IMPLEMENTATION AND EVALUATION OF DEPRESSION IMPROVEMENT PROGRAM IN STROKE CARE (DIPS)

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ABSTRACT

Susan Elizabeth Wilson: Implementation and Evaluation of Depression Improvement Program in Stroke Care (DIPS)
(Under the direction of Mary Lynn Piven)

Background: Post-stroke depression (PSD) is a serious complication of stroke. It often goes undetected and untreated.

Purpose: The primary objective was to evaluate utilization of the Patient Health Questionnaire-9 (PHQ-9), depression treatment algorithm and development of a treatment plan. Secondary objectives were to (1) evaluate timing of PHQ-9 (2) compare the relationship between PSD, severity of stroke, functional disability and discharge location and (3) evaluate patient reported PHQ-9 and proxy family member caregivers results and (4) determine staff satisfaction with project implementation.

Methods: In an observational study, 85 consecutive ischemic stroke (IS), hemorrhagic stroke (ICH), subarachnoid (SAH), and transient ischemic attack (TIA) patients consented to participate during admission between March and August 2017. Patients and proxy caregivers completed the PHQ-9 within the first 48 hours of admission, post-discharge day 7, and post-discharge day 30 to assess for depression. The modified Rankin Score (mRS) assessment tool was used to evaluate functional disability pre-stroke and at discharge.

Results: Subjects were diagnosed with IS (n=68), ICH (n=15), SAH (n=1) and TIA (n=1). During admission, 47.1% reported depression symptoms. There were 16 (p=0.053) incident

cases at day 7 and 13 (p=0.0046) incident cases at day 30. 37.5% were treated during admission based on the initial PHQ-9 score, p=0.0005. Forty-two percent were treated by discharge, p=0.0002. 43.6% were treated by day 7, p=0.0007 and 40.5% treated by day 30, p=0.0002. A significant increase in reported PHQ-9 score from baseline admission occurred later during admission, p=0.0046 and a moderately positive relationship existed between patient reported PHQ-9 and proxy, p<0.0001. A significant relationship occurred between reported minor depression and discharge to a skilled nursing facility (p=0.0163).

Conclusions: This study suggests that implementation of an evidenced-based depression screening and treatment algorithm can improve detection of depression symptoms and treatment of PSD during the acute phase of hospitalization. Patients reported a significant increase in depression symptoms later in the admission and there is moderately positive relationship between patient reported PHQ-9 scores and proxy caregiver. Assessment and treatment of PSD during acute hospitalization with follow-up after discharge should be standard of care for all stroke sub-types.

KEYWORDS: Stroke, post-stroke depression, treatment, screening, proxy, acute hospitalization

To the memory of my father, James Barrett Wilson
You remain my daily inspiration.

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LIST OF ABBREVIATIONS AND SYMBOLS

AACN	American Association of Colleges of Nursing
ADL	Activity of Daily Living
AIM	Activate-Initiate-Monitor
ANOVA	Analysis of Variance
Barthel Index	Barthel Index
CBT	Cognitive Behavioral Therapy
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CRF	Case Report Form
CSC	Comprehensive Stroke Center
CUI	Clinical Utility Index
GED	General Education Diploma
DFSSS	Depression and Functional Status in Stroke Survivors
DIPS	Depression Improvement Program in Stroke
DNP	Doctor of Nursing Practice
DNV	Det Norske Veritas
DSM	Diagnostic and Statistical Manual of Mental Disorders
EBQA	Evidence-Based Quality Assessment
EFT	Ecosystem-Focused Therapy
EHR	Electronic Health Record
EPIC	Electronic Privacy Information Center (Medical Record)
FEWP	Free and Easy Wanderer Plus

FIM	Functional Independence Measure
FMA	Fugl-Meyer Assessment
HDRS	Hamilton Depression Rating
HIPAA	Health Insurance Portability and Accountability Act
ICH	Intracerebral Hemorrhage
IRB	Institutional Review Board
IS	Ischemic Stroke
IT	Information Technology
MADRS	Montgomery Asberg Depression Rating Scale
mRS	Modified Rankin Scale
N	Sample Size
NIHSS	National Institute of Health Stroke Scale
NIMH	National Institute of Mental Health
NP	Nurse Practitioner
NSH	Neuroscience Hospital
NSICU	Neuroscience Intensive Care Unit
OR	Odds Ratio
P	P-Value – represents statistical significance
PCP	Primary Care Provider
PhD	Doctor of Philosophy
PHQ	Patient Health Questionnaire
PI	Principal Investigator
PSD	Post-Stroke Depression

RCT	Randomized Controlled Trial
RN	Registered Nurse
RR	Relative Risk
SAH	Subarachnoid Hemorrhage
SARI	Serotonin Antagonist and Reuptake Inhibitor
SMD	Standard Mean Deviation
SNRI	Selective Noradrenaline Reuptake Inhibitor
SSRI	Selective Serotonin Reuptake Inhibitors
TCA	Tricyclic Antidepressants
TIA	Transient Ischemic Attack
TJC	The Joint Commission
rTMS	Transcranial Magnetic Stimulation
UNC	University of North Carolina at Chapel Hill
X^2	Chi Square
+/-	Plus or Minus
>	Greater Than
<	Less Than

CHAPTER 1: INTRODUCTION

Stroke effects approximately 800,000 people each year in the United States and is the number one reason of disability (American Heart Association/American Stroke Association, 2017). Post-stroke depression (PSD) is a serious complication occurring in at least 36% of patients during the acute and rehabilitation phase (Paolucci, 2008). Comparatively, the estimated prevalence of major depressive disorder in the United States among the general adult population is 6.7% (NIMH, 2015). PSD is significantly associated with a negative impact on recovery (Hadidi, Lindquist, Treat-Jacobson & Savik, 2011), higher hospital costs (Husaini, et al, 2013), and increased mortality (Robinson & Jorge, 2016).

Approximately one-third of stroke survivors will experience depression at any time point after stroke diagnosis (Towfighi, et al, 2016; Robinson & Jorge, 2016; Paolucci, 2008). Research suggests a link between depression and risk of stroke. We know depression worsens chronic diseases, such as cardiovascular disease, hypertension and diabetes, increasing the risk of stroke. However, the direction of this association is not completely understood (Del Zotto, et al., 2014). Further a significant bidirectional relationship between PSD and severity of functional disability exists, negatively influencing recovery (Hadidi, Treat-Jacobson & Lindquist, 2009; Robinson & Jorge, 2016; Towfighi, et al, 2016) and increasing discharge to an institution versus to home (Kramer, Holthaus, Goodrish & Epstein, 2006). Research has shown treatment of PSD or resolution of PSD symptoms positively influences recovery (Chollet, et al., 2011; Nannetti, Paci,

Pasquini, Lombardi & Taiti, 2005). Therefore, recognizing and treating preexisting and post-stroke depression may represent an untapped opportunity to significantly improve stroke recovery.

Stroke severity and functional disability is a predictor of PSD (Robinson and Jorge, 2016) with higher levels of functional disability found in severely depressed patients (Schmid, et al., 2011). However, the impact of PSD may be independent of the severity of stroke disability. Shi et al. (2015) followed 747 patients with a diagnosis of minor stroke for one year and found 26.5% developed PSD. Although the patients had lower rates of disability, the PSD positive patients were less likely to recover from the functional disability compared to patients without PSD symptoms, suggesting that depression poses a risk to functional improvement regardless of disability severity (Zikic et al., 2014). PSD undermines a patients' motivation to engage in rehabilitation, which is especially critical during the acute recovery phase when it is important to participate in rehabilitation.

The majority of stroke survivors affected by PSD are undiagnosed and under-treated during hospitalization (Gaete and Bogousslavsky, 2008). PSD may be under-recognized due to shorter length of stays, passive attitude of medical personnel toward diagnosis, patient and health care worker inability to recognize depression symptoms, difficulty of patient assessment, or physician concern about adverse side effects of treatment (Gaete and Bogousslavsky, 2008; Hollender, 2014; Paolucci, 2008). Further, clinicians are unsure of the appropriate time to screen during hospitalization. The literature suggests antidepressant medications are beneficial in treating PSD and improving motor recovery (Towfighi, et al., 2016; Chollet, et al., 2011) through positive effects on neuroplasticity and neurogenesis (Flaster, et al., 2013; Siepmann, et al., 2015). Additionally, trials published since 2007 suggests there may be a benefit to treating PSD with

psychotherapy (Towfighi, et al., 2016) but lack animal model research exploring the biological response of PSD to psychotherapy (Loubinoux, et al., 2012). Yet, many stroke centers do not provide depression screening, leading to under-identification and under-treatment (Hermann, et al., 2011). El Husseini, et al. (2012) found 67.9% of ischemic stroke patients and 70% of TIA patients with PSD not treated at three-month and twelve-month evaluations. Thus, improving screening for PSD among stroke centers is an essential component of early recognition.

The high prevalence of PSD and increased risk for poor outcomes sparked the American Heart Association/American Stroke Association to publish a scientific statement paper addressing PSD, providing guidance for clinical practice and further research (Towfighi, et al., 2016). Additionally, certifying bodies such as The Joint Commission (TJC) acknowledge the importance of detecting PSD during hospitalization (The Joint Commission, 2017).

Background and significance

UNC Health Care is a 900-bed academic medical center certified by The Joint Commission as a Comprehensive Stroke Center (CSC). This prestigious designation recognizes hospitals that meet rigorous quality measures and standards in treating complex stroke patients. One standard requires CSCs to evaluate stroke survivors for depression during hospitalization.

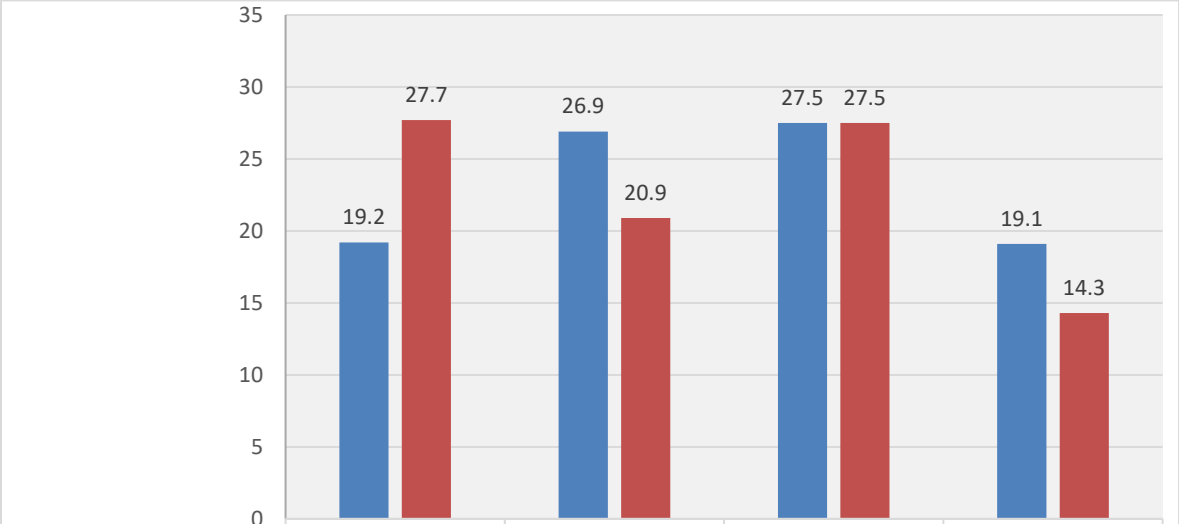
In order to meet TJCs standard for depression screening, the UNC stroke center implemented the Patient Health Care Questionnaire-2 (PHQ-2) in 2011. Nurses screened patients upon admission by asking two questions, ‘if experience little interest in doing things’ and ‘if feeling down’, and documented the results in the medical record. The stroke center did not have a protocol to guide care actions in response to positive assessments for stroke. The PHQ-2 was embedded within the electronic medical record, EPIC, only nursing knew where and how to access the results. This screening occurred less than 60% of the time, lacked a mechanism to

notify the physicians, and therefore did not translate into a treatment plan of care by the neurology or neurosurgical treatment teams.

A common theme emerged during post-discharge patient follow-up phone calls by the stroke nurse practitioner (NP). Many stroke survivors reported symptoms of depression and no desire to participate in rehabilitation. Most patients were not aware of PSD nor were they receiving treatment. The potential need for a quality improvement response prompted the stroke center to evaluate the prevalence and incidence of PSD in patients treated at UNC Health Care. The center subsequently conducted a longitudinal observational study.

Findings from this study identified areas for care improvement. From July 2014 to January 2017, 271 inpatient subjects recruited during the acute treatment period were screened for PSD symptoms (minor and moderate to severe). Researchers found that 33-55% of stroke patients (transient ischemic attack (TIA) 33.3%, ischemic (IS) 47.8%, intracerebral hemorrhage (ICH) 46.9%, and subarachnoid hemorrhage (SAH) 55% (Figure 1.1) exhibited depressive symptoms. Yet, only 21.4% ($p=0.0054$) received treatment upon discharge requiring many patients to start treatment during rehabilitation, potentially delaying response and recovery (Wilson unpublished, 2017). When compared to the literature, UNC patients self-reported higher rates of symptoms. The study team attributed these rates to several potentially confounding factors: (1) inclusion of hemorrhagic strokes and those with mild aphasia, (2) subjects with a history of depression and (3) the possible timing of the performed assessment.

Figure 1.1: Percentage of Reported Minor and Major PSD Symptoms by Stroke Category (Minor = PHQ-9 score 5-9 and Moderate to Severe = PHQ-9 score ≥ 10)



Purpose of Project

Because of the existence of a detection and treatment disparity in stroke patients treated by UNC neurology and neurosurgery and the inverse relationship between PSD and recovery, the purpose of the doctoral of nursing practice (DNP) project, **D**epression **I**mprovement **P**rogram in **S**troke (DIPS), was to fill the identified gap.

The DNP project developed, implemented and evaluated an early detection and treatment algorithm, to determine if an evidenced based protocol would standardize psychiatric care for acute stroke patients and improve detection and treatment. DIPS replaced the PHQ-2 with the PHQ-9, allowing improved detection and development of a treatment plan. DIPS targeted communication between nurses and physicians, to improve notification of PHQ-9 scores. Implementation of DIPS sparked improved PSD education for patients and their caregivers through the addition of PSD information added to the stroke education booklet.

The evidence-based quality assessment (EBQA) methodology (Melnyck and Fineout-Overholt, 2014) provided program guidance, including outcome measures, targeted at (1) utilization of the screening tool and fidelity to DIPS treatment algorithm, (2) patient depression and functional status, (3) timing of PHQ-9 screening, (4) staff satisfaction with the DIPS process and (5) compare pre- and post-project implementation data. Because patients with aphasia or communication limitations are difficult to assess and are often excluded from research evaluating PSD, this study evaluated the correlation between patient-reported PHQ-9 and proxy caregiver-reported PHQ-9. If a correlation exists, nurses and physicians may use a proxy to screen, overcoming barriers to assessment and determine the patient treatment plan.

Project Question

Will DIPS standardize and improve detection and treatment with adherence to best practice recommendations? Will DIPS standardize roles, integrate the care team and provide patient-centered care using existing staff?

CHAPTER 2: REVIEW OF LITERATURE

Review of evidence

A review of the literature incorporated relevant literature and a theoretical framework for evaluating PSD. A computer-aided search of studies published in English was conducted in the following online databases: PubMed, CINAHL, the Cochrane Library and PsycINFO. Various combinations of the following key words included: stroke, cerebral infarction, cerebral hemorrhage, depression, post-stroke depression, early, treatment, acute, screening, prevention, prophylaxis, hospitalization, recovery, and antidepressants. Utilizing the words stroke or depression alone revealed an overwhelming quantity of articles, leading to the narrower search to identify relevant post-stroke depression articles.

Inclusion/Exclusion Criteria

For this review, inclusion criteria included the following: articles published after 2001, patients with stroke diagnosis, diagnosed with depression based on Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria or a validated depression symptom rating scale, adults (age $\geq$ 18), early treatment of depression (< 1 month) and evaluation for improvement in deficits (functional outcome). Exclusion criteria included: (1) non-stroke diagnosis, (2) pediatric (age $\leq$ 17), and (3) treatment started > 3 months after stroke diagnosis.

Results

Of the 126 eligible full-text articles, 105 were excluded based on wrong outcome, design, timing or duplication. The remaining studies included in this review ranged from a Cochrane review as well as evidence-based guidelines (Appendix 1).

Twenty-one articles were included: (1) one Cochrane Review, consisting of 52 randomized controlled trials (RCTs), (2) three additional RCTs not captured in the Cochrane Review, (3) eight non-randomized prospective studies, (4) three systematic reviews, (5) two evidence-based guidelines, (6) a meta-analytical analysis of the literature, (7) two longitudinal studies based on registry data, and (8) an observational study. A recently published statement by the American Heart Association on PSD was also included. Amid the rich literature, the following themes emerged: (1) prevalence and incidence of PSD, (2) associated risk factors, (3) mortality, (4) PSD and functional assessment tools, (5) PSD screening, (6) relationship between PSD and functional status, (7) treatment, (8) timing of treatment from stroke onset, and (9) effect of treatment on PSD and functional outcomes.

Scope of the Problem

Prevalence and incidence of PSD. Depression is a common sequela of stroke. Rates vary depending on clinical setting, with the highest rates occurring in the acute and subacute rehabilitation stage (Salter, et al, 2016). Pooled data revealed an overall mean prevalence of 35.5% for major depression among acute in-patient stroke survivors and in the rehabilitation setting, while 31.8% occurred in the outpatient community setting (Salter, et al, 2016). PSD symptoms persist. In a five-year population based study of 3,689 stroke survivors, Ayerbe, Avis, Wolfe and Rudd (2013), found PSD prevalence of 33% at three months, 28% at one year, 32% at 3 years, and 31% at five years.

Risk factors. Although PSD is common, there remains uncertainty to its etiology and risk factors. Much of the difficulty with determining clear risk factors lies within the methodological limitations of the studies, such as exclusion of patients with hemorrhagic stroke, aphasia or dementia, insufficient sample size preventing multivariate analysis and poor statistical methods (Towfighi, et al., 2016). However, pooling the literature from 1990 to present, the most common risk factors identified include a history of depression, stroke severity, functional disability, cognitive impairment and social isolation (Salter, et al., 2016). Age, sex and socioeconomic status produced inconsistent results in the literature, yet, a trend shows females and older age may be at increased risk, with younger age associated with anxiety and suicide (Salter, et al, 2016).

Additionally, an abundant number of studies have evaluated the location of stroke lesion as a predictor of PSD. Currently, the relationship between PSD and lesion location remains controversial. Several systematic reviews and meta-analyses found no definitive connection between lesion location and risk for PSD (Salter et al, 2016).

Mortality. PSD is associated with increased mortality. Everson, Roberts, Goldberg, and Kaplan (1998) linked the presence of depression symptoms with an increased risk of death through their community-based study of 6,676 adults with no history of stroke, followed over 29 years. Using the Human Population Laboratory Depression Scale, they found that for each point increase, there was an associated 8% increase risk of mortality. A systematic review of 13 studies involving 59,598 subjects confirmed Everson's findings. The pooled odds ratio (OR) for post stroke mortality in patients with depression was 1.22 (95% confidence interval (CI), 1.02-1.47) (Bartoli, et al, 2013).

Mortensen, Johnsen, Larsson and Andersen (2015) evaluated all-cause 30-day mortality in stroke patients treated with antidepressants during admission compared to patients not treated. The population-based study reviewed 5,070 consecutive first-time stroke patients without prior antidepressant use in the Danish Stroke Registry from 2003 to 2010. The adjusted OR of 30-day mortality was 0.28 (95% CI, 0.18-0.43) for patients treated during admission compared to patients not treated indicating early treatment with antidepressants was safe (Mortensen, Johnsen, Larsson, & Anderson, 2015).

PSD Assessment Tools. Because PSD impedes functional recovery, increases mortality and affects quality of life, international guidelines recommend screening for PSD throughout the continuum of care (Eskes, et al, 2015). Despite the recommendation, inconsistent evaluation of PSD may be the reason for the variation in prevalence. Regardless, the gold standard for diagnosing depression is the Diagnostic and Statistical Manual of Mental Disorders, currently in its fifth edition (DSM-5). However, this level of diagnostic evaluation is challenging during the acute phase due to short lengths of admission and lack of access to mental health professionals able to perform the evaluation (Burton & Tyson, 2015).

The literature suggests a range of tools for use in screening PSD. Meader, Moe-Byrne, Llewellyn, and Mitchell (2014) performed a meta-analysis of screening tools to determine accuracy. The authors found three scales, Center of Epidemiological Studies-Depression Scale (CES-D), Hamilton Depression Rating Scale (HDRS), Patient Health Questionnaire-9 (PHQ-9), to be the most favorable choices in the stroke population (Appendix 2). The PHQ-9, used in the DIPS project, is a nine-item questionnaire measuring the nine symptoms of depression based on DSM criteria. Questions are scored based on a four-point Likert scale with total scores ranging from zero to 27 (zero = no depression symptoms, 1-4 = minimum depression symptoms, 5-9 =

mild depression symptoms, 10-14 moderate depression symptoms, 15-19 = moderately severe depression symptoms and 20-27 = severe depression symptoms. The PHQ-9 performed well in regard to sensitivity (0.86) and specificity (0.79). Using clinical utility index (CUI) analysis, the PHQ-9 had high applicability (0.58) for identifying PSD (Meader, Moe-Byrne, Llewellyn, & Mitchell (2014). For purposes of this study, minor depression was defined as a PHQ-9 score of 5-9 and moderate to severe depression as a PHQ-9 score of $\geq$ 10.

Functional Status Assessment Tools. Salter et al. (2013) evaluated reliability, validity and responsiveness among tools commonly used to measure outcomes in stroke rehabilitation. Because there are many measurements of functional status, for purposes of this report only the Barthel Index (BI), Functional Independence Measure (FIM), Fugl-Meyer Assessment of Motor Recovery after Stroke (FMA), Modified Rankin Score (mRS) and National Institutes of Health Stroke Scale (NIHSS) will be referenced due to their extensive use in stroke research and clinical practice (Appendix 3).

The two tools used in the DIPS study were the mRS and the NIHSS. The mRS is a universal outcomes scale based on level of independence and used extensively in clinical trials as a primary outcome measure. It is an ordinal scale ranging from no symptoms (score = 0) to death (score = 6). It has excellent reliability and validity (sensitivity, 0.85 and specificity, 0.87). The NIHSS is a physical assessment tool used to measure the severity of symptoms and quantify neurological deficits associated with stroke and used extensively in the clinical setting by emergency and neuroscience providers and in clinical research trials as a primary outcome. Scores range from zero (no deficits) to 42 (extremely severe deficits). It has adequate reliability and excellent validity ratings (sensitivity 0.72, and specificity, 0.89) (Salter, et al, 2013).

PSD Screening. Stroke deficits, such as aphasia, cognitive limitations, unawareness or denial, present challenges to diagnosing depression. Limitations exist with current screening tools and the most appropriate tool for PSD screening remains unclear. In addition, establishing the appropriate timing of screening and if PSD screening improves outcomes, remains to be determined (Towfighi, et al., 2016). Despite these uncertainties, several international guidelines (British Psychological Society, US Preventative Services Task Force, and Canadian Stroke Guidelines), support PSD screening and the American Heart Association/American Stroke Association rehabilitation guidelines recommend screening and treatment (McIntosh, 2017).

Patients with aphasia and cognitive impairment are often unable to complete screening assessments and present challenges for screening and treatment decision making. Yet, these impairments are significant predictors of PSD (Salter, et al., 2016). Previous work suggests a fair to moderate correlation between patient and family proxy PHQ-9 scores (Pearson $r=0.53$, $p<0.001$) (Williams, et al., 2006; Skolarus, et al., 2010). Therefore, obtaining information from a proxy may be preferable to obtaining no information.

Relationship between PSD and Functional Status. Approximately 14% of stroke survivors fully recover while 25-50% require some level of assistance with activities of daily living (Hadidi, Lindquist, Treat-Jacobson and Savik, 2011). The relationship between PSD and functional disability is bidirectional. Robinson and Jorge (2016) evaluated six studies, affirming that severity of PSD is an independent predictor of stroke severity and related to functional impairment. Nannetti, Paci, Pasquini, Lombardi and Taiti (2005) evaluated 117 stroke patients with 49 diagnosed with PSD. The Fugl-Meyer Assessment, scores were significantly better in the PSD negative group compared to the PSD positive group ($p < 0.05$). In addition, the Barthel Index scores, at three to four weeks post stroke were significantly better in the PSD negative

group ($p < 0.05$). Although most studies report higher levels of functional disability in more severely depressed patients, others have found the impact to be independent of severity, suggesting that depression poses a risk to functional improvement in all stroke patients regardless of disability severity (Zikic, et al, 2014). Shi et al, (2015) followed 747 first-ever minor stroke patients for one year with the goal of investigating the association between PSD and disability in minor stroke. The authors found that PSD was significantly associated with a risk of disability (OR 4.12, 95% CI 2.13-7.90). In patients with PSD at admission and at the six-month follow-up, but not at the one-year period, still had a higher risk of disability (OR 2.83, 95% CI 1.28-6.21) compared to the non-PSD patients. Additionally, over the one-year follow-up period, PSD positive patients had a higher stroke recurrence rate compared to PSD negative patients (9.1% vs 4.4%, $p = 0.027$).

Treatment. In animal studies of ischemic stroke, selective serotonin reuptake inhibitors (SSRI) improved stroke volume through mechanisms of enhanced neuroplasticity, improved cerebral blood flow and anti-inflammation mediated neuroprotection. Yet, the role of these mechanisms remain unclear in human stroke patients (Siepmann, et al., 2015). Documentation of pharmacological and non-pharmacological methods of treating PSD exists in the literature. The most studied drug treatments include selective SSRI and tricyclic antidepressants (TCA) (Salter et al, 2016). Seven studies evaluated SSRIs for treatment effectiveness based on psychometric scales measuring severity of depression symptoms. Time to follow-up in the studies ranged from 6.5 to 26 weeks. Citalopram significantly decreased depression symptoms by 0.54 ($p = 0.03$) standard mean deviation (SMD) compared to the placebo group during six weeks follow-up. Whereas, sertraline did not have the same effect (SMD = 0.17, $p = 0.36$) during a 26-week treatment period. Five trials evaluating fluoxetine found mixed results. The largest effect was

observed during 6.5 to 8 weeks follow-up with the treatment group experiencing a SMD of 0.79 ($p = 0.03$) decrease in depression symptoms compared to placebo and a SMD of 1.14 ($p = 0.00$) decrease after 8 weeks of treatment. However, after 12-weeks of treatment, there was only a modest difference between the treatment group compared to placebo (SMD = 0.16, $p = 0.56$) (Wannagat, Zielasek & Gaebel, 2013). Additionally, the FLAME trial found use of the SSRI, fluoxetine, improved motor recovery compared to those that did not receive fluoxetine (Chollet, et al., 2011). A Cochrane Review evaluating selective serotonin reuptake inhibitors (SSRIs) for stroke recovery did not find a significant excess of seizures, gastrointestinal side effects or hemorrhage in the patients randomized to SSRIs. The review reported the following risks associated with SSRI's: (1) RR for death was 0.76 (95% CI, 0.34 to 1.70), (2) RR for seizure was 2.67 (95% CI, 0.61 to 11.63), (3) RR for gastrointestinal side effects was 1.90 (95% CI, 0.94 to 3.85) and (4) RR of bleeding was 1.63 (95% CI, 0.20 to 13.05) (Mead, et al., 2012).

Seven studies evaluated the effects of nortriptyline (TCA), reboxetine (selective noradrenaline reuptake inhibitor-SNRI), trazodone (serotonin antagonist and reuptake inhibitor-SARI) and free and easy wanderer plus (FEWP), an herbal drug, with a follow-up period ranging from 6.5 to 16 weeks. In patients taking nortriptyline, depression scores were significantly lower compared to the placebo group (SMD = 1.05, $p = 0.02$). Reboxetine had a significantly lower mean depression severity score compared to placebo (SMD of 3.0, $p = 0.000$), while trazodone resulted in 1.23 ($p = 0.007$) SMD less depression and FEWP showed similar results of 1.32 ($p = 0.000$) less depression symptoms compared to placebo (Wannagat, Zielasek & Gaebel, 2013).

Studies evaluating non-pharmacological interventions included cognitive behavioral therapy (CBT), ecosystem-focused therapy (EFT), exercise, care management and transcranial magnetic stimulation (rTMS). There was no significant difference between patients treated with

CBT versus attention-placebo sessions ($p = 0.5$). EFT produced questionable results, with a SMD of 0.79 ($p = 0.06$) indicating a treatment effect even though there was no statistical significance. Likewise, there was no improvement in the exercise group (SMD = 0.17, $p = 0.49$). Nonetheless, the Activate-Initiate-Monitor (AIM) care management model, which taught the patient and family to recognize symptoms of PSD, start antidepressants and provided monitoring for medication adjustment, found significant improvement in depression symptoms compared to standard of care, stroke education without discussion of depression and treatment left to treating physician discretion (51% versus 30%, $p = 0.005$) (Williams, et al, 2007). Additionally, rTMS was superior to sham (placebo). In patient's receiving 12,000 pulses, a 31% decrease in HDRS was recorded compared to 13.6% in the placebo group ($p = 0.04$). In patients receiving 18,000 pulses, HDRS scores decreased by 42.4% compared to 17.5% in the placebo group ($p < 0.001$) (Wannagat, Zielasek & Gaebel, 2013).

Time of treatment from stroke onset. Research suggests a benefit of antidepressants on neuroplasticity and neurogenesis, promoting the development of neurons to improve function and survival (Flaster, Sharma & Rao, 2013). One hypothesis is that brain injury from a stroke creates an inflammatory response provoking the development of PSD. SSRIs have an anti-inflammatory effect on the dopaminergic pathways that mitigate the effects of PSD. The early reduction of inflammation may provide a protective effect on neurons by reducing brain ischemia and further neurological deterioration (Siepman, et al, 2015).

Narushima and Robinson (2003) evaluated early (19 +/- 25 days) versus late (140 +/- 28 days) use of antidepressants in the treatment of PSD. There was no significant difference between the study groups, even though the early treatment group had a slightly lower FIM score (more disabled). The authors reported a significant improvement in the group treated early

compared to the late treatment group based on FIM scores ($p < 0.05$). Additionally, the early treatment group continued to improve over the two-year follow-up, while the late treatment group deteriorated (early treatment group FIM scores: 59.0 at three months, 61.6 at one year and 62.4 at two years; late treatment group FIM scores: 58.2 at three months, 59.5 at one year and 56.7 at two years) (Narushima & Robinson, 2003).

Effect of treatment on PSD and Outcome. PSD has a negative impact on functional and cognitive recovery (Salter, et al, 2016). Schmid, et al, (2011) reported baseline depression severity, stroke severity and medical comorbidities, as three features of PSD influencing functional dependence. The authors found a significant difference in PHQ-9 scores among the depressed group at 12-weeks. Patients that were functionally dependent scored 9.94 versus patients that were functionally independent scored 7.27, $p = 0.019$.

To determine the effects of SSRIs on functional outcome, a Cochrane Review of the literature was performed (Mead, et al., 2012). Fifty-two trials (n=4,060 subjects) were included in the meta-analysis. Thirty-six trials recruited subjects within 0-3 months post-stroke, four at 3 to 6 months, two at 6 to 9 months and 10 did not report timing. Primary outcomes were dependency (measured by the mRS) and disability (measured by different scores such as BI or FIM). Secondary outcomes were neurological impairment (measured by various deficit scores such as the NIHSS). SSRIs were associated with less disability versus controls (SMD = 0.92, 95% CI, 0.62 to 1.23), better neurological recovery (SMD = 1.00, 95% CI, -1.26 to -0.75) and improved depression symptoms (SMD = 1.92, 95% CI, -2.34 to -1.48). Limitations with the Cochrane included considerable heterogeneity between the trials (Mead, et al., 2012).

Conclusions

This literature review provides evidence of a benefit of selective serotonin reuptake inhibitors (SSRIs) in reducing disability in stroke patients when treated during the acute phase, but the degree of benefit remains unclear (Eskes, et al., 2015; Mead, et al., 2012; & Narushima & Robinson, 2003). In current practice, SSRIs are not routinely prescribed with the goal to improve recovery or prevent depression. Yet, given the prevalence of PSD, associated mortality and the negative impact on recovery, screening and treatment should be considered in all stroke patients. Recently published stroke rehabilitation guidelines, recommend patients diagnosed with PSD be treated with antidepressants (class l, level of evidence B) (Winstein, et al., 2016). Therefore, it is reasonable to start treatment during hospitalization, with the goal of improving disability and depression symptoms.

CHAPTER 3: THEORETICAL FRAMEWORK

A search for nursing theory related to PSD used various combinations of post-stroke depression, nursing theory, theory, construct, nursing model, model, nursing framework, and framework occurred. The search for nursing theory related to PSD produced 223 articles, of which only three were relevant to the topic.

Scientific underpinnings

Doctoral of nursing practice (DNP) graduates rely on a diverse scientific foundation to guide practice. This foundation includes teachings from biology, physiology, psychology, social sciences and philosophy (AACN, 2006). Nursing theory includes these sciences to formulate and give meaning to the nursing perspective and practice. PSD affects stroke survivors medically, physically, psychologically and socially (Mast & Vedrody, 2006). DIPS uses the Depression and Functional Status in Stroke Survivors (DFSSS) model (Appendix 4) which has underpinnings in biology, psychology and social sciences as a theoretical framework to provide justification for evaluation and intervention.

Theory of the problem

PSD and functional disability have a bidirectional relationship. The higher the level of disability, the higher the level of depression symptoms and risk for PSD (Hadidi, Lindquist, Treat-Jacobson & Savik, 2011). This relationship may be regarded within the biopsychosocial model. Engel's biopsychosocial model of health and illness considers the interactions between

biological, psychological and social factors in understanding the cause and health care response to illness (Engel, 1977; Engel, 1980). The majority of research focuses on the biomedical etiology of PSD and pharmacologic recommendation for treatment. The biomedical etiology incorporates the hypotheses of stroke lesion location, neuro-inflammation, neuroplasticity, and genetics (Mast & Vedrody, 2006; Mittal, Hum & Schallert, 2016). Because of this focus, it is not surprising that pharmacologic intervention is the first choice of treatment for PSD. Although most patients respond to antidepressants (67.5%), a substantial number continue to exhibit PSD while on therapy (Eriksson, et al, 2004). These non-responders suggest that alternative approaches to understanding and treating PSD is necessary and the inconsistent results seen in the biomedical approach are possibly linked to psychosocial factors. The literature is lacking in addressing the consequences of psychosocial factors in prevention and treatment of PSD. Therefore, a biopsychosocial approach to PSD, addressing the early neuroanatomical damage and later stages of stroke sequelae associated with functional limitations of activities of daily living is indicated (Mast & Vedrody, 2006). A sufficient model considers both the early biological effects of stroke and the later stroke sequelae, such as functional impairments, leading to PSD with strategies targeted at both phases.

Theory of intervention

The conceptual model, DFSSS, supports the relationship between the biopsychosocial effects of PSD and functional status while treatment targets the negative effects associated with depression and functional disability. Treatment considers both early and later stages of PSD through utilization of pharmacologic and rehabilitation strategies (Alfred & Beard, 2002).

Two nursing scientists, Danita Alfred, PhD, RN and Margaret T. Beard PhD, RN, developed the DFSSS Model to predict the relationship between PSD, functional status and

intervening strategies of rehabilitation and antidepressant treatment. The model begins with depression representing the psychological aspect and functional status representing the biological aspect. Intervening treatment strategies attempt to mitigate the effects of depression and functional disability. The predictive theory proposes that PSD and decreased functional status are related and interventions can positively influence patient outcomes on both biological and psychological levels (Alfred & Beard, 2002). This too is the premise of DIPS.

DFSSS is derived from Engel's biopsychosocial model and Huber and Oermann's Model of Outcome Initiative amidst influences from the medical, social, psychological, and outcome sciences (Alfred & Beard, 2002; Engel, 1980; Huber & Oermann, 1999). The biopsychosocial model component attempts to decrease the antagonistic biological and psychological perspectives by assimilating the understanding of how PSD may stem from functional disability and psychosocial response (Pedroso, Souza, Brunoni, & Teixeira, 2015). The model of Outcome Initiative captures quality outcomes by incorporating patient, clinician, organizational and community characteristics influencing health care delivery, which in turn impact patient, clinician, organizational and population outcomes (Huber & Oermann, 1999).

Meta-analytic techniques, showing a significant relationship between depression and decreased functional status, tested the DFSSS model. Forty-five research studies, five of which were randomized controlled trials, examined the effect size between depression and functional status. The binomial effect size display suggested that PSD treatment and rehabilitation could improve levels of function from 29% to 71%. The authors concluded that there is a significant relationship between elevated levels of depression and low levels of function. Additionally, the researchers determined pharmacologic treatment and rehabilitation significantly impact the

negative relationship between depression and functional status (Alfred & Beard, 2002), which continues to be supported in the literature (Mead, et al, 2012).

Extensive literature discusses biological theories on the pathophysiology of PSD and ample literature presents the opposing psychological perspective. This polarity may be part of the problem with developing a comprehensive approach, as PSD is not purely biological or psychological, but multifactorial and more consistent with the biopsychosocial model. The DFSSS model may appeal to diverse health care providers (such as, physicians, nurses, social workers, and mental health providers) because of its foundation in outcome science and biopsychosocial theory and thus, is a strength of the model. Although, 45 studies tested the model, it lacks a reference in the stroke literature or further testing after 2002.

Yet, the DFSSS model is relevant to caring for the stroke survivor with PSD. The simplicity of the framework incorporates the complex relationship between depression and functional status, implying that treatment of the disease process requires the clinician to address the biological, psychological and social influences to improve patient outcomes. This model is an acceptable framework to guide the implementation of DIPS.

CHAPTER 4: METHODOLOGY

Improvement strategy

The Institute of Medicine defined six aims of health care quality, recommending that patient care be timely, effective, efficient, patient centered, safe and equitable (Institute of Medicine, 2001). The primary aim of DIPS is to decrease the gap in PSD detection and treatment by focusing on timeliness and efficiency with the ultimate goal of effectiveness. DIPS is patient centered and equitable (involving all categories of stroke) and safe with close follow-up post discharge.

Evidence Based Practice Change

The DIPS team applied the evidence-based quality assessment (EBQA) methodology, similar to the plan-do-study-act methodology, to implement the changes. EBQA utilizes an evidenced based guideline approach to influence performance, which has been successful in driving physician behavior in stroke care (Smith, 2000). Use of 3A gap analysis determined the need for DIPS (Table 4.1).

TABLE 4.1: 3A GAP ANALYSIS

Reason for Action	**Gap Analysis**	**Completion Plan**
1. High incidence of PSD 2. Assessment failures 3. Missed treatment opportunities Patients with PSD have poor recovery, decreased quality of life, increased mortality and higher medical costs	1. Short lengths of stay 2. Health care team does not recognize PSD symptoms - knowledge deficit 3. Patient and or family caregiver inability to recognize symptoms – knowledge deficit 4. Passive attitude towards diagnosis 5. Difficulty with assessment 6. Lack of knowledge of tools to assist with assessment	1. Healthcare team education – DIPS assessment & treatment algorithm 2. After pilot with Neurology & changes made based on what learned, will roll out with Neurosurgery 3. Share data for feedback 4. Focus group interviews 5. Ask “what – who – when – outcome”
Initial State	**Solution Approach**	**Confirmed State**
1. Up to 55% exhibited any depression symptoms during admission with as high as 28% exhibiting major depression symptoms 2. 58% screened 3. Of those with major depression symptoms, less than 30% were treated	1. Utilize EBQA to implement DIPS project	1. Monthly tracking of outcome measures
Target State	**Rapid Experiments**	**Insights**
1. 85% screened 2. Of those scoring positive for PSD, 85% documentation of treatment & follow-up plan	1. Patients admitted to neurology service 2. Evaluate who needs to be involved for success (nursing, physicians, ancillary staff, NP) 3. Evaluate nursing use of screening tool and medical team use of DIPS algorithm for treatment during admission	1. At the end of the project will evaluate lessons learned 2. Evaluate needed changes 3. Was the project successful and in what form should the program continue? 4. What failures were associated with the project?

Set Priorities (Plan):

In order to implement the project, a core DIPS team was engaged to promote the plan. The DIPS team consisted of nursing and physician leadership from the neuroscience service line, process champions from key stakeholder groups (nurses from 6 neuroscience hospital (6NSH) and neurology stroke fellow) and a stroke survivor. The team reviewed literature and data collected from phase one of the project (patients enrolled to determine prevalence of PSD in UNC HealthCare patients) addressing the importance of detecting and treating PSD to garner buy-in and compliance. The stroke survivor shared their own personal UNC experience, identifying the need for DIPS. Focus groups with key stakeholders provided knowledge on barriers to assessing and treating PSD and resulted in a strategized approach for incorporating DIPS into routine care. The project leader facilitated the team in developing a concept map (Appendix 5) and provided training on DIPS.

Set Guidelines (Do):

The most impactful change with implementing DIPS was a standardized assessment and treatment algorithm (Appendix 6) with increased adherence to best practice recommendations. DIPS standardized roles using current staff, integrated the care team and provided patient-centered care with no increased costs. Implementation of the project occurred in phases, beginning with the neurology service line, making changes based on data collection prior to implementation with neurosurgery. The Core team educated staff, functioning as a direct line of communication.

Measure Performance (Study):

The collection of process metrics and direct feedback occurred prior, during and after project implementation to evaluate success and failures. Project evaluation consisted of monthly

staff reports on performance indicators, collected by the study principal investigator (PI) and stroke data analyst through retrospective chart reviews and continuous feedback from informal stakeholder interviews.

Improve Performance (Act):

After study completion, the core team will determine how to implement the next cycle of the DIPS project. Information learned from the neurology phase will be incorporated to improve the process prior to implementation of the neurosurgery phase.

Healthcare Worker Engagement

Ensuring healthcare team buy-in is complex and often requires multiple levels of interventions. The DIPS program utilized approaches that target professionalism, education and the spirit of academia. Strategies included:

- Face-to-face education – by peers, stroke fellow or NP, grand rounds, resident lectures, journal club, nursing staff meetings
- Reminders through huddles, postings at bedside and computer, conference room educational bulletin board, via patient electronic health record (EHR) audit and feedback (monthly data report)
- Bottom-up motivation – residents, nurses, pharmacist, champions, stroke research team, stroke coordinators
- Use of evidence based guidelines – knowledge and best practice guidelines shared through grand rounds, resident lectures, nursing virtual library and face-to-face
- Small group needs assessment – adapt change to team needs in stepwise approach
- Listen to feedback and adapt – physician and nurse roundtable discussions
- Engage stroke survivor and stroke advisory board - show impact of care

Organizational coherence is an important element to quality improvement efforts focusing on three key elements: people, process and perspectives. This project utilized a

conceptual model of organizational coherence to reduce confusion and resistance, thereby improving engagement of staff (McAlearney, et al., 2013). The three areas of focus included:

1. Social system coherence – improves understanding of individual roles

   Several members of the core DIPS team completed yellow belt training, as well as project training to establish individual roles and responsibilities for improved success.

2. Intra-organizational coherence – consistent process across the unit and departments

   6NSH nurses and neurology physicians received training to ensure that the process was consistently incorporated into assessments and care of the stroke patient. Input from the unit-level, specifically the nurses and residents was key to develop the educational program. The "ground up" level input improved the success of staff buy in for the project. Nursing leaders were project champions for the unit nursing staff, while the stroke fellow and stroke-attending physician represented the resident physicians. Standard patient stroke education incorporated PSD education with the stroke survivor providing mentoring support.

3. Coherent process – consistency to achieve goals and align with mission

   The core team aligned project goals with the mission of the Stroke Center, thereby facilitating efforts to meet patient needs and provide high quality patient-centered care. Incorporation of neuroscience, nursing and physician leadership aided with success and sustainability. The neurology department provided support.

Study Design

DIPS utilized a prospective observational study design with a convenience sample to answer the project research questions. Approval by the University of North Carolina Medical Institutional Review Board (IRB) was obtained prior to study initiation for both phase-one,

population evaluation, (Appendix 7) and phase-two, evidence-based practice change, (Appendix 10). Both studies had IRB approved consent forms (Appendix 8 and 11) and Health Insurance Portability and Accountability Act forms (HIPAA's, Appendix 9 and 12).

Setting

The project took place at UNC Healthcare on 6-Neuroscience Hospital, a 32-bed acute care floor that houses the neurology service. The Department of Neurology provided a letter of support (Appendix 13) with project implementation starting on March 28, 2017.

Study Population and Recruitment

This study occurred in two-phases. Phase one determined depression prevalence and incidence in the stroke population treated at UNC HealthCare. The sample included 271 ischemic (IS) hemorrhagic stroke (ICH), subarachnoid stroke (SAH) and transient ischemic attack (TIA) patients admitted to UNC HealthCare Neurology service between July 18, 2014 and January 24, 2017 that met inclusion criteria and agreed to participate with follow-up for six months. Based on the total yearly population of 950 stroke patients, 5% margin of error, and 95% confidence level, the sample size calculated at 274 subjects.

Phase two. The DIPS study evaluated a process improvement project. The sample included 85 IS, ICH, SAH and TIA patients admitted to UNC HealthCare neurology service between March 28 and August 8, 2017 that met inclusion criteria and agreed to participate with follow-up for 30 days. The neurology service primarily treats IS, ICH and TIA with some overlap with neurosurgery and the neurosurgery service treats SAH solely. Although SAH patients receive treatment by the neurosurgery service, nurses on the 6NSH acute care floor provide care to all stroke patients regardless of categorization. Based on the total yearly

population of 950 stroke patients, 10% margin of error, and 95% confidence level, the sample size calculated at 87 subjects.

Inclusion criteria for both samples included: (1) diagnosis of stroke, (2) age $\geq$ 18, (3) able to obtain consent (may use legally authorized representative) and (4) able to speak English or Spanish. Exclusion criteria included: (1) non-stroke admission, (2) age < 18, (3) severity of illness preventing participation during admission, such as severe cognitive impairment, comfort care and (4) non-English or Spanish speaking. The study team evaluated patients based on ability to answer or point to responses on the questionnaires; thus, aphasia was not an absolute exclusion.

The stroke research team remained aware of all patients admitted to UNC Healthcare with a diagnosis of stroke/TIA through the limited waiver of HIPAA for study screening purposes. In addition, the stroke NP had access to the daily list of stroke patients for continuity of care. Recruitment of patients and their family/caregiver occurred during admission to UNC HealthCare on the 6NSH acute care floor or in the neuroscience intensive care unit (NSICU). To maintain privacy, the study team conducted the consent process in the patient's room. The team made every effort to ensure that the patient's family member/caregiver was present during the consenting process.

Consent Procedures

During admission to UNC HealthCare, the patient and family/caregiver were approached about participating in the study. The team explained the study, reviewed the consent form and allowed time for questions. After a stroke, the patient may be unable to verbalize due to aphasia or experience cognitive deficits. If necessary, the study team explained the study to the legally

authorized representative (LAR) in order to obtain consent. No deviations from the UNC IRB standard operating procedures for LAR consenting process occurred.

Subject Costs and Compensation

Patients participating in this study incurred no financial costs and received no compensation.

Benefits/Risks

This project will help the UNC Stroke Center improve its current process of identifying and treating depression in the stroke population admitted to UNC HealthCare. Studies have shown that depression is associated with poor recovery of activities of daily living and a higher mortality rate as well as longer hospital admissions (McIntosh, 2017). Husaini, et al. (2013) reported a significant increase in hospital costs in depressed stroke patients compared to non-depressed ($77,864 versus $47,790, $p < 0.001$). Early identification and treatment of PSD predicted improvement in functional outcomes and decreased hospital costs (Husaini, et al., 2013).

It is common for stroke patients to experience some emotional distress and/or embarrassment regardless of study participation. A stroke may cause devastating injuries, leading to emotional distress, which may take a period of adjustment. A patient may become upset when asked about their functional status and mood after the stroke. The study team understood the physical and emotional changes associated with stroke and therefore demonstrated patience, compassion and comfort. In addition, staff were aware of referral resources within the hospital to help the patient and family/caregiver cope. Communication with the PCP regarding changes in the PHQ-9 score occurred upon discharge and at each follow-up visit as necessary.

The study team and the stroke NP followed patients for one month after discharge through phone calls at day 7 and day 30. If the PHQ-9 increased from baseline and/or the patient experienced side effects to prescribed antidepressants, the stroke NP made medication adjustments as needed and notified the patient's PCP. If a patient scored positive (> 1) on question 9, assessment for suicidal ideation ensued. Referral to a mental health professional or law enforcement would have occurred based on the NP assessment. Example questions the NP may ask included:

1. Do you have thoughts about ending your life? If so, how often do you have these thoughts? When did the thoughts begin?
2. Did you have stressors/event that caused you to have thoughts of ending your life?
3. Have you devised a plan to end your life? If so, what is your plan?
4. Do you have the means/items with you to carry out your plan? Where are they right now?
5. What have you done to begin to carry out your plan?
6. What would it accomplish to end your life?
7. Have you ever tried to end your life in the past? If so, when did you try this? How did you try to end your life? What was the outcome?
8. Do you want to avoid ending your life?

In order to minimize the risk of loss of confidentiality, case report forms (CRFs) were de-identified (patients were assigned a number) and kept in a locked office building, that is employee badge protected. The key to the de-identified CRF is stored on a secure server protected by the University and password credentials.

Data Maintenance and Security

Data collection using the patient's medical record and personal information provided by the patient and/or family/caregiver occurred at each study time point. For data security, all subjects received an identifier to de-identifying the data. Study materials were stored in a locked office requiring badge authorization for access. Data transmission occurred in person, through original hard copies of source documents, or through notes in EPIC. Study coordinators and investigators collected data points and recorded them on CRFs. De-identified data, entered into the DIPS database, was housed on a secure server, maintained and secured by the University. Access to the study data occurred using password credentials.

Study Procedures

Following consent, subjects will complete a 30-day observational period. The schedule of activities outlines information collected and procedures performed during the study (Appendix 14).

Study Specific Documents

The protocol included use of the mRS (Appendix 15) to determine pre-and post-stroke functional ability and NIHSS (Appendix 16) to assess patients, determining stroke severity. The PHQ-9 assessment tool (Appendix 17) evaluated patients for depression and administered to the family/caregiver as patient-proxy (Kroenke, Spitzer & Williams, 2001). Documentation of the mRS, NIHSS and PHQ-9 in the patient's electronic medical record ensured continuity of care. Development of case report forms (CRF) (Appendix 18) allowed collection of study variables and efficient documentation into the PSD study database. Neurology information technology (IT) support utilized File Maker Pro to create the DIPS database under the guidance of the principal investigator. Following the DIPS treatment algorithm (Appendix 6) and recommended

medication chart (Appendix 19), the neurology resident documented the PHQ-9 score and treatment plan in the EHR. A letter for the patient's primary care provider (PCP) was available explaining the study, PHQ-9 and treatment recommendations (Appendix 20). The PCP received the letter if the patient scored in the depression category on the PHQ-9 and/or if there were changes in the score, indicating depression or worsening of symptoms. Measurement of staff satisfaction occurred through use of an investigator developed online questionnaire (Appendix 21 and 22), designed to measure knowledge of PSD and satisfaction with implementation of the DIPS project.

Outcome Measures

The primary outcome was utilization of the PHQ-9 screening assessment tool by nursing staff with a target utilization of 85%. Since screening is part of the standard of care, education focused on the transition from the PHQ-2 to the PHQ-9. Creation of a research tab to house the PHQ-9 simplified documentation. A second primary outcome was utilization of the DIPS algorithm and development of a treatment plan by the neurology residents, with a target documentation rate of 85%. For purposes of this study, development of a treatment plan was positive if the resident documented an antidepressant was prescribed or reasons for not prescribing. To support resident documentation, a templated section for DIPS supplemented the discharge summary. The third primary outcome was to improve the depression treatment rate from 28.7%, identified in the phase-one study sample. Secondary outcomes included (1) assessment of the association between depression symptoms and functional status, (2) determine if a correlation between patient reported PHQ-9 and proxy reported PHQ-9 results at admission, discharge days seven and 30 exist (3) identify if a difference exist due to completion timing of

the PHQ-9 by the patient during admission and (4) assess staff satisfaction with project implementation.

Data Analysis

Statistical analysis utilized SAS for windows version 9.4. Bivariate relationships between two continuous variables were examined using Pearson's correlation; between a dichotomous or ranked variable and a continuous variable were examined using Spearman's correlation, and between two dichotomous variables using Phi coefficient. Frequency data including prevalence and incidence were examined using Chi square (X^2). A dependent t-test compared time of administration between PHQ-9 responses during admission. Analysis of Variance (ANOVA) evaluated the difference in continuous variables between the PSD positive and PSD negative groups. For this study, a p-value of < 0.05 (two-tailed) presumes significance. Descriptive statistics were used to analyze staff satisfaction with project implementation.

CHAPTER 5: DATA ANALYSIS

Sample Characteristics and Response Rate

The phase-two DIPS sample (Table 5.1) included 85 patients of whom 41 (48.24%) were male and 44 (51.76%) were female. The group's racial identity was primarily white (58.82%) and black (34.12%) with low representation among Hispanic (4.71%) and Asian (2.35%) groups. The mean age was 65.5 (age range 25 to 96). Ischemic stroke represented the largest group (n=68, 80%) followed by ICH (n=15, 17.65%), TIA (n=1, 1.18%) and SAH (n=1, 1.18%). 16.47% (n=14) did not graduate from high school, 34.12% (n=29) held a high school diploma or general education diploma (GED), 28.4% (n=24) reported completing some college, 10.59% (n=9) completed an undergraduate degree and 10.59% (n=9) completed graduate, including masters and doctoral degrees. Work history prior to admission included: (1) nine (10.59%) disabled, (2) 20 (23.53%) working full-time, (3) four (4.71%) identifying as a homemaker, (4) four (4.71%) working part-time, (5) 42 (49.41%) retired, (6) one (1.18%) as a student and (7) five (5.88%) unemployed.

Table 5.1: Phase-Two DIPS Sample (n=85): Demographics of the Participants

Variable	Total (n=85)	Depressed %	Non-Depressed %	p-value
SEX				P = 0.57
Female	44	22 (50%)	22 (50%)	
Male	41	18 (43.9%)	23 (56.1%)	
AGE				P = 0.89
18-45	7	4 (57.1%)	3 (42.9%)	
46-65	32	16 (50%)	16 (50%)	
66-85	39	17 (43.6%)	22 (46.4%)	
$\geq$ 86	7	3 (42.9%)	4 (57.1%)	
RACE				P = 0.27
Black	29	12 (41.4%)	17 (58.6%)	
Caucasian	50	23 (46%)	27 (54%)	
Hispanic	4	3 (75%)	1 (25%)	
Asian	2	2 (100%)	0	
STROKE SUB-TYPE				P = 0.26
ICH	15	4 (26.7%)	11 (73.3%)	
IS	68	12 (17.6%)	56 (82.4%)	
SAH	1	1 (100%)	0	
TIA	1	0	1 (100%)	
EDUCATION				P = 0.53
Not High School Graduate	14	9 (64.3%)	5 (35.7%)	
High School Graduate	29	13 (44.8%)	16 (55.2%)	
Some College	24	12 (50%)	12 (50%)	
Under Graduate College Degree	9	3 (33.3%)	6 (66.7%)	
Graduate Degree	9	3 (33.3%)	6 (66.7%)	
WORK HISTORY				P = 0.08
Disabled	9	7 (77.8%)	2 (22.2%)	

Full-Time	20	7 (35%)	13 (65%)	
Part-time	4	1 (25%)	3 (75%)	
Homemaker	4	4 (100%)	0	
Retired	42	18 (42.9%)	24 (57.1%)	
Student	1	0	1 (100%)	
Unemployed	5	3 (60%)	2 (40%)	
PLACE of DISCHARGE				P = 0.59
Home	59	26 (44.1%)	33 (55.9%)	
Acute Inpatient Rehabilitation	18	9 (50%)	9 (50%)	
Skilled Nursing Facility	8	5 (62.5%)	3 (37.5%)	

Regarding comorbid conditions present prior to stroke onset, the phase-two DIPS sample experienced a wide range of illness, chief among these were hypertension, diabetes, hyperlipidemia and heart disease (Table 5.2).

Table 5.2: Phase-Two DIPS Sample (n=85): Frequency of Associated Illnesses Prior to Admission (Past Medical History)

MEDICAL HISTORY	**DIAGNOSIS PRESENT**
Depression	17 (20%)
Anxiety	11 (12.94%)
Prior Stroke/TIA	16 (18.82%)
Hypertension	64 (75.29%)
Diabetes	30 (35.29%)
Hyperlipidemia	30 (35.29%)
Atrial Fibrillation	8 (9.41%)
Heart Disease	23 (27.06%)

Cancer	17 (20%)
End-Stage Renal Disease	4 (4.71%)
Obstructive Sleep Apnea	5 (5.88%)
Obesity	5 (5.88%)
Tobacco Use	15 (17.65%)
Alcohol Abuse	3 (3.53%)
Substance Abuse	8 (9.41%)

The phase-one sample (n=271) was demographically very similar to the DIPS sample (Table 5.3 and Table 5.4).

Table 5.3: Phase-One Sample (n=271): Demographics of Participants

Variable	**Total (n=271)**	**Depressed %**	**Non-Depressed %**	**p-value**
SEX				P = 0.71
Female	125 (46.1%)	61 (48.8%)	64 (51.2%)	
Male	146 (53.9%)	68 (46.6%)	78 (53.4%)	
AGE				P = 0.56
18-45	39 (14.4%)	20 (51.3%)	19 (48.7%)	
46-65	118 (43.5%)	63 (53.4%)	55 (46.6%)	
66-85	94 (34.7%)	38 (40.4%)	56 (59.6%)	
≥ 86	20 (7.4%)	8 (40%)	12 (60%)	
RACE				P = 0.67
Black	95 (35.1%)	50 (52.6%)	45 (47.4%)	
Caucasian	162 (59.8%)	73 (45.1%)	89 (54.9%)	
Hispanic	9 (3.3%)	4 (44.4%)	5 (55.6%)	
Other	5 (1.8%)	2 (40%)	3 (60%)	
Stroke Sub-type				P = 0.46

Intracerebral Hemorrhage (ICH)	47 (17.3%)	22 (46.8%)	25 (53.2%)	
Ischemic (IS)	163 (60.1%)	78 (47.85%)	85 (52.15%)	
Subarachnoid Hemorrhage (SAH)	40 (14.8%)	22 (55%)	18 (45%)	
Transient Ischemic Attack (TIA)	21 (7.7%)	7 (33.3%)	14 (66.7%)	
Place of Discharge				P = 0.055
Home	190 (70.1%)	84 (44.2%)	106 (55.8%)	
Acute Inpatient Rehabilitation	63 (23.3%)	33 (52.4%)	30 (47.6%)	
Skilled Nursing Facility	18 (6.6%)	13 (72.2%)	5 (27.8%)	

Table 5.4: Phase-One Sample (n=271): Frequency of Associated Illnesses Prior to Admission (Past Medical History)

Medical history	**Diagnosis Present**
Depression	31 (11.4%)
Anxiety	15 (5.5%)
Prior CVA	63 (23.25%)
Hypertension	186 (68.6%)
Diabetes	72 (26.6%)
Hyperlipidemia	106 (39.1%)
Atrial Fibrillation	27 (9.96%)
Heart Disease	54 (19.9%)
Cancer	24 (8.9%)
Tobacco Use	58 (21.5%)
Alcohol Abuse	9 (3.3%)
Substance Use	13 (4.8%)

The total dropout rate by day 30 was 3.5% (n=3) based on the inability to locate patients via telephone follow-up for at least three attempts (n=1), hospitalization (n=1), or hospice/death (n=1).

Depression Symptom Prevalence on Admission, Discharge Day 7 and Discharge Day 30

Admission

Of the 85 subjects enrolled, 17 (20%) had a previous history of depression. Forty (47.06%) subjects reported symptoms of depression during admission (Figure 5.1) with no statistically significant differences between groups (IS, ICH, SAH and TIA) (p=0.26). Twenty-one (24.71%, p=0.68) reported moderate to severe depression symptoms while 19 (22.35%, p=0.56) experienced minor depression symptoms. Of these 40 subjects with depression during admission, 14 (35%) reported a prior history of depression.

Discharge Day 7

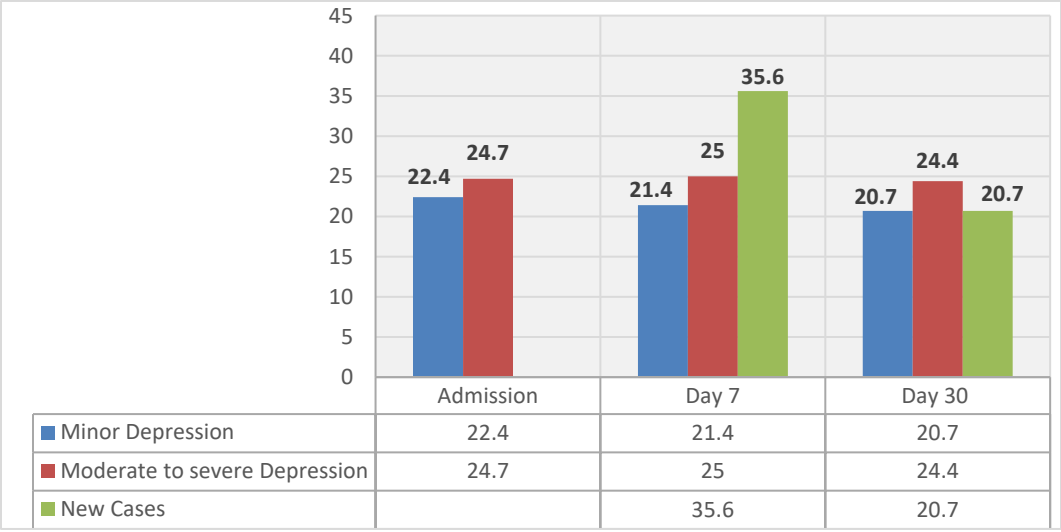
At discharge day 7, 39 (46.43%, p=0.0007) total subjects reported depression symptoms (Figure 5.1). Of the 45 non-depressed patients reporting no depression symptoms during admission, 16 (35.56%) (p = 0.053) patients reported new symptoms of depression at discharge day 7, with one (2.22%) of those reporting moderate to severe depression symptoms (p=< 0.0001) and 15 (33.33%) reporting minor symptoms (p = 0.0253). These results are slightly higher than the phase-one sample that found 24.7% new cases at day 7.

Discharge Day 30

At discharge day 30, thirty-seven (45.12%, p=0.0020) total subjects reported depression symptoms (Figure 5.1). At the day 30 assessment, of the 45 non-depressed patients from the admission period, 13 (28.89%) (p=0.0046) patients reported symptoms of depression with one (2.22%) of those reporting moderate to severe depression symptoms (p=< 0.0001) and 12

(26.67%) reporting minor symptoms (p = 0.0017). Of the 29 non-depressed patients from the day 7 assessment, six (20.69%) patients reported new depression symptoms at day 30. This result is also slightly higher than the phase-one sample that found 11.2% new cases at day 30.

Figure 5.1: Percent Depression Symptoms Reported During Admission, at Discharge Day 7 and at Discharge Day 30



Documentation of PHQ-9 Screening by Nursing

A retrospective chart review of all stroke patients, including those enrolled into the DIPS study, admitted to the neurology service examined rates of PHQ-9 documentation by nursing from April through August 2017. Implementation of the project generated a median documentation rate of 81% (Table 5.5).

Documentation of Treatment Plan by Neurology Treatment Team

A retrospective chart review of all stroke patients, including those enrolled into the DIPS study, admitted to the neurology service examined documentation rates of PHQ-9 scores and treatment plan by the treating physician from April through August 2017. Implementation of the project generated a median documentation rate of the treatment plan at 94% in the discharge

summary (Table 5.5). Although not part of the study guidelines, if the PHQ-9 was not completed by nursing, physicians contacted the study team to request an assessment.

Table 5.5: Documentation rates for PHQ-9 scores by nursing and treatment plan based on PHQ-9 score by physicians in the discharge summary

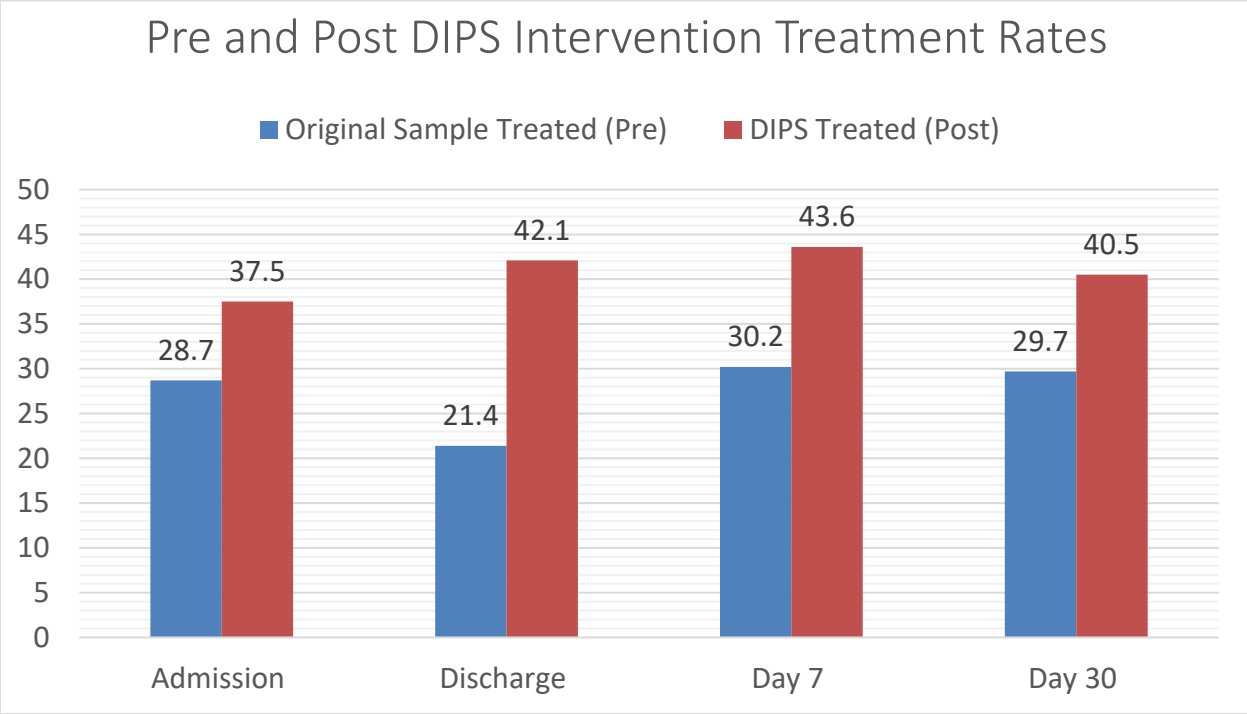
Staff	April	May	June	July	August	Median
Nursing	41% (n=39)	69% (n=26)	97% (n=30)	81% (n=36)	87% (n=31)	81%
Physicians	71% (n=39)	69% (n=26)	100% (n=30)	94% (n=36)	100% (n=31)	94%

Treatment Rate during Admission, at Discharge Day 7 and at Discharge Day 30

During admission

Of the total patients (n=40) reporting any depression symptoms, 15 (37.5%) were on treatment (p=0.0005) at the time of in-patient admission (Figure 5.2). When comparing patients, 10 (47.62%, p=0.0006) patients reported moderate to severe depression and five (26.32%, p=0.0006) reported minor depression symptoms. An additional three patients were on antidepressants that denied depression symptoms as evidenced by a negative PHQ-9. Phase-two results are higher when compared to the phase-one sample where 28.7% received treatment during admission.

Figure 5.2: Pre-and Post-DIPS Intervention Treatment Rates: Admission, Discharge, Discharge Day 7 and Discharge Day 30



Discharge

At discharge, of the total patients (n=40) reporting depression symptoms, 16 (42.11, p=0.0002) were treated with antidepressants (Figure 5.2). Twelve (60%, $p < 0.0001$) had moderate to severe depression symptoms and four (22.2%, $p < 0.0001$) had minor depression symptoms. Out of the nine patients with moderate to severe depression symptoms not treated, discontinuation of antidepressants occurred in one patient due to concern for salt wasting and four patients refused when offered treatment. Out of the 15 with minor depression symptoms not treated, two patients refused treatment. An additional three patients were on antidepressants that denied depression symptoms, reported as a negative PHQ-9.

Ad Hoc Analysis: Project Effect on PSD Treatment among All Stroke Patients

A retrospective chart review of all stroke patients, including those enrolled into the DIPS study, admitted to the neurology service, examined treatment rates at discharge of patients scoring in the minor (PHQ-9: 5-9) and moderate to severe (PHQ-9: $\geq$ 10) category from April through August 2017 (Table 5.6). Compared to the treatment rate in the original sample (28.7%), over time a clinical improvement occurred.

Table 5.6: Treatment Rates at Discharge for All Stroke Patients Scoring in the Minor (PHQ-9: 5-9) and Moderate to Severe (PHQ-9: $\geq$ 10) Category from April through August 2017

Treatment Rates	**April**	**May**	**June**	**July**	**August**
Moderate to Severe Depression Symptoms (PHQ-9 = $\geq$ 10)	100% (2 patients treated) (n=2)	60% (3 patients treated) (n=5)	80% (4 patients treated, 1 refused) (n=5)	80% (4 patients treated, 1 refused) (n=5)	67% (4 patients treated, 1 refused) (n=6)
Mild Depression Symptoms (PHQ-9 = 5-9)	12.5% (1 patient treated) (n=8)	0 (n=4)	57% (4 patients treated, 2 refused) (n=7)	60% (3 patients treated, 1 refused) (n=5)	100% (3 patients treated) (n=3)
Total	30% (n=10)	33% (n=9)	66.7% (n=12)	70% (n=10)	77.78% (n=9)

Discharge Day 7

By discharge day seven, of the total patients (n=84) observed, 39 reported depression symptoms, 17 (43.59%, p=0.0007) were treated with antidepressants (Figure 5.2). There had been no change in the treatment rate for moderate to severe depression symptoms, 57.14%, p=0.0004. However, one additional patient with minor depression symptoms received treatment (n=5, 27.78%, p=0.0004). An additional five patients were on antidepressants that denied

depression symptoms, as evidenced by a negative PHQ-9. Comparatively, prior to project implementation, only 30.2% of the phase-one sample received treatment by discharge day 7.

Discharge Day 30

By discharge day 30, of the total patients (n=82) observed, 37 reported depression symptoms, 15 (40.54%, p=0.002) were treated with antidepressants (Figure 5.2). Ten (50%, $p < 0.0001$) had moderate to severe depression symptoms and five (29.41%, $p = 0.003$) had minor depression symptoms. An additional five patients were on antidepressants that denied depression symptoms, as evidenced by a negative PHQ-9. Comparatively, prior to project implementation, only 29.7% of the original sample received treatment by discharge day 30.

Association of PSD and Severity of Stroke and Functional Disability

Documentation of pre-stroke modified Rankin (mRS) scores occurred on each patient upon admission and post-stroke mRS at the time of discharge. Eight of the 85 subjects (9.4%) were disabled prior to the stroke based on mRS of ≥ 3. Forty-one percent of subjects were categorized as having minor strokes (NIHSS score 1-4), followed by 29.41% as moderate strokes (NIHSS score 5-15). At discharge, 35 of the 85 (41.2%) were disabled, by day 7 after discharge, 31 (36.5%) and by discharge day 30, 27 (31.8%) subjects reported continued disability. Of those with depression symptoms (n=40), 17 (42.5%) were disabled (p=0.28). An analysis of variance found that mean PHQ-9 scores were not significantly greater in the disabled group (M=6.9, SD=6.01) relative to those not disabled (M=5.3, SD=5.36), ($F(1,83)=1.72$, p=0.193). However, when the DIPS sample (n=85) was combined with the original sample (n=271) for a total sample n of 356, an analysis of variance found that mean PHQ-9 scores were significantly greater in the disabled group (M=7.1, SD=5.63) relative to those not disabled (M=5.4, SD=5.3), ($F(1,354)=7.40$, p=0.0068). This was also true for the phase-one sample (n=271). When

independently analyzed there was a significant difference (F(1,269)=5.66, p=0.018) in mean patient reported PHQ-9 scores between those disabled (M=7.1, SD=5.5) and those not disabled (M=5.5, SD=5.3).

Although it was not statistically significant (p=0.595), this study found a higher report of any depression symptoms in patients discharged to a SNF. When compared by degree of symptomatology, there was no statistical significance between moderately to severe depression symptoms and discharge location (p=0.186), however, a significant association existed between minor depression symptoms and discharge location to a SNF (p=0.016). Combining the DIPS sample with the original sample found a statistically significant (p=0.018) report of any depression symptoms compared to no depression symptoms in patients discharged to a SNF (69.23% versus 30.77%) and to AIR (53.85% versus 46.15%) contrasted to those discharged home (56.75% versus 43.25%) (Table 5.7). Similar to the DIPS sample, the combined sample found complaint of moderate to severe depression symptoms not statistically significant (p=0.45), yet a significant association existed between minor depression symptoms and discharge location to a SNF (p=0.005).

Table 5.7: Phase-One Sample plus DIPS Sample (n=356) Percent Depression Symptoms Based on Discharge Location, p=0.018

DISCHARGE LOCATION	**TOTAL**	**DEPRESSED**	**NOT DEPRESSED**
HOME	252 (70.8%)	109 (43.25%)	143 (56.75%)
ACUTE IN-PATIENT REHABILITATION	78 (21.9%)	42 (53.85%)	36 (46.15%)
SKILLED NURSING FACILITY	26 (7.3%)	18 (69.23%)	8 (30.77%)

Timing of PHQ-9 Assessments

Of the 85 subjects enrolled into the study, 73 completed the PHQ-9 assessment at two different time points during admission. The patient completed the initial assessment with assistance of nursing and the second assessment with assistance by the stroke research team. The mean assessment time of completion for the initial assessment was 1.08 days from admission and 2.23 days from admission to the second assessment. A dependent samples t-test compared PHQ-9 on admission (visit 1) and PHQ-9 done later during admission (visit 2). There was a significant difference in scores from the initial PHQ-9 at visit 1 (M=4.59, SD=5.8) and the second PHQ-9 at visit 2 (M=6.16, SD=5.8); $t(72) = -2.93$, $p = 0.0046$.

Caregiver Correlation

In order to assess use of a proxy, both caregivers and study subjects completed the PHQ-9 at each study visit. Agreement between patient and caregiver as proxy was significant at admission, discharge day 7 and discharge day 30 ($p < 0.0001$). A moderately positive relationship between patient report of PHQ-9 and proxy report of PHQ-9 occurred at admission (re=0.494, $p<0.0001$, n=65), discharge day 7 (re=0.634, $p<0.0001$, n=71) and a strongly positive relationship at discharge day 30 (re=0.730, $p<0.0001$, n=70) (Table 5.8). When the two samples were combined, the relationship remained moderately positive at admission (re=0.492, $p<0.0001$, n=260), discharge day 7 (re=0.519, $p<0.0001$, n=254) and discharge day 30 (re=0.588, $p<0.0001$, n=261) (Table 5.9).

Table 5.8: Phase-Two DIPS Sample (n=85): Pearson's Correlation between Patient PHQ-9 and Proxy PHQ-9

	ADMIT PATIENT PHQ-9	DAY 7 PATIENT PHQ-9	DAY 30 PATIENT PHQ-9
ADMIT PROXY PHQ-9	0.49374		
	<0.0001		
	65		
DAY 7 PROXY PHQ-9		0.63412	
		<0.0001	
		71	
DAY 30 PROXY PHQ-9			0.73017
			<0.0001
			70

Table 5.9: Phase-One Sample plus DIPS Sample (n=356) Pearson's Correlation between Patient PHQ-9 and Proxy PHQ-9

	ADMIT PATIENT PHQ-9	DAY 7 PATIENT PHQ-9	DAY 30 PATIENT PHQ-9
ADMIT PROXY PHQ-9	0.49187		
	<0.0001		
	260		
DAY 7 PROXY PHQ-9		0.51861	
		<0.0001	
		254	
DAY 30 PROXY PHQ-9			0.58788
			<0.0001
			261

Staff Satisfaction

Nursing staff and physicians received a seven-question survey (physician n=14 and nurse n=37) (Appendix 21 and 22). Twelve physicians and 16 nurses responded to the questionnaires with a total response rate of 54.9% (physician response rate = 85.7% and nurse response rate = 43.2%)

Depression Improvement Program in Stroke (DIPS) Physician Satisfaction Questionnaire

Figure 5.3: Question #1: Do You Believe Many of Your Stroke Patients Need Help with Depression?

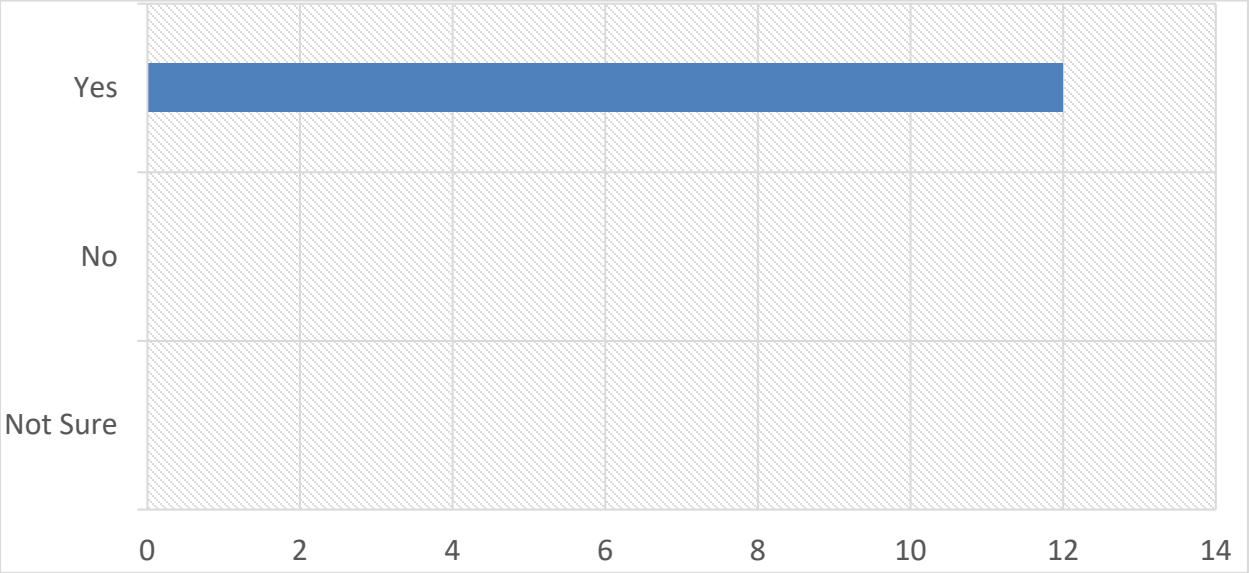


Figure 5.4: Question #2: Did You Receive Education/Information About PSD and the Importance of Treatment for Depression Symptoms in Stroke Patients?

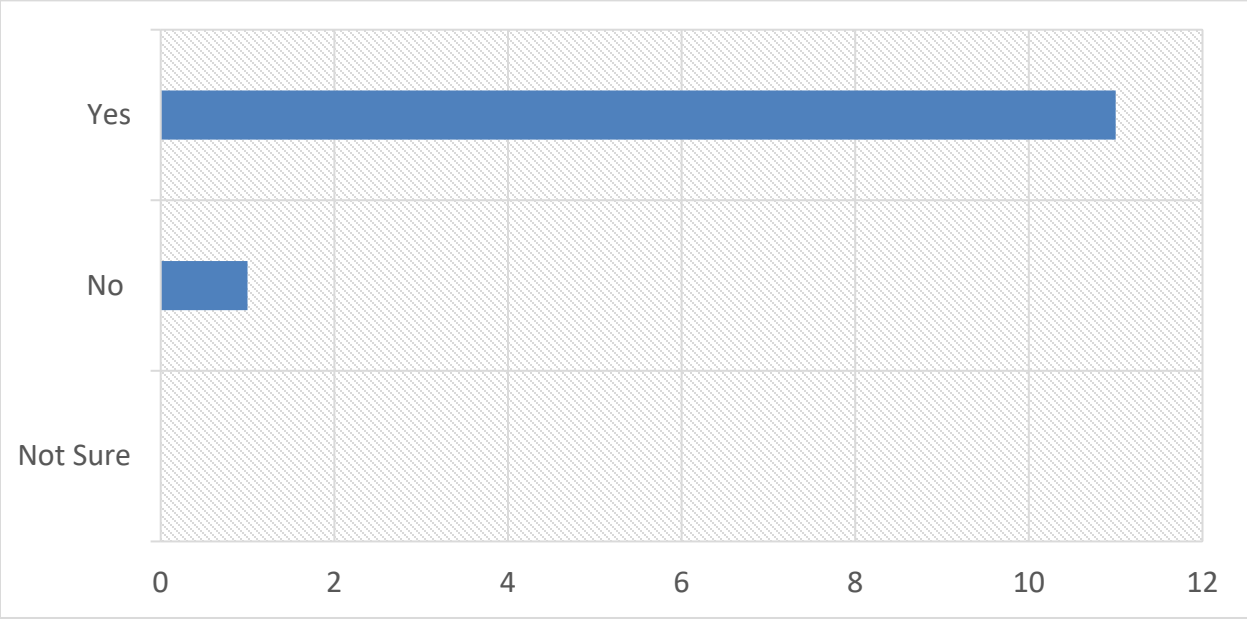


Figure 5.5: Question #3: Do You Explain PSD to Your Patients/Families?

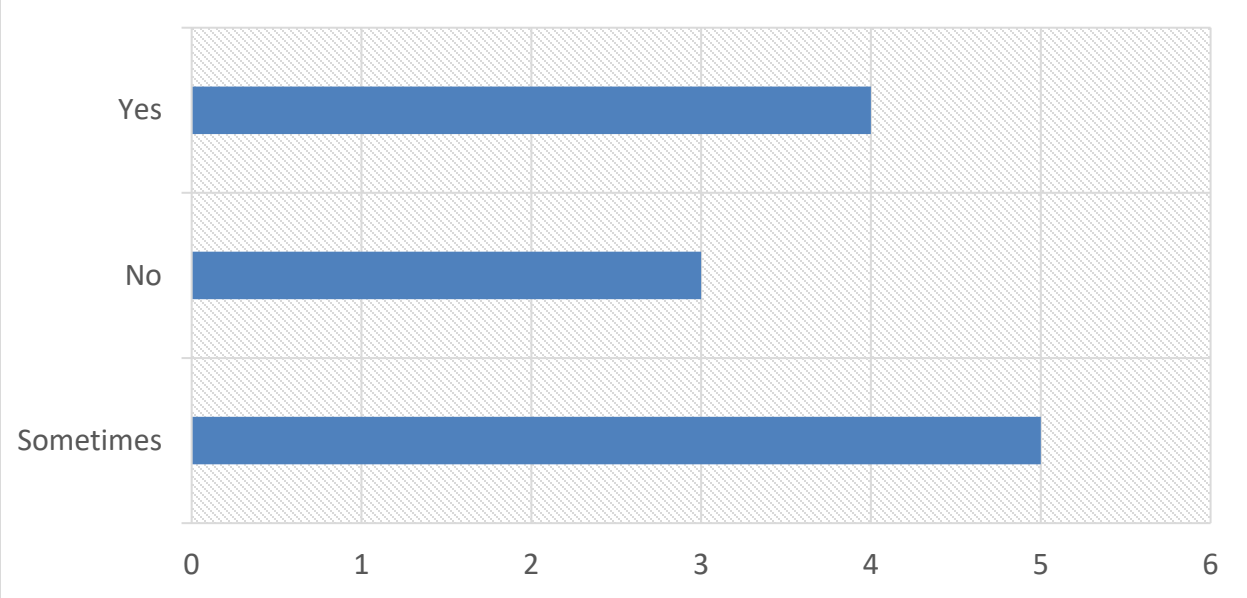


Figure 5.6: Question #4: Do You Understand How to Implement Treatment for PSD Based on the PHQ-9 Score?

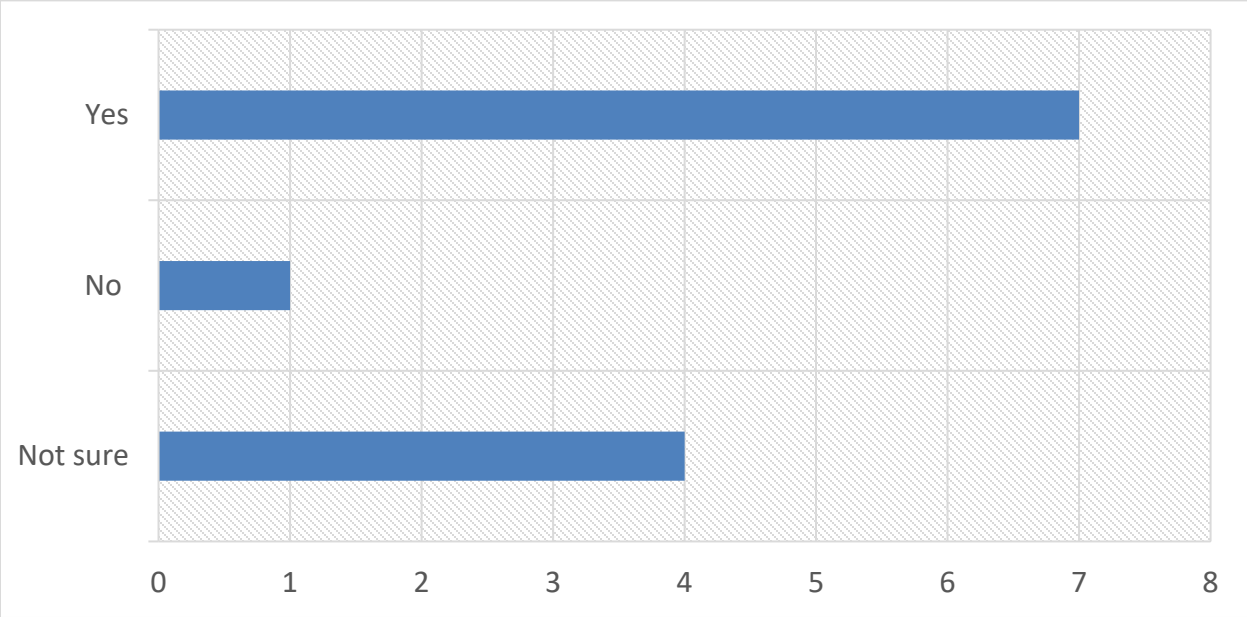
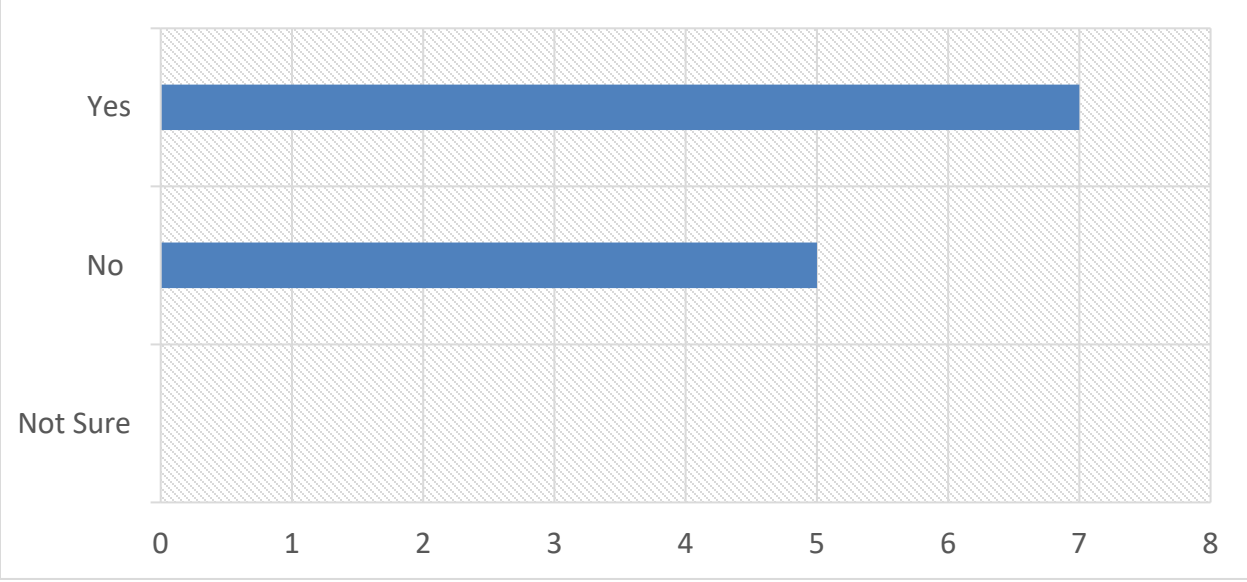


Figure 5.7: Question #5: Do You Know How to Find the PHQ-9 Score within EPIC?



Question # 6: What Went Well with the Implementation of DIPS Program?

Themes of physician comments to question six included (1) increased awareness and standardization of PSD care and (2) increased detection by nursing and physicians (Appendix 23).

Question #7: What Could Be Improved with the PHQ-9 Assessment/Documentation Process?

Themes of physician comments to question seven included (1) continue to improve documentation of PSD response in electronic medical record and (2) continue education and training (Appendix 23).

Depression Improvement Program in Stroke Program (DIPS) Nursing Satisfaction Questionnaire

Figure 5.8: Question #1: Do You Believe Many of Your Stroke Patients Need Help with Depression?

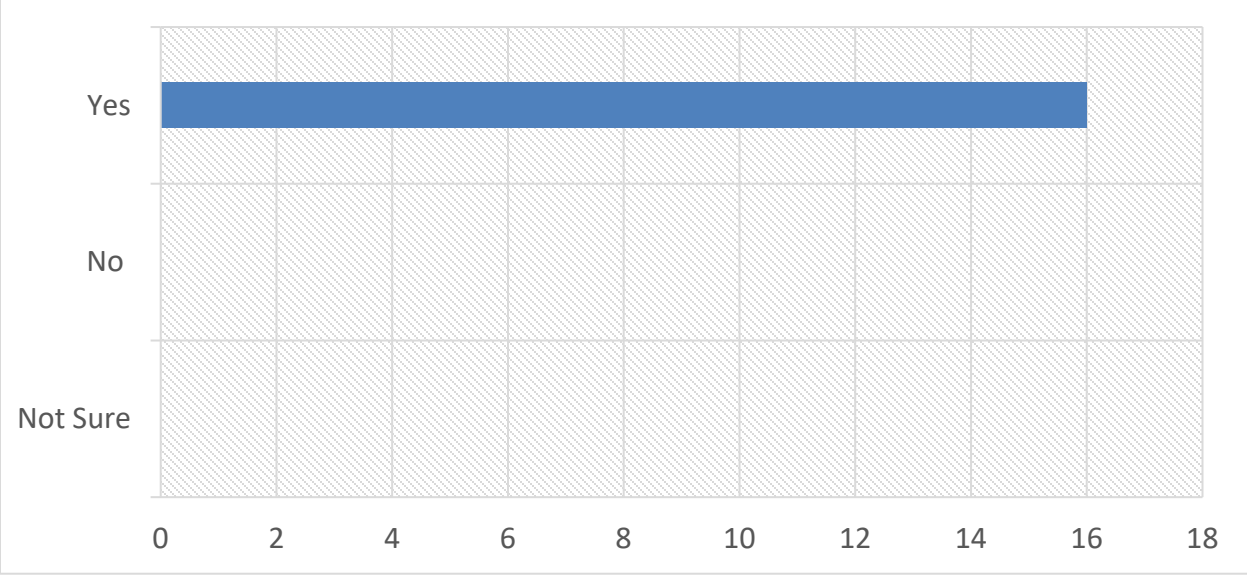


Figure 5.9: Question #2: Did You Receive Education/Information About PSD and the Importance of Screening for Depression Symptoms in Stroke Patients?

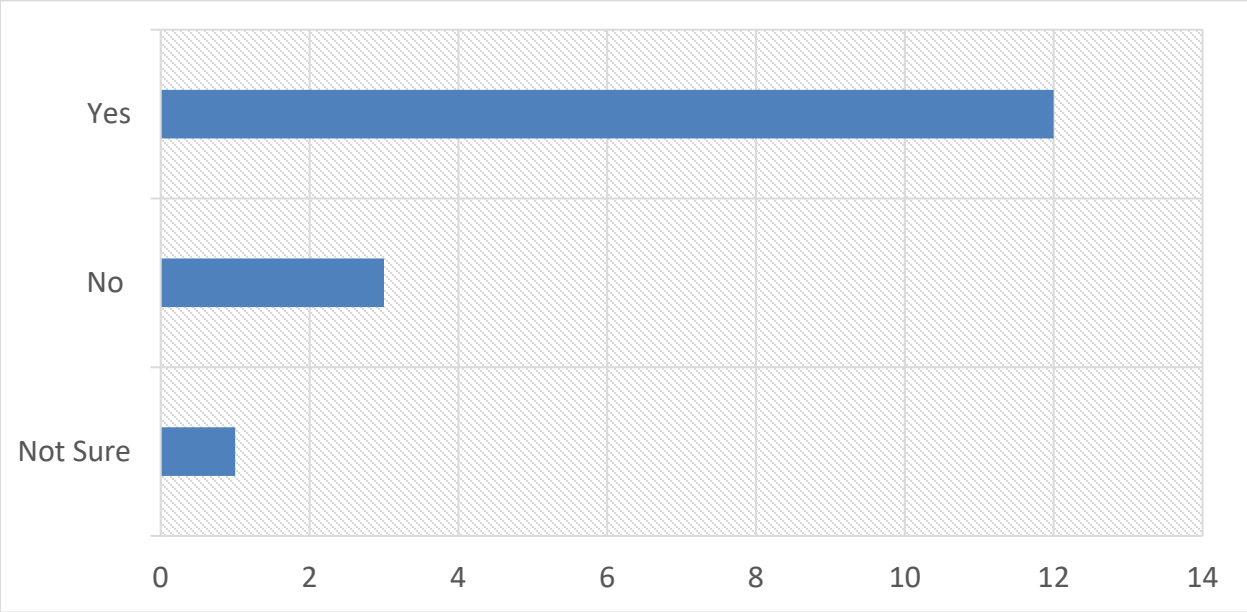


Figure 5.10: Question #3: Do You Explain PSD to Your Patients/Families?

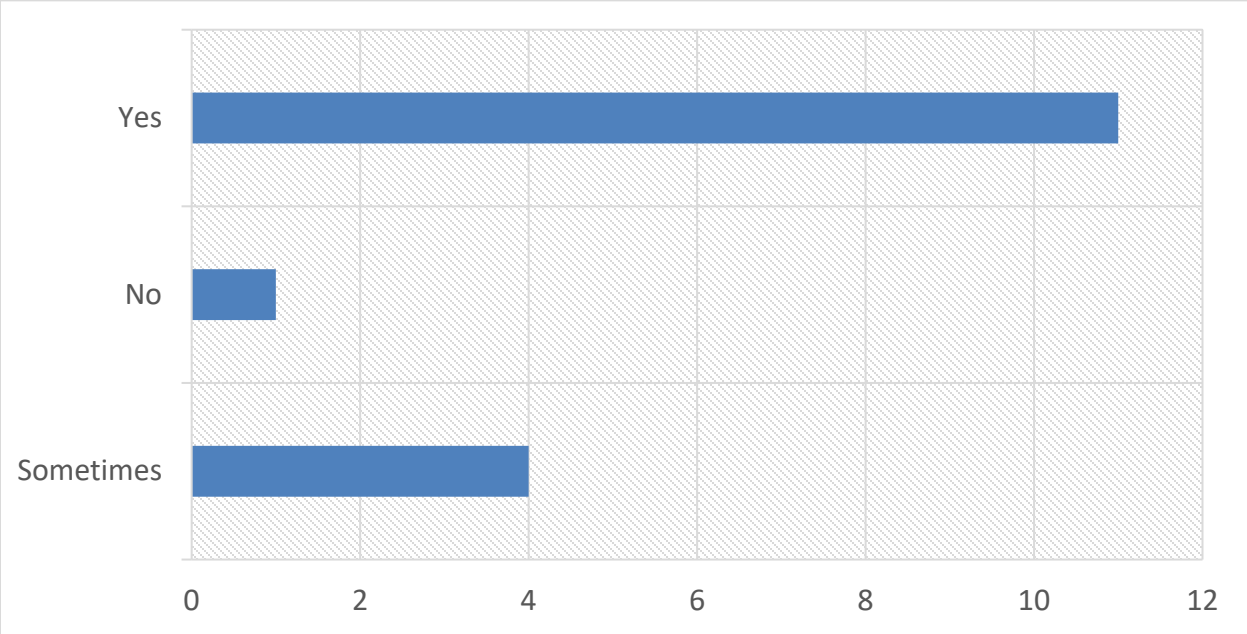


Figure 5.11: Question #4: Since Implementation of the Depression Improvement Program in Stroke (Nurses Screening Using the PHQ-9 and Physicians Considering Treatment Based on The Score), Is There More Focus From the Physician Team on PSD?

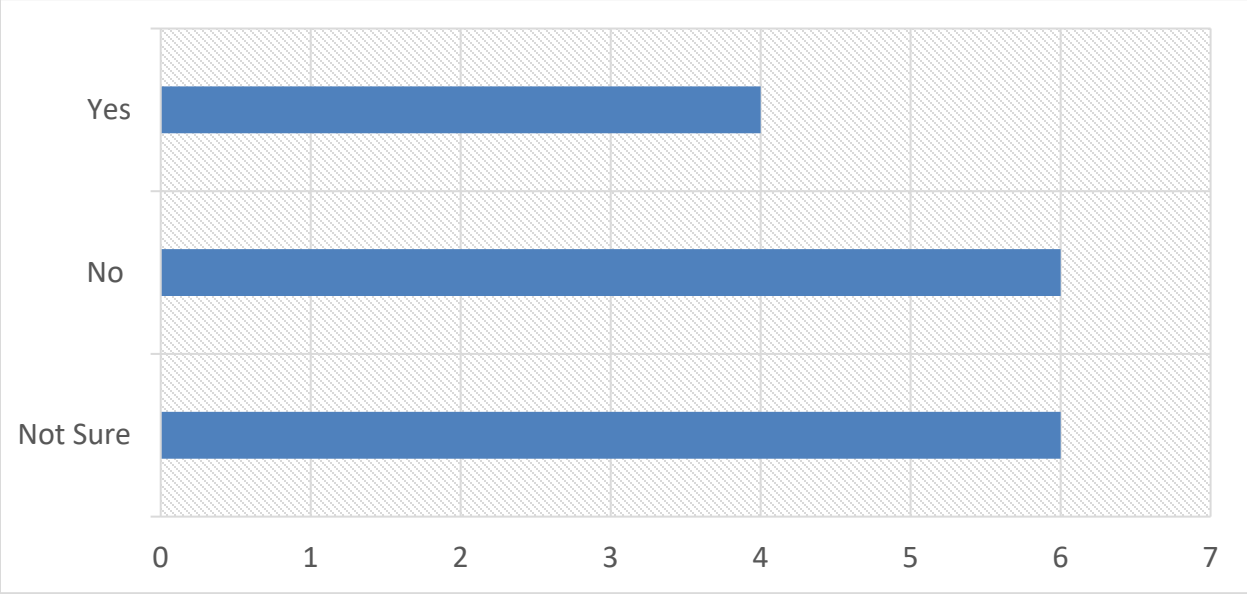
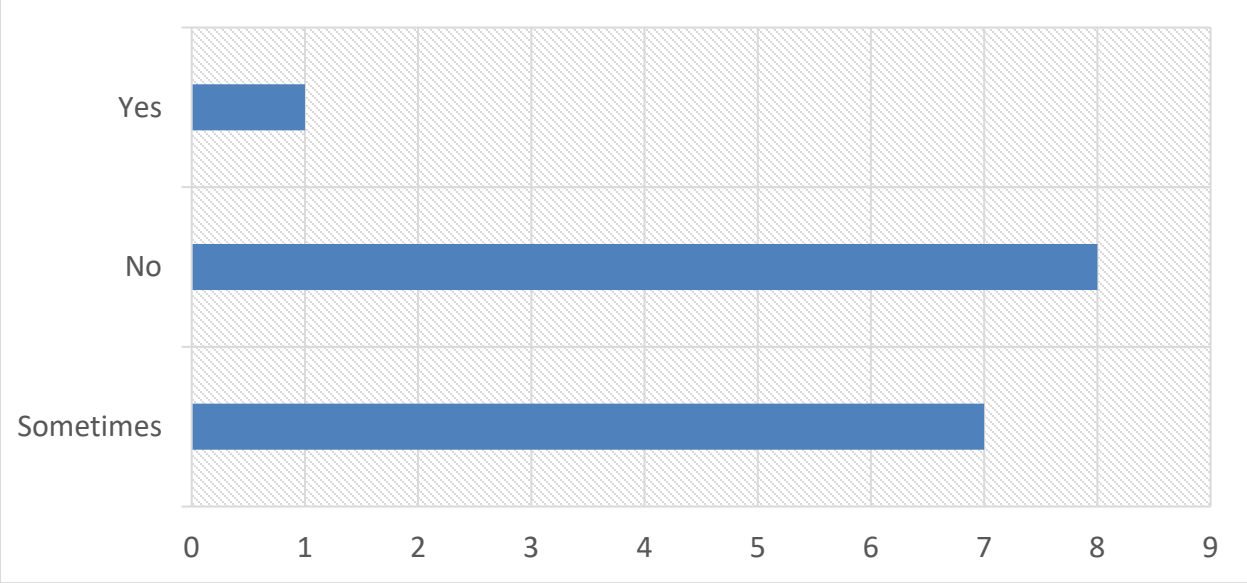


Figure 5.12: Question #5: Do You Report Off the PHQ-9 Score During Shift Report?



Question #6: What Barriers Do You Face in Assessing Your Stroke Patients for Depression?

Themes of nursing comments to question six included (1) patient deficits such as cognitive impairment or aphasia and (2) family unable to answer questions (Appendix 24).

Question #7: What Went Well with the Implementation of DIPS Program?

Themes of nursing comments to question seven included (1) increased awareness, (2) effective PSD education and (3) ease of use in electronic medical record (Appendix 24).

CHAPTER 6: DISCUSSION

This DNP project focused on the Doctoral Education Essential III by determining a need for change, critically evaluating the literature, designing a practice change, implementing and evaluating the quality improvement program (AACN, 2006). The primary goal of DIPS was to improve depression identification and treatment in stroke patients admitted to UNC Health Care in response to identifying a high rate of depression symptoms and a low treatment rate among hospitalized patients. Secondary outcomes measured included: (1) compare the relationship between PSD, severity of stroke, functional status and discharge location, (2) examine the effects of timing on screening, (3) evaluate if there is a correlation between the patient and caregiver as proxy responders to the PHQ-9 and (4) assess staff satisfaction with program process and implementation.

The literature reports PSD prevalence rates of approximately 33%, however these studies may not accurately reflect prevalence during the acute hospitalization phase due to the exclusion of hemorrhagic strokes, aphasic patients and combining hospital and acute rehabilitation settings (Robinson and Spalletta, 2010). Compared to the original sample enrolled from UNC Health Care, this study confirmed the high prevalence of reported depression symptoms during admission. Consistent with the literature (Towfighi, et al., 2016) and the phase-one sample, this study found no statistical differences between sex, age, or race. Additionally, this study found no association with PSD and education or work history.

Primary Outcome #1: Improve Documentation of PHQ-9 Screening by Nursing

Prior to project implementation, nursing screened patients approximately 58% of new admissions using the PHQ-2. This was problematic for three reasons: (1) the low screening rate, (2) use of the PHQ-2 did not aid physicians in determining a treatment plan and (3) physicians were generally not aware of the screening results because these data were not verbally communicated and documentation within the EHR was difficult to find. Implementation of the project in April generated a median PHQ-9 documentation rate of 81% from April through August 2017. Although it did not reach the 85% goal set for the project, significant clinical outcomes were evident as demonstrated by improved treatment rates.

The most influential barrier to nursing documentation was the EHR. Specific stroke documentation flowsheets, known as tabs, are available within the EHR to facilitate documentation, continuity of care and quality improvement. Because UNC Healthcare is part of a network of hospitals, it is impossible to make changes to the EHR without approval from all network hospitals. Approval and modification of the EHR is a six-month process.

Until approval of the PHQ-9 location in the nursing stroke template, nurses tried to use a smart phrase that inserted the PHQ-9 text into the note, for documentation. This first EHR work around was developed during focus group meetings with nursing and implemented in April. Although there was an improvement in documentation (41% to 69%), the nurses voiced annoyance with using the smart phrase. A second focus group meeting occurred with nursing leadership, the stroke center manager and identified nurse champions. Acting as change facilitators, the focus group developed the stroke research tab to overcome deficiencies of HER documentation. The research tab, created by nursing informatics within two weeks, is a separate link to documentation that nurses are able to pull into their main documentation screen and is

present each time they log in. Once available in the EHR, the nurses received education about completing the stroke research tab from members of the focus group, including the stroke NP, nurse leadership, and stroke center manager. Although the research tab added an additional documentation step for nursing, rates of PHQ-9 documentation improved. More importantly, the nurses voiced satisfaction with the research tab. McAlearney, et al., (2013) found within a team or unit, such as 6NSH, a coherence between individuals increases understanding of roles, responsibilities and leads to goal achievement. Engaging the nurses and physicians in building the process and making changes based on early feedback, increased shared understanding, commitment and improved project goal outcomes.

Primary Outcome #2: Documentation of Treatment Plan by Neurology Treatment Team

Prior to project implementation, physicians did not document patient's depression screening results or treatment plan in either their progress notes or their discharge summary. After a grand rounds presentation on PSD, the neurology physicians declared the PHQ-9 score as the "sixth vital sign" for stroke care, and agreed to use the data in determining a treatment plan for PSD. Utilization of a smart phrase allowed the physician to pull the PHQ-9 score into their progress notes. Four strategies supported physician compliance with documentation: (1) peer led education sessions, (2) a treatment algorithm for quick reference on cell phones and posted in the physician workroom, (3) ease of documentation through a templated section for DIPS in the discharge summary and (4) attending physician support increased documentation rates. These efforts resulted in a significant increase in PSD symptom and treatment documentation rates.

As with nursing, physicians valued the process improvement effort and expressed understanding of the need and logic behind the practice change. Sharing best practice through review of the literature at grand rounds and journal club meetings resulted in increased physician

knowledge and support. This level of coherence, deemed social system coherence, (McAlearney, et al., 2013) facilitated consistent action by the physicians surpassing the goal of 85% set at the beginning of the project.

Primary Outcome #3: Improve Treatment Rates

An important primary outcome was improvement of the treatment rate from 21.4%, identified in the phase-one study sample. This outcome was evaluated through data collected on subjects enrolled into the DIPS study and all stroke patients admitted to the neurology service between April and August 2017. The DIPS study sample revealed an improvement in the treatment rate at discharge from 21% to 42% but more importantly improved treatment in moderate to severe depression symptoms from 38% to 57%. In the overall stroke population, admitted between April and August, the treatment rate of reported any depression symptoms improved from 30% to 78%.

No treatment goal was set, as this depends on the individual needs of the patient. The study team did not want the physicians to provide a "cookbook" response to the PHQ-9, but to utilize a patient-centered approach, by further evaluating patient needs as identified by the PHQ-9 screening. A unique benefit to the neurology treatment team was easy access to psychiatry residents. Often when the PHQ-9 returned in the moderate to severe range, the psychiatry resident assisted with evaluation and provided further treatment recommendations. The psychiatry resident added further social system coherence through their support and validation of the importance of the project aims.

Although there is a consensus that treating PSD is appropriate, the right therapy and optimal time of screening continues to be determined (Towfighi, 2016). Yet, the FLAME trial provided encouraging results demonstrating that early treatment with fluoxetine and

rehabilitation therapy improves recovery in patients with ischemic stroke (Chollet, et al., 2011) and these results sparked three large European trials (FOCUS, AFFINITY and EFFECTS) examining treatment of PSD (Mead, et al., 2015). The FLAME trial also supports the theoretical framework, DFSSS, through examination of SSRIs effects on improved level of function.

The findings of this study revealed that use of an evidence-based protocol improves treatment of PSD. Patients screening positive ($\geq$ 5) on the PHQ-9 were more likely to receive treatment after implementation of the DIPS protocol. The DIPS protocol resulted in an improved standard of care for stroke patients reporting depression symptoms.

Secondary Outcome #1: Is There a Correlation between PSD and Disability

Correlation between stroke severity and associated functional disability has emerged as a predictor of PSD (Towfighi, et al., 2016) and discharge location (Zhang, Yang, & Saver, 2015). Additionally, PSD increases the risk of being prematurely institutionalized (Nuyen, et al., 2008). Nguyen, et al. (2007) examined 326 stroke survivors and found a FIM score of < 75 at admission predicted discharge to SNF and when combined with PSD led to limited recovery (Karaahmet, et al., 2017).

The DIPS sample did not show a significant association with disability and reported PSD symptoms. This discrepancy with the literature may be related to the small sample size and/or the higher enrollment of subjects with mild strokes. However, the combination of the DIPS sample with the original sample (n=356), found a significant association with disability and reported depression symptoms at discharge. In the combined sample, patients discharged to a SNF (69.23%) reported higher rates of any depression symptoms than those admitted to AIR (53.85%) or home (43.25%). Surprisingly, in both the DIPS sample and the combined sample, subjects reporting minor symptoms were significantly more likely to be discharged to a SNF and

less likely of discharged home. This suggests that a patient discharged to a SNF is more likely to be depressed and a potential risk factor for developing PSD. In addition, patients reporting minor symptoms are at higher risk of developing moderate to severe symptoms over time.

Secondary Outcome #2: Timing of PHQ-9 Assessments

These results suggest there was a significant increase in report of depression symptoms between visit 1 and visit 2. Currently the optimal time to screen for PSD is unknown (Towfighi, et al., 2016). Karamchandani, et al., 2015 found the PHQ-9 feasible for use during acute hospitalization. Yet, the question of appropriate timing during acute hospitalization remains. Should screening occur at admission or closer to discharge? Some clinicians argue that screening early during the acute phase of hospitalization will only capture the immediate reaction to acute hospitalization/new stroke diagnosis instead of reflecting a true depression syndrome (Karamchandani, et al., 2015). The biopsychosocial model of PSD describes early onset of PSD during the acute phase associated with interruption of neuronal circuits and depression symptoms continuing over time or developing later-onset of depression during the post-acute phase associated with functional deficits (Mast and Vedrody, 2006). The increase in reported depression symptoms over the two days of admission demonstrate a possible link to physical limitations affecting activities of daily living and/or the realization of life altering deficits.

Secondary Outcome #3: Caregiver Correlation

Among stroke patients, aphasia and cognitive disability may interfere with the ability to complete the PHQ-9 therefore; providers may need to rely on caregiver assessment. This study found moderately positive correlation between patient and proxy PHQ-9 scores, which may be due to the higher prevalence of patients reporting minor symptoms. Skolarus et al., (2010) found that median patient PHQ-9 scores compared to proxy were six versus five respectively demonstrating fair agreement based on an intra-class correlation coefficient of 0.41. The gap

between scores widened in light of lower levels of depression responses (Skolarus, et al., 2010). Similarly, Williams, et al. (2006) reported greater agreement between patients and proxy in patients with higher PHQ-9 scores and lower caregiver burden perception. Since the current study did not measure caregiver burden, this factor may need to be considered in future work.

Secondary Outcome #4: Staff Satisfaction

Staff nurses and physicians provided feedback on the DIPS project implementation useful for determining success and identifying areas for improvement. The goal of the questionnaires were to obtain knowledge on staff perception of PSD and gage project execution efficiency. One hundred percent of both physician and nurse respondents felt PSD was an important side effect of stroke requiring attention from the health care team. The majority of respondents received PSD education. Although a majority of physicians felt comfortable with the DIPS algorithm and treatment recommendations, the majority sometimes or did not discuss PSD with their patients. However, the majority of nurses responded that they did discuss PSD with their patients. Surprisingly, the survey identified that the majority of nurses were not sure or did not feel the physicians were concerned with PSD and do not share the PHQ-9 score during shift change report. The surveys revealed that ongoing education is needed and additional strategies to share data highlighting staff engagement and patient outcome successes. Respondents identified improvements to documentation within the electronic medical record as project barriers, which will be a focus prior to implementation of phase three on the neurosurgery service. Additional barriers included difficulty with assessing aphasic and cognitively impaired patients. A reliable way to screen stroke patients with aphasia or comprehensive deficits is not currently available (Robinson and Spalletta, 2010) therefore; proxy responses may offer the best approach currently available.

Strengths and Limitations

This study is a single center study in the southeast with a small sample in the phase-two DIPS study (n=85). However, when combined with the phase-one study (n=271), the sample size was robust at 356. Both samples did represent a diverse population, consistent with the age and racial ethnicities reported in the stroke literature.

The DIPS study had a low attrition rate (3.5%). Of the three patients lost to follow-up by day 30, one had minor depression symptoms and two had moderate to severe depression symptoms during admission. It is difficult to know how these patient responses would have affected the data, but it is possible that higher rates of reported depression and treatment would have occurred at the day 30 assessment.

In both the phase-one sample and the phase-two DIPS study sample, TIA patients may be under-represented. This is because suspected TIA patients completed their evaluations in the emergency department, thus no longer requiring admission to the hospital. Additionally, SAH patients experienced low enrollment in the DIPS study since they were on the neurosurgery service, scheduled for phase three implementation after project evaluation.

The PHQ-9 screening tool provided results of reported depression symptoms and not a depression diagnosis based on DSM criteria structured interviews. The PHQ-9 is a retrospective evaluation of symptoms over the last two weeks. Therefore, it may be difficult for patients to consider the “last two weeks” right after a major life event, which could possibly inflate the rates of depression symptoms reported during hospitalization. However, the PHQ-9 screening tool is based on DSM symptomatology criteria, with good sensitivity (0.86) and specificity (0.79) ratings (Meader, Moe-Byrne, Llewellyn, & Mitchell (2014) and recommended as one of the three most appropriate for evaluating PSD (Towfighi et al., 2016). Trained research staff,

knowledgeable of stroke patients, assisted with completing the PHQ-9 to maintain consistency. Additionally, to improve inter-rater reliability for NIHSS and mRS assessment, all study personnel completed certification training. In addition, all neurology physicians and neuroscience nurses hold NIHSS certification. No validity or reliability data exists for the staff satisfaction questionnaires.

Limitations of project implementation pertained to difficulties and inabilities to change the electronic medical record in a timely manner. However, nursing leadership acting as change agents negotiated and developed acceptable solutions to this barrier. Exceptional results should be taken with caution. A robust research team supported target groups, physicians and nurses, increasing communication and possibly effecting screening rates. Additionally, centers may not have a stroke NP to assist with follow-up post discharge.

Suggestions for Future Research/Quality Improvement

Further research to determine optimal time to administer the PHQ-9 during hospitalization will assist clinicians to appropriately detect and treat PSD and conserve staff resources. Improvement in methodology with strict control over assessment timing and assistance only by the research team will improve reliability and decrease bias.

Further statistical analysis on the correlation between the proxy and patient is important to determine agreement at the question level. Continued evaluation of patients with minor depression symptoms and proxy burden is key to understanding the difficulties in agreement between patient and proxy in certain domains as mood, emotion and energy (Skolarus, et al., 2010). Additionally, the integration of patient and proxy scores needs further exploration to determine the combined PHQ-9 reliability and validity.

Although the DIPS study sample was not powered to validate the DFSS model, the phase-one sample, followed for six months, may provide sufficient information. Examining the data to determine if there was an improvement in patients treated for depression and receiving rehabilitation compared to patients that did not may provide further validation of the model.

Goals of Dissemination

The primary goal of the dissemination plan is to share the DIPS protocol with stroke centers and national organizations to improve understanding of the detrimental effects of PSD and improve mental health care of stroke survivors. Sharing the information with national organizations, such as the American Heart Association/American Stroke Association (AHA/ASA) and certifying bodies, such as The Joint Commission (TJC), will reach a larger audience and may be the impetus for further standards leading to improved post-stroke mental health care nationally.

Dissemination of DIPS has already begun. Neurology residents received outcome data on October 2, 2017 during the weekly resident lecture series. Staff from the stroke center and neuroscience nurses attended the Nov 6, 2017 final defense in support of the project. Presentation of project findings to system hospital's stroke programs will occur on December 1, 2017 with active discussion planned on implementation at system hospitals. The Joint Commission has requested posting of study findings as an educational module for stroke surveyors by December 31, 2017 and DIPS will be presented at the 2018 Mid-Atlantic Heart and Stroke Quality Summit on April 26, 2018. DIPS data will be shared on the stroke center website and presentations to the stroke support groups and the UNC Stroke Advisory Board in 2018 are in the discussion phase.

Conclusion

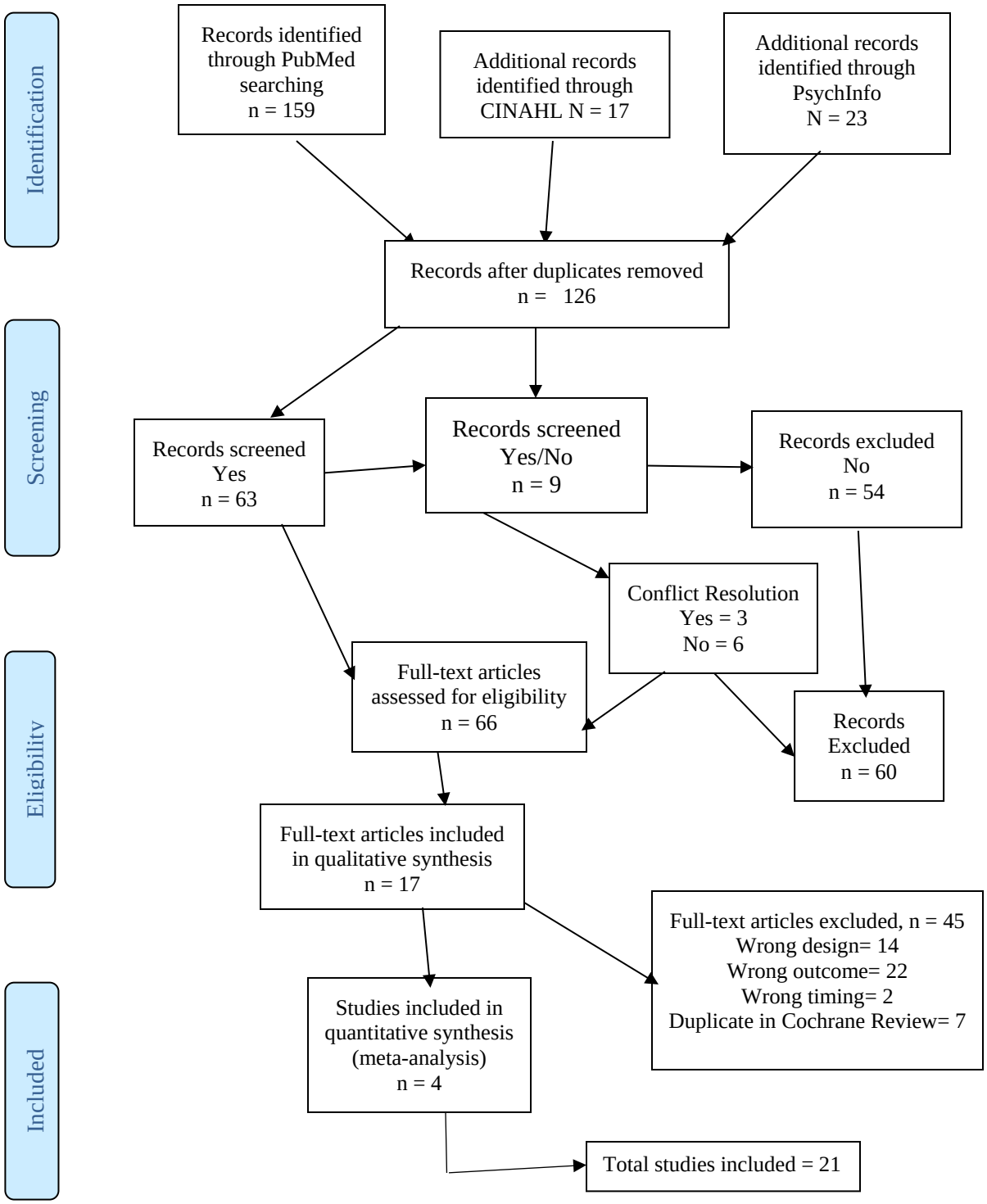
The Joint Commission mandates that certified comprehensive stroke centers screen all stroke patients for depression prior to discharge, yet there is no standard regarding when to screen and treat. Phase one of this study found a high prevalence of depression symptoms reported during hospitalization, but low treatment rates. Additionally, in the combined samples, PSD patients were more likely disabled and discharged to a SNF.

The study suggests that implementation of an evidenced-based depression screening and treatment algorithm can improve detection of depression symptoms and treatment of PSD during the acute phase of hospitalization. Further research on the appropriate timing of screening during hospitalization exists and there may be a clinical rationale for repeated administration of the PHQ-9 during acute hospitalization since the second screening scores increased and new cases were identified at day seven and day 30.

The most impactful change with implementing DIPS was a standardized assessment and treatment algorithm with increased adherence to best practice recommendations. DIPS standardized roles, integrated the care team, provided patient-centered care and was sustainable using current staff with no additional costs.

The literature and data from this study highlight the importance of having an appropriate process in place during hospitalization that offers depression screening, treatment and follow-up after discharge. Given the association of poor functional recovery, increased mortality, increased healthcare costs and low side effect risk, establishing a plan for screening and treatment during acute hospitalization should be standard practice. Based on study findings, a recommendation to stroke certification bodies, such as The Joint Commission and Det Norske Veritas (DNV), include a performance standard that specifically addresses treatment initiation for PSD.

APPENDIX 1: PRISMA FLOW DIAGRAM



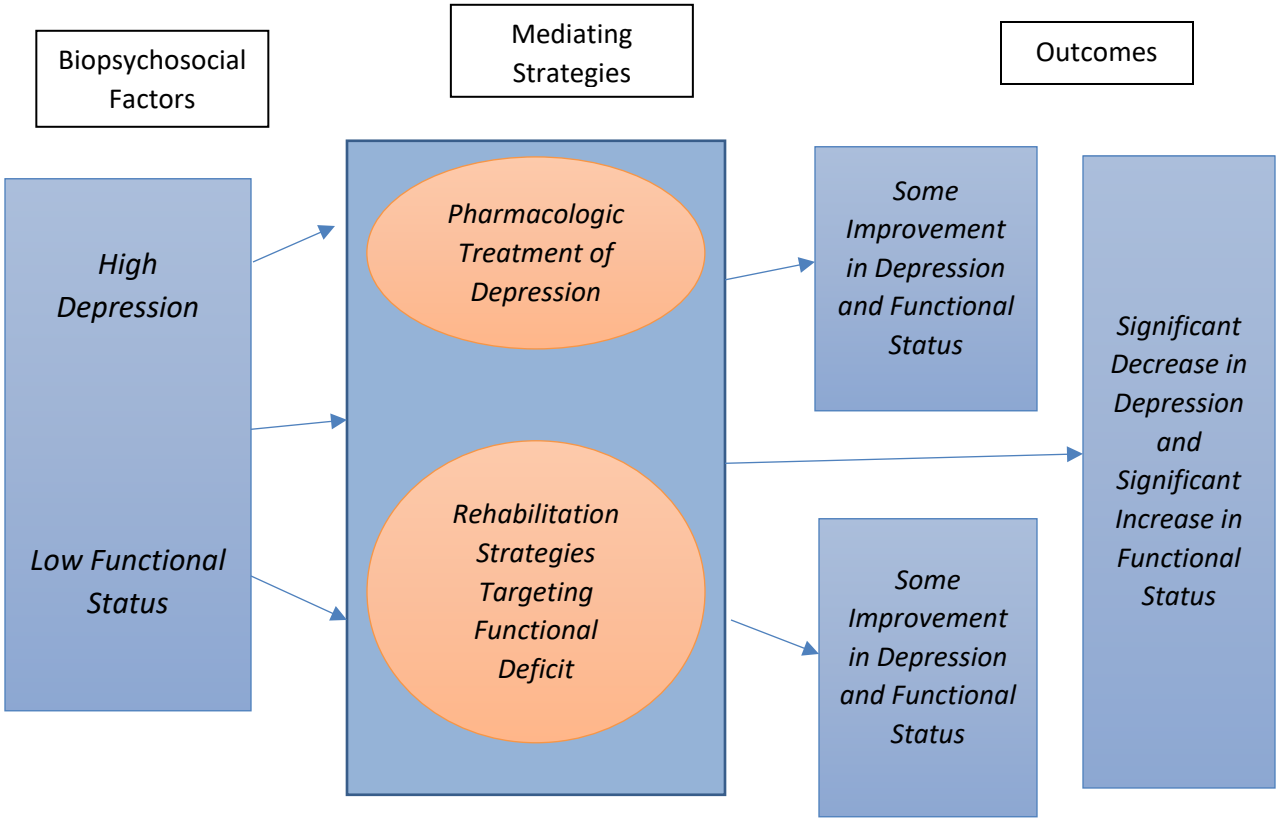
APPENDIX 2: PSD ASSESSMENT TOOLS

Scale Name	Scale Abbreviation	Measure	Range	Threshold	Sensitivity and Specificity
Center of Epidemiological Studies-Depression Scale	CES-D	20-item questionnaire measuring symptoms of depression	0-60	$\geq$ 16 signifies depression	0.86/0.90
Hamilton Depression Rating Scale	HDRS	17-item questionnaire measuring level of depression	0-52	0-7=normal; 8-13=mild; 14-18=moderate; 19-22=severe; $\geq$ 23=very severe depression	0.85/0.79
Patient Health Questionnaire-9	PHQ-9	9-item questionnaire measuring the nine symptoms of depression based on DSM criteria	0-27	0=no depression; 1-4 minimum depression; 5-9 mild depression; 10-14 moderate depression; 15-19 moderately severe depression; 20-27 severe depression	0.86/0.79

APPENDIX 3: FUNCTIONAL STATUS ASSESSMENT TOOLS

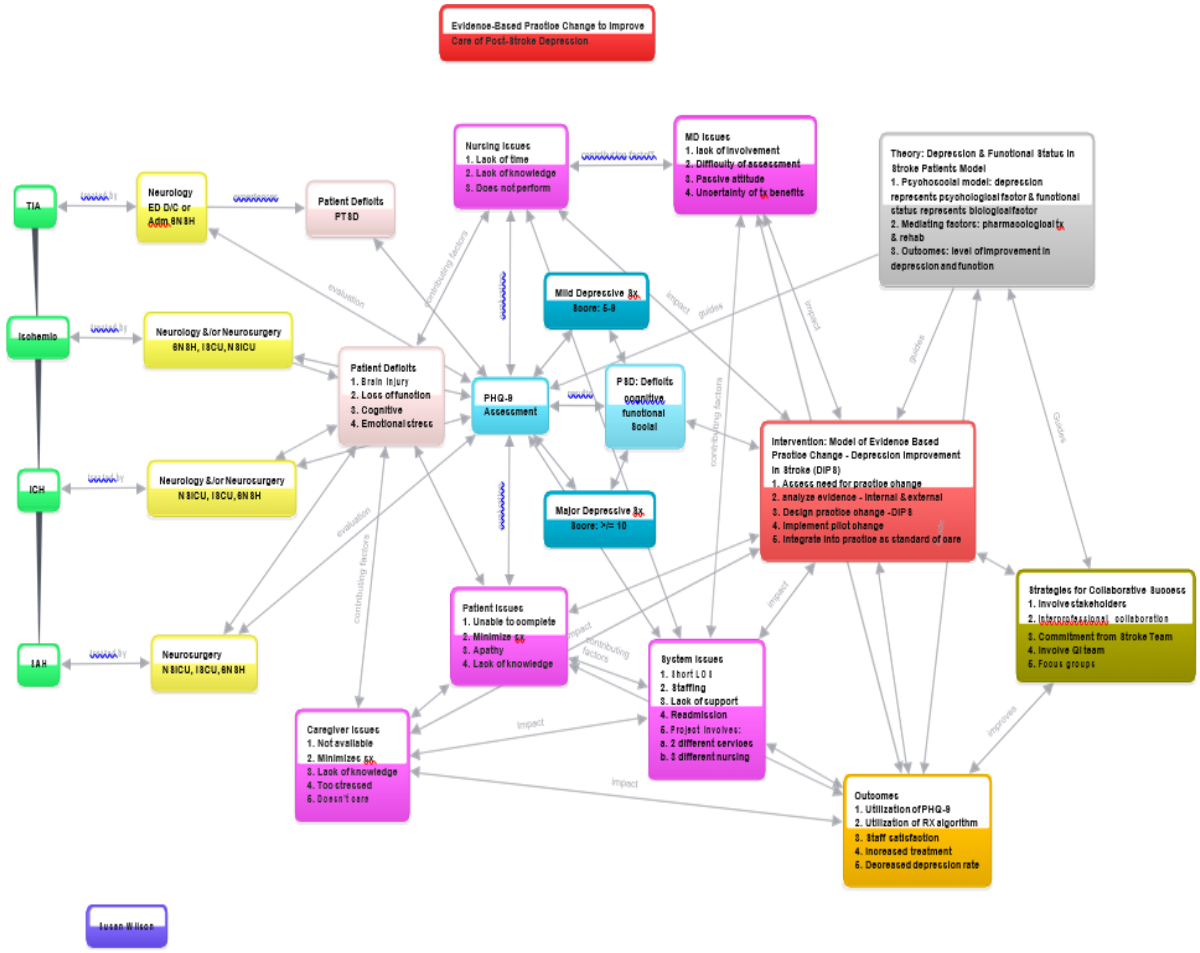
Scale Name	Scale Abbreviation	Measure	Range	Threshold	Sensitivity and Specificity
Barthel Index	BI	Measure of functional independence in activities of daily living	0-100	0-50=severe impairment; 51-75=moderate; 76-100=mild impairment	0.94/0.80
Functional Independence Measure	FIM	Evaluates physical and cognitive disability based on the burden of caring for a patient	18-126	18 = total care; 126 = independent	0.76/0.64
Fugl-Meyer Assessment of Motor Recovery After Stroke	FMA	Lengthy and requires a trained physical therapist, evaluates motor, joint, balance and sensation after stroke	0-100	< 50 = severe motor impairment; 50-84 = marked motor impairment; 85-95 = moderate impairment; 96-99 = slight impairment; 100 = normal	0.77/0.89
Modified Rankin Scale	mRS	Evaluates independence and global disability	0-6	0 = no disability; 1=mild symptom self-care; 2= some assistance; 3= needs assistance walking; 4= not walking; 5=total nursing care; 6= dead	0.85/0.87
National Institutes of Health Stroke Scale	NIHSS	Graded physical exam of stroke severity	0-42	0 = normal; 1-4=minor; 5-15=moderate; 16-20=moderately severe; > 20=severe stroke	0.72/0.89

APPENDIX 4: DEPRESSION AND FUNCTIONAL STATUS IN STROKE SURVIVORS MODEL

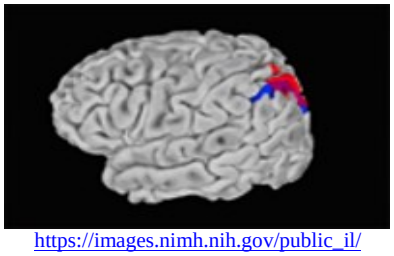


Alfred and Beard, 2002

APPENDIX 5: DIPS CONCEPT MAP



APPENDIX 6: DIPS TREATMENT ALGORITHM



https://images.nimh.nih.gov/public_il/

UNC Department of Neurology

Depression Screening/Treatment Algorithm in Stroke (DIPS)

PHQ-9 Assessment

- 0-4 Not Clinically Depressed → No Treatment Necessary
- 5-9 Mild depression → Consider Antidepressant Especially if Functional Deficits Present and Referral to Psychotherapy
- 10-14 Moderate ≥ 15 Severe Depression → Start Antidepressant and Referral to Psychotherapy

APPENDIX 7: PHASE-ONE STUDY IRB APPROVAL LETTER

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
105 Mason Farm Road
Medical Building #52
CB #7097
University of North Carolina at Chapel Hill Chapel Hill, North Carolina 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federal wide Assurance (FWA) #4801

To: Susan Wilson
Neurology

From: IRB

Approval Date: 7/11/2014
Expiration Date of Approval: 7/10/2015
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Initial
Expedited Category: 7.Surveys/interviews/focus groups
Study #: 14-1380

Study Title: Depression Screening in Acute Stroke Patients

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal.

Study Description:
Purpose: 1. To assess the prevalence and incidence of depression in the UNC stroke population pre- and post-stroke. 2. Describe depression after stroke.

Participants: Stroke patients admitted to UNC HealthCare

Procedures (methods):Patients admitted to UNC Healthcare under the care of the Department of Neurology and /or Department of Neurosurgery will be screened for depression using the PHQ-9 assessment tool. Upon discharge, the patient will receive a phone call within followup time periods and the PHQ-9 will be administered. The PHQ-9 will also be administered to the family/caregiver as a patient-proxy. A six-month phone follow-up will complete the study.

Investigator's Responsibilities:
Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval.
Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb_event.cfm?actn=info&irbid=14-1380.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

Please be aware that additional approvals may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Natalie Aucutt-Walter, Neurology
Anne Beckwith, Neurology
Octavio De Marchena, Neurology
David Huang, Neurology
Angela Lipscomb-Hudson, Physical Medicine and Rehabilitation
Leonardo Morantes Gomez, Neurology
Kevin Robertson, Neurology
Karla Thompson, Physical Medicine and Rehabilitation
Michael Wang, Neurology
Vincent Woolfolk, Neurology

APPENDIX 8: PHASE-ONE IRB APPROVED CONSENT FORM

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: __7.7.14_____
IRB Study #: **14-1380**
Title of Study: Depression Screening in Stroke Patients
Principal Investigator: Susan Wilson, RN, MSN, C-ANP
Principal Investigator Department: Neurology
Principal Investigator Phone number: (919) 843-2387
Principal Investigator Email Address: wilsons@neurology.unc.edu
Co-Investigators: Natalie Aucutt-Walter, MD; David Huang, MD, PhD; Michael Wang, MD; Octavio de Marchena, MD; Leo Morantes Gomez, MD; Anne Beckwith BS; Vincent Woolfolk
Funding Source and/or Sponsor: UNC Department of Neurology

_____

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to determine the rate of depression before and after the diagnosis of stroke as well as the time course of development.

Post stroke depression is common; however, it is under recognized and under diagnosed. Studies have estimated post-stroke depression to occur in 33% of survivors. Depression is associated with poorer outcomes, recovery and quality of life. For this reason, early screening and treatment is important. Starting treatment early, within the first month after stroke diagnosis, is more effective and associated with improved functional outcomes.

Are there any reasons you should not be in this study?
You should not be in this study if:

- You are less than 18 years old
- You do not have a suspected or confirmed diagnosis of stroke or trans ischemic attack (TIA)
- You are not able to participate in the study for 6 months

How many people will take part in this study?
Approximately 650 people will take part in this study at UNC Hospitals.

How long will your part in this study last?
This study will follow you for 6 months.

What will happen if you take part in the study?
The following information and procedures will be obtained by the study team.

a. Admission
   - Demographics (name, age and phone numbers) (standard of care)
   - Name of primary physician (standard of care)
   - Medical history (standard of care)
   - Current medications (standard of care)
   - Functional assessment of how well you were doing prior to your stroke, called pre-modified rankin (pre-mRS) (standard of care)
   - Neurological physical exam called National Institutes of Health Stroke Scale (NIHSS) (standard of care)
   - Patient Health Questionnaire 2 (PHQ-2) – 2 questions performed by admitting nurse (standard of care per UNC Stroke Center)
   - Patient Health Questionnaire 9 (PHQ-9) – completed by patient with assistance by study team
   - PHQ-9 - completed by family/caregiver

b. 7 (+/- 3) day Phone Call post Discharge
   - Complete PHQ-9 by patient
   - Complete PHQ-9 by family/caregiver
   - mRS (standard of care)
   - Study team will question if participating in rehabilitation therapy (standard of care)
   - Study team will question if participating in psychological counseling (standard of care)

c. 30 (+/- 5) day Phone Call or Clinic Follow-up
   - Complete PHQ-9 by patient
   - Complete PHQ-9 by family/caregiver
   - mRS
   - Study team will question if participating in rehabilitation therapy
   - Study team will question if participating in psychological counseling

d. 60 (+/- 7) day Phone Call
   - Complete PHQ-9 by patient
   - Complete PHQ-9 by family/caregiver
   - mRS
   - Study team will question if participating in rehabilitation therapy
   - Study team will question if participating in psychological counseling

e. 90 (+/- 7) day Phone Call
   - Complete PHQ-9 by patient
   - Complete PHQ-9 by family/caregiver
   - mRS
   - Study team will question if participating in rehabilitation therapy
   - Study team will question if participating in psychological counseling

f. 6 (+/- 10 days) month Phone Call
   - Complete PHQ-9 by patient
   - Complete PHQ-9 by family/caregiver
   - mRS
   - Study team will question if participating in rehabilitation therapy
   - Study team will question if participating in psychological counseling
   - Study team will question about any hospitalizations or new diagnosis

What are the possible benefits from being in this study?
It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

What are the possible risks or discomforts involved from being in this study?
As a result of your participation in this study, you are at risk for side-effects listed in this section. You should discuss these with the investigator. It is important that you consider all of the options before you decide to participate in this research study.

Loss of Confidentiality:
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

We will take every measure to protect your privacy and confidentiality. Any information will be coded by a study-specific identification number to protect your confidentiality. Any information stored by the study team will be stored in a locked filing cabinet in a building that is locked to the public. Any electronic data will be stored on a protected server. Study documentation will be kept and securely archived. Your identity will be kept confidential when the results of this study are published.

When telephoning, the study staff will ask if it is a convenient time and will call back if it is not. No messages will be left pertaining to this study.

Psychological Stress:
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the interview. You may stop your participation in the study at any time.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University for the purpose of quality control or safety.

Confidentiality of your records will be strictly maintained. Your information will be kept in locked offices, and on computers that are password protected. A copy of this consent form will go into your medical record. This will allow the doctors caring for you to know what study questionnaires you may be receiving as a part of the study.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. If such problems occur, the researcher will help you get medical care, but The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care.

Any costs for medical expenses not paid by UNC will be billed to you or your insurance company. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything for taking part in this study.

Who is sponsoring this study?
There is no funding for this study. The UNC Department of Neurology Stroke Center is sponsoring this study to gain knowledge in order to improve care to all stroke patients treated at UNC HealthCare.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Legally Authorized Representative Date

_____
Printed Name of Legally Authorized Representative

_____
(Relationship to subject)

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Impartial Witness Date

_____
Printed Name of Impartial Witness

APPENDIX 9: PHASE-ONE IRB APPROVED HIPAA FORM

University of North Carolina at Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

---

IRB Study #: 14-1380
Title of Study: Depression Screening in Stroke Patients
Principal Investigator: Susan Wilson RN, MSN, C-ANP
Mailing Address for UNC-Chapel Hill Department: CB:7025 Neurology, Physicians Office Bldg , 170 Manning Drive ,Chapel Hill, NC 27599-7025 , USA

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

---

1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals that have provided health services or treatment, such as physicians, clinics, hospitals, home health agencies, diagnostic centers, laboratories, treatment or surgical centers associated with UNC Health Care System.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Information about your stroke or TIA. This would include information about medical treatment and rehabilitation as well as any information in your medical records that relates to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers and certain employees of the university if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

HIPAA regulations require that we let people know that sharing the PHI with others who are not covered by HIPAA – such as pharmaceutical company sponsors – will take that PHI outside of HIPAA's coverage. For example, HIPAA generally requires authorization or waiver of authorization as well as certain accounting records for disclosures of individually identifiable information from the medical record, but these HIPAA requirements do not apply to the same individually identifiable health information in the research database. The natural concern for the

research subject is whether this means that there are no confidentiality protections once the PHI has been shared outside of HIPAA coverage. The researcher should explain what confidentiality protections have been set up for the individually identifiable information in this study. In addition to the research study procedures to protect confidentiality, our standard clinical trial language requires the sponsor to protect the confidentiality of any individually identifiable data.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1 on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____

Signature of Research Subject **Date**

_____

Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____
Please explain your authority to act on behalf of this Research Subject:
_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____ _____

Signature of Personal Representative **Date**

APPENDIX 10: PHASE-TWO DIPS IRB APPROVAL LETTER

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
720 Martin Luther King, Jr. Blvd. Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Susan Wilson
Neurology

From: Non-Biomedical IRB

Approval Date: 3/20/2017
Expiration Date of Approval: 5/25/2017
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Modification
Expedited Category: 7.Surveys/interviews/focus groups, Minor Change to Previously Approved Research
Study #: 14-1380

Study Title: Depression Improvement Program in Stroke (DIPS)

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:
Based on data gathered during this study, depressive symptoms occur 30-54% in stroke patients admitted to UNC HealthCare, yet less than 39% are treated. Post-stroke depression (PSD) is associated with increased mortality, negative impact on recovery, higher hospital costs and stroke recurrence. This study extension will evaluate physician utilization of a treatment algorithm based on PHQ-9 scoring. Nursing will assess the patient at admission as standard of care using the PHQ-9. The study will continue consenting the patient and caregiver for an additional PHQ-9 assessment performed during admission to evaluate if timing is a factor in development of PSD symptoms (admission vs 3-4 days later). Follow-up assessments will continue through day 30. This study is discontinuing the day 60, 90 and 6-month follow-up. Every effort will be made to include the patients PCP as was performed in the original study.

New personnel added include Mary Lynn Piven, PhD, RN; Rebecca Kitzmiller, PhD, RN; Michael Forbes, MD

Investigator's Responsibilities:

If applicable, your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=14-1380.

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Anne Beckwith, Neurology
Ariane Cook, Neurology
Michael Cools, Neurosurgery Clinic
Octavio De Marchena, Neurology
Michael Forbes, Neurology
David Huang, Neurology
Rebecca Kitzmiller, School of Nursing
Laura Pinto-Coelho, Neurology
Mary Piven, School of Nursing
Kevin Robertson, Neurology
Deanna Sasaki-Adams, Neurosurgery Clinic
Michael Wang, Neurology

APPENDIX 11: PHASE-TWO DIPS IRB APPROVED CONSENT FORM

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: __4.9.17_____
IRB Study #: **14-1380**
Title of Study: Depression Improvement Program in Stroke (DIPS)
Principal Investigator: Susan Wilson, RN, MSN, C-ANP
Principal Investigator Department: Neurology
Principal Investigator Phone number: (919) 843-2387
Principal Investigator Email Address: wilsons@neurology.unc.edu
Co-Investigators: David Huang, MD, PhD; Michael Wang, MD; Octavio de Marchena, MD; Michael Forbes, MD; Anne Beckwith BS; Laura Pinto-Coelho, BA; Laura Weng; Meghan McPeak; Mary Lynn Piven PhD, RN; Rebecca Kitzmiller, PhD, RN
Funding Source and/or Sponsor: UNC Department of Neurology

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to evaluate the implementation of an assessment and treatment plan with the goal of standardizing psychological care for stroke patients.

Post stroke depression is common; however, it is under recognized and under diagnosed. Studies have estimated post-stroke depression to occur in 33% of survivors. Depression is associated with poorer outcomes, recovery and quality of life. For this reason, early screening and treatment is important. Starting treatment early, within the first month after stroke diagnosis, is more effective and associated with improved functional outcomes.

Are there any reasons you should not be in this study?

You should not be in this study if:

- You are less than 18 years old
- You do not have a suspected or confirmed diagnosis of stroke or trans ischemic attack (TIA)
- You are not able to participate in the study for 30 days

How many people will take part in this study?
Approximately 375 people will take part in this study at UNC Hospitals.

How long will your part in this study last?
This study will follow you for 30 days.

What will happen if you take part in the study?
The following information and procedures will be obtained by the study team.

g. Admission
- Demographics (name, age and phone numbers) (standard of care)
- Name of primary physician (standard of care)
- Medical history (standard of care)
- Current medications (standard of care)
- Functional assessment of how well you were doing prior to your stroke, called pre-modified rankin (pre-mRS) (standard of care)
- Neurological physical exam called National Institutes of Health Stroke Scale (NIHSS) (standard of care)
- Patient Health Questionnaire 9 (PHQ-9) – completed by patient with assistance of admitting nurse (standard of care)
- Patient Health Questionnaire 9 (PHQ-9) – completed by patient with assistance by study team
- PHQ-9 - completed by family/caregiver

h. 7 (+/- 3) day Phone Call post Discharge
- Complete PHQ-9 by patient
- Complete PHQ-9 by family/caregiver
- mRS (standard of care)
- Study team will ask if participating in rehabilitation therapy (standard of care)
- Study team will ask if participating in psychological counseling (standard of care)
- Medication use will be reviewed (standard of care)

i. 30 (+/- 5) day Phone Call or Clinic Follow-up
- Complete PHQ-9 by patient
- Complete PHQ-9 by family/caregiver
- mRS
- Study team will ask if participating in rehabilitation therapy
- Study team will ask if participating in psychological counseling
- Review medication use

- Study team will ask about hospitalizations or new diagnosis since discharge

What are the possible benefits from being in this study?
It is not possible to predict whether you will benefit directly from participation in this study. However, early identification of depression and treatment has been shown to be beneficial to stroke recovery. In addition, your participation may help others in the future as a result of knowledge gained from the research.

What are the possible risks or discomforts involved from being in this study?
As a result of your participation in this study, you are at risk for side-effects listed in this section. You should discuss these with the investigator. It is important that you consider all of the options before you decide to participate in this research study.

Loss of Confidentiality:
There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

We will take every measure to protect your privacy and confidentiality. Any information will be coded by a study-specific identification number to protect your confidentiality. Any information stored by the study team will be stored in a locked filing cabinet in a building that is locked to the public. Any electronic data will be stored on a protected server. Study documentation will be kept and securely archived. Your identity will be kept confidential when the results of this study are published.

When telephoning, the study staff will ask if it is a convenient time and will call back if it is not. No messages will be left pertaining to this study.

Psychological Stress:
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the interview. You may stop your participation in the study at any time.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely,

but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University for the purpose of quality control or safety. Confidentiality of your records will be strictly maintained. Your information will be kept in locked offices, and on computers that are password protected. A copy of this consent form will go into your medical record. This will allow the doctors caring for you to know what study questionnaires you may be receiving as a part of the study.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. If such problems occur, the researcher will help you get medical care, but The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care.

Any costs for medical expenses not paid by UNC will be billed to you or your insurance company. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything for taking part in this study.

Who is sponsoring this study?
There is no funding for this study. The UNC Department of Neurology Stroke Center is sponsoring this study to gain knowledge in order to improve care to all stroke patients treated at UNC HealthCare.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Legally Authorized Representative Date

_____

Printed Name of Legally Authorized Representative

_____

(Relationship to subject)

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

_____ _____

Signature of Impartial Witness Date

_____

Printed Name of Impartial Witness

APPENDIX 12: PHASE-TWO DIPS IRB APPROVED HIPAA FORM

University of North Carolina at Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

---

IRB Study #: 14-1380
Title of Study: Depression Improvement Program in Stroke
Principal Investigator: Susan Wilson RN, MSN, C-ANP
Mailing Address for UNC-Chapel Hill Department: CB:7025 Neurology, Physicians Office Bldg , 170 Manning Drive, Chapel Hill, NC 27599-7025, USA

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

---

1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals that have provided health services or treatment, such as physicians, clinics, hospitals, home health agencies, diagnostic centers, laboratories, treatment or surgical centers associated with UNC Health Care System.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Information about your stroke or TIA. This would include information about medical treatment and rehabilitation as well as any information in your medical records that relates to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers and certain employees of the university if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

HIPAA regulations require that we let people know that sharing the PHI with others who are not covered by HIPAA – such as pharmaceutical company sponsors – will take that PHI outside of HIPAA's coverage. For example, HIPAA generally requires authorization or waiver of authorization as well as certain accounting records for disclosures of individually identifiable information from the medical record, but these HIPAA requirements do not apply to the same individually identifiable health information in the research database. The natural concern for the

research subject is whether this means that there are no confidentiality protections once the PHI has been shared outside of HIPAA coverage. The researcher should explain what confidentiality protections have been set up for the individually identifiable information in this study. In addition to the research study procedures to protect confidentiality, our standard clinical trial language requires the sponsor to protect the confidentiality of any individually identifiable data.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1 on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____

Signature of Research Subject **Date**

_____

Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____

Please explain your authority to act on behalf of this Research Subject:

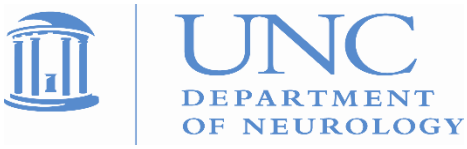
_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____ _____

Signature of Personal Representative **Date**

APPENDIX 13: NEUROLOGY SITE LETTER OF SUPPORT



January 27, 2017

Dr. Mary Lynn Piven, PhD, RN, CS
DNP Project Committee
UNC School of Nursing

RE: Susan E. Wilson RN, MSN, C-ANP DNP Project

Dear Selection Committee,

I am writing this letter in strong support of Susan (Suzi) Wilson and her DNP project proposal entitled "DIPS: The Depression Improvement Program in Stroke," which is aimed at improving the identification and early treatment of post-stroke depression (PSD) at UNC. PSD is underdiagnosed throughout the US, and efforts to address this problem are just beginning at the national level. Here at UNC, Suzi has led research into the natural history of PSD and is the PI of an IRB-approved clinical study that has enrolled over 200 patients to date. From her efforts, the UNC Stroke Center has identified gaps in our identification and treatment of PSD, which Suzi proposes to address as a means of further improving functional outcomes in our stroke and TIA patients.

As her immediate supervisor in my roles as Division Chief and Director of Stroke Center, I am committed to supporting Suzi and her identified team for this project. She will have protected time to conduct the project. I am also committed to participating in the expected activities of the project and providing mentorship and oversight.

I am confident that Suzi has the skill set and drive to complete her project and that her efforts will make a major contribution to improving the quality of stroke care that we provide. I am fully supportive of her efforts and expect that her participation will lead to myriad downstream improvements in and expansion of our Stroke Center improvement efforts.

Sincerely,

David Y. Huang, MD, PhD, FAHA, FANA, FAAN
Professor and Chief, Division of Stroke and Vascular Neurology
Director, UNC Health Care Comprehensive Stroke Center
Department of Neurology
The University of North Carolina at Chapel Hill

APPENDIX 14: SCHEDULE OF STUDY ACTIVITIES

Study Activities	Admission	Day 7	Day 30
Demographics*	X		
Name of primary care provider	X		
Medical History	X		
Current Medications	X	X	X
Functional Assessment – pre-mRS	X	X	X
Neurological physical exam - NIHSS	X		
PHQ-9 – completed by patient with assistance of nurse	X		
PHQ-9 – completed by patient with assistance of research team	X	X	X
PHQ-9 – completed by family/caregiver	X	X	X
Participation in rehabilitation therapy	X	X	X
Participation in psychological counseling		X	X
Hospitalizations or new diagnosis			X

**Name, age, education level, work history and phone numbers (standard of care)*

APPENDIX 15: MODIFIED RANKIN SCALE

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance
3	Moderate disability requiring some help, but able to walk without assistance
4	Moderate to severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent, and requiring constant nursing care and attention
6	Dead

APPENDIX 16: NATIONAL INSTITUTES OF HEALTH STROKE SCALE

Category	Score Description
1a: Level of Consciousness	0 = Alert, keenly responsive 1 = Not alert, but arousable by minor stimulation 2 = Not alert, requires repeated stimulation to attend 3 = Responds only with reflex motor or autonomic effects
1b: Level of Conscious Questions	0 = Answers both questions correctly 1 = Answers one question correctly 2 = Answers neither question correctly
1c: Level of Conscious Commands	0= Performs both task correctly 1 = Performs one task correctly 2 = Performs neither task correctly
2. Best Gaze	0 = Normal 1 = Partial gaze palsy 2 = Forced deviation, or total gaze paresis
3. Visual	0 = No visual loss 1 = Partial hemianopia 2 = Complete hemianopia 3 = bilateral hemianopia (blind including cortical blindness)
4. Facial Palsy	0 = Normal 1 = Minor paralysis (flattened nasolabial fold) 2 = Partial paralysis 3 = Complete paralysis
5a. Motor Arm - Left 5b. Motor Arm - Right	0 = No drift, holds 90° for 10 seconds 2 = Some effort against gravity, drifts down to bed 3 = No effort against gravity, limb falls 4 = No movement 9 = Amputation
6a. Motor Leg – Left 6b. Motor Leg - Right	0 = No drift, holds 90° for 10 seconds 2 = Some effort against gravity, drifts down to bed 3 = No effort against gravity, limb falls 4 = No movement 9 = Amputation
7. Limb Ataxia	0 = Absent 1 = Present in one limb 2 = Present in two limbs
8. Sensory	0 = Normal 1 = Mild to moderate sensory loss 2 = Severe to total sensory loss
9. Best Language	0 = No aphasia 1 = Mild to moderate aphasia 2 = Severe aphasia 3 = Mute
10. Dysarthria	0 = Normal 1 = Mild to moderate dysarthria 2 = Severe, patients speech is unintelligible 9 = Intubated
11. Extinction and Inattention	0 = Normal 1 = Visual, tactile, auditory, or spatial inattention 2 = Profound hemi-inattention to more than one modality

APPENDIX 17: PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Question	Scoring			
	Not at all	Several Days	More than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
Total for each column	0			
Add columns for total score				

PHQ-9 Scores and Proposed Treatment Actions*

PHQ-9 Score	**Depression Severity**	**Proposed Treatment Actions**
0-4	None-minimal	None
5-9	Mild	Watchful waiting; repeat PHQ-9 at follow-up
10-14	Moderate	Treatment plan, considering counseling, follow-up and/or pharmacotherapy
15-19	Moderately Severe	Active treatment with pharmacotherapy and/or psychotherapy
20-27	Severe	Immediate initiation of pharmacotherapy and, if severe impairment or poor response to therapy, expedited referral to a mental health specialist for psychotherapy and/or collaborative management

* Kroenke, K. and Spitzer, R. (2002). *Psychiatric Annals*, 32, 509-521.

APPENDIX 18: CASE REPORT FORM

Patient Initials: _____ Subject #:_____

Depression Improvement Program Study

Screening:

Inclusion Criteria:

(Yes) (NO)

____ ____1) Ability to provide written informed consent

____ ____2) Age ≥ 18 years of age

____ ____3) Diagnosis of Stroke or TIA

Exclusion Criteria:

(**Yes) (NO)**

____ ____1) Non-stroke Admission

____ ____2) Severity of illness preventing participation at admission

____ ____3) Refusal to consent

Admission:

Date of admission: _____/_____/_____ Time: _____
Month Day Year

Informed Consent Signed by Patient or LAR: _____/_____/_____
Month Day Year

Consent documented in chart: _____/_____/_____

Onset Date of Stroke: _____/_____/_____ LKN: _____
Month Day Year

Sex: _____Male _____Female

Race: _____Caucasian _____Black _____Hispanic _____Asian _____Other

Education level: _____

Work Status: Full-time____ Part-time_____ Retired_____ Housewife_____

Unemployed_____ Disabled_____ Student_____

If working, what is occupation: _____?

Date of Birth: _____/_____/_____ Age: _____
Month Day Year

Admission NIHSS: _____ Date: _____/_____/_____
Month Day Year

Admission Modified Rankin Score: _____ Date: _____/_____/_____
Month Day Year

Caregiver Name/Relationship: _____/_____

Phone Contact: _____

Email Contact: _____

Past Medical History:

Current Psychiatric Medications:

Medication	Dose	Route	Frequency

Admission to NSICU: Date_____/_____/_____ Time: _____

Admission to 6NSH floor: Date_____/_____/_____ Time: _____

Admission PHQ-9 Score by Nursing: _____Date:___/____/____ Time: _____

Study Team

Admission Patient PHQ-9 Score: _____ Date: ___/____/____ Time: _____

Admission Caregiver PHQ-9 Score: _____Date:____/_____/____ Time: _____

PHQ-9 Documented in chart: Yes _____No_____

7 (+/- 3) Day Phone Call post Discharge

Patient PHQ-9 Score: _____

Caregiver Proxy PHQ-9 Score: _____

Discharge Date: _____ Diagnosis: _____

Location of Discharge: _____

Length of Hospitalization (# of days):_____

Discharge NIHSS: _____

Discharge mRS: _____ Day 7 mRS: _____

Physician documentation of PHQ-9: Yes_____ No_____

Physician documentation of treatment: Yes_____ No_____

Patient Discharged on antidepressant: Yes_____ No_____

Reason why not: _____

Resident: _____ Attending: _____

Discharge <u>Psychiatric Medications</u>:

Medication	Dose	Route	Frequency

If employed, has the patient returned to work? Yes____ No____ N/A____

Participating in rehab? Yes_____ No_____

Therapies? _____PT _____OT _____ST

Any changes in psychiatric medications since discharge? _____Yes _____No

If so, new or change in psychiatric medications:

Medication	Dose	Route	Frequency

30 (+/- 5) Day Phone Call or Clinic Follow-up

Patient PHQ-9 Score: _____

Caregiver Proxy PHQ-9 Score: _____

mRS: _____

If employed, has the patient returned to work? Yes____ No____ N/A____

Has living situation changed? Yes_____ No_____

If so, how? _____

Participating in rehab? Yes_____ No_____

Therapies? _____PT _____OT _____ST

Hospitalized since enrollment? _____Yes _____No

If so, for what? _____

New diagnoses since enrolled? _____Yes _____No

If so, what? _____

Any changes in psychiatric medications since last phone call? ___Yes ___No

If so, new or change in psychiatric medications:

Medication	Dose	Route	Frequency

APPENDIX 19: ANTIDEPRESSANT MEDICATION CHART

Total Daily Dose Range (mg)							
Brand Name	**Trade Name**	**Class**	**Dose Range**	**Starting Dose**	**Titration**	**Management Strategies**	**Side Effects**
Citalopram	Celexa	SSRI	10 to 40mg	10mg daily with food	Increase by 10mg every 2 weeks	Safe in the elderly, good initial therapy, few interactions, $4 list, generic available	Use with caution if history of hyponatremia or GI bleed (all SSRIs). Nausea, dry mouth, somnolence, diarrhea, tremor
Escitalopram	Lexapro	SSRI	5 to 20mg	5mg daily with food	Increase by 5mg increments	Good in depression and anxiety	Dizziness, insomnia, GI disturbance, weight changes, decrease sex drive
Fluoxetine	Prozac	SSRI	10 to 80mg	10mg daily for 6 weeks	Increase by 10mg every 4 weeks if no response after 6 weeks	Good in forgetful patients, long half-life, $4 list, generic	Nausea, Anorexia, Tremor, Insomnia, Anxiety
Paroxetine	Paxil	SSRI	10 to 40mg	10mg daily with food or QHS if sedating	Increase by 10mg every 2 weeks if no response after 3 weeks	Good in anxious patients (sedating)	Discontinue syndrome - must be tapered. Increased drug interactions. Vision changes, dizziness, anxiety, insomnia, loss of appetite, constipation, dry mouth, decreased sex drive
Sertraline	Zoloft	SSRI	25 to 200mg	25mg daily with food	Increase by 50mg every 2 weeks if no response after 3 weeks	Safe after MI, few interactions, generic available	GI disturbance, weight changes, insomnia, decreased sex drive, dizziness, dry mouth
Duloxetine	Cymbalta	SNRI	20 to 60mg	20mg daily	Increase to 20mg BID after 1 week. If no response after 3 weeks increase to 30mg BID	Good in neuropathic pain; expensive	Stress urinary incontinence, difficulty sleeping, diarrhea, dizziness, dry mouth, decrease appetite
Venlafaxine	Effexor	SNRI	37.5 to 225mg	37.5mg daily with food	Increase to 37.5mg BID if no response after 3 weeks (can be raised by 75mg every 4 days)	Good in anxious patients; can worsen HTN	Discontinuation syndrome, nausea, sexual dysfunction, (insomnia, anxiety, HTN - occur at high doses)
Mirtazapine	Remeron	Serotonin & Norepinephrine Antagonist	15 to 45mg	7.5mg QHS	Increase by 7.5mg every 2 weeks if no response after 3 weeks	Increases appetite, weight gain - use in malnourished patients; good in geriatrics, less sexual dysfunction	Dizziness, strange dreams, vision changes, dry mouth, constipation, weight gain, dry mouth,
Buproprion SR (avoid with history of seizure)	Wellbutrin SR	NDRI	100 to 300mg	100mg daily	Increase to 100mg BID if no response after 3 weeks	Stimulating, less sexual dysfunction, least weight gain	Dry mouth, Nausea, Insomnia, Constipation, Agitation, May lower seizure threshold

APPENDIX 20: DIPS LETTER TO PRIMARY CARE PROVIDER

PCP Physician Name Date
Address
City, ST Zip

Dear Colleague:

Your patient, _____, was recently admitted to UNC Healthcare on _____ with a diagnosis of _____ (type of stroke). During the admission, _____ consented to participate in the Depression Improvement Program for Stroke (DIPS) Study.

Post-stroke depression (PSD) is common, occurring in at least one-third of patients; however, it is under recognized and under treated. PSD is a serious complication and is significantly associated with a negative impact on recovery and higher mortality rates (Towfighi, 2016).

The Patient Health Questionnaire (PHQ-9) is used to assess patients for depression, incorporating DSM-V diagnostic criteria with depressive symptoms in a self-report tool. Williams screened for depression in 316 stroke patients and found that the PHQ-9 at a score of $\geq$ 10 had a sensitivity of 91% and specificity of 89% for major depression and a 78% sensitivity and 96% specificity for any depression diagnosis.

Attached is information about the PHQ-9, which includes treatment recommendations.

This letter is to inform you that, _____ has scored a _____on the PHQ-9. The patient and family is aware of the score and has been encouraged to discuss this at their next medical appointment.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Susan E. Wilson RN, MSN, C-ANP
Associate Professor, Department of Neurology
Adult Stroke Nurse Practitioner
University of North Carolina Stroke Center
CB# 7025 170 Manning Drive
Physicians Office Building, Room G178
Chapel Hill, NC 27599-7025
Phone: (919) 843-2387
Fax: (919) 843-3252

References:

1. Towfighi A, et al. 2016. Poststroke depression: a scientific statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke* 47:1-14.
2. Williams, L., et al. 2005. Performance of the PHQ-9 as a screening tool for depression after stroke. *Stroke*,36:635-638.

APPENDIX 21: DIPS PHYSICIAN SATISFACTION QUESTIONNAIRE

Depression Improvement Program in Stroke Program (DIPS) Physician Satisfaction Questionnaire

Please answer the following questions about the post-stroke depression (PSD) project and help the stroke program continue improving care

	Questions	Yes	No	Not sure
1	Do you believe many of your stroke patients need help with depression?			
2	Did you receive education/information about PSD and the importance of treatment for depression symptoms in stroke patients?			
3	Do you explain PSD to your patients/families?			
4	Do you understand how to implement treatment for PSD based on the PHQ-9 score?			
5	Do you know how to find the PHQ-9 score within EPIC?			

Please provide your thoughtful answer to the last two questions:

1. What went well with the implementation of DIPS program?

2. What could be improved with the PHQ-9 assessment/documentation process?

Prior to project implementation, assessment of depression symptoms averaged 23% and treatment occurred less than 30% of the time. Since project implementation PSD, assessment is approximately 88% and treatment rate has increased to 70%.

Thank you for the excellent care you provide!

APPENDIX 22: DIPS NURSING SATISFACTION QUESTIONNAIRE

Depression Improvement Program in Stroke Program (DIPS) Nursing Satisfaction Questionnaire

Please answer the following questions about the post-stroke depression (PSD) project and help the stroke program continue improving care

	Questions	Yes	No	Not sure
1	Do you believe many of our patients need help with depression?			
2	Did you receive education/information about PSD and the importance of screening for depression symptoms in stroke patients?			
3	Do you explain PSD to your patients/families?			
4	Since implementation of the depression, improvement program in stroke (nurses screening using the PHQ-9 and physicians considering treatment based on the score) is there more focus from the physician team on PSD?			
5	Do you report off the PHQ-9 score during shift report?			

Please provide your thoughtful answer to the last three questions:

1. What barriers do you face in assessing your stroke patients for depression?

2. What went well with the implementation of DIPS program?

Prior to project implementation, assessment of depression symptoms averaged 23% and treatment occurred less than 30% of the time. Since project implementation PSD, assessment is approximately 88% and treatment rate has increased to 70%.

Thank you for the excellent care you provide!

APPENDIX 23: PHYSICIAN COMMENTS TO QUESTIONS #6 AND #7

Question # 6: What Went Well with the Implementation of DIPS Program?

- "Standardization of obtaining PHQ-9"
- "Increased awareness of PSD, its assessment, and its treatment. Good review of common antidepressants"
- "Excellent explanation of need and how to screen. Also good follow-up"
- "Increasing recognition of depression with stroke"
- "More recently, nursing staff seems to be much more consistent about getting PHQ-9 scores on stroke patients. Residents seem to pay more attention to the score if they are reminded about it earlier in the week"
- "Information provided by stroke team (drug list and treatment algorithm) and attending physician support"

Question #7: What Could Be Improved with the PHQ-9 Assessment/Documentation Process?

- "Make the PHQ-9 easier to find in the system"
- "Review of where to find PHQ-9 in EPIC"
- "With turnover, would continue with training as time passes"
- "Would encourage nursing staff to communicate high PHQ-9 scores to the physicians to make them aware earlier, as sometimes physicians don't review the PHQ-9 until at discharge"

APPENDIX 24: NURSING COMMENTS TO QUESTIONS #6 AND #7

Question #6: What Barriers Do You Face in Assessing Your Stroke Patients for Depression?

- "Inability to assess due to patient's cognitive or aphasic status. Family cannot answer on patients behalf"
- "Patient unable to communicate or no family present to ask the questions"
- "The severity of the strokes causing cognitive deficits"
- "Their alertness and cognitive ability"
- "No family or patient is confused"
- "Cognitive impairment; families often not good resource to answer PHQ-9"
- "Sometimes the patients don't want to talk about it and it feels robotic asking all of those questions"
- "Some patients are not "with it" enough to be able to complete the questionnaire. Busy with other things, forget to assess for that piece. I haven't seen anyone do anything with the information gathered from the PHQ-9"
- "Aphasic patients. Also, many patients found that the questions were written in a way that confused them – not straightforward"
- "Aphasia and confusion, time"
- "Communication – aphasia, time during the shift to approach this with patient – it requires a relationship to be developed"
- "Difficulty with patients having aphasia – otherwise none"
- "Cognition problems"
- "EPIC – have to go to different tabs to assess and document. It is confusing having the PHQ-2 in our stroke tab yet we are expected to document the PHQ-9 in a different tab"

Question #7: What Went Well with the Implementation of DIPS Program?

- "Having a place to record PHQ-9 in EPIC so the entire care team could have access to the scores"
- "Patient and staff is becoming more aware of depression after stroke"
- "Effective unit compliance"
- "It was clear on EPIC"
- "I'm a new nurse, so it's too early for me to tell"
- "Honestly, I don't know very much about the DIPS program"
- "Easy for RN to complete during admission and easy follow-up to stroke team"
- "Creating the stroke research tab; recognizing and rewarding staff for their work"
- "Great education about program, easy to use flowsheet"
- "Stroke NP providing education and support. Having her on the unit answering questions and assisting with performing the PHQ-9 was helpful"

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