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Do Call-Backs Help Patients Post Stroke

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REVIEW, APPROVAL AND ACCEPTANCE

The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

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Final DNP Project Report
Do Call-Backs Help Patients Post Stroke?

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Spring 2016

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Dedication

This practice inquiry project is dedicated to my wonderful husband and best friend, Kellan, and our two beautiful girls, Khloe and Anabel. Without their love and support, I would not be where I am today. Kellan, you have supported me from the start and have always believed in me. You keep me grounded and encourage me to do my best. Thank you for loving me and supporting me throughout this challenging endeavor. Also, I would like to dedicate this to my family and friends who have encouraged me, sent up countless prayers and walked alongside me in this journey- thank you!

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Introduction to Final DNP Practice Inquiry Report

Taylor E. Clark

University of Kentucky

Stroke is the fifth leading cause of death in the United States and a person dies every four minutes from a stroke (American Stroke Association, 2015). According to the Center for Disease Prevention (CDC) (2016), Kentucky represented the 11th highest mortality rate for strokes in the United States in 2014. Strokes accounted for 5% of deaths in the state of Kentucky that year (Kentucky Cabinet for Health and Family Services, 2012). Many strokes are preventable with modifications to certain risk factors, such as controlling hypertension (HTN) and diabetes mellitus (DM) (American Stroke Association, 2012).

When a patient shows initial signs or symptoms of a stroke, they are typically admitted to the hospital. After stabilization and medical optimization, some are able to return home with their families, though with many new challenges and changes to confront; such as a modified diet, weakness to one side of the body, or visual changes. Many patients are discharged home with new disabilities, such as paralysis to an arm and/or leg, which may affect their daily life as well as their caregivers' lives.

These patients are expected to continue their lives with new physical deficits and new medications (American Stroke Association, 2012). According to Andersen, Schultz-Larsen, Kreiner, Forchhammer, Eriksen and Brown (2000), almost ten percent of patients discharged home after an initial stroke have another stroke within one year. This sometimes leads to longer hospitalizations, which can be costly.

Follow-up intervention, such as a telephone call, text message or visit from a nurse, post-discharge may be beneficial in reducing readmission rates and complications once a patient is home, along with increasing patient satisfaction and increasing the number of patients who keep their follow-up appointments. The overall purpose of this

practice inquiry project is to determine the benefit, if any, to a call-back intervention implemented for patients post-stroke at a large suburban medical center.

The first manuscript in this document describes the process for developing interprofessional education (IPE). IPE is important when caring for patients at any level, including patients post-stroke, and therefore should be taught at the doctoral level for nurse practitioner students. IPE should also be taught to other professional disciplines, as the scope of caring for a stroke patient spans far beyond nursing. This manuscript discusses a pilot course of Doctorate of Nursing Practice (DNP) students as an independent study class and some of our suggestions for future courses based on the experiences of several DNP students.

The second manuscript is a review of the literature on post-discharge interventions for patients in general, specifically examining the nurse navigator role. This role is commonly used for cancer patients, but several of the articles explored utilizing this role for patients with chronic diseases (i.e. diabetes, asthma or congestive heart failure). This intervention could be beneficial to the stroke population, as the call-back could fall under the role of the nurse navigator. This manuscript explores common themes within the literature, incorporating patient satisfaction, among others.

The purpose of the third manuscript is to evaluate a call-back intervention post discharge, which was implemented on the stroke unit at the University of Kentucky Hospital, and determine if there are any differences in 30-day readmission rates and patient satisfaction scores pre and post-intervention. In essence, the goal of this manuscript is to examine a program already in place by completing a retrospective chart

review on a total of 333 patients post stroke who were discharged between the years 2012 and 2014.

Manuscript 1

Developing Interprofessional Education:

A Nursing Perspective

University of Kentucky

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Developing Interprofessional Education: A Nursing Perspective

Collaborative care teams for the delivery of safe patient care were the motivation behind the Institute of Medicine recommendations in 1999. However, widespread adoption of interprofessional education (IPE) as a means to deliver collaborative care has been slow and often unrealized in academic or patient care environments. In 2011, representatives from the American Association of Colleges of Nursing took part in the Interprofessional Education Collaborative Expert Panel to improve IPE implementation. Core competencies for IPE were established and included: 1) values and ethics for interprofessional practice, 2) roles and responsibilities for collaboration, 3) interprofessional communication and 4) interprofessional teamwork. The Patient Protection and Affordable Care Act (2010) further supported IPE adoption by mandating IPE and interprofessional collaborative practice (IPCP, Zorek & Raehl, 2013), yet the law provides no formal structure for implementation. The adoption of IPE in academic and clinical training programs has been slow due to existing barriers resulting from complex and fragmented health care delivery education systems. The purpose of this manuscript is to describe the experience of a group of healthcare students' participation in an IPE pilot program.

What is IPE?

Preparation for purposeful IPE is necessary for nurse practitioners to approach team-based care (Foret Giddens et al., 2014). However, collaborative, interprofessional care is not intuitive and necessary skills to facilitate successful IPE must be learned. Established curricula with formal expectations must be introduced during academic preparation. A major bottleneck in the implementation of IPE and IPCP initiatives occur

within academic institutions (Zorek & Raehl, 2013). Specifically, because accrediting bodies lack standards and guidelines regarding the incorporation of IPE, academic institutions are not required to offer structured programs introducing and applying IPE concepts (Zorek & Raehl, 2013). As innovative healthcare institutions and providers, the University of Kentucky's colleges of medicine and nursing developed a pilot program to introduce IPE to their students as an elective course. This pilot program was intended to engage participants in a quality improvement project incorporating the components of interprofessional education and applicable skills to arrive at a collaborative solution for an identified fractured process.

The pilot program was divided into a didactic portion and a group project involving practical application of course concepts for quality improvement. The pilot group of students included two resident physicians, one pharmacy resident, and three Doctor of Nursing Practice students. Didactic concepts and skills for effective IPE included: emotional intelligence (EQ), conflict resolution, personality profiles, communication, and leadership. Experts in their respective fields introduced these skills and activities and were arranged to supplement and foster learning and application in the quality improvement process. To implement these skills, the students chose and assessed one problem area using the LEAN process.

Quality Improvement Process

Application of the Lean process in the healthcare setting is not innovating; however, its employment within coursework at an academic institution is novel. The Lean process is an eight-step quality improvement process (Kaplan, 2012). A key component of Lean hinges upon direct involvement of frontline providers, such as

physicians, nurses, and managers when evaluating process flow (Kaplan, 2012). Similarly, IPE functions by engaging providers across professional disciplines in a patient's healthcare regimen to collectively discuss and provide comprehensive care. The pilot group of students unanimously chose turnaround time of laboratory results in obstetrics triage as a process in need of quality improvement (Figure 1).

The group learned to work together to overcome barriers such as scheduling conflicts, division of assigned work, and engaging with various departments within the hospital. We improved our communication skills and developed an understanding of each person's role throughout the project. Mutual respect, positive and negative feedback, and working towards a consensus for the benefit of patient care were accomplished. Students learned to respect viewpoints outside their own with a patient-centered focus.

Recommendations

Recommendations to improve the program would be to incorporate the concepts and skills introduced in the pilot IPE course and to place an emphasis on collaborative care. Additionally, scheduling meetings was a major barrier. This pilot project spanned nine months and it would have been beneficial to have monthly face-to-face meetings prearranged by academic faculty to facilitate student attendance.. We learned from this pilot program that even in its infantile state, IPE curricula within an academic setting can facilitate the development of mutual exchange and respect among students from various professional healthcare disciplines, while opening lines of communication with a patient-centered focus on improving healthcare system outcomes.

Throughout the course of this pilot, we gained an appreciation of necessary skills and expectations to successfully implement IPE in an academic setting, as well as at the patient and systems level. Beginning certification in the Lean process and its application to healthcare, as well as required IPE coursework should be incorporated into mandatory curricula for healthcare professionals to promote uniform, organized, and effective discussion with a focus on quality and efficiency in the delivery of safe patient care. Learning to appreciate each discipline's contributions, points-of-view, and rationales to meet patient needs and goals fostered respect, collaboration, and appreciation of each person's role in patient care within a healthcare system. Skills gained through IPE coursework facilitated these exchanges. It is our recommendation that this course be incorporated broadly into any healthcare provider's core curriculum. This recommendation is supported by the Interprofessional Education Collaborative Expert Panel's (2011) needs assessment and helps meet provisions under the ACA (2010). Lobbying for IPE mandates by accrediting bodies for academic programs should also be considered (Zorek & Raehl, 2013). What an amazing experience to be at the leading edge in the provision of safe, high quality, efficient and patient-centered care by being a part of the quality improvement process through interprofessional education!

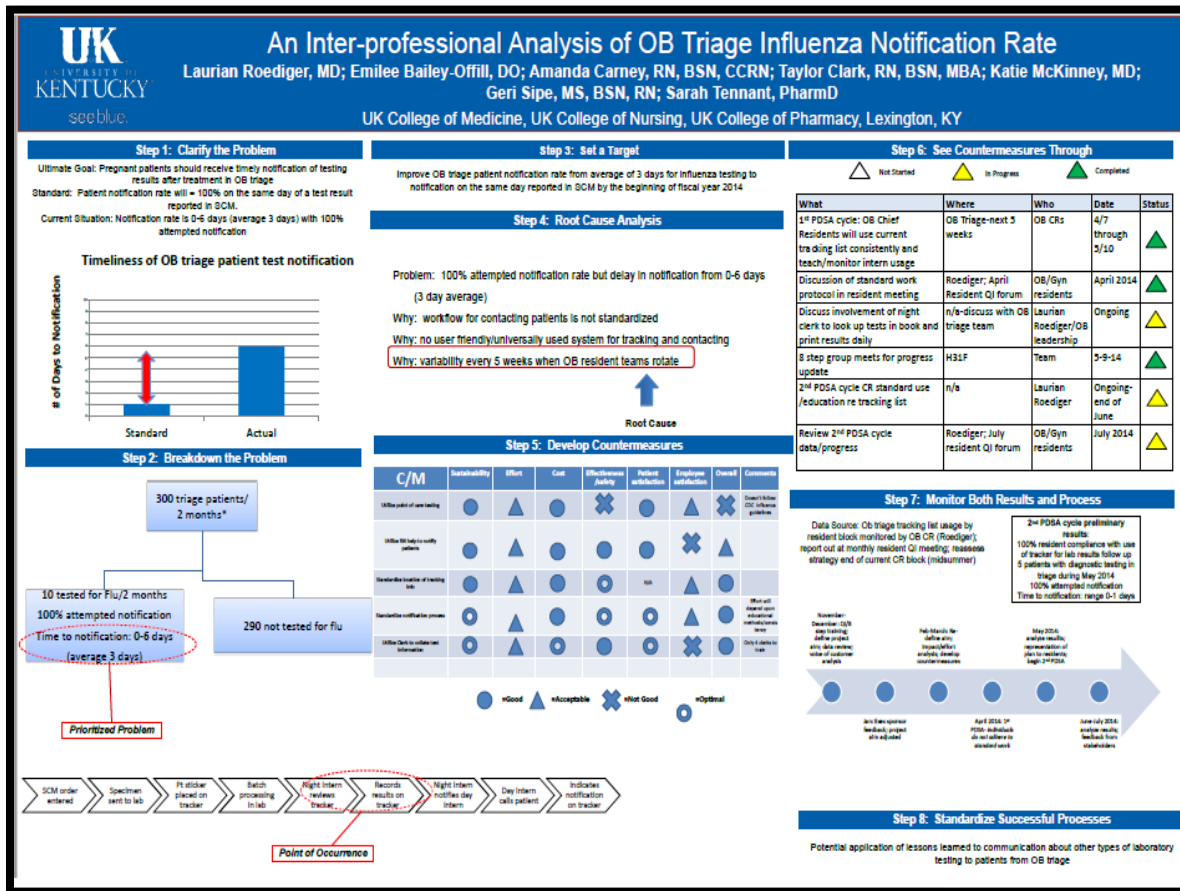


Figure 1: Poster of IPE Improvement Project

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Manuscript 2

Nurse Navigation: What is the Benefit? A Literature Review

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Introduction

Navigating the healthcare system as a patient can be a frightening experience even for healthy individuals, and even more difficult for patients dealing with acute or chronic illnesses. The role of a nurse navigator (NN) may be utilized to help patients along on this journey, as well as increase healthcare regimen adherence and patient satisfaction with their overall healthcare experience.

The NN role is fairly contemporary; it was established to assist oncology patients in traversing the oncology experience and to help eliminate barriers to care during this challenging time (Freeman, 2013). The first NN program was established in 1990 by Harold Freeman, MD, at a hospital in New York City. This program focused on working with underprivileged African American women in Harlem in hopes of decreasing breast cancer mortality rates.. High mortality rates in this vulnerable population were attributed in part to various barriers to receiving optimal care (Freeman, 2013).

Former President George W. Bush signed the Patient Navigator and Chronic Disease Prevention Act in 2005, which provided funding for NN programs (Freeman, 2013). Along with this act, funding in the amount of \$25 million was provided fund research on the NN role and the original program in Harlem, New York. All of the funding and research efforts were allocated toward the NN role with a focus on cancer/oncology patients (Freeman, 2013). The American College of Surgeons determined in 2012, that effective in 2015, there must be a nurse navigation process in place in every oncology program (Freeman, 2013). Doctor Freeman's work on the oncology NN program has proven to be successful with the research funding he achieved,

especially with his research improving cancer survival rates (Oncology Nursing Society, 2013).

Core Competencies

The Oncology Nursing Society felt it was important to develop a list of competencies that the Oncology NN should possess in order to achieve success in the role. These competencies were created in order to span the various venues where an Oncology NN may practice, taking into account their differing knowledge base and specialties, however at times there is nothing but “on the job” training that occurs, which was not the original intention to not receive more training (Oncology Nursing Society, 2013, p. 7). The four core competencies designated for the Oncology NN include: professional role, education, coordination of care, and communication (Oncology Nursing Society, 2013, p. 12). Within each of these core competencies there are key components which help guide the competency.

Duties of the NN role include, but are not limited to: patient and family education, coordination of care, communication between specialties and providers, a listening ear, and consulting other patient care services as needed (Trossman, 2013). The purpose of this literature review is to explore the NN role across all patient populations, to determine its benefit to patient, if any, and to determine if a sole coordinator of care increases patient satisfaction with their health care journey.

Clinical Question

The question being considered for the purposes of this clinical inquiry project is: Does the presence of a NN role increase (adult) patient satisfaction in their personal healthcare experience, and does it increase overall adherence to treatment and follow-up?

Specifically, there was a desire to evaluate an NN program in stroke patients, but the literature in this population is limited, thus the search was expanded to include inpatient and outpatient patient populations. To determine the answers to the clinical inquiry, a thorough review of the literature was conducted to determine how utilization of a NN can affect patient satisfaction and compliance with healthcare regime. Operating on the hypothesis that the NN role decreases barriers to patient care, one may then begin to consider additional ways in which this role could benefit patients.

Methods

Bearing in mind the clinical question, the literature review process was conducted. The principal investigator utilized Google Scholar, followed by MEDLINE, and lastly PubMed. Search terms included: nurse navigator, navigator, stroke nurse navigator, oncology nurse navigator, nurse navigation and satisfaction, nurse navigator programs, research studies, and stroke navigator.

The literature review focused initially on stroke nurse navigation, due to a limited body of research on the utilization of the NN in this population, the search was broadened to include nurse navigation in general. Fifteen articles were returned when the keywords “nurse navigation program” were entered. The search term “nurse navigation” yielded 61 articles. From the sample, articles appropriate to the selection criteria were chosen.

Inclusion and Exclusion Criteria

To be considered for the literature review, the principal investigator included articles published between January 2009 to November 2014 to ensure inclusion of the latest research on NN. The studies ranged from randomized controlled trials (RCT) to qualitative data surveys. One article was considered an outlier as it did not include

information about a NN role, however, the evaluator felt the concepts could be extrapolated and applied to the NN role. Articles which explored the role of lay persons in navigator roles were excluded since this literature review focused specifically on the role of the professional nurse navigator.

A total of six articles were included in the literature review. The information and data in the articles were analyzed and compared. The following section discusses the analysis of the six articles and a synthesis of the data found in each of the articles concerning nurse navigation.

Data Analysis

Included among the six articles for this literature review were two RCTs, one self-report, one survey of nurse executives, one article contained a focus group approach, and an evaluation of a NN program. The clinical focus pertained to the implementation of a nurse navigator role and its subsequent effect on patient satisfaction, and compliance with treatment and follow-up visits. The data analysis will examine four themes found in the articles: adherence to recommended treatment plans, patient satisfaction and improved patient feelings, access to care, and additional findings which were deemed important information to include on the topic.

Adherence to Recommended Treatment Plans

The first theme drawn from the articles examines the effect of the NN on patient adherence to treatment plans. Three of the studies concluded that patients receiving care or assistance from a NN had improved adherence to self-management of their individual illness, medications adherence, and overall adherence with their health care treatment plans (Black et al., 2010; Bretz et al., 2014 & Myers et al., 2012).

Bretz et al. (2014) reported greater medication adherence after patients were enrolled in a program including follow-up care, with 50 of the 72 subjects enrolled reporting “never missing a medication” at 360 days (p. E8). Notably, the nurse navigator role was not specifically utilized in this study, but the implications for the NN are easily deduced, which is why this article was included in the review of the literature.

Adherence to treatment and disease awareness are important aspects of medical care as they allow patients to own their care and feel empowered.

Lack of adherence to medications becomes a costly conundrum for patients, healthcare providers, and insurance companies (Stefanacci & Guerin, 2013). By increasing medication adherence, as well as adherence to medical treatment plans in general, it could be reasonably assumed medical costs, particularly from avoidable readmissions, could be reduced. The study by Bretz et al. (2014) did find fewer hospital readmissions for patients post-stroke who were enrolled in the intervention program, with a percent of 66.7% who did not return to the hospital for any reason at the 365 day follow-up (p. E6).

Patient Satisfaction/Improved Feelings of Patients

Patient perceptions about their healthcare experiences can dramatically impact their care, as well as their overall health outcomes. Patient satisfaction is part of these feelings and dictates their attitude during their spectrum of care. High quality care is something that all healthcare providers should strive to provide to patients, as well as providing emotional support during a trying time, and education when needed.

Improved satisfaction improves outcomes for patients, such as improving mortality rates and decreasing readmission rates (Morris, Jahangir, & Sethi, 2013).

Patient satisfaction is also linked to repayment to healthcare facilities (Center for Medicaid & Medicare Services, 2013). Therefore, patient satisfaction is important on many different levels.

Four of the studies reported an improvement in overall patient satisfaction with care and higher quality of care with the healthcare experience when it involved a NN role as opposed to the traditional healthcare experience (Black et al., 2010; Koh, Nelson & Cook, 2010; Pruitt & Sportsman, 2013 & Wagner et al., 2014). Bretz et al. (2014) reported that almost 100% of the participants enrolled in the intervention program found it helpful and were satisfied (p. E9). In the Koh, Nelson and Cook (2010) study, patients ranked their satisfaction with a nurse navigator program a 4.52 out of 5 on Likert scale (p. 45). Improved satisfaction can also be linked to the cost of care. Wagner et al. (2014) found that the NN intervention reduced costs for patients with lung cancer by \$6,852 cumulatively (p.12). Patient satisfaction and improved quality of care is an important piece of the puzzle and striving to attain this is important for the patient experience.

Access to Care

Access to care was the catalyst that motivated Dr. Freeman to develop the navigator program to help a group of underprivileged poor women in Harlem New York City, New York (Freeman, 2013). These women had poor access to care for various reasons, and by the time they were seen by healthcare professionals, had advanced stage cancers (Freeman, 2013). Koh, Nelson & Cook (2010) reported the time frame from initial cancer biopsy to treatment in this population decreased from 30 days to 26.2 days (p.44). The NN role provided easier access to care, support, and coordination for

patients' health care journeys in several studies (Koh, Nelson & Cook, 2010; Black et al., 2010 & Wagner et al., 2014).

Additional Findings

One interesting finding by Bretz et al. (2014) was self-reported increasing subjective pain levels for those patients post-stroke in the transition program. The authors of this article suggest that patients post-stroke experience pain after discharge and that this is not addressed. This is an area where a NN role would be beneficial by ensuring to explore pain management options for patients. Further, one could reasonably predict improved patient satisfaction scores as a result of decreased levels of pain. This could be an area for future study.

Limitations

A limitation of the review was the limited body of research available on this subject, perhaps as it is still a novel concept. In an article by Pruitt & Sportsman (2013), nurse administrators in Texas were given a survey about the utilization of the NN role, and of the 76 administrators who responded; only 24 percent had implemented a NN role at their facility. As previously stated, only 61 articles were returned when keywords were searched. This could also be reflective of a limited utilization of available search engines; utilizing additional resources may yield a greater number of articles from which to choose.

An additional limitation was the strength of the studies. Of the six articles included for this review, only two were RCTs. Including more RCTs would allow for more reliable, scientific results, which could guide future implementation of such interventions.

Inclusion of patient self-reports and surveys are another limitation of the review, as they leave room for response bias.

Implications for Practice

Overall, the studies included in this review supported implementation of a nurse navigator program or similar intervention. However, future research to determine the utility of the NN role for patients post stroke is warranted. While most of the research utilized in this study focused on the oncology population, one could logically extract implications for other patient populations, including stroke and other neurological diseases.

Further steps can be taken by piloting a stroke NN program within a Comprehensive Stroke Center. Objectives would need to be established for this program to guide implementation and to measure success. This pilot program could include a pre and post survey to determine if the program objectives were achieved by the implementation of a NN role.

Table 1: Evidence Table

Study	First Author (Year)	Conceptual Framework	Design/ Method	Sample/ Setting	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
1	*Black, H. L., et al. J Asthma 2010; 47(8) 913-919	"four functional categories of social support, proposed by House and summarized by Wills & Shinar: instrumental, informational, emotional and validation"	4 focus groups of adults with moderate or severe asthma	completed ongoing randomized controlled trial to improve adherence with inhaled corticosteroids, age 18 and up, classified as having moderate or severe asthma, prescribed an inhaled corticosteroid, 27 participants all together, mostly women and African American	barriers to controlling asthma; PN role before, after and during a visit that promote self-management; and characteristics of a PN	Grounded Theory approach	participants in the intervention group had a greater awareness of their asthma management, able to better understand how a PN could help, able to identify what the role of the PN would be	this research study showed that the role of a PN may help patients in self-management of asthma
2	Bretz, M. N., et al. J Neuro Nursing 2014; 46(4) E3-E13	None	stroke centers were recruited using NSA's Stroke Center Network membership, self-report by patients at 30, 90, 180 and 365 days	193 patients, mean age 63.18 years, ranging between 24-92; approx. 16% participants under 50 years old; 58% were men	readmission within a year after their stroke, medication adherence	dependent sample t tests were conducted comparing the 30 and 360 day follow-up scores of the self-reported surveys; multivariate analysis of variance to compare 30 and 360 day Short-Form Health Survey scores	fewer hospital readmissions, higher medication adherence; participants ages 63-73 reported better health across time than other groups; all participants reported in some way that the program was beneficial	while this study did not employ a Nurse Navigator directly, it does employ some of the things that this role would conduct as far as education and follow-up, which means that there are benefits to this type of program
3	*Koh, C. et al. CI J Onc Nursing 2010; 15(1) 41-48	None	evaluation of nurse navigators (NN) programs	evaluation of NN programs during a 6 month period from Oct 2009-March 2010; breast cancer patients; inclusion	demographics and clinical variables, access to care in a timely manner, barriers to care, patient satisfaction	descriptive statistics; power analysis of 0.74; independent t tests and chi-square tests;	a reduction in timely access to care was noted; navigator programs reduced most barriers to	based on evaluation of Nurse Navigator programs, there may be benefit to reduce issues with access to care and barriers, also

				was 21 yrs. old, able to provide informed consent; diagnosed with either ductal carcinoma in situ or invasive cancer; 55 women		significance set at 0.05 using SPSS	care, average time spent per patient from a navigator was 87.5 minutes, patients with larger tumors required more time with the navigators ; 94% of participants responded positively about navigator, on a Likert scale the score was 4.52 out of 5	they may increase patient satisfaction
4	*Myers, R. E. et al. Cancer Epid, Biomarkers & Prev 2013; 22(1) 109-117	None	randomized, controlled trial with three groups; a Tailored Navigation Intervention (TNI), Standard Intervention Group (SI) and a usual care Control Group	total of 945 patients between three groups; between 2007-2011 in Delaware; ages 50-79 years old with no diagnosis of colon cancer or inflammatory bowel disease; mainly women, white and non-Hispanic, married with an education level beyond high school	endpoint survey that was blinded	intent to treat principle; logistic regression analysis	the TNI group had a positive impact on adherence and screening decision stage	this shows that a Nurse Navigator may help with adherence as seen in this study

5	Pruitt, Z. et al. J of Nur Admin 2013; 43(11) 592-596	None	survey, internet based	580 Nurse Executives (NE) extracted from a database in Texas surveyed, 76 completed survey	an 11 question survey was given to NE with objective measures	examined responses to surveys	most NE with navigator programs stated that they were successful	more studies should be done on this area, but there was usage of Nurse Navigators in several hospitals, mainly cancer patients-which means this could be transitioned to other patient populations
6	Wagner, E. H. et al. J Clin Onc 2013; 31 1-8	None	randomized, controlled trial; cluster; 2 group	adults with recent diagnosis of primary cancer of breast, colorectal or lung; two groups- one with enhanced care and one with navigator for 4 months; 251 participants; mean age 62	Functional Assessment of Cancer Therapy-General (FACT-G) Quality of Life Scale, three subscales of Patient Assessment of Chronic Illness Care (PACIC); self-report measures at different periods of time	differences in scores overall; intent-to-treat	Nurse Navigator intervention programs reported fewer issues with care, including information; lung cancer costs were lower with navigator intervention	implementing a navigator program may be beneficial and has worked for cancer patients

Table 2. Level of Evidence Synthesis Table

	1	2	3	4	5	6
Level I: Systematic review or meta-analysis						
Level II: Randomized controlled trial				X		X
Level III: Controlled trial without randomization						
Level IV: Case-control or cohort study						
Level V: Systematic review of qualitative or descriptive studies		X				
Level VI: Qualitative or descriptive study (includes evidence implementation projects)	X					
Level VII: Expert opinion or consensus			X		X	

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Manuscript 3

Do Callbacks Help Patients Post Stroke?

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Abstract

Aim and Objective: To determine if the implementation of a post-discharge call-back intervention for patients discharged home from the hospital after stroke was associated with a decrease in 30-day readmissions and improved patient satisfaction.

Background: Stroke is a leading cause of death and disability in the United States (American Stroke Association, 2015). Several studies have examined various post-discharge interventions, including a call to the patient and/or family after their return home, to determine the benefit to patients, if any (Zolfaghari, Mousavifar, Pedram & Haghani (2012). Understanding and anticipating patient needs and removing barriers post-stroke may decrease readmission rates as well as increase patient satisfaction with their hospital experience.

Design: A retrospective chart review examining pre-and post-intervention scores for patient satisfaction and 30-day readmissions for stroke patients who received post-discharge call backs from registered nurses (RNs).

Methods: The principal investigator gathered data points from the Stroke Coordinator to assess patient satisfaction utilizing Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores. The principal investigator collected re-admission and demographic data from the Electronic Medical Record (EMR).

Findings: Overall pooled patient satisfaction scores improved from 73.6 percentile in the pre-intervention, to 78.8 percentile in the post-intervention. This number was not statistically significant, but an overall increase was nonetheless noted. Readmission rates declined slightly, 3.3% to 2.7 %, but again there was no statistical significance. Desired p-value was <0.05 for this quality improvement project.

Conclusion: Although not statistically significant, an overall improvement in patient satisfaction was noted, as well as an overall decrease in readmission rates, suggesting that a call-back intervention could benefit patients in their transition after stroke.

Recommended future steps for this quality improvement project include creating streamlined electronic data collection tools for call-backs to enable ongoing monitoring of compliance and further explore quality improvement measures.

Keywords: stroke, call-back intervention, post-discharge intervention, cerebral vascular accident, CVA

Do Callbacks Help Patients Post Stroke?

Introduction

Stroke or cerebral vascular accident (CVA) is the 5th leading cause of death and the number one leading cause of disability in the United States, as well as being a top contributor in the state of Kentucky (American Stroke Association, 2015; Kentucky Cabinet for Health and Family Services, 2012). According to the Centers for Disease Control and Prevention (CDC) (2016), Kentucky was ranked 11th in the nation for deaths due to stroke in 2014. Public reporting of thirty day readmission rates for stroke began in December 2014 (Schwartz, Strait, Keshawarz, Vellanky, Reilly, Curtis,..., Suter, 2014). The city of Lexington, Kentucky was ranked one of the worst performing hospital referral regions for stroke readmissions during the years July 2010-June 2013 (Schwartz, Strait, Keshawarz, Vellanky, Reilly, Curtis,...Suter, 2014).

Background

Transition of care is an important piece of the puzzle to consider for all patients, especially at time of inpatient discharge and thereafter. The Joint Commission (2013) compiled a list of factors which have been identified to contribute to hospital readmissions. Some of these risk factors include, but are not limited to: advanced age, medical co-morbidities, and certain disease processes that are linked to readmission such as diabetes or congestive heart failure, lack of safe living arrangements, lack of assistance at home, financial concerns, and polypharmacy (Joint Commission, 2013). All of these risk factors can be extrapolated for stroke patients, therefore improving the transition of care from hospital to home is key. This includes ensuring the patient has what they need

at home, including assistance, as well as contacting them in some way when they have returned home to assess how they are managing the transition.

A review of the literature revealed several studies which examined a post-discharge intervention for various patient populations, including patients post stroke. Because these patients often have multiple co-morbidities and risk factors for stroke, ensuring they know how to care for themselves upon return home, as well as ensuring adequate access to their required medications are of utmost importance. A study by Zolfaghari, Mousavifar, Pedram & Haghani (2012), described an intervention targeted toward diabetic patients which involved a phone call versus a text message to see if there was an improvement in adherence to the prescribed diabetes regimen. Both interventions were found to be effective. The research found that these interventions improved HgA1C levels in the patients in the telephone group by 0.93% over three months and by 1.01% over three months in the text message group (Zolfaghari et al., 2012).

Another intervention which has been described in the literature is the utilization of the Nurse Navigator (NN) role, which could be an asset to patients during this transition of care. In a study by Wagner et al. (2013), they concluded that cancer patients who were guided by a NN had improved experiences with coordination of care and management during the course of their illness and treatment regimen. This intervention may also promote a more seamless transition of care and is one which could be applied to numerous patient populations.

Another abstract on this topic explored the use of follow-up phone calls for patients post stroke and their effect on patient satisfaction scores. This research revealed that patient satisfaction scores increased in the transition of care section, according to

Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) database (Elkins & Branson, 2015). Elkins and Branson (2015) were able to support a positive relationship between patient call-backs and patient satisfaction scores with regard to transition of care with an increase of 80.7% to 86.5% respectively. This study examined the first two months of call-backs in comparison with the two months prior to the intervention (Elkins & Branson, 2015). Another study found a decrease in readmission rates for patients post-stroke, with readmission rates of 26 and 34 percent in the two intervention groups which were a home visit by physician and meetings with a physiotherapist, versus a rate of 44 percent in the control group (Andersen, Schultz-Larsen, Kreiner, Forchhammer, Eriksen & Brown, 2000).

The Comprehensive Stroke Center where the intervention took place began a post-discharge intervention in 2013 by means of a call-back to patients who were discharged home after a stroke. The callbacks were designed to be completed by registered nurses (RN), which is important because the RNs are trained in caring for stroke patients and understand the importance of the intervention for this patient population. The intent of the program was to ensure all patients who are admitted and diagnosed with a CVA (ischemic or hemorrhagic) or Transient Ischemic Attack (TIA), were telephoned within a week of discharge home and provided follow up support in their transition back into the community. Patients were asked a series of questions about their home/ follow up care for stroke (Appendix A), as well as given an opportunity to ask any questions they may have. This averages to be approximately 45 patients per month (Elkins & Branson, 2015). The Clinical Nurse Expert (CNE) for neurology is the RN that ensures that patients receive a follow-up appointment and that they were able to

get their medications if prescribed. This study retrospectively evaluates this intervention and its effects on patient satisfaction and readmission rates. Compliance to the program objectives, specifically compliance, was also evaluated.

Method

Purpose

The purpose of this study was to determine if the implementation of a post-discharge call-back intervention for patients discharged home from the hospital post-stroke was associated with decreased 30-day readmissions and increased overall patient satisfaction.

Objectives

The objectives of the retrospective chart review were as follows:

- 1) Describe demographics of the study population.
- 2) Determine if the call-back intervention increased patient satisfaction.
- 3) Evaluate the effect of the call-back intervention on hospital readmission rates.
- 4) Determine if the call-backs were performed.

Design

The design for this research was a retrospective analysis of medical records. The study compared pre-implementation data to data one year post-intervention. The independent variable in this study is the patient call-back after discharge. The dependent variables are stroke related 30-day readmission rates and the patient satisfaction scores.

Setting

The Doctor of Nursing Practice (DNP) practice inquiry project was conducted at the University of Kentucky Hospital (UK) in Lexington, Kentucky. UK is a 945 bed Level 1 Trauma Center, and was designated as a Comprehensive Stroke Center by the Joint Commission in 2013. The stroke unit is comprised of 20 progressive care beds for patients with acute stroke, including those who received t-PA during their admission.

Sample

Inclusion criteria were as follows: patients must have been diagnosed with a new ischemic or hemorrhagic stroke or a transient ischemic attack (TIA) during their current hospital admission, must have been discharged directly home, and must have had access to a telephone to receive the call-back intervention. Exclusion criteria are as follows: patients who did not go directly home following discharge from the hospital, patients who were ruled out for stroke and patients who did not have access to a telephone. The total sample was 333, including 174 patients in the pre-intervention (control) group and 159 patients in the post-intervention (experiment) group.

Procedure

Study approval from the UK Hospital Research Council was requested and received in December 2015 (Appendix B). Following internal approval, the application for project approval was submitted to the university Institutional Review Board (IRB). Approval from the IRB was granted in February 2016 (Appendix C). The principal investigator obtained patient lists and satisfaction scores from the hospital stroke program coordinator office. After these data were obtained, the principal investigator created two patient samples by taking every other patient. The raw number of patients in the pre-

intervention group was 658, and 318 patients were included in the post-intervention group. 300 patients were excluded from the pre-intervention group and 20 from the post-intervention group due to not meeting specified study criteria. This achieved the final sample of 174 in the control group and 159 in the experiment group. The principal investigator next began data extraction from the Electronic Medical Record (EMR). The data were then collated using Microsoft Excel, coded, and analyzed using SPSS version 23 (SPSS, Inc., Chicago, IL).

Data Analysis

Descriptive analyses including mean and standard deviation, as well as chi-square and t-tests were used to analyze the patient samples and variables of interest. To examine the changes in 30-day readmission rates, chi-square testing was used. A p-value of <.05 was considered significant for purposes of the study.

Results

Sample Description

Table 1 describes the patient sample utilized for this review. The average age of the patients was not statistically different between groups; pre-intervention age was 61.8 years old, and post-intervention age was 61.2 years old. The age range was 27-93 years old for both groups. There were 188 total males (57% control vs. 55% experiment) and 145 total females (43% control vs. 45% experiment); gender was not statistically different between groups.

The most common educational level among the pre-and-post intervention groups was some level of high school education, encompassing 51% percent of patients for both years. Education further subcategorized into three categories for analysis; less

than high school, high school or equivalent and beyond high school. The percent for high school equivalent for each group was 61 and 60 respectively. Education, when grouped into the three categories was statistically significant with a $p= 0.02$ (Table 1). Figures 1 & 2 discuss the education level breakdown for the pre-and-post intervention patient samples.

Forty-one percent of the total patients used tobacco products within the past 30 days. The breakdown between pre and post intervention smoking is 45% versus 38% respectively. It is also important to note this may not have captured former smokers, just patients who reported using tobacco within the past month.

These descriptors indicate that the patient samples taken were primarily similar with a median age of approximately 61 years old and more males than females. Also, the majority of the patients had not smoked in the past thirty days and had an education level of high school or equivalent.

Patient Satisfaction

After implementing the post-discharge call back, patient satisfaction scores improved overall from the 73.6 percentile to the 78.8 percentile, which are not raw percentages (Figure 4). These scores were based on the number of surveys returned by stroke patients discharged home from UK. There was an overall improvement in the average score from patient HCAHPS surveys, based on how many were returned, which was 125 and 151 respectively; although after analysis it did not prove to be statistically significant, with a p-value of 0.74. The principal investigator was unable to obtain the total number of patients who were mailed a survey.

30-day Readmission Rates

Readmission rates were another important metric examined by this retrospective chart review. Readmission rates decreased from 3.3 percent to 2.7 percent from pre-intervention to post-intervention. When aggregated, the decrease was 0.06% for each year. This was not statistically significant ($p=0.800$). Despite the lack of statistical significance, there was still a decrease in 30-day readmissions. Additional data could be collected to determine reasons for readmission, but this analysis was not performed for the purposes of this study.

Completion of Call-Back

The CNEs for the Neurosciences are the RNs who complete the call-backs. This position is typically filled by a seasoned nurse who has a broad knowledge and skill set of the area that they are working in. Therefore, they have adequate knowledge and understanding of what the patients are experiencing.

Based on the available data, the percentage of call-backs completed for the first year range anywhere from 46-67 percent per month. Several of the months had no data recorded (Figure 3). This means it is unknown how many of the call-backs were completed during these months, which may represent significant missing data.

Discussion

The purpose of this retrospective chart review study has three main aims. The first was to determine if the post-discharge call-back intervention increased overall patient satisfaction. This was determined by an HCHAPS Survey that was completed and mailed back by patients. The results of this aim in regards to the study were that patient satisfaction scores did improve from pre to post intervention, but by a small enough

amount that it was not statistically significant. Elkins & Branson (2015) & Braun, Baidusi, Alroy & Azzam (2009) were also able to demonstrate a positive relationship between a post-discharge call-back and patient satisfaction. The study by Braun, Baidusi, Alroy & Azzam (2009), report that the patients were more satisfied with a one week post-discharge rather than a one month call-back from staff.

One study reported that when a pharmacist contacted patients after discharge they were more satisfied with their medication education (Dudas, Bookwalter, Kerr & Pantilat, 2002). Another study examined call-backs in an Emergency Department and the findings revealed a positive correlation between completed call-backs and patient satisfaction (Guss, Leland & Castillo, 2012). The results of this study are consistent with other study findings and point to an increase in patient satisfaction.

Another aim of this chart review was to determine if a call-back to patients post stroke decreased 30-day readmission rates of these patients. The literature describes a negative correlation between completed callbacks and readmission rates (Harrison, Hara, Pope, Young & Rula, 2011; D'Amore, Murray, Powers & Johnson, 2011). Harrison, Hara, Pope, Young & Rula (2011) report readmission rates of 23.1% less for the intervention group. This upholds the results of this study, though the results were not significant. Harrison, Hara, Pope, Young & Rula (2011) reported that readmission rates for older males were highest. This finding could generate further research comparing demographic differences of patients who are readmitted. The results of this study were congruent with other studies regarding the increase in patient satisfaction and decrease in readmission rates for call-backs post discharge.

Limitations

A limitation of this study is full awareness of readmissions with the knowledge that not all patients readmitted were readmitted to University of Kentucky and may have gone to an outside facility. These readmissions could have altered the results as well if there was full disclosure of readmissions. Therefore, there is an inability to access patient data.

Nonworking phone numbers may also have contributed to incompleteness of call-backs. Bad phone numbers or disconnected numbers were found. Patients may be hesitant to provide their phone number billing concerns. Explaining the importance of a working phone number may help with this limitation.

Another data collection limitation was the HCAHPS survey return percentage. The survey results are broken down by service line. The neurosciences service line included all neurological disorders, not just stroke patients. Based on the numbers we received for patient satisfaction, we are unable to tell how many actual patients returned surveys. Typically, not all patients return these, so there is valuable data left unknown, which could support our increase in patient satisfaction metric. Since the surveys are optional, many people do not fill them out. Also, we are unable to determine which patients return the surveys; therefore we cannot accurately connect these with the patients in our sample.

Finally, we are unable to say for sure that the call-back intervention improved satisfaction alone. There may have been other confounders, such as outcomes, friendly staff or hospital food, which were not examined as part of this practice inquiry project.

Implications to Quality Improvement

This practice inquiry project leaves room for further inquiry. There is much beneficial information still unknown in regards to transitions of care. Further quality improvement efforts can be conducted to continue to evaluate this post-discharge intervention. By constructing an Ishikawa or Fishbone Diagram (Figure 5), we can evaluate the cause and effect of poor transitions of care for patients post stroke. There is a gap in the transition of care from discharge home to follow-up in the clinic. The call-back intervention was just a starting point to try and improve this.

There are numerous other metrics that could be examined to promote quality improvement and patient outcomes measures, including patient satisfaction and hospital readmission rates (Lake, 2015). For example, evaluating gender differences in patient satisfaction scores and readmissions, similar to the work of Harrison, Hara, Pope, Young & Rula (2011) could expose a need for targeted gender-specific interventions at discharge.

Examining additional patient demographic data, such as presence of pre-existing comorbidities, could expose a correlation with readmissions and satisfaction, and may help identify additional quality improvement efforts. It would also be interesting to determine how the facility's patient education levels compare with national averages. This may help guide educational material and intervention efforts. Other areas to examine include smoking beyond the last thirty days and to try and correlate that with readmissions. Also, determining if depression post-stroke causes an increase in readmissions is another area that could give valuable information.

In regards to the HCAHPS, it would also be interesting to see if the patients in the convenience sample could be matched to who returned surveys. This would help the strength of the patient satisfaction portion of the practice inquiry project.

At the completion of this quality improvement study, future steps to continue the momentum of this intervention should be explored. A process to streamline callback data collection is needed, as evidenced by the lack of documentation consistency (Figure 6). Utilizing an Excel spreadsheet versus manual data collection could be a potential solution to this problem. Also, exploring reasons for lack of documentation with the end conductor-i.e. the RN, may aid in identifying barriers to the process. Revolving education for the nurses on the purpose and importance of performing the call-backs should also be considered. Since implementation of the intervention, there has been a document added to the medical record for documenting the call-back. Performing data analysis on later years may show improved documentation of the call-back completion as well as other potential useful information.

Since patients are the primary stakeholders for whom we are focusing for this quality improvement project, we must keep them in mind when deciding on future progress with other interventions. Future quality improvement can also be conducted through implementing another phase of the call-back prior to the scheduled follow-up appointment at the clinic. This intervention could aid in reminding patients to attend their appointment, which further supports the transition of care. This could be done as a pre and post assessment of the intervention. This would potentially give information to see if this intervention also improves rates in which patients show up to the clinic for their appointments. The Plan-Do-Study-Act tool can assist in developing this

improvement plan. (Figure 7). This additional intervention may continue to improve the quality of care that patients receive and continue to foster a smooth transition of care.

Another potential next step would be to explore the Nurse Navigator role to aid with the transition of care for patients. This role has been heavily utilized in the oncology patient population. Having a point person to guide patients' care, especially in a university health system, may mitigate problems, including unnecessary readmissions. This role would need further development and require a pilot on the stroke unit to determine workflow processes and to evaluate benefits in this patient population. A cost analysis should be conducted to demonstrate the financial implications of creating this position. Buy-in from the executive stakeholders and management would need to occur, as they would be allocating funds to create this position.

Conclusion

Transitions of care play a role in a patients' healthcare experience. The transition of care also encompasses discharge, whether it be home or to another facility. It is important to provide a form of contact with patients after discharge to help alleviate 30-day readmission rates, which are costly. Also, this continued contact with a nurse could potentially increase patient satisfaction. This practice inquiry project examined a call-back intervention on the stroke unit at the University of Kentucky Hospital to evaluate whether it influenced readmission rates and improved patient satisfaction.

Other research highlights post-discharge interventions as having a positive impact on readmission rates and increasing patient satisfaction (Harrison, Hara, Pope, Young & Rula, 2011; D'Amore, Murray, Powers & Johnson, 2011; Guss, Leland & Castillo, 2012). While this study did not have any statistically significant results to report, the

overall numbers did improve for patient satisfaction and a decrease in overall readmission rates.

Table 1: Summary of demographic statistics on patient sample (n=333)

	Pre (N=174)	Post (N=159)	Test statistic (p)
	<i>Mean (SD) or n (%)</i>	<i>Mean (SD) or n (%)</i>	
Age	61.8 (13.1)	61.2 (14.0)	p=0.683
Gender			
Male	0.57	0.55	p=0.70 x ² =.15
Female	0.43	0.45	
Smoking			
Yes	0.45	0.38	p=0.19 x ² =1.72
No	0.55	0.62	
Education			p=0.02
Less than HS	11	18	
HS or equivalent	61	60	
Beyond HS	28	22	
Primary diagnosis			p=0.01
Ischemic Stroke	66.1	79.2	
TIA	23.6	5.7	
Hemorrhagic Bleed	10.3	15.1	
Readmission			
Yes	0.06	0.06	p=0.80 x ² =0.06
No	0.94	0.94	

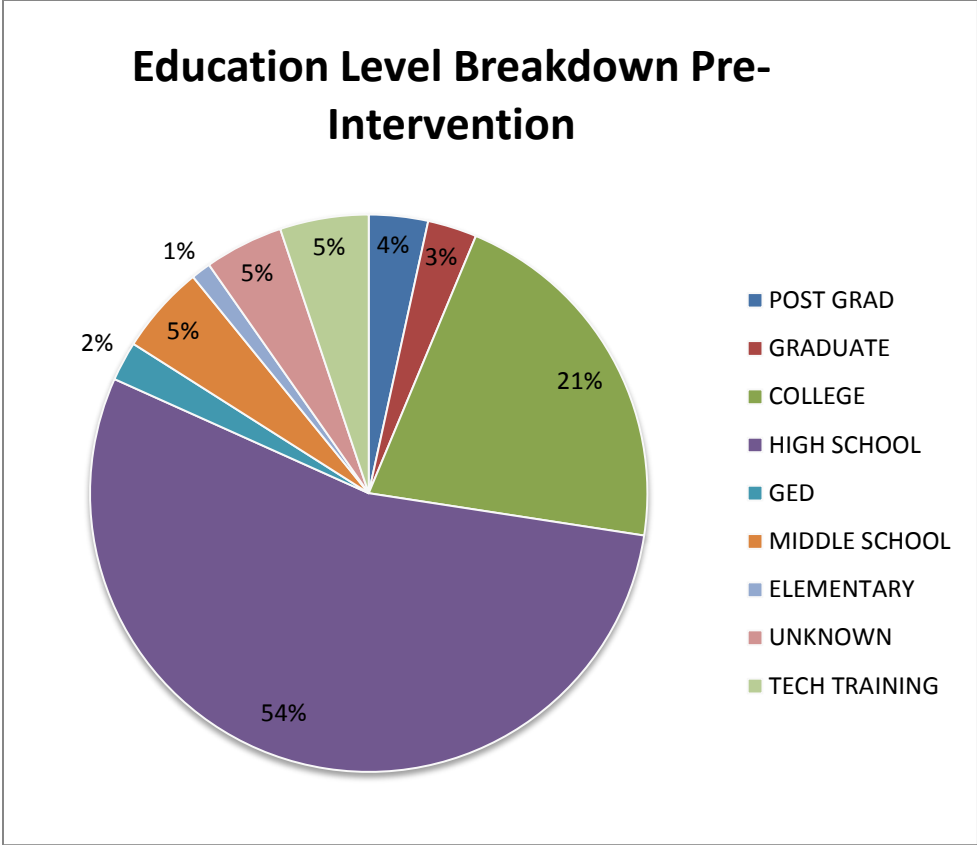


Figure 1. Education Level Breakdown Pre-Intervention

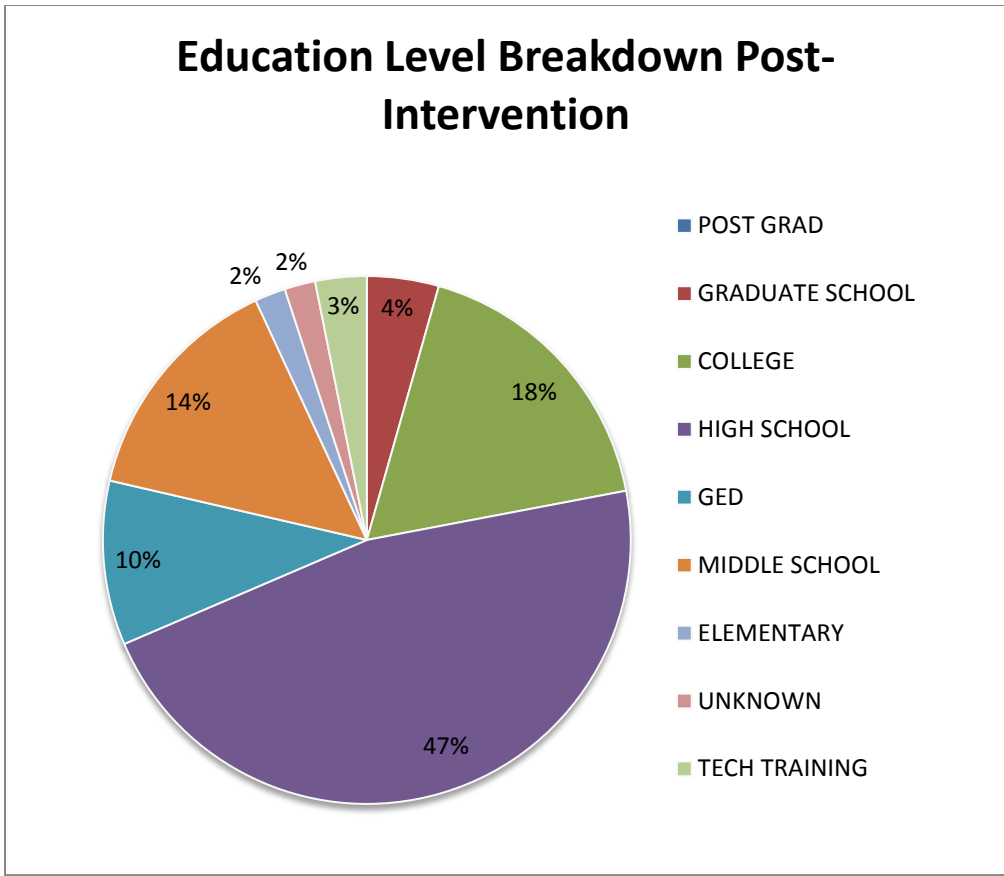


Figure 2. Education Level Breakdown Post-Intervention

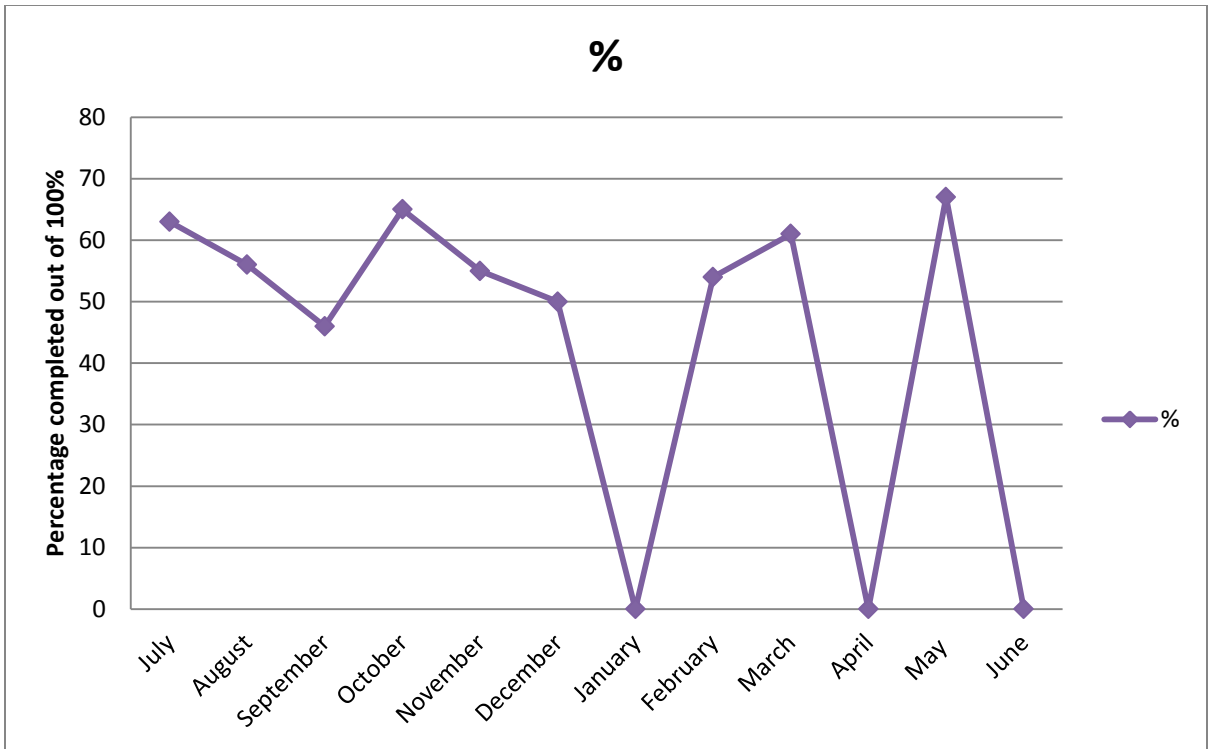


Figure 3. Percentage of Completed Call-Backs Out of 100 Percent

*Note: Zeros represent no data recorded, not necessarily no call-backs completed.

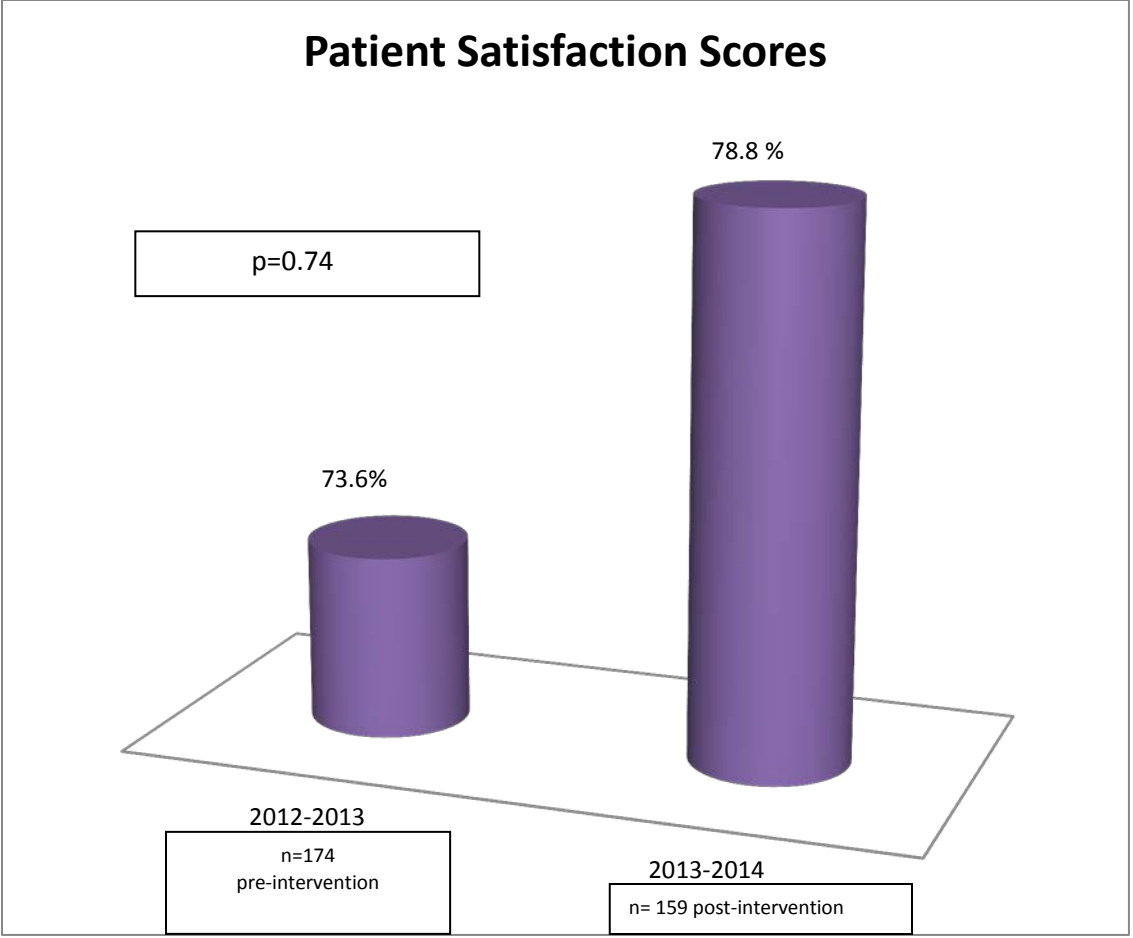


Figure 4. Overall Pooled Patient Satisfaction Scores of Returned Surveys

Quality Improvement Fishbone for Break in Transition of Care for Patients Post Stroke

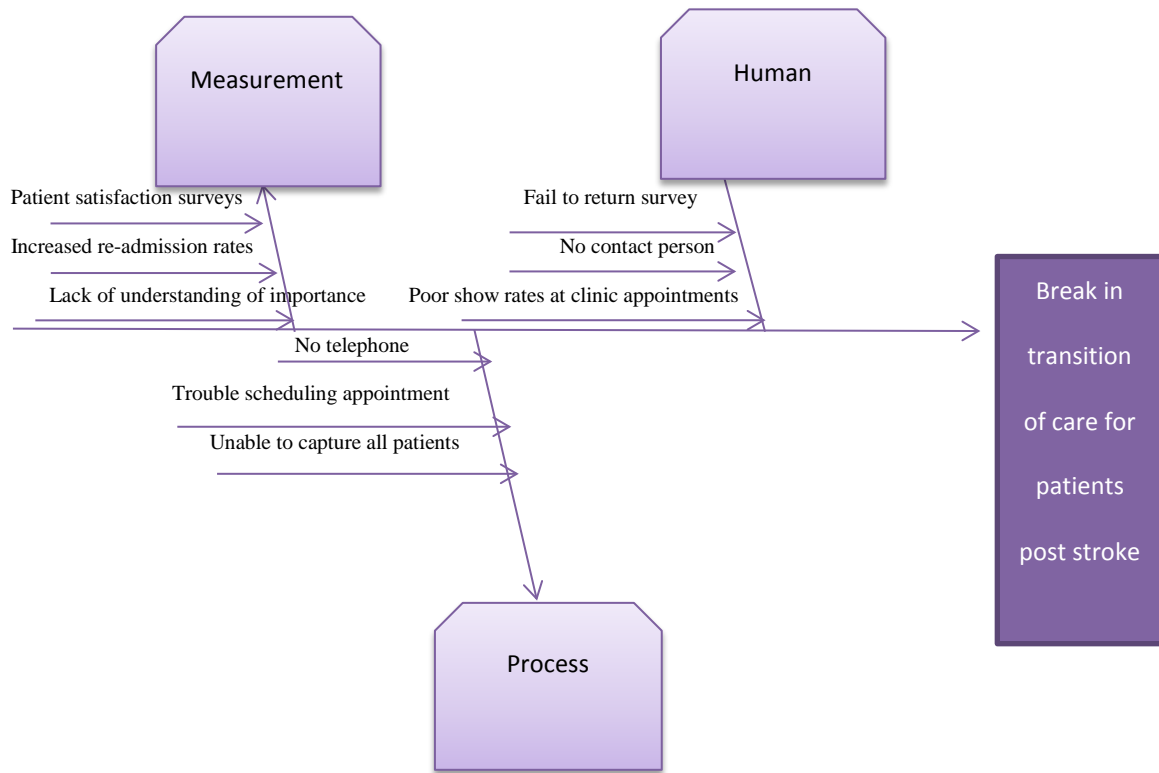


Figure 5. Fishbone Diagram for Quality Improvement

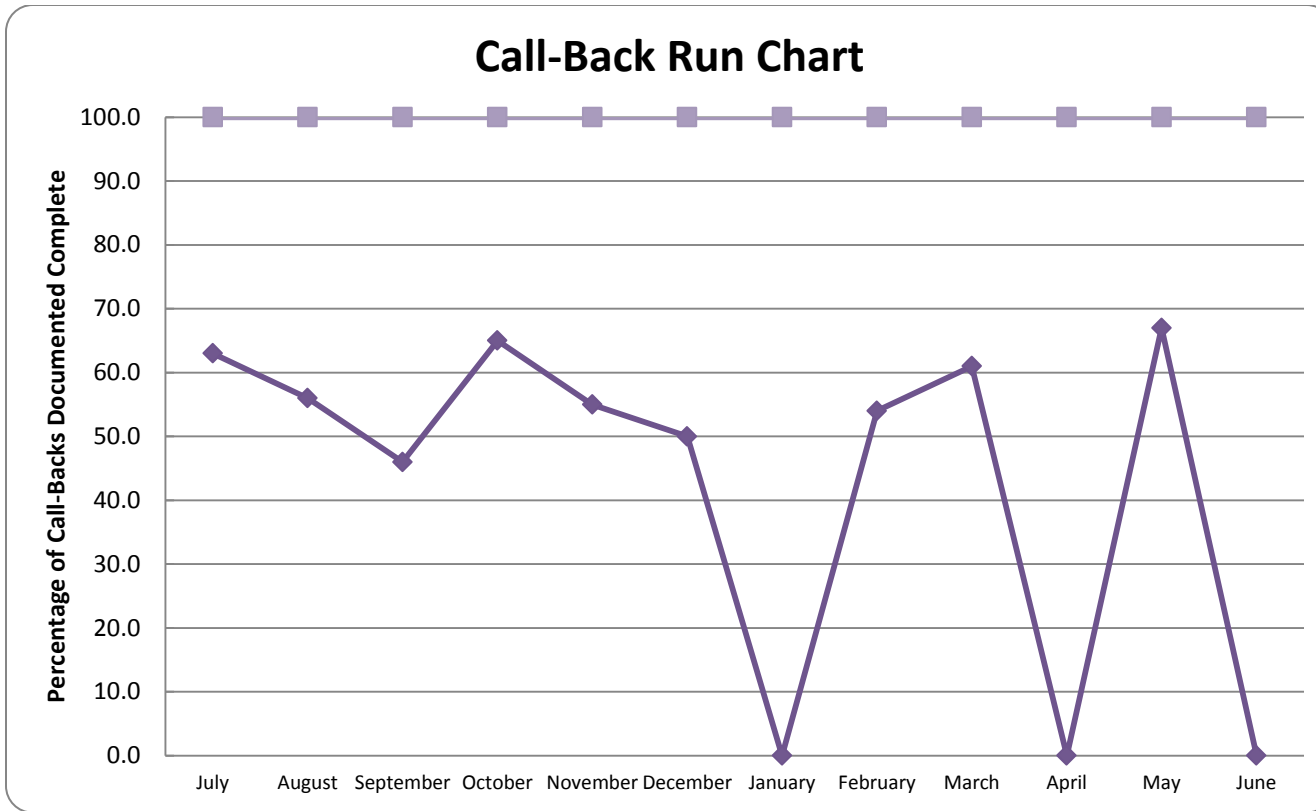


Figure 6. Run Chart of Actual Completed Call-Back with Goal of 100%

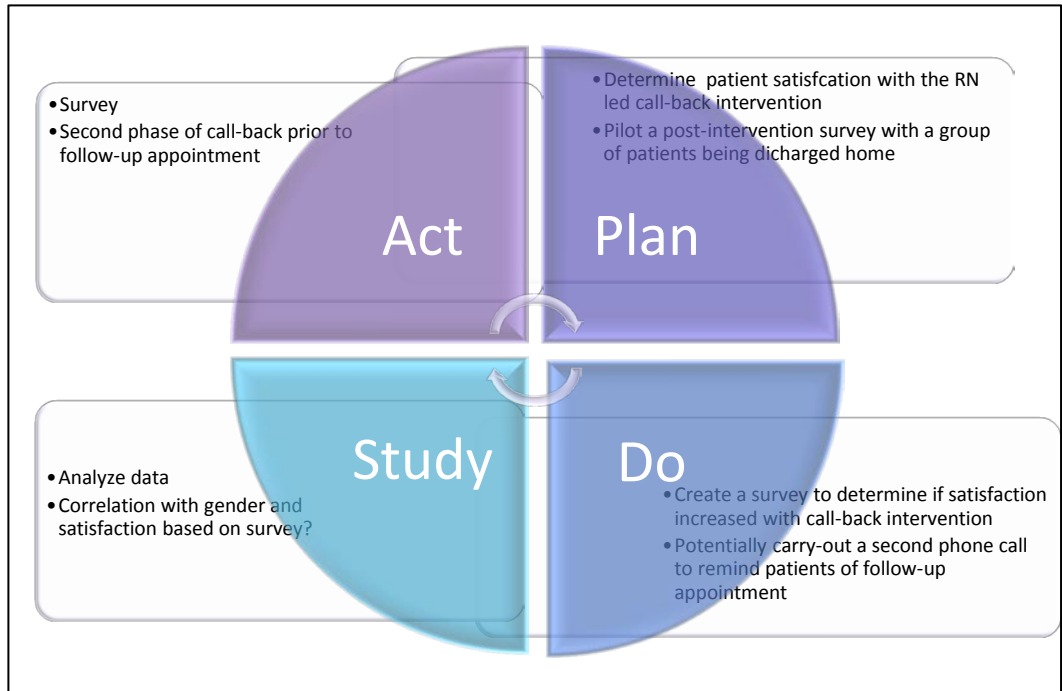


Figure 7. PDSA Tool for Next Steps

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Conclusion to Final Practice Inquiry Project

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Conclusion to Final DNP Practice Inquiry Project

Stroke is a serious health concern. Leading in deaths nationwide as the number five killer, awareness and change in caring for stroke patients is vital (American Stroke Association, 2015). Ensuring patients who are discharged home are equipped with knowledge, have a follow-up appointment and are able to obtain their medications are all very important aspects to consider when promoting seamless transitions of care. A post-discharge intervention may be the key to alleviating a number of 30 day unplanned re-admissions as well as improving patient satisfaction during the transition of care from hospital to home. The transition of care incorporates various healthcare team members who all collaborate to achieve the best outcomes for their patients. This practice inquiry project reviewed an established post-discharge call-back intervention for stroke patients at the University of Kentucky Hospital to determine its effect on readmission rates and overall patient satisfaction.

The first manuscript addressed interprofessional collaboration among providers in an academic healthcare setting. This manuscript outlined interprofessional education and the core components involved with this type of education. This manuscript also provided recommendations for such education to be included in nursing doctoral curriculum to better equip nurse leaders to collaborate and problem solve with members of other healthcare disciplines.

The second manuscript describes the role of a nurse navigator, another type of post discharge intervention. The manuscript reviewed the available literature on this nursing role and its benefit to patients. Six research articles were

presented and reviewed and common themes were abstracted and addressed, including patient satisfaction with the healthcare experience with this intervention. Additional research would provide valuable insights into the utility of the NN in the stroke patient population, as most nurse navigators described in the current body of literature are utilized in the oncology field.

The third and final manuscript described a retrospective chart review of a phone call intervention to stroke patients after their discharge home from the hospital. Patient satisfaction and 30-day readmissions were examined to see if there was a positive change for both of these areas. Both areas did show an improvement from pre-intervention to post-intervention, though not statistically significant. These results are consistent with other research on the topic. Findings suggest that a call-back intervention improves patient satisfaction and decreases readmissions, which is both beneficial to patients and financially advantageous for institutions that elect to implement this intervention.

Appendix A: Stroke Call-Back Script

The screenshot shows a web browser window displaying a form titled "8th Floor Discharge Call-backs: New Item". The form contains several sections with input fields and dropdown menus. Callouts are present to show the options for certain dropdown menus and the content of text boxes.

Form Fields and Callouts:

- Medical Record Number:** Input field.
- Discharge date:** Input field.
- Unit:** Dropdown menu. Callout options: 8 South, 8 East, 8 West.
- Person Making Call:** Input field.
- If unable to make contact, STOP HERE AND ASSIGN REASON:** Dropdown menu. Callout options: No answer or voicemail activated, Wrong number, Disconnected/non-working number.
- How are you doing at home?:** Text area. Callout: Hello [PATIENT'S NAME], this is [YOUR NAME], I am a member of the stroke team [or "I am a nurse on [unit]"] at UK Chandler Hospital. How are you doing at home?
- Stroke Diagnosis:** Input field.
- Signs of a stroke?:** Input field. Callout: So that I may know that you have the information you need, will you please tell me how to recognize the signs of a stroke?
- What will you do if you think you/the patient are having another stroke?:** Input field. Callout: Click if "yes"
- What are your stroke risk factors?:** Input field. Callout: Call 911. Any other response [PLEASE EDUCATE]. What will you do if you think you/the patient are having another stroke?
- What are you doing to work on your risk factors?:** Input field. Callout: Controllable: Cigarette smoker - Quit; Alcohol - Moderate; Weight - Diet & Exercise; High Blood Pressure - Control it (medications, diet, exercise); Atrial Fibrillation - Control it (Contact doctor, medications, treatment); Diabetes - Control it; High Cholesterol - Control it (medications, diet, exercise).
- Did the education packet that the nurse reviewed with you help you and/or your family?:** Input field. Callout: Specify your own value:
- Were you able to get your prescription filled?:** Input field. Callout: If not filled, advise patient/family to notify the physician's office.
- Have you scheduled your follow-up appointment?:** Input field. Callout: If patient has attempted but is unable to make an appointment, please direct them to Customer Relations (237-2178) at end of call.
- Why is your follow-up important to you?:** Input field.
- Do you have any questions about your home care?:** Input field. Callout: Please answer and note any questions about home care or discharge instructions.
- Is there anyone on our team who you would like to recognize?:** Input field. Callout: Enter users separated with semicolons.
- Service Recovery:** Input field. Callout: If the patient states that the care was poor to fair... "Thank you for your honesty. We take our patient's concerns very seriously. I will follow up with my manager. Would you like someone to call you back so that you can discuss your concerns further?"
- Closing (additional notes):** Input field. Callout: List request for call-back with phone number provided.

Additional Callouts:

- Callout: Able to verbalize F.A.S.T. without assistance, Requires assistance to verbalize F.A.S.T, Unable to verbalize [PLEASE EDUCATE], N/A
- Callout: Yes, Unable due to cost, Unable due to transportation, Unable due to illness/condition, I have not attempted to yet, I did not receive a prescription
- Callout: Yes, Attempted, but unable to schedule, Have not attempted to yet, No follow up required
- Callout: Verbalizes need for follow-up, Unable to verbalize [PLEASE EDUCATE]

Appendix B: Letter of Approval from Nursing Research Council



12/09/15

Dear Taylor Clark,

Your proposal entitled *Do Callbacks Make a Difference to Stroke Patients?* was reviewed during the December 9, 2015 meeting of the Nursing Research Council at the University of Kentucky Medical Center, and we are happy to report that your proposal has been approved. If you have not yet obtained approval for your research through the University of Kentucky Institutional Review Board (IRB), you must complete this process as well.

The Nursing Research Council reviews all proposals to conduct scientific inquiry that involve UK nursing staff in an effort to assess for a number of indicators: to determine the feasibility of conducting the proposed research, to establish the level of support from nursing management or administration to conduct the research, to determine the applicability to nursing, to evaluate protection of human subjects, and to assess the completeness of the proposal. If your proposal is amended in any way such that the methods or procedures are modified significantly, your proposal must be re-submitted for review by this Council.

Please contact me if you need further assistance, have questions, or wish to discuss anything.

Sincerely,

Shannon Johnson, RN

Shannon Johnson, RN, BSN


Chair, Nursing Research Council

Office of the Executive Vice President for Health Affairs

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Appendix C: IRB Approval Letter


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Office of Research Integrity
IRB, IACUC, RDRC
315 Kinkead Hall
Lexington, KY 40506-0057
859 257-9428
fax 859 257-8995
www.research.uky.edu/ori/

Expedited Initial Review

Approval Ends February 22, 2017 IRB Number 15-0902-P3H

TO: Taylor Clark, RN
104 Del-Mar Drive
Nicholasville, Kentucky 40356
PI phone #: (859)327-1212

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol Number 15-0902-P3H

DATE: February 24, 2016

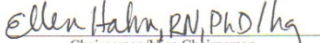
On February 24, 2016, the Medical Institutional Review Board approved your protocol entitled:

Do Callbacks Make a Difference to Stroke Patients?

Approval is effective from February 24, 2016 until February 22, 2017 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of this period, you will be sent a Continuation Review Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigators responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's IRB Survival Handbook web page [<http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#PIresponsibilities>]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [<http://www.research.uky.edu/ori/>]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.


Chairperson/Vice Chairperson

1

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Appendix D: Waiver of Authorization Approval Letter



Office of Research Integrity
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315 Kinkead Hall
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WAIVER OF AUTHORIZATION APPROVAL LETTER

In Compliance with section 164.512(i)(2)(iv)(C) of the HIPAA privacy rules, a representative from Medical IRB# 3 has reviewed the use of Protected Health Information (PHI) by expedited review.

The expedited review was conducted in accordance with 45CFR 46.110 (b)(2), the minor changes provision.

The IRB protocol# 15-0902 meets the criteria for the waiver of authorization according to 164.512(i)(2)(ii), which are as follows:

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of the individual based on:

- An adequate plan to protect the identifiers from improper use/disclosure*
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with the research justification unless health, research or legal justifications to retain the identifiers.*
- An adequate written assurance that the PHI will not be reused or disclosed to any other person unless required by law, authorized oversight or as permitted by the following subpart:*
 - the research could not practicably be conducted without the waiver or alteration;*
 - and**
 - the research could not practicably be conducted without access to and use of the PHI.*

Ellen Hahn, RN, PhD/jh
IRB Chairman or Designee

Feb. 24, 2016
Date

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