disease burden of subsequent strokes in patients who are at higher risk due to previous stroke or transient ischemic attack (Wasserman et al., 2010).

In 2008, 7 million deaths out of 57 million global deaths were attributed to cerebrovascular accidents (Mendis, 2013). The burden of cerebrovascular disease globally showed that 46 million Disability Adjusted Life Years could be attributed to stroke (Mendis,

2013). If current trends of cerebrovascular accidents continue, it is projected that 23 million first ever strokes and 8 million stroke deaths will occur in 2030 (Mendis, 2013). In the absence of risk reducing interventions in the 6 months following a TIA, 5% of patients will die and by 12 months the death rate reaches approximately 25% (Lloyd, Adams, Brown et al, 2010). Five years post initial stroke or TIA, two thirds of patients without proper care will experience neurologic impairment or disability, 22% will have dementia and 15% will be institutionalized (Feigin, Barker-Collo, Parag et al., 2010).

Stroke and TIA in Rural Areas

Small towns and rural areas are currently in a health care crisis (Peterson et al., 2011 & Singh et al., 2014) With most subspecialty services located in metropolitan areas, distance and lack of accessibility creates disparity in evidence-based practice implementation Alkadry, Wilson, & Nicholas, 2006; Brown, Lisabeth, Roychoudhury, Ye, & Morgenstern, 2005; Sacco et. al, 2006). The growing gap between the health of rural and urban Americans is evident and will widen without proper interjection of secondary prevention services (Alkadry, Wilson, & Nicholas, 2006; Brown, Lisabeth, Roychoudhury, Ye, & Morgenstern, 2005; Sacco et. al, 2006).

Flathead County Montana is home to 90,000 citizens and covers an area of 5098 square miles. Approximately 52% of the population of Flathead County are considered to be rural. Montana Stroke Initiative began in 2010 with the goal of providing improved healthcare for rural residents before and during a stroke (Montana Department of Public Health and Human Services, 2010). In 2010, a tele-stroke initiative was implemented to improve access to neurologists who specialize in the care of stroke patients for acute care in the rural community (Montana Department of Public Health and Human Services, 2010). The county seat of Kalispell is home

to Kalispell Regional Medical Center (Kalispell Chamber of Commerce, n.d). Kalispell Regional Medical Center currently provides acute tele-stroke services initiated by The Department of Public Health and Human Services' Montana Stroke Initiative. While there have been significant recent advances to support patients during the acute phase of a stroke in Montana, guidance for primary care providers and patients is currently limited for secondary stroke prevention services in the state, including Northwest Montana .

Secondary Prevention for TIA and Stroke in Montana

Health promotion campaigns across Flathead County aim to provide primary prevention with education and recognition of stroke symptoms (Fogle, 2008). Increasing patient's knowledge and ability to recognize stroke symptoms are critical to reduce severity of an acute event (Sacco et al., 2006). Efforts aimed toward secondary stroke prevention are lacking in both rural and urban areas (Sacco et al., 2006). National trends indicate that disparities remain for what happens to patients after the initial stroke or if American Heart Association secondary prevention strategies are used (Sacco et. al, 2006; Flathead City-County Health Department, 2012).

Current stroke morbidity and mortality data in rural northwestern Montana may reflect a gap between existing guidelines for secondary risk reduction and the current practice of instituting those prevention guidelines. Effective secondary stroke prevention strategies are those that are based on a model of care that is evidenced based, feasible, and meets the unique needs of the population (Sacco et al., 2006).

Successful evidence-based, nurse-led stroke/TIA clinics have been run in the United Kingdom and may serve as models of secondary stroke prevention for rural Montana. In the

United Kingdom, chronic stroke/TIA health care clinics that target the secondary prevention of stroke/TIA have been shown to increase patient compliance in adhering to secondary prevention strategies (Hairon, 2008; Paul et al, 2013). Nurse-run clinics in the United Kingdom are designed to reduce disparities in care and decrease costs for those who have had a stroke or TIA in both the acute and chronic care setting. Clinics are designed and based upon local hospital's and population need (Paul et. al, 2013). Management of secondary stroke prevention in a TIA program has been shown to be safe and cost-effective for reducing incidence of subsequent strokes (Lavallée & Amarenco, 2013). Currently there is an absence of data related to *rural* secondary prevention TIA/Stroke programs. Clinics are designed to be accessible in both an the acute and primary care setting to prevent recurrent stroke (Paul et al, 2013).

A review of the current literature indicates TIA and stroke clinics in the United States have been proposed to synchronize prevention services and diagnostic testing (Jäkel, Plestel, Chapman, Jackson & Purroy, 2012). TIA clinics have been lauded as potential care model to reduce costs and an alternative to hospitalized TIA care (Joshi, Ouyang, & Prabhakaran, 2011). The goal of a TIA/Stroke secondary prevention clinic is to reduce the risk of a future disabling stroke (Johnston et. al, 2011). Stanford University's School of Medicine Stroke Center currently utilizes a coordinated Nurse Practitioner TIA program to limit hospital lengths of stay and to reduce 90-day stroke rates (Albers & Olivot, 2013). A current research study showed that of 223 consecutive patients admitted to the Stanford University Emergency Department and subsequently referred to the Stanford TIA Clinic, the 90-day stroke rates were <1% (Albers & Olivot, 2013). The problem for rural areas, there are no secondary prevention nurse-led models to address prevention care.

An advanced practice nurse is poised to integrate evidence to local communities and enact change at a sustainable level (O'Neil Mundinger, Starck, Hathaway, Shaver, Fugate Woods, 2009; American Association of Colleges of Nurses, 2006). Nurse practitioners are educated didactically and clinically, with a strong emphasis on the clinician's aptitude to integrate research at the local practice level (Vincent, Johnson, Velasquez & Rigney, 2010). In addition, the role of the doctoral prepared nurse practitioner (DNP) as the expert researcher-clinician is to recognize disparities in their community; actively engage community members toward change and lead models of effective care with evaluation of quality outcomes (American Association of Colleges of Nurses, 2006; Chism, 2009). Thus, a nurse practitioner for a secondary prevention TIA/Stroke program is ideally poised to support efforts in eliminating the disparity of the evidence practice gap in stroke prevention in rural northwestern Montana,

Purpose Statement

The purpose of this practice inquiry is to describe the essential elements of nurse practitioner (NP) led TIA/Stroke Clinic to serve rural northwest Montana.

Aims

The specific aims of the practice inquiry are to:

1. Perform a critical analysis of the literature that will identify elements of a NP-led TIA/Stroke clinic that are relevant to rural Montana.
2. Conduct focus groups of neurologists, primary care physicians, and nurse practitioners/physician assistants in rural northwestern Montana to elicit their opinions and preferences for a NP-led TIA/Stroke clinic and to understand barriers and facilitators for the development of that clinic.

3. Using data from Aims 1 and 2, identify key elements of a NP-led rural TIA/Stroke clinic to serve northwestern Montana.

CHAPTER II

BACKGROUND

In Chapter II, the definitions of stroke and transient ischemic attack will be described. The current rates of morbidity and mortality of stroke and TIA in the United States will be discussed, specifically highlighting rural areas and specifically, rural Montana. The role of secondary prevention in stroke and TIA care, along with current models of stroke and TIA outpatient clinical care will be outlined. Proposals for the role of an advanced practice nurse in addressing secondary prevention disparities for rural populations will be described. Finally, the guiding framework for this proposal inquiry will be discussed.

Stroke and Transient Ischemic Attack

A cerebrovascular accident or stroke is the abrupt interruption of blood supply to the brain. The majority of stroke cases are classified as ischemic and the result of a blockage in the arteries leading to the brain. Hemorrhagic strokes occur as a result of bleeding into brain tissue after a blood vessel in the brain bursts (American Stroke Association, 2012).

A transient ischemic attack (TIA) is often referred to as a “mini stroke”. The American Heart Association encourages providers to remember that a TIA is on the continuum of stroke care (Furie et. al, 2011). Both TIA and stroke are indications of impaired cerebral blood flow (Rothwell, Algra & Amarenco, 2011). A TIA is a transient event of neurologic dysfunction caused by focal brain, spinal cord, or retinal ischemia without acute infarction of tissue death. The distinguishing feature of a TIA is that signs and symptoms resolve within 24 hours (Furie et. al, 2011). TIA incidence rates vary across the country. Due to confusion on the definition of TIA, incidence projections vary between 200,000 and 500,000 TIA occurring yearly in the

United States (Easton et. al, 2009). It is suspected that the TIA incidence rate is vastly underreported due to lack of recognition of transitory symptoms (Easton et al. 2009; Johnston et al., 2003).

The greatest risk for a stroke is a previous stroke. Once an individual has a stroke or TIA, estimates indicate that 11.8% of patients will have another cerebrovascular event within 2 years (Brown, Lisabeth, Roychoudhury, Ye & Morgenstem, 2005). Further estimates show that of the 795,000 Americans who experience a stroke each year, 5% to 14% will experience a second stroke within 1 year. Recent data shows that 24% of women and 42% of men will experience a stroke within 5 years after the initial event. The risk for recurrent stroke is not the only adverse event patients with cerebrovascular accidents need to consider. Patients with prior cerebrovascular accidents are also at risk for future cardiac events, such as congestive heart failure, myocardial infarction or peripheral artery disease (Callahan et. al, 2011).

Transient ischemic attack is associated with a “high early risk” of stroke. A TIA is a warning sign of a future possible stroke (Easton et. al, 2009). The American Heart Association (AHA) proposes that as clinicians, identifying and evaluating TIAs presents a fortuitous opportunity to introduce clinical measures and risk reduction therapy. Risk reduction strategies may be successful in reducing the risk of subsequent stroke and permanent impairment (Easton et. al, 2009).

A systematic review exposed that after a TIA, early risk of stroke was 9.9%, 13.4%, and 17.3% at 2, 30, and 90 days, respectively (Wu, 2007). In a review of large randomized control studies, the American Heart Association estimates that of patients who present with stroke, 7% and 40% have had a previous TIA (Easton et. al, 2009).

Effects of a stroke vary and are related to the severity of the infarct and the part of the brain injured. The disease burden of stroke places an emotional, physical, and financial toll on the patient and family. While some patients may rehabilitate at home, many are placed in long term care facilities further placing an emotional burden on families and finances.

Stroke and TIA in Rural Areas

Recent evidence illustrates healthcare disparities for rural individuals in access, quality, and affordability (Braveman, Cuban, Egerter, Williams, Pamuk, 2010). When compared to urban peers, rural individuals have on average higher rates of mortality and morbidity related to both acute and chronic conditions (Centers for Disease Control and Prevention, 2011; Joubert, 2008). United States census data for 2010 showed that over 59 million Americans or 21% of the United States population live in areas classified as rural (United States Census Bureau, 2010). The United States Census Bureau (2010) defines rural as a “core census block that has a population less than 1000 people per square mile.”

Rural Americans have higher rates of diabetes, heart disease, obesity, hypertension, and acute ischemic events (Hamner and Wilder, 2008). Cerebrovascular accidents are a threat to the United States population, and members of the rural community face an even higher risk (American Heart Association, 2012). According to the Institute of Medicine “economic factors, cultural and social differences, educational shortcomings, lack of recognition by legislators and the sheer isolation of living in remote rural areas all conspire to impede rural Americans in their struggle to lead a normal, healthy life” (Institute of Medicine, 2006).

While stroke does not segregate based on race, religion or socioeconomic status, evidence shows that a disproportionate number of rural citizens experience a stroke or its long term

disability compared to urban peers (Sergeev, 2011). (Sergeev, 2011). Disparities in stroke mortality are evident in rural areas due to spatial accessibility and availability of optimal acute and chronic stroke care teams (Sergeev, 2011; Joubert, 2008).

Swaoski, Lutfiyya, Amaro, Akers & Huot (2012) stated that rural older adults understanding of symptoms related to heart attack and stroke were far below the knowledge base of urban equivalents. It is evident after literature review that while rural disparities for TIA/Stroke care exist, and while advances in acute care have been made, less progress has been documented related to secondary stroke prevention in rural areas (Okon et., 2010; Shutlis et. al., 2010; Joubert et al., 2008). Empowering patients with the tools they need to change poor health behaviors can cut disease burden (Sacco et. al, 2006). Establishing models of secondary stroke prevention for rural community providers may assist both providers and patients in their self-care efforts.

Secondary Prevention for TIA and Stroke in the Rural Setting

Recent campaigns in community healthcare have focused efforts on the need to address strokes in the acute phase. The old adage “time equals brain” has become a primary prevention staple again and reminds patients to take warning signs of stroke seriously. In 2010, the Department of Public Health and Human Services’ Montana Stroke Initiative took aim at identifying standards of care and interventions to assist rural hospitals in their ability to effectively treat stroke in the acute phases. The Montana Tele-Stroke initiative is effectively assisting critical access hospitals in treating patients during the acute phase of a stroke. With the use of an on-call neurologist, tele-health supports emergency room physicians in utilizing acute treatment regimens for stroke, such as tPA (Kalispell Regional Healthcare, 2013).

Primary care is a critical component for primary and secondary prevention of cerebrovascular accidents (MacDougall, Amarasinghe & Muir, 2009). Effective treatment of stroke and transient ischemic attacks can decrease disability and adverse outcomes from an acute event (Schwamm et al., 2009). For this practice inquiry, the original questions that arose from clinical experience were “What happens to patients after the acute phase of their stroke is over? Where can patients in rural communities turn for assistance, advice, and follow up in the post-acute phase of stroke or TIA?”

Primary prevention is an important part of reducing the disease burden of stroke (MacDougall, Amarasinghe & Muir, 2009). Effective public health campaigns addressing warning signs of acute stroke can be seen on billboards and public health announcements daily. While primary prevention is necessary, effective organized secondary prevention in Northwest Montana is limited to reduce the possibility of a subsequent stroke (MacDougall, Amarasinghe & Muir, 2009).

Secondary prevention of stroke is imperative. The greatest risk for a subsequent stroke is a previous stroke. According to Rothwell and Johnston (2006), 30% of patients with a prior stroke or TIA have a subsequent CVA. Secondary prevention should be initiated urgently and systematically after the original event (Rothwell, Algra & Amarenco, 2011). Although primary prevention is important for the reduction of the burden of stroke, effective secondary prevention is essential because it focuses on risk reduction for future stroke. Recurrent strokes carry a higher risk for being more injurious than initial strokes and more often associated with disability (Rothwell, Algra & Amarenco, 2011). A specific stroke prevention clinic guided by a nurse

practitioner can be instrumental in helping patients reduce their risk of subsequent stroke or disability for the population of rural northwestern Montana.

Models of TIA/Stroke Programs

Recent evidence supports that assessment and intervention in post-acute stroke and TIA programs can reduce the risk of stroke after a TIA by up to 80% (Rothwell et. al, 2007).

However, only 5% of stroke patients receive appropriate therapy in a timely manner and many do not receive therapy at all (Bergman, 2011; Schwamm et al., 2009). Evidence from both the EXPRESS and SOS-TIA studies confirm that implementation of a rapid-access clinic to assess, initiate, and promote secondary prevention of stroke and TIAs are associated with a 2.1% and 1.2% risk of 90-day stroke (Wasserman et.al, 2010; Rothwell et al., 2007). Compared to systematic review of rates of strokes after TIAs without intervention, the use of a secondary prevention stroke and TIA clinic suggests at least a 6% risk reduction (Wu, 2007).

Current trends in the United Kingdom support the use of post-Stroke and TIA clinics (Martinez-Martinez et. al, 2010). The use of a secondary prevention clinic aims to prevent recurring events by improving modifiable risk factor control (Davis & Donan, 2012 & Cochrane Protocol-see below). In 2011, Nottingham University Hospitals NHS Trust became one of the first hospitalists in the United Kingdom to dedicate a nurse-led clinic to care for post-acute stroke and TIAs. Approximately 15 patients were seen per week and patients were seen within four weeks of their initial event. The clinic was established to support an individual's clinical needs, discuss lifestyle advice and "address inequalities that patients face following a stroke or TIA diagnosis" (Huei, 2012). The goal of the clinic is to empower patients to make positive changes in their lives in the face of a potentially devastated disease.

The use of TIA clinics with round-the-clock access and immediate commencement of preventive management are believed to decrease the risk of stroke compared with expected risk from no intervention therapy (Martinez-Martinez, 2012). The National Stroke Association has urged hospitals to establish Stroke and TIA clinics to effectively prevent recurrent cerebrovascular events (Johnston et al., 2011). Due to the prevalence of a TIA, establishing supportive systems of care can forestall recurrent strokes and TIAs and address prevention measures to decrease incidence and possible severity (Johnston et. al, 2011).

Current United States national stroke guidelines outline specific clinical conditions and lifestyle factors as modifiable risk factors (Furie et. al, 2011). The use of TIA/Stroke clinics can potentially result in reduced recurrence rates due to organized and efficient stratified risk reduction (Johnston et al, 2011; Merwick & Kelly, 2011). The use of TIA and stroke clinics in the early phase of diagnosis can have an positive impact due to reduced hospital admissions and lower incidence of disability (Jackson, Moshinsky & Begg, 2009).

Why an Advanced Practice Nurse Led Program?

The advanced practice nurse is prepared with a comprehensive didactic and clinical background. The advanced practice nurse is poised to provide an inclusive holistic approach for caring for an individual in a way that fosters healthier lifestyles and goal directed patient-provider to assist with secondary prevention outcomes.

The advanced practice nurse has been utilized in several types of secondary prevention clinics in the United States and Europe. Hypertension, anti-coagulation, and congestive heart failure nurse-led clinics have shown success for offering risk reduction strategies and disease management (Woodward et. al, 2010). Woodward et al. (2010) showed that optimal blood

pressure control was sustained and strict blood pressure control was adhered to 7 years following interventions of a nurse-led hypertension clinic. Hendriks et al. (2012) argues that a nurse-led clinic offers superior and consistent care for patients with atrial fibrillation in comparison to usual clinic methods directed by a cardiovascular team. Hendriks et al., (2012) showed that adherence to recommended guidelines was significantly better in the nurse-led group. Mortality rates and hospitalizations were lower with interventions initiated by Hendriks (2010 nurse-led group compared to cardiologist led services. The use of a nurse-led clinic offers a potential cost-effective approach for secondary prevention oriented care, while offering guidance for patients with complex health needs (Turner et al, 2008).

As the United States healthcare system changes, the advanced practice nurse can help navigate patients through an increasingly complex health care system by applying knowledge and scientific foundations for more effective risk reduction and higher quality care. (American Association of Colleges of Nursing, 2004). An advanced practice nurse led clinic will provide the integration of clinical research and considerate guidance to help patients effectively transform their own health.

The nurse practitioner has many responsibilities in addressing patient care. As an advanced practice nurse practitioner, bridging quality clinical outcomes with vanguard research is essential for ensuring effective patient care. As the implementer of research, the nurse practitioner should function in roles of advocate, case manager and expert provider of care. The nurse practitioner can provide the specific function of applying both didactic and clinical skills to promote higher quality healthcare delivery (American Association of Colleges of Nursing, 2006; Chism, 2009). Nurse Practitioners, specifically those trained with advanced doctoral education

can provide patients with research focused clinical interventions that integrate evidence based practice with effective patient education strategies (American Association of Colleges of Nursing, 2006) The added value of a doctorate education is providing nurse practitioners with leadership tools to implement new models of effective care (Erickson et al., 2012)

Guiding Framework

Nursing is a “unique, evolving, ever changing profession for which theory can be used as a guide for practice” (McCarthy & Aquino-Russell, 2009). Nursing revolves on assisting individuals to achieve the highest quality of their potential of living (Parse, 1999). Nurse Practitioners can support and should promote goal directed behavior. The nurse practitioner should be seen as a change agent in assisting an individual toward specific goal related outcomes that promote higher health quality.

For the purpose of this practice inquiry, the Levels of Prevention Model designed by Level & Clark will be the guiding framework to support secondary prevention methods (Leavell & Clark, 1965). The Levels of Prevention Model recognizes that the natural history of any disease exists on a continuum. The levels of prevention can be used by the clinician to “promote health and arrest the disease process” at varying points along the individual patients disease continuum (Leavell & Clark, 1965)

The goal Leavell & Clark proposed was to address prevention at each stage to thwart further disease burden (Leavell & Clark, 1965). Leavell and Clark supported a three-phase model that focuses on primary prevention, secondary prevention, and tertiary prevention. Primary prevention encourages action prior to the onset of disease or the pre-pathological state

(Leavell & Clark, 1965). Primary prevention includes health education, protection for carcinogens, and specific immunization usage.

Secondary prevention is based upon halting disease progression. Secondary prevention is also heralded as “health maintenance.” Secondary prevention is defined by as a “set of measures used for early detection and prompt intervention to control a problem or disease” (Cohen, Chavez, Cheihimi, 2010, pg. 6).

The goal of secondary prevention is to minimize poor health consequences related to the disease and reduce the advancement of disease along the disease continuum (Edelman & Mandle, 2006). According to Edelman and Mandle (2006), activities directed at diagnosis should include prompt intervention to reduce disease severity and enable the client to focus on risk reduction of further disease burden. Secondary prevention includes screening techniques that occur after disease onset but before disease causes significant disability (Potter & Perry, 2009, pg. 75). Secondary prevention, while less effective than primary prevention in reducing disease burden, is imperative for clinical practice due to its potential to thwart progression of disease and disability (MacDougall, Amarasinghe & Muir, 2009).

Based on the current evidence elucidated by national stroke leaders that has resulted in guidelines for secondary stroke prevention, as well as evidence in the literature related to the success of clinics, specifically nurse-led clinics, to address secondary prevention in chronic illness, the development of a TIA/Stroke clinic to identify risk and assist in prompt intervention for patients at risk of a future TIA/Stroke (Sacco et. al, 2006) is essential, but has not been fully explored, especially for communities in the rural US. Thus, this practice inquiry will address this

gap in knowledge by describing the essential elements of a Nurse Practitioner (NP) led TIA/Stroke Clinic to serve rural northwest Montana.

CHAPTER III

METHODS

This chapter describes the methods including study design, setting, sample and data collection measures to effectively assess the literature and the target group's experiences with stroke and TIA prevention and preferences in order to identify the essential elements of a TIA/stroke clinic for rural Montana.

Study Design

A qualitative descriptive design will be used to achieve the Aims of this study. A critical analysis of the literature will be used (Aim 1) to identify previously published information related to TIA/stroke clinics and focus groups will be used (Aim 2) to elicit information from health care professionals in northwestern Montana about the need for and preferences for an advanced practice nurse-run stroke/TIA clinic. Focus groups are suited to this particular inquiry because they allow for relatively rapid assessment of the target group's experiences with stroke and TIA prevention and preferences for a nurse-run stroke/TIA clinic (Cote-Arsenault, Morrison-Beedy, 1999). The method is especially useful in understanding issues regarding healthcare uses and in identifying barriers to use (Halcomb et al., 2007).

Setting

The setting of study is located in northwestern Montana, specifically Flathead County, Lincoln County and Sanders County. As of the 2010, the population of Flathead County included 90,928 residents, Lincoln County 19,687 residents and Sanders County 11413 residents. Currently, there are 65 primary care providers in Flathead County, 7 in Lincoln County and 8 in Sanders County. Six neurologists are actively on a hospital medical staff in

Flathead County. There are no neurologists located in Lincoln or Sanders County.

The three counties of Flathead, Lincoln, and Saunders Counties comprise an area of over 11,500 square miles in northwestern Montana. The geography of northwestern Montana is covered with a mountainous, forest-covered landscape that impairs ability for residents to quickly receive medical care. Currently, there are four active medical hospitals within the three counties. Three hospitals are designated as critical access facilities and one is designated as a Level III Trauma Facility.

Using the United States Census Bureau (2010) definition of rural, a “core census block that has a population less than 1000 people per square mile”, Flathead, Lincoln and Sanders Counties are all considered rural. Flathead County has 17.9 persons per square mile, Lincoln 6.8 persons per square mile, and Sanders 4.1 persons per square mile.

Flathead County’s Rural Living Guide (2012) reminds residents that emergency response times cannot be guaranteed and sometimes not available at all. Due to changing weather, unpredictable roads and distance medical care can sometimes take well over 60 minutes (Flathead County, 2012).

Sample

A purposive sample of neurologists, emergency department physicians, primary care physicians, nurse practitioners, and physician’s assistants will be invited to participate in focus groups to describe their opinions and preferences gaps for a TIA/stroke clinic in northwestern Montana. Purposive sampling will ensure that the participants recruited will be able to provide information needed to answer the research questions of interest for this study (Barbour, 2001; Padgett, 2008). Currently there are 65 primary care providers (including MDs, DOs, PAs, NPs)

in Flathead County, 7 in Lincoln County and 8 in Sanders County (Kalispell Regional Hospital, 2013). Six neurologists are actively on a hospital medical staff of Kalispell Regional Medical Center (Kalispell Regional Healthcare, 2013). There are approximately 12 emergency room physicians on active medical staff at Kalispell Regional Medical Center (Kalispell Regional Healthcare, 2013).

Inclusion criteria are: a health care professional who is either a board certified neurologist or a primary care provider who has experience in treating people with strokes or TIAs. Focus groups need to be small enough to foster discussion yet large enough to obtain a diversity of ideas and opinions (Millwork, 2012). Therefore, focus groups for this study will be composed of 5-12 individuals.

The number of focus groups necessary to answer the research questions is a function of the number of characteristics known as break characteristics, which differentiates the groups from each other (Knodel, 1993). In this practice inquiry, the break characteristics are type of practice (acute care vs. primary care) and role (physicians, nurse practitioners, physician assistants). Acute care (neurologists and emergency room physicians) and primary care practitioners will be recruited from Kalispell Regional Medical Center, and primary care practitioners (physicians, nurse practitioners, physician assistants) will be recruited from a critical access hospital in Libby, Montana. Based on these break characteristics, three focus groups will be conducted. Group 1 will include neurologists and emergency room physicians at Kalispell Regional Medical Center and in Northwest Montana. Group 1 is designed with the intent to understand how those in the acute care setting perceive the need for TIA/Stroke Clinic for the area. Group 2 will include primary care providers (physicians, nurse practitioners and

physician assistants) in Kalispell, Montana. Group 3 will include primary care providers (physicians, nurse practitioners, physician assistants) in Libby, Montana with the focus being on rural care after a TIA/Stroke. In order to recruit potential participants for the focus groups, I will first meet with community medical leaders. At Kalispell Regional Medical Center in Kalispell, Montana, I will meet with the Chief of Medicine to identify neurologists and primary care providers. At St. John's Lutheran Hospital in Libby, Montana, I will meet with the Human Resources Manager to direct me to the appropriate manager of the medical staff. Once potential providers and practices are identified, I will also meet with the practice managers to identify the purpose and aim of the study and ask for potential participants to email or phone me if they would like to participate.

Once the lists of potential participants have been obtained, emails and hand delivered flyers will be delivered to each provider, primary care, and neurology practice identified. At the beginning of the recruitment period on day 1, emails will be sent to each provider. At day 8, flyers will be hand delivered to potential providers. A follow up email will occur on day 16 with a response requested of availability and participation.

The emails and flyers will contain the study purpose, study AIM II (focus groups of rural and regional stakeholders in northwestern Montana for a proposed stroke/TIA clinic) and my contact information. Consent forms will be given to each participant and signed prior to conducting the focus group.

Data Collection and Analysis

Aim 1: Literature Review

For Aim 1, a literature search will be performed. The literature retrieval will be

performed by a comprehensive search of available literature including Medline (PubMed), The Cochrane Collaboration, and CINAHL. Using the PubMed MeSH database search terms will include ("Stroke"[Mesh] AND "Ischemic Attack, Transient"[Mesh]) AND "Outpatient Clinics, Hospital"[Mesh]) it will also include a second search including the terms ("Secondary Prevention"[Majr] AND "Ischemic Attack, Transient"[Mesh]) AND "Stroke"[Mesh]). A second search will include a PubMed search of “TIA Clinics” and “Stroke Clinics”.

Literature will be reviewed and organized based on the American Heart Association Level of Evidence and Classification Guidelines. Assessment of the relevant evidence will be conducted based on the EPHPP Quality Assessment Method (National Collaborating Centre for Methods and Tools, 2008). Through data deconstruction, common elements of stroke-TIA clinics will be identified and summarized. The use of the Johns Hopkins Nursing Evidence Based Practice Research Appraisal (JHNEBP) will be used to organize and analyze the quality of evidence and strength of recommendations (see JHNEBP table).

After a review of the literature, a critical analysis will be constructed to identify elements of a NP-led stroke and TIA clinic that are relevant to rural Montana. The critical analysis will also be used to inform the moderators guide used in Aim 2, described below.

Aim 2: Focus Groups

Three focus groups will be conducted (see above for focus group description). A moderator’s guide will be used for each group (see moderator’s guide). Briefly, there will be time spent on arrival/greeting of participants, introductions, agenda setting, ground rules, and prompting of discussion related to key topics, including use of probes within each topic, and finishing with a clarification/wrap up. The key topics for discussion identified from Aim 1)

include stakeholder perceptions of secondary prevention for TIA/Stroke in northwest Montana, opinions and essential elements of a TIA/Stroke clinic for the community, and perceptions of barriers and facilitators of such a clinic. The moderator's guide was reviewed by content and methods experts, Dr. Ritter, sponsor for this PI, and Drs. Vincent and Sheppard, PI committee members, respectively.

Aim 2: Data Analysis

After each focus group session, a transcriptionist will make a verbatim transcript of the audiotaped data. The researcher will read and approve drafts of the transcripts. Data analysis will precede using qualitative content analysis. Research team members will read the transcripts looking for symbolic domains of meaning and, within domains, relational patterns and themes. The researchers will inductively develop codes and meet to discuss code definitions and the application of codes to all focus group transcripts. The research team will discuss and reach consensus on the refinement of categories and themes.

Aim 3: Model of Nurse Led TIA/Stroke Program for Northwestern Montana

Data from Aims 1 and 2 will be used to construct a model of a nurse-led TIA/stroke program for rural Northwestern Montana. This model could lay the groundwork for the future development of a TIA/Stroke program in northwest Montana.

CHAPTER IV

RESULTS

The purpose of this chapter is to describe findings of the research in a manner that correlates key themes that emerged from the focus groups. Using a conventional content analysis, the results were coded and linked to themes that materialized.

Descriptive Data

Three focus groups were originally planned. One focus group was not held due to numerous scheduling conflicts, thus, two focus groups were ultimately conducted. There were six respondents in the first focus group and eight respondents in the second. Five board certified physicians in neurology and one nurse practitioner who specialized in adult neurology participated in the first focus group. In the second focus group there were five board certified family practice physicians and three board certified family nurse practitioners. In the second group only six of the participants were able to stay the entire time. One physician and one nurse practitioner left the focus group early. The focus groups lasted between 60 to 90 minutes.

Recruitment for the two completed focus groups was done during a pre-scheduled weekly meeting lunch hour. The mean age for all participants was 46.5 years. The majority of the focus group participants were male (n=10, 64.3%). Of the participants, 64.3% were physicians and 35.7% were nurse practitioners. Of the nurse practitioners surveyed, three were family practice board certified and one was an adult nurse practitioner.

A conventional content analysis was chosen as the preferred method for this qualitative study. The goal was to allow themes to emerge directly from the data without the researcher imposing prior thematic elements or codes to the data (Hirsch and Shannon, 2005). The specific

goal was to achieve coding and emerging themes that best represent the participant's viewpoints without the researcher imposing premeditated ideals about implementation strategies. The goal while coding was to effectively allow for opinions that represents the study population to materialize.

The content analysis process was iterative and consisted of a careful reading of the transcripts and resulted in the identification of several code categories. Three overarching themes emerged from the data analysis process: 1) Access to Care Barriers, 2) Cultural Influences on Patient Adherence, and 3) Components of an ideal Secondary Prevention Program.

Access to Care Barriers

The overarching theme of Access to Care Barriers was abstracted through the process of iterative review of the data. Three main categories supporting this theme emerged from the inductive process of qualitative content analysis: Limited Secondary Prevention Programs, Challenges in Providing Care for Secondary Prevention, and Challenges in Providing Stroke Treatment Knowledge.

Limited Secondary Prevention Programs

Several participants expressed frustration with the current secondary prevention environment for patients who have experienced a TIA or Stroke in Northwest Montana. The limited availability of secondary prevention services forces providers to follow their own method for providing secondary prevention care. A neurologist stated, "We don't have a formal program, but we like to see them 2 weeks and 4 weeks after at least."

Initial responses from each focus group echoed similar sentiments regarding the challenges of providing secondary prevention care to individuals who have experienced a stroke. A primary

care family practice physician stated, "...you certainly look at our standard prevention of --- what's our cholesterol numbers, their blood pressure, are they still smoking 5 packs a day, and drinking like a 5th a day and so forth, and so if you want call that conglomerate guideline protocol I suppose we are. " Primary care providers also affirmed that the lack of secondary prevention program causes providers to rely on their own method for secondary prevention, "...the problem we have is there are so many things that come our way with what we are supposed to do. It is hard to know from one year to the next what we should be doing specifically for secondary prevention".

Challenges in Providing Care for Secondary Prevention

In the rural community, neurologists state there are "outreach clinics, but no specific secondary prevention program." The neurologists stated they would like to see patients who have had a TIA or Stroke. One neurologist stated "I'm sure that a lot of people still rely on their primary care providers, ---which unfortunately an internal review showed that AHA guides for stroke follow up are not being followed---."

However, primary care providers expressed frustration with what they termed as the hassles of scheduling follow-up appointments with neurologists. While primary care providers stated they would prefer to refer to neurology, it was often challenging. As one primary care provider noted, "most of the management I think is here (in primary care) because we can't get them to see neuro without a lot of hassle."

Scheduling and follow up care were seen as major hassles and, therefore, a barrier to accessing care. One primary care provider noted "I would say we manage them pretty well on our own in continuity care if one of our patients have a stroke or TIA. We try to keep our

patients in house since it is hard for patients to get into specialty care with neuro or they don't want to go to more than one provider." Another primary care provider stated "That is where it comes down to a tricky problem. We have a great neurology practice, but they are difficult to get into and our patient's don't always like to go." Conversely, one neurologist stated that with the absence of a current formal program they feel patients do not receive follow-up and upwards of "40-50%" of patients post-TIA or Stroke in the community are missed. Neurologists stated that as long as the area was devoid of a secondary prevention program, many patients would fall through the cracks. "We don't have a formal program, but we like to see them 2 weeks and 4 weeks after at least. But I'm not sure we see everybody --in fact I guarantee we miss about 40-50% of people." Other neurologists reiterated concerns about patients not receiving adequate follow-up after experiencing a stroke. Several neurologists identified poor referral patterns from primary care providers, lack of capacity in neurology practices, and no formal secondary prevention programs in the area as contributing to poor follow-up of at risk individuals. A Neurologist stated that "We try to catch people from the ERs to get them on those visits, but it is really scattered."

Neurologists were concerned that the lack of time in their busy practices led to key components of secondary prevention being missed. One neurologist argued that "time in our schedules is also a problem—you know, sort of a limited commodity that we are." A neurology nurse practitioner stated, "... we don't have enough hands to get the patients all the patient's secondary prevention" that one possibly needs.

Challenges in Providing Stroke Treatment Knowledge

Current providers in primary care were concerned that they were not up to date on current guidelines for the treatment of secondary prevention for patients post TIA and Stroke. Some primary care providers expressed concern about trying to stay current when there is so much new evidence being published. As one provider noted "...the problem we have is there are so many things that come our way with what we are supposed to do. It is hard to know from one year to the next what we should be doing specifically for secondary prevention." Another primary care provider stated, "...you certainly look at our standard prevention of --- what's our cholesterol numbers, their blood pressure, are they still smoking 5 packs a day, and drinking like a 5th a day and so forth, and so if you want call that conglomerate guideline protocol I suppose we are. "

A Primary Care Provider stated, "I like using UpToDate.com, but I don't follow a specific secondary prevention guideline." The problem for many of the primary care providers was the issue for continuing with specific guideline management for patients and the time keep current with medical guidelines and myriad of sources. Another primary care provider stated that lack of time was an issue for staying current with management for patients and the myriad of sources available was overwhelming. " With so many references and limited guidance, "I like using the AHA guidelines, but I just do hypertension control and lipid control. Not sure what other things are expected." Still another said, "I would agree with XXX, the problem we have is there are so many things that come our way with what we are supposed to do. It is hard to know from one year to the next what we should be doing specifically for secondary prevention."

The neurologists in the focus group often provide continuing education updates for primary care providers in the area and some of these updates focus on secondary prevention. One

neurologist specifically stated that he does “lots of education, mmm, in those rural sites with primary care providers.” Yet another neurologist noted that these talks are insufficient to keep primary care providers current due to the sheer number of primary care providers and their turnover rate. As this provider stated there are “a large number of primary care providers in a big region, and XXX (man's name) does a great job, but there a lot of transient providers because of the rural location, so he goes out and he teaches and educated, you know, this practice or this clinic, and then the next thing you know those doctors are gone and there's a new crew in.”

Primary Care providers stated that the education by the neurologists was well-received continuing education. As one primary care provider stated “It would be nice if we could have a streamlined approach that would help us know what guidelines for KRMC Neurology we should follow. Like the specific JNC-7 guidelines that KRMC said we should use a few years back for hypertension.”

Cultural Influence on Patient Adherence

The second overarching theme was Cultural Influence on patient Adherence. The following three main categories supporting this theme emerged: Rural Nature of Living, Limited Financial Resources, and Racial and Ethnic Influences.

Rural Nature of Living

It was obvious from comments made in both focus groups that nature of rural living played an important role on patient compliance with recommended healthcare guidelines. The neurologists serve a large geographic area that spans three large rural counties. Distance and the amount of time to travel were seen as a specific barrier to access to care for patients, especially secondary prevention care that patients may not value. The neurologists specifically mentioned

the advent of transition of care programs, which provides acute access to follow up within metropolitan area neurology clinics. A neurologist stated that, “TIA clinics in metro areas and that’s the sort of the management model that they use and those are great. So they have, somebody see them in the ER or in a doctor’s office with stroke like or TIA symptoms, they go to the TIA clinic, they can get in like that--.” Another provider noted that distance and not valuing prevention was an issue in trying to treat patients at risk for another stroke by saying I think the biggest three would be money, people don’t like to drive to come all the way into town, and no one sees the benefit of prevention.” This model specifically guides patients to the appropriate measures to prevent further devastating debilitating strokes. Unfortunately with the current lack of a secondary prevention program, patients are missing out on getting studies done in a timely and efficient manner. Conversely, in metropolitan areas, a neurologist stated “the next day, they get all their studies done, and they get good follow-up. We just don't have that. So we charge patients a lot of money for the acute and then don’t have good checks on them to prevent their next event.” In rural areas, services are limited and patients may need to wait for care that could potentially reduce their risk of a secondary event. A neurology providers stated that in the area “we have this kind of a frontier mentality I think that it's, few people really understand the gravity of stroke, TIA.” Many of the neurology providers fly to remote sites to see patients, but the number of providers willing to do this is waning due to the safety of flying in a remote landscape. Some of the neurologists stated that they could no longer visit remote sites due to the increased risk of flying in winter conditions. One neurologist said that “A couple years ago one of the physicians was killed flying, so a lot switched to driving.” Supporting that statement

another neurologist stated, “What does want to risk their life flying in 6 months of winter here.”

Another neurologist stated, “I used to fly and had an emergency landing so I don’t fly anymore.”

Distance and the patient’s willingness to travel to specialty care were noted as a specific barrier. Primary care providers stated that the geographic distance and the rural nature of living is a major issue. “I think it is a major issue here. Patients are not inclined to drive in the snow or some into town due to the tricky roads.” Another provider said “Oh yes, we just had a patient last week who had his INR done in November and needed to come back for a week checkup back in November. He just arrived for his follow up appointment and had INR of 1.2. Patients don’t like to come in.” Another provider added to this sentiment by saying “While we have state of the art healthcare here now in Kalispell, drive about 40 minutes away and you will still see the ole homestead with Bobby Jo who refuses to come to the big city.”

Limited Financial Resources

With limited access to steady incomes, patients are often have limited financial means due to seasonal work, both groups of providers felt that financial access was a strong barrier to care. One provider expressed this idea by saying, “we have a lot of poor and indigent people here and they have really limited funds.” The financial burden unfortunately changes the way a provider practices “you do what you can with that, but you can't, you can't reach everybody the way you want to.” One neurologist stated that due to the concern that patients will not return for care he does most of the studies for secondary prevention in the hospital, “staying in the hospital costs a lot more money for the patient, but we know it gets done.”

Several of the neurologists stated that a patient’s willingness to discuss their symptoms was motivated by financial ability. Neurologists specified that patients in the acute phase often

ignore symptoms due to worry over money and the financial bill they will face if they go to the hospital. As one neurologist stated “You know, and the other, other limitation, ___ limitation here is that, we have ___ people just don't have money to be admitted -- and so they tend not to, ah, report symptoms or tend not to be seen for things and put it off so there's a lot of people that, I mean you see, ___ and it's finally ___ somebody for reasons that are extremely compelling, it'd have to be, I mean you'll see multiple strokes that they never complained about or you know went silent that -- they had to have had symptoms from but they just don't go.”

Some grant monies have been available to help those in the acute phase of stroke get the diagnostic studies they need, however, those funds may be drying up. One neurologist stated that getting studies was a problem and had to tell patients, “Well sorry, we're, our budget's out of money you can't get your MRI.”

Neurologists affirmed “there is money out there, but, mmm, getting money to come our way to help with secondary prevention is always going to be a problem.” Another neurologist confirmed when asked what barriers were present for secondary prevention, “money. It's not the cool part of stroke.” Another neurologist specified “So, there is money out there, but, mmm, getting money to come our way to help with secondary prevention is always going to be a problem.”

Racial and Ethnic Influences

Health habitus and patient compliance to health advice were issues discussed in both groups. A neurologist stated, “Don't forget smoking. People in Montana like to smoke and drink. But I have to agree, people don't want to pay, don't see the value in prevention.” Another neurologist suggested that patient compliance was a major factor that correlated with rural

disparity, “I would argue that compliant patients are going to be a problem.” Two of the providers in primary care stated that one of the biggest challenges in providing secondary prevention is that patients smoke. “Smoking cessation” was highlighted in both focus groups as a challenging factor in secondary prevention.

A primary care physician stated that one of the main reasons patients don’t like to come in for secondary prevention is due in part to cultural influence, “people from Libby come all the time, I think, part of that may be, maybe they have such small towns it's almost embarrassing or they don't want people their business or they're coming to the center of town, I don't know.”

One neurologist stated “they're cowboys on their own and they have to make their own decisions right, wrong or otherwise.” One primary care nurse practitioner stated “ I think it probably in rural areas is where you, you get patients being missed with prevention in general.” Neurologists added that “we have the Native American reservations.” Two Native American reservations are within the service area of providers in this study, “ You could spend your entire life researching TIA’s in that population.”

Components of a Secondary Prevention Program

The final overarching theme addressed the components of an ideal secondary prevention program. This theme was supported by the following code categories: Overall Support for a Program, Ease of Scheduling, Reducing Hassles, Care Coordination, Continuing Educational for Primary Care Providers, and An Advanced Practice Clinician Led Clinic.

Overall Support for a Program

Both groups were in support of a formal program that would focus on secondary prevention for individuals who had experienced a TIA or Stroke. A secondary prevention

program that would assist primary care providers in rural areas to care for patients who had a TIA of Stroke was a welcomed idea. A neurologist stated, “Let’s do it.” A primary care provider stated that as family practice providers “we don’t have enough hands to get the patients, all the patients, secondary prevention.” A primary care provider stated, “My hope is that you could have a coordinator to monitor and make sure everyone gets things done.” Another primary care provider affirmed, “If we do our job and make the proper recommendations, ah, then, then how do we really know that blood pressure, cholesterol, aspirin and compliance is happening. That is where a program would be really handy.”

Ease of Scheduling and Reducing Hassles

Neurology providers urged for a specific secondary prevention program that eliminated hassles in scheduling and allowed patients timely access to care. A neurologist stated “locally you would have a, you would have a stroke TIA, a vascular neurology clinic where you would have open slots.” The neurologist continued by stating “the people could get scheduled into it, so you'd have, you'd have good follow-up in the acute phase or sub-acute phase, and a Nurse Practitioner could manage that.” Another aspect of the secondary prevention clinic would be to “talk to the patients you know later on that week and make sure everything's been dialed in, and if the clinic was a bit too remote.”

Primary care providers urged for a secondary prevention clinic that “would make sure that it was led by someone who could follow through on coordinating individuals to call patients and keep them on track with the intervals of say first, get all the testing after a stroke done, 2 get the medications and get blood pressure under control, are you getting your doctor appointments,

are you taking your meds, why aren't you taking your meds, why are you not going to your appointments?"

Care Coordination

In both focus groups, coordination of care and/or case management was discussed as possible ways to encourage secondary prevention. A primary care provider stated that confusion could be curtailed by having a coordinator involved in care "At discharge in that hospital, and patients they don't really know who is which and what was for what and they just, and then they, those instructions just come fast." Another primary care provider stated "And I think that's probably the biggest thing is having people who get discharged that are not clear because there's so many people coming at them and they don't know what they're supposed to do, who they're supposed to see, and why they have this appointment, so I think doing the, the calls back and – having that touch, I think that's significant, and I think that's been lacking for years and years and years in healthcare." Another primary care provider specified that "if there's some way to improve knowledge of how the patient is doing and encourage them to, you know, keep the patient doing it. So compliance, management and education. Like our nurse coordinator right here." Both the primary care providers and neurology specialists argued that in terms of focusing on secondary prevention education "we just don't have time for that" due to strains on their current clinical schedule.

A coordinator was discussed by neurologists as someone who could monitor and synchronize care "if you had a fulltime, ah, person you absolutely can do that, they could follow the patients from the hospital – to their home to their outreach clinic."

A neurologist asserted that a goal of a secondary prevention clinic could ensure “follow-up phone calls, the follow-up remote visits, ah, the follow-up with the ___ could certainly be coordinated here and accomplished within a clinic run by a NP for sure.” The same neurologist indicated that a “full time coordinator NP and maybe a couple nurses” could be involved in a secondary prevention clinic. An idea was offered, “if you had an NP I know if she could come in every morning, ah, see where calls came in overnight, see what came through our ER, talk, you know, call the Telestroke program and see what came through ears, that would take 30 minutes-- then she'd have the names and she could track those patients and, and make sure that they're getting appropriate follow-up.”

Another suggestion was that “all strokes were reported to that person, ---- anybody with a diagnosis code of stroke or TIA, whatever from the hospital gets funneled to that person and they're at least --getting a follow-up telephone call within a week. Do you have a follow-up appointment with someone? Do you have a follow-up appointment here? How are your symptoms? Are you taking your medications, do you know why you are taking those medications. I think a nurse practitioner that runs that would be perfect. Could have a few nurses who follow all the guidelines that we in neuro put out.” A primary care provider urged for a “having a nurse practitioner under neuro help coordinate with many clinics and outlying areas would be best. Since there are still so many of 'em, 'cause you know some of 'em have multiple providers that they see – so having someone streamline for all the clinics would help.”

Continuing Education for Primary Care Providers

Continuing education for providers and education for patients was a concern addressed by both focus groups. A primary care provider stated, “A big thing would be keeping up with

the education and having the program educate providers in outlying areas too of what needs to happen. Often, family practice in rural areas are lost in the shuffle of what their receiving trauma facilities are doing. So and educating patients as well. We need someone teaching our patients that TIAs will lead to another stroke. We try to do that, but 15 minute follow up appointments don't get ya too far.”

In reference to the rural patient population education regarding stroke, a neurology nurse practitioner stated “the main thing I see is that I don't think it is harped on how detrimental a second and third stroke can be on a person. “You have that TIA warning, and they get scared, they don't necessarily know how to change, they don't change, and then they get the big one. I think we have done a good job training people to know how acute strokes can kill, but not on how we can prevent them.”

A primary care provider stated in regards to education, “I wouldn't mind like a package, you know, even though I know what they are, having a nice package reminder ---- update each year like, okay, this, this is still the protocol, or this is still what we recommend, or, no this is a little bit different this year, or something.” Echoing the sentiment of the need for provider education due to changes and evolution of healthcare a neurology provider stated that a goal could be “primary care education, too, you, you know the medical ideas for secondary prevention is rapidly changing, it changes all the time.”

A neurology provider stated that there is a “lack of education of where we move patients with what TIA versus stroke... Our program for acute stroke is trying to educate the public, but now we wonder, mmmm, if we should re-educate providers. -- the real, real value of a TIA in

terms of incidence, and, so I mean anything that's transient irrespective of the symptom those are the TIA.”

An Advanced Practice Clinician Led Program

The Neurology focus group asserted that a secondary prevention TIA and Stroke program might involve a “mid-level provider” who “who can keep track of new information from guidelines to make sure we as an organization are current.” A neurology provider promoted the idea of a “midlevel that is on our staff that coordinates the care of post stroke TIA patients in our database and keeps track and coordinates all their labs and then is available for walk ins and patient education.” Another neurology provider stated that a clinic in which patients “ could get scheduled into it, so you'd have, you'd have good follow-up in the acute phase or sub-acute phase, and a Nurse Practitioner could manage that.” A neurology nurse practitioner urged for a “midlevel that is on our staff that coordinates the care of post stroke TIA patients in our database and keeps track and coordinates all their labs and then is available for walk ins and patient education.” A neurology provider stated that from a “mid-level perspective the, the follow-up phone calls, the follow-up remote visits, ah, the follow-up with the ___ could certainly be coordinated here and accomplished within a clinic run by a NP for sure.” The role of a midlevel was discussed in the secondary prevention setting as a “full time coordinator NP.” An idea was proposed by a neurology provider that “if you had an NP, I know if she could come in every morning, ah, see where calls came in overnight, see what came through our ER, talk, you know, call the Telestroke program and see what came through ears, that would take 30 minutes.”

A primary care provider urged for “having a nurse practitioner who runs a program would be great so she can have her thumb on patients so they don’t fall thru the cracks.” A

primary care provider stated, “ We could use 3 more nurse coordinators – but if we had a program with a nurse practitioner guiding it, it would help keep patient’s compliant.” One suggestion from a primary care provider was that “a nurse practitioner under n euro help coordinate with many clinics and outlying areas would be best. Since there are still so many of 'em, 'cause you know some of 'em have multiple providers that they see – so having someone streamline for all the clinics would help.” “A nurse practitioner can create big protocols, keep them current, and order all the tests and meds.” With the barrier of compliance identified, primary care argued, “If we do our job and make the proper recommendations, how do we really know that blood pressure, cholesterol, aspirin and compliance is happening? That is where a program would be really handy.” Finally, a comment was offered (by whom) on the notion of having a doctorally prepared nurse involved in a secondary stroke program. The idea of “having a doctorate level nurse really raises the bar on research and that person could really keep the research flow coming in and keep protocols up to date.” Both focus groups stated that there was strain in attempting to keep up with clinical outcomes while targeting patient populations in a rural region “we reach information overload on our end.”

The idea that a program can specifically monitor and polish guidelines for patients and keep direct contact on a weekly and monthly basis helps bridge the barrier of distance that many patients in Northwest Montana face. Primary care urged the notion that a program would encourage and support patients to make appropriate management decisions for their own care.

Summary

Both focus groups held were well attended and well supported. The third focus group was not held due to scheduling conflicts with providers. Three major theme emerged from the

data analysis process: 1) Access to Care Barriers, 2) Cultural Influences on Patient Adherence, and 3) Components of an ideal Secondary Prevention Program.

In addition to each theme, there were overlapping categories that emerged from the data. Under access to care barriers, categories emerged of Limited Secondary Prevention Programs, Challenges in Providing Care for Secondary Prevention, and Challenges in Providing Stroke Treatment Knowledge. Under Cultural Issues on Patient Adherence categories emerged of Rural Nature of Living, Limited Financial Resources, and Racial and Ethnic Influences. Under Components of an ideal secondary prevention program categories materialized including Overall Support for a Program, Ease of Scheduling, Reducing Hassles, Care Coordination, Continuing Educational for Primary Care Providers, and An Advanced Practice Clinician Led Clinic.

Providers in both focus groups were concerned that secondary prevention for TIA and Stroke in Northwest Montana was an aspect of care that lacked effective management and guidelines. Both groups were in favor of a secondary prevention program run by a DNP who could facilitate active care with up to date guidelines.

Neurologists were concerned that patients were not always seen in the post-TIA and Stroke phases as quickly as they should. Primary care providers were concerned that they did not always have the up to date guidelines to care for patients. Both groups were concerned that patients were often discharged from the hospital from a TIA or Stroke and had no follow up care at all.

Overwhelmingly, support was given for a secondary prevention program specifically tailored to patients who have had a TIA or Stroke. The idea was proposed to have a coordinator who was an Advanced Practice Clinician run the program in the neurology clinic setting.

CHAPTER V

DISCUSSION

The specific aims of the practice inquiry were to 1. Perform a critical analysis of the literature that will identify elements of a NP led TIA/Stroke clinic that are relevant to rural Montana. 2. Conduct focus groups of neurologists, primary care physicians, and nurse practitioners/physician assistants in rural northwestern Montana to elicit their opinions and preferences for a NP-led TIA/Stroke clinic and to understand barriers and facilitators for the development of that clinic. 3. Using data from Aims 1 and 2, identify key elements of a NP-led rural TIA/Stroke clinic to serve northwestern Montana.

A qualitative study design was used with the specific intention of using focus groups to identify key elements specific to secondary TIA/Stroke prevention in Northwest Montana. The setting of the study was located in northwestern Montana, specifically Flathead County and a purposive sample of neurologists, primary care physicians, nurse practitioners, and physician's assistants were invited to participate in focus groups to describe their opinions and preferences gaps for a TIA/stroke clinic in northwestern Montana. After careful review of transcripts and using a conventional content analysis, results were deconstructed to identify emerging themes. The following is a discussion of the findings in relation to the study aims.

Aim 1: Literature Support for a TIA/Stroke Clinic in Rural Montana

Stroke and Transient Ischemic Attack

A review of current literature was conducted to identify critical elements of a rural TIA/Stroke clinic and to determine potential gaps in care for the region. A cerebrovascular accident or stroke is the abrupt interruption of blood supply to the brain. A transient ischemic

attack (TIA) is often referred to as a “mini stroke”. The American Heart Association encourages providers to remember that a TIA is on the continuum of stroke care (Furie et. al, 2011). Both TIA and stroke are indications of impaired cerebral blood flow (Rothwell, Algra & Amarenco, 2011).

The greatest risk for a stroke is a previous stroke. Once an individual has a stroke or TIA, estimates indicate that 11.8% of patients will have another cerebrovascular event within 2 years (Brown, Lisabeth, Roychoudhury, Ye & Morgenstem, 2005). The American Heart Association (AHA) proposes that as clinicians, identifying and evaluating TIAs presents a fortuitous opportunity to introduce clinical measures and risk reduction therapy. Risk reduction strategies may be successful in reducing the risk of subsequent stroke and permanent impairment (Easton et. al, 2009).

Stroke and TIA in Rural Areas

Recent evidence illustrates healthcare disparities for rural individuals in access, quality, and affordability (Braveman, Cuban, Egerter, Williams, Pamuk, 2010). When compared to urban peers, rural individuals have on average higher rates of mortality and morbidity related to both acute and chronic conditions (Centers for Disease Control and Prevention, 2011; Joubert, 2008).

Disparities in stroke mortality are evident in rural areas due to spatial accessibility and availability of optimal acute and chronic stroke care teams (Sergeev, 2011; Joubert, 2008). Primary care is a critical component for primary and secondary prevention of cerebrovascular accidents (MacDougall, Amarasinghe & Muir, 2009). Effective treatment of stroke and transient ischemic attacks can decrease disability and adverse outcomes from an acute event (Schwamm et

al., 2009). For this practice inquiry, the original questions that arose from clinical experience were “What happens to patients after the acute phase of their stroke is over? Where can patients in rural communities turn for assistance, advice, and follow up in the post-acute phase of stroke or TIA?”

Models of TIA/Stroke Programs

Recent evidence supports that assessment and intervention in post-acute stroke and TIA programs can reduce the risk of stroke after a TIA by up to 80% (Rothwell et. al, 2007). However, only 5% of stroke patients receive appropriate therapy in a timely manner and many do not receive therapy at all (Bergman, 2011; Schwamm et al., 2009).

Advanced Nurse Led Programs

The use of a secondary prevention program aims to prevent recurring events by improving modifiable risk factor control (Davis & Donan, 2012). A secondary prevention program has the potential to provide an Advanced Practice Nurse Led Program to provide an inclusive holistic approach for caring for an individual in a way that fosters healthier lifestyles and goal directed patient-provider to assist with secondary prevention outcomes. Hendriks et al., (2012) showed that adherence to recommended guidelines was significantly better in the nurse-led group. Mortality rates and hospitalizations were lower with interventions initiated by the nurse-led group compared to cardiologist led services (Hendriks et al., 2012). The use of a nurse practitioner led program offers a potential cost-effective approach for secondary prevention oriented care, while offering guidance for patients with complex health needs (Harbman, 2014). The added value of a doctorate education is providing nurse practitioners with leadership tools to implement new models of effective care (Cronenwett et al., 2011)

Aim 2: Results

The following three themes emerged from the content analysis: 1) Access to Care Barriers, 2) Cultural Influences on Patient Adherence, and 3) Components of an ideal Secondary Prevention Program

Access to Care Barriers

Both groups stated that one of the major disparities in patients achieving care in rural areas was due to barriers in accessing care. Categories that support this theme are: Limited Secondary Prevention Programs, Challenges in Providing Care for Secondary Prevention, and Challenges in Providing Stroke Treatment Knowledge.

Limited Secondary Prevention Programs

Due to limited secondary prevention programs and resources, both Neurologists and Primary Care providers discussed it was difficult to have patients obtain all the necessary diagnostic testing in both a timely fashion and thoroughly without using an inpatient setting. Leira et al., (2008) previously reported that due to disparity between urban and rural care, it is evident that stroke management practices in rural regions are suboptimal. Due to the increasing advances in stroke management disparities will widen between urban and rural counterparts due to “urban-tested interventions” and their incorporation into the treatment of stroke (Leira et al., 2008).

All participants expressed concern about the lack of specific secondary prevention programs and the effect of this lack on patient outcomes. This lack of specific prevention programs is concerning in light finding is concerning in light of research that demonstrates secondary prevention as being crucial in preventing another stroke or TIA. MacDougall et al

(2009) argued that with the new recognition of TIA and stroke as medical emergencies, support is necessary for the induction of secondary prevention strategies to reduce potential risk or further disease. Due to the high-risk rate of recurrence, secondary prevention programs are seen as viable options for providing low cost risk reduction strategies (MacDougall, Amarasinghe, Muir, 2009).

Neurologists and Primary Care providers were concerned that with a lack of a secondary prevention program for rural Northwestern Montana, patients are lost in the shuffle. Both groups argued that studies are not done in a timely or efficient manner and, as a result, patients are at risk for experiencing poor outcomes. While patients may get adequate acute care, the ongoing follow-up and prevention are limited. Recent studies show that timely follow up can limit stroke mortality, morbidity, and increase patient compliance to treatment (Hankey, 2014).

It is evident that that while rural disparities for TIA/Stroke care exist, and while advances in acute care have been made, less progress has been documented related to secondary stroke prevention in rural areas (Okon et., 2010; Shutlis et. al., 2010; Joubert et al., 2008).

Challenges in Providing Care for Secondary Prevention

While all providers stated that they would like neurologists to guide secondary prevention for patients, limited time in neurology schedules resulted in patients receiving follow-up stroke care from primary care providers. It was perceived by primary care providers that scheduling follow-up in the neurology setting was a “hassle” due to limited time in neurologist’s schedules.

Neurologists agreed that due to the limited number of their specialty over a large geographic area, patients were unable to be seen in a timely fashion that fit with guidelines for care, “time in our schedules is also a problem—you know, sort of a limited commodity that we are.”

Numerous studies have shown that there is critical shortage of available specialty area healthcare providers in rural areas. The growing gap between the health of rural and urban Americans is evident and will widen without proper health care intervention of primary care services that include secondary prevention strategies (Alkadry, Wilson, & Nicholas, 2006; Brown, Lisabeth, Roychoudhury, Ye, & Morgenstern, 2005; Sacco et. al, 2006) Furthermore, the problem of scheduling is only expected to worsen as the need for neurologists across the United States increases. For example, Dall et al (2013) discussed the average wait time for a neurologist for a new patient in 2010 was 28.1 days vs 34.8 days in 2012, and 25.6 days for follow-up visits vs 30 days in 2012.

Another aspect of barriers to care was that Primary Care Providers stated their continuing knowledge and education in providing accurate guideline management for the post-stroke and TIA patient was limited due to time constraints in taking care of a large patient base with a myriad of health problems. This finding is consistent with the literature as suggested by Yarnall et al., (2009) who determined it would take over 21 hours/day for primary care providers to accomplish all the tasks recommended by national guidelines in addition to addressing acute complaints.

Challenges in Providing Stroke Treatment Knowledge

Although local neurologists had previously provided formal TIA/Stroke education, the primary care providers stated they had inadequate training for what neurology providers expected in taking care of the post stroke and TIA patients. A systematic review by Mitchell et al (2011) revealed “stroke patients and their caregivers report that general practice care is reactive- responding to requests for prescriptions, or to an emergency situation or complication.”

This is particularly true in rural areas due to limited prevention guidelines or protocol initiation (Braveman, Cuban, Egerter, Williams, Pamuk, 2010).

Primary care providers also stated that patients were lacking in their knowledge about their risk for subsequent stroke. This finding is consistent with recent studies indicating that in rural areas, patient knowledge is deficient and “better teaching strategies for stroke/TIA patients should be developed” (Sloma et al, 2010).

Cultural Influence on Patient Adherence

The second major theme to emerge from the data was that of cultural influences on patient adherence. The rural nature of living was seen as a major barrier for secondary prevention of TIA and Stroke and was also perceived as a barrier for patients achieving timely, quality care. Both focus group participants noted that the rural nature of living hindered access to care due to time constraints, financial ability to pay for services, and extended dangerous travel conditions. Recent evidence illustrates healthcare disparities for rural individuals in access, quality, and affordability (Braveman, Cuban, Egerter, Williams, Pamuk, 2010). When compared to urban peers, rural individuals have on average higher rates of mortality and morbidity related to both acute and chronic conditions (Centers for Disease Control and Prevention, 2011; Joubert, 2008).

The following three categories support the theme of Culture Influence on Patient Adherence: the Rural Nature of Living, Limited Financial Resources, and Racial and Ethnic Influences.

Rural Nature of Living

Participants stated that the geographic distance and the rural nature of living is a major issue. Snowy or icy roads and needing to travel long distances were seen as impediments to care

seeking. Geographic issues as barriers have been documented in other studies. This study's findings are similar to those of Thomas, DiClemente & Snell (2014) who stated, "understanding the geographic factors that affect a rural area's residents is essential to developing equitable and effective tailored health promotion programs." Thomas, DiClemente & Snell also encouraged recognition of how geographic factors affect rural residents is imperative for the development of sustainable health promotion programs.

Geographic determinants of health limit patient adherence to prevention models of care. Results of this study suggest Northwest Montana's geographic burden of long travel time to healthcare and poor road conditions for the majority of year influence healthcare access and compliance of patients.

Limited Financial Resources

Limited financial resources in rural areas affect both the provider and the resident. The financial burden of rural living unfortunately changes the way a provider practices, exemplified by one provider who stated, "you do what you can with that, but you can't, you can't reach everybody the way you want to." This is consistent with findings from other studies. Rural residents earn less than their urban counterparts and this income disparity is aggravated by a smaller annual tax base, which results in less money to fund health-related programs. Additionally, rural areas have larger numbers of both uninsured patients and Medicare/Medicaid patients and subsequently lower reimbursement levels in rural areas (Singh & Siahpush, 2014). This, in turn, results in fewer resources for healthcare technology or programs (Thomas, DiClemente & Snell, 2014; Beaudoin et al, 2014).

Rural Montana is a poor area and patient adherence can be impacted by limited financial resources (US Census Bureau, 2014). Patient adherence and compliance in Northwest Montana is reduced due to limited financial ability. Limited funds significantly limit the ability for patients to receive services for care they need (Bushnell et al., 2012). Persistent poverty is considered a hallmark of many rural areas and Northwest Montana is no exception (US Census Bureau, 2012). According to the US Census Bureau, Montana's rural residents of Northwest Montana have a 21.3% poverty rate. Poverty rates across the United States according to the US Census Bureau were at 15% in 2012.

Racial and Ethnic Influences

Focus group participants noted that racial and cultural patterns likely impacted patients seeking secondary prevention services and adherence to secondary prevention guidelines. Due to health habits, particularly patient smoking, it was discussed that patients were not always compliant in following health prevention guidelines.

Patient's perception of risk and determinants of health could be a factor in poor patient health compliance. Social norms of smoking and alcohol intake are pervasive in rural communities and shape the culture (Meilleur et al., 2013). The American Lung Association has stated that due to "cultural factors," close to 28% of rural residents use some form of tobacco, almost 3% more than urban counterparts. In Montana, 18.5% of residents currently smoke and 24% in the rural Northwestern Montana counties of Flathead and Lake addressed in the study (CDC, 2014).

Components of an Ideal Secondary Prevention Program

The final overarching theme from the focus group analysis was related to the components of an ideal secondary prevention program. This theme was supported by the following five categories: Overall Support for a Program, Ease of Scheduling and Reducing Hassles, Care Coordination, Continuing Educational for Primary Care Providers, and An Advanced Practice Clinician Led Clinic.

Overall Support for a Program

Together, Primary Care Providers and Neurologists were overwhelmingly supportive of a secondary prevention program or clinic that would tackle the multifaceted aspects of post-stroke and TIA prevention. When asked if a formal program should be initiated, a Neurologist stated, “Let’s do it.” Since primary care providers didn’t have time to provide secondary prevention to all needy patients, a clinic that focused on prevention was seen as desirable. Primary care providers suggested that a coordinator to monitor and make sure everyone gets things done would be an important component of such as clinic. Stirman et al (2012) proposed that stakeholder support is imperative for developing any program in a rural area. Barnidge et al (2013) urged that care coordination and stakeholder support for a rural area program is imperative for successful implementation and long-term program sustainability.

Ease of Scheduling and Reducing Hassles

Timely scheduling of patients for follow-up care was seen as a concern. Neurologists were concerned that patients were not always seen in follow-up for post-TIA and stroke phases as quickly as they should. Primary care providers, while happy to provide care for patients in the secondary prevention role, had limited time to address to all the aspects of secondary prevention

needed. Both groups were concerned that patients were often discharged from the hospital from a TIA or Stroke and had no follow up care at all due to lack of time in schedules from neurology providers.

The findings were similar to concerns related to the study by Allen et al. (2011), which aimed to examine cardiovascular risk increase associated with Healthcare Provider Shortage Areas. Investigators found that shortage of both primary care and specialty clinicians increased patient risk of chronic disease (Allen et al., 2011). Shaw (2013) argued that with the shortage of both primary care and specialty clinicians in the outpatient setting, comprehensive chronic disease care is limited.

The risk of having a second stroke or TIA after initial event in a pooled cumulative risk was 3.1% at 30 days, 11.1% at 1 year, 26.4% at 5 years, and 39.2% at 10 years after initial stroke (Mohan et al, 2011). Thus, reducing the time patients have to wait to be seen in the outpatient setting would potentially reduce risk of future stroke by initiating guidelines for patients sooner (Hankey, 2014).

Care Coordination

Overwhelmingly, support was given for a secondary prevention program specifically tailored to patients who have had a TIA or Stroke. The idea was proposed to have a coordinator who was an Advanced Practice Clinician run the program in the neurology clinic setting. Providers in both focus groups were concerned that secondary prevention for TIA and Stroke in Northwest Montana was an aspect of care that lacked effective management and guidelines. Both groups were in favor of a secondary prevention program run by a Nurse Practitioner who could facilitate active care with up to date guidelines. Mitchell et al. (2008) urged for

coordination of care of all chronic disease. Due to the multidisciplinary aspect of stroke care, a Nurse Practitioner could effectively implement and prescribe medication and treatment changes as well as coordinate care between specialists. The input from both specialist and primary care providers can be guided by a coordinator to address and tailor care to the individual patient (Mitchell, 2008).

Continuing Education for Primary Care Providers

Primary care providers were concerned that they did not always have the up to date guidelines to care for patients. Continuing education is necessary to translate effective evidence-based guidelines into practice. In order for effective care from neurologists to be disseminated, it needs to be supported by a primary care knowledge base to help address and answer patient questions in the rural setting.

An Advanced Practice Clinician Led Program

Focus group participants were in support of a formal program that would focus on secondary prevention for individuals who had experienced a TIA or Stroke and were supportive of that clinic being led by a nurse practitioner. In addition, a secondary prevention program that would assist primary care providers in rural areas to care for patients who had a TIA of Stroke was a welcomed idea.

In addition, a Neurology provider urged that the leader of a stroke and TIA program could also be component of the Neurology service in order to best support local community. A Neurology provider urged that the role of this NP would be to both schedule and see patients in the post-stroke TIA phase, thus addressing the Neurology “limited schedule” hassle that exists. A

neurologist stated “people could get scheduled into it, so you'd have, you'd have good follow-up in the acute phase or sub-acute phase, and a Nurse Practitioner could manage that.”

Based on findings from this study, the role of the nurse practitioner, whether in the Neurology service or practicing independently, would be in close communication with both Primary Care and Neurology Providers. The goals would be to 1. Efficiently and quickly see patients, 2. Use evidenced based research to guide patients in effective secondary prevention management 3. Effectively institute close follow up to help patients manage their risks of a subsequent vascular event.

Several providers commented on the doctoral prepared Nurse Practitioner as provider and researcher. The idea of “having a doctorate level nurse really raises the bar on research and that person could really keep the research flow coming in and keep protocols up to date.” Both the primary care providers and neurology specialists argued that in terms of focusing on secondary prevention education “we just don’t have time for that.” It was evident that both groups stated the strain of attempting to keep up with clinical outcomes while targeting patient populations in a rural region “we reach information overload on our end.”

“A nurse practitioner can create big protocols, keep them current, and order all the tests and meds” according to a Neurologist. With the barrier of compliance identified, primary care argued, “If we do our job and make the proper recommendations, how do we really know that blood pressure, cholesterol, aspirin and compliance is happening? That is where a program would be really handy.” The idea that a program can specifically monitor and polish guidelines for patients and keep direct contact on a weekly and monthly basis helps bridge the barrier of distance that many patients in Northwest Montana face. Primary care urged the notion that a

program would encourage and support patients to make appropriate management decisions for their own care.

Aim 3: Secondary Prevention TIA/Stroke Program

Review from the current literature indicates TIA and stroke programs in the United States have been proposed to sync prevention services and diagnostic testing (Jäkel, Plestel, Chapman, Jackson & Purroy, 2012). TIA programs have been lauded as potential care model to reduce costs and an alternative to hospitalized TIA care (Joshi, Ouyang, & Prabhakaran, 2011). The goal of a TIA/Stroke secondary prevention program is to reduce the risk of a future disabling stroke (Johnston et. al, 2011).

Literature currently supports the implementation of stroke and TIA programs to reduce the incidence rates of subsequent stroke (Sacco et al., 2014). Currently, gaps in care exist in Northwestern rural Montana for stroke care due to post acute follow up, care coordination and provider and patient education. From the literature and data from focus groups, a Nurse Practitioner-led TIA/Stroke Program to serve rural Northwestern Montana is proposed. Therefore, the overall goals are to: 1. Schedule patients for follow-up no more than 72 hours after initial event. 2. Use AHA/ASA evidenced based research to guide patients in effective secondary prevention management 3. Effectively institute close follow up to help patients manage their risks of a subsequent vascular event.

Post Acute Follow Up

Dedicated spots in schedules would be allocated to any patient who experienced a TIA or Stroke and referred to the service. A patient would be scheduled within 1 to 5 business day's time of an initial event, with the goal of no more than 72 hours post initial event. Patients would

be called within 24 hours of discharge by the DNP to go over discharge instructions from their discharging facility prior to their appointment. It has been stated that communication at discharge is essential for the continuity of care for patients transferred from the hospital to ambulatory care (Hohmann, 2013). Providing immediate phone calls to patients could potentially “lead to substantially improved adherence to discharge medication, probably resulting in better secondary stroke prevention” (Hohmann, 2013).

Evidenced Based Secondary Prevention Plan

With the support neurology providers, the clinic would operate with the goal to assist patients who have been discharged from the hospital see a specialized DNP who would use a protocol-based approach. Patients would be seen in accordance with the American Heart Association and American Stroke Association guidelines for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack. The goal would be to use the evidence-based recommendations to provide risk reduction, interventions, and appropriate medication management for patients with previous stroke (AHA, 2014).

Care Coordination

Using suggestions from focus group participants, a detailed component of the Secondary Prevention TIA/Stroke Program would include a protocol given to outlying primary care providers. This protocol could explain the targeted evidence-based recommendations to control risk factors of subsequent cerebrovascular events. The protocol would need to be updated every 6 months and with every new AHA/ASA guideline change or pertinent practice update. Using focus group suggestions, the DNP would act as a coordinator of care to assist patients who live in rural areas get the care they need both remotely and in office without sacrificing evidence based

care. This coordination would require the provider to effectively use methods via phone and telemedicine to assist patients' compliance with their prevention regimens.

Data from this study is similar to data from the study by Warner (2012). Respondents were hopeful for better care coordination between rural primary care providers and neurology providers. In contrast to data from Warner (2012) in which providers emphasized the need for better provider communication, this theme did not specifically emerge in the current study.

Education

Provider education would be given in a lecture format and videotaped to allow Primary Care Providers access year round access to education. Providers will be given emails with current care strategies that specifically discuss secondary prevention treatment regimens. Breakfast or lunch talks done by the Nurse Practitioner would be given at Primary Care Clinics with the goal of highlighting yearly advances in secondary prevention care.

Patient education would be highlighted with both technology based and conventional based materials for all patients and caregivers. A Nurse Practitioner could provide monthly support group and information sessions at clinics throughout the region. Community events could highlight stroke risk with information booths at all the Northwestern Montana County Fairs.

Evaluation

The Nurse Practitioner would be the leader and developer of the program. The Nurse Practitioner would be responsible for developing quality program metrics to evaluate success of a program in limiting the incidence rate of subsequent stroke in rural Northwest Montana. This role would include data collection, analysis, and reporting of results. Evaluation of stroke

outcomes would be addressed from developed performance measures as outlined by the American Heart Association (Reeves et al., 2010).

Strengths and Limitations

Three focus groups were originally planned, however, the third group, consisting of primary care providers could not meet due to scheduling conflicts. While the sampling was smaller than anticipated, we do think the groups adequately reflected the healthcare provider perspective.

The focus group facilitator had challenges in guiding the discussion. The facilitator was inexperienced in leading focus groups and the study would have benefited from an experienced facilitator. Time was lost to irrelevant topics or topics that did not directly support the specific questions outlined in the moderators guide. While much information was relevant for the topic of stroke and TIA care, it did not relate directly for a secondary prevention program nor a nurse-led clinic for those who had experienced a stroke or TIA.

Another limitation was the small size of the groups. Both groups had one to two individuals who dominated the session making the output extremely biased. While the facilitator tried to have more involvement from all participants, it was difficult due to her lack of experience to have all of the participants have equal share in answering the moderators guide questions. Again, a more experienced facilitator might have been able to draw out those who tended to be silent.

Another weakness is having nurse practitioners in group with physicians. The NPs may have been intimidated and not spoken out as freely as if they were in their own group. Findings of this limitation were consistent with a study by Crawford et al. (2012), who stated that nurses and

nurse practitioners often silenced their opinions and voice when communicating with physicians. It was felt with this study that there was a lack of NP voice potentially related to the nurse practitioners intentionally silencing their own voice.

Should a TIA/Stroke program plan go forward, it would be important to publish the results of this study and invite further comment from other interested stakeholders, including healthcare organizations, providers and patients. The practical issues of a future program would need to be addressed in further study in order to proceed with future development of a program. Location, core supporters, overhead and core staffing are all items that would need to be focused on in future study. Topics for future study related to a future program could include addressing logistical concerns, financial accountability and potential evaluation techniques of a program.

Limitations of this project also include a threat to trustworthiness since there was no note taker available. There was also no credibility check due to the nature of study timeframe. Both focus groups were conducted and analyzed without a credibility check after the first group. The feasibility pilot nature of this study limits direct translation to rapid development of a stroke program.

Implications for Nursing Practice

To our current knowledge, the findings from this study are the first documentation of the perceptions of needs and barriers for a stroke/TIA program from stroke/TIA providers in NW Rural Montana. The data supports the idea of exploring the development of a nurse-led stroke/TIA secondary prevention program that would serve NW rural Montana.

This study supports that nurses are ideally suited to lead a rural secondary prevention program for stroke/TIA. This program could serve as a prototype for other NP led rural secondary prevention programs across diverse health conditions.

Next steps for this topic include additional stake holder focus groups, an NP only focus group, and organizational logistical focus groups with administrators and financial leaders of the community.

Conclusion

Stroke and TIA care in rural areas is lacking in general. Rural Montana has an underrepresentation of secondary prevention services for stroke and TIA. This small study is the first of its kind to explore the needs and perceptions of health care providers related to a stroke and TIA program. We found that like other reports from rural sectors, Primary Care Providers and Neurology providers in Northwest rural Montana identified challenges in access to care and cultural influences on patient adherence.

A secondary stroke prevention program is clearly needed and would be welcomed by both neurologists and primary care providers in Northwest Montana. An NP led clinic was supported by providers and would bring value to both patients and providers in the area. Components of a stroke/TIA program to serve Northwest rural Montana include: Nurse Practitioner-led transitional care services, care coordination, and education and program evaluation services. It is the hope that a program of this kind would lead to a reduction of TIA/Stroke and improve quality of life for stroke survivors.

APPENDIX A
MODERATORS GUIDE FOR FOCUS GROUPS

A NURSE PRACTITIONER-LED TIA/STROKE PROGRAM TO SERVE RURAL
NORTHWEST MONTANA

TIMED AGENDA

Time	Topic	Method
10 minutes	Arrival and mingling of participants	Each person will receive a name-tag. The note taker will draw a picture of the seating arrangement and list the participants by number. While taking field notes, the note taker can then use numbers as shorthand for the participants' locations.
	Food	Provided by Research Team to facilitate rapport building among participants and FG leaders
10 min	Introductions	<p>➤ People will be seated.</p> <p>➤ Study Purpose The purpose of this study is to describe the essential elements of Nurse Practitioner (NP) led TIA/Stroke program to serve a rural northwest Montana. The purpose of this focus group is to elicit information from experts in the healthcare field of northwestern Montana to elicit opinions and preferences of a TIA/Stroke and in that would serve the patients in their rural community.</p> <p>Sample All of the people here today have offered to help us (the research team) better understand the elements of a TIA/Stroke program that would serve you and our community, since you are the experts who deal with this disease every day.</p> <p>Informed Consent All of you have been given a copy of the informed consent. Let me review this form. (review). Do you have questions? If you are willing to continue with this focus group, please sign the form.</p> <p>Introductions ➤ Let's go around the table and introduce ourselves.</p>
5 min	Agenda Setting	<p>Let's talk about why we're here and what's going to happen tonight.</p> <ol style="list-style-type: none"> 1. I will introduce 5 topics that we will cover today. The goal is not to rush through the topics, but to spend as much time as we need to get an idea of your experiences and opinions about these topics. 2. We will stop after 75 minutes.

Time	Topic	Method
5 min	Ground Rules	<p>Let's set some rules for how we'll conduct this focus group. I'll list a few, then I want you to add to this list if there are rules you would like to set.</p> <ol style="list-style-type: none"> 1. You are the experts. We invited you to come because we while we know secondary prevention of TIA/Stroke is essential, and we know that TIA/Stroke clinics have been successful in other settings, we don't know if or how this kind of clinic would serve you and our patients in northwest Montana. 2. There are no right or wrong opinions. We aren't looking for certain answers, and we don't expect that everyone will agree. We can all accept a diversity of opinions. 3. Everyone's opinion is important. We don't want anyone to hold back. Each of you should have your opinions heard. 4. Finally, sometimes people say things that are a little sensitive. We should all agree that nothing said in this room will leave the room. 5. Now, are there ground rules you would like to have? (i.e., wait your turn to talk, no interrupting, no monopolizing conversation). <p><i>DEFINE TIA and STROKE for the Group.</i> <i>DEFINE Secondary Prevention for the Group.</i></p>
15 min	Questions	<p>What kind of secondary TIA/Stroke services are available to this community that you use or could use</p> <p>Tell me how you are involved in TIA/Stroke care in northwestern Montana.</p> <p>Are there secondary prevention clinics of any kind in the area?</p> <p>What types of secondary prevention services are you providing for TIA/Stroke patients now?</p> <p>Do you have ideas or suggestions for the improvement of post acute stroke care in your area? Or perhaps how do you think these services could be improved?</p> <p>Are there evidence based guidelines that you use to guide your decisions for secondary prevention for TIA/Stroke, eg, "Get with the Guidelines"</p>

Time	Topic	Method
		<p>Tell me about the continuum of care in NW Montana for patients who present to your office or hospital with symptoms of a secondary TIA/stroke.</p> <p>What are the three (3) biggest challenges/problems in providing best practice care for secondary prevention after a TIA/stroke in NW Montana?</p> <p>How significant are these challenges/problems related to delivering best practice secondary prevention TIA/stroke care to patients? Please give an example.</p> <p>What do you see as the solutions to these challenges/problems?</p> <p>What changes would you like to see made in secondary prevention services for a TIA/stroke care system in northwestern Montana?</p> <p>How does the rural nature of living play a role in secondary TIA/stroke disparity?</p> <p>How long does it take a patient after a TIA/Stroke to receive follow up primary care for secondary prevention services?</p> <p>Are there challenges for northwestern Montana's TIA/stroke system in obtaining clinical information, which is timely, accurate and useful for secondary prevention for TIA/stroke care?</p> <p>How easy is it for you to access care for patients that need more care than you can provide?</p> <p>Topic: What is your opinion about establishing a TIA/Stroke program that would serve the NW Montana community</p> <p>Probes: are the key three (3) key components of quality secondary prevention for TIA/Stroke care that you would wish to see in northwestern Montana?</p> <p>When you think secondary prevention for a TIA/Stroke in northwestern Montana offers, what is the first thing that comes to mind?</p> <p>Topic: If there were a TIA/Stroke program, what would it</p>

Time	Topic	Method
		<p>“look” like?</p> <p>Probes: Design/workflow/workforce services provided/technology/hours of operation</p> <p>What do you think the advantages/disadvantages of a secondary prevention TIA/Stroke program to serve northwestern Montana would be?</p> <p>If there was a TIA/Stroke program to focus on secondary prevention, what essential elements of the clinic would you expect/suggest?</p> <p>Topic: If there were a TIA/Stroke program in NW Montana, what would be the barriers to and facilitators of success?</p> <p>Probes: would you refer patients to a TIA/stroke prevention program? If yes, for what types of care issues?if no, why not?</p> <p>Who would you like to see direct the program? Where should the program be? What hours should it be open, what services do you think are essential to be offered? How could a doctorally prepared nurse facilitate a program?</p> <p>Are there any questions that we did not ask, but feel we should have asked? If so, what would the question(s) be?</p>
<p>➤ Clarify ➤ Wrap-up</p> <p>Go over each question and summarize what has been said. Ask if you missed anything. Then thank the participants for their time.</p>		
	Payment	Participants sign for gift card.

APPENDIX B
DEMOGRAPHIC DATA SHEET

Date: _____

Focus Group Number: _____

Study ID Number: _____

We would like to know a little about you. Please answer the following questions. The information will only be used for statistical purposes.

1. How many years have you been in practice?
2. What medical training did you receive?
3. Are you: Male Female
4. Where do you practice?
5. On average, how many patients with a past medical history of TIA/Stroke do you see in your practice per day/week/month?
6. What evidence based practice guidelines do you use for secondary prevention of TIA/Stroke care?

APPENDIX C

FLYER

Volunteers Needed

Participants needed for focus group study:

A NURSE PRACTITIONER-LED TIA/STROKE SECONDARY PREVENTION PROGRAM
FOR RURAL NORTHWEST MONTANA

Description of Project: Elizabeth King, FNP-BC is conducting focus groups to identify information regarding provider opinions. Participation will take 60 minutes.

To participate: You must be a clinical provider with Kalispell Regional Healthcare in (XXX)

Participants will be compensated with a \$10 gift card.

To learn more, contact the principle investigator of the study, Elizabeth King, FNP-BC,
at 406-471-6130 or elking27@email.arizona.edu

This research is conducted under the direction of Dr. Leslie Ritter, Dr. Deborah Vincent, and Dr. Kate Shepard, University of Arizona College of Nursing Department, and has been reviewed and approved by....

(IRB STAMP)

APPENDIX D
THEMES AND CODES TABLE

Themes Codes Categories	Supporting Quotes
<p>1. Access to Care Barriers Codes that support this theme</p> <p>Limited Secondary Prevention Services</p>	<p>We don't have a formal program, but we like to see them 2 weeks and 4 weeks after at least. But I'm not sure we see everybody --in fact I guarantee we miss about 40-50% of people."</p> <p>2. "But I have to agree, people don't want to pay, don't see the value in secondary prevention."</p> <p>3. "...the problem we have is there are so many things that come our way with what we are supposed to do. It is hard to know from one year to the next what we should be doing specifically for secondary prevention".</p> <p>2. "...you certainly look at our standard prevention of --- what's our cholesterol numbers, their blood pressure, are they still smoking 5 packs a day, and drinking like a 5th a day and so forth, and so if you want call that conglomerate guideline protocol I suppose we are. "</p> <p>4. "... people don't want to spend the money on prevention, they wait til it is too late. Nobody wants to pay for primary care.."</p> <p>2. "But I have to agree, people don't want to pay, don't see the value in secondary prevention."</p> <p>3: "... we don't have enough hands to get the patients all the patient's secondary prevention."</p> <p>3. "I think it probably in rural areas is where you, you get patients being missed with prevention in general."</p>
<p>Hassles of Obtaining Stroke Prevention Care</p>	<p>3. "But, most of the management I think is here because we can't get them to see neuro without a lot of hassle---3:Even, even if they're A-fib and had a stroke, you know, we've managed the protimes."</p> <p>3. "That is where it comes down to a tricky problem. We have a great neurology practice, but they are difficult to get</p>

	<p>into and our patient's don't always like to go.”</p> <p>One primary care provider noted 2. “I would say we manage them pretty well on our own in continuity care if one of our patients have a stroke or TIA. We try to keep our patients in house since it is hard for patients to get into specialty care with neuro or they don't want to go to more than one provider.”</p> <p>3. “For years we just had family practice docs in this area. Only in the past decade did we get lots of specialists in Kalispell. It's hard for the old timers to go to a specialist.”</p>
<p>Provider Issues in Providing Stroke Treatment Knowledge</p>	<p>“I like using UpToDate.com, but I don't follow a specific secondary prevention guideline.” Another primary care provider stated that lack of time was an issue for staying current and myriad of sources available and how overwhelming this could be. ADD THIS with the Direct Quote</p> <p>: I don't know if you'd call it a guideline protocol, but you certainly look at our standard prevention of --- what's our cholesterol numbers, their blood pressure, are they still smoking 5 packs a day, -- -- and drinking like a 5th a day and so forth, and so if you want call that conglomerate guideline protocol I suppose we are.</p> <p>“...there are so many things that come our way with what we are supposed to do. It is hard to know from one year to the next what we should be doing specifically for secondary prevention.”</p> <p>5. ...”It would be nice if we could have a streamlined approach that would help us know what guidelines for KRMC we should follow. Like the specific JNC-7 guidelines that KRMC said we should use a few years back for hypertension. “</p> <p>But is there one particular cookbook formula that we should follow, see there is so much to know and I am not sure that we do that.</p> <p>2: See we can't sit on up-to-date every 10 minutes looking</p>

	<p>for guideline change.</p> <p>3: Maybe a guideline KRMC could adopt and say this is our standard of care would be nice.</p>
<p>2. Cultural Influences on Patient Adherence</p> <p>Rural Nature of Living (distance, weather, independent nature etc)</p>	<p>“That people don’t want to spend the money on prevention, they wait til it is too late. Nobody wants to pay for primary care. “</p> <p>2. “I think it is a major issue here. Patients are not inclined to drive in the snow or some into town due to the tricky roads.”</p> <p>3: “Or the meds that help their primary care.”</p> <p>5:” I think the biggest three would be money, people don’t like to drive to come all the way into town, and no one sees the benefit of prevention.”</p> <p>2: “Don’t forget smoking. People in Montana like to smoke and drink. But I have to agree, people don’t want to pay, don’t see the value in secondary prevention.”</p> <p>3. “Oh yes, we just had a patient last week who had his INR done in November and needed to come back for a week check up back in November. He just arrived for his follow up appointment and had INR of 1.2. Patients don’t like to come in.”</p> <p>2: I think it is a major issue here. Patients are not inclined to drive in the snow or some into town due to the tricky roads.</p> <p>3: That is where it comes down to a tricky problem. We have a great neurology practice, but they are difficult to get into and our patient’s don’t always like to go.</p> <p>4. “I think the biggest three would be money, people don’t like to drive to come all the way into town, and no one sees the benefit of prevention.”</p> <p>2. Don’t forget smoking. People in Montana like to smoke and drink. But I have to agree, people don’t want to pay, don’t see the value in prevention.</p> <p>1. “like people from Libby come all the time, I think, part</p>

<p>Racial/ethnic influences</p>	<p>of that may be, maybe they have such small towns it's almost embarrassing or they don't want people their business or they're coming to the center of town, I don't know. “</p> <p>3. Absolutely, it could be the biggest problem of them all.(referring to rural nature of area)</p> <p>#? ...education of a large number of primary care providers in a big region, and XXX (man's name) does a great job, but there a lot of transient providers because of the rural location, so he goes out and he teaches and educated, you know, this practice or this clinic, and then the next thing you know those doctors are gone and there's a new crew in two, three, four hours to our big hub here of Kalispell. While we have state of the art healthcare here now in Kalispell, drive about 40 minutes away and you will still see the ole homestead with Bobby Jo who refuses to come to the big city.</p> <p>1: Yeah. It, it's challenging. So, you know, there are certain patients that you feel pretty good about waiting 2 or 3 weeks, and then there are certainly people that, you know, we try to get in if we hear about them, you hear the story and we'll get them in about a week, you know, we can, we have some flexibility in our schedule for that. Mmm, but it is, it is challenging and, and so it's, ah, it's kind of a case by case kinda thing and, and I'm sure there's a lot of that that we don't see because it's off our radar 'cause the primary docs are handling it.</p> <p>1: -- we have a lot of poor and indigent people here and they got really limited funds.</p> <p>1: And you do what you can't with that, but you can't, you can't reach everybody the way you want to.</p> <p>3: And to add to the accessibility, mmm, is that we have the Native American reservations.</p> <p>3: What docs want to risk their life flying in 6 months of winter here. Can I add something? system wide is we have this kind of a frontier mentalilty I think that it's, few people really understand the gravity of stroke, TIA, --</p>
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<p>3. Components of ideal Secondary Prevention Program</p> <p>Services</p> <p>Who Provides</p> <p>Cost</p> <p>Location</p> <p>Goals</p>	<p>SERVICES 1: Hmm, well, that one's easy for me. So, mmm, locally you would have a, you would have a stroke TIA, a vascular neurology clinic where you would have open slots, --</p> <p>WHO PROVIDES 1: -- and we, the people could get scheduled into it, so you'd have, you'd have good follow-up in the acute phase or sub-acute phase, and a Nurse Practitioner could manage that. For more rural and frontier sites on our Telestroke network you could actually ___ and XXX (man's name) and I were talking about this a lot, you could, you could actually not do the, you know you could use the Telestroke program but not for the acute events, so you, you have them come back to their local community and, and you set up the Telestroke system, ___ you and talk to the patients you know later on that week and make sure everything's been dialed in, and if the clinic was a bit too remote.</p> <p>1: --Well we have a nurse but she can't only does paperwork for telestroke. and yeah, so she's a quarter time nurse and , mmm, so that's not near enough time to even manage the Telestroke system, but - but if you had a fulltime, ah, person you absolutely can do that, they could follow the patients from the hospital – to their home to their outreach clinic</p> <p>WHO PROVIDES 1: Absolutely. And, and, mmm, and these, you know the, from a mid-level perspective the, the follow-up phone calls, the follow-up remote visits, ah, the follow-up with the ___ could certainly be coordinated here and accomplished within a clinic run by a NP for sure.</p> <p>WHO PROVIDES1: I think it would involve a midlevel, NP who can keep track of new information from guidelines to make sure we as an organization are current. It would involve a full time coordinator NP and maybe a couple nurses. You know if you had an NP I know if she could come in every morning, ah, see where calls came in overnight, see what came through our ER, talk, you know, call the Telestroke program and see what came through ears, that would take 30 minutes.</p> <p>1: And then she'd have the names and she could track those patients and, and make sure that they're getting appropriate follow-up and, for me it wouldn't have to be a 24/7 kind of thing.</p>
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	<p>WHO PROVIDES 3: Yeah I like that idea what we talked about earlier. A midlevel that is on our staff that coordinates the care of post stroke TIA patients in our database and keeps track and coordinates all their labs and then is available for walk ins and patient education.</p> <p>WHO PROVIDES 4: Yes, I think having a NP do it would be great for all of us and be great for outreach areas with telestroke.</p> <p>WHO PROVIDES 2: I think we touched on that a lot above. Having it here, led by a midlevel would be excellent.</p> <p>Timeline:</p> <p>: -- all strokes were reported to that person, --</p> <p>3: -- anybody with a diagnosis code of stroke or TIA, whatever from the hospital gets funneled to that person and they're at least --</p> <p>3: -- getting a follow-up telephone call within a week. Do you have a follow-up appointment with someone? Do you have a follow-up appointment here? How are your symptoms? Are you taking your medications, do you know why you are taking those medications. I think a nurse practitioner who runs that would be perfect. She could have a few nurses who follow all the guidelines that we in neuro put out.</p> <p>WHERE: more of a nurse practitioner stroke/TIA coordinator within the neuro clinic.</p> <p>Goals of Potential Program:</p> <p>1: access, protocols that are within guidelines, and follow through</p> <p>3: Yeah. Cutting patient cost, cutting their distance obligation to get here and keeping in check with guidelines.</p> <p>2: Yep, protocols, keeping compliance my two.</p> <p>4: Keeping patients updated on why they are doing these secondary prevention things.</p>
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APPENDIX E
IRB APPROVAL

Investigator:Advisor: Leslie Ritter PhD

Elizabeth Louise King

Human Subjects Protection Program

HSPP Correspondence Form

1618 E. Helen St.P.O. Box 245137Tucson, AZ 85724-5137 Tel: (520) 626-6721

<http://orcr.arizona.edu/hsp>

Department: Nursing



All documents are filed with the IRB office.

Project No./Title: 13-0780 (UAR Number 1300000780); *A NURSE PRACTITIONER-LED TIA/STROKE PROGRAM TO SERVE RURAL NORTHWEST MONTANA***Expiration Date:**

December 02, 2014 Submit the “*FORM: Continuing Review Progress Report*” no later than 45 days prior to the expiration date.

All documents that were submitted with the application have been reviewed and approved.

Consenting Instruments: ICF(version 2013-11-25)

IRB2 – IRB00001751 Expedited Review – New Project FWA Number: FWA00004218

Approved in accordance with **45 CFR 46.110 and 45 CFR 46.111** as submitted. Effective as of the signature date below.

12-03-2013

Thomas K. Park, PhD, Chair, University of Arizona IRB TKP: CML

cc: Scientific/Scholarly Reviewer

Reminders: No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.

T106: HSPP Correspondence Form Arizona’s First University – Since 1885 Form version: 07/2013

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